IEC Quality Assessment System for Electronic Components (IECQ System)

Rules of Procedure –
Part 3: Approval procedures
IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ Scheme)

Rules of Procedure –
Part 3: Approval procedures

INTERNATIONAL ELECTROTECHNICAL COMMISSION

PRICE CODE ZZ

Withdrawn
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 3: Approval procedures

FOREWORD

This publication has been prepared by the Management Committee (MC) of the IECQ.

Clause 0 is unchanged from the previous edition.

Clause 1 comprises the former Amendment 1 2002 to QC 001002-3 1998, without change.

Clause 2 comprises the former Amendment 2 2004 to QC 001002-3 1998, without change.

Clauses 3, 4, 5 and 6 cancel and replace the corresponding clauses of QC 001002-3 Third edition 1998. They contain editorial up-dating and include requirements from the former ECQAC Permanent Documents.

The text of this publication is based on the following documents:

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<th>Document</th>
<th>Report on voting</th>
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<tr>
<td>IECQ-CECC MC/53/CD</td>
<td>IECQ-CECC MC/69/RM, as corrected by IECQ MC/69A/RM,</td>
</tr>
<tr>
<td>IECQ-CECC MC/54/CD</td>
<td>item 7.2.1</td>
</tr>
<tr>
<td>IECQ-CECC MC/55/CD</td>
<td></td>
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<tr>
<td>IECQ-CECC MC/56/CD</td>
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</tbody>
</table>

Full information on the voting for the approval of this publication can be found in the report on voting indicated in the above table.
0. An introduction to the types of approval available under the IECQ

0.1 Introduction

This clause describes briefly the types of approval available under the IECQ as detailed in the requirements given in clause 2 and the following clauses. These approvals are summarized below with further information given in Figure 1 and Table 1.

0.2 Approval of manufacturers and other organizations

This level of approval is a prerequisite to seeking any other type of approval listed in clause 2 and the following clauses and is applicable to manufacturers, distributors, independent testing laboratories and specialist contractors wishing to become approved under the IECQ.

The requirements of this type of approval are described in clause 2, Requirements for the approval of an organization.

It should be noted that, when carrying out the appraisal, the Supervising Inspectorate (SI) is required to take into account any relevant certificate to ISO 9001 and ISO/IEC 17025 issued by an organization declared competent to do so by the appropriate national authority.

0.3 Approvals available to manufacturers

0.3.1 Choice

A manufacturer has the approvals detailed in 0.3.2 to 0.3.4 available to him. A particular manufacturer’s choice of approval will depend on

— existence of current approvals,
— product range,
— available applicable specifications, and
— expected manufacturing development.

0.3.2 Qualification Approval of electronic components

This type of approval is applicable to an identified electronic component or range of components for which detail specifications exist. Where a detail specification does not exist, it is permissible for a manufacturer to prepare a detail specification in accordance with QC 001002-2, clause 1 or clause 5, for publication within the System. Qualification Approval (QA) is granted to a manufacturer when it has been established that the components meet the requirements of specifications which are approved for use within the IECQ.

The requirements of this type of approval are described in clause 3, Qualification Approval of electronic components.

A prerequisite for obtaining this type of approval is that a manufacturer must have, or obtain, manufacturer’s approval to clause 2 (see 0.2 above).
0.3.3 Capability Approval of an electronic component manufacturing facility

This type of approval is applicable to an identified component manufacturing process for which an applicable IECQ generic or sectional specification describing Capability Approval (CA) exists.

It is granted to a manufacturer when it has been established that his capability for manufacturing processes and quality control methods (including design aspects if applicable) covering a specific component technology fulfils the requirements of the relevant generic specification.

The requirements of this type of approval are described in clause 4, Capability Approval of an electronic component manufacturing activity.

A prerequisite for obtaining this type of approval is that the manufacturer must have or obtain manufacturer’s approval to clause 2 (see 0.2 above).

NOTE  A manufacturer may apply for approval in accordance with clause 2, at the same time as submitting his application for QA or CA under clauses 3 or 4.

0.3.4 Technology Approval for electronic component manufacturers

Technology Approval (TA) is a method of approval which has evolved to meet the needs of manufacturers and incorporates the most recent principles and techniques in the management of quality. It provides for the use of statistical methods and tools, continuous improvement and procedural flexibility.

This type of approval is applicable to an identified electronic component manufacturing activity for which a Technology Approval Schedule (TAS) exists.

The requirements for this type of approval are described in clause 6, Technology Approval of electronic component manufacturers.

A prerequisite for obtaining this type of approval is that a manufacturer must have or obtain manufacturer’s approval to clause 2 (see 0.2 above).

NOTE 1 A manufacturer may apply for approval in accordance with clause 2, at the same time as submitting his application for TA under clause 6. TA will not be granted in advance of manufacturer’s approval.

NOTE 2 A manufacturer approved to clause 2, wishing to obtain TA, should note that there is requirement to produce a Technology Approval Declaration Document (TADD) (see 6.4).

0.4 Approvals available to specialist contractors

This type of approval is applicable to any specialist contractor wishing to obtain Process Approval (PA) to carry out “contracted work” under the IECQ.

This type of approval is applicable where a relevant Process Assessment Schedule (PAS) exists.

The requirements for this type of approval are described in clause 5, Approval of specialist contractors’ processes and/or products within the electronic components industry.

A prerequisite for obtaining this type of approval is that the specialist contractor must have or obtain specialist contractor approval to clause 2 (see 0.2 above).
An organization may hold more than one approval classification under QC 001002-3, clause 2.

Figure 1 — Diagrammatic representation of IECQ approvals
Table 1 — IECQ approvals summary

<table>
<thead>
<tr>
<th>Type of approval required</th>
<th>Account will be taken of these approvals (where they exist)</th>
<th>Type of approval also required</th>
<th>Reference required to these documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC 001002-3, clause 2 - Requirements for the approval of an organization (see 0.2)</td>
<td>ISO 9001 ISO/IEC 17025</td>
<td>not applicable</td>
<td>QC 001002-3, clause 2</td>
</tr>
<tr>
<td>QC 001002-3, clause 3 - Qualification Approval of electronic components (see 0.3.2)</td>
<td>not applicable</td>
<td>Manufacturer’s approval to QC 001002-3, clause 2</td>
<td>QC 001002-3, clauses 2 and 3 a</td>
</tr>
<tr>
<td>QC 001002-3, clause 4 - Capability Approval of an electronic component manufacturing activity (see 0.3.3)</td>
<td>not applicable</td>
<td>Manufacturer’s approval to QC 001002-3, clause 2</td>
<td>QC 001002-3, clauses 2 and 4 a</td>
</tr>
<tr>
<td>QC 001002-3, clause 5 - Approval of specialist contractors’ processes and/or products within the electronic components industry (see 0.4)</td>
<td>not applicable</td>
<td>Specialist contractor approval to QC 001002-3, clause 2</td>
<td>QC 001002-3, clauses 2 and 5 QC 200000 b</td>
</tr>
<tr>
<td>QC 001002-3, clause 6 - Technology Approval for electronic component manufacturers (see 0.3.4)</td>
<td>not applicable</td>
<td>Manufacturer’s approval to QC 001002-3, clause 2</td>
<td>QC 001002-3, clauses 2 and 6 QC 210000 c</td>
</tr>
</tbody>
</table>

a Reference should also be made to the relevant generic specification
b Reference should also be made to the relevant PAS
c Reference should also be made to the relevant TAS
1. Approval and accreditation of a Supervising Inspectorate (SI)

1.1 Description and general requirements

1.1.1 A Supervising Inspectorate (SI) is an organization responsible for the surveillance of all procedures for quality assessment necessary for the System. This includes the evaluation for the approval and surveillance of manufacturers, distributors, specialist contractors and the accreditation of independent testing laboratories, the supervision of the certification of conformity and the audit testing of approved components.

NOTE For the purpose of the IECQ, an audit test is a test carried out on a random basis by an SI, or under its direction, to verify the proper application of the specification and the correctness of the test results of the manufacturer.

1.1.2 An SI

a) shall be free from any influence which could prevent it from acting in an impartial manner,

b) shall have a staff sufficient in number, technical competence and skill to carry out adequately its surveillance and supervisory responsibilities,

c) should have for audit purposes those test facilities which are necessary for all normal measurements within its technological areas as defined in 1.2.2.

Where some of these test facilities are not available in its own institution, the SI shall have access to facilities in an accredited independent testing laboratory which may be outside its own geographical area.

In limited areas of high technology it is acceptable to use complex or specialized test equipment at an approved component manufacturer’s factory. The components of one manufacturer shall not be tested in another component manufacturer’s premises, except with the written agreement of the former. The result of all tests under such conditions shall be confidential to the SI, and

d) shall ensure that its representatives are under an obligation not to disclose any confidential information obtained in the course of their duties.

1.1.3 In order to operate under the System, the SI shall be recognized by a National Authorized Institution (NAI), approved by the Conformity Assessment Bodies Committee (CABC) and accredited by the Management Committee (MC) (see QC 001002-1, subclause 1.4.3).

1.1.4 The jurisdiction of an SI covers all surveillance activities under the System within defined geographical and technological areas, for which approval has been granted.

1.1.5 An SI recognized by an NAI of a participating country can, after the approval by that NAI and by the CABC, delegate the authority for a defined technological area to another SI.

1.1.6 When an SI subcontracts any part of the inspection, it shall ensure that its responsibilities and obligations for the inspection conducted on its behalf are fully met. The SI shall ensure and be able to demonstrate that its subcontractor is competent to perform the services in question and complies with the applicable criteria stipulated in the present clause 1 and with any additional requirements for the work being subcontracted.
1.1.7 The SI shall record and retain details of its investigation of the competence and compliance of its subcontractors, and maintain a register of all subcontracting. These details shall be submitted to the CABC for approval in accordance with 1.7.1.

1.1.8 Details of the SIs and their subcontractors approved to operate under the System shall be included in QC 001006, Register of Participating Countries.

1.1.9 An SI shall ensure that any activities which it performs, or which any subcontractor, independent testing laboratory or other external body performs on its behalf, comply with the relevant clauses of the following documents.

- ISO 10011: Guidelines for auditing quality systems
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- ISO/IEC Guide 62: General criteria for bodies operating assessment and certification/registration of quality systems
- ISO/IEC Guide 65: General criteria for bodies operating product certification systems

1.1.10 An SI may use its own or associated laboratory facilities as a commercial service to industry but they shall meet the requirements of the System for independent testing laboratories. Independence of operation shall be demonstrated to the CABC. Where the laboratory is registered and subject to independent surveillance under its nationally recognized laboratory system, this shall be taken into account.

1.2 Statement of Surveillance Arrangements

A candidate SI shall prepare a document which will form an Annex to the National Statement of Surveillance Arrangements (NSSA) of any participating country of the System in which it is authorised to operate or with which it may be connected in any other way, approved by the MC. It shall contain all essential information, without superfluous repetition of the Rules of the System, and shall be written in one of the official languages of the IEC.

The Annex shall include the following information under the following headings:

1) **Introduction**

This section shall relate the SI’s organization to the System and shall show the general approach to the implementation.

2) **Description of the SI’s organization**

This section shall include

a) an organization chart,

b) a statement showing the responsibilities for the surveillance and calibration functions required by clause 6 of the Basic Rules, with particular reference to the SI,
c) a statement of the geographical area over which the SI proposes to exercise jurisdiction. This area is normally defined by the boundaries of the country, or countries, concerned. Where an SI is asked to operate outside its stated geographical area, and where an active SI exists, agreement between the SIs concerned and of the CABC shall be obtained on a case by case basis,

d) a statement of the technological areas over which the SI proposes to exercise jurisdiction. These technological areas shall be those covered by one or more IEC generic and sectional specifications or such other specifications as may be approved for use under the System (see clause 12 of the Basic Rules, IECQ 01),

e) a description of the arrangements for managing and conducting a comprehensive system of internal quality audits to verify compliance with relevant requirements,

f) a description of the arrangements for appeal against its decisions or those of the relevant Certification Body (CB),

g) a description of the arrangements for the approval of manufacturers, distributors, specialist contractors, and accreditation of independent testing laboratories,

NOTE An SI intending to act additionally as an independent testing laboratory shall include in this section a description of how its laboratory complies with ISO/IEC 17025 as given in 2.4.

h) a description of the arrangements for the implementation of the Qualification Approval of components and Capability, Technology or Process Approval,

i) a description of the arrangements for the implementation of quality conformance inspection and an indication of the frequency of surveillance visits, and

j) a description of the arrangements for the implementation of Attestation of Conformity, QC 001002-2, clause 2.

3) Resources of the SI

This section shall include information on the experienced manpower, the test facilities and the ancillary technical services, available to deal with the technological areas defined in the Annex.

4) Guidance and information documents

This section shall include or make reference to written working instructions which serve as guidance documents to the SI and to any documents providing additional information.

All documents listed shall be made available to participating countries on request.
1.3 Application procedure

1.3.1 A candidate SI wishing to operate under the System shall send an application file to the Secretary of the IECQ (see the flowchart in annex A of this clause).

The application file shall be in electronic form and shall contain the following information:

a) a declaration that the candidate complies with, or undertakes to comply with, the requirements detailed in 1.1;

b) the address of the primary location of the candidate, and country in which an NAI has agreed that it may operate under the IECQ if granted accreditation by the MC;

c) an Annex, as specified in 1.2, for inclusion in the NSSA of the NAI referred to in b) above;

d) a declaration that it will pay such dues with respect to the application as may be determined by the MC;

e) evidence, where applicable, that it has been granted accreditation or recognition of compliance in respect of the documents listed in 1.1.9 by any other responsible authority;

f) a request that one of the SIs acts as its mentor, if the experience in 1.5.1 d) is not available.

1.3.2 Within fourteen days the Secretary shall check that any SI proposed as a mentor accepts this role, and shall circulate copies of the application file to all members of the CABC for consideration and approval of its contents. They shall inform the Secretary within four weeks of the despatch of the application file from the Secretariat

— whether they have any objections against the information presented, and
— where applicable, whether they agree with the choice of the mentor SI (see 1.5.2).

The SIs shall moreover inform the Secretariat whether they are willing to co-operate in an Assessment Team (see 1.4) which will assess the candidate SI.

If no reply is received by the end of the four weeks, it shall be assumed that there are no objections and, if applicable, the choice of a mentor is acceptable, and that the SI is willing to join the Assessment Team.

1.3.3 Objections shall be raised in a letter to the Secretary with a copy to the candidate. The Secretary, in conjunction with the Chairman of the CABC, shall take whatever actions they consider appropriate to overcome the objection.

1.3.4 Within two weeks of the conclusion of the examination period, the Chairman of the CABC shall inform the candidate SI either that

a) the application has been successful, or

b) he/she has been unable to overcome the objection(s) and that, in consequence, the application is rejected.

Following a successful application, the Chairman of the CABC shall, when appropriate, inform the candidate of the name and qualification of the proposed mentor.
1.4 Appointment of the Assessment Team

1.4.1 As soon as the application has been approved, the Chairman of the CABC shall appoint one expert from each of three SIs to form the Assessment Team from amongst those which have stated a willingness to participate.

An SI acting as a mentor for the candidate shall not serve on the Assessment Team.

The members of the Assessment Team should have the following knowledge/experience as appropriate:

- certification and quality assurance;
- application of standards and testing;
- equipment, instruments and their calibration.

Each member of the designated Assessment Team may be assisted by not more than two support staff from his/her SI.

1.4.2 The candidate may submit an objection to the Chairman of the CABC regarding the appointment of one or more of the members of the Assessment Team on commercial grounds which shall be stated in the objection. Alternative member(s) shall be selected in accordance with 1.4.1.

1.4.3 The candidate shall only be responsible for the transportation and living expenses of the three members of the Assessment Team, whether this is an initial visit or, if necessary, a subsequent visit.

The visits within the country of the candidate shall be planned so that they will be completed as expeditiously as possible.

1.4.4 The Assessment Team shall elect one of its members as Chairman. The Secretary of the CABC shall, in consultation with all persons involved, make the arrangements for a visit of the Assessment Team to the candidate. The visit shall take place, unless impractical, within three months and the assessment of the candidate shall be completed within twelve months of the approval of the Annex to the SSA.

1.5 Assessment procedure

1.5.1 The Assessment Team during its visit to the candidate shall verify that

a) the candidate meets the general requirements of 1.1.1 and 1.1.2,

b) the Basic Rules and Rules of Procedure have been implemented in a correct way,

c) the Annex to the NSSA is a correct description of the actual situation,

d) the candidate has sufficient experience with quality assessment of electronic components involving approval procedures similar to those adopted for use within the System and has arrangements for the preparation and maintenance of a list of approved manufacturers, distributors, specialist contractors and accredited independent testing laboratories which it has assessed and intends to approve under the System, and

e) that the measuring and test equipment necessary for the scope of the application is available.
1.5.2 If the experience in 1.5.1 d) above is not available at the time of application, the candidate may request that one of the SIs acts as its mentor (see 1.3.1). The NAI of the candidate’s country shall delegate, to the SI accepting to act as mentor, the responsibility for the surveillance of all procedures for quality assessment necessary for the System in the candidate’s country for an initial period until the candidate has acquired sufficient experience. During the initial period, the mentor shall supervise in the candidate’s country the operation of the candidate and countersign all approvals, certificates and reports as appropriate. These approvals are consequently valid under the System.

The candidate shall inform the CABC when it considers it is ready for the visit by the Assessment Team.

1.5.3 The candidate shall be responsible for arranging such visits to any laboratory and to any manufacturer’s production line as may be considered appropriate by the Assessment Team.

In addition to that shown during the visit, the Assessment Team may discuss with the candidate any other part of its declared technological area.

During the visit to a manufacturer, the Assessment Team shall have access to the documentation referred to in ISO 9001 and required in 3.2 and which is relevant to the component production under review. The earlier provision of this documentation shall be at the manufacturer’s discretion. This documentation may be in any language, the candidate being responsible for providing oral translation into one of the official languages of the IEC at the time of the visit.

1.6 Reporting and decision

1.6.1 During the visit, the Assessment Team shall prepare a draft of its formal report. This draft shall contain all the conclusions of the Assessment Team where these are either the joint opinions of the Assessment Team or those of one or two of its members.

The report shall indicate whether

a) the Assessment Team would unanimously recommend the approval of the candidate; or

b) it would recommend, subject to the correction of some minor deficiencies, the approval of the candidate; or

c) there were important deficiencies and the Assessment Team could not recommend approval until these deficiencies had been corrected and a further visit by one or more members of the team would be necessary to determine whether the corrective action was satisfactory; or

d) the conclusions were applicable to the entire process of approval or only to a part of this process.

The draft report shall be discussed with the candidate and every attempt made to resolve any differences between the Assessment Team and the candidate at the time of the visit. In the case of c) above, the candidate may request that any of the detailed information is treated as confidential.

1.6.2 Within four weeks of the completion of its visit, the Assessment Team shall finalize its report and submit it to the members of the CABC. Where the candidate has requested that the detailed information in 1.6.1c) is treated as confidential, it shall be contained in a separate appendix to the report and shall only be made available to those delegates to the CABC who are members of SIs.
1.6.3 Where the report shows that only minor deficiencies exist, the Assessment Team may agree to accept written evidence that corrective action has been accomplished. When such evidence has been received by the members of the Assessment Team within eight weeks of the conclusion of their visit, a supplement shall be added to the report indicating that the Assessment Team unanimously recommends the approval of the candidate and the report shall be sent to the members of the CABC.

Where the written evidence that the corrective action has been accomplished is not received, the Assessment Team shall recommend that the approval of the candidate is not granted. The Assessment Team shall then issue a supplement to its report, which shall be sent to the members of the CABC.

1.6.5 Where the report shows that important deficiencies have been revealed, the candidate shall have the right to take corrective action within a period of eighteen months. The report shall be circulated to the CABC but, if confidential, the appendix shall be circulated only to those members who are members of SIs. The report shall recommend that the accreditation of the candidate is not granted until the necessary corrective action has been accomplished.

The Assessment Team may either delegate to one of its members the responsibility to visit the candidate again or decide that all the members shall jointly make the visit. This visit shall take place as soon as possible after notification of the completion of the corrective action and, in any case, not later than three months after the notification.

During this visit, a draft supplement to the original report shall be prepared and the candidate shall be informed of its conclusions. Where the candidate has been visited by one member, the draft shall be circulated to the other members of the Assessment Team.

Within four weeks of the completion of the visit the Assessment Team shall finalize its report.

Where the Assessment Team is satisfied that the corrective action has been accomplished, the supplement to its original report shall indicate that the Assessment Team unanimously recommends the accreditation of the candidate and the supplement shall be sent to the members of the CABC.

Where the Assessment Team considers that the corrective action has not been accomplished, it shall report this fact to the CABC.

1.6.6 When deficiencies have not been satisfactorily corrected within a period of eighteen months from the issue of the visit report, the application shall be considered to have been terminated.

1.6.7 If, in 1.6.3, 1.6.4 or 1.6.5, the Assessment Team unanimously recommends in its report the accreditation of the candidate, the recommendation shall be submitted to the full members of the CABC for voting by correspondence (see QC 001002-1, subclause 3.7.2 and 3.7.3). Approval shall not be withheld by any full member except for technically valid and documented reasons.

The decision of the CABC shall be circulated to the MC for accreditation (see QC 001002-1, subclause 2.8.4b).

1.6.8 If the candidate does not agree with the report of the Assessment Team, it shall be allowed to present its case in writing to the CABC prior to this Committee considering the recommendation of the Assessment Team.

The delegates of SIs shall consider this matter during the first scheduled meeting of the CABC following the submission of the report from the Assessment Team and the objections from the candidate, provided these have been submitted at least four weeks prior to this meeting. The CABC shall give a decision in writing within one month of the meeting.
In cases where the next meeting of the CABC is scheduled for a date of six months or more after the submission of the report of the Assessment Team and the objections of the candidate, the latter may request a meeting of the CABC to consider and decide on this matter. The Chairman of the CABC shall immediately arrange for this meeting to be held.

If the CABC concurs with the recommendations of the Assessment Team, and if the candidate still considers that its views were not properly taken account of or that the correct procedures were not followed by the CABC, the candidate may appeal against the decision of the latter to the MC.

During its first scheduled meeting, the MC shall deal with the appeal, provided that the appeal has been submitted at least four weeks prior to the meeting. If the MC agrees with the appeal, the CABC shall be instructed to reconsider the approval of the candidate. If the MC does not agree with the appeal, the candidate shall implement the necessary corrections.

1.7 Changes in the Annex to the NSSA

1.7.1 Changes in an Annex to an NSSA, such as those on 1.2.2) b), c) and d), which could affect the adequate supervision of approved manufacturers, distributors, specialist contractors and accredited independent testing laboratories, shall be submitted to the Secretariat and shall be approved by the CABC before taking effect.

The Secretariat shall circulate the proposed changes to the members of the CABC with a request that they state within four weeks of despatch from the Secretariat whether they have any objections.

Objections to proposed changes shall be accompanied by valid reasons.

If no objections and no requests to discuss the matter at a meeting to be held are received by the end of the four weeks, the relevant SI shall be informed of this and the Secretary shall report this at the next meeting of the CABC.

In all other cases, the matter shall be dealt with at the next meeting of the CABC. The decision of the CABC may be such that an Assessment visit is required, in which case the scope of the visit shall be defined and it shall be assigned to two SIs.

1.7.2 The SI shall within one month notify the Secretariat of changes to the Annex to the NSSA other than those given in 1.7.1

The Secretariat shall circulate such notification to all members.

1.7.3 Each SI is responsible for deciding whether the action on changes should be subjected to the procedures of 1.7.1 or 1.7.2.

