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EA Guidance on the horizontal requirements
for the accreditation of conformity assessment
bodies for notification purposes



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**EA Guidance on the
horizontal requirements
for the accreditation of
conformity assessment bodies
for notification purposes**

PURPOSE

This document contains horizontal criteria for conformity assessment bodies seeking accreditation for the purpose of notification, to carry out as notified bodies, third-party conformity assessment tasks under community harmonisation legislation.

Authorship

The publication has been written by an EA task force appointed by the EA general Assembly.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

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Category: **2 – EA MLA support documents - Mandatory**

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EA Resolution 2009 (23) 20

The General Assembly approves the following implementation phase for EA 2/17: “The EA-2/17 shall be applied by EA member accreditation bodies when accrediting conformity assessment bodies or applicant conformity assessment bodies for the purpose of notification, starting 1 January 2010. By 1 January 2012 all accredited notified bodies shall have been assessed taking into account EA-2/17.

Date of revision: **8th June 2009**

Reason for revision: This revision was made on request of the EA General Assembly. The new version changes the format of the first three chapters which are not part of the requirements, it gives a more comprehensive reference to the conformity assessment body standards and adds the EA general Assembly Resolution 2009(23)20 to bring more clarity to the implementation process.

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1 SCOPE

This document contains horizontal criteria for conformity assessment bodies seeking accreditation for the purpose of notification, to carry out as notified bodies, third-party conformity assessment tasks under community harmonisation legislation. This document is a category 2 document under the EA MLA for all accreditation bodies which accredit conformity assessment bodies for notification purposes.

Note: Category 2 (EA-2/12) EA MLA support documents are documents of a horizontal nature that support the application of the standards used for accreditation. These documents shall be implemented by EA member accreditation bodies for use in their accreditation systems. Their implementation will be assessed as part of the EA MLA peer evaluation process.

The accreditation body does not automatically assume the responsibility of the notifying authority. It is acknowledged that accreditation and notification are two different activities which are performed separately.

In the context of this document the term notified body has been used for all conformity assessment bodies which have applied to become notified or which are already notified to work within the scope of community harmonised legislation. The wording of the Decision 768/2008/EC has been changed accordingly when necessary.

The assessment of notified bodies cannot be made exclusively to this document. This document shall be used in combination with the relevant harmonised standards for conformity assessment bodies (CAB standards) and the related guidance documents issued by EA, ILAC and IAF. It shall also be used together with the requirements specified in the relevant community harmonisation legislation (e.g. sectorial European Directives) and possible national requirements for which the notification is to take place. Other relevant regulatory guidance and requirement documents established at the European and national level, within the scope of the relevant technical harmonisation legislation, should be taken into account if and when applicable.

The references given to the clauses of the CAB standards are only for the purpose of creating a connection between this document and the standards. Repetition of criteria already stated in these standards has been avoided if the criteria exist in all of the standards. However, where criteria are not covered in all of the CAB standards, these criteria have been stated in this document. Consequently, there will be assessment criteria in this document which are covered by none or only some of the CAB standards. A notified body will still have to be assessed to all the criteria stated in this document which are relevant to the module in question when seeking accreditation for the purposes of notification for the conformity assessment procedure in a particular module.

As some of the criteria in this document are based on legal requirements contained in the community harmonisation legislation there are specific interpretations to the standards and in some cases there are additional requirements. Even though EA members who are signatories to the ILAC and IAF MLA shall meet the requirements of ILAC and IAF, in the accreditation of conformity assessment bodies for the purposes of notification, the criteria in this document will take precedence over the guidance documents issued by ILAC and IAF.

The Decision 768/2008/EC as it stands does not constitute the legal requirements. It gives the generally applicable requirements which need to be implemented in the relevant community harmonisation legislation before they become binding. However, the requirements of the Decision do identify the general principles which are meant to apply in the future revisions of the directives.

Column 1 of this document gives assessment criteria specific to notification. Columns 2, 3, 4, 5 and 6 give reference to the relevant clauses of the relevant CAB standards.

Note to column 6: EN ISO/IEC 17024 can only be used when community harmonisation legislation requires certification of persons.

The criteria written in this document in *italics* are taken from the Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products (named in this document “Decision”) or from the Regulation 765/2008/EC of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (named “Regulation” in this document).

2 REFERENCES

The following referenced documents are indispensable for the application of this document.

Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products (named in this document “Decision”)

Regulation 765/2008/EC of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (named in this document “Regulation”)

EN 45011:1998, *General requirements for bodies operating product certification systems*

EN ISO/IEC 17000:2004, *Conformity assessment— Vocabulary and general principles*

EN ISO/IEC 17011:2004, *Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

EN ISO/IEC 17020:2004, *General criteria for the operation of various types of bodies performing inspection*

EN ISO/IEC 17021:2006 *Conformity assessment – Requirements for bodies providing audit and certification of management systems*

EN ISO/IEC 17024:2003 *Conformity assessment – General requirements for bodies operating certification of persons*

3 TERMS AND DEFINITIONS

For the purpose of this document, the terms and definitions given in EN ISO/IEC 17000 and the following apply.

