



REPUBLIC OF CROATIA

STATE OFFICE FOR METROLOGY



Conformity Assessment Procedures of the „New Approach“ of EU illustrated by the Measuring Instruments Directive 2004/22/EC (MID)

Harry Stolz

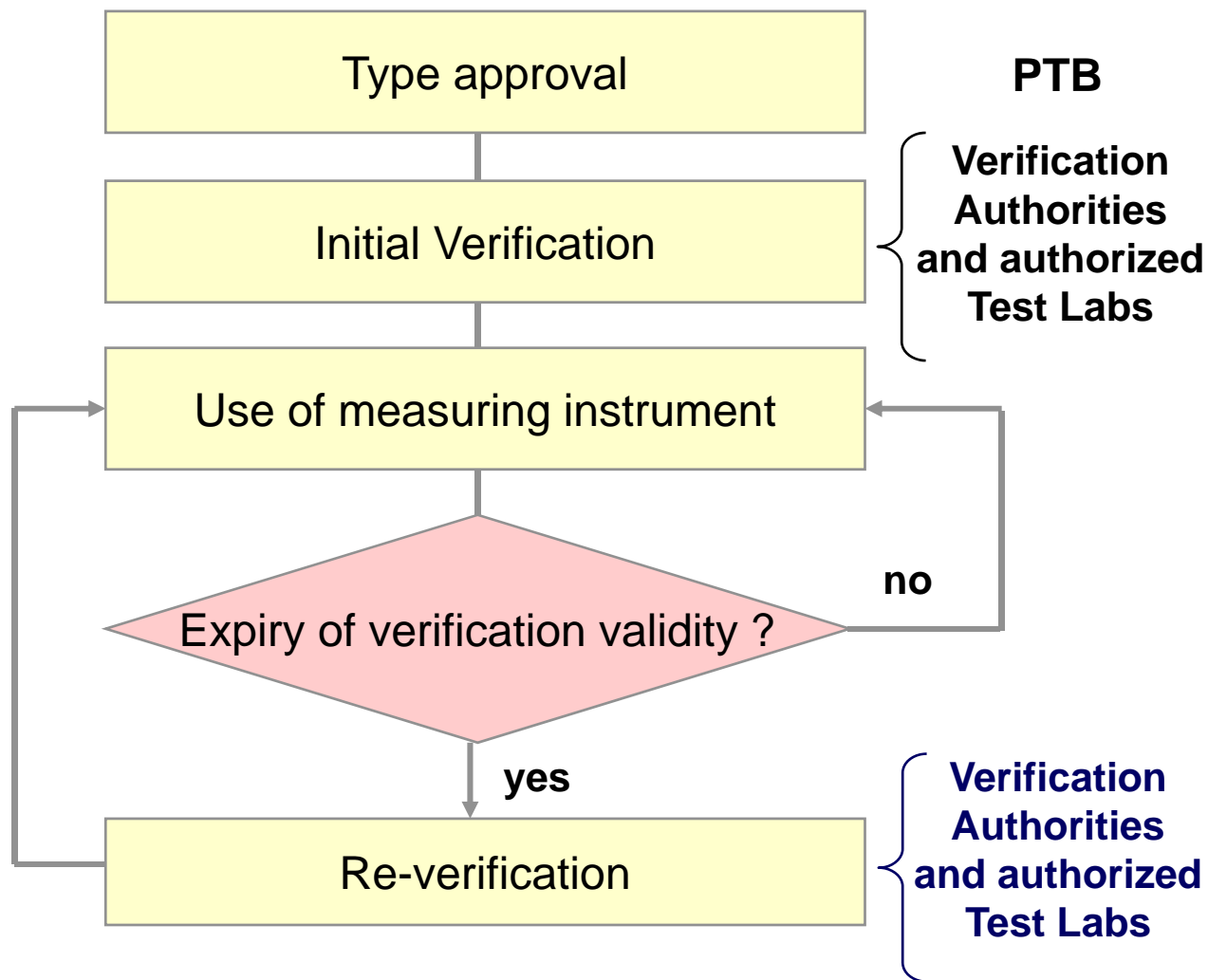
PTB GERMANY
Certification Body



Aim of Legal Metrology



Legal Metrology in Germany before implementation of the Measuring Instruments Directive (MID) on 30 October 2006



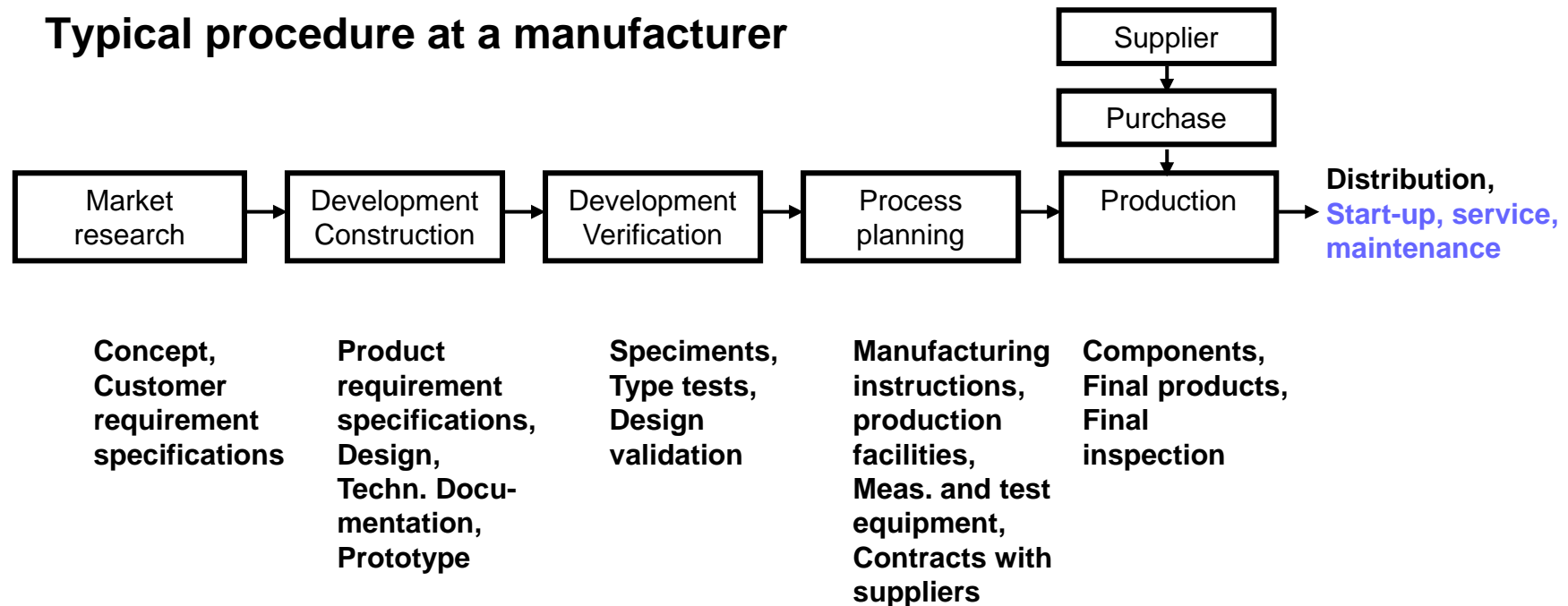
Legal Metrology in Germany **since** implementation of Measuring Instruments Directive (MID) on 30 October 2006

Phase	Responsible	Activity
<ul style="list-style-type: none"> • Development • Production • Bringing onto the market 	<ul style="list-style-type: none"> • Manufacturer 	<ul style="list-style-type: none"> • Conformity Assessment • Declaration of conformity
	Verification Authority	<ul style="list-style-type: none"> • Market Surveillance
<ul style="list-style-type: none"> • Putting into use • Use 	<ul style="list-style-type: none"> • User • Verification Auth., auth. Test Labs • Verification Authority 	<ul style="list-style-type: none"> • Support, Service • Re-verification • Surveillance of users

