



**What is “metrology” and why is it critically important to the automotive industry?**

*(A series of focused articles for quality practitioners)*

*Certification to ISO/TS 16949: 2002 is fast becoming a pre-requisite to doing business in the automotive industry. Failure to comply with the stringent requirements of clause 7.6 will delay or inhibit certification.*



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**ISO/TS 16949: 2002 – Meeting the requirements of clause 7.6, “Control of monitoring and measuring devices”.**

**ABSTRACT:** This article discusses the importance of ISO/TS 16949: 2002 certification in order to do business in the automotive industry and explains the demanding technical requirements of clause 7.6 in simple terms. Current problems in complying with these requirements are discussed and a checklist is included to enable “self-assessment” of the degree of compliance to be conducted.

**INTRODUCTION:** Certification to ISO/TS 16949: 2002, “Quality Management Systems – Particular requirements for the application of ISO 9001: 2000 for automotive production and relevant service part organizations” [1], is rapidly becoming the foundational quality management system in order to conduct business in the automotive industry. Continued non-compliance with this standard has potentially disastrous business consequences some of which are disruptions to logistic supply lines, expensive re-work, production downtime at OEM level etc. Certification to quality management standards such as ISO 9001 and QS 9000 is no longer recognized as sufficient evidence that products, of the quality required in the manufacture or servicing of motor vehicles, consistently meet the increasingly demanding requirements of the automotive industry.

Whilst most companies do not find the general requirements too onerous, meeting the stringent requirements of clause 7.6, “Control of monitoring and measuring devices” [1], is a different matter entirely. In fact meeting these requirements, without the appropriate metrology skills either from within the company, or consulted from outside the company, is a very tall order. Unfortunately, largely due to ignorance of metrology and it’s impact on quality, many companies, attempting to obtain certification to ISO/TS 16949: 2002, fail dismally in meeting the requirements of clause 7.6 adequately.

**SUMMARISED REQUIREMENTS OF CLAUSE 7.6**

The requirements of clause 7.6 are summarized below:-

- The organization shall determine what measurements have to be performed and the equipment needed to perform them to ensure the products manufactured can be proven to conform to the technical specification requirements.
- The organization shall establish processes, to ensure these measurements can be consistently performed, to meet the requirements.
- To ensure valid results the equipment shall
  - be calibrated/verified at suitable intervals against standards which are traceable to national or international measurement standards,
  - be adjusted when necessary,
  - be identified to enable the calibration status to be determined,
  - have the integrity of their calibration/verification protected,
  - be protected from damage and deterioration.
- The organization shall assess the validity of the last measurements performed when it is found that an instrument is

not conforming to requirements.

- Records of calibration/verification shall be kept in a prescribed manner.
- A detailed statistical measurement system analysis [3] shall be conducted to determine its ongoing suitability.
- Any calibration laboratory used to calibrate/verify the performance of testing and measuring instruments, whether internal or external, shall either be accredited to, or be assessed as meeting the intent of, ISO 17025 [2].

**PROBLEMS MEETING THE ABOVEMENTIONED REQUIREMENTS**

The author has spent almost two years working with the automotive industry creating an awareness about metrology and its impact on quality. During this time he has been exposed to many of the problems experienced by the industry in meeting the requirements of clause 7.6 [1]. Examples of such problems are listed below:-

- Lack of understanding of what measurements are required, to prove conformance of product to a technical specification.
- Improper selections of test and measuring equipment to perform the measurements with the required accuracy. (Uncertainty of measurement is not taken into account).
- Lack of adequate systems to ensure that measuring and testing systems can consistently meet the requirements. This includes suitable calibration interval determination, system verification checks etc.
- Although instruments are calibrated/verified, they are often not calibrated to ensure “fitness for purpose”. Typically, the calibration/verification does not establish that the required accuracy can be met, or the instrument is only partially calibrated. Often calibrations/verifications are performed by calibration service providers who are not accredited for the **particular calibration** measurements performed.
- Very little control, if any, is in place for the adjustment of instruments. Often adjustments are executed by the calibration service provider without the permission or knowledge of the customer. The fact that adjustment destroys calibration/verification history is not well understood.
- Many examples exist where the instrument calibration can be tampered with, thereby nullifying the validity of the calibration certificate. This is especially prevalent where the instrument is connected to a computer or software correction factors are required.
- The impact of instruments found not to be within the required accuracy is often not fully analysed. This is probably because it requires an enormous amount of work, and there is potential risk to company business. Unfortunately, the risk associated with the acceptance of potentially non-conforming components is too easily accepted.
- Many calibration certificates do not conform to the minimum requirements. Very often, measurement results quoted



on the certificates are not accompanied by an associated uncertainty of measurement in which case the calibration is null and void!

- Although a Measurement System Analysis is required, there is general ignorance about the requirements as described in the "Measurement Systems Analysis Reference Manual Third edition"[3].
- There are numerous examples of calibrations/verifications having been performed by calibration service providers who are neither SANAS accredited to ISO 17025 [2], nor assessed as having met the intent of ISO 17025. This essentially means the credibility of the calibration/verification results is questionable.

