EU RO Framework Document for the Mutual Recognition of Type Approval

Document Issue Date	5 May 2016
Version	5.0
Status	Controlled
Issued by	EU RO MR Group Secretariat
Distribution	All EU RO Type Approval Departments
Purpose of Document	The document has been designed to help ensure consistency in the EU RO Mutual Recognition Type Approval process. The EU RO MR Type Approval Process consists of three main processes: 1. The **EU RO MR Design Evaluation** involving Engineering evaluation and Witnessing of manufacturing and testing processes; 2. The **EU RO MR Production Quality Assurance (PQA)** which aims to ensure the consistency of production with the approved design and manufacturing process; 3. The **EU RO MR Maintenance Process** which aims to ensure all changes to EU RO MR Documentation go through the appropriate review and approval process; consulting with industry where necessary. This document supersedes the following referenced documents and annexes within the 'Mutual Recognition within ship classification' First Report to the European Commission and the Member States, Oct 2012: • 12.2 EU Recognised Organisations (EU ROs); • 12.5 EU RO Mutual Recognition for Type Approval Terms and Conditions; • 12.6 EU RO Mutual Recognition Procedure for Type Approval (including appendices). -End -

Document Administration

1. **Content**
   The EU RO MR Group Secretariat is responsible for maintaining the content of this document. Members of the EU RO MR group are responsible for reviewing and approving the content;

2. **Changes**
   Anyone wishing to propose changes to this document should contact their EU RO MR Advisory Board or Technical Committee representative. Significant changes will be reviewed by the EU RO MR Advisory Board. Review and approval of document change Requests shall follow the EU RO MR Maintenance Process detailed in this document (see AppendxVIII);

3. **Controlled Issue**
   This document and related annexes are subject to controlled issue and can be found here: http://www.euromr.org/Guidance%20for%20Mutual%20Recognition

4. **Revision History:**

Document Date	Revision No.	Details of Change	Date Issued
2014-01-31	1.0	Document issued.	2014-01-31
2014-07-01	2.0	• Revised Terms & Conditions; • Updated List of Products included in EU RO MR (appendix IV); • New 'Request for Clarification' process (appendix IX); • New 'Alert' Process (appendix X); • Plus other minor editorial changes.	2014-07-01
2015-04-31	3.0	• Revised Terms & Conditions; • Revised General Information; • Revised EU RO MR Type Approval Certificate Information (appendix I); • General editorial updates.	2015-04-17

..Continued

4. Revision History (continued):

Document Date	Revision No.	Details of Change	Date Issued
2015-06-15	4.0	• Updated RO List to reflect Official Journal of the European Union No. 2015/C 162/06 'List of organisations recognised on the basis of Regulation (EC) No 391/2009…' • Revised Terms & Conditions; • Revised General Information; • Revised EU RO MR Type Approval Certificate Information (appendix I); • Updated List of Products included in EU RO MR (appendix IV);	2015-07-01
2016-04-01	5.0	• Revised General Information - addition of clause 11 (application period); • Revision to List of Products included in EU RO MR (appendix III); • Revision to EU RO MR Design Evaluation Scheme (appendix V); • Revised 'Request for Clarification' process (appendix IX);; • General editorial updates	2016-05-05

5. Document Owner

EU RO MR Secretariat - secretariat@euromr.org

- End -

Contents

Terms and Conditions for Mutual Recognition of Type Approval

Note: These terms and conditions form an integral part of the agreement to be established between the certifying EU RO and its client for the provision of mutual recognition type approval services. The terms and conditions are required to enable the uniform application and acceptance of products that are subject to mutual recognition certification and to allow EU ROs access to information that would not normally be available to them where they are not in a direct contractual relationship with the manufacturer.

1. This document establishes a common set of requirements that will be applied to manufacturers of marine equipment or components (product[s]) where such products are to benefit from the Mutual Recognition of Type Approval by the European Union recognised classification societies (hereafter described as EU ROs) under EU regulations.

2. The European Union Recognised Organisation (EU RO) Mutual Recognition Type Approval Certificate (MR TAC) is issued in pursuance of Article 10 of the Regulation (EC) No 391/2009 of the European Parliament and of the Council from 23 April 2009 on Common Rules and Standards for Ship Inspection and Survey Organisations. Technical Requirements applicable to products under MR are adopted by the EU ROs pursuant to same Article 10. These Technical Requirements may be amended from time to time (see Appendix VIII EU RO MR Maintenance Process).

3. The MR TAC is intended to enable Mutual Recognition (MR) of certain type-approved products, through the uniform application of MR Technical Requirements, to enable those products to be installed on board ships for which MR TACs are issued by one or more of the EU ROs.

4. The EU ROs currently are:

- American Bureau of Shipping (ABS);
- Bureau Veritas (BV);
- China Classification Society (CCS);
- Croatian Register of Shipping (CRS);
- DNV GL;
- Korean Register (KR);
- Lloyd's Register Group Ltd. (LR);
- Nippon Kaiji Kyokai General Incorporated Foundation (ClassNK);
- Polish Register of Shipping (PRS);
- RINA Services S.p.A. (RINA);
- Russian Maritime Register of Shipping (RS).

