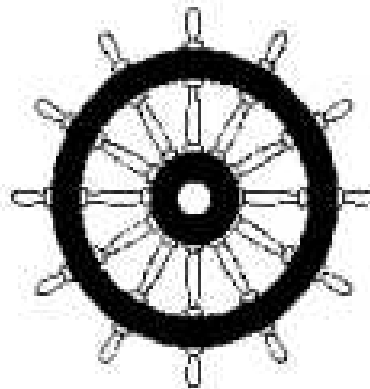

BABT 740

**A Guide to the BABT Implementation
of the Marine Equipment Directive
(96/98/EC)**



BABT is the telecommunications
certification body of



Foreword

This guide overviews the BABT Implementation of Modules B, D, E, F and G of the Marine Equipment Directive (MED), 96/98/EC.

The implementations of Modules D and E are explained in more detail in BABT 791.
The implementation of Module F is explained more fully in BABT 741.

This guide is designed so that the essential information can be read quickly by reading the main text only. Where you require more information, refer to the appropriate shaded text.

The scheme enables a manufacturer of a product within the scope of the MED to affix a Wheel mark including the BABT Notified Body number after satisfying the appropriate module(s) of the MED.

The formal requirements of the scheme are set out in the Certification Regulations.

All BABT publications are available from: <http://www.babt.com>

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1. Introduction

1.1 Scope

This guide overviews the BABT Implementation of Modules B, D, E, F, and G of the Marine Equipment Directive (MED ,96/98/EC including the latest effective amendment).

Furthermore it more fully explains the implementation of Module B (Type examination) and Module G (Unit Verification) of the MED.

1.2 Background

The Merchant Shipping (Marine Equipment) Regulations 1999 (SI 1999 No 1957) provide for the "type approval" of marine equipment, of a safety or pollution prevention nature, for use on board United Kingdom ships. This legislation (as amended most recently by the new SI 2009 No 2021) when considered with, MSN 1734 (M+F)), as amended, implements the European Council (EC) Directive 96/98/EC of 20 December 1996)



1.3 Overview

The MED provides for a number of alternative routes to meet the requirements of the directive. The routes available for particular equipment are dependent upon the standards invoked by the category and nature of the equipment. Refer to MSN 1734 for full details. Overleaf is a diagram listing the various options and their interrelation.

1.4 BABT TCB Scope

1.4.1 Introduction

BABT is currently notified to operate modules B, D, E, F, and G for Navigation and Radio equipment. The schemes to support these operate under the BABT Certification Regulations.

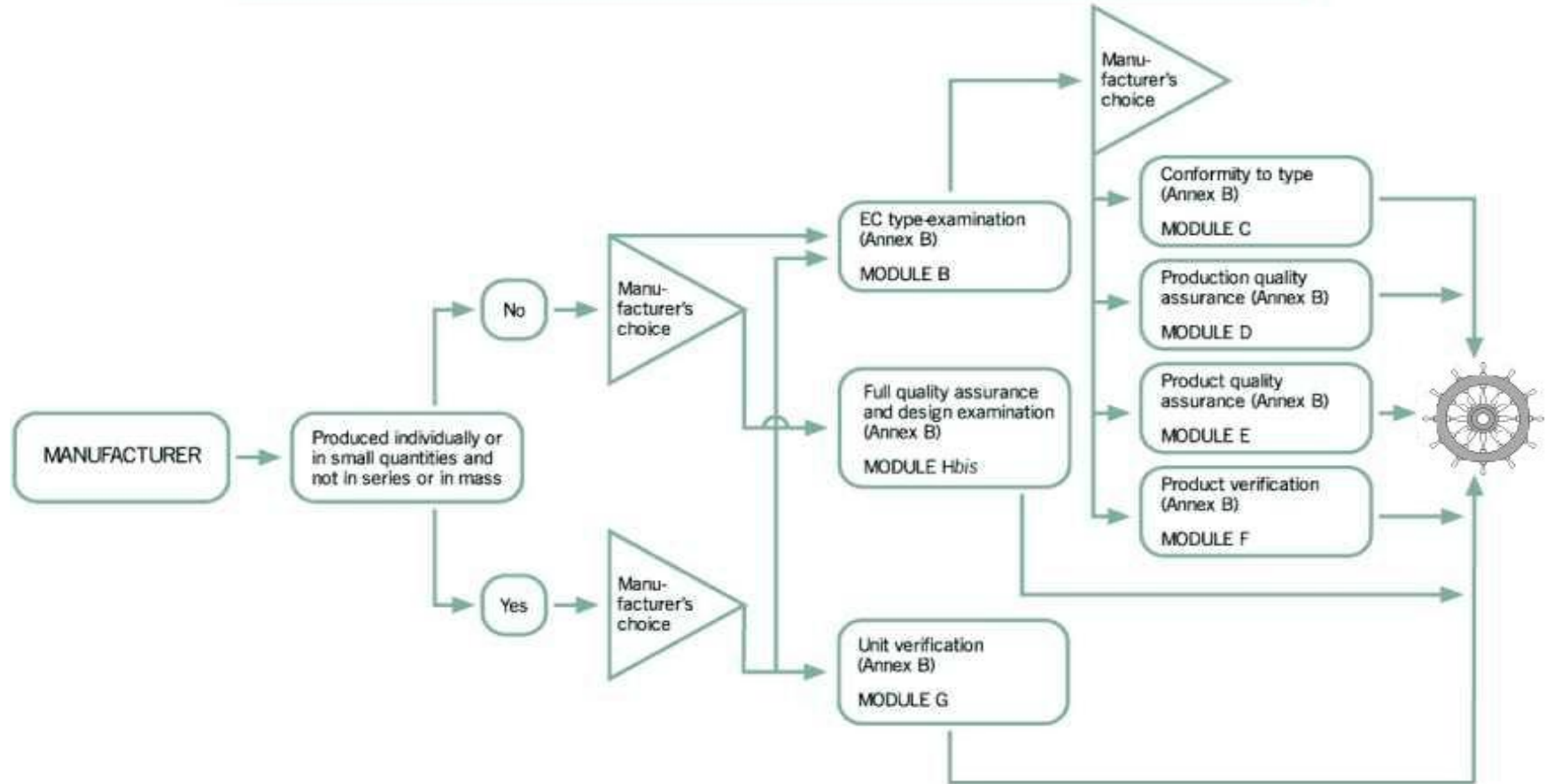
The following lists some devices with accompanying MED references which BABT is able to progress. If you have a Navigation or Radio Communications product which is not listed please discuss this with BABT prior to submitting any application.

