
BABT 746 **A Guide to Applying for a BABT Notified Body Statement under the EMC Directive**

BABT is the Telecommunications
Certification body of TÜV SÜD



Foreword

This guide explains the BABT Implementation of the Annex III of the Electromagnetic Compatibility Directive, 2004/108/EC as invoked by Article 7 of that Directive.

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

The scheme enables a manufacturer of product within the scope of the EMC directive to make use of a Notified Body Statement in support of their declaration of Conformity

The formal requirements of the scheme are set out in the BABT Certification Regulations. The current version of these may be found at www.BABT.com.

All BABT publications are available from:

<http://www.babt.com>

(See the download area in *Information Services*)

or



BABT

Forsyth House
Churchfield Road
Walton on Thames
Surrey KT12 2TD
United Kingdom
Tel: +44 (0) 932 251200
Fax: +44 (0) 1932 251201

Email: customer.services@babt.com

Forsyth House was previously Balfour House

Contents

1. Introduction	1
1.1 Scope	1
1.2 Overview	1
2. Making an application	1
2.1 Who to apply to	1
2.2 Who can apply	1
2.3 Certification Details	1
2.4 Information required for an application	2
2.5 TCF Documentation	3
2.5.1 General.....	3
2.5.2 TCF Contents.....	3
2.6 Progressing the Application	3
2.7 BABT Process	3
2.7.1 Assessment Outcome.....	3
2.7.2 Resulting Actions.....	4
2.7.3 . Records.....	5
3. Regulatory Marking	5
4. References to BABT Notified Body	5
5. Intended Purpose	5
6. Keeping your TCF up to Date	6
6.1 General	6
6.2 Administrative Changes	6
6.3 Significant Changes	6
6.4 Annual Check	6
Annex A Information to be included within a TCF	A-1
A.1 General	A-1
A.2 Index	A-1
A.3 Description of the apparatus	A-1
A.4 Procedures used to ensure compliance	A-3
A.5 Test Data	A-3
A.6 Other Documentation	A-4
Annex B Essential Requirements	B-1
B.1 The EMC Directive Annex I states	B-1
Annex C DECLARATION OF CONFORMITY	C.1

1. Introduction

1.1 Scope

This guide explains the BABT Implementation of the Annex III of the Electromagnetic Compatibility Directive, 2004/108/EC.

1.2 Overview

The BABT Implementation of Annex III of the EMC Directive operates under the BABT Certification Regulations. This implementation does not require any assessment of a manufacturer's quality management system or checking samples at random. Continuation fees are not applicable.

The formal output from BABT is: a Letter or Certificate stating whether in the opinion of BABT the submitted TCF demonstrates compliance to the essential requirements. Where a favourable Statement is given this will be in the form of a Certificate confirming compliance.

Where the TCF does not demonstrate the required compliance the Statement is in the form of a letter informing the applicant of the results of the assessment.

2. Making an application

2.1 Who to apply to

The application should normally be made direct to BABT on form BABT 300. While the actual BABT 300 form may be sent as paper, e-mail, fax, or on a CD the accompanying information should normally be sent on electronic media.

Refer to the foreword for the sources of form BABT 300 and the address to send completed applications to.

Alternatively you may submit your application via any TUV Sud company appointing them as your agents to progress the application.

On receipt of your application, we will generate and send you a confirmation of the application.

Assembly of the TCF: BABT ICM provides a service to assist in the assembly of the TCF.

Where you wish to use this service you should apply to BABT ICM separately for this service from your application for the EMC Notified Body Statement however ICM can then act as your agents in the submission for a BABT Notified Body Statement.

2.2 Who can apply

Applications can be made by or on behalf of both manufacturers and suppliers of IT, telecommunications or radio equipment. The person making the application should be a duly authorised signatory of the applicant and may not be an agent or BABT/TUV employee.

