

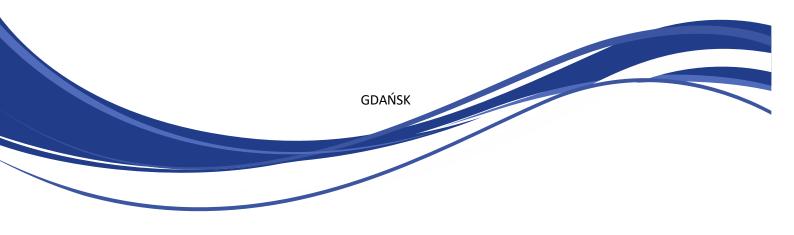
RULES

PUBLICATION 102/P

EU RO MUTUAL RECOGNITION OF TYPE APPROVAL

October 2023

Publications P (Additional Rule Requirements) issued by Polski Rejestr Statków complete or extend the Rules and are mandatory where applicable.



Publication 102/P – EU RO Mutual Recognition Of Type Approval – October 2023, which replaces *Publication 102/P – May 2023* is an extension of the requirements specified in *Part VI – Machinery Installations and Refrigerating Plants* and *Part VIII – Electrical Installations and Control Systems* of *the Rules for the Classification and Construction of Sea-Going Ships,* as well as in other PRS regulatory in where reference to the *Publication has been made.*

The *Publication* was approved by the PRS Board of Directors on 18 May 2023 and enters into force on 24 October 2023.

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PRS/RP, 10/2023

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1 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. Copyright to each and every of the Technical Requirements listed in Appendix III (List of products) and as published on the EU RO MR website will be with the EU ROs listed in para 5 below (**Copyright © 2022. All EU RO MR Group rights reserved**).
- 4. 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.
- 5. The EU ROs currently are:
 - American Bureau of Shipping (ABS);
 - Bureau Veritas (BV);
 - China Classification Society (CCS);
 - Croatian Register of Shipping (CRS);
 - DNV;
 - Indian Register of Shipping (IRS);
 - 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);
- 6. 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.

- 7. 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 12d 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.
- 8. 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.
- 9. 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.
- 10. 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.
- 11. 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.
- 12. 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 or IACS Unified Requirements) may be implemented based only on the amended rules of individual ROs. (note: Version of implemented IACS UR at the time of application is to be used.)

- 13. 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. Similarly, if the applicable version of a technical standard for a given vessel is posterior to the version referred to in the MR TAC, then a revalidation of the MR TAC may be needed for verification of compliance of the product with the applicable version of the technical standard in order to enable acceptance of product for installation on that vessel.
- 14. 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.

2 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) **Nationally Accredited Laboratory** Laboratory holding an accreditation certificate to ISO/IEC 17025 covering the applicable testing standards which is issued by a national accreditation body operating in accordance with ISO/IEC 17011, unless otherwise defined in the applicable Technical Requirement.
 - j) **Product** is material, equipment and component (ME & C);
 - k) **Testing Process** a technical operation to determine if one or more characteristic(s) or performance of a product or process satisfies agreed technical requirements;
 - l) **Type Approval** see IMO Circular MSC.1/Circ.1221 here;
 - m) **Witness** to be physically present at a test in accordance with the agreed technical requirements and be able to give evidence about its outcome;
 - n) 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.
- 6. Each EU RO shall maintain an up-to-date list of EU RO MR TACs that have been issued by that EU RO. EU ROs lists may be viewed online via links displayed on: http://www.euromr.org.
- 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 an EU MR TAC, the EU RO classing this ship is to inform, without delay, the EU RO Steering Committee 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 Steering Committee 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 MR Technical Requirements shall enter into force 6 months after the adoption date to allow for their implementation by the EU ROs.
- 12. A transfer of EU RO MR TAC is possible in certain cases and conditions, as per 'Appendix XI'.

3 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 & 6 below):

Certificate Heading

European Union Recognised Organisation (EU RO) Mutual Recognition Type Approval Certificate in accordance with Article 10.1 of EU Regulation 391/2009.

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 or IACS Unified Requirements as applicable (with identification of the version used for the conformity assessment)

Note: version of implemented IACS UR at the time of application is to be used.

Note: if the standard(s) is(are) used in a version which is(are) not the latest available at the date of MR TAC issuance, following sentence is to be added in the MR TAC:

Standard XXXX:YYYY (Standard AAAA:BBBB, if applicable) used for the conformity assessment process resulting in the issuance of this certificate, was(were) not the latest available version of this(the) standard(s) at the time of certificate issuance.

