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The European Quality Assurance Standards

EN ISO 9000 and EN 45000

in the Community's New Approach legislation

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PREFACE

The scope of this document is to give an overview of the use and implementation of European standards series EN ISO 9000 and EN 45000 in the Community's New Approach legislation.

The document, which supersedes the document CERTIF 92/9 on the same subject, has taken into consideration the different developments in Community legislation and in the quality standards fields, namely:

- the evolution of the EN ISO 9000-1994 (former EN 29000) and EN 45000 standards series;
- the publication of New Approach Directives and of Decision 93/465/EEC on conformity assessment procedures;

as well as the issues brought to light by the development and implementation of the conformity assessment process and the growing consideration across the world of quality systems concepts and quality in general, both by economic operators and public administrations.

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0. INTRODUCTION

0.1. The evolution of Community legislation (from old to new approach)

The free movement of products is at one and the same time one of the principles and one of the aims of the EU Internal Market. The existence of unharmonized standards and technical regulations and of different conformity assessment procedures in the Member States leads to the raising of technical barriers to trade, the effect of which is twofold:

- increased production costs in order to meet various national requirements;
- increased conformity checking costs owing to the mushrooming of testing and certification requirements.

The Community since the beginning of the 1980s, in the field of the elimination of technical barriers to trade, passed through a silent revolution in terms of the mechanisms for ensuring that only safe products get to the market, wherever they come from, inside and outside the Community.

The "Cassis de Dijon" case in 1981 gave the Community the key elements which later were to form the basis for the new Community legislation, fixing the following principles:

- products manufactured in a Member State should benefit from free circulation throughout the Community;
- it is up to the Member States to demonstrate that a product does not fulfil an essential safety and health requirement and no longer to the manufacturer to demonstrate that it does;
- Member States can intervene only when a product does not respect an essential requirement, that means that in all other cases Member States must accept the products on their market.

Following these principles, the Council of the European Communities approved in May 1985 a resolution[1], the New Approach to technical harmonisation and standardization, which combines both the harmonization of regulations and national standards and the mutual recognition of the results of tests and of certification via the adoption of a new strategy based on the four following principles:

- the harmonization Directives determine the essential requirements to be met by products placed on the market if they are to benefit from free movement within the Community;

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[1] OJ 85/C136/01

- the technical specifications governing the production and marketing of products meeting the essential requirements set out in the Directives will be laid down by the European Standardization Bodies (CEN, CENELEC, ETSI) in European Standards (EN, ETS);
- implementation of the European Standards remains voluntary;
- the manufacture of products in line with the harmonized European Standards leads to a "presumption of conformity" with said essential requirements, and normally leads to less burdensome certification process.

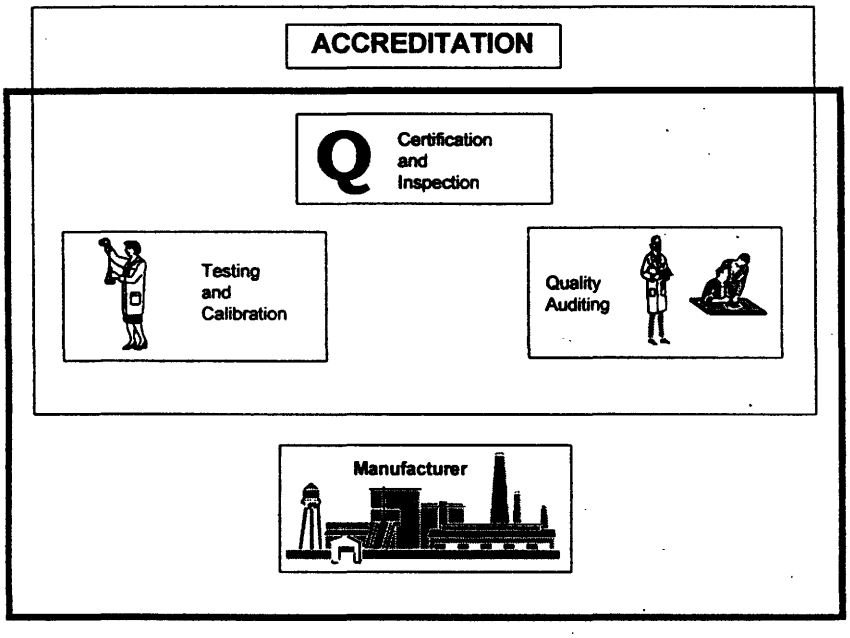
The groundwork for the New Approach formed only one part of the policy devised in order to achieve the Internal Market. The existence of standards specifying essential requirements is a necessary but insufficient prerequisite. It is essential to provide conditions whereby conformity assessment is carried out in accordance with transparent, reliable procedures which guarantee the quality of the results obtained.

To date, seventeen "New Approach" Directives (considering the Directive 73/23/EEC as part of them) have already been approved on this basis, and these cover the following areas:

- simple pressure vessels (87/404/EEC);
- toys (88/378/EEC);
- construction products (89/106/EEC);
- electromagnetic compatibility (89/336/EEC);
- machinery (89/392/EEC);
- personal protective equipment (89/686/EEC);
- non-automatic weighing instruments (90/384/EEC);
- active implantable medical devices (90/385/EEC);
- appliances burning gaseous fuels (90/396/EEC);
- telecommunications terminal equipment (91/263/EEC);
- hot water boilers fired with liquid or gaseous fuels (92/42/EEC).
- electrical equipment designed for use within certain voltage limit (73/23/EEC).
- explosives for civil uses (93/15/EEC);
- medical devices (93/42/EEC);
- equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC);
- recreational craft (94/25/EC)
- lifts (95/16/EC)

In its Resolution of 21 December 1989 on the Global Approach to Certification and Testing[2], the Council stated its aim of providing, within the Internal Market, a homogeneous, transparent and credible technical environment within which public authorities, economic operators and users will be able to have confidence and which will ultimately lead to the existence on the market of higher quality products.

This confidence must be based on technical competence on the part of manufacturers, test laboratories, the bodies responsible for quality audits, certification and inspection bodies, and on transparency in the conformity assessment procedures whether subject to regulations or voluntary (thus covering all of the Internal Market).



BASIC FUNCTIONS INVOLVED
IN THE CONFORMITY ASSESSMENT PROCEDURES

[2]OJ 90/C10/01

The resolution on the Global Approach fixes the guiding principles for Community policy as regards conformity assessment:

- use of the "modules" concerning the different stages of the conformity assessment procedures (modular approach) and of the criteria for the designation and notification of bodies under those procedures;
- generalized use of the European standards relating to quality assurance (EN ISO 9000) and to the requirements to be fulfilled by the above mentioned bodies (EN 45000), and the setting up of accreditation systems;
- promotion of mutual recognition agreements concerning testing and certification in the non-regulatory sphere, under the aegis of the European Organisation for Testing and Certification (EOTC);
- reinforcement of the development of existing quality infrastructures within the Community to minimize their differences;
- promotion of external Community relations with third countries by means of:
  - mutual recognition agreements;
  - co-operation and technical assistance programmes.

Amongst the eight conformity assessment procedures retained for future Directives, the Council decided to include the three models of quality assurance contained in the EN ISO 9001, 9002 and 9003 (former EN 29001, 29002 and 29003) standards, alongside the more traditional product certification procedures such as type testing and unit verification, and even the manufacturers declaration of conformity.

This approach was adopted by Decision 90/683/EEC[3] of 13 December 1990 (as amended and brought up to date by Decision 93/465/EEC[4]), which set out a number of basic principles on how the procedures should be used in Community legislation, such as the one that the Council should leave as wide a choice as possible to the manufacturers and should avoid restricting it to only product certification or to quality system certification.

The decision to leave these two choices was oriented towards allowing manufacturers, in particular SMEs, to operate under the Directives and to leave them the time to move over to quality system certification if and when they were ready, and according to their own economic interests.

The Council accepted to favour the use of accreditation as a transparent and reliable support for notification of the bodies designated by Member States under the Directives, but without making it obligatory.

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[3]OJ 90/L380/13

[4]OJ 93/L220/23

The importance of accreditation for conformity assessment bodies whether operating in the regulated or non regulated area, in order to help them demonstrate independently their technical competence and to ensure transparent and quality driven certification in Europe, was clearly set out by the Council.

One stop accreditation, which can lead to one stop certification and testing, remains nowadays a main objective in this area of activity. To achieve such an objective, mutual recognition can help in the regulated sector, where public authorities are obliged by law to accept certificates issued on the territory of other Member States, to increase the transparency and credibility of their activities, and in the private sector to guarantee a common level of competence of certification bodies, thus eliminating the need for artificial multiple certifications.

To date, several accreditation bodies are members of the EAL (European co-operation for Accreditation of Laboratories) multilateral agreement for laboratory accreditation, while activities are ongoing to enlarge the participation of bodies for accreditation of certification bodies to the EAC (European Accreditation of Certification) multilateral agreement.

It is appropriate, in this context, to define[5] the notion of quality. Strictly speaking the meaning of quality (according to ISO 8402 - 1994) is the "totality of characteristics of an entity (i.e. an activity or a process, a product, an organization, a system or a person, or any combination thereof) that bear on its ability to satisfy stated and implied needs".

As part of Community legislation, quality has thus become an integral part of the "essential requirements" of the Directives whereby the quality of products placed on the market cannot be less than the level of those requirements and any product not meeting those requirements is thus, by definition, banned.

The idea of quality includes within its overall meaning its three institutional pillars standardization, certification and metrology, plus a management pillar, organizational management and quality assurance.

0.2. The integration of quality standards in the new conformity assessment system

The approval by CEN/CENELEC of the EN 29000 series of standards in 1987 (superseded in 1994 by the EN ISO 9000[6] series) and of the EN 45000 series in

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[5]For other definitions see Annex I

[6]In July 1994 the revised edition of the ISO 9000 series of International Standards was published. In addition to approval by ISO, the revised ISO 9000 standards received a parallel positive vote by CEN/CENELEC/ETSI and were adopted as EN ISO 9000 series, superseding the previous EN 29000 (1987) series of standards.

1989 provided support for the needs of economic operators in Europe and may still be considered to be one of the most significant planks in the new Community strategy.

Under the modular approach to conformity assessment, the Council recognized the use of quality assurance as set out in the EN ISO 9000 series of European standards, as a means of demonstrating conformity of products for which the Directives set out the safety levels, and use of operational and assessment criteria set out in the EN 45000 series of European standards, as the means of contributing to demonstrate the technical competence and operational transparency of conformity assessment bodies.

Indeed, the EN ISO 9000 series of standards identify those quality system elements that are needed to generate confidence in manufacturer capacity and efficiency in providing products in line with pre-established requirements.

The EN 45000 series of standards defines the criteria needed in order to establish confidence in the capacity, transparency and technical competence of bodies involved in the conformity assessment procedures.

Experience in the use of EN 45000 standards has revealed a number of difficulties in the operation of the system over these years.

There is a general consensus throughout the public and private operators in the field 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 of the bodies involved in the tasks.

European Standardization Institutions have been involved in this examination and have been requested to make recommendations for action in this area.

1. THE EN ISO 9000 (FORMER EN 29000) SERIES OF STANDARDS

On the current (European and international) market, manufacturers need to give more guarantees concerning product quality. It is no longer enough to provide products that conform and it is thus becoming necessary to demonstrate the manufacturer's capability to provide continuously products that conform.

First of all, manufacturers need to set up quality systems enabling them to guarantee "as a first concern" that the required quality will be obtained at the lowest cost, for reasons of competitiveness and even survival on the market.

Secondly, customers (sometimes public authorities) need to know whether manufacturers quality system provides the necessary assurance concerning product quality. This may have serious consequences for manufacturers in that customers may require different quality system specifications, and so give rise to an excessively cumbersome and bureaucratic system without any further assurance of quality in order to meet those requirements.

It is precisely against this background that approval of the European EN ISO 9000 series of standards plays a very important part in enabling the most suitable quality system model to be selected in the light of the operational and organizational suitability of the company. The EN ISO 9000 series specifies the elements needed in order to set up and manage the quality system; it applies to the generic product categories that encompass all the kinds of products supplied by organizations: hardware, software, processed materials and services.

The series is intended to be used by manufacturer's organization in four situations:

<u>for internal purposes</u>

a. **guidance for quality management:**

   in this situation it provides a quality management approach to installing a quality system that will enhance the manufacturer's quality achievement (EN ISO 9004-1 and other applicable parts of EN ISO 9004 series).

<u>for external purposes</u>

b. **contractual, between first and second parties:**

   in this situation the customer may be interested in certain elements of the manufacturer's quality system which affect the manufacturer's ability consistently to produce products to requirements. The customer thus contractually requires that certain quality system elements and processes, as appropriate, be part of the manufacturer's quality system , by specifying a particular quality assurance model (EN ISO 9001, EN ISO 9002 and EN ISO 9003).

c. **second-party approval or registration:**

in this situation the manufacturer's quality system is assessed by the customer. The manufacturer may be given formal recognition of conformance with the standard (EN ISO 9001, EN ISO 9002 and EN ISO 9003).

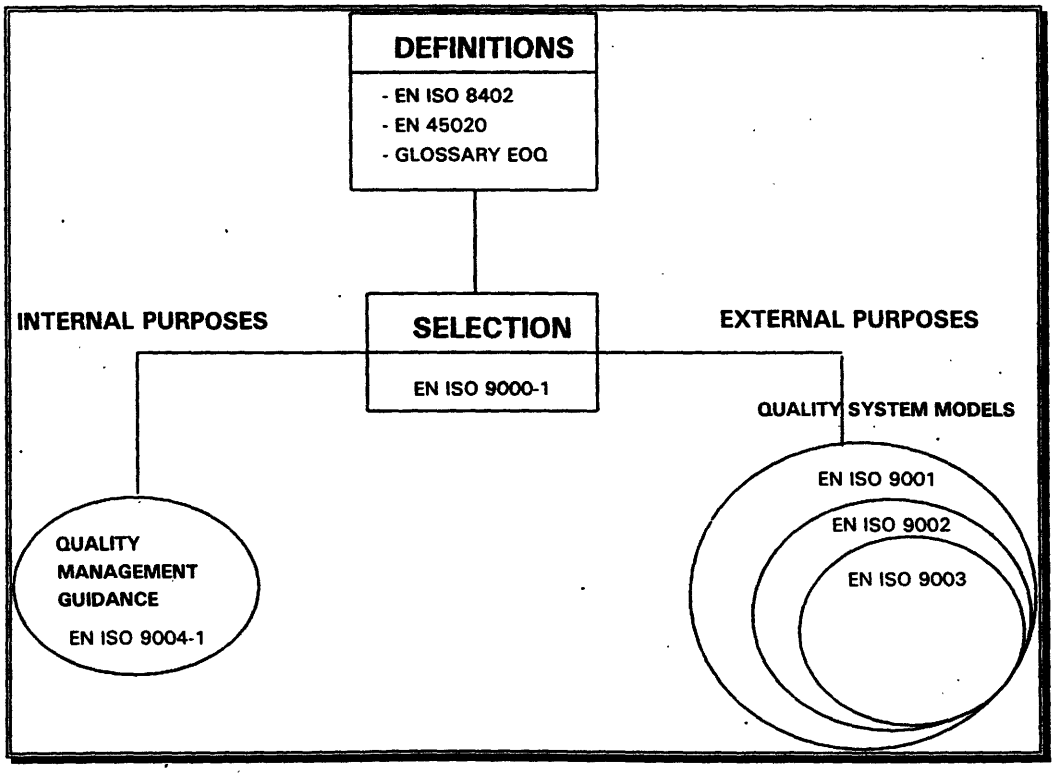
d. **third-party certification or registration:**

in this situation the manufacturer's quality system is evaluated by a certification body, and the manufacturer agrees to maintain the quality system for all customers unless otherwise specified in an individual contract (EN ISO 9001, EN ISO 9002 and EN ISO 9003).

In all situations (a, b, c and d), the setting up of the quality system by an organization is the result of a commitment by its management to boost its own competitiveness and to achieve the quality required by the product in an economically efficient manner.

The three distinct quality system models suitable for the purpose of manufacturers demonstrating their capabilities and for assessment of such manufacturer capability by external parties are:

- Standard EN ISO 9001 which covers the most complete quality system, the elements of which cover all aspects from product design to after sales, via production;
- Standard EN ISO 9002 which covers aspects from production to servicing;
- Standard EN ISO 9003 which covers final inspection and testing.



A table showing the correspondence between the ISO and EN quality standards either in existence or in preparation is set out in Annex II.

1.1. Standard EN ISO 9000-1: Quality management and quality assurance standards. Part 1: guidelines for selection and use

Standard EN ISO 9000-1 can be considered as the "road map" to EN ISO 9000 series and others ISO 9000 standards, since it deals with the general philosophy underlying quality system standards by establishing relationships between the principal concepts in approaching quality and the criteria of selection and use of the entire series.

These basic concepts have been expanded significantly in the 1994 revision, that now includes:

- the five key objectives and responsibilities for quality, with strong emphasis on quality improvements in products and operation system. This builds on the three objectives in the 1987 version that focused on achieving and sustaining product quality;
- the concept of manufacturer's stakeholders (customers, employees, owners, sub suppliers and society) and their expectations;
- the distinction between quality system requirements and product technical requirements. The subject of EN ISO 9000 standards is the quality system itself. This crucial distinction was not clear in the 1987 version, which led to misunderstandings;
- the four facets that are key contributors to product quality: quality due to definition of needs for the product, product design, conformance to product design and quality due to product support. Articulation of these facets are new in international standardization;
- the concept of a process and the need for an organization to identify, organize and manage its network of processes and interfaces (new aspects versus 1987 version);
- the three areas to be addressed for every process being evaluated when assessing a quality system: process definition and documentation, process deployment and process effectiveness;
- the four situations where the EN ISO 9000 series is intended to be used (situations a, b, c and d earlier defined).

This standard clearly sets out the general guidance for selection and use of standards for external quality assurance (situations b, c and d in clause 1.), giving explicit attention to quality system situations in which there are contractual agreements or second-party approval and emphasizing that both customers and manufacturers must benefit from the selected and applied standard . With third-

party certification, the selection of the quality assurance standard should be agreed by the manufacturer and the certifier, taking into account customer needs and manufacturer objectives.

It sets out the responsibilities and the typical means of demonstrating the conformance to the selected model and explicit additional considerations in contractual situations.

1.2. Standard EN ISO 9004-1 - Quality management and quality system elements. Part 1: Guidelines

Standard EN ISO 9004-1 (former EN 29004) is designed to assist organizations in designing, developing and setting up the quality system that is most suited to them.

The standard is not intended for contractual, regulatory, or certification use.

It defines the broad approaches involving the human, technical and administrative factors concerning product quality throughout the life cycle from user determination of needs up to customer satisfaction. The standard describes all of the basic factors enabling a quality system to be set up within an organization in order to boost its competitiveness and achieve the required quality in an economically efficient manner. The factors involved are:

- the organization's aims;
- customer and organization needs and interests;
- benefits, costs and risks;
- management responsibilities;
- principles, documentation and quality system audits;
- the financial aspects of quality system activities;
- marketing;
- design, supplies, production, production control, product checking and the checking of measuring and testing equipment;
- non-conformity and remedial actions;
- handling, storage, delivery, packaging, installation and servicing;
- quality documentation and records;
- staff;
- safety aspects of products and processes;
- statistical methods.

The 1994 revision contains, in addition to changes in wording for clarification and consistency with the revised EN ISO 9000 series, changes relating to:

- structure of the quality system, requiring documented procedures for configuration management to the extent appropriate. Configuration management is a management discipline that applies technical and administrative direction to the design, development, production and use of the product, and that gives visibility of the state of documentation and product during its life-time.
- quality system elements, requiring the organization's management to ensure that the system facilitates and promotes continuous quality improvement;
- financial considerations, enlarging the selection of approaches for gathering, presenting and analysing the elements of financial data reporting, that are:
  - quality-cost approach;
  - process-cost approach;
  - quality-loss approach;

  and identifying the aims of financial reporting of quality activities.

1.3. Standards EN ISO 9001/2/3 - Quality systems- Models for quality assurance

Standards EN ISO 9001, EN ISO 9002 and EN ISO 9003 specify three sets of quality system requirements that can be used for external quality assurance purposes. They represent three distinct models suitable for the purpose of manufacturers demonstrating their capabilities and for assessment of such manufacturer capability by external parties.

The requirements concerning the elements of the quality system specified in the three standards are complementary (not alternative) to the (product) technical requirements and they apply independently of any specific industry or economic sector.

The standards are intended for contractual (second or third party certification) or regulatory use.

The 1994 revision, while moving towards a general harmonization of terminology and definitions of the quality system requirements, incorporates common modifications to the standards relating to clause structure (identical for the three standards) and to quality system requirements as follows:

- Introduction, where the reference to a quality system being suitable "for two-party contractual purposes" has been replaced by "quality systems suitable for ...demonstrating ...capability, and for assessment of such ..capability by external parties";
- Quality policy, enhanced with respect to its relevance to customers' expectations and needs;

- Resources, expanded to include management, work performance, verification activities;
- Quality system, clearly requiring a quality manual that defines the documentation structure of the quality system and stating the extent of documented procedures;
- Quality system procedures, enhanced to clarify the degree of documentation required for the quality system;
- Quality planning, added to cover quality system planning and product quality plans;
- Contract review, expanded to include precontract tender arrangements and contract and ordering requirements;
- Process control, expanded to include additional requirements for maintaining process equipment;
- Corrective and preventive actions, addressed by separate requirements; corrective action directed towards eliminating the causes of actual nonconformities, and the preventive action directed towards eliminating the causes of potential nonconformities.

