

Accreditation and the alternative way for notified bodies according to the new legal framework

Harry Stolz and Dirk Ratschko

Department Q.3
„Legal metrology and technology transfer“

Physikalisch-Technische Bundesanstalt
Braunschweig and Berlin

- 1. Accreditation**
- 2. Regulation (EC) No 765/2008
(accreditation and market surveillance)**
- 3. EA and ILAC/IAF**
- 4. DECISION No 768/2008/EC
(framework for the marketing of products)**
- 5. Alternative way for notified bodies**

‘Accreditation’ shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

Accreditation is part of an overall system, including conformity assessment and market surveillance

The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.

Regulation (EC) No 765/2008 of the European Parliament and the Council setting out the requirements for accreditation and market surveillance:

An overall framework of rules and principles in relation to accreditation

A system of accreditation which functions by reference to binding rules helps to strengthen mutual confidence between Member States as regards the competence of conformity assessment bodies and consequently the certificates and test reports issued by them.

The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.

Safeguard the objectivity and impartiality of national accreditation bodies

To avoid multiple accreditation, which is added cost without added value

2. Regulation (EC) No 765/2008

Each Member State shall appoint a single national accreditation body.

Where a Member State considers that it is not economically meaningful or sustainable to have a national accreditation body or to provide certain accreditation services, it shall, as far as possible, have recourse to the national accreditation body of another Member State.

Where accreditation is not operated directly by the public authorities themselves, a Member State shall entrust its national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition.

The national accreditation body shall operate on a not-for-profit basis.

Each Member State shall ensure that its national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks

The national accreditation body shall be a member of EA (*The European cooperation for Accreditation*)

National accreditation bodies shall establish and maintain appropriate structures to ensure the effective and balanced involvement of all interested parties within both their organisations and EA

Aims of international accreditation:

Mutual recognition of results of accredited bodies to avoid handicaps to trade and multiple accreditation by multilateral agreement and arrangement

With a multilateral agreement and arrangement the results of an accredited body will be accepted (national and international)

EA Multilateral Agreement (MLA)

The European cooperation for Accreditation (EA)

EA is the European network of nationally recognised accreditation bodies located in the European geographical area.

The EA missions consist in:

defining, harmonizing and building consistency in accreditation as a service in Europe, by ensuring common interpretation of the standards used by its members;

ensuring transparency of the operations (including assessments) performed and results provided by its members;

maintaining a multilateral agreement on mutual recognition between accreditation schemes and reciprocal acceptance of accredited conformity assessment services and results;

The EA missions consist in:

managing a peer evaluation system consistent with international practices - EA as a region is a member of ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum);

acting as a technical resource on matters related to the implementation and operation of the European policies on accreditation.

ILAC Mutual Recognition Arrangement

ILAC - the International Laboratory Accreditation Cooperation - is an international cooperation of laboratory and inspection accreditation bodies formed more than 30 years ago to help remove technical barriers to trade.

IAF Multilateral Recognition Arrangement (MLA)

The IAF is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment. Its primary function is to develop a single worldwide program of conformity assessment which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the body accredited.

DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a common framework for the marketing of products:

Standard elements of New Approach directives

- Scope
- Placing on the market and putting into service
- Essential requirements
- Free movement
- Presumption of conformity
- Safeguard clause
- Conformity assessment
- Notified bodies
- CE marking

General responsibilities of notified bodies

Notified bodies shall provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies.

Notified bodies shall operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner.

Notified bodies shall employ the necessary personnel, which has sufficient and relevant knowledge and experience to carry out conformity assessment in accordance with the directive in question.

General responsibilities of notified bodies

Notified bodies shall make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment.

Notified bodies shall be adequately insured to cover their professional activities, unless liability is assured under the national legislation of the notifying Member State.

Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or otherwise ensure that they know the situation of relevant standards.

Notified bodies and conformity assessment

The primary task of a notified body is to provide services for conformity assessment on the conditions set out in the directives. This is a service to the manufacturers in an area of public interest.

Notified bodies are free to offer their conformity assessment services, within their scope of notification, to any economic operator established either inside or outside the Community. They may carry out these activities also on the territory of other Member States or of third countries.

Notified bodies and conformity assessment

Manufacturers are free to choose any notified body that has been designated to carry out the conformity assessment procedure in question according to the applicable directive.

Notification procedure and withdrawal of notification

Notification is an act to inform the Commission and the other Member States that a body, which fulfils the requirements, has been designated to carry out conformity assessment according to a directive.

The Commission publishes a list of notified bodies in the Official Journal of the European Communities for information purposes. The list is constantly updated and can be obtained directly from the Commission services.