Definition: Manufacturer: The manufacturer or his authorised representative established within the European Community or the person responsible for placing the equipment on the market

Optionally, the applicant may in addition authorise BABT to liaise with another party (e.g. a TUV company/agent/consultant) acting on behalf of the applicant in matters relating to the application.

BABT will require evidence that the representative or consulting agency is authorised by the applicant company to act on their behalf and there is a section of the example application form for this purpose

2.3 Certification Details

You should indicate the essential requirements which you wish BABT to review and include in the Notified Body statement.

BABT recommend that both Emissions and Immunity are reviewed. We do not issue statements for subdivided parts of An essential requirement.

You should further indicate whether this is an original submission or a modification to a TCF for which BABT has already issued a certificate (a modification may include extending the scope of the Statement to include further derived models, or essential requirements). A new application is required if you wish to reduce the extent (number of essential requirements) covered in a statement.

Applications may cover either one product or a set of related products having significant design similarities.

OEM, Brandname, or badge engineered products which are identical apart from product naming and cosmetic “Branding” items may be included with the original application. Alternatively separate applications may be made

Derived Products or “Sisters”: with differing features but where there are significant design similarities may be submitted on the same application. However information demonstrating their similarity will be required and additional testing/test results may be required for technical aspects which differ between models.

2.4 Information required for an application

The following information should be supplied as appropriate as a part of the application. Entries for this information are included in form BABT 300.

- **Section A: Applicant Details**

- **Section A.1: Details of the Main Contact within the Applicant Company**

Details of the authorised signatory within the company applying for the certification and responsible for the certification request and order. This named person may not be a consultant or agent, unless the application is accompanied by evidence that the agent is authorised to act on the applicant’s behalf.

- **Section A.2: Other Contact Information**

Where you wish the company name or address to appear on the certificate to differ from that of the primary contact (e.g. where you wish the Company HQ to be on certificates). This should be accompanied with details of the relationship between the contact and the supplied address/company. You may not request the name of a company outside your corporate structure.

Consultant/Agent details where you have used a consultant/agent to assist or submit the application (e.g. If you are submitting through BABT ICM or a TUV PS company this should be their details).

- **Section B: Your Certification Requirements**

As described above.

- **Section C: Product Details**

- **Section C.1: Product(s) Submitted**

This must be clearly stated as this will appear on the certificate and serve as a prime identifier of the certified product(s). It is also helpful (but not mandated) if this is accompanied by a brief description of the product: to assist in understanding the product purpose.

The TCF overall document file identity must be included as this also will appear on the certificate. Where there is no overall TCF identity then the Document number of the TCF Index (or Contents listing) should be provided.

- **Section C.2: Related Products**

An explanation of the relationship between models where you have submitted a TCF covering more than one model. In particular whether one can be derived from another by sub-equipping/depopulation and whether they have substantial areas of circuitry or software in common.

Where your product is an OEM product for which BABT have already issued a Statement please provide details of any differences and a letter from the holder of the original certificate granting you access to their results.

- **Section D: Payment Details**

Information related to your intended method of payment.

Name or address to which invoices and accounts should be sent where the person or address differs from the Main contact listed previously (to be included with supporting information).

Purchase Order or Credit Card details.

Work is carried out on receipt of either payment in advance or a valid purchase order number. Clients applying directly to BABT (i.e. not through any other TUV Group office), who do not currently have approved credit facilities with either BABT or TUV Product Service UK must include a completed Credit Details Form with the application. Alternatively payment in advance is accepted. The appropriate forms may be downloaded from

<http://www.babt.com>

- **Section E: Agreement**

A declaration whether you have any Statements or current applications for a Notified Body statement related to this product with any other Notified Bodies. If so you will be requested to provide either the statement or the identity of the other Notified Body.

A statement that you understand and agree to abide by the BABT Certification Regulations.

The application should also be accompanied with supporting information as detailed in later sections.

2.5 TCF Documentation

2.5.1 General

The completed BABT 300 application form should be accompanied by a TCF.

