Proposal for a Council Directive on marine equipment

(95/C 218/06)

(Text with EEA relevance)

COM(95) 269 final — 95/0163(SYN)

(Submitted by the Commission on 22 June 1995)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 84 (2) thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas in the framework of the common transport policy it is necessary in the sector of maritime transport to lay down further measures to ensure transport safety;

Whereas the Community is seriously concerned about shipping casualties, in particular loss of human lives at sea, as well as pollution of the seas and coastlines of the Member States;

Whereas high safety levels in the performances of the equipment carried on board can undoubtedly contribute to reduce the risk of casualties at sea and pollution of the sea; whereas testing standards and testing methods can highly influence the future performances of the equipment;

Whereas the International Conventions require flag States to ensure the respect of safety requirements of the equipment carried on board and to issue the relevant certificates; whereas to this effect testing standards for certain types of marine equipment have been developed within the relevant International Conventions and by the International standardization bodies;

Whereas, in spite of the existence of international testing standards, there are different levels of national standards implementing the international ones leaving discretionary margins to certification authorities, as well as different levels of qualifications and experience of such authorities;

Whereas it is necessary to lay down common rules to eliminate the lack of harmonization in implementing the international standards, leading both to differing levels of safety for products which the competent national authorities have certified to be in compliance with the relevant international safety standards and to strong reluctance of several Member States to accept without further control for carriage on board ships flying their flag equipment approved by another Member State; whereas these common rules will have the effect of eliminating unnecessary costs and administrative procedures related to the approval of the equipment and of improving thereby the operating conditions and competitive position of Community shipping, as well as of eliminating technical barriers to trade;

Whereas free movement of certain products which could also be used as equipment on board ships flying the flag of a Member State is already ensured in whole or in part by the provisions of various directives including Council Directive 89/336/EEC on the approximation of the laws of the Member States relating to electromagnetic compatibiliy [1], whereas these provisions do not, however, concern also the certification thereof by Member States in accordance with the relevant International Conventions and in consequence equipment to be placed on board to comply therewith must be dealt with exclusively in new common rules;

Whereas the Commission in its communication of 24 February 1993 on a Common policy on safe seas underlines the need to ensure that the margin of interpretation of the international standards left to administrations or testing organizations converges and that rules and standards for marine equipment are effectively applied in a consistent manner in all Member States; whereas the Council of the Union, in its resolution of 8 June 1993, urged the Commission to harmonize the implementation of IMO standards and the approval procedures for marine equipment;

Whereas it is indicated in the abovementioned communication that directives should be adopted addressing in the first place shipborne equipment for which the International Convention for the Safety of Life at Sea (Solas) and the International Convention for the Prevention of Pollution from Ships (Marpol) require the approval by

[1] OJ No L 139, 23. 5. 1989, p. 19.

national administrations in accordance to safety standards set out in the International Conventions or resolutions; whereas representatives of the Industry and of competent national administrations of Member States consider appropriate to address equipment for which the International Conventions require the approval of the national administration as well as mandatory carriage on board;

Whereas action at Community level is the only possible way to find a solution to the abovementioned problems, since Member States acting independently or through the International organizations are not able to establish the same level of safety performance of the equipment because of the discretionary margins always left to the Administrations by the International Instruments; whereas mutual recognition of certificates issued in different Member States is generally impossible because of the existance of the discretion element;

Whereas the adoption of a Council directive is the appropiate procedure for laying down a legal framework to enhance safety performances of the equipment through a uniform and compulsory application of the international testing standards for the equipment, while leaving to the Member States the means of enforcement and the implementation of the Directive;

Whereas it is necessary to eliminate all the discretionary elements left to the National Administrations by setting out clearly in Annex A which tests may alone be used among those referred to in the International Instruments;

Whereas national administrations or organizations acting on their behalf in assessing the safety performances of the equipment carried on board ships flying their flag and in issuing or renewing the relevant safety certificates must ensure compliance with the provisions of this Directive;

Whereas Member States have to designate notified bodies entitled to perform the conformity assessment procedures and they also have to ensure that such bodies are efficient and professionally capable to carry out the tasks they have been appointed to carry out;

Whereas compliance with the international testing standards shall be proven by conformity assessment procedures as laid down in Council Decision 93/465/EEC [1];

Whereas equipment referred to in this Directive should, as a general rule, bear a mark to indicate its compliance with the requirements of the Directive and to be placed on board and into service in accordance with its intended purpose;

Whereas it is necessary to grant an interim period, after the entry into force of the national legislations implementing the Directive, during which equipment manufactured before that date can be placed on board even if it does not bear the mark in order to allow the manufacturers to sell the equipment they have in stock;

Whereas there are pieces of equipment for which the International Conventions require the approval of the administration and the mandatory carriage on board but for which detailed international testing standards do not exist (equipment listed in Annex A.2 to the Directive); whereas, since shipping has an international character and adoption of regional standards would create an economic disadvantage for European shipowners and manufacturers, it is necessary to lay down testing standards at international level; whereas the International Maritime Organization (IOM) is considered the most appropriate body to lay down testing standards, in order to ensure that they are applicable all over the world and not only regionally; whereas when the international testing standards enter into force, measures should be foreseen to take account thereof for the purposes of this Directive;

Whereas Member States shall allow equipment bearing the mark to freely move on their territory, to be placed on the market, to be placed on board and to be used in accordance with their intended purpose; without further evaluation or technical requirements;