…continued

5. The MR TAC applies to certain type approved products (see Appendix III) to be installed on board a ship as defined in Article 2 (a) of the Regulation (EC) No. 391/2009, and which is classed by one or more of the EU ROs listed in paragraph 4 (above).

For products intended to be installed on board a ship that does not fall within the above scope, the requirements of relevant class societies shall apply.

6. The manufacturer will be required to sign a contract with the EU RO providing the MR TAC service and certificate; such contracts will include terms, whereby the manufacturer accepts expressly that:

a. When a product is intended to be installed on board as an element or sub-element of a piece of equipment, part or system of the ship, the EU RO classing the ship that is not the certifying EU RO for the MR TAC of the product may ask for information in addition to that provided in the MR TAC;

b. The manufacturer is explicitly required to provide immediately, when so requested, all information, documentation and/or evidence required by the certifying EU RO of the ship as detailed in the relevant MR Technical Requirement(s)(TR).The language to be used for all requested information, documentation and evidence shall be English;

c. The MR TAC may be suspended or withdrawn by the certifying EU RO issuing it (see 11d below); and

d. Flag national authorities may have their own requirements for the approval of products to be installed aboard ships flying their flag. Both the requirements of national authorities and those of the classification Rules must be complied with by the manufacturers of the products to be installed aboard such ships.

7. The manufacturer must ensure and certify that the product(s) supplied for an individual ship under a MR TAC is (are) marked with suitable identification to ensure traceability.

8. The manufacturer is required to operate and maintain a quality management system certified by an accredited certifying body to the ISO 9001 standard or equivalent and that this certified quality management system is applied in the production of the product(s) for which MR TAC is sought.

9. The manufacturer will be required to agree that it will:

a. Follow the requirements of the certified quality management system and the quality assurance scheme as approved during production;

b. Keep the accrediting body and the certifying EU RO that issued the MR TAC duly informed, in writing, of any intended design change or updating of the production quality assurance scheme for its consideration with regard to the validity of the MR TAC; and,

c. Apply annually for periodical assessment by the EU RO to demonstrate that the production under the MR TAC and the quality assurance scheme are being satisfactorily maintained.

10. Upon satisfactory completion of the conformity assessment procedure of the manufacturer's product(s), the EU RO may issue a MR TAC for the concerned product(s) with a maximum validity of 5 years.

11. The MR TAC of an existing product remains valid until:

a. Its expiry date; or

b. Such time as any material modification of the design or construction is made, without the written approval of the certifying EU RO; or

c. Such time as the manufacturer has not fulfilled its obligations of annual assessment; or

d. Such time as the MR TAC is suspended or withdrawn by the certifying EU RO.

Validity may be extended in case of b, c, or d above, following further review by the EU RO providing the MR TAC according to the MR TAC requirements.

Any changes of MR Technical Requirements (including those resulting from updates and changes to nationally or internationally recognised standards) may be implemented based only on the amended rules of individual ROs.

12. The MR TAC retains its validity, and remains acceptable for installation on vessels, based on the actual Edition of the Rules applicable to such vessels. If the applicable Rules' edition year for a given vessel is subsequent to the year of issuance of the latest update of referenced MR technical requirements (MR TRs), then a revalidation of the MR TAC may be needed, for compliance with latest update of MR TRs in order to enable acceptance of product for installation on that vessel;

13. The manufacturer of a MR TAC product, its heirs and designees are responsible for the archiving and retention of:

a. all records of the design and construction approved by the EU RO;

b. the records of type testing; and

c. the quality records of the production under the MR TAC.

for seven years after the validity of the relevant MR TAC has expired.

-End-

General Information

1. The purpose of this Agreed Procedure is to provide a framework document setting out the minimum steps necessary to enable mutual recognition (MR) of certain type approved products, through the uniform application of agreed technical requirements relating to equipment listed in Appendix III to be placed on board ships for which MR TACs are issued by one or more of the EU ROs listed in Appendix IV.

2. For the purpose of this Agreed Procedure the following definitions shall apply:

a. **Agreed MR Technical Requirements (MR TR)** - a mutually agreed document or documents that prescribe technical requirements to be fulfilled by a design, product, process or service (see appendix VII);

b. **Assessment** - is the process of evaluating a design, product service or process. It involves generating and collecting evidence of the design, product service or process and judging that evidence against defined standards;

c. **Certification** - a procedure whereby a design, product, service or process is assessed for compliance with agreed technical requirements;

d. **Classification** - that specific type of certification, for which the technical requirements are the Rules of the relevant Classification Society;

e. **Design Evaluation** – Two-step process involving Engineering evaluation and Witnessing the manufacturing and testing processes;

f. **Engineering evaluation** - Evaluation of a design of a type of the product to determine compliance with the agreed technical requirements;

g. **Installed on Board a Ship** - the assembling and final placement of components, equipment and subsystems to permit operation of the system on board of the ship;

h. **Manufacturer** - a company producing and/or assembling final products and is responsible for such products;

i. **Product** – is material, equipment and component (ME&C);

j. **Testing Process** - a technical operation to determine if one or more characteristic(s) or performance of a product or process satisfies agreed technical requirements;

k. **Type Approval** - see IMO Circular MSC.1/Circ.1221 Here;

l. **Witness** - to be physically present at a test in accordance with the agreed technical requirements and be able to give evidence about its outcome;

m. **Witnessing the manufacturing and testing processes** - witnessing manufacture as applicable and testing of a type of the product to determine compliance with the agreed MR TRs.

