

**ILAC Template for comments –  
IAF/ILAC Guidance on the Application of ISO / IEC 17011:2004  
Comments by CEOC and EUROLAB**

Closing Date: **23 April 2007**

Document: **IAF/ILAC JWG ISO/IEC 17011:2004**

1	2	(3)	4	5	(6)	(7)
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CEOC and EURO LAB			ge	ISO/IEC 17011 was published in September 2004. The transition period for the implementation of 17011 by accreditation bodies was 18 month. Significant problems with the direct application of 17011 by accreditation bodies or by peer evaluation teams did not arise. We cannot see any need for a guidance on 17011 which may be more confusing than clarifying and propose therefore to make the attempt to perform accreditation and peer evaluation processes without a prescriptive guidance. Our detailed comments below are only relevant in case this advice is not accepted.		
CEOC and EURO LAB			ge	Additional or less requirements are not allowed but can be found in some guidance (less: G.4.1.Note, G.4.3.2.3, G.4.3.7.1, G.7.4.1.1; more: G.7.5.7.1, G.7.5.8.1).		
CEOC and EURO LAB	Introduction	Paragraph 3	ed	The term “mutual recognition agreements” in the first line of paragraph 3 does not reflect the wording of clause 1 of 17011.	Reformulate as follows:  This Guidance forms the basis of mutual recognition <del>arrangements</del> <del>agreements</del> between accreditation bodies, and is considered necessary for the consistent application of ISO/IEC 17011. Members of the <u>Multilateral/Mutual</u> Recognition Arrangement (MLA/MRA), ...	
CEOC and EURO LAB	G.3.1	Note	te	The note explaining “equivalence of accreditation” uses the terms “conformity assessment services accredited” and “accredited product or personnel certification”. These terms are incorrect. Accredited	Reformulated as follows:  Note: “MLA/MRA recognition of “equivalence of accreditation” may have various depths	

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				are CABs and not services or product/personnel certification.	depending on the type of <u>CAB</u> <del>the conformity assessment services</del> accredited. For example, <u>accreditation of CABs providing accredited</u> product or personnel certification could be based on different normative documents.	
CEOC and EURO LAB	G.4.1	Note	te	G.4.1.Note refers to the Note to clause 4.1 of 17011 and is therefore related to governmental accreditation bodies. Other accreditation bodies have, according to clause 4.1 of 17011, to be a registered legal entity and cannot trade under a different name.	Amend G.4.1.Note as follows:  An accreditation body that is part of a larger <u>governmental entity organisation</u> may trade under a different name (and shall have a distinctive accreditation symbol and logo) and be recognised by the MLA/MRA group under that name.	
CEOC and EURO LAB	G.4.3.1.2		te	Which decisions are meant? The top management of the accreditation body has the overall authority and responsibility on the decision on accreditation (clause 4.2.5 d) of 17011).	Make it even more general:  .... subject to approval by any other <u>person, body or organisation</u> .	
CEOC and EURO LAB	G.4.3.2.3	First sentence	te	Clause 4.3.2 of ISO 17011 does not refer only to impartiality but also to principles and major policies of the accreditation system. The mechanism in place should also cover such issues.	Amend G.4.3.2.3 as follows:  Mechanisms should be in place to provide for those parties of the structure in clause 4.3.2 to take effective actions where their input on issues of <u>impartiality, principles and policies of impartiality</u> are not considered by top management. ....	
CEOC and EURO	G.4.3.6.3		te	The accreditation body has, according to clause 4.1 of 17011, always to be a registered legal entity, except the Note to clause 4.1 applies (governmental	Delete G.4.3.6.3.	