Whereas equipment placed on board a ship not registered in a Member State does not necessarily comply with the international testing standards; whereas, if such a ship is transferred to the register of a Member State, its equipment has to be proven, to the satisfaction of that Member State administration, equivalent to the equipment type-approved in accordance with the Directive;

Whereas, in order to verify conformity of the equipment with the Directive, sample checks may be carried out by the Member States at their expense when the equipment has not yet been placed on board; whereas if the equipment has already been placed on board, evaluation of such equipment shall be permitted only when the International Conventions require operational on board performance tests for safety and/or pollution purposes;

Whereas it is appropriate that the Member States may take provisional measures to limit or prohibit the placing on board and the use of equipment in cases where it presents a particular risk to the safety of the crew, the passengers, other persons or to the marine environment,

[1] OJ No L 220, 30. 8. 1993.

provided that the measures are subject to a Community control procedure;

Whereas completely new equipment can be put on the market; whereas European shipowners must be allowed to take advantage of the technical innovation in order not to create an economic disadvantage in comparison with non-European shipowners, provided that such new equipment gives the same guarantees of safety as the equipment covered by the Directive; whereas detailed testing standards for such equipment must be established at international level while nevertheless leaving the possibility of testing or evaluating equipment on board of Community ships to be consistent with the corresponding international requirements;

Whereas it may happen that a piece of equipment must be replaced in a port outside the Community where it is exceptionally not possible to find a piece of EC type-examined equipment; whereas such a ship must be put in a position to continue its navigation;

Whereas it is necessary for a committee composed of the representatives of the Member States to assist the Commission; whereas the committee set up in Article 12 of Council Directive 93/75/EEC can assume this function; whereas there must be a procedure to amend the Directive in order to take due account of progress in international fora and to update the Annex to the Directive; whereas the adequate procedure according to which the committee will act is procedure I of Article 2 of Council Decision 87/373/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The purpose of this Directive is to enhance safety at sea and 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 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, the following definitions shall apply:

'Conformity assessment procedures':

means those procedures set out in Article 10 and Annex B of this Directive.

'Equipment':

means equipment listed in Annexes A.1 and A.2 which must be placed on board a ship for use in order to comply with the International Instruments or is voluntarily placed on board for use, and for which the approval of the flag State administration is required according to the International Instruments.

'International Conventions':

means the 1974 International Convention for the Safety of Life at Sea, the 1966 International Convention on Load Lines, the 1973 International Convention for the Prevention of Pollution from Ships and the 1972 Convention on the International Regulations for Preventing Collisions at sea, together with their Protocols and amendments thereto in force at the date of adoption of this Directive.

'International Instruments':

means the relevant International Conventions and the relevant resolutions and circulars of the International Maritime Organization (IMO), as well as the relevant international testing standards.

'Mark':

means the symbol referred to in Article 11 and set out in Annex D.

'Notified body':

means an organization designated by the competent national administration of a Member State in conformity with Article 9.

'Placed on board':

means equipment installed or placed on board a ship.

'Safety certificates':

means those certificates issued by or on behalf of Member States in accordance with the International Conventions.

'Ship':

means any seagoing vessel covered by the International Conventions, as appropriate:

— 'EU ship':

means a ship for which safety certificates are issued by Member States pursuant to International Conventions,

— 'new ship':

means a ship, the keel of which is laid or which is at a similar stage of construction on or after the date of adoption of this Directive. For the purpose of this definition, a similar stage of construction means 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,

— 'existing ship':

means a ship which is not a new ship.

'Testing standards':

means the standards set out by the International Maritime Organization (IMO), the International Organization for Standardization (ISO), the European Telecommunication Standards Institute (ETSI) and the International Electro-Technical Commission (IEC), in force at the date of adoption of this Directive, and established in accordance with the relevant International Conventions and with the relevant resolutions and circulars of the International Maritime Organization to define the methods of test and test results, only in the form referred to in Annex A.

'Type-approval':

means the procedures of evaluation of 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 EU ship whether or not the ship is situated at the time of construction within the European Community;

(b) an existing EU ship which previously did not carry on board such equipment, or where exquipment which was already carried on board the ship is replaced, whether or not the ship is situated within the European Community at the time when the equipment is placed on board.

2. This Directive does not apply to equipment which on the date of adoption of this Directive has already been placed on board a ship.

3. Notwithstanding the fact that the equipment referred to in paragraph 1 is able to fall within the scope of Council Directives, other than the present Directive, for the purpose of free circulation, and in particular Council Directive 89/336/EEC, the equipment so referred to shall be subject only to the provisions of the present Directive, to the exclusion of all others for that purpose.

Article 4

Each Member State or the organizations acting on its behalf, when issuing or renewing the relevant safety certificates, shall ensure that the equipment on board the ships flying its flag complies with the requirements of this Directive.

Article 5

1. Equipment listed in Annex A.1, placed on board an EU ship on or after the date referred to in Article 21 (1), concerning the entry into force of the national legislations implementing this Directive, shall meet the applicable requirements of the International Instruments referred to in the said Annex.

2. Compliance of equipment with the applicable requirements of the International Conventions and of the relevant resolutions and circulars of the International Maritime Organizations shall be proven exclusively in accordance with the relevant testing standards and the conformity assessment procedures referred to in Annex A.1.