3.1 accreditation: *attestation by a national accreditation body that a conformity assessment body meets the requirements to carry out the specific conformity assessment activities, set by harmonised standards and, where applicable, any additional requirements, including those set out in relevant sectoral schemes (Regulation Article 2 (10))*

3.2 national accreditation body: *the sole authoritative body in a Member State that performs accreditation with authority derived from the State (Regulation Article 2 (11))*

3.3 conformity assessment: *the process demonstrating whether specified requirements relating to a product, process, service, system, person or body are fulfilled (Regulation Article 2 (12))*

3.4 conformity assessment body: *a body that performs conformity assessment activities including calibration, testing, certification and inspection (Regulation Article 2 (16))*

3.5 notified body: *a conformity assessment body notified by a member state to the commission and other member states authorised to carry out third-party conformity assessment tasks under community harmonisation legislation (See Decision, Article R13)*

3.6 harmonised standard: *a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services on the basis of a request issued by the Commission in accordance with Article 6 of that Directive (Regulation Article 2, 9)*

3.7 Community harmonisation legislation: *any Community legislation harmonising the conditions for the marketing of products (Regulation Article 2, 21)*

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4 PRINCIPLES OF IMPARTIALITY (Informative chapter)					
4.1 To obtain and maintain confidence, it is essential that a notified body's decisions are based on objective evidence of conformity (or nonconformity) obtained by the notified body, and that its decisions are not influenced by other interests or by other parties.	4.2.(a)	4.1.4 4.1.5 (b), (d)	4.1 4.2 8.6	4.1.3 4.2.4	4.2.1 6.3.1
4.2 Threats to impartiality include bias that may arise from: a) Self-interest (e.g. overdependence on a contract for service or the fees, or fear of losing the customer or fear of becoming unemployed, to an extent that adversely affects objectivity in carrying out conformity assessment activities); b) Self-review (e.g. Performing conformity assessment activity in which the body evaluates the results of other services it has already provided, such as design or consultancy services); c) Advocacy (e.g. a body or its personnel acting in support of, or in opposition to, a given company, which is at the same time its customer, in the resolution of a dispute or litigation);	This is an explanatory paragraph to the concept of impartiality.				

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<p>d) Over-familiarity, i.e. threats that arise from a body or a person being overly familiar or too trusting instead of seeking objective evidence (e.g. in a management systems conformity assessment context, the development of relationships over time between conformity assessment personnel and the customer in the provision of conformity assessment activities for that customer; in the product certification and laboratory context, this risk is more difficult to manage because the need for assessment personnel, with very specific expertise, often limits the availability of qualified individuals).</p> <p>e) Intimidation (e.g. the body or its personnel can be deterred from acting objectively by threats from or fear of, a client or other interested party);</p> <p>f) competition (e.g. between the assessed company and a contracted technical assessor).</p>					
5 GENERAL REQUIREMENTS					
5.1 Legal and contractual matters					
5.1.1 <i>A notified body shall be established under national law and have legal personality (Decision Article R17,2)</i>	4.2 (d)	4.1.1	3.1	5.1.1	4.2.1 (d)
5.1.2 The notified body shall be a legal entity or a defined part of a legal entity such that it can be held legally responsible for all its activities and so that it can bear rights and obligations.	4.2 (d)	4.1.1	3.1	5.1.1 6.1.1	4.2.1 (d)

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A notified body which is part of government, or is a government department, will be deemed to have legal personality on the basis of its governmental status. The status and structure of such bodies shall be formally documented and the bodies shall comply with all requirements for notification.					
5.1.3 Even though Member States can only notify bodies within their own jurisdiction, notified bodies may have activities and/or personnel outside the respective Member State, or even outside the Community. Certificates are, however, always issued by and in the name of the notified body. The notified body shall inform the accreditation body of its activities outside its respective Member State to ensure that all locations where key activities (see EN ISO/IEC 17011, 7.5.7) take place are adequately assessed.	4.2 4.4(a)	4.1.2 4.1.5(e)	6	5.1.2 5.1.3	4.2.1(b) 6.3.1
5.2 Management of impartiality					
5.2.1 <i>A notified body shall be a third-party body independent from the organisation or the product it assesses.</i> <i>A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, can, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body.</i> (Decision Article R17, 3)	4.2 (a), (e), (o)	4.1.4 + Note 1 and 2 4.1.5(b), (d)	4.1 4.2 4.2.1 Annex A	5.2 6.2 4.2.4	4.2.1 (a), (b) 4.2.2 4.2.4 4.2.5

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<p>5.2.2 <i>A notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of the products for personal purposes.</i></p> <p><i>A notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This applies in particular to consultancy services. (Decision Article R17, 4)</i></p> <p>Note: Consultancy services are understood in the context of this document as participation in the design, production, installation, maintenance or marketing of the assessed products or in the design and implementation of the assessed quality system. This does not preclude exchanging technical information between the manufacturer and the notified body. See also EN ISO/IEC 17021 Clause 3.3.</p>	4.2 (e), (f), (l), (m), (n), (o)	4.1.4 + note 2 4.1.5 (b), (d)	4.1 4.2.1 8.5	5.2 4.2.4	4.2.4 4.2.5 5.1.2 5.2.1 5.2.2
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5.2.3 The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the rules defined by the notified body. The commitment shall include adherence to confidentiality and to independence from commercial and other interests or relationships, arising from any existing or prior association with customers, that may result in a conflict of interest.	5.2.2	4.1.4 4.1.5 (b), (c), (d)	4 Annex A, B, C	5.2 7.3	5.1.2
5.2.4 <i>Notified bodies shall ensure that activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.</i> (Decision Article R17, 4) Note: A subsidiary, in business, is an entity that is controlled by a larger entity. The controlled entity is called a company, corporation, or limited liability company, and the controlling entity is called its parent (or the parent company). Subsidiaries are separate, distinct legal entities for the purposes of taxation and regulation. For this reason, they differ from divisions, which are businesses fully integrated within the main company, and not legally or otherwise distinct from it.	4.4 4.2. (o)	4.5	14.2	4.6 5.2 7.5.1 8.5	4.5

