PROCEDURE FOR INITIAL AUDIT

REV. NO.	DATE	BRIEF RECORD OF REVISIONS
09	01.04.2023	Name of Prepared by and Approved by Changed
08	28.02.2020	Clause 4.1 & 4.2 Modified
07	15.12.2018	Clause 4.5 Modified
06	11.09.2017	Clause 4.1.2 Modified
05	13-03-2016	Section 4.2.1 opening meeting reference to WI added and GD notes removed in section 4.1.5
04	27.02.2016	Designation of Senior Manager-QA to AGM QA, TQ Services changed to TQS
03	27.03.2015	Designation of Head-QA changed to Senior Manager-QA
02	29.03.14	Section 4.2.2 modified prohibiting communication with consultants
01	18-12-2012	Appendix 1 added in line with new revision of ISO 17021-2011
00	03.01.2011	First issue

PREPARED BY: Head-QA	APPROVED BY : Chief of Certification
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1.0 OBJECTIVE

To define process for preparation and conduct of audit of clients.

2.0 SCOPE

Applicable to all audits for clients

3.0 RESPONSIBILITY

As defined in the procedure.

4.0 PROCEDURE

4.1 Preparation for Audit

4.1.1 Upon receipt of conformity of contract from CE, Head-QA co-ordinates with the clients and agrees upon mutually convenient audit dates.

4.1.2 Head-QA has the responsibility and authority for selection of a competent and independent audit team including team leader drawn from internal and / or external resources with suitable NACE codes to match with the client's processes / activities and communicates in format no. CBF-05.

For EMS, aspects involved are evaluated for significance, from the data submitted by the organization, (format no. CBF-50). A competent team is selected to match with the level of significance.

Criteria for selection of audit team is as per procedure CBP-03 is taken into consideration as guidance.

Technical experts in the areas of audit are included in the team as required engaging subcontracted/internal technical experts/ auditors as required in stage-1, Stage-2, Surveillance audits and Recertification audit, as detailed in the procedure ref. no CBP-02.

The role of technical experts during an audit activity shall be agreed to TQ Service and client prior to the conduct of the audit. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor.

NOTE: The technical experts can provide advice to the audit team for the preparation, planning or audit.

4.1.3 Head-QA communicates to clients sufficiently in advance regarding the names of the audit team members and their background information, if requested. If client

has any objection for any reason and if the same is considered valid, the team will be reconstituted.

4.1.4 The team members are communicated relevant information and the Team Leader initiates the audit process for assessing the client.

4.1.5 The audit program and mandays, taking into consideration sampling involved for multi site locations, are derived from IAF Mandatory publications MD 1 and MD 5. The audit program is indicative of the number of sites covered under sampling plan in case of multi site organization. Each site will have a separate audit schedule. (Ref Appendix 1).

In determining the audit time the following are taken into account. Any adjustments or variations, are justified specifying the reasons by Head-QA.

- Scope and complexity of the relevant Management system standard
- The requirements of the relevant management system standard
- Size and complexity of the organization
- Products and processes
- Demonstrated level of management system effectiveness
- The results of any previous audits
- Technology in use and applicable regulatory requirements
- Outsourcing of any activity included in the scope
- Certifications held already.
- Number of sites and multi site locations (sampling of sites if involved is included in the auditor allocation form)

Supporting information including for any justifications made Ex. manday calculation, any concessions given and sampling decided etc is maintained in Client file records. Sufficient information regarding any certifications held already by the client are also collected as this forms the basis for any adjustments made in the audit program.

An audit programme for the full certification cycle shall be developed to clearly identify the audit activity/activities required to demonstrate that the client's management system fulfils the requirements for certification to the selected standard(s) or other normative document(s). The audit programme for the certification cycle shall cover the complete management system requirements.

The audit programme for the initial certification shall include a two-stage initial audit, surveillance audits in the first and second years following the certification decision, and a recertification audit in the third year prior to expiration of certification. The first three-year certification cycle begins with the certification decision. Subsequent cycles begin with the recertification decision (see 9.6.3.2.3) The determination of the audit programme and any subsequent adjustments shall consider the size of the client, the scope and complexity of its

management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.

NOTE 1: Annex E provides a flowchart of a typical audit and certification process.

NOTE 2: The following list contains additional items that can be considered when developing or revising an audit programme, they might also need to be addressed when determining the audit scope and developing the audit plan:

- complaints received by the certification body about the client;
- combined, integrated or joint audit
- changes to the certification requirements;
- changes to legal requirements;
- changes to accreditation requirements;
- organizational performance data (e.g. defect levels, key performance indicators data);
- relevant interested parties' concerns.

