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Alternative Method for Maintaining TL 9000 Certification/Registration

This alternative method for maintaining TL 9000 certification/registration is taken from the International Accreditation Forum, Working Group III, January 21, 1998.

Objectives and Principles

The "Alternative Method for Maintaining TL 9000 Certification/Registration" (AM) is a method to determine if an organization's quality management system meets the ISO 9001 criteria to warrant continuation of an accredited certification by a third party (see Figure E-1). The method is based on utilizing the organization's (first party) internal audit system as a complement to the certifier's/registrar's (third party) own assessment activities.

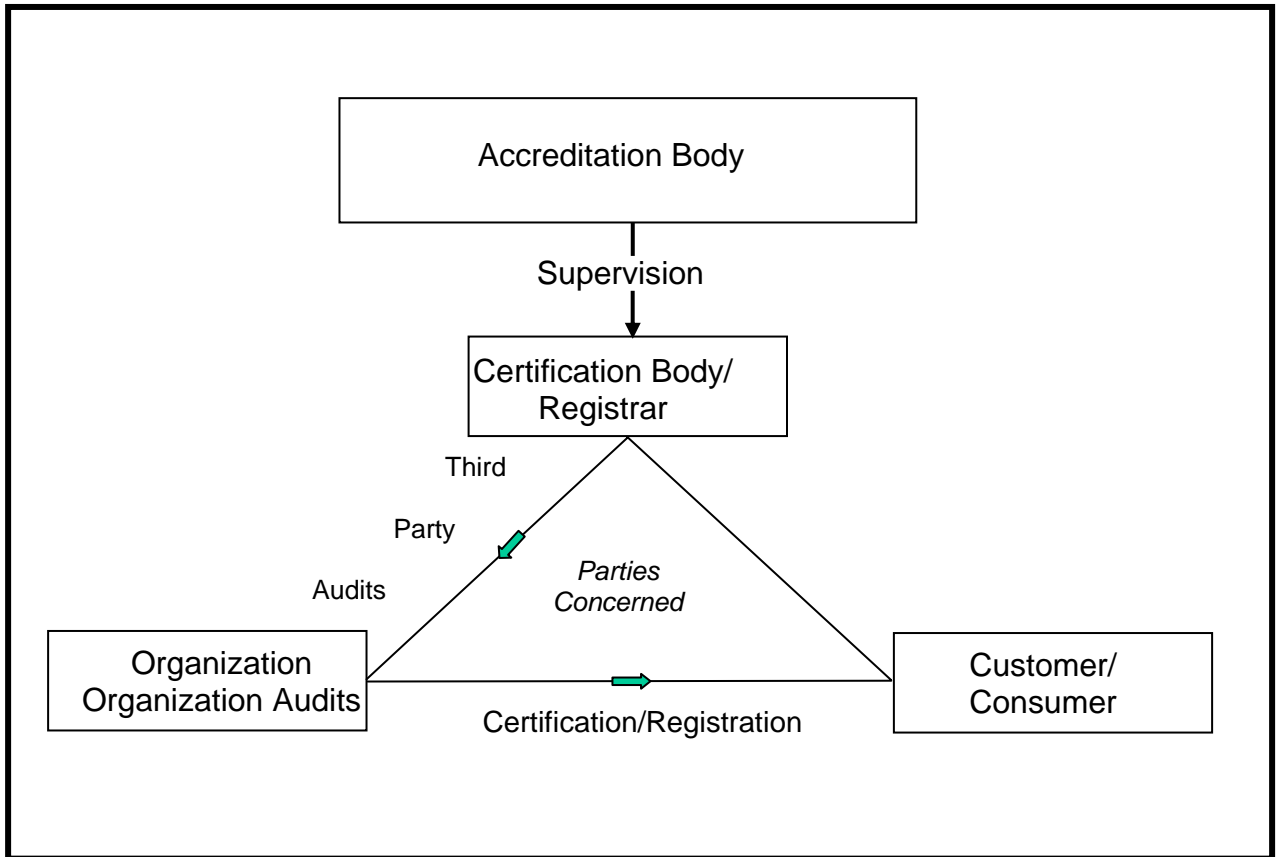


Figure E-1 – Alternative Accreditation Process

The objectives are elimination of unnecessary audit duplication and improving the effectiveness of third party TL 9000 audits and certification/registration. Higher value can be achieved by increasing benefits or

decreasing costs to customers. However, the primary goal is not to decrease costs but is to add value when compared to other more traditional methods of third party auditing. The aim is more added value compared to other methods of third-party auditing.

