

IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ System)

Rules of Procedure –

Part 3: IECQ Approved Component Products, Related Materials & Assemblies Scheme

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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

Rules of Procedure – Part 3: IECQ Approved Component Products, Related Materials & Assemblies Scheme

FOREWORD

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

This publication is directly related to Publication IECQ 01 containing the Basic Rules of the IECQ System.

This second edition of IECQ 03-3 replaces the first edition IECQ 03-3. Main changes to the second edition include:

- Inclusion of requirements for organizations operating from more than one location (site),
- Inclusion of requirements for organisations utilizing one management system on multi-sites,
- Inclusion Annex B (normative) Attestation of conformity which includes requirements for Supplier's Declaration of Conformity,
- Clarification of the integration of the IECQ previously operated scheme Qualification Approval into these rules,
- Inclusion of requirements for the maintenance and transition for existing clients of IECQ previously operated scheme Qualification Approval, Annex C,
- Inclusion of requirements in Annex D for previously operated scheme Capability Approval as IECQ Approved Component category Capability,
- Inclusion of requirements in IECQ 03-3-1 for previously operated scheme Technology Approval as IECQ Approved Component category Technology, as per Decision CABC 2011/15,
- Clarification on the use of Suspension and Cancellation (Withdrawal),
- Inclusion of Reinstatement of IECQ AC Certification,
- Inclusion of requirements for Changes (Modifications),
- Updated requirements for Subcontracting and use of IECQ Approved Process within this scheme,
- Updated requirements for Identification of released lots,
- Inclusion of Annex A (Normative) Flow-chart for the application of Approved Component (IECQ AC),
- Inclusion of Annex E (normative) Requirements for specifications used for Approved Components.

This editorial update 2.1 edition of IECQ 03-3 provides clarification for correct implementation and criteria of Distributors.

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

Document	Report on MC Consultation
IECQ MC/233A/CA	MC/255A/R

Full information on the approval by the MC of this publication can be found in the report indicated in the above table.

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INTRODUCTION

Taking into account the object of the International Electrotechnical Commission (IEC) as given in Article 2 of the Statutes, the particular object of the IECQ System, operated in conformity with the Statutes and under the authority of the IEC, is to facilitate international trade in electronic components of assessed quality, by providing a global framework for independent assessment and certification.

The object is achieved by the implementation of quality assessment procedures in such a manner that organizations, processes, and components certified as conforming to the requirements of an applicable standard or specification, are acceptable to all participants.

The IECQ Schemes provide organizations with a “Supply chain verification tool” for seeking assurance that electronic components, assemblies, processes and related materials conform to declared technical Standards and Specifications.

IECQ Approved Components Certification may be applied to Electronic Components, Products, Related Materials and Assemblies for which a technical standard or specification exists or a client specification accepted for use in the IECQ system. For example this may cover but not be limited to; silicon wafer slabs, integrated and discrete electronic components, connectors, printed wiring boards, components/products/materials that assist in the construction, installation and use of electronic components. E.g. ceramic insulators, heat sinks etc.

Organizations that are holding IECQ Approved Components Certification demonstrate to the international market place that their organization and facilities through testing and other verification criteria comply with the requirements of the IECQ System and the relevant declared technical Standards and Specifications for their scope of activity. Components Products, Related Materials and Assemblies produced within the defined scope of activity of the IECQ Approved Components Certification are recognized as IECQ certified, and can be released with a Declaration of Conformity and confidence that the components are produced using manufacturing processes that have been successfully assessed and under constant surveillance by an independent, internationally accepted IECQ Certification Body.

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Rules of Procedure –

Part 3: IECQ Approved Component Products, Related Materials & Assemblies Scheme

1 Scope

This publication contains the Rules of Procedure of the Scheme of the IECQ, hereinafter referred to as the "Rules", for the Approved Component Products, Related Materials and Assemblies Scheme. (IECQ Approved Component Scheme).

This IECQ Approved Component Scheme Rules of Procedure provides the requirements specific to this scheme and is to be used in conjunction with applicable IECQ System management Basic Rules (IECQ 01), General Rules of Procedures (IECQ 03-1) and Operational Documents (ODs).

2 Normative references

The following publications contain provisions, which, through reference in this text, constitute provisions of these Rules. At the time of publication, the editions indicated were valid. The IECQ Management Committee shall decide the timetable for the introduction of revised editions of the publications.