1.3.1. Standard EN ISO 9001 - Quality systems - model for quality assurance in design, development, production, installation and servicing

This standard is to be used when the need is to demonstrate the manufacturer's capability to design and supply conforming products.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing non conformities at all stages from design through to servicing.

Standard EN ISO 9001 applies in situations where:

a) design is required and the requirements placed upon the product are mainly couched in terms of product performance or where it is necessary to lay down such requirements;

b) confidence in obtaining a product in line with the requirements laid down must be obtained by demonstrating the manufacturer's abilities as regards **design, development, production, installation and servicing**.

The 1994 specific modification, apart from those ones identified above, relates to design control requirements, expanded to include design validation and separate requirements for design review and design verification. More specifically:

- design input, clearly requires to identify and document applicable statutory and regulatory requirements and to take into consideration the results of any contract review activities;

- design review, previously considered an option of the design verification, now requires, at appropriate stages of design, the planning and execution of formal documented design reviews;
- design verification, requires that, at appropriate stages of design, design verification is performed to ensure that the design stage outputs meets the design stage input requirements;
- design validation, not previously included, requires that design validation is performed to ensure that products (normally final product) conforms to defined user needs and/or requirements.

The module Decision (cf. Section 3.) sets out, amongst others, the "full quality assurance" conformity procedure (module H) based on EN ISO 9001 standard as a mean of assessing product conformity to New Approach Directives requirements. The module H procedure provides for supplementary requirements based on product design verification by Notified Bodies. The mentioned changes in EN ISO 9001, apart from the effective improvement of manufacturers' design process control, should lead, when required by Directive, to the facilitation of product design verification activities by those notified Bodies as well.

1.3.2. Standard EN ISO 9002 - Quality systems - Model for quality assurance in production, installation and servicing

This standard is to be used when the need is to demonstrate the manufacturer's capability to supply conforming products to an established design.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing non conformities at all stages from production through to servicing.

Standard EN ISO 9002 applies in situations where:

a) the specified requirements for products are stated in terms of an established design or specification;

b) confidence in obtaining a product in line with specific requirements must be obtained by demonstrating the manufacturer's ability as regards production, installation and servicing.

The 1994 specific modification, apart from those ones identified above, relates to the addition of servicing requirements, not considered in the previous version.

1.3.3. Standard EN ISO 9003 - Quality systems - Model for quality assurance in final inspection and test

This standard is to be used when the need is to demonstrate the manufacturer's capability to detect product non conformity and to control the arrangements regarding final inspection and test.

Standard EN ISO 9003 is applicable in situations where confidence in product conformity is adequate if manufacturer's capacity is satisfactorily demonstrated with regard to the final inspections and checks carried out on the finished product.

The 1994 standard version, apart from modifications identified above, includes new requirements. They relate to contract review, control of customer-supplied product, corrective actions and internal quality audits requirements.

2. THE EN 45000 SERIES OF EUROPEAN STANDARDS

It may be said in general terms that the EN 45000 series of European standards represents for the bodies operating in the conformity assessment framework what the EN ISO 9000 series represents for companies. The EN 45000 series defines organizational, technical competence and operational criteria for those bodies.

The EN 45000 series (broadly based on the ISO Guides) is the series of standards essential in conformity assessment by third parties, in general, and for laying down accreditation systems in particular. It covers the three types of conformity assessment body (certification bodies, test laboratories and inspection bodies) and sets out the criteria for the accreditation bodies, for the assessment and the operation of conformity assessment bodies.

To date, as evidenced by the table below, the EN 45000 series is 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 (a proposal of standard is in process). This is important for the notification of "notified bodies" within the context of the New Approach Directives.

	CERTIFICATION BODIES	TESTING LABORATORIES	INSPECTION BODIES
CRITERIA FOR ACCREDITATION BODIES	prEN 45010	EN 45003	prEN 45010
ACCREDITATION ASSESSMENT CRITERIA	prEN 45010	EN 45003	prEN 45010
OPERATIONAL CRITERIA	EN 45011 - PRODUCTS (+ pr EN 45011) EN 45012 - QUALITY SYSTEMS (+ pr EN 45012) EN 45013 - PERSONNEL	EN 45001	EN 45004

The real life implementation of the conformity assessment standards has brought to light problems which need the support and the involvement of the involved parties (standardising and conformity assessment communities, industry, distributors, consumers and end customers, national and EU public authorities) in order to bring clarity, efficiency and better credibility to the testing and certification policy.

Among other activities, the EN 45000 standards series needs to be completed on the basis of the on going work both in ISO/IEC and CEN/CENELEC TC 1 and, more likely, it needs to be redirected towards conformity assessment bodies' "functions" and not towards bodies' "structures".

This re-direction of the series should facilitate the solution of the "inspection" function, very often carried out either by testing laboratories or by certification bodies, covering the issue of the professional judgement which is inherent in "inspection".

Integration of concepts and criteria of EN 30011 series of standards (equivalent to ISO 10011 series), which relates to the qualification of auditors and the management of audit programmes and the execution of quality audits, into the EN 45000 series is, amongst others, one of the question to be analyzed by future standards restructuring activities.

A table showing the correspondence between the EN and ISO/IEC Guides either in existence or in preparation is set out in Annex III.

2.1. Testing and calibration laboratory standards

2.1.1. Standard EN 45001 (1989) , general criteria for the operation of testing laboratories

Standard EN 45001 lays down the general criteria governing technical competence and the operation of testing laboratories, including calibration laboratories, without taking account of the sector concerned. In particular the standard identifies the following criteria:

- organization and management;
- legal identity;
- impartiality;
- independence and integrity;
- technical competence;
    - quality system;
    - staff;
    - premises and equipment;
    - working procedures;
    - subcontracting;
    - test reports
- co-operation and obligations arising from accreditation.

The actual version of the EN 45001 (1989) was drawn up on the basis of ISO/IEC Guide 25 (1982), which mainly focused on requirements for assessing the technical competence of testing laboratories.

The approach to quality in laboratories has significantly advanced over these years. ISO/IEC Guide 25 has in the meantime reflected the developments in the field.

The existing leapfrogging problem between the two documents will be solved by the ongoing joint revision of ISO/IEC Guide 25 and EN 45001 standard through ISO/IEC and European Standardization bodies co-ordinated efforts and activities. The adoption of common requirements should result in considerable progress as regards mutual acceptance of test results and international trade.

2.1.2. Standard EN 45002 (1989), general criteria for the assessment of testing laboratories

This standard sets out the general criteria to be used by the accreditation bodies in assessing the testing laboratories, including calibration laboratories, with a view to their accreditation.

To date, these criteria, in line with the content and the structure of the ISO/IEC Guide 58 (1993), have been integrated into the EN 45003 standard, which now covers both the accreditation assessment and the accreditation bodies operation criteria.

EN 45002 (1989) has therefore to be considered as replaced by the new EN 45003 (1995).

2.1.3. Standard EN 45003 (1995), General criteria for laboratory accreditation bodies

Standard EN 45003 sets out the general requirements for the operation of a system for accreditation of calibration and/or testing laboratories. In particular the standard identifies the following criteria:

- accreditation body:
  - organization;
  - quality system components;
  - means for granting, maintaining, extending, suspending and withdrawing accreditation;
  - documentation;
- laboratory assessors;
  - requirements;
  - qualification procedures;
  - contracting;
  - records and procedures;
- accreditation process;

- application and assessment;
- sub-contracting of assessment;
- report;
- decision, grant, surveillance and reassessment;
- proficiency testing;
- certificates or reports issued by accredited laboratories;

– relationship between accreditation body and laboratory.

2.2. Standards for certification bodies

Presently, the EN 45000 series covers only the operating criteria of the certification bodies involved in the certification of products, quality systems and personnel.

The standardization activities both at European and international level have significantly advanced over these years. ISO/IEC Guides 61, covering the assessment and accreditation of certification bodies, is on the way to be published and it will be later adopted as new European standard EN 45010.

The three existing standards (1989) lay down in detail the operating criteria for the certification bodies in order that these may be recognised as competent and reliable in implementing certification systems. They identify, in particular:

– the components of the administrative and organization structure;

– staff qualifications;

– certification procedures;

– the required facilities;

– the quality manual;

– the confidentiality criteria;

– the procedures for complaints and for withdrawal and cancellation of licences, certificates and conformity marks.

The application of those standards to specific sectors sometimes requires that the criteria defined are supplemented by interpretations specific to the sectors in question.

2.2.1. Standard EN 45011 (1989), General criteria for certification bodies operating product certification

This European standard lays down in detail the general organizational and operational criteria which must be applied by the certification bodies in implementing and managing reliable and transparent product certification systems.

2.2.2. Standard EN 45012 (1989), General criteria for certification bodies operating quality system certification

This standard sets out in detail the general organizational and operational criteria which must be applied by the certification bodies in the implementation of reliable and transparent management of the certification of company quality systems.

2.2.3. Standard EN 45013 (1989), General criteria for certification bodies operating certification of personnel

This standard lays down the general criteria for the organization and operation that need to be applied by certification bodies when implementing and managing reliable and transparent staff certification systems.

2.3. Standards for inspection bodies

The European standardization bodies CEN/CENELEC have in 1995 adopted a European standard dealing with the operation of inspection bodies (EN 45004) while the criteria for their assessment and accreditation will be integrated in the future European standard EN 45010.

2.3.1. Standard EN 45004 (1995), General criteria for the operation of bodies performing inspections

The standard EN 45004 specifies the general criteria governing the technical competence, organization and operation that the inspection bodies must apply if their departments are to be recognized as competent.

This standard defines three types of inspection body on the base of the conditions (of independence) under which they perform their services. In particular the standard identifies the following criteria:

- administration;
- independence, impartiality and integrity;
- confidentiality;
- organization and management;
- quality system;
- personnel;
- facilities and equipment;
- inspection methods and procedures;
- handling of inspection samples and items;

- inspection reports and inspection certificates;
- sub-contracting, complaints and appeals, co-operation.

2.4. Standards for auditing

The standard series EN 30011 (ISO 10011) deals with quality system audits, qualification of quality system auditors and audit programme management.

2.4.2. Standard EN 30011-1 (ISO 10011-1), Guidelines for quality system audit. Part 1: Audit

The first part of the EN 30011 series sets out in detail the basic principles, criteria and quality system audit practices and provides guidelines for the implementation, planning and performance of quality systems audits.

The standard identifies, in particular:

- audit aims;
- role and responsibilities of auditors and audits;
- principles governing the performance of the various stages of the quality audits.

2.4.3. Standard EN 30011-2 (ISO 10011-2), Guidelines for quality system audit. Part 2: Qualification criteria for quality system auditors

The second part of the EN 30011 series lays down qualification and selection criteria as well as criteria for the maintenance of quality system auditors' qualifications. It identifies, in particular, the principles governing education, experience and personal characteristics of auditors and the characteristics of programmes for their evaluation.

2.4.4. Standard EN 30011-3 (ISO 10011-3), Guidelines for quality system audit. Part 3: Audit programme management

The third part of the EN 30011 series lays down the basic principles for and the essential components of the implementation and management of quality system audit programmes, including the practical application of a code of ethics for auditors.

3. IMPLEMENTATION OF QUALITY STANDARDS BY ECONOMIC OPERATORS UNDER NEW APPROACH DIRECTIVES

The explicit reference to quality standards (EN ISO 9000 and EN 45000 series) in Community legislation, which does not confer any mandatory nature to these standards, was made for the first time in 1989 in the Resolution of 21 December[7], which approves the Global Approach.

Aware as it is of the importance of quality standards in order to put into practice the Community policy stated under the Global Approach, the Council boosted the role of those quality standards in its Decision of 13 December 1990[8] (amended and brought up to date by the Council on 22 July 1993[9]), which approves the "modules" framework dealing with the "conformity assessment procedures" (cf. Annex VI).

Indeed, that Decision points out that the setting up of quality systems by manufacturers in compliance with EN ISO 9000 European standards, confers a presumption of conformity with the requirements of the Directives in respect of quality systems and that compliance with the EN 45000 series of European standards confers a presumption of conformity with the requirements of the Directives related to the notified bodies (for conformity assessment purposes).

Several New Approach Directives draw upon different procedures to enable public authorities to ensure that products placed on the market conform to "essential (health and safety) requirements" as expressed in the Directives.

Those procedures use basic conformity assessment structures, either by a first party (manufacturers) or by a third party (certification bodies, inspection bodies, testing laboratories), which relate to the "design phase" of products and to their "production phase".

The "modules" give the legislator, in relation with the type of products and risks involved, the means for setting up the appropriate procedures for manufacturers in order to demonstrate their product conformity.

We may say, in general terms, that four "conformity assessment routes" may be set up by the following combinations of possible procedures:

- manufacturer's declaration (self-certification) (module A);
- product certification (modules B + C, B + F, module G);
- product in addition to quality assurance certification (modules B + D, B + E);
- quality assurance certification, that includes product audit (module H).

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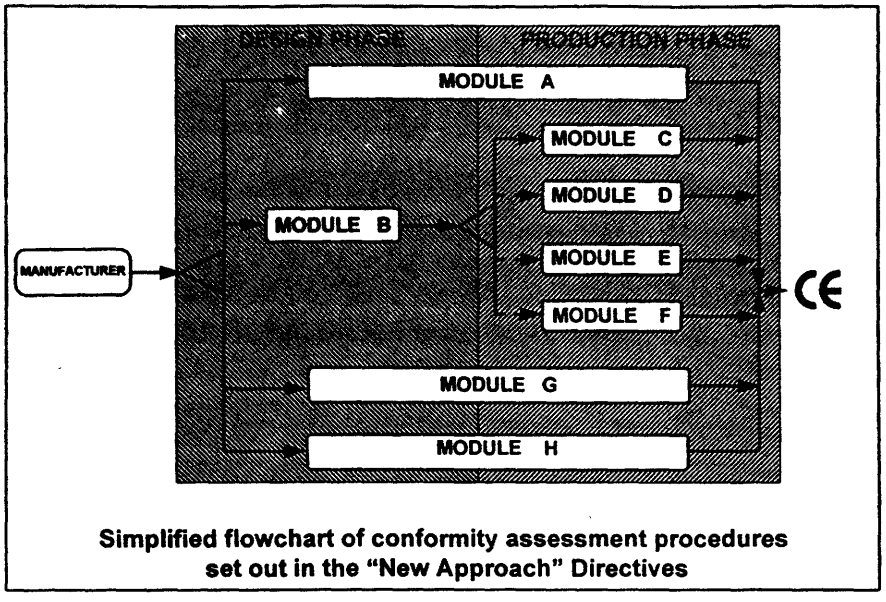
[7] OJ 90/C10/01
[8] OJ 90/L380/13
[9] OJ 93/L220/23



Simplified flowchart of conformity assessment procedures set out in the "New Approach" Directives

The Decision referred to above sets out, amongst other basic guidelines to be used in the technical harmonization (New Approach) Directives, the following principles:

- as a general rule a product should be subject to both phases before being placed on the market;
- the Directives should set a range of possible choices among the different modules which cover the two phases in order to guarantee a high level of safety, for a given product or product sector. In setting the range of possible choices, the Directives will take into consideration the appropriateness of procedures in relation to the type of products, risks involved, etc.;
- whenever Directives provide the manufacturer with the possibility of using modules based on quality assurance techniques, the manufacturer should also be able to have recourse to a combination of modules not using quality assurance, and *vice versa.*

To date, twelve of the seventeen New Approach Directives adopted by the Council refer directly to quality system procedures as a way of demonstrating the product conformity.

Annex VII sets out the Community "conformity assessment procedures" framework to be used in the technical harmonisation Directives (New Approach Directives), while Annex VIII sets out flow charts on the conformity assessment procedures provided for in each of the "New Approach" Directives.

Annex VI lists the harmonized standards, the reference of which have been published in the Official Journal of the European Communities, applicable to each Directive.

3.1. The New Approach Directives

3.1.1. Directive 87/404/EEC (and related amendments) relating to simple pressure vessels

The Directives (cf. Annex V) apply to simple pressure vessels, manufactured in series, subjected to an internal gauge pressure greater than 0,5 bar up to but not exceeding 30 bar, that are intended to contain air or nitrogen and which are not intended to be fired.

Before placing his product on the market, the manufacturer or his authorised representative established in the Community shall, for vessels where the product of PS and V exceeds 50 bar.litre, demonstrate conformity with the essential safety requirements by means of the conformity assessment procedures set out in the Directive 87/404/EEC. These vessels shall bear the CE marking.

At vessel design stage the manufacturer shall:

- for products complying with standards, submit his product to:
  - either the "EC type examination" by a notified body; or
  - the "certification of adequacy" by a notified body stating that the design and manufacturing schedule are satisfactory.
- for products not or partially complying with standards, submit his product to:
  - "EC type examination" by a notified body;

At vessel manufacturing stage the manufacturer may choose also between two different types of conformity procedures:

- where the product of PS and V exceeds 3000 bar.litre, the "EC verification" (art. 11);
- where the product of PS and V does not exceed 3000 bar.litre but exceeds 50 bar.litre:
  - either the "EC declaration of conformity" (art. 12); or
  - the "EC verification" (art. 11).

A manufacturer who follows the "EC declaration of conformity" procedure becomes subject to EC surveillance by a notified body where the product of PS and V exceeds 200 bar.litre.

For vessels where the product of PS and V is 50 bar.litre or less, they must be manufactured in accordance with sound engineering practice in one of the Member States. These vessels do not bear the CE marking.

Although the Directives make no explicit reference to quality system standards, compliance of the manufacturer's quality system with the quality standards EN ISO 9000 may make easier the demonstration of the correct implementation of the requirements of the directive, and in particular that of Article 13(1) which requires

from the manufacturer a document describing the manufacturing processes and all the pre-determined systematic provisions taken to ensure the conformity of the pressure vessels with the Directive.

Member States shall apply the criteria for the assessment of the notified bodies that have been provided for in Annex III of the Directive. Bodies meeting the assessment criteria provided for in the relevant harmonised standards (EN 45000) are presumed to meet the said criteria.

3.1.2. Directive 88/378/EEC (and related amendment) relating to safety of toys

The Directives (cf. Annex V) apply to toys, defined as any product or material designed or clearly intended for use in play by children of less than 14 years of age.

Before placing his product on the market, the manufacturer or his authorized representative established in the Community shall, in order to affix the CE marking, submit it to the conformity assessment procedures set out in Directive 88/378/EEC. It provides manufacturers with two means of demonstrating conformity with the "essential requirements" based on whether the toy conforms to the harmonized standards or it does not conform in whole or in part to them:

- if toys are manufactured in accordance with harmonized standards, the manufacturer shall keep available, for inspection, a technical file (or technical report) describing, amongst other items, the means ensuring the conformity of production with the standards and detailed information on the product design and manufacturing process.
- if toys do not conform in whole or in part to the harmonized standards, the manufacturer shall submit the product to an "EC type examination" carried out by a notified body that certifies conformity of the product with the essential safety requirements. The manufacturer or his authorized representative established in the Community shall confirm the conformity of the product to the approved model and keep available for inspection all the relevant technical documentation.

The Directive makes no requirements in terms of quality system to be set up by the manufacturer as a means of ensuring product conformity.

Member States shall apply the criteria for the assessment of the notified bodies that have been provided for in Annex III of the Directive. Bodies meeting the assessment criteria provided for in the relevant harmonized standards (EN 45000) are presumed to meet the said criteria.

3.1.3. Directive 89/106/EEC (and related amendment) relating to construction products

The Directives (cf. annex V) apply to construction products which are defined as any products manufactured with a view to their incorporation in a permanent manner in construction works.

The performance of these products, evaluated against the essential requirements applicable to the works, are laid down in technical specifications, that is to say, standards elaborated by CEN/CENELEC or European Technical Approvals by EOTA, both, under EC mandates.

A step-by-step procedure has been adopted to elaborate these technical specifications. Draft provisional mandates were delivered to CEN/CENELEC in May '92 and finalised after consultations with Member States, via the Standing Committee of the Directive, to consider further characteristics which are envisaged by present national legislation on works.

A mandate for certain families (40) of products has been given to CEN/CENELEC.

Before being placed on the market, the manufacturer or his authorized representative established in the Union shall, in order to affix the CE marking, submit his product to the conformity assessment procedures set out in the Directive.

The Manufacturer or his authorized representative shall be responsible for the "attestation of conformity" that products are in conformity with the requirements of the relevant technical specifications.

This attestation, as provided in art. 13.3, presupposes that the manufacturer has, within his factory, a control system (quality system) providing assurance that production meets the relevant technical specifications. For certain products provisions have been made for the involvement of an approved certification body in order to assess and monitor the factory production control.

As stated in art 13.4, the attestation procedure shall be specified by the Commission in the mandates, after consultation of the Standing Committee.