Generic Sentence

"This is to certify to the Manufacturer named below, that the Product referred to herein has been inspected for the Manufacturer, pursuant to the relevant requirements of the European Union Recognised Organisation Mutual Recognition procedure, required by Article 10.1 of EU Regulation 391/2009, and has been found in accordance with those requirements. The most demanding and rigorous standard from all EU ROs has been taken as a reference for the development of the Technical Requirement on which present certificate is based."

Generic Statement

When a product is presented with this EU RO MR Type Approval Certificate for given application, its acceptability with regards to the limitations stated in the certificate conditions defined in 1b, 1c and 1d of the applied Technical Requirement will be evaluated by the EU RO in charge of classing the ship or being in charge of the unit/system certification.

In accordance with Article 10 of Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 "on common rules and standards for ship inspection and survey organizations", the following organizations, recognized by the EU on this date, have agreed on the technical and procedural conditions under which they will mutually recognize this certificate:

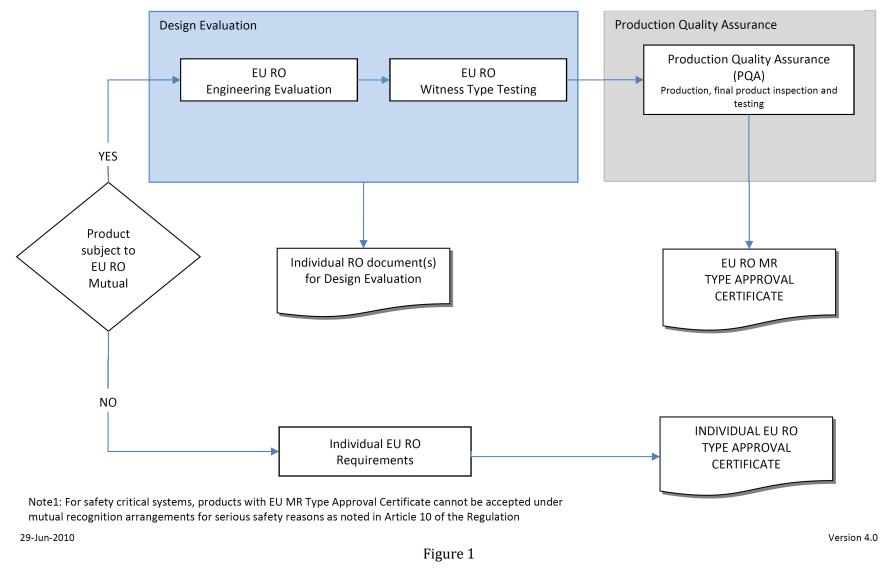
- American Bureau of Shipping (ABS);
- Bureau Veritas (BV);
- China Classification Society (CCS);
- Croatian Register of Shipping (CRS);
- DNV;
- Indian Register of Shipping (IRS);
- Korean Register (KR);
- Lloyd's Register Group Ltd. (LR);
- Nippon Kaiji Kyokai General Incorporated Foundation (ClassNK);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

The scheme for the mutual recognition of class certificates for materials, equipment and components laid down by Article 10(1) of Regulation (EC) No 391/2009 is only enforceable within the Union in respect of ships flying the flag of a Member State. As far as foreign vessels are concerned, the acceptance of relevant certificates remains at the discretion of relevant non-EU flag States in the exercise of their exclusive jurisdiction, notably under the United Nations Convention on the Law of the Sea (UNCLOS). (In accordance with COMMISSION IMPLEMENTING REGULATION (EU) No 1355/2014 amending Regulation (EC) No 391/2009 - recital (25)).

Notes:

- 1) Refer to the agreed MR Technical Requirements for additional MR TAC information that may be specifically applicable to certain products https://www.euromr.org/technical-requirements;
- 2) List of MR TACs issued by the EU ROs can be found by https://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) The manufacturer should notify the RO issued the EU RO MR Certificate of any modification or changes to the equipment/Firmware/Operational System Software Version in order to obtain a valid Certificate.
- 5) MR TACs are valid for a maximum of 5 years as per clause 10 of the Terms & Conditions for Mutual Recognition of Type Approval;
- 6) For more information on the factors affecting the validity of MR TACs, see clause 12, 13 and 14 of the Terms & Conditions of Mutual Recognition of Type Approval.
- 7) For implementation of the amendments to Appendix I of Version 10.0 of the Framework Document by the EU ROs into their internal procedures and MR TAC templates, an application period of 6 months as from 1 July 2019 applies.