Withdrawal of notification takes place when the notified body ceases to fulfil the requirements or its obligations.

Withdrawal is the responsibility of the notifying Member state. It can also be the end result of an infringement procedure.

Reference documents:

- Regulation 765/2008/EC Article 5 (2)
- Decision 768/2008/EC Article R23 (4) and (5)
- EU Policy Paper “SOGS N640 rev1 EN” 2011

Regulation 765/2008/EC Article 5 (Operation of accreditation)

2. When a Member State decides not to use accreditation, it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonisation legislation in question.

Decision 768/2008/EC Article R23 (Notification Procedure)

4. Where a notification is not based on an accreditation certificate as referred to in Article [R22(2)], the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article [R17].

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

5. Alternative way for notified bodies

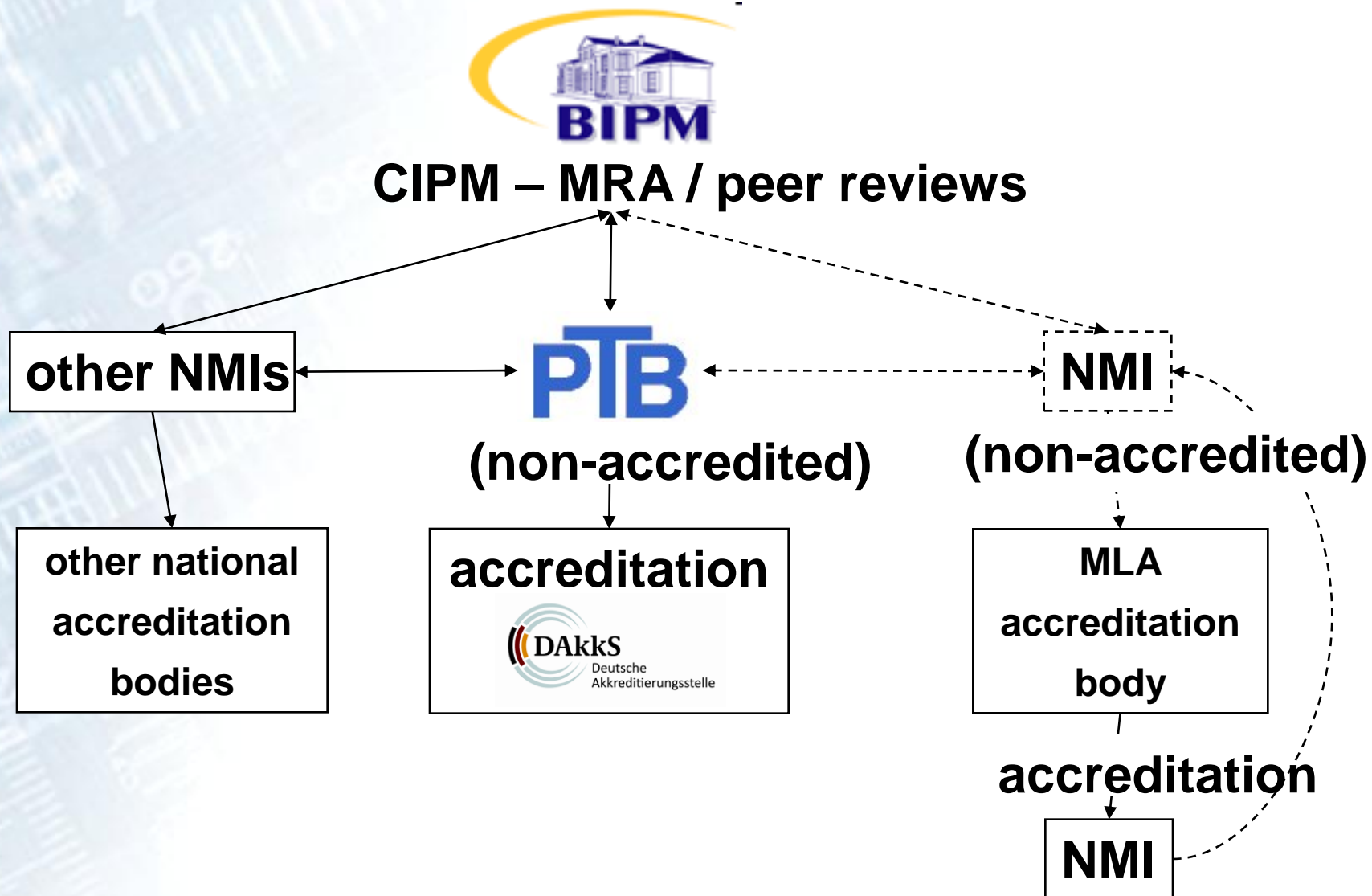
EU Policy Paper “SOGS N640 rev1 EN” 2011

