



## **BABT Production Scheme 340**

**The Production Quality Certification Scheme for Manufacturers of  
Marine, Radio, Telecommunication Terminal Equipment and Electro-  
Technology Products**

BABT is the telecommunications certification body of



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## AMENDMENT RECORD

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### Issue 3 November 2003

Major amendments to improve the document for use with the ISO 9001:2000 standard and clarify its use with the various BABT Certification and Approval schemes.

Although this amendment has made significant changes to the structure of this document, great care has been taken to minimise the affect of the changes on existing PQC holders, allowing expansion of certification coverage as required by our Customers without compromising existing certifications. Specific production test requirements can now be added at the Customer's request.

Specifically the scheme is structured to allow manufacturers to be able to demonstrate by independent assessment that they have taken all measures necessary to ensure compliance of manufactured products with the technical documentation and requirements of the relevant European Directives and voluntary product certification schemes.

The scheme retains its structure as an independent certification allowing existing ISO 9001 certification to be taken into account where appropriate, but defining the minimum quality assurance controls necessary to support these requirements, in cases where the Customer does not wish to hold a separate QMS Certification.

Certification based on documentary approval prior to a certification visit will no longer be available to new applicants as this is no longer appropriate with the extended scope of the scheme.

### Issue 3 January 2004 ( Erratum 1)

Sub-clause 0.1.3 (Page 4) Correct referenced document number

Replace "AP 013" by "BABT AP015"

### Issue 4 March 2006

This issue is unchanged from the previous issue and erratum except for

- Minor Format changes
- Addition of references to Annex F requirements.

All requirement clause numbering from the previous issue has been retained.

The BABT RoHS Ready QMS Certification scheme is derived from and is referenced as Annex F of the PQC Scheme. All the requirements for this scheme are listed in document BABT AP008-F entitled "The BABT Production Scheme 340 for RoHS Compliance".

The general Quality System requirements are the same in both BABT AP008 and BABT AP008-F.

While BABT RoHS Ready QMS Certification will be separate from other Annexes, common surveillance Audits may be conducted to various Annexes including Annex F.

### Issue 5 January 2009

References to the RoHS Ready Scheme have been deleted.

References to the LVD and EMC Directives have been updated to the refer to the updated legislation.

References to EN60950 Edition 3 2000 are replaced with later references.

The Reference to EN 45014 has been replaced by a reference to EN ISO/IEC 17050-1:2004

The Reference EN45012 to has been replaced by a reference to EN 17021 which has superseded it.

References to ISO9001:2008 have been added with references to ISO9001:2000 noting the expiry date of the standard

### Issue 6 May 2010

Add Annexes G and H for Marine Equipment Directive Modules References to the RoHS Ready Scheme have been deleted.

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## PART 0

### INTRODUCTION

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#### 0.0 Scope

- 0.0.1 This document explains the operation of the BABT Production Quality Certification Scheme. This was originally designed to provide an independent assessment service for manufacturers of Radio, Telecommunication Terminal Equipment and other Electro-Technology products and components, including Power Supplies. This document also includes the requirements for Navigation and Radio equipment subject to the Marine Equipment Directive and manufactured under Modules D or E of that directive. These are subsequently referred to as “Products” throughout this document. The scheme is formally operated under the BABT Certification Regulations. . The current versions of these can be found on [www.BABT.com](http://www.BABT.com)
- 0.0.2 The R&TTE Directive 1999/5/EC provides various options for placing Radio and Telecommunication Terminal Equipment on the European market. This scheme is designed to support all of these options irrespective of the need for notified body involvement in the conformity assessment procedure.
- 0.0.3 The scheme provides a production certification assessment service for:
- Manufacture of product under the relevant annexes of the R&TTE Directive
  - Manufacture of product for Holders of FQA agreements under the R&TTE Directive
  - Manufacture of product approved under the BABT CNC scheme
  - Manufacture of product under the BABT Safety scheme
  - Manufacture of components for use in products certified under the R&TTE Directive
  - Manufacture of certain product types under Modules D and E of the Marine Equipment Directive
- 0.0.4 The scheme provides alternative levels of certification depending upon the type and extent of work that is performed and is therefore applicable to both manufacturers and sub-contract manufacturers. Customer specific production test requirements can be assessed and included within the certification.

#### 0.1 BABT Production Quality Certification

- 0.1.1 Certification to the requirements of this scheme will allow manufacturers to demonstrate by independent assessment that they have taken all measures necessary to ensure compliance of manufactured products with the technical documentation and production control requirements of the relevant European Directives, product approval schemes or Customer requirements as appropriate.
- 0.1.2 When an assessment is satisfactorily concluded, BABT issues a “Production Quality Certification” certificate clearly identifying the Scope of Certification of the manufacturing facility(s) together with an annex identifying, as relevant, the products and network interfaces addressed, any specific production tests included in the assessment, and any particular conditions associated with the certification.
- 0.1.3 Specific product tests are referenced in the certificate annex by ‘test number’ in order to negate the impracticality of listing numerous individual standards and tests. The test numbers relate to the tests as described in BABT document number BABT AP015, publicly available from BABT. A maintained listing of the relevant test descriptions will be available on the BABT website. New tests will be included in the list on request, but at the discretion of BABT, provided they reference publicly available standards.

- 0.1.4 In conducting its assessment, BABT will take account of valid **Third Party Quality System certifications to ISO 9001:2008** (or ISO 9001:2000 until 14<sup>th</sup> Nov 2010) **where such organisations hold a recognised accreditation to EN 17021**; hereafter referred to as **ISO 9001**. Such organisations are subsequently referred to in this document as “Third Party”. Any subcontract certification arrangements or mutual recognition arrangements operated by these organisations are specifically excluded.
- 0.1.5 The recognition of existing ISO 9001 certification is to avoid duplication of the assessment of general quality system requirements. BABT’s interest will be restricted in such cases to take account of the specific nature of the procedures relevant to this document. Notwithstanding BABT’s reduced involvement in these cases, satisfactory assessment will result in the issue of a Production Quality Certification certificate.
- 0.1.6 Exceptionally BABT may decline to recognise an existing ISO 9001 certification should we believe it not be in the best interests of the customer or the certification scheme.

Note: Existing Customers will be issued with the new style certificate automatically following their next routine assessment.

## 0.2 Production Quality Certification Requirements

- 0.2.1 Various certification options are defined in this document. The requirements defined in Parts 1 and 2 are applicable for ALL of these options.
- 0.2.2 Part 1 of this document sets out the basic pre-conditions for Production Quality Certification. Quality Systems that are certified by a recognised Third Party as complying with **ISO 9001** will meet these basic pre-conditions, and BABT will only assess the system maintenance elements and any identified areas of concern. Companies not holding a recognised certification will be audited directly against the requirements of this section.
- 0.2.3 Part 2 identifies the minimum additional requirements that must be met for certification under this scheme. This section, in combination with Part 1, identifies the core requirements of the scheme needed to support all PQC certifications, irrespective of the certification scope.
- 0.2.4 The annexes to this document reference the specific requirements applicable to the certification scopes listed in paragraph 0.0.3 above. Individual certifications may address one or more of these scopes. The purpose of the controls required by these annexes is to ensure that a manufacturer continues to supply products that:
- Are not materially different from those specified by the Customer
  - Are not materially different from samples used for conformity assessment against the requirements of relevant European Directives
  - Continue to comply with relevant European Directives on an ongoing basis.
  - Meet the safety and functionality requirements for relevant product certification schemes

These requirements apply in addition to those required by Parts 1 and 2 of this document.

- 0.2.5 Some of the specific requirements in the annexes reference tests that **MUST** be included in the certification in order to qualify for that specific certification scope. Other tests will be included, subject to satisfactory assessment, at the request of the Certification holder, where they wish to demonstrate additional assessed testing capability.
- 0.2.6 Production Quality Certification can only be issued when the requirements of at least one of the attached annexes are met in order to adequately define the scope of certification.

### 0.3 Definitions.

The following is a glossary of terms and definitions used throughout this document and its annexes:

#### **Certificate of Quality Registration**

The certificate granted by BABT when the requirements for Production Quality Certification described in this document have been met.

#### **Critical Components**

Critical Components are those components that have been identified during the design process, or during conformance verification testing, as having features that are critical to the ongoing compliance of manufactured product with the validated design requirements. Such critical components may be subdivided as follows:-

#### **Safety Critical Components**

Those components that have been identified as critical to ongoing compliance of the product with the requirements of:

- The low voltage directive (2006/95/EC), and in particular those components affording Protection consistent with the Principal Elements of the Safety Objectives (Annex I of the Low Voltage Directive)
- The health and safety requirements as defined in the requirements of Article 3.1 (a) of the Radio and Telecommunications Terminal Equipment Directive. (Directive 1999/5/EC of the European Parliament and of the Council).
- Any safety legislation, national or international, applicable in the particular areas or regions of the world in which the product is intended to be sold or used.
- Any safety legislation, national or international, applicable to the particular environment in which a product is intended to be used. (e.g. use in explosive atmospheres)

#### Examples of Safety Critical Components

(Note the definitions of words shown in Capitals are contained in clause 1.2 of EN 60950-1).

