

# Code of Practice for TL 9000 Registrars

## Release 5.0

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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 9000:2005, item 3.6.6)
- **Corrective action** -- action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000:2005, item 3.6.5)
- **Findings include** –
  1. Major Nonconformity
  2. Minor Nonconformity
  3. Opportunities for Improvement
- **Nonconformity** –
  1. Non-fulfillment of a requirement (ISO 9000:2005, item 3.6.2)
  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.
  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.
- **Guidance on categorizing findings** – All nonconformities shall be classified as major or minor. Mistakes or omissions in the operation of a system are made however rigidly imposed such a system may be. This should be borne in mind when considering raising minor nonconformity reports. However, these should then be considered for reporting as an opportunity for improvement and not just ignored. OFI's should not be written to camouflage a minor nonconformity.

The decision in categorizing nonconformities must be made as it relates to the systemic failure of the system and based on risk, not simply human error. All decisions must be based on sound objective evidence that leads to a clear and precise conclusion based on fact.

### Acronyms

AB = Accreditation Bodies

CAR = Corrective Action Request

CB or CRB = Certification Bodies

ORG = Organization

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

SME = Subject Matter Expert

SP = Service Provider(s)

### Associated Documents/References

ISO 9000:2005 Quality Management Systems – Fundamentals and Vocabulary

IAF Guidance to ISO/IEC Guide 62 (Obsolete 9/15/2008)

QF: AB/CRB Validation Audit Process

IISO/IEC 17021 Conformity Assessment-Requirements for Bodies for Providing Audit and Certification of Management Systems

## **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 (visit 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 show the part of the system that was audited on each surveillance visit.

The CB audit team shall provide documented findings at the end of each audit. A written report on the operation audited will 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 registration services for that client, nor may they supply auditors for a period of two years after the services were provided.

Each member of the CB's team performing audits to TL 9000 requirements shall have satisfactorily completed the TL 9000 auditor courses that have been approved by the QuEST Forum. Also, a majority of those responsible for making certification decisions, or at least one with veto authority, shall satisfactorily complete this training. A certificate will indicate satisfactory completion.

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

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

CBs are authorized to cite conformance to TL 9000 on ISO 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 standard.

## **Section 3:    Classification of Audit Findings and Resolution (Formerly Alert 05-007B)**

### **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. Resolution of the nonconformity including correction, root cause, corrective action and acceptable evidence of implementation within the CB's specified timeframe not to exceed 90 days from the Organization's receipt of documented finding(s) at the end of the audit. Exceptions to this shall be agreed to by the CB, fully justified and documented. In most cases a follow-up visit will be required for major nonconformities to verify effective implementation of the corrective action.
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 registered organization shall not receive re-certification if there are any unresolved major nonconformities or overdue minor nonconformities at the time the certificate expires. Failure to meet the deadline for closing a major nonconformance after a surveillance audit shall lead to the withdrawal of the TL 9000 certificate of an already certified/registered organization. The certificate may be reinstated upon resolution of the nonconformance.

**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.
- Purposeful failure to correct minor nonconformities previously raised by the CB.
- 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**

### **Purpose:**

**1) Organization:** To define the information and data that shall be submitted to CBs by organizations in preparation for an initial certification, surveillance or recertification audit, and to establish specific elements to be reviewed by CBs during those audits.

Data provided to CBs prior to audit is intended to enhance the assessors' knowledge, to plan the audit more effectively, and to help the assessor identify strengths, weaknesses and areas of continual improvement. Where negative indicators or significant changes are presented, the CBs are required to review these areas. The noted areas to be audited may be in addition to the established schedule, or may result in a revision to the audit plan.

**2) Certification Body:** To define the requirements for the CB to comply with to ensure a consistent and comprehensive audit approach.

**Scope:** Certification, Surveillance and Recertification Audits

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**Organization Information:**

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

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.

1. List number of people within the registration scope for the site audited.
2. List processes (e.g., development, technical assistance center, coding, manufacturing, training, or repair) executed within the scope of registration at the site to be audited.
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**, (e.g. board manufacturing, development, design) and their locations, in support of the Product(s). This Sample Matrix may be used.

<b>Location &amp; # of Employees (site audited)</b>	<b>Product Name or Reference</b>	<b>Hardware</b>	<b>Software</b>	<b>Services</b>
Dallas <u>470 employees</u>	1100	Cabinet, NPI, Circuit Boards Development -	IMS - Design, NMS	Installation, Service, Technical Assistance Center
	1200	Design		
Outsourced Entity	3200	Mfg, Board	Design	Installation

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 ORG may re-use the last Pre-Audit CB Information Package, but shall clearly highlight what has changed since then.

