EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Chemicals and construction
Construction

Brussels,
June 2006
ENTR/G3

GUIDANCE PAPER A

(concerning the Construction Products Directive 89/106/EC)

THE DESIGNATION OF NOTIFIED BODIES IN THE FIELD OF THE CONSTRUCTION PRODUCTS DIRECTIVE

(Revision Jun 2006)

(originally issued following consultation of the Standing Committee on Construction at the 52nd meeting 22-23 May 2001, as document CONSTRUCT 00/435 Rev 1.
Updated following consultation of SCC Sep 02
Updated following consultation of SCC Nov 05, as document CONSTRUCT 05/724
Updated following consultation of SCC Apr 06, as document CONSTRUCT 06/747)

Preface

Article 20 of the Construction Products Directive (89/106/EC) states that the Standing Committee may, "at the request of its Chairman or a Member State, examine any question posed by the implementation and the practical application of this Directive".

In order to ensure as far as possible a common understanding between the Commission and the Member States as well as among the Member States themselves as to how the Directive will operate, the competent services of the Commission, assuming the chair and secretariat of the Standing Committee, may issue a series of ***Guidance Papers*** *dealing with specific matters related to the implementation, practical implementation and application of the Directive.*

These papers are not legal interpretations of the Directive.

They are not judicially binding and they do not modify or amend the Directive in any way. Where procedures are dealt with, this does not in principle exclude other procedures that may equally satisfy the Directive.

They will be primarily of interest and use to those involved in giving effect to the Directive, from a legal, technical and administrative standpoint.

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: N105;
Telephone: switchboard (+32-2) 299.11.11, Fax: (+32-2) 296.10.65.

construction@ec.europa.eu http://europa.eu.int/comm/enterprise/construction/index.htm

They may be further elaborated, amended or withdrawn by the same procedure leading to their issue.

THE DESIGNATION[1] OF NOTIFIED[2] BODIES IN THE FIELD OF THE CONSTRUCTION PRODUCTS DIRECTIVE

1. Objectives and scope

1.1 This document is intended to provide guidance for Member States when designating and notifying bodies to operate the attestation procedures required under Article 18 of the Construction Products Directive (CPD). This Guidance Paper (GP) does not deal with the operation of Special Procedures (Article 16 of the Directive) or with market surveillance operations.

1.2 The principal objectives are:
to ensure the full implementation of the CPD, taking account of the specific aspects of the CPD and the requirements of the Council Resolution on a Global Approach to Conformity Assessment[3] and other relevant horizontal documents.

to define criteria that allow equivalent assessment of applicant bodies by Member States.

to provide information to Member States on the elements that need to be communicated to the Commission and the other Member States about the individual notifications.

to ensure that full information is available to all interested parties, on the scope and competence of notified bodies and the services provided.

1.3 This document is not itself directly applicable. But its provisions should be applied by Member States in the process of designation and notification.

2. The Legal Basis

2.1 The legal basis[4] applicable to the designation of notified bodies under the CPD is set out in Article 18 and Annex IV of the directive. This GP refers to the Council Resolution of 21.12.89 on a Global Approach to Conformity Assessment and to the "Guide to the implementation of directives based on new approach and global approach" (most recent version, 1999 referred to as "the Guide" in the text), the general provisions of which also apply to the notification process.

---

1 For this paper, designation can be described as being the internal assessment and approval process of the candidate Notified Bodies by the Member State.

2 To avoid confusion with the terminology used for organisations designated by member states under article 10 of the construction Products Directive (Approval Bodies) the Commission Services propose to use of the term "Notified Body" for Bodies notified under article 18 of the CPD, thus avoiding the term 'Designated Body'.

3 OJ C10, 16.10.1990

4 http://ec.europa.eu/enterprise/newapproach/legislation.htm

The general procedures laid down at Community level and described in the Commission document "Methods of co-ordinating the procedures governing the notification and management of notified bodies[5]" have also been taken into account.

3. Implementation of the criteria for the designation of notified bodies

3.1 Main responsibilities of Member States

(a) It is the responsibility of individual Member States to ensure that the criteria set out in Annex IV of the CPD are fully satisfied by notified bodies. Member States may notify to the Commission only bodies that conform to these criteria as a minimum requirement.

(b) Member States may consider for designation and notification only those product certification bodies, factory production control certification bodies, inspection bodies, and testing laboratories that come under their jurisdiction and which therefore are established in their territory (Guide, Section 6.1, 3rd bullet point).

(c) Should a Member State find that a body it has notified ceases to fulfil the conditions of notification, it should inform the body concerned, the Commission and the other Member States. A Member State shall withdraw notification if the body continues to not fulfil these conditions. Such withdrawal does not affect previous attestation work performed by that body unless it is shown that the work is no longer valid (Guide, Section 6.2.2 paras 2 and 3).

(d) Where a Member State withdraws its notification of a body, it shall take appropriate steps to ensure that another notified body processes dossiers of the body concerned in order to ensure continuity (Guide, Section 6.2.2 para 4).

(e) Annex F gives the information and conditions that Member States should check and include in the letters of designation to applicant bodies. Annex G gives the standard letter of notification to the Commission (and the other Member States) that Member States should use, after an identification number has been issued by the Commission services to the applicant body.