If no objections are received by the end of four weeks, the relevant SI shall be informed of this and the Secretary will report this at the next meeting of the CABC.

If objections are received, the matter shall be dealt with at the next meeting of the CABC. Pending the decision of the CABC, the change shall be considered as not having been approved and the relevant SI shall be informed of this fact.
1.7.4 When one or more objections have been received, the SI proposing the change to its Annex to the NSSA may request that the matter be concluded in writing, if it is not possible to hold a meeting of the CABC within six months of the receipt of the objection(s). In this case, it may prepare a written statement disputing the objection(s), which shall be circulated together with the objection(s) to all NAIs and SIs, with a request to state whether they support the objections.

Each specific item of an objection shall be sustained only if supported by at least two further SIs. The voting period shall be terminated when all SIs have replied or four weeks after circulation, whichever is the shorter.

1.7.5 Every five years, the SIs accredited under the System shall send to the Secretariat a recapitulation of the changes applied in their Annexes to NSSAs. The recapitulation shall be subjected to the procedures given in 1.7.1. If no changes have been applied during the five years' period, the SI shall confirm that the existing text is still valid.

1.8 Maintenance, suspension and withdrawal of accreditation of an SI

1.8.1 Maintenance of accreditation

1.8.1.1 Every year, each SI shall provide the following information for consideration by the CABC:

a) a written statement that there has been no change to the procedures in force, or an amendment to the Annex to the NSSA if the changes are small, or a complete re-issue of the Annex to the NSSA if the changes are of a significant nature;

b) the number of approved manufacturers, distributors, specialist contractors and independent testing laboratories and an indication as requested in 1.2.5 of the frequency of surveillance visits;

c) a statement of the resources available with respect to those described in 1.2.7 for manpower and test facilities;

d) list of the different families of components within the SI’s area of technological jurisdiction and which are under surveillance, identifying the associated generic specifications;

e) the number of audit tests or other product verification activities performed either by the SI or on its behalf;

f) information on the annual internal audits conducted in accordance with 1.2, and a statement on verification of the corrective actions required;

g) information, including the result, on any appeals against the decisions of the SI or CB which have needed resolution by the NAI or the CABC. This information shall be given in such a manner that it does not disclose any confidential information.

1.8.1.2 The CABC shall consider the information required by 1.8.1.1 at its next meeting and, if satisfied by the submission, shall so notify the SI in writing within fourteen days.

If the CABC is not satisfied, it may ask for further information to clarify any matters of doubt, either by an oral statement at the meeting or by further documentation. In the second case the final decision shall be made at the following meeting of the CABC. During this period, the accreditation of the SI shall remain in force.
1.8.1.3 At intervals of not more than five years, the arrangements in the Annex to the NSSA shall be re-examined by an Assessment Team, chosen as prescribed in 1.7.1 (last paragraph) to assess the continued technical competence of the SI to exercise its duties. If the SI is servicing only one approval, the re-assessment team may comprise only one assessor.

1.8.2 Suspension and withdrawal of accreditation

1.8.2.1 If evidence has been presented to, and accepted by, the CABC that components which do not conform to the requirements of the System and to the relevant specifications are being released and that the SI, CB and the NAI concerned have been informed and have failed to take any remedial action, the CABC shall immediately suspend the accreditation of the SI.

All NAIs, CBs and SIs shall be informed in writing by the Secretary of the CABC within fourteen days of the decision to suspend the accreditation of the SI.

1.8.2.2 The CABC may require the SI to submit evidence that it has corrected its deficiencies or may decide to convene an Assessment Team to re-assesses the SI. The final decision on the outcome shall be made at the next meeting of the CABC. If the decision is to lift the suspension, the SI may resume its activities immediately and confirmation of the lifting of the suspension shall be given in writing by the Secretary of the CABC within fourteen days to all NAIs, CBs and SIs. If the decision is unfavourable or corrective actions have not been completed within six months, or any other period agreed by the CABC, the procedures of 1.8.2.3 shall be invoked.

1.8.2.3 Where the deficiencies are serious, the CABC may request the MC to withdraw accreditation of the SI. Formal notification of the withdrawal of the accreditation shall be given, in writing, to the SI, by the Secretary of the MC within fourteen days of the decision. The decision, however, shall be binding from the time that it was made by the MC. NAIs, CBs and SIs shall be informed by the Secretary of the MC in writing within fourteen days of the withdrawal of the accreditation. Any subsequent request from the SI to be re-admitted to the System shall be subject to the full procedures specified in clause 1 when new candidates apply for approval.

1.8.2.4 The voting on the decision for renewal or reinstatement of the approval of an SI shall be on the same basis as that for the initial accreditation of an SI.

1.8.2.5 An SI has the right to appeal to the IEC Conformity Assessment Board (CAB) against the decision made by the MC. The decision of the MC shall remain, pending the outcome of the appeal. Such an appeal shall be made within six months of the date of the MC decision.

1.8.2.6 During the period of suspension, or in the case of withdrawal of accreditation, the NAI of the country involved may make arrangements, with the assistance of and subject to approval by the CABC, for other SIs to carry out the surveillance and audit testing work in order to safeguard, to the maximum possible extent, the position of approved organizations.
Annex A to clause 1
(normative)
Flowchart

<table>
<thead>
<tr>
<th>Action Number</th>
<th>Responsible Organization</th>
<th>Action to be undertaken</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Applicant</td>
<td>Submits Application File</td>
</tr>
<tr>
<td>2</td>
<td>MC Secretary</td>
<td>Nominates Mentor (If applicable)</td>
</tr>
<tr>
<td>3</td>
<td>Mentor</td>
<td>Accepts Responsibility</td>
</tr>
<tr>
<td>4</td>
<td>MC Secretary</td>
<td>Submits Information to CABC</td>
</tr>
<tr>
<td>5</td>
<td>CABC</td>
<td>Considers Application Approves, if appropriate</td>
</tr>
<tr>
<td>6</td>
<td>Chairman CABC</td>
<td>Appoints Assessment Team</td>
</tr>
<tr>
<td>7</td>
<td>Assessment Team</td>
<td>Performs Quality Audits</td>
</tr>
<tr>
<td>8</td>
<td>Assessment Team</td>
<td>Submits Assessment Report</td>
</tr>
<tr>
<td>9</td>
<td>CABC</td>
<td>Considers Assessment Report</td>
</tr>
<tr>
<td>10</td>
<td>CABC</td>
<td>Recommends Action</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Satisfactory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Partially Satisfactory</td>
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<tr>
<td></td>
<td></td>
<td>Not Satisfactory</td>
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<tr>
<td></td>
<td></td>
<td>Allow 8 weeks for Corrective Action</td>
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<tr>
<td></td>
<td></td>
<td>Allow 18 months for Corrective Action</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Return to Action 7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>or, withdraw Application</td>
</tr>
<tr>
<td>11</td>
<td>MC</td>
<td>Grants Accredited Status</td>
</tr>
</tbody>
</table>
2. Requirements for the approval of an organization

2.1 Introduction

The IECQ bases its requirements for the approval of the organization of a manufacturer, distributor or specialist contractor (supplier approval) on those of the ISO 9001:2000. The requirements for the organization approval of independent testing laboratories are based on the requirements of ISO/IEC 17025.

2.2 Non-discriminatory access to the System

Any manufacturer or distributor of electronic components, or specialist contractor or independent testing laboratory, shall be allowed non-discriminatory access to the System and specifically to the use of attestation of conformity granted under the supervision of a Supervising Inspectorate (SI), subject to compliance with the Rules of the System.

2.3 Organization approval of a manufacturer, distributor or specialist contractor

2.3.1 Application for approval

Any manufacturer wishing to become an approved manufacturer under the System in order to seek approval of components produced by him, or any distributor, being independent of any manufacturer's production department and wishing to become an approved distributor under the System in order to stock and distribute approved components, or, any specialist contractor wishing to become an approved specialist contractor under the System, shall

a) apply to the Certification Body (CB), giving the information required (see NOTE below),

b) undertake to allow access by the representatives of the SI to all parts of the location relevant to the System. These representatives shall not disclose, without the manufacturer's, distributor's or specialist contractor's prior permission, any confidential information obtained in the course of their duties, and,

c) nominate a Designated Management Representative (DMR).

NOTE A Certification Body (CB) is the organization designated in the national rules that has full responsibility for certification under the System.

In the application, the following shall be indicated.

For a manufacturer:
- the generic and, if relevant, sectional specification against which it is intended to produce components, or in the case of Technology Approval the Technology Assessment Specification(s) (TASs) in the QC 210000 series into which the components fall,
- the location of the factory (factories), or parts thereof, for which approval is sought. A separate application shall be submitted for each location,
- whether the manufacturer wishes to be approved for design control, or not, and
- that the required documentation has been prepared as a basis for the appraisal by the SI and the resources are available to meet the requirements of the System;

For a distributor:
- the type(s) of components that the distributor wishes to supply under the System,
- the names of the approved manufacturers who have authorized the distributor to stock and distribute their components,
- the location of the establishment(s), or parts thereof, for which approval is sought. A separate application shall be submitted for each location, and
- that the required documentation has been prepared as a basis for the appraisal by the SI and the resources are available to meet the requirements of the System;
For the specialist contractor:

- the range of activity, technology, processes and / or technical services for which approval is sought,
- the Process Assessment Schedule(s) (PASs) in the QC 200000 series against which it is intended to provide processes and/or technical services,
- the location of the premises, or parts thereof, for which the approval is sought. A separate application shall be submitted for each location, and
- that the required documentation has been prepared as a basis for the appraisal by the SI and the resources are available to meet the requirements of the System.

2.3.2 Quality System requirements

The relevant provisions of ISO 9001: 2000 shall be met. Implementation of this requirement means that ISO 9001: 2000 shall be applicable as far as relevant for the component(s) or the range(s) of activity, technology(ies), process(es) and/or technical service(s) concerned.

In this subclause, the numbering follows that of ISO 9001: 2000. Where ISO 9001 clauses are not specifically invoked, the provisions of those clauses apply without modification. Where the ISO 9001 clauses are referenced, the additional requirements of the IECQ are given.

4.1 General requirements

For product / process related approvals (other than Qualification Approval), requirements also exist for a Quality Plan. This takes the form of a Capability Manual, Process Manual or Technology Approval Declaration Document (TADD) depending on the type of approval (see System Rules of Procedure for Qualification, Capability, Process and Technology Approval).

Compliance with this clause of the IECQ Rules of Procedure shall be confirmed by the SI periodically. The period between such confirmations shall not exceed three years. Within this period, all requirements shall be verified as part of the normal periodic auditing process.

The organization shall notify the SI in advance of any changes to the location of its approved facilities. If there is reason to suppose that there have been any changes affecting the approval at the new location, the SI may require revalidation of the approval prior to the release of products processed, tested or distributed at the new location.

4.2.2 Quality manual

Exclusions that are permitted under clause 7 of ISO 9001:2000 are restricted under the IECQ, dependent on the approval required. Details are given in Table 2 of this clause.

4.2.4 Control of records

The term "Quality Records" includes records related to activities associated with the System as well as to activities covered by approvals against the requirements of ISO 9001: 2000. These records shall be maintained for a minimum of two years or, if applicable, a period not less than the periodic test frequency if this is longer than two years, and access shall be made available to the SI upon request.

5.5.2 Management representative

The Designated Management Representative (DMR) is the formal contact point for the SI. The DMR facilitates the resolution of issues related to quality. See Annex A and Table 3 of this clause for additional IECQ provisions.

7.2 (and 5.2) Customer related processes (and customer focus)

The purchaser’s (customer’s) requirements, as reflected in the contract, shall refer to the relevant System documents or Customer Detail Specifications where these exist. They may, alternatively, refer to appropriate regional or internationally recognized publications. The organization shall establish and maintain documented procedures for contract review and for the coordination of these activities.

7.3.1 (and 7.1) Design and development planning (and planning of product realization)

Where applicable, requirements for design control shall be implemented in accordance with the System Rules of Procedure for Qualification, Capability, Process and Technology Approval.
7.3.6 (and 7.1) Design and development validation (and planning of product realization)

The requirements of the System for Qualification Approval, Capability Approval, Process Approval and Technology Approval embrace the requirements of clause 7.3.6 of ISO 9001:2000 for design validation.

7.4 Purchasing – Exclusions not permitted in IECQ

7.4.1 Purchasing process

In order to ensure that purchased products conform to a specified requirement, the System defines a mechanism allowing Specialist Contractors / Subcontractors in the electronic components industry to be approved under the System in their own right. This can cover specific services or procedures for the manufacture or assembly of piece-parts and materials (see the Rules of Procedure for Qualification, Capability, Process and Technology Approval).

In satisfying the requirements of ISO 9001 clause 7.4.1, use should be made of the Rule of Procedure for Specialist Contractors as guidance on the assessment of subcontractors. Subcontractors should preferably be approved under the System in accordance with the requirements for Process Approval. See annex B of this clause for additional System provisions relating to subcontracting.

7.4.2 Purchasing information

Purchasing data may be prepared jointly with the subcontractor and shall be clearly defined technically (for example, in a Customer Detail Specification) in order to ensure the quality of purchased products and services.

Component distributors shall be authorized by one or more approved manufacturer to stock, re-pack, release and distribute their approved components.

A distributor approved under the System is permitted to purchase released components from another approved distributor and deliver them provided that:
- the latter has purchased the components directly from an approved manufacturer, and
- both distributors are authorized by the approved manufacturer to deliver the component

7.4.3 Verification of purchased product

The System requires the supplier to verify the satisfactory maintenance quality control procedures performed by his subcontractor (see annex B of this clause).

7.5.1 Control of production and service provision – Exclusion not permitted in IECQ

Whilst servicing in the form of repair is not permitted by the Rules of Procedure, the concept of "after sales service" is reinforced by Process Approval and Technology Approval, that is to say, approved organizations are required to maintain close liaison with customers, to advise on usage applications and to analyze any problems experienced and to assist in the disposal of nonconforming items.

7.5.3 Identification and traceability – Exclusion not permitted in IECQ

The organization shall establish procedures and maintain records for identifying individual batches of product for a minimum period (from the date of product release) of two years, or a longer period as defined by contractual, statutory or legal requirements. These records shall include documentation and specifications covering materials, production and testing, test results and release data.

Further technologically-specific requirements shall be given in the relevant Generic Specification, Technology Approval Schedule or Process Assessment Schedule. Reference shall be made to appropriate marking requirements.

Release of conforming products shall be in accordance with the System requirements for Certificates of Approval and Attestation of Conformity.

7.5.5 (and 8.3) Preservation of product (and control of nonconforming product) – Exclusion not permitted in IECQ

Customer (purchaser) supplied product is material (e.g. raw or partly processed materials, piece-parts, software, testing or production equipment) owned by the customer (purchaser) and which is necessary to complete the product in accordance with the contract. The organization shall accept responsibility for prevention from damage, identification, maintenance, handling, use and storage of the customer (purchaser) supplied product.

Where relevant, particular requirements are given in GSs, PASs or TASs for the following:
anti-static precautions
cleanliness
health and safety aspects of chemicals and materials.

The requirements of ISO 9001:2000 are applied by the System not only to the finished product, but also to partly-processed materials.

The Rule of Procedure for Certificates of Approval and Attestation of Conformity, and the relevant specifications prescribe procedures for the date-coding of components and/or associated packaging. Procedures for ensuring the validity of release are contained in the Rules of Procedure for Qualification, Capability, Process and Technology Approval. Shelf life and revalidation requirements are detailed in the applicable specifications.

For electronic components, sub-assemblies or assemblies, it is necessary to distinguish between

- integral packaging, which is the case or body of the component itself,
- intimate packaging, which is enveloping material which makes immediate contact with components, sub-assemblies or assemblies (sometimes referred to as "primary packaging"), and
- transit or storage packaging, which is protective packaging for delivery of product and transporting / storing items during manufacture (sometimes referred to as "secondary packaging").

Requirements for integral and intimate packaging are given in the relevant technical specification. For the protection of electrostatically sensitive devices (ESDs), the requirements of generic specifications shall apply.

The relevant technical specifications may require the control of humidity and other environmental factors.

8.2.3 Monitoring and measurement of processes

The use of statistical process control (SPC) is optional in most System approvals. However, the use of in-process control techniques, such as SPC, is required for Technology Approval.

8.2.4 Monitoring and measurement of product

Final inspection and testing requirements shall be as defined in the relevant specification, as required by the appropriate generic specification (GS), Process Assessment Schedule (PAS) or Technology Approval Schedule (TAS). A list of authorized signatories shall be maintained.

The SI is permitted to select specimens at random and to subject them to such tests as are relevant for audit testing. The specimens shall be taken from production lots which have passed quality conformance inspection, and shall be returned to the manufacturer after testing, together with a test report. The number of specimens selected by the SI shall not exceed the quantity normally required for approval tests.

If the SI wishes to carry out destructive tests, these tests may, by agreement with the manufacturer, replace those normally carried out by the manufacturer.

Acceptance criteria shall be as defined in the relevant specification. Where applicable, a regional or internationally recognized specification shall be used for parts per million (ppm) Systems, Assessed Process Average, etc.

Compliance with ISO 10012: 2003 is a mandatory requirement of the System. Guidance for the determination of the uncertainty of measurement in accordance with ISO 10012: 2003 is given in annex C of this clause.

8.3 Control of nonconforming product

Repair is the making good of an approved component which has been damaged or has become defective after release, and is not permitted under the Rules of Procedure.

Rework is the rectification of processing errors, prior to the release of the component, by means not differing from those used in the current process or the rework processes to an agreed procedure as permitted by the relevant GS, PAS or TAS.

Specimens found to be nonconforming during lot-by-lot testing shall be withdrawn from the lot and not delivered. Lots rejected in lot-by-lot testing may be re-submitted in accordance with the relevant sampling procedures, for example IEC 60410, and with the requirements prescribed in the relevant specification controlling the sampling procedure. No inspection lot, or part of it, shall be submitted more than twice in total to the lot-by-lot testing unless specifically allowed by the relevant generic, sectional or blank detail specification. In circumstances where a responsible specification authority finds it necessary to make such allowances, the conditions governing further re-submission of rejected lots shall be specified in the relevant
specification in such a manner that the reasons for allowing such further re-submissions are clear and unambiguous.

2.3.3 Appraisal

2.3.3.1 The manufacturer, distributor or specialist contractor shall demonstrate to the SI, in respect of all activities relevant to the System, that the requirements of the System, as given in ISO 9001 : 2000 and amplified in 2.3.2 are being met. In performing the appraisal, account shall be taken of any comparable approvals granted by a recognized international, regional or national accreditation(certification) body. The organization shall invite the SI to see those parts of the manufacturing process which are not considered to be commercially confidential and are appropriate to the approval being sought.

Such parts of the manufacturing process which are considered to be commercially confidential shall nevertheless be under the surveillance of the manufacturer's DMR who shall satisfy the SI of the adequacy of the quality control arrangements. A specialist contractor shall, additionally, demonstrate compliance with the requirements of clause 5 and with the relevant PAS.

2.3.3.2 When the SI has determined that the manufacturer, distributor or specialist contractor has met the requirements of 2.3.3.1, written notice of approval shall be provided to him by the CB.

2.3.3.3 ISO 9001 : 2000 permits organizations to claim exclusions to the requirements contained within clause 7. This document incorporates the requirements of ISO 9001: 2000, but exclusions are only permitted in accordance with Table 2 provided that they are justified to the SI in the organization's Quality Manual.
## Table 2 – IECQ Permitted ISO 9001:2000 Exclusions

<table>
<thead>
<tr>
<th>ISO 9001 : 2000 Clause</th>
<th>Manufacturer</th>
<th>Testing Laboratory</th>
<th>Distributor</th>
<th>Specialist Contractor</th>
<th>Avionics OEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1 Planning of product realization</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
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<tr>
<td>7.2.1 Determination of requirements relating to the product</td>
<td>N</td>
<td>N</td>
<td>N</td>
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<td>N</td>
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<tr>
<td>7.2.2 Review of requirements relating to the product</td>
<td>N</td>
<td>N</td>
<td>N</td>
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<tr>
<td>7.2.3 Customer communication</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>N</td>
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<tr>
<td>7.3 Design and development</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>7.4.1 Purchasing process</td>
<td>N</td>
<td>N</td>
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<tr>
<td>7.4.2 Purchasing Information</td>
<td>N</td>
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<td>N</td>
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<tr>
<td>7.4.3 Verification of purchased product</td>
<td>N</td>
<td>N</td>
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<td>7.5.1 Control of production and service provision</td>
<td>N</td>
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<td>7.5.2 Validation of processes for production and service provision</td>
<td>Y</td>
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<td>7.5.3 Identification and traceability</td>
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<td>N</td>
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<td>7.5.4 Customer property</td>
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<td>7.5.5 Preservation of product</td>
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<td>7.6 Control of monitoring and measuring devices</td>
<td>N</td>
<td>N</td>
<td>Y</td>
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</tr>
</tbody>
</table>

Y May exclude with justification
N May not exclude
2.4 Organization approval of an independent testing laboratory

2.4.1 Application for approval

Any independent testing laboratory wishing to become an approved testing laboratory under the System in order to carry out tests on components within the System, shall

a) apply to the organization designated in the national rules giving the information required,

b) undertake to allow access by the representatives of the SI to all parts of the location relevant to the IECQ. These representatives shall not disclose, without the testing laboratory’s prior permission, any confidential information obtained in the course of their duties, and

c) nominate a DMR.

In the application the independent testing laboratory shall indicate

- the type(s) of tests it wishes to carry out on components under the System,

- the location of the testing laboratory (laboratories), or part thereof, for which approval is sought. A separate application shall be submitted for each location, and

- that it has prepared the required documentation as a basis for the appraisal by the SI and has available the resources to meet the requirements of the System.

2.4.2 Technical competence

The relevant provisions of ISO/IEC 17025 shall be met.

In this subclause, the numbering follows that of ISO/IEC 17025: 1999. Where ISO/IEC 17025 clauses are not specifically invoked, the provisions of those clauses apply without modification. Where the ISO/IEC 17025 clauses are referenced, the additional requirements of the IECQ are given.

4.1 (and 4.1.5 c & i) Organization

The Designated Management Representative (DMR), who may also be the ‘Technical Manager’ of the laboratory, provides a formal contact point for the SI to enable the resolution of issues related to quality. See annex A of this clause for additional IECQ provisions related to the activities of the DMR, a position comparable to that of the ‘Technical Manager’ of the laboratory.

4.2 Quality System

The Quality Manual or supporting documentation shall include any mandatory requirements for Qualification Approval, Capability Approval, Process or Technology Approval as detailed in QC 001002-3, clauses 3, 4, 5 and 6 respectively. For guidance, see ISO 10013: Guidelines for developing Quality Manuals.

4.5 Subcontracting of tests and calibrations

Subcontracting shall be to an independent testing laboratory with the required technical scope approved under the IECQ, except when

- the required service is not available from any approved independent testing laboratory within the System;

- the approved independent testing laboratory demonstrates to the SI that other approved independent testing laboratories known to be operating in the relevant area of technology are unable to undertake the specified testing.

When invoking these provisions, the approved independent testing laboratory shall produce a document which describes the surveillance arrangements by which it can be ensured that the testing to be carried out shall comply with the specification. Where possible the nominated testing laboratory shall be approved to ISO/IEC 17025 by a nationally recognized accreditation body. The document shall define how the nominated testing laboratory

- ensures that its relevant staff possesses the necessary competence and its relevant facilities are completely adequate for the purpose of the subcontracted testing,

- proposes to operate the subcontracted testing, and

- ensures that it has an adequate System for the calibration of its relevant measurement and test equipment and can provided adequate traceability to national standards.

