

Code of Practice for TL 9000 Certification Bodies

Release 7.1

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Section 1 – Introduction

This document is intended for organizations, Certification Bodies and Accreditation Bodies. It contains information designed to improve the contents and consistency of the audit process, including oversight.

Definitions

- **Correction** – action to eliminate a detected nonconformity (ISO 9000)
- **Corrective action** – action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000)
- **Exemptions** are defined in the Measurement Handbook and shall be noted in the organization’s registration profile under “Exemptions”.
- **Exclusions** are defined in the Requirements Handbook and shall be noted in the organization’s registration profile under “Exclusions”.
- **Findings include** –
 1. Major Nonconformity
 2. Minor Nonconformity
 3. Opportunities for Improvement
- **Nonconformity** –
 1. Non-fulfillment of a requirement (ISO 9000).
 2. Breakdown in the quality system, which requires a written corrective action and has to be satisfactorily implemented and verified in order for the nonconformity to be closed.
- **Nonconformity, Major** –
 1. The absence of, or the failure to implement and maintain, all aspects of one or more requirements for certification/registration; or
 2. a number of minor nonconformities against one or more requirements, which when combined, can represent a breakdown of the organization’s systems; or
 3. a minor nonconformity that was previously issued and not addressed effectively.
- **Nonconformity, Minor** – an observed lapse in the organization’s quality system potentially impacting the quality of the product delivered to the customer.
- **Opportunities for Improvement** – Documented statements that may identify areas for potential improvement in the organization’s system, but shall not include specific recommendations nor require action by the organization.

Acronyms

AB	Accreditation Body
CAP	Corrective Action Plan
CB	Certification Body
Pre-Audit CB Information Package	Information provided by the Org to the CB prior to its scheduled certification, surveillance or recertification audit.
QMS	Quality Management System

Associated References

- ISO/IEC 17021-1:2015 Conformity Assessment-Requirements for Bodies Providing Audit and Certification of Management Systems Part 1: Requirements
- IAF MD 1 - IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling
- IAF MD 4 - IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems
- IAF MD 5 - IAF Mandatory Document for Determination of Audit Time of Quality and Environmental Management Systems)
- SamplingQuEST Forum: Certification Suspension Processes

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- QuEST Forum: Management of Registration Profiles
- QFE-005 - TL 9000 Auditor Time Chart
- QFE-013 - Qualification and Experience Requirements for TL 9000 Certification Body Auditors
- QFE-016 - Certification Body Quarterly Data Submission QFP-034 - Third Party Effectiveness Verification Program

Associated (Optional) Documents:

- ISO 9000 Quality Management Systems – Fundamentals and Vocabulary
- QFF-014 COP Checklist Guidelines
- QFF-015 -Optional MHB R5.0 Checklist
- QuEST Forum: Guidance for Monitoring CB Auditor Performance

Section 2 – General CB Requirements

The CB must be accredited by a body recognized by the QuEST Forum. The CB's scope of accreditation shall cover the activity being registered (i.e., Hardware, Software, or Services, or any combination). Recognized Accreditation Bodies are listed on the TL 9000 website (<http://tl9000.org>).

For each three-year interval, 100% of the entire scope of the organization being registered and all applicable TL 9000 requirements and measurements shall be audited. The Audit Report shall clearly document the portions of the quality management system that were audited..

The CB audit team shall provide documented findings at the end of each audit. A written report shall be provided to the organization within 30 days of the conclusion of each audit, or within 30 days of the conclusion of a multi-site audit. The report will include the documented findings, overall audit conclusions, significant audit trails and recommendations.

CBs, or bodies related to a CB, that have provided management system consulting services and/or paid private training to a particular client may not conduct certification services for that client, nor may they supply auditors for a period of two years after the services were provided.

Audits shall be performed only by individuals who fulfill the requirements of the Qualification and Experience Requirements for TL 9000 Certification Body Auditors.

The certification decision shall be made by a qualified TL 9000 Lead Auditor with veto authority. The TL 9000 Lead Auditor conducting the assessment cannot be the auditor making the certification decision. The TL 9000 Lead Auditor requirements are defined in Qualification and Experience Requirements for TL 9000 Certification Body Auditors. .

Quality management system consultants to the organization, if present during the audit, are limited to the role of observer.

All major nonconformities shall be resolved prior to the issuance of the TL 9000 certificate. All nonconformities are handled in accordance with the CB's standard operating procedure(s).