3. Equipment lited in Annex A.1 manufactured before the date of entry into force of the national legislations implementing this Directive may also be placed on the market and on board a ship, the certificates of which are issued by a Member State in accordance with the International Conventions, for a period of two years from the date of entry into force of the national legislations implementing this Directive, if manufactured in conformity with procedures for type-approval already in force in the territory of that Member State before the date of adoption of this Directive.

Article 6

Member States shall not refuse the placing on the market, the placing on board an EU ship, nor refuse the issue or renewal of the safety certificates relating thereto, of equipment referred to in Annex A.1 which complies with the provisions of this Directive.

Article 7

1. The European Community shall forthwith at the date of adoption of this Direcitve submit a request to the International Maritime Organization to establish detailed testing standards for equipment listed in Annex A.2.

2. Such request shall be made by the Commission on behalf of the Community.

3. Member States shall deploy all necessary efforts to ensure that the International Maritime Organization undertakes the development of these standards expeditiously.

4. The Commission will monitor and review the development of the testing standards on a regular basis.

5. When the testing standards referred to in paragraph 1 enter into force for a specific item of equipment, such equipment may be transferred from Annex A.2 to Annex A.1 in accordance with the procedure laid down in Article 19 and therefore the provisions of Article 5 will apply as from that date.

Article 8

In the case of a new ship which, irrespective of its flag, is not registered in a Member State and is to be transferred to the register of a Member State, on transfer, such a ship shall be subject to inspection by the receiving flag Member State to verify that the actual condition of its equipment corresponds with its safety certificates and either conforms to the provisions of this Directive and bears the mark or is equivalent, to the satisfaction of that Member State Administration, to the equipment type-approved in accordance with this Directive. Unless the equipment either bears the mark or that Administration deems that equipment to be equivalent, such equipment shall be replaced.

Article 9

1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 10 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission. The organizations shall submit to the Member State which intends to notify them of complete information concerning, and evidence of, compliance with the criteria set out in Annex C.

2. A Member State which has designated a notified body must withdraw its designation if it finds that the body no longer meets the criteria listed in Annex C. It shall immediately inform the Commission and the other Member States accordingly.

Article 10

1. The conformity assessment procedure, the details of which are listed in Annex B shall be:

(i) EC type-examination (module B) and, prior to the equipment being placed on the market and according to the choice made by the manufacturer or his authorized representative within the Community among those indicated in Annex A.1, all equipment shall be subject to either:

(a) the EC declaration of conformity to type (module C); or

(b) the EC declaration of conformity to type (production quality assurance) (module D); or

(c) the EC declaration of conformity to type (product quality assurance) (module E); or

(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 contain the information specified in Annex B.

3. For equipment produced in small quantities or for unique equipment the conformity assessment procedure may be the EC unit verification (module G).

Article 11

1. Equipment referred to in Annex A.1 manufactured in compliance with the relevant International Instruments and the conformity assessment procedures must 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 the said body is involved in the production control phase, as well as by the last two figures of the year that the mark is affixed. The identification number of the notified body must be

affixed under its responsibility either by the body itself or by the manufacturer or his agent established within the Community.

3. The form of the mark to be used is 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 this is not possible or not warranted on account of the nature of the piece of equipment, it must be affixed to the packaging of the product, to a label or to a leaflet.

5. It is prohibited to affix 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.

6. The mark must be affixed at the end of the production phase.

Article 12

1. Notwithstanding the provisions of Article 6, Member States may take the necessary measures to ensure that sample checks are carried out on equipment bearing the mark which is on their markets and which is not yet placed on board, so as to verify its conformity with this Directive. The sample checks will be carried out at the expense of the Member State.

2. Notwithstanding the provisions of Article 6, after installation on board an EU ship evaluation, by the flag administration of that ship, of equipment which complies with the requirements of this Directive shall be permitted when operational on board performance tests are required by the International Instruments for safety and/or pollution prevention purposes and provided that these do not duplicate the conformity assessment procedures already carried out.

Article 13

1. Where a Member State ascertains by inspection or otherwise that a piece of equipment referred to in Annex A.1, and nothwistanding the fact that it bears the mark, 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 affect the marine environment it shall take all appropriate interim measures to withdraw that piece of equipment from the market or prohibit or restrict its being placed on the market or on board a ship. The Member State shall immediately inform the other Member States and the Commission of this measure and indicate the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to respect the provisions of Article 5 (1) and (2);

(b) incorrect application of the testing standards referred to in Article 5 (1) and (2);

(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 17 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 19,

— the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established in 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 thereof.

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 an EU 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 convormity assessment procedures.

2. Such trials procedures shall in no way discriminate between equipment produced in the flag State and equipment produced in other Member States.

3. Equipment which comes within this Article shall be given a certificate by the Member State which at all times has to be carried together with the equipment and which contains the permission of the flag Member State for the equipment to be placed on board the ship and any restrictions or provisions relating to the use of the equipment.

4. In the event that a Member State permits the placing on board an EU ship of equipment within this Article, that Member State shall communicate forthwith to the Commission and the other Member States the particulars thereof together with the reports of all trials, assessments and conformity assessment procedures.

5. Equipment referred to in paragraph 1 shall be added to Annex A.2 to this Directive in accordance with the procedure laid down in Article 19.