IECQ 01, *IEC Quality Assessment System for Electronic Components (IECQ System) – Basic Rules*

IECQ 02, *General Requirements for the Acceptance of IECQ Certification Bodies into the IECQ System*

IECQ 03-1, *General Requirements for all IECQ Schemes*

ISO 9001, *Quality management systems – Requirements*

ISO/IEC 17000, *Conformity assessment – Vocabulary and general principles*

ISO/IEC 17021, *Conformity assessment – Requirements for bodies providing audit and certification of management systems*

ISO/IEC 17050-1, *Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 65, *General requirements for bodies operating product certification systems*

In the event of conflict between the provisions of this document and any other directly or indirectly referenced provisions, the provisions of this document shall take precedence.

3 Terms and Definitions

The basic definitions concerning conformity assessment contained in ISO/IEC 17000 apply.

For the purpose of the IECQ Approved Component Scheme, the definitions contained in IECQ 01, IECQ 03-1 and the following apply:

3.1

IECQ Approved Component Scheme

Scheme of the IECQ enables the independent conformity assessment of an organization for compliance of Component Products, Related Materials and Assemblies with a defined specification within a given scope

3.2

IECQ Approved Component Certificate

a Certificate issued by an IECQ Certification Body (CB) informing that an organization has the resources and facilities necessary to assure the quality of Component products, assemblies and related materials in compliance with the Standards and Specifications as stated on the Certificate

NOTE the IECQ On-Line Certificate System provides for live on line Certificates of conformity.

3.3

Quality Plan Summary (Process Manual)

a document describing the processes and process control methods specific to the Component Products, Related Materials and Assemblies within the scope of IECQ certification. This may also be known as a Process Plan or Process Manual

NOTE Under previous IECQ schemes this was known as the Capability Manual and may be used for this purpose.

3.4

Component(s)

an electronic device or range of electronic devices, related materials and assemblies that are the subject of IECQ Approved Component Certification

3.5

SDoC

a Supplier's Declaration of Conformity in accordance with ISO/IEC 17050-1, refer to Annex B for specific content and use

3.6

IECQ Qualification Approval (QA)

Qualification Approval is part of the IECQ previously operated scheme now integrated into the IECQ 03-3 Approved Components scheme. In support of the previously operated scheme Qualification Approval and its maintenance for existing clients Annex C has been provided

3.7

IECQ Capability Approval (CA)

the particular requirements for this previously operated scheme are given in Annex D to this document and now form part of this scheme as IECQ Approved Component category Capability

3.8

IECQ Technology Approval (TA)

the particular requirements for this previously operated scheme are given in IECQ 03-3-1 and now form part of the current scheme as IECQ Approved Component category Technology

4 Governing of the IECQ Scheme

This document, IECQ 03-3, sets out the general rules and procedures of the IECQ Approved Component Scheme. These general rules are supplemented by the Scheme's Operational Documents (ODs). These Operational Documents are available to all IECQ Member Bodies, IECQ CBs, and Applicants who have applied for an IECQ Approved Component Certificate.

5 Principles of the IECQ Approved Component Scheme

IECQ Approved Component Certificate

Subclause 5 of IECQ 03-1 applies except as follows:

5.1 The IECQ Approved Component Scheme provides the means for organizations to obtain an IECQ Approved Component Certificate that is intended to provide the international market with confidence that items listed on the IECQ Approved Component Certificate comply with the technical specification(s) listed on the same Certificate by way of the organization having implemented processes in accordance with the technical and quality management system requirements of the IECQ Approved Component Scheme. This is ensured through independent conformity assessment and ongoing surveillance by an IECQ CB of an organization's business and quality management systems and site assessments for compliance with the establishment and implementation of system procedures within the organization's business and quality management systems.

5.2 The IECQ Approved Component Scheme bases its requirements for the conformity of the organization on those of the ISO 9001. This document needs to be read in conjunction with ISO 9001.

5.3 An organization may operate from more than one location (site) where:

- each site is capable of demonstrating via at least 2 site assessments per year that it complies with the requirements.

5.4 Under the surveillance plan for maintenance of certification noted in 8.6, IECQ CBs issuing IECQ Approved Component Certificates shall conduct site assessments on a programme agreed between the IECQ CB and the Organization.

