Physikalisch-Technische Bundesanstalt

Braunschweig und Berlin

Certification Body
Quality Management System Evaluation of Measuring Instrument Manufacturers

Preparation for a procedure to approve a quality system (list of preliminary questions) "General information"

1. Address

Company:

Street:

Postcode/Place:

Phone:

QM-Representative

E-Mail:

2. Information regarding the company

Group to which the company belongs:

Products:

Essential vendor parts:

The information was compiled by:

Name:

Phone:

Function in the company:

Place, date:

The list of preliminary questions is property of PTB and may be used only for internal purposes. It must not be made accessible to third parties. It serves to prepare an audit.
Please answer the following questions. For documented procedures, a brief explanation with reference to the source of information will be sufficient. Please mark any questions which are not applicable and give, where appropriate, a brief explanatory statement.

Sites / staff members

Site	Development *	Production *	Sale/after sales service *	Total number of staff members at site **	Number of staff members working for measuring instruments within the scope of quality system approval **	Notes
	☐	☐	☐			
	☐	☐	☐			
	☐	☐	☐			
	☐	☐	☐			

Note:: *) mark with “X“, **) enter number of staff members

3. Information regarding the quality system

Corpus of technical regulations

☐ DIN EN ISO 9001:2000

☐ other standards:

Requirements in quality system integrated from

☐ Harmonised standards, normative documents (e.g. OIML R49)

☐ Directive 2004/22/EG (MID)

☐ other directives, such as

Products covered by the quality system

○ all ○ only the following

Sites covered by the quality system

○ all ○ only the following

Existing quality system certifications/approvals/accreditations
e.g. *ISO 9001-certification, quality system approval according to non-automatic weighing instruments (NAWI), state approved test centre, accredited test laboratory.*

If present, please define: ☐

<please select>		Nr:		Issued by:	
<please select>		Nr:		Issued by:	
<please select>		Nr:		Issued by:	

4. Requirements for approval procedures at manufacturers' of measuring instruments (MID)

Existing type examination certificates or design examination certificates for which an approval of the quality system is applied for:

Procedures for development, production and testing of measuring instruments are integrated in the quality system? ◯ yes ◯ no

- Development	☐ at the company ☐ outsourced, where?	
- Production/Assembly	☐ at the company ☐ outsourced, where?	
- Adjustment/Final test	☐ at the company ☐ outsourced, where?	
- Sealing of the devices	☐ at the company ☐ outsourced, where?	
- Marking with metrology label	☐ at the company ☐ outsourced, where?	

- Purchase of metrologically relevant components from sub-suppliers ◉ yes ◯ no

If present, please define

Sub-supplier:

- Agreements for quality assurance are existing?
To ensure the compliance of the regulation of metrologically relevant characteristics ◯ yes ◯ no

Type of inspection of the sub-suppliers?

Quality policy includes legal requirements	◯ yes	◯ no
Procedures and competences for in-plant implementation, application and monitoring of requirements under verification law/ verification-technological requirements from regulations and type examination certificates are documented	◯ yes	◯ no
Documented procedures for production, testing and marking of measuring instruments are available	◯ yes	◯ no
Is a separation made in the handling of documented procedures and quality management plans between measuring instruments for application "subject to legal control"(MID) and "not subject to legal control"	◯ yes	◯ no
Handling of documents and regulations	◯ yes	◯ no
Adequate measuring and test equipment and their verification/calibration	◯ yes	◯ no
Description of involving after-sales service companies in the quality management system, e.g. in respect of assembly, final test and start-up	◯ yes	◯ no
List of measuring instrument types, which are designed to be marked with a conformity label within the QM-approval	◯ yes	◯ no
List of the staff members who are authorised to give conformity declarations and labelling the measuring instruments	◯ yes	◯ no
Training of the staff members, responsible for the conformity declaration	◯ yes	◯ no
Records of final tests	◯ yes	◯ no

5. Statement regarding the use of consulting services

Have you engaged consulting services (e.g. corporate consultant) for your quality management system?

◯ yes ◯ no who?

Note: The certification body shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the consultancy organisation and the certification body poses an unacceptable threat to the impartiality of the certification body. (ISO/IEC 17021:2006, Abs. 5.2.7)

A preliminary talk with the certification body (CB), or a pre-audit represent no consulting services.