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KAN 47

47

Accreditation of conformity assessment bodies

Akkreditierung von Konformitätsbewertungsstellen

VFA

KAN Kommission Arbeitsschutz und Normung

About this report

KAN has the task of safeguarding German occupational safety and health interests during the harmonization of standards within the European Single Market and of assuring the participation of the social partners in standardization processes. It therefore pursues the objective of ensuring that not only German and European but also international standardization gives the best possible consideration to OSH issues. KAN comprises five representatives each from employers' organizations, employees' organizations and the state and one representative each from the German Social Accident Insurance (DGUV) and DIN Deutsches Institut für Normung e.V.

KAN analyses OSH-related issues and identifies scope for improvement in standardization activity. One measure for this purpose is the commissioning of studies and reports.

Background

The European Single Market and the elimination of barriers to trade are founded to a significant degree upon suitable procedures for the testing, certification and monitoring of product conformity. Procedures for accreditation have an essential role in assuring confidence in the technical competence, ability, impartiality and integrity of the bodies performing conformity assessments. Harmonized standards and their consistent application are of great importance in this context, and must therefore satisfy the requirements of the European legal framework.

A study commissioned by KAN in 2003 and published as KAN Report 30 had already analysed the principles of the German and European accreditation and notification systems. In this study, proposals were developed for a uniform and cohesive body of regulations and standards for the conformity assessment of bodies.

Regulation (EC) No. 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, and in particular Decision No. 768/2008/EC on a common framework for the marketing of products, make provision for a presumption of conformity. In accordance with this principle, a conformity assessment body (such as a test and certification body) which demonstrates in an accreditation procedure that it satisfies in whole or part the criteria of the relevant harmonized standards the references of which have been published in the Official Journal of the European Union is also presumed to satisfy the requirements for example of the relevant directive. On 16 June 2009, the titles of the relevant harmonized standards concerning accreditation and conformity assessment were published for the first time in the Official Journal by the European Commission.

Purpose of the study

Based upon the results of the 2003 study published in KAN Report 30, the present study examined whether the relevant standards, published in June 2009, for the accreditation of conformity assessment bodies are sufficiently complete and meaningful to satisfy the requirements of Community law.

The project partners were to find answers to the following questions:

1. Do the provisions of the standards the references of which were published in the Official Journal of the EU pursuant to Regulation (EC) No. 765/2008 and to Decision 768/2008/EC cover all the requirements of these legal instruments and of the directives based on the New Approach? For example:
- Requirements concerning technical competence
- Identical criteria for independence
- Binding obligations for insurance
- Identical conditions for subcontracting in all cases

2. Is the relationship between standards and the individual conformity assessment modules for which they are to be applied sufficiently clear that the Member States are able to perform assessment without having to make reference to multiple standards with substantially differing content for virtually every module?

3. Have the relevant standards – particularly the EN ISO 17000 series – adopted the "Common Elements" proposed in KAN Report 30, i.e. universally valid, common requirements for bodies seeking notification (deriving from precisely defined minimum criteria formulated in the EU directives and in Regulation (EC) No. 765/2008 and Decision No. 768/2008/EC)? Or do corresponding guidelines exist?

4. Should a gap exist between the requirements of the relevant harmonized standards and the respective specific (technical) requirements of the EU directives relating to bodies seeking notification, how could it be closed?
What contribution could be made here by the "recognized body" (cf. Article 14 of Regulation (EC) No. 765/2008)?

KAN wishes to thank the project partners (Ms. Jun.-Prof. Dr. Dagmar Gesmann-Nuissl (project manager), Prof. Dr. jur. Dr. rer. pol. Jürgen Ensthaler, Dr. Rainer Edelhäuser) for conducting the project, and the following experts in the supervisory project working group for supervising and supporting it:
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Summary by KAN

A) Presumption of conformity

1. **Of the harmonized standards studied, EN ISO/IEC 17020:2004 is the only standard to state all of the provisions formulated in Article R 17 of Decision 768/2008/EC. Even this standard, however, does not satisfactorily support the requirements deriving from Article R 17.**

2. **The situation feared in Chapter 5.3.2 of KAN Report 30 has arisen: for the sake of worldwide acceptance, support for the legally binding European requirements has been partly dropped during updating of the standards governing conformity assessment.** European requirements cannot be given adequate consideration (or the will is lacking for this to happen), and the binding effect of the CASCO Policy upon the resulting standards is clearly insufficiently strong. The existing (and also future) CASCO standards concerning bodies are of only limited suitability for substantiating the presumption of conformity. As is shown in particular by the analysis of the current standards, the requirements described in them neither cover the entire catalogue of requirements formulated in Article R 17, nor are the individual requirements sufficiently detailed to substantiate the presumption of conformity. **The "exclusively ISO/CASCO solution" proposed in KAN Report 30 must therefore be deemed not practicable.**

3. Now as before, the harmonized standards governing conformity assessment bodies and listed in Commission Communication 2009/C 136/08 fail to correspond clearly to the tasks of the notified bodies as described in the modules of the decision. **In order for each standard nevertheless to indicate unambiguously which of its requirements support which requirements in the catalogue in Article R 17, i.e. in respect of what the standard in question actually gives rise to a presumption of conformity, an informative Annex Z would for example be necessary**.

4. a) Under the interpretation of the new legal instruments, publication of the references of the harmonized standards in the Official Journal of the EU is not sufficient for them to give rise automatically to the full scope of the desired presumption of conformity. The original presumption of conformity, deriving from Decision 93/465/EEC, is repealed. **The presumption of conformity now comes into effect only when the standards satisfy the minimum requirements of the *"Common Elements"* formulated in Article R 17 and the modules of Article R 18 of Decision 768/2008/EC.** In other words: irrespective of whether a conformity assessment body satisfies the provisions to which it is subject, the presumption of conformity does not take effect should the standard not support these conditions, or not do so adequately.

   b) In addition, the harmonized standards must be examined not only against the requirements of Decision 768/2008/EC, including the modules formulated within it, but also on a case-by-case basis against the

actual form taken by these requirements in the specific directives concerned. This means that clarification is necessary of the extent to which a standard may be deemed to give rise to the presumption of conformity.

c) **For accreditation and notification of bodies to be comparable throughout Europe, the specific technical requirements for certain product/technology areas must also be brought into line.** This sector-specific expertise can be defined sufficiently precisely neither by the directives, nor by the standards. For this purpose, the Member States should formulate measurable minimum requirements in the relevant directive working groups, in order for the general formulations such as "all technical knowledge" and "sufficient and appropriate experience" used in the decision/in the directives and the standards to be adequately substantiated and to permit consistent evaluation.

B) Cohesiveness of the system as a whole

5. **Comparison of the requirements in the ISO/PAS which essentially determine standardization work with those defined in Article R 17 reveals only limited congruence between these two catalogues of criteria.** Although similar regulatory issues are addressed, there is little agreement in terms either of the level of detail, or of the structure of the requirements:

   a) Firstly, **requirements in the ISO/PAS**, for example concerning independence, **fall short, in some cases considerably, of the needs of the area subject to statutory regulation**. This is the case for example for the issue of "related bodies": CASCO WG 23 has rejected by majority decision the adoption of a clear description of the relationship between "body" and "legal entity" in ISO/PAS 17001 governing impartiality. With this approach, ISO/CASCO thus neglected to create an indispensable basis for application of the requirements to notified bodies, for example for adequate description of the independence. This basis is particularly important for the standards' suitability with regard to the presumption of conformity.

   b) Secondly, **Article R 17 of Decision 768/2008/EC falls short in places of the requirements that are now usual, i.e. the "state of the art".** This applies in particular to the process- and management-related requirements, for which Article R 17 contains only vague formulations.

   c) In addition, **the provisions of Article R 17 do not conclusively describe the individual requirements relating to the notified body**. For example, adoption of the highly relevant criterion of "independence" does not extend beyond the term itself. This suggests that it is the function of the standards to provide suitable interpretations of these terms. It is thus possible that a standard may well require impartiality (independence), but that the associated criteria stated are not sufficient to give rise to the presumption of conformity.

6. Different descriptions, deviating from R 17, **of the same terminology and subject-matter** in the various different standards make comparison difficult.

7. **For these reasons, many essential areas of regulation are not described in the harmonized standards, or their descriptions differ or lack the requisite clarity. This too is a reason why considerable scope still exists for differences in interpretation between the Member States.** It is therefore possible that provisions, which may be comprehensive, concerning impartiality in a standard within the ISO 17000 ff. series may not be referred to in full for the presumption of conformity because the requirements of Article R 17 in Annex I of Decision 768/2008/EC are less rigorous.

8. Comparison with the recommendations made in KAN Report 30 shows **that these incongruities in the system could essentially have been avoided**:

   a) Article R 17 adopts a series of recommendations made in KAN Report 30 which had previously been present neither in the Modules Decision nor in the requirements of the modules (such as legal personality; reproducibility of procedures; evaluation of expertise at regular intervals; mandatory participation in standardization activities; etc.). At the same time, uncertainties remain in the area of organization regarding the internal responsibilities, internal decisions concerning the selection and training of personnel and document control, despite these being requirements that are essential to and indispensable for confidence in the work of conformity assessment bodies.

   b) The formulations of the ISO/CASCO-PAS requirements also generally fall well short of the recommendations made in KAN Report 30, which are more specific, in some cases considerably so. This is particularly the case with regard to the aspects of organization and responsibilities, independence (and impartiality), confidentiality and secrecy, and management systems (with the exception of complaints/appeals).

KAN's recommendations

KAN requests that the **German Federal Government** lobby the European Commission

- to call upon the standards organizations to add an Annex Z to each harmonized standard. This measure is to clarify the standards' consistency with the requirements formulated in Article R 17. The informative Annex Z must also state clearly to what extent the module-specific requirements have been substantiated. Where necessary, this measure should be performed separately for each sectoral directive.

- for the references of harmonized standards to be published in the Official Journal of the EU only if they include an Annex Z.

- for the standards organizations to appoint a Consultant with the task of reviewing these harmonized standards.

- to adapt the decision, particularly Article R 17 of Annex I, to the state of the art, or for that matter to the more extensive terms of the original recommendations made in KAN Report 30.

In view of the fact that it has not yet proved possible to assure the equivalence of requirements in the CASCO standards by means of ISO/PAS Common Elements, KAN requests that **DIN** call for

- requirements concerning identical subject-matter to be reflected in identical formulations within the various CASCO standards;

- all requirements formulated in R 17 to be substantiated in the various CASCO standards;

- CEN/CLC TC 1 to adapt ISO standards to European requirements where necessary, in accordance with its mandate.

KAN charges the **KAN Secretariat** with the task of drafting a proposal for Annex Z for the standards analysed in the study and submitting this proposal to the standardization process.

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Accreditation of conformity assessment bodies

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1 Present situation

1.1 Development of the framework conditions: from the early years to the New Legislative Framework

The most significant objective of the EC Treaty (now the Treaty on the Functioning of the European Union) was the creation of the European Single Market by implementation of the four basic economic freedoms: the freedom of movement of goods, services, persons and capital. Of these, the freedom of movement of goods, i.e. the unrestricted circulation of goods and products within the European Union, has always been of key importance. Harmonized provisions were intended to enhance the safety of products in order to protect all European consumers and to support the interest of business in the free and unregulated traffic in goods.

During the "**early years**", however, it soon emerged that this understanding of the freedom of movement of goods could not be assured by European primary law (former Article 28 of the EC Treaty; Article 34 of the TFEU) alone, but that a form of European harmonization that aimed for a high level of acceptance and for the necessary confidence in the products in circulation would also require flanking systems in secondary law.

Initially, the idea was pursued of regulating the characteristics of products at the highest level by means of European statutory regulations (legal instruments). This, the "**Old Approach**", resulted however in the Member States, with their own legal traditions, generally failing to find a common denominator, and it therefore not being possible either to converge or actually to harmonize the national rules.

In consideration of this issue, the "**New Approach**" to the harmonization of technical regulations was presented in 1985 in the European Commission's white paper, and shortly afterwards adopted in the legislation by a Council Resolution.[1] A fundamental change in legal strategy thus occurred: the principle of detailed harmonization pursued up until that time (the "Old Approach) was abandoned. Henceforth, the harmonization of safety requirements for products was to be implemented by the **binding specification** by the European Union only of product-specific[2] or hazard-specific[3] **essential safety requirements** (in the form

[1] Council Resolution of 7 May 1985 setting out a new approach to technical harmonisation and to standardisation, OJ EU C 136, 4.6.1985.
[2] Product-specific directives are also termed "vertical directives". These include the Toys Directive (88/378/EEC), the Lifts Directive (95/16/EC) and also the Recreational Craft Directive (94/25/EC).
[3] Hazard-specific directives are also termed "horizontal directives", since they cover the most diverse of product types giving rise to a specific hazard which in the view of the European legislature should be regulated. Typical examples of horizontal directives are the EMC Directive (2004/108/EC) and the General Product Safety Directive (2001/95/EC).

of directives); the substantiation or technical form of these provisions was to be transferred, in the form of mandates, to the European standards organizations.[4]

In accordance with this procedure, 38 directives have been adopted since 1983 which set out these essential requirements for various product areas.[5] As a result, the European legislature has succeeded in its aim of assuring the safety of the products in circulation, but without specifying the technical solutions to be used by manufacturers in achieving this aim (consumer protection with far-reaching preservation of manufacturers' prerogative).[6] Mandating is also able to assure greater technical flexibility, since standards – unlike rigid directives – are indisputably better suited to reflecting the instantaneous state of technical development.

In order for the balance between the interests of economic players (manufactures) in free and unhindered access to markets and those of consumers in the greatest possible product safety to be assured, both now in the future, the European Union made provision within the New Approach for **four key modules**[7] (see Fig. 1), the mutual action of which has remained largely unchanged:

- **Standardization**

  The standardization module is a natural consequence of the procedure described above, i.e. that of setting out essential safety requirements for products in binding form within EU directives, and transferring the task of substantiating these requirements to harmonized standards. This process does not as such result in the harmonized standards acquiring legal force. Their observance is however not merely optional: where a manufacturer observes the harmonized standards, the Member States are obliged to assume that the products and (manufacturing) methods satisfy the minimum requirements of the directive, and that the products have therefore been manufactured in observance of the applicable legislation. A manufacturer who is willing to observe the requirements of the directive by designing his product in accordance with the relevant harmonized standards thus enjoys a privilege regarding the burden of proof: the national market surveillance authorities are obliged in the first instance to presume, in his favour, that a product which he has manufactured in compliance with the standard

[4] Cf. with regard to the procedure: Guide to the Implementation of Directives Based on New Approach and Global Approach, Office for Official Publications of the European Communities, Luxembourg, 2000. This procedure also satisfactorily met the requirements of the principle of subsidiarity.
[5] For a list of New Approach directives, see http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist.html (15 September 2010).
[6] Kapoor/Klindt, "New Legislative Framework" im EU-Produktsicherheitsrecht – Neue Marktüberwachung in Europa?, in: EuZW 2008, pp. 649 (650).
[7] Cf. also the explanations in the Blue Guide with regard to the four pillars of this approach.

also satisfies the essential requirements of the directive (presumption of product conformity).

- **Conformity assessment**

  The **second module**, the one to be given particular consideration in this study, is that of conformity assessment. The manufacturer must ensure that his products comply with the essential requirements of the directives and standards, i.e. he must have their conformity examined and demonstrated before placing them on the market. For this purpose, he must follow an assessment procedure described in the directives. Depending upon the hazard level presented by the product, the manufacturer may follow this procedure himself under his own responsibility (see below), or involve a neutral test body (a "notified" body). In either case, the conformity of the product is indicated by the CE mark.

  In order to ensure that the test, certification and monitoring bodies performing assessment exhibit equivalent competence throughout Europe, the New Approach was extended at the end of the 1980s by means of the Global Approach to cover testing and certification[8]. The essential idea here was to lay down uniform and transparent minimum requirements not only for products, but also for the activity of the conformity assessment bodies (for details, see 2.1).

  Provision was also made for a generally recognized authority or state body to confirm that the conformity assessment bodies satisfy the requirements of the directives and standards which they are required to meet in order to perform assessments within their particular scope.

  Finally, and once again in the interests of European harmonization, the procedures for the performance of conformity testing and assessment were described in eight conformity assessment modules (A – H) which the manufacturer/notified body must apply according to the relevant regulation (directive or standard) (the "**Modules Decision**").[9]

- **CE marking and manufacturer's responsibility**

  The third module describes the responsibility of the manufacturer, as alluded to above, for the conformity of his products. The manufacturer is at liberty to declare, on his own responsibility, that his products satisfy the safety requirements set out in the EU directives and standards, and

[8] Council Resolution on a global approach to conformity assessment, OJ C 10, 16.1.1990, p. 1.

[9] Council Decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives, OJ EC 1990 No L 380, p. 13, as amended by Council Decision of 22 July 1993 (93/465/EEC), OJ EC 1993 No L 220 (the "Modules Decision"). The objective of the Modules Decision was to bring the individual conformity assessment procedures more closely into line with each other (the EU directives had previously contained diverging, uncoordinated conformity assessment procedures), in order in particular to increase the transparency of conformity assessment. The decision is addressed to the European legislature, and lists a total of eight modules by means of which conformity assessment can be demonstrated. It constitutes a form of "construction kit" for the adoption of harmonization directives. Cf. KAN Report 30, pp. 54 ff. for details.

to document this by application on his own responsibility of the CE mark to his products.

- **Market surveillance**

  Finally, the fourth module ensures that, once the products have been placed on the market, the market is monitored by the authorities responsible for market surveillance in the individual Member States. These bodies have the function of monitoring observance of the provisions of Single Market legislation, and punishing violations of them.

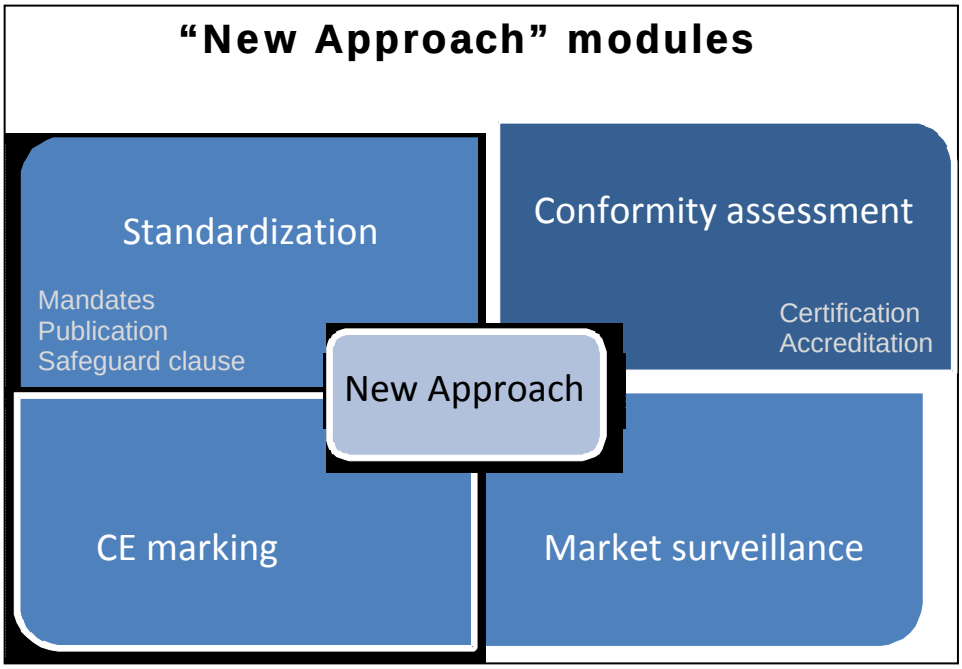

Fig. 1: "New Approach" modules

To this day, the overall concept described here continues to be a successful instrument for the elimination of technical barriers to trade, and its application is to be extended in the future to further sectors. For this purpose, the European legislature modernized the statutory framework for completion of the Single Market in 2008 with the **New Legislative Framework**, and at the same time amended the principles of the free movement of goods with regard to product safety aspects. The New Approach to the harmonization of technical regulations in Europe thus received a long-awaited "facelift"[10] on 23 June 2008, and has the function of overcoming the weaknesses of the New Approach identified in the past[11]. Specifically, these weaknesses are:

- the risk of competition being distorted owing to deviations in practices and requirements concerning the notification of conformity assessment bodies by the national authorities;

[10] This formulation is used by Kapoor/Klindt, Die Reform des Akkreditierungswesens im Europäischen Produktsicherheitsrecht, in: EuZW 2009, p. 134.
[11] Cf. Ambitions and objectives in COM (2007), 37 final. Also in the recitals of the legislative acts for the New Legislative Framework. See also Wloka, Die EG-Verordnung ist verabschiedet, in: BAM (eds.), DAR-aktuell, June 2008.

- differences in market-surveillance modalities between different countries and the associated differences in the treatment of noncompliant or dangerous products placed on the market;
- the lack of confidence in the competence of national certification bodies owing to wide differences in quality standards;
- the lack of confidence in CE marking;
- the inconsistent implementation and enforcement of the "New Approach".

The revision of the New Approach was also to create a more precise framework for the future for conformity assessment, accreditation and market surveillance.

The New Legislative Framework, which in this respect ushers in the "new era" for the New Approach, essentially comprises three European legal instruments, termed the "**Goods Package**":

- Regulation 764/2008/EC of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC.
- Regulation 765/2008/EC of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Council Regulation 339/93/EEC.
- Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

As part of this "Goods Package", the former Modules Decision 93/465/EEC was repealed, and Decision 768/2008/EC enacted in its place. Together with Decision 768/2008/EC, Regulation 765/2008/EC was also published, which supplements the decision governing the common statutory framework, referred to above, with provisions governing market surveillance and the accreditation of the conformity assessment bodies ("notified bodies"), and at the same time repeals the former Regulation 339/93/EEC.

