



Maritime and Coastguard Agency

## Type Approval of Marine Equipment (EC Notified Bodies)

Notice to Manufacturers, Shipbuilders, Shipowners, Ship Operators and Managers, Designers and Marine Consultants, Masters and Officers of Merchant Ships, Skippers of Fishing Vessels and Owners of Yachts and Pleasure Craft

*This Notice supersedes Merchant Shipping Notice No.M.1645 and MGN 43. The following text is to be inserted in MSN 1688 - end of para 1, and MSN 1714 - end of para 3:*

*'In the case of a ship of a Member State of the European Union, the performance standards applicable to equipment installed on or after 1 January 1999 are specified in the Merchant Shipping (Marine Equipment) Regulations 1999, as they may be amended from time to time.'*

### Summary

The purpose of the Marine Equipment Directive is to enhance safety at sea and the prevention of marine pollution through the uniform application of the relevant international instruments relating to marine equipment for which EC type approval safety certificates are issued. This Notice gives information and guidance about the procedures for obtaining type approval in conformity with the Directive through Notified Bodies nominated by the United Kingdom.

#### Key Points:-

- In recent years there has been significant development of specifications and testing requirements for many items of equipment which should ensure that equipment is manufactured to consistent standards.
- To gain type approval, equipment must satisfy testing standards and be manufactured in accordance with the EC conformity-assessment procedure as set out in Annex A of this Notice. The conformity assessment modules referred to in Annex A are contained in Annex B.
- The advantages of this type approval process are that the equipment will be accepted without detailed examination of each individual item on EU flagged ships and the shipowner can purchase equipment with similar assurance.
- The Directive will ensure the free movement of such equipment within the Community.

## 1 Introduction

1.1 The Merchant Shipping (Marine Equipment) Regulations 1999 SI (1999 No 1957) provide for the "type approval" of marine equipment, of a safety or pollution prevention nature, for use on board United Kingdom ships. This legislation implements the European Community (EC) Directive 96/98/EC of 20 December 1996 on Marine Equipment and

98/85/EC of 11 November 1998. Directive 98/85/EC contains an Annex A which amends Annex A of Council Directive 96/98/EC. After 30 April 1999, the testing standards in the amended Annex A must be used to obtain an EC type approval certificate. However, for equipment manufactured between 1 January 1999 and 30 April 1999, manufacturers may use the testing standards contained in Annex A of 96/98/EC.

- 1.2 The MCA has nominated organisations listed in Annex 1 of this Notice and accordingly those bodies are nominated as “Notified Bodies” (as referred to in the Merchant Shipping (Marine Equipment) Regulations 1999) to carry out approvals and undertake the examination, testing and certification of the equipment listed in Annex A of this Notice.
- 1.3 For equipment not listed but which requires type approval, manufacturers should contact the MCA or one of the Nominated Bodies listed in MSN 1735 for information.
- 1.4 Manufacturers with existing MCA type approval certificates will need to contact the Notified Bodies listed in Annex 1 of this Notice for information on the need for assessment and the marking to the new standards. All new equipment must comply with the international standard specified in Annex A.
- 1.5 Equipment will not be considered to comply with the relevant international standards unless -
- .1 it satisfies the testing standards as specified in Annex A; and
  - .2 it has been manufactured in accordance with the EC conformity-assessment procedure as set out in Annex B and has been labelled with the mark of conformity, identification number and the last two digits of the year in which the mark was affixed as shown in Annex C to this Notice.
- 1.6 Unless there is a change in the required standards, existing type approved equipment already fitted on board ship will continue to be accepted providing it operates satisfactorily. If it needs to be replaced, it must be replaced with equipment which complies with the MS (Marine Equipment) Regulations 1999.
- 1.7 Equipment requiring type approval for new ships or existing ships should be type approved to the latest standards. The replacement of certain original equipment on existing ships is acceptable provided that equipment is approved to the appropriate international standard. If there is any doubt either the MCA or Notified Body should be contacted for clarification.

## **2 Type Approval Procedure**

### **2.1 The application procedure for Type Approval for EC type-examination can be found at Annex 2.**

2.2 The manufacturer or his authorised representative established within the community, must in respect of an EC type-examination certificate issued to him, keep a copy of the technical documentation submitted with the application and the EC type-examination certificate and any additions to it, for at least 10 years after the last item of equipment that the certificate relates to has been manufactured.

## **3. Issue of Type Approval**

3.1 Providing that the Notified Body is satisfied the equipment complies in all respects with the specifications laid down by international standards and the relevant conformity-assessment procedure as described in Annex B is followed, subject to the provisions below, the Notified Body will issue a certificate of type approval in respect of the equipment stating the terms and conditions of approval. All new certificates of type approval will be valid for a period of up to 5 years.

3.2 A certificate of type approval refers only to equipment identical to that assessed. It is also a condition of issue of the certificate that a manufacturer shall consult with the Notified Body prior to the incorporation of any alteration to the build standard of the equipment for which the type approval certificate was originally issued.

3.3 Notified Bodies may require further testing and assessment to be undertaken in the event of a modification, or series of modifications, being considered to constitute sufficient departure from the build standard of the equipment that the certificate of type approval was originally issued.

## **4. Information About Type Approvals**

4.1 Information concerning Type Approved Equipment and how to obtain type approval for equipment as listed in the appendices to the Annex can be obtained from:-

American Bureau of Shipping (Europe)  
American Bureau of Shipping House  
1 Frying Pan Alley  
London E1 7HR  
Tel: 0171 247 3255  
Fax: 0171 377 2453

Lloyds Register of Shipping  
Type Approvals Department  
Engineering Services  
Lloyd's Register House  
29 Wellesley Road  
Croydon CRO 2AJ  
Tel: 0181 681 4040  
Fax: 0181 681 6814

Defence Evaluation & Research  
Agency (DERA),  
Fraser  
Fort Cumberland Road  
Portsmouth PO4 9LJ  
Tel: 01705 334503  
Fax: 01705 830017

BSI : British Standards Institution  
Maylands Avenue  
Hemel Hempstead  
Herts, HP2 4SQ  
Tel : 01442 230442  
Fax: 01442 231442

4.2 For equipment not listed which requires to be type approved, contact the MCA at:

MSPP2C Bay 2/17  
Maritime and Coastguard Agency  
Spring Place, 105 Commercial Road  
Southampton SO15 1EG  
Tel: 01703 329186  
Fax: 01703 329204  
July 1999

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**ANNEX 1**

**TYPE APPROVAL OF MARINE EQUIPMENT  
NOTIFIED BODIES**

The Notified Bodies listed in Column 1 in the following tables are specified as those bodies which may undertake type approval of the product or production range of equipment listed in Column 2 of the table. For details of the specific procedures, modules and equipment the Notified Body has been authorised to carry out by the United Kingdom, the relevant Notified Body must be contacted.

