



EUROPEAN COMMISSION

DIRECTORATE-GENERAL III
INDUSTRY

Directorate B : Legislation and standardization and telematics networks
Standardization

Brussels, 14 June 1995

M/096

Mandate to CEN/CENELEC/ETSI for a study on the feasibility of the conversion of the criteria for conformity assessment bodies set out in the EN 45000 series standards to a functional activity basis

1. BACKGROUND.

1.1 The development of standards in the area of conformity assessment.

In 1986, the Commission, at the request of the Council, drew up a new policy in the field of conformity assessment, leading to the issue of the Commission Communication of 15 June 1989 on a Global Approach to Certification and Testing (OJEC C 267/3 of 19 October 1989) and the Council Resolution of 21 December 1989 on a global approach to conformity assessment (OJEC No. C 10/1 of 16 January 1990).

The intention of the Commission was to rely on the professionals in the field, on condition that means were found to demonstrate their technical competence. This implied that criteria had to be found for the evaluation of such bodies, and that independent means for evaluating them had to be devised.

Accordingly, in 1987 the Commission issued a mandate to CEN (BC/CEN/14/87) to draw up European standards giving criteria and recommendations for the evaluation of such bodies. This became the EN 45000 series of standards, which set out (1989) the criteria for testing laboratories and certification bodies (for products, personnel and quality systems), the procedures for assessing laboratories, and the criteria for accreditation bodies that evaluate laboratories. This series was largely based on existing ISO/IEC Guides. The criteria for inspection bodies have been only recently covered by EN 45004 (95) standard.

1.2 Difficulties encountered in practice.

Experience in the use of these standards has revealed a number of difficulties in the operation of the system set up by the European standards. These may be summarised as follows:

- the incompleteness of the series;
- the inspection problem;

- a certain lack of clarity as to the links between the EN 45000 series and the modules for conformity assessment set out in Council Decision 90/683/EEC (amended and brought up to date by Council Decision 93/465/EEC);
- the relationship with ISO/IEC work.

A detailed analysis of these issues, anticipated by the Commission paper CERTIF 94/5 and largely discussed among Member States officials for Standardization and operators involved in the conformity assessment area, is attached at Appendix A.

It is considered that there is now sufficient practical experience for the development of an overall position which will bring clarity, efficiency and improved credibility to these standards. In particular, there is a need to consider the question of the extent to which the criteria of the EN 45000 series can be reorganised to reflect the functions being carried out rather than the structures involved in the tasks. It is the purpose of this mandate to request the European Standardization Institutions to examine these questions and to make recommendations for action in this area.

2. DESCRIPTION OF THE MANDATED WORK.

CEN, CENELEC and ETSI, in close co-operation with EOTC, are requested to carry out a study on the conversion of the criteria of the EN 45000 series of standards in such a way as to reflect the *functions* of the conformity assessment process rather than the structure of the bodies involved in the process.

In carrying out the study, the European Standardization Institutions shall review the entire position relating to the existing and planned parts of the EN 45000 series of standards and related issues, and address each of the problems mentioned in clause 1 above and treated in detail in Appendix A.

The European Standardization Institutions shall make proposals for a new structure for this series of standards to reflect these orientations, and for its extension to include aspects of the conformity assessment and accreditation process that are not currently covered or on the way to be covered. The proposals shall include:

- The number and proposed content of the standards;
- A list of, and definitions for, the functions and activities to be covered;
- The relationships between the functions;
- The means of ensuring that the European standards remain coherent with international work, particularly that of ISO/IEC.

The study shall take account of requirements - existing, and in preparation - at international and European level, for example, those of the ISO/IEC. A list (not intended

to be exhaustive) of documents to be taken into consideration in the course of the study is attached at Appendix B.

The study shall address the question of the integration of the ISO 10 011 series of standards for the qualification of auditors into the new structure proposed for the replacement of the EN 45000 series.

3. BODIES TO BE ASSOCIATED.

The study shall be carried out by the appropriate structures of the European Standardization Institutions in close co-operation with EOTC and with the broadest possible constituency of interested parties. In particular, in drawing up the report and recommendations, the views of economic operators shall be taken fully into account, as well as those specifically involved in conformity assessment, in particular through effective participation through CEN/CENELEC TC1.

