

Validation Audit
Frequently Asked Questions
June 23, 2010

Validation Audit FAQs dated November 5, 2009	Responses
Is there quantitative data to justify this effort?	No. There have been documented Service Provider complaints to Accreditation Bodies, based on supplier audits. In addition, there have been comments (relative to both ISO & TL) that there are bought certificates. The intention of the Validation Audit is to gather data to provide the QuEST Forum 90% confidence that at least 90% of the certificates are valid based on the sampling plan. While this effort came about due to the comments, the QuEST Forum realizes that oversight of the third-party process is needed and data must be gathered to determine what, if any, improvements are needed. The data will provide objective evidence relative to the integrity of the 3rd-party process.
Why not implement witness audits?	Witness audits were considered, but it was decided by consensus that this was not the approach to take. The decision was based on the fact that when a CB would be observed, their performance would be at their best. In addition, witness audits would be significantly more costly to support. Witness audits do not provide the detailed data the Validation Audit Process will provide.
The Validation Audit documents states that the validation audits will be paid by a flat fee estimated at \$150 US dollars per certified TL 9000 registration. What does TL 9000 registration mean?	Each individual TL ID/Profile is a TL registration. For example if your company has 5 TL IDs/Profiles then you will be charged 5 x \$150 = \$750 US dollars.
What are other industries doing for oversight?	Aerospace conducts witness audits. The IAF has proposed several actions to improve ISO oversight including Validation Audits.
How many of these audits will take place?	23 audits will complete the project which is a statistically-based number based on the number of sites.
Who is conducting the audit?	The Accreditation Bodies are conducting the audits.
What is audited during the Validation Audit?	The foundational elements of a Quality Management System. Please reference the Validation Audit Report at [link] .
Will the results of the Validation Audit be published?	All results, excluding individual's names, are to be shared with Validation Audit Project Management Office. Please reference the Validation Audit Process Definition and Criteria document at [link] . Only summary results without company details will be submitted to OSWG. OSWG will communicate the results and any further recommendations to QF Members.
Is this a one-time process?	Yes. The results of the entire sample will be analyzed at the conclusion. OSWG will then determine if any other actions are needed.
Is the sample based on certificates or sites?	The sample is based on sites.

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Is it possible that a CB may be audited more than once?	Yes.
Is it possible for the same CB auditor to be audited more than once?	No.
What is the purpose of a QuEST Forum Observer	The QuEST Forum expert will observe how the AB conducts this one-time Validation Audit Process to verify that the process is followed per the QuEST Forum intent.
Why does the AB need to be observed?	QuEST Forum wants assurance that the AB is executing the Validation Audit Process accurately.
What happens if the organization determines that the QF Observer will create a conflict of interest?	VAPMO will attempt to arrange an organizational acceptable QF Observer. If the organization does not accept any proposed QF Observers, the audit moves forward without a QF Observer.
Is it possible that an AB will be observed more than once?	Yes. If the QuEST Forum QFO determines that the AB's execution is not satisfactory, a second audit will be observed after additional AB training to ensure compliance to the Validation Audit Process.
What happens if a CB audit is scheduled at the same time?	VAPMO has a two week window to schedule the Validation Audit. It could be scheduled before or after the CB audit.
What happens if an AB refuses to participate in the Validation Audit Process?	The AB's recognition is subject to revocation.
What happens if the Organization refuses to participate in the Validation Audit Process?	If the rationale for refusal is not acceptable to the VAPMO per the exceptions noted in the process, the Organization's certification is subject to suspension and/or revocation.
What happens if the Organization is late in paying the one-time fee?	The QuEST Forum directs the CB to suspend the Organization's certificate and if not resolved, the certificate will be revoked.
What happens if the Organization does not pay the one-time required fee?	The QuEST Forum directs the CB to revoke the Organization's certificate.
When an additional site is selected due to conflicts, does this result in a skewed sample?	No. The statistical process employed is designed to accommodate sites that are excluded.
What happens if there is another audit, e.g., ISO 14001 scheduled at a selected site?	There is a two-week window to schedule the audit with the organization. If per the exceptions noted in the Validation Audit Project Process document the VA cannot be scheduled within the two-week window, the site will be discarded and VAPMO will move to the next sample on the list.
Is a site audit schedule negotiable to accommodate business impact?	There is a two-week window to schedule the audit with the organization. If per the exceptions noted in the Validation Audit Project Process document the VA cannot be scheduled within the two-week window, the site will be discarded and VAPMO will move to the next sample on the list.
Is there a way to be sure that all CBs are audited?	The sample is stratified by country and based on sites, it is not based on CBs. Therefore, not all CBs will be audited in the 23 site sample.

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Can a CB be present during the Validation Audit?	If requested by the Organization, the CB may be present as an observer.
Can an AB prevent a CB from being present for a VA?	No.
If a CB asks to be present, does the organization have to pay them?	CBs would only be present if the Organization invited them. Any payment would be up to the Organization and CB.
Can a CB bill an organization for preparing data for the AB?	The CB is required to provide the AB with the Pre-Audit Information Package. There is no charge associated with the CB providing this record.
Will the ABs and QF Observer be trained?	Yes.
What is the QF Observer and what do they do?	QF TL 9000 expert who observes 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.
How do we ensure independence of the AB auditors if they are doing a validation audit on their CB?	The QF Observer is in place to ensure the VA process is executed as defined. The audit is not of the CB but of an organization to determine if the third-party process is working and whether they have a valid certificate in place.
To ensure independence of validation audit, why don't you select a different AB from the CB's AB?	The same CB's AB is conducting the audit to leverage the existing infrastructure for corrective action to address any unacceptable certificates.
How do you ensure the QFO is knowledgeable with the requirements of ISO/IEC 17021 and ISO 19011 to appreciate the the roles and responsibilities of ABs and CBs?	QFOs were selected based on their knowledge and independence by the VAPMO subteam. They also attend the VA training and must pass the VA Exam.
My company is a QuEST Forum member. Do we have to pay the \$150 fee?	The fee is NOT based on membership, but on TL 9000 registrations. The fee is an allocation of the expected costs of the Validation Audit Project among those registrations, regardless of membership status.