CBs are authorized to cite conformance to TL 9000 on ISO 9001 certificates, when they: a) contract with an organization to follow this Code of Practice, and b) are accredited by a QuEST Forum-recognized Accreditation Body to issue TL 9000 certificates.

The CB must have a process to settle disputes over interpretations of the TL 9000 standard.

All CBs shall submit quarterly audit data to QuEST Forum per QFE-016 CB Quarterly Data Submission document. Failure to do so will result in CB suspension as detailed in the CB Quarterly Data Submission document.

Section 3 – Classification of Audit Findings and Resolution

Nonconformity Process

CBs shall have a documented process to close major and minor nonconformities identified in a TL 9000 audit.

The process for closing nonconformities shall include:

1. A Corrective Action Plan (CAP) for each nonconformity shall be received by the CB within 30 days following the Organization's receipt of the audit report. This CAP shall include containment/correction, root cause analysis, and an implementation due date. CBs are required to respond to the proposed CAP in a timely manner. Resolution by the organization of a major nonconformity requires acceptable evidence of implementation of the CAP within the CB's specified timeframe, not to exceed 90 days from the Organization's receipt of the audit report. Resolution by the organization of a minor nonconformity requires acceptable evidence of implementation of the CAP no later than the next scheduled audit. Exceptions to these resolution timeframes shall be approved by the CB, fully justified by the organization and documented. A follow-up visit within the 90-day timeframe will be required for major nonconformities to verify effective implementation of the corrective action unless otherwise justified and documented.
2. A TL 9000 certification shall not be issued until: (a) all major nonconformities are fully resolved; and (b) minor nonconformities are fully resolved or corrective action plans are defined consistent with the above timing requirements.
3. A certified organization shall not receive re-certification if there are overdue minor nonconformities from the previous audit or any unresolved major nonconformities at the time the certificate expires. Failure to meet the deadline for closing a major nonconformity after a surveillance audit shall lead to the withdrawal of the TL 9000 certificate. The certificate may be reinstated on resolution of the nonconformity.

CBs shall have a documented process to ensure that findings raised during audits are being recorded in accordance with the findings definition listed in Section 1. This process shall include an evaluation of the quantity and type of audit findings raised: majors, minors, and opportunities for improvements. The process shall include investigation and, where necessary, performance improvement of individual auditors who consistently misclassify audit findings.

NOTE: See "Guidance for Monitoring Auditor Performance" on the tl9000.org website for additional information on factors to be considered in these evaluations and other guidance.

Examples of Major and Minor Nonconformities:

Major Nonconformities:

- The omission of all aspects of a specific requirement of the Requirements or Measurements Handbooks.
- Systemic failure of the organization to implement and maintain effective internal audit and management review processes.
- Failure to achieve the fundamental aim of a system element. For example, the fundamental aim of calibration is to ensure the measuring equipment conforms to the requirements for its intended use.
- Failure to follow legal/statutory requirements applicable to the product or service.
- Multiple minor non-conformities within the same element of the standard, process or part of the system which when combined represent a breakdown of the organization's systems.
- Where judgment and experience can reasonably demonstrate the likelihood of non-conforming product being shipped or nonconforming service provided resulting from the inability to control processes or as a direct result of a system failure.
- Failure to correct minor nonconformities previously raised by the CB unless evidence is in place showing progress and tracking to an established implementation due date.

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- Consistent submission of data inconsistent with the counting/exclusion rules in the Measurements Handbook or conscious lack of resubmitting previous data when it is known to be inaccurate.

Minor Nonconformities:

- An observed lapse in following a process, procedure or the management system where judgment and experience can demonstrate there is minimal risk to the product being supplied.
- Any failure of the audited system to satisfy the effective implementation of a requirement of the TL 9000 Requirements or Measurements Handbooks, that is not considered to be a major nonconformity.

Section 4 – Consistent Audit Approach Definition and Criteria for Certification Body and Organization

There are three areas requiring consistency by the CB and Organization. Each section below describes the requirements.

Pre-Audit Information

The CB is required to obtain the following information and data from the Organization a minimum of three weeks (or within an agreed timeframe) prior to scheduled audit:

1. List number of people within the registration scope for the site audited.
2. List processes (for example, development, technical assistance center, coding, manufacturing, training, or repair) and applicable Requirement and Measurement Handbooks' requirement elements executed within the scope of registration. For each site to be audited, list the processes executed at the site. Note: An example applicability matrix is available on the tl9000.org website.
3. List Product Categories applicable at the site undergoing audit.
4. List Product(s) under TL 9000 registration by location separated by Hardware, Software and Services **and list all major outsourced entities**, for example, board manufacturing, development, design) and their locations, in support of the Product(s).
5. Provide information on significant organizational changes, acquisitions, outsourcing or significant changes that have occurred since the last audit or registration contract approval.
6. The organization may re-use the last Pre-Audit CB Information Package, but shall clearly highlight what has changed.