3.2 Interpretation of Annex IV of the Directive

(a) Compliance, demonstrated to the notification authority concerned, with the relevant requirements from the appropriate standards in the EN 45000 series (made specific to the requirements of the task and/or product(s) in question), together with proof of civil liability insurance, is considered as satisfactory demonstration of compliance with the criteria contained in Annex IV of the CPD.

(b) The Member States agree to verify at intervals the minimum conditions of all conditions set out in Annex IV of the Directive and not just conditions 1 and 2.

---

[5] CERTIF 93/1 Rev 3.

(c) When the Commission and the Member States have doubts about the competence of a notified body, it is their responsibility to act (Guide, Section 6.2.2 para 1). In such cases, the Commission may request, from the Member State concerned, appropriate documented evidence of the basis for notification.

3.3 Basis for assessments of notified bodies

(a) The standards that should be used as a basis for proof of compliance, within a defined scope of demonstrated competence, with the requirements of Annex IV are:

For bodies performing product certification:	EN 45011 "General requirements for certification bodies operating product certification systems"
For bodies performing FPC certification:	EN 45012 "General requirements for certification bodies operating assessment and certification oblige/registration of quality systems" And/or EN 45011
For bodies performing FPC inspection:	EN 45012 And/or EN ISO/IEC 17020 "General criteria for the operation of various types of bodies performing inspection"
For testing laboratories:	EN ISO/IEC 17025:2000 “General requirements for the competence of testing and calibration laboratories”

Note:

i) There being no unanimous agreement among Member States on the use of EN 45012, Member States may use the relevant clauses of EN 45011 and/or EN ISO/IEC 17020:2004 as the basis for demonstrating satisfaction of the requirements of CPD Annex IV as an alternative.

ii) In some member states the concept of inspection bodies does not apply under the CPD since all tasks related to FPC certification are carried out by a single FPC certification body. In other member states, FPC inspection bodies are subcontracted by an FPC certification body to carry out parts of the work for which the FPC certification body is itself ultimately responsible.

iii) For CE marking under the CPD, quality systems certification is not mandatory.

(b) Not all parts of the above standards are essential to demonstrate compliance with Annex IV. The requirements of Annex IV of the CPD can be demonstrated by compliance with those criteria listed in:

Annex A	for product certification bodies
Annex B	for FPC certification bodies
Annex C	for inspection bodies
Annex D	for testing laboratories
Annex E	for third parties performing calculation.

Those clauses of the relevant EN 45000 standards (or EN ISO/IEC 17025:2000 and EN ISO/IEC 17020:2004) that are not mentioned in these annexes are not a necessary requirement of the CPD.

(c) The tasks of bodies involved in FPC inspection and/or certification relate only to those aspects of an FPC system needed to satisfy the requirements of the CPD and as defined in Guidance Paper B "The definition of factory production control in technical specifications for construction products".

(d) In notifying a body to the Commission, a Member State must ensure that the body has the necessary specific product knowledge and certification/inspection and/or testing capability (Guide, section 6.1, 3rd bullet point, and para 3).

For certification and inspection bodies this is preferably demonstrated by reference to the title(s) and scope(s) of harmonised European technical specifications and/or Guidelines for European Technical Approvals (ETAGs). For test laboratories it is most easily demonstrated by reference to European test standards or parts thereof or by reference to test methods required for ETAGs.

(e) The versions of reference of the standards that have been used are EN 45012:1998, EN 45011:1998, EN ISO/IEC 17020:2004, EN ISO/IEC 17025:2000.

3.4 Sub-contracting by notified bodies

(a) The following summarises the conditions under which a CPD notified body may sub-contract (see also point 4.11). For a more complete account, see the Guide, section 6.5.

A notified body can have part of its work carried out by another body on the basis of established and regularly monitored competence.

The body subcontracted by the notified body must be technically competent, and display independence and objectivity according to the same criteria and under the same conditions as the notified body. However, notification of subcontractors is not necessary. The Member State that has notified the body which subcontracts part of its work, must ensure effective monitoring of the competence of both notified and non-notified bodies.

The notified body shall keep a register of all its subcontracting activities, and update it systematically. The notified body shall ensure that its subcontractors have the necessary competence and that they maintain this competence. This information shall be available to the notifying authority.

A further condition for subcontracting is that the conformity assessment procedure can be subdivided into technical operations and assessment operations, and that the methodology used to carry out the technical operations is sufficiently precise. The body subcontracted by the notified body must, nevertheless, carry out substantial and coherent parts of these technical operations.

Subcontracting must be based on a contract, which makes it possible to ensure transparency and confidence of the notified body's operations.

A subcontracting notified body remains responsible for all the activities covered by the notification. Subcontracting does not entail the delegation of powers or responsibilities.

Certificates are always issued in the name and under the responsibility of the notified body. The notified body cannot under any circumstances subcontract all of its activities, as that would make the notification meaningless.

> Notified bodies may for example subcontract tests while continuing to assess their results and, in particular, to validate the test report in order to evaluate whether the requirements of the directive are met. Similarly, subcontracting is possible in the field of certification of FPC systems by using external persons as auditors, provided that the notified body carried out the evaluation of the audit results.