Article 15

Notwithstanding the provisions of Article 5, for reasons of testing or evaluating equipment and only when the following conditions are complied with a flag State administration may permit equipment which does not comply with the conformity assessment procedures or does not come within Article 14 to be placed on board an EU ship:

(a) the equipment will be given a certificate by the Member State which at all times must be carried together with the equipment and which contains the permission of the Member State for the equipment to be placed on board the EU ship and any restrictions or provisions relating to the use of the equipment;

(b) the equipment must not be relied upon in place of EC type-examined equipment and shall not replace the EC type-examined equipment. The EC type-examined equipment must remain on board the EU ship.

Article 16

1. Where the equipment needs to be replaced in a port outside the Community and in exceptional circumstances duly to be 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-examined, other equipment may be placed on board in accordance with the procedure below:

(a) the equipment shall be accompanied by documentation issued by a recognized organization equivalent to a notified body, where an agreement between the Community and the third country concerned has been concluded for mutual recognition of such organizations;

(b) should it prove impossible to comply with the provisions under 1 (a), equipment approved by a non-mutually recognized organization may be placed on board, subject to the provisions of 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 must ensure, at the earliest opportunity, that the equipment referred to in paragraph 1, along with its testing documentation, complies with the relevant requirements of the International Instruments.

Article 17

The Commission shall be assisted by the committee set up by Article 12 of Directive 93/75/EC in accordance with the procedure laid down in Article 19.

Article 18

The Directive may be amended in accordance with the procedure laid down in Article 19, in order to:

— apply for the purposes of this Directive subsequent amendments of International Instruments,

— update Annex A, both by introducing new equipment and by transferring equipment from Annex A.1 to Annex A.2 and vice versa.

Article 19

Where reference is made to this Article, the following procedure shall apply:

(a) the representative of the Commission shall submit to the committee referred to in Article 17 a draft of the measures to be taken;

(b) the committee shall deliver its opinion within a time limit which the chairman may lay down according to the urgency of the matter;

(c) the opinion shall be recorded in the minutes; in addition each Member State shall have the right to have its position recorded in the minutes;

(d) the Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 20

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

Article 21

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 June 1998. Member States shall apply these provisions from 1 January 1999.

When Member States adopt the provisions referred to in the first subparagraph, these shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The procedure for such reference shall be adopted by Member States.

2. The Member States shall immediately communicate to the Commission the text 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 22

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

Article 23

This Directive is addressed to the Member States.

ANNEX A

ANNEX A.1

EQUIPMENT WITH DETAILED TESTING STANDARDS ALREADY EXISTING IN INTERNATIONAL INSTRUMENTS (1)

1. Life saving appliances

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards (2)	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
1	Lifebuoys	Regulation III/4	Regulation III/7.1,31	IMO Resolution A 689 (17)	X	X	X	X		
2	Lifebuoy self-igniting lights	Regulation III/4	Regulation III/7.1,31.2	IMO Resolution A 689 (17)	X	X	X	X		
3	Lifebuoy self-activating smoke signals	Regulation III/4	Regulation III/7.1,31.3	IMO Resolution A 689 (17)		X	X	X		
4	Life-jackets	Regulation III/4	Regulation III/7.2,32	IMO Resolution A 689 (17)		X	X	X		
5	Life-jacket lights	Regulation III/4	Regulation III/7.2,32.3	IMO Resolution A 689 (17)	X	X	X	X		
6	Immersion suits	Regulation III/4	Regulation III/7.3,33	IMO Resolution A 689 (17)		X	X	X		
7	Immersion suits — life-jackets	Regulation III/4	Regulation III/7,32,33	IMO Resolution A 689 (17)		X	X	X		
8	Thermal protective aids	Regulation III/4	Regulation III/34	IMO Resolution A 689 (17)		X	X	X		
9	Rocket parachute flares (pyrotechnics)	Regulation III/4	Regulation III/35	IMO Resolution A 689 (17)		X		X		
10	Hand flares (pyrotechnics)	Regulation III/4	Regulation III/36	IMO Resolution A 689 (17)		X		X		
11	Buoyant smoke signals (pyrotechnics)	Regulation III/4	Regulation III/37	IMO Resolution A 689 (17)		X		X		
12	Line throwing appliances (pyrotechnics)	Regulation III/4	Regulation III/49	IMO Resolution A 689 (17)		X		X		
13	Inflatable life-rafts	Regulation III/4	Regulation III/38,39	IMO Resolution A 689 (17)		X				X
14	Rigid life-rafts	Regulation III/4	Regulation III/38,40	IMO Resolution A 689 (17)		X				X