While BABT will accept the TCF in paper format we prefer that the TCF is sent via electronic media (e.g. On a CD, or via e-mail attachments). Documents should be in Word, Excel, Adobe PDF, or images in JPEG formats. Where you wish to use other formats or employ encoding please contact BABT prior to submission to ensure we will have ready access to the files.

All documentation should be readily identifiable with either revision indication or an issue date. Multiple paged documents should have indications (page numbers or listed sections) to ensure they are complete.

2.5.2 TCF Contents

Since each TCF is unique there is no fixed structure or mandated set of contents. However the TCF should contain the following information.

- Index or Content list
- Description of the apparatus
- Procedures to ensure compliance
- Test Data
- User Instructions

An expanded list with details of the contents is included for information in Annex A of this document.

2.6 Progressing the Application

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

- ask you to pay an application fee. The fee relates to the assessment of the application as well as the issuing of the Statement.
- inform you of the BABT reference number assigned to your application. This number should be quoted in all further correspondence.
- * advise you of any obvious omissions of items required for assessment (e.g. Test Reports)

When BABT has received all the required items the assessment the application will be allocated to an engineer. BABT reviews the supplied TCF for completeness, consistency and whether it demonstrates the product will be compliant with the requirements of the relevant articles of the EMC directive.

If during the assessment the Engineer concludes that

- Required documentation is omitted; or
- The TCF includes unexplained inconsistencies; or
- Documentation is incorrect or incomplete; or
- Test Results are inconsistent or omitted;

then the reviewing Engineer will contact the main contact with details of the concerns and seek a suitable response.

Where information is missing from an application or the reviewing Engineer raises a query further work on that application will be suspended at an appropriate time and will only be resumed after the response .

2.7 BABT Process

2.7.1 Assessment Outcome

After assessment of an application and supporting documentation:

- * if in the opinion of BABT the TCF demonstrates compliance with the requested essential requirements of the Directive, BABT will issue a Statement and a Certificate confirming compliance;

Certificate

Certificates are issued in the name of the Applicant Company which is referred to as the holder.

- Certificates and their associated Annex also include:
- the address of the holder (or an alternate address where identified within the application),
- The product identity(ies) (including any variants/models),
- the reference to the TCF presented to BABT
- The EMC Essential Requirements covered by the Certificate
- information related to the interface type(s)
- The Standards used within the TCF
- Test Reports used in the TCF
- Other data necessary for identification of the product, and any conditions for its validity. Guide

, The Certificate only relates to the inspected TCF, and accordingly has no expiry date.

- * if the TCF in the opinion of BABT does not demonstrate comply with the requirements of the Directive, BABT will issue a letter informing the applicant of the results of the assessment.

Inconsistent or Omitted test results

If during the assessment BABT concludes that additional testing is required then you may either:

- request BABT to provide an unfavourable Statement citing the absent or inconsistent results; or
- suspend the assessment and obtain the additional required tests results.

Where the testing option is taken then this must take place at either a test facility recognised by BABT (refer to document BABT 766 for details), or at any other Test facility accredited to ISO/IEC 17025 (or equivalent). In the latter case BABT may require evidence of accreditation for the tests being performed

Once the required testing has been performed the test report should be sent to BABT and the Assessment resumed.

Note: BABT may charge an additional fee for reviewing such reports.

Changes to the TCF during assessment

If you make changes to the TCF after initial submission BABT which require re-assessment by BABT we may charge an additional fee for repeated work.

2.7.2 Resulting Actions

Where you obtain a compliant Statement in the form of a certificate from BABT then:

- You may draw up a Declaration of Conformity to the EMC directive (a proforma Declaration may be found in Annex C of this guide);
- when you have met all the requirements of all directives applicable to your product then you may mark your product with the CE mark. Refer to the next section of this guide for more details.

Where BABT are minded to issue an unfavourable Statement, or apply specific unrequested conditions within a certificate on the installation or use of the apparatus BABT will inform the client in writing.

