Council Directive 96/98/EC of 20 December 1996 on marine equipment
Official Journal L 46, 17 February 1997, pp. 25-56

Having regard to the Treaty establishing the European Community, and in particular Article 84 (2) thereof,
Having regard to the proposal from the Commission (1),
Having regard to the opinion of the Economic and Social Committee (2),
Acting in accordance with the procedure laid down in Article 189c of the Treaty (3),
(1) Whereas within the framework of the common transport policy further measures must be adopted to ensure safety in maritime transport;
(2) Whereas shipping accidents are a matter of serious concern to the Community, in particular those that cause loss of human life and pollution of the Member States' seas and coastlines;
(3) Whereas the risk of shipping accidents can be effectively reduced by means of common standards that ensure high safety levels in the performance of the equipment carried on board ships; whereas testing standards and testing methods can have great influence on the future performance of equipment;
(4) Whereas international conventions require flag States to ensure that the equipment carried on board ships complies with certain safety requirements and to issue the relevant certificates; whereas to that end testing standards for certain types of marine equipment have been developed by the international standardization bodies and by the International Maritime Organization (IMO); whereas the national testing standards implementing the international standards leave a margin of discretion certification authorities, which themselves have different levels of qualifications and experience; whereas that leads to varying levels of safety for products which the competent national authorities have certified as complying with the relevant international safety standards and to great reluctance on the part of Member States to accept that without further verification ships flying their flags carry equipment approved by other Member States;
(5) Whereas common rules must be laid down to eliminate differences in the implementation of international standards; whereas such common rules will result in the elimination of unnecessary costs and administrative procedures relating to the approval of equipment, the improvement of operating conditions and of the competitive position of Community shipping and the elimination of technical barriers to trade by means of the mark of conformity affixed to equipment;
(6) Whereas in its resolution of 8 June 1993 on a common policy on safe seas (4) the Council urged the Commission to submit proposals for harmonizing the implementation of IMO standards and the procedures for the approval of marine equipment;
(7) Whereas action at Community level is the only possible way of achieving such harmonization, since Member States acting independently or through international organizations cannot establish the same level of safety performance in equipment;
(8) Whereas a Council Directive is the appropriate legal instrument as it provides a framework for uniform and compulsory application of the international testing standards by Member States;
(9) Whereas it is appropriate in the first place to address equipment the carriage of which on board ship and the approval of which by national administrations in accordance with safety standards laid down in international conventions or resolutions is mandatory under the main international conventions;
(10) Whereas there are various Directives that ensure the free movement of certain products which could be used inter alia, as equipment on board ships but which do not concern the Member States' certification of equipment in accordance with the relevant international conventions; whereas equipment to be placed on board ships must therefore be regulated exclusively by new common rules;
(11) Whereas new testing standards must be laid down, preferably at international level, for equipment for which such standards do not already exist or are not sufficiently detailed;

(12) Whereas Member States should ensure that the notified bodies that assess the compliance of equipment with testing standards are independent, efficient and professionally competent to carry out their tasks;
(13) Whereas compliance with international testing standards can best be demonstrated by means of conformity-assessment procedures such as those laid down in Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity-assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization Directives (5);
(14) Whereas nothing in this Directive restricts the right granted to a flag State administration by international conventions to carry out operational-performance tests on board a ship for which it has issued a safety certificate, provided such tests do not duplicate the conformity-assessment procedures;
(15) Whereas equipment covered by this Directive should, as a general rule, bear a mark to indicate its compliance with the requirement of this Directive;
(16) Whereas Member States may in certain cases take provisional measures to limit or prohibit the use of equipment bearing the mark of conformity;
(17) Whereas the use of equipment not bearing the mark of conformity may be allowed in exceptional circumstances;
(18) Whereas a simplified procedure involving a regulatory committee must be followed for the amendment of this Directive,
HAS ADOPTED THIS DIRECTIVE:

Article 1
The purpose of this Directive shall be to enhance safety at sea and the prevention of marine pollution through the uniform application of the relevant international instruments relating to equipment listed in Annex A to be placed on board ships for which safety certificates are issued by or on behalf of Member States pursuant to international conventions and to ensure the free movement of such equipment within the Community.