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LAB				accreditation bodies). G.4.3.6.3 is therefore not needed.		
CEOC and EURO LAB	G.4.3.7.1		te	A related body is always a separate legal entity (Note 1 to clause 4.3.7) or a separate part of a government (Note 2 to clause 4.3.7). Guidance 4.3.7.1 allows that other parts of a legal entity the accreditation body belongs to are related bodies with the consequence that the other parts of such a legal entity could offer or provide those conformity assessment services that CABs perform. This is clearly in contradiction to the impartiality concept of 17011 and would compromise the confidence in the activities of accreditation bodies as well as of CABs.  The proposed amendments are therefore important to avoid such conflicting situations.	Amend G.4.3.7.1 as follows:  If the accreditation body <del>identified in G.4.3.6.3</del> is also part of a larger organisation, any other <u>legal</u> entity within the larger organization is a related body and provisions of clause 4.3.7 apply. <u>Other parts of the legal entity, the accreditation body belongs to, have to fulfil the requirements of clause 4.3.6.</u>	
CEOC and EURO LAB	G.4.6.2.		te	It should be clear that the requirements are the requirements of the standard, not the additional requirements induces by an interpretation.	The accreditation body may not develop documents which amplify, add to or otherwise amend the requirements of the International Standards and mandate the use of these documents in the assessment processes.	
CEOC and EURO LAB	G.7.4.1.1		te	If joint assessments with other MLA/MRA partner are not considered to be contracting of external individual assessors or experts (Note to clause 7.4.1) the subcontracting rules of clause 7.4 have to be applied also to joint assessments with other MLA/MRA partner including written consent of the CAB (clause 7.4.2 d)).	Delete G.7.4.1.1 or add "Nevertheless the written consent of the CAB is necessary."	

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CEOC and EURO LAB	G.7.5.6.1		te	The scope of 17011 (clause 1) cannot be expanded by resolutions of IAF and/or ILAC.	G.7.5.6.1 has to be altered as follows: Where a CAB seeks/maintains accreditation for one or more of the conformity assessment services listed in paragraph 3 of clause 1 <del>(or other services determined by IAF and/or ILAC resolution to be a conformity assessment activity and the object of accreditation)</del> , each of these services ....	
CEOC and EURO LAB	G.7.5.7.1		te	The educational guidance for the accreditation of inspection bodies is more confusing than clarifying. It contains a mixture of explanation on clause 7.5.7 and 7.7.3. Concerning visiting premises of the inspection body from which one or more key activities are performed the note to clause 7.5.7 of 17011 was formulated with “as appropriate” to avoid visiting all working places of inspection bodies having in mind that decisions are taken by inspectors often on-site. The explanations in the guidance are in this respect contradicting. The issues mentioned which “would be expected to necessitate a visit to the particular premise as part of the accreditation assessment” (e.g. contract review, records, standards and equipment) would change the “as appropriate” in a “must”. The consequence would be that all locations where inspections are carried out are “key activity premises” and have therefore to be visited by the accreditation body. The inspection body is responsible for the	Delete or alter G.7.5.7.1 as follows: Inspection Body accreditation: In inspection, the decisions on the result of the conformity assessment are often made by the inspector on-site and form part of the inspection itself. With reference to the Note on clause 7.5.7, it is not necessary to visit every location where inspection decisions are made prior to accreditation. In this case, the inputs to the inspection process leading to the decision on the result of the conformity assessment are, for example, selection and monitoring of competent inspectors and provision of appropriate tools. In the inspection field, the Note to clause 7.5.7 should be understood as follows: Key activities include: policy formulation, process and/or procedure development, process of initial selection of inspectors and,	

