

**Use of Listed Production Tests with the
BABT Production Scheme 340**

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1. Introduction

The production testing requirements for products manufactured under the BABT PQC scheme were traditionally included in BABT PS 340. This significantly affected flexibility of the test requirements and inhibited the inclusion of new tests on an ongoing basis as new European standards were issued.

In addition, with the reduced level of regulatory involvement in the various routes to place equipment on the European market, it was felt that it was not appropriate to impose specific test requirements on manufacturers, but rather to assess the totality of production processes, inclusive of the conduct of such tests, to ensure adequacy of the overall controls to maintain ongoing compliance of the manufactured product with the initial design requirements.

This document also covers specified tests for use in support of RoHS compliance procedures and processes by manufacturing facilities operating under a BABT RoHS Ready QMS Certificate. This scheme (also referred to as a RoHS PQC or PQC Annex F) has been derived from the historic BABT PQC scheme and has a common structure.

Separation of the tests themselves permits rapid updating as requirements change and allows manufacturers to have their test capability included in the annex to their PQC or RoHS Ready QMS certificate, even when such testing is of a very specific nature.

2. Background and General Approach

2.1. Background

In general, design prototypes are tested extensively, as part of the design verification and validation process, in order to ensure that products are capable of meeting regulatory, inter-working and market requirements

In manufacture, such extensive testing is not normally required. Limited tests are conducted to confirm that products continue to meet the design and regulatory requirements. The extent of both the testing required and any limitations imposed can only be ascertained by analysis of the parametric inter-dependencies in any particular design combined with a risk analysis of the manufacturing processes involved.

Over the years BABT developed sets of tests applicable to specific categories of products, approximating to these requirements, but based on experience. These tests have been retained in the list for use by our Certified Manufacturers.

On a similar basis the well-established production safety test requirements have been retained together with the associated implementation requirements.

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Recognising the need to fulfil the above requirements in an environment of rapid technological advance, BABT have developed this scheme so that newly developed tests can be rapidly added to a published list at the request of any certified manufacturer and included in the annex to any manufacturer's PQC or RoHS Ready QMS certificate following verification of their test capability.

2.2. General Approach

It is the responsibility of the manufacturers, designers of products, and responsible personnel or agents raising declarations of product conformity to ensure, via a design release or contract review process, that production processes, controls and tests are adequate to ensure ongoing compliance of manufactured product with the defined requirements. The published list of tests is provided to assist this process. BABT can only give guidance on their selection, application and implementation.

The list of tests may be downloaded from the BABT document library under document number BABT AF038 entitled '2BABT Listed Production Tests'. Printing of the lists on a copyright free basis is permissible provided that such lists are not used by other organisations offering similar or competitive schemes.

The tests are presented in tabular form using the following prefixes:

- **Table S:** The original Safety related tests from BABT 340 PS issue 6 [Note: These are still listed in Annex D of BABT AP008-BABT PS 340] These tests are still considered appropriate, although not necessarily exhaustive, for verification of ongoing compliance with the requirements of the Low Voltage Directive, (2006/95/EC).
- **Table H** New Health and Safety Tests. "
- **Table F:** The original Functionality tests from BABT 340 PS issue 6 [Note: These are still listed in Annex D of BABT AP008-BABT PS 340] and relate to requirements originally specified for manufacturing products under the TTE . Although some of these tests reference standards more applicable to previous directives, they are retained because of their usefulness in addressing the inter-operability requirements of a design. The test numbering from BABT 340 PS issue 6 is retained but is prefixed by the "F" character
- **Table G** New Functional and General tests
- **Table E:** Specific tests to address EMC emission and susceptibility to ensure the ongoing compliance of manufactured product with the requirements of the EMC directive, the EMC requirements as defined in the R&TTE directive and any other applicable product requirements for EMC emission and susceptibility
Note: EMC Compliance may be ensured by a combination of specific Tests and Special processes (as defined in the Table P)
- **Table P:** Special Processes or procedures to address compliance where in-line or end of line tests may not be appropriate , or adequate to ensure compliance.
It is recognised that for some characteristics (e.g. EMC Compliance) , the use of relevant process controls during manufacture, including the proper inspection of critical features of the assembled product, are probably much more significant than the need for specific final product tests,
The inclusion of a reference to this test number in the annex to a manufacturer's PQC certificate will include the need for the manufacturer to have access to appropriately trained staff and a documented procedure to review, identify and adequately control the particular critical processes involved.
- **Table R: New tests in support of RoHS compliance**

