EU RO Framework Document
for the
Mutual Recognition of Type Approval

<table>
<thead>
<tr>
<th>Document Issue Date</th>
<th>1 July 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>2.0</td>
</tr>
<tr>
<td>Status</td>
<td>Controlled</td>
</tr>
<tr>
<td>Issued by</td>
<td>EU RO Mutual Recognition Secretariat</td>
</tr>
<tr>
<td>Distribution</td>
<td>All EU RO Type Approval Departments</td>
</tr>
</tbody>
</table>

**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 **Design Evaluation** involving Engineering evaluation and Witnessing of manufacturing and testing processes;
2. The **Production Quality Assurance (PQA)** which aims to ensure the consistency of production with the approved design and manufacturing process;
3. The **EU RO 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 (inc. appendices).

-End -
Document Administration

1. Content
The EU RO MR Secretariat is responsible for maintaining the content of this procedure. Members of the EU RO MR group are responsible for reviewing 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 Change Request Process detailed in this document (see annex VIII);

3. Controlled Issue
This document and related annexes are subject to controlled issue.

4. Revision History:

<table>
<thead>
<tr>
<th>Document Date</th>
<th>Revision Number</th>
<th>Details of Change</th>
<th>Date Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014-01-31</td>
<td>1.0</td>
<td>• Document issued.</td>
<td>2014-01-31</td>
</tr>
<tr>
<td>2014-07-01</td>
<td>2.0</td>
<td>• Revised Terms &amp; Conditions;</td>
<td>2014-07-01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Updated List of Products included in EU RO MR (appendix IV);</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• New ‘Request for Clarification’ process (appendix IX);</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• New ‘Alert’ Process (appendix X);</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Plus other minor editorial changes.</td>
<td></td>
</tr>
</tbody>
</table>

5. Document Owner
EU RO MR Secretariat
c/o Lloyd’s Register
71 Fenchurch Street
London EC3M 4BS
Tel: +44 (0)20 7423 2406
Email: secretariat@euromr.org

- End -
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terms and Conditions</td>
<td>4</td>
</tr>
<tr>
<td>General Information</td>
<td>7</td>
</tr>
<tr>
<td><strong>Appendix I</strong> EU RO MR Type Approval Certificate Information</td>
<td>10</td>
</tr>
<tr>
<td><strong>Appendix II</strong> Flow chart technical and procedural conditions for EU RO Mutual Recognition of Type Approval Certificates</td>
<td>11</td>
</tr>
<tr>
<td><strong>Appendix III</strong> List of Products included in EU RO MR</td>
<td>12</td>
</tr>
<tr>
<td><strong>Appendix IV</strong> List of EU Recognised Organisations (EU ROs)</td>
<td>13</td>
</tr>
<tr>
<td><strong>Appendix V</strong> EU RO MR Design Evaluation Scheme</td>
<td>15</td>
</tr>
<tr>
<td><strong>Appendix VI</strong> EU RO MR Production Quality Assurance (PQA)</td>
<td>16</td>
</tr>
<tr>
<td><strong>Appendix VII</strong> Link to Agreed Technical Requirements</td>
<td>17</td>
</tr>
<tr>
<td><strong>Appendix VIII</strong> EU RO MR Maintenance Process</td>
<td>18</td>
</tr>
<tr>
<td><strong>Appendix IX</strong> EU RO MR Request for Clarification (RfC) Process</td>
<td>19</td>
</tr>
<tr>
<td><strong>Appendix X</strong> EU RO MR Material, Equipment &amp; Component Non-Compliance (‘Alert System’)</td>
<td>22</td>
</tr>
</tbody>
</table>
Terms and Conditions

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.