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5.2.5 <i>Notified bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially from persons or groups of persons with an interest in the results of those activities. . (Decision Article R17, 5)</i>	5.1.1 5.2.2	4.1.4	4.2.1	7.1	5.1.1 5.1.2 5.1.3 5.2
5.2.6 If the notified body forms a part of a legal entity, the requirements for impartiality and independence apply also for the other parts of the same legal entity.	4.2 (o)	4.1.4	4.2.1	4.2.4 5.2.2 6.1.1	4.2.1 4.2.2 4.2.4 4.2.5
5.2.7 The notified body shall ensure that activities of external organisations (separate legal entities) with which the conformity assessment body or the legal entity of which it forms a part has relationships (related organisation) do not compromise the independence, impartiality and integrity of its conformity assessment activities. Note: Relationship that may compromise the independence, impartiality and integrity can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducements for the referral of new clients, etc.	4.2 (o)	4.1.4	4.2.1	5.2.2 5.2.3	4.2.4 (c)

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5.2.8 <i>The impartiality of the notified body, its top level management and assessment personnel shall be guaranteed. The remuneration of the notified body's top level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments. (Decision Article R17, 8)</i>	4.2 (a), (e)	4.1.5 (b)	4 Annex A, B, C 8.6	5.2	4.2.2 5.1.2
5.2.9 The notified body shall have documented procedures for the identification, review and resolution of all cases where a potential conflict of interest is identified, perceived or proven. If threats to impartiality are identified, the notified body shall document and be able to demonstrate how it eliminates or minimizes such threats.	4.2 (a), (l)	4.1.4 4.1.5 (d)	4.2.1	5.2.2 6.2	4.2.2
5.2.10 The impartiality requirements do not preclude the possibility of the national authorities responsible for market surveillance to use in given situations the facilities and/or the expertise of a notified body. However, to safeguard impartiality it is important to make a clear distinction between conformity assessment and market surveillance. Therefore, it is to be considered as inappropriate for notified bodies to be responsible for market surveillance. If a notified body and a market surveillance authority come under the same superior authority, the lines of responsibility shall be so organised that there is no conflict of interest between these activities.	4.2 (l)	4.1.4	3.2 3.5 4.2 6.2	5.2	4.2.1 (a) 4.2.2 4.2.4 (b)

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5.3 Liability and financing					
<p>5.3.1 <i>Notified bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment. (Decision Article R17, 9)</i></p> <p>5.3.2 The scope and overall financial value of the liability insurance shall correspond to the level of risks associated with the activities of the notified body. The notified body is expected to be able to show what factors have been taken into account when determining the necessary level of the contracted insurance.</p> <p>Note : It is not the role of accreditation bodies to approve the level of insurance cover held by Notified Bodies.</p> <p>5.3.3 The cover must include both public liability and professional indemnity insurance, and should extend to the whole of the European Economic Area (EEA), and, if the applicant intends to carry out work outside the EEA, should extend to include the applicable markets. The Notified Body will be required to maintain cover during its period of appointment.</p> <p>5.3.4 The manufacturer always retains the overall responsibility for the conformity of the product with all the requirements of the applicable directive(s), even if some stages of the conformity assessment are carried out under the responsibility of a notified body.</p>	4.2 (h)	Does not specifically require liability insurance.	3.4	5.3.1	4.2.4 (a)

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5.4 Identification number of notified bodies					
5.4.1 <i>The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control phase.</i> <i>The identification number of the notified body shall be affixed by the body itself or under its instructions, by the manufacturer or his authorised representative. (Decision Article R12, 3)</i>	This chapter reflects specific requirements on CE marking for notified bodies according to the requirements of the relevant community harmonization legislations. Therefore, these will have to be implemented based on the requirements in the specific legislation for which the conformity assessment body wishes to be notified.				
5.4.2 The notified body, as proprietor of its identification number that is intended for use in combination with the CE marking or other official markings required within the framework of the community harmonised legislation, shall have a policy governing its protection and use.	14 14.3	5.10.2 (c) 5.10.9	13.4	8.4.1 8.4.3 8.4.4	6.3.2 6.3.3 (a), (b)
5.4.3 The notified body shall take effective measures to ensure that the identification number is not used in a misleading manner.	14 14.3	5.10.2 (c) 5.10.9	13.4	8.4.1 8.4.3 8.4.4	6.3.2 6.3.3 (a), (b)
5.4.4 The notified body shall take suitable action to deal with misleading use of the identification number to prevent further misuse.	14 14.3	5.10.2 (c) 5.10.9	13.4	8.4.1 8.4.3 8.4.4	6.3.2 6.3.3 (a), (b)
6 STRUCTURAL REQUIREMENTS					
6.1 Role as notified body					
6.1.1 <i>At all times and for each conformity assessment procedure and for each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary descriptions of procedures according to which conformity assessment is</i>	4.3 4.2 (h)	5.4	10.2	8.6.1 9.1.1	6.1.1