Article 2
For the purposes of this Directive:
(a) 'conformity-assessment procedures` shall mean the procedures set out in Article 10 and Annex B;
(b) 'equipment` shall mean items listed in Annexes A.1 and A.2 which must be placed on board a ship for use in order to comply with international instruments or are voluntarily placed on board for use, and for which the approval of the flag State administration is required according to international instruments;
(c) 'radiocommunications equipment` shall mean equipment required by Chapter IV of the 1984 Solas Convention, as amended with regard to the Global Maritime Distress and Safety System (GMDSS) in 1988, and two-way VHF radiotelephone apparatus required by Regulation III/6.2.1 of the same Convention;
(d) 'international conventions` shall mean:
- the 1996 International Convention on Load Lines (LL66),
- the 1972 Convention on the International Regulations for Preventing Collisions at Sea (Colreg),
- the 1973 International Convention for the Prevention of Pollution from Ships (Marpol) and
- the 1974 International Convention for the Safety of Life at Sea (Solas),
together with their Protocols and the amendments thereto in force on the date of the adoption of this Directive;

(e) 'international instruments` shall mean the relevant international conventions, the relevant resolutions and circulars of the International Maritime Organization (IMO), and the relevant international testing standards;
(f) 'mark` shall mean the symbol referred to in Article 11 and set out in Annex D;
(g) 'notified body` shall mean an organization designated by the competent national administration of a Member State in accordance with Article 9;
(h) 'placed on board` shall mean installed or placed on board a ship;
(i) 'safety certificates` shall mean the certificates issued by or on behalf of Member States in accordance with international conventions;
(j) 'ship` shall mean a ship falling within the scope of international conventions; warships shall not be covered;
(k) 'Community ship` shall mean a ship for which safety certificates are issued by or on behalf of Member States under international conventions. This definition shall not include a Member State administration's issuing a certificate for a ship at the request of a third country's administration;
(l) 'new ship` shall mean a ship the keel of which is laid or which is at a similar stage of construction on or after the date of the entry into force of this Directive. For the purposes of this definition, 'a similar stage of construction` shall mean the stage at which:
(i) construction identifiable with a specific ship begins
and
(ii) assembly of that ship has commenced, comprising at least 50 tonnes or 1 % of the estimated mass of all structural material, whichever is less;
(m) 'existing ship` shall mean a ship which is not a new ship;
(n) 'testing standards` shall mean the standards set by
- the International Maritime Organization (IMO),
- the International Organization for Standardization (ISO),
- the International Electrotechnical Commission (IEC),
- the European Committee for Standardization (CEN),
- the European Committee for Electrotechnical Standardization (Cenelec)
and
- the European Telecommunication Standards Institute (ETSI)
in force on the date of the adoption of this Directive, and established in accordance with the relevant international conventions and with the relevant IMO resolutions and circulars to define testing methods and test results, but only in the form referred to in Annex A;
(o) 'type-approval` shall mean the procedures for evaluating equipment produced in accordance with the appropriate testing standards and the issue of the appropriate certificate.

Article 3
1. This Directive shall apply to equipment for use on board:
(a) a new Community ship whether or not the ship is situated within the Community at the time of construction;
(b) an existing Community ship
- where such equipment was not previously carried on board
or
- where equipment which was previously carried on board the ship is replaced, except where international conventions permit otherwise,
whether or not the ship is situated within the Community when the equipment is placed on board.
2. This Directive shall not apply to equipment which on the date of the entry into force of this Directive has already been placed on board a ship.
3. Notwithstanding the fact that the equipment referred to in paragraph 1 may fall within the scope of Directives other than this Directive for the purpose of free movement, and in particular Council Directives 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member

States relating to electromagnetic compatibility (6) and 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (7), that equipment shall be subject only to this Directive, to the exclusion of all others for those purposes.

Article 4
Each Member State or the organizations acting on its behalf shall ensure, when issuing or renewing the relevant safety certificates, that the equipment on board Community ships for which it issues safety certificates complies with the requirements of this Directive.

Article 5
1. Equipment listed in Annex A.1 that is placed on board a Community ship on or after the date referred to in the second subparagraph of Article 20 (1) shall meet the applicable requirements of the international instruments referred to in that Annex.
2. The compliance of equipment with the applicable requirements of the international conventions and of the relevant resolutions and circulars of the International Maritime Organization shall be demonstrated solely in accordance with the relevant testing standards and the conformity-assessment procedures referred to in Annex A.1. For items listed in Annex A.1, where both IEC and ETSI testing standards are given, those standards shall be alternatives and a manufacturer or his authorized representative established within the Community may determine which of them is to be used.
3. Equipment listed in Annex A.1 and manufactured before the date referred to in paragraph 1 may also be placed on the market and on board a Community ship the certificates of which were issued by or on behalf of a Member State in accordance with international conventions during the two years following that date if it was manufactured in accordance with procedures for type-approval already in force within the territory of that Member State before the date of the adoption of this Directive.

Article 6
1. No Member State shall prohibit the placing on the market or the placing on board a Community ship of equipment referred to in Annex A.1 which bears the mark or for other reasons complies with this Directive or refuse to issue or renew the safety certificates relating thereto.
2. A radio licence shall be issued in accordance with the international radio regulations by the competent authority before the relevant safety certificate is issued.

