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BS 9000 : Part 5 : 1989

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British Standard

General requirements for a system for electronic components of assessed quality

Part 5. Specification of qualification approval and conformance testing procedures

Foreword

This Part of BS 9000 has been prepared under the direction of the Electronic Components Standards Policy Committee (ECL/-). It forms part of a revision of BS 9000 : Part 1 : 1981 and BS 9005 : 1985, both of which are now withdrawn. The revision comprises a vital and necessary restructuring of these standards coupled with the incorporation of text from BS 9000 : Part 2 : 1972 and from various circular letters from PD 9004. The restructuring has resulted in BS 9000 : Part 1 : 1981 and BS 9005 : 1985 being replaced by the following publications.

- Part 1 Specification of general procedures
- Part 4 Specification of procedures for the approval of an organization
- Part 5 Specification of qualification approval and conformance testing procedures
- Part 6 Specification of capability approval procedures
- Part 7 Specification of lot formation, release procedures and certified test records
- Part 8 Drafting requirements
 - Section 8.1 Generic, sectional and blank detail specifications produced under qualification approval
 - Section 8.2 Generic and sectional specifications produced under capability approval

NOTE. A cross-reference between BS 9000 : Part 1 : 1981 and this revision is given in appendix A, table 1 of BS 9000 : Part 1 : 1989.

These publications describe, and specify, the BS 9000 system. They are not intended to apply to the United Kingdom implementation of either the CECC* or IECQ† systems.

It has been decided, after considering the implications of the intended completion of the Internal Market by December 1992, that a complete 'stand alone' publication describing and specifying the UK implementation of the CECC system is needed. A similar 'stand alone' publication for the UK implementation of the IECQ system is also envisaged. BS 9000 : Part 2 and BS 9000 : Part 3 will be revised to implement these decisions.

This revision of BS 9000 : Part 1 : 1981 gives a more complete description of the requirements for capability approval and for the drafting of specifications. The revision will be applied to all approval exercises and to all generic, sectional and blank detail specifications drafted after the date of its publication. The requirements contained in the revision will also apply to the revision of existing BS 9000 standards.

BS 9000 : Part 4 specifies procedures for the approval of organizations. It is intended that the appropriate Part of BS 5750 be invoked in due course as a requirement for approval. It should be noted that BS 9000 : Part 4 contains requirements specific to the System‡ not covered by BS 5750.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

*CENELEC Electronic Components Committee (System for Europe).

†IEC Quality Assessment System for Electronic Components.

‡ For definition of 'the System', see 2.1.1 of BS 9000 : Part 1 : 1989.

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Specification

1 Scope

This Part of BS 9000 specifies the procedures and requirements for the granting of qualification approval to manufacturers and class A integrated circuit (IC) design houses under the System.

Approved class A IC design houses (see BS 9000 : Part 4) are included in the term 'approved manufacturer' in this standard where the requirements apply to such design houses. Requirements specific to approved IC design houses are given in clause 6 of BS 9000 : Part 4 : 1989.

NOTE. The titles of the publications referred to in this standard are listed on the inside back cover.

2 General

Qualification approval is appropriate for components manufactured to a standard design using an established production process and conforming to a published detail specification as defined in 5.4 of BS 9000 : Part 1 : 1989. Where no detail specification has been published, an approved manufacturer is permitted to originate one, in which case he shall apply to BSI for a detail specification number using the form given in appendix A and following the procedures given in section A of PD 9004 : Part 1 : 1986.

Before an approved manufacturer is permitted to release and deliver components as conforming to the System, he shall demonstrate that the components satisfy the appropriate specifications and he shall have obtained qualification approval under the System.

3 Qualification approval procedures

3.1 General

3.1.1 Manufacturer's approval. Manufacturers shall have obtained manufacturer's approval (see clause 2 of BS 9000 : Part 4 : 1989) prior to making an application for qualification approval.

Subject to eligibility (see 3.1.2), qualification approval of a component shall be granted when the approved manufacturer has demonstrated his ability to comply with the detail specification.

Qualification approval testing shall be carried out on inspection lots which are representative of the extent of the normal or intended production and of the design and range of values. Where a wide range of values is covered by one detail specification, e.g. for resistors, samples shall be drawn from the highest, medium and lowest values. Where structural similarity can be demonstrated, the approval shall be extended over the whole range of components without the necessity to test each and every type of component for structurally-similar features.

All specimens submitted for qualification approval testing shall be suitably identified.

NOTE. The specified marking need not appear on the specimens except for those specimens required for salt spray testing or for tests for durability of marking.

Qualification approval shall be granted on the satisfactory completion of the first 1000 h of endurance tests, provided all other tests have been completed satisfactorily and provided that clause 3 has been complied with. However, endurance tests of up to 2000 h duration shall continue to their completion and the final results shall be the subject of an appendix to the main qualification approval test report. If the results of the completed endurance tests are unsatisfactory, the procedure in the event of failure in periodic tests (see 7.6) shall apply and the results shall be recorded in the appendix to the main qualification approval test report.