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards (2)	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
15	Float free arrangements for life-rafts; hydrostatic release units	Regulation III/4	Regulation III/38.6.3	IMO Resolution A 689 (17)		X	X	X		
16	Lifeboats	Regulation III/4	Regulation III/41 to 46	IMO Resolution A 689 (17)		X			X	X
17	Rigid rescue boats	Regulation III/4	Regulation III/47.1 and 2	IMO Resolution A 689 (17)		X			X	X
18	Inflated rescue boats	Regulation III/4	Regulation III/47	IMO Resolution A 689 (17)		X			X	X
19	Launching appliances using fall and a winch (davits)	Regulation III/4	Regulation III/48.1 and 2	IMO Resolution A 689 (17)		X	X	X	X	X
20	Float free launching appliances	Regulation III/4	Regulation III/48.1 and 3	IMO Resolution A 689 (17)		X	X	X		
21	Free fall launching appliances	Regulation III/4	Regulation III/48.1,3 and 4	IMO Resolution A 689 (17)					X	
22	Launching and embarkation appliances	Regulation III/4	Regulation III/48.1,2,3,4, 5,6 and 7	IMO Resolution A 689 (17)		X			X	X
23	Life-raft launching appliances	Regulation III/4	Regulation III/48.1 and 6	IMO Resolution A 689 (17)		X	X	X	X	X
24	Embarkation ladders	Regulation III/4	Regulation III/48.7	IMO Resolution A 689 (17)		X	X	X		
25	Retro-reflective materials	Regulation III/4	Regulation III/30.2.7	IMO Resolution A 658 (16)	X	X	X	X		
26	Two-way VHF radiotelephone apparatus	Regulation III/4	Regulation III/6.2.1	IMO Resolution A 694 (17) IMO Resolution A 762 (18) IEC 945, draft IEC 1097-12	X	X	X	X	X	
27	Radar transponder SART	Regulation III/4	Regulation III/6.2.2	IMO Resolution A 530 (13) IMO Resolution A 697 (17) IMO Resolution A 694 (17) IEC 945 and 1097-1 CCIR 628	X	X	X	X		
28	Radar reflector	Regulation III/4	Regulation III/38.5.1.14 Regulation III/41.8.30	IMO Resolution A 384 (X) ISO 8729	X	X	X	X	X	X

(1) Where module H appears in column six, module H plus design assessment certificate it to be intended.

(2) Where IMO Resolutions are cited, these standards are those contained in relevant parts of the Annexes to the Resolutions and exclude the provisions of the Resolutions themselves.

2. **Marine pollution prevention**

Item No	Item designation	Regulation Marpol 73/78 as amended where 'type-approval' is required	Applicable Regulation Marpol 73/78 as amended	International testing standards	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
29	Oil filtering equipment (for an oil content of the effluent not exceeding 15 p.p.m.)	Regulation 16 (7)	Regulation 16 (4) and (5)	IMO Resolution A 393 MEPC 60 (33)	X	X	X	X		
30	Oil/water inferface detectors	Regulation 15 (3) (b)	Regulation 15 (3) (b) Annex I	MEPC 5 (XIII)	X	X	X	X		
31	Oil content meters	Regulation 16 (5)	Regulation 16 (2)	IMO Resolution A 393 MEPC 60 (33)	X	X	X	X		
32	Process units intended for attachment to existing oily-water separating equipment (for an oil content of the effluent not exceeding 15 p.p.m.)	Regulation 16 (5)	Regulation 16 (5)	IMO Resolution A 444 (XI)	X	X	X	X		
33	Oil discharge monitoring and control system for an oil tanker	Regulation 15 (3) Annex I	Regulation 15 (3) Annex I	IMO Resolution A 586 (14)	X	X	X	X		
34	Sewage treatment plants	Regulation 8 (b) Annex IV	Regulation 8 (b) Annex IV	MEPC 2 (VI)	X	X	X	X	X	X

3. **Fire protection**

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
35	Not readily igniting materials for primary deck covering	Regulation II-2/34.8 Regulation II-2/49.3	Regulation II-2/34.8	IMO Resolution A 214 (VII) IMO Resolution A 687 (17) IMO MSC/Circ. 549	X	X				
36	Portable fire extinguishers	Regulation II-2/6.1	Regulation II-2/6	EN 3		X	X	X		

4. **Navigation equipment**

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
37	Magnetic compass	Regulation V/12 (r)	Regulation V/12 (b)	IMO Resolution A 382 (X) IMO Resolution A 694 (17) IEC 945 ISO 449, 2269, 10316	X	X	X	X	X	
38	Gyro compass	Regulation V/12 (r)	Regulation V/12 (d)	IMO Resolution A 694 (17) IMO Resolution A 424 (XI) IEC 945 ISO 8728	X	X	X	X	X	
39	Radar equipment	Regulation V/12 (r)	Regulation V/12 (g) Regulation V/12 (h)	IMO Resolution A 477 (XII) IMO Resolution A 694 (17) IEC 936 and 945	X	X	X	X	X	
40	ARPA	Regulation V/12 (r)	Regulation V/12 (j)	IMO Resolution A 422 (XI) IMO Resolution A 694 (17) IEC 945 and 872	X	X	X	X	X	
41	Echosounding equipment	Regulation V/12 (r)	Regulation V/12 (k)	IMO Resolution A 224 (VII) IMO Resolution A 694 (17) ISO 9875 IEC 945	X	X	X	X	X	
42	Speed and distance measuring equipment	Regulation V/12 (r)	Regulation V/12 (l)	IMO Resolution A 478 (XII) IMO Resolution A 694 (17) IEC 945 and 1023	X	X	X	X	X	
43	Rate of turn indicator	Regulation V/12 (r)	Regulation V/12 (n)	IMO Resolution A 526 (13) IMO Resolution A 694 (17) IEC 945	X	X	X	X	X	
44	2182 kHz homing equipment	Regulation V/12 (r)	Regulation V/12 (q)	IMO Resolution A 694 (17) IEC 945	X	X	X	X	X	
45	Direction finder	Regulation V/12 (r)	Regulation V/12 (p)	IMO Resolution A 665 (16) IMO Resolution A 694 (17) IEC 945	X	X	X	X	X	