Article 7
1. After the date of the entry into force of this Directive, the Community shall submit a request to the IMO or to the European standardization organizations, as appropriate, for the establishment of standards, including detailed testing standards, for the equipment listed in Annex A.2.
2. The request referred to in paragraph 1 shall be made:
- by the Presidency of the Council and by the Commission, when it is submitted to the IMO,
- by the Commission, in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (8), when it is submitted to the European standardization organizations. The mandates issued by the Commission shall aim for the development of international standards through procedures for cooperation between the European bodies and their counterparts at international level.
3. Member States shall do their utmost to ensure that the international organizations, including the IMO, develop those standards expeditiously.
4. The Commission shall monitor the development of the testing standards on a regular basis.

5. Should the international organizations, including the IMO, fail or refuse to adopt appropriate testing standards for a specific item of equipment within a reasonable time, standards based on the work of the European standardization organizations may be adopted in accordance with the procedure laid down in Article 18.
6. When the testing standards referred to in paragraphs 1 or 5 are adopted or enter into force, as appropriate, for a specific item of equipment, that equipment may be transferred from Annex A.2 to Annex A.1 in accordance with the procedure laid down in Article 18 and, Article 5 shall apply from the date of that transfer.

Article 8
1. In the case of a new ship which, irrespective of its flag, is not registered in a Member State but is to be transferred to the register of a Member State, such a ship shall, on transfer, be subject to inspection by the receiving Member State to verify that the actual condition of its equipment corresponds to its safety certificates and either complies with this Directive and bears the mark or is equivalent, to the satisfaction of that Member State's administration, to equipment type-approval in accordance with this Directive.
2. Unless the equipment either bears the mark or that administration considers it to be equivalent, it shall be replaced.
3. Equipment which is considered equivalent pursuant to this Article shall be given a certificate by the Member State which shall at all times be carried with the equipment and which gives the flag Member State's permission for the equipment to be placed on board the ship and imposes any restrictions or lays down any provisions relating to the use of the equipment.
4. In the case of radiocommunications equipment, the flag State administration shall require that such equipment does not unduly affect the requirements of the radio-frequency spectrum.

Article 9
1. Member States shall notify the Commission and the other Member States of the bodies which they have designated to carry out the procedures for in Article 10 together with the specific tasks which those notified bodies have been designated to carry out and the identification numbers assigned to them beforehand by the Commission. Each organization shall submit to the Member State which intends to designate it complete information concerning, and evidence of compliance with the criteria laid down in Annex C.
2. At least once every two years each Member State shall cause an audit of the duties its notified bodies are undertaking on its behalf to be carried out by the administration or by an impartial external organization appointed by the administration. That audit shall ensure that each notified body continues to comply with the criteria laid down in Annex C.
3. A Member State which has designated a body shall withdraw its designation if it finds that that body no longer complies with the criteria laid down in Annex C. It shall immediately inform the Commission and the other Member States accordingly.

Article 10
1. The conformity-assessment procedure, details of which are listed in Annex B, shall be:
(i) EC type-examination (module B) and, before equipment is placed on the market and according to the choice made by the manufacturer or his authorized representative established within the Community from the possibilities indicated in Annex A.1, all equipment shall be subject to:
(a) the EC declaration of conformity to type (module C);
(b) the EC declaration of conformity to type (production-quality assurance) (module D);
(c) the EC declaration of conformity to type (product-quality assurance) (module E);
(d) the EC declaration of conformity to type (product verification) (module F); or
(ii) EC full-quality assurance (module H).

2. The declaration of conformity to type shall be in written form and shall give the information specified in Annex B.
3. Where sets of equipment are produced individually or in small quantities and not in series or in mass, the conformity-assessment procedure may be the EC unit verification (module G).
4. The Commission shall keep an up-to-date list of approved equipment and applications withdrawn or refused and shall make it available to interested parties.

Article 11
1. Equipment referred to in Annex A.1 which complies with the relevant international instruments and is manufactured in accordance with the conformity-assessment procedures shall have the mark affixed to it by the manufacturer or his authorized representative established within the Community.
2. The mark shall be followed by the identification number of the notified body which has performed the conformity-assessment procedure, if that body is involved in the production-control phase, and by the last two digits of the number of the year in which the mark is affixed. The identification number of the notified body shall be affixed under its responsibility either by the body itself or by the manufacturer or his authorized representative established within the Community.
3. The form of the mark to be used shall be as set out in Annex D.
4. The mark shall be affixed to the equipment or to its data plate so as to be visible, legible and indelible throughout the anticipated useful life of the equipment. However, where that is not possible or not warranted on account of the nature of the piece of equipment, it shall be affixed to the packaging of the product, to a label or to a leaflet.
5. No marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the mark referred to in this Directive shall be affixed.
6. The mark shall be affixed at the end of the production phase.

