Introduction to the Marine Equipment Directive

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Background

• International Shipping is regulated by the IMO who have issued a number of conventions.
• Each country remains responsible for commissioning shipping under its flag. (Referred to as Flag Administrations).
• Marine Equipment Directive enacts IMO regulations for equipment intended on commissioned ships
• Applies to Solas vessels
Marine Equipment Directive

• Issued as council Direction 96/98/EC
  – MED now on Amendment 5 of directive.
  – disappplies EMC Directive, LVD and R&TTE for equipment in its scope

• SI 1999:1957 The Merchant shipping (Marine Equipment) regulations 1999 is the UK implementation of the MED
  – SI 2009:2021 amends this and adds Hovercraft.

• UK Maritime and Coastguard Agency document MSN 1734 describes the Type approval.
  – Amendment to MCA MSN 1734 track the MED amendments to bring the standards into UK law
• Article 1: Aim: Enhance safety and prevent marine pollution.
  – MED has no formal Essential requirements but Safety and Marine Pollution (plus protection of spectrum for radio products[ Article 8: Clause 2] ) are the guiding principles.

• Article 5: Method of compliance.
  – Note clause 2: “compliance demonstrated ..solely in accordance with full compliance to the relevant testing standards. “

• Article 11: Defines use of the Wheelmark
  – Annex D defines the Wheel mark
  – The mark is the Wheel mark and NOT the CE mark
• The MED lists the Standards for conformance in the Directive
  – MED lists the Standards against equipment
  – Harmonised standards lists are not used
  – Listed Standards must be used in their latest published version (e.g. When version 1.2 of a standard is published it must be used even if version 1.1 is listed;
  – Differently numbered Standards which supersede a listed one are not to be used until listed

• Updates to the standards, and types of equipment regulated are published in MED Amendments.
• MED Amendments normally come into effect about 12 months after they are published.
• The current Amendment is Amendment 5 (Commission Directive 2009/26/EC)
  – Amendment 6 (2010/68/EU has been published and comes into effect on 10\textsuperscript{th} December 2011
  – Work is underway on Amendment 7.

• Amendment 5 replaces Annex A of the Directive
  – Section A.1 relates to BABT NB activities
  – Section A.2 is relevant for the National Approvals where full Standards lists have not been adopted
• Section A.1 relates to our activities
  – Group A.1/1 is for Lifesaving apparatus and is not relevant to BABT
  – Group A.1/2 is for Marine pollution protection and is not relevant to BABT
  – Group A.1/3 is for Fire Protection apparatus and is not relevant to BABT
  – Group A.1/4 is for Navigation Equipment which is relevant to BABT
  – Group A.1/5 is for Radio communication Equipment which is relevant to BABT
  – Group A.1/6 is for Colreg 72 apparatus and is not relevant to BABT
• Listing structure
  – No : Item Number which is used on Certificates to identify the equipment type. Note may change between amendments.
  – Item Description: the equipment type. Used on Certificates
  – Regulation SOLAS 74 columns: These are the basis for the standardisation and provide context.
  – Testing Standards
    • Two sets: EU and ISO sets
    • Must use all standards in one set
    • Must use each standard in its latest form (refer to Note C at start if section A.1)
  – Modules for Conformity: Each item will have its own set. (Next amendment removes “module G” for Navigation equipment)
Note: Module C and Module Hbis are currently not invoked by any item.
## Table 5/1 · Basic modules ·