3.1.2 Eligibility for qualification approval. A component is eligible for qualification approval in accordance with the System if supervision (see 3.2.1) by the approved person(s) of one or more approved manufacturers is applied to the manufacturing process, either in its entirety or commencing at the primary stage of manufacture.

3.1.3 Application for qualification approval. An approved manufacturer seeking to obtain qualification approval for a component or a range of structurally-similar components shall apply in writing to BSI, using the form given in appendix B.

3.2 Subcontracting

3.2.1 General. Under qualification approval, all the manufacturing processes involved in the particular component shall be under the direct surveillance of the approved manufacturer's approved person, with subcontracting permitted as specified in 3.2.2 to 3.2.5.

NOTE. The generic or sectional specification is permitted to exclude subcontracting of all or specified stages on technical grounds.

The verification of bought-in piece parts and materials shall be under the direct surveillance of the approved manufacturer's approved person.

3.2.2 Specialized processes. It is permitted for any specialized processes of the primary or subsequent stages defined in the generic specification to be carried out by a specialist processor provided that the approved person satisfies the National Supervising Inspectorate that the subcontracted work complies with the relevant specification either:

- (a) by on-receipt testing and/or inspection; or
- (b) by the approved person being responsible for the necessary surveillance of the work of the subcontractor, together with any necessary on-receipt testing and/or inspection.

3.2.3 Subcontracting to another approved manufacturer. Any processes, including design, are permitted to be carried out in another facility which is approved under the BS 9000 or CECC systems, provided that the manufacturer seeking approval:

- (a) obtains the agreement of the National Supervising Inspectorate that the proposed work can be so divided;
- (b) verifies that the subcontracted work falls within the other manufacturer's approval.

- (c) prepares adequate specifications for the control of the work undertaken by the subcontractor.

3.2.4 Manufacture in more than one CECC member country. In the case of manufacturing stages carried out in more than one member country of the CECC system and not in any extension of the approved manufacturer's approval, and when conditions for the approval of manufacturers are fulfilled by each manufacturer concerned:

- (a) the approved manufacturer who performs the final stage leading to the finished product, which shall as a minimum be the inspection and testing to the detail specification, is permitted to submit a request to BSI for the qualification approval of the component.

The request shall contain details of:

- (1) the division of the different stages between the approved manufacturers concerned;
- (2) the arrangements proposed for the control and certification of quality of part-manufactured components delivered to the manufacturer submitting the request for qualification approval;
- (b) the UK National Supervising Inspectorate shall inform the National Supervising Inspectorates of the countries in which the various stages are performed of the request referred to in item (a), and shall proceed with the qualification approval provided that these National Supervising Inspectorates agree to:
 - (1) confirm the correctness of the information contained in the request;
 - (2) certify that the established procedures have been, and shall continue to be, applied to these stages;
 - (3) immediately advise the UK National Supervising Inspectorate of any suspension or withdrawal of supervision of the approved manufacturer(s) concerned.

3.2.5 Subcontracting to an unapproved manufacturer (route 2). If an approved manufacturer wishes to subcontract operations corresponding to the primary stage or any subsequent stages to an unapproved manufacturer, he shall:

- (a) carry out an appraisal of the competence of the subcontractor to undertake the work;
- (b) obtain the agreement of the National Supervising Inspectorate that the proposed work can be subcontracted;
- (c) prepare adequate specifications for the control of the subcontracted work;
- (d) produce a document which describes the scheme of surveillance covering assessment, testing and any other verification necessary to ensure that the approved manufacturer's approved person exercises adequate control over the quality of the subcontracted work.

Where an approved manufacturer subcontracts operations to an unapproved manufacturer, a report on the scheme of surveillance shall be submitted in writing by the National Supervising Inspectorate to BSI for approval.

This scheme of surveillance shall be endorsed, rejected or amended by BSI at intervals of two years.

NOTE. This procedure is commonly known as the 'route 2' procedure.

3.3 Incorporated components

3.3.1 General. Where an approved component released under the System incorporates components other than piece parts, their use shall comply with 3.3.2 to 3.3.4.

NOTE. The distinction between incorporated components and piece parts is that incorporated components have a distinctive electronic function in an electronic circuit, whereas piece parts do not.

3.3.2 The use of BS 9000 or CECC approved components.

Wherever possible, incorporated components shall be approved to a BS 9000 or CECC detail specification. Such components shall be approved using the normal BS 9000 or CECC release procedures (see BS 9000 : Part 7). Under these conditions no other assessment of the incorporated components is required.

3.3.3 The use of unapproved components. Where incorporated components are not procured to a BS 9000 or CECC detail specification, the approved manufacturer's approved person shall verify their quality prior to their incorporation, and shall:

- (a) be satisfied that the quality and performance of an unapproved component is adequate for its purpose;
- (b) ensure the existence of a specification for the unapproved component covering all the aspects necessary to ensure its satisfactory performance as part of the final product;
- (c) establish a quality programme to verify that the unapproved component continues to be supplied in accordance with item (b);
- (d) institute sufficient goods inward inspection procedures to ensure continued satisfactory performance of the final product.