It is, therefore, necessary to proceed, in parallel, with the elaboration of mandates and the decision on the attestation, adopting the same definition of products or families of products.

Since the system of conformity shall be determined according to the criteria set out in art. 13.4 (a), (b), (c) and (d) (that is to say, mainly to the essential requirements) and the particulars set out in Annex III, the choice shall depend on the characteristics of the products specified in the mandates.

In the case where a harmonized standard cannot or cannot yet be prepared, a specific procedure, the European technical approval (the favourable technical assessment of the fulfilment of the essential requirements for the building works for which the product is used) is provided. Decision 94/23/EC defines the common procedural rules when submitting an application for European technical approval.

The Directive does not lay down in detail the elements of the quality system to be set up (factory production control system) and does not explicitly refer to any standard concerning quality systems, although the interpretative documents refer explicitly to the EN ISO 9000 standards.

The advantages to be gained from setting up a quality system in line with those continue to be very clear, above all, in view of the obligations under Community law in respect of public procurement which, as a result of the reference this makes to European standards, adds significant weight to the EN ISO 9000 standards.

Member States shall apply the criteria provided for in Annex IV of the Directive for the assessment of the bodies involved in the conformity process. Bodies meeting the assessment criteria provided for in the relevant harmonized standards (EN 45000) are presumed to meet the said criteria.

3.1.4. Directive 89/336/EEC (and related amendments) relating to electromagnetic compatibility

The Directives (cf. Annex V) apply to any apparatus, equipment, system or installations containing electrical and/or electronic components, liable to create electromagnetic disturbance or whose functioning is liable to be affected by such disturbance.

Before being placed on the Community market, a product has to conform with the essential requirements stated in art. 4 of the Directive. The manufacturer or his authorized representative within the territory of the Community has to follow one of the conformity assessment procedures set out in art. 10 of the Directive:

- as regards products other than radio transmitters, the directive provides for the manufacturer's declaration of conformity according to the following:
  - if the manufacturer has followed the relevant harmonized standards, he has to draw up a declaration of conformity (self-certification route);
  - if the manufacturer has not applied the relevant harmonized standards, or he has chosen not to apply them, or they do not exist, or he has applied them only in part, then he has to draw up a Technical Construction File and submit this to a Competent Body in order to obtain a certificate or a technical report.
- as regards radio transmitters, the manufacturer has to submit a specimen representative of his production to a notified body for the EC type examination certification. The manufacturer or his authorised representative then has to draw up a declaration of conformity to the approved type.

No reference is made to the setting up of a quality system, which continues to be the initiative and responsibility of the manufacturer.

Member States have to apply the criteria listed in Annex II to the Directive in assessing the bodies to be appointed as notified body or as competent body. Bodies meeting the assessment criteria laid down in the harmonized standards concerned (EN 45000) are presumed to meet the criteria referred to above.

3.1.5. Directive 89/392/EEC (and related amendments) relating to machinery

The Directives (cf. Annex V) apply to machinery, generally defined as an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material, and to safety components (not bearing CE marking) placed on the market separately.

Before placing his product on the market, the manufacturer or his authorized representative established in the Community shall submit it to the conformity assessment procedures set out in Directive 89/392/EEC, that is:

- for all machinery and safety components, apart from those referred to in Annex IV, he will prepare a technical construction file and a declaration of conformity with the essential requirements of the Directive according to Annex V requirements;
- for machinery and safety components referred to in Annex IV manufactured in accordance with the standards referred to in art. 5(2), he will draw up a manufacturer's declaration of conformity:
  - after forwarding the technical file to a notified body, which acknolewdge the receipt of the file; or
  - on the basis of the certification of adequacy of the technical file by a notified body; or
  - following the "EC type-examination" by a notified body.
- for the machinery and safety components referred to in Annex IV not complying, in whole or in part, with the standards referred to in art. 5(2) or if there are no such standards, he will draw up the manufacturer's declaration of conformity with the type following "EC type-examination" by a notified body.

The notified body involved in the EC type-examination of safety components shall verify the suitability of such components for fulfilling the safety functions declared by the manufacturer.

Each machine must bear the CE marking and be accompanied by an EC declaration of conformity. Safety components are not allowed to bear the CE marking, but must be accompanied by an EC declaration of conformity.

No reference is made to a quality system, which continues to be the initiative and the responsibility of the manufacturer.

Member States shall apply the minimum criteria for the assessment of the notified bodies that have been provided for in Annex VII of the Directive. Bodies meeting the assessment criteria provided for in the relevant harmonized standards (EN 45000) are presumed to meet the said criteria.

3.1.6. Directive 89/686/EEC (and related amendments) relating to personal protective equipment

The Directives (cf. Annex V) apply to personal protective equipments (PPE), which shall mean any device or appliance to be worn or held by an individual for protection against one or more safety and health hazards.

Before placing his product on the market, the manufacturer or his authorized representative established in the Community shall, in order to affix the CE marking, submit it to the conformity assessment procedures set out in Directive 89/686/EEC.

It requires that the manufacturer draws up for all PPE a technical file comprising all relevant data on the means used to ensure that they comply with the basic requirements related to them. The manufacturer must also, according to product category:

- either issue a manufacturer's declaration of conformity for PPE of simple design as described in art. 8,3;
- or issue a declaration of conformity after the model was submitted to the "EC type examination" by a notified body;
- or, for PPE of complex design as described in art. 8,4a, issue a declaration of conformity after submission of the model to an "EC type examination" by a notified body, followed by:
  - either the assessment of the production quality system by a notified body (system for ensuring EC quality of production by means of monitoring); or
  - the set up of the manufacturing quality control system for the final product complemented by random checks of the manufactured products by a notified body (EC quality control system for the final product).

The Directive does not specify any quality system standard, but the requirements provided for setting up the production quality system are in line with standard EN ISO 9002.

The Member States shall apply the minimum criteria set out in Annex V of the Directive in order to designate the bodies to be notified. Bodies meeting the criteria laid down for the relevant harmonized standards that apply (EN 45000) are presumed to meet the criteria set out in Annex V to the Directive.

3.1.7. Directive 90/384/EEC (and related amendment) relating to non automatic weighing instruments

The Directives (cf. Annex V) apply to all non-automatic weighing instruments, which shall mean any weighing instrument requiring the intervention of an operator during weighing.

Before placing on the market instruments intended to be used according to art. 1 (2a), the manufacturer or his authorized representative established in the Community

shall, in order to affix the CE marking, submit his product to the conformity assessment procedures set out in the Directive. It provides for:

- either the "EC type examination" (for certain instruments it shall not be compulsory - art. 8.1a) accompanied by a technical file concerning the design, manufacturing and operation of the product followed by:
  - either an "EC declaration of type conformity" after assessment of the production quality system by a notified body;
  - or the "EC verification " of the products by a notified body verifying and attesting their conformity to the type;
- or the "EC unit verification" by a notified body certifying the conformity of the instrument with the directive's requirements.

Instruments intended for applications other than those defined in art. 1 (2a) shall not bear the CE marking.

The Directive does not identify any standard for the quality system, but the requirements provided for setting up the production quality system are in line with standard EN ISO 9002.

Member States shall apply the minimum criteria defined in Annex V of the Directive when designating the bodies to be notified. The bodies meeting the criteria laid down by the relevant harmonized standards (EN 45000) are presumed to meet the criteria defined in Annex V to the Directive.

3.1.8. Directive 90/385/EEC (and related amendments) relating to active implantable medical devices

The Directives (cf. Annex V) apply to active implantable medical devices, which means to any active medical device (that is to say to any device intended by the manufacturer to be used for human beings in the diagnosis, prevention, monitoring, treatment or alleviation of a disease or injury, in the investigation, replacement or modification of the anatomy or of a physiological process, and in the control of conception, and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means), relying for its functioning on a source of electrical energy (or any source of power other than that directly generated by the human body or gravity), intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Before placing his product on the market, the manufacturer shall submit it to the conformity assessment procedures set out in Directive 90/385/EEC.

Except for custom-made devices and for devices intended for clinical investigations, the manufacturer may choose:

- either to follow the procedure relating to the "EC declaration of conformity" (approval and monitoring of complete quality system by a notified body), complemented by the examination of the design of the product;
- or to submit a model to "EC type examination" by a notified body in combination with:
  - either the "EC verification" of devices by a notified body;
  - or the "EC declaration of conformity" (approval and monitoring of production quality system by a notified body).

The "EC type examination" and the "EC verification" may be followed also by the authorised representative of the manufacturer established in the Community.

The manufacturer of his authorised representative established in the Community shall affix the CE marking before the placing on the market of the device.
The manufacturer must draw up a specific declaration for custom-made devices and for those intended for clinical investigations. These devices shall not bear the CE marking.

The Directive does not identify any standard for quality systems, but the requirements provided for setting up the quality systems are in line with EN ISO 9001, for the complete quality assurance system, and EN ISO 9002, for the production quality assurance system, supplemented respectively by EN 46001 and EN 46002 (additional quality system requirements in respect of this sector).

Member States shall apply the minimum criteria set out in Annex 8 of the Directive 90/385/EEC for the designation of the conformity assessment bodies (notified bodies). Bodies meeting the requirements laid down in the corresponding harmonized standards (EN 45000) are presumed to meet the said criteria.

3.1.9. Directive 90/396/EEC (and related amendment) relating to appliances burning gaseous fuel

The Directives (cf. Annex V) apply to *appliances* burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing and having, where applicable, a normal water temperature not exceeding 105°C. Forced draught burners and heating bodies to be equipped with such burners are also considered as gas appliances.

The Directives apply as well to *fittings,* which are safety devices, controlling devices or regulating devices and subassemblies, other than forced draught burners and heating bodies to be equipped with such burners, separately marketed for trade use and designed to be incorporated into an appliance burning gaseous fuel or assembled to constitute such an appliance.

Before placing his product on the market, the manufacturer or his authorized representative established in the Community shall, for appliances and fittings,

demonstrate conformity with the essential requirements by means of the conformity assessment procedures set out in the Directive.

The means of certification of conformity of series-manufactured appliances shall be:

- the "EC type examination" by a notified body; and
- prior to placing them on the market, at the choice of the manufacturer:
  - either the "EC declaration of conformity" to type by a notified body;
  - or the "EC declaration of conformity" to type after the approval of the production quality system by a notified body;
  - or the "EC declaration of conformity" to type after the approval of the final product quality system by a notified body;
  - or "EC verification" by the notified body.

These procedures shall be applied also in respect of fittings with the exception of the affixing the CE marking and, where appropriate, the drawing-up of the declaration of conformity. A certificate shall be issued declaring the conformity of the fittings with the provisions of the Directive.

In the case of production of an appliance as a single unit or in small quantities, "EC verification" by single unit may be chosen by the manufacturer.

The Directive does not identify any quality system standard, but the requirements provided for setting up the quality system are in line with EN ISO 9002, as regards the production quality system, and EN ISO 9003, for the final product quality system.

In order to assess the technical competence of the notified bodies the Member States must apply the minimum criteria set out in Annex V of the Directive. Those assessment bodies meeting the assessment criteria laid down by the relevant harmonized standards (EN 45000) are presumed to meet the criteria set out in that Annex.

3.1.10. Directive 91/263/EEC (and related amendment) relating to telecommunications terminal equipment and Directive 93/97/EEC related to satellite earth station equipment

The Directive 91/263/EEC (cf. Annex V) applies to telecommunications terminal equipment (TTE) intended to be connected to the public telecommunications network in order to transmit, process or receive data.

Before placing his product on the market, the manufacturer or his authorized representative established in the Community shall, in order to affix the CE marking, submit it to the conformity assessment procedures set out in the related Directives.

The manufacturer may opt for submitting telecommunications terminal equipment to:

- either "EC type examination" by a notified body accompanied by: either,
  - an "EC declaration of conformity" with the type, with the notified body implementing product checks at random intervals; or
  - an "EC declaration of conformity" with the type, after the approval of the production quality assurance system by a notified body;
- or to the "EC declaration of conformity ", after approval of the full quality assurance system by a notified body.

Directive 93/97/EEC extends the field of application of Directive 91/263/EEC to satellite earth station equipment, defined as equipment capable of being used either for transmission only, or for transmission and reception, or for reception only, of radio-communications signals by means of satellites or other space-based systems.

Satellite earth terminal equipments are subject to the same conformity assessment provisions referred to in Directive 91/263/EEC. Manufacturers, for some specific equipment elements (art. 9 and art. 10) may opt, as an alternative to the said procedures, for the "Community internal production control procedure", consisting in the preparation of a technical file enabling the assessment of the product (design, manufacturing and product operation details) and of a manufacturer's declaration of conformity with the technical documentation.

Annexes III and IV of Directive 91/263/EEC clearly refer to European standards EN 29001 (now EN ISO 9001), for the complete quality assurance system, and EN 29002 (now EN ISO 9002), for the production quality assurance system, in order to provide a presumption of conformity with the Directive.

In order to designate the bodies that must carry out the conformity assessment activities provided for by these Directives, Member States shall apply the minimum criteria laid down in Annex V of Dir. 91/263/EEC. Bodies meeting the criteria arising from the relevant harmonized standards (EN 45000) are presumed to meet the said criteria. This is reinforced by attempts being made to clarify and adapt implementation of the EN 45000 to IT&T sectors via the preparation of manuals or guides.

3.1.11. Directive 92/42/EEC concerning efficiency requirements for new hot water boilers fired with liquid or gaseous fuels

The Directive (cf. Annex V) determines the efficiency requirements applicable to new hot-water boilers fired by liquid or gaseous fuels with a rated output of no less than 4 kW and no more than 400 kW.

Before placing his product on the market, the manufacturer or his authorized representative established in the Community, in order to affix the CE marking, shall submit it to the conformity assessment procedures set out in Directive 92/42/EEC in order to assess the useful efficiency requirements, set out in art. 5(1), which shall be referred to both at rated output and at part load.

Member States may decide to apply a specific system of labels enabling the energy performance of boilers to be clearly ascertained. The system shall apply to boilers the efficiency of which is superior to the requirements set out in art. 5(1) and according to the following:

- if efficiencies at rated output and at part load are equal or greater than the relevant values for standard boilers, a boiler shall be awarded an "★" as set out in Annex I, section 2;
- if efficiencies at rated output and at part load are three or more points higher than the relevant values for standard boilers, a boiler shall be awarded "★★";
- every extra step of efficiency of three points at rated output and at part load will allow the attribution of an extra "★".

Boilers in conformity with the efficiency requirements stipulated in art. 5 (1) must bear the CE marking and be accompanied by the EC declaration of conformity.

The conformity of series-produced liquid fired boilers shall be certified by:

- the "EC type examination" (module B); and followed, according to the choice of manufacturer, by:
  - the "conformity to type" procedure (module C); or
  - the "production quality assurance" procedure (module D); or
  - the "product quality assurance" procedure (module E).

The procedures for assessing the conformity of gas fired boiler efficiency are those used in order to assess the conformity to essential requirements set out in Directive 90/396/EEC.

The Directive does not identify any quality system standard, but the requirements provided for setting up the quality system are in line with EN ISO 9002, in respect of the production quality system, and EN ISO 9003, in respect of the final product quality system.

In order to assess the technical competence of the notified bodies the Member States must apply the criteria set out in Annex V of the Directive. The conformity assessment bodies meeting the assessment requirements laid down by the relevant harmonized standards (EN 45000) are presumed to conform with the said criteria.

3.1.12. Directive 73/23/EEC (and related amendment) concerning electrical equipment designed for use within certain voltage limits

The Directive (cf. Annex V) establishes the objectives relating to safety applicable to electrical equipment intended for use with a voltage rating of between 50 and 1000 volts for alternating current and between 75 and 1500 volts for direct current. It covers all safety aspects of this equipment, including protection from hazards of mechanical origin.

Before placing his product on the market, the manufacturer shall demonstrate the conformity of the equipment with technical standards, as they are defined in art. 5,6 and 7.

Where goods conform with the technical standards, the presumption that they conform to them is:

- either certified by the "conformity mark" or "certificate of conformity" issued by a body notified in accordance with procedure laid down in art. 11;
- or by the manufacturer's "declaration of conformity".

Where goods do not conform with the technical standards, it may be established that they do conform with the safety requirements (art. 2) by means of a "conformity report" drawn up by a notified body.

The Directive, drawn up in 1973, has been aligned, to some extent, with New Approach Directives by Directive 93/68/EEC (CE marking Directive).

It integrates within Directive 73/23/EEC the new provisions relating to the CE marking and, as a consequence, the reference to conformity marks has been eliminated. The affixing on equipment of any marking liable to deceive third parties as to the meaning and form of the CE marking is prohibited. Any other marking may be affixed, provided that the visibility and legibility of the CE marking is not thereby reduced.

It now requires that, before being placed on the market, the manufacturer or his authorized representative established in the Community, in order to affix the CE marking, shall:

- establish technical documentation covering the design, manufacture and operation of the electrical equipment; and
- draw up an EC declaration of conformity, ensuring and declaring that the electrical equipment satisfies the requirements of the Directive.

Article 14 of Directive 93/68/EEC states also that until 1 Jan. 1997 Member States shall allow the placing on the market and bringing into service of products which comply with the marking arrangements in force before 1 Jan. 1995.

This means that until 1 Jan. 1997, the manufacturer, or his authorized representative established in the Community, will have the choice to place on the market:

- either a product complying with the provisions of the actual wording of the Directive 73/23/EEC (not amended version);
- or a product complying with the provision of the Directive, as amended by Directive 93/68/EEC.

After 1 Jan. 1997, the end of the transitional period, the manufacturer, or his authorized representative established in the Community, shall comply with the amended version of the Directive.

Article 8(2), unchanged by Dir. 93/68/EEC, states that in the event of a challenge the manufacturer or importer may submit a report, drawn up the authorized national body, on the conformity of the electrical equipment with the safety objectives.

The Directive makes no requirements in terms of quality system to be set up by the manufacturer as a means of ensuring product conformity.

3.1.13. Directive 93/15/EEC relating to explosives for civil uses

The Directive (ref. Annex V) applies to explosives, defined as those materials and articles considered to be such in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations.

Before placing his product on the market, the manufacturer or his authorized representative established in the Community shall, in order to affix the CE marking, submit it to the conformity assessment procedures set out in the Directive.

The manufacturer may opt for submitting his product to:

- either "EC type examination" by a notified body followed, according to his choice, by:
  - either the "conformity to type" (module C), with the notified body checking randomly the products;
  - or the "production quality assurance" procedure (module D) by a notified body;
  - or the " product quality assurance" procedure (module E) by a notified body;
  - or the "product verification" (module F) by the notified body;
- or the "unit verification" (module G) by a notified body.

The Directive does not identify any quality system standard, but the requirements provided for setting up the quality systems are in line with EN ISO 9002, as regards the production quality system, and EN ISO 9003, for the final product quality system.

In order to assess the technical competence of the notified bodies the Member States must apply the criteria set out in Annex III of the Directive. Those assessment bodies meeting the assessment criteria laid down by the relevant harmonized standards (EN 45000) are presumed to meet the criteria set out in that Annex.

3.1.14. Directive 93/42/EEC relating to medical devices

The Directive (cf. Annex V) applies to medical devices and accessories, where "*medical device*" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings.

An "*accessory*" means an article which, whilst not being a device, is intended specifically by its manufacturer to be used together with a device to enable the accessory to be used in accordance with the use of the device intended by the manufacturer of the device.

Devices are divided into classes according to classification rules set out in Annex IX of the Directive. The application of those rules are governed by the intended purpose of the device.

Before devices are produced and marketed, the manufacturer or his authorized representative established in the Community, depending on the product classification, shall, in order to affix the CE marking, submit his products to:

for class I devices:

- *for sterilized devices and devices with measuring function,* the "EC declaration of conformity" and, according to his choice, either:
  - the "EC verification" by a notified body, or
  - the approval of the "production quality system" by a notified body, or
  - the approval of the "product quality system" by a notified body .

  Note: by derogation, the EC declaration of conformity in conjunction with the declarations referred to in the three alternative procedures forms a single declaration.
- *for other devices,* the "internal production control", that means preparation of technical documentation allowing assessment of the conformity of the product with Directives requirements.

for class IIa devices

at manufacturer's choice:

- either the "EC declaration of conformity" and, according to his choice, either:
  - the "EC verification" by a notified body, or
  - the approval of the "production quality system" by a notified body, or
  - the approval of the "product quality system" by a notified body .

  Note: these alternative procedures are mandatory *for the sterilized devices.* By derogation, the EC declaration of conformity in conjunction with the declarations referred to in the three alternative procedures forms a single declaration.
- or the approval of the "full quality assurance system" by a notified body (annex II), with the exception of the application of the examination of the design of the product;

for class IIb devices

at manufacturer's choice:

- either the "EC type examination" followed, according to his choice, by either

- the "EC verification" by a notified body, or
- the approval of the "production quality system" by a notified body, or
- the approval of the "product quality system" by a notified body.

- or the approval of the "full quality assurance system" by a notified body (annex II), with the exception of the application of the examination of the design of the product;

for class III devices,

at manufacturer's choice:

- either the "EC type examination" followed, according to his choice, by either:
  - the "EC verification" by a notified body, or
  - the approval of the "production quality system" by a notified body;
- or the approval of the "full quality assurance system" by a notified body (annex II), including the application of the examination of the design of the product by a notified body.