This "Goods Package" represents a paradigm shift and formulates the requirements upon the market surveillance systems more closely and intensively. Its essential regulatory aspects are the requirements for the market players, the detailed criteria imposed by the authorities upon the conformity assessment and monitoring bodies with the objective of raising the quality of the conformity assessment of products, the policy of commitment from industry itself for future EU directives, and the comprehensive changes in European accreditation law for product certifications.

1.2 Presentation of the new European overall concept

The new European overall concept (see Fig. 2) – which is governed by a regulation and thus became applicable immediately to all Member States on 1 January 2010 (Article 44 of Regulation 765/2008/EC) without a further transposing measure – retains certain proven structures in the first instance. The "essential requirements" pertaining to technical products will for example continue to be defined in abstract form in directives, and their support, i.e. their technical and organizational substantiation, will largely remain the preserve of the standardization bodies, who possess a closer relationship to the technology.

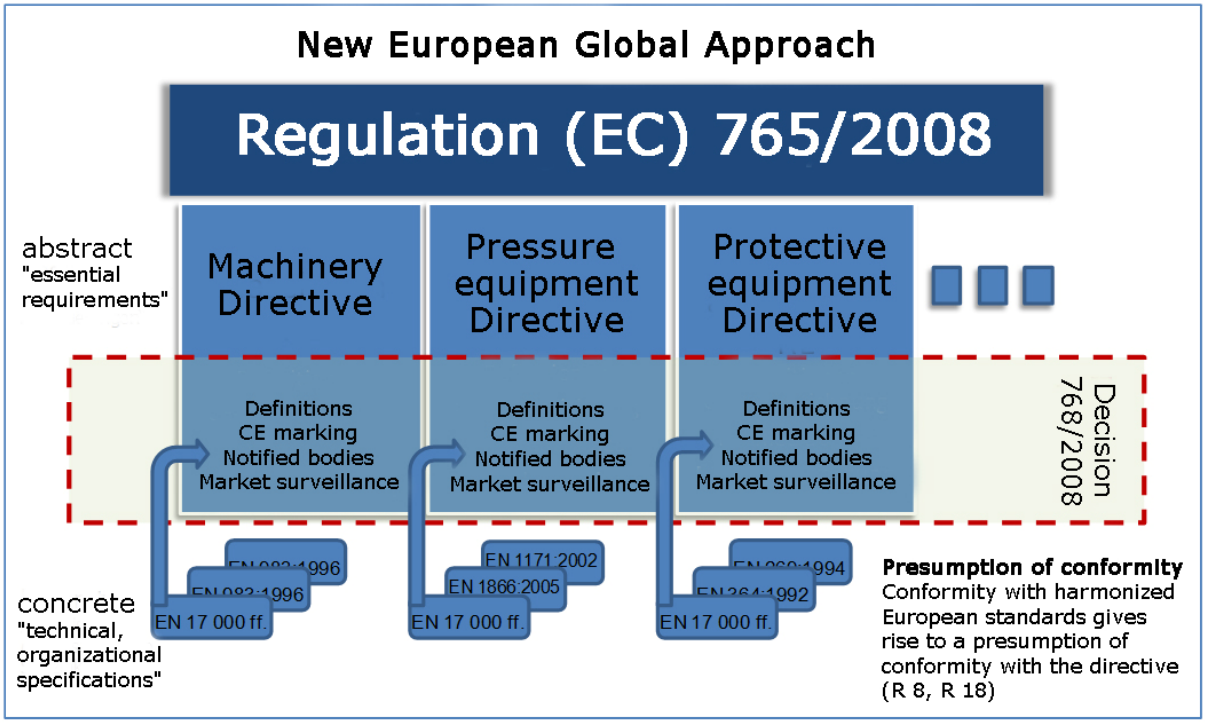

Fig. 2: New overall European concept in accordance with the New Legislative Framework

By contrast, a crucial new development is the concept of Decision 768/2008/EC, which on the one hand repeals the Modules Decision 93/465/EEC (see Article 8 of Decision 768/2008/EC), and in turn asserts validity both for future directives and for the revision of existing directives (Recital 2 of Decision 768/2008/EC)[12].

The decision, which is now to provide the **building-blocks** for all future directives and for the revision of existing directives, contains common definitions[13], principles, and in accordance with Annex I, reference provisions for application in **all** sectoral legal instruments (cf. for example the Machinery Directive, Medical Devices Directive, etc.). The reference provisions thus

[12] See also 4.1.3. below.

[13] They became necessary, since the statutory regulations governing the free movement of goods employed a whole series of concepts, some of which had been defined very differently or not at all, and did not therefore contribute to legal clarity. The decision therefore results in the introduction of clear definitions for certain fundamental concepts.

represent a declaration of intent on the part of the European legislature to formulate future product directives **in a very particular way** and with the use of **similar, recurring elements**, and to adapt existing directives to the criteria of these reference provisions when they are due for revision[14] (Article 7 of Decision 768/2008/EC; Recital 7 of Decision 768/2008/EC). These provisions and their binding force upon the legislature are intended to bring about greater harmonization and conformity in the sectoral directives in all areas stated in the decision – for example with regard to the requirements concerning the bodies charged with conformity assessment (cf. Decision 768/2008/EC Annex I R17). This constitutes at least partial abandonment of the approaches taken in the past, attributable to the subsidiarity principle: the criteria have once again become more rigid, and the leeway granted to the Member States reduced accordingly.

Where the (future) directives and standards take up these basic modules (for example requirements concerning notified bodies, Article R17) or have already done so in the past, it is therefore logical that the decision also extends the presumption of conformity to these (new) areas[15]. In consideration of Article R17, Annex I Article R18 of Decision 768/2008/EC therefore states:

> R18 Presumption of conformity
>
> Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article [R17] in so far as the applicable harmonised standards cover those requirements.

[14] Cf. also Honnacker, Produktsicherheit und Wettbewerb, p. 57.
[15] Refer to Section 4.1.2 below for details of the presumption of conformity to which Decision 768/2008/EC Annex I Article R18 gives rise.

2 Conformity assessment within the harmonized area

2.1 Global Approach

As already discussed, confidence in the products also depends to a considerable degree upon the confidence in the conformity assessment systems. The European legislature therefore supplemented the New Approach at an early stage with the Global Approach for Certification and Testing[16], which described a uniform method of conformity assessment.

The starting-point was the Council Decision concerning the modules to be employed in the technical harmonization directives for the various phases of the conformity assessment procedure (the "Modules Decision")[17]. The objective of the Modules Decision was to bring the individual conformity assessment procedures more closely into line with each other, in particular in order to enhance the transparency of conformity assessment. The decision was addressed to the European legislature, and listed a total of eight modules in accordance with which conformity could be demonstrated. It thus constituted a system of "building-blocks" for the adoption of harmonization directives.

In accordance with the Modules Decision, the relevant harmonization directives were to set out the "essential requirements" applicable not only to product testing, but henceforth also to the test and certification bodies, in order for an adequate minimum standard throughout the Single Market also to be assured in this area.

The harmonization directives to be adopted were to be based upon the provisions of the Modules Decision, particularly its "General Guidelines", and address the particular, product-specific requirements in a modular manner, including in the area of conformity assessment. Harmonization directives were therefore expected to be geared towards the general criteria and sectoral requirements of the modules. Finally, all further necessary technical and organizational details (substantiation of the minimum criteria concerning the notified bodies) were to be transferred to mandated standards (at that time, the EN 45000 ff. series of standards) in order to prevent the directives from becoming overloaded, as provided for by the New Approach.

[16] OJEC No C 267, 19.10.1989.
[17] Council Decision OJ EC 1990 No L 380, p. 13 in the latest version in force of 22.7.1993 (93/465/EEC), OJ EC 1993 No L 220.

The Modules Decision (General Guidelines I A m of Decision 93/465/EC) thus also contained the following provision governing the presumption of conformity:

> General Guidelines, I A m
>
> "...notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate or other documentary evidence, are presumed to conform to the requirements of the directives [i.e. general criteria + criteria of the modules]… "

2.2 Minimum criteria for notified bodies under the Global Approach

The requirements concerning notified bodies were however addressed **only rudimentarily** in the "General Guidelines" of the Modules Decision. Only the technical competence (A I k, l); scope for subcontracting (A I l); confidentiality of information (A I i); retention of test documentation, monitoring mechanisms and appeals procedures (modules) were addressed.

A compilation from the harmonized directives (at that time, the EN 45000 series) enabled, albeit with difficulty, further minimum criteria to be described, which however were **not found consistently** in the various EU directives and which, owing to a lack of harmonized criteria, were also **not in any way systematic**.[18] The criteria which could (sympathetically) be compiled in this way were as follows:

- The body and its personnel must be independent of the interests of development, manufacturing, sales, etc.
- The body and its personnel must conduct assessments and tests in a competent and trustworthy manner, without susceptibility to influence.
- Subcontractors must observe the provisions of the relevant directive.
- The tasks with which the body is charged must be carried out either by the body itself, or under its responsibility.
- The body must possess the test equipment required for fulfilment of its tasks.
- The body must take out a liability insurance policy.
- The body must employ sufficient personnel, who must also be able to demonstrate that they are well trained for their tasks, have knowledge of relevant regulations, and are capable of conducting correspondence as required.

[18] Ensthaler et al., KAN Report 30, pp. 110–112.

- Personnel must not be bound by instructions with regard to their testing and certification tasks; their remuneration must not be related to the number of assessments completed or to their results.
- Personnel are bound by confidentiality.

2.3 Criticism and recommendations formulated in KAN Report 30: "Common Elements"

This nebulous situation was then also pointed out in KAN Report 30, "Accreditation of test and certification bodies".[19] The main points of criticism made in KAN Report 30 were as follows:

- The criteria set out in the harmonization directives for notified test and certification bodies are too abstract, inconsistent, and in some cases even contradictory.
- The standards in the EN 45000 series relevant to the technical competence of test and certification bodies do not adequately substantiate the directive; they do not cover all aspects of the directive to which they relate.
- This leads to wide discretionary powers and variation in the level of expertise among test and certification bodies in Europe.
- The minimum criteria, which are difficult to identify and are formulated very generally, are **not** therefore **sufficient** to assure uniformly high standards within Europe.

In consideration of all these points of criticism, the research group concluded at the time that the presumption of conformity set out in the Modules Decision 93/465/EC to which the EN 45000 series of standards (see above under 2.1) gives rise is substantively highly questionable and that it **cannot** be assumed that a body possessing accreditation in accordance with these standards satisfies the minimum criteria set out in the EU directives in accordance with the New Approach.[20]

In order to resolve the problem, the research group proposed a catalogue of generic, common requirements for notified bodies[21] – the "**Common Elements**" (refer to the broad overview in Fig. 3) – and recommended that they be set out either directly in European secondary law (directive or regulation) or in the form of harmonized standards.[22]

[19] Ensthaler et al., KAN Report 30, pp. 55 ff., 110 f.
[20] Ensthaler et al., KAN Report 30, p. 126.
[21] Ensthaler et al., KAN Report 30, pp. 112 – 126.
[22] Ensthaler et al., KAN Report 30, p. 126.

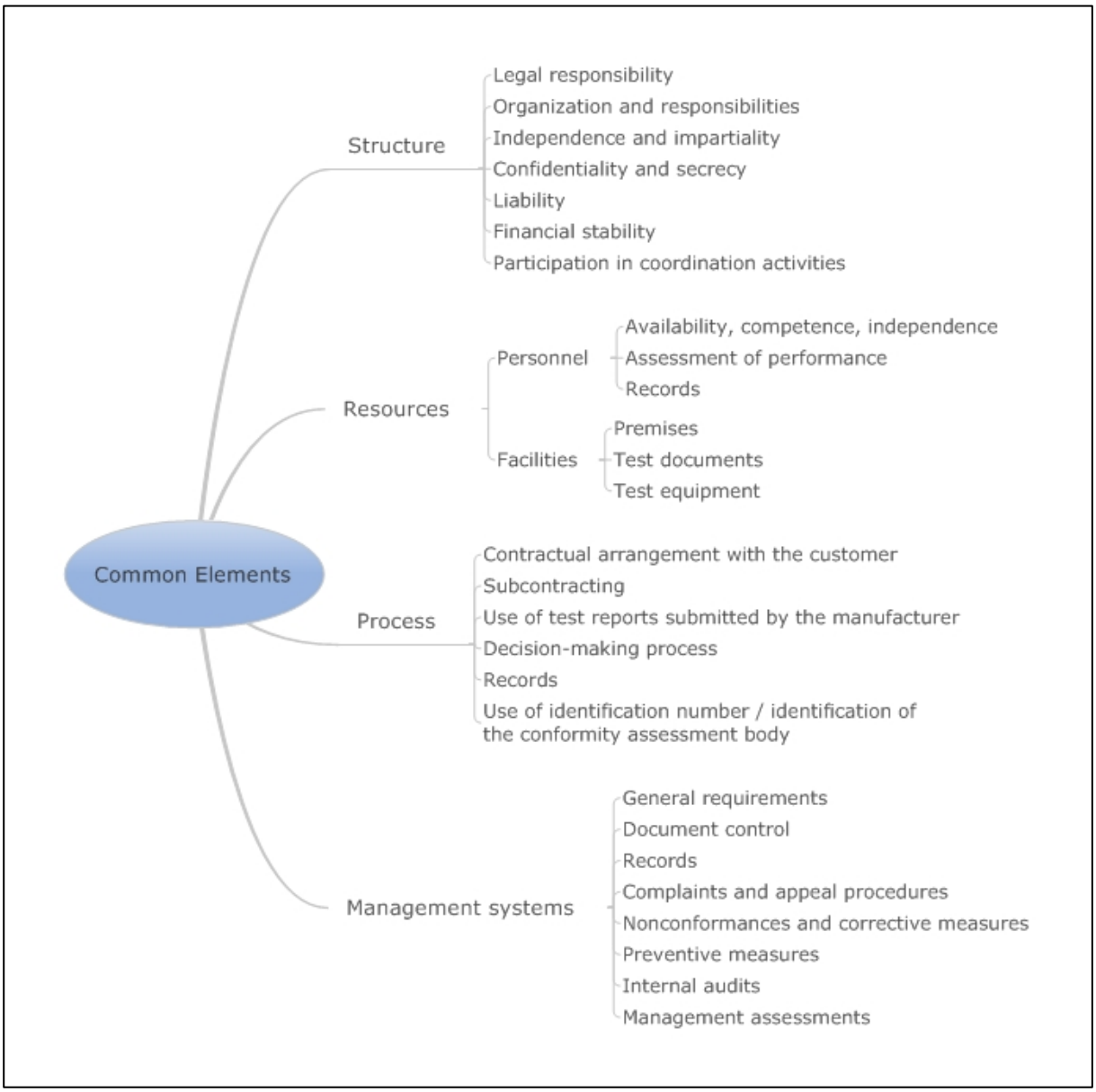

Fig. 3: Abstract overview of the common requirements concerning notified bodies proposed in KAN Report 30

The extent to which Decision 768/2008/EC, particularly Articles R17 and R20 in Annex I – which now describe the requirements for conformity assessment bodies – addresses the results of KAN Report 30, is presented in detail in Section 4.3.1. The following can however be noted in the first instance:

- Article R17 (supplemented by Article R20) states the minimum criteria at a central point in an EU Decision, and defines them as indispensable parts of the harmonized directives.
- Article R17 now incorporates areas which were not previously stated as "minimum criteria", either in the "general guidelines" of the Modules Decision, nor in the requirements of the modules, but which were addressed and recommended in KAN Report 30 (for example: legal personality; repeatability of the methods; evaluation of technical expertise

at regular intervals; mandatory participation in standardization activity, etc.).

- The substance of the decision however still falls short of the recommendations made in KAN Report 30. This is discussed in detail in Section 4.3.1 below.

2.4 Developments in standardization: ISO CASCO Publicly Available Specifications (PAS)

If the developments in ISO/CASCO[23], the technical committee of the International Standards Organization (ISO) responsible for developing the principles of conformity assessment, are also considered with regard to the recommendations of KAN Report 30 described in 2.3, the mutual influence is seen to be essentially positive. As discussed in Section 5.3.2 of KAN Report 30, the time was opportune for the proposals drafted in it to be introduced into standardization. A closer analysis however reveals differences between the CASCO standards in their objectives regarding the Global Approach and thus the failure of the "pure ISO/CASCO solution" proposed at the time.

At its General Assembly in 2000, CASCO adopted the decision to convene a working group to address the identification of Common Elements (not to be confused with the Common Elements of KAN Report 30, described in 2.3). The group was created because development of standardization in the area of conformity assessment had shown that requirements for essentially identical areas of regulation within the individual standards, for example for test/calibration laboratories, inspection bodies and product and system certification bodies, had continued to diverge further; the consequence of this, which is still evident today, was that conformity assessment bodies performing several of these tasks were confronted with a plethora of requirements, formally different but substantively the same. The mission of the working group was as follows:[24]

> **Task** –The working group is to identify Common Elements in ISO/IEC Standards for conformity assessment bodies and their activities to ensure full implementation of the *policy on Common Elements in CASCO Standards (*)*. Consideration will be given to the result of the Joint Working Group CEN/CENELEC/TC 1 – ISO/CASCO, *Investigation of the future structure of the conformity assessment standards and guides*.
>
> *(*)* ***Policy on Common Elements in CASCO Standards***
> *CASCO Standards shall be adequately coordinated to ensure that Common*

[23] http://www.iso.org/iso/resources/conformity_assessment/objectives_and_structure_of_casco.htm

[24] Document CASCO WG23/1, May 2000, underlining added in the text

Elements in their texts have equivalent contents, unless there is justification for variations and/or deviations from the Common Elements.

In order to achieve this goal, the CASCO Chairman's Advisory Group (CAG), as part of its management task of reviewing and coordinating the work of the CASCO WGs, shall review the working drafts of CASCO Standards developed by the relevant CASCO WGs and make the necessary coordination with the relevant CASCO WG Convenors at appropriate development stages of the projects. Working drafts of CASCO Standards shall be endorsed by the CASCO CAG in terms of the adequacy of any included Common Elements before the relevant projects are moved to the Committee Stage (i.e. CD vote among the CASCO member bodies).

The first session of CASCO Working Group 23, "Common Elements in ISO/IEC Standards for conformity assessment activities", was held in 2001. The group essentially identified the following three levels of requirements[25]:

- **Generic Common Elements** for all conformity assessment tasks
- **Sectoral Common Elements** for groups of conformity assessment bodies conducting conformity assessments of the same type, such as certification, testing and inspection
- **Specific elements** for concrete tasks

Only the first two levels formed the subject of discussion in CASCO WG 23; the discussion of concrete conformity assessment tasks was left to the individual standardization groups.

Following extensive discussion, agreement was reached to develop criteria for the following Common Elements:

- **Appeals**
- **Complaints**
- **Confidentiality**
- **Impartiality**
- **Management Systems**
- **Related Bodies**
- **Structural Requirements**

Besides this substantive work, the group also discussed the structure of the requirements and of future standards in detail, in order to prevent situations such as those which had arisen with the EN 45011 and EN 45012 standards (for product certification and system certification bodies respectively) from arising in

[25] Cf. document CASCO WG 23/22 January 2003

the future. In these cases, almost identical provisions had been formulated in a completely different order, leading to unnecessary confusion when these standards were applied in parallel. The new objective was to provide a uniform basic structure for the future standards, extending to the part governing the requirements, in order to facilitate parallel application.

The result was a decision by CASCO[26] to assign the requirements for a given Common Element to one or more of the following categories:

a) General requirements

b) Structural requirements

c) Resource requirements

d) Process requirements

e) Management system requirements

This classification essentially follows that for the Common Elements in KAN Report 30 (see Section 2.3 above), although the general and structural requirements of the latter had been grouped together.

A further difference resulted from deviations in the procedure followed in CASCO WG 23 for the "process requirements". In contrast to the original approach, consistent with the procedure in KAN Report 30, of only describing requirements concerning the conformity assessment task proper (e.g. testing, certification) in this section, process requirements in some cases of a general nature (for example for the handling of complaints) were subsumed in CASCO in this part. In the classification presented by KAN Report 30, these are found under "Management Systems".

CASCO thereby formulated a decision with inherently far-reaching consequences for the continued development of standards for conformity assessment bodies. This decision was intended to prevent creeping divergence of both the requirements and the structure of the standards. The classification has since also been adopted in CASCO basic specifications and confirmed as "CASCO policy"[27]. Inherent to this decision is the principle that the Common Elements are to be used in an identical manner in future standards, unless sound arguments exist for deviations in formulation.

[26] CASCO Resolution 12/2002, confirmed by "New Work Item Proposal (NP) for ISO/IEC Publicly Available Specifications (PASs) to address common elements in CASCO documents and fulfilment of CASCO Resolution", see CASCO 15/2003

[27] See QS-CAS-PROC/01 ISO Committee on Conformity Assessment (CASCO) – Structure, process and rules of operation, Section 6.3, August 2008

The Common Elements were and are intended solely as internal specifications for the CASCO working groups.[28] The results of the work were however published in the form of "Publicly Available Specifications" (PAS). This category of ISO document was regarded by CASCO as being the most suitable means of assuring swift agreement and publication.

Altogether, the following five documents were drawn up:

- **ISO/PAS 17001 Technical Rule**, 2005-10 Conformity assessment – **Impartiality** – Principles and requirements
- **ISO/PAS 17002 Technical Rule**, 2004-08 Conformity assessment – **Confidentiality** – Principles and requirements
- **ISO/PAS 17003 Technical Rule**, 2004-08 Conformity assessment – **Complaints and appeals** – Principles and requirements
- **ISO/PAS 17004 Technical Rule**, 2005-10 Conformity assessment – **Disclosure of information** – Principles and requirements
- **ISO/PAS 17005 Technical Rule**, 2008-07 Conformity assessment – **Use of management systems** – Principles and requirements

The first ISO/PAS were published in 2004. As a comparison with the objective of the work described above shows, certain changes were agreed in the course of the discussions, which were at times heated. Certain Common Elements were described, logically, in a single document (such as complaints and appeals). Other topics, which were essentially related, were dealt with in separate documents for which provision had not originally been made (such as confidentiality and the disclosure of information).

