

Validation Audit Process Definition and Criteria

[See Revision History at end of document](#)

[Rev 1 January 14, 2010](#)

[Rev 2 October 26, 2010](#)

[Rev 3 May 26, 2011](#)

[Rev 4 January 12, 2012](#)

Project Purpose: Twenty-three one-day audits, each conducted by two independent auditors, used to assure and confirm the integrity of the TL 9000 3rd party certification process. The purpose of the validation audit is to gather data to assess the effectiveness of the certification process. Based on the analysis of the data from this project, further actions may be proposed by the QuEST Forum Oversight Workgroup (“OSWG”). Participation in the one-time project is a requirement to maintain TL 9000 certification.

Project Duration: The validation audit process is a one-time project which concludes when the sample of ~~23~~12 audits is completed and the results are submitted to Validation Audit Project Management Office (“VAPMO”) for analysis by the QuEST Forum AB/CB Subteam. The sample shall be completed within a two-year timeframe.

TL 9000 3rd Party Certification Process Definition: Written assurance provided by an accredited CB (“Certification Body”) that audits an organization’s management system and verifies that it conforms to the requirements of the TL 9000 standard. Conformance to the TL 9000 Standard is the responsibility of the organization. TL 9000 conformance is verified through audits and is the responsibility of the CB with oversight by the AB (“Accreditation Body”). QuEST Forum is responsible for governance of the 3rd party certification process.

Validation Audit Definition: An audit of the organization’s quality management system to confirm there are no Major nonconformities in the required elements (as found in Section 4 of the Code of Practice for TL 9000 Registrars) that could question the integrity of the 3rd party certification process. The audit will be conducted by the CB’s AB.

Preliminary Results: Minor nonconformities will not be reported by the Validation Audit team. If a Major(s) nonconformity(ies) is(are) identified, it will be documented in the validation audit report and the AB will initiate an investigation to determine whether there was a breakdown in the 3rd party certification process.

Applicable Documents:

ISO/IEC 17021 Conformity assessment – Requirements for bodies providing audit and certification of management systems

ISO 19011 Guidelines for quality and/or environmental management systems auditing

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TL 9000 Quality Management System Requirements Handbook
TL 9000 Quality Management System Measurements Handbook
Code of Practice for TL 9000 Registrars
TL 9000 Certification Validation Audit Report
TL 9000 Certification Validation Audit Process Sampling Plan
Validation Audit Process Flowchart

Cost Structure:

1. The validation audits will be paid by a flat fee estimated at \$150 US dollars per certified TL 9000 registration.
2. The organization will be invoiced separately by each certified TL 9000 registration.
3. An organization with more than one certified TL 9000 registration may make a single payment covering all of its invoices.
4. Payment is due within 60 days upon receipt of invoice. Organization non-payment may result in a TL 9000 certification suspension until the payment is received.
5. The flat fee covers the AB's costs of audit time, travel expenses and local translator fees if applicable.
6. The flat fee covers the QF TL 9000 expert's travel expenses. The QF TL 9000 expert will not charge a daily rate for audit observation time.
7. QF will bill and collect the fee directly from the certified organizations.
8. The QF will manage reimbursement to the ABs and QF TL 9000 expert.

Rating System:

1. Acceptable Certification
2. Unacceptable Certification - a condition where a certification would be invalid, for example, undocumented systemic issue found or resolution timeframe for Major nonconformities exceeded.

Validation Audit Project Planning and Implementation Process:

Validation Audit Project Management Office (aka "VAPMO") is a sub-team defined by the QuEST Forum Oversight Workgroup.

1. VAPMO sub-team members are required to sign Non-Disclosure Agreements maintained by QuEST Forum.
2. Proposes schedule based on Sampling Plan defined below and abides by established rules outlined in this process. Assigns an audit number to the schedule. Updates schedule as informed by the AB. The sample shall be completed within a two-year timeframe.
3. Confirms that the sample site is appropriate based on AB's review of the Pre-Audit Information Package obtained from the CB by the AB. [Note: VAPMO

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obtains from AB the selected sites in advance to schedule the QFO as the QFO availability is limited. Org name is not provided until QFO commitment is received.]