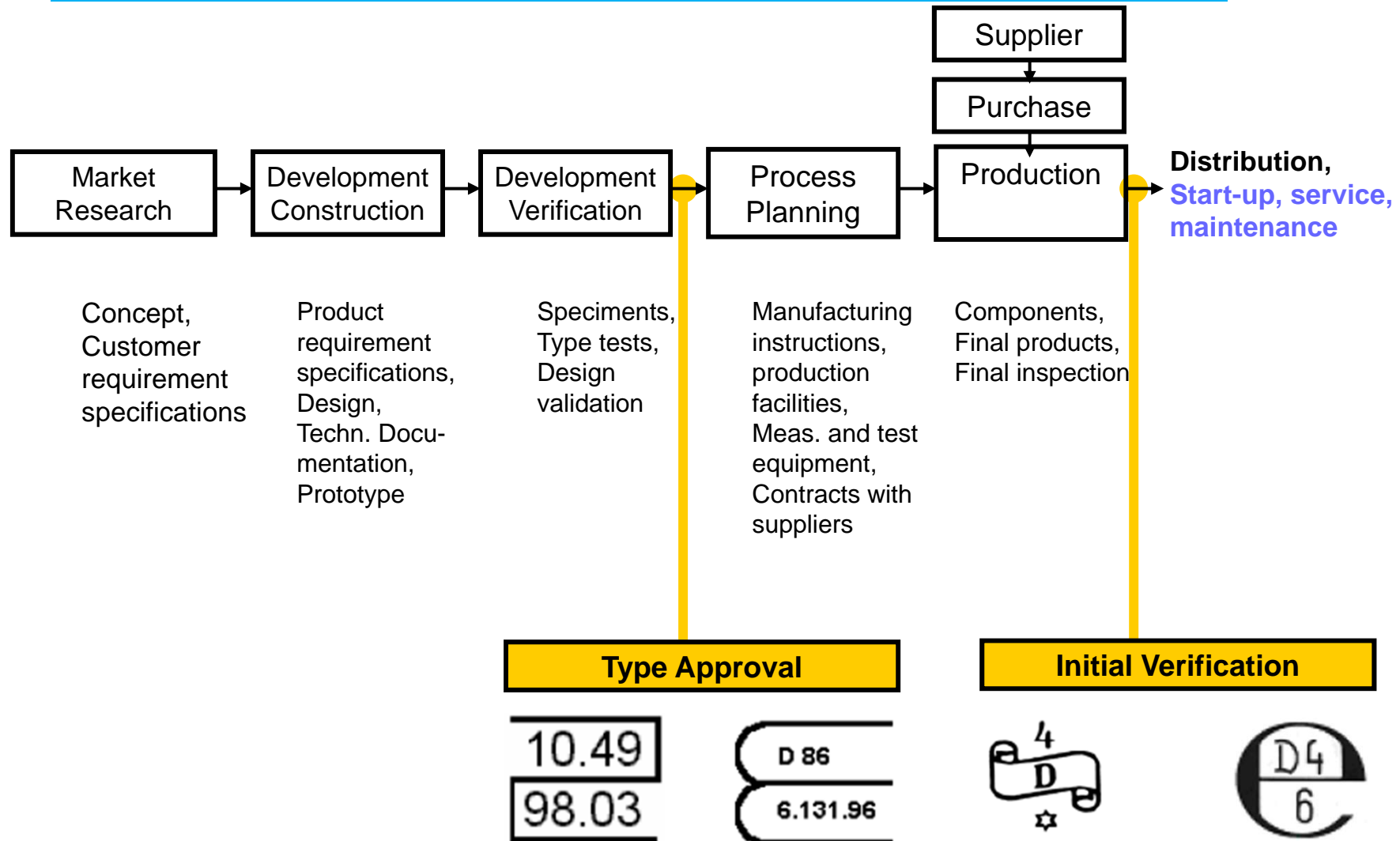


Market introduction of new measuring instruments

Typical procedure at a manufacturer



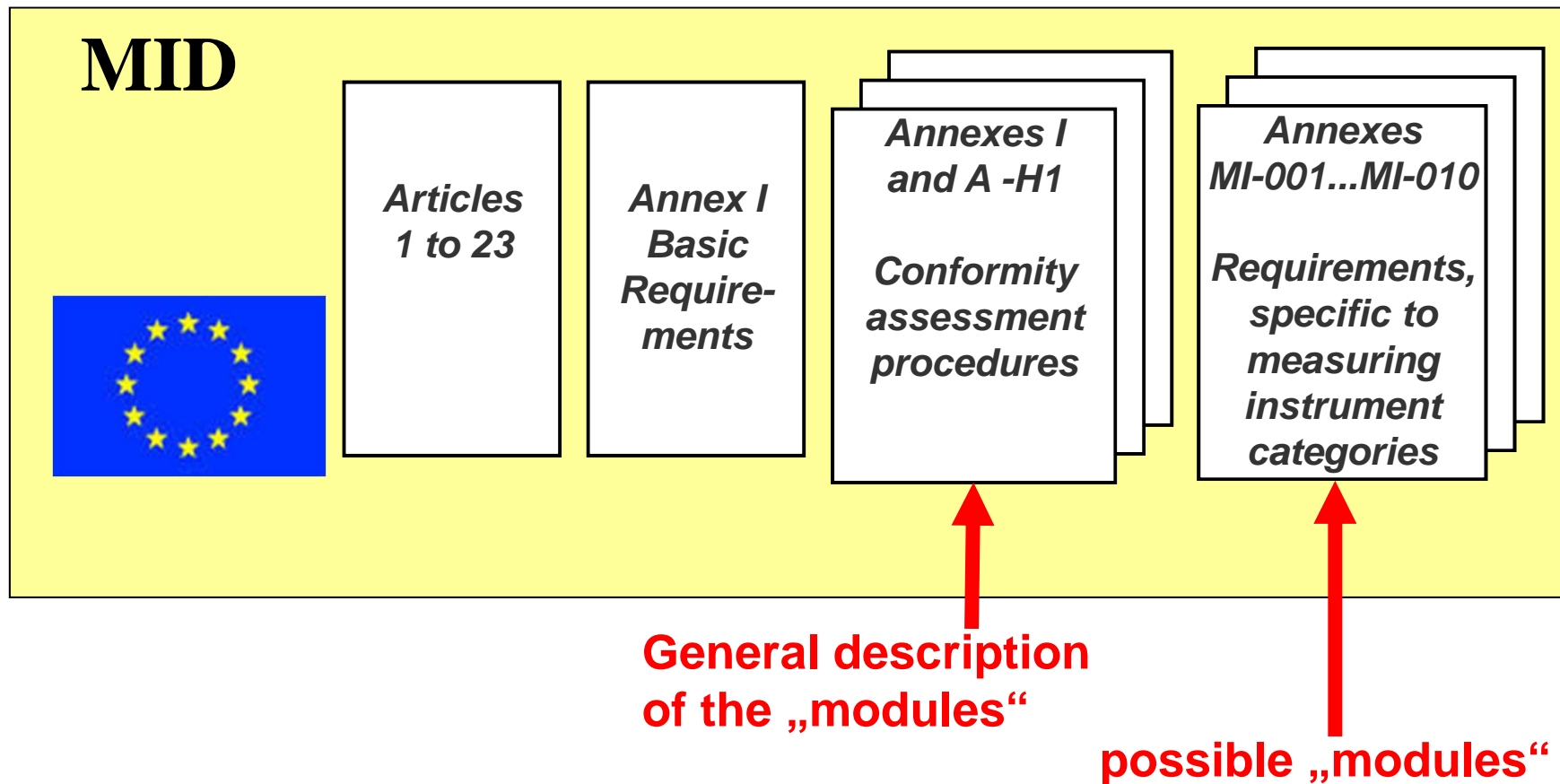
Legal inspections according to the **old German verification law (before MID)**



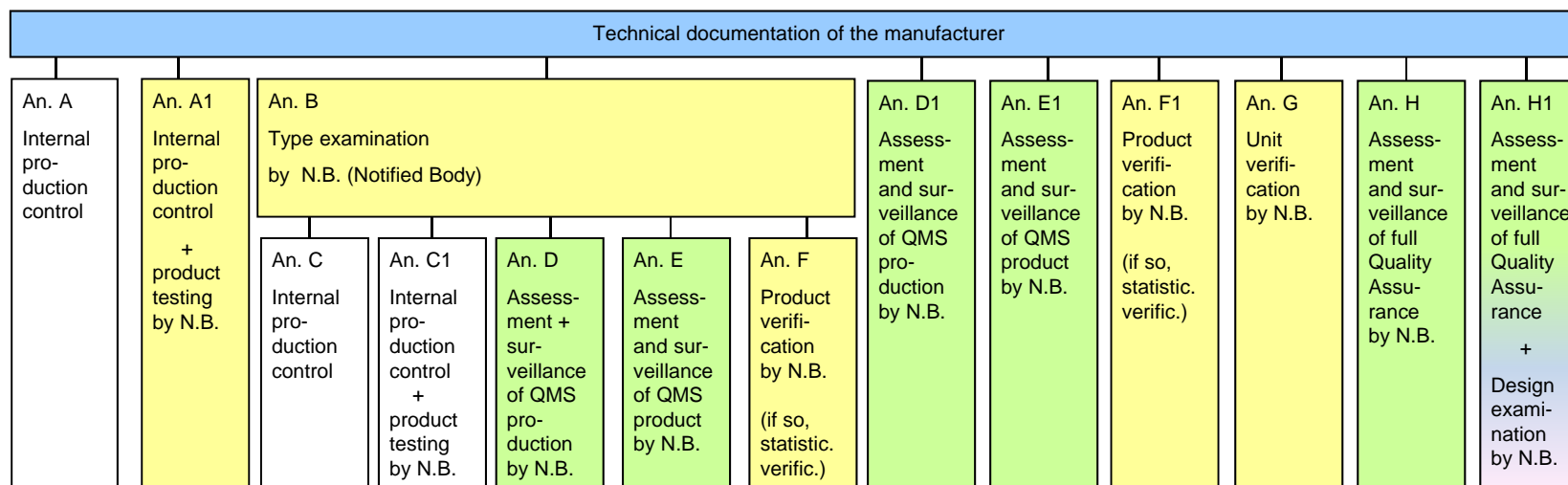
Measuring Instruments Directive 2004/22/EC (MID)