For equipment not listed but which requires type approval, please contact the Maritime and Coastguard Agency.

**TABLE A**

Column 1	Column 2
<b>NOTIFIED BODY</b>	<b>EQUIPMENT CATEGORY</b>
Lloyd’s Register of Shipping	Life Saving Appliances Marine Pollution Prevention Fire Protection
American Bureau of Shipping (Europe)	Life Saving Appliances Marine Pollution Prevention Fire Protection
Defence Evaluation and Research Agency	Life Saving Appliances Radio Communication Equipment Navigation Equipment
British Standards Institution	Life Saving Appliances Fire Protection

## 1 Application for Type Approval for EC type-examination

- 1.1 An application for EC type-examination in respect of equipment shall be made in writing by the manufacturer or his authorised representative within the Community (referred to as applicant in this Notice) to a Notified Body. The application must include:
- .1 the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that person;
  - .2 a written declaration that the same or a similar application has not been lodged simultaneously with other Notified Bodies;
  - .3 the technical documentation stated in Annex D to this Notice; and
  - .4 place at the disposal of the Notified Body sufficient specimens representative of the production envisaged. The Notified Body may request further specimens if needed for carrying out the test programme.
- 1.2 In order to assess conformity of the product with the requirements of the relevant regulations and test standards, the technical documentation must cover the design, build standard, manufacture and functioning of the equipment.
- 1.3 Type approval tests are to be conducted at a United Kingdom Accreditation Services (UKAS) or equivalent National Body accredited laboratory unless no such laboratory is available. In that instance, an alternative laboratory recognised by the Notified Body as offering suitable and satisfactory guarantees of technical application of EN 45001 or ISO/IEC Guide 25 may be used.
- 1.4 On an application made to it under paragraph (1) above a Notified Body is to;
- .1 examine the technical documentation submitted by the applicant and verify that the equipment has been manufactured in accordance with the technical documentation;
  - .2 agree with the applicant the location where the examination and necessary tests are to be carried out; and
  - .3 carry out, or have carried out, the appropriate examination and necessary tests to determine if the applicable international standards are satisfied.
- 1.5 Where the Notified Body is satisfied, after performing its functions under paragraph 1.4 above, that the product satisfies the applicable international standards, it shall issue an EC type-examination certificate to the applicant.
- An EC type-examination certificate issued in accordance with the above shall include;
- .1 the name and address of the manufacturer;
  - .2 details of the equipment to which it relates;
  - .3 the results of any examinations or tests carried out;
  - .4 conditions (if any) of its validity; and
  - .5 the information necessary to identify the approved product.
- 1.6 A list of the relevant parts of the technical documentation including drawings and instructions will be annexed to the certificate and a copy kept by the Notified Body.
- 1.7 Where a Notified Body refuses to issue an EC type-examination certificate, it shall give in writing detailed reasons for its decision to the applicant with a copy to the MCA.
- 1.8 If an applicant applies for an EC type-examination for equipment in respect of which an EC type-examination certificate has been refused, the application to the Notified Body shall include the following relevant documentation:
- .1 the original examination and test results;
  - .2 the detailed reasons provided by the Notified Body for the previous refusal; and

- .3 details of all modifications made to the equipment since the previous application.
- 1.9 If any modifications are made to equipment in respect of which an EC type-examination certificate has been issued, the applicant shall inform the Notified Body that issued the certificate.
- 1.10 If any modifications are such that they may affect the equipment's compliance with applicable international standards, the Notified Body shall satisfy itself, by further examinations and tests if necessary, that the equipment as modified complies with the applicable international standards and, if so satisfied, shall -
  - .1 approve the modifications to the equipment; and
  - .2 issue an addition to the original EC type-examination certificate in respect thereof.
- 1.11 A Notified Body must;
  - .1 on request, provide flag state members and other Notified Bodies with all relevant information concerning the EC type examination certificates and additions thereto it has issued, including any it has withdrawn;
  - .2 on request, provide other Notified Bodies with copies of the EC type-examination certificates and additions thereto it has issued; and
  - .3 on request provide other Notified Bodies with the annexes to the EC type-examination certificates it has issued.

**Annex A.1: Equipment for which detailed testing standards already exist in international instruments<sup>(1)</sup>**

IN ADDITION TO THE TESTING STANDARDS SPECIFICALLY MENTIONED A NUMBER OF PROVISIONS, WHICH MUST BE CHECKED DURING TYPE-EXAMINATION (TYPE APPROVAL) AS REFERRED TO IN THE MODULES FOR CONFORMITY ASSESSMENT IN ANNEX B, ARE TO BE FOUND IN THE APPLICABLE REQUIREMENTS OF THE INTERNATIONAL CONVENTIONS AND THE RELEVANT RESOLUTIONS AND CIRCULARS OF THE IMO

**1. Life-saving appliances**

Item No	Item designation	Regulation SOLAS 74 as amended where 'type approval' is required	Applicable regulations SOLAS 74 as amended, and the relevant resolutions and circulars of the IMO <sup>(2)</sup>	Testing standards <sup>(3)</sup>	Modules for conformity assessment <sup>(4)</sup>					
					B+ C	B+ D	B+ E	B+ F	G	H
A.1/1.1	Lifebuoys	Regulation III/4	Regulation III/7.1 & III/34 Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		
A.1/1.2	Position-indicating lights for life-saving appliances	Regulation III/4	Regulation III/7.1.3, III/22.3.1, III/32.2.2 & III/34 Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		

<sup>(1)</sup> Where module H appears in column six, module H plus design-examination certificate is to be understood.