The CB is required to undertake the following Pre-Audit Requirements:

1. Obtain the required Pre-Audit CB Information Package within required timeframe.
2. Use the Pre-Audit CB Information Package provided by the Organization in planning the subsequent audit.
3. Pre-Audit CB Information Package is a required record.

NOTE: Organizations who plan their surveillance and recertification audits close to the surveillance and recertification audit deadline are at risk of having their certificates suspended if Pre-Audit CB information package requirements are not met. It is recommended that surveillance and recertification audits be planned well in advance of deadlines.

On-Site Audit Requirements

While on site the CB is required to:

1. Comply with most current version of ISO/IEC 17021 Conformity Assessment-Requirements for Bodies for Providing Audit and Certification of Management Systems.
2. Confirm Pre-Audit CB information Package data is still current.

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3. Review effectiveness of the corrective action system processes to include sampling of corrective actions that are overdue and corrective actions not considered overdue but are still open after nine months.
4. When reviewing documentation requirements ensure that current practice is reflected in the documented procedure and aligns with the applicable TL 9000 release.
5. Review a sampling of customer TL 9000 audit findings and customer satisfaction results since the last CB audit.
6. Follow-up on progress of any relevant formal complaints registered with the CB against the organization.
7. Review root cause of pertinent product recalls to identify processes for additional focus within the audit.
8. Use the process audit approach for TL 9000 Measurements to include collection, validation and submittal in accordance with Section 7 below.
9. For those processes audited, the process review shall include an assessment of the effectiveness of that process.

CB Installation Site Audit Guidance (Applicable to organizations with 7.1.1 and 7.1.4 in their scope)

Upon initial certification and at least once during each 3 year certification cycle the CB shall conduct at least one audit of an active installation site. This audit may be conducted per IAF MD4. All applicable process requirements shall be covered during this allocated time. The organization shall coordinate all necessary arrangements with the customer and the audit team for site access.

During the remaining audit of the 3 year certification cycle when an on-site audit of an active installation is not performed:

- The organization shall have an installer available at the managing location or via phone conference for process auditing purposes.
- The organization shall provide evidence for all applicable installation process requirements that can be substantiated remotely. (e.g. training records, test records, calibration records.)
- If the CB determines that the audit results require an on-site visit of an active installation the organization shall make appropriate arrangements within a reasonable time frame.

Post-Audit Requirements

CB is required to monitor audit reports to ensure conformance with ISO/IEC 17021-1 auditing requirements and include evidence that items in the Code of Practice are addressed and documented in the audit report even if the item is not applicable.

Section 5 – Electronic Audit (e-Audit) Requirements

The CB will follow the guidelines as defined in IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (“CAAT”) for Accredited Certification of Management Systems (IAF MD-4).

Auditor(s) and auditee(s) participating in the e-audit must be fluent in electronic data transferring.

The following areas cannot be audited using e-audit techniques:

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- laboratories
- warehousing-distribution centers
- manufacturing sites
- repair centers

Section 6 – AB Oversight Requirements

AB is required, during any TL 9000 CB oversight audit, to verify that this Code of Practice for TL 9000 Certification Bodies is followed.

ABs are required to verify compliance to the listed documents in the **Associated References** section of the Code of Practice for TL 9000 Certification Bodies.

Section 7 – Responsibilities for Measurement Audits

During the audit each CB has responsibility to verify that all measurement processes are in place and effective to insure the validity of TL 9000 measurements, including definitions and requirements. The information below can be used to help clarify the expectations of the CB Auditor. This guidance is not intended to identify any additional requirements - only clarifications to those that exist in the TL 9000 handbooks. As these are only clarifications, they are not expected to result in a need for additional audit days.