In establishing the degree of surveillance necessary, account shall be taken of any current approvals and/or registration held by the nominated testing laboratory. Before authorizing the subcontracted testing, the approved independent testing laboratory shall demonstrate to the SI that the proposed surveillance arrangements comply with the specification.
4.12 Control of records

Records shall be maintained for a minimum of two years or, if applicable, a period not less than the periodic test frequency if this is longer than two years, and access shall be made available to the SI upon request.

5.4 Test and calibration methods and method validation

The purchaser's (customer's) requirements, as reflected in the contract, shall refer to the applicable generic or sectional specifications or Customer Detail Specifications where they exist, or alternatively, refer to appropriate regional or internationally recognized publications.

Details of standards, specifications or other requirements available within the IECQ are given in QC 001004, Specifications List.

5.5 Equipment

Compliance with ISO 10012: Quality assurance requirements for measuring equipment: Part 1: Metrological confirmation System for measuring equipment, is a mandatory part of the IECQ.

5.8 Handling of test and calibration items

Product identification and traceability are specified requirements of the IECQ in accordance with QC 001002-3, clauses 3, 4, 5 and 6. Where relevant, particular requirements are given in GSs, PASs or TASs for the following:

- anti-static precautions;
- humidity or other environmental factors;
- cleanliness;
- health and safety aspects of chemicals and materials.

5.10.3 Test reports

Guidance for the determination of the uncertainty of measurement in accordance with ISO 10012-1 are given in annex C to this clause. Acceptance criteria shall be defined in the applicable specification. Where applicable, a regional or internationally recognized specification shall be used for parts per million (ppm) Systems, Assessed Process Average, etc..

2.4.3 Appraisal

2.4.3.1 The independent testing laboratory shall demonstrate to the SI, in respect to all activities relevant to the System, that:

- it meets the requirements of the System,
- it meets the requirements of ISO/IEC 17025, or equivalent regional or national standard, and
- that it is sufficiently free from external influences which would prevent it from acting in an impartial manner.

In performing the appraisal, account shall be taken of any comparable approvals granted by a recognized international, regional or national accreditation (certification) body.

2.4.3.2 When the SI has determined that the independent testing laboratory has met the requirements of 2.4.3.1, written notice of approval shall be provided to the laboratory by the CB.

2.5 Extension of organization approval

2.5.1 Extension of a manufacturer's approval

2.5.1.1 On application, a manufacturer's approval shall be extended to include additional components as described in the relevant generic or sectional specification when the SI has determined that the extension meets the requirements of 2.3.3.1.

2.5.1.2 When a manufacturer wishes to act as a distributor and/or testing laboratory for components of another manufacturer, he shall comply, in addition, with the requirements of the relevant parts of 2.3 and / or 2.4.
2.5.1.3 A manufacturer may have his approval extended to cover a factory of his company, located in a country which does not have an SI approved for the technical scope concerned, irrespective whether this country is an IECQ member country. See the requirements detailed in B3.1.

2.5.1.4 When a manufacturer wishes to act as a specialist contractor on behalf of other manufacturers, he shall comply, in addition, with the requirements of clause 5.

2.5.2 Extension of a distributor’s approval and/or additional sources of supply

2.5.2.1 Extension of a distributor’s approval

On application, a distributor’s approval shall be extended to include additional approved manufacturers when the SI has determined that the extension meets the requirements of the System.

2.5.2.2 Sources of supply from approved distributors

A distributor approved under the System is permitted to purchase released components from another approved distributor and deliver them provided that

a) the latter has purchased the components directly from an approved manufacturer, and
b) both distributors are authorized by the approved manufacturer to deliver the components.

2.5.2.3 Approval of distributors wishing to act in another role

When an approved distributor wishes to perform assembly, testing, modification or marking of components released to him partly finished by an approved manufacturer, he shall comply, in addition, with the relevant parts of 2.3 and / or 2.4 for those operations which he wishes to perform.

2.5.3 Extension of a specialist contractor’s approval

2.5.3.1 On application, a specialist contractor’s approval shall be extended to include activities, technologies, processes and/or technical services when the SI has determined that the extension meets the relevant requirements of 2.3.3.1 with respect to clause 5.

2.5.3.2 When a specialist contractor wishes to act as a manufacturer or as a distributor and/or testing laboratory for a manufacturer of components, he shall comply with the additional requirements of 2.3 and / or 2.4.

2.6 Maintenance of organization approval

2.6.1 General

Approvals shall be maintained through a programme of surveillance during which relevant quality system and product or process requirements are audited.

The programme may be comprised of site visits, review of internal audit reports, electronic surveillance or combinations of each and shall take into account such factors as the maturity and complexity of the processes, the experience with the organization, and changes in the supplier’s organization and procedures. The programme shall be agreed between the SI and the client and shall include provision for unanticipated events which may require unplanned site visits.

In establishing surveillance frequency, particular emphasis shall be given to the demonstrated maturity and the documentation supporting the conduct and effectiveness of the internal audit activity. The interval between site visits shall include the equivalent of a full reassessment and in no case shall this interval exceed three years.
NOTE: The following guidance is intended to indicate typical practice:

New organizations and/or significant new products should normally give rise to an audit frequency of either one or two visits in the first year. Subsequent audit frequency is determined by the SI following a documented review of audit history.

Further tightening or relaxation of the assessment frequency should be determined by the SI as dictated by regular reviews of assessment data.

It is anticipated that many IECQ assessments will be conducted co-incident with assessments for other certification (e.g.: ISO 9001).

When the SI has determined that the requirements of the System for approval are being met the approval shall be maintained by the organization which granted it.

2.6.2 Frequency of surveillance

The frequency of on-site surveillance shall be established in accordance with the principles set forth in 2.6.1. In no case however, shall the interval exceed three years.

2.7 Withdrawal or suspension of organization approval

2.7.1 Except as described in 2.7.2, when some part of the requirements described above for the approval, or for the extension of the approval, of a manufacturer, or of a distributor, independent testing laboratory or specialist contractor, is no longer observed, the approval or the extension of the approval shall be withdrawn by the organization which granted it. If an approval of an organization is withdrawn, any relevant extension of approval shall also be withdrawn.

2.7.2 If the causes which may justify the withdrawal of approval are temporary, and it is demonstrated that they may be remedied after a brief delay, the approval shall be suspended by the organization which granted it.

2.7.3 The approval may also be withdrawn at the request of the manufacturer, distributor, independent testing laboratory or specialist contractor.

NOTE Adequate notice should be given of any intention to withdraw the product or service provided.

2.7.4 The approval of a manufacturer or distributor may be withdrawn if the manufacturer or distributor knowingly or intentionally makes any incorrect references to the manufacturer approval or misleading use of manufacturer approval information. The approval shall be withdrawn if a manufacturer or distributor fails to take corrective action in this respect within one month of being requested to do so by the relevant CB.

2.7.5 A manufacturer, distributor, independent testing laboratory or specialist contractor shall have the right to appeal, in accordance with the national arrangements, against the withdrawal of the approval.

2.8 Reference to ISO 9001 and ISO/IEC 17025 in the On-Line Certificate Database

2.8.1 Manufacturers approved under the System who have been shown to comply with the requirements of ISO 9001, where either Capability Approval or design control is included in the scope) shall be identified as such in the On-Line Certificate Database.

2.8.2 Independent testing laboratories approved under the System who have been shown to comply with the recommendations of ISO/IEC 17025 shall be identified as such in the On-Line Certificate Database.
Annex A to clause 2
(normative)
Requirements for Designated Management Representative (DMR)

A.1 The organization's Designated Management Representative (DMR) and, if applicable, the organization's Local DMR (see annex B.3.1 e) of this clause) shall be acceptable to the SI as both technically and administratively competent for the purposes of the System.

NOTE The term Designated Management Representative (DMR) may also be used as a generic term covering Company Chief Inspector, Local Company Chief Inspector and, in the case of an independent testing laboratory, Technical Manager.

A.2 In addition to being responsible for maintaining liaison with the SI, the DMR shall have defined authority for ensuring that the organization complies with the requirements of the System. The DMR's duties, associated with requirements of the System, are summarized for the organizations of a manufacturer, distributor, independent testing laboratory and specialist contractor in Table 3. When applicable for a manufacturer or specialist contractor, these duties may be delegated to the Local DMR at a remote site to which approval has been extended for the subcontracted stages, processes or services provided.

withdrawn
Table 3 – Summary of Designated Management Representative’s duties

<table>
<thead>
<tr>
<th>Specialist Contractor</th>
<th>Manufacturer</th>
<th>Distributor</th>
<th>ITL&lt;sup&gt;a&lt;/sup&gt;</th>
<th>The designated Management Representative (DMR) shall have defined responsibilities for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>ensuring compliance with the requirements of the System 1</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the quality of the component(s), part-processed component(s), piece part(s) or material that is(are) released and/or the processes or technical services provided 2</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the correct testing of components received by the testing laboratory 3</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>investigating cases of returned nonconforming product(s) 4</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the quality of the component(s), part-processed component(s), piece part(s) or material for which the validity of release has expired 5</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>re-submission of components to the manufacturer or to an approved testing laboratory if the period of validity of release has expired 6</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>maintaining liaison with the SI 7</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>maintaining liaison with the DMR of the relevant approved component manufacturer(s) on all matters concerning the quality of released components and/or delayed delivery 8</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the maintenance of the identity of lots held in stock and their relation to the manufacturer’s attestation of conformity 9</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>ensuring that the results of inspection tests are recorded and for holding them at the disposal of the SI 10</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the application of the Mark and / or the issuing of the Declaration of Conformity in respect of lots which are to be delivered, after verifying that they have been released as complying with the relevant specification invoked in the contract 11</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>ensuring that all re-consignments have been stored or, where necessary re-packed, under suitable conditions and that they have not been used or modified or repaired, and that they are accompanied by an Attestation of Conformity 12</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>ensuring the availability of inspection and test schedules for the use of inspection staff 13</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the competence and continuing effectiveness of inspection staff 14</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>ensuring adequate review of all customers enquiries, drawings, technical documents and contracts and for bringing discrepancies to the attention of the customer and SI 15</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>ensuring that applicable specifications issued by the company comply with the relevant blank detail specification/PAS/TAS 16</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the compliance with the relevant specification of all piece parts and materials obtained from subcontractors, suppliers and specialist contractors 17</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the maintenance of records, including records of internal audits, to demonstrate the effectiveness of the inspection organization 18</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>the confidentiality of test results which shall not be disclosed to other individuals or organizations without the written permission of the customer 19</td>
</tr>
<tr>
<td>S M D</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>notifying the SI immediately of any change to an issued certificate to ISO 9001and / or ISO 17025 which is relevant to the organization’s IECQ approval. 20</td>
</tr>
</tbody>
</table>

<sup>a</sup>ITL = Independent Testing Laboratory
Annex B to clause 2  
(normative)  
Subcontracting in the IECQ

B.1 Introduction

The following subcontracting requirements apply to IECQ approved organizations in addition to those contained within ISO 9001: 2000.

B.2 Subcontracting to manufacturers or specialist contractors with IECQ approval

This clause applies to manufacturers and specialist contractors with IECQ approval irrespective of their geographical location.

B.2.1 The application for Qualification Approval(QA), Capability Approval(CA), Technology Approval(TA) or Process Approval(PA) shall additionally contain

- details of the division of the manufacturing stages between the manufacturers and / or specialist contractors concerned, including name, address and approval identity, and
- details of the arrangements for the certification of the quality of components, or partly processed materials, when they are transferred from one approved manufacturer or specialist contractor to another, together with the details of the means whereby changes to the agreed arrangements are communicated to the SI.

B.2.2 The SI of the organization seeking QA, CA, TA or PA shall

a) co-ordinate the activities,
b) seek confirmation from the SIs of the other countries concerned that the information contained in the application is correct, and  
c) ensure that
   - the organization possesses at the approved location sufficient engineering capacity and / or technical expertise to develop, maintain and control the manufacturing processes that it is wished to subcontract, or that
   - the stages concerned are adequately covered by the scope of the specialist contractor’s existing approvals within the System.

B.3 Subcontracting to a remote site which is part of the same parent organization (Extended Manufacturing Approval)

B.3.1 A manufacturer may have the approval extended to cover a factory of the company, located in a country which does not have an SI approved for the technical scope concerned, whether this country is an IECQ member country or not, provided that:

a) the requested extension concerns components for which the application of this procedure is permitted by the relevant generic specifications,
b) the requirements of ISO 9001 are met by this factory for the subcontracted activity(ies),
c) the SI is satisfied that the manufacturer is capable of manufacturing, in the already approved factory located in an IECQ member country, components belonging to the generic and, if relevant, sectional specifications for which the extension is sought,
d) the SI is satisfied that the DMR exercises adequate control in the other factory,
e) the SI is satisfied that, if a Local DMR carries out the duties described in annex A of this clause for the stages performed in this factory, the Local DMR is responsible only to the DMR for these duties,
f) the SI is willing to visit, or can arrange for another SI to visit, that other factory to perform the required surveillance, and

g) the visiting SI has notified the CABC, for the components concerned, by extending the geographical limits stated in its SSA.
The application for product certification (QA, CA, TA or PA) shall additionally contain:

- details of the division of the manufacturing stages between the approved manufacturer and the company's factory located in a non-IECQ member country, and
- details of the arrangements agreed with the SI for the certification of the quality of components taking into account the transfers carried out in the course of manufacture together with details of the means whereby changes to the agreed arrangements are communicated to the SI.

The SI of the manufacturer seeking product certification (QA, CA, TA or PA) shall:

a) ensure that the DMR of the approved manufacturer has effective responsibility for quality control procedures performed under the supervision of the local DMR on the production in the non-IECQ member country, and

b) ensure that:

- the manufacturer possesses at the approved location sufficient engineering capacity and / or technical expertise to develop, maintain and control the manufacturing processes that it is wished to subcontract, or that
- the stages concerned are adequately covered by specialist contractors' existing approvals within the System.

B.4 Subcontracting to unapproved contractors

B.4.1 The application for product certification (QA, CA, TA or PA) shall additionally contain:

- details of the division of the manufacturing stages between the approved manufacturer and the subcontracting factory,
- details of the arrangements agreed with the SI for the certification of the quality of components taking into account the transfers during the manufacture, and in particular, the procedures for the assessment of quality of the subcontracted manufacturing stages, together with details of the means whereby changes to the agreed arrangements are communicated to the SI.

The manufacturer shall demonstrate to the SI by any suitable means that the quality of the final component will not be adversely affected by the use of these subcontracted stages of manufacture.

B.4.2 The SI of the manufacturer/specialist contractor seeking product certification (QA, CA, TA or PA) shall:

a) ensure that the approved manufacturer's DMR is able to verify the satisfactory maintenance of the quality control procedures performed by the subcontractor in accordance with B.3.1 a) or B.3.1 b) and B.4.1, and

b) ensure that:

- the manufacturer possesses at the approved location sufficient engineering capacity and / or technical expertise to develop, maintain and control the manufacturing processes that it is wished to subcontract, or that
- the stages concerned are adequately covered by the specialist contractors' existing approvals within the System.

The SI shall confirm in writing to the CB that the details contained in the application for product certification satisfy the requirements of the System.

B.5 Sharing of testing facilities
B.5.1 Where two or more manufacturers within the same parent group wish to share a testing facility under the System, they shall apply to the relevant SI(s) for an extension to their organization approval(s) and shall demonstrate compliance with the relevant requirements of this Rule of Procedure and, in particular, of B.5.2 and/or B.5.3 below.

Manufacturers making an initial application for organization approval wishing also to apply for approval of a shared testing facility shall indicate in their application whether they propose to invoke B.5.2 and/or B.5.3 below.

B.5.2 The subcontracting manufacturer shall ensure that the approved manufacturer(s) to whom testing is to be subcontracted has(have) inspection facilities and testing laboratories adequate for their purpose and that they are operated by a staff with the necessary competence.

B.5.3 The manufacturer who is acting as a subcontractor for testing purposes shall, in the initial application or application for extension of approval, identify the specific tests to be performed, the component types involved and the names of the approved manufacturers who will be supplying the components for testing.

B.5.4 A manufacturer wishing to change the approved arrangements for subcontracting of testing shall re-apply to the relevant SI(s) as indicated in B.5.1.

B.5.5 The extension of approval to cover shared testing facilities shall be subject to periodic reassessment by the relevant SI(s).
Annex C to clause 2

IECQ policy on uncertainty of measurement and inset limits

C.1 Objective

Specifications for electronic components used in the IECQ give the parametric limits that define the acceptability of the component. These limits do not take into account the uncertainty of measurement caused by test and measuring equipment inaccuracies, test methods, environmental conditions and, sometimes, operator participation.

The purpose of this annex is to define mandatory IECQ policy on the calculation of measurement uncertainty and insetting limits to ensure uniform implementation of the rules of IECQ. The special case of outsetting limits is also covered.

C.2 Definitions

C.2.1 uncertainty of measurement

a statement of the limits of the range within which the true value of the measurement is expected to lie in relation to the recorded result with a defined confidence level

C.2.2 measuring equipment

all of the instruments which are necessary in order to carry out a measurement. The definition makes it clear that items such as cables, connectors, handlers, handler cards or other fixtures used in conjunction with a measurement indicating instrument are subject to the requirements of this policy

C.2.3 inset limits

tightened limits resulting from an allowance applied to the specified limits of a parameter to take into account all influence quantities on the indication of a measuring instrument so as to ensure that out of limit devices are not accepted due to measurement errors

C.2.4 outset limits

relaxed limits resulting from an allowance applied to the specified limits of a parameter to take into account all influence quantities on the indication of a measuring instrument so as to ensure that in limit devices are not rejected due to measurement errors

C.3 Calculation of measurement uncertainty

The assessment of uncertainty of measurement of a performance requirement can be broken down into three stages:

1) identification of possible error contributions;
2) quantifying the size of each listed contribution;
3) calculating the total uncertainty of measurement.

C.4 Policy

C.4.1 A measurement uncertainty value shall be calculated for each performance requirement which is related to Qualification Approval, Capability Approval, Technology Approval, Process Approval, screening, lot-by-lot and periodic tests as defined by the specifications of the IECQ.

C.4.2 Each measurement uncertainty value shall be used to apply an inset, of at least this value, to the relevant specification limits as defined in C.4.1.
C.4.3 This inset shall be applied in accordance with C.5.2 for manufacturers and C.5.3 for SIs.

C.4.4 Test reports and test records, compiled to show compliance with Qualification Approval, Capability Approval, screening, lot-by-lot and periodic tests as defined by the applicable specifications, shall list the uncertainty value for each performance requirement.

C.5 Calculation of inset and outset Limits

C.5.1 The fundamental principle is that the limits should be inset from the specified values by the corresponding uncertainty of measurement. This increases the probability that measurement results which fall within the tightened limits, including marginal values, are genuinely within specification limits such that only truly conforming devices are accepted.

The exception to insetting limits occurs when SIs conduct product audit tests. In this situation, to ensure that, as far as possible, uncertainty of measurement does not cause good products to fail, SIs outset the limits. This increases the possibility that measurement results that fall outside the relaxed limits, including marginal values, are genuinely outside specification limits such that only truly non-conforming devices are rejected.

C.5.2 For a component manufacturer the upper specified value of a parameter being ‘x’, the lower specified value of the parameter being ‘y’ and the uncertainty of measurement being ‘a’, the “inset limits” for the parameter are (x-a) and (y+a).

C.5.3 For an SI the upper specified value of a parameter being ‘x’, the lower specified value of the parameter being ‘y’ and the uncertainty of measurement being ‘b’, the “outset limits” for the parameter are (x+b) and (y-b).

The smaller the uncertainty of measurement, the lower the values of ‘a’ and ‘b’ become and the closer the manufacturer’s and SI’s inset/outset limits approach the specification limits.

C.6 Examples

Setting “inset limits” and “outset limits”

C.6.1 Example 1: Resistor Measurement

Specified resistance value: 100 ohms ± 10% = 90 ohms to 110 ohms
Uncertainty of measurement calculated to be: ± 1.2% = ± 1.08 ohms and ± 1.32 ohms
Inset Limits: 91.08 ohms to 108.68 ohms
Outset Limits: 88.92 ohms to 111.32 ohms

C.6.2 Example 2: Resistor Measurement

Initial measurement 105.00 ohms
Specified resistance value 0.5% = ± 0.53 ohms
=104.47 ohms to 105.53 ohms
Uncertainty of measurement calculated to be ± 0.1% = ± 0.10 and ± 0.11 ohms
Inset Limits: 104.57 ohms to 105.42 ohms
Outset Limits: 104.37 ohms to 105.64 ohms

C.6.3 Example 3: Transistor Measurement (gain)

Specified limits: 60 ± h 21E 80
Uncertainty of measurement calculated to be: 5
Inset Limits: 65 to 75
Outset Limits: 55 to 85
C.6.4 Example 4: Comparison between initial and final measurement results

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial measurement:</td>
<td>102,05µF</td>
</tr>
<tr>
<td>Specified tolerance:</td>
<td>Variation @ 1%</td>
</tr>
<tr>
<td>Uncertainty of measurement calculated to be</td>
<td>0,1%</td>
</tr>
<tr>
<td>Inset Limits:</td>
<td>101,13µF to 102,97µF</td>
</tr>
<tr>
<td>Outset Limits</td>
<td>100,93µF to 103,17µF</td>
</tr>
</tbody>
</table>

C.7 References (Information only)

The following document may provide useful information on uncertainty of measurement:

Standard ECMA - 181 Uncertainty of measurement as applied to type approval of products (issued by ECMA TC 12).
3. Qualification Approval of electronic components

3.0 Introduction

The Qualification Approval procedure is applicable to any electronic component, or range of components (for example, a range of resistors differing only in resistance values, tolerances and/or power ratings) when the appropriate specifications are notified in QC 001004, Specifications List, for use within the IECQ System.

3.1 Procedure for Qualification Approval (QA)

3.1.1 Eligibility for QA

3.1.1.1 QA may be granted only to a manufacturer who has been granted manufacturer's approval in accordance with the requirements of clause 2 including, as appropriate, those of ISO 9001 and, additionally, the requirements of this clause. These approvals may be carried out in parallel, although QA shall not be granted in advance of manufacturer's approval.

3.1.1.2 A component is eligible for QA in accordance with the System if the manufacturing process, commencing not later than that manufacturing operation which is called the "primary stage" (see QC 001002-2, clause 1) is carried out by one or more manufacturers approved in accordance with the requirements of clause 2 and under the direct supervision of the relevant Designated Management Representative (DMR) or local DMR.

The rules for the extension of manufacturer's approval given in clause 2 apply.

3.1.2 Use of specialist contractors and subcontracting

3.1.2.1 The primary stage and/or subsequent stages may be carried out by specialist contractors (see clause 2) or, under certain conditions, subcontracted (see 3.1.2.3 and 3.1.3).

3.1.2.2 The generic or sectional specification may

— either forbid this subcontracting on technical grounds, or

— where it is considered necessary, include any special requirements, for example for specified successive stages to be performed by the same manufacturer, or

— permit the subcontracting unreservedly.

Such restrictions shall not apply to arrangements made concerning specialist contractors.

3.1.2.3 When subcontracting is permitted by the generic or sectional specification, this may be undertaken provided that the DMR is able to demonstrate to the Supervising Inspectorate (SI) that the process(es) concerned is (are)

a) performed in a manner which satisfies the appropriate requirements of the relevant Process Assessment Schedule (PAS), where such exists, or

b) carried out satisfactorily.

3.1.2.4 To verify the satisfactory conduct of subcontracted operations in accordance with 3.1.2.3a) or b), the manufacturer shall ensure that the QA testing and quality conformance testing will be performed under his control in an approved laboratory located in an IECQ member country, or exceptionally in accordance with 3.1.2.7.
3.1.2.5 The manufacturer, when applying for QA, shall state whether stages of the manufacturing process are carried out by specialist contractor(s) in accordance with 3.1.2.1 or are subcontracted in accordance with 3.1.2.3 and shall identify these stages (see 3.1.3).