3. This Agreed Procedure shall apply to ships as defined in Article 2 of the Regulation (EC) No 391/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2009 (as amended) on common rules and standards for ship inspection and survey organisations.

4. The conformity-assessment procedure for products listed under the EU RO Agreed Procedure for Mutual Recognition of Type Approval, details of which are listed in Appendix II, shall be subject to:

a. EU RO Design Evaluation (DE) (see Appendix V); and

b. Production Quality Assurance (PQA) Assessment (see Appendix VI).

For those products which do not fall within the scope of the EU RO Agreed Procedure for Mutual Recognition of Type Approval the individual EU RO Requirements will apply.

A flow chart of the conformity assessment procedures provided for EU RO Mutual Recognition and individual EU RO requirements is provided at Appendix II.

5. The EU RO MR Type Approval Certificate (MR TAC) shall contain:

a. The information as specified in Appendix I of this document as a minimum; and

b. Only the logo of the EU RO issuing the MR TAC; and

c. Each MR TAC is to be issued with a specific number to ensure traceability using the numbering system defined by the EU RO issuing the MR TAC. Additionally, the MR TAC shall be readily available for viewing online by all EU ROs and other interested parties via the links displayed on: http://www.euromr.org/links-to-mr-certificates

6. Each EU RO shall maintain an up-to-date list of EU RO MR TACs that have been issued by that EU RO.

7. Individual ROs are responsible for:

a. Giving detailed reasons to a manufacturer when an MR TAC is refused; and

b. Making available information when an MR TAC is withdrawn.

8. Manufacturer's responsibility

a. Where a manufacturer reapplies for type-approval for products for which an MR TAC has been refused, his submission to the EU RO

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 product or manufacturing process;

b. The manufacturer shall provide other ROs, on request, with relevant information on Design Evaluation documentation that has been amended or superseded.

9. In cases where the EU RO classing the ship refuses material, equipment or components, issued with a EU MR TAC, the EU RO classing this ship is to inform, without delay, the EU RO Advisory Board Chairman, Secretary and Members. Such information is to include, in writing:

- the type of product;
- the references of the EU RO MR TAC;
- the reason(s) for refusal.

The EU RO MR Advisory Board Chairman shall, in turn, inform the EU RO MR Technical Committee Chairman and Technical Committee Members. See also Appendix X - EU RO MR Material, Equipment & Component Non-compliance ('Alert System').

10. The EU RO MR Technical Committee shall meet on an annual basis, or as required, to review the Agreed Technical Requirements of existing products identified in Appendix III and to consider new products for inclusion in the Appendix as required.

11. New and revised existing Technical Requirements shall enter into force 6 months after the adoption to allow for their implementation by the EU ROs.

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APPENDIX I

EU RO MR Type Approval Certificate Information

The EU RO MR Type Approval Certificate (MR TAC), issued by the certifying EU RO using its own certificate format, logo and numbering system, shall contain the following information as a minimum *(see notes 1 & 2 below):*

Certificate Heading

Mutual Recognition Type Approval Certificate

Certificate number

Each EU RO MR Type Approval Certificate is to be issued with the certifying EU RO's specific number to ensure traceability

Company Information

Manufacturers Name

Street Address, City, State, Postal Code, Country

Product Information

Product

Model

Intended Service

Description

Ratings

Restrictions (limitations as outlined by the Technical requirements)

Test reports with identification number and date

Manufacturer's documentation/identification number for product or series with date