In these circumstances the client has up to 28 days to make representation to BABT why a favourable Statement should be made, or why the proposed condition should be lifted.

Appeal Timescale

Where you do not wish to make representation to overturn the Statement it is helpful if this is indicated to BABT as soon as possible such that the process can be formally concluded without delay.

Where BABT issue an unfavourable Statement this shall be communicated to you in writing, with a copy being sent to the UK administration [Department for Business Innovation and Skills (BIS)] for information.

It is then your choice whether to

- rectify the concerns and apply for another Statement; or

- rectify the concerns and follow another option as appropriate to your equipment (e.g. follow the standards route); or
- desist from marketing the product in the EU

You are entitled to make a formal appeal if you believe that you have been unjustly denied a certificate. In all cases, the decision of the appeals panel is final. Full details of the appeals procedure are given in the Certification Regulations

2.7.3 . Records

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

You are required to maintain records the records defined in the Directive for 10 years.

3. Regulatory Marking

The CE marking in respect of the Directive shall be applied only to equipment for which a valid Declaration of Conformity exists.

It is not permitted to associate any Notified Bodies identification after the CE mark to indicate the involvement of a Notified Body.

CE Mark

You may obtain an electronic copy of the CE Mark from either Customer Services or from the BABT Web site (see the Foreword of this guide for details).

Notified Bodies and interaction with the R&TTE Directive

BABT are appointed as a Notified Body under both the EMC Directive and the R&TTE Directive

Some products have different applications which fall under the EMC and R&TTE directives as appropriate (e.g. Wireline apparatus which may be either Terminal Equipment or Network infrastructure equipment dependant on where they are installed).

Where applications are made in parallel BABT is able to review a TCF for compliance to the EMC requirements of both directives and issue separate statements appropriate to each

Where a Notified Body under the R&TTE directive has issued an Opinion (or a Full Quality Assurance Approval) covering the same product the product label must display the R&TTE NB number (e.g. 0168 for BABT) after the CE mark.

4. References to BABT Notified Body

While it is not permitted to attach the BABT Notified Body Number (0168) to the CE mark it is permitted to reference BABT (including the number) in the Declaration of Conformity (referencing the Annex III conformity procedure and in compliance statements in user documentation).

No non-regulatory Product Mark is available for EMC under this Scheme.

5. Intended Purpose

You are required to provide information with the product to enable use in accordance with the intended purpose of the apparatus. This must be in a form suitable to accompany the product.

6. Keeping your TCF up to Date

6.1 General

During the lifetime of a certified product, BABT understands that it is likely that you will want to make a number of changes.

It is your responsibility to ensure that after each change the TCF and resultant Declaration of Conformity remain valid.

BABT offers a number of services to maintain the currency of your certificate (and validate the currency of your TCF) and these are detailed below.

Since an Annex III Statement does not involve any continuing compliance element, use of the following services will involve a separate fee.

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

6.2 Administrative Changes

Where BABT have issued a certificate and details on the certificate unrelated to compliance with the EMC Directive require change (e.g. Company address, Product name) then you may apply to BABT for an updated Certificate based upon the original assessment.

6.3 Significant Changes

Where a significant change to a certified product has occurred and BABT has previously issued an EMC certificate, you may apply to BABT with details of the change and an updated TCF.

The application may be made in writing or by electronic means, making reference to the BABT reference number of your original application.

Alternatively you may either apply to BABT for a completely new assessment or progress the change through an appropriate EMC option.

6.4 Annual Check

It is noted that even when single changes do not significantly affect compliance, the accumulation of changes may result in non-compliance.

Accordingly where BABT have issued an EMC certificate we encourage you to resubmit the TCF with a request to "refresh" the Certificate.

The TCF should be accompanied with details of all changes to the product since the original (or latest) certificate.

Annex A Information to be included within a TCF

A.1 General

Each TCF is unique accordingly there is no fixed structure or mandated set of contents. The following list identifies data and documents normally found within a TCF to support the declaration of conformity.