1.4.2 BABT Scope

Product Type	Reference MED Amend 5 Annex A.1
Echo-sounding equipment	A.1/4.6
GPS equipment	A.1/4.14
9GHz SAR transponder (SART)	A.1/4.18
Electronic Chart Display and Information System (ECDIS) with backup and raster chart display system RCDS	A.1/4.30
Universal automatic identification system (AIS)	A.1/4.32
Radar Equipment CAT1	A.1/4.34
Radar Equipment CAT2	A.1/4.35
Radar Equipment CAT3	A.1/4.36
Radar High Speed Craft Applications CAT 1H, CAT 2H, CAT 3H	A.1/4.37
Radar Equipment approved with a chart option. CAT 1HC, CAT 2HC, CAT 3HC.	A.1/4.38
VHF radio installation capable of transmitting and receiving DSC and radiotelephony	A.1/5.1
VHF DCS watch-keeping receiver	A.1/5.2
NAVTEX receiver	A.1/5.3
406 MHz EPIRB (COSPAS-SARSAT)	A.1/5.6
MF radio installation capable of transmitting and receiving DSC and radiotelephony	A.1/5.10
MF radiotelephone DSC watch-keeping receiver	A.1/5.11
MF/HF radio installation capable of transmitting and receiving DSC, NBDP & radiotelephony	A.1/5.14
Radiotelephone MF/HF DSC watch-keeping receiver	A.1/5.15
Portable Survival craft two-way VHF radio telephone apparatus	A.1/5.17
Fixed Survival craft two-way VHF radio telephone apparatus	A.1/5.18

1.5 Approval Options and Modules

21. Flow chart for the conformity assessment procedures provided for in Directive 96/98/EC on marine equipment



1.6 Definitions and Terms

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 and manufactured, and 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.

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

Importer

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.

Agent

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. 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.

Applicant

The applicant must be either the Manufacturer or the Authorised Representative. An Application may not be made in the name of an Agent who is not also the Authorised Representative.

Brand Name Application

An Application for a Module B or G certificate naming the Brand name Company as the Manufacturer. This application is based on making use of an existing Module B or G Certificate which names the Original Product Manufacturer. Brand name products are normally the same as the original product with the exception of cosmetic difference (e.g. Labels, enclosure colours) and often follow the same production line processes as the original products.

1.7 Overview

BABT schemes support applications under Module B, Module D, Module E, Module F, and Module G. They all operate under the BABT Certification Regulations which may be found on the BABT web site.

1.8 Module B: Type Examination

Under this module a sample of your product is tested for compliance with appropriate standards listed for use with the MED (refer to MSN 1734 (including any relevant amendments current at the time of application for details) and a test report produced detailing the results.

BABT will evaluate this report against the requirements of the standard, the requirements of the MED, and correlate this with the build and user information for the product.

When BABT are satisfied all the necessary requirements are met a Module B Type examination certificate is issued.

Further details of the application requirements and process for type examination follow later in this document.

1.9 Module D: Production Quality Assurance

Under this module you must document and operate a quality assurance system such that all production items falling within the scope of the MED are compliant with the requirements of the MED with their performance traceable to the original tested sample.

The formal requirements for the scheme are listed in MSN 1734 (Annex B) including any amendments current at the time of application.

The BABT implementation of this Module is described in BABT 791. The assessment standard for this scheme is BABT AP008 BABT PS 340 (Production Quality Certification). For Module D Parts 1, 2 and Annex G of BABT AP008 BABT PS 340 apply.