4 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



5 APPENDIX III - LIST OF PRODUCTS INCLUDED IN EU RO MR

Tier 1 (Original release date January 2013)

- 1. Circuit Breakers
- 2. Contactors
- 3. Electric Driven Motors
- 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 release 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 Cables Heating Cables
- 19. Expansion Joints
- 20. Flameproof Luminaire (Lighting Fixture)
- 21. Plastic Piping Systems (Components)
- 22. Spark Arresters

Tier 3 (Original release date July 2014)

- 23. Adjustable Steel Chock
- 24. Air Compressor
- 25. Battery Chargers
- 26. Boiler Remote Level Indicator
- 27. Cable Trays & Ducts (Glass Reinforced Plastic)
- 28. Cable Trays & Ducts (Metallic)
- 29. Connecting Systems for Cable Repair (Cable Splices)
- 30. Electrical Actuators for Valves
- 31. Insulation Panels for Provision Rooms & Chambers
- 32. Pneumatic Actuators for Valves
- 33. Solenoid Valve Assembly
- 34. Stationary Lighting Fixtures/Flood Light Projectors

Tier 4 (Original release date July 2015)

- 35. Circuit Breakers with Electronic Devices
- 36. Contactors with Electronic Devices
- 37. Tachometer
- 38. Temperature Gauges and 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

Tier 5 (Original release date July 2016)

- 45. AC Semiconductor Controllers
- 46. Control and Protective Switching Devices
- 47. Electronic Power Units for Valve Control
- 48. Electro-Pneumatic Level Transmitters (EPLT)
- 49. Flow Gauges/Transmitters
- 50. Level Gauges/Transmitters
- 51. LV Soft Starters
- 52. Pilot Devices
- 53. Pressure Gauges Transmitters
- 54. Valves for Fuel Oil Systems
- 55. Valves for Cargo Systems

Tier 6 (Original release date January 2018)

- 56. Anti-Acid Paints (Batteries' Storage Rooms)
- 57. Electrical Insulation Mats
- 58. Gaskets and Seals for Piping Systems
- 59. Non-Metallic Gratings
- 60. Touch Screen
- 61. Valves Boiler Water Systems (Class III)
- 62. Valves Steam Systems (Class III, Non-Essential Systems)

Tier 7 (Original release date January 2019)

- 63. Differential Pressure Switches
- 64. Dual Temperature and Pressure Switches
- 65. Flow Switches
- 66. Level Switches
- 67. Position Switches
- 68. Pressure Relief Valve in Class III Piping System
- 69. Pressure Switches
- 70. Temperature Switches

2019 (Original release date January 2020)

71. Insulation Monitoring Device (IMD)

Tier 9 (Original release date January 2022)

- 72. Cable glands
- 73. Corrosion-resistant paints
- 74. Electric space heating equipment
- 75. Electric motor starters other than soft starters
- 76. Inverters
- 77. Resilient mountings of machinery
- 78. Strainers
- 79. Vertical surface reference system for DP system
- 80. Wind velocity and direction gauge for DP system
- 81. Power supply units (<5 kVA)

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

6 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) – www.ccs.org.cn/ccswzen/ Croatian Register of Shipping (CRS) – www.crs.hr DNV – http://www.dnv.com/ Indian Register of Shipping – www.irclass.org Korean Register of Shipping – www.irclass.org 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

7 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.

c) applicable Technical requirements, along with a list of applicable standards and their version*

- *: It is strongly recommended to use the latest available version of applicable standards as use of a superseded standard may prevent acceptance of the product onboard some vessels (see article 13 of the Terms and Conditions for Mutual Recognition of Type Approval enclosed in this Framework document).
- 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 cases where the tests are conducted at a Nationally Accredited Laboratory^{*}, 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. For electrical, electronic and programmable products, where applicable Technical Requirements define type testing to be performed according to IACS UR E10 standard or to equivalent international standards, all type tests shall normally to be carried out on the same unit. Using different units for the different type tests is acceptable provided that all EMC tests are carried out on the same unit (1), and all environmental and mechanical tests are carried out on the same unit (2).
- 10. For programmable electronic products, the version of each type of installed software (Firmware/ Operational System Software Version: [major version.minor version]) at the time of testing is to be identified and to be recorded in the test report.
- 11. 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

^{*} The scope must be accredited for the relevant applicable standards as specified in the individual MR Technical Requirements (see <u>www.euromr.org/technical-requirements</u>).

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.

- 12. The applicant must inform the EU RO that issued the MR Type Approval Certificate (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.
- 13. The applicant must provide, upon request, the Design Evaluation documents to each EU RO.