Serial subcontracting (subcontracting by the subcontractor) is prohibited in order 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.

Note that although it is not necessary to notify subcontractors (see bullet point 2 above), the Commission encourages their notification under the CPD. This has a number of advantages, for example increasing transparency, opening up competition, allowing such bodies to appear on the Commission web site, and allowing them to participate in the work of the Group of Notified Bodies.

3.5 Notified bodies linked to a manufacturer

(a) The Guide (Section 6.3) includes the following provisions:

"Notified bodies are and must remain third parties independent of their clients and other interested parties".

"The structure of the body shall safeguard impartiality, especially if the body has other activities than those as a notified body. Further, the body shall have policies and procedures that distinguish between the tasks carried out as a notified body and any other activity in which the body is engaged, making this distinction clear to their customers."

"To safeguard objectivity, impartiality and operational integrity the body and its staff (whether directly employed or subcontracted) responsible for the activities carried out as a notified body may, for instance, neither be the manufacturer, his authorised representative, a supplier or their commercial competitor…."

(b) This general principle should be applied as far as possible to all notified bodies. However, it has to be recognised that in some cases it might be impossible to avoid notifying a body which is in some way linked to a manufacturer.

In these cases the concern is to ensure that the laboratory operates in a totally impartial way. The organisation must, of course, satisfy the criteria of CPD Annex IV. The notifying Member State should also, however, pay particular attention to the criterion of impartiality. The closer the relationship between the laboratory and the production unit, the stricter will have to be the means of satisfying the impartiality requirement and the stringency with which this is verified and policed.

This is dealt with in EN ISO/EIC 17025:2000, clause 4.1.4, which states “When products are tested by bodies (e.g. manufacturers) who have been concerned with their design, manufacture or sale, provision for a clear separation of different responsibilities and an appropriate statement shall be made.” Once notified, however, such a body would be entitled to undertake attestation operations for any client including those for its parent body.

3.6 Civil liability insurance

(a) Annex IV of the Directive requires that notified bodies should subscribe to civil liability insurance unless the liability is covered by the State under national law (with due regard to the principles of the Treaty). It is considered that the reference to "civil liability insurance" should be assumed to be a reference to professional indemnity insurance.

(b) The EN 45000 standards contain no requirements for insurance and the CPD provides no guidance on the value of insurance cover to be maintained. Member States should require notified bodies to provide annual evidence of adequate professional indemnity insurance cover, taking account of the turnover and nature of the risks likely to be incurred by the body concerned.

4. The process of notification

4.1 " Member States shall notify the Commission and the other Member States of the certification and inspection bodies and the testing laboratories which they have designated for the tasks which must be carried out for the purposes of technical approval, certificates of conformity, inspections and tests, in accordance with this Directive, together with their names and addresses and the identification numbers assigned to them beforehand by the Commission. Member States shall indicate the products which fall within the competence of the bodies and laboratories and the nature of the tasks to be assigned to them” (CPD Article 18).

The Commission is responsible for publishing and keeping up to date a list of bodies and their competencies.

4.2 The relevant attestation of conformity decision is the basis for identifying the scope of the notification. Member States are strongly recommended to stick exactly to the wordings used in the relevant AoC decision when selecting the product range of the notification. The nature of the tasks can be limited to 4 choices: product certification, certification of factory production control system, inspection of factory production control system, testing

4.3 Member States are free to notify at any time. It will usually be inappropriate, however, to notify before the adoption of the decision on the system of attestation of conformity for the product or product family in question. Member States should as precise as possible align the scopes of the notifications with the relevant attestation of conformity decision, the relevant harmonised standards or ETA Guidelines/ETAs, or appropriate test methods.

4.4 In advance of availability of finalised harmonised technical specifications or test standards, some member states prefer to provisionally notify their attestation bodies. Just as for fully notified bodies, provisionally notified bodies have to participate in co-ordination work at European level, through the Group of Notified Bodies.

4.5 It is the responsibility of the Member States to notify any changes, including withdrawal of notification, to the Commission.

4.6 Member States should, in addition to any continuous surveillance they may wish to undertake, regularly seek confirmation of the fulfilment of the terms and conditions by the bodies it notifies. It is recommended that this should be done at least once every four years but may be done more frequently.

4.7 There is no limit on the number of bodies that can be notified to undertake a given test or to certify FPC or product conformity for a given product. There is also no limit on the number of types of tests and/or product assessments for which any one body can be notified. A body can apply for designation against any of the tasks described in CPD Annex III Section 2, or any combination of these, provided that it meets the requirements of competence for each task.

4.8 Notification of bodies to the Commission does not automatically mean that tasks performed by them can lead to the affixing of the CE marking. Such CE marking can only take place once all the necessary conditions have been fulfilled, i.e. the availability of a harmonised technical specification together with all the necessary test and/or assessment methods.

4.9 Fully and provisionally Notified Bodies must accept the commitment to the development of practical attestation procedures at European level. This will involve regular co-operation with other notified bodies on a technical level and exchange of relevant information in the notified field of activity, with the aim of creating confidence through the harmonisation of practices and ensure reproducibility of attestation results.