Term of Validity *(see notes 3- 5 below)*

Place of Issue

Issue Date

Expiration Date

Rules & Standards

Technical requirement reference

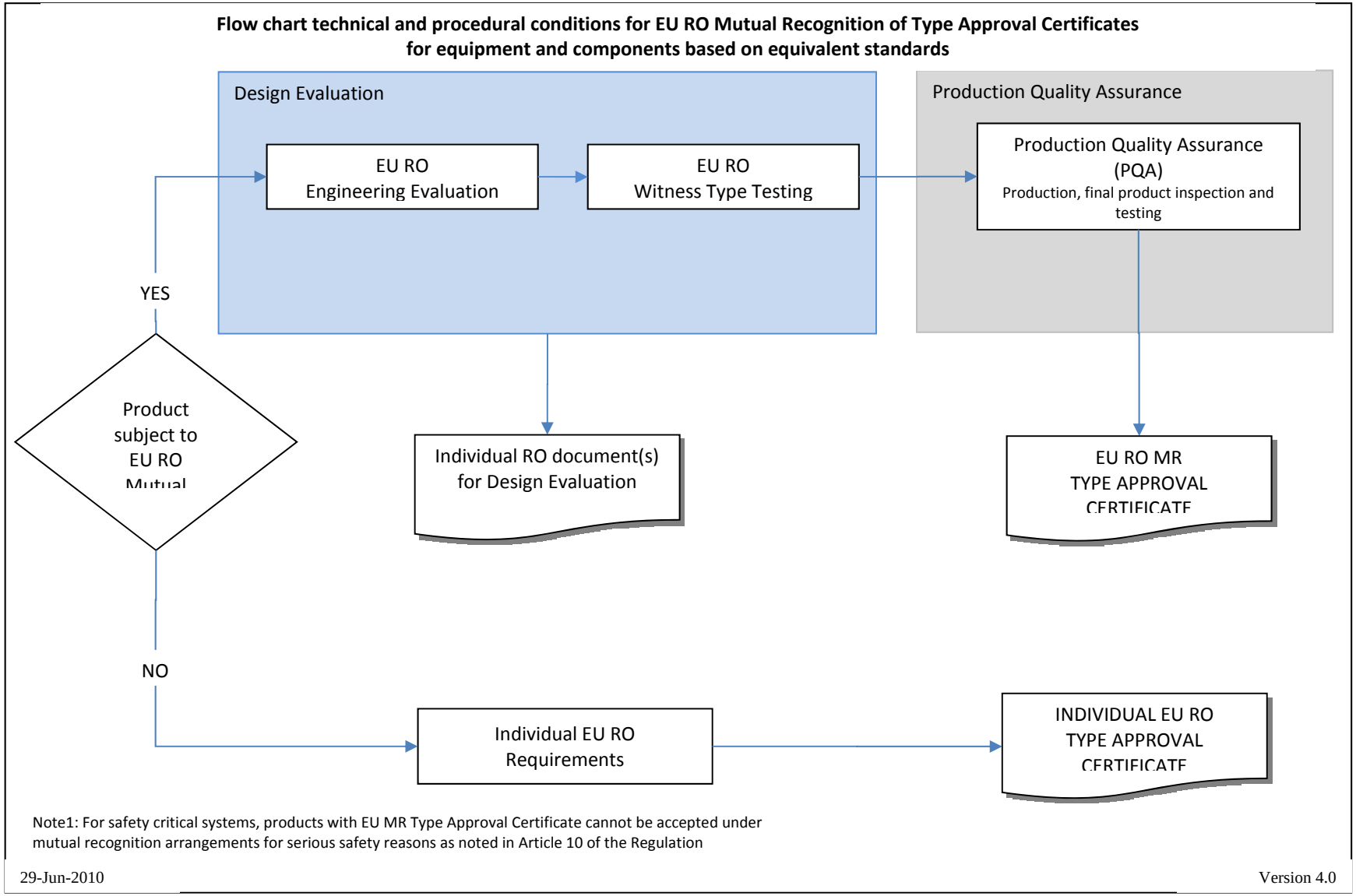
Other standards as applicable

Notes:

1) *Refer to the agreed MR Technical Requirements for additional MR TAC information that may be specifically applicable to certain products - http://www.euromr.org/technical-requirements;*
2) *Links to MR TACs issued by the EU ROs can be found by visiting http://www.euromr.org/links-to-mr-certificates.*
3) *As per clause 9 of the Terms & Conditions for Mutual Recognition of Type Approval, the manufacturer will be required to agree that it will fulfil the obligations arising out of its quality assurance scheme as approved during production. The manufacturer certifies it has kept the accredited certification body and the EU RO that issued the MR TAC duly informed of any intended design changes or updating of the production quality assurance scheme for its consideration with regard to the validity of the MR TAC. The manufacturer will apply annually for periodical assessment by the EU RO to show that the production under the MR TAC and the quality assurance scheme are being satisfactory maintained;*
4) *MR TACs are valid for a maximum of 5 years as per clause 10 of the Terms & Conditions for Mutual Recognition of Type Approval;*
5) *For more information on the factors affecting the validity of MR TACs, see clause 11, 12 and 13 of the Terms & Conditions of Mutual Recognition of Type Approval.*

- End –

APPENDIX II


Flow chart technical and procedural conditions for EU RO Mutual Recognition of Type Approval Certificates for equipment and components based on equivalent standards
Design Evaluation
EU RO Engineering Evaluation
EU RO Witness Type Testing
Production Quality Assurance
Production Quality Assurance (PQA)
Production, final product inspection and testing
YES
Product subject to EU RO Mutual
Individual RO document(s) for Design Evaluation
EU RO MR TYPE APPROVAL CERTIFICATE
NO
Individual EU RO Requirements
INDIVIDUAL EU RO TYPE APPROVAL CERTIFICATE
Note1: For safety critical systems, products with EU MR Type Approval Certificate cannot be accepted under mutual recognition arrangements for serious safety reasons as noted in Article 10 of the Regulation
29-Jun-2010
Version 4.0

APPENDIX III

List of Products included in EU RO MR

Tier 1 (Original adoption date January 2013)

1. Electric Driven Motors < 20 kW
2. Circuit Breakers
3. Contactors
4. Fuses
5. Display Monitors, Video Screens, Terminals
6. LV Enclosures & Boxes
7. LV Transformers
8. Mechanical Joints
9. Resin Chocks
10. Switches
11. Sensors

Tier 2 (Original adoption date July 2013)

12. Accumulator Battery
13. Air Pipe Automatic Closing Device
14. Cable Ties
15. Class III Pipe Fittings
16. Computers and PLCs
17. Electrical/Electronic Relays
18. Electric Heating Cables
19. Expansion Joints
20. Flameproof Luminaire Lighting Fixtures
21. Plastic Piping Systems (components)
22. Spark Arresters