Article 12
1. Notwithstanding Article 6, each Member State may take the measures necessary to ensure that sample checks are carried out on equipment bearing the mark which is on its market and which has not yet been placed on board, in order to ensure that it complies with this Directive. Sample checks which are not provided for in the modules for conformity assessment in Annex B shall be carried out at the expense of the Member State.
2. Notwithstanding Article 6, after the installation of equipment which complies with this Directive on board a Community ship, evaluation by that ship's flag State administration of that equipment shall be permitted when operational on-board performance tests are required by international instruments for safety and/or pollution-prevention purposes, provided that they do not duplicate the conformity-assessment procedures already carried out. The flag State administration may require the manufacturer of the equipment, his authorized representative established within the Community or the person responsible for marketing the equipment within the Community to provide the inspection/testing reports.

Article 13
1. Where a Member State ascertains by inspection or otherwise that, notwithstanding the fact that it bears the mark, a piece of equipment referred to in Annex A.1, when correctly installed, maintained and used for its intended purpose, may compromise the health and/or safety of the crew, the passengers or, where applicable, other persons, or adversely affect the marine environment from the market or prohibit or restrict its being placed on the market or being used on board a ship for which it issues the safety certificates. The Member State shall immediately inform the other Member States and the Commission of that measure and indicate the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to comply with Article 5 (1) and (2);
(b) incorrect application of the testing standards referred to in Article 5 (1) and (2); or
(c) shortcomings in the testing standards themselves.
2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:
- the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the testing standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 18 within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedure referred to in Article 18,
- the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community.
3. Where a non-complying piece of equipment bears the mark, the appropriate measures shall be taken by the Member State which has authority over whomsoever affixed the mark; that Member State shall inform the Commission and the other Member States of the measures it has taken.
4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

Article 14
1. Notwithstanding the provisions of Article 5, in exceptional circumstances of technical innovation, the flag State administration may permit equipment which does not comply with the conformity-assessment procedures to be placed on board a Community ship if it is established by trial or otherwise to the satisfaction of the flag State administration that such equipment is at least as effective as equipment which does comply with the conformity-assessment procedures.
In the case of radiocommunications equipment, the flag State administration shall require that such equipment does not unduly affect the requirements of the radio-frequency spectrum.
2. Such trial procedures shall in no way discriminate between equipment produced in the flag Member State and equipment produced in other States.
3. Equipment covered by this Article shall be given a certificate by the flag Member State which shall at all times be carried with the equipment and which gives the flag Member State's permission for the equipment to be placed on board the ship and imposes any restrictions or lays down any provisions relating to the use of the equipment.
4. Where a Member State allows equipment covered by this Article to be placed on board a Community ship, that Member State shall forthwith communicate the particulars thereof together with the reports of all relevant trials, assessments and conformity-assessment procedures to the Commission and the other Member States.
5. Equipment such as is referred to in paragraph 1 shall be added to Annex A.2 in accordance with the procedure laid down in Article 18.
6. Where a ship with equipment on board which is covered by paragraph 1 is transferred to another Member State, the receiving flag Member State may undertake the measures necessary, which may include tests and practical demonstrations, to ensure that the equipment is at least as effective as equipment which does comply with the conformity-assessment procedures.

Article 15
1. Notwithstanding Article 5, a flag State administration may permit equipment which does not comply with the conformity-assessment procedures or is not covered by Article 14 to be placed on board a Community ship for reasons of testing or evaluation, but only when the following conditions are complied with:

(a) the equipment must be given a certificate by the flag Member State which must at all times be carried with the equipment and which gives the flag Member State permission for the equipment to be placed on board the Community ship and imposes any restrictions or lays down any provisions relating to the use of the equipment;
(b) the permission must be limited to a short period of time;
(c) the equipment must not be relied on in place of equipment which meets the requirements of this Directive and must not replace such equipment, which must remain on board the Community ship in working and ready for immediate use.
2. In the case of radiocommunications equipment, the flag State administration shall require that such equipment does not unduly affect the requirements of the radio-frequency spectrum.