For devices intended for clinical investigations and custom-made devices the manufacturer must draw up a statement according to Annex VIII criteria. These devices shall not bear the CE marking

For devices, bearing the CE marking, *marketed as systems or procedures packs*, for which an complementary CE marking is not needed, the manufacturer must:

- draw up a declaration according to article 12 (2) criteria. If the devices are marketed *in sterile condition*, the declaration must be followed, at his choice, by either:
  - the "EC verification" by a notified body, or
  - the approval of the "production quality system" by a notified body, or
  - the approval of the "product quality system" by a notified body.

  Note: the application of these procedures and the intervention of the notified body
  are limited to the aspects relating to the obtaining of sterility.

The Directive does not identify any quality system standard, but the requirements provided for setting up the quality systems are in line with EN ISO 9001 (supplemented by EN 46001), as regards the full quality system, EN ISO 9002 (supplemented by EN 46002), as regards the production quality system, and EN ISO 9003, for the final product quality system.

In order to assess the technical competence of the notified bodies the Member States must apply the criteria set out in Annex XI of the Directive. Those assessment bodies meeting the assessment criteria laid down by the relevant harmonized standards (EN 45000) are presumed to meet those criteria.

3.1.15. Directive 94/9/EC relating to equipment and protective systems intended for use in potentially explosive atmospheres

The Directive (cf. Annex V) applies to equipment and protective systems intended for use in potentially explosive atmospheres. Safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for, or contributing to, the safe functioning of equipment and protective systems with respect to the risks of explosion are also covered by the scope of the Directive.

Equipments are classified into equipment-groups I and II, for which the following definitions apply:

- *equipment-group I,* applies to equipment intended for use in underground parts of mines, and to those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust;
- *equipment-group II,* applies to equipment intended for use in other places liable to be endangered by explosive atmospheres.

Equipment-groups are classified into categories (M1 and M2 for group I, 1 and 2 for group II) defining the required level of protection. The classification criteria are set out in Annex 1 of the Directive.

Before placing equipments on the market, the manufacturer or his authorized representative established in the Community, may, in order to affix the CE marking, submit, at his choice, his products to:

- either the "unit verification" by a notified body;

or, depending on the equipment-group and category classifications, to the following procedures:

- the "internal control of production", that means preparation of technical documentation allowing assessment of the conformity of the product with Directives requirements;
- the "EC type examination" by a notified body followed, according to his choice, by either the "EC verification" by a notified body, or the approval of the "production quality system" by a notified body;
- the "EC type examination" by a notified body followed, according to his choice, by either:
  - the declaration of "conformity to type" by the manufacturer, or
  - the approval of the "product quality system" by a notified body.

Components intended to be incorporated into equipment or a protective system follow the said conformity procedures, with the exception of the affixing the CE marking. They must be accompanied by a certificate of conformity as referred to in art. 8 (3) of the Directive.

The Directive does not identify any quality system standard, but the requirements provided for setting up the quality systems are in line with EN ISO 9002, as regards the production quality system, and EN ISO 9003, for the product quality system.

In order to assess the technical competence of the notified bodies the Member States must apply the criteria set out in Annex XI of the Directive. Those conformity assessment bodies meeting the assessment criteria laid down by the harmonized standards (EN 45000) are presumed to meet those criteria.

3.1.16. Directive 94/25/EC relating to recreational craft

The Directive (cf. Annex V) applies to recreational craft, partly completed boats and components referred to in Annex II of the Directive when separate and when installed.

Recreational craft shall mean any boat of any type, regardless of the means of propulsion, from 2.5m to 24m hull length, measured according to the appropriate harmonized standards intended for sports and leisure purposes.

Devices are divided into classes according to classification rules set out in Annex I of the Directive. The application of those rules is governed by the intended purpose of the device.

Before products are produced and placed on the market, the manufacturer or his authorized representative established in the Community, shall apply the following procedures for boat design categories A, B, C and D as referred to in Annex I of the Directive.

for categories A and B

1) for boats of less than 12 m hull length,

- the "internal production control" plus testing (module Aa);

2) for boats from 12 m to 24 m hull length, at manufacturer's choice:

- either the "EC type examination" (module B) by a notified body followed, according to his choice, by either:
  - the "EC declaration of conformity" to type (module C), or
  - the approval of the "production quality system" (module D) by a notified body, or
  - the "product verification" (module F) by a notified body;
- or the "unit verification" (module G) by a notified body;
- or the approval of the "full quality assurance system" (module H) by a notified body.

for category C

1) *for boats from 2.5 m to 12 m hull length*:
   - *where the harmonized standards (sections 3.2 and 3.3 of Annex I) are complied with,* the "internal production control" (module A);
   - *where the harmonized standards (sections 3.2 and 3.3 of Annex I) are not complied with*: the "internal production control" plus testing (module Aa);

2) *for boats from 12 m to 24 m hull length,* at manufacturer's choice:
   - either the "EC type examination" (module B) by a notified body followed, according to his choice, by either:
     - the "EC declaration of conformity" to type (module C), or
     - the approval of the "production quality system" (module D) by a notified body, or
     - the "product verification" (module F) by a notified body;
   - or the "unit verification" (module G) by a notified body;
   - or the approval of the "full quality assurance system" (module H) by a notified body.

for category D

1) *for boats from 2.5 m to 24 m hull length,* the "internal production control" (module A);

2) *for components referred to in Annex II of the Directive,* at manufacturer's choice:
   - either the "EC type examination" (module B) by a notified body followed, according to his choice, by either:
     - the "EC declaration of conformity" to type (module C), or
     - the approval of the "production quality system" (module D) by a notified body, or
     - the "product verification" (module F) by a notified body;
   - or the "unit verification" (module G) by a notified body;
   - or the approval of the "full quality assurance system" (module H) by a notified body.

The Directive does not identify any quality system standard, but requirements provided for setting up the quality systems are in line with EN ISO 9001, as regards the full quality system, and EN ISO 9002, as regards the production quality system.

In order to assess the technical competence of the notified bodies the Member States must apply the criteria set out in Annex XIV of the Directive. Those conformity assessment bodies meeting the assessment criteria laid down by the relevant harmonized standards (EN 45000) are presumed to meet those criteria.

3.1.17. Directive 95/16/EC relating to lifts

The Directive (cf. Annex V) applies to lifts permanently serving buildings and constructions and to certain safety components (cf. Annex IV) for use in such lifts. For the purpose of this Directive, lift means an appliance serving specific levels, having a car moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal and intended for the transport of persons, persons and goods, goods alone if the car is accessible, that is to say, a person may enter it without difficulty, and fitted with controls situated inside the car or within reach of a person inside.

Before safety components are placed on the market, the manufacturer or his authorized representative established in the Community, must either:

- submit the model of the safety component for EC type examination by a notified body (module B) and for production checks by a notified body (module C);
- or, submit the model of the safety component for EC type examination by a notified body (module B) and operate a product quality assurance system (module E) assessed and surveyed by a notified body;
- or, operate a full quality assurance system (module H) assessed and surveyed by a notified body.

and affix the CE marking on each safety component and draw up an EC declaration of conformity.

Before being placed on the market, a lift must either:

- if it was designed in accordance with a lift having undergone an EC type examination by a notified body, it shall be constructed, installed and tested by implementing either:
  - the final inspection, by which a notified body performs appropriate tests and checks defined by the applicable standard(s), or equivalent tests, to ensure conformity of the lift with the relevant requirements of the Directive; or
  - the product quality assurance system (module E) assessed and surveyed by a notified body; or
  - the production quality assurance system (module D) assessed and surveyed by a notified body.
- or, if it was designed in accordance with a "model lift" having undergone an EC type examination by a notified body, it shall be constructed, installed and tested by implementing either:
  - the final inspection, by which a notified body performs appropriate tests and checks defined by the applicable standard(s), or equivalent tests, to ensure conformity of the lift with the relevant requirements of the Directive; or
  - the product quality assurance system (module E) assessed and surveyed by a notified body; or

- the production quality assurance system (module D) assessed and surveyed by a notified body.

- or, if it was designed in accordance with a lift for which an assessed and surveyed full quality assurance system was put in place, supplemented by an examination of the design if the latter is not wholly in accordance with harmonized standards, it shall be constructed, installed and tested by implementing in addition either:
  - the final inspection, by which a notified body performs appropriate tests and checks defined by the applicable standard(s), or equivalent tests, to ensure conformity of the lift with the relevant requirements of the Directive; or
  - the product quality assurance system (module E) assessed and surveyed by a notified body; or
  - the production quality assurance system (module D) assessed and surveyed by a notified body.

- or, having undergone the unit verification procedure (module G), by which a notified body examines the technical dossier and performs appropriate tests and checks defined by the applicable standard(s), or equivalent tests, to ensure conformity of the lift with the relevant requirements of the Directive;

- or, having been subject to the full quality assurance system (module H), supplemented by an examination of the design if the latter is not wholly in accordance with the harmonized standards.

The installer, in all cases referred above, shall affix the CE marking on the lift and draw up an EC declaration of conformity.

The Directive explicitly refer to European standards EN 29001 (now EN ISO 9001), for the complete quality assurance system, EN 29002 (now EN ISO 9002), for the production quality assurance system, and EN 29003 (now EN ISO 9003), for the product quality assurance system, in order to provide a presumption of conformity with the Directive.

In order to designate the bodies that must carry out the conformity assessment activities provided for by this Directive, Member States shall apply the minimum criteria laid down in Annex VII. Bodies meeting the criteria arising from the relevant harmonized standards (EN 45000) are presumed to meet the said criteria.

3.2. Summary table of conformity assessment procedures provided for in the New Approach Directives.

	DESIGN + PRODUCTION MODULES							PRODUCTION MODULES		
Directives	A	B+C	B+D	B+E	B+F	G	H	D (+ tf)	E (+ tf)	F (+ tf)
87/404/EEC Simple pressure vessels	x (+)	x			x					x
88/378/EEC Toys	x	x								
89/106/EEC Construction products	x		x					x		
89/336/EEC Electromagnetic compatib.	x x (+)	x								
89/392/EEC Machinery	x	x								
89/686/EEC Personal protective equip.	x	x x (+)	x							
90/384/EEC Non automatic weighing instruments			x		x	x		x		x
90/385/EEC Active implantable medical devices			x		x		x (+)			
90/396/EEC Appliances burning gaseous fuels		x (+)	x	x	x	x				
91/263/EEC Telecommunications terminal equipment	x (1)	x (+)	x				x			
92/42/EEC Hot-water boilers fired with liquid or gas fuel		x (+)	x	x						
73/23/EEC Electrical equipment designed for use within certain voltage limits	x									
93/15/EEC Explosives for civil uses		x (+)	x	x	x	x				
93/42/EEC Medical devices	x (+)		x	x	x		x (+)	x	x	x

(continue)

	DESIGN + PRODUCTION MODULES							PRODUCTION MODULES		
Modules **Directives**	**A**	**B+C**	**B+D**	**B+E**	**B+F**	**G**	**H**	**D (+ tf)**	**E (+ tf)**	**F (+ tf)**
94/9/EC **Equip. and protect. systems intended for use in potent. explosive atmospheres**	x	x	x	x	x	x				
94/25/EC **Recreational craft**	x x (+)	x	x		x	x	x			
95/16/EC **Lifts**		x(+)	x	x	x	x	x x(+)			

Legenda:

x = procedure provided for by the Directive

tf = technical file

(+) = with supplementary requirements

Note

(1) Applicable to specific equipment elements defined in art. 9 and 10 of Directive 93/97/EEC, which supplements Directive 91/263/EEC.

4. GENERAL CONSIDERATIONS ON QUALITY ASSURANCE STANDARDS APPLICATION

Although the EN ISO 9000 series of European standards and EN 45000 standards are not mandatory under Community law, the setting up of quality systems meeting the requirements of the directives is so, unless the directives leave a choice of another system. Compliance with those standards yields obvious advantages to economic operators not only in terms of the internal management of their companies or organizations but also in terms of presumption of conformity with Community directives, and, moreover, the probability of answering the appropriate public procurement requirements.

It must be made clear that the EN ISO 9000 standards are not product standards and thus do not specify the final characteristics of products. They set out the various components of the quality system to be set up by companies in order to demonstrate their capacity to provide products that conform and that, in this situation, may be applied to any product regardless.

One of the most frequently made criticisms is that the setting up of a quality system may be highly (or even too) expensive for SMEs. In order to analyse that question it is first of all necessary to try to answer another question: "Why should a quality system be set up?"

There are two basic reasons:

- firstly, in order to assure that products continuously meet the technical and quality specifications or in order to meet customer requirements;
- secondly, in order to obtain those results at the lowest cost.

When the setting up of a quality system by companies is driven by economic and strategic reasons it will fulfil those two basic aims and thus improve product quality, customer satisfaction and company competitiveness.

If the quality system is set up in order solely to meet the certification goal, the company's organization may be reluctant to adopt and operate the new prescriptions, as they may perceive them as being imposed arbitrarily without any quality and economic benefit to the company. In such circumstances the quality system may be seen as adding only cumbersome activities and as creating unnecessary bureaucracy.

It is important to stress, as Dr. Juran did at the 33rd Conference held by the European Quality Organization in Vienna in 1989, that:

> "Certification is, without doubt, highly important but it does not confer quality on products which do not possess it. Certification is not an end in

itself, but is an excellent instrument in order to guarantee and improve product quality."

However, when a quality system is set up account must be taken of the specific characteristics of products and also of the manufacturing process and technology used. These specific needs, depending on the sector or type of industry, are in the process of spawning a body of other supplementary standards which will add the aspects that are specific to each sector of economic activity to the basic EN ISO 9000 standards. For example:

- EN 29004-2, Quality Management and quality system components. Part 2, User guidelines for services;

- EN 29000-3, Quality management and quality assurance standards. Part 3, Guides for the application of Standard ISO 9001 to the development, provisions and maintenance of software.

- EN 46001 and EN 46002, Specific requirements concerning the implementation respectively of EN ISO 9001 and EN ISO 9002 in the industries that produce medical devices;

For the EN 45000 series, ECITC (European Committee for IT&T Testing Certification, Sector Committee of EOTC) and EAL (European co-operation for Accreditation of Laboratories) are currently finalizing a guide for the application of the EN 45000 series for the IT & T sector.

Finally, the EN ISO 9000 and EN 45000 series of standards are standards covering the quality management of companies and conformity assessment values and they can thus be used with advantage by the public authorities in all sectors of activity and in particular protection of the environment, energy, foodstuffs and not only in the traditional industrial sector where they were devised. This use even becomes economically essential once it enables duplication to be avoided of the procedures and activities that are intended to check company conformity with the legal provisions by means of reliable, transparent and credible procedures which cover all of the various aspects of the company as a whole.

ANNEX I

DEFINITIONS

Only those conformity assessment terms considered to be the most essential for the overall comprehension of the text are set out here. The definitions chosen are those which provide the greatest coherence among the various concepts.

For other definitions use may be made of either EN 45020 (equivalent to ISO Guide 2), and EN ISO 8402 (equivalent to ISO 8402).

Product

Result of activities or processes.

Note: A product may include hardware, software, processed materials, service or a combination thereof.

Quality

Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

Quality management

All activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system.

Quality system

Organizational structure, procedures, processes and resources needed to implement quality management.

Note: The quality system should be as comprehensive as needed to meet the quality objectives.

Quality assurance

All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality.

Quality audit

Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives..

Note: Standard ISO 10011 - Guides for quality system audits (in three parts: Part 1 - Audits; Part 2 - Criteria for auditor qualifications; Part 3 - Management of quality audit programmes) provides useful information on the carrying out of organizations' quality system audits.

Test

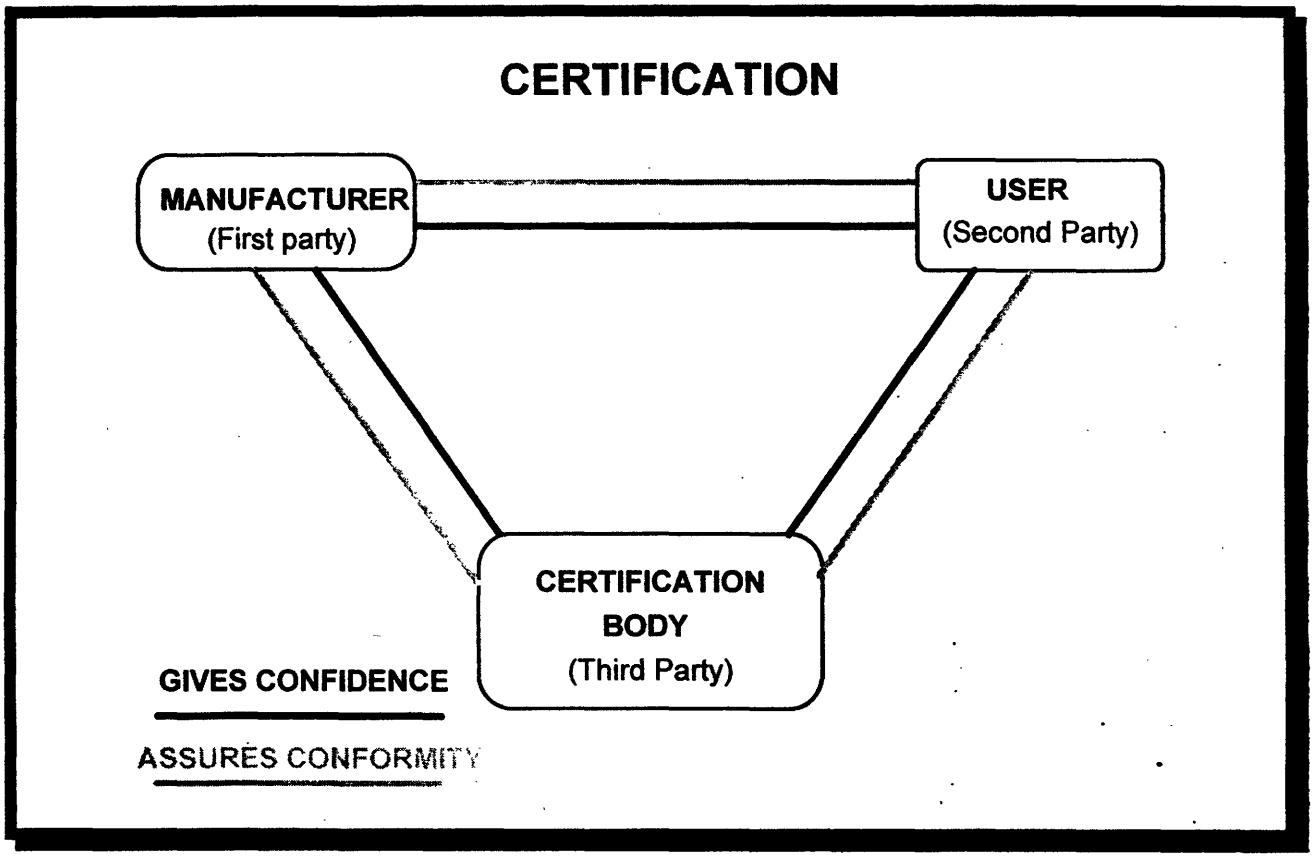
Technical operation that consists of the determination of one or more characteristics of a given product, process or given service according to a specified procedure.

Inspection

Evaluation for conformity by measuring, observing, testing or gauging the relevant characteristics.

Accreditation

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.



Certification

Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements.

Notification

The act by means of which a public authority in a Member State notifies the Commission and other Member States that a body or bodies are responsible for assessing conformity under a Community directive.

Notification may be divided into two acts:

- the act of identifying the body deriving from the political responsibility of the national authorities;
- the act of recognizing technical competence, thus enabling objectivity, transparency and a meeting of the criteria to be assured.

Member State authorities may check the technical competence of the conformity assessment bodies that is needed for notification either on the basis of the authorities' own means (the authorities have their own inspectors or quality auditors) or on the basis of any national accreditation system.

The conformity assessment bodies notified by the Member States under the Community directives are generally identified as Notified Bodies.

Sub-contracting (by the notified bodies)

Sub-contracting within the terms of this document only concerns the subcontracting, by notified bodies, of certain technical tasks that have been covered by a detailed, strictly confined description: e.g., testing, examination, comparison, quality auditing. These activities must be carried out on the basis of pre established technical specifications that are based on objective criteria in order to ensure total transparency.

The sub contracting body must be technically competent and be able to demonstrate independence and objectivity on the basis of the same criteria and under the same conditions as the notified bodies. Compliance with EN 45000 standards enables a presumption to be made that those conditions are met.

In any case, the notified body will ensure that sub contracted tasks are assessed and monitored in line with the requirements imposed, and remains responsible for all of the activity covered by the notification.

The notified body cannot under any circumstances subcontract all of its activities, as that would make the notification meaningless. It cannot subcontract assessment and appraisal activities, which are the essential tasks for which it was notified.