<sup>(2)</sup> ITU Recommendations cited are those referred to in the international conventions and the relevant resolutions and circulars of the IMO.

<sup>(3)</sup> Where IMO Resolutions are cited, only the testing standards contained in relevant parts of the Annexes to the Resolutions are applicable and exclude the provisions of the Resolutions themselves.

<sup>(4)</sup> The manufacturer has choice of which conformity assessment module(s) he wishes the Notified Body to conduct. The manufacturer need only comply with one of the Boxes marked with an X.

A.1/1.3	Lifebuoy self-activating smoke signals	Regulation III/4	Regulation III/7.1 & III/34 Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		
A.1/1.4	Lifejackets	Regulation III/4	Regulation III/7.2 & III/34 Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66) EN 394, EN 396 + A1, EN 399 + A1		X	X	X		
A.1/1.5	Immersion suits and anti-exposure suits	Regulation III/4	Regulation III/7.3 & III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X	X	X		
A.1/1.6	Immersion suits and anti-exposure suits classified as lifejackets	Regulation III/4	Regulation III/7.3 & III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		
A.1/1.7	Thermal protective aids	Regulation III/4	Regulation III/22.4, III/32.3 & III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		
A.1/1.8	Rocket parachute flares (pyrotechnics)	Regulation III/4	Regulation III/6.3 & III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X		X		
A.1/1.9	Hand flares (pyrotechnics)	Regulation III/4	Regulation III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X		X		
A.1/1.10	Buoyant smoke signals (pyrotechnics)	Regulation III/4	Regulation III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X		X		
A.1/1.11	Line-throwing appliances (pyrotechnics)	Regulation III/4	Regulation III/18 & III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X		X		

A.1/1.12	Inflatable liferafts	Regulation III/4	Regulation III/21, III/31 & III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X				
A.1/1.13	Rigid liferafts	Regulation III/4	Regulation III/21, III/31 & III/34, Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X				
A.1/1.14	Automatically self-righting liferafts	Regulation III/4 & III/26.2.4	Regulation III/26.2 & III/34, IMO Resolution MSC 48(66), IMO MSC Circ. /809	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66) and modified by the appendix to MSC Circ./809 <sup>2</sup>		X				
A.1/1.15	Canopied reversible liferafts	Regulation III/4 & III/26.2.4	Regulation III/26.2 & III/34, IMO Resolution MSC 48(66) IMO MSC Circ./809	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54 (66) and modified by the Appendix to MSC Circ./809		X				
A.1/1.16	Float-free arrangements for liferafts; (hydrostatic release units)	Regulation III/4	Regulation III/13.4 & III/34, Resolution MSC 48(66) IMO MSC Circ./811	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X	X	X		
A.1/1.17	Lifeboats	Regulation III/4	Regulation III/21, III/31 & III/34, IMO Resolution MSC 48 (66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X			X	
A.1/1.18	Rigid rescue boats	Regulation III/4	Regulation III/21, III/31, III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X			X	
A.1/1.19	Inflated rescue boats	Regulation III/4	Regulation III/21, III/31, & III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X			X	

<sup>1</sup> The modification by the Appendix to MSC Circ./809 is only applicable if the equipment is to be fitted on ro-ro passenger ships.

A.1/1.20	Fast rescue boats	Regulation III/4 & III/26.3.1	Regulation III/26.3 & III/34 IMO Resolution MSC 48(66), IMO MSC Circ./809	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66) and modified by the Appendix to MSC Circ./809 <sup>1</sup>		X			X	
A.1/1.21	Launching appliances using fall and winch (davits)	Regulation III/4	Regulation III/23, III/33 & III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X	X	X	X	
A.1/1.22	Float-free launching appliances for survival craft	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X	X	X		
A.1/1.23	Launching appliances for free-fall lifeboats	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)					X	
A.1/1.24	Liferaft launching appliances	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66)		X	X	X	X	
A.1/1.25	Fast rescue boat launching appliances	Regulation III/4 & III/26.3.2	Regulation III/26.3 & III/34, IMO Resolution MSC 48(66) IMO MSC Circ./809	IMO Resolution A.689 (17) as amended by IMO Resolution MSC.54(66) and modified by the Appendix to MSC Circ/809 <sup>2</sup>		X	X	X		
A.1/1.26	Release mechanism for lifeboats, rescueboats and liferafts launched by a fall or falls	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		
A.1/1.27	Marine evacuation systems	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X			X	

<sup>1</sup> The modification by the Appendix to MSC Circ./809 is only applicable if the equipment is to be fitted on ro-ro passenger ships.

<sup>2</sup> The modification by the Appendix to MSC Circ/809 is only applicable if the equipment is to be fitted on ro-ro passenger ships.

A.1/1.28	Means of rescue	Regulation III/4	Regulation III/26.4 & III/34, IMO Resolution MSC 48(66) IMO MSC Circ./810	IMO Resolution A.689 (17) as amended by resolution MSC.54(66), MSC Circ./810 (section 3)		X				
A.1/1.29	Embarkation ladders	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		
A.1/1.30	Retro-reflective materials	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.658 (16) Annex 2		X	X	X		
A.1/1.31	Survival craft two- way VHF radio telephone apparatus	Regulation III/4	Regulation III/6.2.1, IMO Resolution A.694 (17), IMO Resolution A.809 (19), IMO Resolution A.813 (19)	ETS 300.162, ETS 300.225, EN 300.828, EN 60945; IEC 61097-12, IEC 60945		X	X	X	X	
A.1/1.32	9GHz SAR transponder (SART)	Regulation III/4, IV/14 & X/3	Regulation III/6.2.2, IV/7.1.3, X/3, IMO Resolution A.530 (13), IMO Resolution A.694 (17), IMO Resolution A.802 (19), IMO Resolution A.813 (19), ITU-R M.628-2	EN 61097-1, EN 60945-3; IEC 61 097-1, IEC 60945		X	X	X	X	
A.1/1.33	Radar reflector for lifeboats and rescue boats	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.384 (X) EN 8729; ISO 8729		X	X	X	X	
A.1/1.34	Compass for lifeboats and rescue boats	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	ISO 613, 10316		X	X	X	X	
A.1/1.35	Portable fire extinguishing equipment for lifeboats and rescue boats	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66) IMO Resolution A.602(15)	EN 3-1/A1, 3-2, 3-3, 3-4, 3-5, 3-6		X	X	X		