It remains the responsibility of the manufacturer (or the person placing the product on the EU market) to hold the TCF and maintain its accuracy.

For applications to BABT we prefer that the TCF is sent via electronic media (e.g. On a CD, or via e-mail attachments). Documents should be in Word, Excel, Adobe PDF or JPEG formats. Where you wish to use other electronic formats or employ encoding please contact BABT prior to submission to ensure we will have ready access to the files. Where you submit the TCF in paper form BABT may charge a handling fee.

All documentation should be readily identifiable with either revision indication or an issue date. Multiple paged documents should have indications (page numbers or listed sections) to ensure they are complete.

The documentation to be included broadly falls into the following categories:

- TCF Index
- Description of Apparatus
- Procedures used to ensure conformity
- Test Data
- Other documentation

A.2 Index

The TCF should be structured in a logical format and have either a table of contents or an index.

Where the TCF covers multiple variants of a product the index/table of contents should be in sufficient detail to readily determine common items and documentation specific to single variants.

A.3 Description of the apparatus

The following documentation should be considered:

A.3.1 Overview

This should be an overview or brief description of the purpose of the apparatus and where more than one model of the apparatus is included in the TCF it should contain brief details of the relationships and differences between models.

A.3.2 Identification of Equipment

This should be a list of all model names and associated numbers of all product models included within the TCF. Where documentation is included using prototype names, or names from other markets then the relationship with the models named within the TCF should be detailed.

A.3.3 Block Diagram and/or Cross Connection Matrix

You may include a block diagram showing the following details (for simple apparatus a complete circuit diagram may be satisfactory):

- points of connection to communications networks via any wire or optical interfaces
- points of connection to communications networks via any radio interfaces, showing antennas (internal or external)
- any other radio/wireless interfaces
- other ports (including ac power, dc power, signal & control)
- indicators of key functionality
- connections to earth (protective or functional).

Block Diagram and Cross Connection Matrix: The provision of a block/circuit diagram can help to ensure that all parties quickly reach a common understanding of the relevant tests and certifications required. For complex equipment with switching capabilities, include a cross connection matrix showing the possible connections through the equipment between the various ports and/or terminating stations, if relevant to the assessment.

A.3.4 Technical description explaining the block Diagram

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

A.3.5 Circuit Diagrams and PCB layout Diagrams

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

These should show all network or radio interface circuits, active speech processing devices, audio hybrids and transducers, line signalling components, power supplies, ports and all network-affecting circuit elements including any components providing user isolation. Circuit elements need only be shown in sufficient detail to explain the above. Circuit diagrams should exactly reflect the actual samples submitted for test.

A.3.6 Parts List (Bill of Materials)

You should include parts lists (BOMs) for those areas of circuit detail identified in the circuit diagrams. Critical tolerances should be identified where applicable and the manufacturers of safety-critical components, all transducers and components affecting the signal path, including all second sources, should be stated. If more than one source of a critical component (e.g. line interface IC) is to be used, samples from all sources should be submitted for assessment.

A.3.7 Data Sheets

Data sheets for any safety critical components including Gas discharge tubes and other voltage dependant devices.

A.3.8 Software and Firmware Versions

The version of any software or firmware supplied with the equipment which may affect compliance with the R&TTE must be declared.

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

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

A.3.9 Photographs or Illustrations

Photographs or illustrations showing the external features of the complete equipment.

A.4 Procedures used to ensure compliance

A.4.1 Compliance Strategy

You should include documentation describing the compliance strategy including the measures for externally supplied sub-assemblies.

A.4.2 List of Standards applied

You should include a list of all relevant standards applied to ensure conformity. This list should include the issue level of the standard.

A.4.3 Justifications

Where relevant you should include the following justifications:

- **Justification of Tests not performed**

If there are any aspects for which testing has not been performed then a clear technical justification for this shall be provided. This should include details of what alternative processes have taken place to establish compliance to the essential requirements.