NOTE 3: If specified by the industry specific certification scheme, the certification cycle can be different from three years (Ref – CBF 26)

The audit scope shall describe the extent and boundaries of the audit, such as sites, organizational units, activities and processes to be audited. Where the initial or re-certification process consists of more than one audit (e.g. covering different sites), the scope of an individual audit may not cover the full certification scope, but the totality of audits shall be consistent with the scope in the certification document.

4.1.6 The audit team is assigned the following tasks as minimum:

- To examine and verify the client's policies, structure, processes, procedures, records and related documents relevant to the management system
- To verify that the above are relevant to intended scope
- To determine that the processes and procedures are established, implemented and maintained and effective in implementation of the standard requirements and to provide confidence in the client's management system.
- To communicate, for its action, any inconsistencies between client's policy, objectives / targets (consistent with the requirements / expectations in the relevant management system or other normative requirements) and the results

4.1.7 In case of changes in scope, like Mandays / additional verifications required, these are also indicated in the allocation format CBF – 05 so that the team is made aware of the changes.

It is ensured that scope changes are reviewed prior to conduct of Audit. However, if any changes are noted by the team leader, during audit on site, the team leader may decide for any changes or may refer to COC/ Head-QA / nominee for decision.

4.1.8 Head-QA obtains declaration for confidentiality (format no. CBF-25A) from audit team as applicable. The appointed audit team is supplied with appropriate working documents, applicable standards, applicant's manual, procedures, formats etc.

4.1.9 For each audit, the Audit Team Leader prepares a detailed audit schedule (form no. CBF-20) taking into consideration ISO 17021 and applicability matrix obtained from the Organization and communicates to client, audit team members and any other concerned for making necessary arrangements.

4.1.10 The audit schedule and names of audit team members are conveyed to client with sufficient notice for any changes if needed.

4.2 Requirements of Audit Process.

Audits are conducted on site only and the audit shall comprise of the following elements as detailed. Work Instructions are also provided covering these activities.

4.2.1 Opening meeting

Audit team conducts an opening meeting as per work instruction WI 01 with applicant organization's Senior Management / representatives prior to commencement of the audit. The Audit Team Leader chairs the meeting and requests the company personnel who will be involved in audit to be present at the meeting to

- confirm the audit schedule
- provide short summary how the audits are undertaken
- confirm communication channels
- provide guides and necessary logistics
- Provide an opportunity for auditee to ask questions.

4.2.2 Communication during the audit

Depending upon the scope and complexity of the audit, a formal arrangement is made for communication within the audit team and with the auditee during the audit. Communication with Consultants of the auditee Company is strictly prohibited.

Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the audit team leader shall report this to the client and, if possible, to TQ Services to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to TQ Services.

4.2.2 Roles and responsibilities of Guides

When guides are appointed by the Management, they should assist the audit team and act on the request of the Audit Team Leader. Guide(s) are assigned to the audit team to facilitate the audit. The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit.

NOTE 1 : The responsibilities of a guide can include:

- Establishing contacts and timing for interviews;
- arranging visits to specific parts of the site or organization;
- Ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;
- Witnessing the audit on behalf of the client;
- Providing clarification or information as requested by an auditor.

NOTE 2 : Where appropriate, the auditee can also act as the guide.

4.2.4 Collecting and verifying information

During collection of information by audit team, appropriate sampling is done relevant to the audit objectives, criteria, scope including information relating to interfaces between the functions, activities and processes. The collected information is to be verifiable and is recorded (format no. CBF-22).

4.2.5 Generating audit findings

The Audit Team Leader evaluates audit evidence against audit criteria to generate audit findings. These indicate either conformity or nonconformity with audit criteria. These findings can identify opportunities for improvement without specifying any solutions.

4.2.6 Preparation of Audit conclusions

The audit team shall meet and agree upon the following prior to the closing meeting

- To review the audit findings and any other information collected with respect to audit objectives

- To agree on the audit conclusions
- To prepare recommendations regarding out come of audit.
- To review the corrections or corrective action plan, if required, submitted by the organization for any nonconformities raised during the audit.

4.2.7 Closing meeting

The closing meeting is chaired by the Audit Team Leader and provides the organization with details of audit and any nonconformities, recommendation for certification or otherwise.

4.2.8 The designated time for full day visit is 8 hours including ½ hour for lunch. To check some of the actual operations the time can be mutually agreed with the client.

4.2.9 If any exceptional circumstances arise, the Audit Team Leader reviews with the Management Representative of the organization for taking any suitable action.

4.3 Pre-audit

4.3.1 These activities are optional and does not constitute part of any certification process and are carried out when requested by the client to a mutually agreed scope, manday requirements and coverage in audit. The findings are reported as areas of concern.

4.3.2 TQS performs these pre audits at applicant's location in order to evaluate the appropriateness of the QMS/EMS considering the complexities in operations / possible environmental aspects respectively.

