PTB Procedure QM-Approval MID

Criteria and procedures
for the approval of the quality system of
measuring instruments manufacturers
according to 2004/22/EC

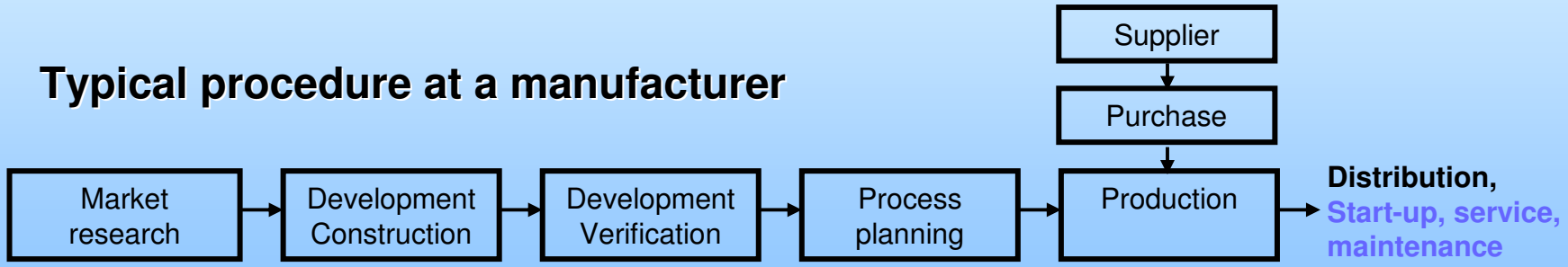
PTB Braunschweig/Germany
Certification Body
Quality Management Review of Measuring Instrument Manufacturers
www.ptb.de/en/org/q/q3/q32

Structure

- Introduction
- Comparison ISO 9001-certification / QM-approval
- Procedure of the QM-approval
- Contact

Roll-out of new measuring instruments

Typical procedure at a manufacturer



Concept, Customer requirement specifications

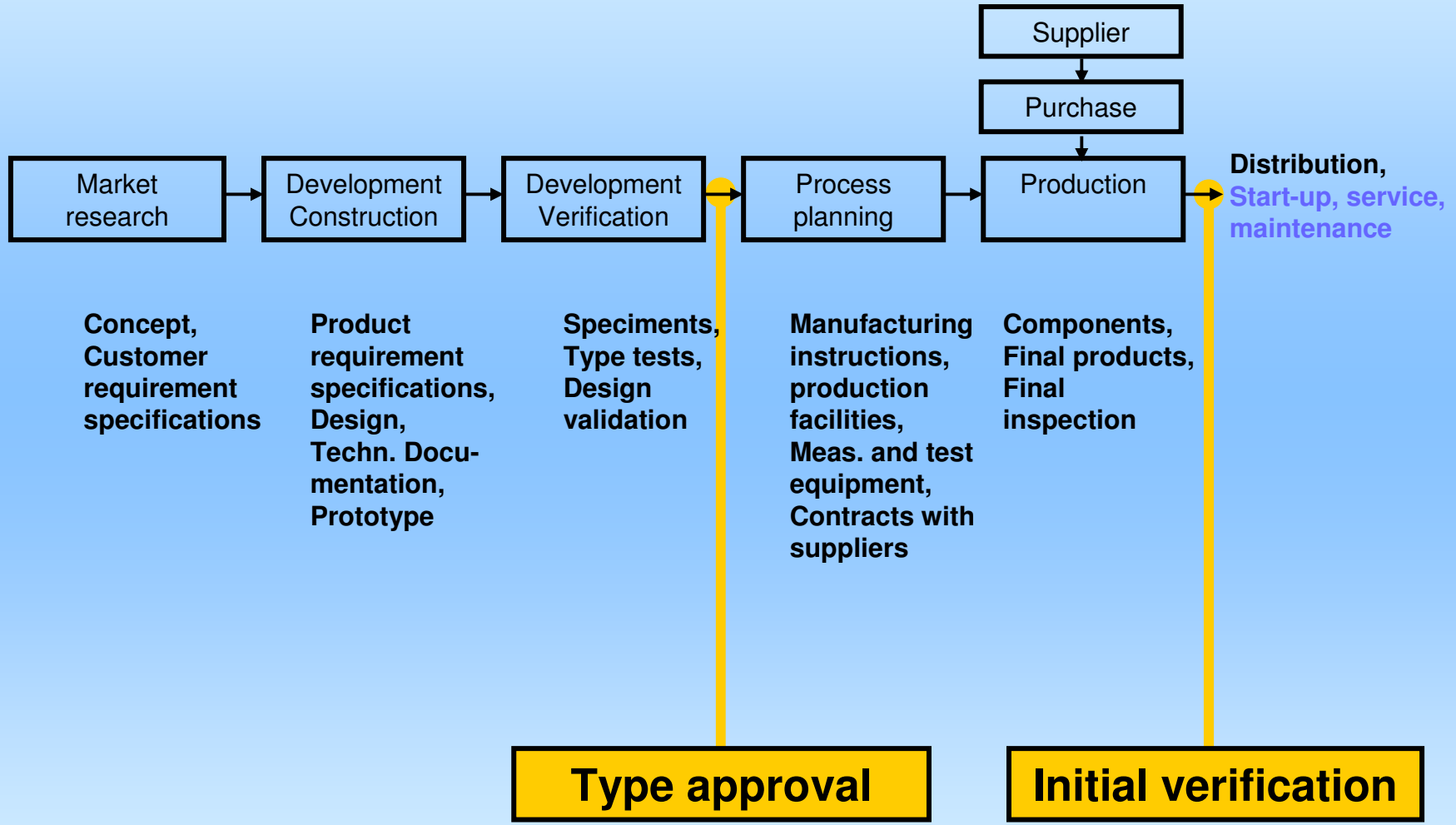
Product requirement specifications, Design, Techn. Documentation, Prototype