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<i>carried out, ensuring the transparency and the ability of reproduction of these procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities (Decision Article R17, 6(b))</i>					
6.1.2 The distinction mentioned in 6.1.1 between the role as a notified body and other activities shall be made clear to the customers of the notified body and the market in general. Thus, marketing material shall not give any impression that any other activity carried out by the body has the same status as the tasks undertaken when it acts as a notified body under the applicable directive(s).	4.2.1	4.1.4	4.2.1	8.1.2	4.2.4 4.2.5
6.2 Cooperation with other bodies					
6.2.1 <i>Notified bodies shall participate in, or ensure that their assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group. (Decision Article R17, 11)</i>	In general standards on Conformity Assessment Body Competence Criteria do not “require” cooperation with other bodies. This requirement is specific for notified bodies and is to be assessed based on the requirements of the harmonised community legislation to the degree required by such legislation.				
6.2.2 , Notified bodies may be required to attend notified body group meetings. If a notified body does not attend meetings of the notified body groups, it shall have a mechanism to keep informed of the decisions and documents produced by the relevant notified body groups.”	In general standards on Conformity Assessment Body Competence Criteria do not “require” cooperation with other bodies. This requirement is specific for notified bodies and is to be assessed based on the requirements of the harmonised community legislation to the degree required by				

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	such legislation.				
6.2.3 Notified bodies shall take part directly or be represented in European standardisation. This means that as a minimum, notified bodies shall have a mechanism to ensure that they are informed of the current state of the standards in their field of activity within the scope of their notification.	In general standards on Conformity Assessment Body Competence Criteria do not “require” cooperation with other bodies. This requirement is specific for notified bodies and is to be assessed based on the requirements of the harmonised community legislation to the degree required by such legislation.				
7 RESOURCE REQUIREMENTS					
7.1 Personnel					
7.1.1 <i>At all times and for each conformity assessment procedure and for each kind or category of products in relation to which it has been notified, the conformity assessment body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks; (Decision Article R17, 6(a))</i>	4.2 (j)	5.2.1	8.1	7.1	4.2.7 5.1.3
7.1.2 <i>The personnel responsible for carrying out the conformity assessment activities shall have the following:</i> <i>a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for which the conformity</i> <i>b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;</i>	5.1.1 5.2.1 5.2.3	5.2.1 + note 2	6.3 6.4 6.5 6.6 8.2	7.1 7.2 7.4	4.2.7 5

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<p>b) <i>satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;</i></p> <p>c) <i>appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of the relevant Community harmonisation legislation and relevant implementing regulations;</i></p> <p>d) <i>the ability required to draw up the certificates, records and reports to demonstrate that the assessments have been carried out. (Decision Article R17, 7.)</i></p>					
<p>7.1.3 In all types of conformity assessment, including assessment of the quality assurance systems under the relevant modules, the education, technical knowledge and experience of the notified body personnel shall relate to products and conformity assessment procedures in question. In particular, knowledge and experience shall relate to relevant regulatory requirements and enforcement policies, European and international standardisation activities, relevant technologies, production methods and verification procedures, and normal conditions of use of the product in question. Consequently, the personnel shall have explicit knowledge of the specific directive(s) in question and keep this knowledge updated.</p>	5.1.1 5.2.1 5.2.3	5.2.1 + note 2	6.3 6.4 6.5 6.6 8.2	7.1 7.2 7.4	4.2.7 5

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<p>The notified body shall be in a position to manage, control and be responsible for the performance of all its resources and maintain comprehensive records controlling the suitability of all the staff it uses in particular areas, whether they are employees, employed on contract or provided by external bodies.</p> <p>The knowledge of relevant technologies and production methods means that the personnel shall be well acquainted with the technology used for the manufacturing of the products they evaluate, of the way in which products submitted to their evaluation are used or are intended to be used, and of the defects that may occur during use or in service. The personnel are further required to understand the significance of deviations found with regard to the normal use of the products concerned.</p> <p>The criteria for the competence of personnel shall be expressed, with reference to the relevant products or product categories, in terms of theoretical education, practical training, experience, the knowledge of the product with respect to the essential requirements of the relevant directive(s) and the evaluation requirements.</p> <p>The requirements on staff concerned with conformity assessment shall be in line with any harmonised criteria developed by the relevant notified body group established for the purpose of a consistent application of the directive in question. Whenever available, the notified bodies shall apply the recommendations of the relevant notified body group(s), unless they can justify an equivalent approach.</p>					
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<p>7.1.4 The personnel are required to have the technical knowledge and skills to make professional judgements as to conformity with essential requirements, in particular when the manufacturer has not applied harmonised standards for his product.</p>	4.2 (j) 5.2.1	Even though ISO/IEC 17025 does allow for opinions and interpretations and requires competent personnel to do so, this particular aspect of the work of notified bodies is not covered by this standard.	8.2	7.1	4.2.7
<p>7.1.5 Assessors and technical experts from external sources and temporary personnel shall work under the quality management system of the NB.</p>	4.4 (b)	5.2.3	8.1	7.1.3	4.5.2 (b) 5.1.3