4.10 The forum for this co-operation is the Group of Notified Bodies (GNB) for the CPD. All notified bodies are automatically a member of this group and in particular a member of one or more of its sector groups. Notified Bodies will take the results of the work of the GNB into account.

4.11 Notified Bodies need to be able to demonstrate that they are actively involved in the activities of the GNB. Lack of involvement will lead to the withdrawing of the notification by the notifying authorities.

4.12 Where a body seeking notification proposes to sub-contract a part of its activities, a list of sub-contractors which it may use must be kept and systematically updated by the body. Any change to this list should be considered as a change to the terms of the notification, and must therefore be made known to the Member State. The list of sub-contractors should be available without delay to the Commission and other Member States if requested, but there is no requirement for such sub-contractors to be themselves notified.

4.13 A body appearing on a list of sub-contractors may itself be a notified body for the same tasks for which it is a sub-contractor, or for other tasks.

4.14 The scope of the notifications of the Notified Bodies will be made publicly available on NANDO[6]. Only notifications that follow the publication of the title and reference of the relevant harmonised EN or ETAG in the OJEU (no pre-notification) will be included in the NANDO Database.

[6] http://ec.europa.eu/enterprise/newapproach/nando

ANNEX A: INTERPRETATION OF ANNEX IV REQUIREMENTS FOR BODIES CARRYING OUT PRODUCT CONFORMITY CERTIFICATION

A1. The requirements set out in Annex IV of the CPD are considered to correspond to the following clauses in EN 45011:1998. The application of this standard should take account of the size and complexity of the organisation being assessed and of the tasks that it wishes to carry out, and should not lead to the imposition of unnecessary bureaucracy.

Annex IV Criteria		Relevant Clauses of : EN 45011
IV.1 Availability of:	personnel	4.2 Organisation: (j) 5 Certification body personnel 9 Preparation for evaluation : 9.3
	means and equipment	Where the certification body operates its own testing and/or inspection activities, these activities shall conform with the relevant requirements of EN ISO/IEC 17025 and EN 45012/EN ISO/IEC 17020:2004. Also see "IV.2 Technical competence" below.
IV.2 Technical competence		4.1 General provision 4.1.3, 4.1.4 4.2 Organisation (b) (c) (f) (k) (l) (p) 4.3 Operations 4.4 Subcontracting 4.5 Quality system 4.6 Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification 4.7 Internal audits and management reviews 4.8 Documentation on: 4.8.1(a) (b) (c) (d) (f), 4.8.2 4.9 Records 7 Appeals, complaints and disputes 9 Preparation for evaluation: 9.1, 9.4 10 Evaluation 11 Evaluation report 12 Decision on certification 13 Surveillance: 13.1, 13.2, 13.3
Professional Integrity		4.2 Organisation: l (m) (n)
IV.3 Impartiality		4.1 General provisions: 4.1.1, 4.1.2 4.2 Organisation: (a) (e) (o) 4.4 Subcontracting 4.9 Records: 4.9.1 9 Preparation for evaluation: 9.3
IV.4 Professional secrecy		4.2 Organisation: (0) 4.4 Subcontracting 4.9 Records: 4.9.1 4.10 Confidentiality

A.2 The above clauses provide the basis for assessment against the Annex IV criteria. However, in order to comply fully with the requirements of Article 18 and also to promote mutual confidence in the assessment process the following requirements should also apply:

- **Scope of designation :**
  This should be defined in relation to harmonised technical specifications and/or Guidelines for ETAs recognised for the purposes of the CPD.

- **Method of assessment :**
  Assessment must be made against the Annex IV criteria.

  This may be achieved through a formal accreditation scheme by a recognised accreditation body, based on EN 45011, plus the specific requirements of the CPD and the harmonised technical specification for the product concerned.

ANNEX B: INTERPRETATION OF ANNEX IV REQUIREMENTS FOR BODIES CARRYING OUT FPC CERTIFICATION

B1. The requirements set out in Annex IV of the CPD are considered to correspond to the following clauses in EN 45012:1998. The application of this standard should take account of the size and complexity of the organisation being assessed and of the tasks that it wishes to carry out, and should not lead to the imposition of unnecessary bureaucracy.

Where clauses in EN 45012 refer to quality systems, these should be interpreted as FPC systems as defined under the CPD.

Annex IV Criteria		Relevant Clauses of : EN 45012
IV.1 Availability of:	personnel	2.1.2 Organisation: (j) 2.2 Certification/registration body personnel
	means and equipment	Covered by "IV.2 Technical competence" below
IV.2 Technical competence		2.1.1 General provisions: 2.1.1.3,4 2.1.2 Organisation: (b) (c) (f) (k) (l) (p) 2.1.3 Subcontracting 2.1.4 Quality system 2.1.5 Conditions for granting, maintaining, extending, reducing, suspending and withdrawing certification/registration: 2.1.5.1,3,4 2.1.6 Internal audits and management reviews 2.1.7 Documentation: 2.1.7.1(a) (b) (c) (d) (f); 2.1.7.2 2.1.8 Records 2.4 Appeals, complaints and disputes 3.2 Preparation for assessment 3.3 Assessment 3.4 Assessment report 3.5 Decision on certification/registration 3.6 Surveillance and reassessment procedures (In addition, the certification body shall require the supplier to inform it of any changes which may affect the conformity of the product)
	Professional Integrity	2.1.2 Organisation: (m) (n) 2.1.3 Subcontracting 2.1.8 Records: 2.1.8.1 2.2 Certification/registration body personnel: 2.2.3.2(f); 2.2.4
IV.3 Impartiality		2.1.1 General provisions: 2.1.1.1,2 2.1.2 Organisation: (a) (e) (o) 2.2 Certification/registration body personnel, 2.2.3.2(f); 2.2.4
IV.4 Professional secrecy		2.1.2 Organisation: (o) 2.1.3 Subcontracting 2.1.8 Records: 2.1.8.1

