

General requirements for a system for electronic components of assessed quality —

Part 4: Specification of procedures for the approval of an organization

Committees responsible for this British Standard

This British Standard was prepared by the Electronic Components Standards Policy Committee (ECL/-), upon which the following bodies were represented:

- Association of Electronics, Telecommunications and Business Equipment Industries
- BEAMA Ltd.
- British Standards Society
- British Telecommunications plc
- Electronic Components Industry Federation
- Ministry of Defence
- National Supervising Inspectorate
- Society of British Aerospace Companies Limited

This British Standard, having been prepared under the direction of the Electronic Components Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 31 October 1991

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First published October 1989
Second edition October 1991

The following BSI references relate to the work on this standard:
Committee reference ECL/-
Draft for comment 90/31840 DC

ISBN 0 580 19955 X

Amendments issued since publication

Amd. No.	Date	Comments

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Foreword

This Part of BS 9000 has been prepared under the direction of the Electronic Components Standards Policy Committee (ECL/-). It is a revision of BS 9000-4:1989, which is withdrawn.

This edition of BS 9000-4 introduces technical changes to bring the standard up-to-date but it does not reflect a full review of the standard. In particular, this edition of BS 9000-4 invokes the appropriate Parts of BS 5750 for the approval of manufacturers, distributors, design houses and assessors, and BS 7501 for the approval of independent test laboratories. However, this Part of BS 9000 also contains requirements, specific to the System¹⁾, not covered by BS 5750 and BS 7501.

BS 9000 comprises the following Parts.

- *Part 1: Specification of general procedures;*
- *Part 2: Specification for the national implementation of the CECC²⁾ system;*
- *Part 3: Specification for the national implementation of the IECQ³⁾ system;*
- *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.*

It should be noted that there are identical ISO and EN specifications to BS 5750 and BS 7501, to which reference is made in this Part of BS 9000. Details are as follows:

- BS 5750-1 is identical to ISO 9001 and EN 29001
- BS 5750-2 is identical to ISO 9002 and EN 29002
- BS 5750-3 is identical to ISO 9003 and EN 29003
- BS 7501 is identical to EN 45001

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 18, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ For definition of “the System”, see 2.1.1 of BS 9000-1:1989.

²⁾ CENELEC Electronic Components Committee (System for Europe).

³⁾ IEC Quality Assessment System for Electronic Components.

1 Scope

This Part of BS 9000 specifies the procedures for the approval of organizations.

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

2 Approval of manufacturers

2.1 General

A manufacturer wishing to become an approved manufacturer under the System in order to seek qualification or capability approval for components produced by him, shall:

- a) apply in writing to BSI using the form given in Appendix A;
- b) allow access by the National Supervising Inspectorate to all parts of the location relevant to the assessment. Representatives of the National Supervising Inspectorate shall not disclose any confidential information obtained in the course of their duties.

2.2 Quality system requirements

2.2.1 General

The manufacturer shall demonstrate to the National Supervising Inspectorate that he meets, as a minimum, the requirements of BS 5750-2 and the requirements of the appropriate generic/sectional specification together with the additional requirements given in clause 2 of this Part of BS 9000.

The manufacturer shall also demonstrate to the National Supervising Inspectorate that he possesses sufficient engineering capability to develop and/or maintain, and control, the technology for which he is seeking approval.

In carrying out the BS 9000 assessment, the National Supervising Inspectorate shall take account of any relevant BS 5750 certification issued by an organization which is accredited to the National Accreditation Council for Certification Bodies (NACCB).

2.2.2 Manufacturers of integrated circuits

When assessing applications for manufacturer's approval from manufacturers of integrated circuits, the National Supervising Inspectorate shall permit route 2 subcontracting arrangements (see 3.2.5 of BS 9000-5:1989 and 3.2.5 of BS 9000-6:1989) to be taken into account.

2.3 Accommodation for the National Supervising Inspectorate

Upon request, appropriate accommodation shall be provided by the manufacturer for the National Supervising Inspectorate.