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7.1.6 Monitoring					
7.1.6.1 The notified body shall ensure the satisfactory performance of the conformity assessment activities including the review and attestation process by establishing, implementing and maintaining procedures for monitoring the performance and competence of the personnel involved. In particular, the notified body shall review the performance and competence of its personnel in order to identify training needs.	5.2.3	5.2.1 5.2.2	6.4	7.2.10 7.2.11 7.2.12	This standard does not mention monitoring. However it is often part of the internal mechanisms used by the CB to supervise its activities and persons involved.
7.1.6.2 The notified body shall conduct monitoring e.g. by on-site observations, or by using other techniques such as review of conformity assessment reports and feedback from customers to evaluate performance of conformity assessment personnel and to recommend appropriate follow-up actions to improve performance. The notified body shall maintain evidence that its personnel is continuing to perform competently.	5.2.3	5.2.1 5.2.2	6.4	7.2.10 7.2.11 7.2.12	This standard does not mention monitoring. However it is often part

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					of the internal mechanisms used by the CB to supervise its activities and persons involved.
7.2 Equipment					
7.2.1 <i>The notified body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities. (Decision Article R17, 6.)</i>	4.2 (i)	5.3.1 5.5.1	9.1	4.3	This standard does not specifically address equipment as it is about certification of persons.

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7.2.2 The equipment outside the permanent control of the notified body may include equipment owned by the manufacturer. Notified bodies may use such equipment, provided that access to the equipment is assured, the equipment is fit for purpose and adequately maintained.	4.4	5.3.1 5.5.1	9.3	7.5.1 7.5.4	This standard does not specifically address equipment as it is about certification of persons.
7.3 Outsourcing (subcontracting)					
7.3.1 <i>Where the notified body subcontracts specific tasks connected with the assessment of conformity or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article R17 (of the Decision) and inform the notifying authority. (Decision Article R20, 1.)</i>	4.4.(b)	4.5.1	14.2	7.5.1 7.5.4	4.5.2
7.3.2 <i>Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established. (Decision Article R20, 2.)</i>	4.4. (a)	4.5.3	14.4	7.5.3	4.5.2

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7.3.3 <i>Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.</i> (Decision Article R20, 3.)	4.4.(c)	4.5.2	14.2	7.5.4	This standard does not require agreement of the client.
7.3.4 <i>Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or subsidiary and the work carried out by them.</i> (Decision Article R20, 4.)	4.4 (b)	4.1.2	14.3	7.5.4 10.3.4	4.5.2 (c)
7.3.5 In this guidance, the term subcontracting includes also having recourse to a subsidiary as defined in the note to 5.2.4	This is an explanatory note	This is an explanatory note	This is an explanatory note	This is an explanatory note	This is an explanatory note
7.3.6 Notified bodies may subcontract defined technical tasks. The notified bodies may not under any circumstances subcontract evaluation of results and decision on conformity, as that would make the notification meaningless. For example, notified bodies may subcontract tests while continuing to assess the results of the tests and in particular to validate the test report in order to evaluate whether the requirements of the relevant legislation are met.	4.2 (b) 4.4 (a) 12.2	4.5.1 4.5.3	14.4	5.1.3 6.1.2 (f) 7.5.2	4.5.1 4.5.2 (a)

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<p>7.3.7 The bodies acting as subcontractors for the notified bodies need not be notified as such but shall meet the relevant requirements for the respective tasks, for example the requirements in EN ISO/IEC 17025 for testing and in EN ISO/IEC 17020 for inspection.</p> <p>The notified bodies shall ensure that their subcontractors maintain the necessary competence. This can be done either by employing accredited subcontractors or for example by carrying out regular evaluations and by keeping regularly informed of the details regarding the performance of the tasks of the subcontractors. The notified bodies shall also be able to provide a proof of the compliance of their subcontractors with the requirements laid down in the relevant standard and the relevant directive. Documentation issued to subcontractors as a result of a successful assessment shall state that this is only for the purposes of the contract and is not certification or accreditation.</p>	4.4 (b)	4.5.1	14.2	7.5.3	4.5.2
<p>7.3.8 Subcontracting shall be carried out under a contract (a direct private law contractual link) which makes it possible to ensure transparency and confidence of the notified body's operations. Serial subcontracting (i.e. subcontracting of subcontracted work) is prohibited to avoid undermining the coherence of the system and the confidence in it. The conditions for subcontracting apply to any subcontractor whether or not established within the Community.</p>	4.4	4.5.1	14.2	7.3 7.5	4.5.1
<p>7.3.9 The manufacturer may supply test reports or other data as part of its technical documentation. The notified body may take account of these</p>	4.4	4.5	14.4	7.5	4.5