3.1.2.6 If subcontractors not approved within the IECQ System are used, the manufacturer shall describe the method of control of all the subcontracted stages or operations.

3.1.2.7 Before tests are carried out by laboratories not approved under the IECQ System, the approved manufacturer shall take all reasonable steps to ensure that the required service is not available from any approved independent testing laboratory within the IECQ System.

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

Where tests are carried out by testing laboratories not approved within the IECQ System, the approved manufacturer shall produce a document which describes the surveillance arrangements by which he shall ensure that the testing to be carried out shall comply with the specification. Where possible, the nominated testing laboratory shall be approved to ISO/IEC 17025 by a nationally recognized accreditation body. The document shall define how the nominated testing 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, and

c) ensures that 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 and/or registrations held by the nominated testing laboratory.

Prior to permitting testing, the approved manufacturer shall demonstrate to the SI that his proposed surveillance arrangements comply with the specification.

The procedures given in this subclause shall be applied separately to any subsequent programme of testing, including those carried out for periodic testing for the maintenance of an approval.

3.1.3 Application for QA

3.1.3.1 When an approved manufacturer wishes to obtain QA for a component or range of structurally similar components within the scope of his manufacturer's approval, he shall submit an application in writing to the SI, see also annex A to this clause. In this application he shall state

a) that he carries out at the approved location all the processes, tests, measurements, etc. subsequent to and including the primary stage of manufacture, or

b) that all stages of manufacture are carried out by manufacturers or specialist contractors approved within the System, some of whom may be located in other countries (see 3.1.3.2), or by distributors acting in another role (see clause 2), or

c) that defined stages are subcontracted in accordance with 3.1.2.3a) or b) and 3.1.2.4, or

d) that defined stages are carried out in one of his company's factories located in a non-IECQ member country, whereas the QA and quality conformance testing may be performed either in a laboratory approved under the System, or, in the above mentioned factory which is under the direct surveillance of the SI (see 3.1.3.4), or, in a laboratory as described in 3.1.2.7.

The application shall also give the following details of the components for which QA is being sought:
e) the component or range of components and type reference(s);
f) the nominal parameters (for example, rated voltage, rated current, resistance, capacitance);
g) other information, for example, materials and style;
h) the desired date for the start of the QA testing.

3.1.3.2 When the conditions of 3.1.3.1b) apply, the application for QA shall contain
— details of the division of manufacturing stages between the manufacturers or specialist contractors concerned, and
— details of the arrangements agreed with the SI(s) involved for the certification of the quality of components, or partially manufactured components, when they are transferred from one approved manufacturer, specialist contractor or distributor acting in another role to another, together with details of the means whereby changes to the agreed arrangements are communicated to the responsible SI.

The SI of the manufacturer seeking QA shall
— co-ordinate the activities,
— seek confirmation from the SIs of the other countries that the information contained in the application is correct, and
— ensure that the manufacturer possesses sufficient engineering capability and/or technical expertise to develop, maintain and control the manufacturing processes that he wishes to subcontract, or that the stages of manufacture concerned are adequately covered by the specialist contractors' existing approvals under the System.

3.1.3.3 When conditions of 3.1.3.1 c) apply, the application for QA shall contain
— details of division of the manufacturing stages between the approved manufacturer and the subcontracting factory, and
— details of the arrangements agreed with the SI(s) involved for the certification of the quality of components taking into account the transfers during the manufacture and, in particular, the procedures for the assessment of quality of the subcontracted manufacturing stages, together with details of the means whereby changes to the agreed arrangements are communicated to the responsible SI.

The manufacturer shall demonstrate to the SI by any suitable means that the quality of the final component will not be adversely affected by the use of these subcontracted stages of manufacture.

The SI of the manufacturer seeking QA shall
— ensure that the approved manufacturer's DMR is able to verify the satisfactory maintenance of the quality control procedures performed by his subcontractor in accordance with 3.1.2.3a) or b) and 3.1.2.4, and
— ensure that the manufacturer possesses sufficient engineering capability and/or technical expertise to develop, maintain and control the manufacturing processes that he wishes to subcontract, or that the stages of manufacture concerned are adequately covered by the specialist contractors' existing approvals under the System.

The SI shall confirm in writing to the CB that the details contained in the application for QA satisfy the requirements of the System.
3.1.3.4 When the conditions of 3.1.3.1d) apply, the application for QA shall contain

— details of the division of the manufacturing stages between the approved manufacturer and his company's factory located in a non-IECQ member country, and

— details of the arrangements agreed with the SI involved for the certification of the quality of the components taking into account the transfers carried out in the course of manufacture together with details of the means whereby changes to the agreed arrangements are communicated to the responsible SI.

The SI of the manufacturer seeking QA shall

— ensure that the DMR of the approved manufacturer has effective responsibility for quality control procedures performed under the supervision of the local DMR on the production in a non-IECQ member country, and

— ensure that the manufacturer possesses sufficient engineering capability and/or technical expertise to develop, maintain and control the manufacturing processes that he wishes to subcontract, or that the stages of manufacture concerned are adequately covered by the specialist contractors' existing approvals under the System.

3.1.3.5 When the manufacturer is ready to commence QA testing he shall give notice to the SI of his intention to start tests and establish together with the SI a test plan and a time schedule for the execution of the approval tests.

3.1.3.6 The SI shall check the application for completeness of all required information and existence of the relevant detail specification. If any details are missing, further information shall be requested from the applicant. If the information is complete, the SI shall send the manufacturer a confirmation of application.

3.1.4 QA testing

QA testing may be carried out on

a) a fixed sample as defined in the generic or sectional specification. In this case the sample shall be drawn from current production, or

b) a specified number of inspection lots (with a minimum of three) taken in as short as possible a period of time, as well as the performance of the periodic tests on a sample taken from at least one of these lots, or

c) sample quantities drawn from one lot only, sufficient to give acceptance on zero rejects. If the lot size is less than the resulting sample size, 100% testing shall be carried out. Normal sampling requirements for destructive tests shall apply. For inspection lots less than 25, the sample for destructive tests may comprise of components taken from several inspection lots whose total quantity exceeds 25.

This procedure is only permitted when subsequent inspection lot sizes are predicted not to exceed 280 components (see NOTE), and the additional requirements given below shall be applied to lot sentencing following the granting of QA in this manner.

All released components shall be individually subjected to the non-destructive tests specified in the detail specification, until satisfactory results have been achieved on cumulative quantities equal to the sample sizes required to give acceptance on three rejects for the lot-by-lot tests, or one reject for the periodic tests.
Lot sizes may not subsequently be increased above those declared until satisfactory results have been achieved for all tests, on at least a sufficient quantity of components to meet the requirements given in this subclause (3.1.4) for the increased lot size.

NOTE: When structural similarity is invoked for a subgroup, the relevant inspection lot size is the total of all types considered similar for that subgroup.

When components cover a range of values or characteristics, the sample shall contain specimens which are representative of the range for which QA is being sought. The sample shall also be representative of the manufacturing process.

The tests shall be carried out by either the approved manufacturer, an approved independent testing laboratory, an SI or, exceptionally, in accordance with the requirements specified in 3.1.2.7.

The results of the tests shall be recorded in a QA Report prepared by the manufacturer in accordance with annex B to this clause and authenticated by the DMR and verified by the agreement (countersignature) of the SI that the QA Report meets the requirements of the specification. A copy of this report shall be submitted to the CB as a recommendation. Any other reproduction and release of this report is the sole prerogative of the manufacturer.

3.1.5 Granting of QA

The CB shall validate the recommendation and grant the QA when the requirements of 3.1.4 have been met.

3.1.6 QA certificate

When QA has been granted, a certificate shall be issued to the manufacturer in accordance with QC 001002-2, clause 2. The component or range of components shall be listed in the On-Line Certificate Database.

The above information shall be communicated to any customer on request.

3.1.7 Maintenance of QA

3.1.7.1 Maintenance of QA is assured when the conditions detailed in the relevant specification are fulfilled.

3.1.7.2 Otherwise, this QA shall be verified

a) if the production programme is such that the periodic tests cannot be carried out with their normal frequency, or

b) if the conformity of the components in production to the QA components is doubtful or potentially so, for example, following a technical modification, or

c) when a change has been made to the specification.

3.1.7.3 The procedure for the verification described in 3.1.7.2 is the same as that followed for the QA itself. The number of tests may be fewer, as decided by the DMR in consultation with the SI, but the sampling requirements for each test are unchanged.

3.1.7.4 Subject to the requirements above, there is no limit to the duration of the validity of the QA.
## 3.1.8 Procedure in the event of failure in a periodic test

### 3.1.8.1 When a sample fails to satisfy the requirements of a periodic test the DMR (or, where applicable, the local DMR) shall immediately

- suspend further releases under the Mark, or Certificate, of Conformity of the component in question,
- initiate an investigation to determine the reasons for failure, and
- report the situation to the SI.

### 3.1.8.2 The DMR (or, where applicable, the local DMR) shall maintain this suspension until the investigation has been concluded and the SI has been informed of the results. The DMR (or, where applicable, the local DMR) shall then proceed according to the appropriate conditions in 3.1.8.3, 3.1.8.4 or 3.1.8.5.

### 3.1.8.3 If the failure is concluded to have been due solely to an error in test procedure,

a) release under the Mark, or Certificate, of Conformity shall be resumed immediately, and

b) the correct test procedure shall be applied to a sample drawn from the first available inspection lot. If the sample fails the corrected test, action shall be taken as in 3.1.8.1.

### 3.1.8.4 If the failure is concluded to be due to an identified manufacturing fault which can immediately be corrected,

a) release under the Mark, or Certificate, of Conformity of corrected lots shall be resumed immediately,

b) the test shall be repeated on the first available corrected lot, and

c) if the result of the repeated test is unsatisfactory, the procedure defined in 3.1.8.5 or 3.1.8.6 shall be applied as appropriate.

### 3.1.8.5 If the failure is concluded to be due to an identified manufacturing fault which cannot be corrected immediately, but defective components can be detected and rejected by an appropriate eliminating test acceptable to the DMR (or, where applicable, the local DMR),

a) release under the Mark, or Certificate, of Conformity of accepted components shall be resumed immediately, and

b) elimination before submission for acceptance shall be continued until the necessary steps to correct the manufacturing fault have been taken, and until satisfactory results for the periodic test in question have been obtained on a sample from the first available lot presented for inspection after correction.

### 3.1.8.6 If the failure is concluded to be due to an identified manufacturing fault which cannot be corrected immediately and defective components cannot be removed by the application of an eliminating test, the SI shall recommend to the CB (see 3.1.12) that they suspend QA and withdraw the right to use the Mark, or Certificate, of Conformity for the component in question. QA and the right to use the Mark, or Certificate, of Conformity shall be reinstated when the manufacturer can demonstrate, by the successful submission of a sample from a production lot to the periodic test, that the manufacturing fault has been eliminated.

### 3.1.8.7 If the failure cannot be attributed with certainty to a specific error in test procedure or to an identified manufacturing fault, samples from subsequent lots shall then be subjected to all tests in the subgroup of the periodic test in which the failure occurred, on a lot-by-lot basis, and these lots may
be released if these samples pass the test successfully. The sample size shall be that designated for the subgroup.

Except where otherwise specified in the generic specification, normal periodic testing shall be resumed when two successive lots have successfully passed the tests in the subgroup in question, or as otherwise specified in the generic specification.

3.1.8.8 If the requirements of 3.1.8.4, or 3.1.8.5 or 3.1.8.6 are not fulfilled within a reasonable period of time, QA shall be re-examined and may be withdrawn.

3.1.8.9 If the duration of the periodic test in question exceeds three months and if special conditions would be appropriate to the particular type of component and the nature or extent of the failure, the relevant specification shall prescribe any special procedure to be followed.

3.1.9 Modifications likely to affect QA

The manufacturer shall report to the SI any modifications likely to affect the validity of the QA, and the SI shall decide whether it is necessary to repeat all or some of the QA tests. The relevant specification may give more detailed information.

3.1.10 Withdrawal of QA

QA shall be withdrawn only by the CB (see 3.1.5) and only if one or more of the following conditions apply:

a) at the request of the manufacturer;
b) the production of the component in question is terminated or suspended for an abnormally long period. In the latter case an agreement between the manufacturer and the SI is required to determine the period which is to be considered abnormally long;
c) the Rules of Procedure have not been correctly applied;
d) the manufacturer’s approval is withdrawn;
e) persistent non-conformance with the specification;
f) as a consequence of actions which may be taken under 3.1.8.8.

3.1.11 Reinstatement of QA

If QA has been withdrawn in accordance with 3.1.8.8 or 3.1.10 it may be reinstated by a procedure in which the tests are limited to the area of failure.

3.1.12 Suspension of QA

In the case of temporary or minor non-conformity, QA may be suspended by the CB (see 3.1.5) instead of being withdrawn. A period, not exceeding six months, shall be prescribed in which the manufacturer has to demonstrate that he has remedied the faults previously found.

3.2 Release for delivery and validity of release

3.2.1 General

Quality conformance inspection and periodic testing requirements for components are given, either directly or by reference, in published detail specifications.
3.2.2 Validity of release

A release for delivery is valid for five years unless a shorter period is specified in the detail specification. The relevant specification shall prescribe the tests which shall be repeated in order to revalidate the release.

3.2.3 Quality conformance inspection

3.2.3.1 General

Quality conformance is established after carrying out tests demonstrating that the inspection lots (see 3.3) have achieved the quality prescribed in the specification. The manufacturer shall carry out these tests, or arrange to have them carried out in a laboratory approved under the System. The detail specification shall prescribe those tests which have to be performed. The acceptability of the lot is determined by the requirements of the specification.

When quality conformance inspection is performed according to 3.2.3.1d) in a factory located in a non-IECQ member country, samples of each inspected lot manufactured in that factory shall, for a period of time determined by the SI be sent to the manufacturer in the IECQ member country. These samples shall be used for audit testing by the SI or by the manufacturer on behalf of the SI, and the results of these audit tests compared with the results of the quality conformance inspection to validate the sentencing of each lot.

3.2.3.2 Lot-by-lot tests

Lot-by-lot tests are carried out on each inspection lot. These tests may be divided into two groups:

Group A, covering visual and dimensional inspection of the components and the principal characteristics of the components (initial measurements);
Group B, covering additional important characteristics.

Each group may be divided into two or more subgroups.

3.2.3.3 Periodic tests

Periodic tests are carried out at fixed intervals on samples taken from lots which have already satisfied the lot-by-lot tests. These periodic tests are generally brought together and designated Group C tests. These can be divided into subgroups, for example, on the basis of the interval at which the samples are taken.

Sometimes a Group D may be included containing additional tests required for the maintenance of QA.

3.2.3.4 Destructive tests

Specimens which have been subjected to destructive tests shall not be included in lots to be delivered. Specimens subjected to non-destructive tests may be included in lots to be delivered provided they satisfy the specified tests.

3.2.3.5 Use of in-process testing

In-process testing may be substituted for the relevant test(s) of the quality conformance testing provided that the manufacturer demonstrates that the in-process testing is such that the corresponding requirements of the specification would have been met at the final stage of inspection.
3.2.3.6 Test severity
A manufacturer may carry out any test at a greater severity than that specified, but the component after testing shall satisfy the limits prescribed in the specification.

3.2.3.7 Alternative test methods
The test and measurement methods given in the relevant specification are intended to unify test and measurement procedures. They are not necessarily the only methods which can be used except when specifically designated as referee or reference methods. The approved manufacturer shall demonstrate to the SI that any alternative methods he uses will give results equivalent to those obtained by the specified method.

3.2.3.8 Measurement uncertainty
The limits prescribed in specifications are true values. When carrying out the specified tests the approved manufacturer shall employ sufficient inset from the specified limits to cover the uncertainty of his measurement (see annex C of clause 2).

3.2.4 Non-conforming components in lot-by-lot tests
Specimens found non-conforming during lot-by-lot testing shall be withdrawn from the lot and not delivered. Lots rejected in lot-by-lot tests may be resubmitted in accordance with the requirements prescribed in the relevant specification.

3.2.5 Non-conformances in periodic tests
The DMR shall keep records of non-conformances observed in samples subjected to periodic tests where the repetition of such non-conformances may lead to the suspension or withdrawal of QA (see 3.1.10 and 3.1.12).

3.2.6 Release or rejection of lots
Except when otherwise prescribed in the relevant specification, the lots shall be released or rejected on the basis of the lot-by-lot tests (see 3.2.3.2). The failure of the sample submitted to one of the periodic tests shall entail the rejection of the lot from which the sample came unless release has already taken place due to the length of the test.

3.2.7 Identification of released lots
Lots released by manufacturers or distributors shall be unambiguously identified by a Mark, or Certificate, of Conformity, the affixing, or issue, of which is under the surveillance of the SI. This Mark, or Certificate, means that the components have been released in accordance with the requirements of the relevant detail specification (see QC 001002-2, clause 2, Certificates of approval and attestation of conformity).

Only components approved against a detail specification registered within the System may receive the Mark, or Certificate, of Conformity.

Authorization to affix, or to issue, the Mark, or Certificate, of Conformity is suspended or withdrawn if there is persistent non-conformity with the specification (see 3.1.10 and 3.1.12) or if the provisions of this clause 3 are not observed.

3.2.7.1 Release prior to the issue of an approval certificate
An approved manufacturer is permitted to release approved components prior to the issue of an approval certificate provided that

a) the QA test report for the component(s) has been countersigned by the SI, and
b) A draft approval certificate has been accepted by the SI, and the approved manufacturer has
submitted to the CB a written statement announcing his intention to release approved
components together with a copy of this draft approval certificate. This statement shall be
countersigned by the SI.

In releasing approved components, the approved manufacturer shall

a) annotate the Certificate of Conformity with the text "Released in accordance with
QC 001002-3, subclause 3.2.7.1", and

b) be responsible for any corrective action which may be required of him by the CB if for any
reason the QA is subsequently withheld or the content of the approval certificate is significantly
different from the original draft agreed by the SI.

3.2.8 Switching rules for reduced inspection in Group C

3.2.8.1 Application

The procedure is applicable to subgroups of Group C tests having a periodicity of twelve months or
less when specifically permitted by the generic, or sectional, specification. It shall not be applied to
Endurance tests unless otherwise prescribed in the relevant specification.

The relevant specification shall describe any limitations with respect to values, styles, etc., of a
component in the use of this procedure.

3.2.8.2 Switching rules

3.2.8.2.1 Where components have met all the following requirements when subjected to the
inspection of the applicable subgroups, the periodicity of further inspection in these subgroups may,
at the discretion of the DMR and after notification to the SI, be extended to twice that specified in the
relevant specification. These requirements are

a) the inspection requirements specified in the relevant specification for each applicable subgroup
shall have been successfully complied with for three consecutive periods, and

b) No non-conforming components have been found in each subgroup over the period of twelve
months, and

c) Switching rules are permitted by the applicable Generic Specification

3.2.8.2.2 The periodicity of inspection shall immediately revert to that specified in the relevant
specification when any of the following occurs:

a) a failure to meet the requirements of the applicable subgroup;

b) a significant change in design, material or process that might have an influence on the result of
the inspection of the applicable subgroup, or,

c) non-conformities have been reported to the SI, or identified by the SI.

3.2.8.2.3 In addition to the relaxation of test period detailed above, it is permissible to undertake
normal, reduced or tightened sampling as detailed in the guidance to the specified IEC 60410 or ISO
2859-1 sampling plan.
3.2.9 Customer returns and appropriate corrective action

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 manufacturer's bonded store for release.

Where a manufacturing or test defect is confirmed, the approved manufacturer shall follow the appropriate procedures as detailed under 3.1.8.

Approved manufacturers shall notify the SI every six months of non-conformities on components released under the System. Notification shall be given in writing and may be presented during a surveillance/audit visit, or otherwise as agreed with the SI.

3.3 Inspection lots

3.3.1 Formation of inspection lots

An inspection lot may be formed by the aggregation of several production lots provided that

a) the production lots are manufactured under essentially the same conditions (materials, processes, machines, personnel, etc.), and,

b) quality control and inspection during manufacture is performed to the extent necessary, in accordance with directives established by the appropriate departments of the manufacturer in consultation with the DMR, and,

c) the results of this inspection indicate for each production lot that the quality of materials and processing is maintained within the limits necessary for the production of components satisfying the requirements of the specification, and,

d) the period over which production lots may be aggregated into one inspection lot should normally not exceed one week, and shall not exceed one month unless permitted by the relevant specification.

The programme for the aggregation of production lots into inspection lots shall be determined by the DMR and shall be submitted for approval to the SI.

3.3.2 Structurally similar components

Structurally similar components are components produced by the same manufacturer with essentially the same design, materials, processes and methods. They are such that the results of a given test carried out on one of these components can be recognised as being valid for the others of the group. They are separately identifiable.

The relevant specification shall give the requirements for grouping structurally similar components for the purpose of testing for QA and quality conformance inspection.

3.4 Specifications

3.4.1 Generic and sectional specifications

The appropriate requirements of QC 001002-2, clause 1, Standards and specifications, shall apply.

3.4.2 Detail specifications for components

The detail specifications shall comply with the requirements of the blank detail specifications.

3.5 Frequency of surveillance by the SI

Approved manufacturers holding Qualification Approval require a more severe surveillance visit
regime that those manufacturers which only hold organisation approval. This reflects the additional liability resultant from holding a product approval.

3.5.1 Normal frequency of surveillance

The normal frequency of surveillance shall be two visits per year.

3.5.2 Reduced frequency of surveillance

At the discretion of the SI, the frequency of surveillance of the approved manufacturer may be reduced to one visit per year provided that the following conditions apply:

a) the manufacturer has held approval for a minimum of two years;

b) no product-related failure to comply with the IECQ system rules has been identified during the previous three surveillance visits, other than product failures permitted by the relevant specification (e.g.: limited failures during maintenance testing are permitted by some Standards).

c) no product or process failures have occurred during a two year period, other than product failures permitted by the relevant specification as detailed above.

3.5.3 Suspension of reduced frequency of surveillance

Manufacturers subject to reduced frequency of surveillance which subsequently fail to comply with the conditions of 3.5.2 shall revert to normal frequency of surveillance.
Annex A to clause 3 (normative)

Flow-chart for the application of Qualification Approval

1. Application for Qualification Approval
   QC 001002-3; 3.1.3

2. Check of the application
   QC 001002-3; 3.1.3.6

3. Confirmation of application
   QC 001002-3; 3.1.3.6

4. Choice of Samples
   QC 001002-3; 3.1.4

5. Test schedule
   QC 001002-3; 3.1.3.5

6. Perform tests
   QC 001002-3; 3.1.4

7. Qualification Approval report
   QC 001002-3; 3.1.4

8. Requirements fulfilled?
   QC 001002-3; 3.1.6

   - No
     → Recommendation for Qualification Approval
     QC 001002-3; 3.1.4
     → Granting of Qualification Approval
     QC 001002-3; 3.1.5

   - Yes
     → Recommendation for Qualification Approval
     QC 001002-3; 3.1.4
     → Granting of Qualification Approval
     QC 001002-3; 3.1.5
Annex B to clause 3
(normative)
Qualification Approval Report

B.1 General

The overall format of an approval report is flexible and the specific style can be chosen to suit individual preferences but, as a minimum, the report shall contain the following information:

B.2 Preface

The approval report shall be prefaced as follows:

— approval report title, reference number and date;
— detail specification, issue number and associated product references;
— name, address and approval number of manufacturer;
— name, address and status of independent testing laboratory (if appropriate);
— name and address of the responsible SI;
— a dated declaration signed by the DMR as follows:

“I certify that the requirements of the System have been met and that all samples tested were either
1) taken from, and are representative of, current production; or
2) manufactured using current/intended production methods and materials.”