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
46	Omega equipment	Regulation V/12 (r)	Regulation V/12 (p)	IMO Resolution A 479 (XII) IMO Resolution A 694 (17) IEC 945 and 1010	X	X	X	X	X	
47	Loran-C equipment	Regulation V/12 (r)	Regulation V/12 (p)	IMO Resolution A 694 (17) IEC 945 and 1075	X	X	X	X	X	
48	Decca navigator equipment	Regulation V/12 (r)	Regulation V/12 (p)	IMO Resolution A 694 (17) IEC 945 and 1135	X	X	X	X	X	
49	GPS equipment	Regulation V/12 (r)	Regulation V/12 (p)	IMO Resolution A 694 (17) IEC 945 draft IEC 1108-1	X	X	X	X	X	

5. **Radio-communication equipment**

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
50	VHF radio installation	Regulation IV/14	Regulation IV/7.1.1	IMO Resolution A 609 (15) IMO Resolution A 694 (17) IEC 945 and 1097-8	X	X	X	X	X	
51	VHF DSC	Regulation IV/14	Regulation IV/7.1.2	IMO Resolution A 694 (17) IEC 945 and 1097-3 CCIR 493, 541, 689	X	X	X	X	X	
52	SART radar transponder	Regulation IV/14	Regulation IV/7.1.3	IMO Resolution A 530 (13) IMO Resolution A 697 (17) IMO Resolution A 694 (17) IEC 945 and 1097-1	X	X	X	X	X	
53	NAVTEX	Regulation IV/14	Regulation IV/7.1.4	IMO Resolution A 525 (13) IMO Resolution A 694 (17) IEC 945 and 1097-6 CCIR 540 and 625	X	X	X	X	X	

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
54	EGC equipment	Regulation IV/14	Regulation IV/7.1.5	IMO Resolution A 664 (16) IMO Resolution A 694 (17) IEC 945 draft IEC 1097-6	X	X	X	X	X	
55	HF marine safety information (MSI) equipment (HF NBDP receiver)	Regulation IV/14	Regulation IV/7.1.5	IMO Resolution A 700 (17) IMO Resolution A 694 (17) IEC 945 and 1097-11 CCIR 491, 492, 625, 688	X	X	X	X	X	
56	406 MHz Epirb	Regulation IV/14	Regulation IV/7.1.6	IMO Resolution A 662 (16) IMO Resolution A 763 (18) IMO Resolution A 696 (17) IMO Resolution A 694 (17) IEC 945 and 1097-2	X	X	X	X	X	
57	L-Band Epirb	Regulation IV/14	Regulation IV/7.1.6	IMO Resolution A 661 (16) IMO Resolution A 694 (17) IEC 945 draft IEC 1097-5 CCIR 632-SDM	X	X	X	X	X	
58	2182 kHz watch receiver	Regulation IV/14	Regulation IV/7.2	IMO Resolution A 383 (X) IMO Resolution A 694 (17) IEC 945 IEC 1097-15	X	X	X	X	X	
59	Two-tone alarm signal generator	Regulation IV/14	Regulation IV/7.3	IMO Resolution A 421 (XI) IMO Resolution A 694 (17) IEC 945 IEC 1097-16	X	X	X	X	X	
60	VHF Epirb	Regulation IV/14	Regulation IV/8.3	IMO Resolution A 612 (15) IMO Resolution A 694 (17) IEC 945 IEC 1097-13 CCIR 632	X	X	X	X	X	
61	MF radio installation	Regulation IV/14	Regulation IV/9.1.1 Regulation IV/10.1.2	IMO Resolution A 610 (15) IMO Resolution A 694 (17) IEC 945 and 1097-10	X	X	X	X	X	

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	Applicable Regulation Solas 74 as amended	International testing standards	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
62	MF radiotelephone	Regulation IV/14	Regulation IV/9.1.1 Regulation IV/10.1.2	IMO Resolution A 613 (15) IMO Resolution A 694 (17) IEC 945 — 1097-9 CCIR 493, 541	X	X	X	X	X	
63	Inmarsat — A SES	Regulation IV/14	Regulation IV/10.1.1	IMO Resolution A 570 (14) IMO Resolution A 698 (17) IMO Resolution A 694 (17) IEC 945 Inmarsat System Definition Manual (SDM)	X	X	X	X	X	
64	Inmarsat — C SES	Regulation IV/14	Regulation IV/10.1.1	IMO Resolution A 570 (14) IMO Resolution A 663 (16) IMO Resolution A 694 (17) IEC 945 Inmarsat SDM draft IEC 1097-4	X	X	X	X	X	
65	MF/HF radio installation	Regulation IV/14	Regulation IV/10.2.1	IMO Resolution A 613 (15) IMO Resolution A 694 (17) IEC 945 and 1097-10	X	X	X	X	X	
66	Radiotelephone	Regulation IV/14	Regulation IV/10.2.1	IMO Resolution A 694 (17) IEC 945 and 1097-9	X	X	X	X	X	

ANNEX A.2

EQUIPMENT WITHOUT DETAILED TESTING STANDARDS ALREADY EXISTING IN INTERNATIONAL INSTRUMENTS

1. **Life saving appliances**

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	International testing standards
1	Evacuation, slide launching and embarkation	Regulation III/48.5	