- **Justification for using test data from a different standard**

Where you test data from other standards this may be included instead of the harmonised standard with a justification for using this to demonstrate compliance to the relevant essential requirement. For example you may have test data from testing to a non harmonised standard derived from the same global standard.

- **Justification for omitting tests**

Where the functionality of your equipment does not encompass a normal sub-set of tests from a standard you should provide a justification for omitting those tests;

Where due to design constraints, or industry wide lack of test capability tests cannot be performed then you should include justifications (with appropriate supporting data) why the apparatus complies with the requirement

A.5 Test Data

A.5.1 Test Reports

These should follow the guidelines in ISO/IEC 17025 Clause 5.10.

A.5.2 Design Calculations

Where you use design calculations instead of independent test data, or to supplement it these should be clearly included.

A.5.3 Test Methods

Where the standards used do not include test methods or where alternate test methods have been used they should be detailed with justifications for their appropriateness to demonstrate the requirement.

Details should include the equipment used, the calibration status of test equipment, and the estimated measurement uncertainty.

A.5.4 Justifications

The following justifications should be included as appropriate:

- **Related Products/Models**

Where the TCF covers a range of related products or models the test reports shall be sufficient to cover the range taking into consideration the supporting documentation of similarity between products. Where differences in implementation could effect particular requirements testing to those requirements should take place on sufficient variants to cover each different implementation. The justifications to limit testing should either be included with the data or product descriptions

- **Validity of Test Results obtained prior to modification**

Where you include test results obtained using apparatus at a build level different from the current level then there should be a justification of the continuing validity of those results. This may be in the form of a positive assertion of the results, or a negative assertion of any effect on the compliance held against individual engineering changes

A.6 Other Documentation

A.6.1 User/Installation/Special Instructions

You should supply (in English) a draft or published set of User Instructions, or for complex equipment, those sections of the user instructions which relate to compliance with the EMC directive. They should:

- contain all the information required for conformance to the relevant standard;
- include either a copy of the Declaration of conformity, or a shortform declaration to the EMC directive with details of where to obtain the full D of C;
- not give details of adjustments which can take the equipment outside compliance - unless it is made clear how to adjust the equipment to maintain compliance and that any non-compliant setting would invalidate the certification.

A.6.2 Notified Body Statement

Where you have obtained a Notified Body Statement covering any of the Essential requirements for this product you should present this in the TCF.

Where a TCF review by another Notified Body is pending or occurring in parallel with the BABT review this fact should be recorded in draft in the TCF to be replaced by the Statement Assuming a positive outcome.

A.6.3 Declaration of Conformity

The TCF should contain a Declaration of Conformity to the EMC. This may be in draft form at the time of submittal to BABT but must be formally issued prior to application of the CE mark on products.

Products subject to more than one directive:

You may either draw up a separate Declaration of Conformity to each Directive requiring this document, or you may draw up a single Declaration of conformity citing all the relevant directives and providing information required by each of them (e.g. The EMC Directive requires standards be listed, the R&TTE requires the "essential requirements be cited).

Annex B Essential Requirements

B.1 The EMC Directive Annex I states

The apparatus shall be so designed that:

- (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment and other equipment cannot operate as intended;
- (b) it has a level of immunity to electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use .

Annex C DECLARATION OF CONFORMITY

We,

.....
(manufacturer's name)

of

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

declare under our sole responsibility that the product

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

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

.....
.....
.....
We hereby declare that [the above named product is in conformity to the requirements of Article 1.3 of Directive 2004/108/EC.

The conformity assessment procedure referred to in Annex III of Directive 2004/108/EC has been followed with respect to Essential Requirements Annex I <<1a and/or 1b >> with the involvement of the following Notified Body:

**BABT, Forsyth House, Churchfield Road, Walton-on-Thames,
KT12 2TD, UK**

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

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

.....
(name)

.....
(title)

.....
(signature of authorised person)

.....
(date)