— SI signature and date.

B.3 Index, page identification and detail specification

The approval report shall contain an index summarizing its contents and identifying the respective page numbers for major sections.

All approval report pages shall be numbered.

It is recommended that a copy of the applicable detail specification be included as an annex to the approval report.

B.4 Test plan and summary of results

Details of all samples shall be given, including batch identity and date code.

The approval report shall contain a summary of the test plan agreed with the SI and attributes data for the respective test samples, preferably in tabular format.

Where structural similarity is being claimed, full details shall be given, including reference(s) to previously agreed approval reports (when applicable).

B.5 Test equipment and results

The test and measurement equipment used during the Qualification Approval exercise shall be uniquely identified and its calibration status shown.

The measurement uncertainty associated with each test shall be stated and taken into account when determining pass/fail criteria.
For every test method, the report shall state the method used by reference to the appropriate standard or detail specification. Where a non-standard method is used, full details shall be given.

All test conditions shall be described. If full details are given in the applicable detail specification, reference to the particular subgroup will suffice.

The test results shall be specified accurately, clearly and completely. The results of each test sequence/subgroup shall be dated and identified as to the individual who performed the test.

Where there is a large amount of test data, it is recommended that a statistical form of presentation is used.

B.6 Failure identification and analysis

Any failures which occur during Qualification Approval testing shall be identified and the failure cause analyzed. The results of this analysis shall be included in the test report. Where corrective action is indicated, details shall be given.
4. Capability Approval of an electronic component manufacturing activity

4.0 Introduction

The Capability Approval procedure shall be used only when provided for in the relevant generic specification.

4.1 Definitions

4.1.1 Capability Approval

an approval granted to a manufacturer when it has been established that his capability for manufacturing processes and quality control methods (including design aspects as applicable) covering a specific component technology, fulfils the requirements of the relevant generic specification

4.1.2 capability qualifying component (CQC)

a test specimen, which may be specially designed for this purpose, or taken from production, which is used for verifying capability in accordance with the relevant generic specification

4.1.3 incorporated components

incorporated components are components which form the constituent parts of a larger, more complex, electronic component

4.1.4 rework

rework is the rectification of processing errors prior to the release of the components by means not differing from those used in the current process or the rework processes as permitted by the generic specification

4.1.5 repair

repair is the making usable of an approved component which has been damaged or has become defective after release.

4.2 Procedure for Capability Approval (CA)

4.2.1 Eligibility for CA

4.2.1.1 CA may be granted only to a manufacturer who has been granted manufacturer’s approval in accordance with the requirements of clause 2 including, as appropriate, those of ISO 9001 and, additionally, the requirements of this clause. Results from an approval to clause 3, Qualification Approval of electronic components, may be taken into account. These approvals may be carried out in parallel, although CA shall not be granted in advance of manufacturer’s approval.

4.2.1.2 A component manufacturer is eligible for CA in accordance with the System if the manufacturing process, commencing not later than that manufacturing operation which is called the “primary stage” (see QC 001002-2, clause 1) is carried out by one or more manufacturers approved in accordance with the requirements of clause 2 and under the direct supervision of the relevant Designated Management Representative (DMR) or local DMR.

The rules for the extension of manufacturer’s approval given in clause 2 apply.

4.2.2 Use of specialist contractors and subcontracting

4.2.2.1 The primary stage and/or subsequent stages may be carried out by specialist contractors (see clause 2) or, under certain conditions, subcontracted (see 4.2.2.3 and 4.2.3 ).

4.2.2.2 The generic or sectional specification may
either forbid this subcontracting on technical grounds, or

— where it is considered necessary, include any special requirements, for example for specified successive stages to be performed by the same manufacturer, or

— permit the subcontracting unreservedly.

Such restrictions shall not apply to arrangements made concerning specialist contractors.

4.2.2.3 When subcontracting is permitted by the generic or sectional specification, this may be undertaken provided that the DMR is able to demonstrate to the Supervising Inspectorate (SI) that the process(es) concerned is (are)

a) performed in a manner which satisfies the appropriate requirements of the relevant Process Assessment Schedule (PAS), where such exists, or

b) carried out satisfactorily.

4.2.2.4 To verify the satisfactory conduct of subcontracted operations in accordance with 4.2.2.3a) or b), the manufacturer shall ensure that the CA testing and quality conformance testing will be performed under his control in an approved laboratory located in an IECQ member country, or exceptionally in accordance with 4.2.2.7.

4.2.2.5 The manufacturer, when applying for CA, shall state whether stages of the manufacturing process are carried out by one or more specialist contractors in accordance with 4.2.2.1 or, are subcontracted in accordance with 4.2.2.3 and shall identify these stages (see 4.2.4).

4.2.2.6 If subcontractors not approved within the System are used, the manufacturer shall describe the method of control of all the subcontracted stages or operations.

4.2.2.7 Before tests are carried out by laboratories not approved under the System, the approved manufacturer shall take all reasonable steps to ensure that the required service is not available from any approved independent testing laboratory within the System.

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

Where tests are carried out by testing laboratories not approved within the System, the approved manufacturer shall produce a document which describes the surveillance arrangements by which he shall ensure that the testing to be carried out shall comply with the specification. Where possible, the nominated testing laboratory shall be approved to ISO/IEC 17025 by a nationally recognized accreditation body. The document shall define how the nominated testing 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, and

c) ensures that 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 and/or registrations held by the nominated testing laboratory.

Prior to permitting testing, the approved manufacturer shall demonstrate to the SI that his proposed surveillance arrangements comply with the specification.
The procedures given in this subclause, 4.2.2.7, shall be applied separately to any subsequent programme of testing, including those carried out for periodic testing for the maintenance of an approval.

4.2.3 Incorporated components

4.2.3.1 General requirements

Where components or assemblies manufactured and released under CA incorporate components other than piece parts, the requirements of 4.2.3.2, 4.2.3.3 and 4.2.3.4 shall apply.

NOTE The distinction between incorporated components and piece parts is that incorporated components have a distinctive electrical function in an electronic circuit, whereas piece parts (e.g.: a heat sink) do not.

4.2.3.2 Incorporated components covered by an applicable specification

Wherever possible, incorporated components shall be covered by an applicable specification. Such components shall be procured using the normal IECQ release procedures. Under these conditions no other assessment of the components is required.

Where these components are not procured to an applicable detail specification, the approved manufacturer's DMR shall verify their quality in accordance with 4.2.3.3.

4.2.3.3 The use of unapproved incorporated components

For the incorporation of unapproved components, the approved manufacturer's DMR shall

a) be satisfied that the quality and performance of the components are adequate for their purpose,

b) ensure the existence of a component specification covering all the aspects necessary to ensure their satisfactory performance as part of the final product,

c) carry out an adequate approval test programme maintaining a record of the results, and

d) institute sufficient "goods inward" inspection procedures to ensure continued satisfactory performance of the final product.

4.2.3.4 The incorporation of part finished components

Where part finished components are procured direct from a manufacturing source other than a specialist contractor (see clause 5), the approved manufacturer's DMR shall ensure that they comply with 4.2.3.2 and/or 4.2.3.3, 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, and

c) adequate storage and handling facilities are available for the part finished component.

Any other technical requirements, specific to particular components, shall be specified in the generic specification, and these shall be considered as additional to the requirements of a), b) and c) above.

4.2.4 Application for CA

4.2.4.1 When an approved manufacturer wishes to obtain CA, he shall submit an application in writing to the SI. In this application he shall state the scope of the proposed CA, preferably in the
form of a first draft of the information required under 4.6, and clearly defining the range of technologies and/or the range of components he wishes to manufacture in accordance with the stated generic and/or sectional specification.

He shall also state

a) that he carries out at the approved location all the processes, tests, measurements, etc. subsequent to and including the primary stage of manufacture, or

b) that all stages of manufacture are carried out by manufacturers or specialist contractors approved within the System, some of whom may be located in other countries (see 4.2.3.2), or by distributors acting in another role (see clause 2), or

c) that defined stages are subcontracted in accordance with 4.2.2.3a) or b) and 4.2.2.4, or

d) that defined stages are carried out in one of his company's factories located in a non-IECQ member country, whereas the quality conformance testing may be performed either in a laboratory approved under the System, or, in the above mentioned factory which is under the direct surveillance of the SI (see 4.2.3.4), or, in a laboratory as described in 4.2.2.7.

4.2.4.2 When the conditions of 4.2.4.1b) apply, the application for CA shall contain

— details of the division of manufacturing stages between the manufacturers or specialist contractors concerned, and

— details of the arrangements agreed with the SI(s) involved for the certification of the quality of components, or partially manufactured components, when they are transferred from one approved manufacturer, specialist contractor or distributor acting in another role to another, together with details of the means whereby changes to the agreed arrangements are communicated to the responsible SI.

The SI of the manufacturer seeking CA shall

— co-ordinate the activities,

— seek confirmation from the SIs of the other countries that the information contained in the application is correct, and

— ensure that the manufacturer possesses sufficient engineering capability and/or technical expertise to develop, maintain and control the manufacturing processes that he wishes to subcontract, or that the stages of manufacture concerned are adequately covered by the specialist contractors' existing approvals under the System.

4.2.4.3 When conditions of 4.2.4.1c) apply, the application for CA shall contain

— details of division of the manufacturing stages between the approved manufacturer and the subcontracting factory, and

— details of the arrangements agreed with the SI(s) involved for the certification of the quality of components taking into account the transfers during the manufacture and, in particular, the procedures for the assessment of quality of the subcontracted manufacturing stages, together with details of the means whereby changes to the agreed arrangements are communicated to the responsible SI.

The manufacturer shall demonstrate to the SI by any suitable means that the quality of the final component will not be adversely affected by the use of these subcontracted stages of manufacture.

The SI of the manufacturer seeking CA shall
— ensure that the approved manufacturer's DMR is able to verify the satisfactory maintenance of the quality control procedures performed by his subcontractor in accordance with 4.2.2.3a) or b) and 4.2.2.4, and

— ensure that the manufacturer possesses sufficient engineering capability and/or technical expertise to develop, maintain and control the manufacturing processes that he wishes to subcontract, or that the stages of manufacture concerned are adequately covered by the specialist contractors' existing approvals under the System.

The SI shall confirm in writing to the CB that the details contained in the application for CA satisfy the requirements of the System.

4.2.4.4 When the conditions of 4.2.4.1d) apply, the application for CA shall contain

— details of the division of the manufacturing stages between the approved manufacturer and his company's factory located in a non-IECQ member country, and

— details of the arrangements agreed with the SI involved for the certification of the quality of the components taking into account the transfers carried out in the course of manufacture together with details of the means whereby changes to the agreed arrangements are communicated to the responsible SI.

The SI of the manufacturer seeking CA shall

— ensure that the DMR of the approved manufacturer has effective responsibility for quality control procedures performed under the supervision of the local DMR on the production in a non-IECQ member country, and

— ensure that the manufacturer possesses sufficient engineering capability and/or technical expertise to develop, maintain and control the manufacturing processes that he wishes to subcontract, or that the stages of manufacture concerned are adequately covered by the specialist contractors' existing approvals under the System.

4.2.4.5 When the manufacturer's proposed declaration of capability meets the requirements of the specification and he is ready to demonstrate this capability, he shall give notice to the SI of his intention to start approval tests, and establish together with the SI a test plan and a time schedule for the execution of the approval tests.

4.2.5 Description of capability

The manufacturer shall provide the SI with a description of his capability, relevant to the technologies and/or range of components for which the approval is being sought. Where confidential processes are involved the manufacturer is only required to provide the information necessary for the CA.

The SI is not allowed to copy company confidential documents, to remove them from the manufacturer's premises, or to disclose without the manufacturer's prior permission such information to third parties (see 2.3.1)

The description of capability (which may be in the form of a Capability Manual if provided for by the national rules) shall, either directly or by reference to the manufacturer's internal documents

a) define in accordance with the relevant specifications the scope and limits of the capability for which he is seeking approval;

b) state the design rules when required by the relevant specification;

c) provide a description of the main features of construction of the component(s) (as applicable);

d) provide a process flow chart;
e) list the specifications used for the CQCs and the materials and parts used;
f) list the specifications for the inspection to be carried out during the manufacturing process;
g) define how modifications are notified.

The relevant generic or sectional specification may give more detailed information concerning the description of capability to be supplied by the manufacturer.

### 4.2.6 Demonstration and verification of capability

#### 4.2.6.1
The DMR shall prepare a programme in accordance with the relevant specification for the assessment of the claimed capability. This programme shall include reference to:

a) the specification of the CQCs, and

b) the test and inspection requirements and/or process controls.

The tests shall be carried out by either the approved manufacturer, an approved independent testing laboratory, an SI or, exceptionally, in accordance with the requirements specified in 4.2.2.7.

When the CQCs are designed and produced solely for the purpose of obtaining CA, the manufacturer shall ensure that the same processes and inspection procedures are applied to normal production. The manufacturer shall ensure that the CQCs collectively cover all of the defined limits of the capability (see 4.2.5a)).

#### 4.2.6.2
If during the initial CA demonstration a CQC sample fails to meet the specified requirements and exceeds the permitted number of failures, the manufacturer shall either

a) amend the scope of his declared capability, or

b) conduct an investigation into the failure to establish its cause as being either a failure of the test itself, for example test equipment failure or operator error, or design or process failure.

If, in b), the cause of failure is established as a failure of the test itself then, subject to the agreement of the SI, either the CQC which apparently failed or a new one, if appropriate, shall be returned to the test schedule after the necessary corrective action has been taken. If a new CQC is to be used, it shall be subjected to all of the tests in the given sequence of the test schedule(s) appropriate to the original CQC.

If, in b), the cause of failure is established as a design or process failure, a test programme agreed between the manufacturer and the SI shall be performed to demonstrate that the cause of the failure has been eradicated and that all corrective measures have been carried out and documented (see 4.2.6.3). When this has been accomplished, the full test sequences shall be repeated using new CQCs.

#### 4.2.6.3
The results of the tests shall be recorded in a CA Report authenticated by the DMR and verified by the agreement (countersignature) of the SI that the CA Report meets the requirements of the specification. A copy of this report shall be submitted to the CB. Any other reproduction and release of this report is the sole prerogative of the manufacturer

### 4.2.7 Granting of CA

CA shall be granted by the CB when the requirements of 4.2.6 have been met.

When CA is granted, a certificate described in 4.2.8 shall be issued to the manufacturer and the approval is entered in the On-Line Certificate Database.
4.2.8 **CA certificate**

The certificate issued to the manufacturer by the CB shall contain the following information:

a) the IECQ reference number, the issue number and date of the generic and other specifications which define the CA requirements. If required by the national rules, the national identification of the specifications may be added;

b) the identification of the manufacturing technology;

c) the name of the manufacturer and place(s) of manufacture;

d) the manufacturer’s reference number for the Capability Manual, or other documentation defining the limits of the capability, on which the approval is based;

e) an abstract of the description of the capability, as required for inclusion in the On-Line Certificate Database (see 4.2.5);

f) the identity of the CB and authenticating signature.

The above information shall be communicated to any customer on request.

4.2.9 **Maintenance of CA**

Maintenance of CA is assured when the conditions for maintenance detailed in the relevant specification are fulfilled.

Such conditions include

— duration of time for which CA remains valid,
— periodicity and programme for any testing of CQCs for maintenance of CA, and
— conditions under which quality conformance inspection leads to maintenance of CA.

4.2.10 **Procedure in the event of a CQC failure during maintenance of CA**

4.2.10.1 This procedure applies when the CQC sample fails to meet the specified test requirements and exceeds the permitted number of failures.

4.2.10.2 When a CQC sample fails to satisfy the requirements the DMR (or, where applicable, the local DMR), shall immediately

a) suspend further releases under the Mark, or Certificate, of Conformity of those components whose conformance could be affected by the failure,

b) initiate an investigation to determine the reasons for the failure, and

c) report the situation to the SI.

4.2.10.3 The DMR (or, where applicable, the local DMR) shall maintain this suspension until the investigation has been concluded and the SI has been informed of the results. The DMR (or, where applicable, the local DMR) shall then proceed according to the appropriate conditions in 4.2.10.4, 4.2.10.5 or 4.2.10.6.

4.2.10.4 If the failure is concluded to have been due solely to an error in test procedure, this shall be corrected and release resumed once satisfactory results have been obtained.
4.2.10.5 If the failure is concluded to be due to an identified manufacturing fault which can immediately be corrected,

a) the test shall be repeated on the corrected CQC sample,

b) release under the Mark, or Certificate, of Conformity of corrected lots shall be resumed immediately after satisfactory results are obtained, and

c) if the result of the above repeated test is unsatisfactory, the procedure defined in 4.2.10.6 or 4.2.10.7 shall be applied as appropriate.

4.2.10.6 If the failure is concluded to be due to an identified manufacturing fault which cannot be corrected immediately, but defective components can be detected and rejected by an appropriate eliminating test acceptable to the DMR (or, where applicable, the local DMR),

a) release under the Mark, or Certificate, of Conformity of accepted components shall be resumed immediately, and

b) elimination before submission for acceptance shall be continued until the necessary steps to correct the manufacturing fault have been taken, and until satisfactory results for the test in question have been obtained on a sample from the first available lot presented for inspection after correction.

4.2.10.7 If the failure is concluded to be due to a manufacturing fault which cannot be corrected immediately and defective components cannot be removed by the application of an eliminating test, the SI shall recommend that the CB suspend CA and withdraw the right to use the Mark, or Certificate, of Conformity for the components in question. CA and the right to use the Mark, or Certificate, of Conformity shall be reinstated when the manufacturer can demonstrate, by the successful submission of new CQCs, that the manufacturing fault has been eliminated.

4.2.10.8 If the requirements of 4.2.10.5, 4.2.10.6 or 4.2.10.7 are not fulfilled within a reasonable period of time, the CA shall be re-examined and may be withdrawn.

4.2.10.9 If CA has been suspended in accordance with 4.2.10.8, it may be reinstated provided that the requirements of 4.2.10.5, 4.2.10.6 or 4.2.10.7 have been satisfied.

4.2.11 Modifications likely to affect CA

The manufacturer shall report to the SI any modifications likely to affect the validity of the CA, and the SI shall decide whether it is necessary to repeat all or some of the CA tests. The relevant specification may give more detailed information.

4.2.12 Withdrawal of CA

CA shall be withdrawn only by the CB (see 4.2.7) and only if one or more of the following conditions apply:

a) at the request of the manufacturer;

b) the production of components in the technology in question is terminated or suspended for a period greater than that given in the relevant specification for the maintenance of capability;

c) the Rules of Procedure have not been correctly applied;

d) the manufacturer's approval is withdrawn;

e) persistent non-conformance with the specification;

f) as a consequence of actions which may be taken under 4.2.10.8.
4.3 Release for delivery

4.3.1 Quality conformance inspection

4.3.1.1 The quality conformance inspection requirements shall be given in the detail specification.

4.3.1.2 Quality conformance is established after carrying out tests demonstrating that the inspection lots released have achieved the quality prescribed in the specification. The manufacturer shall carry out these tests, or arrange to have them carried out in a laboratory approved under the System. The customer detail specification shall prescribe those tests which have to be performed. The acceptability of the lot is determined by the use of the sampling plans stated in the relevant specification.

Lot-by-lot tests are carried out on each inspection lot. These tests may be divided into two groups:

Group A, covering visual and dimensional inspection of the components and the principal characteristics of the components (initial measurements);

Group B, covering additional important characteristics.

Each group may be divided into two or more subgroups.

NOTE See 4.2.9 for tests carried out to support the maintenance of CA.

4.3.2 Release for delivery and validity of release

4.3.2.1 The manufacturer shall be able to demonstrate to the SI that components released under the CA relate to the CQCs tested and lie within the declared capability.

4.3.2.2 A release for delivery is valid for five years unless a shorter period is specified in the detail specification. The relevant specification shall prescribe the tests which shall be repeated in order to revalidate the release.

4.3.2.3 An approved manufacturer is permitted to release approved components prior to the issue of a CA certificate provided that

a) the CA test report for the CQC(s) has been countersigned by the SI, and

b) a draft approval certificate has been accepted by the SI, and the approved manufacturer has submitted to the CB a written statement announcing his intention to release approved components together with a copy of this draft approval certificate. This statement shall be countersigned by the SI.

In releasing approved components, the approved manufacturer shall

a) annotate the Certificate of Conformity with the text "Released in accordance with QC 001002-3, subclause 4.3.2.3", and

b) be responsible for any corrective action which may be required of him by the CB if for any reason the CA is subsequently withheld or the content of the approval certificate is significantly different from the original draft agreed by the SI.

4.3.3 Customer returns and appropriate corrective action

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 manufacturer's bonded store for release.
Where a manufacturing or test defect is confirmed, the approved manufacturer shall follow the appropriate procedures as detailed under 4.2.10.

Approved manufacturers shall notify the SI every six months of non-conformities on components released under the System. Notification shall be given in writing and may be presented during a surveillance/audit visit, or otherwise as agreed with the SI.

### 4.3.4 Destructive tests

Specimens which have been subjected to destructive tests shall not be included in lots to be delivered. Specimens subjected to non-destructive tests may be included in lots to be delivered provided they satisfy the specified tests.

### 4.3.5 Use of in-process testing

In-process testing may be substituted for the relevant test(s) of the quality conformance testing provided that the manufacturer demonstrates that the in-process testing is such that the corresponding requirements of the specification would have been met at the final stage of inspection.

### 4.3.6 Test severity

A manufacturer may carry out any test at a greater severity than that specified, but the component after testing shall satisfy the limits prescribed in the specification.

### 4.3.7 Measurement uncertainty

The values prescribed in specifications are true values. When carrying out the specified tests the approved manufacturer shall employ sufficient inset from the specified limits to cover the uncertainty of his measurement (see annex C of clause 2).

### 4.3.8 Temporary restriction of release

If any aspect of a CA becomes deficient, the approval may continue with the agreement of the SI, provided that release of components is restricted to the remaining areas of the capability not affected by the deficiency, and that the deficiency is corrected within a period agreed between the manufacturer and the SI. The relevant specification may give more detailed information.

### 4.4 Specifications

#### 4.4.1 Generic and sectional specifications

In addition to the appropriate requirements of QC 001002-2, clause 1, Standards and specifications for Qualification Approval and Capability Approval, the following provisions shall apply.

The generic and/or sectional specification(s) shall prescribe how CA is to be implemented for a specific component technology. A description of the limits of capability relevant to the component technology shall be given. They shall specify the test schedules to be used in the capability test programme, maintenance of the CA, and quality conformance inspection and give information concerning the CQCs to be used. Where appropriate, they shall also define the requirements for add-on and/or incorporated components.

#### 4.4.2 Detail specification for CQCs

Each CQC shall be covered by a detail specification (for printed boards referred to as Capability Detail Specification) which shall provide all information against which the CQC shall be inspected and tested in accordance with the requirements of the generic and/or sectional specification.

#### 4.4.3 Detail specifications for components for release
The detail specification shall comply with the generic or sectional specification and, when read in conjunction with them, shall adequately describe the component. It shall also give the necessary information for quality conformance inspection.

The ownership rights of a detail specification may be vested in the customer and/or manufacturer, and the contents may be held by both to be confidential.

When a component covered by the CA procedure is intended to be registered by the IECQ and listed in the On-Line Certificate Database, the manufacturer registering the detail specification shall

a) ensure that the detail specification is in accordance with the requirements (if any) for published detail specifications,

b) ensure that the requirements given in the Rules of Procedure for the registration of detail specifications are complied with, and

c) ensure that publication is not prohibited by ownership rights of the detail specification.