2. **Fire protection**

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	International testing standards
2	Materials other than steel for pipes penetrating 'A' or 'B' class division	Regulation II-2/18.2.1	For plastic pipes: IMO Resolution A 753 (18)
3	Materials other than steel for pipes covering oil or fuel-oil	Regulation II-2/18.2.2	
4	Non portable and transportable extinguishers	Regulation II-2/6.1 Regulation II-2/7.1.3, 7.2.3 and 7.3.1	
5	Fireman's breathing apparatus	Regulation II-2/17.1.2	
6	Sprinkler systems (limited to sprinkler heads and to the method of automatic sprinkling and signalling)	Regulation II-2/12.3, 36.1.2 and 36.2 Regulation 41-2 paragraphs 5 and 52.2	ISO 6182
7	Nozzles for fixed pressure water-spraying fire-extinguishing systems for machinery spaces	Regulation II-2/10.1	
8	Nozzles for fixed pressure water-spraying fire-extinguishing systems for special category spaces	Regulation II-2/37.1.3	IMO Resolution A 123 (V)
9	Cold weather starting of generator sets (starting devices)	Regulation II-1/44.2	
10	Fire hoses	Regulation II-2/4.7.1	
11	Dual-purpose nozzles	Regulation II-2/4.8.4 Regulation II-2/41 — 2 paragraph 1.5	
12	Electric safety lamp	Regulation II-2/17.1.1.4	
13	Smoke detectors	Regulation II-2/13.3.2	
14	Heat detectors	Regulation II-2/13.3.3	
15	Primary deck covering toxic and explosive hazards	Regulation II-2/34.8 Regulation II-2/49.3	IMO Resolution A 687 (17)

Item No	Item designation	Regulation Solas 74 as amended where 'type-approval' is required	International testing standards
16	'A' and 'B' class bulkheads and decks, fire integrity	Regulation II-2/3.3.5 Regulation II-2/3.4.4	IMO Resolution A 754 (18)
17	Devices to prevent the passage of flame into the cargo tanks in oil tankers	Regulation II-2/59.1.5 Regulation II-2/59.1.9.4 and 59.2	IMO MSC/Circ. 373/Rev. 1 IMO MSC/Circ. 450/Rev. 1
18	Non-combustible material used in 'A', 'B' and 'C' class divisions	Regulation II-2/3.1 Regulation II-2/3.3.4 Regulation II-2/3.4.3 Regulation II-2/3.5	IMO Resolution A 472 (XII)

ANNEX B

MODULES FOR CONFORMITY ASSESSMENT

EC TYPE-EXAMINATION (MODULE B)

1. A notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of the International Instruments that apply to it.

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

   The application shall include:

   — the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,

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

   — the technical documentation, as described in point 3.

   The applicant shall 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 carrying out the test programme.

3. The technical documentation shall enable the conformity of the product with the requirements of the relevant International Instruments to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and functioning of the product.

4. The notified body shall:

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

   4.2. perform or have performed the appropriate examinations and necessary tests to check whether the requirements of the relevant International Instruments have actually been applied;

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

5. Where the type meets the provisions of the relevant International Instruments, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type.

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

   If the manufacturer is denied a type certification, the notified body shall provide detailed reasons for such denial.

6. The applicant shall 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 the conformity with the requirements or the prescribed

(1) A type may cover several versions of the product provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product.

conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.

7. Each notified body shall communicate to the other notified bodies 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 shall be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorized representative shall keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least 10 years after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

CONFORMITY TO TYPE (MODULE C)

1. The manufacturer or his authorized representative established within the Community ensures and declares that the products concerned are in conformity with the 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 shall affix the mark to each product and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate and with the requierements of the International Instruments that apply to them.

3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is estabilshed within the Community, the obligation to keep the technical documentation available shall be the responsiblity of the person who places the product on the Community market.

PRODUCT QUALITY ASSURANCE (MODULE D)

1. The manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the 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 EC monitoring as specified in point 4.

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and shall be subject to monitoring as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessemt of his quality system with a notified body of his choice, for the products concerned.

The application shall 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 shall ensure compliance of the products with the type as described in the EC type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer shall 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 shall contain in particular 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 to monitor the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team shall have at least one member with experience of evaluation in the product technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall 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 shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It shall notify its decisions to the manufacturer. The notification shall contain 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 shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage and shall 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 ot the personnel concerned, etc.

4.3. The notified body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national autorities:

— the documentation referred to in the second indent of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decision and reports from the notified body which are referred to in the final paragraph of points 3.4, 4.3 and 4.4.

6. Each notified body shall give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

PRODUCT QUALITY ASSURANCE (MODULE E)

1. The manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate. The manufacturer or his authorized representative established within the Community shall 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 shall operate an approved quality system for final inspection and testing as specified in paragraph 3 and must be subject to the surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system for the products concerned, with a notified body of his choice.

The application shall include:

— all relevant information for the product category envisaged,

— the quality system's documentation,

— the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2. Under the quality system, each product shall be examined and appropriate tests shall be carried out in order to ensure its conformity 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. This quality system documentation must ensure a common understanding of the quality programmes, plans, manuals and records.

It must contain in particular 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 to monitor the effective operation of the quality system,

— quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team shall have at least one member with experience as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It shall notify its decisions to the manufacturer. The notification shall contain 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 shall allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage and shall 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 shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. At the time of such visits the notified body may carry out tests or have them carried out to check the proper functioning of the quality system where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending 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 point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decision and reports from the notified body which are referred to in the final paragraph of points 3.4, 4.3 and 4.4.