A.1/1.36	Lifeboat propulsion engine	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		
A.1/1.37	Rescue boat propulsion engine	Regulation III/4	Regulation III/34, IMO Resolution MSC 48(66)	IMO Resolution A.689 (17) as amended by resolution MSC.54(66)		X	X	X		

## 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, and the relevant resolutions and circulars of the IMO	Testing standards <sup>(3)</sup>	Modules for conformity assessment					
					B+ C	B+ D	B+ E	B+F	G	H
A.1/2.1	Oil-filtering equipment (for an oil content of the effluent not exceeding 15 p.p.m.)	Annex I, Regulation 16 (4), (5) & (7)	Annex I, Regulation 16 (1) & (2)	MEPC 60 (33)		X	X	X		
A.1/2.2	Oil/water interface detectors	Annex I, Regulation 15 (3) (b)	Annex I, Regulation 15 (3) (b)	MEPC 5 (XIII)		X	X	X		
A.1/2.3	Oil-content meters	Annex I, Regulation 16 (5)	Annex I, Regulation 16(2)	MEPC 60 (33)		X	X	X		
A.1/2.4	Process units intended for attachment to existing oily water separating equipment (for an oil content of the effluent not exceeding 15 p.p.m.)	Annex I, Regulation 16 (5)	Annex I, Regulation 16 (5)	IMO Resolution A.444 (XI) MEPC 60 (33)		X	X	X		
A.1/2.5	Oil discharge monitoring and control system for an oil tanker	Annex I, Regulation 15 (3)	Annex I, Regulation 15 (3)	IMO Resolution A.586 (14)		X	X	X		

<sup>(1)</sup> Where IMO Resolutions are cited, only the testing standards contained in relevant parts of the Annexes to the Resolutions are applicable and exclude the provisions of the Resolutions themselves.

A.1/2.6	Sewage treatment plants	Annex IV, Regulation 8 (b)	Annex IV, Regulation 8 (b)	MEPC 2 (VI)		X	X	X	X	
A.1/2.7	Shipboard incinerators	Annex VI Regulation 16 (2)	Annex VI Regulation 16 (2)	MEPC 76(40)		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, and, the relevant resolutions and circulars of the IMO	Testing standards <sup>(1)</sup>	Modules for conformity assessment					
					B+ C	B+ D	B+ E	B+F	G	H
A.1/3.1	Primary deck coverings	Regulation II-2/34.8, Regulation II-2/49.3	Regulation II-2/34.8, Regulation II-2/49.3	IMO Resolution A.687(17) IMO MSC/Circ. 549, IMO Resolution MSC 61(67) Annex 1, Parts 2 & 6, & Ann.2		X				
A.1/3.2	Portable fire extinguishers	Regulation II-2/6.1	Regulation II-2/6, IMO Resolution A.602 (15)	EN 3-1/A1, 3-2, 3-3, 3-4, 3-5, 3-6		X	X	X		
A.1/3.3	Fireman's outfit: (protective clothing)	Regulation II-2/17.1.1.1	Regulation II-2/17.1.1.1	EN 366, EN 469 or EN 531, EN 532, EN 20811		X				
A.1/3.4	Fireman's outfit: boots	Regulation II-2/17.1.1.2	Regulation II-2/17.1.1.2	EN 344, EN 344-2, EN 345, EN 345-2		X				
A.1/3.5	Fireman's outfit: gloves	Regulation II-2/17.1.1.2	Regulation II-2/17.1.1.2	EN 659		X				
A.1/3.6	Fireman's outfit: helmet	Regulation II-2/17.1.1.3	Regulation II-2/17.1.1.3	EN 443		X				
A.1/3.7	Self-contained compressed-air-operated breathing apparatus	Regulation II-2/7.1.2	Regulation II-2/17.1.2.2	EN 137		X				

A.1/3.8	Air-supplied breathing apparatus for use with a smoke helmet or smoke mask	Regulation II-2/17.1.2	Regulation II-2/17.1.2.1	EN 138, EN 139		X				
A.1/3.9	Sprinkler systems equivalent to that referred to in SOLAS Regulation II-2/12	Regulation II-2/36.1.2, II-2/36.2, II-2/41-2.5	Regulation II-2/12, II-2/36.1.2, II-2/36.2, II-2/41-2.5	IMO Resolution A.800 (19)		X			X	
A.1/3.10	Nozzles for fixed pressure water-spraying fire-extinguishing systems for machinery spaces	Regulation II-2/10.1	Regulation II-2/10.1	IMO MSC Circ./668 as amended by IMO MSC Circ./728		X	X	X		
A.1/3.11	'A' and 'B' Class divisions, fire integrity	Regulation II-2/3.3.5, II-2/3.4.4	Regulation II-2/3.3.5, II-2/16.1.1, II-2/3.4.4,	IMO Resolution A.754 (18), IMO Resolution MSC.61 (67) Annex 1, Part 3 and Annex 2		X	X	X		
A.1/3.12	Devices to prevent the passage of flame into the cargo tanks in oil tankers	Regulation II-2/59.1.5, II-2/59.1.4, II-2/59.2	Regulation II-2/59.1.5, II-2/59.1.4, II-2/59.2	IMO MSC/Circ.450/Rev.1 IMO MSC/Circ.677		X	X	X		
A.1/3.13	Non-combustible materials used in 'A', 'B' and 'C' class divisions	Regulation II-2/3.1, II-2/3.3.4, II-2/3.4.3, II-2/3.5	Regulation II-2/3.1, II-2/3.3.4, II-2/3.4.3, II-2/3.5	IMO Resolution A.799 (19), IMO Resolution MSC.61(67) Annex 1, Part 1 and Annex 2		X	X	X		
A.1/3.14	Materials other than steel for pipes penetrating 'A' or 'B' Class division	Regulation II-2/3.3.5, II-2/3.4.4 II-2/18.2.1	Regulation II-2/18.2.1	IMO Resolution A.753 (18), IMO Resolution A.754 (18), IMO Resolution MSC .61 (67) Annex 1, Part 3		X	X	X		