<table>
<thead>
<tr>
<th>Module</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong> Internal control of production</td>
<td>Covers internal design and production control. This module does not require a notified body to take action.</td>
</tr>
<tr>
<td><strong>B</strong> EC type-examination</td>
<td>Covers the design phase, and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificate is issued by a notified body.</td>
</tr>
<tr>
<td><strong>C</strong> Conformity to type</td>
<td>Covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B. This module does not require a notified body to take action.</td>
</tr>
<tr>
<td><strong>D</strong> Production quality assurance</td>
<td>Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9002, with the intervention of a notified body responsible for approving and controlling the quality system for production, final product inspection and testing set up by the manufacturer.</td>
</tr>
<tr>
<td><strong>E</strong> Product quality assurance</td>
<td>Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9003, with the intervention of a notified body responsible for approving and controlling the quality system for final product inspection and testing set up by the manufacturer.</td>
</tr>
<tr>
<td><strong>F</strong> Product verification</td>
<td>Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.</td>
</tr>
<tr>
<td><strong>G</strong> Unit verification</td>
<td>Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.</td>
</tr>
<tr>
<td><strong>H</strong> Full quality assurance</td>
<td>Covers the design and production phases. Derives from quality assurance standard EN ISO 9001, with the intervention of a notified body responsible for approving and controlling the quality system for design, manufacture, final product inspection and testing set up by the manufacturer.</td>
</tr>
</tbody>
</table>

## Table 5/2 · Simplified flow chart of conformity assessment procedures ·
Compliance Routes Available through BABT

- **Module B Type Examination + Module D (Production Quality Assurance)**
  - (leading to a Certificate of Conformity)

- **Module B Type Examination + Module E (Product Quality Assurance)**
  - (leading to a Certificate of Conformity)

- **Module B Type Examination + Module F (Product Verification (Certificate of Conformity))**

- **Module G Unit Verification (Certificate of Conformity)**
Responsibilities

• Various parties may be involved in the compliance:
  – Manufacturer
  – Authorised Representative
  – Importer
  – Fabricator
  – Agent
  – Applicant
  – Notified Body (e.g. BABT)
Definition: Manufacturer

• A manufacturer is the person who is responsible for designing and manufacturing a product with a view to placing it on the Community Market on his own behalf.

• The Manufacturer has an obligation to ensure that a product intended to be placed on the community market is designed, manufactured, and has its conformity assessed to the essential requirements.

• The Manufacturer must always retain the overall control and have the necessary competence to take responsibility for the product.
Definition: Authorised Representative

- The Manufacturer may appoint any natural or legal person to act on his behalf as an Authorised Representative.
  - The Authorised Representative must be established inside the community.
  - An Authorised Representative may be addressed by the authorities of the Member states instead of the manufacturer with regard to the latter’s obligations under this Directive.

- The Manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.
An Importer (a person responsible for placing the product on the market) is any natural or legal person established in the Community who places a product from a third country on the Community market.

The Importer must ensure that he is able to provide the market surveillance authorities with the necessary information regarding the product where the Manufacturer is not established in the Community and has no Authorised Representative in the Community.
• For applications for Marine Equipment Directive Modules D or E the Term “Fabricator” is used to denote the person or organisation which performs the production phase of a product realisation whether they are a sub-contracted company or the product Manufacturer.
• An Agent is a natural or legal person, established either within the community or elsewhere in the world, appointed by the Manufacturer to act on his behalf with respect to the application.
  – Authorised Representatives are assumed to be authorised to act as Agents

• Where the Agent is not the nominated Authorised Representative
  – the application must include a letter from either the Manufacturer or the Authorised Representative authorising BABT to communicate with the Agent for matters related to the application.
  – The Agent may only act in relation to the application and has no ongoing obligations.
• The Applicant must be either the Manufacturer or the Authorised representative. An application may not be made by an Agent who is not also the Authorised Representative.

• An Agent may with suitable authorisation sign an application on behalf of the manufacturer but the application must list the manufacturer as Applicant.
• A Notified Body is The certification Body appointed to review one of the compliance options and when satisfied issue the relevant Certificate

• While normally the same NB performs the Module B and Module D/E/F Activities for a given product different ones may be involved in which instance the one controlling the production phase is the one to be listed on the D of C
• Brand Name products are normally the same as the original product with the exception of cosmetic differences (e.g. labels, enclosure colours, etc) and often follow the same production line processes as the original products.

