

TL 9000 Informational Alert

1. Originating Workgroup:	2. Alert Number:
Workgroup: Oversight Contact: contact@questforum.org	16-003A
3. Documentation Affected:	4. Issue Date:
 QFP-034 3rd Party Effectiveness Verification Program TL 9000 Accreditation Body Implementation Requirements 	February 12, 2016

5. Reason for Alert:

To announce the release and implementation of a new QuEST Forum process document QFP-034 3rd Party Effectiveness Verification

6. Description:

To further improve the oversight and effectiveness of the TL 9000 third party certification process, QuEST Forum has developed a new program for assessment of the process. This document, QFP-034 "3rd Party Effectiveness Verification", contains three primary areas:

- Documentation of the existing quarterly data to be reported by all TL 9000 Certification Bodies
- A new set of data to be reported quarterly by all TL 9000 Accreditation Bodies
- A new process requiring certain actions by the Accreditation Body when Certifications Bodies quarterly data shows a consistent level of audit findings per audit day significantly lower than the overall average.

Implementation of the new process document has been added to the "TL 9000 Accreditation Body Implementation Requirements" document.

Both documents became effective January 1, 2016.

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See below:



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The first group of Certification Bodies for which action is needed under the new process have been identified. To allow those Accreditation Bodies that have not been actively involved in the development of the new process time to study the new document, those names will not be forwarded to the Accreditation Bodies for at least two weeks after distribution of this Alert. Once forwarded, the first feedback defined by this process will be required from the AB within 30 days.

A data system is being developed for the collection of the new quarterly Accreditation Body data. More information on the use of the system will be provided when it is available. It is anticipated the first set of data to be submitted will be for the first calendar quarter of this year 2016 and will be required to be submitted within 7 weeks of the end of the quarter.

For convenience, QFP-034 is included below.

Document Title: Third Party Effectiveness Verification Program	Document Number: QFP-034
Owner: AB Approval Board	Version: 1
Approved by: Oversight Work Group	Effective Date: 2016-01-01

1. Purpose

This program is data driven to determine that the accredited TL 9000 certification process is in place, effective and consistently applied globally. The accredited third party certification process depends on organizations implementing the requirements and measurements of TL 9000 properly and effectively to demonstrate conformance to a QuEST Forum authorized accredited certification body during initial, surveillance and recertification audits. Accreditation Bodies and Certification Bodies are also required to effectively operate a system in conformance to QuEST Forum requirements. Accreditation bodies are to demonstrate conformance to QuEST Forum. Each certification body is to demonstrate conformance to its Accreditation Body, which is approved by the QuEST Forum.

Listings of the QuEST Forum approved Accreditation Bodies and accredited Certification Bodies may be found on the web site tl9000.org under resources. http://www.tl9000.org/abcb/cb.html

2. Definitions

- AB Approval Board Team of QuEST Forum member individuals with no conflict of interest and with an
 executed confidentiality agreement with respect to CB performance on file with QuEST Forum, responsible for
 review, recognition and re-review of accreditation bodies in the QuEST Forum TL 9000 program as well as
 responsibilities within this process.
- CB Certification Body
- AB Accreditation Body
- OSWG QuEST Forum Oversight Work Group
- UTD University of Texas at Dallas
- Trigger 1 An approved value based on a particular measurement that when reached drives an AB to perform an AB investigation (e.g. assessment) of a CB's TL 9000 activities
- Trigger 2 An approved value based on a particular measurement that when reached drives an AB to:
 - Perform an investigation (e.g. assessment) of a CB's TL 9000 activities,
 - o Perform a market surveillance of a CB's TL 9000 certified organization

3. Responsibilities

- <u>UTD</u> Responsible for capturing data, generating scorecards, and providing trigger notifications
- <u>CB</u> Responsible for collecting and submitting data required to UTD for scorecard generation
- <u>AB</u> Responsible for:
 - Collecting and submitting data required to UTD for scorecard generation
 - Performing CB investigations at the direction of the QuEST Forum
 - Performing Market Surveillance at the direction of the QuEST Forum
- AB Approval Board Responsible for:
 - Setting scorecard triggers for OSWG approval
 - o Notifying ABs for required actions to be taken when scorecard triggers are reached
 - Approving Market Surveillance Audit plans
 - o Evaluating corrective action plans as a result of AB investigations or Market Surveillance
- OSWG Responsible for:
 - Approving this process
 - Approving scorecard triggers
 - Appointing the AB Approval Board, to ensure confidentiality and avoid conflict of interest