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reports if it can take full responsibility for the results. Under certain conditions the test results of the manufacturer can be acceptable for the purposes of conformity assessment. When this is allowed it is explicitly said so in the relevant legislation. The notified body shall document the justification for taking into account information from the manufacturer and other sources, i.e. sources outside its own body.					
7.3.10 In its assessment activities the notified body shall take into account quality system approvals by the same or any other notified body and certificates issued by any accredited certification body, if the notified body is able to ensure that these approvals or certifications (referring to the same or another product category) cover the applicable provisions of the directive in question. In the process of ensuring itself of the fulfilment of the requirements of the relevant directive the notified body shall evaluate all documents on which the quality system approval is based, including audit reports, management reviews and control plans. Based on this evaluation the notified body shall determine whether or not any reduction can be made in the scope of the assessment. Notified bodies shall have procedures that detail how quality system approvals by other notified bodies and certificates issued by accredited certification bodies are taken into account. Note: Certification according to ISO 9001 alone does not mean that the requirements of a directive are met.	4.4. note 2 and 3	Not relevant in testing and calibration	Not relevant in inspection	9.1.1	Not relevant in certification of persons
7.3.11 Notified bodies are required to keep an updated register of all their subcontracting activities.	4.9.1	4.5.4	14.3	7.5.4	4.5.2 (c)

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8 INFORMATION REQUIREMENTS AND CONFIDENTIALITY					
8.1 Information requirements					
The information obligations of a notified body are normally specified in the relevant community harmonization legislation and their national transpositions.	This chapter reflects specific information requirements for notified bodies according to the requirements of the relevant community harmonization legislations. Therefore, these will have to be implemented based on the information requirements in the specific legislation for which the conformity assessment body wishes to be notified.				
8.1.1 Notified bodies shall inform the notifying authority of the following: <ol style="list-style-type: none"> 1. any refusal, restriction, suspension or withdrawal of certificates; 2. any circumstances affecting the scope of and conditions for notification; 3. any request for information on conformity assessment activities performed which they have received from market surveillance authorities; 4. on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting. (Decision Article R28, 1.) 	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1

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8.1.2 <i>Notified bodies shall provide the other bodies notified under the same community harmonisation legislation carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results. (Decision Article R28, 2.)</i>	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1	See comments to 8.1
8.1.3 The notified body may have communication obligations towards the notifying authority, the accreditation body and its clients concerning its activities, based on legal requirements or contractual arrangements. Some of these obligations are defined in the directives, some are defined in horizontal documents issued by the bodies of the Commission and some are requested by the national notifying authorities. The notified body needs to have knowledge on its information obligations and shall fulfil these obligations.	8.1	4.7	5	8.6.1	4.3.3 6.1.1
8.1.4 Notified bodies should on request provide general information to the manufacturer and his authorised representative regarding the directive in question, charging, whenever the case, the related costs.	8.1	4.7.1	3.3	8.6.1	6.1.1

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8.2 Confidentiality					
8.2.1 <i>The personnel of the notified body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under the relevant community harmonisation legislation or any provision of national law giving effect to it, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected. (Decision Article R17, 10.)</i>	4.10.1	4.1.5(c)	5	8.5	4.7
8.2.2 The confidentiality arrangements shall ensure that no results or other proprietary information are disclosed to any other party than the manufacturer or its authorised representative. When the notified body is required by the relevant legislation or authorised by contractual arrangements to release confidential information, the client or individual concerned shall, unless prohibited by the relevant legislation, be notified of the information provided.	4.10.2	4.1.5 (c)	5	8.5.3	4.7
8.2.3 Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be treated as confidential.	4.10.1	4.1.5. (c)	5	8.5.4	4.7
8.2.4 Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the notified body's behalf, shall keep confidential all information obtained or created during the performance of the notified body's conformity assessment activities, except as required by law.	4.10.1 5.2.2	4.1.5 (c)	5	8.5.5	4.7

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9 PROCESS REQUIREMENTS					
9.1 General requirements					
9.1.1 <i>The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to such a body by the provisions of the relevant community harmonisation legislation and for which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. (Decision Article R17, 6.)</i>	4.3	5.4	10.1	9.1.1	4.2.7
9.1.2 <i>At all times and for each conformity assessment procedure and for each kind or category of products for which it is notified, the conformity assessment body shall have at its disposal the necessary procedures to perform their activities taking into consideration the size, the sector, the structure of the undertakings, the degree of complexity of the product technology in question and the mass or serial nature of the production process. (Decision Article R17, 6.)</i>	4.3	5.4	10.1	9.1.1 9.1.2 9.1.3 9.1.4	6.2.3
9.2 Scope of activities					
9.2.1 In the context of notified bodies, attestation of the conformity of a product, product design, management system or person with specific requirements (or general requirements on the basis of professional judgement,) is based on the assessment of conformity to the essential requirements of the relevant directive(s).	1.2	5.4	1.1	4.4.2	4.1.1

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9.2.2 In the context of notified bodies a conformity assessment system is understood as comprising all activities required by a specific conformity assessment module or a set of modules applicable to a given product according to the relevant directive(s). Conformity to the relevant standard(s) for conformity assessment bodies on the part of the notified body constitutes an element of presumption of conformity to the requirements of the directive(s), but is not in itself sufficient without demonstration of technical capability within the scope of the directive(s). The notified body shall consider elements such as knowledge of the products and conformity assessment procedures in question, technology involved, production techniques, the application of harmonised standards, regulatory requirements set up by the directive and applicable documents identifying current practice.	1.2	5.4	10.1	4.4.2	4.1.1
9.2.3 A notified body shall take the responsibility for a complete module or for several complete modules (or distinct tasks if identified in the relevant directive). It shall have the necessary competence, and access to all resources required, to carry out the conformity assessment activity according to a complete module or for several complete modules. Consequently, the body cannot be notified for part of the module. A notified body wishing to offer services according to several conformity assessment procedures shall fulfil the relevant requirements for the respective tasks. However, since the scope of most directives can be relatively wide and heterogeneous, a notified body need not be qualified to cover all products falling within the scope of the directive.	1.2	5.4	10.1	4.4.2	4.1.1