Speciments, Type tests, Design validation

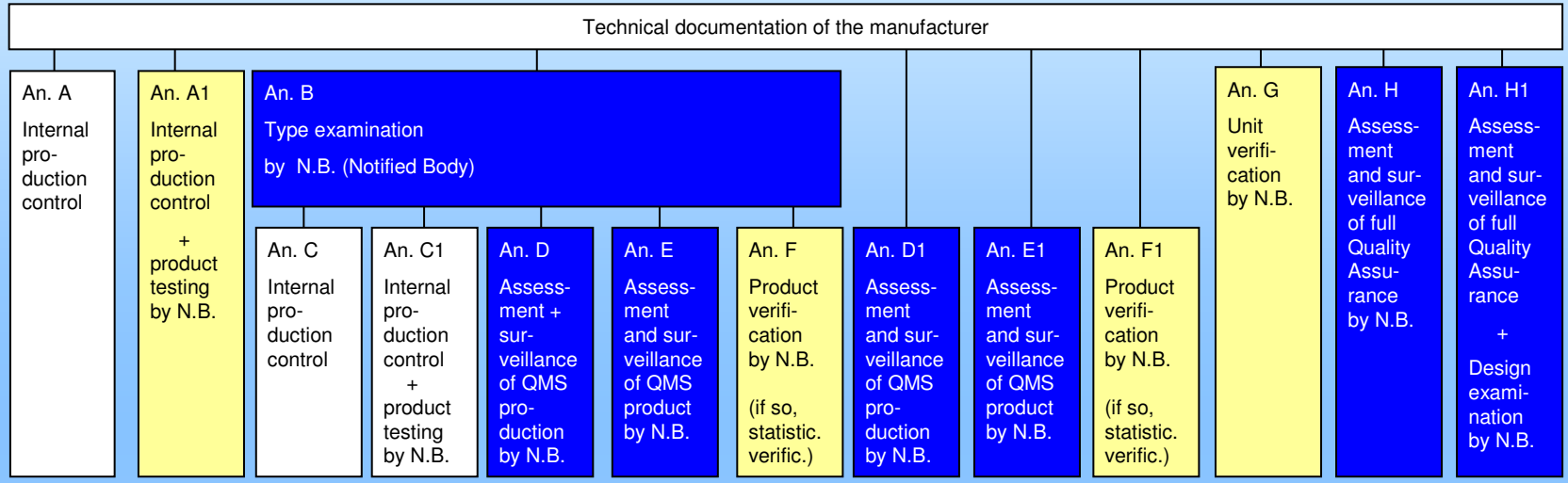
Manufacturing instructions, production facilities, Meas. and test equipment, Contracts with suppliers

Components, Final products, Final inspection

Legal inspections according to the old German verification law



Possible Conformity assessment procedures (modules) according to directive 2004/22/EC (MID)