6 Organizational structure

The Organization (Client/Applicant/Certificate Holder)

An Organization shall have the responsibilities, specified in Subclause 7.2.3 of IECQ 03-1 and the following:

- a) shall maintain and document a QMS (Quality Management System) in accordance with the requirements of IECQ Approved Component Scheme Rules of Procedure and supporting IECQ Operations Documents and make available copies of that documented QMS should the IECQ CB require it for certification purposes;
- b) shall not significantly vary the QMS and its related processes under which any IECQ Approved Component Certificate is issued during the period of the certification unless it has given the IECQ CB notice in writing of its intentions to do so, and has received confirmation in writing from the IECQ CB that such variations do not render the Certificate invalid. It is expected that changes may be made as a result of continuous improvement practices. However, when such changes result in significant changes to the QMS and its related processes and therefore compliance of the final product, the IECQ CB shall be notified;

- c) the organization shall facilitate any arrangement allowing the IECQ CB to conduct assessment at subcontractors involved in the design, manufacturing, testing of the product.

7 IECQ Approved Component Certification, Documentation Requirements

7.1 IECQ Approved Component Certificate for an Organization

7.1.1 IECQ Approved Component Certificate Contents

The IECQ Approved Component Certificate shall have the listed content as detailed in Subclause 8.1.4 of IECQ 03-1 and the following as a minimum:

- Clear unambiguous detailed description of the Scope of Activity(ies), (the component or range of components, related materials and/or assemblies and type reference(s) including related technologies, materials and style)
- For additional or specific criteria, if required to be publicly listed, shall be attached as an "Attached Schedule" to the IECQ Approved Component Certificate utilizing the IECQ Templates. For example: nominal parameters – rated voltage, rated current, resistance, capacitance, etc.
- Clear unambiguous detailed reference to the relevant international accepted standard or specification against which the organization has demonstrated compliance, including Revision and Date of Revision shall be included in the "Scope of Activities" field

7.2 IECQ Approved Component Assessment (IECQ ACA Report)

Evidence of Compliance Summary and Assessment Reporting Form

7.2.1 Content

The report as a minimum shall contain the following:

a) 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 organization;
- name, address and status of independent testing laboratory (if appropriate);
- name and address of the responsible IECQ CB;
- a dated declaration signed by the DMR as follows:

"I certify that the requirements of the Scheme 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."

- IECQ CB signature and date.

b) 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.

c) 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 IECQ CB 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).

d) Test equipment and results

The test and measurement equipment used during the IECQ Approved Component 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.

e) Failure identification and analysis

Any failures which occur during Approved Component 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.

7.2.2 Layout

The overall format of the IECQ ACA Report is flexible and the specific style can be chosen to suit individual preferences.

7.2.3 Issue

Upon acceptance of the report, IECQ CBs shall verify that the IECQ ACA Report prepared by the organization, which has been authenticated by the DMR, meets the requirements of the specification and refers to all of the location(s) of the organization's activities and subcontracting arrangements. Evidence of this verification and issue shall be by countersignature of the IECQ CB.

7.2.4 Restrictions

The IECQ ACA Report's are documents used in the preparation of IECQ Approved Component Certificate of conformity and basis for on-going surveillance of the organization; they shall not be used in any form of advertising or sales promotion in a way that the information may be misrepresented. Reproduction and release of this report is the sole prerogative of the organization.

8 IECQ Approved Component Certification procedure

8.1 General

IECQ Approved Component assessments of an organization are based on the general requirements of IECQ 03-1, requirements of ISO 9001 including as detailed in IECQ 03-1 Clause 9.2 and requirements within this document.

8.2 Application

IECQ Approved Component Certification may be applied to any electronic component, or range of components (for example, a range of resistors differing only in resistance values, tolerances and/or power ratings) Products, Related Materials and Assemblies when the appropriate specifications are identified to the IECQ Certification Body (IECQ CB) to whom the application is made. The organization shall demonstrate compliance of such component(s) to internationally accepted standards or specifications falling within the scope of the IECQ System, see IECQ 01 Basic Rules.