4. General Process Description

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The basic concept of this evaluation process is to collect data from both accreditation and certification bodies that indicates the effectiveness of the accredited third party certification system with respect to TL 9000 (see the data items to be collected below). QuEST Forum will aggregate that data and develop normative performance values for each measurement criterion. Once that normative performance value is known, trigger values to indicate deviation from the norm and drive performance improvement activities are established. Those trigger values will be developed by the AB Approval Board and presented to the OSWG for approval. See Figure 1 for a flow chart of the process.

Two trigger values of increasing severity are established.

- Trigger value 1 (least severe) drives a request that the appropriate AB perform an investigation of the identified CB and report back Root Cause Analysis, related actions and timeframes for completion by the CB. (See accreditation body investigation below)
- Trigger value 2 (greater severity) indicates a much larger deviation from the norm and will not only require an AB investigation, but also a market surveillance by the AB of an organization certified by the CB to further analyze the performance of the CB. (See market surveillance below). Should the AB determine during the investigation that Market Surveillance is not appropriate, it may propose an exception to QuEST. Such requests must be submitted with the specified 30-day time frame.

4.1 Accreditation Body Investigation

Each QuEST Forum approved AB must conform with international standard ISO/IEC 17011, be a member of the International Accreditation Forum (IAF) and as such respond to complaints of interested parties (QuEST). The methods of resolving complaints or concerns must be part of the documented systems within the AB. Since QuEST has confidence in the requirements of the IAF and ISO/IEC 17011, we have confidence that the internal processes of each AB will suffice for any QuEST forum requested investigation. The AB shall report back to the QuEST Forum with results of its investigation within 60 days of notification by QuEST Forum of Trigger 1 being reached. The AB Approval Board must approve any extension to this timeframe within 30 days of notification.

3/1/16 Trigger 1 4/5/16 5/10/16 Reached by CB Window for Time **AB Approval Board Reviews Extension Expires Investigation Report & Takes** Any Required Actions 3/7/16 - 4/29/16 AB Performs Investigation 4/1/16 5/1/16 3/5/16 5/5/16 **AB Approval Board Notifies AB Reports Submits** AB to perform investigation **Investigation Report** To QuEST

Trigger 1 – Example timeline

4.2 Accreditation Body Market Surveillance - IAF Informative Document (ID) 4

There have been growing concerns in recent years about the effectiveness of the third party certification methodology in ensuring that expected outcomes from management system certification are being achieved consistently around the globe. As a result of work carried out by the ISO 9000 Advisory Group (IAG) and the IAF Technical Committee, the Page 2 of 6

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philosophy "Output Matters!" has become widely recognized and forms a core element of the Strategic ISO/IAF "Action Plan to monitor and improve the effectiveness of Accredited Management System Certification".

Consistent with this philosophy, one of the specific actions in the ISO/IAF Action Plan (Item 3.3) was "Development of criteria for the performance of 'Market Surveillance visits' " by the ABs at the certified organizations to check the effectiveness of the management system. A methodology for conducting such visits was developed within IAF ID-4. The IAF informative document provides direction on how short market surveillance visits might be used by ABs or others in order to complement traditional oversight techniques.

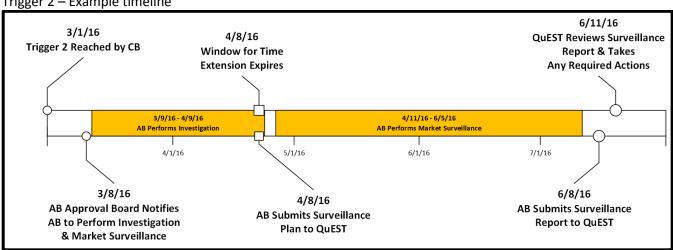
This procedure requires ABs to perform market surveillance on each CB that reaches scorecard Trigger level 2.