- Any component carrying alternating current in a PRIMARY (i.e. mains) CIRCUIT;
- Any component providing BASIC, SUPPLEMENTARY OR REINFORCED INSULATION between different categories of circuit within the equipment (e.g. transformers, optocouplers, relays);
- Protective devices (e.g. fuses);
- Insulating materials (e.g. printed wiring boards) where the FLAMMABILITY CLASSIFICATION is specified for safety;
- Insulating materials (e.g. transformer insulating tapes) where the Comparative Tracking Index (see 2N of EN60950) is specified for safety;
- Devices (e.g. fans, heatsinks) provided to maintain equipment temperatures within safe limits.
- Devices providing Network protection from excessive voltages
- Devices providing Network protection from ports for connecting other apparatus

- Devices providing User protection from the network
- Limiting devices, the failure of which could result in a safety hazard. (e.g. Power output limiters or circuitry limiting battery charging rates where excessive charging could result in overheating or explosion).

### **Safety Critical Sub-Assembly**

Any assembled collection of components containing 'safety critical components' as defined above, or any assembled collection of components or software, the overall condition of which could affect compliance of the final product with the relevant safety requirements as defined above.

### **EMC Critical Component**

Those components that have been identified as critical to ongoing compliance of the product with the requirements of:

- The EMC requirements as defined in the requirements of Article 3.1 (b) of the Radio and Telecommunications Terminal Equipment Directive, (Directive 1999/5/EC) of the European Parliament and of the Council.
- The EMC Directive (2004/108/EC)
- Any EMC legislation, national or international, applicable in the particular areas or regions of the world in which the product is intended to be sold or used.
- Any EMC legislation, national or international, applicable to the particular environment in which a product is intended to be used. (e.g. use in hospitals etc.)

#### **Examples of EMC Critical components.**

- Metallic screens and conductive sealing gaskets
- Screened connectors, cables, plugs and sockets, filter capacitors, ferrite beads etc.

### **EMC Critical Sub-Assembly**

Any assembled collection of components containing 'EMC critical components' as defined above, or any assembled collection of components, the overall condition of which could affect compliance of the final product with the relevant EMC requirements as defined above.

Examples of EMC Critical Sub-Assemblies

- Switch Mode Power Supplies
- Most sub-assemblies intended to operate at Radio frequencies.
- Sub-assemblies that involved EMC critical processes during their construction such as the fitting of conductive sealing gaskets or the tightening of EMC grounding screws to a specific torque etc.

### **Network Critical Component.**

Those components that have been identified as critical to ongoing compliance of the product with:

- Any interworking requirements as may be applicable under the requirements of Article 3.3 of the Radio and Telecommunications Terminal Equipment Directive. (Directive 1999/5/EC of the European Parliament and of the Council.)
- Any requirements relating to the use of the frequency spectrum (e.g. accuracy of frequency) as may be applicable under the requirements of Article 3.2 of the Radio and Telecommunications Terminal Equipment Directive. (Directive 1999/5/EC of the European Parliament and of the Council.)
- Any interworking or functionality requirements as defined in the relevant BABT scheme requirements, (e.g. CNC)
- Any particular interworking or functionality requirements as defined by the Customer.
- Any interworking or functionality requirements claimed within the published documentation for the product.

Examples of Network Critical Components

- DTMF Dialler / Receiver
- Radio Transmitter module

### **Network Critical Sub-Assembly**

Any assembled collection of components containing 'network critical components' as defined above, or any assembled collection of components or software, the overall condition of which could affect compliance of the final product with the relevant interworking and functionality requirements as defined above.

**Note:** Where critical components or sub-assemblies have been identified during the design and design verification processes, these should be identified in the product build documentation together with the particular features of such components giving rise to their criticality, and any special controls needed to ensure ongoing product compliance.

### **Certificate of Conformity**

A certificate provided by a supplier of products, components or sub-assemblies stating compliance with various parametric or order requirements. Such certificates should be dated, traceable to the particular products, components or sub-assemblies involved, and bear the authorising signature of the responsible person in the supplier's organisation. This should not be confused with a 'declaration of conformity' to an EU Directive.

### **CNC**

BABT's 'Certified for Network Connection' scheme as defined in document BABT 721, 'A Guide to the Certified for Network Connection Scheme'.

**Customer**

An organisation or person that receives a product. A customer could be internal or external to the organisation.

**Declaration of Conformity**

A formal document declaring that particular products satisfy the requirements of EU Directives that apply to them. The format for such declarations should be as defined in EN ISO/IEC 17050-1. This should not be confused with 'certificates of conformity' as defined above.

**EMC**

Electro-Magnetic Compatibility. References in this document to EMC requirements refers to the protection requirements contained in Directive 2004/108/EC (the EMC Directive), Article 3.1(b) of Directive 1999/5/EC (the R&TTE Directive) or other applicable directives and requirements as relevant to Customer requirements, regions of the world in which the equipment is to be used, and any particular environmental requirements relating to the defined usage of the product.

**ISO 9001 Certification**

Certification to the requirements of ISO 9001:2008 (or ISO 9001:2000 until 14<sup>th</sup> Nov 2010)), by a certification body holding accreditation to EN 17021 by an accreditation body recognised by BABT.

**Note:** For BABT to take account of an existing ISO 9001 certification within a PQC assessment, the scope of the certification must be relevant to that of the PQC.

**LVD**

Low Voltage Directive. Directive 2006/95/EC.

**Note:** Article 3.1(a) of the R&TTE Directive references the LVD Directive but with no voltage limit applying.

**Manufacturer**

For the purposes of this document, the term 'manufacturer' relates to the organisation seeking or holding Production Quality Certification.

**Note:** The term 'manufacturer' is used in a different context in other related documents, such as the R&TTE Directive. Care is therefore needed to avoid possible mis-interpretation.

**Fabricator**

The production phase of a product realisation may be performed by the person responsible for the product design for placing it on the market (Under new approach Directives [e.g. the R&TTE, or EMC Directives this person is referred to as the "Manufacturer"]; The production phase of a product realisation may also be performed by a sub-contract manufacturer. For applications for Marine Equipment Directive Modules D or E [including Annexes G or H of this document] 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-contract manufacturer or the product designer. .

**MED**

Marine Equipment Directive (96/98/EEC) with Amendments effective at the time of Audit

**Ongoing (or continuing) Compliance**

The ability of all manufactured product to comply with specified requirements as defined during the design, design verification and design validation processes. This would include the ongoing compliance with any essential requirements as defined in any declaration of conformity for the particular product concerned.

#### **PQA**

Production Quality Assurance.

In the context of the R&TTE this term is relates to an obsolete approval scheme operated by BABT under Directive 98/13/EC and earlier directives. The current PQC Scheme was developed taking this earlier Scheme as a basis.

In the context of the Marine Equipment Directive this relates to Module D which is the production phase and follows Module B. BABT as a Notified Body is responsible for approving and controlling the quality system for production, final product inspection, and testing.

The term PQA is not used in the body of this document except related to the Marine Equipment Directive.

#### **PQC**

Production Quality Certification. The scheme as defined in this document. The scheme allows manufacturers to demonstrate third party certification of their production processes, procedures, controls and tests, leading to ongoing compliance of their manufactured product with a range of product certification, Customer defined and Directive related requirements. Where this term is used it shall be construed as including the relevant requirements of the Marine Equipment Directive as supplemented in the relevant Annexes.

#### **PrQA**

Product Quality Assurance: In the context of the Marine Equipment Directive this relates to Module E which is the production phase and follows Module B. BABT as a Notified Body is responsible for approving and controlling the quality system for production, final product inspection, and testing.

#### **R&TTE**

The Radio and Telecommunications Terminal Equipment Directive, (Directive 1999/5/EC of the European parliament and of the Council).

**Note:** Of particular relevance are the essential requirements as defined in Articles 3.1(a) Health and Safety, 3.1(b) EMC, 3.2 Use of the frequency spectrum, and 3.3 Interworking, harm to the network and other related requirements that may be added by the commission at a later date under Article 15 of the directive.

#### **Relevant Annexes**

The annexes of this document that are applicable to the scope of the PQC certification requested or held by the manufacturer and defined in any PQC certificate issued to the manufacturer.

#### **This Document**

The whole of this document, inclusive of any relevant annexes as defined above.

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## PART 1

### PRE-CONDITIONS TO SUPPORT PRODUCTION QUALITY CERTIFICATION

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#### 1.0 Scope

1.0.1 This part describes the minimum level of general quality assurance control necessary to support the additional requirements as defined in Part 2 of this document and the relevant associated annexes.

**Note: For applications for Marine Equipment Directive Module D or E {Annexes G and H of this document} these requirements apply to the Fabricator rather than the Manufacturer unless specified otherwise.**

1.0.2 In the case of a Quality System certified to **ISO 9001**, the requirements of this Part are deemed to be met. BABT will however verify the effectiveness of the certification by reviewing the system maintenance elements. These are; internal audit, management review, corrective & preventative actions and customer complaints. It should be noted that relevant elements of the certified quality system may be verified if findings are indicative of a failing in those elements.

1.0.3 Where a recognised **ISO 9001** certification has been taken into account by BABT when granting PQC certification, the manufacturer must advise BABT immediately, in writing, of any changes to the validity or scope of the certification. The responsibility for this shall be clearly defined within the manufacturer's documented quality system.

#### 1.1 Quality System Requirements

The elements outlined below are the key requirements that must be in place if **ISO 9001** is **NOT held** by the Customer. The requirements are based on ISO 9001 and should be readily met by quality systems designed to comply with either ISO9001:2008 or ISO9001:2000 (until November 2010).