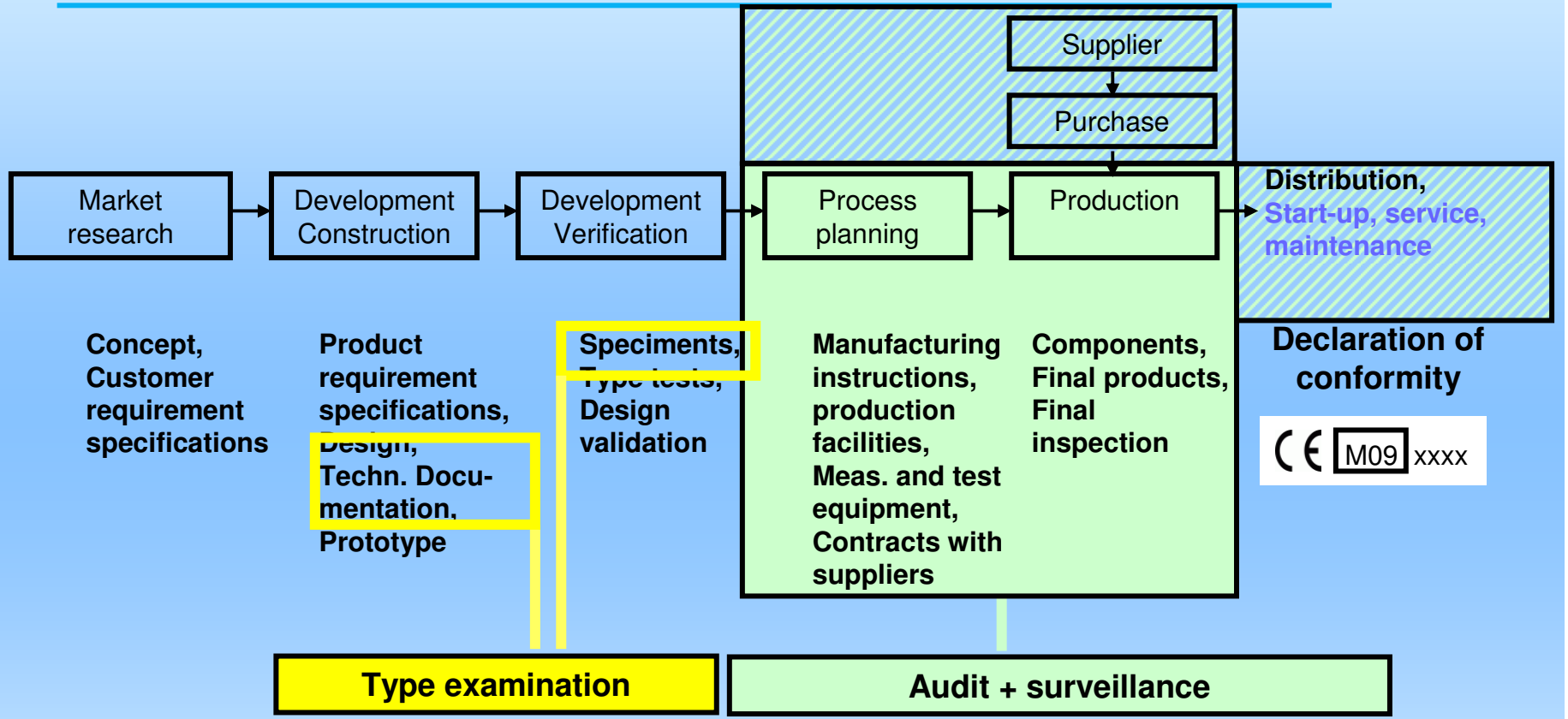


•**MI-001**, Water meters:		B+D, B+F, H1
•**MI-002**, Gas meters and volume conversion devices		B+D, B+F, H1
•**MI-003**, Active electrical energy meters		B+D, B+F, H1
•**MI-004**, Heat meters		B+D, B+F, H1
•**MI-005**, Measuring systems for the continous and dynamic measurement of quantities of liquids other than water		B+D, B+F, G, H1
•**MI-006**, Automatic weighing instruments	mechanical systems: electromechanical systems: electronic systems or systems containing SW:	B+D, B+E, B+F, D1, F1, G, H1 B+D, B+E, B+F, G, H1 B+D, B+F, G, H1
•**MI-007**, Taximeters		B+D, B+F, H1
•**MI-008**, Material measures	I – Material measure of length II – Capacity serving measures	B+D, D1, F1, G, H A1, B+D, B+E, D1, E1, F1, H
•**MI-009**, Dimensional measuring instruments	mechanical or electromechanical: electronic or with SW:	B+D, B+E, B+F, D1, E1, F1, G, H, H1 B+D, B+F, G, H1
•**MI-010**, Exhaust gas analysers		B+D, B+F, H1

PTB-Offer: Modules B, D, D1, E, E1, H, H1

H. Stolz, PTB Germany, by 08/2009

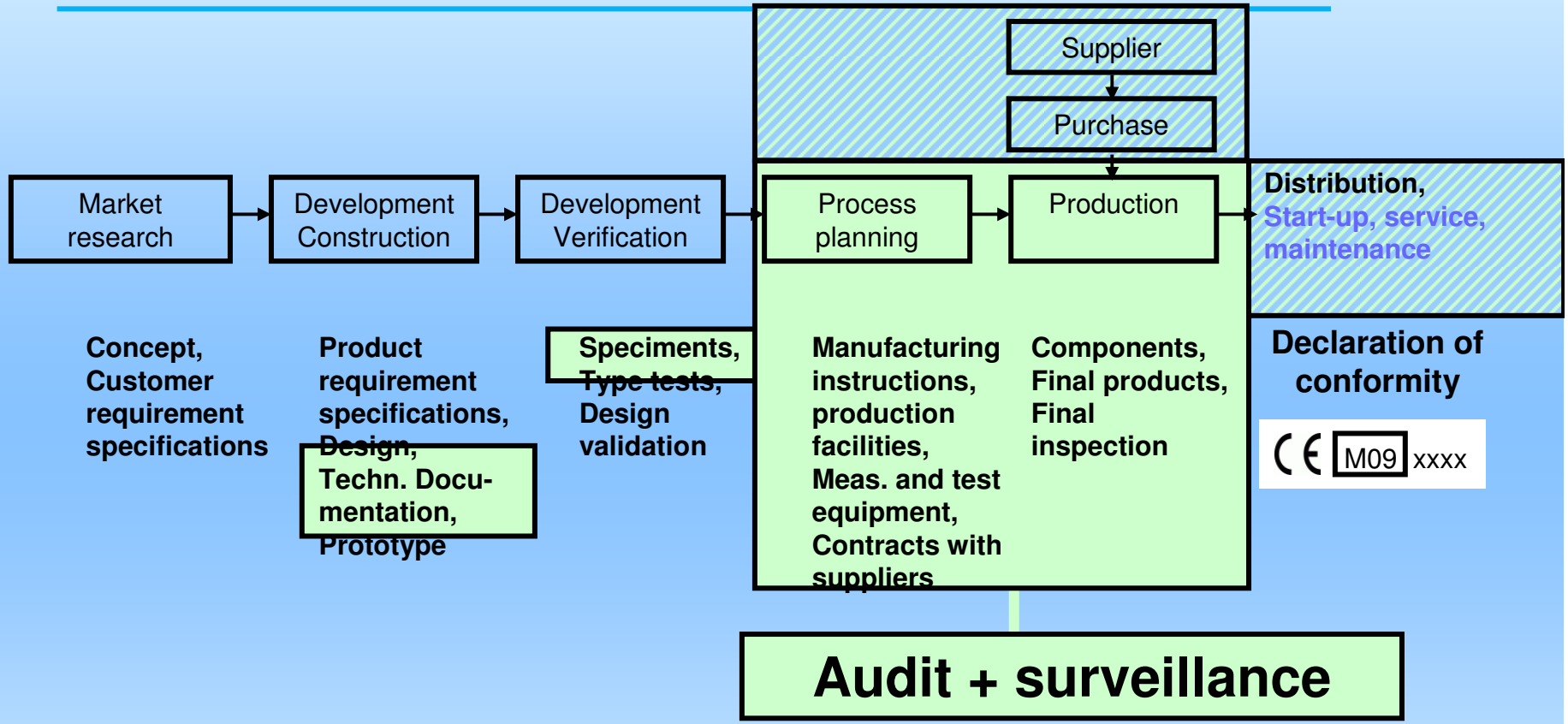
MID Conformity assessment procedures
Modules B + D