			
EUROPEAN COMMISSION ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL Regulatory policy Regulatory approach for the free movement of goods			
NOTE TO THE SENIOR OFFICIALS GROUP ON STANDARDISATION AND CONFORMITY ASSESSMENT POLICY			
Title:	CERTIF 2010-08 REV1 - Notification without accreditation (Art. 5.2 of Regulation 765/2008)		
	Annabel Brewka, DG Enterprise & Industry, Unit C1 (entr-reg-approach-for-free-circ@ec.europa.eu)		
Doc. N.:	SOGS N640 REV1 EN	Issue Date:	11 January 2011
Version:	REV1	Meeting:	
Status:	Final		
Abstract: The present paper provides guidance with regard to the assessment process not based on accreditation to support the notification of conformity assessment bodies under technical harmonisation legislation.			

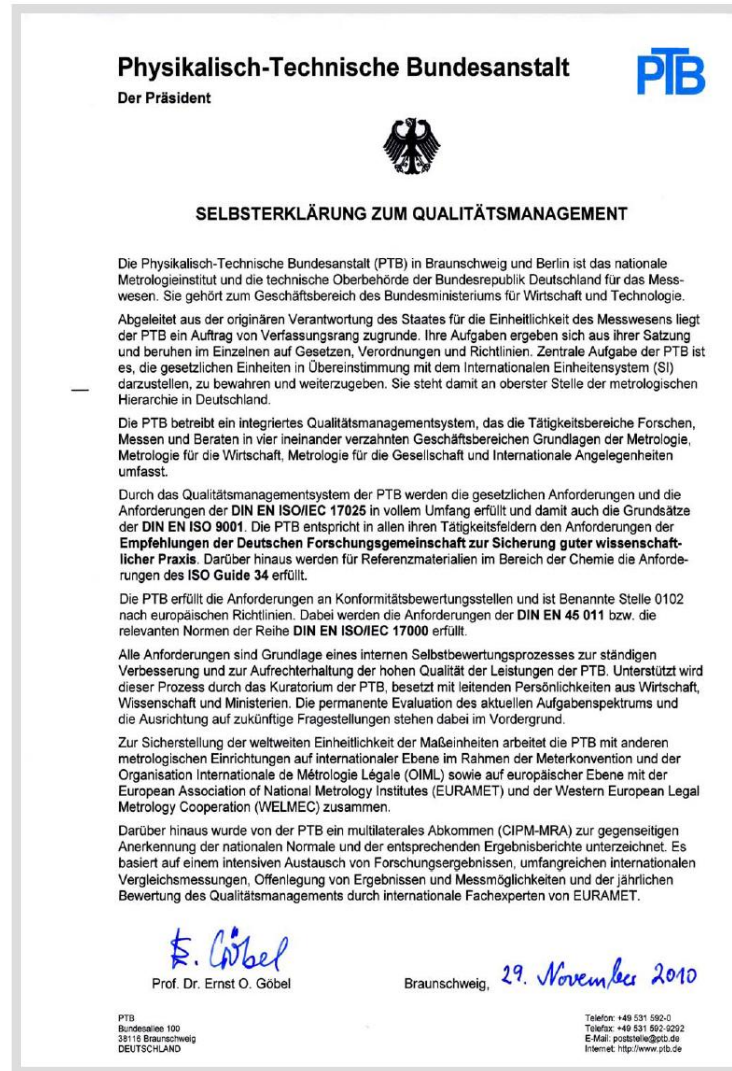
Procedure:

1. **N.B. candidate awareness** of general conditions, rights, obligations and requirements
2. Formal **application** to Notifying Authority
3. **Assessment** process against applicable requirements, such as
 - Assessment performed by Notifying Authority itself
 - Peer review performed by an international certification scheme (?)
 - Peer assessment acc. to ISO/IEC 17040 by other bodies (?)
 - ~~Assessment by Accreditation Body~~ (no “light accreditation”)
4. **Decision** by Notifying Authority
5. Systematic **surveillance** and related sanction mechanism
6. Demonstration of **national authorities own technical competence**
7. Submission of **proofing documents** to EU-COM and EU-member states
8. 2 months **objection period** (in spite of 2 week with accreditation)

5. Alternative way for notified bodies



5. Alternative way for notified bodies



Self declaration concerning quality management:

- signed by the President of PTE on 29 November 2010
- fulfillment of all requirements of ISO/IEC 17025
- fulfillment of the basic principles of ISO 9001
- fulfillment of ISO GUIDE 34 for reference materials
- note on CIPM MRA
- to be found on www.ptb.de