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**STANDARDISATION MANDATE TO CEN/CENELEC/ETSI
CONCERNING THE USE OF QUALITY SYSTEMS IN THE CONTEXT OF
COMMUNITY "NEW APPROACH" DIRECTIVES**

1. GROUNDS

- 1.1. On 22 July 1993 the Council adopted Decision 93/465/EEC¹ concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives.
- 1.2. This Decision has been applied in most of the "New approach" directives. It comprises three quality assurance modules:
 - module D: production quality assurance;
 - module E: product quality assurance;
 - module H: full quality assurance.
- 1.3. For each of these modules, harmonised standards may be used. These are EN 29002 (now EN ISO 9002) in the case of module D, EN 29003 (now EN ISO 9003) in the case of module E and EN 29001 (now EN ISO 9001) in the case of module H.
- 1.4. ISO is currently preparing a new version of the standards in the ISO 9000 series. The text under examination comprises two standards, the future ISO 9001:2000 "Quality management systems - Requirements" and ISO 9004:2000 "Quality management systems – Guidance for performance improvement". These standards will be accompanied by ISO 9000:2000 "Quality management systems - Fundamentals and vocabulary".

¹ OJ L 220, 30.8.1993, p. 23.

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- 1.5. The future ISO 9001:2000 standard will combine in a single document the quality assurance systems of the current ISO 9001, ISO 9002 and ISO 9003. Furthermore, it will cover services as well as products.
- 1.6. The future ISO 9001:2000 standard is primarily aimed at meeting customer requirements. However, organisations applying the standard for the purposes of the "New Approach" directives must meet the requirements of these directives. Guidelines are therefore needed to assist organisations to apply the standard in a manner that permits a presumption of conformity with these directives.

2. DESCRIPTION OF THE MANDATED WORK

2.1. Phase I

2.1.1. In parallel with the adoption of ISO 9001:2000, CEN, CENELEC and ETSI shall draw up an informative annex to this standard.

2.1.2. The annex must:

- be applicable to the legislative texts adopted under the new approach which call for a quality assurance system;
- ensure that the quality assurance system addresses the essential requirement laid down in the applicable directive(s);
- ensure, when applied, a presumption of conformity to the applicable directive(s);

2.1.3. To this end, the annex must in particular:

- provide a list of clauses of the standard corresponding to each of the points of the quality assurance modules laid down in Council Decision 93/465/EEC.
- indicate which clauses of the standard are not directly relevant to the application of the various modules;
- provide for the quality assurance system to incorporate an internal audit to examine all the changes made to production in order to determine whether they are compatible with the requirements of the directives. If the changes are significant, the notified body responsible for the external audit will have to be contacted as provided for in the legislation.

2.1.4. The proposed text must follow the terminology and numbering of the future ISO 9001:2000 standard as closely as possible in the interests of coherence, to enable a manufacturer with a quality assurance system based on ISO 9001:2000 (not linked to the European legislation) to indicate which parts of the system correspond to the directive.

2.1.5. CEN, CENELEC and ETSI shall work in liaison with ISO/TC 210 "Quality management and corresponding general aspects for medical devices", which is preparing a standard for applying quality assurance systems to medical devices that can probably be generalised.

- 2.1.6. A high degree of compatibility with EN ISO 9001, EN ISO 9002 and EN ISO 9003 should be ensured in order to avoid discontinuity between the current situation and the future application of EN ISO 9001:2000.
- 2.1.7. CEN, CENELEC and ETSI must ensure appropriate consultation and collaboration with ISO/TC 176/SC 2 in the execution of this mandate. Manufacturers, notified bodies, the European Commission and the authorities responsible for designating notified bodies in the Member States should also be involved or consulted.
- 2.1.8. The draft informative annex shall be submitted to the Commission, which shall inform national authorities via the 98/34 Committee.

2.2. Phase II

- 2.2.1 The Commission shall, after consulting the 98/34 Committee, either:
- request CEN, CENELEC and ETSI to adopt the informative annex produced in phase I, or
 - request CEN, CENELEC and ETSI to prepare, on the basis of the informative annex produced in phase I, a separate standard for the use of quality systems in the context of the “New Approach” directives.

3. EXECUTION OF THE MANDATE

- 3.1. CEN, CENELEC and ETSI shall present a draft informative annex to the Commission no later than **3 months** following the adoption of ISO 9001:2000. The work to be undertaken and the results must be co-ordinated, compatible and mutually acceptable to CEN, CENELEC and ETSI. This annex must be adopted by CEN, CENELEC and ETSI **no later than the date of withdrawal** of EN ISO 9001:1994, EN ISO 9002:1994 and EN ISO 9003:1994. The three language versions (DE, EN, FR) must be available on this date, together with the correct titles in the other Community languages.
- 3.2. If the Commission requests the standard foreseen in phase II, the same conditions as under 3.1 shall be applied, for the adoption of the European standard (EN).
- 3.3. In addition, CEN, CENELEC and ETSI shall submit to the Commission, no later than **3 months** following the acceptance of this mandate, a report on all standardisation activities they are undertaking relating to quality assurance systems, including any sector-specific standards. This report shall also describe the co-ordination mechanisms they have put in place to ensure coherence among these activities.
- 3.4. Any European standard(s) adopted must be incorporated into national standards and any divergent national standards must be removed from the catalogues of the national standardisation bodies in the Member States within six months of adoption of the European standards.

3.5. The acceptance of this standardisation mandate by CEN, CENELEC and ETSI will open the standstill period referred to in Article 7 of Directive 98/34/EC of 22 June 1998.²

² OJ L 204, 21.7.1998, p. 37, as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).