4.5 Register of detail specifications

The component manufacturer shall maintain a register of detail specifications. This register shall be available to the SI.

4.6 The On-Line Certificate Database

4.6.1 When CA is granted and the certificate described in 4.2.8 is issued to the manufacturer, the approval is listed in the On-Line Certificate Database, together with an abstract of the description of the CA.

4.6.2 At the request of the manufacturer, individual components may be listed in the On-Line Certificate Database, provided that

— the component(s) is (are) within the scope of the CA, and

— the component fully meets the requirements of a detail specification which has been published in accordance with QC 001002-2, clause 1, Standards and specifications for Qualification Approval and Capability Approval.
4.7 Rework and repair

4.7.1 Rework (see 4.1.4)

When necessary, the generic specification shall prohibit or restrict rework for all or for specific components.

All rework procedures shall be fully described in the relevant documentation produced by the manufacturer.

All rework shall be carried out under the surveillance of the DMR or, where appropriate, the local DMR.

All rework shall be carried out prior to the formation of the inspection lot offered for inspection to the requirements of the detail specification.

4.7.2 Repair (see 4.1.5)

Components which have been repaired shall not be released under the System.

4.8 Frequency of surveillance by the SI

Approved manufacturers holding Capability Approval require a more severe surveillance visit regime that those manufacturers which only hold organisation approval. This reflects the addition liability resultant from holding a product approval.

4.8.1 Normal frequency of surveillance

The normal frequency of surveillance shall be two visits per year.

4.8.2 Reduced frequency of surveillance

At the discretion of the SI, the frequency of surveillance of the approved manufacturer may be reduced to one visit per year provided that the following conditions apply:

a) the manufacturer has held approval for a minimum of two years;

b) no product-related failure to comply with the IECQ system rules has been identified during the previous three surveillance visits, other than product failures permitted by the relevant specification (e.g. limited failures during maintenance testing are permitted by some Standards);

c) no product or process failures have occurred during a two year period, other than product failures permitted by the relevant specification as detailed above.

4.8.3 Suspension of reduced frequency of surveillance

Manufacturers subject to reduced frequency of surveillance which subsequently fail to comply with the conditions of 4.8.2 shall revert to normal frequency of surveillance.
Annex A to clause 4
(normative)
Requirements for the form and content of a Capability Manual

A.0 General requirements

A.0.1 Form of the Capability Manual

It is preferred that the documentation be prepared on A4-size paper and in loose leaf form, with each section beginning on a new page and with the section titles and their sequence as given in this annex and Table 4 (see following page).

The document shall be given a document identity within the manufacturer's quality assurance system and have suitable provision for showing its issue and state of amendment.

Draft issues of the Capability Manual shall be given alphabetical issue references until accepted by the SI. It shall then be raised to Issue 1 at the stage at which CA is recommended.

Amendments shall not be made in hand-written form. When changes are required, new pages showing the relevant amendment number shall be issued.

The Capability Manual shall be raised in issue when a change is made. In addition the manufacturer has the option to give an issue status to each page or to each section. Where the scope of capability is extensive and the description is accordingly complicated, it is usually advantageous to give each page a discrete issue status.

There shall be a means for recording that amendments have been incorporated and a means for summarizing the nature or purpose of the amendments. This shall be subject to the change note procedures laid down in the manufacturer's Quality Manual. There shall be an index or "contents list". This may conveniently show the issue status of each section, or page, as the case may be.

A.0.2 Introductory pages

Preliminary pages: These are the introductory pages concerned mainly with the structure of the document as indicated in the foregoing advice. For example:

Title page: "Capability Manual": "--- The technology and specification to be noted here ---".
Document identity and Issue, manufacturer's name, telephone, telex and telefax numbers etc..
Authorization by the DMR.

Distribution list: This lists the holders of copies of the Capability Manual to whom amendments are to be sent. Copies shall be identified in respect of each recipient.

Amendment record: This is the facility for recording the incorporation of amendments authorized by the DMR.

List of amendments: This provides an indication of the purpose or nature of each amendment. It may be convenient to combine this function with the amendment record mentioned above.

NOTE This clause 4 requires that all amendments have to be agreed with the SI.

Contents list: This shall give the sections in the sequence shown in Table 4. It may be convenient to combine this function with the issue status of each page (or section).

If there is a need to draw on documentation contained within the Quality Manual (see 2.3.2), in applicable specifications or any controlled "in-house" documentation, this may be done by making reference to it, or by its inclusion.

Table 4 — Content of a Capability Manual
A.1 Scope of Capability Approval (CA)

This section shall include

a) a summary of those products covered by the relevant generic specification for which capability is claimed,

b) the manufacturer's policy for dealing with other electronic components which form an integral part of the finished component (see NOTE to A.8.2),

c) claims additional to those prescribed in the generic specification,

d) assessment levels (where appropriate), and

e) screening levels (where appropriate).

A.2 Technology/range of components

The technology/range of components on which the "capability" is based shall be described. The description shall make reference to the basic generic technology and identify the main distinguishing features such as

— materials,

— manufacturing processes,

— finish/encapsulation,

— limiting geometries/design,

— application,

— limiting performance, and
other features, where appropriate.

A.3 Subcontracting

In this section the manufacturer shall state whether or not any stages of manufacture in the particular component technology, including design and processing, are subcontracted to another facility. The statement shall define which of the cases a) to d) given in 4.2.4.1 apply.

The requirements of the generic and other relevant specifications shall be followed.

A.4 Limits of capability

This section shall include a complete list of the limits of capability for which the approval is sought.

These limits represent the extent to which the manufacturer exploits the limits defined in the relevant generic or sectional specification and will be the basis against which the capability is to be assessed.

The factors which need to be considered when drafting this section, primarily concern the effect on component performance imposed by the design, the limitations inherent in the materials and manufacturing processes used.

Therefore the list of limiting features shall comprise

a) structural features covering the range of product and materials used, for example, in terms of maxima or minima (or both),

b) limiting mechanical performance. Where this varies over the range of product, for example, because of different structures or sizes, the change-over points should be identified,

c) limiting environmental performance. Where this varies over the range of product, for example, because of different methods of protection, the change-over points should be identified, and

d) limiting electrical performance, for example, voltage, frequency, according to the technology employed.

NOTE This list may be combined with the list of CQCs. See A.11.1.

A.5 Description of the capability

The description of the capability (see 4.2.5) is a written declaration by the manufacturer identifying the scope and limits of his CA. It shall be written in accordance with the requirements given in the generic or sectional specification, for ultimate publication in the On-Line Certificate Database, and a copy shall be included in this section of the Capability Manual. Where a specification does not provide guidance on the contents of the description, they shall consist of a concise statement of the scope and limits of the capability, stating the technology, type and range of components covered and their environmental category.

To prevent any possible misunderstanding of the content of the description, the inclusion of the following statement as part of the description may be considered useful:

"It may not be possible to achieve all the limits of the capability in combination. Such combinations are determined by the agreed customer detail specification for the component ordered."
A.6 Manufacturer to customer interface

In this section the manufacturer shall describe the procedures by which he deals with a customer's orders. These procedures commence from the point at which an initial enquiry is received, through the point at which it is established that the customer's requirements for IECQ releases can be satisfied within the declared limits of his capability, to the point of production. It shall therefore cover such matters as the assistance given to the customer in preparing the customer's detail specification and the need (if any) for design confirmatory specimens.

A.7 Design rules, (when required, see 4.2.5)

In this section the manufacturer should state his design rules and indicate his routine, which may be presented as a flow chart (see annex B of this clause), for the development of a design from the initial enquiry stage to the point at which the drawings and specification are sealed for production.

Although reference should be given to the manufacturer's own documentation covering the electrical aspects of design, the emphasis should be on those aspects which determine the durability and reliability of the component upon which the CA is based. For example, once outline factors such as housing and size have been decided as potentially suitable for the customer's application, the means of determining the mechanical, thermal, climatic and environmental aspects of the design should be made clear.

While it is acknowledged that much design work may be iterative in nature, it is suggested that this is shown as a step sequence or a chart, which considers the selection of piece parts and material to be used in relation to their defined limits of performance and the appropriate factors of safety to be applied.

A.8 Materials list

This list shall include or reference all essential materials, components and bought in piece parts to be used in the construction of components for release under CA. The system used for appraising suppliers (Vendor Qualification Procedure) shall be stated. (A reference to internal procedures used is acceptable).

The list should preferably be given in a tabular form, and show for each material/piece part the following information:

A.8.1 Raw materials

a) the specification references against which they are purchased (for example, an International Standard, data sheet, drawing and/or internal purchase procedure references);

b) incoming goods inspection document references.

A.8.2 Components/piece parts

a) the specification references against which they are purchased (for example, an International Standard, data sheet, drawing and/or internal purchase procedure references);

b) incoming goods inspection document references.

NOTE If the manufactured component incorporates other electronic components the procedures for the assessment of these components shall be stated and shall take account of the requirements for incorporated components given in 4.2.3.
A.9 Manufacture

A.9.1 Manufacturing methods

A brief description of the range of facilities and control procedures (for example, Statistical Process Control) used in the production of the relevant components shall be given together with details of the technologies and limits claimed.

Information should be given on methods for interconnection, assembly, encapsulation and finishes. (Where applicable).

A.9.2 Process flow chart

A comprehensive flow chart(s) shall be given showing each process stage. At each stage, reference shall be given, as appropriate, to the relevant specification and process, process control and quality assurance.

Information feedback paths, permitted rework loops, etc., shall be shown.

A.9.3 Rework policy (see 4.7)

Under this heading the manufacturer shall state his policy concerning rework, and identify each feature for which rework would be permissible. This shall include the number of times rework may be carried out. Account shall be taken of any restrictions or prohibitions of rework activity given in the generic or sectional specification.

Permitted rework shall be indicated on the process flow chart together with references to such additional specifications as may be required to enable the rework to be undertaken. These specifications shall show how it is ensured that the reworked components meet all the original requirements and that the validity of inspection prior to reworking is retained.

A.10 Procedure in the event of CQC or product failure

The Capability Manual shall describe how the manufacturer intends to satisfy the requirements of:

a) 4.2.6.2 in respect of the failure of CQCs during the demonstration and verification of capability,

b) 4.2.10 in respect of failure of CQCs during maintenance of CA, and

c) 4.12e) in respect of persistent non-conformity with the specification.

Particular attention shall be paid to the need for

d) a procedure for a clear analysis of the cause of failure in the case of a), b) and c) above,

e) the suspension of release under the Mark, or Certificate, of Conformity in the case of b) and c) above, and

f) the timely reporting to the SI of the failures and the corrective actions.

A.11 Test programme for CA

A.11.1 CQC detail specifications

The Capability Manual shall include or reference a detail specification for each CQC, in accordance with 4.4.2.

The CQCs, together with the processes and limits which they assess, should be listed. This list may conveniently be displayed in matrix form (see annex C of this clause).
NOTE The limits of a manufacturer's CA are assessed by means of CQCs. Where specimens are taken from production for this purpose, such components become in effect CQCs, and should be so treated by providing them with specifications appropriate to this purpose.

A.11.2 Total CQC test programme

The total CQC test programme to meet the requirements of 4.2.6 shall be prepared in accordance with the generic and other relevant specifications. It shall list the various CQCs together with the accept/reject criteria, grouping and sequences of tests. This may be shown as a schematic, tabular or matrix presentation.

A.12 Maintenance of CA

The manufacturer shall outline his approach to maintenance of CA, together with the means by which he intends the requirements contained in the generic and other relevant specifications to be met. This register shall also make reference to and identify the CQCs being used.

The manufacturer shall state his programme for maintenance which shall include limits of capability, the CQCs and the periodicity of tests covering the whole of the maintenance period.

One method of recording the CQC tests required for the maintenance of CA would be to prepare a matrix, one axis giving the CQC number and the other the process or limit which the CQC assesses. When a process or limit has been assessed the date of test and the test report number should be entered into the relevant square.

A.13 Modifications to the CA

The manufacturer shall declare his procedures for controlling modifications to his established capability. This shall include his responsibility for notifying and agreeing with the SI his intended modification(s) and, where necessary, the formulation of a test programme to demonstrate the revised claimed limits or the continued validity of the approval. This section shall also detail the procedures for amending the Capability Manual and the description of the capability as appropriate.

A.14 Test methods and inspection

The Capability Manual shall describe or reference the manufacturer's process and test documentation, and shall address the following as applicable.

A.14.1 In process testing

a) critical process steps for the technology;

b) methods of implementing Statistical Process Control (SPC) when applicable;

c) methods used for analyzing process drift and failures;

d) analysis of product variability;

e) corrective action procedures (to overcome potential causes of failure under c) and d) above;

A.14.2 Screening

Use of screening procedures appropriate to the technology.
A.14.3 Quality conformance inspection
Tests performed as a mandatory requirement for quality conformance inspection.

A.14.4 Reliability testing
Procedures for determining product reliability.

A.15 Register of product specifications covered by the CA
The Capability Manual shall include a reference to a register of customer detail and standard catalogue item specifications covered by the manufacturer’s CA.
Annex B to clause 4  
(informative)

Further guidance concerning the content of A.7: Design rules

The routine for the development of a design from enquiry to specification may conveniently be illustrated in a flow chart format to show the division of departmental responsibilities, including documentation (especially the customer's detail specification) and the stages at which the manufacturer and his customer are in consultation.

The purpose of this section is to show how consistency in engineering design is achieved in the translation of a customer's requirements into a design which draws upon the manufacturer's company policies, including the standard methods, if any, applied to the selection of piece parts, materials, etc., taking into account such conflicting considerations as optimum electrical performance, cost, size and reliability. (Thus, the text to be given here, should be such that different designers, independently working to it, would arrive at much the same design solution for a given customer's requirement.).
Annex C to clause 4
(informative)

Example of a matrix showing capability limits and the CQCs used to prove them

Coaxial ferrite devices

Assessment of the claimed capability is achieved by testing the required number of samples of each of the declared CQCs given in the following table:

Table 5 — Matrix of capability limits and CQCs

<table>
<thead>
<tr>
<th>Limits</th>
<th>CQC</th>
<th>01</th>
<th>02</th>
<th>03</th>
<th>04</th>
<th>05</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GHz</td>
<td>6 / 18</td>
<td>9 / 16,5</td>
<td>0,5 / 0,56</td>
<td>1 / 2</td>
<td>2 / 4</td>
</tr>
<tr>
<td>Function</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isolator (2-port)</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Circulator (3-port)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Operating frequency extremes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0,5 GHz</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 GHz</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bandwidth</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broad</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Narrow</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Power rating extremes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Circulator only)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak 2 000 W max.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Mean 100 W max.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Isolator load</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 W</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean power rating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 55 °C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+ 100 °C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Withdrawn
Table 5 — Matrix of capability limits and CQCs (continued)

<table>
<thead>
<tr>
<th>Limits</th>
<th>CQC</th>
<th>01</th>
<th>02</th>
<th>03</th>
<th>04</th>
<th>05</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHz</td>
<td></td>
<td>6 / 18</td>
<td>9 / 16,5</td>
<td>0,5 / 0,56</td>
<td>1 / 2</td>
<td>2 / 4</td>
</tr>
<tr>
<td>Size of body (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>min.</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>max.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Width</td>
<td>25,9</td>
<td>27</td>
<td>50,8</td>
<td>70</td>
<td>41,3</td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>22,4</td>
<td>24</td>
<td>50,8</td>
<td>70</td>
<td>41,3</td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td>14,6</td>
<td>23</td>
<td>19,1</td>
<td>21,3</td>
<td>19,1</td>
<td></td>
</tr>
<tr>
<td>Mass (g)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>min.</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>max.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Disc type</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Magnet type</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Circuit material</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Connector type</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Tab</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>SMA</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>TNC</td>
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<td>X</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Connector finish</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td></td>
<td>Ni</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Cu</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Passivated stainless steel</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Table 5 — Matrix of capability limits and CQCs (concluded)

<table>
<thead>
<tr>
<th>Limits</th>
<th>CQC</th>
<th>01</th>
<th>02</th>
<th>03</th>
<th>04</th>
<th>05</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GHz</td>
<td>6 / 18</td>
<td>9 / 16,5</td>
<td>0,5 / 0,56</td>
<td>1 / 2</td>
<td>2 / 4</td>
</tr>
<tr>
<td>Mechanical performance</td>
<td>Shock 294 m/s², 18 ms</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Vibration 10-60 Hz 0.75mm peak to peak max. 60-2000Hz 98 m/s² max.</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climatic performance</td>
<td>RH 98 % Upper temp 40 °C Cycles 2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Annex D to clause 4  
(normative) 
Capability Approval Report

B.1 General

The overall format of an approval report is flexible and the specific style can be chosen to suit 
individual preferences but, as a minimum, the report shall contain the following information:

B.2 Preface

The approval report shall be prefaced as follows:

— approval report title, reference number and date;
— detail specification, issue number and associated product references;
— name, address and approval number of manufacturer;
— name, address and status of independent testing laboratory (if appropriate);
— name and address of the responsible SI;
— a dated declaration signed by the DMR as follows:
  “I certify that the requirements of the System have been met and that all samples tested were either
  3) taken from, and are representative of, current production; or
  4) manufactured using current/intended production methods and materials.”
— SI signature and date.

B.3 Index, page identification and detail specification

The approval report shall contain an index summarizing its contents and identifying the respective 
page numbers for major sections.

All approval report pages shall be numbered.

It is recommended that a copy of the applicable detail specification be included as an annex to the 
approval report.

B.4 Test plan and summary of results

Details of all samples shall be given, including batch identity and date code.

The approval report shall contain a summary of the test plan agreed with the SI and attributes data 
for the respective test samples, preferably in tabular format.

Where structural similarity is being claimed, full details shall be given, including reference(s) to 
previously agreed approval reports (when applicable).

B.5 Test equipment and results

The test and measurement equipment used during the Capability Approval exercise shall be uniquely 
identified and its calibration status shown.

The measurement uncertainty associated with each test shall be stated and taken into account when 
determining pass/fail criteria.
For every test method, the report shall state the method used by reference to the appropriate standard or detail specification. Where a non-standard method is used, full details shall be given.

All test conditions shall be described. If full details are given in the applicable detail specification, reference to the particular subgroup will suffice.

The test results shall be specified accurately, clearly and completely. The results of each test sequence/subgroup shall be dated and identified as to the individual who performed the test.

Where there is a large amount of test data, it is recommended that a statistical form of presentation is used.

B.6 Failure identification and analysis

Any failures which occur during Capability Approval testing shall be identified and the failure cause analyzed. The results of this analysis shall be included in the test report. Where corrective action is indicated, details shall be given.
5. **Approval of specialist contractors’ processes and/or products within the electronic components industry**

5.0 **Introduction**

The electronic components industry has, as a part of its manufacturing infrastructure, a supporting industry of specialist contractors providing a wide range of specialized services, processing, and manufacture of piece parts and material.

This clause is published to permit specialist contractors to be approved in their own right. Manufacturers of finished electronic components shall seek approval under clause 2 in combination with clauses 3, 4 or 6 if they wish to qualify finished electronic components. However, such manufacturers may also seek approval for specific services or processes or for the manufacture of piece parts and material in accordance with this clause 5. This approach recognizes the diverse infrastructure of the electronic components industry and makes it possible for a total electronic component manufacturing capability to be assessed as a totality, taking account of the separate operations of several companies, each of which contributes piece parts, materials, processing or technical services to the final product.

Examples of specialist contractors are design bureaux, packagers, electroplaters, PCB mass laminators.

A key feature of Process Approval is the Process Assessment Schedule (PAS).

The PAS introduces a number of new concepts including

- Process Specifications,
- audit preparation plans,
- audit checklists,
- internal audit, and
- training.

Individual PASs provide for demonstration, verification and quality conformance inspections specific to the relevant service, process, piece part, etc., as applicable.

This clause develops the relevant requirements of IECQ organisation approval as invoked in clause 2 to create a system which

a) recognizes the need of the electronic components industry to subcontract work, and

b) readily accommodates new technological developments

The Process Approval procedure shall be used only in association with the appropriate PAS in the QC 200000 series and the relevant Process Specification(s).

NOTE There are no references to the Mark of conformity in this clause since this clause is not applicable to approved processes and technical services.

5.1 **Definitions**

5.1.1 **Process Approval (PA)**

an approval granted to a specialist contractor when it has been established that his processes or technical services and quality control methods (including design aspect as applicable) covering a specific technology or activity, fulfil the requirements of the appropriate PAS in the QC 200000 series and the relevant Process Specification
5.1.2  
**process capability**  
ableity of a specialist contractor to perform designated activities and to achieve results which fulfil specified requirements as defined within the scope of the specialist contractor’s process manual

5.1.3  
**process**  
a (repeatable) activity or series of activities relevant to the manufacture of electronic components, piece parts or material

5.1.4  
**Process Manual**  
a document describing the processes and process control methods specific to the activities of a given specialist contractor

5.1.5  
**specialist contractor**  
a contractor providing a specialist process capability or technical service to the electronic components industry

5.1.6  
**technical service**  
a facility provided by a specialist contractor when he performs a set of non-manufacturing technical functions which are required for the production of electronic components, e.g. design of components provided by Design Houses

5.1.7  
**quality factor**  
those aspects of the process and specialist contractor’s organization that significantly affect the quality and reliability of the components, process or technical service provided

5.1.8  
**internal quality audit preparation programme**  
a programme prepared by the specialist contractor from basic information given in the PAS which includes all the requirements necessary for a specialist contractor to prepare for an internal quality audit. It includes the quality audit checklist

5.1.9  
**quality audit checklist**  
a series of technical and quality prompts to be used by the specialist contractor/SI when undertaking quality audits

5.1.10  
**external quality audit preparation programme**  
a programme prepared by the specialist contractor in advance of an external quality audit, which is intended to assist the SI in its conduct of that audit. It includes the quality audit checklist

5.1.11  
**preventative action**  
action taken to eliminate possible causes of future non-conformities or undesirable deviations

5.1.12  
**Customer Detail Specification (CDS)**  
for the purpose of Process Approval, the CDS as defined in QC 200000, annex G may be a published applicable specification. The document may be prepared jointly by the manufacturer/specialist contractor

5.1.13  
**Process Assessment Schedule (PAS)**
a specification in the QC 200000 series which describes the Assessment Schedule relevant to a
specialist contractor’s declared process (as defined in 5.1.3). For a given process or specialist
activity, the PAS states how this clause 5 should be applied by a specialist contractor. PASs are
technology dependent

NOTE PASs shall be written in accordance with QC 200000, Process Assessment Schedules for
requirements under the IECQ for approval of specialist contractors’ processes and/or products within
the electronic components industry.

5.1.14
Process Specifications
documents prepared in accordance with the requirements of annex D of QC 200000, to define the
minimum mandatory technical requirements for the whole or for a part of the activity defined in a
given PAS. When a published IECQ Process Specification exists for a defined area of activity, this
may be invoked in related PASs as a mandatory requirement for all specialist contractors seeking a
Corresponding Process Approval. A Process Specification is normally associated with a single PAS
and is subject to normal voting and publication procedures for IECQ Specifications.

NOTE 1 Each PAS shall contain one or more Process Specifications.

NOTE 2 In cases where existing Process Specification(s) is (are) inappropriate or insufficient for a
given application, the specialist contractor shall prepare one or more specialized Process
Specification(s) suitable for that application

5.1.15
demonstration and verification
activity undertaken to establish and maintain compliance with the requirements of a PAS

NOTE This applies to the Process Approval in its entirety.

5.1.16
customer quality conformance inspection
activity undertaken to demonstrate compliance with the CDS

NOTE This applies to the piece part, process or service supplied to each specific customer

5.1.17
non-conformance
a deviation from the relevant specification which affects form, fit or function

5.1.18
maintenance period
the defined period of time in respect of which action for the maintenance of approval is required

NOTE Within the IECQ, “maintenance” signifies “maintenance of approval”.