A.1/3.15	Materials other than steel for pipes conveying oil or fuel oil	Regulation II-2/3.3.5, II-2/18.2.2	Regulation II-2/18.2.2	IMO Resolution A.753 (18)		X	X	X		
A.1/3.16	Fire doors	Regulation II-2/3.3.5, II-2/3.4.4, II-2/30.2, II-2/31.1, II-2/47	Regulation II-2/30.2, II-2/31.1, II-2/47	IMO Resolution A.754 (18), IMO Resolution MSC.61(67) Annex 1, Part 3		X	X	X		
A.1/3.17	Fire door control systems	Regulation II-2/30.4.15	Regulation II-2/30.4.15	IMO Resolution A.754 (18), IMO Resolution MSC.61(67) Annex 1, Part 4		X	X	X		
A.1/3.18	Surface materials and floor coverings with low flame-spread characteristics	Regulation II-2/3.8, II-2/34.7, II-2/49.2	Regulation II-2/3.8, II-2/3.23.4, II-2/3.23.5, II-2/16.1.1, II-2/32.1.4.3.1, II-2/34.2, II-2/34.3, II-2/49.1, II-2/50.3.1	IMO Resolution A.653 (16), IMO Resolution MSC.61(67) Annex 1, Part 2, 5 & Annex 2 ISO 1716 <sup>1</sup>		X	X	X		
A.1/3.19	Draperies, curtains and other suspended textile materials and films	Regulation II-2/3.23.3	Regulation II-2/3.23.3	IMO Resolution MSC.61 (67) Annex 1, Part 7		X	X	X		
A.1/3.20	Upholstered furniture	Regulation II-2/3.23.6	Regulation II-2/3.23.6, Regulation II-2/34	IMO Resolution A.652 (16), IMO Resolution MSC.61(67) Annex 1, Part 8		X	X	X		
A.1/3.21	Bedding components	Regulation II-2/3.23.7	Regulation II-2/3.23.7, Regulation II-2/34	IMO Resolution A.688 (17), IMO Resolution MSC.61(67) Annex 1, Part 9		X	X	X		

<sup>(1)</sup> Where the surface material is required to have a certain maximum calorific value, this shall be measured in accordance with ISO 1716.

A.1/3.22	Fire dampers	Regulation II-2/3.3.5, II-2/16.11	Regulation II-2/16, II-2/32, II-2/48	IMO Resolution A.754 (18), IMO Resolution MSC.61(67) Annex 1, Part 3 and Annex 2		X	X	X		
A.1/3.23	Non-combustible duct penetrations through 'A' class divisions	Regulation II-2/3.3.5, II-2/16.11, II-2/18.1.1	Regulation II-2/16, II-2/32, II-2/48	IMO Resolution A.754 (18), IMO Resolution MSC.61(67) Annex 1, Part 3 and Annex 2		X	X	X		
A.1/3.24	Electric cable transits through 'A' class divisions	Regulation II-2/3.3.5, II-2/18.1.1, II-2/18.1.2	Regulation II-2/18.1.1, II-2/18.1.2	IMO Resolution A.754 (18), IMO Resolution MSC.61(67) Annex 1, Part 3 and Annex 2		X	X	X		
A.1/3.25	Windows and side scuttles	Regulation II-2/3.3.5, II-2/33	Regulation II-2/33	IMO Resolution A.754 (18), IMO Resolution MSC.61(67) Annex 1, Part 3 and Annex 2, MSC Circ/727		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, and the relevant resolutions and circulars of the IMO <sup>(1)</sup>	Testing standards <sup>(2)</sup>	Modules for conformity assessment					
					B+C	B+D	B+E	B+F	G	H
A.1/4.1	Magnetic compass	Regulation V/12 (r), Regulation X/3	Regulation V/12 (b), Regulation X/3, IMO Resolution A.382 (X), IMO Resolution A.694 (17)	EN 61162-1, EN 60945, ISO 449, ISO 613, ISO 694, ISO 1069, ISO 2269, ISO 10316		X	X	X	X	
A.1/4.2	Electromagnetic compass	Regulation V/12 (r), Regulation X/3	Regulation V/12 (b), Regulation X/3, IMO Resolution A.694 (17) IMO Resolution A.813 (19)	EN 61162-1 EN 60945 ISO 11606 IEC 60945		X	X	X	X	
A.1/4.3	Gyro compass	Regulation V/12 (r)	Regulation V/12 (d), IMO Resolution A.424(XI) IMO Resolution A.694 (17), IMO Resolution A.813 (19)	EN 61162-1, EN 60945, EN 8728; IEC 61162-1, IEC 60945, ISO 8728		X	X	X	X	
A.1/4.4	Radar equipment	Regulation V/12 (r)	Regulation V/12 (g), Regulation V/12 (u), IMO Resolution A.477 (XII) IMO Resolution A.694 (17) IMO Resolution A.813 (19) IMO Resolution MSC64 (67) Annex 4	EN 60936, EN 60945, EN 61162-1; IEC 60936, IEC 60945, IEC 61162-1		X	X	X	X	

<sup>(1)</sup> ITU Recommendations cited are those referred to in the international conventions and the relevant resolutions and circulars of the IMO.

<sup>(2)</sup> Where IMO Resolutions are cited, only the testing standards contained in relevant parts of the Annexes to the Resolutions are applicable and exclude the provisions of the Resolutions themselves.