##### 1.1.1 Management Responsibility

The manufacturer's management with executive responsibility shall:

- a. define and document its policy for quality, including its objectives for, and commitment to, quality.
- b. define the responsibility and authority of all personnel who are involved in implementing the manufacturing quality requirements.
- c. review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of the manufacturer's stated quality policy and objectives. Records of such reviews shall be maintained.
- d. appoint a management representative who, irrespective of other responsibilities, shall have authority for:

ensuring that a quality system is established, implemented and maintained in accordance with this document; and

reporting on the performance of the quality system to the manufacturer's management for review and as a basis for improvement of the quality system.

#### 1.1.2 Quality Manual

The organisation shall establish and maintain a quality manual that includes:

- a. The scope of the quality management system
- b. The documented procedures established in support of the quality management system
- c. A description of the interaction between the processes of the quality management system

#### 1.1.3 Contract Review of requirements related to the product

The mechanism for generating and reviewing contract requirements related to the product shall ensure that:

- a. The product requirements are adequately defined
- b. Differences between the contracts and any previously expressed requirements are resolved
- c. The organisation has the capability to meet the defined requirements.

#### 1.1.4 Document and Data Control

- a. The documents and data shall be reviewed and approved for adequacy by authorised personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established.
- b. Changes to documents or data shall be reviewed and approved by the same functions/organisations that performed the original review and approval, unless specifically designated otherwise.
- c. Obsolescent documents shall be assured against unintended use and suitably identified if they are to be retained for any purpose.

#### 1.1.5 Process Control

- a. The manufacturer shall identify and plan all processes that directly affect product quality to ensure that they are carried out under controlled conditions. Documented work instructions shall be available as necessary.
- b. The manufacturer shall identify plan, and validate production processes that cannot be easily verified by subsequent inspection (e.g. soldering) and shall ensure that these processes are carried out under controlled conditions and by qualified personnel.
- c. The manufacturer shall demonstrate in-process inspection and final test procedures necessary to establish product conformity to the specified requirements.
- d. The manufacturer shall provide methods of handling, storage, packaging, preservation and delivery that prevent damage or deterioration to critical parts or products.
- e. Material and assemblies must be clearly identified throughout production with respect to their inspection/test status.

#### 1.1.6 Control of Inspection Measuring and Test Equipment

The manufacturer shall ensure that processes are in place for the control, calibration and maintenance of inspection, measuring and test equipment (including test software), whether owned by the manufacturer or otherwise, that is used to demonstrate conformance of the product to specified requirements. Calibration must be traceable to National or International Standards and must be recorded. In the event that traceability is not possible, then the methods used to calibrate the equipment must provide demonstrable confidence in the ability of the equipment to fulfil the required testing functions.

#### 1.1.7 Quality Records

The manufacturer shall establish and maintain records to demonstrate continued compliance with the specified requirements and the effective operation of the quality system. Records shall be maintained by the use of permanent media, with appropriate procedures for their security and integrity.

#### 1.1.8 Training

The manufacturer shall ensure that personnel performing activities related to conformance of the product with specified requirements are qualified on the basis of appropriate education, training and/or experience as required. Appropriate records of training shall be maintained.

#### 1.1.9 Internal Audits

The manufacturer shall establish and maintain documented procedures defining the responsibilities and requirements for planning and conducting audits, reporting results and maintaining records. Audits shall be implemented to verify whether quality activities comply with planned arrangements and to determine the continuing effectiveness of the quality system. Management shall take timely corrective action to eliminate any non-conformity identified, and follow-up audit activities shall verify and record the implementation and effectiveness of the corrective and preventative actions taken.

**Note: For Applications for Annex G or H under the Marine Equipment Directive this requirement applies to both the Holder/Applicant and the Fabricator where they are not operating the same quality system.**

#### 1.1.10 Customer Complaints

The manufacturer shall establish and maintain documented procedures for the handling of customer complaints. The implementation and effectiveness of the corrective and preventative actions taken shall be verified and recorded.

**Note: For Applications for Annex G or H under the Marine Equipment Directive this requirement applies to both the Holder/Applicant and the Fabricator where they are not operating the same quality system.**

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## PART 2

### ADDITIONAL REQUIREMENTS FOR PRODUCTION QUALITY CERTIFICATION

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#### 2.0 Scope

- 2.0.1. This part identifies the minimum additional requirements that must be met for certification under this scheme. In combination with Part 1, it identifies the core requirements of the scheme needed to support all PQC certifications, irrespective of the certification scope.

The requirements of this part **plus** those of the relevant annexes describe the requirements applicable for the individual certification scopes.

**Note: For applications for Marine Equipment Directive Module D or E {Annexes G and H of this document} these requirements apply to the Fabricator rather than the manufacturer unless specified otherwise.**

#### 2.1 Field of Application

- 2.1.1 Where complex or modular equipment is manufactured at more than one site, it is not necessary to demonstrate full compliance with this document at each site if the overall requirements are met in full and agreed by the customer.

#### 2.2 Quality System Requirements

##### 2.2.1 Management Responsibility

- a. A management representative shall be appointed having the responsibility and authority for the implementation of the overall requirements of this document as applicable to the scope of the PQC certification requested or held by the Company. (This may or may not be the person having the overall responsibility for implementation of the ISO 9001 requirements). Any change of management representative must be notified immediately to BABT.
- b. The quality system, procedures and processes, in so far as they affect compliance with the requirements of this document, shall be reviewed on at least an annual basis for their continuing suitability and effectiveness. Records of such reviews shall be maintained. (This may, or may not, be combined with an ISO 9001 QMS review as defined in Part 1 of this document. Where separate ISO 9001 certification is held, this requirement does not impose an annual review on the whole of the certified quality system, but only on those elements identified in this document and the relevant associated annexes)

##### 2.2.2 PQC Compliance Plan

- a. A BABT Compliance Plan (formerly known as BABT Quality Plan), or equivalent documentation acceptable to BABT, shall be produced to define and describe how compliance with this document is achieved within the manufacturer's quality system. The plan shall address all elements within the scope of the PQC certification, and be available as a controlled document in both English and the local working language. Supporting documented procedures and processes should be referenced.
- b. Where the Quality System is certified to **ISO 9001**, the Compliance Plan need only address Part 2 of this document and any relevant annexes. However, the third party certification body, registration number, and scope of certification are to be defined.

### 2.2.3 Document and Data Control

- a. Any changes to the documented Quality System, that affect compliance with the requirements of any part of this document and relevant associated annexes must be advised to and agreed by BABT before being implemented into the quality system.
- b. Where the application of clause 1.0.2 has been accepted by BABT, this change requirement only applies to those changes that affect compliance with the requirements of Part 2 of this document and any relevant associated annexes.

### 2.2.4 Purchasing / Receiving Inspection

The manufacturer shall ensure that purchased components, sub-assemblies or assemblies conform to the requirements as specified by the customer.

All critical components and sub-assemblies must be specified with respect to both their particular type and manufacturer. (Note: This does not prohibit purchase of such components or sub-assemblies from a distributor.) Where applicable, the requirement for a certificate of conformity shall be referenced in the purchase order or contract, together with any particular certification requirements.

The manufacturer shall establish a process to obtain assurance that received components are compliant with the specified requirements and ensure that incoming components, sub-assemblies or assemblies are not used or processed until they have been inspected or otherwise verified for conformance to the defined requirements. Verification shall be in accordance with documented procedures.

Critical components, on receipt, must be treated in one of the following ways:

- a. each batch must be accompanied by a C of C or other evidence stating that the components comply with their published specification and confirming that any agreed parameters have been 100% tested. Where applicable, for safety critical components / sub assemblies the Certificate of Conformity shall state that the electrical strength characteristics have been 100% tested.

**Note 1:** When critical components are purchased from a distributor obtaining the appropriately worded certificate of conformity may be difficult. In order to meet the Certificate of Conformity requirements it will be acceptable if a signed Certificate of 100% Test of the critical parameters is obtained from the manufacturer for the component, valid for 12 months, to support a distributor's commercial C of C that is received with each batch.

**Note 2:** When components are received as a 'kit of parts,' one certificate for each delivery of kits is acceptable in lieu of a set of certificates for the critical components. The certificate should identify the critical components concerned, confirm the basis of compliance with the requirements and confirm that records demonstrating compliance will be made available on request. (Such records may include C of Cs from the original component suppliers, test results or copies of contractual agreements as appropriate).

- b. the components must be supplied under a contract or agreement that imposes a quality control process to ensure the test requirements of clause 2.2.4 (a) are met. The contract or agreement should be reviewed with the supplier on at least an annual basis and a record of such reviews maintained.

**Note:** The above requirements still apply when critical components are supplied on a 'free-issue' basis by the Customer. In this situation, either each delivery should be accompanied by a C of C addressing the requirements of clause 2.2.4 (a) or a contract should exist with the Customer that includes the requirements of clause 2.2.4 (b)

- c. the manufacturer must procure the components in accordance with a published specification that includes their critical parameters and must inspect and test each batch of components on a sample basis to verify that they comply with that specification.

**Note:** These tests must be carried out on components selected in accordance with an internationally recognised sampling plan (e.g. MIL STD 105E, Level 2) with an AQL of 1.0 or better. The sample plan selected must have an “accept on 0 reject on 1” basis. Any samples found to be non-compliant shall be rejected. If the rejection criteria of the sampling plan are reached, the whole batch shall be rejected. Rejected batches shall not be subject to re-sampling without prior corrective action. Rejected batches may be 100% tested for all relevant parameters in order to accept fully tested items.