Where you hold an existing Module D Certificate from another Notified Body you may apply to “Transfer” this to BABT for some or all your product scopes. Application details for transfers may be made using document BABT 789 (Application for transfer of a MED Module D or Module E Quality Management Certificate to BABT).

Normal Applications for Module D should be made using document BABT 339 (Application for MED Module D (Production Quality Assurance) or Module E (Product Quality Assurance) Certificate).

1.10 Module E: Product Quality Assurance

Under this module you must document and operate a quality assurance system relevant for a particular product/ or product range such that all production items in that range which fall within the scope of the MED are compliant with the requirements of the MED with their performance traceable to the original tested sample.

The formal requirements for the scheme are listed in MSN 1734 (Annex B) including any amendments current at the time of application.

The BABT implementation of this Module is described in BABT 791. The assessment standard for this scheme is BABT AP008 BABT PS 340 (Production Quality Certification). For Module E Parts 1, 2 and Annex H of BABT AP008 BABT PS 340 apply.

Where you hold an existing Module E Certificate from another Notified Body you may apply to “Transfer” this to BABT for some or all your products. Application details for transfers may be made using document BABT 789 (Application for transfer of a MED Module D or Module E Quality Management Certificate to BABT).

Normal Applications for Module E should be made using document BABT 339 (Application for MED Module D (Production Quality Assurance) or Module E (Product Quality Assurance) Certificate).

1.11 Module F: Product Verification

Under this module you identify the number of product items you intend to manufacture within a specified time. A product sampling plan is then agreed under which you will test the sample to an agreed test plan and supply the reports to BABT. These are inspected or tested (as appropriate) to ensure they are representative of the original tested products. Obligations remain upon the manufacturer with respect to individual unit inspection and test, product marking, and record retention. The formal requirements for the scheme are listed in MSN 1734 (Annex B) including any amendments current at the time of application.

Details of this scheme are provided in document BABT 741.

1.12 Module G: Unit Verification

This module is only suitable for single or very small numbers of production items. Each unit is examined and tested by the notified body for compliance to the standards and MED requirements. It is similar to the Type Examination module but since each item is examined has no requirement for production controls.

A Module G Certificate constitutes a Certificate of Conformity and permits the wheel mark to be affixed on products.

Further details of the application requirements and process for Unit Verification follow later in this document.

2. Making an application for a Type Examination Certificate or a Unit Verification Certificate

2.1 How to apply

The application is an order for BABT’s certification services and should be made direct to BABT in Octagon House .

Applications will be accepted by post, or email, to customer.services@babt.com.

The application must be made using form BABT 775 and must be accompanied by the required information to support the assessment. On receipt of your application, BABT will generate and send you a confirmation of the application.

Where TUV Product Service Ltd have taken the order for testing and certification you should discuss with your contact the best way to deliver the application to BABT.

Regular Customers of BABT may request an FTP upload address as an alternative to e-mail or post but must advise BABT Customer service when an application is fully uploaded.

2.2 Who can apply

Applications can be made by manufacturers or Authorised Representatives of equipment under the MED.

Normally the person making the application should be a duly authorised signatory of the applicant. Applications may also be made in the name of the manufacturer by an Authorised Representative or suitably authorised Agent.

Please note the Certificate will be issued listing the applicant company as holder. For Module B Certificates related applications for Modules D,E, or F have to be made in the name of the Module B Certificate holder.

2.3 Type of Application

2.3.1 Type

The application should be made for either Type Examination (Module B) or Unit Verification (Module G).

Applications may be made for either Original Certificates, Modifications to existing Certificate, or a Certificate for Brand names of products.

2.3.2 Original Applications

The main information in this guide applies to applications for original certificates.

2.3.3 Modifications

Please refer to the section "Keeping your Type Examination Certificate up to date for specific information related to Modifications.

For Modification to Brandname products please also refer to the following section.

2.3.4 Brandname applications

Brand name products are normally the same as the original product with the exception of cosmetic difference (e.g. Labels, enclosure colours) and often follow the same production line processes as the original products. Brandname applications may only be made where a substantial amount of the testing applied to the original product still applies to the Brand name. (e.g. A Brand name product may have a different housing which would require additional EMC testing, but should not vary in functionality or key characteristics) .

Where there are any technical differences BABT reserve the right to require a brand name application be re-classified as an original application with original supporting data.

An Application for a Technical modification to a Brandname which is not also applied to the Original product may result in the link to the Original product being broken such that future test results cannot be read across from the original product.

A Brandname application must be accompanied by the following:

- A statement of the differences between the original product and the Brandname product
- Where some differences are not cosmetic
 - A justification for using test data from the original product
 - Additional relevant testing for the technical differences
- Where the Original product was not tested to the versions of the relevant standards current at the time of application for the Brandname certificate then either (or a selection of both) :
 - A justification showing the previous test results meet the requirements of the current issue of the standard; or
 - Testing to the updated standard (entirely or in part)

Where there are multiple Brand names, test results from other Brand names to the latest standard may be used provided there is evidence that permission from that holder has been given (It will not in this

instance be presumed even if the original holder is an agent for both)

- Where you have appointed an Agent a letter from the Manufacturer appointing them

The original Manufacturer may be appointed to act as the agent of the Brand name manufacturer. This may be beneficial where original and Brand name applications are made in parallel as the same person is authorised to make a response to common concerns in several applications.