A.1/4.5	Automatic radar plotting aid (ARPA)	Regulation V/12 (r)	Regulation V/12 (j), IMO Resolution A.422 (XI), IMO Resolution A.694 (17), IMO Resolution A.813 (19), IMO Resolution A.823 (19)	EN 60872, EN 60945, EN 61162-1; IEC 60872, IEC 60945, IEC 61162-1		X	X	X	X	
A.1/4.6	Echosounding equipment	Regulation V/12 (r), Regulation X/3	Regulation V/12 (k), Regulation X/3 IMO Resolution A.224 (VII), IMO Resolution A.694 (17), IMO Resolution A.813(19), IMO Resolution MSC.74(69) Annex 4	EN 9875, EN 61162-1 EN 60945; IEC 9875, IEC 61162-1 IEC 60945,		X	X	X	X	
A.1/4.7	Device to indicate speed and distance	Regulation V/12 (r), Regulation X/3	Regulation V/12(1) Regulation X/3, IMO Resolution A.478 (XII), IMO Resolution A.694 (17), IMO Resolution A.813 (19), IMO Resolution A.824 (19)	EN 61023, EN 61162-1, EN 60945;  IEC 61023, IEC 61162-1, IEC 60945		X	X	X	X	
A.1/4.8	Rudder angle, rpm, pitch indicator	Regulation V/12 (r)	Regulation V/12 (m), IMO Resolution A.694 (17), IMO Resolution A.813 (19)	EN 60945  IEC 60945		X	X	X	X	
A.1/4.9	Rate-of-turn indicator	Regulation V/12 (r), Regulation X/3	Regulation V/12(n) Regulation X/3, IMO Resolution A.526 (13), IMO Resolution A.694 (17), IMO Resolution A.813 (19)	EN 61162-1 EN 60945;  IEC 61162-1, IEC 60945		X	X	X	X	
A.1/4.10	Direction finder	Regulation V/12 (r), Regulation X/3,	Regulation V/12(p), Regulation X/3, IMO Resolution A.529 (13), IMO Resolution A.665 (16), IMO Resolution A.694 (17), IMO Resolution A.813 (19)	EN 60945;  IEC 60945		X	X	X	X	

A.1/4.11	Loran-C equipment	Regulation V/12 (r), Regulation X/3	Regulation V/12(p), Regulation X/3, IMO Resolution A.529 (13), IMO Resolution A.694 (17), IMO Resolution A.813 (19), IMO Resolution A.818 (19)	EN 61075, EN 61162-1 EN 60945;  IEC 61075, IEC 61162-1 IEC 60945		X	X	X	X	
A.1/4.12	Chayka equipment	Regulation V/12,(r) Regulation X/3	Regulation V/12(p), Regulation X/3, IMO Resolution A.529 (13), IMO Resolution A.694 (17), IMO Resolution A.813 (19), IMO Resolution A.818 (19)	EN 61075, EN 61162-1 EN 60945;  IEC 61075, IEC 61162-1 IEC 60945		X	X	X	X	
A.1/4.13	Decca navigator equipment	Regulation V/12 (r), Regulation X/3	Regulation V/12 (p), Regulation X/3, IMO Resolution A.529 (13), IMO Resolution A.694 (17), IMO Resolution A.813 (19), IMO Resolution A.816 (19)	EN 61135, EN 61162-1 EN 60945;  IEC 61135, IEC 61162-1 IEC 60945		X	X	X	X	
A.1/4.14	GPS equipment	Regulation V/12 (r), Regulation X/3	Regulation V/12 (p), Regulation X/3, IMO Resolution A.529 (13), IMO Resolution A.694 (17), IMO Resolution A.813 (19), IMO Resolution A.819 (19)	EN 61108-1, EN 61162-1 EN 60945;  IEC 61108-1, IEC 61162-1 IEC 60945		X	X	X	X	

A.1/4.15	GLONASS equipment	Regulation V/12 (r), Regulation X/3	Regulation V/12 (p), Regulation X/3, IMO Resolution A.529 (13), IMO Resolution A.694 (17), IMO Resolution A.813 (19), IMO Resolution MSC.53(66)	EN 61108-2, EN 61162-1 EN 60945;  IEC 61108-2, IEC 61162-1 IEC 60945		X	X	X	X	
A.1/4.16	Auto-pilot (heading control system)	Regulation V/19	Regulation V/19 IMO Resolution A.342(IX), as amended by IMO Resolution MSC 64(67) Annex 3, IMO Resolution A.694 (17), IMO Resolution A.813 (19)	ISO/TR 11674, EN 61162-1, EN 60945;  ISO/TR 11674, IEC 61162-1, IEC 60945		X	X	X	X	
A.1/4.17	Mechanical pilot hoist	Regulation V/17 (b)	Regulation V/17 (b), IMO Resolution A.426 (XI), IMO MSC/Circ.568/Rev.1	IMO Resolution A.667 (16), ISO 799						

## 5. Radio-communication equipment

Item No	Item designation	Regulation SOLAS 74 as amended where 'type approval' is required	Applicable regulations SOLAS 74 as amended, and the relevant resolutions and circulars of the IMO <sup>(1)</sup>	Testing standards <sup>(3)</sup>	Modules for conformity assessment					
					B+ C	B+ D	B+ E	B+F	G	H
A.1/5.1	VHF radio installation capable of transmitting and receiving DSC and radiotelephony	Regulation IV/14, Regulation X/3	Regulation IV/7.1.1, Regulation X/3, IMO Resolution A.524 (13), IMO Resolution A.694 (17), IMO Resolution A.803 (19), IMO Resolution A.813 (19), IMO Resolution MSC68(68) Annex 1, ITU-R 493, ITU-R 541	ETS 300 162-2, ETS 300 338, EN 300 828, EN 60945;  IEC 61097-3, IEC 61097-7 IEC 60945		X	X	X	X	
A.1/5.2	VHF DSC watchkeeping receiver	Regulation IV/14, Regulation X/3	Regulation IV/7.1.2 Regulation X/3, IMO Resolution A.609 (15), IMO Resolution A.694 (17), IMO Resolution A.803 (19), IMO Resolution A.813 (19), IMO Resolution MSC68(68) Annex 1, ITU-R 493, ITU-R 541	ETS 300 162-2, ETS 300 338, ETS 300 828, EN 301 033, EN 60945;  IEC 61097-3, IEC 61097-8, IEC 60945		X	X	X	X	
A.1/5.3	NAVTEX receiver	Regulation IV/14, Regulation X/3	Regulation IV/7.1.4, Regulation X/3, IMO Resolution A.525 (13), IMO Resolution A.694 (17), IMO Resolution A.813 (19), ITU-R 540, ITU-R 625	ETS 300 065 + A1, EN 301 011, EN 60945;  IEC 61097-6, IEC 60945		X	X	X	X	

<sup>(1)</sup> ITU Recommendations cited are those referred to in the international conventions and the relevant resolutions and circulars of the IMO.