The organization seeking approval shall submit or make available the following documentation (non exhaustive) for review by the IECQ CB in addition to that specified in Subclause 9.3 of IECQ 03-1:

- Their Quality Plan Summary (Process Manual), relevant to the range of activity (activities), (the component or range of components product(s), related materials and/or assemblies) for which they are seeking IECQ Approved Component Certification in accordance with the relevant international standard or specification, as accepted by the IECQ CB, against which it is intended to demonstrate compliance
- IECQ Approved Component documented requirements and statement that resources are available to meet the requirements of this Scheme
- In the IECQ Approved Component application the organization shall state:
 - the generic and, if relevant, sectional specification or relevant international accepted standard or specification against which it is intended to produce components and/or product and/or related materials and/or assemblies;
 - a clear detailed description/statement of location(s) the organization carries out all the processes, tests, measurements, etc. subsequent to and including the primary stage of manufacture. This description/statement shall include full details of any outsourcing activities, including use of other organizations approved within the IECQ System, organizations not within the IECQ System, or the use of subcontracting and which defined stages are outsourced to these external resources, to which resources and arrangements for ensuring quality and compliance. See Clause 8.12 Subcontracting in the IECQ Approved Component Scheme.
- The application shall also give the following details of the component(s) for which approval is sought:
 - type reference(s) for the component or range of components, assemblies, related materials; i.e. how the components and items are to be known/referred;
 - the nominal parameters and/or criteria (for example, rated voltage, rated current, resistance, capacitance);
 - other information or specific criteria, for example, materials and style;
 - the desired date for the start of the IECQ Approved Component testing.

When the organization is ready to commence IECQ Approved Component testing it shall give notice to the IECQ CB of their intention to start tests and establish together with the IECQ CB a test plan and a time schedule for the execution of the approval tests.

The IECQ CB 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 IECQ CB shall send the organization a confirmation of application.

8.2.1 Requirements for the content of a Quality Plan Summary (Process Manual)

The organization shall provide the IECQ CB with their Quality Plan Summary, relevant to the range of activity (activities), (the component or range of components product(s), related materials and/or assemblies) for which they are seeking an IECQ Approved Component Certificate. Where confidential processes or techniques are involved, the organization is only required to provide the information necessary for the IECQ CB to determine that the IECQ scheme requirements have been met.

The IECQ CB is not allowed to copy company confidential documents, to remove them from the organization's premises, or to disclose such information to third parties without the organization's prior approval.

The Quality Plan Summary shall, either directly or by reference to the organization's internal documents as appropriate,

- a) state compliance with the minimum requirements for quality factors given in the international accepted standard or specification and related component specification(s);
- b) define in accordance with the international accepted standard or specification the process(es), technologies and component criteria for which they are seeking certification;
- c) state the design rules when required by the relevant international accepted standard or specification;
- d) provide a description of the nominal parameters of the process(es), technology(ies), component(s), component(s) construction, piece part(s) or material (as applicable);
- e) provide a process and test flow chart of the component(s) for which IECQ Approved Component certification is sought;
- f) list the manufacturing facilities and the inspection, measuring and test equipment relevant to the range of component(s) for which they are seeking certification;
- g) list or make reference to the specifications for the raw material, piece parts, incorporated components and/or part-finished components used as applicable;
- h) list or make reference to the specifications for the inspection to be carried out during the operations which are described in the Quality Plan Summary;
- i) define their procedures for testing, identification and traceability;
- j) define how modifications are notified (as applicable);
- k) describe their training policy; and
- l) describe their internal auditing procedure.

8.3 IECQ CB Assessment Team for IECQ Approved Component Assessments

The IECQ CB's assessment team for IECQ Approved Component Products, Related Materials and Assemblies assessments shall be comprised as follows:

Assessment team members	Function	Qualifications
IECQ CB assessors	Assessment of general IECQ Approved Component elements; and management of audit process	IECQ Lead Assessor – Quality Systems and Electronic Components and Systems. Qualified to IECQ OD 010
IECQ CB assessors shall be electrical and electronic component expert	As necessary to form assessment team	IECQ Assessor or Lead Assessor – Quality Systems and Electronic Components
Specialist	Provide specific knowledge and understanding	Relevant experience and knowledge of the organization's industry and product involvement

The number of assessors and assessment days is dependent on the size of the enterprise and the complexity of the assessment.

An IECQ CB assessment team shall be lead by a qualified IECQ CB lead assessor with expertise and competence in the IECQ Approved Component Scheme and the technology under assessment with responsibility for assuring all elements of the assessment plan are covered including IECQ requirements, applicable IECQ Approved Component Products, Related Materials and Assemblies processes.

NOTE The term “IECQ Lead Assessor” is detailed in IECQ OD 010.