2.1.9 Confidentiality

B.2 The above clauses provide the basis for assessment against the Annex IV criteria. However, in order to comply fully with the requirements of Article 18 and also to promote mutual confidence in the assessment process the following requirements should also apply:

- **Scope of designation :**
  This should be defined in relation to harmonised technical specifications and/or Guidelines for ETAs recognised for the purposes of the CPD.

- **Method of assessment :**
  Assessment must be made against the Annex IV criteria.

  This may be achieved through a formal accreditation scheme by a recognised accreditation body, based on EN 45012, plus the specific requirements of the CPD and the harmonised technical specification for the product concerned.

ANNEX C : INTERPRETATION OF ANNEX IV REQUIREMENTS FOR INSPECTION BODIES

C1. The requirements set out in Annex IV of the Directive are considered to correspond to the following clauses in EN 45012:1998 (see below for the relevant clauses of EN ISO/IEC 17020:2004). The application of this standard should take account of the size and complexity of the organisation being assessed and its technical scope and should not lead to the imposition of unnecessary bureaucracy. The tasks of FPC inspection are somewhat different to those of FPC certification and EN 45012 should be applied with this difference in mind. Where relevant, references in EN 45012 to "certification" and/or "registration" should be read as "inspection". Where relevant, references to certificates should be read as inspection reports since inspection bodies do not issue certificates.

Annex IV Criteria		Relevant Clauses of : EN 45012
IV.1 Availability of:	personnel	2.1.2 Organisation: (j) 2.2 Certification/registration body personnel
	means and equipment	Covered by "IV.2 Technical competence" below.
IV.2 Technical competence		2.1.1 General provisions: 2.1.1.3,4 2.1.2 Organisation: (c) (f) (k) (l) (p) 2.1.3 Subcontracting (a) (b) 2.1.4 Quality system 2.1.5 Conditions for granting, maintaining, extending, reducing, suspending and withdrawing certification/registration: 2.1.5.4 2.1.6 Internal audits and management reviews 2.1.7 Documentation: 2.1.7.1(a) (c) (d) (f); 2.1.7.2 2.1.8 Records 2.4 Appeals, complaints and disputes 3.2 Preparation for assessment 3.3 Assessment 3.4 Assessment report
Professional Integrity		2.1.2 Organisation: (m) (n) 2.1.3 Subcontracting (a) (b) 2.1.8 Records: 2.1.8.1 2.2 Certification/registration body personnel: 2.2.3.2(f); 2.2.4
IV.3 Impartiality		2.1.2 Organisation: (a) (e) (o) 2.2 Certification/registration body personnel, 2.2.3.2(f); 2.2.4
IV.4 Professional secrecy		2.1.2 Organisation: (o) 2.1.3 Subcontracting 2.1.8 Records: 2.1.8.1 2.1.9 Confidentiality

C2. Where assessment is based on EN ISO/IEC 17020:2004 the following clauses of that standard are considered relevant (note that, for Clause 13 of EN ISO/IEC 17020:2004, it is only the aspect relating to inspection reports that is relevant).

Annex IV Criteria		Relevant clauses of EN ISO/IEC 17020	
IV.1	Availability of : personnel	8	Personnel
	means	10	Inspection methods and procedures
	equipment	9	Facilities and equipment
IV.2	Technical competence	3.3	Documentation
		6	Organisation and management
		7	Quality system
		10	Inspection methods and procedures
		11	Handling inspection samples and items
		12	Records
		13	Inspection reports [and inspection certificates]
		15	Complaints and appeals
	Professional integrity	4	Independence, impartiality and integrity
IV.3	Impartiality	4	Independence, impartiality and integrity
IV.4	Professional secrecy	5	Confidentiality
IV.5	Civil liability insurance	3.4	Administrative requirements

C3. The above clauses provide the basis for assessment against the Annex IV criteria. However, in order to comply fully with the requirements of Article 18 and also to promote mutual confidence in the assessment process the following requirements should also apply:

- **Scope of designation :**

  This should be defined in relation to harmonised technical specifications and/or Guidelines for ETAs recognised for the purposes of the CPD.

- **Method of assessment :**

  Assessment must be made against the Annex IV criteria.

  This may be achieved through a formal accreditation scheme, by a recognised accreditation body, based on EN 45012 or alternatively on EN ISO/IEC 17020:2004, plus the specific requirements of the CPD and the harmonised technical specification for the product concerned.