Components or sub-assemblies which have been recognised by BABT as certified or separately approved in their own right need only be checked to ensure that they are of the correct type, appropriately marked and undamaged. This includes components carrying the certification marks of BABT or TÜV PS. Components holding type approval from other nationally and internationally recognised organisations may also be accepted on this basis, provided that the type approval scheme includes regular assessment of the ongoing manufacturing capability within its requirements (e.g. BSI, UL etc.) and that a valid copy of the type approval certificate is obtained from the component manufacturer and held on file.

Any rejected critical items must be placed in a bonded (secure) store prior to being scrapped or re-worked. A bonded (secure) store should be a segregated area where controlled access is required to place and remove stock according to a published procedure, but does not necessarily have to be secured by lock and key.

#### 2.2.5 Process Control

The Manufacturer shall define and implement processes and controls to ensure and monitor product conformance to customer requirements, applicable European Directives, third party approval requirements, certification agency requirements and, where relevant, external standards.

#### 2.2.6 Quality Records

Retention times for quality records shall be clearly defined in the quality system documentation and be appropriate for the processes involved.

- a. The following records shall be retained for at least 1 year or until the next BABT audit whichever is the longer:
  - Inspection records (C of Cs etc.).
  - Test records.
  - Vendor audits of critical suppliers. (Where applicable)
- b. The following records shall be kept for at least 10 years after the last product has been manufactured:
  - The Quality Manual and BABT Compliance Plan(s) or equivalent documentation.
  - Details of any amendments to the Quality System documentation together with the notification of agreement from BABT where required (see Clause 2.2.3).
  - Reports from BABT on all routine surveillance audits and unannounced audits, and any product tests arising from such audits.

### 2.2.7 Internal Quality Audits

- a. The effective implementation of the quality system, procedures and processes, in so far as they affect compliance with the requirements of this document and any relevant associated annexes shall be verified at least once per calendar year by means of internal audit. The audit results and follow up actions shall be formally documented and made available to BABT on request. Where separate ISO 9001 certification is held, this requirement does not impose an annual audit on the whole of the certified quality system, but only on those elements identified in this document and the relevant associated annexes
- b. Where separate ISO 9001 certification exists, and the above audit is combined with an ISO 9001 QMS audit, the planning documents and audit records should clearly identify coverage of the individual requirements as defined in this document.

### 2.2.8 Listed Production Tests

Reference to specific tests may be included in the annex to the Certificate of Quality Registration at the Customer's request subject to compliance with the requirements of this clause. (see part 0 clause 0.1.3)

Individual test numbers will only be included where:

- a. Suitable measurement equipment is available to conduct the listed test. (In certain cases the certificate may contain a restriction. – e.g. 'customer supplied test equipment')
- b. Suitably trained personnel are available to conduct the test and relevant training records are available where appropriate.
- c. Suitable documentation and/or process controls are in place to ensure the traceability, repeatability and reliability of the test results. (Where test equipment is in storage, maintained calibration is not a requirement provided it can be demonstrated that adequate procedures and processes exist to ensure compliance with this requirement before the equipment is brought back into service)
- d. Procedures exist to ensure the notification to BABT of any change in circumstances affecting the test capability for the listed tests. (e.g. Trained personnel leaving the company etc.)
- e. The above has been verified by BABT either during external audit, or, in the case of additional tests not involving the need for additional training or new specialist test equipment, by verification of suitable submitted documentation. In the latter case, the testing will be witnessed during the next routine assessment visit.

NOTE: Production tests normally form part of an overall process to ensure ongoing compliance of manufactured product with the initial design requirements. or to confirm compliance with critical features such as safety isolation etc. As such, the testing invoked may not fully reflect a requirement in the original design standard.

## ANNEX A

### Supplementary Requirements for the Manufacture of Product under annex II of the R&TTE Directive

#### 1. Introduction.

This annex applies to the manufacture of product to be placed on the European market under the requirements of annexes II, III or IV of Directive 1999/5/EC, and for which a Declaration of Conformity with the relevant essential requirements of the Directive exists. The requirements outlined in this PQC scheme and annexure relate only to appropriate manufacturing controls as required by clause 6 of annex II of the Directive. They also address the Customer –Supplier interfaces in order to assure the operation of a suitable process of quality assurance and control leading to the ongoing compliance of the manufactured product with the validated design requirements. They do not address requirements related to the design, design verification or design validation associated with the preparation of declarations of conformity. The requirements of annex II of the Directive are invoked by both annexes III and IV of the Directive in full. As these annexes do not invoke any additional requirements in relation to the actual process of manufacturing the product, this scheme is appropriate for product placed on the European market under any one of these three annexes.

#### 2. Implementation.

2.1. In addition to the general requirements defined in Parts 1 and 2, the documented quality system shall:

- a. Include a policy statement on compliance with the relevant requirements of the R&TTE Directive.
- b. Define the person(s) responsible for the implementation of the requirements of the R&TTE Directive.
- c. Ensure that all personnel involved in implementing the requirements have appropriate knowledge, experience and training, in particular for the purposes of conducting product testing to demonstrate ongoing compliance with the essential requirements defined in Article 3 of the Directive.
- d. Reference the processes and procedures involved in ensuring ongoing compliance of the product with the essential requirements of the R&TTE Directive.

#### 2.2. Contract Review

Manufacturers of product that falls within the scope of the R&TTE Directive must ensure that adequate information is available, prior to commencement of manufacture, to define all the relevant processes and test procedures sufficient to ensure ongoing compliance of the product with the relevant essential requirements. Evidence that a Contract Review has been performed must be available which demonstrates that:

- a. Adequate information is provided defining the build standard of the product.
- b. A Declaration of Conformity to the R&TTE Directive exists for the product to be manufactured, traceable to the above build standard.
- c. Where relevant, submitted information includes details of the user information to be shipped with the product and any specific marking requirements for both the product and the packaging supporting the requirements of Article 6(3) of the Directive
- f. Full information is provided detailing any component parts or processes critical to compliance of the product with the essential requirements defined in Article 3 of the Directive, and that the capability exists to address any additional controls and processes required. Critical components must be specified by both the type and manufacturer used.

- g. Full details of any testing required to ensure the compliance of manufactured product with the essential requirements of Article 3 of the Directive has been provided and that adequate capability to conduct such testing is available. (Where 100% testing is not appropriate, applicable sampling rates shall also be defined)
- h. Full details of any CE marking to be applied to the product, (including all appropriate Notified Body numbers and, where applicable, the alert symbol) have been provided, together with authorisation to affix the marking as required by Article 12 of the Directive.
- i. Details of any additional ongoing compliance checks needed to ensure ongoing compliance with the essential requirements of the Directive have been provided and that any stop ship arrangements, should any non-compliances be identified as a result of such additional testing, have been agreed.

Note: For Original Equipment Manufacturers, such reviews could form part of the design release process, rather than being addressed in a separate internal contract review, however, under these circumstances, evidence must be available in the production facility that all the above issues have been adequately addressed and that relevant production personnel were present at such reviews.

### 2.3. Process Control Requirements

Prior to shipment of CE marked product to the Customer, the manufacturing processes must ensure that:

- a. The build standard of the product is as agreed with the Customer and matches the information supporting a valid declaration of conformity to the essential requirements of the R&TTE Directive.
- b. Any testing required to demonstrate ongoing compliance with the essential requirements of the R&TTE Directive has been satisfactorily completed with compliant results.
- c. Results of any periodic validation tests notified to the manufacturer do not indicate non-compliant results.
- d. No stop notices have been placed on the product by the Customer or other relevant authority.
- e. Any CE marking has been checked on an appropriate sampling basis for conformance with the requirements of Annex VII of the R&TTE Directive and includes the use of appropriate Notified Body number(s) and, where applicable, the alert symbol.
- f. The product is properly identified with type, batch and/or serial number and the name of the Manufacturer or person responsible for placing the product on the market.
- g. Non-compliant product cannot get into the marketplace, and any relevant marking is removed or obliterated either prior to disposal or during the disposal process. (e.g. Incineration).

**End of Annex A**

## ANNEX B

### Supplementary requirements for the manufacture of product for holders of FQA agreements under the R&TTE Directive

#### 1. Introduction.

This annex applies to the manufacture of certified product on behalf of holders of a Full Quality Assurance Approval with a notified body. The relevant requirements are defined in annex V of Directive 1999/5/EC. The requirements outlined in this PQC scheme and annex relate only to appropriate manufacturing controls and the Customer –Supplier interfaces in order to assure the FQA holder of the operation of a suitable process of quality assurance and control leading to the ongoing compliance of the manufactured product with the essential requirements of the Directive. They do not address requirements related to the design, design verification or design validation associated with the preparation of declarations of conformity. Manufacture of the product is only one part of the overall process and it is the FQA holder's responsibility to ensure overall compliance with the requirements. In this context, contract review becomes a 'Key Issue' as it is essential that the processes conducted by product manufacturer are adequately defined, integrated, controlled and visible to the FQA holder.

#### 2. Implementation.

2.1 The requirements of Annex A to this document apply in full, with the following clarification.

a. Where CE marking is applied to the product, this shall include the notified body number. (0168 for BABT), and, where applicable, the alert symbol. The correct notified body number should be agreed during the contract review process.

2.2 The FQA holder shall be allowed all reasonable access to the production facility for the purposes of auditing the manufacturing quality system, quality controls and tests applied to the certified product, or investigating any associated complaints, problems or concerns.