Modules B+D: Type examination (B) and approval of quality system for production (D) **MI-001…MI-010**

Applicable for large batch production with an existing ISO 9001-certificate

MID Conformity assessment procedures
Module D1

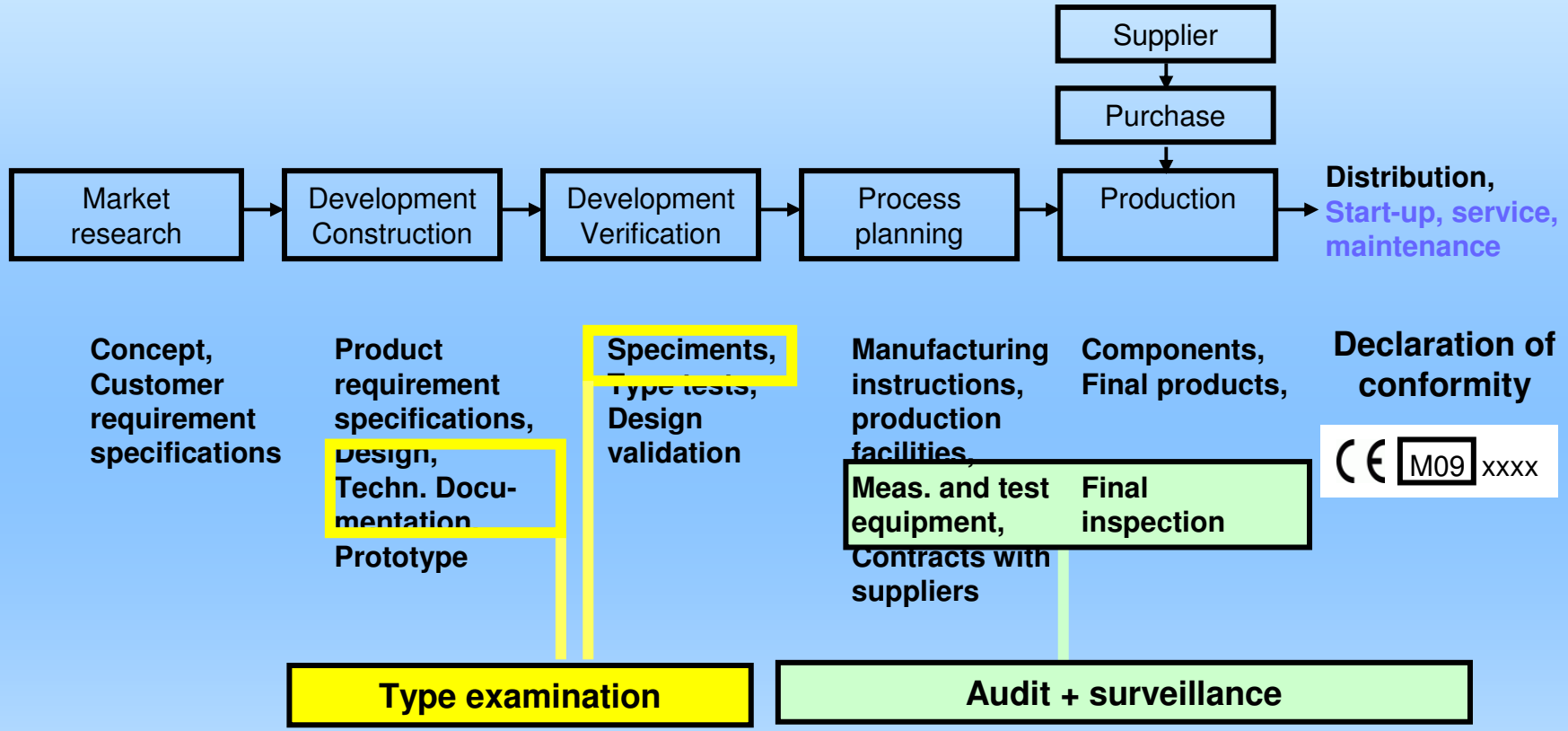


Module D1: Approval QMS Production (D1) *– c.f D without B –*

Applicable for „simple“batch production with an existing ISO 9001-certificate

MI-006 (mech.), MI-008, MI-009 (mech., el.mech.)