2.4 Calibration

Calibration practices and requirements shall comply with BS 5781.

2.5 Quality organization

2.5.1 Approved person(s)

This Part of BS 9000 assigns responsibilities to an approved person within the organization who can be the management representative, as defined in BS 5750, or his nominee.

In the case of companies controlling several locations, it is permissible to nominate an approved person who is responsible for the overall quality organization and who has an approved person at each location.

2.5.2 Inspection stamps and other marks of identification

All supplies inspected and released by an approved manufacturer, or packages containing them, shall bear the impression of an inspection stamp which identifies both the manufacturer and the individual inspector responsible.

The use of a particular inspection stamp shall be restricted to the inspector to whom it is allocated.

The manufacturer's approved person shall maintain a record of the date of issue and withdrawal of inspection stamps. When inspection stamps are withdrawn for any reason, they shall not be replaced by other stamps bearing the same identification marks until at least 6 months have elapsed since withdrawal and then only with the concurrence of the National Supervising Inspectorate.

The loss of an inspection stamp shall be reported without delay to the National Supervising Inspectorate and un-issued stamps with the same identity shall be impounded.

The mark of an approved inspection stamp shall be distinct from all other marks.

2.6 Quarantine and/or bonded store

2.6.1 The system of storage and delivery organized in agreement with the approved person shall make it possible to separate clearly and to identify the rejected lots, the lots undergoing tests and the lots released, and to relate the delivery lots to the inspection lots from which they are taken. For this purpose the results of the tests made on these inspection lots shall be kept for at least 3 years or a period not less than the periodic test frequency if this is longer than 3 years.

NOTE This will require the provision of suitable storage accommodation and records.

2.6.2 In a bonded store, an approved component shall be segregated from all other components. The segregation may be undertaken in any suitable way with the agreement of the National Supervising Inspectorate.

2.6.3 The storage arrangements shall ensure that goods held in quarantine and bonded store do not deteriorate due to storage conditions. Supplies for processing, assembly or despatch shall be issued only from the bonded store.

2.6.4 Access to quarantine and bonded stores shall be restricted to personnel specifically authorized by the approved person.

2.7 Customer returns and appropriate corrective actions

2.7.1 Released components returned to the approved manufacturer as non-compliant shall be placed in the approved manufacturer's quarantine store and recorded in the "customer returns" log.

2.7.2 The returned components shall be re-inspected under the direction of the approved person in accordance with the detail specification. If compliance is verified, the approved components shall be returned to the approved manufacturer's bonded store for return to the approved distributor or customer and recorded accordingly.

2.7.3 If compliance is not verified, an investigation under the direction of the approved person shall be carried out to ascertain the cause of the non-compliance. The conclusions of this investigation, and the corrective actions which have been implemented as a result shall be recorded and shall be made available to the National Supervising Inspectorate upon request.

2.7.4 An approved component returned for non-technical reasons, provided that the package is unopened and undamaged and its original labelling is intact, may be returned to the approved organization's bonded store for release.

2.7.5 Where a manufacturing or test defect is confirmed, the approved manufacturer shall follow the procedures detailed in **7.6.10** of BS 9000-5:1989 or **12.4.2** of BS 9000-6:1989, as appropriate.

2.7.6 Approved manufacturers shall notify the National Supervising Inspectorate every 6 months of all confirmed quality failure returns on component(s) released under the System. In the event of no quality failures a nil return should be submitted.

NOTE A quality failure is the inability of a released component to comply with a performance requirement of the relevant specification.

2.8 Notification of approval

2.8.1 General

Following a satisfactory appraisal report and allocation of a factory code by the National Supervising Inspectorate, the manufacturer shall be notified of approval by BSI by formal letter. Approval shall take effect from the date of the notifying letter.

An approved manufacturer who is granted an extension of a previous approval (see **2.11**) shall be similarly notified. A revised certificate of approval shall be issued in due course.