Organisation of the Measuring Instruments Directive

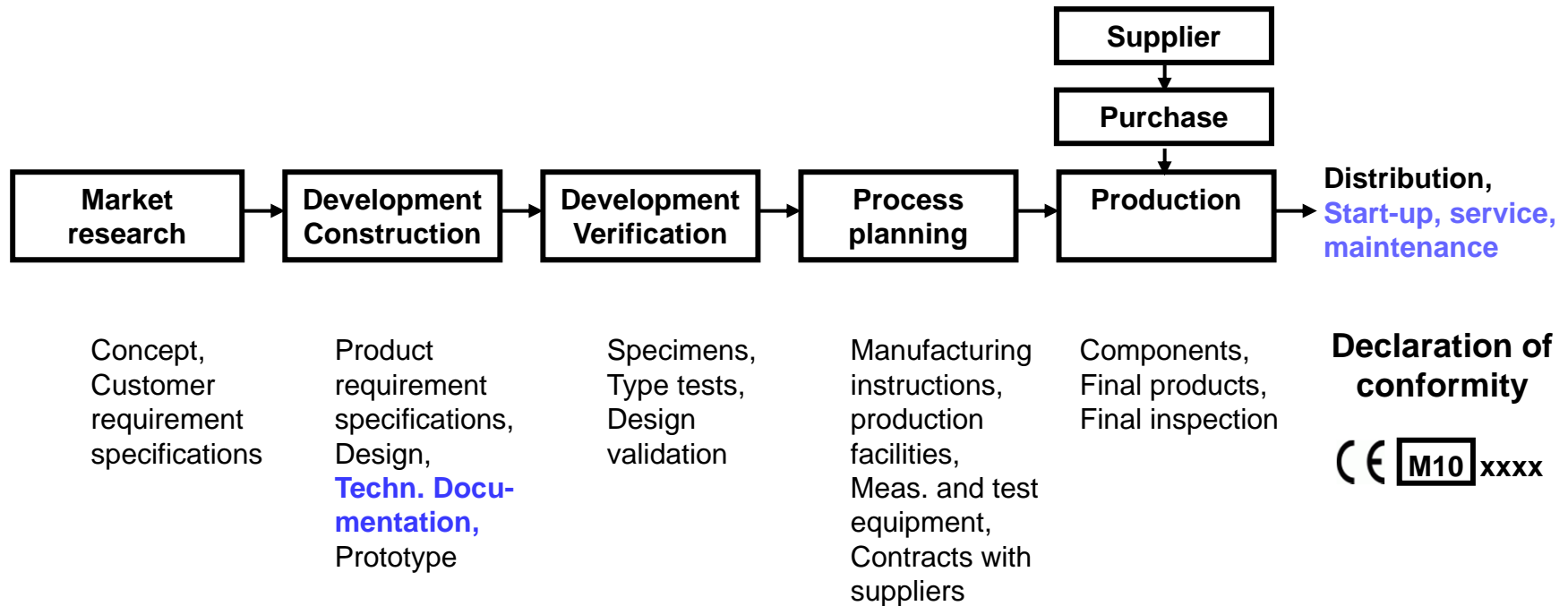


Possible Conformity assessment procedures according to directive 2004/22/EC (MID)



•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 continuous and dynamic measurement of quantities of liquids other than water		B+D, B+F, G, H1
•MI-006, Automatic weighing instruments	mechanical systems:	B+D, B+E, B+F, D1, F1, G, H1
	electromechanical systems:	B+D, B+E, B+F, G, H1
	electronic systems or systems containing SW:	B+D, B+F, G, H1
•MI-007, Taximeters		B+D, B+F, H1
•MI-008, Material measures	I – Material measure of length	B+D, D1, F1, G, H
	II – Capacity serving measures	A1, B+D, B+E, D1, E1, F1, H
•MI-009, Dimensional measuring instruments	mechanical or electromechanical:	B+D, B+E, B+F, D1, E1, F1, G, H, H1
	electronic or with SW:	B+D, B+F, G, H1
•MI-010, Exhaust gas analysers		B+D, B+F, H1

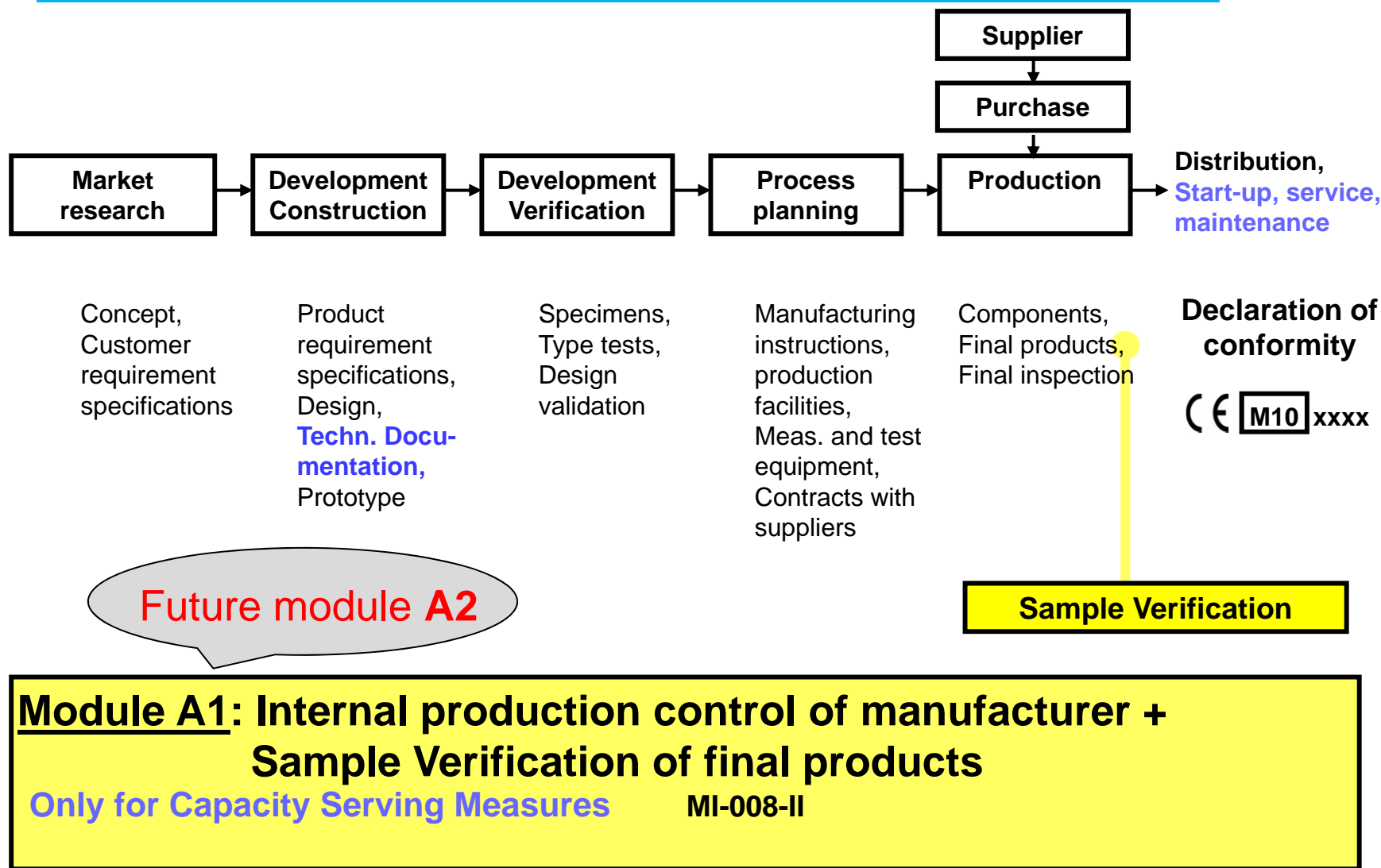
Alternatives of conformity assessment according to MID (Modules)