MID Conformity assessment procedures Modules B + E

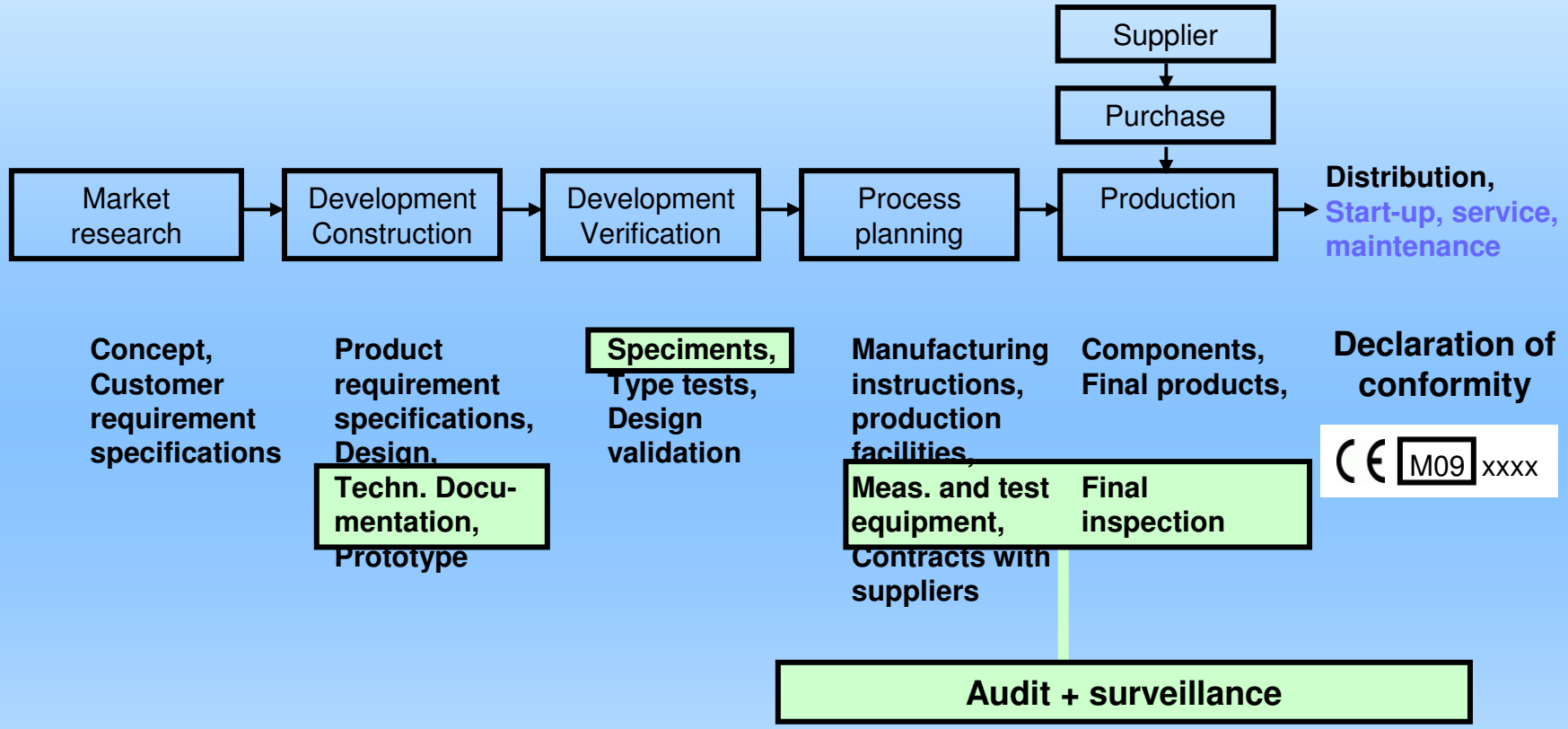


Modules B+E: Type examination (B) and approval of quality system for final inspection (E)

Only applicable in final inspection covers all MID-relevant attributes

MI-006 (mech., el.mech.), MI-008-II, MI-009 (mech., el.mech.)

MID Conformity assessment procedures
Module E1



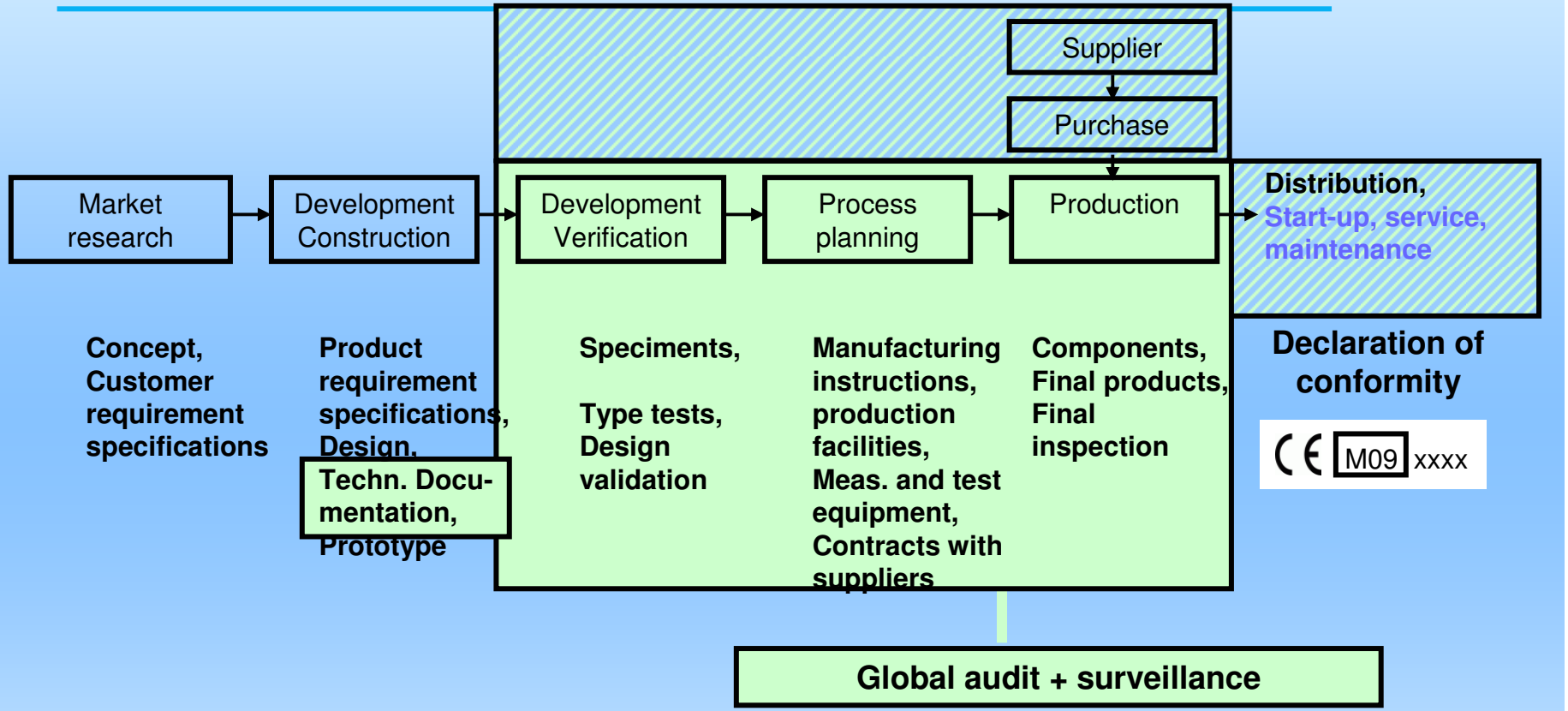
Module E1: Approval of quality system for final inspection (E)