<sup>(2)</sup> Where IMO Resolutions are cited, only the testing standards contained in relevant parts of the Annexes to the Resolutions are applicable and exclude the provisions of the Resolutions themselves.

A.1/5.4	EGC receiver	Regulation IV/14, Regulation X/3	Regulation IV/7.1.5, Regulation X/3, IMO Resolution A.570 (14), IMO Resolution A.664 (16), IMO Resolution A.694 (17), IMO Resolution A.813 (19)	ETS 300 460 + A1, EN 300 829, EN 60945;  IEC 61097-4, IEC 60945		X	X	X	X	
A.1/5.5	HF marine safety information (MSI) equipment (HF NBDP receiver)	Regulation IV/14, Regulation X/3	Regulation IV/7.1.5, Regulation X/3, IMO Resolution A.694 (17), IMO Resolution A.700 (17), IMO Resolution A.806 (19), IMO Resolution A.813 (19), ITU-R 491, ITU-R 492, ITU-R 625, ITU-R 688	ETS 300 067 & A1, EN 60945;  IEC 61097-11, IEC 60945		X	X	X	X	
A.1/5.6	406 MHz EPIRB (COSPAS-SARSAT)	Regulation IV/14, Regulation X/3	Regulation IV/7.1.6, Regulation X/3, IMO Resolution MSC56 (66), IMO Resolution A.662 (16), IMO Resolution A.694 (17), IMO Resolution A.696 (17), IMO Resolution A.763 (18), IMO Resolution A.810 (19), IMO Resolution A.813 (19), ITU-R 633	ETS 300 066-2, EN 60945;  IEC 61097-2, IEC 60945		X	X	X	X	
A.1/5.7	L-band EPIRB (INMARSAT)	Regulation IV/14, Regulation X/3	Regulation IV/7.1.6 Regulation X/3 IMO Resolution A.661 (16), IMO Resolution A.662 (16), IMO Resolution A.694 (17), IMO Resolution A.812 (19), IMO Resolution A.813 (19), ITU-R 632-3	ETS 300 372 EN 60945;  IEC 61097-5, IEC 60945		X	X	X	X	

A.1/5.8	2182 KHz Watch receiver	Regulation IV/14, Regulation X/3,	Regulation IV/7.2, Regulation X/3, IMO Resolution A.383 (X), IMO Resolution A.694 (17), IMO Resolution A.813 (19), ITU-R M 219, ITU-R 693	ETS 300 441, EN 301090; EN 60945;  IEC 61097-15, IEC 60945		X	X	X	X	
A.1/5.9	Two-tone alarm signal generator	Regulation IV/14, Regulation X/3	Regulation IV/7.3, Regulation X/3, IMO Resolution A.421 (XI), IMO Resolution A.571 (14), IMO Resolution A.694 (17), IMO Resolution A.813 (19), ITU-R 219	ETS 300 373 + A1, EN 60945;  IEC 61097-9, IEC 60945		X	X	X	X	
A.1/5.10	MF radio installation capable of transmitting and receiving DSC and radiotelephony	Regulation IV/14, Regulation X/3	Regulation IV/9.1.1, Regulation IV/10.1.2, Regulation X/3, IMO Resolution A.334 (IX), IMO Resolution A.610 (15), IMO Resolution A.694 (17), IMO Resolution A.804 (19), IMO Resolution A.813 (19), IMO Resolution MSC 68 (68) Annex 2, ITU-R M 219, ITU-R M 493, ITU-R M 541	ETS 300 338, ETS 300 373 + A1, EN 60945;  IEC 61097-3, IEC 61097-9, IEC 60945		X	X	X	X	
A.1/5.11	MF radiotelephone DSC watchkeeping receiver	Regulation IV/14, Regulation X/3	Regulation IV/9.1.2, Regulation IV/10.1.3, Regulation X/3, IMO Resolution A.610 (15), IMO Resolution A.694 (17), IMO Resolution A.804 (19), IMO Resolution A.806 (19), IMO Resolution A.813 (19), IMO Resolution MSC68(68) Annex 2, ITU-R 493, ITU-R 541	ETS 300 338, ETS 300373, EN 301 033, EN 60945;  IEC 61097-3, IEC 61097-8, IEC 60945		X	X	X	X	

