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**NOTE TO THE SENIOR OFFICIALS GROUP ON
STANDARDISATION AND CONFORMITY ASSESSMENT POLICY**

Title:	CERTIF 2009-06 REV6 - CROSS BORDER ACCREDITATION ACTIVITIES		
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Abstract:			
<p>This working paper concerns the interpretation of the cross border accreditation policy as enshrined in Art. 7 of Regulation (EC) 765/2008 in relation to multinational conformity assessment bodies.</p> <p>The present document contains a common understanding on how the relevant cross-border accreditation provisions should be implemented in relation to multinational conformity assessment bodies. It is the result of the discussions which took place within various fora such as SOGS, the EAAB and within EA.</p>			
Keywords:	Accreditation, cross border accreditation, multinational conformity assessment bodies		
References:	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products		



Cross border accreditation

1. INTRODUCTION

The paper concerns the interpretation of the cross border accreditation provisions of Art.7 of Regulation (EC) 765/2008 (“the Regulation”) in relation to multinational conformity assessment bodies. Bearing in mind that the ultimate say on matters of EU law rests with the European Court of Justice, this draft paper contains a proposal for a common understanding and pragmatic solution on the implementation of the cross-border accreditation regime which is the result of the discussions held between all interested parties involved (public authorities, EA and its members, conformity assessment bodies and the Industry).

The application of Art.7 of the Regulation must be done in the light of the Single market principles such as the freedom of establishment and the freedom to provide services and account must be taken of other pieces of legislation such as Directive 123/2006/EC on Services in the Internal Market (the "Services Directive"), whilst guaranteeing the full respect and application of the fundamental principles and objectives of the European accreditation policy. This is valid in particular for the non-competition principle, which is a necessary condition for accreditation to be the last level of control of the adequacy of conformity assessment services.

2. BACKGROUND

According to Art. 7.1 of the Regulation, conformity assessment bodies (CABs), whether third-party or first-party/in-house bodies, are required when requesting accreditation to do so with the national accreditation body (NAB) of the Member State in which they are established. This general rule allows for exceptions: the possibility of a conformity assessment body to request accreditation with a NAB in another Member State is limited to cases where

- there is no NAB in its own Member State [Art. 7.1(a)],
- the NAB does not offer the requested accreditation service [Art. 7.1(b)]
- the NAB has not received a positive outcome in the peer evaluation in relation to the conformity assessment activity for which accreditation is requested [Article 7.1(c)].

Art. 7.1 of the Regulation is closely linked to and is a logical consequence of the non-competition principle embodied in Article 6 of the same Regulation. It is important to prevent

conformity assessment bodies from shopping around for accreditation certificates, thus creating a “market for accreditation” leading to the commercialisation of accreditation which jeopardizes the added value and role of accreditation as a public authority activity and last level of control of the conformity assessment chain..

3. PROBLEM DEFINITION

Against this background, the issue to be tackled concerns multinationally active CABs, i.e. CABs having their head office in one Member State and which exercise their activity in another or several Member States. This activity can be carried out in another Member State on a temporary basis (free provision of services)¹ or on a permanent basis by means of one or more local entities such as subsidiaries, branches or agencies (freedom of establishment)².

CABs may provide their services to clients in other Member States on the basis of free provision of services without having to be established there. The accredited conformity assessment results given on the basis of free provision of service will be recognised by the public authorities and accepted on the basis of the mutual recognition principle set out in Article 11(2) of the Regulation. Indeed, under this provision, *"National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation under Article 10, and thereby accept, on the basis of the presumption referred to in paragraph 1 of this Article, the accreditation certificates of those bodies and the attestations issued by the conformity assessment bodies accredited by them."*

Business operators are free to organise and structure themselves in the way they think is best to serve their clients, for example to get established in various Member States and to operate via local entities.

In this case the question arises for the need for an accreditation for the multinational organisation as a whole or of parts of that organization in the locations where they are established and operate: can the operations of the local entity be covered by the accreditation of the head office issued by the NAB where the head office is established or shall the local entity be accredited by the local NAB?