- c.f. E without B -

Simple meas. instruments, if final inspection covers all MID-relevant attributes

MI-008-II, MI-009 (mech., el.mech.)

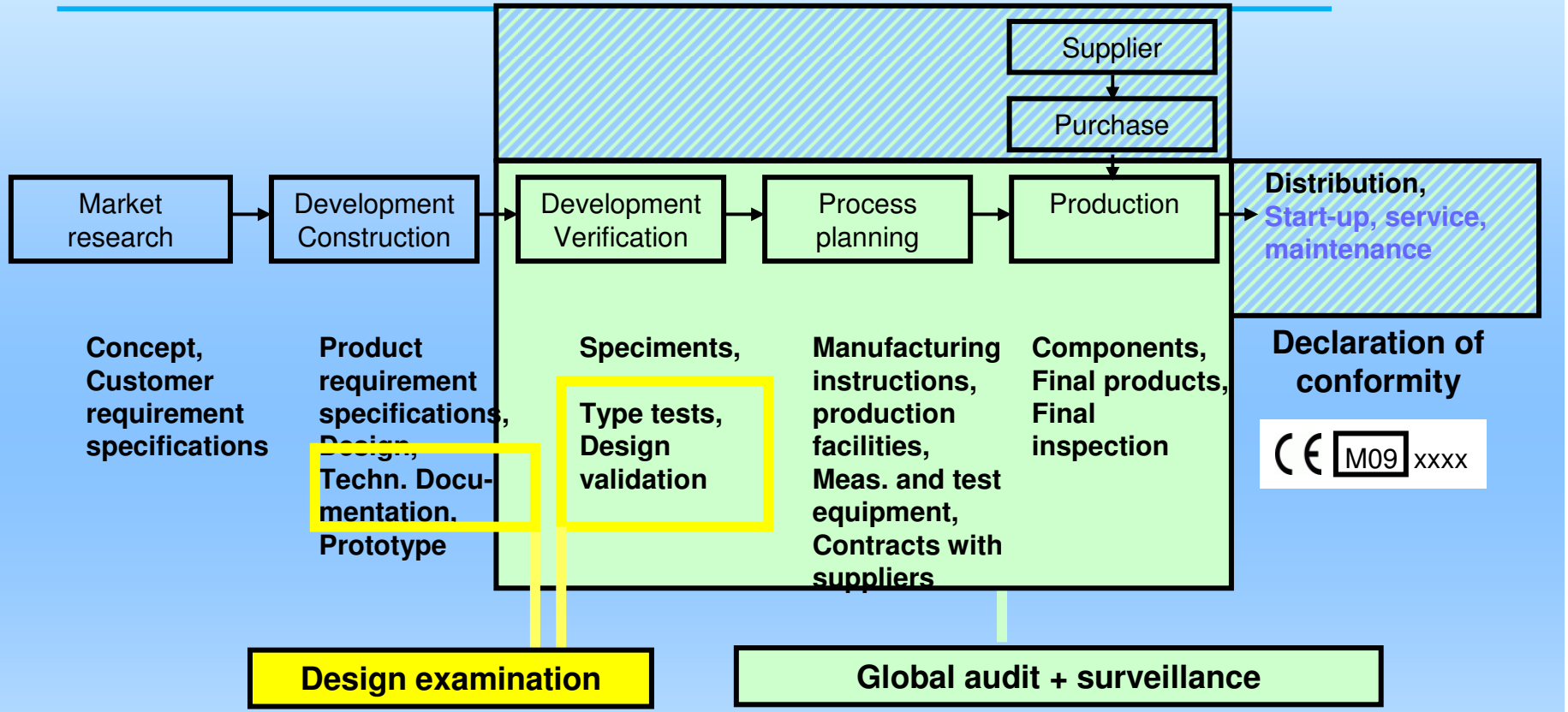
MID Conformity assessment procedures Module H



Module H: **Approval of quality system for development and production** **MI-008-I, MI-008-II, MI-009 (mech., el.mech.)**

Only applicable for material measures and simple dimensional measuring instruments

MID Conformity assessment procedures Module H1



Module H1: Design examination and approval of quality system for development and production MI-001…MI-007, MI-009, MI-010

Applicable for manufacturers with own type test equipment and ISO 9001-certificate

Difference between B+D and H1

- Module D bases on the specifications given in the type-examination certificates (module B), which must not be issued until the instruments have successfully passed the type examination tests.
  The audit done by the notified body largely covers production and final testing.