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Where the notified body does not cover all products within the scope of a directive, the products for which it is competent shall be defined.					
9.2.4 For notified bodies, the accreditation scope shall make reference to the directive(s) and module(s) containing the requirements, as well as the specific product(s) or product categories that the notified body is competent to assess.	1.2	5.4	10.1	4.4.2	4.1.1
9.3 Operational obligations for notified bodies					
9.3.1. <i>Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant community harmonisation legislation. (Decision Article R27, 1)</i>	4.1.3	5.4	10.1	9.2	6.2.3
9.3.2. <i>Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. The conformity assessment bodies shall perform their activities taking into consideration the size, the sector, the structure of the undertakings involved, the relative complexity of the technology used by the products and the serial character of production. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product by the provisions of the relevant community harmonisation legislation. (Decision Article R27, 2)</i>	4.1.3	5.4	10.1	9.1.4	4.3.5

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9.3.3 <i>Where a notified body finds that requirements laid down in of the relevant community harmonisation legislation or corresponding harmonised standards or technical specifications have not been met by the manufacturer, it shall require the manufacturer to take appropriate corrective measures and it shall not deliver any conformity certificate. (Decision Article R27, 3)</i>	4.6.1 11 (b)	5.8.3	11.2	9.1.15	4.3.6
9.3.4 <i>Where, in the course of the monitoring of conformity following the delivery of certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw its certificate if necessary. (Decision Article R27, 4)</i>	4.6.2 11 (b) 13	Monitoring of conformity after the testing or inspection has been performed and report issued, is not part of the work of a laboratory or an inspection body. This can be done if requested in the specific directive.		9.3.3	4.3.6 6.4
9.3.5. <i>Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate. (Decision Article R27, 5)</i>	4.6.2 11 (b) 13	Monitoring of conformity after the testing or inspection has been performed and report issued, is not part of the work of a laboratory or an		9.6.1 9.6.2	4.3.6 6.4

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		inspection body. This can be done if requested in the specific directive or the client.		
9.4 Conformity assessment criteria				
9.4.1 The essential requirements on which conformity assessment is to be based are laid down in the relevant community harmonisation legislation. Whereas harmonised standards provide a presumption of conformity with the essential requirements, the application of these standards by manufacturers remains voluntary. A manufacturer who does not follow harmonised standards has the obligation to prove and document that his products are in conformity with essential requirements. For that purpose the manufacturer may use methods of its own choice, including any existing technical specifications, as long as the notified body is able to verify that the methods ensure compliance with the essential requirements of the directive in question. The recommendations laid down by the bodies of the European Commission active within the scope of the applicable directive do not need formal approval by the notified body before being implemented. These documents are presumed to be the accepted current practice. Among such bodies are the standing committees, notified body groups and other forms for European or national co-ordination of the activities of notified bodies, and committees dealing with relevant standardization work.	4.3 4.1.3	4.1.2 5.4.1 5.4.2 5.4.4	10.1 10.3	9.2 4.1 4.3 6.1

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When harmonised standards are not available, do not specify the evaluation method to be applied, or where the specified method is not adequate (e.g. due to changes introduced as a result of technical development of the product(s)) the notified body may use other methods than those stated in harmonised standards or draw up a method for the product or group of products in question. In all cases the notified body shall be able to demonstrate that the method used covers the evaluation of the compliance of the product with all the essential requirements of the directive. A method developed by the notified body coordination groups is assumed to be appropriate.					
9.4.2 The procedures of the notified body shall specify steps to be taken when the manufacturer reports a design change of a product for which the notified body has already issued an EC type-examination certificate. The steps shall include <ul style="list-style-type: none"> • an assessment of whether or not the changes affect the conformity of the product with the essential requirements or the prescribed conditions for the use of the product; • a decision on which additional investigations are needed as a result of the changes made to the product design. 	4.6.2 (c) 13.2	4.4.1 5.8.3	10.1	8.6.3	4.3.6 6.4

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9.4.3 Presumption of conformity according to quality assurance modules presupposes that the quality system of the manufacturer takes into consideration the specific requirements of the products for which the standards are implemented. In particular, the quality system shall be implemented and applied in such a way that it ensures the full application of the essential requirements in question. The NB shall also evaluate and confirm that the manufacturer's quality system is implemented in such a way that ensures the product continues to be manufactured consistent with the technical requirements contained in the technical file and the product continues to satisfy the essential requirements.	Not relevant for product certification bodies unless the scheme requires it in which case reference is to Clause 10.	Not relevant for testing and calibration.	Not relevant for inspection unless the client requires it in which case the reference is to Clause 10.	9.1.1	Not relevant for certification of persons
9.5 Preparation for assessment and contract review					
9.5.1 When establishing the contract, the notified body shall take into account the course taken by the manufacturer, for example whether or not he has applied harmonised standards for the product in question, the module(s) chosen, etc.	8.2.2	4.4.1	10.5	5.1.2 9.1 9.2.1 9.2.2	6.2.1