4.3.3 Coverage (as mutually agreed)

- Manual adequacy and comments on documentation
- Scope and objectives
- Adequacy of internal audits and management review
- Handling of customer complaints in QMS.
- Performance of selected processes (implementation of QMS in selected processes)
- Response to external communication for EMS.
- Compliance to the requirements of the standard as applicable to functions / departments in case of EMS
- To verify adequacy of application of legal and other requirements and availability / validity of authorizations / consents in EMS.

4.4 Initial audit

4.4.1 It is a requirement that all initial audits (certification audits) are carried out in two stages, stage-1 and stage-2.

4.4.2 Stage-1 audit

The stage-1 audit is carried out on site, to determine readiness and covers the following activities.

- Review of client's management system documentation for its adequacy.
- to evaluate the client's location and site specific conditions
- to undertake discussions with client's personnel
- Regarding scope of management system, processes and locations
- To determine any other normative requirements to be adhered to in addition to applicable standard.
- To evaluate Applicable legal, regulatory or other requirements and compliance status.
- To review the status and understanding regarding the requirements of the governing standard
- Evaluation of aspects, impacts in case of EMS
- Evaluation of Objectives set at different levels and functions
- To evaluate internal audits and management review for its planning and implementation adequacy to substantiate readiness for stage 2
- To identify resources required for stage 2
- To plan for stage 2 taking into consideration the implementation status
- To determine the preparedness for stage -2.

4.4.3 The findings records are maintained (by use of checklists)

- CBF – 45 for ISO 9001 – 2015
- CBF – 53 for ISO 14001 – 2015

Stage – 1 findings are communicated to the client and to Head-QA, identifying areas of concerns which could lead to a non conformity during stage -2. The client is responsible for communicating the actions taken on these concerns to Head-QA. In case any adjustments are required in the audit plan the same will be taken into account while planning the stage – 2 audit.

4.4.4 The time period between stage 1 and stage 2 is not to exceed 90 days normally. In case it is required to extend this period for any specific reason, the same shall be approved by Head-QA through auditor allocation form.

4.5 Stage-2 audit

The objective of stage-2 audit is to evaluate the implementation and its effectiveness. The findings of stage 1 audit are also taken into account while planning and conducting stage 2 audit. The stage 2 audits are carried out at site only and covers the following as a minimum.

- Review of system manual for adequacy (format no. CBF-42) and if acceptable, the team leader endorses the manual. Manual may require changes as a result of stage 1 audit.
- Verify with objective evidence on conformity with all the requirements of standard and other normative documents
- Key performance measures, performance monitoring against objectives / targets and traceability to management policies and objectives
- Compliance to the applicable legal and regulatory requirements
- Performance of internal audits, management reviews and its conclusions on the management system.
- Operational controls of client's process.
- Management responsibility for the client's policies.
- Links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document) any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data, internal audit findings and conclusions
- Verifying the effectiveness of corrective actions taken on Observations/Area of Concern raised during previous audit (Stage 1 Audit)

These are ensured by using checklist (format no CBF-54 for EMS) and use of auditors notes format CBF – 22 with guidance on process approach audit methodology as documented in WI – 05

4.6 The team leader (preferably the same person who carried out stage 1) will co-ordinate with the clients to obtain the requisite documentation and reviews the system manual for adequacy (format no. CBF-42) and prepares a plan covering detailed audit schedule (format no.CBF-20). The team is considered acceptable to the organization unless a need for any change is communicated to the team leader or Head-QA.

4.7 Audits are carried out covering applicable clauses in the respective processes and ensures that all clauses (except exclusions if any) of the standard are covered in the entire organization. This is ensured by using Audit plan and audit matrix (format no. CBF- 40).

4.8 If any non-conformities are reported (Format no CBF 23), these are reviewed with the respective auditee. TQS require that actions are to be taken by the organization to identify root cause and to take corrections and corrective actions

as required, to eliminate the causes of nonconformities, within an agreed time frame (within 60 days). Upon receipt of information regarding satisfactory implementation of corrective actions, these are verified for effectiveness and closed if found acceptable to the auditor.

Categorization of NCs:

Sl. No	Type of Non-conformities	Description
1	Major NC **NOTE: No recommendation for grant of certification can be made with major NC noted**.	• It relates to the absence of implementation of a procedure or the total break down of the System (QMS/ EMS) • A number of minor nonconformities listed against the same requirements of the appropriate standard, may represent a total break down of a system and thus could be collectively a major nonconformity • A situation that raises significant doubt about the ability Organization's management system to achieve its outputs
2	Minor NC	• It relates single observed lapse in system or process.
3	Observation	• It relates to a matter about which the auditor is concerned or any trends which may lead to nonconformity.
4	Opportunity for Improvement	• Situations that can be brought to the notice of the Organization which can improve efficiency or effectiveness without suggesting solutions.