8 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 fulfil 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.
- 3.4 For products where the function of the product is based on software the quality management system of the manufacturer has to maintain procedures for the life cycle activities and the version control.
- 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).

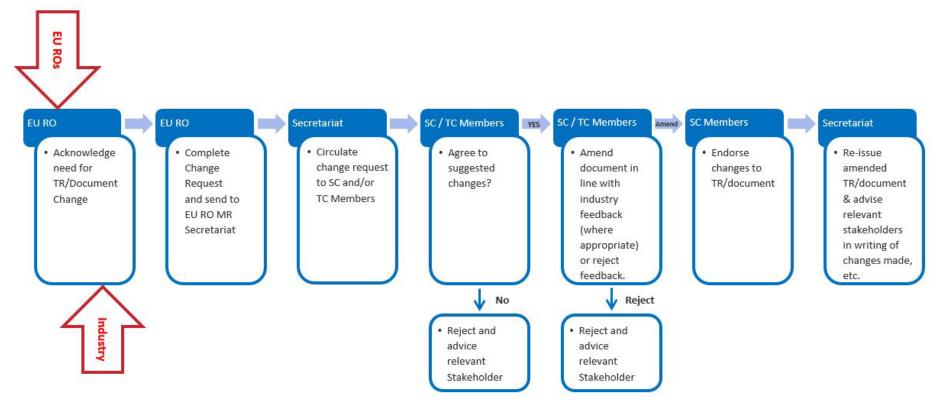
9 APPENDIX VII – AGREED TECHNICAL REQUIREMENTS

Controlled copies of the Agreed Technical Requirements can be obtained from:

https://www.euromr.org/technical-requirements

10 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 Steering Committee follow the process in the below figure describing the EU RO MR Maintenance Process.
- 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 Steering Committee.



EU RO MR Maintenance Process

A) Receiving RO F) Steering . Committee . Committee nmittee Committee Identify need for RfC considered: Review Technical Publish TI on the Record details of Draft Technical Review Technical Conduct annual clarification; RfC and forward • Valid? - assign Interpretation Interpretation Interpretation website review of TIs to to Technical (TI) and send to (TI): (TI) consider Complete RfC to Lead RO: Keep record of TI Committee for Technical whether related form & send to • Acceptfor further Accept- send Not Valid? consideration. Committee for TR is to be EU RO to Steering approve ready consideration by Reject and Secretariat: approval. Committee for for publishing; the TC at the amended in line explain with TI decision to EU approval; • Reject -explain annual review of TIs. • Yes? Start RO • Reject -explain decision to Change reasons for Technical Request rejecting draft Committee/EU Process (see TI and advise RO and advise appendix VII) further action further action to be taken. to be taken. No? No further action.

11 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.

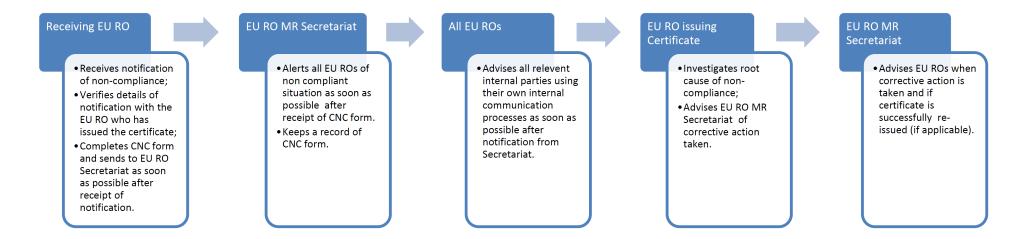
- 2. A Request for Clarification (RfC) requires the requesting entity to provide sufficient information on the subject for which clarification is being sought, along with the related technical background, a clear definition of the problem to enable the Receiving RO to create a distinct proposal for how to achieve clarification ² see step A) in the process above.
- 3. The proposed Request for Clarification (RfC) shall be verified by the EU RO MR Technical Committee (and EU RO MR Steering Committee 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.

² 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.

- 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 Steering Committee for agreement steps E) and F). Once agreed, it will then be published as a final version on <u>www.euromr.org/technical-requirements</u> 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 SC;
 - i) Date of SC 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 Steering Committee, the Receiving RO shall advise the requesting entity accordingly. All records of rejected RfC (including reasons) will be kept as a record and searchable resource by the EU RO MR Secretariat.

- 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 relevant 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).

12 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.