2.3 The manufacturer shall implement a process to ensure that FQA holders are notified of all changes to the manufacturing processes affecting the manufacture of their certified product prior to their introduction.

2.4 The means of addressing any changes to the build standard of the product and/or to the agreed production test and manufacturing process requirements shall be agreed during the contract review process, together with the names, authorities and signatures of the relevant responsible personnel.

**Note:** As an FQA holder has the overall responsibility for compliance with the requirements of annex V of the Directive they may invoke additional requirements on a manufacturing sub-contractor to those identified in this document.

**End of Annex B.**

## ANNEX C

### Supplementary requirements for the manufacture of product approved under the BABT CNC Scheme

#### 1 Introduction.

This annex addresses the manufacture of products holding BABT CNC Certification, supporting the use of the BABT Octagon Marks

BABT Production Quality Certification is used to demonstrate the operation of suitable processes of quality assurance, quality control, manufacturing process control and manufacturing testing, leading to the ongoing compliance of the certified products with specific parametric requirements agreed with BABT as relevant to the individual products concerned.

The extent of production testing required and the parameters to be tested are verified against a production 'test plan' agreed with BABT.

Guidance relating to the overall requirements of the CNC is given in document BABT 721, 'A Guide to the BABT Certified for Network Connection Scheme'.

#### 2 Implementation.

2.1 In addition to the general requirements defined in Parts 1 and 2, the documented quality system shall:

- a. Include a policy statement on compliance with the relevant requirements of the BABT CNC Scheme.
- b. Define the person(s) responsible for the implementation of the above requirements.
- c. Ensure that all personnel involved in implementing the requirements have appropriate knowledge, experience and training, in particular for the purposes of conducting product testing to demonstrate ongoing compliance with the CNC requirements as detailed in the relevant product test plans and related CNC certificates.
- d. Reference the critical processes and procedures involved in manufacture of product that ensuring the ongoing compliance of the product with the defined requirements as listed in the annexes to the relevant CNC certificates.

2.2 Contract Review

Manufacturers must ensure that adequate information is available, prior to commencement of manufacture, to define all the relevant processes and test procedures sufficient to ensure ongoing compliance of the product with the relevant CNC requirements. Evidence that a Contract Review has been performed must be available which demonstrates that:

- a. A CNC Certificate and Annex exists for the product to be manufactured
- b. A production test plan, agreed with BABT, exists for the product to be manufactured.
- c. Adequate information is provided defining the build standard of the product.
- d. Where relevant, submitted information includes details of the user information to be shipped with the product and any specific marking requirements for both the product and the packaging.

- e. Full information is provided detailing any component parts or processes critical to compliance of the product with the relevant CNC requirements, and that the capability exists to address any additional controls and processes required. Critical components must be specified by both the type and manufacturer used.
- f. Adequate capability is available to conduct the testing as defined in the production test plan agreed with BABT. (Where 100% testing is not appropriate, applicable sampling rates shall be defined)
- g. Full details of any marking to be applied to the product, have been provided, (e.g. A BABT Octagon mark, with a CNC segment.), together with authorisation to affix the marking and any associated conditions that must be met prior to applying the mark.

Note: For Original Equipment Manufacturers, such reviews could form part of the design release process, rather than being addressed in a separate internal contract review, however, under these circumstances, evidence must be available in the production facility that all the above issues have been adequately addressed and that relevant production personnel were present at such reviews.

### 2.3 Process Control Requirements

Prior to shipment of certified product to the Customer, the manufacturing processes must ensure that:

- a. The build standard of the product matches the information supporting a valid a valid BABT CNC Certificate. Any changes to this build standard must have been agreed with BABT or a BABT appointed CLE.
- b. Any testing required to demonstrate ongoing compliance with the relevant CNC requirements as defined in the agreed production test plan, has been satisfactorily completed with compliant results.
- c. Results of any periodic validation tests notified to the manufacturer do not indicate non-compliant results.
- d. No stop notices have been placed on the shipment of the product by the Design Department, the Quality Assurance/Quality Control Department, the Customer, BABT or other relevant authority.
- e. Any marking associated with the CNC scheme has been checked on an appropriate sampling basis for conformance with the relevant marking requirements
- f. The product is properly identified with type, batch and/or serial number and the name of the Manufacturer or person responsible for placing the product on the market.
- g. Non-compliant product cannot get into the marketplace, and any relevant marking is removed or obliterated either prior to disposal or during the disposal process. (e.g. Incineration).

**End of Annex C**

## ANNEX D

### Supplementary requirements for the manufacture of product approved under the BABT Safety scheme

#### 1 Introduction.

This annex addresses the manufacture of products or components holding BABT Safety Certification, supporting the use of the BABT safety and Octagon Marks. BABT Production Quality Certification is used to demonstrate the operation of suitable processes of quality assurance, quality control, manufacturing process control and manufacturing testing, leading to the ongoing compliance of the certified products or components with specific safety requirements as listed in the annexes to the relevant product or component certificates.

The normative document used for the assessment of electrical safety compliance by BABT is EN 60950 (Latest version – See the Official Journal of the European Communities for the validity dates of previous versions of this standard). Other standards, or versions of this standard, may also be used as relevant.

Many factors may affect the safety of product and compliance with the requirements of the low voltage directive (2006/95/EC). Compliance with the requirements listed in this scheme can not be taken to imply compliance with the requirements of the LVD, but rather that an appropriate manufacturing environment exists in which to control the critical compliance factors listed in the product and/or component certificates.

It should be noted that for product falling within the scope of the R&TTE directive, (1999/5/EC), Article 3.1(a) of this directive invokes the health and safety requirements contained in the low voltage directive, but with no lower voltage limit applying.

This annex also addresses the requirements of Annex R2 of EN 60950-1:2006 in so far as these are applicable to any manufactured product or component.

Production Quality Certificates used to demonstrate compliance with the additional R2 requirements must include 'Manufacture of products under the BABT Safety scheme' within the defined scope and include the following statement:

'Includes a documented program of quality control and testing supporting the use of the reduced clearance distances permitted by tables, 2J, 2K, 2L and G2 of EN 60950-1:2006, and providing assurance (or equivalent assurance) to that required by Annex R2 of this standard for specific product types as documented in the compliance plan.'

This additional statement will be included on request subject to the satisfactory demonstration of compliance with the additional requirements.

#### 2. Implementation.

2.1. In addition to the general requirements defined in Parts 1 and 2, the documented quality system shall:

- a. Include a policy statement on compliance with the relevant requirements of the BABT Safety Certification Scheme and the Low Voltage Directive.
- b. Define the person(s) responsible for the implementation of the above requirements.
- c. Ensure that all personnel involved in implementing the requirements have appropriate knowledge, experience and training, in particular for the purposes of conducting product testing to demonstrate ongoing compliance with the safety requirements as detailed in the relevant product or component certificates.
- d. Reference the critical processes and procedures involved in manufacture of product that ensuring the ongoing compliance of the product with the specific safety requirements as listed in the Annexes to the relevant product or component certificates.

2.2. Products, or types of product, making use of the requirements of Annex R2 of EN 60950-1:2006 shall be referenced in the compliance plan as advised to and agreed by BABT. The plan should identify the critical clearances concerned, together with the inspection, test and sampling criteria used to demonstrate continuing conformance with the requirements. As an alternative to the requirements defined in table R2 of EN 60950-1:2006, inspection, testing and process controls providing an equivalent level of assurance may be documented and submitted to BABT for agreement. Written confirmation of BABT's acceptance should be maintained on file for a period of 10 years after the last product has been manufactured. Records to demonstrate compliance with the agreed procedures must also be maintained for a similar period.

### 2.3 Contract Review

Manufacturers must ensure that adequate information is available, prior to commencement of manufacture, to define all the relevant processes and test procedures sufficient to ensure ongoing compliance of the product with the relevant safety requirements. Evidence that a Contract Review has been performed must be available which demonstrates that:

- a. Adequate information is provided defining the build standard of the product.
- b. A copy of the relevant product/component certification(s) exists for the product to be manufactured, traceable to the above build standard.
- c. Where relevant, submitted information includes details of the user information to be shipped with the product and any specific marking requirements for both the product and the packaging.
- d. Full information is provided detailing any component parts or processes critical to compliance of the product with the relevant safety requirements, and that the capability exists to address any additional controls and processes required. Critical components must be specified by both the type and manufacturer used.
- e. Full details of any testing required to ensure the compliance of manufactured product with the relevant safety requirements has been provided and that adequate capability to conduct such testing is available. (Where 100% testing is not appropriate, applicable sampling rates shall also be defined)
- f. Full details of any marking to be applied to the product, have been provided, (e.g. CE mark, BABT Octagon mark, BABT Safety mark etc.), together with authorisation to affix the marking and any associated conditions that must be met prior to applying the mark.
- g. Details of any additional ongoing compliance checks needed to ensure ongoing compliance with the relevant safety requirements have been provided and that any stop ship arrangements, should any non-compliances be identified as a result of such additional testing, have been agreed.

**Note:** For Original Equipment Manufacturers, such reviews could form part of the design release process, rather than being addressed in a separate internal contract review, however, under these circumstances, evidence must be available in the production facility that all the above issues have been adequately addressed and that relevant production personnel were present at such reviews.