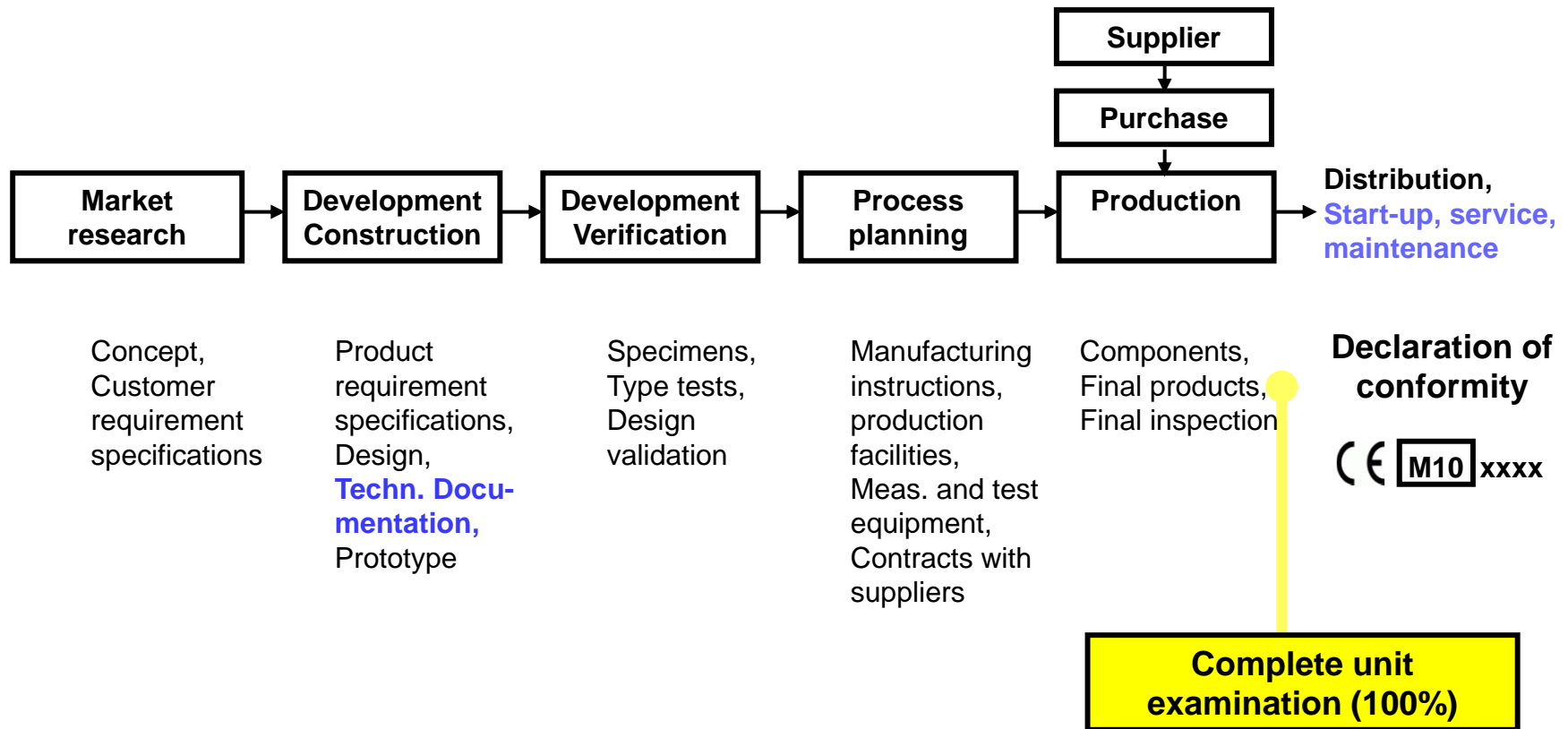
Module A: Conformity Declaration on base of internal production control of manufacturer (without notified body)

Not scheduled for MID so far!!!

Alternatives of conformity assessment according to MID (Modules)



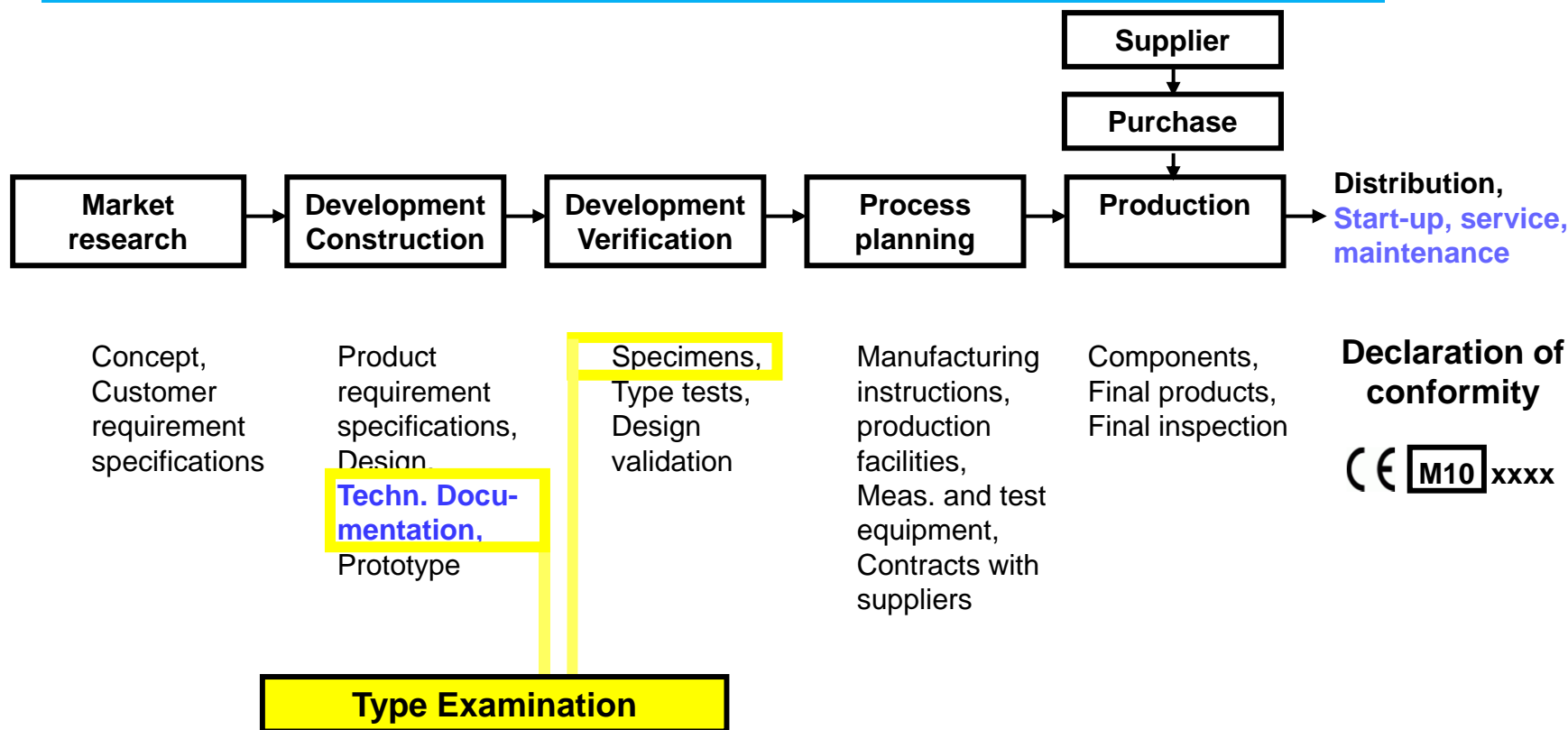
Alternatives of conformity assessment according to MID (Modules)



Module G: Unit verification of each single instrument

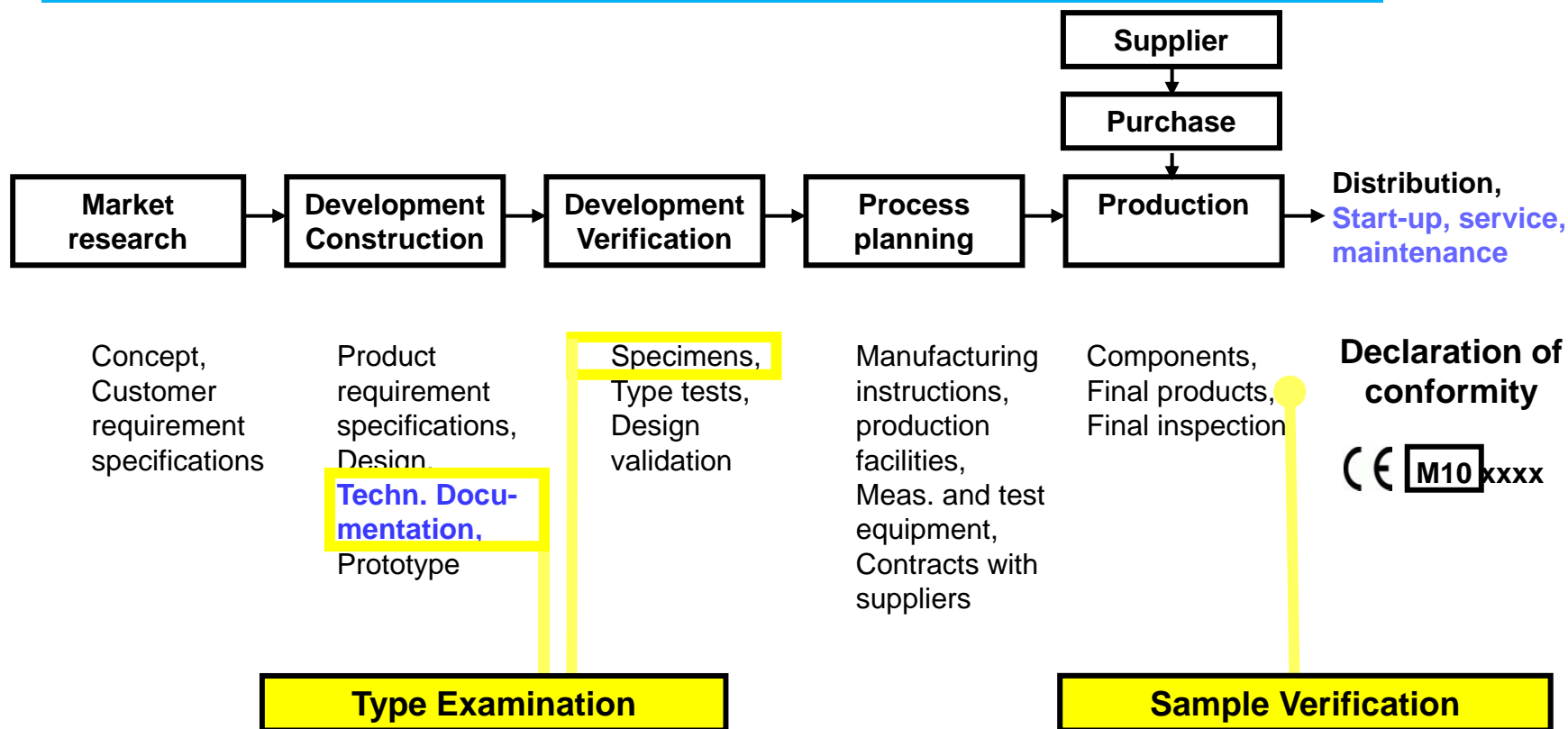
Applicable for non-mass-produced single instruments MI-005, MI-006, MI-008, MI-009

Alternatives of conformity assessment according to MID (Modules)



Modules B+C: Type examination (B) and internal production control (C) of manufacturer
Module C not scheduled for MID so far!!!