- Module H1: The intrinsic type examination is performed by the manufacturer himself (product tests by the notified body are possible within the surveillance audits). Within the design examination the notified body evaluates the technical documentation and the result of the design validation of the manufacturer.
  The audit done by the notified body also covers development.

Difference between D and D1

- Module D: The notified bodies audits and surveils, whether the quality managements system of the manufacturer secures, that instruments meet the stipulations stated in the type examination certificate and in the technical documentation and the other requirements of the MID.

- Module D1: Within the audit the notified bodies evaluates the technical documentation of the manufacturer and surveils, whether the quality managements system of the manufacturer secures, that instruments meet the stipulations stated in the technical documentation and the other requirements of the MID.

Comparison
ISO 9001-Certificate / QM-Approval

	ISO 9001-Certification	QM-Approval
Purpose of QM-Systems	Compliance with customer requirements Decrease of failure costs Continuous improvement	Securing of the compliance of measuring instruments with legal requirements
Purpose of certificates	Get customer confidence	Authorisation of conformity declaration
Scope of certificate	**All processes and products of an organisation**	Measures of quality assurance for **certain product categories** (includes if necessary further organisations – i.E. subcontractors)
Typical procedure	Application / audit / evaluation / decision / surveillance	Application / audit / evaluation / decision / surveillance
Validity period	3 years	3 years
Surveillance period	Annual surveillance visits	Annual surveillance visits + unexpected visits

Effect of an existing ISO 9001-Certificate for Quality System Approval

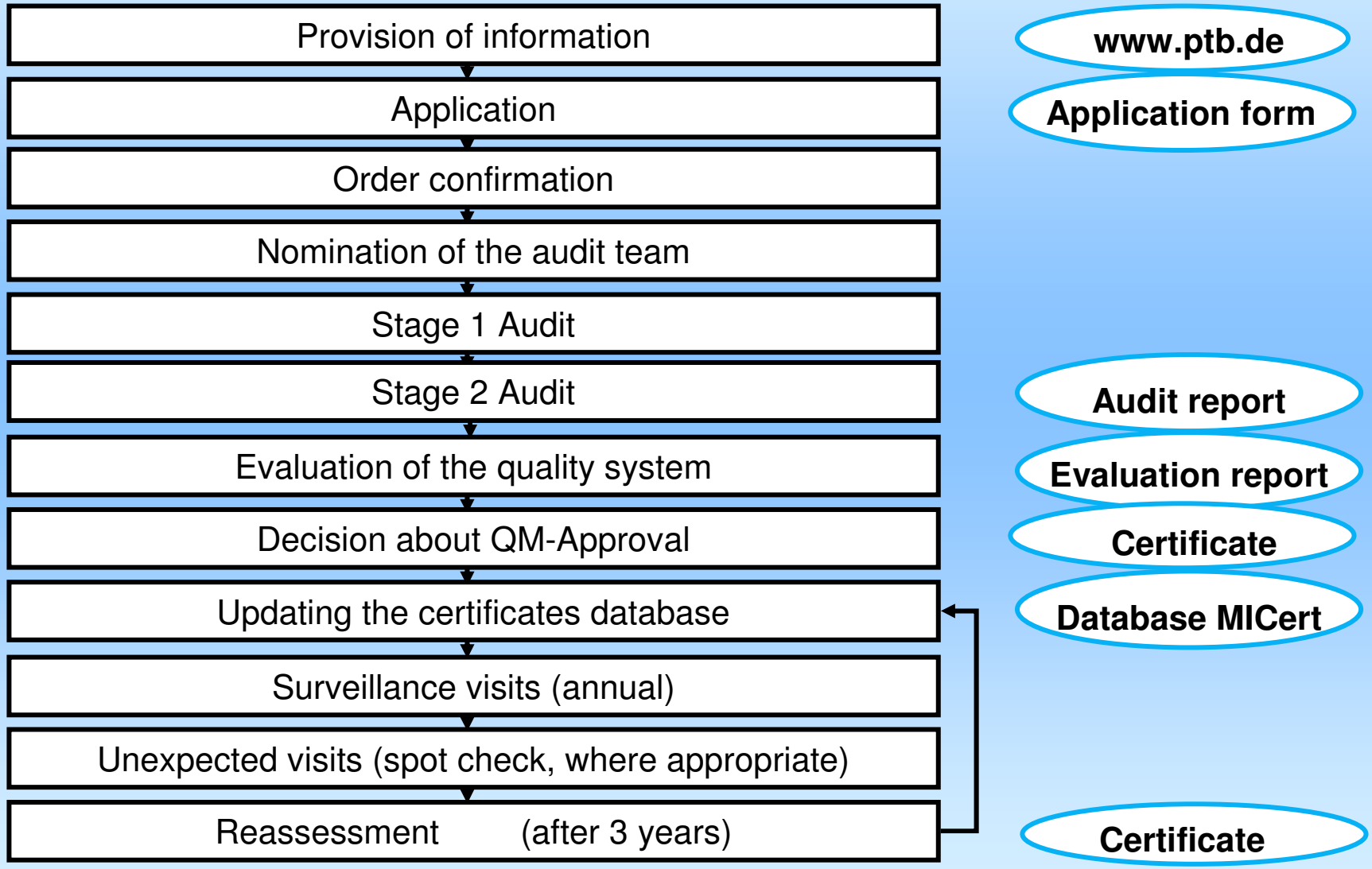
- An present ISO 9001-Certificate does not replace the approval audit by the notified body
- ISO 9001-Certification is not a requirement for the approval of the quality system, but helpful (lower costs, audit of notified body is restricted to the „technical delta“)
- Some notified bodies offer ISO 9001-Certification in addition to the approval of the quality system (not PTB)