Article 16
1. Where equipment needs to be replaced in a port outwith the Community and in exceptional circumstances which shall be duly justified to the flag State administration where it is not practicable in terms of reasonable time, delay and cost to place on board equipment which is EC type-approved, other equipment may be placed on board in accordance with the following procedure:
(a) the equipment shall be accompanied by documentation issued by a recognized organization equivalent to a notified body, where an agreement has been concluded between the Community and the third country concerned on the mutual recognition of such organizations;
(b) should it prove impossible to comply with (a), equipment accompanied by documentation issued by a Member State of the IMO which is a party to the relevant conventions, certifying compliance with the relevant IMO requirements, may be placed on board, subject to paragraphs 2 and 3.
2. The flag State administration shall be informed at once of the nature and characteristics of such other equipment.
3. The flag State administration shall, at the earliest opportunity, ensure that the equipment referred to in paragraph 1, along with its testing documentation, complies with the relevant requirements of the international instruments and of this Directive.
4. In the case of radiocommunications equipment, the flag State administration shall require that such equipment does not unduly affect the requirements of the radio-frequency spectrum.

Article 17
This Directive may be amended in accordance with the procedure laid down in Article 18, in order:
- to apply subsequent amendments of international instruments for the purposes of this Directive,
- to update Annex A, both by introducing new equipment and by transferring equipment from Annex A.2 to Annex A.1 and vice versa,
- to add the possibility of using modules B + C and module H for equipment listed in Annex A.1,
- to include other standardization organizations in the definition of 'testing standards` in Article 2.

Article 18
1. The Commission shall be assisted by the committee set up by Article 12 of Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods (9) in accordance with the procedure laid down in this Article.
2. The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the

Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.
(b) If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If the Council has not acted within two months of the date of the referral to it, the Commission shall adopt the measures proposed.

Article 19
The Member States shall offer each other mutual assistance with a view to the effective implementation and enforcement of this Directive.

Article 20
1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 June 1998.
They shall apply those measures from 1 January 1999.
When Member States adopt the measures referred to in the first subparagraph, these shall contain references to this Directive or shall be accompanied by such references on their official publication. The methods of making such references shall be laid down by the Member States.
2. The Member States shall immediately communicate to the Commission the texts of the provisions of national law which they adopt in the field governed by this Directive. The Commission shall inform the other Member States thereof.

Article 21
This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 22
This Directive is addressed to the Member States.

Done at Brussels, 20 December 1996.
For the Council
The President
S. BARRETT

(1) OJ No C 218, 23. 8. 1995, p. 9.
(2) OJ No C 101, 3. 4. 1996, p. 3.
(3) European Parliament opinion of 29 November 1995 (OJ No C 339, 18. 12. 1995, p. 21), Council common position of 18 June 1996 (OJ No C 248, 26. 8. 1996, p. 10) and European Parliament Decision of 24 October 1996 (OJ No C 347, 18. 11. 1996).
(4) OJ No C 271, 7. 10. 1993, p. 1.
(5) OJ No C 220, 30. 8. 1993, p. 23.
(6) OJ No L 139, 23. 5. 1989, p. 19. Directive as last amended by Directive 93/68/EEC (OJ No L 220, 31. 8. 1993, p. 1).
(7) OJ No L 399, 30. 12. 1989, p. 18. Directive as last amended by Directive 93/95/EEC (OJ No L 276, 9. 11. 1993, p. 11).
(8) OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by the 1994 Act of Accession.
(9) OJ No L 247, 5. 10. 1993, p. 19.

ANNEX A

Annex A.1: Equipment for which detailed testing standards already exist in international instruments (1)

ANNEX B

Modules for conformity assessment

EC TYPE-EXAMINATION (MODULE B)

1. A notified body must ascertain and attest that a specimen, representative of the production envisaged, complies with the provisions of the international instruments that apply to it.

2. The application for the EC type-examination must be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application must include:

-the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well,

- a written declaration that the same application has not been lodged simultaneously with any other notified body,

- the technical documentation as described in point 3.

The applicant must place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called 'type` (1). The notified body may request further specimens if needed for the test programme.

3. The technical documentation must make it possible to assess the product's compliance with the requirements of the relevant international instruments. It must, as far as is relevant for such assessment, cover the design, the building standard, manufacture, installation and functioning of the product in accordance with the description of technical documentation set down in the Appendix to this Annex.

4. The notified body must:

4.1. examine the technical documentation and verify that the type has been manufactured in accordance with the technical documentation;

4.2. perform the appropriate examinations and necessary tests or have them performed to check whether the requirements of the relevant international instruments have actually been met;

4.3. agree with the applicant the location where the examinations and necessary tests will be carried out.

5. Where the type meets the provisions of the relevant international instruments, the notified body must issue an EC type-examination certificate to the applicant. The certificate must give the name and address of the manufacturer, details of the equipment, the conclusions of the examination, the conditions of its validity and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If a manufacturer is refused a type-certification, the notified body must give detailed reasons for that refusal.