- Where the Original Manufacturer is not the Agent of the Brandname holder then a letter from the original Certificate holder authorising the use of their test and technical data in support of the Brandname application. (Agents who are the Original Manufacturer are assumed to authorise themselves).
- Either
 - A copy of the Brandname User manual; or
 - A statement that the only changes (if any) to the Original Holder User manual will be changes related to the Product name and manufacturer.
- Any of the other items required for original application where they differ significantly with that of the original product.

3. Information required on the application form

3.1 Section A: Applicant Details

Section A.1 identifies the person within the organisation with whom BABT will communicate. The Company name and Address are used as the address for the Certificate.

Where you are an Authorised Representative applying under your own company name it is **MANDATORY** that you provide full contact details of the manufacturer including a contact name within the manufacturers company. This information must be part of the application.

Where you are a manufacturer established outside the Community it is recommended that you appoint an Authorised Representative within the community.

Where an Authorised Representative has been appointed please provide full contact details of the Authorised Representative on headed paper from the manufacturer.

You may identify a consultant/agent to act on your behalf who is not formally appointed as an Authorised Representative. BABT require that you include a formal letter appointing the Agent (on headed paper and signed by an responsible person within the applicant company). Note: BABT will require this for every instance you send in an application and do not assume that an authorised agent for one application is authorised for another. While BABT will accept legal power of Attorney appointments we do not require these.

3.2 Section B : Your Certification requirements.

3.2.1 Marine Equipment Directive Certification

For Type of Assessment and Type of Application refer above.

For Unit Verification we require to know the location where this will take place. Where you select Test Laboratory and TUV Product Service at Titchfield is the choice please just identify this with the application. For all "Other Locations" and Test Laboratories please provide the full postal address.

3.2.2 Recognition of Marine Equipment Directive Certificates in North America

Where you wish to also market the product in the USA you may require a US Coast Guard (USCG) number. Please indicate as appropriate if you wish BABT to allocate/obtain this. For certain Navigation products BABT are able to allocate this number under the terms of the MRA (Council Decision 2004/425/EC). Otherwise BABT are able to request the number from USCG making use of the Module B Certificate and supporting information.

Where you wish to also market the product in Canada you may require acceptance from Transport Canada Please indicate as appropriate if you wish BABT to obtain this making use of the Module B Certificate and supporting information.

Note: Where BABT allocate a number under the MRA there is no fee; otherwise an appropriate additional fee will be applied to cover the necessary work.

Where FCC and Industry Canada Approval is required separate applications for these may be made to BABT using the appropriate forms/mechanism. (See BABT Web site for details)

3.3 Section C: Product Details

3.3.1 Products Submitted

This information is normally used to identify the product on the certificate. BABT will check this information with other identifying information within the application; any unexplained differences will cause delays in certification.

3.3.2 Product Type

Please identify the product type of your equipment after making reference to the list of types of product at the start of this document. BABT are only appointed for certain types of products. If your type of product does not appear on the list please contact the Head of the BABT Certification body in advance of the application to make sure that BABT is able to progress the application.

For some products it is helpful if you provide additional information to assist in BABT understanding the scope of the certification. Please provide this information either on the form, or in a separate document.

3.3.3 Number of Production Items

Please provide this estimate.

3.3.4 Related Products

If your product is derived from one for which you currently hold a BABT Certificate and you wish to make use of any of the previous data please indicate this and provide the BABT Certificate number related to that product

While this could reduce the assessment time we will need a clear justification within the Technical file for the use of the earlier results.

Likewise for Brandname products or applications covering more than one model we require details of the differences between the models

Note: Where an application covers more than one model BABT may charge an additional portion of our fee for assessing the additional model(s).

3.4 Commercial Information

Please complete this information.

Clients applying directly to BABT (i.e. not through any other TUV Group office) who do not currently have approved credit facilities with either BABT or TUV Product Service UK must include a completed Credit Details Form with the application. Alternatively payment in advance is accepted. The appropriate forms may be downloaded from www.babt.com.

3.5 Agreement

This forms the contract with the Certification body. It must be completed and signed on or on behalf of the applicant. Normally it is signed by the listed main contact.

3.6 Annex A

This section is intended as a brief checklist of possible contents of a Technical File sent with the application. It is not mandatory that this annex be completed or included with the application form does not have to be included

Refer later for more details on the contents of a technical file.