### 2.4. Process Control Requirements

Prior to shipment of certified product to the Customer, the manufacturing processes must ensure that:

- a. The build standard of the component/product matches the information supporting a valid BABT Safety Certificate. Any changes to the build standard as defined in the BABT certificate must have been agreed with BABT or a BABT appointed CLE.
- b. Any testing required to demonstrate ongoing compliance with the relevant safety requirements has been satisfactorily completed with compliant results.
- c. Results of any periodic validation tests notified to the manufacturer do not indicate non-compliant results.
- d. No stop notices have been placed on the shipment of the product by the Design Department, the Quality Assurance/Quality Control Department, the Customer, BABT or other relevant authority.

- e. Any BABT and/or CE marking has been checked on an appropriate sampling basis for conformance with the relevant marking requirements
- f. The product is properly identified with type, batch and/or serial number and the name of the Manufacturer or person responsible for placing the product on the market.
- g. Non-compliant product cannot get into the marketplace, and any relevant marking is removed or obliterated either prior to disposal or during the disposal process. (e.g. Incineration).

## 2.5 Final Test Requirements

2.5.1. All equipment or components incorporating isolation barriers or utilizing protective earth connections for one or more of the purposes listed below must be tested during production in accordance with the requirements of clauses 2.5.2 to 2.5.8 below:

- i. network protection from excessive voltages; or
- ii. network protection from ports for connecting other apparatus; or
- iii. user protection from the network; or
- iv. protection consistent with the Principal Elements of the Safety Objectives (Annex A of the Low Voltage Directive)

2.5.2 All safety tests appropriate to a particular product must be performed on a 100% basis.

2.5.3 Safety testing should normally be performed on completed product after final assembly. Should this not be practicable, testing at an earlier stage will be considered. In this case the overall testing plan will need to be submitted to BABT for approval.

2.5.4 The extent of the safety tests may vary according to the type and construction of the product. They shall generally be in accordance with the requirements of Table 1 of this annex and the associated notes. Alternative test arrangements, where circuit configuration or risk of damage prevents the direct application of Table 1, should be agreed with BABT. Test methods must ensure that barrier devices are not tested in series. Isolation components being tested in their own right should be tested in accordance with their published specification rather than the test voltages detailed in Table 1, however the same test principles apply.

2.5.5 All equipment, together with test connectors, jigs, connecting leads (including those specific to a product under test), etc., which is used to perform safety testing must be subjected to a regular confidence check by simulating "just fail" conditions. The "just fail" load should be applied across all the points of test and should be of a value such as to cause the trip current of the test equipment just to be exceeded, giving a "fail" indication if the test equipment is operating correctly. These confidence checks should be performed at intervals that will allow previous production to be re-tested if incorrect functioning is detected

2.5.6 The results of the confidence checks must be formally recorded along with a reference to the person performing the test. The "just fail" load must be calibrated and included in the formal calibration system.

2.5.7 Any equipment that requires adjustment/re-work or fails any of the safety tests must be fully re-tested for both safety and functionality.

2.5.8 It is normally expected that safety testing would be conducted before final functional testing. Any exceptions to this requirement should be agreed in writing by BABT.

- 2.5.9 For all equipment incorporating acoustic interfaces, where acoustic shock protection relies on specific components and possibly their correct orientation, the integrity of such components and their correct orientation must be verified at some stage during the production process. (eg. By in circuit testing of PCBs or the execution of an acoustic shock test on the final product in accordance with the requirements of Table 1 test S7)
- 2.5.10 For equipment or components dependant on the requirements of Annex R2 of EN 60950-1:2006, the requirements of clauses 2.5.10 (a) to (d) below also apply:
- a. Relevant Electric strength testing as defined above shall be conducted on a 100% basis on the final product in all cases
  - b. Where clearance distances are measured directly these will be measured on a sample basis (AQL 4%, 95% confidence level or better). The use of properly calibrated gauges is suitable for this purpose. Reject batches shall be subject to full investigation and rectification of the cause prior to the shipping of any product.
  - c. Any samples used for the verification of breakdown voltage shall be appropriately marked, discarded and scrapped.
  - d. Any additional electric strength testing performed for the purpose of demonstrating compliance with the requirements of Annex R2 of EN 60950-1:2006 shall be conducted under the same conditions and controls as those defined in clauses 2.5.1.1 to 2.5.1.5 above. (Note that where testing is conducted only 100 volts below the breakdown level the accuracy and repeatability of the test voltage may be critical in order to ensure that the testing does not damage or cause partial damage to the product. BABT would assess both the process and calibration controls in this area to ensure suitability for purpose.
- 2.5.11 Where the possibility of other safety hazards exists in any particular certified product, appropriate production controls should be agreed with BABT in order to ensure ongoing compliance of the product with relevant safety requirements and legislation. Such controls may include final product testing either on a 100% basis or on a sample basis when combined with other relevant production process controls. (eg. SAR testing for GSM product, verification of charging circuitry for rechargeable batteries etc.)

## ANNEX D TABLE 1

## ELECTRICAL AND ACOUSTIC SAFETY TESTS

No	Test Connection Points	Test Title	Test Condition	Test Limits	Notes
S1	Connection Point 1: Main protective earth connection within equipment. Connection Point 2: Other user accessible parts of equipment that have been connected to protective earth for safety reasons (and are hence protectively earthed).	Earth Continuity	Max. test voltage: 12V ac or dc Min. test current: 1.5 times current rating of the primary fuse. Max. Test Current 25A	Measured Resistance to be 0.1 ohm or less.	1, 2, 3, 12-15
S2	Connection Point 1: Live and Neutral conductors shorted together. Connection Point 2: Protective earth connection.	Electric Strength for Basic Insulation	Test Voltage: 1500V ac or 2121V dc Test time: 2 seconds min. 6 seconds max.	No breakdown	4, 7, 8, 9, 10, 12-15
S3	Connection Point 1: NTP connectors shorted together. Connection Point 2: Conductive parts separated from the NTP by Basic or Supplementary Insulation, shorted together.	Electric Strength for Basic and Supplementary Insulation	Test Voltage: 1500V ac or 2121V dc Test time: 2 seconds min. 6 seconds max.	No breakdown	5, 7, 8, 10, 12-15
S4	Connection Point 1: Live and Neutral conductors shorted together. Connection Point 2: Unearthed User accessible conductive parts or unearthed SELV outputs of a power supply shorted together.	Electric Strength for Reinforced Insulation	Test Voltage: 3000V ac or 4242V dc Test time: 2 seconds min. 6 seconds max.	No breakdown	6, 7, 8, 9, 10, 12-15
S5	Connection Point 1: Live and Neutral conductors shorted together. Connection Point 2: NTP connectors that are not protectively earthed, shorted together.	Electric Strength for Reinforced Insulation	Test Voltage: 3000V ac or 4242V dc Test time: 2 seconds min. 6 seconds max.	No breakdown	6, 7, 8, 9, 10, 12-15
S6	Connection Point 1: NTP connectors shorted together. Connection Point 2: Conductive parts, protective earth and auxiliary ports complying with the limits of SELV shorted together	Separation between interface I <sub>a</sub> and user accessible parts	Test Voltage: 1000V ac or 1414V dc Test time: 2 seconds min. 6 seconds max.	No breakdown	10,11, 12-15
S7	Where acoustic shock protection relies on specific components and possibly their correct orientation then the integrity of these circuits must be verified.	Acoustic Shock	BS 6450: Part 2: 1983: Clause 6.2.10 or TBR8: Annex C or BS 6317: 1982: Clause 13.9 or 85/013: Issue 4: Clause 5.2.9	+24dBPa	14
S7 A	Alternative test	Acoustic Shock	EN50332-1 Clause 6.5 or EN50332-2 Clause 6.2.5	100dB Max spl or 90dB L <sub>a</sub> eq (as applicable)	17



**Electrical Safety Tests: Notes**

1. The test as described is for Class I equipment, i.e. equipment that relies on a protective earth connection for providing safety.
2. As an alternative location for connection point 1 for equipment incorporating a mains supply cord, the supply earth connection (normally the earth pin of the mains plug) of the cord shall be used. In this case the measured resistance shall be not greater than  $0.1 + R$  ohm, where R is the resistance of the earth lead within the supply cord.
3. On equipment where the protective earth connection to a sub-assembly, or to a separate unit, is by means of one core of a multicore cable that also supplies mains power to that sub-assembly or unit, the resistance of the protective earthing conductor in that cable shall not be included in the resistance measurement (as is the case with the mains cord resistance, see note 2). Where the cable is protected by a suitably rated protective device (which takes into account the impedance of the cable), the minimum test current may be reduced to 1.5 times the rating of this protective device.
4. The test as described is for Class I equipment. Normally the protective earth connection is the earth pin of the mains plug.
5. This test is applicable to Network Terminating Points (NTPs) connecting to either analogue or digital networks, but see note 11.
6. Where the user accessible conductive part, or the NTP connection, is isolated from primary circuits by Reinforced or Double insulation, but is either:
  - (a) connected to protective earth for functional reasons or,
  - (b) separated from protective earth by less than supplementary insulation.

then it may not be possible to conduct this test without overstressing Basic insulation (which is only designed to withstand 1500Vac, for further explanation see the relevant notes to EN60950-1, Clause 5.2.2). In this case, the individual components providing the Reinforced or Double insulation shall be tested in accordance with test No.5, but the finished equipment may be tested in accordance with test No.2. When testing such finished equipment, any user accessible conductive parts that are not connected to earth in the equipment shall be connected to protective earth when performing test No.2.