4. EXECUTION OF THE REQUEST.

- 4.1 CEN, CENELEC and ETSI shall deliver a joint and mutually agreed report, covering the issues described in clause 2 above, and including a proposed structure for a revised series of European standards to replace the current EN 45000 series, to the Commission within three months of the acceptance of this mandate.
- 4.2 Following consideration of this report by the Commission, the issue of a further mandate for a programme of standards to replace the EN 45000 series is envisaged.

APPENDIX A

DETAILS OF QUESTIONS TO BE ADDRESSED.

A Identified problems

1) Incomplete nature of the series.

When work started on the series in the Community, it was within the context of drawing up the first technical tools of the "Global approach" to testing and certification, and the work was limited to treating the Community priorities, which were just that at the time: testing and certification. The series therefore firstly set out the criteria for calibration and testing activities and for organisations certifying products, personnel and quality systems. The "inspection" gap has been only recently filled up by EN 45004 (95) standard.

The series is still incomplete in that it does not set out the assessment procedures and operating criteria for the accreditation bodies carrying out the accreditation of certification bodies and of "inspection bodies", which is so important to support notification of "notified bodies", within the context of new approach directives.

2) The "inspection problem"

The very manner in which the EN 45001 and EN 45011/12/13 are written has made it extremely difficult for the standardisation bodies to fill in the "inspection gap", because the present series are oriented towards setting criteria for bodies and not for functions. This has created difficulties in that the "inspection" function is very often carried out either by testing laboratories or by certification bodies and yet none of the present EN 45000 series of standards really cover the issue of the professional judgement which is inherent in "inspection". In fact the definition of "inspection" under the EN 45004 standard could well cover all activities of conformity assessment.

By defining bodies rather than functions, it has proved very difficult to draw up a clear definition of inspection, in between testing laboratories and certification bodies. Moreover, the standards being written for bodies have tried to write certain criteria in relation to the structure of certain types of bodies. Thus the independence of certification bodies is considered to be obtained through the existence of a balanced governing board. This has led to the question whether the definition of criteria in relation to structures is still appropriate or whether the whole issue should not be redirected towards function criteria.

The discussions arisen in CEN/CENELEC TC1 during the preparation of EN 45 004 standard have clearly underlined all these difficulties.

3) Links between the EN 45 000 series and the "modules " Decision.

The lack of clarity concerning some of the conformity assessment functions is reflected in the Council Decision on modules, and the question often arises as to which standard a notified body has to be accredited for which directive. This leads to different solutions in different countries and even for different directives (insofar as the notifying authorities are not always the same for different directives.).

There have been questions as to whether those notified for type examination are testing or certifying, whether those notified for other modules are certifying or "inspecting", and there is the question of the appropriate standards for the bodies which have to carry out module H, full quality assurance, but related to the product, etc...

This means that public authorities will have to follow closely the developments in the standards field and even take part, to ensure that the ensuing solutions are acceptable to the legislator. Whether this may lead to the possibility of adapting the modules remains an open question.

4) Relations with ISO/IEC work.

CEN/CENELEC adopted the EN 45 000 series in 1989 on the basis of the existing ISO/IEC guides. In the meantime ISO/IEC have adapted guide 25 and are examining a number of others. ISO/IEC are developing guides for the accreditation bodies carrying out the accreditation of certification bodies, whilst the question is being examined at the European level by the European Accreditation for Certification (EAC). Meanwhile there is resistance at the European level from a number of laboratories to modify the EN 45 001 standard to bring it into line with the new guide 25 because the laboratories which are accredited to the old version do not want to reinvest in a new accreditation without the guarantee that there will be brought a certain degree of stability, for the future.

The question of "leapfrogging" between the international and European levels is a serious one which has been recognised by the standardisation organisations but which they find difficult to tackle fully. It should be recognised that part of the problem is one of timing, in that the completion of European Union policies calls for a greater sense of urgency than international activities are capable of addressing at present in this area. The public authorities (national and community) should feel involved as a party concerned in the discussion and should bring pressure to bear on the issue.

APPENDIX B

DOCUMENTS TO BE CONSULTED

EN 45001
EN 45002
EN 45003
EN 45004
prEN 45010
EN 45011
EN 45012
EN 45013
EN 45014
ISO/CASCO 226
ISO/CASCO 227
ISO/CASCO 228
45 ACC
45 ASS
ISO Guides (relevant)
EN ISO 9000 (relevant parts)

and document CEN/CLC/TC1 N 093.