Alternatives of conformity assessment according to MID (Modules)

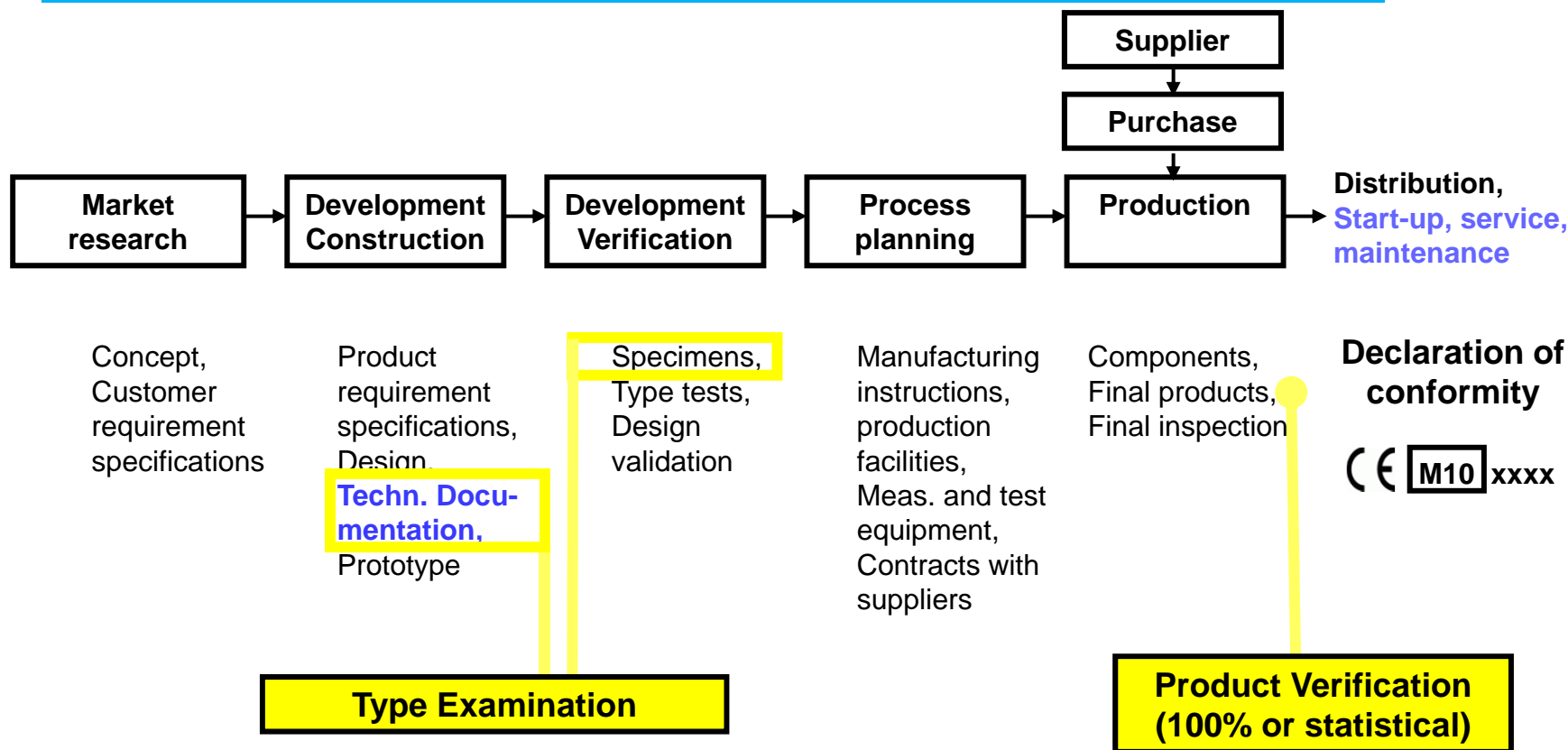


Modules B+C1: Type examination (B) and Sample Verification (C1)

Module C1 not scheduled for MID so far !!!

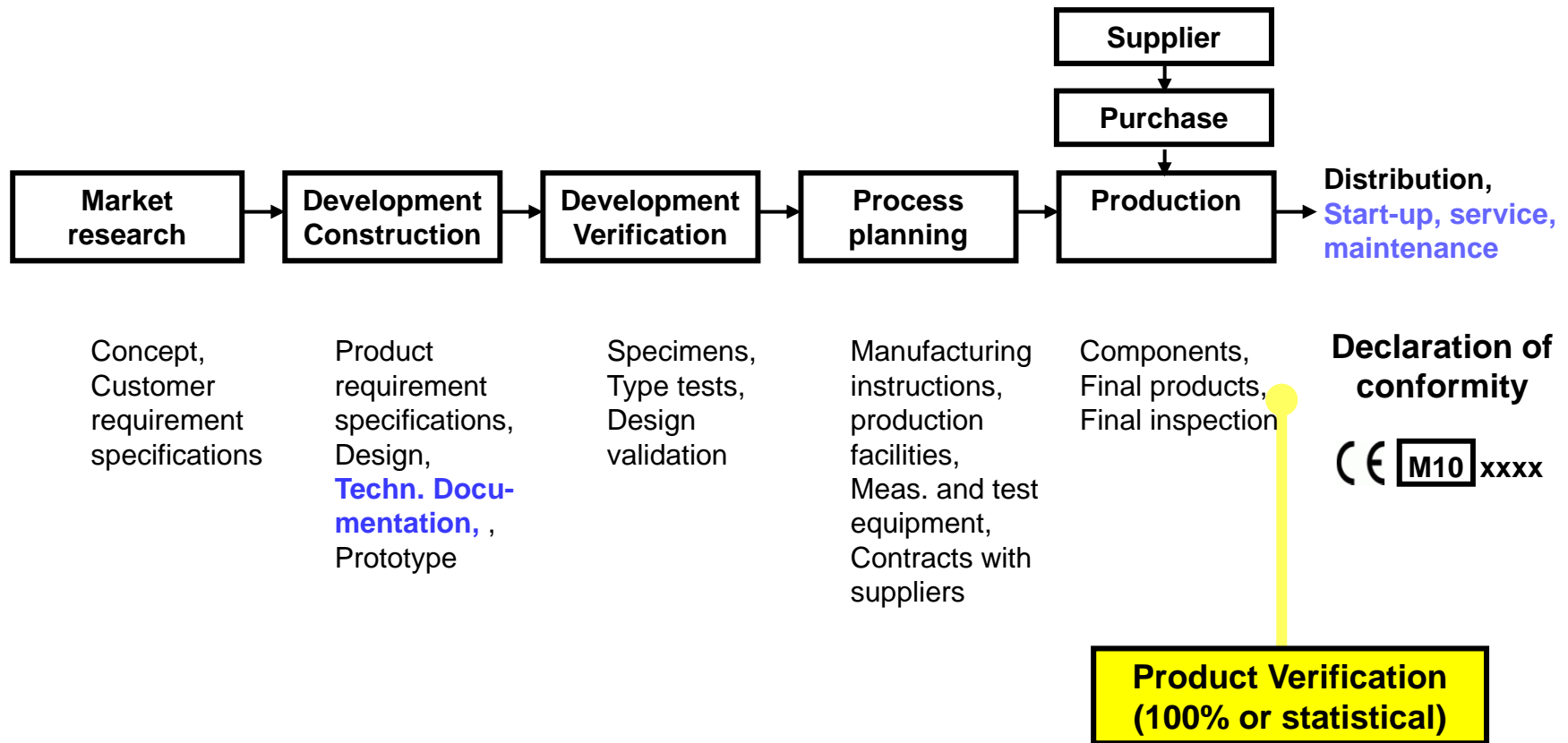
Future module C2

Alternatives of conformity assessment according to MID (Modules)