ANNEX D : INTERPRETATION OF ANNEX IV REQUIREMENTS FOR TESTING LABORATORIES

D1. The requirements set out in Annex IV of the Directive are considered to correspond to the relevant clauses in EN ISO/IEC 17025:2000 "General requirements for the competence of testing and calibration laboratories". The application of either of these standards should take account of the size and complexity of the organisation being assessed and its technical scope and should not lead to the imposition of unnecessary bureaucracy.

a) Relevant clauses of EN45001:1989

Annex IV Criteria		Relevant clauses of EN ISO/IEC 17025	
IV.1	Availability of : personnel	5.2	Personnel
	means	5.3.1.	Availability
		5.3.2.	Premises and Environment
	equipment	5.3.3	Equipment
IV.2	Technical competence	5	Technical Competence
	Professional integrity	4	Impartiality, independence and integrity
IV.3	Impartiality	4	Impartiality independence and integrity
IV.4	Professional secrecy	5.4.6	Confidentiality and security

b) Relevant clauses of EN ISO/IEC 17025:2000

Annex IV Criteria		Relevant clauses of EN ISO/IEC 17025
IV.1	Availability of : personnel	4.1 Organisation: 4.1.5 a, f, g 5.2 Personnel
	Means	4.1 Organisation: 4.1.5 h 4.5 Subcontracting of tests and calibrations 4.6 Purchasing services and supplies 5.3 Accommodation and environmental conditions
	Equipment	5.5 Equipment 5.6 Measurement traceability: 5.6.1 General: 5.6.2.2 Testing (labs) 5.6.3 Reference standards and reference materials

IV.2	Technical competence	4.1 Organisation: 4.1.3, 4.1.5 e,i 4.2 Quality system: 4.2.1, 4.2.2 a to d, 4.2.3 4.3 Document control 4.4 Review of requests, tender & contracts 4.7 Service to the client 4.8 Complaints 4.9 Control of non conforming testing and/or calibration work 4.10 Corrective action 4.11 Preventive action 4.12 Control of records 4.13 Internal audits 4.14 Management reviews 5.4.7 Control of data 5.4.7.1., 5.4.7.2a, c 5.8 Handling of test and calibration items 5.9 Assuring the quality of test and calibration results
	Professional integrity	4.1 Organisation: 4.1.4, 4.1.5 b, d
IV.3	Impartiality	4.1 Organisation: 4.1.4, 4.1.5 d,e
IV.4	Professional secrecy	4.1 Organisation: 4.1.5 c, e 4.12 Control of records: 4.12.1.3 5.4.7 Control of data: 5.4.7.2b

Notes:

1. EN ISO/IEC 17025 covers both testing and calibration laboratories. For the purposes of this guidance paper only provisions relating to test bodies are relevant. Clauses referring to "testing/calibration laboratories" should be read as "testing laboratories".

2. Certain clauses in EN ISO/IEC 17025 refer to sampling capability. Information on sampling and the treatment of results is given in the relevant technical specification. Where this information is not given or is incomplete in the technical specification, proposals will be made by the relevant Sector Group of Notified Bodies.

3. Clause 5.4 "Test and calibration methods and method validation", subclauses 5.4.1 to 5, cover the capability of test laboratories to develop their own tests. These clauses are not included in the table above because, under the CPD, test methods are set out in the technical specifications. If further elaboration of test methods is needed, this is the task of the relevant CEN Technical Committee or EOTA Working Group, possibly advised by the relevant Sector Group of Notified Bodies.

   However, some aspects are relevant to laboratories carrying out CPD Article 4.4 procedures. For example:

   5.4.5.2 The laboratory shall validate standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

4. Clause 5.4.6 covers estimation of uncertainty of measurement including use of statistical methods. Clause 5.10 covers the content and format of test reports. These clauses are not included in the table above because,

under the CPD, these matters should be dealt with in the technical specifications and/or by the relevant Sector Groups of Notified Bodies.

D2. The above clauses provide the basis for assessment against the Annex IV criteria. However, in order to comply fully with the requirements of Article 18 and also to promote mutual confidence in the assessment process the following requirements should also apply:

- **Scope of designation :**

  Scope shall be defined by reference to relevant products and one or more tests or types of tests recognised for the purpose of the CPD.

  When the harmonised test methods are not available (pre-notification) then the characteristics as identified in the relevant mandate can be used to identify the tasks of the notified testing laboratory.

- **Method of assessment :**

  Assessment must be made against the Annex IV criteria.

  This may be achieved through a formal accreditation scheme, by a recognised accreditation body, based on EN ISO/IEC 17025 plus the specific requirements of the CPD and the harmonised technical specification for the product concerned.

ANNEX E: INTERPRETATION OF ANNEX IV REQUIREMENTS FOR THIRD PARTIES PERFORMING CALCULATION IN SUPPORT OF AoC.

E1. The requirements set out in Annex IV of the Directive are considered to correspond to the relevant clauses in EN ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" which replaced the previous version. The application of this standard should take account of the size and complexity of the organisation being assessed and its technical scope and should not lead to the imposition of unnecessary bureaucracy.