**Certification Body Requirements:**

**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.

**On-Site Audit Requirements:**

4. Comply with most current version of ISO 19011 Guidelines for Quality and/or Environmental Systems Auditing.
5. Comply with most current version of ISO/IEC 17021 Conformity Assessment-Requirements for Bodies for Providing Audit and Certification of Management Systems.
6. Confirm Pre-Audit CB information Package data is still current.
7. 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.
8. When reviewing documentation requirements ensure that current practice is reflected in the documented procedure and aligns with the applicable TL 9000 release.
9. Review a sampling of customer TL 9000 audit findings and customer satisfaction results since the last CB audit.
10. Follow-up on progress of any relevant formal complaints registered with the CB against the organization.

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11. Review root cause of pertinent product recalls to identify processes for additional focus within the audit.
12. Process Audit approach for TL 9000 Measurements to include collection, validation and submittal in accordance with Section 6 below.
13. For those processes audited, the process review shall include an assessment of the effectiveness of that process.

### Post-Audit Requirements:

CB is required to monitor audit reports to ensure conformance with ISO 19011 and ISO/IEC 17021 auditing requirements and include evidence that items in this document are addressed and documented in the audit report even if the item is not applicable.

## Section 5: AB Oversight Requirements

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

## Section 6: Responsibilities for Measurement Audits (formerly Alert #03-005A)

During the audit each QuEST Forum CB has responsibility to verify that all Measurement processes are in place and effective to insure the validity of TL 9000 QMS Measurements, including definitions and requirements. A guide/job aid is available that should help clarify the expectations of the CB Auditor. This guidance is not intended to identify any additional requirements - only clarifications to those that exist today 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 4.0 Sections 3.5.2 subsections a, c-j, and the collection/submission portion of b, can be verified prior to going on-site.
  - b. Measurements validation, in accordance with Measurements Handbook 4.0 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 4.0 section 5.4.1.c.1 and Measurements Handbook 4.0 sections 3.2 subsections a and b.
2. Ensure the TL 9000 measurements are used systemically by the organization. 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 Requirements Handbook 4.0 section 8.5.2 and its associated notes and Measurements Handbook 4.0 sections 3.1.a, 3.5.2 subsections i and j.
3. If any measurements are identified as "EXEMPT", as defined in Measurements Handbook 4.0, sections 3.2.b and 4.2.8.b, the documented rationale for the exemption shall be reviewed and accepted as 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 QuEST Forum recommends the claimed exemption also be noted on the organization's registration profile.
4. The CB auditor shall verify that measurements are being used in customer/organization relationship, in accordance with Measurements Handbook 4.0 section 3.1.b.

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5. The CB auditor shall verify that measurements are reported to the Measurements Administrator [UTD] in full accordance with the Measurements Handbook 4.0 sections 3.1.c, 3.2 subsections a and b, 3.5.2 subsections b - g, and 3.5.2.k. This would include a review of the Data Submission Reports for:
  - a. "Passed" designation
  - b. "EXEMPT" designations
  - c. Any notes or advisories on the Data Submission Reports; 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 Report are in full compliance with the Handbook and item 3 above
  - g. There is a Data Submission Report 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..
6. 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 4.0 sections 3.1.a, 3.5.2 subsections i and j, and 3.5.5.c, and Requirements Handbook 4.0 section 8.5.2 and associated notes.
7. 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 4.0 sections 3.2 subsections a and b, and 3.5.2.c. This can be done prior to the on-site activities.
8. CB auditors shall review the actual data submissions, verifying proper implementation of the counting rules for required measurements. This check would also review data consistency covering a minimum one-year period (an exception to this is when a registered organization and/or new product have been registered for less than one year. For this case, data shall be reviewed for at least as long as official submissions have been generated. Also note – the only other exception is for the initial registration audit. For this case, only the single pre-registration data submission needs to be verified). This shall be done to fulfill Measurements Handbook 4.0 requirement 3.3.1.a and in accordance with sections 3.5.2 subsections a and b.

While the sample size for the above requirement is left up to the auditing organization, 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.
9. CB auditors shall confirm that the registration information (i.e. scope and product category) contained in the RMS is current and accurate during each assessment, to support the verification of Measurements Handbook 4.0 sections 3.4.1 and 3.5.2.c. This can be started prior to the on-site activities.
10. CB auditors shall confirm that the product categories chosen by the organization are correct for their products, in accordance with Measurements Handbook 4.0 section 3.5.2.c. This can be done prior to the on-site activities.