2.8.2 Approval numbers and certificates of approval

Once approved, a manufacturer shall be allocated an approval number which shall appear on the certificate of approval and which shall be printed on all certificates of conformity or test reports issued by the approved manufacturer. Approval numbers are permitted to be printed on letter headings, advice notes, invoices, etc. The approval number, the name, the approved location, and the scope of the approval shall be included in the list of approved manufacturers published in PD 9002.

2.9 Surveillance of an approved manufacturer

2.9.1 General

The approved manufacturer's approved person shall ensure that the conditions of the approval continue to be satisfied. The National Supervising Inspectorate shall exercise surveillance to ensure that approved conditions are maintained, by visits after the first 6 months and thereafter at a frequency of not less than two per year.

2.9.2 Surveillance checks by the National Supervising Inspectorate

The National Supervising Inspectorate shall keep under regular surveillance an approved manufacturer's quality control arrangements. To this end the National Supervising Inspectorate shall have the right, as it deems necessary, to verify the effectiveness of any element of the approved manufacturer's quality controls relevant to the System.

The National Supervising Inspectorate is permitted to select specimens and to subject them to such tests as are relevant for audit testing. Unless otherwise required by the National Supervising Inspectorate, this testing shall be carried out in the National Supervising Inspectorate's own laboratories. The specimens shall be taken from production lots which have passed quality conformance inspection, and shall subsequently be returned to the approved manufacturer with a report. The number of specimens to be provided shall not exceed the quantity normally required for approval tests.

If the National Supervising Inspectorate wishes to carry out destructive tests then, by agreement with the manufacturer, it is permitted for these tests to take the place of those which would otherwise be carried out by the manufacturer.

If the National Supervising Inspectorate is not satisfied on any point of the operation of the System, it shall take up the matter immediately with the manufacturer's approved person.

2.9.3 Periodic confirmation of manufacturer's approval

The approval shall be subject to reassessment of compliance with this Part of BS 9000 by the National Supervising Inspectorate on behalf of BSI over a period not exceeding 3 years from the date of the approval.

Before approval can be confirmed, the manufacturer shall ensure the following:

- a) that the approved person provides a written statement that the conditions of approval have been maintained, subject to any stated changes previously authorized by the National Supervising Inspectorate;
- b) that arrangements for correcting any unsatisfactory features, notified in writing at the time of review, have been agreed by the National Supervising Inspectorate.

Failure to meet these conditions shall result in suspension or withdrawal of approval.

2.10 Approval of a manufacturer acting as a distributor or a test laboratory

When an approved manufacturer wishes to act as an approved distributor and/or as an approved independent test laboratory for components produced by another manufacturer, he shall comply, in addition to clause 2, with clause 3 and/or clause 4 of this Part of BS 9000.

2.11 Extension of manufacturer's approval

Where a manufacturer wishes to extend his scope of approval he shall apply in writing to BSI, using the form given in Appendix A, for an extension of his manufacturer's approval in respect of other families or sub-families of components.

2.12 Approval for the assembly of an approved manufacturer's connector piece parts at the premises of an approved distributor

2.12.1 General

Approved manufacturers of connectors who wish to have the final assembly of their connector piece parts undertaken at the premises of an approved distributor shall comply with 2.12.2 and shall ensure compliance with 2.12.3 by the approved distributor. The procedures agreed between the manufacturer and the distributor shall establish means by which the approved manufacturer's approved person shall be responsible for ensuring that the assembly of connectors at the approved distributor will be carried out in conditions which would be applicable at his own premises.

2.12.2 The approved manufacturer

In addition to the requirements for manufacturer's approval (clause 2) and for qualification and/or capability approval (BS 9000-5 and BS 9000-6, respectively) the following shall apply.