7. The test voltage specified may be increased at the discretion of the manufacturer. However, BABT do not require any higher test voltages.
8. The pass/fail criteria for electric strength tests are that no breakdown shall occur. In practice the trip current on the test instrument will need to be set so that it does not trip when subject to the normal leakage current (predominant for a.c. testing) or insulation resistance current for the equipment and test voltage concerned. Trip current levels should be set to a minimum practical level.
9. For an item of equipment supplied with a UK 13A mains plug having a leakage of 3.5mA or less, the following maximum trip currents are acceptable in accordance with EN 60950. For hand-held class II equipment lower trip currents are appropriate. Please see EN60950-1: Clauses 5.1.6 and 5.1.8.

Test Voltage	1500 Vac	3000 Vac	2121 Vdc	4242 Vdc
Trip Current	42mA	84mA	1.5mA	3.0mA

10. The two-second minimum for the test duration shall apply where operator judgement against a time standard is used. Where the timing is carried out automatically, the minimum test time may be reduced to one second



(The one second minimum is in accordance with the note regarding production tests in EN60950-1 Clause 5.2.2). The six-second maximum is advisory, however BABT deprecate longer production test times and repeated electrical strength testing as they can cause damage to insulation.

11. This test is applied only to Digital Terminating Equipment as an option to test 3.
12. Where appropriate, the sequence of safety tests shall be Earth Continuity followed by Electric Strength.
13. Where the integrity of each test may be demonstrated, it is possible to combine certain of these tests.
14. Where tests on sub-assemblies have been conducted under BABT surveillance, it is not necessary to re-test the complete assembly if overall compliance with the appropriate tests is demonstrated to BABT and if final assembly arrangements do not affect the integrity of the sub-assembly tests.
15. When the above tests are to be applied to Power Supply Units the low voltage outputs are considered to be the NTP
16. The tests listed in Table 1 are the same numbered tests as listed on BABT website.
- 17: The appropriate test and limit depends upon the equipment in manufacture.

**End of Annex D**

## ANNEX E

### Supplementary requirements for the manufacture of components for use in products certified under the R&TTE Directive

#### 1. Introduction.

This annex applies to the manufacture of components for use in products that have been certified under the R&TTE Directive. The overall responsibility for compliance of the final product with the essential requirements defined in article 3 of directive 1999/5/EC resides with the manufacturer or person placing the product on the European market. There are also requirements to have appropriate quality controls in order to ensure ongoing compliance of the product with these essential requirements. Such controls would, by inference, also relate to various components having a critical function within the product. The requirements outlined in this PQC scheme and annex relate only to appropriate manufacturing controls and the Manufacturer - Customer interfaces in order to assure the component user of the operation of a suitable process of quality assurance and control leading to the ongoing compliance of the manufactured components with the relevant specification requirements as agreed by the user. They do not address requirements related to the design, design verification or design validation associated with the preparation of declarations of conformity.

#### 2. Implementation.

2.1 For 'Relevant Components' and components certified under the BABT safety scheme, the following requirements apply in addition to the general requirements defined in Parts 1 and 2.

- a. For 'Relevant Components' coming directly within the scope of Directive 1999/5/EC, the requirements of Annex A or Annex B of BABT AP008 apply in full. There are no other requirements in this annex. (Note: The term 'relevant component' is defined in article 2 of directive 1999/5/EC. For information, this is taken to refer to a part of a product that performs the communications function if this is not the whole function of the product.)
- b. For components certified under the requirements of the BABT safety scheme, the requirements of Annex D apply in full. Additional requirements may apply in this section if the component has 'network critical' in addition to 'safety critical' features. (e.g. a certified line transformer providing both isolation and an impedance/level matching function)

2.2 For components that are not 'Relevant Components' and not certified under the BABT safety scheme, the following requirements apply in addition to the general requirements defined in Parts 1 and 2.

2.2.1 The documented quality system shall:

- a. Define the critical features of the components involved.
- b. Reference the critical processes and procedures involved in manufacture of product that ensuring the ongoing compliance of the product with the specific critical features as defined above.
- c. Ensure that all personnel involved in implementing the requirements have appropriate knowledge, experience and training, in particular for the purposes of conducting product testing to demonstrate ongoing compliance with the specification requirements of the critical features defined above.
- d. Define the person(s) responsible for the implementation of the above requirements.

**2.2.2** Manufacturers must ensure that adequate information is available, prior to commencement of manufacture, to define all the relevant processes and test procedures sufficient to ensure ongoing compliance of the product with the relevant critical requirements. Evidence that a review has been performed must be available which demonstrates that:

- a. Adequate information is provided defining the build standard of the product.
- b. A copy of the relevant component specification(s) exist(s) for the component to be manufactured.
- c. User information to be shipped with the product and any specific marking requirements for both the product and the packaging are adequately defined.
- d. Full information is provided detailing any parts or processes critical to compliance of the component with the relevant specifications.
- e. Full details of any testing required to ensure the compliance of manufactured component with the relevant critical requirements has been provided and that adequate capability to conduct such testing is available. (Where 100% testing is not appropriate, applicable sampling rates shall also be defined)
- f. Full details of any marking to be applied to the product, (e.g. CE or BABT marks) have been provided, together with any associated conditions that must be met prior to applying the mark.
- g. Details of any additional ongoing compliance checks needed to ensure ongoing compliance with the relevant safety requirements have been provided and that any stop ship arrangements, should any non-compliances be identified as a result of such additional testing, have been agreed.

Note: For sub-contract component manufactures the above requirements should be addressed as part of a formal contract review with the Customer

**2.2.3** Prior to shipment of components to the Customer, the manufacturing processes must ensure that:

- a. Any changes to the build standard or specification of the component have been advised to and agreed with the Customer
- b. Any testing required to demonstrate ongoing compliance with the relevant safety requirements has been satisfactorily completed with compliant results.
- c. Any testing required to demonstrate ongoing compliance with the relevant functional requirements has been satisfactorily completed with compliant results
- d. Results of any periodic validation tests notified to the manufacturer do not indicate non-compliant results.
- e. No stop notices have been placed on the shipment of the product by the Design Department, the Quality Assurance/Quality Control Department, the Customer, or other relevant authority.
- f. Any marking has been checked on an appropriate sampling basis for conformance with the relevant marking requirements
- g. The product is properly identified with type, batch and/or serial number.
- h. Any Customer required certificates of conformity have been prepared, reviewed and authorised. Such review and authorisation shall be undertaken only by defined personnel with appropriate knowledge and experience.
- i. Non-compliant product cannot get into the marketplace, and any relevant marking is removed or obliterated either prior to disposal or during the disposal process. (e.g. Incineration).

**2.2.4** Final Test Requirements.

- a. All safety testing shall be conducted in line with the requirements of Annex D clause 2.5
- b. Functional testing should be conducted to ensure the ongoing compliance of any none-safety critical features as declared in clause 2.2.1 above. For all such tests the requirements of part 2 clause 2.2.8 apply irrespective of whether these are required to be listed on the PQC certificate or not.

**End of Annex E.**



## ANNEX F

Note: Annex F formerly contained RoHS ready manufacturing requirements. These have been deleted from this document and are entirely contained in document BABT AP008-F.

## ANNEX G

### Supplementary Requirements for the Production Quality Assurance under Module D of the Marine Equipment Directive

#### 1. Introduction.

This annex applies to the manufacture of product to be placed on the European market under the requirements of Module D of Directive 96/98/EC as amended by all effective amendments, and for which a Declaration of Conformity with the relevant essential requirements of the Directive exists. The requirements outlined in this PQC scheme and annexure relate only to appropriate manufacturing controls as required for Module D in annex B of the Directive. They also address the Customer –Supplier interfaces in order to assure the operation of a suitable process of quality assurance and control leading to the ongoing compliance of the manufactured product with the validated design requirements. They do not address requirements related to the design, design verification or design validation associated with the preparation of Declarations of Conformity.

Unlike most other Annexes of this document, the Certificate Holder must be either the Holder of the Type Examination Certificates covered by this certificate, or be an Authorised Representative of the Manufacturer. Notwithstanding this, these requirements (as well as the general requirement in Parts 1 and 2 of this document) are applied to the Fabricator unless stated otherwise in this Annex.

#### 2. Implementation

2.1.1 The Quality System of the Fabricator shall comply with Parts 1 and 2 of this document.

In addition the documented quality system of the Fabricator shall:

- a. Include a policy statement on compliance with the relevant requirements of the Marine Equipment Directive
- b. Define the person(s) responsible for the implementation of the relevant requirements of the Marine Equipment Directive.
- c. Ensure that all personnel involved in implementing the requirements have appropriate knowledge, experience and training, in particular for the purposes of conducting product testing to demonstrate ongoing compliance with the essential requirements defined in Article 5 of the Directive.
- d. Reference the processes and procedures involved in ensuring ongoing compliance of the product with the relevant requirements of Marine Equipment Directive.
- e. Include a Test Plan, which has been agreed between the Module D Certificate holder and BABT for each product listed within the scope of the Module D Certificate.

2.1.2 Where the holder does not operate the same documented quality system as the fabricator, the holder shall:

- a. Make available at the time of Audit at the Fabricator's facility documentation demonstrating their compliance to the requirements of Clauses 1.1.9 and 1.1.10 of this document.
- b. At least once a year plan and conduct an Audit of the Fabricator against the appropriate requirements of the Marine Equipment Directive and this document.
- c. Ensure that at the time of Audit by BABT, copies of the Audit reports, findings, and corrective actions (including their status) , are available at the Fabricator's premises (or by electrical means from that location).

