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NQA GUIDANCE FOR ISO/TS 16949
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NQA Guidance for ISO/TS 16949 Applicants and Registered Clients



Introduction

ISO/TS 16949:2002 emphasizes the development of a process oriented quality management system that provides for continual improvement, defect prevention, reduction of variation and waste in the supply chain and effectively meeting customer requirements. The certification process will encompass the requirements of the technical specification as well as any customer specific requirements that go beyond the standard.

Reading the expectations contained in this document will help an organization understand their role in the certification process.

Additional guidance that should be utilized includes:

- ISO/TS 16949 Technical Specification
- IATF Guidance to ISO/TS16949:2002
- Rules for achieving IATF recognition

Frequently asked questions, sanctioned interpretations, customer specific requirements contained on the IATF web site www.iaob.org

Request for Certification

NOT all organizations may qualify for ISO/TS 16949:2002 certification, an organization must be in the automotive supply chain and carry out manufacturing and/or add value to products used in an automobile or other road going vehicle to obtain ISO/TS 16949:2002 certification. Companies not yet supplying automotive parts may be issued a letter of conformance providing they can demonstrate that they are on an active bid list. If an organization produces both automotive and non-automotive products, then the scope of the ISO/TS 16949:2002 certificate can only include the automotive products, other non automotive products and services may be included on an ISO9001:2000 certificate if required, additional audit days and charges may apply

An organization applying for certification should complete the NQA-USA TS questionnaire and supply information pertaining to the employee numbers, site locations, remote and support functions, shift working and pattern, scope of certification, a list of automotive customers, present certifications held and with whom, any special status placed on the organization by its customers and whether the organization has been deemed product design responsible by one or more of its customers.

Decertification Process

ONCE an organization is certified, the decertification process can begin with information coming from the following sources:

- Organization (e.g. significant changes in ownership, interruption of activity)
- NQA (nonconformities found during an audit, delayed surveillance audits, noncompliance with a clause of the certification contract by the organization)
- From an ISO/TS 16949:2002 recognizing customer (e.g. poor quality performance of the organization)
- Claims from other customers of the organization or information from the field

Based on the analysis of this information, a decision to suspend the certification is made (a certification that is put on probation, does not affect its validity.) Within 90 days, the certification will be fully reinstated if acceptable corrective action is provided by the organization. If corrective action is not provided or cannot be verified, the certification may be withdrawn.

Organizations currently certificated to QS 9000 but not qualifying for ISO/TS 16949:2002 recognition may transition to ISO9001:2000 at any time. However beyond December 2006 organizations will be required to undergo a full assessment under IAF guidance/rules. Under current OEM customer specifics (big three) Tooling and Equipment providers will be required to update their QS-9000/TE certification to ISO9001:2000 by December 2006; all upgrade visits will need to be carried out by IATF approved audit staff.

Transfer of Certification

IF an organization wishes to transfer their ISO/TS 16949:2002 certification from another certification body to NQA, then, in addition, to the above requested application information, NQA will also request a copy of the organizations existing, current certificate(s).

NQA will conduct a review of the following information:

- Evidence that the existing certification is valid.
- The previous audit report and any applicable corrective action
- Key performance indicators and trends
- Quality manual
- Evidence of customer satisfaction and/or any special status conditions

A transfer audit must then be performed (duration must be equivalent to a re-certification audit, following the successful completion of which an organization will be awarded an NQA ISO/TS 16949:2002 certificate with a validity of three years from the date of the transfer.

Quotation, Contract and Scheduling

NQA will use the information from the TS questionnaire to determine the number of days and locations to visit during the three-year period of the certification per the latest edition of the "Rules for achieving IATF recognition". NQA will forward a quotation for your organization's consideration, if you have any questions concerning this quotation please contact the quote originator outlined on the quotation for clarification. Once NQA has received a copy of your signed quotation then the stage 1 (readiness audit) audit can be scheduled.