- a) The scope of the extension of the approved manufacturer's responsibilities shall be limited to that of the assembly of his own connector piece parts and sub-assemblies and the quality conformance inspection as given in the lot-by-lot tests of the relevant detail specification.
- b) For periodic tests, samples shall be taken from the approved distributor's production on the same basis as if they had been produced by the approved manufacturer and these samples shall be added to the specimens for test taken from the approved manufacturer's own production.
- c) The procedures established in accordance with items a) and b) shall be by mutual agreement between the approved manufacturer and an approved distributor and to the satisfaction of the approved manufacturer's approved person. Full documentation shall be prepared.
- d) The approved manufacturer shall:
 - 1) provide evidence of adequate and continuing surveillance of the procedures and work in operation at the approved distributor;
 - 2) approve the appointment at the approved distributor's operation of a person responsible to act on the approved manufacturer's behalf;

3) provide all necessary process instructions, operator training programmes and assembly inspection requirements consistent with those in operation at his own premises;

4) provide tools, jigs and equipment necessary for the assembly operation and test equipment appropriate for quality conformance inspection; those items shall be within his own control and calibration system;

5) release assembled connectors with a certificate of conformity in accordance with 4.1.2 of BS 9000-7:1989 and the relevant section of the quality manual. The approved person may appoint an approved signatory to act on his behalf at the approved distributor. The certificate of conformity shall identify the connectors assembled by the approved distributor and shall be used to authorize the transfer to the approved distributor's own stock.

e) The procedures established in order to claim compliance with items a) to d) shall be described in the approved manufacturer's quality manual. The manual shall include copies of letters of agreement between the approved manufacturer and approved distributor. Changes to the agreed procedures shall not be made without the agreement of the National Supervising Inspectorate.

2.12.3 The approved distributor

In addition to the requirements for distributor approval (see clause 3) and for release of components, the following shall apply.

a) The approved distributor shall provide to the satisfaction of the approved manufacturer's approved person:

- 1) an adequate working environment and supervision for the assembly and testing operation, segregated from all other parts of his premises;
- 2) for the marking of each connector with an identification code distinguishable from the approved manufacturer's own factory code;
- 3) adequate quarantine and bonded store facilities;
- 4) evidence that the connectors are being released under the conditions of distributor approval;
- 5) satisfactory staffing, and arrangements and operator training allowing assembly as required by the approved manufacturer;
- 6) adequate security facilities for the storage of proprietary information and data;

7) an assurance of confidentiality of the approved manufacturer's processes;

8) a person responsible for liaison between himself and the approved manufacturer and authorized distributor.

b) The procedures established in order to claim compliance with item a) shall be described in the approved distributor's manual of organization and procedures. The manual shall include copies of letters of agreement between the approved distributor and approved manufacturer.

Changes to these agreed procedures shall not be made without the agreement of the National Supervising Inspectorate.

2.12.4 Withdrawal or suspension of approval

The approval to assemble at an approved distributor shall be withdrawn or suspended by the approved manufacturer when one or more of the following applies:

- a) the approved distributor advises BSI Quality Assurance (QA) that he no longer wishes it to continue (in which case approval is withdrawn);
- b) the NSI advises BSI QA that the arrangements at the approved distributor's premises are no longer satisfactory (see 2.12.3) (in which case approval is suspended subject to corrective action for reinstatement);
- c) the distributor's approval (see clause 3) is withdrawn.

2.12.5 Appeal

A manufacturer or distributor wishing to appeal against a decision to withdraw or suspend approval (see 2.12.4) shall lodge an appeal in accordance with clause 4 of BS 9000-1:1989. The decision shall stand pending the result of the appeal.

2.13 The manufacturer's approved person

2.13.1 This Part of BS 9000 assigns responsibility to an approved person within the organization who can be the management representative as defined in BS 5750, or his nominee.

2.13.2 The additional duties of the approved person required for this Part of BS 9000 shall be:

- a) to be responsible for complying with the System and for the publication and maintenance of the quality manual;
- b) to cooperate with the National Supervising Inspectorate;