



TL 9000 Informational Alert

1. Originating Workgroup: Workgroup: Oversight Work Group Contact: Tom Yohe (thomas.f.yohe@alcatel.com)	2. Alert Number: 05-007A
3. Documentation Affected: Not Applicable	4. Issue Date: 2006/02/01
5. Reason for Alert: The QuEST Forum has found there to be significant differences between Certification Bodies (CB's) in the classification of audit findings and the process for handling any non-conformities resolution process. The attached "TL 9000 Nonconformity Process" document has been developed to foster more consistency across the TL 9000 CB's and to improve the TL 9000 audit process overall.	
6. Description: The attached definitions and Nonconformity process are to be used by all CB's when conducting a TL 9000 audit. This document becomes effective as of the issue date noted above and should be applied to all audits conducted after that date. It is not the QuEST Forum's expectation that CB's should reclassify nonconformities identified in completed TL 9000 audits. The attached should be used for all audits in process as of the date of issue.	
7. Comments: Document attached.	



TL 9000 Finding Classifications and Nonconformity Process

TL 9000 Audits

The intent of an assessment is to verify conformance with the TL 9000 Requirements and Measurements Handbooks. The outcome of an assessment will be either reported conformance or nonconformance, which may be supported by opportunities for improvement. Any failure to meet a requirement shall be considered a nonconformance.

References

ISO 9000:2000
IAF Guidance to ISO/IEC Guide 62
ISO 17021 (when released)

Definitions

Correction –

- action to eliminate a detected nonconformity (ISO 9000:2000, item 3.6.6)

Corrective action --

- action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000:2000, item 3.6.5)

Nonconformity –

- non-fulfillment of a requirement (ISO 9000:2000, item 3.6.2)
- 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 –

- The absence of, or the failure to implement and maintain, all aspects of one or more requirements for certification/registration.
- A number of minor nonconformities against one or more requirements, which when combined, can represent a breakdown of the organization's systems; or
- 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.

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.



TL 9000 Finding Classifications and Nonconformity Process

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 date of the final audit report. 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:
 - all major nonconformities are fully resolved
 - 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 revocation 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.