3. The MR TAC is intended to enable Mutual Recognition (MR) of certain type-approved products, through the uniform application of 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\(^1\) are:
   - American Bureau of Shipping (ABS)
   - Bureau Veritas (BV)
   - China Classification Society (CCS)
   - DNV GL
   - Korean Register of Shipping (KRS or KR)
   - Lloyd’s Register (LR)
   - Nippon Kaiji Kyokai (NK or ClassNK)
   - Polish Register of Shipping (PRS)
   - Registro Italiano Navale (RINA)
   - Russian Maritime Register of Shipping (RS)

\(^1\): On the 14 May 2014, the European Commission granted EU Recognised Organisation (EU RO) status to the Croatian Register of Shipping (CRS) pursuant to Regulation (EC) No 391/2009 of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations. The first exchanges between CRS and the EU RO MR Group about their incorporation into the EU RO’s Mutual Recognition programme will take place in July 2014.
5. The MR TAC applies to products to be installed aboard EU RO-classed ships as defined in Article 2 (a) of the Regulation (EC) No 391/2009. For those products intended to be installed on board a ship that do not fall within the scope of the above definitions, the individual EU RO requirements will apply.

6. The manufacturer will be required to sign a contract with the EU RO providing the MR TAC service and certificate; such contract 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 issuer of the MR TAC of the product may ask for information in addition to that provided in the MR TAC;

   b. The manufacturer shall provide immediately, when so requested, information, documentation and/or evidence required by the EU RO classing the ship;

   c. The MR TAC may be suspended or withdrawn by the EU RO issuing it (see 10d 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 certification relates to the products for which MR TAC is sought.

9. 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 is 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.

10. 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; 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 EU RO; or

e. Such time as the EU RO Mutual Recognition Technical Committee considers it necessary to change the Technical Requirements on which the MR TAC was based.

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

11. The manufacturer of a MR TAC product, its heirs and designee are responsible for the archiving and retention of all records of the design and construction approved by the EU RO, the records of type testing, and the quality records of the production under the MR TAC for seven years after the validity of the relevant MR TAC expires.
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 Type Approval Certificates are issued by one or more of the EU Recognised Organizations (EU ROs) listed in Appendix IV.

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

   a) Agreed Technical Requirements - 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) Parties – see IMO definition;

   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 technical requirements.

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 on common rules and standards for ship inspection and survey organisations:
   a. ‘ship’ means a ship falling within the scope of the international conventions;
   b. ‘international conventions’ means the International Convention for the Safety of Life at Sea of 1 November 1974 (SOLAS 74) with the exception of chapter XI-2 of the Annex thereto, the International Convention on Load Lines of 5 April 1966 and the International Convention for the Prevention of Pollution from Ships of 2 November 1973 (MARPOL), together with the protocols and amendments thereto, and the related codes of mandatory status in all Member States, in their up-to-date version;

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 Annex V) and;
   b. Production Quality Assurance (PQA) Assessment (see Annex VI).

**For those products that 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 MR Type Approval Certificate shall contain as a minimum the information as specified in Appendix I.

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

7. Individual ROs are responsible for:
a. Giving detailed reasons to a manufacturer when an MR Type Certificate is refused

b. Making available information when an MR Type Certificate is withdrawn.

8. Manufacturer’s responsibility

a. Where a manufacturer reapplies for type-approval for products for which an MR Type Certificate 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 case the EU RO classing the ship refuses a material, equipment or component, issued with a EU MR Type Approval Certificate, 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 MR Type Approval Certificate;
- the reasons for refusal.

The EU RO MR Advisory Board Chairman shall, in turn, inform accordingly the EU RO MR Technical Committee Chairman and Technical Committee Members. See also Appendix IX - EU RO MR Material, Equipment & Component Non-Compliance (‘Alert System’).

