



BAPT Production Scheme 340

**Amendment to Issue 6 of the Production Quality Certification Scheme
for Manufacturers of Marine, Radio, Telecommunication Terminal
Equipment and Electro-Technology Products**

BAPT is the telecommunications certification body of





CONTENTS

	Page
AMENDMENT RECORD	3
Annex G Supplementary requirements for Production Quality Assurance under Module D of the Marine Equipment Directive	34-36
Annex H Supplementary requirements for Product Quality Assurance under Module E of the Marine Equipment Directive	37-39

AMENDMENT RECORD

Amendment Issue 1

Issue 6 May 2010

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

Issue 6 Amendment issue 1

Replace Annexes G and H

Add to Section 0.3 Definitions

Marine Equipment Critical Components

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

- The Marine Equipment Directive requirements applicable to the particular Product Type as defined in Annex A.1 of the relevant Amendment to the Directive listed in the Type Examination Certificate..

Replace the existing Annex G with:**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.

The Certificate Holder must be the Holder of the Type Examination Certificates covered by this certificate. 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 Holder shall**

- a. Include a policy statement on compliance with the relevant requirements of the Marine Equipment Directive in their Quality System
- b. produce the PQC Compliance Plan referred to in Part 2 clause 2.2.2. This plan shall include details of which aspects are the responsibility of the Fabricator to control within their quality system
- c. supply the List of Marine Equipment Critical Components to the fabricator (as specified in Part 2 Clause 2.2.4).
- d. Specify the acceptance criteria for Marine Equipment Critical Components to be applied by the Fabricator.

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 BAPT, 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).

2.1.3 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. Define the person(s) responsible for the implementation of the relevant requirements of the Marine Equipment Directive.
- b. 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.
- c. Reference the processes and procedures involved in ensuring ongoing compliance of the product with the relevant requirements of Marine Equipment Directive.
- d. Include a Test Plan, which has been agreed between the Module D Certificate holder and BAPT for each product listed within the scope of the Module D Certificate.

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. The PQC Compliance plan has been supplied by the Holder and agreed by the Fabricator
- h. 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.
- 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, where the fabrication is performed within the same company structure 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. The Holder of the Module D Certificate shall keep copies of all Declarations of Conformity for at least 10 years after the product was manufactured.
- f. The Fabricator shall keep copies of all Declarations of Conformity until the next BABT visit or for at least 1 year after the product was manufactured (Whichever is the longer)

2.4. Purchasing/Receiving Inspection

The fabricator shall ensure that the acceptance criteria for Critical Components are applied as specified by the holder.

Clauses 2.2.4 a, b, and c and the previous sentence "Critical components, on receipt must be treated in one of the following ways" do not apply under this Annex.

2.5. 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

Replace the existing Annex H with:**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.

The Certificate Holder must be the Holder of the Type Examination Certificates covered by this certificate. Notwithstanding 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 Holder shall**

- a. Include a policy statement on compliance with the relevant requirements of the Marine Equipment Directive in their Quality System
- b. produce the PQC Compliance Plan referred to in Part 2 clause 2.2.2. This plan shall include details of which aspects are the responsibility of the Fabricator to control within their quality system
- c. supply the List of Marine Equipment Critical Components to the fabricator (as specified in Part 2 Clause 2.2.4
- d. Specify the acceptance criteria for Marine Equipment Critical Components to be applied by the Fabricator.

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 BAPT, 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).

2.1.3 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. Define the person(s) responsible for the implementation of the relevant requirements of the Marine Equipment Directive.

- b. 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.
- c. Reference the processes and procedures involved in ensuring ongoing compliance of the product with the relevant requirements of Marine Equipment Directive.
- d. Identify and maintain a list of all products to be covered under this module.
- e. 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.

2.2 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. The PQC Compliance plan has been supplied by the Holder and agreed by the Fabricator
- h. 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.
- 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.
- j. 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, where the fabrication is performed within the same company structure, 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. The Holder of the Module E Certificate shall keep copies of all Declarations of Conformity for at least 10 years after the product was manufactured.
- d. The Fabricator shall keep copies of all Declarations of Conformity until the next BAPT visit or for at least 1 year after the product was manufactured (Whichever is the longer)

2.4. Purchasing/Receiving Inspection

The fabricator shall ensure that the acceptance criteria for Critical Components are applied as specified by the holder.

Clauses 2.2.4 a, b, and c and the previous sentence “Critical components, on receipt must be treated in one of the following ways” do not apply under this Annex.

2.5. 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