Where a manufacturer reapplies for type-approval for equipment for which a type-certificate has been refused, his submission to the notified body must include all relevant documentation, including the original test reports, the detailed reasons for the previous refusal and details of all modifications made to the equipment.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product, which must receive additional approval where such changes may affect compliance with the requirements or the prescribed conditions for use of the product. Such additional approval must be given in the form of an addition to the original EC type-examination certificate.
7. Each notified body must, on request, provide flag Member State administrations and the other notified bodies with the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.
8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.
9. The manufacturer or his authorized representative established within the Community must keep with the technical documentation copies of EC type-examination certificates and their additions for at least 10 years after the last product has been manufactured.

CONFORMITY TO TYPE (MODULE C)
1. A manufacturer or his authorized representative established within the Community must ensure and declare that the products concerned conform to type as described in the EC type-examination certificate and satisfy the requirements of the international instruments that apply to them. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity.
2. The manufacturer must take all measures necessary to ensure that the manufacturing process ensures that the manufactured products conform to type as described in the EC type-examination certificate and comply with the requirements of the international instruments that apply to them.
3. The manufacturer or his authorized representative established within the Community must keep a copy of the declaration of conformity for at least 10 years after the last product has been manufactured.

PRODUCTION-QUALITY ASSURANCE (MODULE D)
1. A manufacturer who satisfies the obligations of point 2 must ensure and declare that the products concerned conform to type as described in the EC type-examination certificate. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for production, final-product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.
3. Quality system
3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice for the products concerned.
The application must include:
- all relevant information for the product category envisaged,
- the documentation concerning the quality system,
- the technical documentation of the approved type and a copy of the EC type-examination certificate.
3.2. The quality system must ensure that the products conform to type as described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality-system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.
It must, in particular, include an adequate description of:
- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the manufacturing, quality-control and quality-assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
3.3. The notified body must assess the quality system to determine whether it satisfies the requirements laid down in point 3.2. It must presume compliance with those requirements in respect of quality systems that implement the relevant harmonized standard.
The auditing team must have at least one member with experience of assessment in the product technology concerned. The assessment procedure must include a visit to the manufacturer's premises.
The manufacturer must be notified of the decision. The notification must include the conclusions of the examination and the reasoned assessment decision.
3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.
The manufacturer or his authorized representative established within the Community must keep the notified body that has approved the quality system informed of any intended updating of that quality system.
The notified body must assess the modifications proposed and decide whether the modified quality system will still satisfy the requirements laid down in point 3.2 or whether a reassessment is required.
The manufacturer must be notified of its decision. The notification must include the conclusions of the examination and the reasoned assessment decision.
4. Surveillance under the responsibility of the notified body
4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection and testing and storage and must provide it with all necessary information, in particular:
- the quality-system documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with audit reports.
4.4. In addition, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or cause tests to be carried out to check that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.
5. The manufacturer must, for at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:
- the documentation referred to in the second indent of the second paragraph of point 3.1,

- the updating referred to in the second paragraph of point 3.4,
- the decision and reports from the notified body referred to in the final paragraph of point 3.4, point 4.3 and point 4.4.
6. Each notified body must, on request, provide flag Member State administrations and the other notified bodies with the relevant information concerning the quality-system approvals issued and withdrawn.

PRODUCT-QUALITY ASSURANCE (MODULE E)
1. A manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned conform to type as described in the EC type-examination certificate. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for final inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.
3. Quality system
3.1. The manufacturer must lodge an application for assessment of his quality system for the products concerned with a notified body of his choice.
The application must include:
- all relevant information for the product category envisaged,
- documentation concerning the quality system,
- the technical documentation of the approved type and a copy of the EC type-examination certificate.
3.2. Under the quality system, each product must be examined and appropriate tests must be carried out in order to ensure its compliance with the relevant requirements of the international instruments. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality-system documentation must ensure common understanding of the quality programmes, plans, manuals and records.
It must, in particular, include an adequate description of:
- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the examinations and tests that will be carried out after manufacture,
- the means of monitoring the effective operation of the quality system,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
3.3 The notified body must assess the quality system to determine whether it satisfies the requirements laid down in point 3.2. It must presume compliance with the requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team must have at least one member with experience as an assessor in the product technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.
The manufacturer must be notified of the decision. The notification must include the conclusions of the examination and the reasoned assessment decision.
3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it in an appropriate and efficient manner.
The manufacturer or his authorized representative established within the Community must keep the notified body that has approved the quality system informed of any intended updating of that quality system.