• A Brand Name Application is an application for a certificate in the name of the different holder (and/or Manufacturer) making use of an existing BABT Certificate.
  – Brandnames are also called co-licences.
  – Brandnamed products with the same holder and manufacturer may be listed on the original certificate.
• For Module B Type Examination Certificates
  Brandnames of the certificate is based on making use of the data supporting an existing Certificate

• An application for a Module D/E PQC/PrQC Brandname certificate may only be made where the same fabricator operates the same processes for the Brandname as the Original product

• A module D Brandname application is based on performing single audits covering both the original and brandname products.
<table>
<thead>
<tr>
<th>Product Type</th>
<th>MED Amend 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naval Acoustic Survey System (NAS)</td>
<td>Anne A.1</td>
</tr>
<tr>
<td>Electronic Chart Display and Information System (ECDIS) with backup</td>
<td>A.1/4.30</td>
</tr>
<tr>
<td>and raster chart display system RCDS</td>
<td></td>
</tr>
<tr>
<td>Universal automatic identification system (AIS)</td>
<td>A.1/4.32</td>
</tr>
<tr>
<td>Radar Equipment CAT1</td>
<td>A.1/4.34</td>
</tr>
<tr>
<td>Radar Equipment CAT2</td>
<td>A.1/4.35</td>
</tr>
<tr>
<td>Radar Equipment CAT3</td>
<td>A.1/4.36</td>
</tr>
<tr>
<td>Radar High Speed Craft Applications CAT 1H, CAT 2H, CAT 3H</td>
<td>A.1/4.37</td>
</tr>
<tr>
<td>Radar Equipment approved with a chart option. CAT 1HC, CAT 2HC, CAT 3HC.</td>
<td>A.1/4.38</td>
</tr>
</tbody>
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## Radio Scope

<table>
<thead>
<tr>
<th>Product Type</th>
<th>MED Amend 5 Annex A.1 ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>VHF radio installation capable of transmitting and receiving DSC and radiotelephony</td>
<td>A.1/5.1</td>
</tr>
<tr>
<td>VHF DCS watch-keeping receiver</td>
<td>A.1/5.2</td>
</tr>
<tr>
<td>NAVTEX receiver</td>
<td>A.1/5.3</td>
</tr>
<tr>
<td>406 MHz EPIRB (COSPAS-SARSAT)</td>
<td>A.1/5.6</td>
</tr>
<tr>
<td>MF radio installation capable of transmitting and receiving DSC and radiotelephony</td>
<td>A.1/5.10</td>
</tr>
<tr>
<td>MF radiotelephone DSC watch-keeping receiver</td>
<td>A.1/5.11</td>
</tr>
<tr>
<td>MF/HF radio installation capable of transmitting and receiving DSC, NBDP &amp; radiotelephony</td>
<td>A.1/5.14</td>
</tr>
<tr>
<td>Radiotelephone MF/HF DSC watch-keeping receiver</td>
<td>A.1/5.15</td>
</tr>
<tr>
<td>Portable Survival craft two-way VHF radio telephone apparatus</td>
<td>A.1/5.17</td>
</tr>
<tr>
<td>Fixed Survival craft two-way VHF radio telephone apparatus</td>
<td>A.1/5.18</td>
</tr>
</tbody>
</table>
Module B/G
• A formal Application to BABT (use form BABT 775)
  – Certificates are issued to the Company who submit the Application (either the Manufacturer or Authorised Representative)
    • Where an Authorised Rep applies must provide the Manufacturer details

• A Technical Data File supporting the application

• Refer to BABT 740 for details
• Requirements are based on Clause 3 of Annex B of the Directive

• **Index:** Recommendation where files are not self-evident

• **Purpose and Block Diagram:** Needed for understanding of the product

• **Circuit Diagrams/PCB Layouts:** Used mainly for identification but may indicate undeclared “ports”

• **Parts List:** Used mainly for identification and checking production items

• **Software/Firmware versions:** Important as displayed information is within Directive
• **Photographs/Illustrations**: Used for identification and external features

• **Compliance Strategy**: This can assist in establishing how the compliance is maintained

• **User Instructions/Installation Instructions**: Needed to ensure required information is available;

• **DoC**: A draft is helpful but only mandatory for Module G (Unit Verification)