Modules B+F: Type Examination (B) and Product Verification (F)
 Applicable for small batch production of instruments MI-001 bis MI-007, MI-009, MI-010
 (corresponds to former type approval and initial verification)

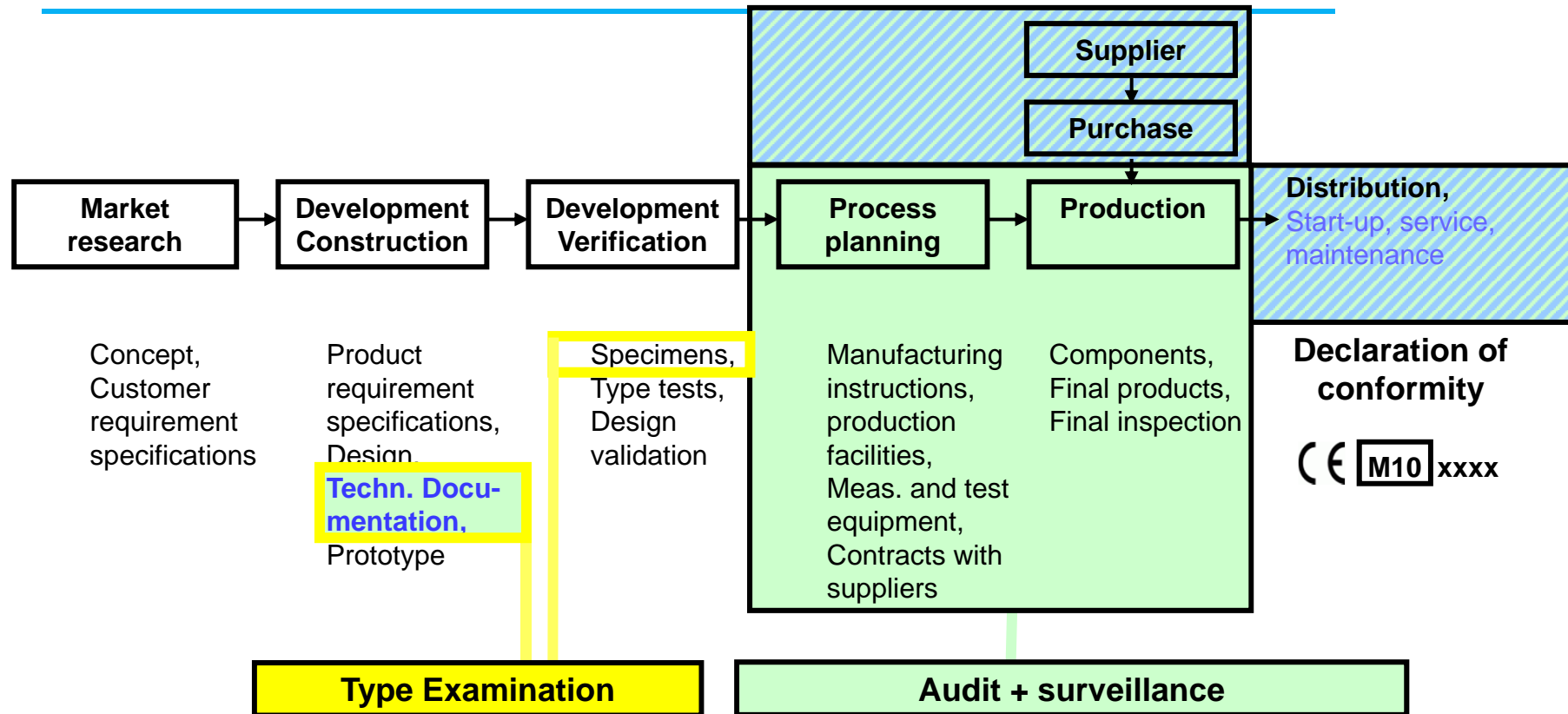
Alternatives of conformity assessment according to MID (Modules)



Module F1: Product Verification (F1) - see *F without Type Examination*

Applicable for „simple“ products MI-006 (mech.), MI-008, MI-009 (el.mech.)

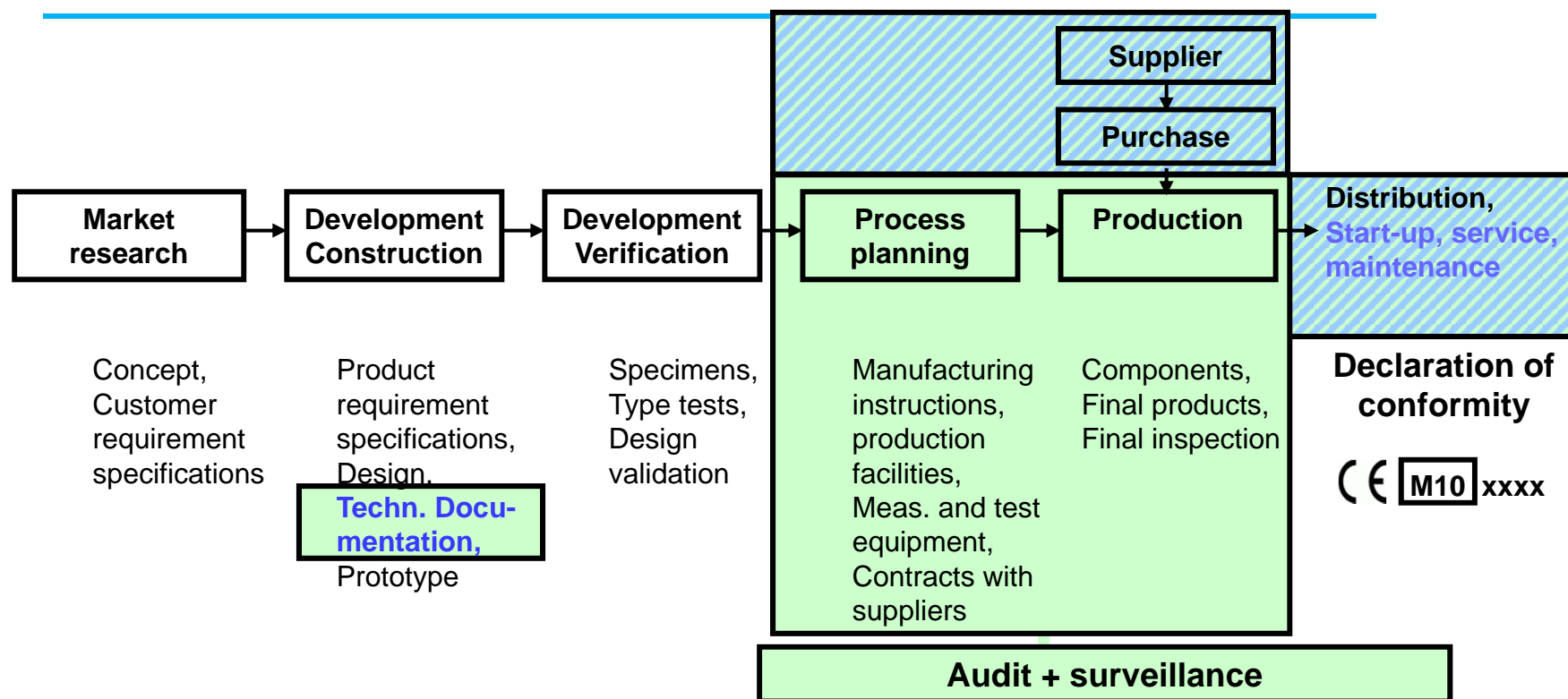
Alternatives of conformity assessment according to MID (Modules)



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

Alternatives of conformity assessment according to MID (Modules)