ANNEX II

TABLE ISO/CEN QUALITY STANDARDS

ISO				CEN
ISO STANDARD	**STAGE**	**DATE**	**REVISION**	**EN STANDARD**
ISO 8402: Quality Management and quality assurance standards - Vocabulary.	IS	1994		EN ISO 8402 (95)
ISO 9000-1: Quality management and quality assurance standards. Part 1: Guidelines for selection and use.	IS	1994		EN ISO 9000-1 (94) (former EN 29000)
ISO 9000-2: Quality management and quality assurance standards. Part 2: Generic guidelines for the application of ISO 9001, ISO 9002, ISO 9003.	IS	1993		
ISO 9000-3: Quality management and quality assurance standards. Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software.	IS	1991		EN 29000-3 (93)
ISO 9000-4/IEC 300.1: Quality management and quality assurance standards. Part 4: Guide to dependability programme management.	IS	1993		
ISO 9001: Quality systems - Model for quality assurance in design, development, production, installation and servicing.	IS	1994		EN ISO 9001 (94) (former EN 29001)
ISO 9002: Quality system - Model for quality assurance in production, installation and servicing.	IS	1994		EN ISO 9002 (94) (former EN 29002)
ISO 9003: Quality systems - Model for quality assurance in final inspection and test.	IS	1994		EN ISO 9003 (94) (former EN 29003)
ISO 9004-1: Quality management and quality system elements. Guidelines.	IS	1994		EN ISO 9004-1 (94) (former EN 29004)
ISO 9004-2: Quality management and quality system elements. Part 2: Guidelines for services.	IS	1991		EN 29004-2 (93)
ISO 9004-3: Quality management and quality system elements. Part 3: Guidelines for processed materials.	IS	1993		

(continue)

ISO				CEN
ISO STANDARD	**STAGE**	**DATE**	**REVISION**	**EN STANDARD**
ISO 9004-4: Quality management and quality system elements. Part 3: Guidelines for quality improvement.	IS	1993		
ISO 10005: Quality management. Guidelines for quality plans.	IS	1995		
10006: Quality management. Guidelines on quality assurance for project management.	CD		1996	
ISO 10007: Quality management. Guidelines for configuration management.	IS	1995		It will be published in 1996 as EN ISO 10007
9004-8: Quality management and quality system elements. Part 8: Guidelines on quality principles and their application to management practices.	NP		1997	
ISO 10011-1: Guidelines for auditing quality systems. Part 1: Auditing.	IS	1990		EN 30011/1 (93)
ISO 10011-2: Guidelines for auditing quality systems. Part 2: Qualification criteria for quality systems auditors.	IS	1991		EN 30011/2 (93)
ISO 10011-3: Guidelines for auditing quality systems. Part 3: Management of audit programmes.	IS	1991		EN 30011/3 (93)
ISO 10012-1: Quality assurance requirements for measuring equipment. Part 1: Metrological confirmation system for measuring equipment.	IS	1992		EN 30012/1 (93)
10012-2: Quality assurance requirements for measuring equipment Part 2: Measurement assurance.	DIS		1996	
ISO 10013: Guidelines for developing quality manuals.	IS	1995		
10014: Guide to the economics of quality management.	CD		1996	
10015: Continuing education and training guidelines.	NP		1997	
0016: Inspection and test records. Presentation of results.	NP		1996	
10017: Application of statistical methods.	NP		1998	

ANNEX III

TABLE OF EN 45000 STANDARDS

AND RELATING ISO REFERENCES

EN STANDARD	DOC. BASE	STAGE	DATE	ACTUAL ISO REFER.
EN 45001 - General criteria for the operation of testing laboratories	ISO/IEC Guides 25 (1982), 38 (1983) and 43 (1984)	EN Standard	1989	ISO/IEC Guide 25 (1990)
EN 45002 - General criteria for the assessment of testing laboratories	ISO/IEC Guide 38 (1983)	EN Standard	1989	
EN 45003 - General criteria for laboratory accreditation bodies	ISO/IEC Guide 58 (1993)	EN Standard	1995	ISO/IEC Guide 58 (1993)
EN 45004 - General criteria for the operation various types of bodies performing inspection		EN Standard	1995	
prEN 45010 - General requirements for assessment and accreditation of certification/registration bodies	ISO/CASCO 226	EN Proposal		ISO/CASCO 226 (it will be published as ISO/IEC Guide 61)
EN 45011 - General criteria for certification bodies operating product certification	ISO/IEC Guide 28 (1982), 40 (1983)	EN Standard	1989	ISO/IEC Guide 40 (1983). i
pr EN 45011 - General criteria for certification bodies operating product certification	ISO/CASCO 228	EN Proposal		ISO/CASCO 228 (it will be published as new ISO/IEC Guide 40).
EN 45012 - General criteria for certification bodies operating quality system certification	ISO/IEC Guides 40 (1983), 48 (1986)	EN Standard	1989	ISO/IEC Guides 40 (1983), 48 (1986),
prEN 45012 - General requirements for bodies operating assessment and certification/registration of quality system	ISO/CASCO 227	EN Proposal		ISO/CASCO 227 (it will be published as ISO /IEC Guide 62)
EN 45013 - General criteria for certification bodies operating certification of personnel	ISO/IEC Guide 40 (1983)	EN Standard	1989	
EN 45014 - General criteria for suppliers' declaration of conformity	ISO/IEC Guide 22 (1982)	EN Standard	1989	ISO/IEC Guide 22 (1982) (under revision)
EN 45020 - General terms and their definitions concerning standardization and related activities	ISO/IEC Guide 2 (1991)	EN Standard	1993	ISO/IEC Guide 2 (1995)
prEN 45ASS - General requirements for operation and recognition: assessment procedures		EN Proposal		ISO/CASCO 226
prEN 45ACC - General requirements for operation and recognition: accreditation procedures		EN Proposal		ISO/CASCO 226

ANNEX IV

THE EN ISO 9000 (former EN 29000) STANDARDS IN THE MEMBER STATES

	Quality management and quality assurance standards. Part 1: Guidelines for selection and use.	Quality systems - Model for quality assurance in design, development, production, installation and servicing.	Quality system - Model for quality assurance in production, installation and servicing.	Quality systems - Model for quality assurance in final inspection and test.	Quality management and quality system elements. Part 1: Guidelines
	ISO 9000-1 (1994)	ISO 9001 (1994)	ISO 9002 (1994)	ISO 9003 (1994)	ISO 9004-1 (1994)
	EN ISO 9000-1(1994)	EN ISO 9001(1994)	EN ISO 9002 (1994)	EN ISO 9003 (1994)	EN ISO 9004-1 (1994)
Austria	ÖNORM EN 29000	ÖNORM EN 29001	ÖNORM EN 29002	ÖNORM EN 29003	ÖNORM EN 29004
Belgium	NBN EN ISO 9000-1	NBN EN ISO 9001	NBN EN ISO 9002	NBN EN ISO 9003	NBN EN ISO 9004-1
Denmark	DS EN ISO 9000-1	DS EN ISO 9001	DS EN ISO 9002	DS EN ISO 9003	DS EN ISO 9004-1
Finland	SFS EN ISO 9000-1	SFS EN ISO 9001	SFS EN ISO 9002	SFS EN ISO 9003	SFS EN ISO 9004-1
France	NF EN ISO 9000-1	NF EN ISO 9001	NF EN ISO 9002	NF EN ISO 9003	NF EN ISO 9004-1
Germany	DIN EN ISO 9000-1	DIN EN ISO 9001	DIN EN ISO 9002	DIN EN ISO 9003	DIN EN ISO 9004-1
Greece	ELOT EN ISO 9000-1	ELOT EN ISO 9001	ELOT EN ISO 9002	ELOT EN ISO 9003	ELOT EN ISO 9004-1
Ireland	IS EN ISO 9000-1	IS EN ISO 9001	IS EN ISO 9002	IS EN ISO 9003	IS EN ISO 9004-1
Italy	UNI EN ISO 9000-1	UNI EN ISO 9001	UNI EN ISO 9002	UNI EN ISO 9003	UNI EN ISO 9004-1
Luxembourg	TIM EN ISO 9000-1	TIM EN ISO 9001	TIM EN ISO 9002	TIM EN ISO 9003	TIM EN ISO 9004-1
Netherlands	NEN EN ISO 9000-1	NEN EN ISO 9001	NEN EN ISO 9002	NEN EN ISO 9003	NEN EN ISO 9004-1
Portugal	NP EN ISO 9000-1	NP EN ISO 9001	NP EN ISO 9002	NP EN ISO 9003	NP EN ISO 9004-1
Spain	UNE EN ISO 9000-1	UNE EN ISO 9001	UNE EN ISO 9002	UNE EN ISO 9003	UNE EN ISO 9004-1
Sweden	SS EN ISO 9000-1	SS EN ISO 9001	SS EN ISO 9002	SS EN ISO 9003	SS EN ISO 9004-1
United Kingdom	BS EN ISO 9000-1	BS EN ISO 9001	BS EN ISO 9002	BS EN ISO 9003	BS EN ISO 9004-1

ANNEX V

THE NEW APPROACH DIRECTIVES

NEW APPROACH DIRECTIVES	O J E C	Adoption date	Application date	Transitional period
Simple pressure vessels				
Dir. 87/404/EEC	L 220/48/87	01/01/90	01/07/90	17/09/90 - 01/07/92
Dir. 90/488/EEC (amend. Dir. 87/404/EEC)	L 270/25/90	01/07/91	01/07/91	
Safety of toys				
Dir. 88/378/EEC	L 187/01/88	30/06/89	01/01/90	
Construction products				
Dir. 89/106/EEC	L 40/12/89	27/06/91	27/06/91	
Electromagnetic compatibility				
Dir. 89/336/EEC	L 139/19/89	01/07/91	01/01/92	30/06/92 - 31/12/95
Dir. 92/31/EEC (amend. Dir. 89/336/EEC)	L 126/11/92	28/07/92	28/10/92	
Machinery				
Dir. 89/392/EEC	L 183/09/89	01/01/92	01/01/93(1)	31/12/92 - 31/12/94(2)
Dir. 91/368/EEC (amend. Dir. 89/392/EEC)	L 198/16/91	01/01/92	01/01/93	
Dir. 93/44/EEC (amend. Dir. 89/392/EEC)	L 175/12/93	01/07/94	01/01/95(3)	14/06/93 - 31/12/96
Personal protective equipment				
Dir. 89/686/EEC	L 399/18/89	31/12/91	01/07/92	30/06/92 - 30/06/95
Dir. 93/95/EEC (amend. Dir. 89/686/EEC)	L 276/11/93	29/01/94	29/01/94	
Non automatic weighing instruments				
Dir. 90/384/EEC	L 189/01/90	01/07/92	01/01/93	01/07/92 - 01/07/2002
Active implantable medical devices				
Dir. 90/385/EEC	L 189/17/90	01/07/92	01/01/93	31/12/92 - 31/12/94
Dir. 93/42/EEC (amend. Dir. 90/385/EEC)	L 169/01/93	01/07/94	01/01/95	31/12/94 - 14/06/98
Appliances burning gaseous fuels				
Dir. 90/396/EEC	L 196/15/90	01/07/91	01/01/92	01/01/92 - 31/12/95
Telecommunications terminal equipment				
Dir. 91/263/EEC	L 128/01/91	06/11/92	06/11/92	
Dir. 93/97/EEC (suppl. Dir. 91/263/EEC).	L 290/01/93	01/05/92	01/05/92	
New hot-water boilers fired with liquid or gaseous fuel				
Dir. 92/42/EEC	L 167/17/92	01/01/93	01/01/94	21/05/92 - 31/12/97
Electrical equipment designed for use within certain voltage limits				
Dir. 73/23/EEC	L 77/29/73	19/08/74	19/08/74	
Directive 93/68/EEC (the "CE marking Directive") amending all above listed (12) Directives	***L 220/01/93***	***01/01/94***	***01/01/95***	***01/01/95 - 01/01/97***

(continue)

NEW APPROACH DIRECTIVES	O J E C	Adoption date	Application date	Transitional period
Explosives for civil uses [a] Dir. 93/15/EEC	L121/20/93	30/06/94	01/01/95	31/12/94 - 31/12/2002
Medical devices Dir. 93/42/EEC	L 169/01/93	01/07/94	01/01/95	01/01/95 - 14/06/98
Equipment and protect. systems intended for use in potentially explosive atmospheres Dir. 94/9/EC	L 100/1/94	01/09/95	01/03/96	23/03/94 - 30/06/2003
Recreational craft Dir. 94/25/EC	L 164/15/94	16/12/95	16/06/96	16/06/94 - 16/06/98
Lifts Dir. 95/16/EC	L 213/1/95	01/01/97	01/07/97	29/06/95 - 30/06/99

NOTES:

(1) 1 July 1995 shall apply for the equipment referred to in Directives 86/295/EEC, 86/296/EEC and 86/663/EEC.

(2) 31 December 1995 shall apply as end date for the equipment referred to in Directives 86/295/EEC, 86/296/EEC and 86/663/EEC.

(3) 1 July 1994 shall apply for art. 1(10) excluding a,b,c; art 1(11) a,b; art. 1(12) c,d,e,f.

ANNEX VI

THE HARMONIZED STANDARDS

BY NEW APPROACH DIRECTIVE

NEW APPROACH DIRECTIVES	Harmonized Standards published in the Official Journal of the European Community
Simple pressure vessels Dir. 87/404/EEC	EN 286-1 EN 286-2 EN 286-3 EN 286-4
Safety of toys Dir. 88/378/EEC	EN 71-1 EN 71-2 EN 71-3 HD 271 S 1 Am1 to HD 271 S 1 Am2 to HD 271 S 1 EN 71-4 Am3 to HD 271 S 1 EN 71-5 EN 71-6 EN 71-3 (rev.)
Construction products Dir. 89/106/EEC	No standards published in the Official Journal
Electromagnetic comp atibility Dir. 89/336/EEC	EN 50065-1 EN 55011 EN 55013 EN 55014 (86) EN 55015 (86) EN 55020 (87) EN 55022 EN 60555-2 EN 60555-3 EN 50081-1 EN 50082-1 Am1 to EN 50065-1 EN 50081-2 Am11 to EN 55013 EN 55014 (93) EN 55015 (92) EN 55020 (93) Am1 to EN 60269-1 EN60282-1 EN 60687 Am1 to EN 60945 EN 61036 EN 61037 EN 61038 EN 50082-2 AmA12 to EN 55013 AmA2 to EN 55014 AmA1 to EN 55015 AmA1 to 60555-3 EN 55022 EN 55104 EN 60601-1-2 EN 60945 EN 61000-3-2 EN 61000-3-3
Machinery Dir. 89/392/EEC	EN 292-1 EN 292-2 EN 294 EN 349 EN 418 EN 457 EN 775 EN 23741 EN 23742 EN 289 EN 60204-1 EN 474-1 EN 563 EN 608 EN 25136 EN 28094 EN 28662-1 EN 31252 EN 31253 EN 1152 EN 690 EN 115
Personal protective equipment Dir. 89/686/EEC	EN 132 EN 133 EN 134 EN135 EN 136 EN 140 EN 141 EN 142 EN 148-1 EN 148-2 EN 143 EN 144-1 EN 146 EN 147 EN 149 EN 136-10 EN 137 EN 145-2 EN 148-3 EN 169 EN 170 EN 171 EN 250 EN 341 EN 344 EN 345 EN 346 EN 347 EN 348 EN 352-1 EN 352-2 EN 353-1 EN 353-2 EN 354 EN 355 EN 358 EN 360 EN 361 EN 362 EN363 EN 364 EN 365 EN 367 EN 368 EN 369 EN 371 EN 372 EN 373 EN 381-1 EN 400 EN 401 EN 403 EN 405 EN 412 EN 138 EN 145 EN 207 EN 208 EN 269 EN 340 EN 366 EN 374-1 EN 374-2 EN 374-3 EN 379 EN 388 EN 393 EN 394 EN 395 EN 396 EN 399 EN 402 EN 404 EN 407 EN 420 EN 421 EN 458 EN 463 EN 464 EN 468 EN 471 EN 510 EN 24869-1 EN 24869-3 EN 139 EN 270 EN 530
Non automatic weighing instruments Dir. 90/384/EEC	EN 45501 (92)/AC (93)

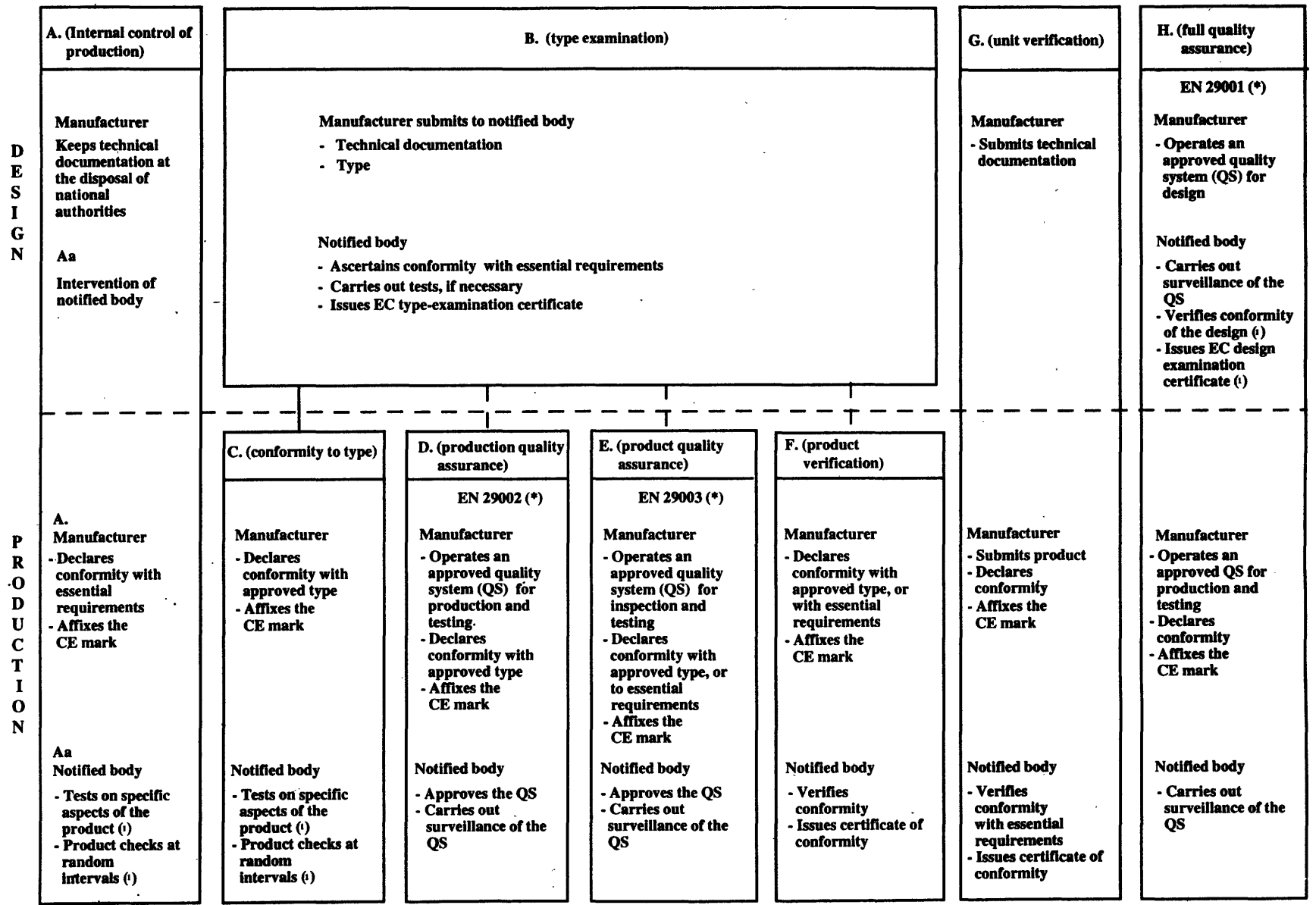
(Continue)

NEW APPROACH DIRECTIVES	Harmonized Standards published in the Official Journal of the European Community
Active implantable medical devices Dir. 90/385/EEC	EN 550 EN 552 EN 554 EN 30993-3 EN 30993-4 EN 30993-5 EN 46001 EN 46002
Appliances burning gaseous fuels Dir. 90/396/EEC	EN 291 EN 298 EN 377 EN 437 EN 297 EN 549 EN 126 EN 203-2
Telecommunications terminal equipment Dir. 91/263/EEC	TBR 3 TBR 4 TBR 5 TBR 6 TBR 7 TBR 8 TBR 9 TBR 10 TBR 12 TBR 14
New hot-water boilers fired with liquid or gaseous fuel Dir. 92/42/EEC	No standards published in the Official Journal
Electrical equipment designed for use within certain voltage limits Dir. 73/23/EEC	Standards published in the following Official Journal: 92/C 210/12 93/C 18/04 93/C 319/02 94/C 169/04 94/C 199/03
Explosives for civil uses Dir. 93/15/EEC	No standards published in the Official Journal
Medical devices Dir. 93/42/EEC	EN 550 EN 552 EN 554 EN 30993-3 EN 30993-4 EN 30993-5 EN 46001 EN 46002 EN 60601-1-2
Equipment and protective systems intended for use in potentially explosive atmospheres Dir. 94/9/EC	No standards published in the Official Journal
Recreational craft Dir. 94/25/EC	EN 28846 EN 28847 EN 28848 EN 28849 EN 29775
Lifts Dir. 95/16/EC	No standards published in the Official Journal