5.1.19
maintenance of approval
various activities, including testing, performed to demonstrate that the approval remains valid during
a defined maintenance period

5.1.20
failure analysis
the logical, systematic examination of a failed item to identify and analyze the failure mechanism, the
failure cause and the consequences of failure.

NOTE A specialist contractor should, where applicable, define his policy and procedures with
regards to the following three aspects of failure analysis:
data analysis, i.e. the examination of data for trends, correlations, etc. The statistical techniques and models used shall be stated;

— history and background, i.e. the extent to which batch records, customer interviews and other information, not included in formal fault reporting, shall be considered;

— physical failure analysis, i.e. the reverse engineering of failed samples and/or recreation methods used to locate the physical failure mechanism. The extent, method and reporting of such analysis shall be stated.

5.1.21
test vehicles
the generic term for a device or test structure used to verify, analyze or monitor engineering processes or electrical/physical attributes

5.2 Procedure for Process Approval (PA)

5.2.1 Eligibility for PA

5.2.1.1 PA may be granted only to a specialist contractor who has been granted organizational approval in accordance with the relevant requirements of clause 2 and who also satisfies the requirements of this clause 5 in respect of his process(es) or technical service(s).

The specialist contractor may be responsible for one or more unrelated processes, each of which shall be subject to separate approval. If the specialist contractor wishes to have responsibility to release complete electronic components he shall make application for approval as a “manufacturer” and meet the “manufacturer” requirements of clause 2 together with clauses 3, 4 or 6 as appropriate.

5.2.1.2 A specialist contractor is eligible for PA in accordance with the System if direct supervision by the Designated Management Representative (DMR) is applied to all the processes or technical services which are to be covered by the PA, as defined in his Process Manual and the relevant PAS.

The specialist contractor shall demonstrate compliance with the relevant PAS within the declared range of activity, technology, processes and/or technical services to be covered by his PA, as defined in his Process Manual.

5.2.2 Subcontracting

5.2.2.1 The approved specialist contractor shall not subcontract operations which are covered by the scope of his PA, as defined in his Process Manual and the relevant PAS.

The specialist contractor may subcontract operations outside the scope of his PA to non-approved organizations, provided that the DMR is able to demonstrate to the SI that the process(es) concerned is (are) performed in a manner which satisfies the appropriate requirements of this clause.

5.2.2.2 The specialist contractor, when applying for PA, shall state whether any individual operations of his process(es) and/or services are subcontracted and shall identify these operations.

5.2.2.3 When the conditions of 5.2.2.2 apply, the application for PA shall contain

— details of the division of individual operations between the specialist contractor and the subcontractor, and

— details of the arrangements agreed with the SI for the approval of the quality of subcontracted operations. These details should take into account the transfer of products or services between the specialist contractor and the subcontractor, and in particular
— the procedures for the assessment of quality of the subcontracted operations, and
— details of the means whereby changes to the agreed arrangements are communicated to
  the SI.

The specialist contractor shall demonstrate to the SI that the quality of the process(es) and/or
services will not be adversely affected by the use of these subcontracted operations.

The SI of the specialist contractor seeking PA shall ensure that the specialist contractor’s DMR is
able to verify the satisfactory maintenance of the quality control procedures performed by his
subcontractor.

The SI shall confirm in writing to the Certification Body (CB), that the details contained in the
application for PA satisfy the requirements of the System.

5.2.3 Incorporated components, piece parts and material

5.2.3.1 Incorporated components, piece parts and material released under an IECQ
Certificate of Conformity.

Where incorporated components, piece parts and material are supplied by an approved source within
the IECQ System and released under an IECQ Certificate of Conformity in accordance with the
requirements of the relevant clause of QC 001002-3, no other assessment of the incorporated
components, piece parts or material is required.

5.2.3.2 The use of incorporated components, piece parts or material not covered by an
IECQ Certificate of Conformity.

To permit the use of incorporated components, piece parts and material which are not covered by an
IECQ Certificate of Conformity, the approved specialist contractor’s DMR shall

a) be satisfied that the quality and (where relevant) performance of the components, piece parts
   and material are adequate for their purpose,

b) ensure the existence of (a) specification(s) covering the incorporated components, piece parts
   and material in respect of all the aspects necessary to ensure their satisfactory performance as
   part of the final product, piece part or material,

c) carry out an adequate approval test programme, maintaining a record of the test results in
   accordance with the procedures of a) and b) above, and retaining verification samples when
   necessary, and

d) institute sufficient “goods inward” inspection procedures to ensure continued satisfactory
   performance of the final product, piece part or material.

5.2.3.3 Incoming part-finished components, piece parts and material for incorporation in
finished components.

Where part-finished components, piece parts and material are procured direct from a manufacturing
source, the approved specialist contractor’s DMR shall ensure that they comply with 5.2.3.1 and/or
5.2.3.2, and in addition ensure that

a) the design of the part-finished components, piece parts or material is compatible with the
   assembly technique to be employed,

b) the assessment of quality and performance of the part-finished components, piece parts or
   material takes into account the assembly methods to be employed, and
c) adequate storage and handling facilities are available for the part-finished components, piece parts and material.

Any other technical requirements, specific to particular components, piece parts or material, shall be specified in the PAS or Process Specification, and these shall be considered as additional to the requirements of a), b) and c) above.

Where incoming part-finished components, piece parts or material are procured for further processing, the approved specialist contractor’s DMR shall ensure that they comply with 5.2.3.1 and/or 5.2.3.2 and a), b), c) above.

5.2.4 Application for PA

5.2.4.1 A specialist contractor may apply for approval in accordance with clause 2 in respect of his organization at the same time as submitting his application for PA under this clause 5. The specialist contractor shall apply in writing to the CB with a copy to the SI, stating the scope of the proposed PA, preferably in the form of a first draft of the information required under 5.6, and clearly defining the activity (process and/or technical service including related technologies) for which he seeks approval, in accordance with the relevant PAS in the QC 200000 series and the relevant Process Specification(s).

In this application, the specialist contractor shall state that he carries out at the approved location all the processes, tests, measurements, etc., relevant to the scope of his proposed PA.

5.2.4.2 When the specialist contractor’s proposed Process Manual meets the requirements of the relevant PAS in the QC 200000 series and the related Process Specification(s) and the specialist contractor is ready to demonstrate his competence, he shall give notice to the SI of his wish to undergo assessments, and provide the SI with a test programme and corresponding timetable of tests. The SI shall confirm its acceptance in writing.

5.2.5 Requirements for the content of a Process Manual

The specialist contractor shall provide the SI with his Process Manual, relevant to the range of activity (activities), and/or technical service(s) for which he is seeking PA in accordance with the relevant PAS. Where confidential processes or services are involved, the specialist contractor is only required to provide the information necessary for the PA.

The SI is not allowed to copy company confidential documents, to remove them from the specialist contractor’s premises, or to disclose such information to third parties (see 2.3.1) without the specialist contractor’s prior approval.

The Process Manual shall, either directly or by reference to the specialist contractor’s internal documents

a) state compliance with the minimum requirements for quality factors given in the PAS and/or Process Specification(s),

b) define in accordance with the PAS the process(es) or technical service(s) for which he is seeking approval,

NOTE When required by the PAS, these statements shall take the form of a Process Specification.

c) state the design rules when required by the relevant PAS and/or Process Specification(s),

d) provide a description of the main features of the process(es), technical service(s), the construction of the components, piece part(s) or material (as applicable),

e) provide a process flow chart of the process(es) for which PA is sought,
f) list the processing facilities and the inspection, measuring and test equipment relevant to the range of activity(ies), technology(ies) and/or technical service(s) for which he is seeking approval,

g) list or make reference to the specifications for the raw material, piece parts, incorporated components and/or part-finished components used,

h) list or make reference to the specifications for the inspection to be carried out during the operations which are described in the Process Manual,

i) define his procedures for identification and traceability,

j) define how modifications are notified,

k) describe his training policy, and

l) describe his internal auditing procedure.

The relevant PAS shall give more detailed information concerning the description of process capability to be supplied by the specialist contractor.

5.2.6 Demonstration and verification

5.2.6.1 The DMR shall prepare a programme in accordance with the relevant PAS for the assessment of the processes or technical services for which he is seeking PA. This programme shall include reference to

a) the process procedures and specifications, and

b) the test and inspection requirements and/or process controls.

When the programme is designed solely for the purpose of obtaining PA, the specialist contractor shall ensure that the same processes and inspection procedures are applied to normal operations. The specialist contractor shall ensure that the programme covers all of the defined limits contained in the Process Manual.

5.2.6.2 If during the initial PA demonstration one or more non-compliance(s) in respect of the relevant Process Specification(s) are observed, the specialist contractor shall

a) amend the scope of his process manual, with the agreement of the SI, or

b) conduct an investigation into the non-compliance(s) in order to establish its (their) cause(s).

If the cause(s) of the non-compliance(s) is (are) established as a design, process or operational failure, a special programme agreed between the specialist contractor and the SI shall be performed to demonstrate that the cause(s) of the non-compliance(s) has (have) been corrected and that all corrective actions have been carried out and documented (see 5.2.6.4). If this is accomplished, the full PA programme shall be recommenced.

If it proves impossible to correct the non-compliance(s), the specialist contractor shall amend the scope of his Process Manual, with the agreement of the SI.

5.2.6.3 The results of the PA demonstration shall be recorded in a PA report authenticated by the DMR.

The PA report, shall be verified by the agreement (countersignature) of the SI that it meets the requirements of the relevant PAS(s) or Process Specification(s).
A copy of this report shall be submitted to the CB. Any other reproduction and release of this report is the sole prerogative of the specialist contractor.

5.2.7 Granting of PA

PA shall be granted by the CB when the requirements of 5.2.6 above have been met.

If one or more of the requirement(s) of 5.2.6 has (have) not been met, the SI shall recommend to the specialist contractor either

— to discontinue his application for approval, or
— to carry out appropriate modifications before resubmitting his application.

5.2.8 PA certificate

When PA has been granted, a certificate shall be issued to the specialist contractor by the CB.

The approval shall be listed in the On-Line Certificate Database (see 5.6).

The certificate shall contain the following information:

— the IECQ reference number, the issue number and date of the PAS(s) and Process Specification(s) and other specifications which define the PA requirements. If required by the national rules, the national identification of the specifications may be added;
— identification of the technology(ies), process(ess) or technical service(s) involved;
— name of the specialist contractor and place(s) where he conducts his operations;
— reference number for the Process Manual, or other documentation defining the limits of the specialist contractor’s operations, on which the approval is based;
— an abstract of the description of the processes or technical services, as required for inclusion in QC 001005 (see 5.6);
— identity of the CB and authenticating signature.

5.2.9 Maintenance of PA

Maintenance of PA is assured when the conditions for maintenance detailed in the relevant PAS in the QC 200000 series and the relevant Process Specification(s) are fulfilled.

The specialist contractor shall maintain a record of the progress of the maintenance programme. At the end of each maintenance period, the specialist contractor shall provide the SI with a copy of the completed maintenance record.

5.2.10 Procedure in the event of identified confirmed non-conformance and customer complaints

5.2.10.1 This procedure applies when, for example

— parameter deviations are identified in one or more process steps,
— one or more non-conformity(ies) are identified in final screening,
— one or more non-conformity(ies) are identified after reliability tests, or
— a customer complaint is reported and confirmed.

5.2.10.2 In the circumstances described in 5.2.10.1, the DMR shall immediately
a) initiate an investigation to determine the reasons for failure, and
b) report the situation to the SI.

5.2.10.3 The DMR shall maintain this suspension until the investigation has been concluded and the SI has been informed of the results. The DMR shall then proceed according to the appropriate conditions in 5.2.10.4, 5.2.10.5 or 5.2.10.6.

5.2.10.4 If the failure is concluded to have been due solely to an error in quality auditing, this shall be corrected. The DMR shall reinstate the process or technical service once the error has been verified and corrected and satisfactory results have been obtained.

5.2.10.5 If the failure is concluded to be due to an identified manufacturing, processing or operational fault which can immediately be corrected
a) a revaluation shall be made of the corrected process or service, and
b) if the result of the above is unsatisfactory, the procedure defined in 5.2.10.6 or 5.2.10.7 shall be applied as appropriate.

5.2.10.6 If the failure is concluded to be due to an identified manufacturing, processing or operational fault which cannot be corrected immediately, but the output of defective processes or technical services can be detected and rejected by an appropriate eliminating test acceptable to the DMR then the process or technical service shall be reinstated immediately under the Certificate of Conformity.

Elimination before release shall be continued until the necessary steps to correct the manufacturing, processing or operational fault have been taken, and until satisfactory results for the test in question have been obtained.

5.2.10.7 If the failure is concluded to be due to an identified manufacturing, processing or operational fault which cannot be corrected immediately, and the output of defective processes or technical services cannot be removed by the application of an eliminating test, the SI shall recommend that the CB suspend PA and withdraw the right to use the Certificate of Conformity for the process or technical service in question. PA and the right to use the Certificate of Conformity shall be reinstated when the specialist contractor has demonstrated that the processing or operational fault has been eliminated.

5.2.10.8 If the requirements of 5.2.10.4, 5.2.10.5, 5.2.10.6 or 5.2.10.7 are not fulfilled within a reasonable period of time, which shall not be more than that defined in the PAS, approval shall be re-examined.

5.2.10.9 If PA has been suspended in accordance with 5.2.10.7, it may be reinstated provided that the requirement of 5.2.10.5, 5.2.10.6 or 5.2.10.7 have been satisfied.

5.2.10.10 The specialist contractor shall report to the SI, prior to its introduction, any modification likely to affect the validity of the PA, and the SI shall decide whether it is necessary to repeat all or some of the PA assessment.

NOTE The relevant PAS may give more detailed information.

5.2.10.11 PA shall be withdrawn only by the body which granted it (see 5.2.7) and only if one or more of the following conditions apply:

a) at the request of the specialist contractor;
b) the activity in question is terminated or suspended for a period greater that that given in the
PAS for the maintenance of PA;

c) the Rules of Procedure are not correctly applied;

d) approval to clause 2 is withdrawn;

e) recurrence of non-conformity(ies);

f) failure to rectify identified non-conformities.

5.3 Provision of processes or technical services

5.3.1 Customer quality conformance inspection

5.3.1.1 The quality conformance inspection requirements shall be given in the CDS appropriate to
the customer concerned.

5.3.1.2 Quality conformance is established after carrying out tests demonstrating that the lots
released have achieved the quality prescribed in the CDS. The specialist contractor shall carry out
these tests, or arrange to have them carried out in a laboratory approved under the System.

When a PAS requires mandatory tests (i.e. tests to be included in all CDSs), it shall also recommend
appropriate sampling plans. Such mandatory tests shall only be required where they are both
relevant to all specialist contractors likely to use the PAS, and applicable to all likely customers.

When required by the CDS lot-by-lot tests are carried out on each inspection lot. These tests may be
sub-divided into appropriate groups.

NOTE See 5.2.9 for assessment and audits carried out to support the maintenance of PA.

5.3.1.3 Each PAS shall include a list of tests which may be included in a customer quality
conformance inspection.

5.3.2 Release and validity of release

5.3.2.1 When required by the SI the specialist contractor shall demonstrate that the processes or
technical services provided and the partly-processed component(s), piece part(s) or material
released under PA are within the scope of his PA.

5.3.2.2 A release for delivery is valid for five years unless a shorter period is specified in the PAS.
The relevant specification shall prescribe the tests which shall be repeated in order to revalidate a
release.

5.3.2.3 An approved specialist contractor is permitted to release approved services, products or
processes prior to the issue of a PA certificate provided that

— the Process Manual has been countersigned by the SI, and

— a draft approval certificate has been accepted by the SI, and the approved specialist contractor
has submitted to the CB a written statement announcing his intention to release approved
services, products of processes together with a copy of this draft approval certificate. This
statement shall be countersigned by the SI.

In releasing services, products or processes, the approved specialist contractor shall
a) annotate the certificate of conformity with the text “Released in accordance with QC 001002-3, subclause 5.3.2.3”, and

b) be responsible for any corrective action which may be required of him by the CB if for any reason PA is subsequently withheld or the content of the approval certificate is significantly different from the original draft agreed by the SI.

5.3.3 Certificate of Conformity (identification of lots or items released)

Lots released or technical services provided by a specialist contractor shall be unambiguously identified by a Certificate of Conformity, the issue of which is under surveillance of the SI. This Certificate means that the lots or technical services have been released or provided in accordance with the requirements of the relevant specification.

The Mark of Conformity shall not be used by a specialist contractor in conjunction with lots released or services provided.

Authorization to issue the Certificate of Conformity is suspended or withdrawn if there is non-conformity with the specification or if the provisions of this clause 5 are not observed.

5.3.4 Destructive tests

Specimens which have been subjected to destructive tests shall not be included in lots to be delivered. Specimens subjected to non-destructive tests may be included in lots to be delivered provided they satisfy the specified tests.

5.3.5 Use of in-process testing

In-process testing may be substituted for the relevant test(s) of the quality conformance inspection provided that the specialist contractor demonstrates that the in-process testing is such that the corresponding requirements of the relevant PAS or Process Specification would have been met at the final stage of inspection.

5.3.6 Test severity

5.3.6.1 In-process test

A specialist contractor may carry out any test at a greater severity than that specified, but the component, piece part or material after testing shall satisfy the limits prescribed in the PAS or Process Specification.

5.3.6.2 Final item test

Test severity level shall be the subject of agreement between the specialist contractor and individual customers.

5.3.7 Temporary restriction of release

If any aspect of a PA becomes deficient, the approval may continue with the agreement of the SI, provided that the release of components, piece parts or material is restricted to the remaining areas of the operation not affected by the deficiency, and that the deficiency is corrected within a period agreed between the specialist contractor and the SI. The relevant PAS or Process Specification may give more detailed information.

5.4 Specifications

5.4.1 Process Assessment Schedules (PASs)
PASs shall be prepared and published in accordance with the guidance given in QC 200000. Quality factors likely to influence the quality of the output of the PA shall be included in the PAS, and flow charts shall be provided to indicate the sequence of activities covered by the PA.

5.4.2 Process Specifications

In addition to the appropriate requirements of QC 001002-3 and the appropriate PAS in the QC 200000 series, the following provisions shall apply.

The Process Specification(s) shall prescribe how PA is to be implemented for a specific activity, technology, process or technical service. A description of the process limits relevant to the incorporated components, part-finished components, piece parts or material technology, process or service shall be given.

The Process Specification(s) shall specify the test schedules and other methodology to be used in the process assessment programme, maintenance of the PA, and quality conformance inspection and give information concerning the testing samples to be used or alternative methods of verifying the PA. Where appropriate, they shall also define the requirements for incorporated components, part-finished components, piece parts or material.

5.4.3 CDSs for processed components, piece parts or material for release

The CDS shall comply with the relevant PAS(s) and, when read in conjunction with it (them), shall adequately describe the processed components, piece part or material. It shall also give the necessary information for quality conformance inspection.

The ownership right of a CDS may be vested in the customer and/or specialist contractor, and the contents may be held by both to be confidential.

5.5 Register of Customer Detail Specifications

The specialist contractor shall maintain a register of CDSs. This register shall be available to the SI.

5.6 The On-Line Certificate Database

The PAS shall designate the information on the process(es) and/or technical service(s) covered by the approval giving details concerning the technology(ies), methods of manufacture and performance standards for inclusion in the On-Line Certificate Database.
5.7 Rework and repair

5.7.1 Rework

When necessary, the PAS shall prohibit or restrict rework for all or for specific components, piece parts or material.

All rework procedures shall be fully described in the relevant documentation produced by the specialist contractor.

All rework shall be carried out under the surveillance of the DMR.

All rework shall be carried out prior to the formation of the inspection lot offered for inspection to the requirements of the CDS.

5.7.2 Repair

Components, piece parts or material which have been repaired shall not be released under the System.

5.8 Frequency of surveillance by the SI

Approved Specialist Contractors holding Process Approval require a more severe surveillance visit regime that those Specialist Contractors which only hold organization approval. This reflects the additional liability resultant from holding a process approval.

5.8.1 Normal frequency of surveillance

The normal frequency of surveillance shall be two visits per year.

5.8.2 Reduced frequency of surveillance

At the discretion of the SI, the frequency of surveillance of the approved specialist contractor may be reduced to one visit per year provided that the following conditions apply:

a) the manufacturer has held approval for a minimum of two years;

b) no product or process related failure to comply with the system rules has been identified during the previous three surveillance visits, other than product failures permitted by the relevant specification (e.g.: limited failures during maintenance testing are permitted by some Standards).

c) no product or process failures have occurred during a two year period, other than product failures permitted by the relevant specification as detailed above.

5.8.3 Suspension of reduced frequency of surveillance

Specialist Contractors subject to reduced frequency of surveillance which subsequently fail to comply with the conditions of 5.8.2 shall revert to normal frequency of surveillance.
Annex A to clause 5
(informative)
Documents for use in association with clause 5

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Figure 2 — Associated documents
6. Technology Approval of electronic component manufacturers

6.0 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. It extends the existing suite of IECQ approval concepts by adding the following principles as mandatory aspects of Technology Approval:

1) the foundation of Technology Approval is a formal system for quality management, within the organization. This requires that all employees are actively involved in the commitment to quality;

2) the use of in-process control methods (of which Statistical Process Control (SPC) is an example) as defined in a Technology Approval Schedule (TAS) and tools to demonstrate adequate control of processes and products. A programme shall be in operation at the initial approval to this clause;

3) continuous quality improvement strategy and its demonstration;

4) monitoring the overall technologies and operations associated with the design and manufacturing processes as well as the components themselves;

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

6) 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 System and all quality related matters within the approved organization, and in which the manufacturer is capable of operating at least one of the main technical 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

6.1.7 Technology Review Board (TRB)
a board, established to control, stabilise, monitor and improve the quality and reliability of products
and services, comprising representatives from key departments (for example, marketing, sales,
design, technology development, manufacture, testing and quality assurance).

6.1.8 Contractor Manufacturer Board (CMB)
a board comprising one or more representatives from each company participating in a Technology
Approval, established to focus communication and control the interface between companies.

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 IECQ Organisation approval in
accordance with the requirements of clause 2, 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 Organization approval with respect to TA is based on a Technology Approval Schedule
(TAS) and not on a generic specification.

6.2.1.2 Extension of organization approval
In applying the rules for extension of organization approval described in subclause 2.5, design,
manufacture, screening 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 Supervising Inspectorate (SI), 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
to this clause.

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) (see annex C to this clause).

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

a) **Management structure.**

The manufacturer at the Control Site shall establish a declared Technology Review Board (TRB) and a Contractor Manufacturer Board (CMB) or equivalent organizations.

i) **Technology Review Board (TRB)**

- a TRB or equivalent organization shall be established to control, stabilise, monitor and improve the approved manufacturing lines;
- the TRB is responsible for the overall control of the TA, and for conducting periodic systems reviews;
- the TRB shall have procedures in place for assessing the current status of the quality and reliability of components;
- the TRB is responsible for the development of an overall quality plan for TA and shall consist of representatives of all functions described in that plan such as marketing, sales, design, technology development, manufacture, testing and quality assurance, as applicable.

ii) **Contractor Manufacturer Board (CMB)**

In the case of several companies involved in a single TA, a CMB or equivalent organization shall be established to control the interface(s) between the companies. The CMB shall consist of at least one representative from each company and be responsible for the overall control of the interface(s).

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 includes the information detailed in the following items. Requirements for the form and content of the TADD are given in annex C to this clause.
NOTE It is not intended that the TADD should duplicate existing company documentation. It is therefore permissible for the TADD to make reference to existing documents under each individual clause heading.