The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements laid down in point 3.2 or whether a reassessment is required.
The manufacturer must be notified of its decisions. The notification must include the conclusions of the examination and the reasoned assessment decision.
4. Surveillance under the responsibility of the notified body
4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of inspection, testing and storage and must provide it with all necessary information, in particular:
- the quality-system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with audit reports.
4.4. In addition, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or cause tests to be carried out to check that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.
5. The manufacturer must, for at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:
- the documentation referred to in the third indent of the second paragraph of point 3.1,
- the updating referred to in the second paragraph of point 3.4,
- the decision and reports from the notified body referred to in the final paragraph of point 3.4, point 4.3 and point 4.4.
6. Each notified body must on request provide flag Member State administrations and the other notified bodies with the relevant information concerning the quality-system approvals issued and withdrawn.

PRODUCT VERIFICATION (MODULE F)
1. A manufacturer or his authorized representative established within the Community must check and attest that the products subject to point 3 conform to the type as described in the EC type-examination certificate.
2. The manufacturer must take all measures necessary to ensure that the manufacturing process ensures that the products conform to type as described in the EC type-examination certificate. He must affix the mark to each product and must draw up a declaration of conformity.
3. The notified body must carry out the appropriate examinations and tests in order to check that the product complies with the requirements of the international instruments either by examination and testing of every product as specified in point 4 or by examination and testing of products on a statistical basis, as specified in point 5, at the choice of the manufacturer.
3a. The manufacturer or his authorized representative established within the Community must keep a copy of the declaration of conformity for at least 10 years after the last product has been manufactured.
4. Verification by examination and testing of every product
4.1. All products must be individually examined and appropriate tests must be carried out in order to verify their conformity to type as described in the EC type-examination certificate.
4.2. The notified body must affix its identification symbol or cause it to be affixed to each approved product and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorized representative established within the Community must ensure that he is able to supply the notified body's certificate of conformity on request to the flag Member State administration.
5. Statistical verification
5.1. The manufacturer must present his products in the form of homogeneous lots and must take all measures necessary to ensure that the manufacturing process ensures the homogeneity of each lot produced.
5.2. All products must be available for verification in the form of homogeneous lots. A random sample must be drawn from each lot. Products in a sample must be individually examined and appropriate tests must be carried out to ensure that they comply with the requirements of the international instruments which apply to them and to determine whether the lot is to be accepted or rejected.
5.3. In the case of accepted lots, the notified body must affix its identification symbol or cause it to be affixed to each product and must draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which are found not to comply.
If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent that lot's being put on the market. In the event of frequent rejection of lots the notified body may suspend statistical verification.
The manufacturer may, under the responsibility of the notified body, affix the latter's identification symbol during the manufacturing process.
5.4. The manufacturer or his authorized representative established within the Community must ensure that he is able to supply the notified body's certificates of conformity on request to the flag Member State administration.

UNIT VERIFICATION (MODULE G)
1. The manufacturer must ensure and declare that the product concerned, which has been issued with the certificate referred to in point 2, complies with the requirements of the international instruments that apply to it. The manufacturer or his authorized representative established within the Community must affix the mark to the product and draw up a declaration of conformity.
2. The notified body must examine the individual product and carry out appropriate tests to ensure that it complies with the relevant requirements of the international instruments.
The notified body must affix its identification number or cause it to be affixed to the approved product and must draw up a certificate of conformity concerning the tests carried out.
3. The aim of the technical documentation is to enable compliance with the requirements of the international instruments to be assessed and the design, manufacture and operation of the product to be understood.

FULL-QUALITY ASSURANCE (MODULE H)
1. A manufacturer who satisfies the obligations of paragraph 2 must ensure and declare that the products concerned comply with the requirements of the international instruments that apply to them. The manufacturer or his authorized representative established within the Community must affix the mark to each product and draw up a written declaration of conformity. The mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for design, manufacture, final-product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4. 3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.
The application must include:
- all relevant information for the product category envisaged and
- documentation concerning the quality system.
3.2. The quality system must ensure that the products comply with the requirements of the international instruments that apply to them.
All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality-system documentation must ensure common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.
It must, in particular, include an adequate description of:
- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the technical design specifications, including standards, that will be applied and the assurance that the essential requirements of the international instruments that apply to the products will be met,
- the design-control and design-verification techniques, processes and systematic actions that will be used in the design of the products pertaining to the product category covered,
- the corresponding manufacturing, quality-control and quality-assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.
3.3. The notified body must assess the quality system to determine whether it satisfies the requirements laid down in point 3.2. It must presume compliance with the requirements in respect of quality systems that implement the relevant harmonized standard.
The auditing team must have at least one member with experience as an assessor in the product technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.
The manufacturer must be notified of the decision. The notification must include the conclusions of the examination and the reasoned assessment decision.
3.4. The manufacturer must undertake to fulfil the obligations arising from the quality system as approved and to uphold it so that it remains adequate and efficient.
The manufacturer or his authorized representative established within the Community must keep the notified body that has approved the quality system informed of any intended updating of that quality system.
The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements laid down in point 3.2 or whether a reassessment is required.
The manufacturer must be notified of its decisions. The notification must include the conclusions of the examination and the reasoned assessment decision.
4. EC surveillance under the responsibility of the notified body
4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing and storage and must provide it with all necessary information, in particular:

- the quality-system documentation,
- the quality records as provided for in the design part of the quality system, such as the results of analyses, calculations, tests, etc.,
- the quality records as provided for in the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with audit reports.