#### SOLUTIONS TO THE PROBLEMS DESCRIBED ABOVE

In the final analysis, it is not difficult to meet the requirements of clause 7.6 provided the necessary metrology skills are available. It follows therefore that the reason there are so many problems is precisely because these skills are not available or utilised. In an effort to enable the industry to conduct self-assessment of their own degree of compliance to the requirements of clause 7.6, the author has drawn up the following questionnaire/checklist.

#### Clause 7.6 Self Assessment Checklist

##### 1. Clause 7.6

- 1.1. Have the required tests/measurements been clearly identified?
  - 1.2. Has an analysis been conducted to determine the measurement accuracy required? What uncertainty is acceptable?
  - 1.3. What instruments have been identified that will perform the measurement/test? (Are they fit for the intended purpose?)
  - 1.4. Have the instrument accuracy specifications been correctly interpreted? (especially taking into account environmental tolerance)
- ##### 2. Clauses 7.6 a) to e)
- 2.1. Is the instrument calibrated – does it have a calibration certificate?
  - 2.2. Is the calibration service provider SANAS accredited for the parameter and/or range and accuracy required to perform the calibration?
  - 2.3. Is the accuracy requirement of the measuring instrument known and communicated in writing with the calibration service provider?
  - 2.4. Is the accredited Measurement Capability of the calibration service provider small enough to support the accuracy required of the measuring instrument?
  - 2.5. Does the calibration certificate bear the SANAS logo and is an associated uncertainty of measurement quoted on the calibration certificate for each of the measurement results?
  - 2.6. Are the reported measurement results, expanded by their associated uncertainty of measurement, capable of meeting the accuracy requirements?
  - 2.7. Is the process by which the calibration interval is selected, technically sound? (Are aspects such as drift, historical performance, accuracy specifications, whether adjustments have been performed or not, etc. taken into account?)

- 2.8. Has the instrument been calibrated at the same points as the previous time thereby providing a useful history?
- 2.9. Is it possible for the user of the calibrated instrument to alter the calibration in any way, either by way of changing software or physically performing an adjustment?
- 2.10. What controls (in between calibrations) are in place to ensure the instrument is still performing as when it was calibrated? (confidence checks to confirm it has not been damaged or abused in any way)
- 2.11. What action is taken if the calibration results indicate the instrument is out of specification?

##### 3. Clause 7.6 last paragraph

- 3.1. When software is used as part of a measurement system, is there any evidence that it has been "validated", i.e. that it performs the measurement and manipulates the data correctly, and that the version in use is the same unaltered one which was validated?

##### 4. Clause 7.6.1

- 4.1. Does the statistical evaluation of the measurement system analysis take into account the stability and calibration of the measuring equipment?
- 4.2. Does the MSA analyse the combined effects of several measuring instruments to derive the measurement? (e.g. Force and distance measurement to derive torque)

##### 5. Clause 7.6.2

- 5.1. Does the calibration certificate contain a statement of compliance with an identified accuracy specification?
- 5.2. Does the calibration certificate contain a list of standards against which the instrument was calibrated and/or a statement of traceability? (Note a list alone is not necessarily traceable.)
- 5.3. Are records available demonstrating control over non-conforming instruments and adjustment? (Instruments which are found to be out of accuracy specification when calibrated)

##### 6. Clause 7.6.3.1 (Internal calibration/test service provider)

- 6.1. Is the internal laboratory SANAS accredited?
- 6.2. Are the accredited Measurement Capabilities suitable for the calibrations/tests being performed?
- 6.3. If not accredited, does the laboratory have a documented scope of its technical measurement capabilities?
- 6.4. If not accredited, does the laboratory have "validated" calibration or test procedures?
- 6.5. If not accredited, is there evidence of staff having been evaluated against suitable criteria for competence?
- 6.6. Are copies of the latest version of the applicable in-house, national or international standards available in the laboratory?

##### 7. Clause 7.6.3.2 (External calibration/test service provider)

- 7.1. Is the calibration/test service provider laboratory SANAS accredited?
- 7.2. Are the accredited Measurement Capabilities suitable for the calibrations/tests being performed?
- 7.3. If the laboratory is NOT accredited, is there recorded evidence of the laboratory having been audited for technical suitability and competency by the customer receiving the calibrations or tests?

#### SUMMARY

Certification to ISO/TS 16949: 2002 is fast becoming a pre-requisite to doing business in the automotive industry. While meeting the general requirements of the standard is easy for most successful businesses, compliance to the technically demanding requirements of clause 7.6 can be far more difficult. Since non-compliance to these requirements could inhibit certification which could have major business consequences, the use of the checklist included in the article should enable a "self-assessment" to highlight the problems before they are detected by a certification auditor.

#### REFERENCES

- [1] ISO/TS 16949, "Quality management systems – Particular requirements for the application of ISO 9001: 2000 for automotive production and relevant service part organisations", 2002.
- [2] ISO 17025, "General requirements for the competence of testing and calibration laboratories", 2005.
- [3] MSA Workgroup, "Measurement Systems Analysis Reference Manual", Third Edition, March 2002.