Pre-assessment

IF a pre-assessment is requested by the organization, this will occur prior to the readiness review. This activity is optional and is not required to achieve certification. Only 1 pre-assessment can be performed by NQA at any single site. Participation by an auditor in the pre-assessment activity will prevent that auditor from returning to the company (or group of companies for a corporate client) to perform any TS certification activities for two years. The pre-assessment cannot exceed 80% of the audit days of the initial certification audit.

Initial Certification

THE initial certification is a two stage process that begins with a readiness review, a called a stage 1 audit which is followed by a Main Assessment, called a stage 2 audit.

On-Site Readiness Review (Stage 1 Audit)

THE readiness review is an on-site audit to determine if the organization is ready for the stage 2 audit. The outcome of the readiness review will be a determination that the organization is either ready or not for the ISO/TS 16949:2002 stage 2 assessment. No non-conformances will be documented during this audit.

To prepare for the readiness review the organization will be requested to complete the Readiness Review checklist. The lead auditor will utilize data on this form when conducting the review. It is the responsibility of the company to complete this form and have it and any supporting documentation available for review by the auditor at the start of the stage 1 audit. Organizations who fail to complete the form prior to the arrival of the auditor may be subject to additional on site activities and charges

The following list is the documentation and actions that will need to have been completed by the organization prior to the stage one assessment, the auditor will review the contents of this list in determining whether the organization is ready for TS certification. Failure to provide requested information and records will lead to a 'Not ready' recommendation!

Nonconformance Response Expectations

CLIENTS are expected to use their own internal corrective action system in response to non-conformances and may use their own associated forms or those provided by NQA to document actions taken. In either case the completed documentation should, show evidence of containment, establish root cause, perform corrective action and verify implementation of corrective actions for all NQA identified non-conformances.

The client's corrective action forms must reference the NQA non-conformance number and be submitted to NQA within 90 days of the closing meeting. NQA would recommend that organizations submit a corrective action plan to NQA within 20 days of the closing meeting, and that the evidence to support 100% non-conformance resolution be submitted within 60 days if possible. The reason being, that if NQA is not satisfied that the actions taken by an organization to resolve the non-conformance then additional evidence will be requested. If NQA is not a position to resolve the non-conformance within the 90 day limit then the audit is terminated and the certification process is started again with a stage one readiness review.

100% non-conformance resolution means the following

- Containment of the condition to prevent risk to the customer
- A documented evidence such as action plan, instructions , records to demonstrate the elimination of the non conforming condition, including the assigned responsibilities or verification follow up visit
- This have been achieved within 90 days of the end of the site visit

Certificate Issuance

CERTIFICATES will be issued only if there is 100% compliance to the specification, which means that non-conformances found during the audit are 100% resolved. (NB resolved does not necessarily indicate closed, non-conformance resolution can include a plan to close the findings within a defined period of time). Certificate issuance typically takes four weeks from the date that the corrective action is received and accepted by NQA.

Surveillance Audit Expectations

THE process approach to auditing will be utilized for surveillance audits. All shifts including dedicated non-rotating weekend shifts will be visited during every surveillance visit. Typically the first two surveillance visits will be carried out 6 and then 12 months after the date of the closing meeting of the first stage 2 audit. Following recommendation from the auditor and in consultation with the organization, the client may be able to transfer onto an annual program after the second surveillance visit.

The auditor will expect to examine as a minimum during the surveillance visit the following;

- customer complaints and organization response,
- organization internal audit and management review results and actions,
- progress made toward continuous improvement targets,
- effectiveness of the corrective actions and verifications since the last visit,
- new customers since the last audit,
- Sections 4 and 5, as well as elements 8.1, 8.2, 8.3, and any design elements of ISO/TS 16949:2002 will be subject to audit at least once in a 12 month period.
- Product Realization processes and all customer specific requirements will be sampled to cover all processes within a three-year period.
- Surveillance audits will be carried out no more than three months prior to plan, and no later than one month after planned date. Re-certification audit can be carried out up to 3 months prior to but not after the three year anniversary of the first stage 2 audit.

Please do not schedule the TS stage one audit until all of the documentation and actions outlined below have been completed as the outcome will be not ready and a second stage 1 audit will need to be booked.