The cross-border provision laid down in Art. 7 is perceived to be very stringent and unnecessarily burdensome for multinational CABs with local entities/sites established in other Member States working under the supervision of the head office and under the same quality system and management, as implying costly duplications of assessments. The risk of suffering a competitive disadvantage compared to third-country organizations is feared. The Regulation does not apply to third-country bodies which are therefore free to request accreditation (even multiple accreditations) with the European NABs of their own choice. In case of a strict legal interpretation of Article 7, due to their structures, multinational CABs may not benefit from the advantage of one accreditation certificate sufficient for the whole

¹ This can happen in the four following modes: a) the CAB (service provider) moves temporarily to the service recipient's Member State to provide its services and then comes back; b) the service recipient moves temporarily to the Member State of the CAB to receive the service; c) neither the service recipient nor the CAB moves, whereas the service is done from a distance (for ex. over the email and/or by phone); d) both the CAB and the service recipient move to another (third) Member State where the service will be provided

² Differently from subsidiaries which have separate legal personality, agencies or branches or offices do not need to be separate legal entities. It follows from Art. 49 TFEU providing for the freedom of establishment and the case law of the ECJ that the same undertaking can be established at the same time in one or more other Member States.

territory of the EU, although avoiding multiple accreditation is one of the objectives of the Regulation³.

Practice shows, however, that for a long time the majority of multinational CABs have been having their local entities accredited by local NABs, resulting in multiple accreditations from various NABs, for reasons linked to commercial arguments more than to necessity. Moreover, it appears that a number of these organizations are fully prepared to continue with this practice, for the same reasons. According to the concerned parties, such multiple accreditations are due to the demand from local regulators and/or from the local market not recognizing the equivalence of the accreditations issued by the different NABs signatories to the European Co-operation for accreditation multilateral agreement (EA MLA). In light of the mutual recognition principle provided for in Art. 11.2 of the Regulation, such statements in relation to public authorities are no longer acceptable, as national authorities are obliged to recognize the equivalence of the services delivered and to accept the accreditation certificates issued by the NABs which have successfully passed the peer evaluation managed by EA and which are as a result, signatories to the EA MLA for the relevant accreditation activity.

The acceptance by the market place indeed remains a challenge and problem to be tackled. End users still perceive some European NABs and related accreditation certificates and logos to be more valuable than others. To overcome these perceptions and resistances the EA MLA should be promoted through activities targeting the CABs and their clients. CABs should contribute to convince the market that the accreditation given by the EA MLA signatories are equivalent by abstaining from promoting one or another NAB which hinders the process of acceptance of the equivalence of services offered by the NABs and fosters the use of multiple accreditations. Instead, the value and quality of accredited certificates, independently of which NAB has accredited them, should be promoted. Within this context a statement on the accreditation certificate attesting the equivalence of the accreditations issued by EA MLA signatories and the introduction of a single European accreditation symbol, an EA symbol, to be used by the signatories to the EA MLA could be further considered. Such measures, in particular the latter, may go beyond the Regulation but could possibly be an effective tool to foster the understanding and visibility of the EA MLA and thereby the acceptance of the equivalence of the EA MLA signatories.

4. SOLUTION

4.1. General terms

1. Duplication of unnecessary assessments and burdens on multinational CABs should be avoided. This is required by the principle of non-duplication, which is to be inferred from the case law about Art. 56 TFEU and is explicitly set out in Art. 10(3) of the Services Directive.
2. Market needs in relation to accreditation should be met, but without compromising the fundamental principles of the European accreditation policy.
3. Adequate controls of local entities of multinational CABs must be assured.

³ Recital 19: "...The objective of this Regulation is to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union, and to avoid multiple accreditation, which is added cost without added value...."

4. Exchange of information and effective cooperation between NABs for assessment, re-assessment and surveillance of local sites of multinational CABs is necessary. Based on mutual recognition of all assessments carried out by EA members, any duplication of assessments of organisational aspects or requirements should be strictly avoided.
5. If necessary and on reasoned request, relevant information on carrying out accreditation against national legislative requirements of another Member State and/or requirements set out in relevant national sectoral schemes shall be provided by the local NAB to the national authorities of the other Member State. National authorities of the Member States in which the local NAB is established should be kept informed thereof.
6. It should be underlined that the solution proposed has no effect on the civil liability regimes across the European Union.