Advantages to the organization are:

- recognition of a common and consistently implemented quality management system,
- reduced costs of maintaining certification/registration as a result of:
 - reduced on-site days of certifiers/registrars,
 - site sampling which reduces plant interruptions, and
 - enhanced monitoring of internal audits by certifiers/registrars,
- more robust internal audit system, and
- improved communication among certifiers/registrars and registered organizations.

Advantages to third parties are:

- improving effectiveness of third-party auditing, and
- in depth auditing possible by monitoring internal audits.

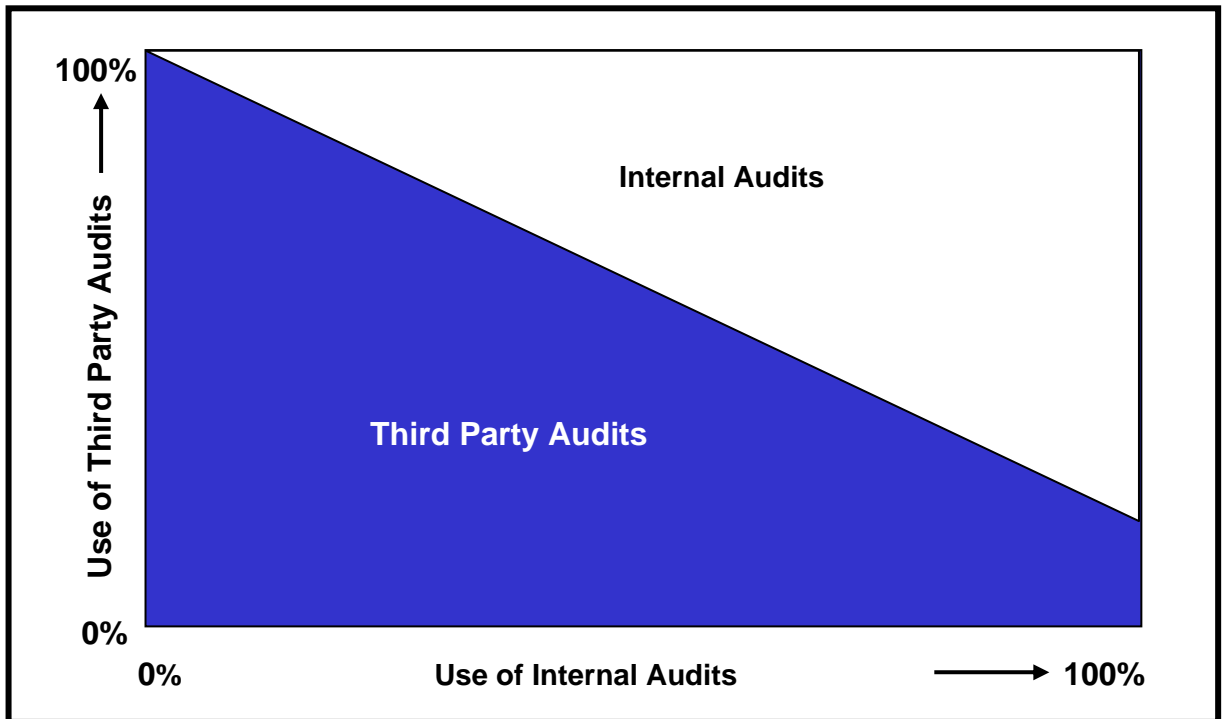


Figure E-2 – Internal Audits

The extent to which internal audit results are taken into account depends on a number of factors such as the structure of the quality organization, the maturity of the quality management system, and the possibility for verification by the certification body/registrar. When appropriate, existing guidelines for sampling may apply in external audits.