3.3.4 The incorporation of part-finished, e.g. unencapsulated, components

3.3.4.1 There are two possible sources of part-finished components:

- (a) direct from a manufacturer (see 3.3.4.2); or
- (b) via an approved assessor of unencapsulated add-on components (see clause 5 of BS 9000 : Part 4 : 1989) (see 3.3.4.3).

3.3.4.2 Where an approved manufacturer wishes to incorporate part-finished components procured direct from a manufacturer, his approved person shall ensure that they comply with 3.3.3 and in addition ensure that:

- (a) the design of the part-finished component is compatible with the assembly technique to be employed;
- (b) the assessment of quality and performance of the part-finished component takes into account the assembly methods to be employed;
- (c) adequate storage and handling facilities are available for the part-finished components.

3.3.4.3 Where part-finished components are procured from approved independent assessors of unencapsulated add-on components, the approved manufacturer's approved person shall ensure compliance with items (a) to (c) of **3.3.4.2**.

3.3.4.4 Any additional technical requirements, e.g. test schedules, specific to particular components shall be specified in the relevant generic specification and these shall be considered as additional to the requirements of **3.3.4.2** and **3.3.4.3**.

3.4 Granting of qualification approval

3.4.1 Qualification approval testing

3.4.1.1 General. The approved person shall notify BSI of his intention to start qualification approval testing using the form specified in appendix B. Testing shall be carried out in accordance with either a published detail specification or a draft detail specification that has been accepted by the National Supervising Inspectorate for ultimate publication.

The tests shall be carried out by either the approved manufacturer, an approved independent test laboratory, a test laboratory approved within the CECC system or, exceptionally, when they are not available, in accordance with **3.4.1.2**.

3.4.1.2 Tests carried out by test laboratories not approved within the BS 9000 and CECC systems. As a preliminary condition, the approved manufacturer shall take all reasonable steps to ensure that the required service is not available from any approved independent test laboratory within the BS 9000 or CECC systems.

The approved manufacturer shall demonstrate to the National Supervising Inspectorate that the approved independent test laboratories known to be operating in the relevant area of technology are unable to undertake the specified testing.

The approved manufacturer shall produce a document which describes the scheme of surveillance by which he can ensure that the testing to be carried out shall comply with the specification. The scheme of surveillance shall define how the nominated test laboratory:

- (a) ensures that its relevant staff possesses the necessary competence and its relevant test facilities are completely adequate for the purpose;
- (b) proposes to operate the test;
- (c) ensures it has an adequate system for the calibration of its relevant measurement and test equipment and can provide adequate traceability to national standards.

In establishing the degree of surveillance necessary, account shall be taken of any current approvals/registration held by the nominated test laboratory.

Prior to permitting testing, the approved manufacturer shall demonstrate to the National Supervising Inspectorate that his proposed scheme of surveillance complies with the specification.

The procedures given in **3.4.1.2** shall be applied separately

to any subsequent programme of testing, including those carried out for periodic testing for the maintenance of qualification approval.

3.4.2 Qualification approval test reports. Where the qualification tests have been carried out by approved independent test laboratories or in accordance with **3.4.1.2**, or have been carried out at more than one approved location, reports on the separately performed tests shall be submitted in their entirety as appendices to the main test report.

Test reports shall include the following information:

(a) General:

- (1) front page as appendix C;
- (2) inspection lot sizes and sample sizes;
- (3) relationship to structurally-similar components (see clause 6) quoting qualification approval reference (if applicable);

NOTE. For components which are structurally-similar and which are in current production, use may be made of production test records, and reference made to a qualification approval test report previously approved by the National Supervising Inspectorate.

- (4) reference to manufacturing documents;
- (5) a list of test equipment used, with the appropriate measurement uncertainties.

(b) **Summary of tests.** This shall be a summary of all the tests carried out for each inspection lot and shall include the following:

- (1) description of alternative test methods (see **5.3.1**) (if applicable);
- (2) test conditions;
- (3) number of specimens tested;
- (4) acceptable quality level;
- (5) number of failures allowed;
- (6) number of failures found, together with reference to the relevant pages of the report.

(c) **Measurement record.** This shall be a record of the parametric measurements and those measurements taken before and after the various mechanical, environmental and endurance tests for which post-test limits or final measurements are specified in the detail specification.

For complex components such as integrated circuits, key parametric information may be provided in lieu of the parametric measurements on the basis of either:

- (1) the approved manufacturer's own statistical information; or
- (2) data-logged measurements of a limited number of devices (minimum 5).

Where (1) is invoked, the approved manufacturer shall demonstrate to the National Supervising Inspectorate that the statistical information is valid and relevant to the product for which qualification approval is sought.

Where (2) is invoked, the measurements may be made on key parameters of the component as agreed between