4. Assigns a QF TL 9000 expert to observe the AB conducting the audit. Each AB will be observed once unless the results require another audit to be observed. The QF Observer will observe the two AB auditors conducting the validation audit to ensure the AB is complying with the Validation Audit process. The QF Observer is selected from the QuEST Forum database based on location and relationship to organization. An attempt will be made to have the first audit conducted by each AB observed by a QF Observer.
5. Upon notification from AB of the confirmed Validation Audit date, will provide the name of the ~~confirms organization's approval of selected~~ QF observer to the AB for communication of same to the organization. Observer information to include name of observer's company. Note: Organization makes the final decision on QF TL 9000 expert observer participant.
 - a. Back-up observers are arranged.
 - b. If an observer cannot be agreed upon, the audit is still conducted without an observer. The next sample validation audit selected for that AB will include an observer.
6. Obtains organization's Non-Disclosure Agreement ("NDA") form for completion by auditor and observer if applicable.
7. Obtains and maintains NDAs required of auditors and QF observer. Provides copies of the signed NDAs to the organization prior to the Validation Audit. **No information about the observed company's process, compliance or audit results may be divulged.**
8. Consolidates validation audit results for reporting to AB/CRB and OSWG on a quarterly basis. **Maintains anonymity of audited organizations in generated reports.**
9. **At the end of the sampling process, summarizes and reports TL 9000 elements associated with Major nonconformities to AB/CRB and OSWG.**
10. **Should an AB auditor not make the audit, the audit will take place with one AB auditor in one audit day. In this situation, a full validation audit may not be feasible.**

AB Responsibilities:

AB must:

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- conform to Guidelines for Quality and/or Environmental Management Systems Auditing ISO 19011
- comply with the Validation Audit Process otherwise their QuEST Forum recognition will be revoked.

A. Pre-Validation Audit Requirements:

1. Auditor qualification for the ABs is TIEA (“Telecommunications Industry Experienced Auditor”) or TL 9000 Lead Auditor.
2. Obtain Pre-Audit CB Information Package from the CB as specified in the Code of Practice. Verify information package submittal.
3. Obtain CB’s Audit Plan/Schedule associated with the Pre-Audit CB Information Package.
4. Verify appropriate elements were planned for and assessed based on Pre-Audit CB Information Package.
5. Notifies and coordinates schedule with Organization.
6. Notifies the organization’s Primary and Alternate Registration Administrators and CB thirty days prior to the Validation Audit [Note: Where international flight arrangement are required, a 60-day notification is permitted to allow for scheduling]. An additional two weeks is allowed to accommodate site shutdowns, management representative unavailability or for a previously scheduled third-party assessment. The site will be discarded if the audit cannot be scheduled within the prescribed timeframe, and VAPMO will move to the next sample on the list.
7. Informs VAPMO of confirmed Validation Audit date.
- ~~7-8.~~ When required, obtains Organization approval of QFO.
- ~~8-9.~~ Obtain and review progress of any relevant formal complaints registered with the CB against the organization.

Note: The foregoing is to provide the AB w/baseline information prior to coming on site.

B. On-Site Validation Audit Requirements:

Note: All records sampled shall be from the most recent twelve (12) month period. Organization shall be audited to its TL 9000 Certificate scope. Organizations may have its CB present as observers during the Validation Audit.

1. Review the last CB assessment for those organizational changes that may have impacted the QMS. Determine whether organizational changes had been appropriately evaluated, including organization’s and CB’s due diligence in proactively reviewing and addressing any changes impacting QMS. For informational purposes, identify any changes that occurred since the CB assessment. (Example, merger, acquisition, downsizing, etc.)
2. Evaluate the effectiveness of Corrective Action System. In the review, include a sample of corrective actions that are overdue or still open after nine months.

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3. Review the status of any nonconformities from previous CB assessment(s).
4. Evaluate effectiveness of Internal Quality Audit Program/System.
5. Review a sample of customer TL 9000 audit findings (2nd party audit) to ensure actions were taken and effectively implemented.
6. Review the effectiveness of the organization's use of customer satisfaction results.
7. Evaluate the effectiveness of Management Review and performance against established quality objectives.
8. Ensure that current practices within scope of the Validation Audit are accurately reflected in the documented procedures and align with the current TL 9000 release.
- 9-10. Evaluate the TL 9000 measurements system as appropriate to the site.

C. Process for Majors Found:

1. Should it be determined that one or more of the foregoing elements result in a Major, an immediate investigation shall be performed to attempt to determine the starting timeframe of the Major and gather historical evidence in the appropriate medium, i.e. e-copy or hardcopy objective evidence.