The individual documents consist of several pages of redundant explanations, generally a small number of substantive requirements, and in some cases further supplementary explanatory principles. The requirements are divided into three categories which differ in the extent to which they are binding. The following distinctions are made:

- **Obligatory requirements:** these **must be adopted** unchanged by WGs (only specification of the task)
- **Recommended requirements:** these **can be adopted** by WGs should the WGs wish to adopt more explicit provisions in the standard; the formulations are recommendations, changes are possible

[28] Cf. the introduction and the section headed "Scope" in ISO/PAS 17001 to 17005: "This Publicly Available Specification is intended to apply to the drafting of documents on conformity assessment by ISO/CASCO" and "It is an internal tool for use in the ISO/IEC standards development process by ISO/CASCO working groups when considering the element of impartiality in preparation of their documents. This Publicly Available Specification is not a stand alone normative document to be used directly in conformity assessment activities."

- **Suggested requirements:** these **can be** considered

This is illustrated by the following example from PAS 17001: 6.2.2 Recommended requirements:

> **6.2.2.1** The body shall not offer or provide conformity assessment as well as design or consultancy services that relate to the same object of conformity assessment for the same customer, as this poses an unacceptable threat to impartiality.

Even from this example, it can be seen that the requirements have been formulated in relatively general terms and are often less explicit than the minimum criteria defined in the EU directives. The following is taken verbatim from the generalized requirements from KAN Report 30, Section 5.1:

> The notified body, its top-level management, and the staff charged with conducting the conformity assessment activities shall not be identical to the designer, manufacturer, supplier, installer, or user or operator of the products assessed for conformity by the notified body, nor may they be acting on behalf of any of the persons involved in these activities. They may not be involved either directly or as representatives in the planning, construction, sale, installation or maintenance of these products.

A more detailed comparison of the obligatory requirements defined in the PAS can be found in Annex 1. The requirements of the two other categories (recommended/suggested requirements) were not considered in this case, since no guarantee can be given that the future standards structured according to the principles of the Common Elements will contain such requirements.

The comparison shows that the formulations of the ISO/CASCO PAS requirements generally fall well short of the requirements proposed in KAN Report 30, which are in some cases substantially more explicit. This particularly applies to the following aspects:

- Organization and responsibilities
- Independence (and impartiality)
- Confidentiality and secrecy
- Management system (exception: in complaints/appeals)

In the Management section, the differences referred to above can be seen from the structure of the two approaches. Whereas for many essential subordinate aspects of the management system requirements, the PAS formulate only the requirement for relevant arrangements (for example for the control of

documents), the corresponding descriptions in the Common Elements of the KAN Report are considerably more detailed.

The complaints and appeals are an exception. These aspects are governed by the separate ISO/PAS 17003, to which the management system requirements make reference. This standard also reveals the differences in the structure, since it also defines process requirements, in addition to general requirements.

With the adoption of ISO/PAS 17005 concerning the application of management systems, work was terminated in 2008 and the working group dissolved. The "structural requirements" which were originally planned were not developed.

Where the area subject to statutory regulation is concerned, the result falls far short of the expectations, since many essential areas subject to regulation are not described clearly, if indeed at all.

The same applies to the subject of "related bodies": CASCO WG 23 reached a majority decision opposing the adoption in ISO/PAS 17001, governing impartiality, of a clear description of the relationship between "body" and "legal entity": this approach is inadequate for the application of the requirements to notified bodies.

ISO/PAS and CASCO standards are written for bodies; these bodies may however be parts (subordinate units) of legal entities, and not therefore identical with the legal entity of which they form a part. The requirements thus relate only to these subordinate units. Conversely, the requirements concerning notified bodies always refer to the legal entity performing the task as a notified body. This legal entity is named. The consequence is that firstly, on their own, the requirements from the PAS are of only limited suitability as requirements for notified bodies; secondly, ISO/CASCO neglected to create an indispensable basis for application of the requirements to notified bodies, for example for adequate description of the independence. As will be shown in Section 4.3.2, this basis is particularly important for the standards' suitability with regard to the presumption of conformity.

3 Mandate M/417 and CEN/CENELEC TC1

In the context of the "New Legislative Framework" (NLF), the European Commission issued an inherently far-reaching mandate to the European standards organizations (ESOs) at the end of 2007 in the form of Mandate M/417[29], which covers existing and future standards. The mandate was supplemented by a comprehensive list of proposals concerning harmonized standards for accreditation bodies, conformity assessment bodies, quality assurance and environmental standards, and general standards. The tasks described in the mandate are to:

a) Identify all international standards and/or standardisation documents (e.g. guides) from ISO, IEC, (...) that are relevant to the NLF and/or to the sectoral policies mentioned under §2. (...)

b) If they meet European requirements, adopt the relevant International standards at European level or endorse standardisation documents that are not adoptable. At the same time existing conflicting European standards (if any) must be repealed.

c) ESOs should issue a report covering the areas a) and b). The report may serve as a basis for further mandates. The report may serve also to reinforce the EU's contribution to the dialogue with third countries.

The standards organizations were also called upon to present a list of all international standards identified by them and their justification for certain standards not being adopted/supported.

Within CEN, the mandate was dealt with by the CEN Technical Board (BT). BT in turn assigned the tasks, with the exception of the quality assurance and environmental standards, to the responsible Technical Committee 1, "Criteria for conformity assessment bodies" (TC 1), jointly created by CEN and CENELEC[30]. This committee, the current chair of which is German, thus acquires a key role. Its tasks are:[31]

1 Proactively to coordinate the participation of member bodies in the activities of ISO CASCO. This includes common views and common proposals to ISO/CASCO;

[29] Standardization mandate issued to CEN, CENELEC and ETSI on the use of harmonized standards in support of the New Legislative Framework and sectoral certification systems, M/417 EN, Brussels, 4 December 2007
[30] Cf. document CEN/CENELEC TC 1 N 379, 25 April 2008
[31] Cf. CEN/CENELEC document N256, 2001

Common views can only be expressed on topics that are not related to specific conformity assessment documents (standards etc) as this is the responsibility of the national standardization bodies....

2 **to develop European standards (or other deliverables) where considered necessary** and no equivalent ISO document exists or is foreseen;

3 to **decide on acceptance of ISO conformity assessment documents as European standard**;

Note – CEN/CLC TC1 has its own responsibilities. It therefore must have the possibility to develop its own standards but must also have the possibility not to accept documents developed by ISO/CASCO. So tasks 2 and 3 are both important;

4 to **support the European Commission** by means of standardization; ...

If these general tasks and those of the mandate are compared to the CASCO standards listed in Commission Communication 2009/C 136/08, the question arises regarding the extent to which CEN/CENELEC fulfilled the above tasks, and what was reported by the standards organizations to the European Commission.

The report presented by the standards organizations is not available to the authors of this report. In 2009 however, the European Commission published a list of standards, no longer subdivided[32] (see Fig. 4, below), without it being evident from this list how the presumption of conformity to which these standards give rise is to be understood, and precisely to what this presumption of conformity applies.

The list contains for example basic/generic standards such as ISO 9000 and ISO/IEC 17000 containing definitions and general principles; the terms defined, such as accreditation[33] or notification, are however far less explicit than those described in the legal instruments of the NLF, or are used with different meanings.

[32] European Commission: Commission communication in the framework of the implementation of the Regulation No 765/2008/EC of the European Parliament and of the Council, Decision 768/2008/EC of the European Parliament and of the Council, Regulation No 761/2001/EC of the European Parliament and of the Council (2009/C 136/08), OJ EU C 136/29, 16.6.2009

[33] Accreditation in accordance with EN ISO/IEC 17000 = confirmation (5.2) by a third party that formally states that a conformity assessment body (2.5) possesses the competence to conduct certain conformity assessment tasks, whereas accreditation in accordance with Regulation No 765/2008/EC = confirmation by a national accreditation body that a conformity assessment body satisfies the requirements set out in harmonized standards and where applicable additional requirements, including those of relevant sectoral accreditation systems, for the performance of a particular conformity assessment task

Commission communication in the framework of the implementation of the Regulation (EC) No 765/2008 of the European Parliament and of the Council, Decision 768/2008/EC of the European Parliament and of the Council, Regulation (EC) No 761/2001 of the European Parliament and of the Council

(Publication of titles and references of harmonised standards)

(2009/C 136/08)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 9000:2005 Quality management systems — Fundamentals and vocabulary (ISO 9000:2005)	—	
CEN	EN ISO 9001:2008 Quality management systems — Requirements (ISO 9001:2008)	—	
CEN	EN ISO 14001:2004 Environmental management systems — Requirements with guidance for use (ISO 14001:2004)	—	
CEN	EN ISO 14020:2001 Environmental labels and declarations — General principles (ISO 14020:2000)	—	
CEN	EN ISO 14021:2001 Environmental labels and declarations — Self-declared environmental claims (Type II environmental labelling) (ISO 14021:1999)	—	
CEN	EN ISO 14024:2000 Environmental labels and declarations — Type I environmental labelling — Principles and procedures (ISO 14024:1999)	—	
CEN	EN ISO 14031:1999 Environmental management — Environmental performance evaluation — Guidelines (ISO 14031:1999)	—	
CEN	EN ISO 14040:2006 Environmental management — Life cycle assessment — Principles and framework (ISO 14040:2006)	—	
CEN	EN ISO 14044:2006 Environmental management — Life cycle assessment — Requirements and guidelines (ISO 14044:2006)	—	
CEN	EN ISO/IEC 17000:2004 Conformity assessment — Vocabulary and general principles (ISO/IEC 17000:2004)	—	
CEN	EN ISO/IEC 17011:2004 Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2004)	—	
CEN	EN ISO/IEC 17020:2004 General criteria for the operation of various types of bodies performing inspection (ISO/IEC 17020:1998)	—	
CEN	EN ISO/IEC 17021:2006 Conformity assessment — Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2006)	—	
CEN	EN ISO/IEC 17024:2003 Conformity assessment — General requirements for bodies operating certification of persons (ISO/IEC 17024:2003)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005) EN ISO/IEC 17025:2005/AC:2006	—	
CEN	EN ISO/IEC 17040:2005 Conformity assessment — General requirements for peer assessment of conformity assessment bodies and accreditation bodies (ISO/IEC 17040:2005)	—	
CEN	EN ISO/IEC 17050-1:2004 Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements (ISO/IEC 17050-1:2004)	—	
CEN	EN ISO/IEC 17050-2:2004 Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation (ISO/IEC 17050-2:2004)	—	
CEN	EN ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing (ISO 19011:2002)	—	
CEN	EN 45011:1998 General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)	—	

(1) ESO: European Standardisation Organisation:
— CEN: Avenue Marnix 17, B-1000 Brussels, Tel. +32 25500811; Fax +32 25500819 (http://www.cen.eu)
— CENELEC: Avenue Marnix 17, B-1000 Brussels, Tel. +32 25196871; Fax +32 25196919 (http://www.cenelec.org)
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, Tel. +33 492944200; Fax +33 493654716 (http://www.etsi.org).

Note 1 Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European Standardisation Organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 2 The new (or amended) standard has the same scope as the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Note 3 In case of amendments, the referenced standard is EN CCCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCCC:YYYY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to the Directive 98/34/EC (1) of the European Parliament and Council amended by the Directive 98/48/EC (2).

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the Community languages.

— This list replaces all the previous lists published in the *Official Journal of the European Union*. The Commission ensures the updating of this list.

More information about harmonised standards on the Internet at:
http://ec.europa.eu/enterprise/newapproach/standardization/harmstds

(1) OJ L 204, 21.7.1998, p. 37.
(2) OJ L 217, 5.8.1998, p. 18.

Fig. 4: List of standards published by the European Commission

From an internal communication between TC 1 and CEN BT[34], it can be inferred that TC 1 was not given sufficient time for the task. According to the Commission communication, the standards of the EN ISO/IEC 17000 series listed in it "should be considered for possible inclusion in the mandate". The comment "Reference document" was assigned to the basic/generic standard EN ISO/IEC 17000. Other information or constraints were not stated.

At a session of TC 1 in November 2008, it was reported[35] that the list sent to CEN BT had been accepted and forwarded to the European Commission. It was also established at the session that CEN/CENELEC TC 1 had no direct influence upon the content of CASCO standards, since they are subject to the normal CASCO process for standardization and amendments. However, the intention was expressed to create "task forces" where necessary in order to co-ordinate European influence and to examine standards in consideration of European interests. Results of these activities are not yet available.

If the reported list of standards is considered in the light of the results of KAN Report 30 and a response received from CASCO WG 21 to a generic comment submitted by Germany during the development of ISO/IEC 17021, it is difficult to understand the inherent caution of these activities, since during development of ISO/IEC 17021, DIN had already set out clearly that the requirements described fell short in some cases of those necessary for a presumption of conformity with regard to notified bodies, to which CASCO WG 21 had responded tersely with "Noted. This standard is not intended to satisfy the criteria for Regulatory Bodies"[36].

[34] Cf. CEN/CENELEC TC 1 document N 387
[35] Cf. CEN/CENELEC TC 1 document N 395
[36] Cf. CASCO document WG 21/054

4 Current approach: Decision 768/2008/EC

4.1 Decision 768/2008/EC

4.1.1 Status of Decision 768/2008/EC

This decision replaces Decision 93/465/EEC (see Article 8 of Decision 768/2008/EC). The legal status of the new decision as a common instrument of the European Parliament and of the Council remains unchanged; it thus contains no provisions which require a different status. The decision is a legal instrument sui generis. It binds the organs of the EU, i.e. including the Community legislature, in the area of the "New Approach directives". The decision states the conditions under which the future Community legislature must create New Approach directives. The decision has been published in the Official Journal of the European Union, and thus has direct legal effect upon the Member States[37] (former Article 249 (4) of the EC Treaty, Article 288 (4) of the TFEU): where the Community legislature makes reference in future to the decision, the content of the decision also becomes directly binding upon the Member States. Should a newly issued directive not adopt the content of the decision, a Member State could, invoking the published decision, refuse to observe the directive owing to the violation of EU law.

The obligations upon the Member States arising from the decision include recognition of the test result of a conformity assessment body where the presumption of conformity described in Decision 768/2008/EC Annex I Article R18 takes effect for the body concerned in the manner described above (cf. also Article 11 (2) of Regulation 765/2008/EC).

The Community legislature enacting New Approach directives is bound by the decision in that the legislature is now subject to a binding framework with regard to the development of "Community harmonisation legislation" (Article 2 of Decision 768/2008/EC).

Owing to an (explicit) reference in Decision 768/2008/EC itself (in Article 2), the Annex of the decision forms part of the decision and is thus binding in the same way as the body of the decision.

The recitals preceding the decision have a binding effect, at least upon the organs of the European Union. One purpose of recitals is to explain the purpose of the standard, and – in conjunction with this – to assist in interpretation,

[37] Refer in this context to the explanations in KAN Report 30, p. 59.

including that of the individual provisions of the decision. The recitals thus also have the character of administrative regulations binding upon the organs to which the decision is addressed. The European Commission is thus bound by the guiding principles of the decision. Recital 40 is of particular importance in this context. This recital states with regard to the presumption of conformity for conformity assessment bodies that where conformity exists with the standards, the relevant sectoral legal provisions **should** be presumed satisfied. The presumption can in principle therefore be **challenged**, although this is possible, in consideration of the overall concept, **only for reasoned exceptions**.

4.1.2 Scope of Decision 768/2008/EC including its annexes: particular aspects compared to the Modules Decision which it replaces, particularly regarding the presumption of conformity

The presumption of conformity due to Decision 93/465/EEC has been withdrawn. In 93/465/EEC, conformity with the sectoral mandated standards was sufficient to give rise to the presumption of conformity, without review of the standards' content. This was justified, since the standards had to have been mandated by the Commission, and their compliance with the requirements of the relevant directives was therefore probable.

The new decision constitutes a sea change. Compliance with the directive is no longer assumed merely because the criteria of the mandated standards are satisfied. Instead, the decision (Annex I, Article R18 in conjunction with Article R17) permits a presumption of conformity only if the standards satisfy the minimum criteria of Article R17 (Annex I of Decision 768/2008/EC). In other words: by reformulating these minimum requirements positively, Article R17 supports at the same time the rebuttal of the presumption of conformity. Irrespective of whether a conformity assessment body satisfies the provisions of a standard which concern it, the presumption of conformity does not apply if the criteria of Article R17 are not satisfied.

Recital 40 of Decision 768/2008/EC is also of (additional) relevance for rebuttal of the presumption of conformity. This recital stipulates that the presumption of conformity does not necessarily apply when the standards are satisfied, but only that it should apply by default.

Decision 768/2008/EC thus considerably extends the **qualification** of the presumption of conformity.

- Even prior to the new decision, the presumption of conformity was constrained in that it was based upon a reference substantiating a legislative measure. The sectoral directives are substantiated by standards. Where such standards which substantiate legislative

measures are concerned, it is assumed in jurisprudence and court decisions that any presumption of conformity can also be rebutted.[38]

- The new Decision 768/2008/EC additionally creates, through Article R17 in Annex I, a catalogue of requirements the criteria of which must be satisfied for the presumption of conformity, and the recitals of this decision also state that even where these criteria are satisfied (standards and catalogue of Article R17), only that conformity "should" be presumed.

Decision 768/2008/EC, Annex I Article R17 contains a catalogue of criteria which must be met before conformity may be presumed. When set out on this scale, criteria generally raise the question whether a catalogue constitutes a **conclusive** provision, or whether it is open to the interpretation that under certain particular circumstances, further criteria could be set out which must be met before conformity may be presumed.

The catalogue of Article R17 states the individual requirements applicable to the notified body (conformity assessment body) in such detail that the legislature's intention can be assumed to have been that of regulation in full, i.e. of not intending to permit further additions to the catalogue of criteria/requirements.

With regard to the **terms used to describe** the discrete requirements applicable to the notified body, however, the information in Article R17 is not conclusive: the terms used are certainly open to interpretation or could be defined more precisely (in technical terms), provided such interpretations or definitions remained consistent with the catalogue of requirements of Article R17. This can be inferred not least from R17 (8), in which the very relevant criterion of "independence" is included as a concept but not described in any greater detail. This clearly suggests that Article R17 is open to interpretation.

The term "independence" is a (very) imprecise legal term, one requiring suitable interpretation according to the purpose of standardization. Its interpretation, like that of other undefined legal terms listed in R17, should take account of the fact that the criteria for interpretation must not be taken from the standards, precisely because these are to be examined against the criteria of the decision.[39]

It must therefore also be pointed out that the catalogue of Article R17 is inconsistent in essential areas with the paradigm shift in the conformity assessment procedure made by the Council and the Parliament with Decision 768/2008/EC and Regulation 765/2008/EC. Under Decision 93/465/EEC, now withdrawn, the conformity assessment procedure was still linked very closely to the principle of subsidiarity; the conducting of accreditation in particular was a

[38] Refer in this context to the explanations in KAN Report 30, p. 59.
[39] For interpretation, refer to the more detailed description of the Common Elements in KAN Report 30; see also Section 4.3.1 of the present study below.

matter for the Member States alone. The sole requirement was that (in the area subject to regulation) an accreditation procedure be followed in which the country in question would at least have the final responsibility. Accreditation is now governed more comprehensively by the regulation under discussion. The objective here is for the system to become both more transparent and more trustworthy. It would however then also have been logical for the criteria for the presumption of conformity to have been presented more comprehensively/substantively in Article R17.

As the present study will show, considerable room exists for differences in interpretation at Member-state level. It is then also possible that provisions, possibly comprehensive, governing impartiality formulated in a standard in the ISO 17000 ff. series will not be referred to extensively for the presumption of conformity because the requirements of Decision 768/2008/EC Annex I Article R17 could be interpreted by some to be more modest. The opposite situation may however also arise, i.e. that according to another interpretation, the requirements of the standard are insufficient.

It would therefore have been logical to define the criteria relevant to the presumption of conformity more comprehensively during harmonization of the conformity assessment procedure. The description of the Common Elements in KAN Report 30 would be very helpful in this respect (see Section 2.3 above and Section 4.3.1 below).

4.1.3 Entry into force of Decision 768/2008/EC

Article 8 of Decision 768/2008/EC specifies that the preceding Decision 93/465/EEC be repealed. It further states: "References to the Decision repealed shall be construed as references to this Decision."

With its publication in the Official Journal, the decision has thus come into force. It could now be argued that all legally significant measures taken with respect to the preceding decision, now repealed, should now be reviewed again against the new decision. An interpretation based upon the wording of the decision would justify this view.

Although a case could be made for this legal view, it is unlikely to be adopted. Decision 768/2008/EC, like the repealed Decision 93/465/EC, can also be interpreted as having an essential scope of regulation applying to the future, i.e. to future directives (see Article 2 of Decision 768/2008/EC).