Useful WELMEC-Guide for Measuring Instrument Manufacturers:

WELMEC Guide 8.6 „Measuring Instruments Directive 2004/22/EC
Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2000 is applied“

http://www.welmec.org/publications/8-6.asp

Procedure of the QM-Approval



Application documents which have to be submitted

- Filled and signed application form + list of preliminary questions
- Acceptation of the General Terms and Conditions of Certification of the PTB
- Copies of existing QM-Certificates
  (e.g. ISO 9001 certificates, accreditation certificates)
- List of the measuring instrument types which are designated for the Conformity Declaration with regard to the quality system approval applied
  (with number of design examination certificates / type examination certificates if existing)
- Copies of type-examination-certificates (for modules D, E, unless not issued by PTB)
- Technical documentation of the measuring instruments (for modules D1, E1, H, H1)
- Quality plans for several measuring instrument types,
  (i.e. short description of the key elements of production to make sure that the requirements of the MID will be met,
  e.g. quality system approval of suppliers, 100% final inspection including calibration, justification and sealing or placing into operation on site by own service technicians)
- Quality Management Manual of the company
- List of all documents subordinated to the QMM and relevant to the quality system approval

All documents have to be submitted in German or English !!!

Further documents will be requested by the audit team during the approval procedure

Audit-team for quality system assessment

Audit-team has to provide as follows:

- Well-founded knowledge on legal metrology
- Knowledge in quality management (auditor training)
- Expertise in corresponding measuring instruments category

Typical audit team:

Lead Auditor + **Expert**

Both registered in the list of auditors of the certification body of PTB

The certification body of PTB is equipped with competent auditors and experts from the technical PTB divisions and from the German verification authorities.

Estimated charges

(non-binding experience values)

Computation of fees according to effort and the work performed

- Basis: Regulations Governing the Charges for Services Supplied by PTB
- ca. 1.000 € /day /person plus travel expenses

Effort depends on

- Scope of the measuring instruments category
- Complexity of development-/ manufacturing process
- Number of locations and potential contractual partners to be taking into account
- Potential additional labour (i.e. translations, additional audits)

Typical effort for the initial approval

(Module D, 1 instrument category, 1 location, German language, ISO 9001-Certificate present)

- Stage 1 Audit:
  Lead Auditor: ½-1 day on location + travel time, ½ day pre-/post processing
- Stage 1 Audit:
  Lead Auditor: 1-2 days on location + travel time, 1-2 days pre-/post processing
  1 Expert: 1-2 days on location + travel time, 1-2 days pre-/post processing
- Certification Body: 1 day

Changes on an approved QM-System

Examples for notifiable Changes:

- Relocation or extension of sites
- Change of a subcontractor for metrological relevant components
- Change of testing methods in final inspection of the production
- Basic changes in production process
- Lapse of ISO 9001-Certification
- Add new measuring instrument types on the scope of quality system approval

-> notification to audit team or certification body

-> review by the notified body

-> potential changes of QM-Approval

Contact

EG Type Examination Certificates acc. to MID Annex B and EG Design Examination Certificates acc. to MID Annex H1:

MID-Annex	PTB-Dept.	Contact Person/Certifier	
MI-001	1.5	Dr. Rinker	michael.rinker@ptb.de
MI-002	1.4	Dr. Kramer	rainer.kramer@ptb.de
MI-003	2.3	Dr. Kahmann	martin.kahmann@ptb.de
MI-004	7.6	Dr. Rose	juergen.rose@ptb.de
MI-005	1.5	Dr. Rinker	michael.rinker@ptb.de
MI-006	1.1	K. Schulz	karsten.schulz@ptb.de
MI-007	1.3	Dr. Jäger	frank.jaeger@ptb.de
MI-008	5.4	I. Lohse	ingo.lohse@ptb.de
MI-009	5.4	I. Lohse	ingo.lohse@ptb.de
MI-010	3.2	Dr. Ulbig	peter.ulbig@ptb.de

QM-Approval acc. to MID Annexes D, D1, E, E1, H and H1:

all	Q.3	M. Urner	markus.urner@ptb.de
		Dr. Stolz	harry.stolz@ptb.de

Contact

General questions on MID and legal metrology in Germany:

PTB Working Group Legal Metrology (Q.31)

Dr. Mengersen christian.mengersen@ptb.de

General questions on conformity assessment services of PTB:

Head of Certification Body (Q.32)

Dr. Stolz harry.stolz@ptb.de

Other notified bodies:

NANDO Information System

http://ec.europa.eu/enterprise/newapproach/nando/).

Other hints (e.g. guidelines, harmonised standards):

European Cooperation in Legal Metrology (WELMEC)

http://www.welmec.org

EU-Website Measuring Instruments

http://ec.europa.eu/enterprise/prepack/ms_inst/index_measin_en.htm