4. Progressing the Application

When BABT has received your application and evaluated the initial information, we will:

- ask you to pay an application fee. The fee relates to the assessment of the application. Where you have identified a specific contact to whom to send the invoice it will be sent to them; otherwise it will be sent to the main contact;
- inform you of the BABT reference number assigned to your application. This number should be quoted in all further correspondence;
- review your application for completeness and consistency;
- Where information is missing from an application or the reviewing Engineer raises a query further work on that application will be suspended at an appropriate time and will only be resumed after the response. Where BABT is satisfied we will formally issue the Type Examination Certificate or Unit Verification Certificate (as appropriate). BABT will advise you when this occurs;
- If there is a significant shortfall which either cannot be remedied, or where the remedy is not submitted in a timely fashion BABT may dismiss the application. Note: If additional testing is required BABT will expect to be advised when this is due for completion;

Each certificate will detail the applicant, product identity(ies), and standards complied with; the certificate annex will detail information relevant technical information and the identities of the test reports.

Each Certificate has a validity of 5 years from the time of issue.

5. Information to accompany an application

5.1 General

You should submit a Technical Documentation File to accompany the application. This file shall contain all the necessary information to evaluate compliance to the requirements and to record the build status of the product in sufficient detail to ensure later verification against product supplied against that certificate.

The application supporting documentation should be submitted electronically as Adobe PDF, MS-Word, or jpg files (as applicable) in the required directory/folder structure.

Documentation identification and Issue status

All documents submitted electronically should be clearly named to indicate their purpose and contents. Documents submitted in paper format should be identified by document number and issue status (e.g. Issue number or date); For multi-page documents each page should hold such information and a page number indication.

5.2 Technical Documentation File Index

Where there are multiple similar files or the purpose of individual files is not immediately evident it is recommended that you provide an index to the information to assist with the review process.

5.3 Purpose of Equipment and identification of equipment

For multipurpose equipment, or systems where the functions are split between specific apparatus it is helpful if you include an expanded description of each item (Note: Extracts of sections of the supplied User Manual are not required.)

Where you are seeking a certificate including more than one model we need clear information identifying each model and the differences between models.

5.4 Block Diagram

You should include a block diagram showing the following dependent upon the complexity of the apparatus.

- points of connection to other apparatus, power sources, and antenna(s)
- any other radio/wireless interfaces
- indicators of key functionality
- connections to earth (protective or functional)
- For radio devices a diagram showing the frequency of all oscillators in the apparatus.
- For complex equipment with switching capabilities, include a cross connection matrix showing the possible connections through the equipment between the various ports and/or terminating stations, if relevant to the assessment

The provision of a block/circuit diagram is essential to help ensure that all parties quickly reach a common understanding of the relevant tests and certifications required

The block/circuit diagram should be accompanied by a brief technical description explaining how the equipment interacts with the communications networks concerned.

5.5 Circuit Diagrams and PCB layout Diagrams

Detailed circuit diagrams and PCB layout diagrams are required for all circuits which may have an effect on conformity.

Circuit Diagrams and PCB layout Diagrams must show all network or radio interface circuits, active speech processing devices, hybrids and transducers, line signalling components, power supplies, ports and all network-affecting circuit elements including any components providing user isolation. Circuit elements need only be shown in sufficient detail to explain the above. Circuit diagrams should match up with the actual samples submitted for certification.

5.6 Parts List (Bill of Materials)

Parts lists for those areas of circuit detail identified in the circuit diagrams and data sheets for any Radio Critical component.

Parts List: Critical tolerances should be identified where applicable and the manufacturers of safety-critical components, all transducers and components affecting the signal path, including all second sources, should be stated.

If more than one source of a critical component (e.g. line interface IC) is to be used, samples from all sources should be submitted for assessment

5.7 Software and firmware Versions

The version of any software and firmware supplied with the apparatus which may affect compliance with the certification requirements must be declared.

Software : Where the relevant software is installed separately from the hardware (e.g. device drivers in PCs) then installation conditions must be provided either as a part of the software installation package or in the user guide.

Where special software is provided to enable testing, then the version of such software must be recorded with a clear statement about the relationship of this software to the production sample.

5.8 Photographs or Illustrations

Photographs or illustrations showing the external features of the complete equipment are required where the user instructions/supplied Installation instructions do not include this information.

5.9 Compliance Strategy

You should include details of the compliance strategy. This should include

- details of the Standards and IMO regulations related to this product;
- any limitations in applicability of standards or tests that have been used

5.10 User Instructions

You should supply (in English) a draft or published set of User Instructions, and where relevant Installation Instructions. For complex equipment you may only include the sections of the user instructions relating to the compliance of the equipment with the standards and IMO regulations rations.

User Instructions should contain all the information for installation, use and maintenance required for conformance to the relevant standards, and should not give details of adjustments which can take the equipment outside compliance - unless it is made clear how to adjust the equipment to maintain compliance and that any non-compliant setting would invalidate the certification.

The presence of user instructions at the earliest stages of assessment, even if in draft form, will give you the best possible chance of an accurate test schedule being written rapidly and a smooth assessment.

If the User guide does not provide photographs or illustrations showing the external features of the complete equipment, this shall be provided separately

5.11 D of C

You should include a draft (or actual) Declaration of Conformity to Type within the Technical Documentation File. The format of the declaration should be as defined in EN ISO/IEC 17050-1. An example of a D of C is included in Annex A of this document.