The following CB auditor responsibilities shall be clearly defined:

1. The CBs shall verify that the organization has a documented system in place that covers:
 - a. Measurements collection: Much, if not all, of Measurements Handbook sections 3.5.2 subsections a), c) through j), and the collection/submission portion of b), can be verified prior to going on-site.
 - b. Measurements validation in accordance with Measurements Handbook section 3.5.2. The CB shall audit to the depth necessary to assure effective implementation of TL 9000 requirements (see item 8 below).
 - c. Measurements reporting, in accordance with Requirements Handbook section 5.4.1.C.1 (RHBr5.5) or 6.2.1.C.1 (RHBr6) and Measurements Handbook sections 3.2 subsections a) and b).
2. Ensure the TL 9000 measurements are used internally by the organization per Measurements Handbook section 3.1 Requirements for Measurements Usage. This includes reviews by management, quality/strategic objective setting for continual improvement, result/trend reviews, and corrective action plans for any performance deviating from the organization's defined quality/strategic objectives, in accordance with Requirement Handbook sections 5.4.1.C.1 (RHBr5.5) or 6.2.1.C.1 (RHBr6), 5.6 (RHBr5.5) or 9.3 (RHBr6), 8.5.2 (RHBr5.5) or 10.2 (RHBr6) and Measurement Handbook sections 3.1 first hyphen, 3.5.2 subsections i) and j).
3. If any measurements are identified as "EXEMPT", as defined in Measurements Handbook, sections 3.2 b) and 4.2.8 b), the documented rationale for the exemption shall be reviewed and accepted if valid by the CB auditor. The CB auditor shall ensure this documentation has been available for review if requested by the organization's customers. The claimed exemption(s) also shall be noted on the organization's registration profile.
4. The CB auditor shall verify that measurements are being used in customer/organization relationships, in accordance with Measurement Handbook section 3.1.
5. The CB auditor shall verify that necessary information is being shared by the organization with its suppliers in accordance with the Measurement Handbook section 3.5.2 n) and o).

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6. The CB auditor shall verify that measurements are reported to the TL 9000 Administrator [UTD] in full accordance with the Measurement Handbook sections 3.1 third hyphen, 3.2 subsections a) and b), 3.5.2 subsections b) through h), and 3.5.2 k). This is to include a review of the Data Submission Receipts for:
 - a. "Passed" designation
 - b. "EXEMPT" designations
 - c. Any notes or advisories on the Data Submission Receipts and
 - d. Probations

Additionally, the CB Auditor shall verify the following:

- e. Any claimed exemptions are documented and valid
 - f. All items shown "EXEMPT" on the Data Submission Receipt are in full compliance with the Measurement Handbook and item 3 above
 - g. There is a Data Submission Receipt for every product category listed in the organization's scope and each match the organization's registration options (Hardware, Software, and/or Services) as appropriate to the product category.
7. If current performance shows an undesirable deviation from the organization's defined quality/strategic objectives for TL 9000 Measurements, the CB auditor shall verify that corrective action has/is being taken, is documented, and progress is being tracked, in accordance with Measurements Handbook sections 3.1 a), 3.5.2 subsections i) and j), and 3.5.5 c), and Requirements Handbook section 8.5.2 (RHBr5.5) or 10.2 (RHBr6).
 8. The CB auditor shall verify that measurements collected are consistent with scope of registration, registration option [HSV], and product category, in accordance with Measurements Handbook sections 3.2 subsections a) and b), and 3.5.2 c). This can be done prior to the on-site activities.
 9. CB auditors shall review the actual data submissions, verifying proper implementation of the counting rules for required measurements. This check is to review data consistency covering a minimum one-year period except when the organization and/or new product have been certified for less than one year in which case the data shall be reviewed for at least as long as the organization and/or new product has been certified.

For the initial registration audit, pre-certification data submissions (minimum of 3 consecutive months' data) require verification. This shall be done to fulfill Measurements Handbook requirement 3.3.1 first hyphen and in accordance with sections 3.5.2 subsections a) and b).

10. When an Organization upgrades its registration to a new version of the Measurements Handbook as part of its Surveillance or Re-certification Audit, at least the most recent month's data submission shall use the new version of handbook. CB auditors will verify that all relevant counting rule changes have been properly implemented for the required measurements.
11. While the sample size for the above requirement is left to the CB, it is expected that the depth of assessment for the sampled measurements assures accurate and comprehensive calculation, counting rules, reporting mechanisms, and validation of the measurements. The actual time spent auditing the measurements shall be documented and shall be verified by the technical report reviewer.
12. CB auditors shall confirm that the registration information (for example, scope, product category, and locations) contained in the Registration Management System ("RMS") is current and accurate during each assessment, to support the verification of Measurements Handbook sections 3.4.1 and 3.5.2 c). This can be started prior to the on-site activities.
13. CB auditors shall confirm that the product categories chosen by the organization are correct for their products, in accordance with Measurements Handbook section 3.5.2 c). This can be done prior to the on-site activities.