8.4 IECQ Approved Component Testing

IECQ Approved Component testing may be carried out on

- a fixed sample as defined in the generic or sectional specification. In this case the sample shall be drawn from current production; or
- 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
- 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 IECQ Approved Component 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 (8.4) 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 IECQ Approved Component is being sought. The sample shall also be representative of the manufacturing process.

The tests shall be carried out by either the organization, an IECQ Independent Testing Laboratory (IECQ ITL) or an IECQ CB.

The results of the tests shall be recorded in an IECQ ACA Report prepared by the organization in accordance with Clause 7.2.

8.5 Completion (Granting of Certification)

Granting of Certification shall be conducted in accordance with Subclause 9.7 of IECQ 03-1.

8.6 Surveillance

8.6.1 General

In addition to the requirements in Subclause 9.8.1 and 9.12 of IECQ 03-1 the following applies.

Additionally periodic surveillance assessments conducted by the IECQ CB that issues the IECQ Approved Component certification shall include a review of the periodic test results, the suitability of the nominal frequency at which they have been undertaken by the organization, as well as the traceable use of the Mark and Certificate of Conformity.

8.6.2 Special Surveillance

In addition to the requirements in Subclause 9.8.2 of IECQ 03-1 the following applies.

The IECQ Approved Component 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 IECQ Approved Component components is doubtful or potentially so, for example, following a technical modification; or
- c) when a change has been made to the specification.

The procedure for the verification is the same as that followed for the IECQ Approved Component itself. The number of tests may be fewer, as decided by the DMR in consultation with the IECQ CB, but the sampling requirements for each test are unchanged.

8.6.3 Frequency of surveillance

Organizations holding IECQ Approved Component certification require a more severe surveillance visit regime, owing to the additional liability resultant from holding such certification.

8.6.3.1 Normal frequency of surveillance

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

8.6.3.2 Reduced frequency of surveillance

At the discretion of the IECQ CB, the frequency of surveillance of the organization may be reduced to one visit per year provided that the following conditions apply:

- a) the organization 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.

8.6.3.3 Suspension of reduced frequency of surveillance

Organizations subject to reduced frequency of surveillance which subsequently fail to comply with the conditions of 8.6.3.2 shall revert to normal frequency of surveillance.

8.7 Ensuring conformity

In addition to the requirements in Subclause 9.10 of IECQ 03-1 the following applies.

The organization has the responsibility to ensure that all component(s) product(s), related materials and or assemblies produced under their IECQ Approved Component Certificate is in conformity with the stated specification. Failure to do so could lead to suspension or cancellation of the IECQ Approved Component Certificate.

8.8 Suspension or Cancellation (withdrawal)

In addition to the requirements in Subclause 9.13 of IECQ 03-1 an IECQ Approved Component Certificate may be suspended or cancelled by the issuing IECQ CB if

- a) the production of the component in question is terminated or suspended for an abnormally long period. In the latter case an agreement between the organization and the IECQ CB is required to determine the period which is to be considered abnormally long;
- b) persistent non-conformance with the specification;
- c) as a consequence of actions which may be taken under 8.10.8.

At the discretion of the IECQ CB in situations of temporary or minor non-conformity, IECQ Approved Component Certification may be suspended by the CB instead of being cancelled. A period, not exceeding six months, shall be prescribed in which the organization has to demonstrate that they have remedied the faults previously found.

8.9 Reinstatement of IECQ Approved Component Certificate

Subclause 9.14 of IECQ 03-1 applies except as follows:

A Cancelled IECQ Approved Component Certificate, which has been cancelled in accordance with 8.8 or 8.10.8, at the discretion of the issuing IECQ CB may be reinstated once all causes have been resolved in full, by a procedure in which the tests are limited to the area of failure, the IECQ CB shall formally record the justification for the reduced tests within their files, on each occasion.

8.10 Procedure in the event of failure in a periodic test

8.10.1 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 IECQ CB.

8.10.2 The DMR (or, where applicable, the local DMR) shall maintain this suspension until the investigation has been concluded and the IECQ CB has been informed of the results. The DMR (or, where applicable, the local DMR) shall then proceed according to the appropriate conditions in 8.10.3, 8.10.4 or 8.10.5.

8.10.3 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 8.10.1.

8.10.4 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 8.10.5 or 8.10.6 shall be applied as appropriate.

8.10.5 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.