In this respect, however, problems exist with transition, particularly with regard to the requirements concerning conformity assessment bodies. Where conformity assessment bodies do not yet satisfy the requirements of Article R17 but have

nevertheless been notified in the past, it will not be possible simply to deny these bodies, with regard to the aspect stated above, the right to continue to conduct conformity assessments on the basis of the former decision. **In the authors' view, the Commission ought to adopt a policy on how conformity assessment bodies that do not (yet) satisfy the catalogue of requirements of Article R17 should be dealt with during a transitional period.**

4.2 The starting-point of the comparative study: Article R17 of Decision 768/2008/EC

The starting-point of the comparative studies below (see Section 4.3) is Article **R17 of Decision 768/2008/EC**[40]. Its text is as follows:

Requirements relating to notified bodies

> 1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
>
> 2. A conformity assessment body shall be established under national law and have legal personality.
>
> 3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.
>
> 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, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.
>
> 4. A conformity assessment 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 such products for personal purposes.
>
> A conformity assessment 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, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or

[40] OJ EC L 218/82, 13.08.08.

integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment 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 shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by … [reference to relevant part of the legislation] and in relation to 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.

At all times and for each conformity assessment procedure and 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:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It 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.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Community harmonisation legislation and of its implementing regulations;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment 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.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under … [reference to the relevant part of the legislation] or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are 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.

4.3 Focus: minimum criteria / requirements concerning notified bodies – comparative study

The comparative studies that now follow will examine several aspects relating to Decision 768/2008/EC Annex I Article R17 which are relevant to the presumption of conformity and are necessary in order to answer the questions defined in the task of the study, namely:

- Has Decision 768/2008/EC adopted the "Common Elements" proposed in KAN Report 30? → see 4.3.1
- Has Decision 768/2008/EC adopted the recommendations of the ISO/CASCO Publicly Available Specifications/do the requirements described in these documents satisfy those of Article R17? → see 4.3.2

- Do the mandated standards EN ISO/IEC 17000 ff. contain the "requirements relating to notified bodies" stated in Decision 768/2008/EC? → see 4.3.3
- Have the standards published by the Commission (EN ISO 17000 series) adopted the "Common Elements" proposed in KAN Report 30? → see 4.3.4

4.3.1 Comparison of Article R17 with the "Common Elements" of KAN Report 30

In the course of the study, the "Common Elements" from KAN Report 30 (see pp. 112-126 of the report) were compared with the requirements formulated in Decision 768/2008/EC Annex I Articles R17 and R20, in order to determine the extent to which the European legislature had followed the recommendations of KAN Report 30 with regard to the requirements relating to conformity assessment bodies.

Detailed examination revealed the following picture. The requirements formulated in KAN Report 30 are compiled on the left-hand side of the table, their equivalents (though not always with the same wording) in Decision 768/2008/EC on the right-hand side.

Table 1: Comparison of Article R17 with the "Common Elements" of KAN Report 30

KAN Report 30		**Decision 768/2008**	
No.	Content	Article	Content
	Structure/Organization		
1	The conformity assessment body must be a registered legal person or a part of a registered legal person.	R 17 para. 2	The conformity assessment body shall have legal personality.
2.1	Structure and *modus operandi* of a conformity assessment body shall be such that confidence in their conformity assessment activities is assured.		
2.2	The conformity assessment body shall be responsible for its activities and Decisions (issue to withdrawal).	R 17 para. 6	The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it.
2.3	The conformity assessment body shall possess a description of its legal status.		
2.4	The conformity assessment body shall document the responsibilities and authority.		

KAN Report 30		Decision 768/2008	
2.4	The conformity assessment body shall document the performance and results of the conformity assessment activities.		
2.5	The conformity assessment body shall appoint the top level management (group(s) or person(s)) who shall possess complete authority and bear complete responsibility.		
2.6	The conformity assessment body shall document its organizational structure.		
3.1	The conformity assessment body shall be organized and operated in such a manner as to ensure independence, objectivity and impartiality in its activities.	R 17 para.3	A conformity assessment body shall be an independent third-party body.
3.1	The conformity assessment body shall introduce and maintain a documented structure for assurance of its impartiality.	R 17 para. 8	The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.
3.2	The arrangements and procedures of the conformity assessment body shall not be discriminatory.	R 17 para. 6 b	The conformity assessment body shall ensure the transparency and the ability of reproduction of its procedures.
3.3	The conformity assessment body shall not be subject to any influence, in particular of a financial nature, upon their evaluation and the results of their conformity assessments.	R 17 para. 5	The conformity assessment body shall be free from all pressures and inducements, particularly financial.
3.4	The conformity assessment body shall ensure that each conformity assessment decision is taken by competent persons who shall not be identical to the parties performing the conformity assessment activities concerned.		
3.5	The conformity assessment body shall not offer or provide any activities or supplementary services which call into question its competence, objectivity, impartiality or independence.	R 17 para. 4	The conformity assessment body shall not engage in any activity that may conflict with its independence of judgement or integrity.
3.6	The conformity assessment body and its staff shall not be identical to the designer, manufacturer, etc. of the products assessed.	R 17 para. 4	The conformity assessment body, its top level management and personnel shall not be the designer, manufacturer, etc. of the products which they assess.

KAN Report 30		Decision 768/2008	
3.7	The conformity assessment body shall not have offered or have performed consultancy concerning the design, manufacture, etc. of the products concerned.	R 17 para. 3	The conformity assessment body shall be independent of the organisation or the product it assesses.
3.8	The conformity assessment body and its personnel shall not bear any responsibility for market surveillance.		
3.9	The conformity assessment body shall ensure that associated bodies (see Section 3.10) do not jeopardize the confidentiality, objectivity and impartiality.	R 17 para. 4	Subsidiaries/subcontractors shall not affect the confidentiality, objectivity or impartiality of the conformity assessment.
3.11	The conformity assessment body shall establish, investigate and document any conflicts of interest.	R 17 para. 6 b	The conformity assessment body shall have appropriate policies and procedures in place that distinguish between conformity assessment tasks and other activities.
4.1	The conformity assessment body shall take suitable precautions to ensure the confidentiality of the information which comes into its possession.	R 17 para. 10	The personnel shall observe professional secrecy with regard to all information obtained, except in relation to the competent authorities of the Member State.
4.2	The conformity assessment body shall take suitable precautions to ensure the confidentiality of the information which comes into its possession – professional secrecy of the personnel employed.		
4.3	The conformity assessment body shall take suitable precautions to ensure that confidential information is not communicated to other parties.		
5	The conformity assessment body shall have taken precautions to enable it to cover claims for liabilities (take out liability insurance).	R 17 para. 9	Conformity assessment bodies shall take out liability insurance.
6	The conformity assessment body shall have at its disposal the financial resources required to conduct its business operations and shall provide evidence of said resources.		
7	The conformity assessment body shall participate in national and international co-ordination activities.	R 17 para. 11	Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities.

KAN Report 30		Decision 768/2008	
	Resources / Personnel		
1.1	The conformity assessment body shall operate with the highest degree of professional integrity and the greatest technical expertise.		
1.1	The conformity assessment body shall have at its disposal its own personnel for proper performance of the technical, scientific and administrative tasks.	R 17 para. 6 a und 7 a	At all times, the conformity assessment body shall have at its disposal the necessary personnel with technical knowledge and experience.
1.2	The personnel charged with conducting conformity assessment activities shall possess adequate knowledge and be suitably qualified.	R 17 para. 7 b	The personnel of the conformity assessment body shall have satisfactory knowledge of the requirements of the assessments they carry out.
1.3	The personnel shall be impartial, independent and objective.		
1.4	The conformity assessment body shall be transparent for the parties concerned.		
1.5	The conformity assessment body shall require all personnel to undertake formally to observe the rules, particularly concerning confidentiality and independence.	R 17 para. 7 c	The personnel shall have appropriate knowledge and understanding of the requirements of the applicable standards.
1.6	The conformity assessment body shall establish procedures for the selection and training of the persons employed.		
2.1	The conformity assessment body shall monitor and assure the performance and competence of the personnel involved.		
2.2	The conformity assessment body shall evaluate the performance of each person employed on a regular basis (at least every three years).		
3	The conformity assessment body shall maintain records of the relevant qualifications, training, etc. of each person employed.		
	Resources / Facilities		
1	The conformity assessment body shall possess or have access to suitable premises and facilities.	R 17 para. 6 c	The conformity assessment body shall have the means necessary to perform its tasks; it shall have at its disposal procedures for the performance of its conformity assessment activities.

KAN Report 30		Decision 768/2008	
2	The conformity assessment body shall ensure that the test principles and other documents required are completely up-to-date.		
3	The conformity assessment body shall possess suitable premises in order to be able to ensure the secure storage of documents and records		
4	The conformity assessment body must ensure the serviceability and accuracy of test equipment.		
		R 17 para. 7 d	The personnel shall have the ability to draw up certificates, records and reports.
	Process		
1	The conformity assessment body shall make contractual arrangements with the customer.		
2.1	The conformity assessment body may transfer certain activities to subcontractors.	R 20 para. 1	The conformity assessment body may have recourse to subcontractors.
2.2	The conformity assessment body shall ensure that the subcontracted activities are performed in accordance with detailed documented procedures.	R 20 para. 1	The conformity assessment shall ensure that the subcontractor meets the requirements set out in Article R 17.
2.3	The conformity assessment body shall describe the conditions under which the activities are subcontracted.	R 20 para. 2	The conformity assessment body shall take full responsibility for the subcontractor.
2.4	A proper contractual agreement under private law shall be in place between the conformity assessment body and its subcontractors.	R 20 para. 3	Activities may be subcontracted only with the agreement of the client.
2.5	The conformity assessment body shall ensure that the subcontracted body and its personnel are competent.		
2.6	The conformity assessment body shall maintain a list of its subcontractors and record the results of monitoring of their competence.	R 20 para. 4	The conformity assessment bodies shall keep the relevant documents concerning the assessment of the qualifications of the subcontractor.
2.7	Subcontractors may be assumed to be competent when they are accredited.		
3.1	The conformity assessment body may consider test reports presented by the manufacturer.		
3.2	The conformity assessment body must satisfy itself that the test reports have been issued by conformity assessment bodies which are competent.		

KAN Report 30		Decision 768/2008	
3.3	The conformity assessment body shall assume full responsibility for the test results employed.		
4.1	The conformity assessment shall ensure that the information and documents required for the decision are available in full.		
4.2	The conformity assessment body shall decide whether the requirements of the laws and regulations are met.		
4.3	The conformity assessment body shall issue the requisite conformity assessment certificates and dispatch them to the customer.		
4.4	The conformity assessment certificates must satisfy the provisions set forth in the laws and regulations.		
5	The conformity assessment body shall maintain records of the decision process and hold the records in safe keeping.		
6	The conformity assessment body shall have arrangements in place for the protection of the identification number with which it has been issued and ensure that the number is not abused.		
7.1	The conformity assessment body shall maintain all relevant information at its customers' disposal (e.g. requirements to be met, fees/prices, etc.).		
7.2	The conformity assessment body shall inform the competent authority immediately of changes concerning its legal form or organization, any incidents, etc.		
7.3	The conformity assessment body shall upon request provide public access to the status of the conformity assessment certificates.		
	Management systems		
1	The conformity assessment body shall maintain a (quality) assessment system.		
2	The conformity assessment body shall lay down procedures for the control of all documents.		
3	The conformity assessment body shall have procedures for controlling the storage of records.	R 17 para. 6 b	The conformity assessment body shall have descriptions of procedures in accordance with which conformity assessment is carried out.
4	The conformity assessment body shall establish a procedure for the handling of complaints.		

KAN Report 30		Decision 768/2008	
5	The conformity assessment body shall establish procedures for the identification and control (e.g. corrective measures) of nonconformances.		
6	The conformity assessment body shall establish procedures and measures by which nonconformities may be identified and preventive measures taken.		
7	The conformity assessment body shall audit its activities. Audits must be performed at least annually and by personnel possessing sound expertise.		
8	Top-level management of the conformity assessment body shall establish procedures for regular assessment of its management, assessing current performance and the possibilities for improvement.		
		R 17 para. 8	The remuneration of the top level management shall not depend on the number of assessments carried out.

Overall, **the process- and management-oriented requirements** in particular **are seen to be largely absent** from Article R17 of the decision. Aspects in the area of organization with regard to internal responsibilities, to internal decisions regarding the selection of personnel and their training, and to document control also remain vague. Since, however, these requirements are all crucial to confidence in the work of the conformity assessment bodies and according to present knowledge must be regarded as indispensable, Article R17 falls considerably short of the recommendations made in KAN Report 30.

4.3.2 Comparison with the ISO/CASCO Publicly Available Specifications (ISO/PAS)

A similar comparison was performed to examine the extent to which Decision 768/2008/EC had adopted the requirements formulated in the ISO/PAS, i.e. to what extent these requirements corresponded to those in Article R17 of Decision 768/2008/EC. The detailed comparison between the requirements can be found in Annex 2. The observations can be summarized as follows:

The comparison of the requirements in the ISO/PAS with those defined in Article R17 reveals very little congruence between these two catalogues of criteria. Although similar regulatory content is addressed, there is little correspondence either in terms of the level of detail, or with regard to the structure of the requirements.

As already discussed in Section 2.4, this is due in part to the requirements formulated in the ISO/PAS falling short, in some cases considerably, of the needs of the area subject to statutory regulation, for example in the area of independence; at the same time, Article R17 falls short of what are now considered normal requirements, or the "state of the art". This is particularly the case, as already discussed in Section 4.3.1, with regard to requirements relating to management systems. In this area, Article R17 contains only vague formulations, such as: "At all times (...) a conformity assessment body shall have at its disposal the necessary: (...) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures." Explicit requirements, such as those referred to at least by key terms in ISO/PAS 17005 – and set out in detail as Common Elements in KAN Report 30 – are not contained in Article R17.

4.3.3 Comparison with EN ISO/IEC 17000 ff.

The study likewise examined the extent to which requirements formulated in Article R17 of Decision 768/2008/EC are evident or addressed in the mandated standards listed by the European Commission (see Fig. 4 above), the EN ISO/IEC 17000 ff. series.

4.3.3.1 Overview (table) and detailed discussion

The results of this study are presented in the first instance in table form (Table 2), and – where necessary – supplemented by further comments (see below).

If the overview shown in the table is considered in the first instance in an abstract manner and completely neutrally, it can be seen that only two of the standards listed by the European Commission consider the full catalogue of Article R17: EN ISO/IEC 17011:2005 and 17020:2004, of which in fact only the latter relates to conformity assessment bodies.[41] Accordingly, EN ISO/IEC 17020:2004 is the only standard among those examined to adopt the catalogue of Article R17 in full. Even this standard, however, does not satisfactorily support the requirements deriving from Article R17 (as will be shown below).

Detailed analysis:

Excerpts are presented below of the paragraphs in the standards in the EN ISO/IEC 17000 ff. series which correspond to the requirements deriving from Article R17 of Decision 768/2008/EC. The standard is first stated, followed by the

[41] This section does not compare the contents of the requirements stipulated in R17 with the provisions within the respective standards; this comparison is not made until Section 4.3.4.

relevant paragraph(s) of Article R17, and then in turn by the passages in the standards relating to these paragraphs of Article R17.

Table 2: Comparison with the standards EN ISO/IEC 17000 ff.

Standard: EN ISO / IEC			17011: 2005	17020: 2004	17021: 2006	17024: 2003	17025: 2005	17040: 2005	EN 45011: 1998	17065 CD 2
Requirements relating to certification bodies Decision 768/2008/EC, Annex I – Article: R17 (1) – (11)	Paragraph 1: satisfies **all** of the following requirements		**+**	**+**	**-**	**-**	**-**	**-**	**-**	**-**
	Paragraph 2: legal compliance, legal personality		4.1 4.2.3	3.1	5.1	4.1.1 4.2.1 d)	-	-	4.2 d), g)	4.1
	Paragraphs 3, 4, 5, 8: independence, impartiality		4.3	4	4.2 5.2 6.2	4.1.1 4.2.2 4.2.4 c)	4.1.5 b) 4.1.5 d)	7.5.6	4.2 a), e), l), m), n), o)	4.2 4.3.3 5.1.1 5.2 6.1.3 b), c) 9.6.4 b) A.2
	Paragraph 5: technical skill		4.2.6 7.5.2	8	4.3 7.1.1	4.2.7	4.1.5 5.2	-	4.2 j) 4.4 b)	6.1.1.2 6.1.2 9.6.1 9.6.4 a) A.3
	Resources	Paragraphs 6 a), 7: personnel (quantitative/ qualitative)	6	8.1 ff.	7.1 7.2 4.3	4.2.7 5.2	4.1.5 a) 4.1.5 d) 5.2	4.4 5 7.5	4.2 j) 5	6.1.1 8.5.1 8.6.2
		Paragraphs 6 b), c): procedures/processes	7.1.1	10	7.2.5 9.1	4.3.1 4.3.2 4.3.6	4.6	Annex B	4.6.2, 4.8 4.9	6.2.1 7.2 8
		Paragraph 6: technical resources	4.5.2	9	5.3.2	4.2.4 a)	4.1.5 b) 5.3 5.5	Annex A	4.2 i)	4.3.3
	Paragraph 9: liability		4.5.1	3.4	5.3	-	4.1.1	-	4.2 h)	4.3.2 8.6.1
	Paragraph 10: confidentiality, secrecy		4.4	5	4.6 8.5	4.7 4.8	4.1.5 c)	8	4.9.1 4.10 5.2.2 a)	6.1.3 a) 7.5 8.11.2 A.4
	Paragraph 11: participation in co-ordination activities		4.6.2	16	-	-	-	-	-	-

DIN EN ISO/IEC 17020:2004

General criteria for the operation of various types of bodies performing inspection (ISO/IEC 17020:1998)

R17 (2): legal compliance, legal personality

3.1 The inspection body, or the organization of which it forms a part, shall be legally identifiable.

R17 (3), (4), (5), (8): independence, impartiality

4 Independence, impartiality and integrity

4.1 General
The personnel of the inspection body shall be free from any commercial, financial and other pressures which might affect their judgement. Procedures shall be implemented to ensure that persons or organizations external to the inspection body cannot influence the results of inspections carried out.

4.2 Independence
The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions it shall meet the minimum criteria stipulated in one of the normative annexes A, B or C.

4.2.1 Type A inspection body
The inspection body providing “third Party” services shall meet the criteria of annex A (normative).

4.2.2 Type B inspection body
The inspection body which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and has been established to supply inspection services to its parent organization shall meet the criteria of annex B (normative).

4.2.3 Type C inspection body
The inspection body which is involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects or of similar competitive items and may supply inspection services to other Parties not being its parent organization shall meet the criteria of annex C (normative).

R17 (5): technical skill

8 Personnel

8.1 The inspection body shall have a sufficient number of permanent personnel with the range of expertise to carry out its normal functions.

8.2 The staff responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be

carried out. They shall have the ability to make professional judgements as to conformity with general requirements using examination results and to report there on. They shall also have relevant knowledge of the technology used for the manufacturing of the products inspected, of the way in which products or processes submitted to their inspections are used or are intended to be used, and of the defects which may occur during use or in service. They shall understand the significance of deviations found with regard to the normal use of the products or processes concerned.

8.3 The inspection body shall establish a documented training system to ensure that the training of its personnel, in the technical and administrative aspects of the work in which they will be involved, is kept up-to date in accordance with its policy. The training required shall depend upon the ability, qualifications and experience of persons involved. The inspection body shall establish the necessary stages of training for each of its personnel. These may include:
a) an induction period;
b) a supervised working period with experienced inspectors;
c) continuation training, throughout employment, to keep pace with developing technology.

8.4 Records of academic or other qualifications, training and experience of each member of its personnel shall be maintained by the inspection body.

8.5 The inspection body shall provide guidance for the conduct of its staff.

8.6 The remuneration of persons engaged in inspection activities shall not directly depend on the number of inspections carried out and in no case on the results of such inspections.

R17 (6) a), (7): resources – personnel (quantitative / qualitative)

see above, R 17 (5), 8.1 ff.

R17 (6) b), c): resources – procedures / processes

10 Inspection methods and procedures

10.1 The inspection body shall use the methods and procedures for inspection which are defined in the requirements, against which conformity is to be determined.

10.2 The inspection body shall have and use adequate documented instructions on inspection planning and on standard sampling and inspection techniques, where the absence of such instructions could jeopardize the efficiency of the inspection process. Where applicable, this requires sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing and Interpretation of results.

10.3 When the inspection body has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented.

10.4 All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the inspection body shall be maintained up-to-date and be readily available to the staff.

R17 (6): resources – equipment

9 Facilities and equipment

9.1 The inspection body shall have available to it suitable and adequate facilities and equipment to permit all activities associated with the inspection services to be carried out.

9.2 The inspection body shall have clear rules for the access to and the use of specified facilities and equipment.

9.3 The inspection body shall ensure the continued suitability of the facilities and the equipment mentioned in 9.1 for their intended use.

9.4 All such equipment shall be properly identified.

9.5 The inspection body shall ensure that all such equipment is properly maintained, in accordance with documented procedures and instructions.

9.6 The inspection body shall ensure that, where appropriate, equipment is calibrated before being put into service and thereafter according to an established programme.

9.7 The Overall programme of calibration of equipment shall be designed and operated so as to ensure that wherever applicable measurements made by the inspection body are traceable to national and International Standards of measurement where available. Where traceability to national or International Standards of measurement is not applicable, the inspection body shall provide satisfactory evidence of correlation or accuracy of inspection results.

9.8 Reference standards of measurement held by the inspection body shall be used for calibration only and for no other purpose. Reference standards of measurement shall be calibrated by a competent body that can provide traceability to a national or International Standard of measurement.

9.9 Where relevant, equipment shall be subjected to in-service checks between regular recalibrations.

9.10 Reference materials shall where possible be traceable to national or International Standard reference materials.

R17 (9): liability

3.4 The inspection body shall have adequate liability insurance unless its liability is assumed by the State in accordance with national laws or by the organization of which it forms a part.

R17 (10): confidentiality, secrecy

5 Confidentiality
The inspection body shall ensure confidentiality of information obtained in the course of its inspection activities. Proprietary rights shall be protected.

R17 (11): participation in co-ordination activities

16 Cooperation
The inspection body is expected to participate in an exchange of experience with other inspection bodies and in the standardization processes as appropriate.