Tier 3 (Original adoption date July 2014)

23. Adjustable steel chocks
24. Air Compressors
25. Battery Chargers
26. Cable trays & ducts (glass reinforced plastic)
27. Connecting systems for cable repair (cable splices)
28. Electrical actuators for valves
29. Insulation panels for provision rooms and chambers
30. Boiler remote level indicators
31. Pneumatic actuators for valves
32. Cable trays & ducts (metallic)
33. Solenoid valve assembly
34. Stationary lighting fixtures, flood-light projectors

Tier 4 (Original adoption date July 2015)

35. Circuit Breakers with Electronic Devices
36. Contactors with Electronic Devices
37. Tachometers
38. Temperature Gauges & Transmitters
39. Thermal Insulation of Organic Foams for Piping
40. Valves for Bilge Systems
41. Valves for Freshwater Systems
42. Valves for Lubricating Oil & Hydraulic Oil Systems
43. Valves for Sanitary Systems
44. Valves for Seawater Systems

For a list of MR Technical Requirements under development, see http://www.euromr.org/tr-development

APPENDIX III

- End -

APPENDIX IV

List of EU Recognised Organisations (EU ROs)

American Bureau of Shipping (ABS) - www.eagle.org

Bureau Veritas (BV) - www.veristar.com

China Classification Society (CCS) - http://www.ccs.org.cn/ccswzen/

Croatian Register of Shipping (CRS) – www.crs.hr

DNV GL – www.dnvgl.com

Korean Register (KR) - www.krs.co.kr

Lloyd's Register Group Ltd. (LR) - www.lr.org

Nippon Kaiji Kyokai General Incorporated Foundation (ClassNK) - www.classnk.or.jp

Polish Register of Shipping (PRS) - www.prs.pl

RINA Services S.p.A. (RINA) - www.rina.org/en

Russian Maritime Register of Shipping (RS) - www.rs-class.org/en

- End -

APPENDIX V

EU RO MR Design Evaluation Scheme

Procedure:

1. An application for the Design Evaluation must be submitted by the manufacturer or product designer (hereinafter 'applicant') to the EU RO and shall include:

   a) the name and address of the manufacturer or product designer; and
   b) the technical documentation as described in point 2 below.

2. The technical documentation shall make it possible to assess the product's compliance with the agreed technical requirements.

3. The EU RO will review the submitted technical documentation to confirm compliance with the agreed technical requirements. The language to be used for all documentation shall be English. The technical documentation includes (but is not limited to) type test reports, product descriptions, operation manuals, assembly drawings, dimension drawings, etc.

4. The applicant shall issue a statement verifying that the product to be tested has been manufactured in accordance with the technical documentation.

5. Where required, the EU RO will agree the location where the examinations and necessary tests will be carried out with the applicant.

6. Type tests shall always be witnessed by the EU RO's surveyor. However, in such cases where the tests are conducted at a Nationally Accredited Laboratory[1], the presence of the EU RO's surveyor may be omitted.

7. The type tests shall be conducted on the test specimen(s) selected from production line or at random from stock in the presence of an EU RO surveyor in accordance with the agreed type test program.

8. Where the type tests are conducted at a Nationally Accredited Laboratory without the presence of the EU RO surveyor, the applicant shall provide assurance to the EU RO surveyor selecting the test specimen(s), that the test specimen(s) to be sent to and tested at the Laboratory shall be verified in accordance with an agreed procedure.

9. Where the product meets the relevant agreed technical requirements, the EU RO will issue an individual Design Evaluation document to the applicant. The document must give the name and address of the applicant, details of the product, the conclusions of the examination, the conditions of its validity and the necessary data for identification of the approved product.

10. The applicant must inform the EU RO that issued the MR TAC and which holds the technical documentation of any modification of the design, which must receive additional approval, where such changes may affect compliance with the agreed TR or the prescribed conditions for use of the product. Such additional approval, if given, must be in the form of an addition to the original EU RO MR TAC.

11. The applicant must provide, on request, the Design Evaluation documents to each EU RO.
- End -

[1] *The scope of accreditation must cover the relevant applicable standards as specified in the individual MR Technical Requirements (see www.euromr.org/technical-requirements)"*

APPENDIX VI

EU RO Production Quality Assurance (PQA)

Procedure:

1. A manufacturer who satisfies the obligations of point 2 below must ensure that the product(s) concerned conform to type as described in valid EU RO Design Evaluation documents. The documents must be issued by the EU RO responsible for the whole EU RO Type Approval process (hereinafter called "the EU RO"), i.e. both Design Evaluation and Production Quality Assurance. The manufacturer must ensure that the product(s) supplied for an individual ship under a MR TAC is (are) marked with suitable identification to ensure traceability.

2. The manufacturer must operate a quality management system certified by an accredited certifying body as meeting the requirements of ISO 9001 or industry equivalent. The Production Quality Assurance scheme must be approved by the EU RO for production, final-product inspection and testing of the product(s) subject to EU RO MR Type Approval as specified in point 3 below and must be subject to surveillance as specified in point 4 below. The approval shall only be valid as long as the Quality Management System certificate is valid. The manufacturer has to inform the EU RO if the Quality Management System certificate is suspended, withdrawn or not renewed.