ANNEX VII

THE CONFORMITY ASSESSMENT PROCEDURES TO BE USED IN THE TECHNICAL HARMONIZATION DIRECTIVES (NEW APPROACH DIRECTVES)

CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

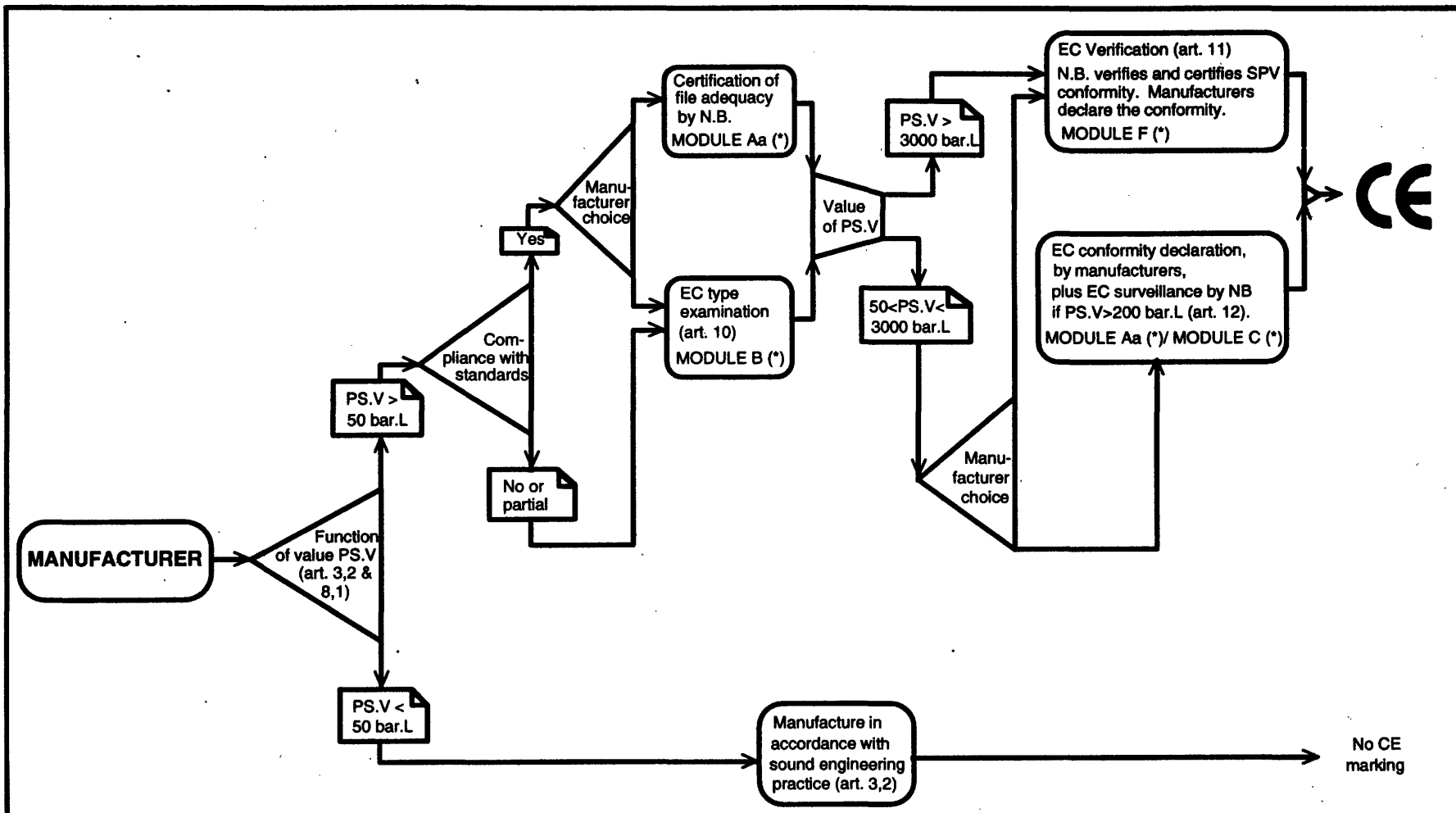


(1) Supplementary requirements which may be used in specific directives

(*) Renamed EN ISO 9001 (EN 29001), EN ISO 9002 (EN 29002) and EN ISO 9003 (EN 29003) in 1994 standards updating.

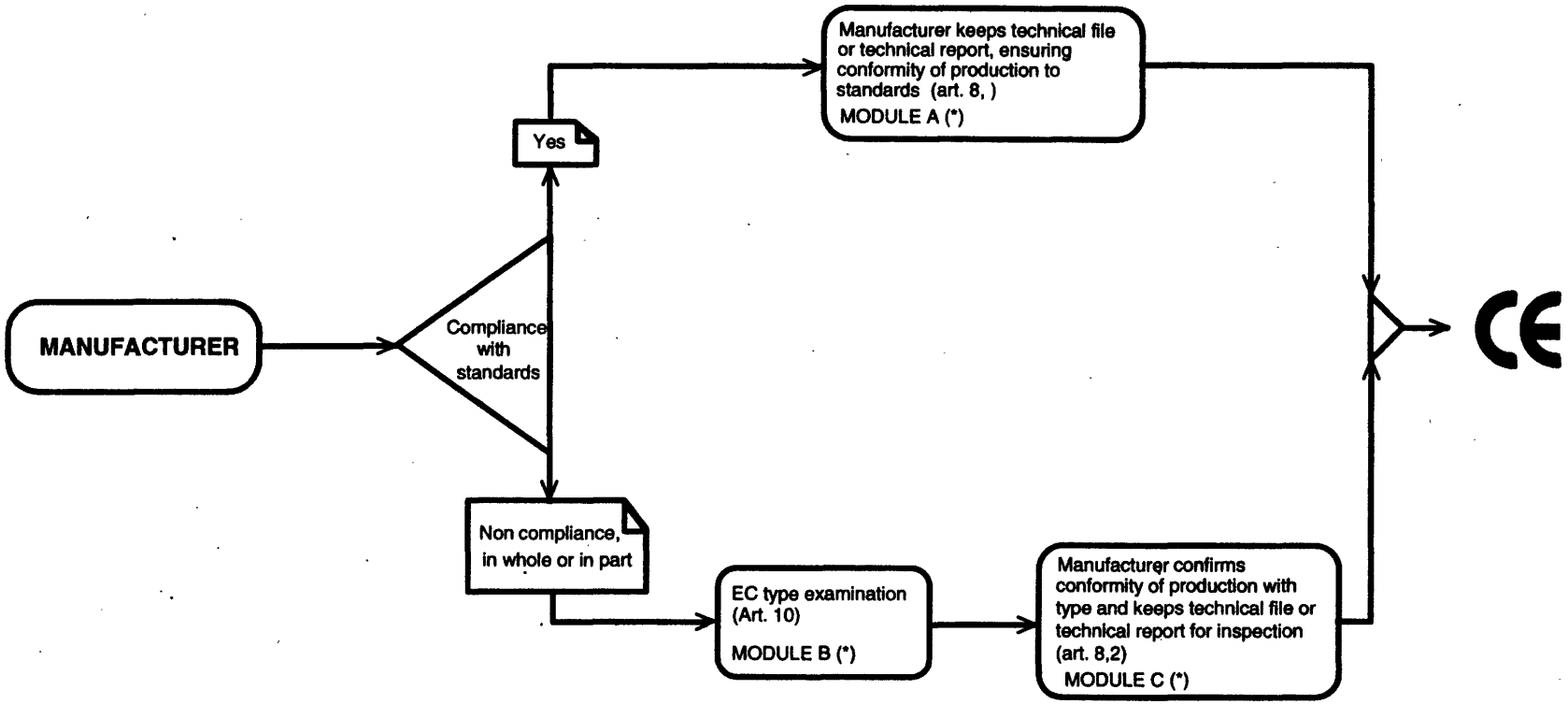
ANNEX VIII

FLOWCHARTS OF THE CONFORMITY ASSESSMENT PROCEDURES PROVIDED FOR IN THE NEW-APPROACH DIRECTIVES



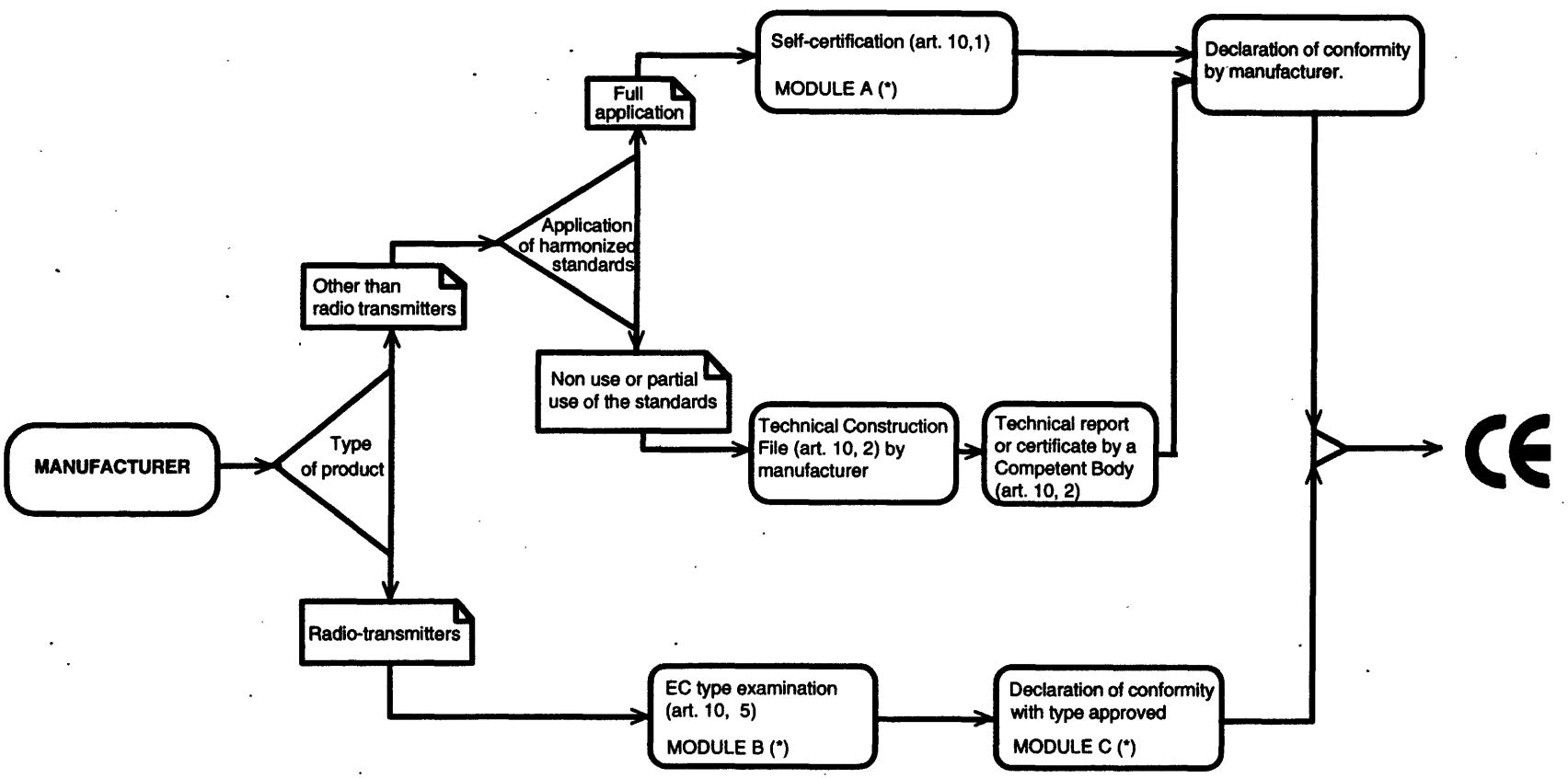
Flowchart for the conformity assessment procedures provided for in Directive 87/404/EEC on simple pressure vessels

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



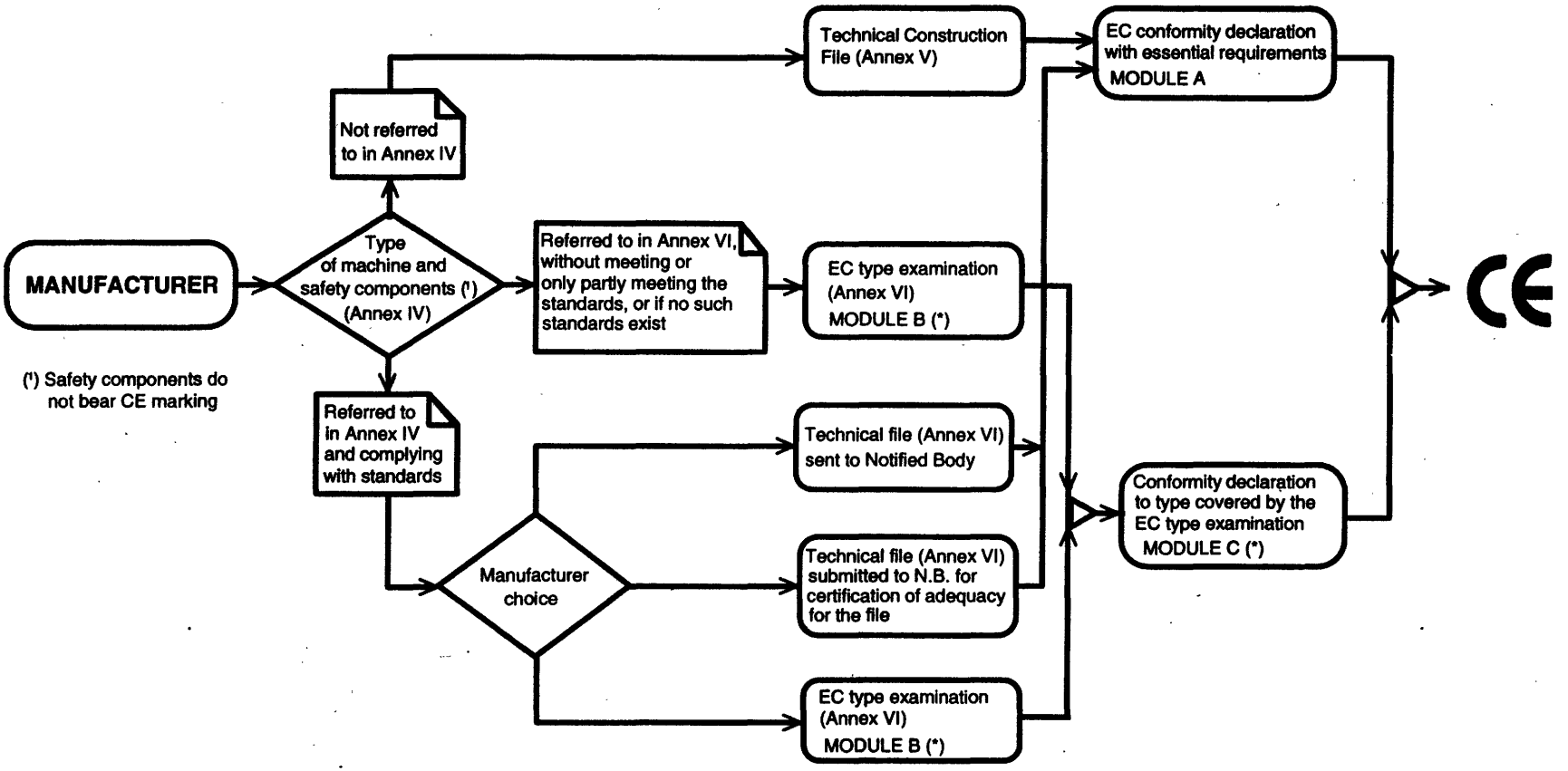
Flowchart for the conformity assessment procedures provided for in Directive 88/378/EEC on safety of toys

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



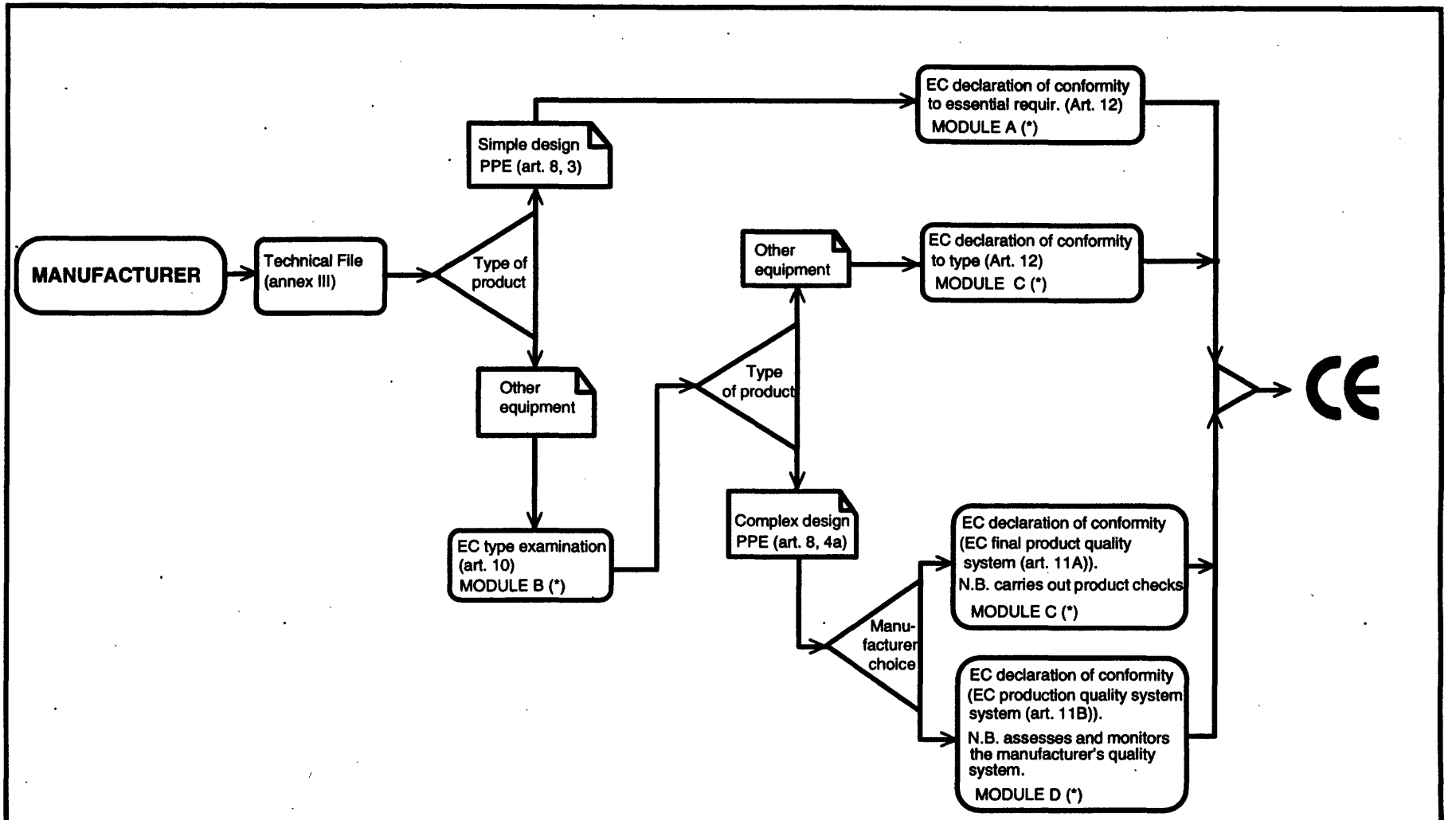
Flowchart for the conformity assessment procedures provided for in the Directive 89/336/EEC on electromagnetic compatibility