6. Testing and test reports

6.1 Introduction

The Technical Documentation File must include a test report showing compliance with the appropriate standard. The test report must come from an acceptable source of test reports.

6.2 Requirements for Test Facilities

BABT normally require that the test reports are issued by a test laboratory accredited by UKAS or another national accreditation body where the scope of accreditation includes the required test report.

Where there is no laboratory with the required standard within its scope, or where there is a clear justification for making use of an unaccredited test facility which is not recognised by BABT you should contact BABT prior to commissioning testing.

BABT Recognised Test Facility (RTF) List.

BABT maintain a list of test facilities recognised by them for use within our certification schemes. This list includes externally accredited Test Laboratories and non accredited facilities which have demonstrated they meet the essential requirements of ISO/IEC 17025 (or equivalent) to BABT.

Details of acceptable sources of Test Data and RTF listing may be found in document BABT 766.

This document may be found on the BABT Web site : <http://www.babt.com>

7. Verification of the test program.

Where you opt to test at TUV Product Service UK and advise them this is with the intent of applying to BABT for a certificate we will allocate a BABT Certifier to confirm the commissioned testing is sufficient to demonstrate the compliance.

Where you choose another test facility you may request that BABT check the test program but will have to authorise the Test Laboratory to communicate with BABT, and to supply all supporting information to BABT.

7.1 On site testing (Testing outside a Test Organisation site)

Where you require on-site testing then you should advise BABT of the site where the equipment may be tested/inspected.

You should confirm whether the Testing organisation is suitably accredited/recognised to perform such tests outside their normal location.

If your selected Testing organisation does not hold suitable accreditation for testing outside their laboratory site you must request they identify the process by which they will ensure the validity of their intended testing and provide such to BABT in advance of the commencement of testing.

Where you are applying for Unit Verification and it is impractical to send the unit(s) for test at a test facility you should advise BABT of the site where the equipment may be tested/inspected.

Observation Testing:

Certain standards require specific display information. Manufacturers may with the agreement of BABT perform such tests at their own facility. The Results of the observation/inspection tests should be recorded in an appropriate report listing the requirements with compliance information. The report shall also include full evidence (e.g. Photographs) of a sample of the tests. BABT will reserve the right to request evidence of other selected tests.

Declarations

Where a standard permits compliance to a requirement be declared, or where BABT have agreed to accept such in lieu of test the Declaration must be made on company headed paper and signed by a person suitably qualified to make the declaration.

7.2 Requirements for un-accredited testing

Where you perform testing at a location (or on your own site) which is unaccredited for the particular test in addition to agreeing the location with BABT prior to the start of testing you shall:

- Where you have tested using the test methods invoked in the standards make a statement confirming this in the report
- Where you have used any test method not specified in a standard provide details of the test method followed (either in the report or separately)
- Provide details of the competence of the person performing the test (e.g. experience/training/qualification)
- Provide details of test equipment used and the calibration status of the equipment
- Provide Measurement Uncertainty values for critical tests

7.3 Supply of Information

BABT recommend that you as much of the supporting information for your product to your test facility as early as possible, preferably with a copy of your application to BABT. This will assist in the preparation of test plans and early identification of any differences within the documentation (e.g. Product Names, revision status).

7.4 Test Plans

Where you have not previously tested and submitted a type of product to BABT we recommend that you discuss your test plan with BABT in advance of commissioning the testing. This will reduce the risk of under or over testing and may assist in the evaluation of the submitted technical documentation.

7.5 Test Reports

The test report(s) must follow the requirements for test reports included within ISO/IEC 17025 clause 5.10 .

Where the build level of the sample tested differs from that for which certification is sought the Technical Documentation File must include a justification that the test results are representative of the build level listed in the application.

Related Products: Where the application (or set of applications) covers a range of related products the test reports shall be sufficient to cover the range taking into consideration the supporting documentation of similarity between products. Where differences in implementation could affect particular requirements testing to those requirements should take place on sufficient variants to cover each different implementation.

7.6 Aspects of Testing

7.6.1 Choice of Samples

You may submit a pre-production sample for testing if assessment is required before a production model is ready.

Where you are applying for certification for a range of models you should discuss with the test facility and/or BABT how best to minimise the amount of testing required (and so limit the cost) by choosing a representative model or models from the range for the full programme of tests.

However, in this situation more than others, close co-operation and detailed technical information are required in order to make the right choice. In certain cases, it may be necessary for the facility to see models other than the representative model(s), for identification and specific tests. For example, equipment which is electrically identical with a representative model but which has a different casing may require testing of the electrical, mechanical or acoustic properties of that casing.

Pre-production samples: Such a sample should be technically identical with the proposed production model except for minor substitute features. Examples are:

- fabricated parts for which moulding or castings are planned
- handmade items which will eventually be fully tooled
- differences in appearance, colour and arrangement of keys.