10. The EU RO Mutual Recognition 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.

- End -
APPENDIX I

EU RO MR Type Approval Certificate Information

The EU RO MR Type Approval Certificate shall contain as a minimum the following information:

Certificate Heading
   Mutual Recognition Type Approval Certificate

Certificate number
   Each EU RO MR Type Approval Certificate is to be issued with a 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)

Term of Validity
   Place of Issue
   Issue Date
   Expiration Date

Rules & Standards
   Technical requirement reference
   Other standards as applicable

- End -
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

Product subject to EU RO Mutual Recognition

YES

Individual RO document(s) for Design Evaluation

NO

Individual EU RO Requirements

Production Quality Assurance

Production Quality Assurance (PQA)
Production, final product inspection and testing

EU RO MR TYPE APPROVAL CERTIFICATE

INDIVIDUAL EU RO TYPE APPROVAL CERTIFICATE

Note 1: 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
APPENDIX IV

List of Products included in EU RO MR

Tier 1 (issued 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 (issued 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
22. Spark Arrestors

Tier 3 (issued 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

- End -
List of EU Recognised Organisations (EU ROs):

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

Bureau Veritas (BV) - www.bureauveritas.com

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

DNV GL – www.dnvgl.com

Korean Register of Shipping (KRS or KR) - www.krs.co.kr

Lloyds Register of Shipping (LR) - www.lr.org

Nippon Kaiji Kyokai (NK or ClassNK) - www.classnk.or.jp

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

Registro Italiano Navale (RINA) - www.rina.org/en

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

Note: On the 14 May 2014, the European Commission granted EU Recognised Organisation (EU RO) status to the Croatian Register of Shipping (CRS) pursuant to Regulation (EC) No 391/2009 of the European Parliament and of the Council on common rules and standards for ship inspection and survey organisations. The first exchanges between CRS and the EU RO MR Group about their incorporation into the EU RO’s Mutual Recognition programme will take place in July 2014.

- 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 to the EU Recognized Organization(s) and must include:
   a) the name and address of the manufacturer or product designer;
   b) the technical documentation as described in point 2 below.

2. The technical documentation must 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.

4. Verifies where required, that the product to be tested has been manufactured in accordance with the technical documentation.

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

6. The extent of witnessing is specified in each applicable Technical Requirement. In case the tests are conducted at a Nationally Accredited Laboratory\(^2\), the presence of the RO’s surveyor may be omitted, provided the option is expressively noted in the applicable Technical Requirement.

7. Where the product meets the relevant agreed technical requirements, the EU RO will issue an Individual RO document(s) for Design Evaluation 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.

8. The applicant must inform the EU RO(s) that hold the technical documentation concerning the EU RO MR Type Approval Certificate of any modification of the design, which must receive additional approval where such changes may affect compliance with the agreed technical 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 EU RO MR Type Approval Certificate.

9. The applicant must provide on request the Design Evaluation documents to each EU RO for which they want Mutual Recognition.

- End -

\(^2\) The scope of accreditation must cover the relevant applicable standards.
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) list of manufacturing/production sites other than the TA applicant site

   c) the documentation concerning the quality management system and its certification 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 Production Quality Assurance scheme to determine whether it gives reasonable confidence that the concerned product(s) can be consistently produced in compliance with the type of 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 manufacturing/production sites other than the TA applicant site. 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 verify that the quality system Production Quality Assurance scheme 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 type approval certificate for the concerned product(s) with a maximum validity of 5 years. The document must give the name and address of the manufacturer and place of manufacture, if at a different location, conditions of its 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 can be obtained from:

EU RO MR Secretariat
c/o Lloyd’s Register
71 Fenchurch Street
London EC3M 4BS
Tel: +44 (0)20 7423 2406
Email: secretariat@euromr.org

From September 2014, controlled copies of the Agreed Technical Requirements will be available from www.euromr.org

- 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 Advisory 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 1 July each year. ②

EU RO MR Change Request Process

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

- End -
1. A Request for Clarification (RfC) for 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 \(^3\) - see step A) in the process above.

\(^3\) 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 Interpretation (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 for all EU ROs’ information as well as that of 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 Issued;
   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.
6. An annual review of TIs will be conducted by the EU RO MR Technical Committee in September each year and a decision will be taken on each TI 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,

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 Change Request Process (see appendix VIII).

- End -
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 certificate. 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 recognised organisation shall immediately inform the other recognised organisations, 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 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 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 -