Once Trigger 2 is reached, the relevant AB will be directed by the AB Approval Board to use IAF ID-4 as a basis for the market surveillance with the addition of certain TL 9000 specific requirements:

- Conformance with the QuEST Forum Code of Practice
- Any additional requirements issued by the AB Approval Board team based on a specific concern

The selection of the organization to be assessed for the market surveillance and the duration of the assessment Approval Board for approval within 30 days of notification that Trigger 2 is reached. Any information that could identify the organization being assessed shall be omitted from the plan.

The AB shall report back to the QuEST Forum with results of their Market Surveillance within 90 days of notification by QuEST Forum of Trigger 2 being reached. The AB Approval Team must approve any extension to these timeframes within 30 days of notification that Trigger 2 has been reached.



Trigger 2 – Example timeline

4.3 Required Data to be collected and reported by Certification Bodies (may be modified periodically) **Quarterly Basis**

- Number of Surveillance Audits
- Number of Certification / Re-certification Audits
- Number of certificates issued
- Number of major non-conformities
- Number of minor non-conformities

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- Number of OFIs
- Number of Audit Days by Certification/Re-certification/Surveillance
- Minimum number of audit days per Certification/Re-certification/Surveillance

4.4 Required data to be collected and reported by Accreditation Bodies (may be modified periodically) Quarterly Basis

(Each AB will submit data on each CB it accredits individually)

- Total number of NC against CB by AB (Major vs. Minor)
- # NC issued to CB Soft Grading
- # NC issued to CB Audit Report Technical Review Effectiveness
- # NC issued to CB Appropriate Time spent on Measurements
- # NC issued to CB Effective Measurements Auditing
- # NC issued to CB for improper personnel competence
- # NC issued to CB for questioning the conclusion based on improper or insufficient evidence
- # NC issued to CB for not completing the planned audit program
- # NC's issued to CB for not completing ISO/IEC 17021-1 required processes and QF Additions for the type of audit being performed.
- # CB Suspensions and Withdrawals (as % of Accreditations)
- # Witnessed audits conducted
- # Office Assessments Conducted

4.5 Establishing trigger levels

The initial analysis of the AB Approval Board Team indicates that one set of triggers shall be set at this time:

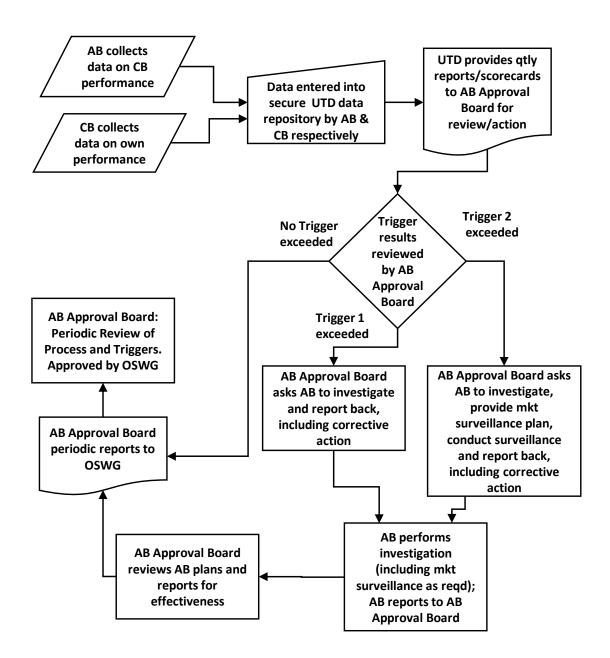
Measurement	Sampling Period	Trigger 1	Trigger 2
Total Major and Minor NCs per	The most recent one	25% below the norm	40% below the norm
audit day	year period		

The AB Approval Board will continue to monitor the data submitted quarterly by both the ABs and the CBs. As appropriate, the normative levels and trigger point used will be adjusted and presented to OSWG for approval.

It is anticipated that additional triggers will be set in the future based on the measurements defined above. Any additional triggers will be presented to the OSWG for approval.

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Figure 1 High Level Process Flow



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5. REVISION HISTORY

Latest Date Reviewed (Version update not required if document not revised):

Change to Revision	Description/DCR Number	Effective Date	Name
Original	Initial Release	01/01/2016	D. Sanicola