The AM approach is applicable only if a number of requirements (qualification/eligibility criteria) have been met by the organization and can be verified by the certification body/registrar. The AM approach is in general:

- available to any organization that meets the qualification criteria, without any discrimination with respect to size of sites, number of sites or sector of industry,
- restricted to third-party surveillance and re-assessment audits, and
- applicable only if:
 - a) the organization's quality management system fully conforms to all TL 9000 requirements as determined by an accredited third-party registrar,
 - b) the organization's internal audit system is effective and its results accurately reflect the actual status of the quality management system and its conformance to TL 9000,
 - c) the organization is capable of demonstrating with its management review that the management is in full control and command of goals/objectives and routinely takes adequate preventive and corrective actions, and
 - d) independent third-party auditing is utilized to assure the impartiality and effectiveness of the organization's internal audits.

Qualification/Eligibility Criteria for Organizations

The organization must have a quality management system in conformance with TL 9000 for a period of at least three years. Accredited certification/registration meets the intent of this requirement.

The organization shall demonstrate customer satisfaction within its industry of operation, by:

- customer satisfaction responses, and
- acceptable delivered quality, warranty/customer returns and delivery.

The organization can demonstrate having a centrally coordinated system for:

- internal auditing which adheres to ISO 19011-2002, and
- corrective and preventive actions based on audit results and customer complaints.

The organization's management shall demonstrate its commitment to quality and continual improvement of quality objectives and results in a quantified way over a period of time exceeding two years.

Internal auditors should have a sufficient background in the activities they evaluate and a good knowledge of the applicable procedures.

Qualification Assessment by Certification Body/Registrar

As a first step in the application of the AM approach, the accredited certification body/registrar will carry out a qualification assessment in which the qualification criteria are verified.

The certification body/registrar reserves the right to select the audit sites and TL 9000 elements to be sampled.

In the verification of the criteria, the certification body/registrar looks for evidence of effectiveness of the organization's quality performance over the last three years. This evidence shall be gathered based on earlier surveillance audit results, results from independent customer satisfaction surveys, and customer complaints.

The certification body/registrar shall have access to results of all phases of the management control process for quality, including results of management reviews and corrective and preventive actions. The auditing results will be reviewed by the certification body/registrar.

In addition, the certification body/registrar investigates and verifies the effectiveness of the organization's internal audit system and the conformance to the relevant criteria, namely:

The organization must have an effective internal audit system in which audit teams are independent from the unit/activity to be audited to avoid conflicts of interest.

- Internal audits shall regularly cover all requirements of TL 9000.
- Internal audits shall be scheduled on the basis of the status and importance of the activities.
- Internal audits shall be carried out in accordance with ISO 19011-2002.
- Internal lead auditors shall be qualified in accordance with ISO 19011-2002 by an external independent organization.

Qualification/Eligibility Criteria for Certification Bodies/Registrars

In order to utilize the AM approach, the certification body/registrar must be able to design an approach that meets the unique requirements of the organization's quality management system. The design process of the certification body/registrar must operate in full conformance to TL 9000. The accreditation body may verify the design capability of the certification body/registrar.

In principle, the qualification criteria for registrars who want to apply the AM approach can be derived from qualification criteria for the organization if:

- the certification body/registrar has been accredited in accordance with ISO/IEC Guide 62 (EN 45012) requirements for at least three years,
- the certification body/registrar can demonstrate improvement of service quality objectives and results over a period of three years.

If the certification body/registrar finds evidence that any of the requirements of the AM program, or its implementation thereof, are not being satisfied (or no longer being satisfied), then the AM program shall be suspended. The certification body/registrar shall then apply its normal procedures with full audit coverage of all sites and activities of the organization. This option, on the part of the registrar, is to be incorporated in a contractual agreement.

When appropriate, existing IAF guidelines (e.g., for sampling rates) will be applied in the AM audit program of the certification body/registrar. The design of the AM audit program will be different for each case, because it must be tailored to the specific circumstances.