Tests will be included in the annexes to PQC or RoHS Ready QMS certificates by reference to the test numbers only. The inclusion of a test number indicates the assessed capability to perform the test. The level of implementation of the test, (100% or sample basis) is no longer relevant on this basis.

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2.3. Mechanism and Criteria for the inclusion of Additional Tests.

Manufacturers who wish to apply for currently unlisted tests to be included in the annex to their PQC or RoHS Ready QMS certificate may do so in accordance with the following requirements and conditions.

New applicants should prepare details of the required tests as outlined below and submit them to BABT at the same time as their PQC/RoHS PQC application.

Manufacturers already holding PQC or RoHS Ready QMS certification should prepare details of the required tests as outlined below and submit them to BABT with a request to update the annex to their certificate. (A small charge will be made for processing the amendment to their certificate.)

Submissions should normally contain the following information and be e-mailed to

Customer.Service@BABT.com :

In the email itself:

- The name and address of the Organisation proposing the test.
- Name and position of the proposer within the above organisation.
- Telephone number and email address of the proposer.
- PQC facility number for existing certified manufacturers.
- Date of submission of the PQC application if not already a certified facility.
- Date from which the proposed test will be implemented in the manufacturing facility. (or confirm 'ALREADY IMPLEMENTED')
- Any additional specific or product related information that the proposer wishes to include in support of his application.

As an attachment to the email (preferably in word or excel format):

- A definition of the proposed test including:

Test Purpose: The hazard or function that the test intended to check

Test application: The type of equipment addressed by the test

Related standards. Reference to requirement(s) within published standards related to the requested test. (Note: the test does not have to fully implement the requirement of the standard but only provide a degree of assurance of compliance)

Descriptive overview Short description of the proposed test. (This is not intended to be exhaustive; it is an overview for inclusion in the table of tests)

Test connection points: Define the points where the test stimulus will be applied and the points where the effect of the stimulus will be measured;

Test conditions: Define the nature duration and level(s) of the stimuli.

Test limits: The Pass/fail criteria. (If parametric please specify compliance range)

Additional notes: notes on any conditioning required prior to test; any special configuration requirements etc.

Please note that NO proprietary information should be included in this attachment as your submission of this information to BABT implies your agreement to our publishing these details on the internet or otherwise for the use of other BABT customers.

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On receipt, BABT will review the proposed test against the following criteria:

- That the request is from a bonafide PQC/ RoHS PQC listed facility or from a facility that has formally applied for such certification. (Note; This requirement is introduced in order to provide a sensible control on the lists of qualifying tests and avoid the need to consider a plethora of 'good ideas' prior to the identification of a real application for the test. BABT will not enter into correspondence with regard to any request unless this condition has been met.)
- That the test is relevant to the product sectors addressed by the PQC/RoHS PQC scheme.
- That the test is, in BABT's opinion, sufficiently well defined for general use. (BABT may contact you for additional information should this requirement not initially be met.)
- That intellectual property rights are clear and no additional permission has to be obtained for third parties to use the test.

Once BABT have established that the above criteria have been met, the applicant will be notified of the approved test number(s) and the test(s) will be added to the appropriate table in BABT AF038 to enable other manufacturers to make use of them.

The facility will be contacted with a request for details of the particular test implementation invoked, (equipment, procedures, processes, records etc.) and a decision made as to whether their certificate annex can be updated on a documentary basis or whether a prior inspection visit is required. (This decision will be made on the basis of the adequacy of the submitted documentation, the known capability of the facility from previous audit visits, and the technological similarity of the required tests, to other tests for which certification is already held.)

Where tests are included on the basis of a documentary assessment, these will be reviewed in full during the next BABT audit visit.