• Other items
  – Letters: Agent or Authorised Rep identification from Manufacturer
  – Justification for using results from other product
  – Declarations (Some items only require a declaration)
• Test Reports
  – Must come from an acceptable source (Preferably Accredited) but may be Manufacturers Test Facility
  – Testing must be part of a consistent set of requirements (EU or International) to the latest versions of the listed Standards
Module B/G Outcome

• For Module B a Type Examination Certificate and Annex with 5 year validity
  – May be presented to other non-EU Flag Administrations as proof of meeting the relevant IMO requirements.
  – Needs a Module D/E or F Certificate before can be wheelmarked

• For Module G a Unit Examination Certificate of Conformity and Annex with 5 Year Validity
  – Only Valid for the Specific items tested/inspected
  – Listed item(s) may be wheelmarked.
Basis

- Basis is to ensure that Type approved Products in volume production remain meeting the Standards.
- The Facility which builds the product (Fabricator) must have a compliant Quality Management System to ensure the above.
- BABT base our requirements on Manufacturing aspects of ISO9000 with additional focused requirements for MED Products.
- Very little difference between Modules D and E so will be addressed together.
• Base Standard is BABT AP008 (Production Quality Certification) Currently with Amendment 1
• Part 1 applies certain ISO9000 requirements
• Part 2 applies general Production Quality Controls
• Annex G applies specific requirements for Module D
• Annex H applies specific requirements for Module E
Key Requirements (1)

• Module B Certificate Holder must have overall control of the process even where the production phase is in a third party premises
  – Through details in Contract Review
  – Through Audits of the facility
  – By defining the key production Tests to be performed
  – By defining an overall Compliance Plan
  – Maintain a list of products to be manufactured under the Module D/E Certificate
  – Responsible for all Complaints and Surveillance queries
The Production Test Plan must be agreed between the Module B Certificate Holder and BABT and include:

- Pass/Fail criteria
- Test Equipment Specifications (including Calibration)
- Competence requirements for testers
- Details of any Sampling where all defined tests are not performed on 100% of the products
• The Fabricator (person who performs the Production Phase) must
  – Operate a compliant Quality System
  – Perform Testing according to the agreed plan
  – Only use defined components
  – Only apply the Wheelmark to products on the Holders list and for which a valid D of C has been supplied
• Module D or E Production Phase Certificate in the name of the Holder of the related Module B Certificates (3 yr Validity)
• For every Combination of B+D or B+E a Certificate of Conformity which authorises the use of the Wheelmark (5 Year Validity)
• There must be a Module B Certificate in place

• BABT Module F Scheme has 2 phases
  – Agreement of required tests (Test Plan) and Sampling process
  – Review of test results for a Batch/Lot of product

• Agreement normally made once

• Separate Reviews and certificates issued for each batch
Module F

• BABT 741 is the guide for Module F
• BABT 776 is the application form for a Module F Agreement
• Applicant must be the Main Module B Certificate holder
• An Agreement can cover more than one related Product (i.e. Brandnames and derived products may be included)
Brief Review of Module F Agreement

• Application must identify
  – whether every item or only a sample will be tested
  – Where sample testing is to take place the Sampling procedure which includes
    • the method for the selection of the sample;
    • the proposed lot/batch size
    • the process to obtain the results; and
    • the process to be followed if any of the sample fail to meet the requirements.
  – the product names and the certificate numbers of the supporting Module B TECs
  – The Estimated number of items to be shipped in the first year and the Estimated Lot/Batch size
• When satisfied BABT will issue a formal agreement letter with a validity of 5 years.

• The Client may then when ready select the first batch/Lot and test it according to the plan

• The Test Results must be in a form of a report from the agreed type of test source (e.g. Test Laboratory, or Own test equipment)

• When all required testing complete for a batch The Module B Holder may apply for a Module F Certificate of Conformity
Application for a Module F Certificate of Conformity

- Made by Module B Holder
- Referencing:
  - Module B Certificate
  - Module F Agreement
- Including
  - The Test Reports
  - Copy of Draft D of C
• Outcome
• If the Report + Supporting Data is satisfactory a Module F Certificate of Conformity is raised for all the items within the batch (Validity 5 years)
• Additional Batches may be tested and submitted under the original Agreement.
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