4.9 On completion of the audit, the team compiles and analyses all the information and evidence gathered during stage 1 and Stage 2, reviews the findings and decides on audit conclusions. Procedure CBP 08 refers.

4.10 The team leader compiles the report for each audit, taking into consideration ISO 17021 and conveys the team findings and recommendation on certification to the organization in the closing meeting. Opportunities for improvements may be included without specifying any solutions. It is ensured that no recommendation is made for grant of certificate with any open NCs. Any clarifications needed or appeals / complaints raised will be resolved by team leader. If the matter requires reference to management of TQS either the client or team leader communicates

this for resolution (procedure ref. no. CBP-13 for handling appeals and complaints).

Decisions may be

- Recommended for grant of certification when system implementation is fulfilling the requirements.
- Not recommended and requires a follow up audit (limited visit) or require submission of documentary evidences of CAs taken against minor NCs...
- Not recommended and the decision will be reviewed subject to submission of objective evidence regarding correction/corrective action taken in case of major NC.
- A full re-audit

In case of NC resolution, either for follow up or review by objective evidence, time limit is 90 days maximum from the last day of audit, unless for any specific reason approved by Head-QA.

4.9 A report is prepared and copies are issued to the client and TQS as per format CBF-21. Head-QA owns the responsibility for maintaining the reports at Head Office.

When planning Surveillance audit the following are adhered to

- First surveillance start date not to exceed 12 months from Certification Decision Date.
- Next surveillance audit may be within an interval of nine months to 13 months from the last day of initial stage 2 or recertification audit.

4.10 Where a re-audit is decided, the whole process shall be repeated.

5 Verification of corrections / corrective actions

In case decision is made for verification of NCs based on objective evidence , upon receipt of report on corrections / corrective actions taken, the action taken by the organization is reviewed for effectiveness by the team leader (preferably) or any other auditor.

In case, follow up audit is recommended, Corrective actions taken are verified at site. Upon verification, if it is found that NCs are effectively resolved or closed, a final report as mentioned above is issued.

NCs are considered resolved when.

- the correction or corrective action initiated prevent risk to the customer

- It is demonstrated that actions are in place to eliminate the cause of NC which can be verified during surveillance audits.

The effectiveness of corrective actions is monitored in surveillances also as a part of monitoring of effectiveness.

6 Report review at Head Office

6.1 Upon receipt of reports, these are reviewed for adequacy by an independent person not involved in the audit and the decision is made to recommend for grant of certificate or otherwise (format no. CBF-06). Clarifications are obtained as required.

Decision is made for certification by review of the following

The information provided by the audit team is sufficient with respect to standard requirements and scope for certification including team recommendations

- Review of any NCs reported for closure and corrections and any Corrective actions taken inclusive of any other similar situations
- Review for confirmation of information provided to TQS at the time of application (during contract review)
- whether to grant or not to grant, together with any conditions or observations

6.2 Based on the review as noted above and recommendations made by Head-QA or nominee, COC makes a final decision. When accepted, certificate is prepared and issued.

6.3 The certificate is valid for 3 years from the date on which decision for grant of certification is made.

6.4 A directory of certified clients (format no. CBF-16) defining scope is maintained by Head-QA.

7.0 REFERENCES

Procedure for Outsourcing	---	CBP-02
Procedure for Audit Reporting	---	CBP-08
Procedure for certification decision And issue of certification documents	---	CBP-10
Procedure for safeguarding confidentiality Of information	---	CBP-12
Procedure for Documents Control	---	CBP-14
Procedure for Records Control	---	CBP-15

8.0 RECORDS

Client's file which consists of all the relevant records is maintained by Contracts Executive.

Appendix 1

Considerations for the audit programme, scope or plan

1 General

This annex includes a list of items that a certification body can consider when developing or revising an audit programme, scope or plan.

2 List of items for consideration

The list includes the following:

a) the scope and complexity of the client's management system;
b) products and processes (including services);
c) size of the client organization;
d) sites to be audited;
e) language of the client organization and languages spoken and written;
f) the requirements of sector or regulatory schemes;
g) client and their customers' requirements and expectations;
h) the number and timing of shifts;
i) audit time required for each audit activity;
j) competence of each member of the audit team;
k) the need to audit temporary sites;
l) results of the stage 1 audit or of any other previous audits;
m) results of other surveillance activities;
n) demonstrated level of management system effectiveness;
o) eligibility for sampling;
p) customer complaints;
q) complaints received by the certification body about the client;
r) combined, integrated or joint audits;
s) changes to the client's organization, products, processes or its management system
t) changes to the certification requirements;
u) changes to legal requirements;
v) changes to accreditation requirements;
w) risk and complexity;
x) Organizational performance data [e.g. defect levels, key performance indicators (KPI) data, etc.];
y) interested parties' concerns;
z) Information gained during previous audits.