- 1) Quality Manual and Procedures for each site audited:
The quality manual must contain the scope of the quality management system, including justification for exclusions. Product design is the only permissible exclusion and can only be taken for non-design responsible organizations. Process design cannot be excluded.

The quality manual must contain documented procedures OR reference to them.

The quality manual must contain a description of the interaction between the processes of the quality management system. This document is **crucial** in NQA's evaluation of whether an organization has adequately grasped the concepts of a process orientated management system. Defining an organizations processes and then documenting their sequence and interaction is the first step for an organization in creating a process orientated management system. If this activity is effectively carried out then the identified processes will be utilized throughout the QMS for the assignment of monitoring and measuring activities, internal audit planning and the satisfaction of customer expectations.

- 2) Twelve (12) months of evidence of key performance indicators, including:
 - Customer satisfaction
 - Customer complaints,
 - Any instances of shipping control or special status imposed by customer due to poor performance
 - On time delivery
 - Customer scorecards
 - Internal and external PPM
 - Employee motivation and awareness
 - Continual Improvement issues
 - Supplier performance

Any negative trends or performance data must show evidence of a reaction plan to address the underlying issues including root cause analysis. The auditor will examine these plans to verify their effectiveness.

- 3) Internal Audits for the past 12 Months. Including one complete audit conforming to the requirements of ISO/TS 16949:2002, i.e.
 - Quality management system audit
 - Manufacturing process audit
 - Product audit
- 4) List of Qualified Internal Auditors & Qualification requirements. (Some customer's require specific training and competency of internal auditors, see customer specific requirements for details)
- 5) Management Reviews from last 12 Months. (At least one review must comply with the requirements of ISO/TS 16949:2002 and include an evaluation of the results of a complete cycle of ISO/TS 16949:2002 process, product and system audits).
- 6) Any other customer metrics or operational performance trends for last 12 Months
- 7) For all automotive customers requiring ISO/TS 16949:2002 certification the auditor will need to establish whether there are any additional customer specific requirements (e.g. supplier quality manuals and have them available for review by the auditor).

The auditor will review this information to determine if the organization is ready for a main audit and that the scope of certification is appropriate.

If the required items are NOT present and complete, then the Stage 1 audit shall judge the organization "not ready." If during the Stage 1 audit obvious major non conformances with respect to the organization's effective implementation of the management system are found, the organization shall be judged "not ready" and will require a second stage one visit to be carried out

No non conformances will be identified during the readiness review. However, areas of concern that may result in a non-conformance during the stage 2 conformance audit will be identified.

Excluding Product Design

PRODUCT design is the only clause that can be excluded from a ISO/TS 16949:2002 compliant management system. However, the process design elements of 7.3 cannot be excluded. Since with the exception of those clauses that pertain to product design exclusively, i.e. 7.3.2.1, 7.3.3.1 all other clauses are equally applicable to process as product design and hence cannot be excluded. NB. only the customer will define product design responsibility and thus whether the exclusion of product design is permissible.

Main Assessment (Stage 2 Audit)

A Main assessment must take place within 90 days of the approval of the readiness review.

NQA will utilize a process audit approach for the stage 2 audit. All processes will be audited during the visit. Where organizations are operating shifts these will all need to be audited as part of the visit, as will weekend shifts which are dedicated and non-rotating. The audit plan will focus on the management and customer orientated processes, with the on-site support processes being audited as audit trails developed during the audit. Remote supporting functions will be visited prior to the Main Assessment (e.g. remote sales, design center, engineering, warehouse, etc).

The auditor will expect process owners to be identified and that processes be monitored, measured and analyzed to determine their effectiveness. Effectiveness of the system is considered to be how well the system is deployed as demonstrated by the measures defined by the organization to meet customer satisfaction and company objectives.

If non-conformances or opportunities for improvement are identified they will be documented. A follow-up audit may be required to verify corrective actions taken by the organization to resolve non-conformances. All non-conformances must be resolved within 90 days of the closing meeting. If not achieved, then the certification process begins again starting with the stage 1 readiness review.