3. Production Quality Assurance scheme

3.1. The manufacturer must submit an application for assessment of his Production Quality Assurance scheme according to point 2 above with the EU RO. The application must include:

- a) all relevant information for the product(s) envisaged
- b) full list of all manufacturing/production sites
- c) the documentation concerning the quality management system and its certification at all manufacturing sites, including:
  - i. the quality management system certificate issued by the certifying body,
  - ii. the manufacturing, quality-control and quality-assurance techniques, processes and systematic actions that will be used;
  - iii. the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
  - iv. the quality records, such as inspection reports and test data, calibration data, damage and claim records, qualification reports of the personnel concerned, etc.;
  - v. the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.2. The EU RO shall assess the documented Production Quality Assurance scheme to determine whether it gives reasonable confidence that the concerned product(s) can be consistently produced in compliance with the product(s) covered by the Design Evaluation document(s). The assessment procedure must also include a review of the quality management system documentation and a visit to the manufacturer's premises and all manufacturing/production sites. A report of the audit assessment is provided to the manufacturer.

3.3. The manufacturer must undertake to fulfill the obligations arising out of the Production Quality Assurance scheme as approved and to uphold it so that it remains adequate and efficient. The manufacturer must keep the EU RO that has evaluated the Production Quality Assurance scheme informed of any intended updating of that Production Quality Assurance scheme for its consideration with regard to the validity of the EU MR Type Approval Certificate. The manufacturer is to apply for periodical assessment to the EU RO at an annual frequency to enable the EU RO that issued the TAC to verify that the Production Quality Assurance is maintained and applied. Audit reports are to be provided to the manufacturer.

4. Periodical Assessment by the EU RO

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved Production Quality Assurance scheme.

4.2. The manufacturer must allow the EU RO access for inspection purposes to the locations of manufacture, inspection and testing and storage and must provide it with all necessary information, in particular:

a) the Production Quality Assurance scheme documentation and the design evaluation documentation;
b) the quality records, such as inspection reports and test data, calibration data, damage and claims records, qualification reports of the personnel concerned, etc.;
c) additional testing as per the Technical Requirements may be required by the EU RO.

5. Upon satisfactory completion of the Design Evaluation and Production Quality Assurance evaluation, the EU RO may issue an EU MR TA C for the concerned product(s) with a maximum validity of 5 years. The document must give the name and address of the manufacturer and all manufacturing sites, any conditions of the TAC's validity and the necessary data for identification of the approved product(s).

- End -

APPENDIX VII

Agreed Technical Requirements

Controlled copies of the Agreed Technical Requirements are available from:
http://www.euromr.org/technical-requirements

- End -

APPENDIX VIII

EU RO MR Maintenance Process

1. Change Requests and/or feedback for the Agreed Technical Requirements (Appendix VII) and/or any EU RO MR Document (including procedures) shall be made in writing to the relevant EU RO (Appendix IV) marked for the attention of their EU RO MR Technical Committee Representative. The EU RO MR Technical Committee and Advsisory Board follow the process in **figure 1 below**.

2. Change Requests include (but are not limited to) procedural updates, test requirement updates, rule changes or industry feedback and can vary in significance from a simple editorial change to a technical parameter or test change that may require industry consultation.

3. Amendments and revisions to documents including the Agreed Technical Requirements are endorsed (where appropriate) by the EU RO MR advisory Board and are re-issued on or around 31 March each year[2].

