

Validation Audit  
Frequently Asked Questions  
Final

Validation Audit FAQs	Responses
Were there quantitative data to justify this effort?	No. There were documented Service Provider complaints to Accreditation Bodies, based on supplier audits. In addition, there were comments (relative to both ISO & TL) that there were bought certificates. The intention of the Validation Audit was 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 realized that additional oversight of the third-party process was needed and data was gathered to determine what, if any, improvements were needed. The data provided objective evidence relative to the integrity of the 3rd-party process.
Why weren't witness audits implemented?	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 have been significantly more costly to support. Witness audits do not provide the detailed data the Validation Audit Process provided.
What have other industries done for oversight?	Aerospace conducts witness audits. The IAF has proposed several actions to improve ISO oversight including Validation Audits.
How many of these audits took place?	12 audits were completed during the project, which is a statistically-based number based on the number of sites.
Who is conducted the audits?	The Accreditation Bodies conducted the audits.
What was audited during the Validation Audits?	The foundational elements of a Quality Management System. Items that would be covered during any audit, certification, surveillance, or re-certification.
Were the results of the Validation Audits published?	All results, excluding individual's names, were shared with Validation Audit Project Management Office. Only summary results without company details were submitted to OSWG. OSWG communicated the results along with further recommendations to the QuEST Forum membership.
Was this a one-time process?	Yes. The results of the entire sample were analyzed at the conclusion. OSWG then determined other needed actions.
Was the sample based on certificates or sites?	The sample was based on sites.
Was it possible that a CB was audited more than once?	Yes.
Was it possible for the same CB auditor to be audited more than once?	No.
What was the purpose of a QuEST Forum Observer	The QuEST Forum expert observed how the AB conducted this one-time Validation Audit Process to verify that the process was followed per the QuEST Forum intent.
Why did the AB need to be observed?	QuEST Forum wanted assurance that the AB is executed the Validation Audit Process accurately.

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What happened if the organization determined that the QF Observer created a conflict of interest?	VAPMO attempted to arrange an organizational acceptable QF Observer. If the organization did not accept any proposed QF Observers, the audit moved forward without an QF Observer.
Was it possible that an AB was observed more than once?	Yes. If the QuEST Forum QFO determined that the AB's execution was not satisfactory, a second audit was observed after additional AB training to ensure compliance to the Validation Audit Process.
What happened if a CB audit was scheduled at the same time?	VAPMO has a two week window to schedule the Validation Audit. It would be scheduled before or after the CB audit.
What happened if an AB refused to participate in the Validation Audit Process?	The AB's recognition was subject to revocation. No AB refused to participate
What happened if the Organization refused to participate in the Validation Audit Process?	If the rationale for refusal was not acceptable to the VAPMO per the exceptions noted in the process, the Organization's certification was subject to suspension and/or revocation. This did not occur during the program.
What happened if the Organization was late in paying the one-time fee?	The QuEST Forum would have directed the CB to suspend the Organization's certificate and if it was not resolved, the certificate would have been revoked. This did not happen.
What happened if the Organization did not pay the one-time required fee?	The QuEST Forum would have directed the CB to revoke the Organization's certificate. This did not happen.
When an additional site was selected due to conflicts, did this result in a skewed sample?	No. The statistical process employed was designed to accommodate sites that are excluded.
What happened if there is another audit, e.g., ISO 14001 scheduled at a selected site?	There was 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 could be scheduled within the two-week window, the site was discarded and VAPMO moved to the next sample on the list.
Was a site audit schedule negotiable to accommodate business impact?	There was 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 could not be scheduled within the two-week window, the site was discarded and VAPMO moved to the next sample on the list.
Was there a way to be sure that all CBs were audited?	The sample was stratified by country and based on sites, it was not based on CBs. Therefore, not all CBs were audited in the 12 site sample.
Could a CB be present during the Validation Audit?	If requested by the Organization, the CB could be present as an observer.
Could an AB prevent a CB from being present for a VA?	No.
If a CB asked to be present, did the organization have to pay them?	CBs could only be present if the Organization invited them. Any payment was up to the Organization and CB.
Could a CB bill an organization for preparing data for the AB?	The CB was required to provide the AB with the Pre-Audit Information Package. There was no charge associated with the CB providing this record.

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Were the ABs and QF Observer be trained?	Yes.
What was the QF Observer and what did they do?	The QF Observer was a QF TL 9000 expert who observed the AB conducting the audit. Each AB was observed once unless the results required another audit to be observed. The QF Observer observed the two AB auditors conducting the validation audit to ensure the AB complied with the Validation Audit process. The QF Observer was selected from the QuEST Forum database based on location and relationship to the organization. An attempt was made to have the first audit conducted by each AB observed by a QF Observer.
How was the independence of the AB auditors ensured if they are doing a validation audit on their CB?	The QF Observer was in place to ensure the VA process was executed as defined. The audit was not of the CB but of an organization to determine if the third-party process was working and whether they had a valid certificate in place.
To ensure independence of validation audit, why wasn't a different AB from the CB's AB selected?	The same CB's AB conducted the audit to leverage the existing infrastructure for corrective action to address any unacceptable certificates.
How was it ensured that the QFO was knowledgeable with the requirements of ISO/IEC 17021 and ISO 19011 to appreciate the and responsibilities of ABs and CBs?	QFOs were selected based on their knowledge and independence by the VAPMO sub-team. They also attended the VA training and passed the VA Exam.
How was this project paid for?	There was a US\$150 fee applied to all TL 9000 certified organizations. This paid for all travel expenses for the AB assessors and QF Observers.