D. What is communicated to the organization?

1. AB informs organization of audit results.
2. Should audit results include a Major, AB informs organization of details gathered surrounding the Major/systemic finding and advises them that the certification will not be automatically withdrawn based on the Validation Audit.
3. AB informs the organization that the CB will contact the organization within 30 days from the Validation Audit date to determine required actions, including, but not limited to, executing CB's process for addressing Majors.
4. AB informs organization that if the issue is not addressed appropriately as outlined in the Code of Practice, the certification would be at risk.

Post-Validation Audit Requirements:

E. Reporting:

1. ABs are required to complete the TL 9000 Certification Validation Audit Report. A draft copy of the validation audit report is provided to the Organization before leaving the site and emailed to CB. The validation audit report documents what was communicated to the organization regarding audit results and next steps.
2. The final validation audit report includes the completion of Section 5 of the Validation Audit Report and is provided by the AB to the CB within 15 calendar days.

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3. ABs attend Validation Audit Project Management Office quarterly meeting providing general report with resolution status. General report includes status of validation audits and results of completed audits.
4. All results, excluding individual's names, are to be shared with Validation Audit Project Management Office.

F. Course of Action for Unacceptable CB Assessment:

1. Should root cause analysis determine CB is not conforming, CB is issued a nonconformance by AB office, with report to VAPMO.
2. CB is required to provide an action plan within 30 days for approval by AB and implement effective corrective action within 90 days.
3. AB and CB will coordinate effective corrective action activities through closure.
4. AB verifies corrective action is implemented and effective.
5. If corrective action is ineffective, or not implemented, CB's TL 9000 accreditation is suspended. Recertifications within the suspension period are allowed, but no new certifications are allowed.
6. Suspensions must be rectified within six (6) months.
7. If the conditions for suspension are not satisfied, the CB's TL 9000 accreditation is revoked.
8. ABs will update CB status on QF website. For suspensions, No pro-active communication by the AB to the CB's clients or to the QF community at large is allowed.
9. ABs must have an appeal process for CBs to use.
10. CBs can submit a complaint to QF regarding AB decision, following the appeal process.

Sampling Process:

1. Hypothesis: CB's processes are identifying issues and documenting same.
2. Sample: Random site sample is stratified by country. CBs may be reaudited but there will be no duplication of an individual auditor or organization. VAPMO will exclude sites from the sample that are not appropriate such as offsite warehouses or where site activities do not address Section 4 "Audit Detail" as listed in TL 9000 Certification Validation Audit Report. Note: Should AB determine upon review of Pre-Audit CB Information Package that the site is not appropriate for the Validation Audit, the AB will contact VAPMO for selection of another site and cancels audit. When a site is excluded a new site from the same region is randomly selected.
3. Sampling plan attached.
4. Selection of site sampling is pulled from the sites listed on the QuEST Forum website.
5. Validation Audit Project Management Office ("VAPMO") Established –At a defined time have Statistical SME to send #s to the VAPMO and TL 9000 Administrator would send the listing to VAPMO. VAPMO will consolidate site

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with random # selection. The selected #s are completed independently from the numbered list of certificates by site.

6. AB will maintain site validation schedule along with confidentiality of schedule and communicate to VAPMO. The random back-up sampling schedule will be used to prevent duplication of auditors being audited.
7. The sampling plan must be completed in its entirety before final recommendations are proposed.

Revision History

Rev 2 incorporates (October 26, 2010):

May 27-28, 2010 AB Training – Corrected course action for notification regarding CB status. Notification is limited to suspensions on QF website. (*Course of Action for Unacceptable CB #8*)

May 27-28, 2010 AB Training – Under VAPMO Responsibilities added following note: [Note: VAPMO obtains from AB the selected sites in advance to schedule the QFO as the QFO availability is limited. Org name is not provided until QFO commitment is received.]

October 26, 2010 VAPMO Subteam Meeting re International Timing: Under AB Pre-Validation Requirements included following note: [Note: Where international flight arrangement are required, a 60-day notification is permitted to allow for scheduling].

May 26, 2011 amended to indicate it is AB's responsibility to obtain the Organization's approval of a QuEST Forum Observer when required. This was originally VAPMO's responsibility.

January 12, 2012 amended to reflect the sample size for the Validation Audits is now 12. It was 23.