APPENDIX VIII

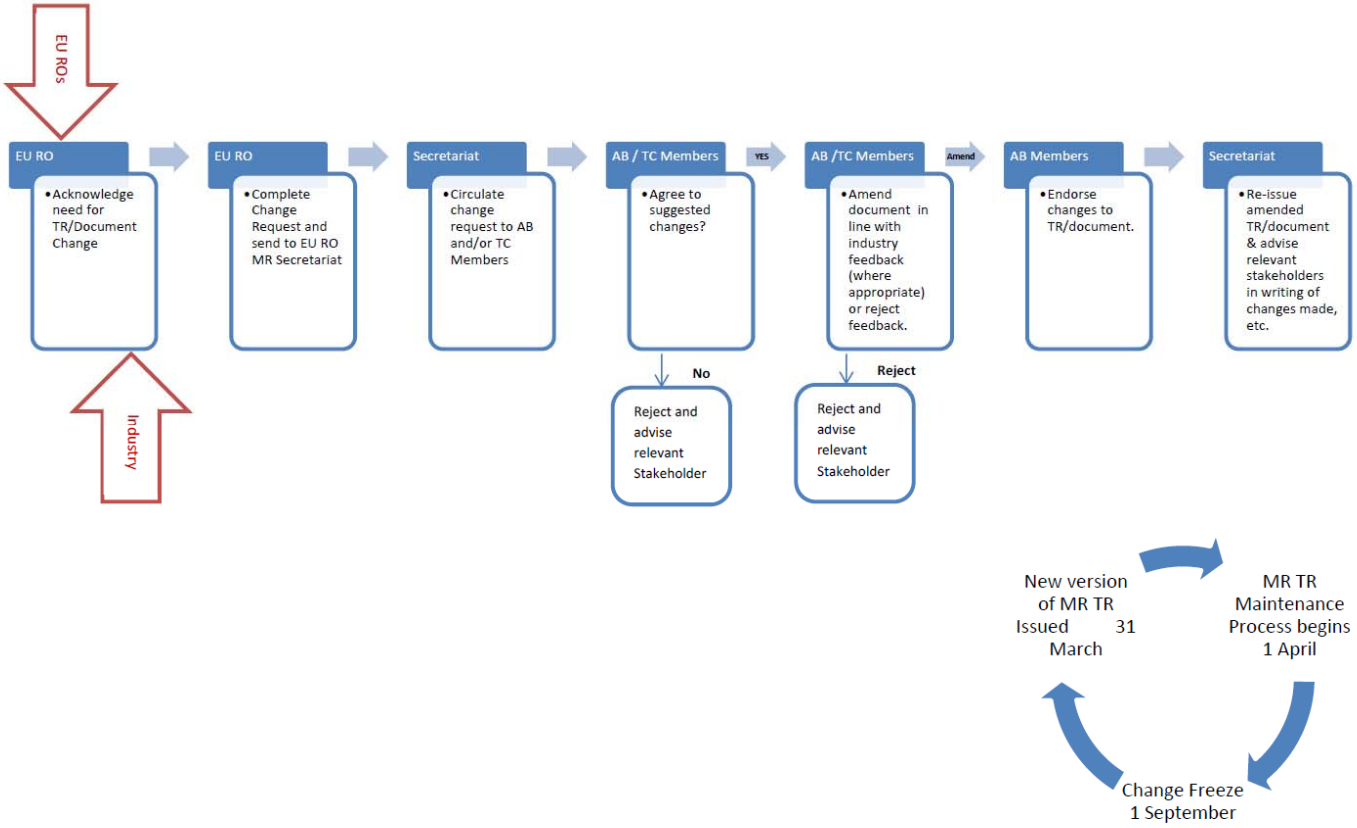


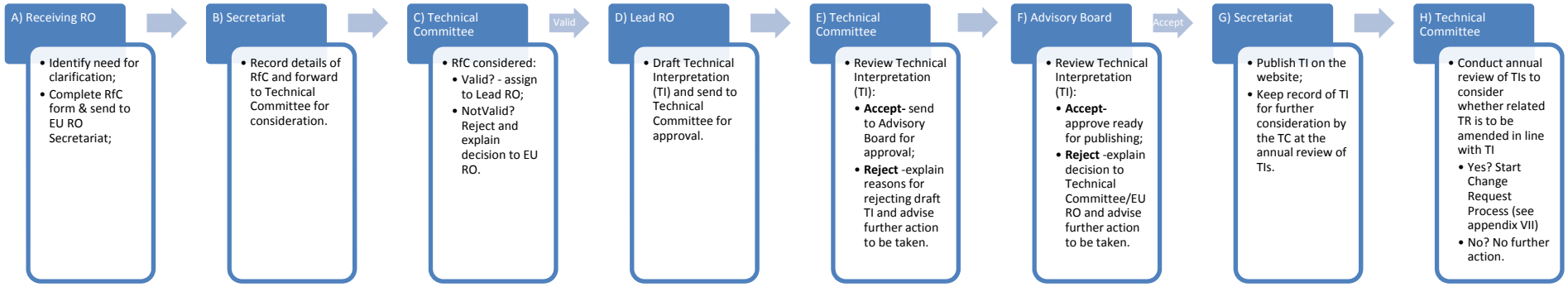
Figure 1 EU RO MR Maintenance Process

2-The deadline for submissions of a change request (i.e. change freeze) is 1 September each year to ensure changes are considered for inclusion in the following 31 March reissue. Any change requests received after that date may not be reviewed until the year after.

- End -

APPENDIX IX

EU RO MR Request for Clarification (RfC) Process



1. A Request for Clarification (RfC) for the purpose of unique understanding of the Agreed Technical Requirements (Appendix VII) and/or any EU RO MR Document (including procedures) shall be made in writing by the requesting entity to the relevant EU RO (Appendix IV), marked for the attention of their 'EU RO MR Technical Committee Representative'. The EU RO MR Technical Committee Representative (hereinafter referred to as the Receiving RO) will then follow the process above.

2. A Request for Clarification (RfC) requires the requesting entity to provide sufficient information on the subject for which clarification is being sought, along with the related technical background, a clear definition of the problem to enable the Receiving RO to create a distinct proposal for how to achieve clarification [1] - see step A) in the process above.

[1] The receiving RO shall provide the TC with their expert's view together with the RfC form (available from the Secretariat) in order to help facilitate the creation of a Technical Interpretation.

APPENDIX IX

3. The proposed Request for Clarification (RfC) shall be verified by the EU RO MR Technical Committee (and EU RO MR Advisory Board where necessary) to ensure that the proposal does not conflict with basic provisions of the Design Evaluation (DE) (Appendix V), the Product Quality Assurance (PQA) regime (Appendix VI) and the EU RO MR 'Simplified Risk Based Model' see step C) in the process above.