8. Certificates and Records

8.1 Certificates

Module B and G Certificates are issued with a 5 year expiry date and comprise of a front certificate sheet and an associated annex.

The following information is listed on the Certificate and Annex

- Applicant Company name and Address
- Manufacturers Company name and Address if different from the applicant
- Reference to the MED Product Type according to Annex A1.
- Product Name and Model identification (and for Unit Verification the serial numbers/unique identity of each item covered by the certificate)
- Date of Certificate Issue and Expiry
- BABT Notified Body Number (i.e. 0168)
- Standards to which the Product demonstrated compliance
- List of Documentation reviewed by the NB (e.g. Test Reports, User Information , Build Information)
- Name of any identified Authorised Representative
- Conditions of Validity
- Name and Signature of person within the Notified Body issuing the Certificate

8.2 Records

BABT maintain records of all the details on a certificate; of each submission and the resulting evaluation for 10 years after the last significant file activity.

The Manufacturer or his Authorised representative is required to maintain records the records defined in Module B (or Module G for Unit Verification) of the Directive for 10 years.

9. Regulatory Marking.

9.1 Options

9.1.1 Module B

Module B must always be paired with either Module D, E, or F. The product may only be marked with the Wheel mark by a manufacturer in possession of a pair of certificates covering Module B and one of the others.

9.1.2 Module G

Module G is a standalone option. Accordingly the Wheel Mark may be applied to units covered by the Module G certificate.

9.2 Wheel Mark

The Wheel mark in respect of the Directive shall be applied only equipment for which a valid Certificate of Conformity and Declaration of Conformity exists. This shall be followed by number of the Notified Body who have issued the Certificate covering the selected production conformity module and a year indication. The BABT notified body number is given in the example below.

The yy should be replaced by the last 2 digits of the year in which the wheel mark was placed on the product.

The formal definition and size constraint of the mark are given in MSN 1734 Annex C.



10. Annual Continuation of the Certificate

There is no annual fee for the continuation of either a Module B (Type examination) or Module G (Unit Verification) certificate. However modifications to certificates are charged for in line with the resource required to progress the change.

11. Keeping your Type Examination Certificate up to Date

11.1 General

Over the lifetime of a product and the supporting certificate, BABT understands that it is likely that you will want to make a number of changes.

Review each change: Whilst not all changes will be significant to the certification, each change, however small must be considered for its potential effects and their relevance to the certification and conformance to the relevant standards.

11.2 Authorisation of Changes to Certified Equipment and Certificate Information

11.2.1 General

Changes may be authorised by one of the following dependant on the category of change

- BABT or
- a BABT-appointed Certification Liaison Engineer (CLE) or
- the Holder acting on their own responsibility

Changes fall into the following broad categories:

- Changes to product supporting items unrelated to the product certification. This include such items as packaging, warranty cards, cabling for non-certified ports
- Changes to the Certificate unrelated to the product realisation (e.g. Address of Holder)
- Changes to aspects of the product solely covered by other certification schemes or requirements
- Changes to the certified product which are believed not to have potential to affect compliance to the requirements covered by the certificate
- Changes to the certified product which potentially affect the compliance to requirements covered by the certificate and thus need testing
- Changes to extend the scope of the certification (which may or may not entail changes to the product)
- Changes to Standards
- Expiry of the Type Examination Certificate

11.2.2 Certified Liaison Engineer(CLE)

You can nominate one of your own engineers or one of your manufacturer’s engineers as a CLE. This optional facility is a powerful feature of the scheme as it permits a fast track for some product changes while maintaining the integrity of the certification.

When appointed by BABT, the CLE acts on our behalf to assess design changes and component changes where these changes are within the scope of the authorising authority given to the CLE.

Full details of the CLE scheme are given in BABT document 731.

11.2.3 Changes to product supporting items unrelated to the certified product

Frequently the scope of the certification is less than the whole supplied product. Packaging, information sheets, cables for uncertified ports, and adapters often form a part of the finished manufactured product but are not usually relevant to the certification. These are normally not submitted as part of the product to be certified.

Items outside the scope of the certified product are not subject to any BABT control.

11.2.4 Changes to the Certificate unrelated to the product realisation

All changes to the name, or address of the Holder or the Authorised Representative must be advised to BABT. BABT will review the Change and if satisfied that the integrity of the Certification remains will up-issue the Certificate.

For such changes the Expiry date of the Certificate will remain the same as the previous issue.

Note: It is the responsibility of the Holder to identify every instance of Certificate which is affected by a change(e.g. Module B, Module D and C of C Certificates)

11.2.5 Changes to aspects of the product covered by other compliance schemes or requirements

Where the product has aspects of design necessary to comply with mandatory or optional requirements from other schemes, then changes within that area of design which do not impinge on an area covered by the BABT certification, may be made without redress to BABT.

Regulatory requirements: Certificate holders are required to maintain compliance with regulatory and legal requirements pertaining to their certified products at all times

11.2.6 Changes to the certified product which do not affect conformity to the certification requirements

Where a CLE has been appointed, changes which are within the scope of his/her authority will be assessed using the change control procedure agreed at the time of their appointment as a CLE. The CLE may authorise the change without involving BABT.