DIN EN ISO/IEC 17021:2006

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

R17 (2): legal compliance, legal personality

5.1 Legal and contractual matters

5.1.1 The certification 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 certification activities. A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

5.1.2 The certification body shall have a legally enforceable agreement for the provision of certification activities to its client. In addition, where there are multiple offices of a certification body or multiple sites of a client, the certification body shall ensure there is a legally enforceable agreement between the certification body granting certification and issuing a certificate, and all the sites covered by the scope of the certification.

5.1.3 The certification body shall be responsible for, and shall retain authority for, its decisions relating to certification, including the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification.

4.2 Impartiality

4.2.1 Being impartial, and being perceived to be impartial, is necessary for a certification body to deliver certification that provides confidence.

4.2.2 It is recognized that the source of revenue for a certification body is its client paying for certification, and that this is a potential threat to impartiality.

4.2.3 To obtain and maintain confidence, it is essential that a certification body's decisions be based on objective evidence of conformity (or nonconformity) obtained by the certification body, and that its decisions are not influenced by other interests or by other parties.

4.2.4 Threats to impartiality include the following.
a) Self-interest threats: threats that arise from a person or body acting in their own interest. A concern related to certification, as a threat to impartiality, is financial self-interest.
b) Self-review threats: threats that arise from a person or body reviewing the work done by themselves. Auditing the management systems of a client to whom the certification body provided management systems consultancy would be a self-review threat.

c) Familiarity (or trust) threats: threats that arise from a person or body being too familiar with or trusting of another person instead of seeking audit evidence.
d) Intimidation threats: threats that arise from a person or body having a perception of being coerced openly or secretively, such as a threat to be replaced or reported to a supervisor.

5.2 Management of impartiality

5.2.1 The certification body shall have top management commitment to impartiality in management system certification activities. The certification body shall have a publicly accessible statement that it understands the importance of impartiality in carrying out its management system certification activities, manages conflict of interest and ensures the objectivity of its management system certification activities.

5.2.2 The certification body shall identify, analyse and document the possibilities for conflict of interests arising from provision of certification including any conflicts arising from its relationships. Having relationships does not necessarily present a certification body with a conflict of interest. However, if any relationship creates a threat to impartiality, the certification body shall document and be able to demonstrate how it eliminates or minimizes such threats. This information shall be made available to the committee specified in 6.2. The demonstration shall cover all potential sources of conflict of interests that are identified, whether they arise from within the certification body or from the activities of other persons, bodies or organizations.

5.2.3 When a relationship poses an unacceptable threat to impartiality (such as a wholly owned subsidiary of the certification body requesting certification from its parent), then certification shall not be provided.

5.2.4 A certification body shall not certify another certification body for its management system certification activities.

5.2.5 The certification body and any part of the same legal entity shall not offer or provide management system consultancy. This also applies to that part of government identified as the certification body.

5.2.6 The certification body and any part of the same legal entity shall not offer or provide internal audits to its certified clients. The certification body shall not certify a management system on which it provided internal audits within two years following the end of the internal audits. This also applies to that part of government identified as the certification body.

5.2.7 The certification body shall not certify a management system on which a client has received management system consultancy or internal audits, where the relationship between the consultancy organization and the certification body poses an unacceptable threat to the impartiality of the certification body.

6.2.1 The structure of the certification body shall safeguard the impartiality of the activities of the certification body and shall provide for a committee
a) to assist in developing the policies relating to impartiality of its certification activities,
b) to counteract any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent objective provision of certification activities,

c) to advise on matters affecting confidence in certification, including openness and public perception, and
d) to conduct a review, as least once annually, of the impartiality of the audit, certification and decision-making processes of the certification body.

Other tasks or duties may be assigned to the committee provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

6.2.2 The composition, terms of reference, duties, authorities, competence of members and responsibilities of this committee shall be formally documented and authorized by the top management of the certification body to ensure
a) representation of a balance of interests such that no single interest predominates (internal or external personnel of the certification body are considered to be a single interest, and shall not predominate),

b) access to all the information necessary to enable it to fulfil its functions (see also 5.2.2 and 5.3.2), and
c) that if the top management of the certification body does not respect the advice of this committee, the committee shall have the right to take independent action (e.g. informing authorities, accreditation bodies, stakeholders). In taking independent action, committees shall respect the confidentiality requirements of 8.5 relating to the client and certification body.

6.2.3 Although this committee cannot represent every interest, a certification body should identify and invite key interests. Such interests may include: clients of the certification body, customers of organizations whose management systems are certified, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, or representatives of non-governmental organizations, including consumer organizations.

R17 (5): technical skill

4.3 Competence
Competence of the personnel supported by the management system of the certification body is necessary to deliver certification that provides confidence. Competence is the demonstrated ability to apply knowledge and skills.

7.1.1 The certification body shall have processes to ensure that personnel have appropriate knowledge relevant to the types of management systems and geographic areas in which it operates. It shall determine the competence required for each technical area (as relevant for the specific certification scheme), and for each function in the certification activity. It shall determine the means for the demonstration of competence prior to carrying out specific functions.

R17 (6) a), (7): resources – personnel (quantitative/qualitative)

7.1.2 In determining the competence requirements for its personnel performing certification, the certification body shall address the functions undertaken by management and administrative personnel in addition to those directly performing audit and certification activities.

7.1.3 The certification body shall have access to the necessary technical expertise for advice on matters directly relating to certification for technical areas, types of management system and geographic areas in which the certification body operates. Such advice may be provided externally or by certification body personnel.

7.2 Personnel involved in the certification activities

7.2.1 The certification body shall have, as part of its own organization, personnel having sufficient competence for managing the type and range of audit programmes and other certification work performed.

7.2.2 The certification body shall employ, or have access to, a sufficient number of auditors, including audit team leaders, and technical experts to cover all of its activities and to handle the volume of audit work performed.

7.2.3 The certification body shall make clear to each person concerned their duties, responsibilities and authorities.

7.2.4 The certification body shall have defined processes for selecting, training, formally authorizing auditors and for selecting technical experts used in the certification activity. The initial competence evaluation of an auditor shall include a demonstration of applicable personal attributes and the ability to apply required knowledge and skills during audits, as determined by a competent evaluator observing the auditor conducting an audit.

7.2.5 The certification body shall have a process to achieve and demonstrate effective auditing, including the use of auditors and audit team leaders possessing generic auditing skills and knowledge, as well as skills and knowledge appropriate for auditing in specific technical areas. This process shall be defined in documented requirements drawn up in accordance with the relevant guidance provided in ISO 19011.

7.2.6 The certification body shall ensure that auditors (and, where needed, technical experts) are knowledgeable of its audit processes, certification requirements and other relevant requirements. The certification body shall give auditors and technical experts access to an up-to-date set of documented procedures giving audit instructions and all relevant information on the certification activities.

7.2.7 The certification body shall use auditors and technical experts only for those certification activities where they have demonstrated competence.

7.2.8 The certification body shall identify training needs and shall offer or provide access to specific training to ensure its auditors, technical experts and other personnel involved in certification activities are competent for the functions they perform.

7.2.9 The group or individual that takes the decision on granting, maintaining, renewing, extending, reducing, suspending or withdrawing certification shall understand the applicable standard and certification requirements, and shall have demonstrated competence to evaluate the audit processes and related recommendations of the audit team.

7.2.10 The certification body shall ensure the satisfactory performance of all personnel involved in the audit and certification activities. There shall be documented procedures and criteria for monitoring and measurement of the performance of all persons involved, based on the frequency of their usage and the level of risk linked to their activities. In particular,

the certification body shall review the competence of its personnel in the light of their performance in order to identify training needs.

7.2.11 The documented monitoring procedures for auditors shall include a combination of on-site observation, review of audit reports and feedback from clients or from the market and shall be defined in documented requirements drawn up in accordance with the relevant guidance provided in ISO 19011. This monitoring shall be designed in such a way as to minimize disturbance to the normal processes of certification, especially from the client's viewpoint.

7.2.12 The certification body shall periodically observe the performance of each auditor on-site. The frequency of on-site observations shall be based on need determined from all monitoring information available.

4.3 Competence
Competence of the personnel supported by the management system of the certification body is necessary to deliver certification that provides confidence. Competence is the demonstrated ability to apply knowledge and skills.

R17 (6) b), c): resources – procedures / processes

7.2.5 The certification body shall have a process to achieve and demonstrate effective auditing, including the use of auditors and audit team leaders possessing generic auditing skills and knowledge, as well as skills and knowledge appropriate for auditing in specific technical areas. This process shall be defined in documented requirements drawn up in accordance with the relevant guidance provided in ISO 19011.

9.1 General requirements

9.1.1 The audit programme shall include a two-stage initial audit, surveillance audits in the first and second years, and a recertification audit in the third year prior to expiration of certification. The three-year certification cycle begins with the certification or recertification decision. The determination of the audit programme and any subsequent adjustments shall consider the size of the client organization, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits. Where a certification body is taking account of certification or other audits already granted to the client, it shall collect sufficient, verifiable information to justify and record any adjustments to the audit programme.

9.1.2 The certification body shall ensure that an audit plan is established for each audit to provide the basis for agreement regarding the conduct and scheduling of the audit activities. This audit plan shall be based on documented requirements of the certification body, drawn up in accordance with the relevant guidance provided in ISO 19011.

9.1.3 The certification body shall have a process for selecting and appointing the audit team, including the audit team leader, taking into account the competence needed to achieve the objectives of the audit. This process shall be based on documented requirements, drawn up in accordance with the relevant guidance provided in ISO 19011.

R17 (6): resources – equipment

5.3.2 The certification body shall evaluate its finances and sources of income and demonstrate to the committee specified in 6.2 that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

R17 (9): liability

5.3.1 The certification body shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

R17 (10): confidentiality, secrecy

4.6 Confidentiality
To gain the privileged access to information that is needed for the certification body to assess conformity to requirements for certification adequately, it is essential that a certification body keep confidential any proprietary information about a client.

8.5 Confidentiality

8.5.1 The certification body shall, through legally enforceable agreements, have a policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of certification activities at all levels of its structure, including committees and external bodies or individuals acting on its behalf.

8.5.2 The certification body shall inform the client, in advance, of the information it intends to place in the public domain. All other information, except for information that is made publicly accessible by the client, shall be considered confidential.

8.5.3 Except as required in this International Standard, information about a particular client or individual shall not be disclosed to a third party without the written consent of the client or individual concerned. Where the certification body is required by law to release confidential information to a third party, the client or individual concerned shall, unless regulated by law, be notified in advance of the information provided.

8.5.4 Information about the client from sources other than the client (e.g. complainant, regulators) shall be treated as confidential, consistent with the certification body's policy.

8.5.5 Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification body's activities.

8.5.6 The certification body shall have available and use equipment and facilities that ensure the secure handling of confidential information (e.g. documents, records).

8.5.7 When confidential information is made available to other bodies (e.g. accreditation body, agreement group of a peer assessment scheme), the certification body shall inform its client of this action.

DIN EN ISO/IEC 17024:2003

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

R17 (2): legal compliance, legal personality

4.1.1 The policies and procedures of the certification body and their administration shall be related to the criteria in which certification is sought, shall be fair and equitable among all candidates, and shall comply with all applicable regulations and statutory requirements. The certification body shall not use procedures to impede or inhibit access by applicants and candidates except as provided for in this standard.

4.2.1 The certification body shall be structured as to give confidence to interested parties in its competence, impartiality and integrity. In particular, the certification body shall…
d) have documents establishing it as a legal entity or part of a legal entity.

R17 (3), (4), (5), (8): independence, impartiality

see above, R 17 (2), 4.1.1

4.2.2 The certification body shall have a documented structure which safeguards impartiality including provisions to assure the impartiality of the operations of the certification body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system, without any particular interest predominating.

4.2.4 The certification body shall:
c) assure that the activities of bodies related to it do not compromise the confidentiality and impartiality of its certification.

R17 (5): technical skill

4.2.7 The certification body shall employ or contract enough people with the necessary education, training, technical knowledge and experience to perform certification functions relating to the type, range and volume of work performed, under a responsible management.

R17 (6) a), (7): resources – personnel (quantitative/qualitative)

see above, R 17 (5), 4.2.7

5.2 Requirements for examiners

5.2.1 Examiners shall meet the requirements of the certification body based upon applicable competence standards and other relevant documents. The selection process shall ensure that examiners assigned to an examination or part of an examination shall at least:

a) be familiar with the relevant certification scheme;
b) have a thorough knowledge of the relevant examination methods and examination documents;
c) have appropriate competence in the field to be examined;
d) be fluent both in writing and orally in the language of examination, and
e) be free from any interest so that they can make impartial and non-discriminatory judgements (assessments).

5.2.2 If an examiner has a potential conflict of interest in the examination of a candidate, the certification body shall undertake measures to ensure that confidentiality and impartiality of the examination is not compromised (see clause 4.2.5). The measures shall be recorded.

R17 (6) b), c): resources – procedures / processes

4.3.1 The certification body shall define the methods and mechanisms to be used to evaluate the competence of candidates; and shall establish appropriate policies and procedures for the initial development and continued maintenance of these methods and mechanisms.

4.3.2 The certification body shall define a process for the development and maintenance of certification schemes which includes the review and validation of the scheme by the scheme committee.

4.3.6 The certification body shall evaluate the methods for examination of candidates. Examinations shall be fair, valid and reliable. Appropriate methodology and procedures (such as collecting and maintaining statistical data) shall be defined to reaffirm, at least annually, the fairness, validity, reliability and general performance of each examination and all identified deficiencies corrected.

R17 (6): resources – equipment

4.2.4 The certification body shall:
a) have the financial resources necessary for the operation of a certification system and to cover associated liabilities.

R17 (10): confidentiality, secrecy

4.7 Confidentiality
The certification body shall, through legally enforceable commitments, keep confidential all information obtained in the process of its activities. These commitments shall cover all individuals working within the body, including committee members, and external bodies or individuals acting on its behalf. Such information shall not be disclosed to an unauthorized party without the written consent of the organisation or individual from whom the information was obtained, except where the law requires such information to be disclosed. When the certification body is required by law to release such information, the organisation or individual concerned shall be informed beforehand what information will be provided.

4.8 Security
All examinations and related items shall be maintained in a secure environment by the certification body, or its subcontractors, to protect the confidentiality of these items throughout their useful life.

DIN EN ISO/IEC 17025:2005

General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)

R17 (3), (4), (5), (8): independence, impartiality

4.1.5 The laboratory shall
b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

R17 (5): technical skill

4.1.5 The laboratory shall
a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);
g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

5.2 Personnel

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

R17 (6) a), (7): resources – personnel (quantitative/qualitative)

4.1.5 The laboratory shall
a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

in addition, see R 17 (5), 5.2

R17 (6) b), c): resources – procedures / processes

4.6 Purchasing services and supplies

4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

R17 (6): resources – equipment

4.1.5 The laboratory shall
b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

5.3 Accommodation and environmental conditions

5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

5.3.3 There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.5 Equipment

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements o f this International Standard are met.

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:
a) the identity of the item of equipment and its software;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) checks that equipment complies with the specification (see 5.5.2);
d) the current location, where appropriate;
e) the manufacturer's instructions, if available, or reference to their location;
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
g) the maintenance plan, where appropriate, and maintenance carried out to date;
h) any damage, malfunction, modification or repair to the equipment.

5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedures (see 4.9).

R17 (9): liability

4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

R17 (10): confidentiality, secrecy

4.1.5 The laboratory shall
c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results; …

DIN EN ISO/IEC 17040:2005

Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies (ISO/IEC 17040:2005)

R17 (3), (4), (5), (8): independence, impartiality

7.5.6 Provision shall be made to assure the objectivity of team members, taking into account any conflicts of interests.

R17 (6) a), (7): resources – personnel (quantitative/qualitative)

4.4 The management committee or person shall ensure that persons involved in the peer assessment process are competent and can perform their duties objectively.

5 Human resource requirements

5.1 Qualifications and selection

5.1.1 The qualification criteria shall be defined and documented for the people carrying out the peer assessment process. Elements of ISO 19011:2002, Clause 7, may be adapted for use in various types of assessments.

5.1.2 The qualification criteria of the people carrying out the peer assessment process shall match the personal attributes and competence that would be required of a person performing the activity that is the object of the peer assessment.

5.1.3 Competence criteria shall match the nature of the peer assessments to be performed (see Introduction).

5.1.4 The process for the selection, training and continuing evaluation of the people required for the conduct of the peer assessment process shall be defined and documented.

7.5 Appointment of peer assessment team

7.5.1 The management committee or person shall appoint a peer assessment team that is qualified to perform the peer assessment process.

7.5.2 One member of the team shall be appointed as team leader who will take full responsibility for the peer assessment process and related communications with the applicant and the management committee or person. Depending upon the scale of the peer assessment process, a one-person team may be appointed; that is, the team leader may perform the entire peer assessment process.

7.5.3 The people assigned to conduct a particular peer assessment process shall have practical experience of the activities to be assessed.

7.5.4 Wherever possible, the team shall include people from a balanced selection of agreement group member bodies.

7.5.5 Assignment of people to the team shall take into account their ability to work together effectively.

R17 (6) b), c): resources – procedures / processes

Annex B1 – 4
(informative)

Assessment techniques for use by peer assessment teams

R17 (6): resources – equipment

Annex A
(informative)

Financial aspects
The peer assessment process involves the expenditure of considerable resources in order
- to set up the peer assessment process,
- to manage and maintain the process,
- to conduct individual peer assessment processes, and
- to conduct on-going activities to assure the conformity of agreement group members, where necessary.

R17 (10): confidentiality, secrecy

> 8 Confidentiality
> The agreement group shall make appropriate arrangements to safeguard the confidentiality of the information obtained in the peer assessment process and these shall be documented. These arrangements shall cover all individuals working within the agreement group, including committee members, and external bodies or individuals acting on its behalf. Such information shall not be disclosed to an unauthorized party without the written consent of the organization or individual from whom the information was obtained, except where the law requires such information to be disclosed. When the agreement group is required by law to release confidential information, the body shall, unless prohibited by law, be notified of the information provided.

The presentation of the standards shows that in some cases, the **same issue is dealt with differently in terms** not only of the language, but also **of the defined requirements**. This will be shown again below with reference to the highly relevant criterion of independence.

4.3.3.2 Independence and impartiality in Article R17

Owing to the great importance of "independence" for the quality of the conformity assessment body – which is also evident from the comparatively comprehensive description in Article R17 of Decision 768/2008/EC – this characteristic will be considered in greater detail with regard to the presumption of conformity.

The study begins by listing the terms for independence and impartiality employed in R17:

- **Complete independence**
  (3 – Paragraph 1) (...) a third-party body independent of the organisation or the product it assesses.

- **Independence of involved associations by the absence of conflicts of interest**
  (3 – Paragraph 2) A body belonging to a business association or professional federation representing undertakings involved in the design, (...) of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered completely independent.

- **Independence of personnel**
  (4 – Paragraph 1) (...) top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, (...) of the products which they assess, nor the authorised representative of any of those parties.

(4 – Paragraph 2) (...) personnel responsible for carrying out the conformity assessment tasks (...) shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities.

- **Financial independence**

  (5) Personnel of conformity assessment bodies shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities especially as regards persons with an interest in the results of the assessment.

- **Independence of resources**

  (6 – final paragraph) The conformity assessment body shall have access to all resources necessary to perform conformity assessment.

- **Independence of employee remuneration**

  (8 – Paragraph 2) The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

- **Independence of subsidiaries or subcontractors**

  (4 – Paragraph 3) Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the objectivity or impartiality of their assessment activities.

  (8) The impartiality of the conformity assessment bodies (including their personnel) shall be guaranteed.

The reference numbers/paragraphs in brackets above refer to the reference of the terms for independence in R17 of Decision 768/2008/EC.

Now that the requirements of Article R17 have been stated, the standards listed by the European Commission will be studied with regard to whether and in what way they have addressed the "independence and impartiality" in the meaning of Article 17.

The following procedure was followed:

In the first step, the standards to be examined were read selectively by inspection of their tables of contents, in order for content clearly relating to independence and impartiality to be identified in advance.

In the second step, the standards were then studied systematically according to the key words selected beforehand from Article R17 in the Annex of Decision

768/2008/EC, in order to permit subsequent analysis of their context. The key words employed were the German terms for independence, impartiality, third party, conflict of interest, authorized representative, subsidiary, subcontractor, confidentiality, objectivity, influence, equipment, organization, remuneration, influencing.

Where a term relating to independence or impartiality was found in the standard under examination, the section/paragraph was entered in the corresponding line of the table of results shown below (Table 3), and the relevant paragraphs cited again separately (see below).

Table 3: Table of results for independence and impartiality

	Standard	17020: 2004	17021 :2006	17024 :2003	17025 :2005	19011 :2002	EN 45011: 1998
1. Indepen-dence	1.1 Complete independence	4.1, A1, A2	---	4.2.1 a)	---	4 d)	4.2 a)
	1.2 Independence of industry bodies	---	---	---	---	---	4.2 o)
	1.3 Independence of personnel	A.2, B.2, C.1	5.2.1, 5.2.10 7.3, 7.5.3 c)	5.1.2	4.1.5 b)	5.3.2 d), 6.2.4 e) 6.4.2, 7.2 a)	5.2.2 a)
	1.4 Financial independence	4.1	4.2.2	4.2.4 a) 4.3.5	4.1.5 b)	5.3.2 a)	4.1.2, 4.2. m/n)
	1.5 Independence of resources	8.1, 9.1	---	4.2.4 b) 4.2.7	4.1.5 a) 5.5.1	6.2.3	4.2 j)
	1.6 Independence of employee remuneration	---	4.2.4 a) 5.2.12	---	4.14.1	---	---
2.1 Impartiality of subsidiaries/subcontractors		---	7.5.3 5.2.8	4.2.2 4.5.1	4.1.4	---	4.4, 4.4 b)

Cited paragraphs:

EN ISO/IEC 17020:2004

General criteria for the operation of various types of bodies performing inspection (ISO/IEC 17020:1998)

Complete independence/financial independence

4.1 General
The personnel of the inspection body shall be free from any commercial, financial and other pressures which might affect their judgement. Procedures shall be implemented to ensure that persons or organizations external to the inspection body cannot influence the results of inspections carried out.