4.4. In addition the notified body may pay unannounced visits to the manufacturer. During such visits, the notified body may carry out tests or cause tests to be carried out to check that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:
- the documentation referred to in the second indent of the second paragraph of point 3.1,
- the updating referred to in the second paragraph of point 3.4,
- the decision and reports from the notified body referred to in the final paragraph of point 3.4, point 4.3 and point 4.4.

6. Each notified body must, on request, provide flag Member State administrations and the other notified bodies with the relevant information concerning the quality-system approvals issued and withdrawn.

7. Design examination

7.1. The manufacturer must lodge an application for examination of the design with a single notified body.

7.2. The application must make it possible to understand the design, manufacture and operation of the product and to assess compliance with the requirements of international instruments.

It must include:
- the technical design specifications, including standards, that have been applied and
- the necessary supporting evidence for their adequacy, in particular where the standards specified in Article 5 have not been applied in full. Such supporting evidence must include the results of tests carried out by an appropriate laboratory of the manufacturer's or on his behalf.

7.3. The notified body must examine the application and where the design complies with those provisions of the international instruments that apply it must issue an EC design-examination certificate to the applicant. The certificate must include the conclusions of the examination, the conditions of its validity, the data necessary for identification of the approved design and, if relevant, a description of the product's functioning.

7.4. The applicant must keep the notified body that has issued the EC design-examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design-examination certificate where such changes may affect compliance with the relevant requirements of the international instruments or the prescribed conditions for use of the product. Such additional approval must be given in the form of an addition to the original EC design-examination certificate.

7.5. The notified bodies must, on request, provide flag Member State administrations and the other notified bodies with the relevant information concerning:
- the EC design-examination certificates and additions issued and
- the EC design-approvals and additional approvals withdrawn.

Appendix to Annex B

Technical documentation to be supplied by the manufacturer to the notified body

The provisions set down in this Appendix apply to all modules of Annex B.
The technical documentation referred to in Annex B must comprise all relevant data and means used by the manufacturer to ensure that equipment complies with the essential requirements relating to it.
The technical documentation must make it possible to understand the design, manufacture and operation of the product, and must make it possible to assess compliance with the requirements of the relevant international instruments.
The documentation must, so far as they are relevant to assessment, include:
- a general description of the type,
- conceptual-design, build standard and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes, including the operation of the product,
- the results of design calculations made, impartial examinations carried out, etc.,
- impartial test reports,
- manuals for installation, use and maintenance.
Where appropriate, the design documentation must contain the following:
- attestations relating to the equipment incorporated in the appliance,
- attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance,
- any other document that makes it possible for the notified body to improve its assessment.
(1) A type may cover several versions of the product provided that the differences between the versions do not affect the level of safety or the other requirements concerning the performance of the product.

ANNEX C

Minimum criteria to be taken into account by Member States for the designation of bodies
1. Notified bodies must fulfil the requirements of the relevant EN 45000 series.
2. A notified body must be independent and must not be controlled by manufacturers or by suppliers.
3. A notified body must be established within the territory of the Community.
4. Where type-approvals are issued by a notified body on behalf of a Member State, the Member State must ensure that the qualifications, technical experience and staffing of the notified body are such as will enable it to issue type-approvals which comply with the requirements of this Directive and to guarantee a high level of safety.
5. A notified body must be in a position to provide maritime expertise.
A notified body is entitled to perform conformity-assessment procedures for any economic operator established within or outwith the Community.
A notified body may perform conformity-assessment procedures in any Member State or State outwith the Community using either its home-based means or the personnel of its branch office abroad.
If a subsidiary of a notified body performs conformity-assessment procedures, all documents relating to the conformity-assessment procedures must be issued by and in the name of the notified body and not in the name of the subsidiary.
A subsidiary of a notified body which is established in another Member State may, however, issue documents relating to conformity-assessment procedures if it is notified by that Member State.

ANNEX D

Mark of conformity
The mark of conformity must take the following form:
>REFERENCE TO A FILM>
If the mark is reduced or enlarged the proportions given in the above graduated drawing must be respected.
The various components of the mark must have substantially the same vertical dimension, which may not be less than 5 mm.
That minimum dimension may be waived for small devices.