Where a CLE has not been appointed, you must send full details of changes to BABT for authorisation. If, exceptionally, BABT determines that testing is necessary, you will be advised. You may then negotiate directly with the test laboratory concerning the test work to be performed.

Modifications to embedded software: BABT may accept modifications to software, which is stored in memory within the certified product, provided that you can give an assurance that the new version does not affect conformance to the relevant standards and is uniquely identified. If BABT determines that testing is necessary you will be advised

11.2.7 Changes to the certified product which potentially affect conformity to the certification requirements covered by the certificate and thus need testing

Where a change to the certified part of a product requires testing BABT must authorise the change to enable the certification to be maintained.

You should either

- send full details of the changes and any supplementary information in duplicate to your test laboratory (with an instruction to forward one set with the completed test report to BABT) , and a copy of the covering letter (only) to BABT ; or
- send two duplicate packages one to your test laboratory and one to BABT. The letter to BABT should indicate your intended test facility.

In both cases it is your responsibility to ensure the resulting test report is sent to BABT.

When testing is required, you are not obliged to use the original test laboratory but may use any Test facility which meets the requirement for the original testing.

Version of standards to be used for Testing:

Changes of this type are considered to be intended to maintain the existing certification. Furthermore it is normal that only limited testing takes place to demonstrate continued compliance. As such the version of standards listed on the Certificate should be used. If this is not possible then BABT should be advised before testing is commenced to determine whether a new certification is required.

Where the change has been tested using standards listed on the Certificate the Certificate Annex may be up-issued without changing the Certificate front page, or altering the expiry information.

11.2.8 Changes to the certified product which extend the scope of the certification

Such changes must be advised to BABT prior to commissioning any testing.

BABT will determine whether this change may be progressed as above for “changes which potentially affect the conformity”, or whether a new Certification is required.

Where BABT determine a new Certification is required the product will be subject to the set of requirements (including Standards Issue) current at that time. Test Data obtained related to the original Certification may be used if still valid.

In such instances a “new” Module B Certificate would be issued with a new expiry date.

Where you extend the functionality of the product invoking differing standards, then you must obtain a “new” certificate.

11.2.9 Changes to Standards

While the Type examination Certificate remains within its expiry date there is no obligation to track changes to the standards listed.

If you wish to update your certificate to show later versions of a standard then this will require a new assessment using the set of standards current at that time which will result in a “New” Certificate with a new expiry date.

11.2.10 Expiry of the Type Examination Certificate

If you wish your certificate to be renewed you must present BABT with a full set of test data to a set of standards current at the time of the expiry. Where you use test reports obtained for the original certification it must be accompanied with a justification for its use with for the renewal.

You may either provide a completely new pack of supporting information, or a statement of the relevance of the previous documents to the current product.

11.2.11 Charges by BABT for processing changes.

In general charges are related to the amount of work required to perform the review and issue of documentation.

Where a complete review is required the standard fee for a new application will be made.

11.2.12 Documentation to accompany a request for change

You may advise BABT of a planned change to a product (or change requiring a variation to the Certificate) by e-mail, or letter to BABT Customer Service citing your Certificate number.

You must accompany this request with relevant information related to the type of change.

12. Changes to Unit Verification Products

In general since Certificates of Conformity based upon Unit Verification deal with a very limited number of units changes after the certificate is issued are not expected.

However should a situation arise where changes are required then the details of the change should be made to BABT who will assess whether any technical verification is required. A Fee appropriate to the effort involved will be invoiced.

Should additional unit items be required after the certificate has been issued a new application should be made to BABT. This may however refer to relevant details of the original application.

13. Monitoring by BABT

13.1.1 Causes for monitoring

Under the MED the Notified Body who issued the Certificate of Conformity have the primary responsibility for the Approval.

If BABT receives any complaints or significant concerns about a product for which BABT have issued a TEC we shall note the concern and forward the information to the Notified Body who issued the Certificate of Conformity. BABT will not progress any Changes or extension of Certification for that product until the issue is clarified by the Notified Body who issued the Certificate of Conformity.

Annex A Pro forma Declaration of Conformity

We,

.....
(manufacturer's name)

of

.....
.....
.....
(address)

declare under our sole responsibility that the product

.....
.....
.....
(detailed description of product including name, type, model and supplementary information such as lot, batch or serial number, sources and number of items)

to which this declaration relates, is in conformity with the following standards and/or other normative documents.

Type Examination Certificate Number

.....
(or Replace Type with Unit for Unit Examinations)

Standards:

.....
.....
.....
We hereby declare that the above named product is in conformity to all the relevant requirements of Directive 96/98/EC.

The following Notified Body is responsible for the product surveillance

Notified Body Number :

.....
.....
(name and address of Notified Body)

The technical documentation relevant to the above equipment will be held at:

.....
.....
.....
(name and address of EU representative)

.....
(name)

.....
(title)

.....
(signature of authorised person)

.....
(date)