A.1
The inspection body shall be independent of the parties involved. The inspection body and its staff responsible for carrying out the inspection shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the items which they inspect, nor the authorized representative of any of these parties.

Independence of personnel

A.2
The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, Installation, use or maintenance of the items inspected, or similar competitive items.

B.2
The inspection body and its staff shall not engage in any activities that may conflict with their Independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, Installation, use or maintenance of the items inspected, or similar competitive items.

C.1
The inspection body shall provide safeguards within the organization to ensure adequate Segregation of responsibilities and accountabilities in the Provision of inspection services by organization and/or documented procedures.

Independence of resources

8.1
The inspection body shall have a sufficient number of permanent personnel with the range of expertise to carry out its normal functions.

9.1
The inspection body shall have available to it suitable and adequate facilities and equipment to permit all activities associated with the inspection services to be carried out.

EN ISO/IEC 17021:2006

Conformity assessment - Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2006)

Independence of personnel

5.2.1
The certification body shall have top management commitment to impartiality in management system certification activities. The certification body shall have a publicly accessible statement that it understands the importance of impartiality in carrying out its management system certification activities, manages conflict of interest and ensures the objectivity of its management system certification activities.

5.2.10
To ensure that there is no conflict of interests, personnel who have provided management system consultancy, including those acting in a managerial capacity, shall not be used by the certification body to take part in an audit or other certification activities if they have been involved in management system consultancy towards the client in question within two years following the end of the consultancy.

7.3 Use of individual external auditors and external technical experts
The certification body shall require external auditors and external technical experts to have a written agreement by which they commit themselves to comply with applicable policies and procedures as defined by the certification body. The agreement shall address aspects relating to confidentiality and to independence from commercial and other interests, and shall require the external auditors and external technical experts to notify the certification body of any existing or prior association with any organization they may be assigned to audit.

7.5.3 The certification body
c) shall ensure that the body that provides outsourced services, and the individuals that it uses, is not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised.

Financial independence

4.2.2
It is recognized that the source of revenue for a certification body is its client paying for certification, and that this is a potential threat to impartiality.

Independence of employee remuneration

4.2.4 Threats to impartiality include the following:
a) Self-interest threats: threats that arise from a person or body acting in their own interest. A concern related to certification, as a threat to impartiality, is financial self-interest.

5.2.12
All certification body personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.

Impartiality of subsidiaries/subcontractors

7.5.3 The certification body
a) shall take responsibility for all activities outsourced to another body,
b) shall ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the certification body and also to the applicable provisions of this International Standard, including competence, impartiality and confidentiality, and
c) shall ensure that the body that provides outsourced services, and the individuals that it uses, is not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised.

5.2.8
The certification body shall not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to the impartiality of the certification body (see 7.5). This does not apply to individuals contracted as auditors covered in 7.3.

EN ISO/IEC 17024:2003

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

Complete independence

4.2.1
The certification body shall be structured as to give confidence to interested parties in its competence, impartiality and integrity. In particular, the certification body shall:
a) be independent and impartial in relation to its applicants, candidates and certified persons, including their employers and their customers, and shall take all possible steps to assure ethical operations.

Independence of personnel

5.1.2
The certification body shall require its employed or contracted persons to sign a document by which they commit themselves to comply with the rules defined by the certification body, including those relating to confidentiality and those relating to independence from commercial and other interests, and from any prior and/or present link with the persons to be examined that would compromise impartiality.

Financial independence

4.2.4
The certification body shall:
a) have the financial resources necessary for the operation of a certification system and to cover associated liabilities.

4.3.5
Certification shall not be restricted on the grounds of undue financial or other limiting conditions, such as membership in an association or group. Successful completion of an approved training course may be a requirement of a certification scheme but recognition/approval of training courses by the certification body shall not compromise impartiality, or reduce the demands of the evaluation and certification requirements.

Independence of resources

4.2.4
The certification body shall:
b) have policies and procedures that distinguish between the certification of persons and any other activities.

4.2.7
The certification body shall employ or contract enough people with the necessary education, training, technical knowledge and experience to perform certification functions relating to the type, range and volume of work performed, under a responsible management.

Impartiality of subsidiaries/subcontractors

4.2.2
The certification body shall have a documented structure which safeguards impartiality including provisions to assure the impartiality of the operations of the certification body; this structure shall enable the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system, without any particular interest predominating.

4.5.1
When a certification body decides to subcontract work related to certification (e.g. examination) to an external body or person, a properly documented agreement covering the arrangement, including confidentiality and prevention of a conflict of interest, shall be drawn up. The decision on certification shall not be subcontracted.

EN ISO/IEC 17025:2005:

General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)

Complete independence/financial independence

4.1.5 The laboratory shall
b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

Independence of resources

a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

5.5.1
The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements o f this International Standard are met.

Independence of employee remuneration

4.14.1
The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

Impartiality of subsidiaries/subcontractors

4.1.4
If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflict of interest.

EN ISO/IEC 19011:2002

Guidelines for quality and/or environmental management systems auditing [referred to in 17000:2005 – Bibliography]

Complete independence

4 d)
Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions.

Financial independence

5.3.2 Audit programme resources
When identifying resources for the audit programme, consideration should be given to

a) financial resources necessary to develop, implement, manage and improve audit activities.

Independence of personnel

d) the availability of auditors and technical experts having competence appropriate to the particular audit programme objectives.

6.2.4 Selecting the audit team
When the audit has been declared feasible, an audit team should be selected, taking into account the competence needed to achieve the objectives of the audit. If there is only one auditor, the auditor should perform all applicable duties of an audit team leader. Clause 7 contains guidance on determining the competence needed and describes processes for evaluating auditors. In deciding the size and composition of the audit team, consideration should be given to the following:
e) the need to ensure the independence of the audit team from the activities to be audited and to avoid conflict of interest;

6.4.2 Assigning work to the audit team
The audit team leader, in consultation with the audit team, should assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments should take into account the need for the independence and competence of auditors and the effective use of resources, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure the achievement of the audit objectives.

7.2 Personal attributes
Auditors should possess personal attributes to enable them to act in accordance with the principles of auditing described in clause 4.

An auditor should be:
a) ethical, i.e. fair, truthful, sincere, honest and discreet.

Independence of resources

6.2.3 Determining the feasibility of the audit
The feasibility of the audit should be determined, taking into consideration such factors as the availability of
- sufficient and appropriate information for planning the audit,
- adequate cooperation from the auditee, and
- adequate time and resources.

Where the audit is not feasible, an alternative should be proposed to the audit client, in consultation with the auditee.

Differences in terminology:

As the above table of results shows, not all standards satisfy all the quality requirements for the corresponding criterion stated under the term "independence" in Article R17.

Comparison is made even more difficult by the fact that the criteria for independence are **described differently** from one standard to the next (refer to the cited paragraphs in this regard), even though there generally appears to be **no objective reason for this difference in the terminology**. The criteria for independence are in some cases different, some standards requiring independence in terms of its individual elements, others only that independence be an objective, that risks to independence be identified, or that measures be stated by which independence can be attained.

For the reasons stated above, it is difficult to perform a meaningful comparison of the individual standards by means of a quantitative method with regard to the criteria stated in Article R17. Attention is therefore drawn below once again to the essential differences by way of their descriptions:

- **17020 (inspection bodies)**

  The requirements deriving from Article R17 are met almost word for word in this standard.

- **17021 (management systems)**

  No requirement for institutional, complete independence.

  Impartiality is stated as being mandatory with regard to the independence of personnel. The standard also makes reference to the management of conflicts of interest and assuring the objectivity of the certification tasks.

  Accordingly, in contrast to 17020 (inspection bodies), organization structures which exclude partiality are not a requirement.

  Conversely, a positive observation is that a change in certifier for the same client is required within a certain period (7.2.).

  Financial independence is assured (as in 17020).

  Independence of resources is not an explicit requirement; the independence of resources is however derived from general principles concerning independence, as described in the standard under 5.2.12. The description is however in substantial need of interpretation.

- **17024 (bodies certifying persons)**

  Complete independence is (probably) satisfied. Here too, the definition in Article R17 (3) is clearer, making reference to an independent "third-party body", whereas 17024 states that the body "shall be independent". This is a broad formulation and less clear than the formulation in Article R17 (independent third-party body); it does not require institutional independence.

  Independence of personnel is satisfied, as required in Article R17.

  Financial independence is formulated very broadly and is described positively, but is consistent with Article R17.

- **17025 (test and calibration laboratories)**

  Full independence in the sense of independent third parties in accordance with Article R17 (3) is not assured; no institutional independence. Instead, independence is to be attained only through various stated organizational measures concerning the equipment of the laboratory and also, where the personnel also fulfil other functions, criteria for their independence, in order to enable them to perform the test tasks independently. Performance of internal audits, independence of employee remuneration from the number of test tasks.

  An explicit provision is that should the test body be part of an organization that performs other tasks besides tests, the influences must be stated openly in order for conflicts of interest to be identified at an early stage.

  The criteria for independence, as they are described, merely manage a deficiency; true independence is not a criterion.

- **19011 (quality management / environmental management)**

  Full independence in the sense of R17 (3) is a requirement; compliance with Article R17 with regard to the independence of personnel can also be observed.

  The descriptions concerning financial independence are unusual and are formulated somewhat vaguely. The standard states for example that this "should" exist and that "consideration should be given" to various criteria in this context.

  With regard to the independence of resources, the standard contains formulations that differ from and are once again vague compared to those of other standards. The standard states that the need for resources should be determined. If this need is not met, an alternative should be proposed to the client.

To summarize: the standards also differ in their provisions concerning the characteristic of independence, with the result that different assessment results are also possible for this important area.

4.3.3.3 Relationship between the standards and the modules, and provisions within the standards governing technical skill

A further deficit is the unspecified relationship between the standards and the conformity assessment tasks to be conducted by the notified bodies, i.e. the tasks set out in the modules. Direct correspondence between standard and module does not exist (refer here to KAN Report 30 Section 3.2.2.3 (4)).

The interim result at the time

> "This cross-referencing of the applicable standards in the EN 45000 series to the individual modules, which is contained in the 'Blue Guide' and which is not legally binding, neither has any basis in fact, nor is it conducive to a

uniform standard in Europe. In some cases, standards are offered for selection for one and the same module the terms of which are not compatible, i.e. which do not govern the same facts. A selection between standards, particularly standards the terms of which are not comparable, may lead to substantial differences in quality between the Member States. It allows a presumption of conformity neither to be inferred, nor created."

also applies to the standards in the EN ISO/IEC 17000 series[42] and the newly defined modules in Decision 768/2008/EC.

The modules can essentially be related to the three functions of the functional approach defined in EN ISO/IEC 17000:[43]

- Selection
- Determination
- Review and attestation.

However, the modules are generally heterogeneous and frequently combine several activities for determination, review (termed “assessment” in the modules) and attestation which are not found in the same combination in a single standard.

Module H1 for example, "Conformity based on full quality assurance plus design examination", contains various activities determination such as "testing" and "auditing". The "review and attestation" in this module is also divided into two parts: one in the context of assessment of the quality assurance system, the other in the context of EC design examination. In this case, the body shall "examine the application, and where the design meets the requirements of the legislative instrument that apply to the product it shall issue an EC design examination certificate to the manufacturer".

For this latter task, the standard for product certification bodies, currently EN 45011, is generally used.[44] Section 1.2 e) concerning the scope makes explicit reference to the assessment of development documentation.

A further standard, the scope of which covers the "Examination of a product design... and determination of their conformity with specific requirements", is the standard governing inspection bodies, EN ISO/IEC 17020 (General criteria for the operation of various types of bodies performing inspection). The section headed "Scope" explicitly states that this standard is not applicable to test laboratories and certification bodies. These two standards differ substantially, particularly with regard to their requirements for "review and attestation".

[42] Cf. SOGS N612 EN "CERTIF 2009–08 USING STANDARDS TO ASSESS THE COMPETENCE OF CON-FORMITY ASSESSMENT BODIES IN THE CONTEXT OF THE NEW LEGISLATIVE FRAMEWORK", For information and discussion, November 2009.
[43] EN ISO/IEC 17000:2004. Conformity assessment – Vocabulary and general principles, Section A 1.
[44] EN 45011:1998 General requirements for bodies operating product certification systems.

However, if the requirements of the standards relating to the personnel are considered, they are found to vary in their explicitness, and also to be based upon different concepts. As the following comparison (between R17, and EN 45011 and EN ISO/IEC 17021 governing requirements placed upon the personnel) shows, both standards contain similarly abstract formulations to those in R17.

Even this brief comparison shows that:

1. all documents contain similarly general requirements such as "personnel **with technical knowledge and sufficient and appropriate experience**", which leave relatively **wide room for interpretation**;
2. the requirements formulated in R17 are in some cases substantially more explicit than those stated in EN 45011. Paragraph 7 in particular lists explicit requirements relating to qualifications, whereas EN 45011 – like EN ISO/IEC 17021 (management system certification) – leaves definition of the qualification criteria to the certification body;
3. similarly to R17, EN ISO/IEC 17020 defines explicit requirements relating to the personnel in some cases; here too however, it is clear that the standard does not elaborate upon these requirements, which are already defined in R17, or does so only insubstantially.

Table 4: Comparison between R17, and EN 45011 and EN ISO/IEC 17021 - requirements placed upon the personnel

R 17	**EN 45011**	**EN ISO/IEC 17020**
5. Conformity assessment 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** ...		**8.1** The inspection body shall have a **sufficient number of permanent personnel** with the range of expertise to carry out its normal functions.
6. ... At all times and for each conformity assessment procedure and 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**: a) **personnel with technical knowledge and sufficient and appropriate experience** to perform the conformity	5.1.1 The personnel of the certification body **shall be competent** for the functions they perform, including making required technical judgements, framing policies and implementing them.	**8.2** The staff responsible for inspection shall have **appropriate qualifications, training, experience and a satisfactory knowledge of the requirements** of the inspections to be carried out. They shall have the ability to make professional judgements as to conformity with general requirements using examination results and to report there on.

R 17	EN 45011	EN ISO/IEC 17020
assessment tasks;		They shall also have relevant knowledge of the technology used for the manufacturing of the products inspected, of the way in which products or processes submitted to their inspections are used or are intended to be used, and of the defects which may occur during use or in service. They shall understand the significance of deviations found with regard to the normal use of the products or processes concerned.
7. The **personnel responsible for carrying out conformity assessment activities shall have** the following: (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified; (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;	**5.2 Qualification criteria** 5.2.1 In order to ensure that evaluation and certification are carried out effectively and uniformly, the minimum relevant criteria for the competence of personnel shall be defined by the certification body.	They shall have the ability to make professional judgements as to conformity with general requirements using examination results and to report there on.
(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Community harmonisation legislation and of its implementing regulations; (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.	5.2.3 Information on the relevant qualifications, training and experience of each member of the personnel involved in the certification process shall be maintained by the certification body. Records of training and experience shall be kept up to date, in particular the following: … c) educational qualification and professional status; d) experience and training in each field of the certification body's competence; … f) performance appraisal.	They shall also have relevant knowledge of the technology used for the manufacturing of the products inspected, of the way in which products or processes submitted to their inspections are used or are intended to be used, and of the defects which may occur during use or in service. They shall understand the significance of deviations found with regard to the normal use of the products or processes concerned.

The standards governing the bodies therefore essentially neither support the requirements stated in R17 relating to the personnel, nor do they constitute a suitable yardstick for comparable accreditation and notification in Europe. A major deficit thus remains, particularly regarding the **specific technical requirements for certain areas of products and technology**.

4.3.4 Comparison of the Common Elements in KAN Report 30 with the "Common Elements" of the EN ISO / IEC 17000 ff. series of standards

The study then examined to what extent the Common Elements (refer again to the abstract overview in Fig. 5 below) stated in KAN Report 30 (in Section 5.2, pp. 112 ff.) are also found in the standards the references of which were published in 2009 by the European Commission.

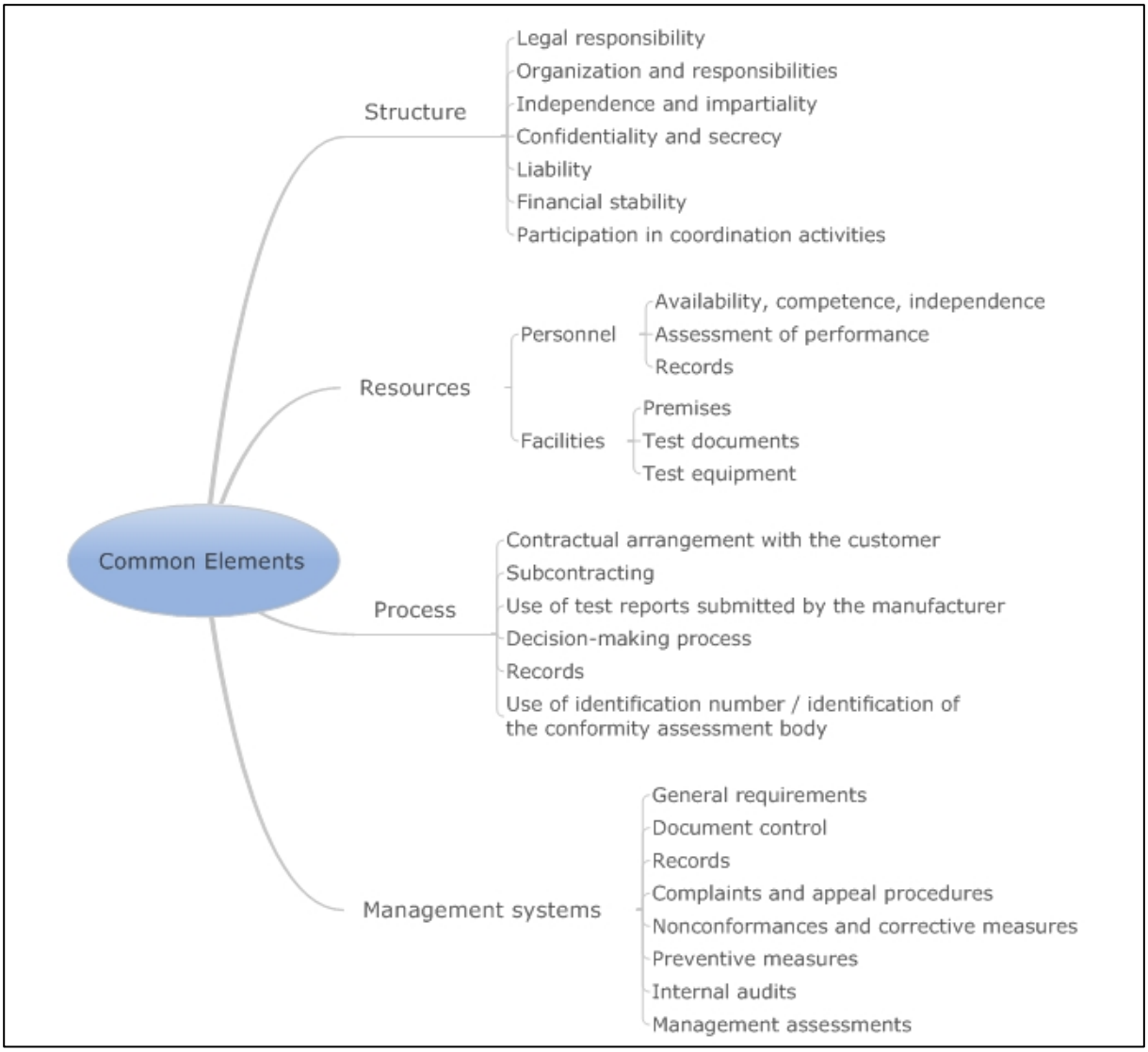

Fig. 5: Abstract overview of the common requirements concerning notified bodies proposed in KAN Report 30

The following are excluded from this examination:

- EN ISO/IEC 17000:2004: only concepts and general principles.
- EN ISO/IEC 17050-1:2004(+ corrected version 2007): only for the declaration of conformity of suppliers.
- EN ISO/IEC 17050-2:2004: only for the declaration of conformity of suppliers.

ISO/IEC 17065 CD 2:2010-08 "Conformity assessment – Requirements for bodies certifying products, processes and services" – which is currently available only in draft form and which the Commission cannot therefore by definition make reference to at this stage – has been examined separately (see Table 6).

Tables 5a, b and c below indicate the sections of the respective harmonized standards in which the Common Elements of KAN Report 30 can be found, or whether any provisions at all are to be found which at least correspond to the Common Elements.