6. Each notified body shall forward to the other notified bodies 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 checks and attests that the products subject to the provisions of point 3 are in conformity with the type as described in the EC-type examination certificate.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures conformity of the products with the type as described in the EC type-examination certificate. He shall affix the mark to each product and shall draw up a declaration of conformity.

3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the product 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 must keep a copy of the declaration of conformity for a period ending 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 shall be carried out in order to verify their conformity with the type as described in the EC-type examination certificate.

4.2. The notified body must affix or cause to be affixed, its identification symbol 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 must ensure that he is able to supply the notified body's certificate of conformity on request.

5. **Statistical verification**

5.1. The manufacturer must present his products in the form of homogeneous lots and shall take all measures necessary in order 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 shall be drawn from each lot. Products in a sample shall be individually examined and appropriate tests, shall be carried out to ensure their conformity with the requirements of the International Instruments which apply to them and to determine whether the lot is accepted or rejected.

5.3. In the case of accepted lots, the notified body must affix, or cause to be affixed, its identification symbol to each product and shall 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 were found not to be in conformity.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent the putting on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the 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 must ensure that he is able to supply the notified body's certificates of conformity on request.

UNIT VERIFICATION (MODULE G)

1. This module describes the procedure whereby the manufacturer ensures and declares that the product concerned, which has been issued with the certificate referred to in point 2, conforms to 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 the appropriate tests, to ensure its conformity with the relevant requirements of the International Instruments.

The notified body must affix, or cause to be affixed, its identification number on the approved product and shall draw up a certificate of conformity concerning the test carried out.

3. The aim of the technical documentation is to enable conformity 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. The manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the International Instruments that apply to them. The manufacturer or his authorized representative established within the Community shall 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 shall operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and must be subject to the surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body.

The application shall include:

— all relevant information for the product category envisaged,

— the quality system's documentation.

3.2. The quality system shall ensure compliance of the products 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. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

— the quality objectives and the organizational structure, responsibilites 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 when designing 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,

— quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

— the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with the requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team shall have at least one member with experience as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall 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 shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It shall notify its decisions to the manufacturer. The notification shall contain 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 shall allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and shall provide it with all necessary information in particular:

— the quality system documentation,

— the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as foreseen by 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 shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out to check the proper functioning of the quality system where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending 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 subparagraph of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decision and reports from the notified body which are referred to in the final subparagraph of points 3.4, 4.3 and 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

Technical documentation supplied by the manufacturer to the notified body

The technical documentation referred to in Annex B must comprise all relevant data or means used by the manufacturer to ensure that equipment complies with the essential requirements relating to them.

The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the relevant International Instruments.

The documentation shall contain so far as is relevant for assessment:

— a general description of the type,

— conceptual design and manufacturing drawings and schemes of components, subassemblies circuits, etc.,

— descriptions and explanations necessary for the understanding of the said drawings and schemes, including the operation of the product,

— results of design calculations made, examinations carried out, etc.,

— test reports,

— manuals for installation, use and maintenance.

Where appropriate, the design documentation must contain the following elements:

— attestations relating to the equipment incorporated in the applicance,

— attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance,

— an other document making it possible for the notified body to improve its assessment.

ANNEX C

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

1. Notified bodies must fulfil the requirements of the EN 45000 series.

2. 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.

3. The notified body must be in a position to provide maritime expertise.

A notified body is entitled to perform the conformity assessment procedures for any economic operator established within or outside the Community.

A notified body may perform the conformity assessment procedures in any Member State or State outside the EC using either their home based means or using the personnel of their branch office abroad.

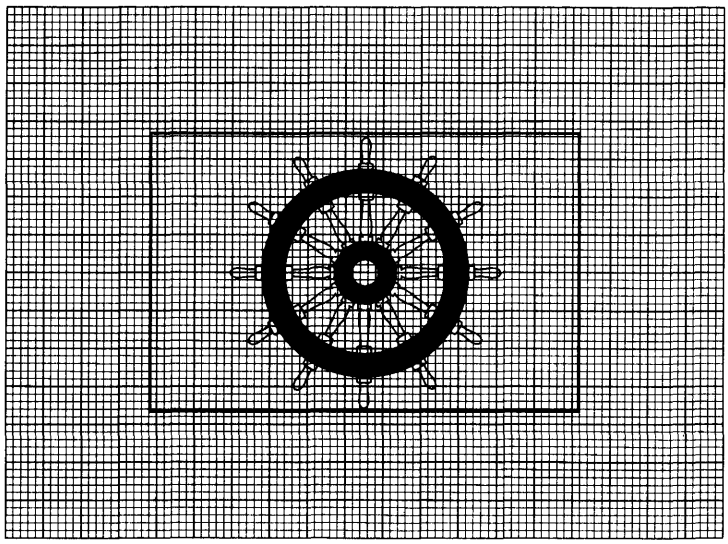
In the event that a subsidiary of the notified body performs the conformity assessment procedures, all documents relating to the conformity assessment procedures shall be issued by and in the name of the notified body and not in the name of the subsidiary.

However, a subsidiary of a notified body which is established in another Member State may issue documents relating to the conformity assessment procedures if it is notified by that Member State.

ANNEX D

MARK OF CONFORMITY

The conformity mark shall take the following form:



If the mark is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the mark have substantially the same vertical dimension, which may not be less than 5 mm.

This minimum dimension may be waived for small-scale devices.