13 APPENDIX XI – EU RO MUTUAL RECOGNITION TAC TRANSFER PROCEDURE

Below procedure describes the steps to be followed in case of change of European Union Recognized Organization ("**EU RO**") when a material, equipment or component has already been certified in accordance with the EU RO MR Technical Requirements in compliance with Regulation (EC) No 391/2009 Art. 10.1.

Pre-requisite

In order to apply the present EU RO Mutual Recognition Type Approval Certificate ("**EU MR TAC**") transfer procedure, material, equipment, or component shall hold a valid EU MR TAC. Additionally, the transfer shall be initiated by a formal request issued by the manufacturer indicated on the EU MR TAC.

Eligible cases of MR TAC transfer between EU RO under such procedures When the EU RO member which has issued the concerned EU MR TAC has been de-recognized from the EU RO Mutual Recognition Group, at any moment in the 5 years validity's period of EU MR TAC.

Transfer procedure

1. Application

Manufacturer shall address a formal request in writing to the gaining EU RO and provide the following information:

- Copy of EU MR TAC (all pages) issued by previous EU RO
- Copy of EU MR Production Quality Assessment documents (all pages) issued by previous EU RO
- Copy of EU MR Design Evaluation evidence with corresponding documentation, in particular type tests reports endorsed by attending EU RO surveyor or issued by accredited laboratories
- Quality management system certificate of compliance with ISO 9001 standard or industry equivalent
- Copy of last audit report performed by previous EU RO
- Provide the organisation chart of the manufacturer.
- Information on changes foreseen in the organisation and/or production of the manufacturer, and/or product definition / specification, as relevant
- 2. Gaining EU RO duties

Upon receipt of manufacturer's request, gaining EU RO shall review the transmitted documents against latest version of corresponding Technical Requirement.

a. EU MR Design Evaluation

If the concerned material, equipment, or component is found to be compliant with the corresponding Technical Requirements, EU MR Design Evaluation evidence can be re-issued by gaining EU RO, keeping the same validity and/or same possible limitations and/or conditions as the previous one. If it happens at time of renewal, a new 5-year validity's period is to be defined, if applicable

If nonconformities are identified by the new EU RO the necessary corrective actions are to be performed including but not limited to the provision of any missing documents, identification of any missing test or witnessing by the new EU RO of any additional test performed. Upon satisfactory completion of such corrective actions, EU MR Design Evaluation evidence can be re-issued by gaining EU RO, with new validity. Some possible new limitations and/or conditions may also be added.

In any cases, all documents should be kept in the file of gaining EU RO.

b. EU MR Production Quality Assessment

Whether the annual assessment audit is due or not, a renewal audit is to be performed by gaining EU RO as soon as new EU MR Design Evaluation evidence is issued by gaining EU RO. Following the issuance of a new EU MR Design Evaluation evidence the gaining EU RO shall perform a renewal audit independently of the date of the next annual assessment audit.

Upon satisfactory completion of such renewal audit by the gaining EU RO, Production Quality Assessment document can be re-issued by gaining EU RO, with the same validity and/or same possible limitations and/or conditions as the new EU MR Design Evaluation. If it happens at the time of renewal, a new 5-year validity's period is to be defined, if applicable.

c. EU MR TAC

Upon re-issuance of EU MR Design Evaluation and EU MR Production Quality Assessment document by the gaining EU RO, EU MR TAC can be re-issued by gaining EU RO, with the same validity and same possible limitations and/or conditions as the new EU MR Design Evaluation. If it happens at the time of renewal, a new 5-year validity's period is to be defined.

3. Information to be indicated on the attestations and certificates

On any EU RO MR Attestation or Certificate (Design Evaluation, Type Approval or Production Quality Assessment) issued by the gaining EU RO after a change of EU, reference to all previous attestation(s) and certificate(s) number(s), date(s) of issuance, date(s) of validity with name of previous EU RO(s) shall be indicated.

4. Information to EU RO Group

Previous EU RO is to be informed upon completion of change of EU RO as soon as all necessary attestations and certificates are issued.

At time of the annual transmission of certificates issued in the past year, EU MR TAC renewed at time of a transfer are to be specially flagged.

List of amendments effective as of 24 October 2023

| Item | Title/Subject | Source |
|----------------|--|---|
| In many places | Amendments in Terms and Conditions for Mutual Recognition of Type Approval, §13 (<u>Page 6</u>) Amendments in Appendix I – EU RO MR Type Approval Certificate Information (<u>Page 9</u>) | EU RO Framework Document for MR of Type Approval V17.0 |