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



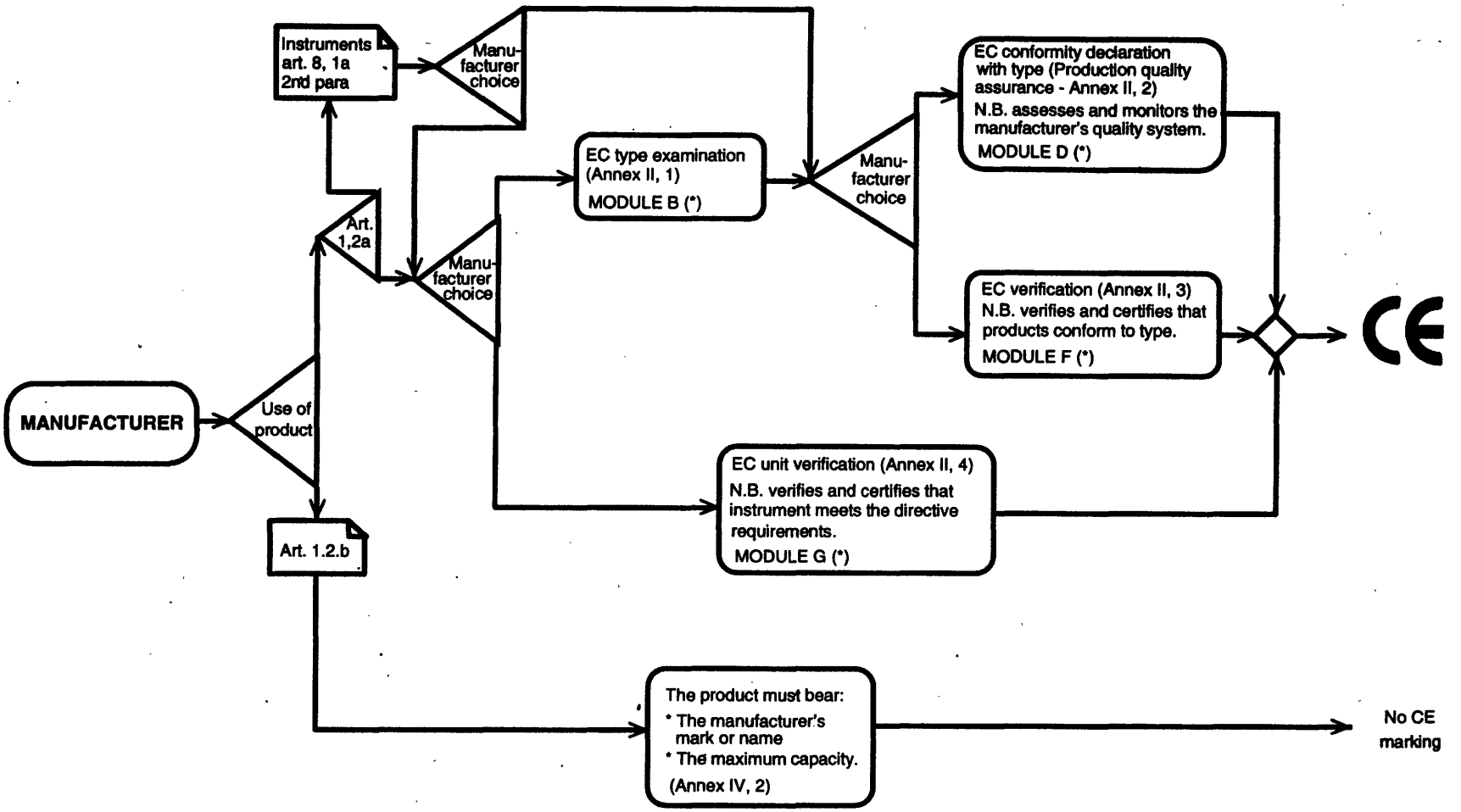
Flowchart for the conformity assessment procedures provided for in Directive 89/392/EEC on machinery

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



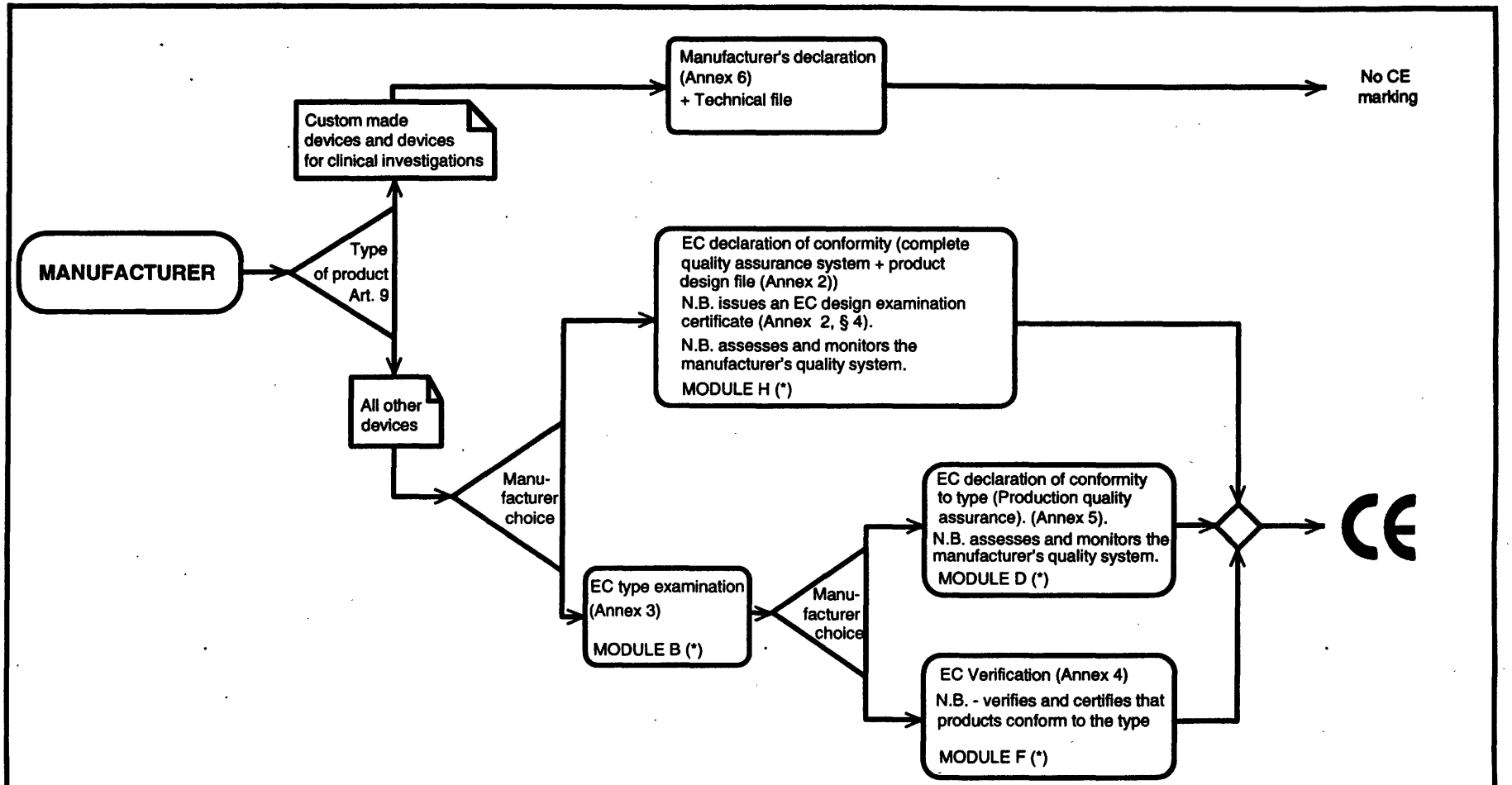
Flowchart for the conformity assessment procedures provided for in Directive 89/686/EEC on personal protection equipment (PPE)

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



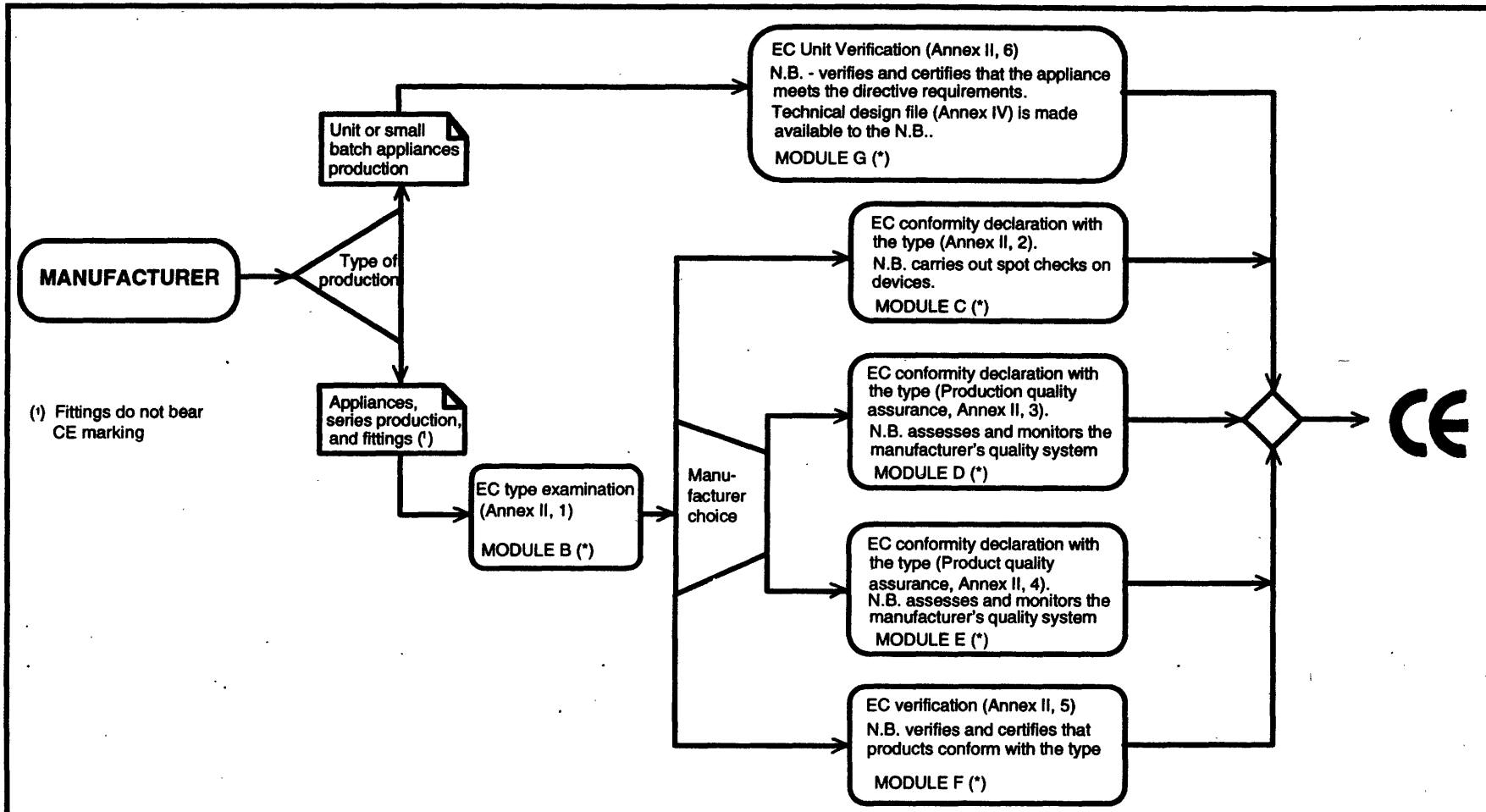
Flowchart for the conformity assessment procedures provided for in Directive 90/384/EEC on non-automatic weighing instruments

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



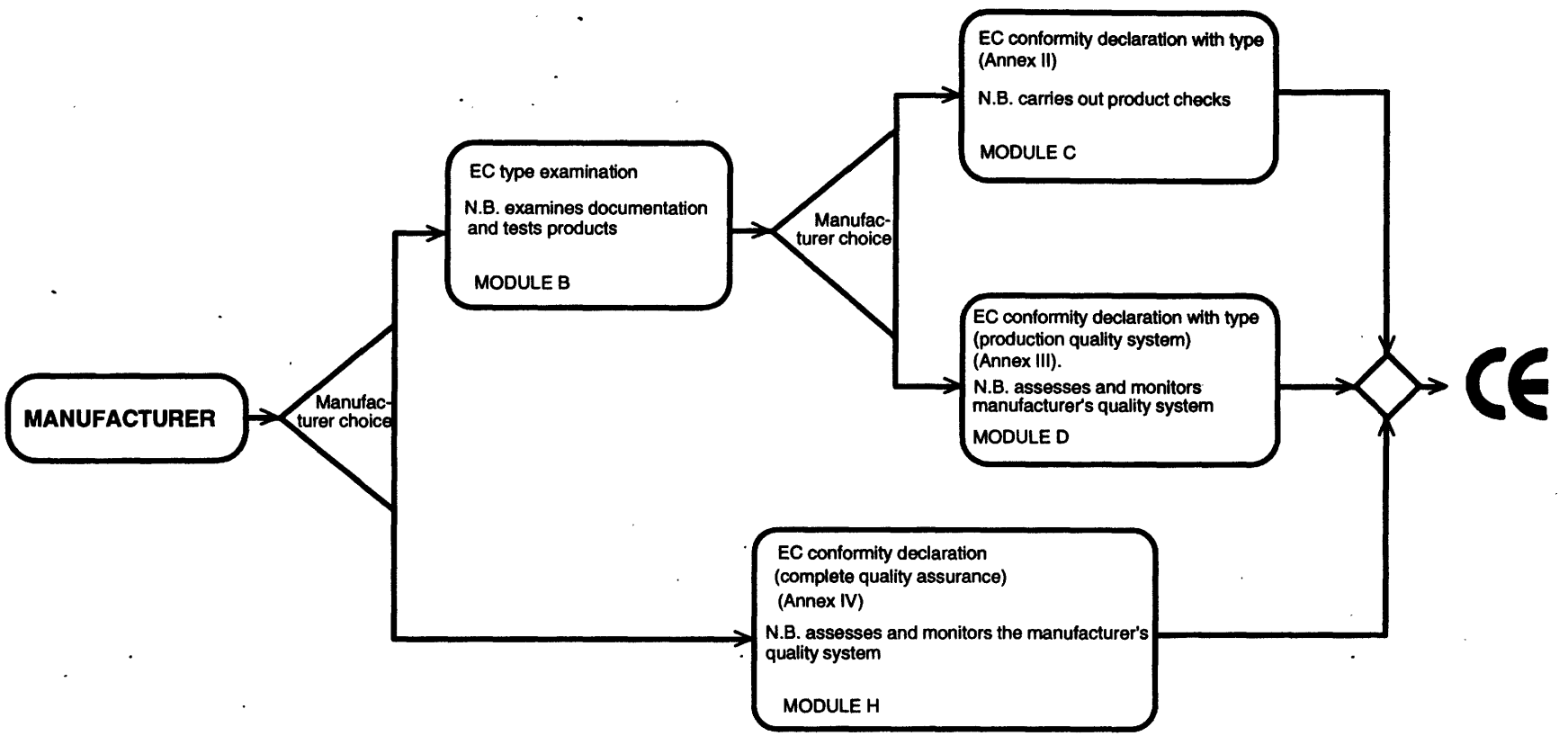
Flowchart for the conformity assessment procedures provided for in Directive 90/385/EEC on active implantable medical devices

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.



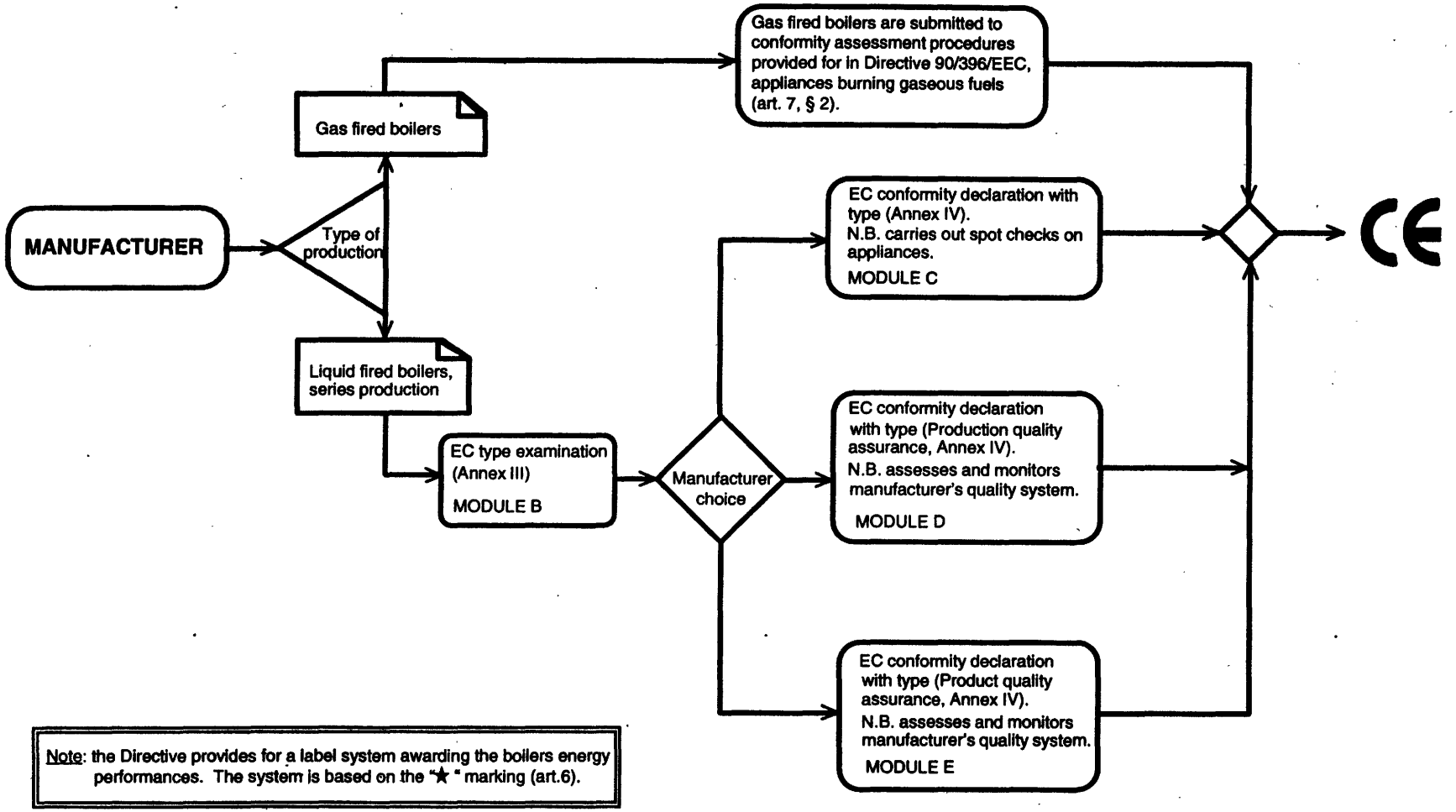
Flowchart for the conformity assessment procedures provided for in Directive 90/396/EEC, on appliances burning gaseous fuels

(*) These procedures were approved before the adoption of the Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

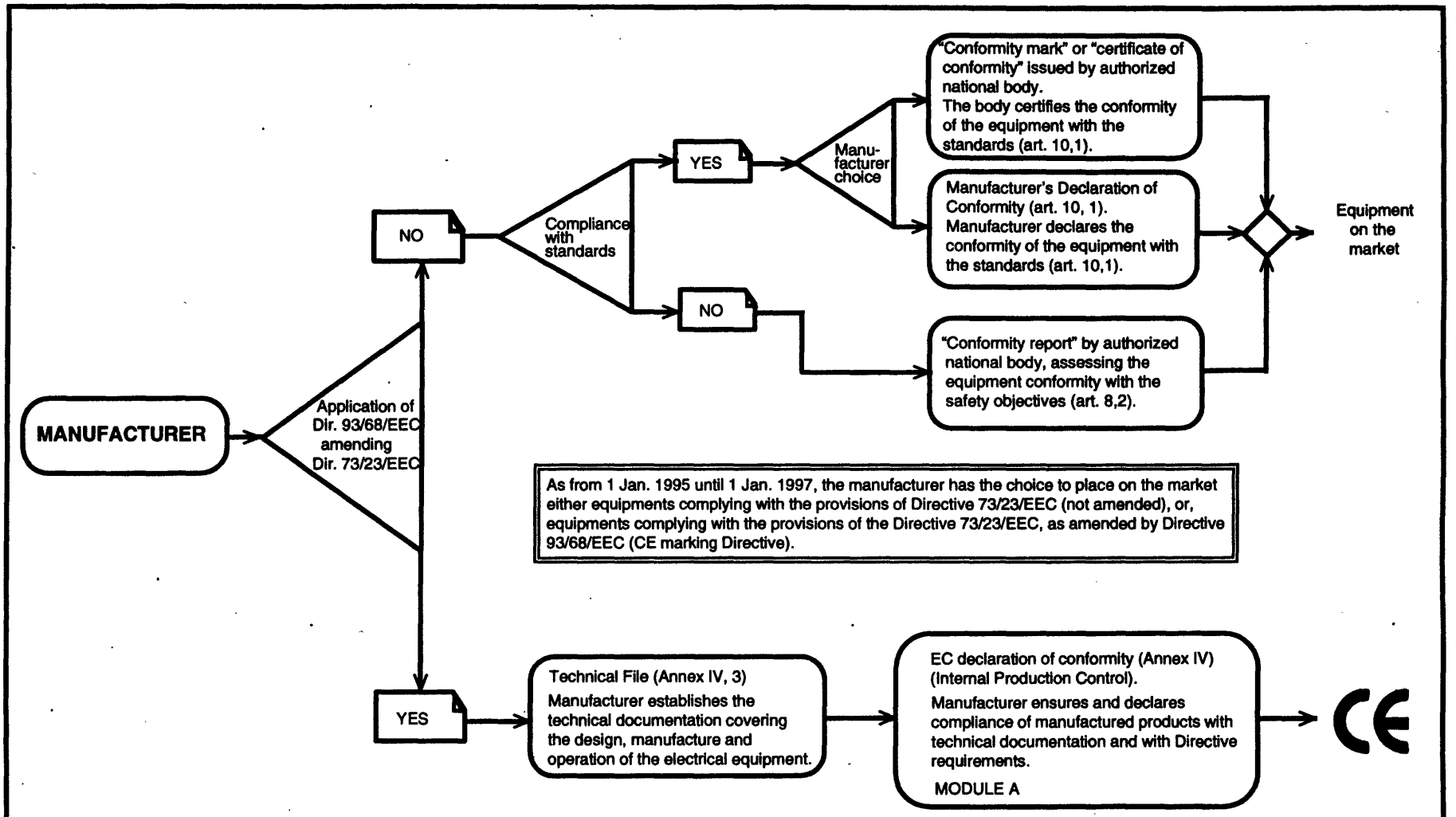


Flowchart for the conformity assessment procedures provided for in Directive 91/263/EEC on telecommunications terminal equipment and on satellite earth station equipment (Directive 93/97/EEC (*))

(*) For specific equipment elements (art. 9 and 10), Directive 93/97/EEC provides the manufacturer with the internal production control procedure (Module A, Annex) as an alternative to the above conformity assessment procedures.