## 2.2. Contract Review

Fabricators of product that falls within the scope of the Marine Equipment Directive must ensure that adequate information is available, prior to commencement of manufacture, to define all the relevant processes and test procedures sufficient to ensure ongoing compliance of the product with the relevant essential requirements. Evidence that a Contract Review has been performed must be available which demonstrates that:

- a. Adequate information is provided defining the build standard of the product.
- b. A Declaration of Conformity to the Marine Equipment Directive exists for the product to be manufactured, traceable to the above build standard.
- c. Where relevant, submitted information includes details of the user information to be shipped with the product and any specific marking requirements for the product to the requirements of the Directive.
- d. Full information is provided detailing any component parts or processes critical to compliance of the product with the appropriate technical requirements defined in the Directive, and that the capability exists to address any additional controls and processes required. Critical components must be specified by both the type and manufacturer used.
- e. Copies of the Type examination Certificates for each product to be manufactured must be supplied.
- f. Full details of the testing/inspection required to ensure the compliance of manufactured product with the appropriate technical requirements of the Directive has been agreed between the Type Examination Certificate holder and the manufacturer and that adequate capability to conduct such testing is available. (Where 100% testing is not appropriate, applicable sampling rates shall also be defined).
- g. Full details of the Wheel marking to be applied to the product, (including all appropriate Notified Body numbers) have been provided, together with authorisation to affix the marking as required by Article 11 of the Directive.
- h. Details of any additional ongoing compliance checks needed to ensure ongoing compliance with the essential requirements of the Directive have been provided and that any stop ship arrangements, should any non-compliances be identified as a result of such additional testing, have been agreed.

Note: For Original Equipment Manufacturers, such reviews could form part of the design release process, rather than being addressed in a separate internal contract review, however, under these circumstances, evidence must be available in the production facility that all the above issues have been adequately addressed and that relevant production personnel were present at such reviews.

## 2.3. Document and Build Control Requirements

- a. The Holder of the Module D certificate shall maintain a list of all TECS and Products which are manufactured at the Fabricator's facility under the Module D Certificate.
- b. The current issue of the list must be available at the Fabricator's facility at all times.
- c. All changes to the product must be agreed by the company listed as holder of the Type Examination Certificate. This includes any temporary manufacturing changes.
- d. Any agreement/advice of change from the holder of the Type Examination Certificate must include details of any updates to the Type Examination Certificate, and any required updates to the Declaration of Conformity.
- e. Declarations of Conformity must be kept for at least 10 years after the product was manufactured.

#### 2.4. Process Control Requirements

Prior to shipment of Wheel marked product to the Customer, the manufacturing processes must ensure that:

- a. The build standard of the product is as agreed with the Customer and matches the information supporting a valid Declaration of Conformity to the essential requirements of the Marine Equipment Directive.
- b. Testing required to demonstrate ongoing compliance with the appropriate technical requirements of the Marine Equipment Directive has been satisfactorily completed with compliant results.
- c. Results of any periodic validation tests notified to the manufacturer do not indicate non-compliant results.
- d. No stop notices have been placed on the product by the Customer or other relevant authority.
- e. The Wheel marking has been checked on an appropriate sampling basis for conformance with the requirements of Annex D of the MED and includes the use of appropriate Notified Body number and year indication.
- f. The product is properly identified with type, batch and/or serial number and the name of the Manufacturer or person responsible for placing the product on the market.
- g. Non-compliant product cannot get into the marketplace, and any relevant marking is removed or obliterated either prior to disposal or during the disposal process. (e.g. incineration).

**End of Annex G**

## ANNEX H

### Supplementary Requirements for the Product Quality Assurance under Module E of the Marine Equipment Directive

#### 1. Introduction.

This annex applies to the manufacture of product to be placed on the European market under the requirements of Module E of Directive 96/98/EC as amended by all effective amendments, and for which a Declaration of Conformity with the relevant essential requirements of the Directive exists. The requirements outlined in this PQC scheme and annexure relate only to appropriate manufacturing controls as required by for Module E in annex B of the Directive. They also address the Customer –Supplier interfaces in order to assure the operation of a suitable process of quality assurance and control leading to the ongoing compliance of the manufactured product with the validated design requirements. They do not address requirements related to the design, design verification or design validation associated with the preparation of Declarations of Conformity.

Unlike most other Annexes of this document the Certificate Holder must be either the Holder of the Type Examination Certificates covered by this certificate, or be an Authorised representative of the Manufacturer. Notwithstanding this these requirements (as well as the general requirement in Parts 1 and 2 of this document) are applied to the Fabricator unless stated otherwise in this Annex.

#### 2. Implementation.

##### 2.1.1 The Quality System of the Fabricator shall comply with Parts 1 and 2 of this document

In addition the documented quality system of the Fabricator shall

- a. Include a policy statement on compliance with the relevant requirements of the Marine Equipment Directive
- b. Define the person(s) responsible for the implementation of the relevant requirements of the Marine Equipment Directive.
- c. Ensure that all personnel involved in implementing the requirements have appropriate knowledge, experience and training, in particular for the purposes of conducting product testing to demonstrate ongoing compliance with the essential requirements defined in Article 5 of the Directive.
- d. Reference the processes and procedures involved in ensuring ongoing compliance of the product with the relevant requirements of Marine Equipment Directive.
- e. Identify and maintain a list of all products to be covered under this module.
- f. Include a Test Plan, which has been agreed between the Module E Certificate holder and BABT for each product listed within the scope of the Module E Certificate.

##### 2.1.2 Where the holder does not operate the same documented quality system as the fabricator the holder shall

- a. Make available at the time of Audit at the Fabricator's facility documentation demonstrating their compliance to the requirements of Clauses 1.1.9 and 1.1.10 of this document
- b. At least once a year plan and conduct an Audit of the Fabricator against the appropriate requirements of the Marine Equipment Directive and this document.

- c. Ensure that at the time of Audit by BABT, copies of the Audit reports, findings, and corrective actions (including their status) , are available at the Fabricator's premises (or by electrical means from that location).

## 2.2 Contract Review

Fabricators of product that falls within the scope of the Marine Equipment Directive must ensure that adequate information is available, prior to commencement of manufacture, to define all the relevant processes and test procedures sufficient to ensure ongoing compliance of the product with the relevant essential requirements. Evidence that a Contract Review has been performed must be available which demonstrates that:

- a. Adequate information is provided defining the build standard of the product.
- b. A Declaration of Conformity to the Marine Equipment Directive exists for the product to be manufactured, traceable to the above build standard.
- c. Where relevant, submitted information includes details of the user information to be shipped with the product and any specific marking requirements for the product to the requirements of the Directive.
- d. Full information is provided detailing any component parts or processes critical to compliance of the product with the appropriate technical requirements defined in the Directive, and that the capability exists to address any additional controls and processes required. Critical components must be specified by both the type and manufacturer used.
- e. Copies of the Type Examination Certificates for each product to be manufactured must be supplied.
- f. Full details of the testing/inspection required to ensure the compliance of manufactured product with the appropriate technical requirements of the Directive has been agreed between the Type Examination Certificate holder and the manufacturer and that adequate capability to conduct such testing is available. (Where 100% testing is not appropriate, applicable sampling rates shall also be defined)
- g. Full details of the Wheel marking to be applied to the product, (including all appropriate Notified Body numbers) have been provided, together with authorisation to affix the marking as required by Article 11 of the Directive.
- h. Details of any additional ongoing compliance checks needed to ensure ongoing compliance with the essential requirements of the Directive have been provided and that any stop ship arrangements, should any non-compliances be identified as a result of such additional testing, have been agreed.
- i. Any additions to the list of products to be covered by this module must be agreed by the Notified Body prior to being added. The Notified Body shall be advised of any changes to processes or testing which will be required to add the additional product. Deletions of products to the list must be advised to the Notified Body in advance of any audit.

Note: For Original Equipment Manufacturers, such reviews could form part of the design release process, rather than being addressed in a separate internal contract review, however, under these circumstances, evidence must be available in the production facility that all the above issues have been adequately addressed and that relevant production personnel were present at such reviews.

## 2.3. Document and Build Control Requirements

- a. All changes to the product must be agreed by the company listed as holder of the Type Examination Certificate (this includes any temporary manufacturing changes) .
- b. Any agreement/advice of change from the holder of the Type Examination Certificate must include details of any updates to the Type Examination Certificate, and any required updates to the Declaration of Conformity.
- c. Declarations of Conformity must be kept for at least 10 years after the product was manufactured.

#### 2.4. Process Control Requirements

Prior to shipment of Wheel marked product to the Customer, the manufacturing processes must ensure that:

- a. The build standard of the product is as agreed with the Customer and matches the information supporting a valid declaration of conformity to the essential requirements of the Marine Equipment Directive.
- b. Any testing required to demonstrate ongoing compliance with the appropriate technical requirements of the Marine Equipment Directive has been satisfactorily completed with compliant results.
- c. Results of any periodic validation tests notified to the manufacturer do not indicate non-compliant results.
- d. No stop notices have been placed on the product by the Customer or other relevant authority.
- e. The Wheel marking has been checked on an appropriate sampling basis for conformance with the requirements of Annex D of the MED and includes the use of appropriate Notified Body number and year indication.
- f. The product is properly identified with type, batch and/or serial number and the name of the Manufacturer or person responsible for placing the product on the market.
- g. Non-compliant product cannot get into the marketplace, and any relevant marking is removed or obliterated either prior to disposal or during the disposal process. (e.g. incineration).

**End of Annex H**