



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)		
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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.			
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References:	Regulation (EC) no 765/2008 setting out requirements fro accreditation and market surveillance relating to the marketing of products		



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Notification without accreditation - Article 5.2 of Regulation 765/2008

1 Objective of the paper

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. It describes the main elements on which such an assessment process should be based on. It is not the aim of this paper to set up an “Article 5.2” assessment methodology or to provide a detailed description and list of documents to be sent in by the notifying authorities.

2. Background

Member States notify - via the designated notifying authorities - to the Commission and to the other Member States those conformity assessment bodies they have decided to authorise to carry out specific tasks pertaining to the conformity assessment procedures laid down in the applicable piece of technical harmonisation legislation.

By taking the political and legal decision which bodies to notify, Member States take the final responsibility for the technical competence and independence of such bodies which they must therefore verify by the means of an adequate assessment process.

According to the New Legislative Framework, the verification of the technical competence and independence during a notification process can be supported from a technical point of view either by an accreditation according to the 17000 series of harmonised standards taking into account the sector specific requirements stemming from the applicable harmonisation legislation and other normative documents if applicable, or, if it is decided not to use accreditation, by an alternative assessment process.

While not obligatory under the New Legislative Framework, and although accreditation and the alternative evaluation procedure are legally equivalent, the preference of the use of accreditation to support notification is clearly expressed in the New Legislative Framework through the facilitated notification procedure for notification based on accreditation. Accreditation as an independent and impartial assessment carried out by a competent authoritative third party, i.e. the designated national accreditation body, should be considered by the notifying authorities as the privileged instrument for the

assessment of the technical competence and impartiality of a candidate notified body. This because

- accreditation being a standard based total, reduces the differences in the criteria applied for notification
- accreditation provides for established complaint and appeal procedures
- accreditation provides for the possibility to object to an assigned assessor
- accreditation provides for established procedures and plans for regular surveillance at close intervals to monitor the continued fulfillment by the accredited CAB of the applicable requirements
- the existence of the EA peer evaluation system ascertaining conformity to the requirements of Regulation 765/2008, EN ISO/IEC 17011 and other applicable requirements and therefore verifying the competence of the national accreditation bodies to assess CABs in view of notification, makes accreditation the most transparent assessment system in place, able to give sufficient guarantees and confidence.

To date, we do not have a comparable and substantially equivalent alternative assessment system based on codified rules and procedures, which entails a similar level of harmonisation and transparency in comparison with accreditation. In particular no other assessment method provides for a systematic, structured and widely accepted process of evaluation of those assessing the competence of conformity assessment bodies, which clearly represents an added value of the accreditation tool. This is why the New Legislative Framework has considerably strengthened the role and use of accreditation in the regulated area.

3. Assessment under Article 5.2 of Regulation 765/2008

When a Member State nevertheless decides for whatever reasons to use an alternative assessment method and not to base its notification on accreditation, according to Article 5.2 of Regulation 765/2008 “*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*”.

In order to ensure the necessary level of confidence in the impartiality and technical competence of conformity assessment bodies and in the issued test reports and conformity assessment certificates issued by them, national authorities, when carrying out the assessment without accreditation, should give detailed and comprehensive information describing on how the candidate Notified Body has been assessed as qualified to carry out the tasks for which it is notified and showing that it fulfils the applicable criteria relating to Notified bodies. This information linked to a given notification is made available through the NANDO tool to the Commission and the other Member States.

The alternative evaluation procedure should be based at least on the following elements:

- candidate Notified Bodies should be made aware of general conditions, their rights and obligations and requirements relating to the assessment carried out in view of notification
- existence of a formal application procedure
- Assessment process against applicable requirements. The assessment should consist in
 - a review of documents verifying the completeness and appropriateness from a substantial point of view with regard to conformity to the applicable requirements
 - an on-site assessment to check technical and procedural aspects such as availability and appropriateness of facilities/equipment, technical competence of staff, existence of an appropriate management system and to check other aspects demonstrating that conformity to requirements is properly implemented. The assessment must include witnessing of technical activities
- production of an assessment report
- decision making process
- existence of a systematic surveillance and related sanction mechanism providing for periodic surveillance including on-site visits, in order to verify the continued fulfilment of requirements by the Notified Body
- demonstration of the national authorities own technical competence for assessing conformity assessment bodies for the purpose of notification under technical harmonisation legislation

When choosing to go down the route of the alternative assessment process rather than of formal accreditation, national authorities should indicate the reasons why accreditation is not chosen to back up the notification process. Moreover, national authorities should not outsource the assessment of conformity assessment bodies that seek to become Notified Bodies to the national accreditation body, without asking for accreditation. Such “light accreditation” using the service and competence of national accreditation bodies without the recourse to accreditation is a practice which undermines the accreditation and should therefore not be used. It should be noted that in some cases national accreditation bodies are obliged to carry out the assessment of candidate Notified Bodies as this is required by existing national laws or bylaws.