A.1/5.12	Immarsat-B SES	Regulation IV/14, Regulation X/3	Regulation IV/10.1.1, Regulation X/3, IMO Resolution A.570 (14), IMO Resolution A.694 (17), IMO Resolution A.698 (17), IMO Resolution A.808 (19), IMO Resolution A.813 (19)	IEC 61097-10, IEC 60945		X	X	X	X	
A.1/5.13	Immarsat-C SES	Regulation IV/14, Regulation X/3	Regulation IV/10.1.1 Regulation X/3, IMO Resolution A.570 (14), IMO Resolution A.663 (16), IMO Resolution A.664 (16), IMO Resolution A.694 (17), IMO Resolution A.807 (19), IMO Resolution A.813 (19), IMO Resolution MSC68(68) Annex 4	ETS 300 460 + A1, EN 300 829, EN 60945;  IEC 61097-4, IEC 60945		X	X	X	X	
A.1/5.14	MF/HF radio installation capable of transmitting and receiving DSC, NBDP and radiotelephony	Regulation IV/14, Regulation X/3	Regulation IV/10.2.1, Regulation X/3, IMO Resolution A.613 (15), IMO Resolution A.694 (17), IMO Resolution A.806 (19), IMO Resolution A.813 (19), IMO Resolution MSC68(68) Annex 3, ITU R 476, ITU-R 492, ITU R 493, ITU R 541, ITU R 625	ETS 300 338, ETS 300 373 + A.1, ETS 300 067 + A1, EN 60945;  IEC 61097-3, IEC 61097-9, IEC 61097-11, IEC 60945		X	X	X	X	
A.1/5.15	Radiotelephone MF/HF DSC watch keeping receiver	Regulation IV/14 Regulation X/3,	Regulation IV/10.2.2, Regulation X/3, IMO Resolution A.613 (15), IMO Resolution A.694 (17), IMO Resolution A.806 (19), IMO Resolution A.813 (19), IMO Resolution MSC68(68) Annex 3, ITU R 493	ETS 300 338, ETS 300 373, EN 301 033, EN 60945;  IEC 61097-3, IEC 61097-8, IEC 60945		X	X	X	X	

A.1/5.16	Aeronautical two way VHF radio telephone apparatus	Regulation IV/14, Regulation X/3	Regulation IV/7.5, Regulation X/3, IMO Resolution A.694 (17), IMO Resolution A.813 (19), ICAO Convention Annex 10 Radio Regulations	TS 101 089, EN 60945, IEC 60945		X	X	X	X	
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### 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"<sup>(1)</sup>. 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

<sup>(1)</sup> 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.

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 fulfill 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 fulfills 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 examination 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 fulfill 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 fulfills 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; and
- 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 fulfill 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 fulfills 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:

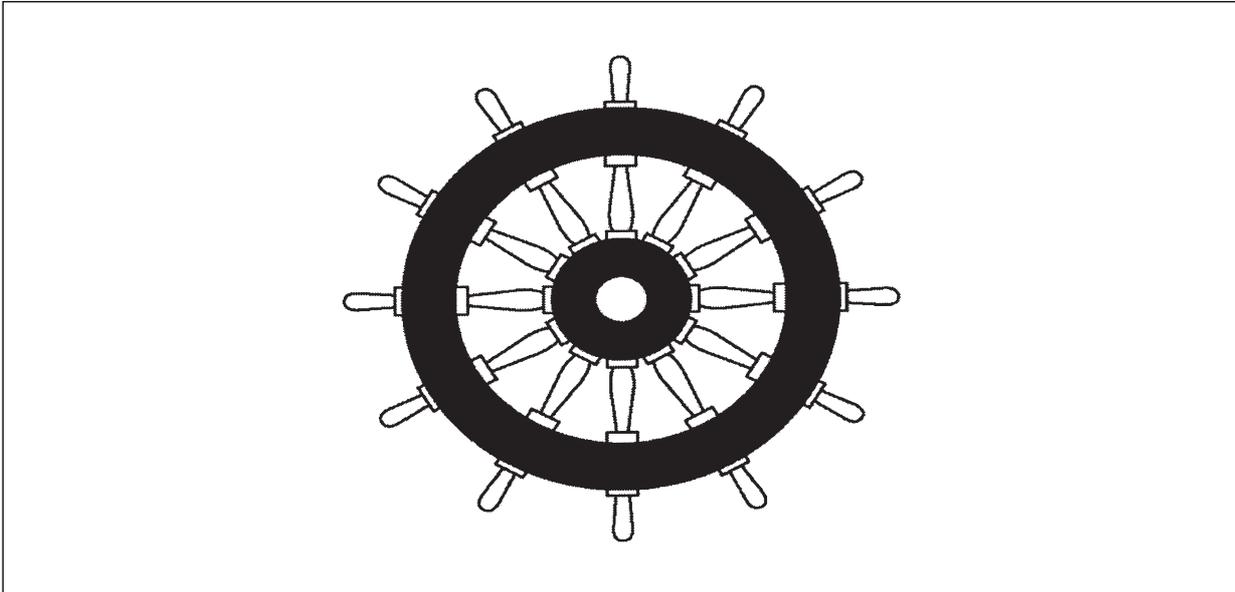
- a general description of the type,
- conceptual-design, build standard and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc,
- descriptions and explanations necessary for the understanding of those drawings and schemes, including the operation of the product,
- the results 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.

### Mark of conformity

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

That minimum dimension may be waived for small devices.

**TECHNICAL DOCUMENTATION SUPPLIED BY THE  
MANUFACTURER TO THE NOTIFIED BODY**

1. The technical documentation must comprise all relevant data or means used by the manufacturer to ensure that the equipment complies with the relevant international standard.
2. The technical documentation must enable understanding of the design, manufacture and operation of the product and assessment of conformity with the relevant international standards.
3. The technical documentation shall, so far as is relevant to the particular assessment include:-
  - .1 a general description of the specimen;
  - .2 conceptual design, build standard and manufacturing drawings and schemes of components, and relevant supporting drawings;
  - .3 descriptions and explanations necessary for the understanding of those drawings and schemes referred to in (2) above, including any necessary descriptions and explanations of the equipment;
  - .4 results of design calculations made, impartial examinations carried out, etc.;
  - .5 impartial test reports; and
  - .6 manuals for installation, use and maintenance.
4. Where appropriate, the design documentation must contain the following elements:-
  - .1 attestations relating to the equipment incorporated in the appliance;
  - .2 attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the specimen; and
  - .3 any other document making it possible for the notified body to better perform its assessment.
5. A specimen may cover several versions of the equipment provided that the differences between the versions do not affect the level of safety or the other relevant international standards.

## ANNEX E

(Annex C of EU Marine Equipment Directive)

### 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.

A notified body is entitled to perform conformity-assessment procedures for any economic operator established within or outwith the Community.
2. A notified body must be independent and must not be controlled by manufacturers or by suppliers.

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.
3. A notified body must be established within the territory of the Community.

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.
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.

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.
5. A notified body must be in a position to provide maritime expertise.