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				<p>competence (clauses 8.2 and 8.3 of 17020 and guidance 8.1b, 8.2 and 8.3 of IAF/ILAC-A4) and monitoring (clause 6.4 and 6.6 of 17020 and 6.4 of IAF/ILAC-A4) of the inspectors and not the accreditation body. 17011 require in clause 7.7.3 the witnessing of a representative number of staff by the accreditation body. Concerning the sampling procedures is 17011 flexible and allows witnessing in a flexible way.</p> <p>The accreditation procedure, the extent and frequency of visits depend on the proven stability the services of inspection bodies have reached (see clause 7.11.3 of 17011). We recommend therefore to refrain from developing special guidance for inspection bodies and to leave it to the accreditation bodies to act flexible taking into account the individual performance of an inspection body. <b>The guidance G.7.7.3.1 is sufficient also for the accreditation of inspection bodies.</b></p>	<p>as appropriate, contract review, planning conformity assessments, review and approval of conformity assessments.</p> <p><del>Issues for consideration as to whether a premise is one where key activities are carried out include:</del></p> <ul style="list-style-type: none"> <li><del>• Decisions regarding acceptance of work separate from head office, and deciding whether the inspection job can be done (contract review);</del></li> <li><del>• Records of inspections (e.g. quality system records, inspection details) not kept at head office;</del></li> <li><del>• Standards system documentation and quality systems documentation (including training records);</del></li> <li><del>• Specific equipment (such as calibrated instruments) kept from head office.</del></li> </ul> <p><del>Such issues would be expected to necessitate a visit to the particular premise as part of the accreditation assessment.</del></p> <p><del>As the most critical contribution to inspection decisions is the inspector, it follows that inspectors must also be witnessed performing inspections. The witnessing of inspectors needs to be such that the effectiveness of systems can be verified, and the competence of individual inspectors conforms to the inspection body's own</del></p>	
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					<p>records. It is essential that the choice of inspectors to be witnessed is made by the accreditation body (not the inspection body), and takes into account critical factors (e.g. new employees, the risks and the complexity of the inspection activity, physical capabilities of older staff).</p> <p>A key purpose of the assessment is to verify that the inspection body has a robust quality system with records showing witnessing activities of its own inspectors.</p> <p>The planning of witnessing of inspectors should be carried out according to clause 7.7.3 taking into account the complexity and any other relevant factors of the inspections concerned using appropriate assessment techniques (e.g. observing inspections, interviewing inspectors, post-inspections, etc.).</p> <p>The following information should be considered when determining the appropriate level of witnessing. The list is not exhaustive and in any given case, an accreditation body may not use all of these to make a decision.</p> <ul style="list-style-type: none"> <li>• Scope of accreditation requested;</li> <li>• The extent to which inspectors are required to exercise professional judgement;</li> <li>• Total number of inspectors;</li> <li>• Frequency of each type of inspection;</li> </ul>	
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					<ul style="list-style-type: none"> <li>• Number of locations of the inspection body;</li> <li>• Past history of performance during (re)assessment;</li> <li>• Personnel certification or other formal qualifications held by inspectors;</li> <li>• The training system of the inspection body;</li> <li>• Effectiveness of internal monitoring of inspectors;</li> <li>• Organisational stability and risk awareness of the inspection body;</li> <li>• Any statutory requirements.</li> </ul> <p>The accreditation body should document the analysis/rationale used to determine the number of inspectors to be witnessed to cover the scope of accreditation.</p> <p>It should also be recognised that the factors influencing the level of witnessing may change over time as knowledge of the inspection body is gained and a records of performance is established.</p> <p>National legal requirements, regulations, standards or other relevant authority may stipulate levels of witnessing. Any such adjustments should be made explicit in scope statements by reference to the relevant law, regulation, etc.</p>	
CEOC	G.7.5.8.1		te	To define the <i>timeframe</i> as the reassessment period	Delete G.7.5.8.1 or amend it as follows:	

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and EURO LAB				in an IAF/ILAC guidance is neither in line with clause 7.5.8 nor with clause 7.11.3 2 <sup>nd</sup> paragraph (intervals depending on the proven stability) nor with the competition laws (arrangements with cost impact on customers) in most countries.	The <i>defined timeframe</i> for surveillance assessments should ensure that there is <u>are</u> sufficient surveillance on-site visits to ensure that as a minimum, all premises that undertake key activities are visited over the reassessment period <u>unless the proven stability of the CAB services (clause 7.11.3.2) allows a longer period.</u>	
CEOC and EURO LAB	G.7.8.3.1		ed	What is meant with “absolute” accreditation requirements?	Alter as follows: ... accreditation (the CAB’s fulfilment of the <u>absolute specified</u> accreditation requirements) ....	
CEOC and EURO LAB	G.7.15.1.1 and 7.15.3.1		te	ILAC-P9 is not an International Standard. The <del>use of the</del> term “normative” should therefore not be used	Delete “normative”.	
CEOC and EURO LAB	G.7.15.2.2:			Acceptable criteria (amongst others) could include: • Those provided by competent proficiency testing providers e.g. those accredited to ILAC-G13/ISO Guide 43; We fully agree but laboratory accreditation to ISO 17025 needs to be added.	either to delete the phrase “e.g. those accredited to ILAC G13/ISO Guide 43” or to add: “...Guide 43 or accredited as laboratories to ISO/IEC 17025”	

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