E2. It is being recognised, in accordance with CPD, Annex III (3), that calculation may replace testing in the framework of initial type calculation. The requirements set out below are considered to apply to third parties, i.e. third parties performing "Initial type calculation", but also including certification and inspection bodies. For certification and inspection bodies, the specific requirements related to calculation should be considered in addition to those specified in Annexes A, B or C of this Guidance paper.

Relevant clauses of EN ISO/IEC 17025:2005

Annex IV Criteria		Relevant clauses of EN ISO/IEC 17025:2005
IV.1 Availability of:	Personnel	4.1 Organisation: 4.1.5 a, f, g, k 5.2 Personnel[7] Management shall authorize personnel to use computers in the information system. Policies shall be established which define who may use the computer system, who may access data and who is authorized to enter and change results or modify computer programmes

[7] **Further requirements for personnel carrying out the design (calculation)**

Annex IV Criteria - IV.2 Technical competence: Personnel

Option 1

a. The Notified Body defines minimum competence criteria for evaluation personnel regarding education, training and experience, referring to:

i Essential requirements of security established in the relevant Directive

ii harmonised technical specifications and design codes of application for products.

iii evaluation of conformity procedures established in the Directive corresponding to the evaluation to carry out

iv knowledge of the products (technology, methods of production, use of products and defects that may occur in its use and putting into service, understanding that the meaning of the deviations found in relation to the safety in use in such products).

b. The above mentioned criteria should cover the fitness to evaluate the product and to make professional statements of their conformity with the essential requirements of the directive. The criteria are fully documented and in line with any other harmonised criterion developed by the Group of NBs designated for the application of the relevant directive. The NB applies the recommendations of the Group of NBs unless reasons to deviate from such recommendations in the particular case are justified.

c. The NB duly qualified personnel available and with the necessary competence regarding the requirements established to carry out the activities of the revision of the design.

Option 2

The Notifying Authority needs to ensure that personnel of the body performing calculation (or its subcontractor) who undertake the evaluation are entitled to perform such calculations according to the specific requirements of the Member State by which the body has been designated.

	Means	4.1 Organisation: 4.1.5 h 4.5 Subcontracting of tests and calibrations 4.6 Purchasing services and supplies 5.3 Accommodation and environmental conditions Particular emphasise shall be laid to environmental conditions related to computer hardware.
	Equipment	5.5 Equipment Where required, notified bodies shall have at their disposal, hard- and software to perform the calculations in accordance with the relevant technical specification. To assume responsibility, the notified body shall judge whether manufacturer's calculations suffice or need to be performed with the notified body's equipment. When computers are used for the collection, processing, recording, reporting, storage or retrieval of data, the notified body performing calculation shall ensure that: a) computer software is documented and suitably validated as adequate for use, b) procedures are established and implemented for protecting the integrity of data at all times (e.g. no connection to internet), c) computers are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data, and d) computer programmes and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorized persons. 5.6 Measurement traceability: 5.6.1 General
IV.2 Technical competence		4.1 Organisation: 4.1.3, 4.1.5 e, i 4.2 Quality system: 4.2.1, 4.2.2 a to d, 4.2.5 4.3 Document control 4.4 Review of requests, tender & contracts 4.7 Service to the client 4.8 Complaints 4.9 Control of non conforming testing and/or calibration work 4.11 Corrective action 4.12 Preventive action 4.13 Control of records 4.14 Internal audits 4.15 Management reviews 5.4.7 Control of data 5.4.7.1., 5.4.7.2a, c 5.8 Handling of test and calibration items 5.9 Assuring the quality of test and calibration results
Professional integrity		4.1 Organisation: 4.1.4, 4.1.5 b, d

IV.3 Impartiality	4.1 Organisation: 4.1.4, 4.1.5 d, e
IV.4 Professional secrecy	4.1 Organisation: 4.1.5 c, e 4.13 Control of records: 4.13.1.3 5.4.7 Control of data: 5.4.7.2b

Notes:

1. EN ISO/IEC 17025:2005 covers both testing and calibration laboratories. For the purposes of this guidance paper only provisions relating to third parties performing attestation activities for those cases where calculation replaces testing to determine performances test bodies are relevant. Clauses referring to "testing/calibration laboratories" should be read as "third parties performing attestation activities for those cases where calculation replaces testing to determine performances".

2. Certain clauses in EN ISO/IEC 17025:2005 refer to sampling capability. Information on sampling and the treatment of results is given in the relevant technical specification. Where this information is not given or is incomplete in the technical specification, proposals will be made by the relevant Sector Group of Notified Bodies.

3. Clause 5.4 "Test and calibration methods and method validation", subclauses 5.4.1 to 5, cover the capability of test laboratories to develop their own tests. These clauses are not included in the table above because, under the CPD, calculation methods are set out in the technical specifications. If further elaboration of calculation test methods is needed, this is the task of the relevant CEN Technical Committee or EOTA Working Group, possibly advised by the relevant Sector Group of Notified Bodies.

   However, some aspects are relevant to laboratories carrying out CPD Article 4.4 procedures.