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9.5.2 Where required in the specific directive or as a consequence of the conformity assessment module employed, the contract shall contain a requirement that the manufacturer inform the notified body of any change of the product design that may affect either the conformity of the product with the essential requirements or the prescribed conditions for the use of the product.	8.2.1	4.4.1	10.5	8.6.3	6.1.2
9.5.3 Contracts concerning conformity assessment by notified bodies shall always be in written form.	8.2.1	4.4.1	10.5	5.1.2	6.1.2
9.5.4 The requirements to which the product will be assessed and the conformity assessment method selected shall be made clear to the manufacturer during the contract review phase.	5.1.2	4.4.1 5.4.2	10.5	8.1.1	6.1.1
9.6 Assessment					
9.6.1 As the procedures of the notified body refer to essential requirements applicable to a wide variety of products, they cannot cover in detail all possible situations. However, all details of the specific implementation of the general procedures for specific cases shall be recorded to ensure traceability.	10	5.4.2	10.2	9.2	6.2
9.6.2 In the case of tests or examinations based on a prototype notified bodies shall verify from drawings, specifications and other documents provided by the manufacturer that the prototype is typical of intended production.	10	5.8.3	11.2	9.2	6.2 6.3

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9.6.3 Recommendations in other international documents concerning the time to be spent on assessment, re-assessment and surveillance do not cover the workload needed to check the product related aspects in the work of a notified body, as defined by the relevant directive(s).	Such Recommendations do not exist	Such Recommendations do not exist	Such Recommendations do not exist	9.1.4	Such Recommendations do not exist
9.6.4 The intended changes to manufacturers' quality systems, which manufacturers shall report to notified bodies, shall be treated in the same manner as applications for amendments to the product. The assessment procedure to be used may depend on the specific requirements of the applicable directive(s). The notified body shall communicate its decision to the manufacturer, stating its conclusions of the examination of the intended changes and an assessment decision supported by objective reasons.	Not relevant for product certification	Not relevant for testing and calibration	Not relevant for inspection	9.3 9.4 9.5.2	Not relevant for certification of persons
9.6.5 Whenever required by the relevant directive the notified body shall perform unannounced visits to the manufacturer. The notified body needs to have procedures on when and how unannounced visits shall be initiated.	This is a requirement which comes from the specific community harmonization legislation and will have to be met when it is required of the specific legislation to which the conformity assessment body has requested to be notified.				
9.7 Decision on conformity and assessment report					
9.7.1 For a notified body the final step of the activities is the decision on conformity. The result of this decision may be the issuance of a certificate or a refusal to issue a certificate. The notified bodies shall have appropriate structures and procedures for the conduct of conformity assessment and the issuing of certificates. They shall ensure that these structures and procedures are subject to a review process. When the	12	5.10.1 5.10.5	13.1 13.3	9	6

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notified body refuses to issue a certificate, it shall give detailed reasons for its refusal. An appeal procedure shall be available					
9.7.2 The notified body shall ensure that decisions concerning conformity assessment are made by person(s) different from those who carried out the determination activity.	4.2 (f)	5.2.5	13.3	9.1.14 9.7.3	6.3.1
9.7.3 Notified bodies issue conformity certificates. The title and minimum content of these certificates are stated in the applicable module and the directive in question. The conformity certificate shall state the products or product categories covered. The conformity certificate has to be supported by results of all examinations, tests and other activities carried out in order to assess the conformity of the product with the essential requirements of the directive. This information may be available to the customer as part of the conformity certificate, as a technical report or on request.	12.3	5.10	13.1	9.2.4 9.4.3 9.9	6.3
9.8 Records					
9.8.1 The established retention time for records shall be in accordance with any requirements specified by the customer and the relevant directive or its national transposition.	4.9	4.13.1.2 4.13.2.1	12.3	9.9	4.6
10 MANAGEMENT SYSTEM REQUIREMENTS					
10.1 Complaints and appeals					

EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes	EN 45011	EN ISO/IEC 17025	EN ISO/IEC 17020	EN ISO/IEC 17021	EN ISO/IE C 17024
(1)	(2)	(3)	(4)	(5)	(6)

10.1.1 The notified body shall have a documented procedure to receive, evaluate and make decisions on complaints and appeals.	7 4.2 (p) 4.5.3 (m)	4.8	15	9.7.1 9.8	4.2.6
10.1.2 A description of the complaints and appeals handling procedure shall be available to any interested party on request. Whenever possible, the notified body shall acknowledge receipt of the complaint or appeal, and provide the complainant or appellant with progress reports and the outcome.	7 4.5.3 (m)	4.8	15	9.7.5	4.2.6
10.1.3 The appeals procedure shall include provision for the following: - the opportunity for the appellant to formally present its case; - provision of an independent element or other means to ensure the impartiality of the appeals process (see 10.1.4); - provision to the appellant of a written statement of the appeal findings including the reasons for the decisions reached.	4.5.3 (m)	4.8	15	9.7.5	4.2.6
10.1.4 Personnel, including those acting in a managerial capacity, shall not be employed to investigate any appeals if they have been involved in the subject of the appeal within the last 2 years.	Impartiality is required for all processes of all conformity assessment bodies. However, the standards do not specify a 2 year limit.				
10.1.5 Investigation and decision on appeals shall not result in any discriminatory action.	4.1.1	4.8	15	4.2.3	4.2.6

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