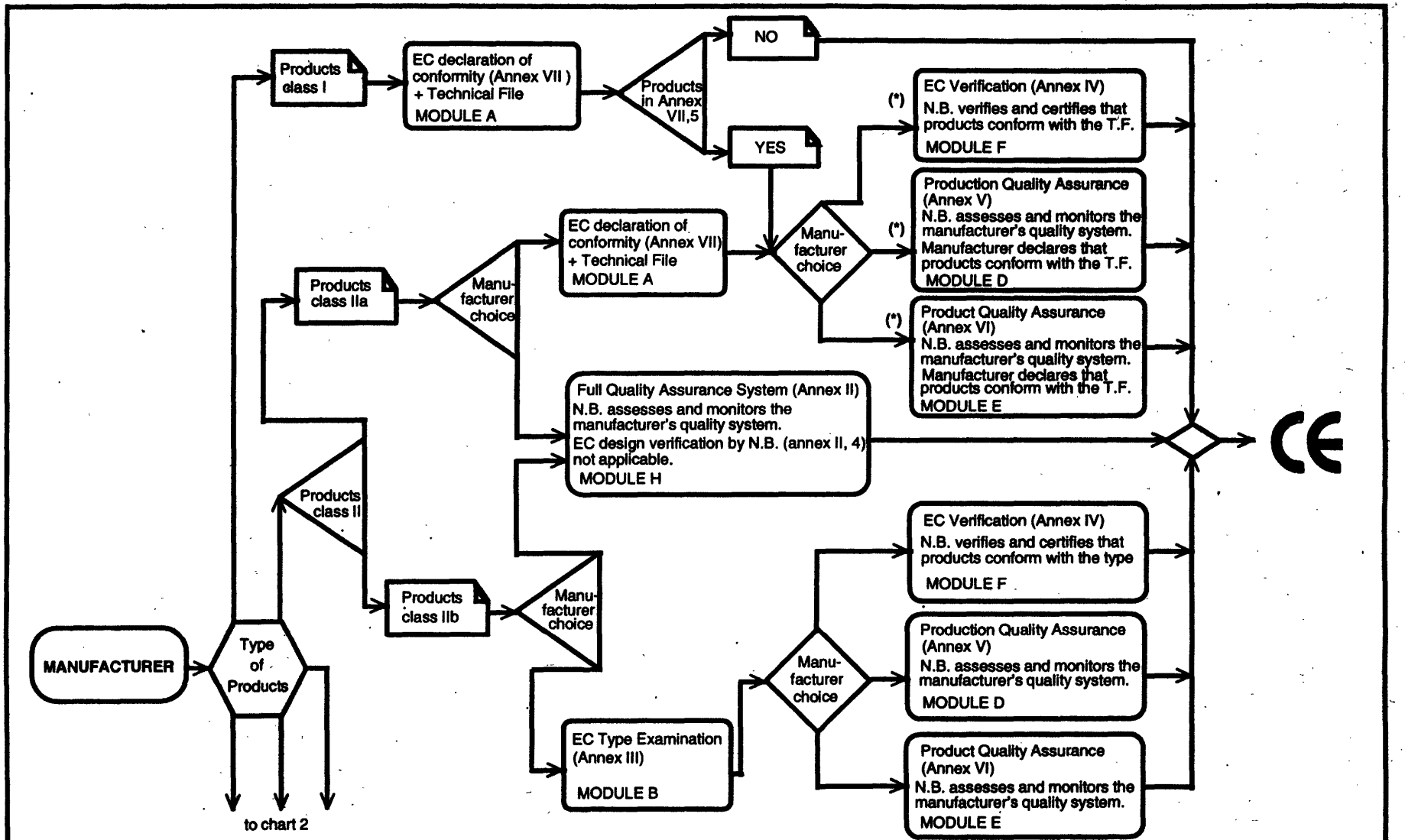


Flowchart for conformity assessment procedures provided for in Directive 92/42/EEC, on efficiency requirements for new hot water boilers fired with liquid or gaseous fuel



Flowchart for the conformity assessment procedures provided for in Directive 73/23/EEC on electrical equipment designed for use within certain voltage limits

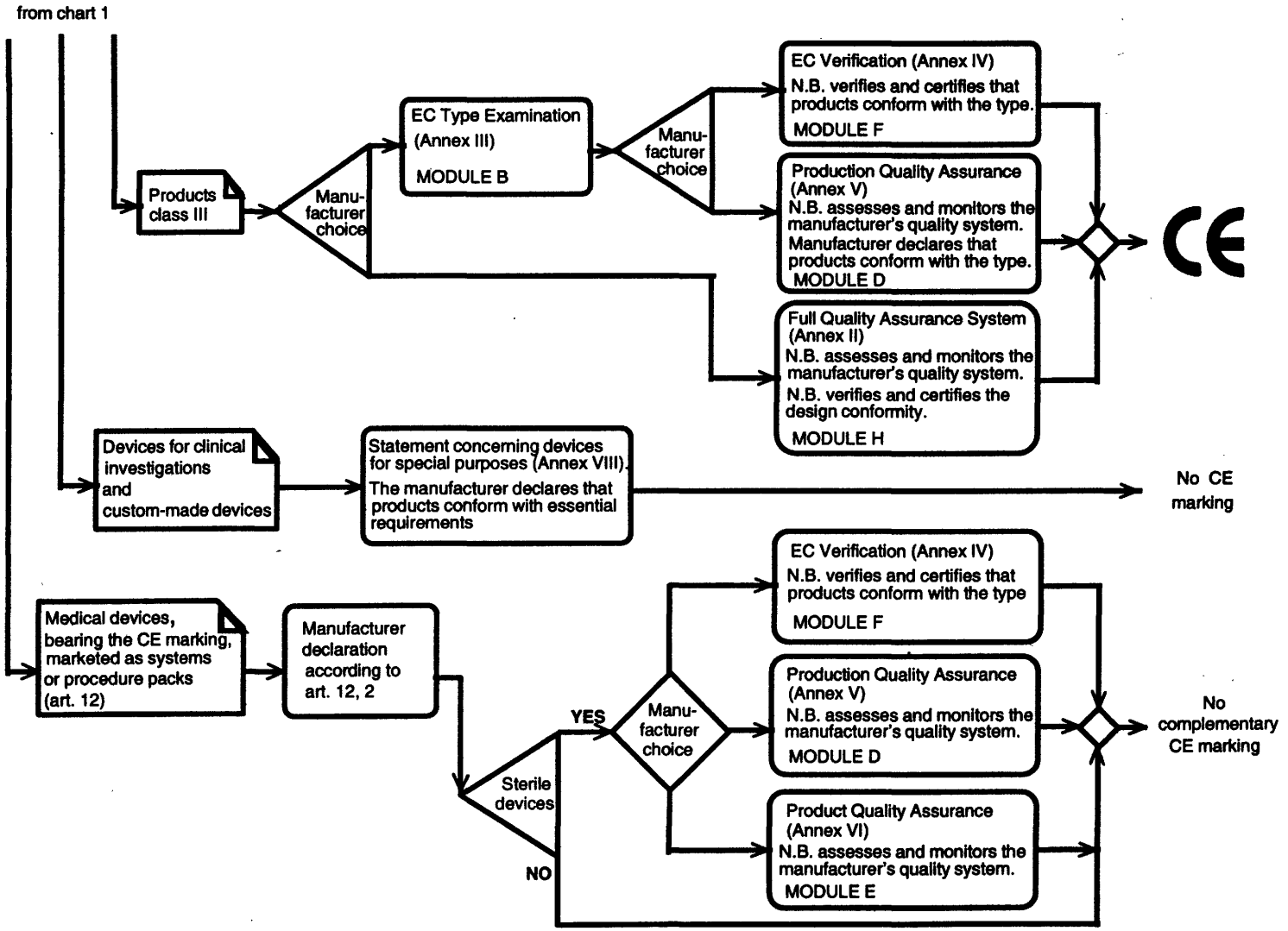
Note: in the event of a challenge the manufacturer may submit a "report by a national authorized body" on the conformity of the equipment with the safety objectives (art. 8,2).



Flowchart for the conformity assessment procedures provided for in Directive 93/42/EC on medical devices

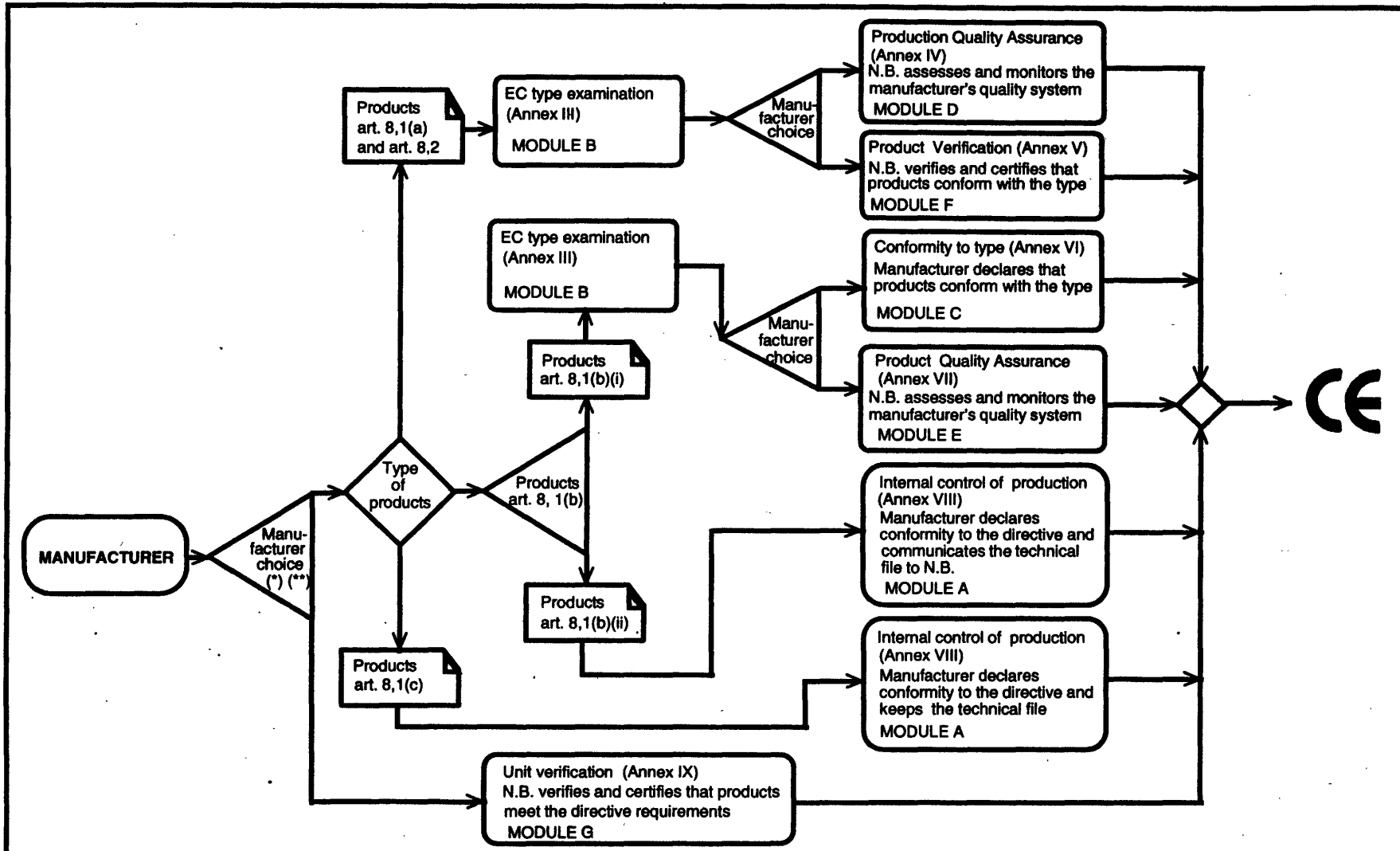
(*) Third party assessment relate to a) obtention of sterile device, b) metrological aspects.

Chart 1 of 2



Flowchart for the conformity assessment procedures provided for in Directive 93/42/EC on medical devices

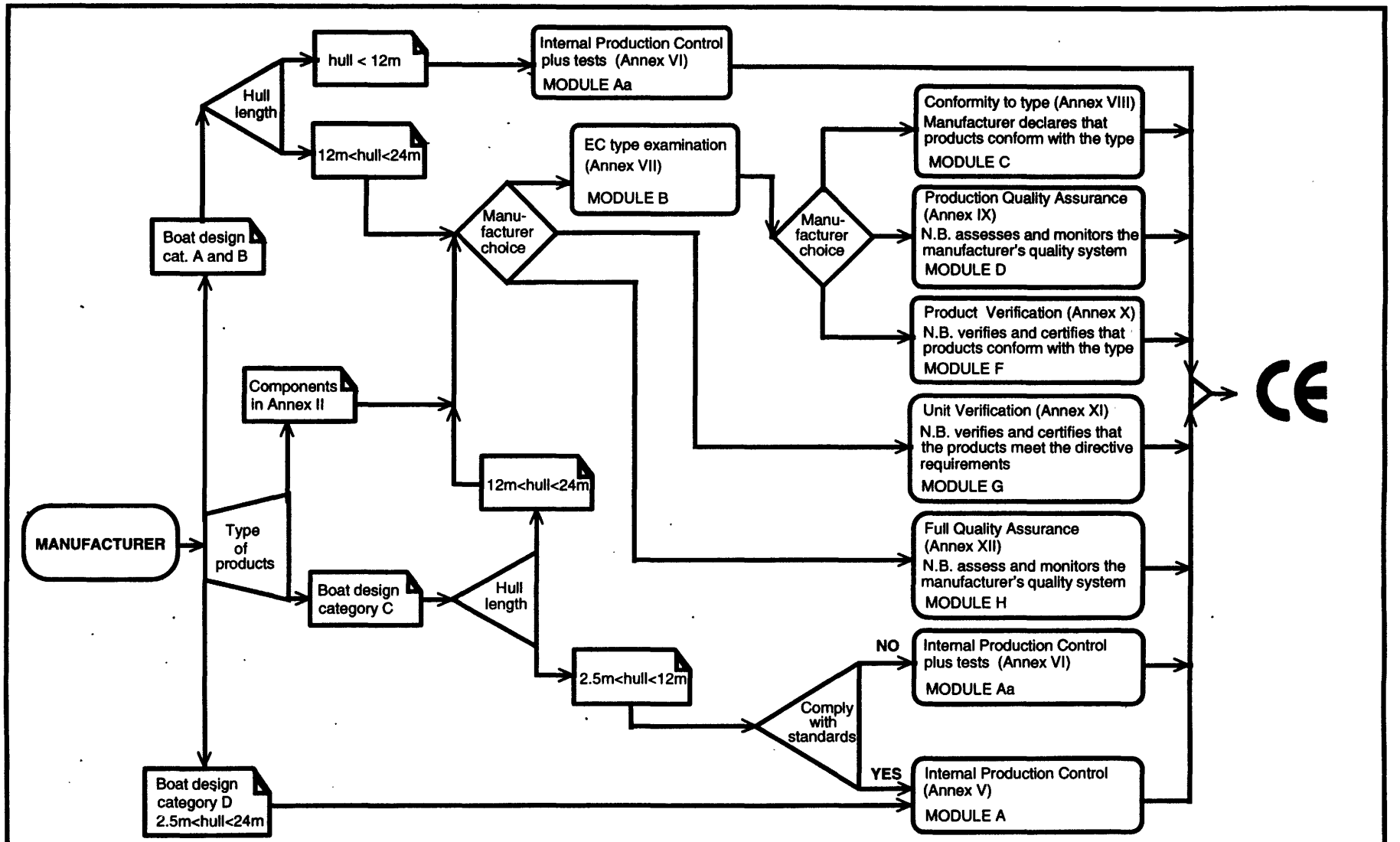
Chart 2 of 2



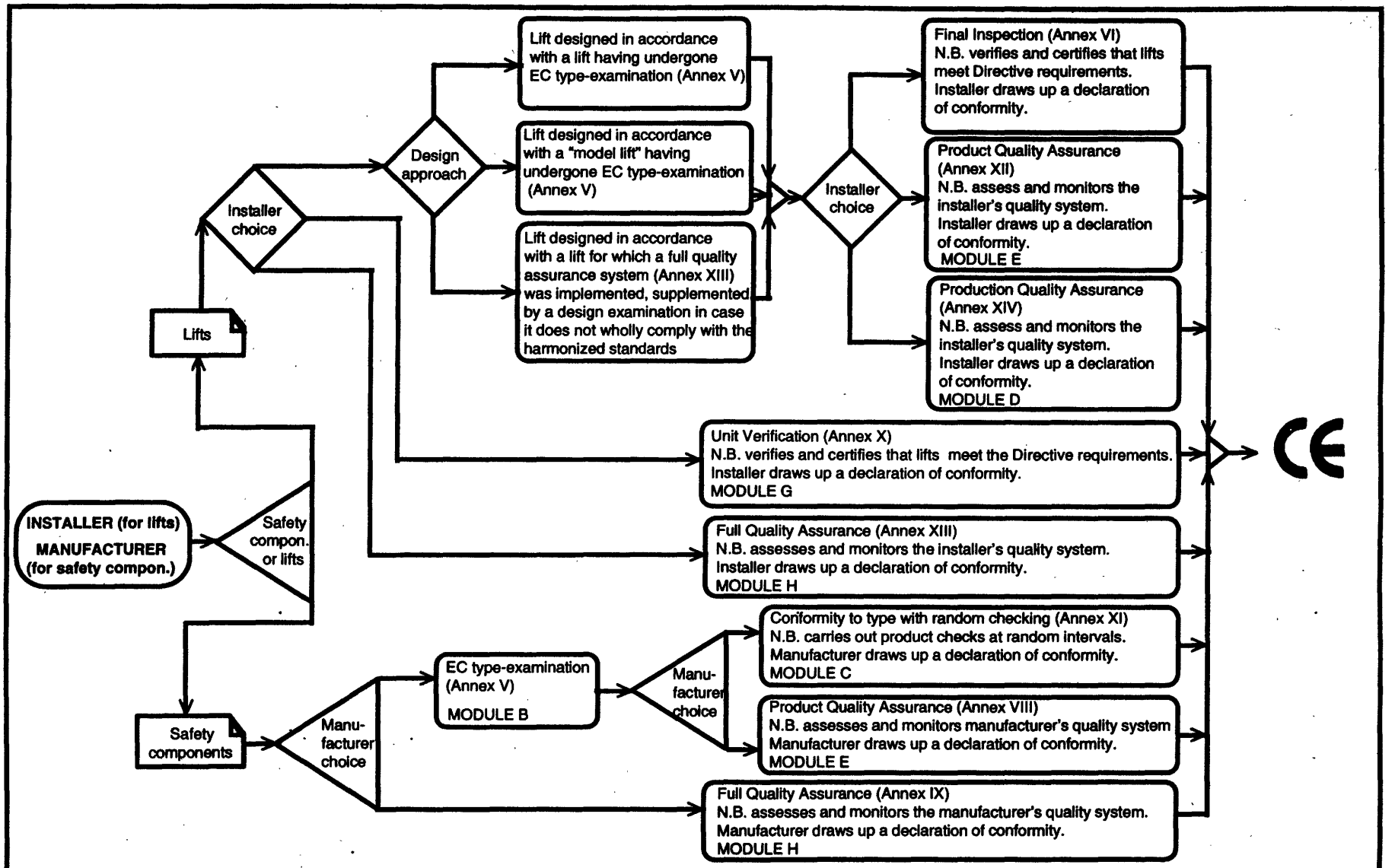
Flowchart for the conformity assessment procedures provided for in Directive 94/9/EC on equipment and protective systems intended for use in potential explosive atmospheres

(*) All referred procedures shall be applied in respect of components, with the exception of the affixing of the CE marking (art. 8,3).

(**) Manufacturer may follow the "internal control of production" (Annex VIII) procedure with regard to the safety aspects referred to in point 1.2.7 of Annex II of the Directive.



Flowchart for the conformity assessment procedures provided for in Directive 94/25/EC on recreational craft



Flowchart for the conformity assessment procedures provided for in Directive 95/16/EC on lifts