Table 5a: Comparison of standards with the Common Elements of KAN Report 30

Common Elements		**EN ISO/IEC 17011:2005**	**EN ISO/IEC 17020:2004**
Structure	Legal responsibility	4.1, 4.2.3	3.1
	Organization and responsibilities	4.2.4, 4.2.5, 8	3.2, 6
	Independence and impartiality	4.3	4
	Confidentiality and secrecy	4.4	5
	Liability	4.5	3.4
	Financial stability	4.5	
	Participation in co-ordination activities	4.6.2	
Resources	Personnel	6	8
	Facilities		9
Process	Contractual arrangement with the customer		
	Subcontracting	7.4	14
	Use of test reports submitted by the manufacturer		
	Decision-making process		10
	Records	7.6, 7.14	12
	Use of the identification number / identification of the conformity assessment body		
Management systems	General requirements	5.1	7.1, 7.2
	Document control	5.3	7.3, 7.6
	Records	5.4	
	Complaints and appeal procedures	5.9	15
	Nonconformances and corrective measures	5.5	7.8
	Preventive measures	5.6	7.5
	Internal audits	5.7	7.7
	Management assessments	5.2.3, 5.8	7.9

Table 5b: Comparison of standards with the Common Elements of KAN Report 30

Common Elements		**EN ISO/IEC 17021:2006**	**EN ISO/IEC 17024:2003**	**EN ISO/IEC 17025+ A2:2007**
Structure	Legal responsibility	5.1		
	Organization and responsibilities	4.4, 6.1	4.2	4.1
	Independence and impartiality	4.2, 5.2, 6.2	4.2.1	4.1.5
	Confidentiality and secrecy	4.6, 8.5	4.7, 4.8	4.1.5 (b)
	Liability	5.3		
	Financial stability	5.3	4.2.4	
	Participation in co-ordination activities			
Resources	Personnel	4.2, 7.1, 7.2	4.2.7, 5	4.6, 5.2
	Facilities			4.6, 5.3, 5.5
Process	Contractual arrangement with the customer	5.1.2	6.1	4.4
	Subcontracting	7.5	4.5	4.5, 5.10.6
	Use of test reports submitted by the manufacturer	8.2		
	Decision-making process		6.3	
	Records	8.2	4.6	5.10.3
	Use of the identification number / identification of the conformity assessment body	8.4	6.6	
Management systems	General requirements	10	4.4	4.2, 5.9
	Document control	10.3.3	4.4.1, 4.4.3	4.3
	Records	9.9, 10.3.4		4.13
	Complaints and appeal procedures	4.7, 9.7, 9.8		4.13
	Nonconformances and corrective measures	10.3.7		4.9, 4.11
	Preventive measures	10.3.8		4.12
	Internal audits	10.3.6		4.14
	Management assessments	10.3.5		4.15

Table 5c: Comparison of standards with the Common Elements of KAN Report 30

Common Elements		EN ISO/IEC 17040:2005	EN 45011:1998
Structure	Legal responsibility		
	Organization and responsibilities	4.2, 4.3	4.1.1, 4.1.3, 4.2
	Independence and impartiality		4.1.2, 4.1.4
	Confidentiality and secrecy	8	4.10
	Liability		
	Financial stability	Annex A	
	Participation in co-ordination activities		
Resources	Personnel	4.4, 5	5
	Facilities	Annex B	
Process	Contractual arrangement with the customer		8
	Subcontracting		4.4
	Use of test reports submitted by the manufacturer	7.9	11
	Decision-making process		
	Records	6, 7.1	
	Use of the identification number / identification of the conformity assessment body		14
Management systems	General requirements		4.5
	Document control		4.8
	Records		4.9
	Complaints and appeal procedures	9	7, 15
	Nonconformances and corrective measures		
	Preventive measures		
	Internal audits		4.7.1
	Management assessments		4.7.2

Following detailed examination, it may be stated that the criteria in the Common Elements of KAN Report 30, particularly those concerning the areas of "process" and "management systems", are not fully attained by the standards published in 2009. The table reveals where deficits exist in this respect.

From the comparison of the mandated standards the references of which were published in the Official Journal with the Common Elements described in KAN Report 30, it is further evident that frequently, different formulations have been used to describe the same subject-matter, which could without doubt also permit interpretations which might ultimately lead to different results. The situation found here is the same as that in the comparison of the provisions of Article R17 of the Annex of the decision with the harmonized standards listed by the European Commission (see 4.3.3 above): in that case, too, particularly for the element of "independence", the new standards, i.e. those the references of which

were published in the Official Journal, were found to contain different formulations which could also lead to diverging interpretations.

Merely for the sake of completeness, and in consideration of possible future developments, the extent was examined to which the requirements set out in KAN Report 30 are considered in ISO/IEC 17065 CD 2 (Conformity assessment – Requirements for bodies certifying products, processes and services), which as yet is available only in draft form (Table 6). Deficits can be observed here similar to those in the above standards.

Table 6: Comparison of ISO/IEC 17065 CD 2 with the Common Elements of KAN Report 30

Common Elements		**ISO/IEC 17065 CD 2**
Structure	Legal responsibility	4.1
	Organization and responsibilities	5.1, 8.5.1, 8.6.2
	Independence	4.2, 4.3.3, 5.1.1, 5.2, 6.1.3 b) c), 9.6.4 b), A.2
	Confidentiality and secrecy	6.1.3 a), 7.5, 8.11.2, 9.4.2, A.4.2
	Liability	4.3.2, 8.6.1
	Financial stability	4.2.2, 4.4.4, 5.1.4
	Participation in co-ordination activities	---
Resources	Availability, competence, independence	5.1.3 l), 6.1.2, 8.3 c), A.3
	Assessment of performance	---
	Records	---
	Premises	---
	Test documentation	3.8, 6.2.1, 9.3
	Test equipment	4.3.3
Process	Contractual arrangement with the client	4.1.2.1
	Subcontracting	6.2.2
	Use of test reports submitted by the manufacturer	---
	Decision-making processes	8.1, 8.2
	Records	4.1.2.2 c), 7.3, 8.4.4
	Use of the identification number of the conformity assessment body	4.1.1.2 e), 4.1.3
Management systems	General requirements	---
	Document control	9.3
	Records	9.2.4
	Complaints and appeals procedures	8.1.2

Common Elements		ISO / IEC 17065 CD 2
	Nonconformances/corrective measures	9.7
	Preventive measures	9.8
	Internal audits	9.6
	Management assessment	9.5

4.3.5 Conclusion

It can be summarized that the procedure involving ISO/PAS Common Elements could in principle be suitable for assuring the equivalence of requirements in the CASCO standards. In order for a body of standards to remain stable in the future and to serve the presumption of conformity, a criterion would however be that both the scope of the areas of regulation described in the ISO/PAS requirements and the depth of their regulation must be sufficiently precise for the area of the notified bodies.

A further requirement for such a procedure is that within the CASCO WGs, the necessary will must be found – or must prevail – for this to be implemented. If the different working drafts and the current committee draft (CD) of the future ISO/IEC 17065 concerning product certification are considered, it can be seen that the corresponding CASCO policy, described in Section 2.4, has not had a sufficiently binding effect.

Irrespective of the aspect of the binding effect, the general issue of CASCO's objectives remains that of developing global standards for bodies without intending, and – understandably – being able to address European issues adequately.

Developments have therefore shown clearly that the formulation in Section 5.3.2 of KAN Report 30: "A danger therefore exists that the needs deriving from the requirements of the European system may have to be put aside during continued standardization of conformity assessment, in the interests of worldwide acceptance of standards" was accurate, and that this situation has indeed arisen. The situation continues to be that shown in Figure 13 of this section of KAN Report 30 (see Fig. 6).

The existing and also the future CASCO standards relating to bodies (shown in the illustration, above right) are of only limited suitability for substantiating the presumption of conformity. As is shown by the analysis of the ISO/PAS (see Sections 2.4 and 4.3.2) and also of the current standards (see Sections 4.3.3 and 4.3.4), their requirements **neither cover the full catalogue of requirements of Article R17, nor are the individual requirements sufficiently detailed to substantiate the presumption of conformity**. The

"exclusively ISO/CASCO solution" proposed in KAN Report 30 must therefore be regarded as having failed.

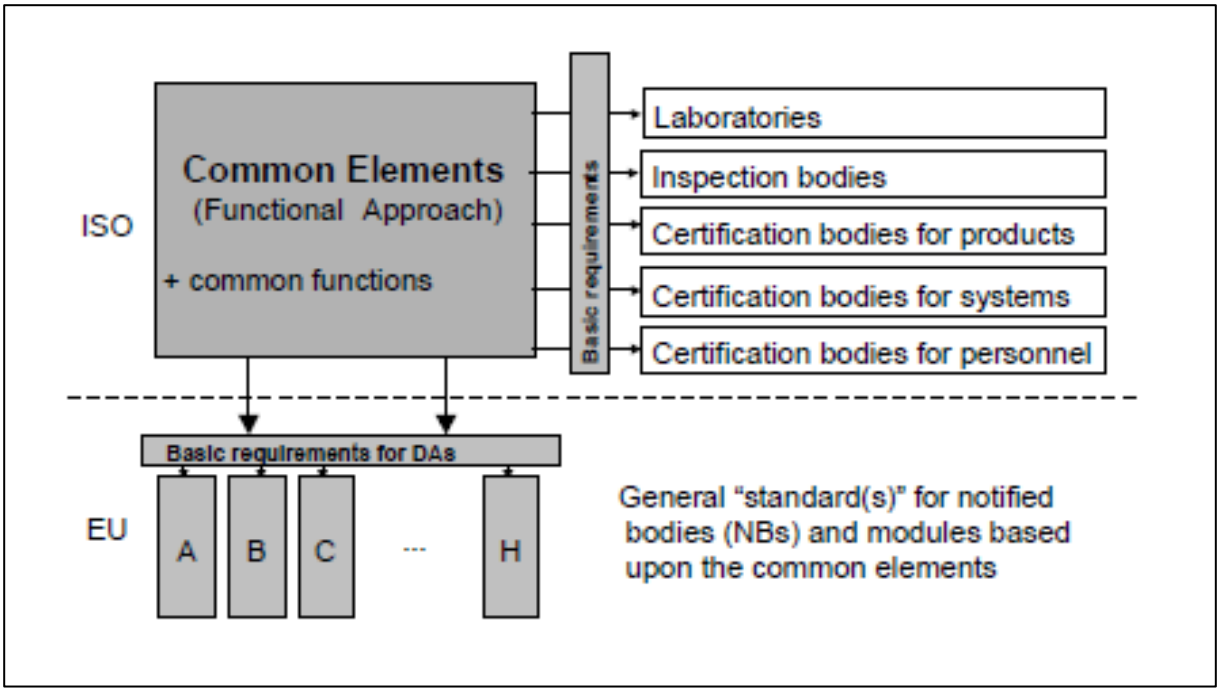

Fig. 6: Possible implementation of the "Common Elements" in standardization[45]

A further point of criticism is **that the standards are still not cross-referenced to the individual tasks of the notified bodies as specified in the modules**.

This means that the harmonized standards listed in Commission Communication 2009/C 136/08 must state categorically which requirements of the standard concerned substantiate which requirements of the catalogue contained in Article R17, i.e. what the presumption of conformity of the standard concerned relates to. (This information can for example take the form of an informative Annex Z.)

Article R17 is however a catalogue of proposals which is to be considered by the European legislature (at least in the future) during amendments to sectoral legal instruments. Other regulatory solutions are however possible for certain sectoral requirements[46]. This implies that before the standards may substantiate a presumption of conformity, they must first be reviewed, not (only) abstractly against the requirements of Decision 768/2008/EC, but also on a case-by-case basis against the requirements of the relevant sectoral legal instrument. Besides review of the general requirements (catalogue of requirements from Article R17), the standard's suitability for the relevant modules (e.g. Module H1 – full quality assurance with design examination and special surveillance of the final test) must therefore also be considered, since the presumption of conformity that the standard is intended to substantiate otherwise remains undetermined. Here too,

[45]Taken from Ensthaler et. al, KAN Report 30, p. 129.
[46] Cf. 768/2008/EC, Recital 5

the specific, i.e. sectoral legal instrument must be considered, since particular aspects of the modules are otherwise lost (cf. Directive 93/42/EEC with the additional function of the notified body of examining discrete technical documentation in the context of quality assurance modules[47]).

[47] Cf. Directive 93/42/EEC, Annexes II, V and VII (medical devices).

5 Recommendation

Before a recommendation is now made, the questions addressed by the research group will once again be answered in brief.

1. Do the provisions of the standards the references of which have been published in the Official Journal of the EU for the implementation of Regulation 765/2008/EC and Decision 768/2008/EC satisfy all the requirements of these legal instruments and of the New Approach directives?

   No: the requirements were generally met only partly, not in full. Furthermore, as detailed examination of the formulations has also revealed, they are interpreted differently, and therefore permit different interpretations by other parties.

2. Are the standards to be applied for the individual conformity assessment modules assigned sufficiently clearly for Member States to be able to perform assessment without the need to make reference to several standards with significantly differing content for virtually every module?

   No: the modules are not clearly cross-referenced to the standards; the relationship remains blurred and unclear. In the narrower sense (independence etc.), the Common Elements are often identical, if allowance is made for the differences in formulation; the technical qualifications that are required are however defined differently, owing to the differences in concepts between the standards, with the result that applications are possible which cannot be justified substantively. This can be demonstrated by the above examples (see Section 4.3.3.3, above).

   In order for this deficit to be eliminated, we recommend that the ***standards be revised swiftly and a uniform catalogue of requirements*** *consistent with Article R17* ***added to them****.* ***This catalogue of requirements would also have to take account of the module-specific aspects, for example by way of an informative Annex Z****. The informative Annex Z would in turn have to contain a clear indication of whether, and to what extent, satisfaction of the (module-specific) requirements is able to give rise to the presumption of conformity. The standards would therefore have to adopt, in the first instance, all aspects of Article R17 (following its completion); beyond that, it would be necessary to specify the area/tasks for which the requirements of the standards (and thus also the aspects/requirements of R17) apply in order for the presumption of conformity to take effect. The generic issue would doubtless remain that international standards concerning bodies would have to address the specifically European aspects; in the authors' view, implementing this requirement in the short term will certainly be difficult for this reason.*

In addition, the European Commission would in any case have to adopt a position during the transitional period on how the Member States should deal with conformity assessment bodies that do not (yet) satisfy the requirements profile of Article R17.

3. Have the relevant standards – particularly the EN ISO 17000 series – adopted the "Common Elements" proposed in KAN Report 30, i.e. universally valid, common requirements for bodies seeking notification (deriving from precisely defined minimum criteria formulated in the EU directives, and in Regulation 765/2008/EC and Decision 768/2008/EC)? Or do corresponding guidelines exist?

   No: in the relevant standards (EN ISO 17000 series), the Common Elements stated in KAN Report 30/the requirements for notified bodies stated in Decision 768/2008/EC Annex I Article R17 have been adopted only in part, and in widely diverging ways.

   Article R17 fails to deal with certain aspects addressed in KAN Report 30, and in part even falls short of the provisions in the standards. At the same time, however, the standards do not always address all Common Elements, nor all aspects of Article R17. The situation is therefore conflicted, and altogether unsatisfactory.

4. How might a gap, should one exist, be closed between the requirements contained in the relevant harmonized standards and the relevant specific (technical) requirements in the EC Directives for bodies seeking notification? What contribution could the "recognised body" (cf. Article 14 of Regulation 765/2008/EC) make in this context?

   With Decision 768/2008/EC Annex I Article R17, the European legislature has in principle adopted the correct strategy. It has created a horizontal decision, applicable across all modules, which also defines binding requirements for the notified bodies; it has therefore followed the suggestions/recommendations contained in KAN Report 30. The European legislature has not, however, followed this strategy to its logical conclusion, but only half way: Article R17 implements only a part of the Common Elements, and omits certain other areas completely, areas which must however now be regarded as indispensable (such as management systems).

   In order for this gap to be closed, it is proposed that on the one hand, ***Article R17 be structured more clearly*** *(geared to the structure of the Common Elements) and that* ***the requirements that are still missing be adopted****; the formulations must, in the view of the authors, be selected very clearly and unambiguously, in order to eliminate all room for interpretation. The benefit of such a solution would be that it would ultimately produce a* ***Community legal instrument*** *which would* ***no longer leave any leeway for the (international) standardization organizations*** *and which would take effect horizontally in accordance with the concept of the New Legislative Framework as a whole. The procedure is also consistent with what is probably the prevailing policy in Europe, namely of intervening by regulatory means, as can be seen in the tightening of regulations in the areas of accreditation and market surveillance.*

> *In order for bodies seeking notification to be accredited and notified consistently in Europe, however, this procedure* ***must be supplemented by a more detailed specification of the technical requirements for certain products/areas of technology and if necessary for the associated conformity assessment tasks (modules)****. The reason for this need is that neither the catalogue of requirements in R17, nor the standards are able to provide a yardstick that is applied in the same way by the Member States. For general formulations which appear both in the decision and in standards, such as "competence required", "range of expertise" or "sufficient appropriate experience",* ***measurable minimum requirements must be agreed by the Member States*** *in order for equivalent assessments to be possible.*
>
> *The experience to date with the directive networks set up in 2009 by the European Cooperation for Accreditation (EA) under its Horizontal Harmonisation Committee (HHC) has shown that the national accreditation bodies have only limited familiarity with the directives. Since responsibility for notification lies with the notifying authorities, it is recommended that these minimum requirements be developed not by the "body recognised" under Article 14 of Regulation 765/2008/EC, but by the Member States in the working groups for the directives concerned.*

The research group's recommendation is therefore that Decision 768/2008/EC Annex I Article R17 be revised and substantiated. In addition, the Member States should, in the working groups for the respective directives, draw up measurable minimum requirements underpinning the particular technical requirements for certain classes of product and areas of technology and if necessary describing the respective conformity assessment tasks. These requirements would serve as "sectoral accreditation systems" forming a basis for accreditation and notification.

Annex 1

Comparison of the Common Elements in KAN Report 30 with the requirements stated in ISO/PAS 17001 to 17005

The following tables compare the requirements proposed as Common Elements in KAN Report 30, Section 5.2 (left-hand column) and the obligatory requirements of the technical rules (Publicly Available Specifications, PAS) developed by CASCO WG 23

ISO/PAS 17001 Technical Rule, 2005-10 Conformity assessment – **Impartiality** – Principles and requirements

ISO/PAS 17002 Technical Rule, 2004-08 Conformity assessment – **Confidentiality** – Principles and requirements

ISO/PAS 17003 Technical Rule, 2004-08 Conformity assessment – **Complaints and appeals** – Principles and requirements

ISO/PAS 17004 Technical Rule, 2005-10 Conformity assessment – **Disclosure of information** – Principles and requirements

ISO/PAS 17005 Technical Rule, 2008-07 Conformity assessment – **Use of management systems** – Principles and requirements

It is clear on the one hand that the formulations in ISO/PAS fall short, in some areas considerably, of the requirements proposed by KAN (for example concerning independence). This is particularly conspicuous in the "Structure" table, since several elementary areas of regulation such as legal responsibility, liability, financial stability and participation in co-ordination tasks have no equivalents in the ISO/PAS. Equally, the reporting requirements (cf. "Process (excerpt)" table A3) have only rudimentary equivalents in the ISO/PAS.

Finally, the "Management system" table shows that the essential subject-matter of regulation has been addressed in the corresponding ISO/PAS by key terms. With the reduction to key terms of requirements such as the control of documents, control of records or management assessment, however, the declared objective of future standards containing identical requirements is unlikely to be attained.

