

Rules of Procedure of the IEC Quality Assessment System for Electronic Components (IECQ) —

**Part 3: Approval procedures, including
a new clause on Technology Approval**

ICS 31.020

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by Technical Committee L/9, Electronic components policy committee, to Subcommittee L/9/3, Quality assessment procedures, upon which the following bodies were represented:

- Federation of the Electronics Industry
- National Supervising Inspectorate (BSI PC)

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National foreword

This British Standard reproduces verbatim QC 001002-3:1995 and implements it as the UK national standard.

This British Standard is published under the direction of the Electrotechnical Sector Board whose Technical Committee L/9 has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on interpretation, or proposals for change, and keep UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

Cross-references

Publication referred to	Corresponding British Standard
QC 001002:1986	BS QC 001002:1991 <i>Rules of Procedure of the IEC Quality Assessment System for Electronic Components (IECQ)</i>
QC 001002-2:1995	BS QC 001002-2:1997 <i>Documentation, including a new clause on regulations for Technology Approval Schedules</i>
QC 001005:1995	BS QC 001005:1995 <i>Register of firms, products and services approved under the IECQ system, including ISO 9000</i>
ISO 9001:1994	BS EN ISO 9001:1994 <i>Quality systems. Model for quality assurance in design, development, production, installation and servicing</i>
ISO 9002:1994	BS EN ISO 9002:1994 <i>Quality systems. Model for quality assurance in production, installation and servicing</i>

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 12, 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 Approval of a national supervising inspectorate

See QC 001002:1986 clause 9 and Amendment 2:1994.

2 Requirements for the approval of an organization

See QC 001002:1986 clause 10 and Amendment 2:1994.

3 Qualification approval of electronic components

See QC 001002:1986 clauses 11 and 12, and Amendment 2:1986.

4 Capability approval of an electronic component manufacturing facility

See QC 001002:1986 clauses 11 and 12, and Amendment 2:1986.

5 Approval of specialist contractors' processes and/or products within the electronic components industry

Under consideration

6 Technology approval of electronic component manufacturers

Introduction

Technology Approval is a method of approving a complete technological process (design, process realization, product manufacture, test and shipment) covering the approval aspects common to all products as determined by the technology under consideration. This method has evolved to meet the needs of users and manufacturers and incorporates many of the latest principles and techniques in the management of quality, that is to say TQM. It extends the existing approval concepts by adding the following principles as mandatory aspects of Technology Approval:

- 1) the use of in-process control methods (of which SPC is an example) as defined in the TAS and tools to demonstrate adequate control of processes and products. SPC methods shall be in operation at the initial approval to this clause or within a period of 12 months from approval being granted;
- 2) continuous quality improvement strategy and its demonstration;
- 3) monitoring the overall technologies and operations associated with the design and manufacturing processes as well as the components themselves;

4) procedural flexibility due to the approval being based on a company's own quality assurance management system and market sector requirements;

5) the acceptance of a manufacturer's operational documentation to provide a means for rapid approval or extension of approval.

6.1 Definitions

The terms and definitions specific to this clause are as follows:

6.1.1

control site

the location of the manufacturer having overall responsibility for operation of the IECQ System and all quality related matters within the approved organization, and in which the manufacturer is capable of operating at least one of the processes within the scope of the Technology Approval

6.1.2

quality indicator

a statistical measure of the relative quality of a process

6.1.3

test vehicle

the generic term for a product-related device or test structure used to verify, analyze or monitor engineering processes or electrical/physical features

6.1.4

critical process step

a step which has a major influence on the outcome of the process

6.1.5

technology approval declaration document (TADD)

a document describing the manufacturer's organization and scope of technology. The content of a TADD is fully described in annex C to this clause

6.1.6

technology approval schedule (TAS)

a technology dependent document, written in accordance with the requirements of QC 210000 describing the minimum declarations, technical requirements and controls to be demonstrated and maintained under a manufacturer's Technology Approval

6.2 General procedures

6.2.1 *Eligibility for Technology Approval*

6.2.1.1 *Relationship between Organization Approval and Technology Approval (TA)*

TA may only be granted to a manufacturer who already holds Manufacturer's Approval in accordance with the requirements of QC 001002-3, clause 2 including, as appropriate, those of ISO 9001 or ISO 9002 and, additionally, the requirements of this clause. These approvals may also be carried out in parallel, although TA shall not be granted in advance of Manufacturer's Approval.

NOTE 1 Organization approval with respect to TA is based on a Technology Approval Schedule (TAS) and not on a Generic specification.

6.2.1.2 *Off-site operations*

Design, manufacture and test may take place in any geographic location provided that the TA is managed from an IECQ approved manufacturing facility, which shall act as the Control Site.

6.2.1.3 *Control Site*

The Control Site shall have local capability to perform at least one of the main technical processes, as defined in the TAS, within the scope of the TA.

6.2.2 *Application for TA*

The manufacturer shall apply in writing to the National Certification Body (NCB), with a copy to the National Supervising Inspectorate (NSI), stating the scope of the proposed TA, as defined in the appropriate TAS, or draft TAS, and clearly defining the activities and technologies for which the approval is sought. An example of the application form is given in annex A.

6.3 Management responsibility

6.3.1 *Management commitment*

The manufacturer shall provide a statement of his corporate management's commitment to continuous quality improvement and customer satisfaction. This statement shall be supported by evidence of its implementation. The statement shall be included in the manufacturer's Technology Approval Declaration Document (TADD).

6.3.2 *Operational infrastructure*

In addition to the manufacturer's Quality Manual, as covered by QC 001002-3, clause 2, the TADD shall define his operational infrastructure (if not already contained within the manufacturer's Quality Manual). This infrastructures shall include

a) *Management structure.*

The manufacturer at the Control Site shall establish a declared organization called, for example, Technical Review Board (TRB).

The TRB shall manage the TA and ensure the conduct of periodic system reviews.

A TRB, or equivalent, shall control, stabilise, monitor and improve the approved manufacturing line.

The TRB shall have a methodology in place for assessing the current status of the quality and reliability of its components.

The TRB shall be responsible for the global optimization of the controlled technology.

b) *Additional responsibilities of the Designated Management Representative (DMR)*

The DMR shall be responsible, on behalf of the manufacturer's corporate management, for providing leadership and facilitating progress in all sites covered by the TA.

The DMR shall ensure that corporate management policy relevant to the TA is reviewed and revalidated internally on an annual basis, as a minimum.

The DMR, as a part of the management structure, shall be a member of the TRB.

c) *Technical decision-making*

The manufacturer at the Control Site shall declare the procedures by which decisions are made on all matters related to the TA.

6.4 TA requirements

6.4.1 *TADD*

The manufacturer shall generate a TADD as part of his application for TA. The TADD shall relate to the entire scope of the proposed TA and be fully maintained during the life of the approval.

6.4.2 *Requirements for a TADD*

The manufacturer shall produce a TADD which gives a detailed amplification of each of the following items:

- a) management commitment to quality;
- b) description of the technology and processes;
- c) definitions of the relevant sites and operations;
- d) test vehicles;
- e) internal audit plan;
- f) quality improvement programme;
- g) statistical methods of evaluation;
- h) management of non-conforming products or activities;
- i) new product introduction programme;
- j) inter-relationship with subcontractors;
- k) company definitions and symbols;
- l) reference to the register of components covered by TA.