   For example: *5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.*

4. Clause 5.4.6 covers estimation of uncertainty of measurement including use of statistical methods. Clause 5.10 covers the content and format of test reports. These clauses are not included in the table above because, under the CPD, these matters should be dealt with in the technical specifications and/or by the relevant Sector Groups of Notified Bodies

5. Clause 4.10 covers improvement. This clause is not included in the table above because, under the CPD, continuous improvement, although important, is not a requirement.

E3. The above clauses provide the basis for assessment against the Annex IV criteria. However, in order to comply fully with the requirements of Article 18 and also to promote mutual confidence in the assessment process the following requirements should also apply:

- **Scope of designation (Attestation of conformity system 3 notified bodies only):**

  Scope shall be defined by reference to relevant products and one or more calculations or types of calculations recognised for the purpose of the CPD. When the harmonised calculation methods are not available then the characteristics as identified in the relevant mandate can be used to identify the tasks of the notified third party performing attestation activities where calculation replaces testing to determine performances.

- **Method of assessment :**

  Assessment must be made against the Annex IV criteria.

This may be achieved through a formal accreditation scheme, by a recognised accreditation body, based on EN ISO/IEC 17025:2005 plus the specific requirements of the CPD and the harmonised technical specification for the product concerned.

ANNEX F: GUIDANCE FOR MEMBER STATES ON LETTERS OF DESIGNATION OF NOTIFIED BODIES

E1 Member States are each responsible for designating testing laboratories, product certification bodies, factory production certification bodies and inspection bodies (Art. 18.1).

E2 The precise format of designation may vary, depending on the legal requirements and specific arrangements in each Member State. However, in the interest of creating the maximum of mutual confidence in the organisations concerned, formal letters of designation should at least be consistent in the points that they deal with.

E3 All letters of designation should, as a minimum, cover the following points (which are also of relevance for the letter of Notification towards the Commission and the other Member States) :

1. The legal basis for designation.

2. Identification of the applicant

3. Identification number issued by the Commission services.

4. Period for which designation is valid.

5. Further details when relevant

6. Requirement either of continued compliance with EN 45000 as necessary for CPD purposes, or otherwise state how compliance with the Annex IV criteria is to be demonstrated.

7. Full contact details of contact person nominated in the body responsible for designation under the CPD.

   This person will be granted access to the Group of Notified Bodies CIRCA. There is a requirement to promptly inform the notifying authority and the administrative secretariat of the GNB of each change in contact details. For large organisations, with a broad notification, more persons can be nominated.

8. Title and number of the relevant Attestation of Conformity Decision

9. Description of the product(s)/intended use(s) that are subject of the notification.

   Member States are requested to stick exactly to the wordings used in the relevant AoC decision. This is to increase transparency, smooth administrative procedures and allow building an effective Notifications database.

10. Definition of the tasks for which the body is notified according to the CPD. There are only 4 possibilities:

    product certification
    certification of factory production control system
    inspection of factory production control system.

testing

11. Reference to harmonised European technical specifications (Number, date and version).

For certification and inspection bodies it will in most cases be sufficient to refer to the harmonised product standard or the relevant ETA Guideline. For test laboratories it will be necessary to refer to individual European test standards or parts thereof or test methods referred to by ETAs in all cases where the notification is not covering the complete set of tests required by the harmonised technical specifications.

Examples:

EN xxxx:2001
ETAG 001:1997

12. Additional information

Note: Member States can choose to write the letter of notification in any of the official languages of the community. However, for easy communication, we recommend that the information is also available in English.

E4 Notification also gives the presumption that the following provisions are enforced by the Member State (often delegated to the designating authority or the accreditation body):

- Requirement for information on important changes in personnel or equipment to be communicated to the designating authority/accreditation body.

- Requirement of annual evidence of civil liability insurance cover.

- Obligation to take part in proficiency testing, if required.

- Requirement for the notified body to be active in the Group of Notified Bodies.

- Requirement that full records shall be kept for at least 10 years from the last date of manufacture of the product, particularly of applications for tests; certification or inspections and of the results.

- Provision for the designating authority to have access to these records.

- Conditions under which designation may be withdrawn, including failure to comply with the Annex IV criteria.

- In the case of withdrawal of designation, requirement for the records to be transferred to the designating authority, or continued access to be assured.

- Provision for the designating authority to be given access to carry out any inspections it may consider necessary in order to ensure compliance with the terms of designation.

ANNEX G: NOTIFICATION OF A BODY PURSUANT TO ARTICLE 18 OF THE CONSTRUCTION PRODUCTS DIRECTIVE 89/106/EEC

The numbers in ( ) refer to the clauses of annex E (E3)

Date:

From: **To:** (other Member States, Secretariat General of the Commission)

1. Reference:	Directive No. **89/106/EEC** (1)

2.A. Name of body, acronym, address, telephone, fax, email

(2)

2.B. Identification number of the body (3)

3. Period of validity:

Period of validity (4)

☐ Unlimited

☐ Valid until .....

…….. (5)

4. Technical qualification of the body (accreditation or other official authorization):

(6)

5. Authorised contact person(s) in notified Body.
Name, address if different from above, direct telephone, local fax, personal Email.

(7)

6. Tasks performed by the body:

AoC	Product(s)/intended use	tasks	Specifications
(8)	(9)	(10)	(11)

7. Additional information

(12)