4.2. Multi-site accreditation

The CAB with local sites (regardless of their legal personality), provided that the latter operate under the same global quality system and management and that the head office has the means to substantially influence and control their activities, can be considered as being only one organisation with regard to the conformity assessment activity carried out. Such a CAB is therefore allowed to request accreditation with the NAB of the head office whose scope can also cover the activities performed by the local site, including those located in another Member State.

The multi-site accreditation is however only permitted under the Regulation if the accredited CAB maintains the final responsibility for the activities performed by local sites covered by the scope of the multi-site accreditation. The accreditation certificate issued by the NAB where the head office is established names one legal entity - the head office - and it is this legal entity which holds the accreditation and which is responsible for the accredited activities of the CAB, including any activity performed by the local site that forms part of the scope of the accreditation. Where these local sites carry out key activities (as listed in EN ISO/IEC 17011⁴), then the accreditation certificate (in its annexes) shall clearly identify the address of these site offices.

The local site is entitled to offer directly to the local market conformity attestations under the multisite accreditation, but only on behalf of the accredited CAB. These accredited certificates and reports are therefore issued under the accreditation, name and address of the head office without the logo of the local site. However this does not impede mentioning on the conformity assessment certificate or report the contact details of the local site issuing the certificate or report in question.

The multi-site accreditation is meant for use only by companies within the same organisation and where the head office maintains the responsibility for the activities performed and certificates/reports issued by the local sites. The responsibility shall be demonstrated on the basis of contractual or equivalent legal relationships between the head office and the local entity and internal regulations that further specify these relationships in terms of management and responsibilities.

⁴ Key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the result of conformity assessments

The solution of the multi-site accreditation can be applied to all types of local entities (subsidiaries, branches, agencies, offices etc), regardless of their legal personality and is in principle valid for all types of CABs, including laboratories, inspection and certification bodies as long as they carry out clearly identified and relevant activities for the purpose of accreditation.

The multi-site accreditation solution is excluded when the above mentioned conditions are not fulfilled, i.e. the CAB can not be considered as one organisation with regard to conformity assessment and the head office does not maintain the ultimate responsibility for the activities of the local entities. In this case the local sites being separate legal entities should apply for their own accreditation with the local NAB. As a consequence it can be considered that the local entity carries out the conformity assessment service completely independently of the head office.

In case of the multi-site accreditation, initial assessment and reassessments must be carried out in close cooperation between the respective local NAB and the NAB of the head office taking the accreditation decision, while surveillance must be carried out in cooperation with or by the local NAB. The multinational CAB must fully cooperate with the NABs involved. Local entities cannot reject the participation of the local NAB in the assessment, reassessments and surveillance process. Harmonised rules for co-operation between NABs exist in the form of the EA cross frontier policy. Multi-site accreditation needs to be managed under the EA cross frontier policy in order to guarantee the involvement of the local NAB. EA is therefore requested to review its existing cross frontier policy for cooperation between EA members, so as to fully implement the multi-site accreditation, without complicating or compromising the proper execution of the peer evaluation.

4.3. About Subcontracting

The multi-site accreditation does not supersede sub-contracting, which remains a viable solution in case a CAB may wish to sub-contract part of its activities to legal entities located and operating in the same or other Member States, which however do not belong to the same organisation, i.e. are not part of a multinational CAB. In this case, the subcontractor is not covered by the accreditation of the CAB. The accredited CAB may subcontract specific parts of its conformity assessment activities to a different legal entity according to the applicable CAB standard to which it is accredited and only to the extent allowed in this standard. The CAB must be able to demonstrate to the NAB that subcontracted activities are carried out in a competent and reliable manner consistent with relevant requirements of the applicable normative documents for the activities in question. The accredited conformity assessment attestation must be issued exclusively under the name and responsibility of the accredited CAB, i.e. the legal entity holding the accreditation. The contractual relationship with the client remains with the accredited CAB.