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

6.4.3 Use of specialist contractors and subcontracting

6.4.3.1 Any stage of manufacturing may be carried out by specialist contractors or, under certain conditions, subcontracted to non-approved organizations (see 6.4.3.3, 6.4.3.4 and 6.4.3.6).

6.4.3.2 The TAS may allow all forms of subcontracting, or forbid it on technical grounds. The TAS may, if necessary, include any special requirements, for example for specific successive stages to be performed by the same manufacturer.

6.4.3.3 When subcontracting is permitted by the TAS, this may be undertaken provided that the DMR is able to demonstrate to the SI that the process(es) concerned is (are)

a) performed in a manner which satisfies the appropriate requirements of the relevant Process Assessment Schedule(s) (PAS(s)) in the QC 200000 series, or
b) carried out satisfactorily in accordance with criteria defined, or referred to, in the TADD.

6.4.3.4 To verify the satisfactory conduct of subcontracted operations in accordance with 6.4.3.3a) or b), the manufacturer shall ensure that when quality conformance testing is performed under his control in an approved laboratory, it shall be located in an IECQ member country, or exceptionally in accordance with 6.4.3.7.

6.4.3.5 The manufacturer, when applying for TA, shall state whether stages of the manufacturing process are carried out by one or more specialist contractors in accordance with 6.4.3.1, or are subcontracted in accordance with 6.4.3.3, and shall identify the stages.

6.4.3.6 If subcontractors not approved within the System are used, the manufacturer shall describe the method of control of all the subcontracted stages or operations.

6.4.3.7 Where tests are carried out by testing laboratories not approved within the System, the approved manufacturer shall produce a document which describes the surveillance arrangements by which he shall ensure that the testing to be carried out shall comply with the specification. Where possible, the nominated testing laboratory shall be approved to ISO/IEC 17025 by a nationally recognized accreditation body. The document shall define how the nominated testing laboratory

a) ensures that its relevant staff possesses the necessary competence and its relevant test facilities are completely adequate for purpose,
b) proposes to operate the test, and
c) ensures that 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 and/or registrations held by the nominated testing laboratory.

Prior to permitting testing, the approved manufacturer shall demonstrate to the SI that his proposed surveillance arrangements comply with the specification.

The procedures given in this subclause, 6.4.3.7, shall be applied separately to any subsequent programme of testing, including those carried out for periodic testing for the maintenance of an approval.

6.4.4 Incorporated components

Where components or assemblies, manufactured and released under TA, incorporate components other than piece parts, these incorporated components shall be manufactured under TA or under another quality system resulting in the same quality level which shall be demonstrated to the SI.

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

6.5 Verification

6.5.1 Verification of process in accordance with the TADD

As part of the verification of the processes, the manufacturer shall provide evidence to the SI of compliance with the content of the TADD as defined in 6.4.

6.5.2 Process capability verification

The manufacturer shall verify his declared process boundaries in respect of design and manufacturing in accordance with the applicable TAS.

The manufacturer shall demonstrate the process capability for the following aspects:

a) Administration

The manufacturer shall demonstrate satisfactory management of the administrative tasks relating to the associated manufacturing technologies.

b) Design

Design verifications shall follow suitability to manufacture, fitness for use and conformance with customer requirements.

c) Manufacturing

Manufacturing verification shall follow the production flow and critical process stages, including in-process control, process characterization and evaluation, parametric monitoring and final product testing).

Characterization and evaluation of process performance shall be performed on test vehicles, evaluation components or final products, and shall include reliability aspects.

In-process control, as defined in the TADD, shall be demonstrated.

6.5.3 Control of internal and external interfaces
The manufacturer shall demonstrate that the interfaces between the processes are under control and have been verified.

Listed below are some examples:

— customer requirements to design;
— design to production;
— design to test;
— design to maintenance and customer support;
— supplier to production;
— production to test;
— test to delivery;
— delivery to customer;
— subcontractor to manufacturer.

6.5.4 Demonstration plan

As part of the approval exercise, the manufacturer shall produce components and/or test vehicles which are representative of his normal production and perform tests necessary to demonstrate that final product fulfils specification requirements, including quality and reliability objectives. The requirements for test vehicles, and their associated test methods, shall be described in the relevant TAS.

NOTE The values prescribed in specifications are limit values. When carrying out the specified tests the approved manufacturer shall employ sufficient inset from the specified limits to cover the uncertainty of measurement (see annex C to clause 2).

6.6 Product documentation

6.6.1 Contractual specifications

The following forms of specification may be used as the basis of contractual arrangements between manufacturer and customer. The content of such documents shall be covered by the manufacturer’s document control procedures and shall satisfy the appropriate requirements of QC 001002-2, clause 1:

— detail specifications registered in QC 001004, Specifications List;
— Customer Detail Specifications(CDS) agreed between the customer and the manufacturer;
— manufacturer’s product data (the manufacturer’s published data (including guidance to customer and/or application notes if required), provided such documents are identified by internal manufacturer’s reference and revision status).

6.6.2 Register of detail specifications

The manufacturer shall maintain a company register of detail specifications used under his TA. This register shall be made available to the SI.

6.6.3 Registration of approval

6.6.3.1 Abstract of TA

An abstract of the scope of the TA, including general product ranges covered, shall be registered in the On-Line Certificate Database.
6.6.3.2 Registration of approved components.

Individual components approved under TA as listed in the register of components referenced in the TADD (6.4.2m)) shall be declared to the SI for registration in the On-Line Certificate Database, except those defined in a CDS where the customer does not wish it. The component identity shall include the data reference and revision status as declared in 6.6.1.

6.7 Procedure for TA

6.7.1 Submission of the TADD

6.7.1.1 The TADD together with the implementation programme shall be submitted to the SI.

6.7.1.2 The SI shall assess the TADD using annex C to this clause and the relevant TAS in consultation with the manufacturer and advise the latter of its acceptance or rejection with an explanation in the case of a rejection.

6.7.2 Acquisition of results

Process capability data, acquired prior to or during the implementation of the process capability plan, is used to demonstrate that all processes are under control.

The main results shall be sent to the SI before any audit is planned to help in its preparation. The manufacturer is not required to wait until the TADD is assessed to start acquisition of data.

6.7.3 Internal audits

The manufacturer shall undertake internal audits against the TADD requirements. The results of these audits, or a summary of them, including corrective actions, shall be put at the disposal of the SI.

If any non-conformities are found during an internal audit the manufacturer shall analyse the cause and take the necessary corrective action.

6.7.4 Statement of readiness

A statement of readiness in respect of the requirements for TA as defined in the manufacturer’s TADD may be made to the SI when the manufacturer is satisfied that these requirements have been met and can be demonstrated, as indicated by his own internal audit. That is to say that, the conditions described in 6.1 to 6.6 have been met and the manufacturer is satisfied that the quality indicators calculated from the manufacturing data satisfy the required standard as described in the TAS. The manufacturer shall accept the right of the SI to audit and verify the claims made (see annex B to this clause).

6.7.5 SI validation audit

6.7.5.1 Validation of TADD implementation

The SI shall audit the manufacturer’s implementation of the TADD including in particular the performance of the TRB and CMB where appropriate.

6.7.5.2 Examination of internal audit data

The SI auditing team shall examine the data resulting from the manufacturer’s internal audit.
6.7.5.3 Proposal for issue of TA validation

Following confirmation of validation by the SI, the manufacturer can execute the demonstration testing. The manufacturer may, at his risk, start the demonstration testing before SI validation.

6.7.6 Execution of the demonstration plan

The manufacturer shall produce components/test vehicles to meet the requirements of the appropriate TAS. They shall be tested in accordance with the demonstration plan described in the TADD.

A formal report in accordance with annex XX (to be defined), shall be submitted to the SI for validation and countersignature.

6.7.7 Assessment and certification

6.7.7.1 Examination of demonstration data

The SI shall examine the data in respect to the demonstration plan.

6.7.7.2 Proposal for issue of TA certification

Following a satisfactory assessment, the manufacturer shall propose to the SI a list of products he intends to release under TA. The SI shall propose to the CB that a TA certificate be issued.

6.7.7.3 Granting of TA

TA shall be granted by the CB when the requirements of 6.7.7.2 have been met.

6.7.7.4 TA Certificate

When TA has been granted, a certificate shall be issued to the manufacturer by the CB.

The approval shall be listed in the On-Line Certificate Database.

The certificate shall contain the information as required by QC 001002-2, clause 2.

6.7.8 Release of certified products

6.7.8.1 Attestation of Conformity

Having received a TA certificate, the manufacturer may provide a Certificate of Conformity, in accordance with QC 001002-2, clause 2 to all products defined within the scope of the TA certificate.

6.7.8.2 Release prior to the issue of an approval certificate

An approved manufacturer is permitted to release components under the System prior to the issue of a TA certificate provided that

a) a successful audit has been carried out by the SI against the TADD,

b) the test report for the demonstration components / test vehicles has been countersigned by the SI, and

c) a draft approval certificate has been accepted by the SI, and the approved manufacturer has submitted to the CB, together with a copy of this draft approval certificate, a written statement announcing his intention to release components prior to the issue of an approval certificate. This statement shall be countersigned by the SI.
In releasing components prior to the issue of an approval certificate, the approved manufacturer shall

d) annotate the Certificate of Conformity with the text, “Released in accordance with QC 001002-3, subclause 6.7.8.2”, and

e) be responsible for any corrective action which may be required of him by the CB if, for any reason, the TA is subsequently withheld or the content of the approval certificate is significantly different from the original draft agreed by the SI.

6.7.9 Maintenance of approval

6.7.9.1 Manufacturer’s documentation

It is the manufacturer’s responsibility to maintain all internal documentation in a state which defines the current operations, processes and products covered. Operational changes which affect the TADD shall be notified to the SI. Amendments to the TADD which could affect the validity of the approval shall be submitted to the SI, whose agreement shall be obtained in order for the approval to be maintained.

NOTE The technical content of the TADD shall relate to, but shall not extend beyond, the range of activities covered by the TAS.

6.7.9.2 Manufacturer/SI periodic review

The manufacturer and the SI shall review the TADD with particular reference to performance against the quality improvement programme at least every 12 months. Any necessary corrective actions shall be agreed between the manufacturer and the SI and implemented by the manufacturer.

6.7.9.3 Re-declaration of conformance

Where changes occur in quality data or indices which fall outside the limits declared in the TADD, the manufacturer shall advise the SI and indicate what corrective action is being taken.

6.7.10 Change control procedure

NOTE All changes to the TA which take the operating parameters beyond the boundary conditions declared in the TADD shall be evaluated by the TRB prior to implementation and update of the TADD as described below.

6.7.10.1 Changes to the overall quality plan

The overall quality plan as defined in the TADD shall be kept up to date and reflect all “major” changes (see 6.7.10.2.1 and 6.7.10.2.3) including updating of the overall process flow.

The overall quality plan shall be subject to periodic review by the SI.

6.7.10.2 Changes to the design/manufacturing information

6.7.10.2.1 Classification of changes

Capability limits shall be described, qualitatively and quantitatively, during the initial certification audit and the documents describing the elements agreed between the SI and the manufacturer. Following this initial agreement each descriptive element shall be classified “major” or “minor”.

In order to determine the extent of requalification required by the manufacturer following the introduction of internally agreed amendments/extensions to the design and/or processes, the criticality and significance of the changes shall be assessed by the TRB. The potential effect of the changes on performance, quality, reliability and, where applicable, interchangeability, shall be taken into account and the changes nominated as “major” or “minor”.
Reference to the relevant TAS will provide guidance.

6.7.10.2.2 Minor changes

Changes classified as minor can be made and fully implemented following approval by the TRB of the supporting documentation and data. A minor change will usually only require a change to the company’s internal documentation and the notification to the SI shall be made available at the TA periodic review.

Any related new products shall be covered for release by implementing the manufacturer’s declared procedure for new product introduction. The supporting test vehicles and/or product approval data shall be made available to the SI at the TA periodic review. No amendments to the TA certificate will be made.

6.7.10.2.3 Major changes

Changes classified as major shall require some declared level of demonstration/re-demonstration which will be decided and assessed by the TRB.

In most instances a major change will necessitate a change to both the manufacturer’s TADD and to the TA certificate, and will affect the declared boundaries of the approval.

The proposed changes and requalification plan, etc., in the form of an amended TADD shall be submitted to the SI, which has the right to request further appraisal of the manufacturer’s changes.

6.7.10.2.4 SI review of amended TADD

The SI shall either advise the manufacturer of its acceptance of the amended TADD or undertake discussion with the manufacturer to establish a resubmission programme.

6.7.10.2.5 Declaration of readiness to the amended TADD

On declaring readiness in respect of the requirements of the amended TADD the manufacturer should submit the following to the SI:

a) the changed design/process capability data;

b) the demonstration/re-demonstration results/report;

c) a request that an amended certificate, if applicable, be issued by the authority designated in the national rules;

d) a request that approval be granted for the release of products related to the implementation of the changes described therein (invoking 6.7.8.2, if applicable).

6.7.10.2.6 SI option to audit in respect of the amended TADD

The SI shall audit the manufacturer if it is considered necessary.

6.7.10.2.7 Release of products affected by the amended TADD

If the SI considers an audit unnecessary for the changes to TA, or immediately upon the completion of a satisfactory audit, the SI shall propose to the authority designated in the national rules that a new or amended TA Certificate shall be issued upon receipt of which the manufacturer may release products manufactured within the changed TA.

6.7.11 Withdrawal of TA
TA shall be withdrawn only by the body which granted it (see 6.7.7.3) and only if one or more of the following conditions apply:

a) at the request of the manufacturer;

b) the production of the components covered by the TAS is terminated, or is suspended for a period greater than that given in the TAS;

c) the Rules of Procedure are not correctly applied, for example, failure to maintain the TADD to include correct current information pertinent to the approval;

d) the manufacturer's approval (see clause 2) is withdrawn.

6.8 Frequency of Surveillance by the SI

Approved manufacturers holding Technology Approval require a more severe surveillance visit regime that those manufacturers which only hold Organisation Approval. This reflects the additional liability resultant from holding a product approval.

6.8.1 Normal frequency of surveillance

The normal frequency of surveillance shall be two visits per year.

6.8.2 Reduced frequency of surveillance

At the discretion of the SI, the frequency of surveillance of the approved manufacturer may be reduced to one visit per year provided that the following conditions apply:

a) the manufacturer has held approval for a minimum of two years;

b) no product or process-related failure to comply with the IECQ system rules has been identified during the previous three surveillance visits, other than product failures permitted by the relevant specification (e.g.: limited failures during maintenance testing are permitted by some Standards).

c) no product or process failures have occurred during a two year period, other than product failures permitted by the relevant specification as detailed above.

6.8.3 Suspension of reduced frequency of surveillance

Manufacturers subject to reduced frequency of surveillance which subsequently fail to comply with the conditions of 6.8.2 shall revert to normal frequency of surveillance.
Annex A to clause 6
(informative)
Application for Technology Approval

To: SI

1 Manufacturer's name:

2 Address for correspondence:
   Telephone number:................. Fax number:.................. E-mail address:..................

3 Manufacturer's approval number (if held):

4 Address of approved location(s) of manufacture:
   Telephone number: ..................... Fax number:...................... E-mail address:..................

5 Designated Management Representative(DMR):
   Address:......................................................................................................................
   Telephone number:..................

6 Applicable IECQ TAS number and issue:

7 Description of component technology and proposed range of approval in the form of a draft abstract for publication in the On-Line Certificate Database (for extension to Technology Approval, give change in scope):

8 Manufacturing stages for which it is intended to use approved specialist contractors:

9 Manufacturing stages for which it is intended to use subcontractors:

10 Give names, approved location(s) and approval numbers of approved independent testing laboratories to be used. State tests which will be carried out by each laboratory named:

11 Names and addresses of non-IECQ approved testing laboratories to be used and the tests which will be undertaken by each testing laboratory shall be given:

Date .......................... Signature .........................................................

Designated Management Representative(DMR)
Annex B to clause 6
(informative)
IECQ Audit
Statement of Readiness
Company Declaration

To: SI     Attention:

With reference to the IECQ Rules of Procedure, QC 001002-3, clause 6, Technology Approval of:-

Company Name and Address

Site to be audited

We have reviewed our Technology and Manufacturing lines against the requirements of IECQ Rules of Procedure, QC 001002-3, clause 6 and declare that we consider that the requirements are met.

Comments, attached audit report.

From:
Signature
Designated Management Representative(DMR)

Signature
Fax number: Date
Annex C to clause 6
(normative)
Form and content of a Technology Approval
Declaration Document (TADD)

This annex defines the requirements for writing a TADD in accordance with clause 6.

C.1 Purpose of the TADD

A manufacturer seeking TA shall prepare a declaration document, which is known as a TADD. The purpose of a TADD is to provide a clear description of those parts of the manufacturer's organization (sites, operations and products) which are to be the subject of a TA. To achieve this the TADD shall comply with 6.3.1 and the relevant items of 6.4.2 and with this annex.

C.1.1 General requirements

The TADD should be prepared in loose-leaf form, with each section beginning on a new page and with section titles and sequence as given in C.2.

The TADD shall be given a document identity within the manufacturer's system and shall indicate its issue number and state of amendment.

Draft issues of the TADD shall be given alphabetical issue references until accepted by the SI. It shall then be raised to Issue 1 at the stage at which the TA is recommended.

Amendments shall not be made in hand-written form. When changes are required, new pages showing the relevant amendment number shall be issued.

The TADD shall be raised in issue number when a change is made. In addition the manufacturer has the option to give an issue status to each page or to each section. Where the scope of technology is extensive and the description is complicated, it is usually advantageous to give each page a discrete issue status.

There shall be a means for recording that amendments have been incorporated and a means for summarizing the nature or purpose of the amendments. This shall be subject to the change note procedures laid down in the manufacturer’s Quality Manual. There shall be an index or ‘contents list'. This may conveniently show the issue status of each section, or page, as the case may be.

Individual sections may then be written as single volumes, making it easier for technical or editorial amendments and change of issue status. The TADD can be subdivided in a generic TADD covering all common items and task specific TADDS for each main technical process. Irrespective of the format of the TADD, it shall include as its initial element a covering document expressing the management's commitment to quality. This may be supplemented by an introduction to the company and a résumé of the sections of the TADD.

C.2 Content of the TADD

C.2.1 Introductory pages

Title page: document identity and issue, manufacturer's name, address, telephone, e-mail and telefax numbers etc. Authorization by the Designated Management Representative (DMR).

Distribution list: this lists the registered holders of copies of the TADD. Copies shall be identified in respect of each recipient.

Amendment record: this is the facility for recording the incorporation of amendments authorized by the DMR.
List of amendments: this provides an indication of the purpose or nature of each amendment. It may be convenient to combine this function with the amendment record mentioned above.

Contents list: this shall give the sections of the TADD in sequence. It may be convenient to combine this function with the issue status of each page (or section).

If there is a need to draw upon documentation contained within the Quality Manual (see clause 2), applicable specifications or any controlled "in-house" documentation, this may be done by making reference to it, or by its inclusion.

C.2.2 Main text: The following subjects shall be addressed in the main text of the TADD.

C.2.2.1 Management responsibility

a) Management commitment to quality. The TADD shall contain the management’s statement on its commitment to quality, continuous quality improvement and customer satisfaction.

b) Management structure

i) TRB or equivalent organisation. The organisation, responsibilities and procedures of the TRB shall be declared.

ii) CMB or equivalent organisation. In the case of several companies involved in a single TA, the organisation, responsibilities and procedures of the CMB shall be declared.

c) Additional responsibilities of the DMR. The TADD shall state any responsibilities of the DMR which are in addition to those required by clause 2. The relationship of the DMR in relation to the management structure (including TRB and CMB) shall be declared.

d) Technical decision making. The TADD shall declare the procedures by which decisions are made on all matters relating to the TA. Where appropriate, these may be declared during the description of the TRB, the CMB or the responsibilities of the DMR.

C.2.2.2 Overall quality plan

The overall quality plan shall consist of the following activities as a minimum:

— Quality improvement programme: The manufacturer shall describe in the TADD a Quality Improvement Programme, starting from a defined base which shall indicate the present situation. The programme shall provide for the maintenance of records of comparative quality performance for all technologies covered by the TADD. Measurement of improvement shall be based on the quality indicators which are used to support the approval. The programme shall also contain training elements designed to support the quality improvement programme;

NOTE Quality improvement goals are an essential feature of any improvement plan. The TADD should describe the corporate and operational aims and explain how specific goals are set at operational levels.

— Failure analysis programme: This programme outlines the procedures that the manufacturer self-imposes to test and analyze failed components to determine each failure category from all stages of manufacturing and the field, and take corrective action based on the findings;

— SPC plan: The TADD shall describe the SPC and/or other statistically valid methods used by the manufacturer, for example design of experiments, mathematical modelling and correlation;

— Corrective action plan: This plan shall describe the specific steps followed by the manufacturer to correct any process which is out of control or found to be defective;
Change control plan: The plan addressing the process by which a manufacturer handles changes to the technology;

Test vehicle assessment: The frequency, testing methods and criteria for evaluation including correlation of test structure and product, are to be determined by the TRB. The manufacturer’s test vehicles evaluation plan shall be described in the relevant TAS.

C.2.2.3 Description of technology and processes

The manufacturer shall include in his TADD a description of all technologies, processes and products included in the approval. This shall address basic technologies, process descriptions, critical process steps and/or key parameters, design rules, materials and related facilities etc. The minimum technical requirements for a specific technology are detailed in the relevant TAS.

C.2.2.4 Definitions of relevant sites and operations

The TADD shall identify the location(s) of the control site, manufacturing sites, their organization, responsibilities and the operations being performed. All the major manufacturing stages shall be covered including clear identification of any operations which are subcontracted or carried out by 'Specialist contractors' (see clause 5). Only site(s) and operations which are required for the declared technologies should be included.

C.2.2.5 Process capability plan

The manufacturer shall describe in detail his plan for the verification and demonstration of the capability of all manufacturing processes.

C.2.2.6 Test vehicles

The TADD shall describe the test vehicles, associated tests, software and other tools which are used on a regular basis to demonstrate design and manufacturing process capability.

C.2.2.7 Internal audit programme

The manufacturer shall define his internal audit programme.

C.2.2.8 Demonstration plan

The manufacturer shall describe his plan to demonstrate that all applicable manufacturing routes operate correctly and that the designed and manufactured component fulfils the specification as well as quality and reliability objectives.

C.2.2.9 Management of non-conforming products or activities

NOTE The term “activities” covers administration, systems and manufacturing.

A description shall be given of all procedures to be carried out if non-conforming product or activities are discovered. This shall include failure analysis, corrective actions and records, and shall cover products during manufacture, after final test and customer returns.

C.2.2.10 New product introduction programme

a) Documentation

The manufacturer shall document in the TADD his new product introduction programme, when the new product is manufactured under the scope of the TAS. The TADD shall describe the product development cycle including how the product's conformance is verified and how the product is released to production.
b) Characterization

The manufacturer shall document in the TADD procedures for the characterization of new products. Characterization shall form part of the new product introduction cycle and shall be designed to identify the critical product parameters and the specified performance.

C.2.2.11 Interrelationship with subcontractors

The TADD shall define the interrelationship requirements for all subcontractor operations.

C.2.2.12 Company definitions and symbols

IEC definitions and symbols shall be used whenever possible. However, if the manufacturer uses non-standard definitions and symbols not specified by the IEC, they shall be defined in the TADD.

C.2.2.13 List of components covered by TA

The TADD shall reference a register listing all components covered by the TA.
Figure 3 — Initial Technology Approval (TA)
Figure 4 — Changes to TA