4. If the proposed Request for Clarification (RfC) is verified and accepted, the EU RO MR Technical Committee will assign a lead RO to draft a Technical Intrepration (TI) – see step D) in the process above. The draft TI will be reviewed and approved by the EU RO MR Technical Committee and then forwarded to the EU RO MR Advisory Board for agreement – steps E) and F). Once agreed, it will then be published as a final version on www.euromr.org/technical-requirements for information and notification of publication will be sent to the requesting entity. All TIs will be kept as a record and searchable resource by the EU RO MR Secretariat. The Secretary will ensure that the following information is gathered in respect for each TI:

    a) Date received by Secretariat
    b) Date referred to TC
    c) TI Number
    d) Date sent from TC to Lead RO
    e) Name & contact details of Lead RO
    f) Date of TI submission from Lead RO to TC
    g) Date of TI approval by TC
    h) Date TI referred to AB;
    i) Date of AB agreement of TI;
    j) Date TI Published;
    k) Applicable TR(s) to be amended YES/NO;
    l) Any relevent comments;
    m) CRF No (s) (if applicable).

5. In cases where the Request for Clarification (RfC) (or subsquent TI) is rejected by the EU RO MR Technical Committee and/or EU RO MR Advisory Board, the Receiving RO shall advise the requesting entity accordingly. All record of rejected RfC (including reasons) will be kept as a record and searchable resource by the EU RO MR Secretariat.

APPENDIX IX

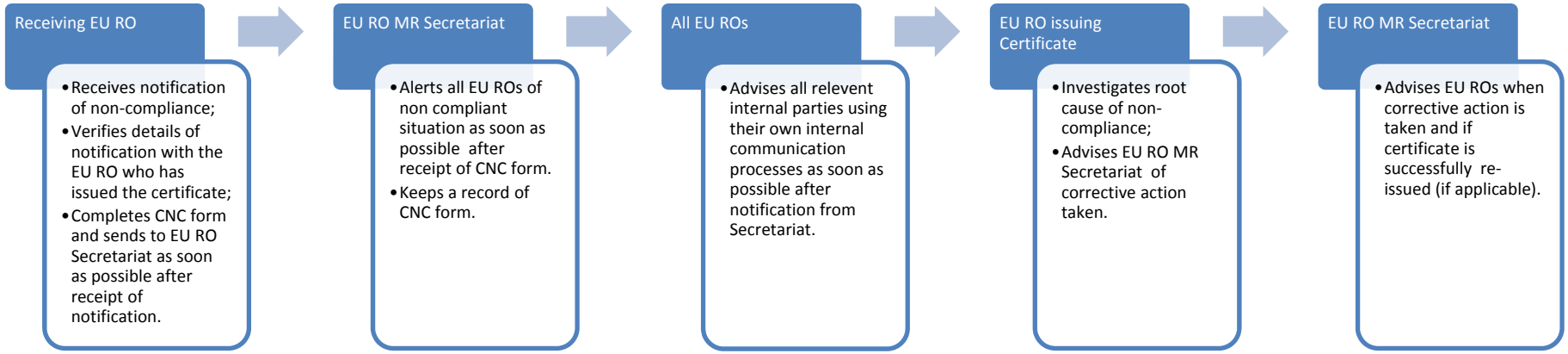
6. An annual review of TIs will be conducted by the EU RO MR Technical Committee in September each year to ensure ongoing relevance and a decision will be taken on each TI to as to whether the related Agreed Technical Requirement should be amended to incorporate the outcome of the TI – see step H) in the process above. Where a TI is considered to be out of date or no longer relavant the necessary actions will be taken to update or rescind the document.

7. If it is agreed that the Agreed Technical Requirement should be amended, the EU RO MR Technical Committee will assign a lead RO to complete the EU RO MR Maintenance Process (see Appendix VIII).

- End -

APPENDIX X

EU RO MR Material, Equipment & Component Non-Compliance ('Alert System')



1. The purpose of the 'Alert System' is to ensure that all EU ROs are informed when a mutually recognised product is not in compliance with its MR TAC. Regulation (EC) 391/2009 article 10.1 paragraph 3 states:

   Where a recognised organisation ascertains by inspection or otherwise that material, a piece of equipment or a component is not in compliance with its certificate, that organisation may refuse to authorise the placing on board of that material, piece of equipment or component. The EU RO shall immediately inform the other EU ROs, stating the reasons for its refusal.

2. The EU RO that receives the notification of a potential non-compliance situation (hereinafter referred to as the Receiving EU RO) shall first verify the details with the EU RO that has issued the certificate (hereinafter referred to as the Issuing EU RO) before completing the Certificate Non-Compliance (CNC) Form and sending it, by email, to the EU RO MR Secretariat as soon as possible after receipt of notification.

3. The EU RO MR Secretariat shall advise all EU ROs, by email, of the non-compliant situation as soon as possible after receipt. The EU RO MR Secretariat will keep a record of:

   a. Date received by Secretariat;

b. Date referred to all EU ROs;

c. Date Certificate EU ROs advised of corrective action and/or new certificate.

4. All EU ROs shall advise their relevant internal stakeholders using their own internal communication processes as soon as possible after notification from the EU RO MR Secretariat.

5. The Issuing EU RO shall investigate the root cause of the non-compliant situation and advise EU RO MR Secretariat of any corrective actions taken and whether the certificate is re-issued or not.

6. The EU RO MR Secretariat shall advise all EU ROs when corrective action is taken by the Issuing EU RO and whether the certificate is successfully re-issued or not.

- End –