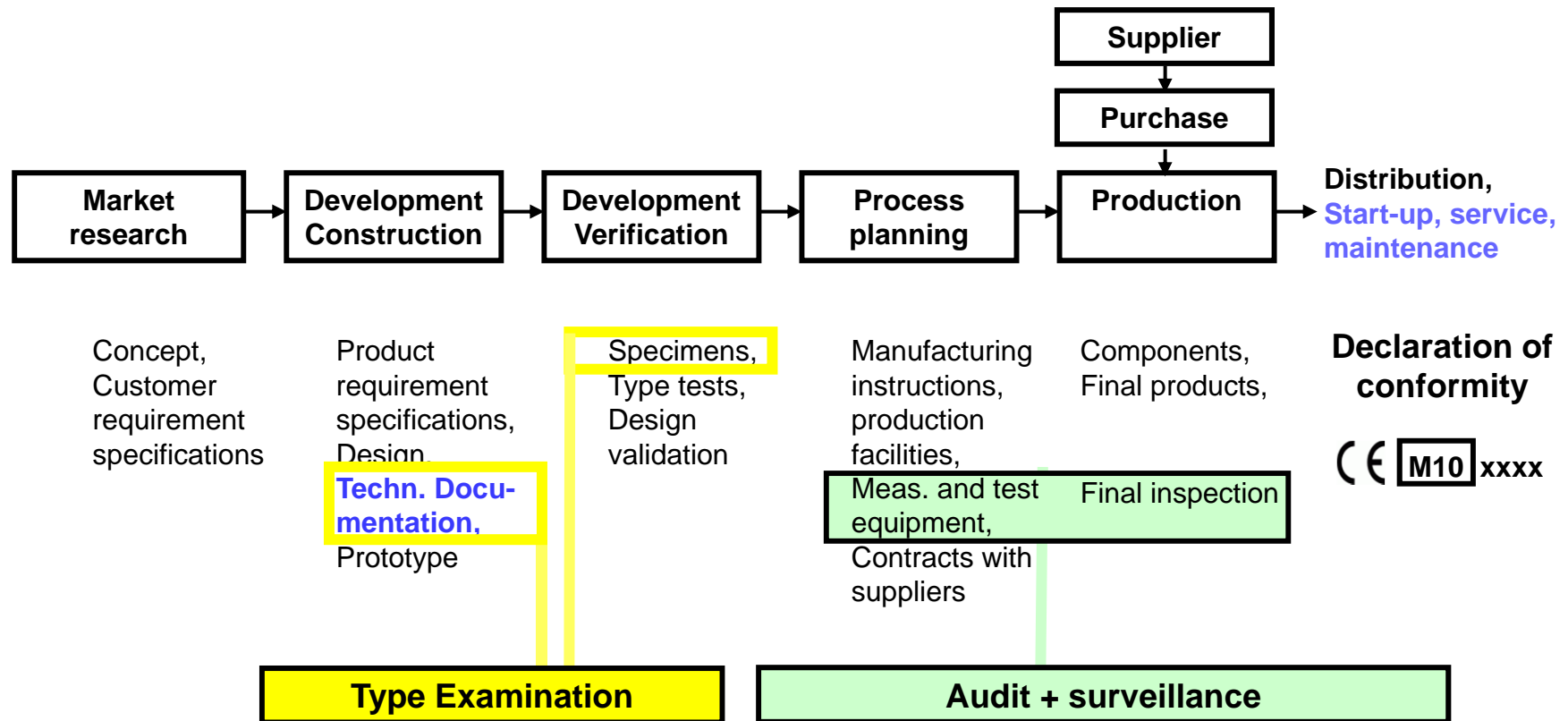


Module D1: Approval of quality system for production (D1)

– see D without B –

Applicable for „simple“ large batch production with ISO 9001-certificate
MI-006 (mech.), MI-008, MI-009 (mech., el.mech.)

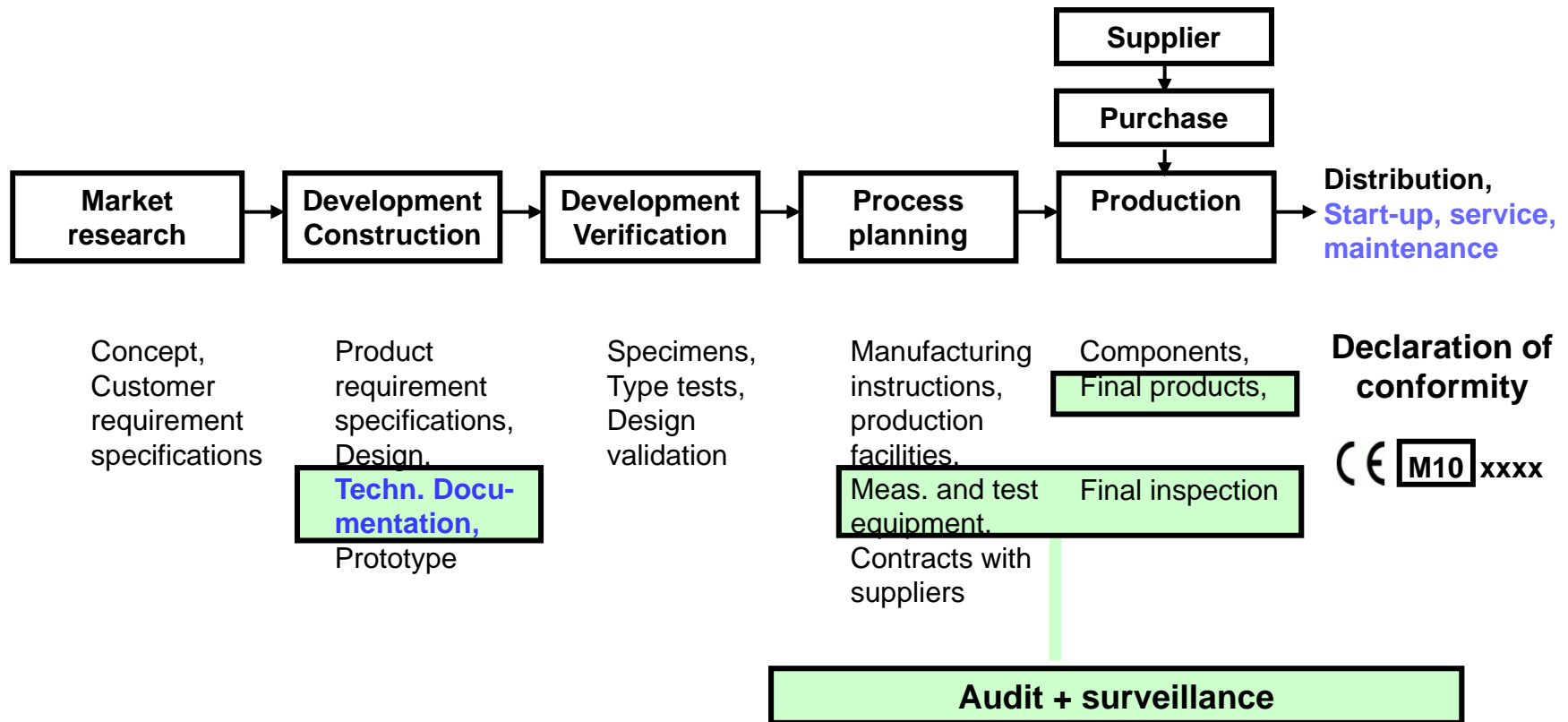
Alternatives of conformity assessment according to MID (Modules)



Modules B+E: Type Examination (B) and Approval of Quality System for final examination (E)

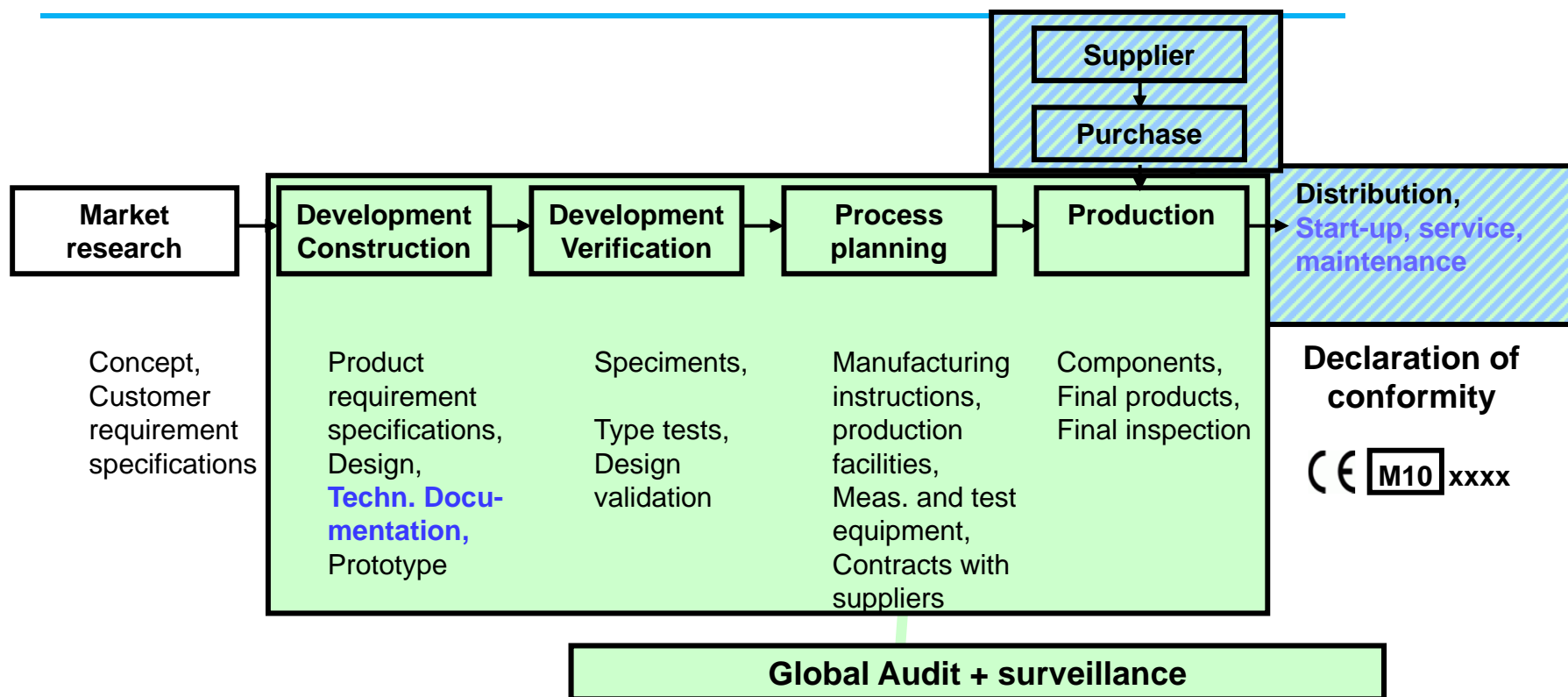
Only applicable, if final examination meets all characteristics, relevant to MID
MI-006 (mech., el.mech.), MI-008-II, MI-009 (mech., el.mech.)