Table A1: "Structure"

Common Elements - KAN Report 30 Chapter 5.2	PAS 17001 – Impartiality	PAS 17002 – Confidentiality
5.2.1 Structure		
1 Legal responsibility		
The conformity assessment body must be a registered legal person or a part of a registered legal person.		
Note: owing to their governmental status, state conformity assessment bodies are deemed to be legal persons. Where the conformity assessment body forms part of a larger government body, the government shall be responsible for identification of the conformity assessment bodies in a manner which permits no conflict of interest with the state accreditation bodies or market surveillance authorities. Pursuant to these provisions, the conformity assessment body shall be regarded as a "registered legal person".		
2 Organization and responsibilities		
2.1 Structure and modus operandi of a conformity assessment body shall be such that confidence in their conformity assessment activities is assured.	6.3 Structural (Obligatory) requirements: Conformity assessment activities shall be structured and managed so as to safeguard impartiality.	
2.2 The conformity assessment body shall be responsible for its activities and decisions, including the issue, maintenance, extension, restriction, suspension and withdrawal of conformity assessment certificates.		
2.3 The conformity assessment body shall possess a description of its legal status which shall include where applicable the names of its owners and, where these are not the same persons, the names of the persons with control over the conformity assessment body.		
2.4 The conformity assessment body shall document the functions, responsibilities and authority of top-level management and of further personnel who may have an influence upon the performance and results of the conformity assessment activities.		
2.5 The conformity assessment body shall appoint the top-level management (group(s) or person(s)) who shall possess complete authority and bear complete responsibility for		

Common Elements - KAN Report 30 Chapter 5.2	PAS 17001 – Impartiality	PAS 17002 – Confidentiality
a) the development of arrangements for the modus operandi of the conformity assessment body;		
b) supervision of implementation of the arrangements and procedures;		
c) supervision of the conformity assessment body's finances;		
d) decisions taken by the conformity assessment body;		
e) contractual agreements;		
f) the delegation of authority to committees or individuals, where necessary, for the performance of defined activities in the name of top-level management.		
2.6 The conformity assessment body shall document its entire organizational structure by the recording of authority and responsibilities.		
3 Independence and impartiality	**6.2 General (Obligatory) requirements**	
3.1 The conformity assessment body shall be organized and operated in such a manner as to ensure independence, objectivity and impartiality in its activities, and shall introduce and maintain a documented structure for assurance of its impartiality.	6.2.1.1 Conformity assessment activities shall be undertaken impartially.	
	6.2.1.5 The body shall have top management commitment to impartiality.	
3.2 The arrangements and procedures of the conformity assessment body shall not be discriminatory and shall be carried out in a nondiscriminatory manner. The conformity assessment body shall make its services available to any party seeking conformity assessment which falls within the body's scope of activity.		
3.3 The conformity assessment body and its personnel shall not be subject to any influence, in particular of a financial nature, upon their evaluation and the results of their conformity assessments, in particular to influence by persons or groups of persons with an interest in the results of the activities.	6.2.1.2 The body shall be responsible for the impartiality of its conformity assessment activities and shall not allow commercial, financial or other pressures to compromise impartiality.	
3.4 The conformity assessment body shall ensure that each conformity assessment decision is taken by competent persons or committees. These shall not be identical to the parties performing the conformity		

Common Elements - KAN Report 30 Chapter 5.2	PAS 17001 – Impartiality	PAS 17002 – Confidentiality
assessment activities concerned.		
3.5 The conformity assessment body and other parts of the legal person to which it belongs shall not offer or provide any activities or supplementary services which call into question their competence, objectivity, impartiality or independence.		
3.6 The conformity assessment body, its top-level management, and the staff charged with conducting the conformity assessment activities shall not be identical to the designer, manufacturer, suppler, installer, user or operator of the products assessed by the body for conformity, nor may they be a representative of a person involved in these activities. They must be independent both of the manufacturers for whom the body conducts conformity assessment activities and of their competitors, and shall not be involved either directly or as representatives in the planning, construction, sale, installing or maintenance of these products.		
3.7 The conformity assessment body and its personnel - whether directly employed or subcontracted - shall not offer or perform or have offered or have performed consultancy services to the manufacturer, the representative, a supplier or their competitors, in particular consultancy services concerning the design, manufacture, marketing or maintenance of the products concerned, within the context of its conformity assessment activities. This does not however preclude the exchange of technical information between the manufacturer of the products and the conformity assessment body.		
3.8 The conformity assessment body and its personnel shall not bear any responsibility for market surveillance.		
Note: should the conformity assessment bodies and market surveillance authorities in a Member State be responsible to the same authority, the areas of competence shall be organized such that no conflict of interest exists between the two bodies.		
3.9 The conformity assessment body shall ensure that the activities		

Common Elements - KAN Report 30 Chapter 5.2	PAS 17001 – Impartiality	PAS 17002 – Confidentiality
performed by associated bodies (see Section 3.10) do not jeopardize the confidentiality, objectivity and impartiality of its conformity assessment activities. An associated body in the context of Section 3.10 shall not be the designer, manufacturer, supplier, installer or operator of the products the conformity of which is assessed by the conformity assessment body.		
3.10 An associated body is a legal person in its own right which is associated with the conformity assessment body in one or more of the following ways: • common ownership with influence upon the conformity assessment activities of the conformity assessment body; • common top-level management for the activities described in Section 2.5; • common personnel for the conformity assessment activities of the conformity assessment body; • contractual agreements with a bearing upon the conformity assessment activities of the conformity assessment body; • common names and logo and/or symbols	6.2.1.4 If a risk to impartiality is identified, the body shall be able to demonstrate how it eliminates or minimizes such risk.	
Note: in the context of Section 1, a separate part of the public administration outside the governmental conformity assessment body shall be regarded as an associated body.		
3.11 The conformity assessment body shall have in place documented procedures for the identification, examination and resolution of all cases in which a conflict of interest is suspected or proven. It shall establish, investigate and document the relationship to the associated bodies in order to identify conflicts of interest, irrespective of whether they have their origin in the conformity assessment body or the activities of the associated body. Should conflicts be identified, suitable measures shall be taken.	6.2.1.3 The body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel (see 6.4.1). However, such relationships do not necessarily present a body with a risk to impartiality. NOTE A relationship that threatens the impartiality of the body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing	

Common Elements - KAN Report 30 Chapter 5.2	PAS 17001 – Impartiality	PAS 17002 – Confidentiality
	(including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.	
4 Confidentiality and secrecy		
4.1 The conformity assessment body shall take suitable precautions to ensure the confidentiality on all levels, including those of its committees and subcontractors, of the information which comes into its possession during the proper performance of its conformity assessment activities.		a) The body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of conformity assessment activities. The body shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.
4.2 The conformity assessment body shall ensure by legally binding contracts with the personnel employed that professional secrecy and the regulations implementing the provisions of Section 4.1 are observed.		
4.3 Confidential information shall not be communicated to other parties without the written consent of the organization or person concerned, except vis-à-vis the competent authorities or in cases where required by legislation.		b) When the body is required by law or authorized by contractual arrangements to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided. c) Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be treated as confidential.
5 Liability		
The conformity assessment body shall have taken precautions to enable it to cover claims for liabilities arising from		

Common Elements - KAN Report 30 Chapter 5.2	PAS 17001 – Impartiality	PAS 17002 – Confidentiality
its conformity assessment activities. It shall take out liability insurance, unless such liability is assumed by the state on the basis of national legislation or the conformity assessment activities are conducted by the Member State itself.		
6 Financial stability		
The conformity assessment body shall have at its disposal the financial resources required to conduct its business operations and shall document and provide evidence said resources. The conformity assessment body shall be in possession of a description of its source(s) of income.		
7 Participation in co-ordination activities		
The conformity assessment body shall participate in national and international co-ordination activities by and between the conformity assessment bodies organized by government bodies in order to attain maximum coherence of conformity assessment activities.		
Note: participation in international co-ordination activities shall not be mandatory where a principle of delegation is agreed at national level and it is assured that the body remains informed of the decisions and documents drawn up by the relevant group of conformity assessment bodies and applies said decisions and documents.		

Table A2: “Resources/Personnel”

Common Elements – KAN Report 30 Chapter 5.2	**PAS 17001 – Impartiality**	**PAS 17002 – Confidentiality**
5.2.2.1 Personnel		
...		
1.3 The impartiality of the personnel must be guaranteed (see also Chapter 5.2.1, Section 3). Remuneration of the personnel may not stand in relation to the number of conformity assessments conducted by them, nor to the results of the same.		
1.4 The conformity assessment body shall record the scope and limits of the duties, responsibilities and authority of each person concerned.		
1.5 The conformity assessment body shall require all personnel to undertake formally by signature or equivalent form of confirmation to observe the rules laid down by it. The obligation shall consider aspects concerning confidentiality, economic independence and possible conflicts of interest, and all existing and previous relationships to the clients concerned.	**6.4 Resource (Obligatory) requirements:** All personnel of the body, either internal or external, that could influence the conformity assessment activities, shall act impartially.	5.3.1 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the body's behalf, shall keep confidential all information obtained or created during the performance of the body's conformity assessment activities, except as required by law.

Table A3: “Process” (Excerpt)

Common Elements – KAN Report 30 Chapter 5.2 – Process	**PAS 17003 – Complaints and appeals**	**PAS 17004 – Disclosure of information**
7 Duty to report		
7.1 Vis-à-vis customers		
The conformity assessment body shall maintain the following information at its customers' disposal which is to be updated at appropriate intervals:		
a) information on the conformity assessment programme to be performed;		The body [...] shall upon request provide a general description of the conformity assessment system and the status of the attestation for objects of conformity it has assessed.
b) information on the requirements to be met (laws and regulations, basic requirements, harmonized standards, etc.);		
c) general information on the fees/prices of conformity assessments;		
d) a description of the rights and duties of the conformity assessment bodies and of customers;		
e) information on complaints and appeals procedures.	b) A description of the handling process for complaints and appeals shall be available to any interested party on request.	
7.2 Vis-à-vis authorities		
The conformity assessment body shall inform the competent authority immediately of:		
a) essential changes in particular concerning its legal form, organization, *modus operandi*, personnel and subcontractors;		
b) any incidents coming to its attention relating to products within the scope of the conformity assessment certificates which it has issued;		
c) all conformity assessment certificates issued, suspended, withdrawn or denied, except where regulated to the contrary in the case concerned or by statute.		
7.3 Vis-à-vis third parties		
The conformity assessment body shall upon request provide public access to the status of the conformity assessment certificates which it has issued, except where otherwise regulated by statute.		

Table A4: “Management systems”

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	**PAS 17005 – Use of management systems**	**PAS 17003 – Complaints and appeals**
Management systems		
The conformity assessment body shall introduce, implement and maintain a management system and continually improve its effectiveness in compliance with the requirements laid down for conformity assessment bodies.344 The following sections define general requirements applicable to the management system of conformity assessment bodies.	**5.2.1** The body shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this <insert correct description; e.g. International Standard>. In addition to meeting the requirements of clauses <insert the relevant clauses of the International Standard in question> the body shall implement a management system in accordance with 5.2.4 (option A) or with 5.2.5 (option B). 5.2.2 The ISO/CASCO working groups shall elaborate clauses covering the aspects listed below. The body shall a) identify the processes needed for the management system and their application throughout the body, b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the body in accordance with the requirements of this <insert correct description; e.g. International Standard>. NOTE Processes needed for the management system referred to above can include processes for management activities, provision of resources and other conformity assessment processes.	

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	PAS 17005 – Use of management systems	PAS 17003 – Complaints and appeals
	5.2.2 The ISO/CASCO working groups shall elaborate clauses covering the aspects listed below. The body shall a) identify the processes needed for the management system and their application throughout the body, b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the body in accordance with the requirements of this <insert correct description; e.g. International Standard>. NOTE Processes needed for the management system referred to above can include processes for management activities, provision of resources and other conformity assessment processes.	
	5.2.3 Where a body chooses to outsource any process that affects conformity with requirements, the body shall ensure control over such processes. Control of such outsourced processes shall be identified within the management system.	
1 General requirements		

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	PAS 17005 – Use of management systems	PAS 17003 – Complaints and appeals
1.1 Top-level management of the conformity assessment body shall define and document arrangements and quality targets, including a quality policy, for its activities and shall demonstrate its obligation regarding the quality and compliance with the requirements laid down for conformity assessment bodies. Management shall ensure that the fundamental arrangements are understood, implemented and maintained at all levels of the conformity assessment body. The objectives shall be measurable and shall conform to the fundamental arrangements applicable to the conformity assessment body.		
1.2 The conformity assessment body shall operate a management system appropriate to the nature, area and scale of its activities. All applicable requirements shall be addressed either in the manual or in the associated documents. The conformity assessment body shall ensure that the manual and the associated documents are accessible to all personnel. It shall further ensure that the procedures of the system are implemented effectively.		
1.3 Top-level management of the conformity assessment body shall designate a member of the managerial staff who - independent of other responsibilities – shall have responsibility and authority to:		
a) ensure that the processes required for the management system are introduced, implemented and maintained;		
b) report to top-level management on the performance of the management system and any need for improvements.		
	5.2.4 (Option A) As a minimum, the management system of the body shall address the following:	
2 Document control	management system manual, including policies and responsibilities;	

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	PAS 17005 – Use of management systems	PAS 17003 – Complaints and appeals
The conformity assessment body shall lay down procedures for the control of all documents relating to its conformity assessment activities. The procedures shall define the measures required to: a) confirm the appropriate nature of documents prior to issue;	control of documents;	
b) revise and update documents where necessary and to re-attest them;		
c) assure that amendments and the current revision status of the documents are identifiable;		
d) assure that the relevant versions of the documents concerned are available to the personnel, to subcontractors and to customers where they are needed;		
e) assure that the documents remain legible and easily identified;		
f) assure that documents of external origin are marked and their distribution controlled;		
g) prevent accidental use of outdated documents and to mark such documents appropriately should they be retained for any purpose;		
h) assure where relevant the confidentiality of documents.		
3 Records	control of records;	
3.1 The conformity assessment body shall lay down procedures for the identification, collection, registration, access, filing, storage, care and disposal of its records.		
3.2 The conformity assessment body shall have at its disposal procedures for controlling the storage of records for a period corresponding to its contractual and legal obligations. Access to these records shall be controlled in accordance with the confidentiality agreements.		
4 Complaints and appeals procedure	complaints and appeals (ISO/PAS 17003).	

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	**PAS 17005 – Use of management systems**	**PAS 17003 – Complaints and appeals**
The conformity assessment body shall establish a procedure for the handling of complaints. The conformity assessment body shall:		**6.2 a)** The conformity assessment body shall have a documented process to receive, evaluate and make decisions on complaints and appeals. **b)** A description of the handling process for complaints and appeals shall be available to any interested party on request. **c)** Upon receipt of a complaint, the body shall confirm whether the complaint relates to conformity assessment activities that it is responsible for and, if so, shall deal with it. **d)** The body shall be responsible for all decisions at all levels of the handling process for complaints and appeals. **e)** Investigation and decision on appeals shall not result in any discriminatory actions.
a) reach a decision concerning the justification for the complaint;		
b) assure that complaints concerning customers of the conformity assessment body are first dealt with by the customers themselves;		
c) designate for the investigation of complaints a person or group of persons who are competent and independent of the subject of the complaint;		
d) take corresponding measures and assess their effectiveness;		
e) inform the customers of the final decision(s) of the conformity assessment body;		
f) maintain records concerning all complaints, final decisions and follow-up measures taken.		
5 Nonconformances and corrective measures	corrective actions;	

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	PAS 17005 – Use of management systems	PAS 17003 – Complaints and appeals
The conformity assessment body shall establish procedures for the identification and control of nonconformances within its own activities. The conformity assessment body shall further take corrective measures, where necessary, to eliminate the cause of the nonconformances and to prevent their recurrence. The corrective measures must be appropriate to the consequences resulting from the difficulties which have arisen. The procedures shall encompass the following:		
a) identification of nonconformances (e.g. from complaints and internal audits);		
b) identification of the causes of nonconformances;		
c) assessment of the need for measures to ensure that the nonconformances do not recur;		
d) establishment and timely implementation of the necessary corrective measures;		
e) recording of the results from the corrective measures taken;		
f) review of the corrective measures taken and their efficacy.		
6 Preventive measures	preventive actions;	
The conformity assessment body shall establish procedures by which scope for improvement may be identified and preventive measures taken, in order to exclude potential causes of nonconformances. The preventive measures shall be commensurate with the consequences of the potential problems. The procedures for preventive measures shall establish requirements for		
a) recognition of possible nonconformances and their causes;		
b) establishment and implementation of the requisite preventive measures;		
c) recording of the results from the measures taken;		
d) examination of the efficacy of the preventive measures taken.		
7 Internal audits	internal audits;	

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	PAS 17005 – Use of management systems	PAS 17003 – Complaints and appeals
7.1 The conformity assessment body shall audit its activities in order to demonstrate that they satisfy the requirements established for conformity assessment bodies and that the management system is being implemented and maintained.		
Note: ISO 19011 provides guidance documents for the performance of internal audits.		
7.2 Internal audits must generally be performed at least annually. The frequency of internal audits may be reduced should the conformity assessment body be able to demonstrate that its management system has been implemented effectively and has proved stable. An audit programme shall be planned which makes allowance for the status and the significance of the areas to be audited and the results of past audits.		
7.3 The conformity assessment body shall ensure that:		
a) Internal audits are performed by personnel possessing sound expertise in conformity assessment issues, in the performance of audits and in the requirements placed upon conformity assessment bodies;		
b) internal audits are performed by persons other than those performing the activity to be audited;		
c) the personnel responsible for the area to be audited is informed of the audit results;		
d) timely and appropriate measures are taken;		
e) all possibilities for improvement are identified.		
8 Management assessments	management review;	
8.1 Top-level management of the conformity assessment body shall establish procedures for regular assessment of its management system in order to assure the latter's sustained suitability and efficacy with regard to fulfilment of the relevant requirements and of the established quality policy and quality targets. These assessments should normally be performed once each year.		

Common Elements – KAN Report 30 Chapter 5.2 – Management systems	PAS 17005 – Use of management systems	PAS 17003 – Complaints and appeals
8.2 The inputs for the management assessments shall contain, where available, the current performance and the possibilities for improvement with regard to		
a) audit results;		
b) results of assessments, where applicable;		
c) participation in international activities, where applicable;		
d) feedback from interested parties;		
e) performance of the conformity assessment process;		
f) nonconformance trends;		
g) follow-up measures from past management assessments;		
h) attainment of targets;		
i) changes which may influence the management system;		
j) analysis of complaints and appeals.		
8.3 The results of the management assessment shall contain measures relating to:		
a) improvement of the management system and its processes;		
b) improvement of services and of the conformity assessment process in compliance with the relevant standards and the expectations of the interested parties;		
c) the need for resources;		
d) definition or redefinition of fundamental arrangements and objectives.		

Annex 2

Comparison of the requirements formulated in Decision 768/2008/EC Chapter R4, Article R17 with the requirements formulated in ISO/PAS 17001 to 17005

The table below shows a comparison between (in the left-hand column) the requirements formulated in Article R17 of Decision 768/2008/EC, and the obligatory requirements of the technical rules (Publicly Available Specifications, PAS) developed by CASCO WG 23 (in the right-hand columns).

> **ISO/PAS 17001** Technical Rule, 2005-10 Conformity assessment – **Impartiality** – Principles and requirements
>
> **ISO/PAS 17002** Technical Rule, 2004-08 Conformity assessment – **Confidentiality** – Principles and requirements
>
> ISO/PAS 17003 Technical Rule, 2004-08 Conformity assessment - **Complaints and appeals** - Principles and requirements (requirements not shown, since R17 has no equivalent)
>
> **ISO/PAS 17004** Technical Rule, 2005-10 Conformity assessment – **Disclosure of information** – Principles and requirements
>
> **ISO/PAS 17005** Technical Rule, 2008-07 Conformity assessment – **Use of management systems** – Principles and requirements

The sub-headings in the left-hand column have been added in the interests of greater clarity and comparability with the tables in Annex 1. They are intended to facilitate the identification of related regulatory content. Owing to the differences in approach between the formulations in R17 and in the ISO/PAS, precise comparison of the requirements is not always possible. The sub-headings are also intended to illustrate that the structure in R17 leaves room for improvement, in order for systematic checking of compliance with requirements to be possible at notified bodies.

Table A5: Comparison of requirements formulated in Article R17 with obligatory requirements formulated in CASCO PAS

Decision 768/2008/EC Chapter R4, Article R17 (*subtitles by author*)	**PAS 17001 – Impartiality**	**PAS 17005 – Use of management systems**
Legal responsibility		
2. A conformity assessment body shall be established under national law and have legal personality.		
Independence and impartiality (I)		
3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.	6.2.1.1 Conformity assessment activities shall be undertaken impartially.	
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, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.		
4. A conformity assessment 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 such products for personal purposes.		
A conformity assessment 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, or 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 shall in particular apply to consultancy services.	6.4.1 All personnel of the body, either internal or external, that could influence the conformity assessment activities, shall act impartially.	
Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.		

Decision 768/2008/EC Chapter R4, Article R17 (*subtitles by author*)	PAS 17001 – Impartiality	PAS 17005 – Use of management systems
Competence (I) and independence (II)		
5. Conformity assessment 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 shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.		
Resources, competence (II), procedures		
6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by … [reference to relevant part of the legislation] and in relation to 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. At all times and for each conformity assessment procedure and 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: (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks; (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;		5.2.1 The body shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this <insert correct description; e.g. International Standard>. In addition to meeting the requirements of clauses <insert the relevant clauses of the International Standard in question> the body shall implement a management system in accordance with 5.2.4 (option A) or with 5.2.5 (option B). 5.2.2 The ISO/CASCO working groups shall elaborate clauses covering the aspects listed below. The body shall a) identify the processes needed for the management system and their application throughout the body, b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the

Decision 768/2008/EC Chapter R4, Article R17 (*subtitles by author*)	PAS 17001 – Impartiality	PAS 17005 – Use of management systems
		operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes. These processes shall be managed by the body in accordance with the requirements of this <insert correct description; e.g. International Standard>. NOTE Processes needed for the management system referred to above can include processes for management activities, provision of resources and other conformity assessment processes.
		5.2.3 Where a body chooses to outsource any process that affects conformity with requirements, the body shall ensure control over such processes. Control of such outsourced processes shall be identified within the management system.
		5.2.4 (Option A) As a minimum, the management system of the body shall address the following: [bullet points and reference to **ISO/PAS 17003 Complaints and Appeals** omitted since R17 does not specify any requirements concerning management systems]
Competence (III)		

Decision 768/2008/EC Chapter R4, Article R17 (*subtitles by author*)	PAS 17001 – Impartiality	PAS 17005 – Use of management systems
7. The personnel responsible for carrying out conformity assessment activities shall have the following:		
(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;		
(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;		
(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Community harmonisation legislation and of its implementing regulations;		
(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.		
Independence and impartiality (III)		
8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.	6.3.1 Conformity assessment activities shall be structured and managed so as to safeguard impartiality. 6.2.1.2 The body shall be responsible for the impartiality of its conformity assessment activities and shall not allow commercial, financial or other pressures to compromise impartiality.	
The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.	6.2.1.3 The body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel (see 6.4.1). However, such relationships do not necessarily present a body with a risk to impartiality. NOTE A relationship that threatens the impartiality of the body can be based on ownership, governance, management, personnel, shared resources, finances, contracts,	

Decision 768/2008/EC Chapter R4, Article R17 (*subtitles by author*)	PAS 17001 – Impartiality	PAS 17005 – Use of management systems
	marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.	
	6.2.1.4 If a risk to impartiality is identified, the body shall be able to demonstrate how it eliminates or minimizes such risk.	
	6.2.1.5 The body shall have top management commitment to impartiality.	
Liability insurance		
9. Conformity assessment 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.		
Confidentiality		
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under … [reference to the relevant part of the legislation] or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.	**PAS 17002 – Confidentiality** 5.2 a) The body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of conformity assessment activities. The body shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.	**PAS 17004 – Disclosure of information** The body, or the issuer of a supplier's declaration of conformity, shall upon request provide a general description of the conformity assessment system and the status of the attestation for objects of conformity it has assessed.

Decision 768/2008/EC Chapter R4, Article R17 (*subtitles by author*)	PAS 17001 – Impartiality	PAS 17005 – Use of management systems
	b) When the body is required by law or authorized by contractual arrangements to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided. c) Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be treated as confidential.	
	5.3.1 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the body's behalf, shall keep confidential all information obtained or created during the performance of the body's conformity assessment activities, except as required by law.	
Participation in co-ordination activities		
11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are 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.		