Alternatives of conformity assessment according to MID (Modules)



Module E1: Approval of Quality System for final examination (E1)
 – see *E without B* –
 Simple measuring instruments,
 if final examination meets all attributes, relevant to MID
 MI-008-II, MI-009 (mech., el.mech.)

Alternatives of conformity assessment according to MID (Modules)

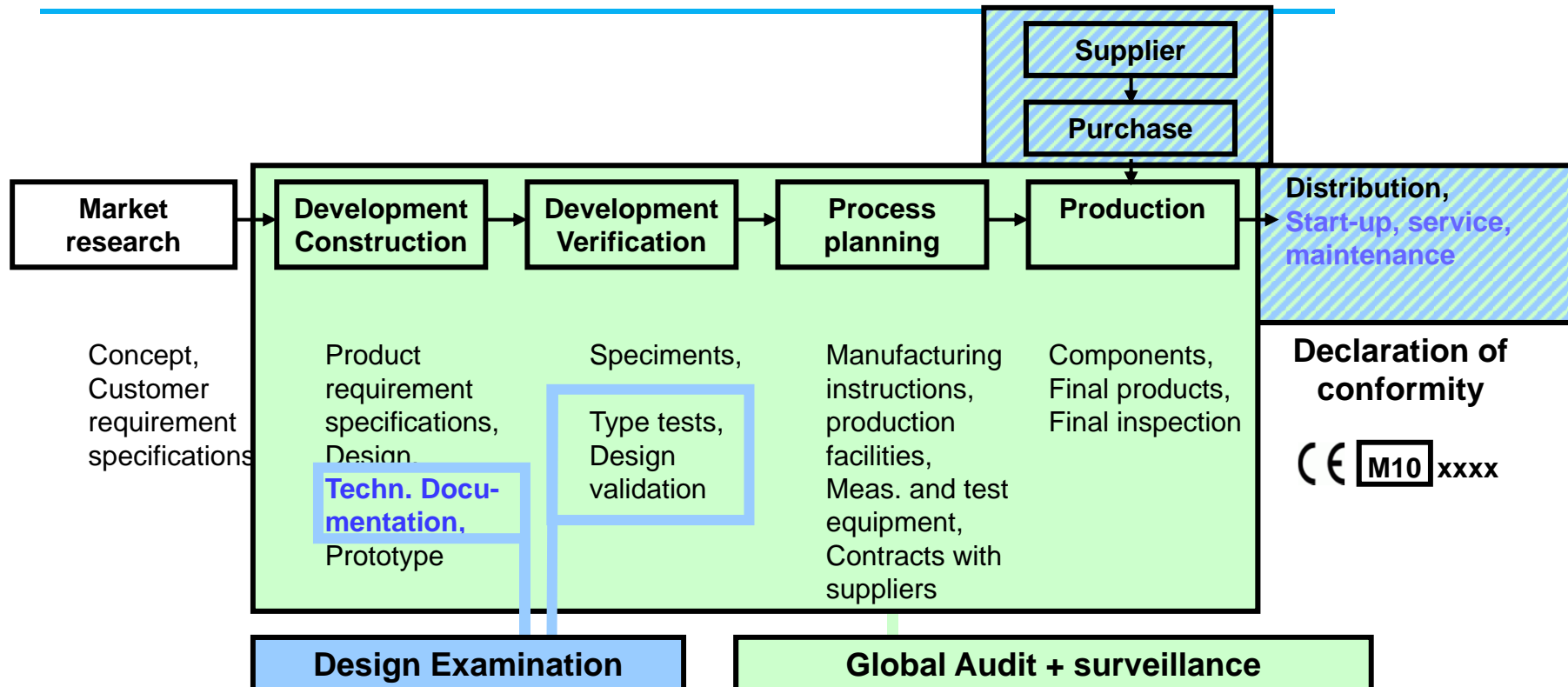


Module H: Approval of quality system for development and production

Only for Material Measures and simple length measuring instruments

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

Alternatives of conformity assessment according to MID (Modules)

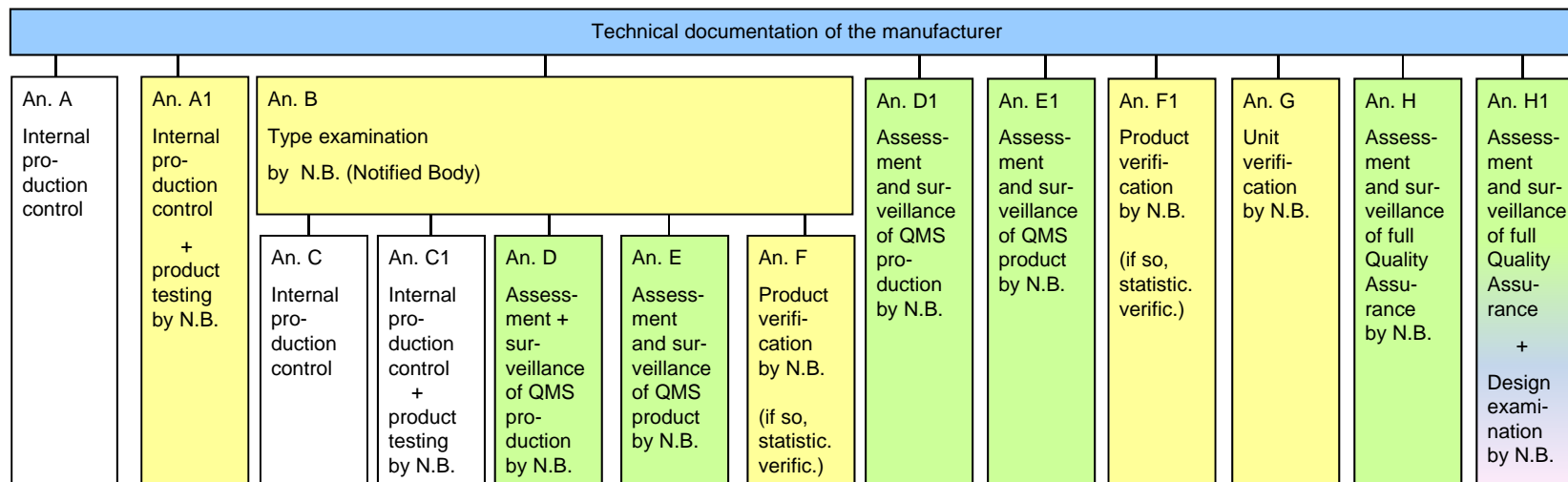


Module H1: Approval of quality management system for development and production + Design examination

MI-001...MI-007, MI-009, MI-010

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

Possible Conformity assessment procedures 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 continuous and dynamic measurement of quantities of liquids other than water | | B+D, B+F, G, H1 |
| •MI-006, Automatic weighing instruments | mechanical systems: | B+D, B+E, B+F, D1, F1, G, H1 |
| | electromechanical systems: | B+D, B+E, B+F, G, H1 |
| | electronic systems or systems containing SW: | B+D, B+F, G, H1 |
| •MI-007, Taximeters | | B+D, B+F, H1 |
| •MI-008, Material measures | I – Material measure of length | B+D, D1, F1, G, H |
| | II – Capacity serving measures | A1, B+D, B+E, D1, E1, F1, H |
| •MI-009, Dimensional measuring instruments | mechanical or electromechanical: | B+D, B+E, B+F, D1, E1, F1, G, H, H1 |
| | electronic or with SW: | B+D, B+F, G, H1 |
| •MI-010, Exhaust gas analysers | | B+D, B+F, H1 |

Consequences for previous Metrology Authorities



- The **manufacturer is solely responsible** for the conformity of measuring instruments put to the market
- Notified bodies are **conformity assessment service providers** for manufacturers
- Monopoly loss
(Notified Bodies shall coordinate **at a European level !!!**)
- Conformity assessment of notified bodies are private services in spite of administrative act
(-> **General term and conditions of certification, certification contract**)
- The authorisation of notified bodies is limited to the contractual agreement with the manufacturer , it is restricted until putting into the market.
(Possible form of pressure: **refusal or withdrawal of certificates**)
- Market surveillance is independent of notified bodies
(A granted certificate does not ensure **successful access to the market**)
- Notified bodies shall follow the respective conformity assessment standards:
EN 45011 (->ISO/IEC 17065), ISO/IEC 17025, ISO/IEC 17020, ISO/IEC 17021
- Separation of conformity assessment services as a notified body and official (legal) tasks of Metrology Authorities (e.g. market surveillance)



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Further Information

New approach of EU:

<http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/>

Notified Bodies(NANDO-Database):

<http://ec.europa.eu/enterprise/newapproach/nando/>

EU-Webpage Measuring Instruments:

http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/measuring-instruments/index_en.htm

WELMEC:

<http://www.welmec.org>

Thank you for
your attention !!!