8.10.6 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 IECQ CB shall suspend IECQ Approved Component and withdraw the right to use the Mark, or Certificate, of Conformity for the component in question. IECQ Approved Component and the right to use the Mark, or Certificate, of Conformity shall be reinstated when the organization can demonstrate, by the successful submission of a sample from a production lot to the periodic test, that the manufacturing fault has been eliminated.

8.10.7 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.

8.10.8 If the requirements of 8.10.4, or 8.10.5 or 8.10.6 are not fulfilled within a reasonable period of time, IECQ Approved Component shall be re-examined and may be cancelled.

8.10.9 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.

8.11 Changes (Modifications)

In addition to IECQ 03-1 clause 9.9 the following shall apply.

The organization shall report to the IECQ CB any changes likely to affect the validity of the IECQ AC. (For example changes to materials used and/or the processes involved).

The IECQ CB shall decide whether it is necessary to repeat all or some of the IECQ AC tests. The relevant standard/specification may give more detailed information.

8.12 Subcontracting and use of IECQ Approved Process

8.12.1 The primary stage and/or subsequent stages may be carried out by companies who hold approval to IECQ 03-2 (Approved Process) or, under certain conditions, subcontracted (see 8.12.4).

8.12.2 The organization shall only subcontract operations, which are covered by the scope of their IECQ Approved Component Certification, for which the Quality Plan Summary details the methods of control used.

8.12.3 Standards or specifications (Generic or sectional) 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 do not apply to companies holding IECQ Approved Process certification.

8.12.4 When subcontracting is permitted (for example by the generic or sectional specification), this may be undertaken provided that the DMR is able to demonstrate to the IECQ CB that the process(es) concerned is (are) –

- performed in a manner which satisfies the appropriate requirements of the relevant Process Assessment Schedule (PAS) or standard, where such exists, or
- carried out satisfactorily.

8.12.5 To verify the satisfactory conduct of subcontracted operations in accordance with 8.12.4, the manufacturer shall ensure that the IECQ AC testing and quality conformance testing will be performed under their control in an approved laboratory located in an IECQ member country, or exceptionally in accordance with 8.12.7.

8.12.6 The organization, when applying for IECQ Approved Component Certification, shall state whether any individual operations of their process(es) are carried out by IECQ AP certified subcontractor(s) in accordance with 8.12.1 or are subcontracted in accordance with 8.12.4 and shall identify these operations.

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

8.12.8 When the conditions of 8.12.6 apply, the application for IECQ Approved Component Certification shall contain:

- details of the division of individual operations between the organization and the contractor(s) or subcontractor(s) as per 8.12.6; and
- details of the arrangements that need to be agreed with the IECQ CB for the approval of the quality of subcontracted operations. These details should take into account the transfer of products or services between the organization and the contractor/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 IECQ CB.

8.12.9 Before tests are carried out by laboratories not approved under the IECQ System, the organization 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 organization shall demonstrate to the IECQ CB that IECQ approved independent testing laboratories known to be operating in the relevant area of technology are unable to undertake the specified testing.

Where testing laboratories not approved within the IECQ System carries out tests, the organization shall include in their Quality Plan Summary (Process Manual) or produce a document that describes the surveillance arrangements by which they shall ensure that the testing to be carried out shall comply with the specification or standard. Where possible, the nominated testing laboratory shall hold accreditation to ISO/IEC 17025 by a Body that is a member of ILAC (International Laboratory Accreditation Co-operation). The document shall define how the nominated testing laboratory

- ensures that its relevant staff possesses the necessary competence and its relevant test facilities are completely adequate for the purpose,
- proposes to operate the test, and
- 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 accreditations, approvals and/or registrations held by the nominated testing laboratory.

Prior to permitting testing, the organization shall demonstrate to the IECQ CB that his proposed surveillance arrangements comply with the specification.

The organization shall demonstrate to the IECQ CB by any suitable means that the quality and compliance of the final component will not be adversely affected by the use of these subcontracted arrangements.

The IECQ CB of the organization seeking IECQ Approved Component Certification shall ensure that the specialist contractor's DMR is able to verify the satisfactory maintenance of the quality control procedures performed by their subcontractor.

IECQ CB shall confirm that the details contained in the application for IECQ Approved Component Certification satisfy the requirements of the Scheme.

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.

8.13 Release for delivery and validity of release

8.13.1 General

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

8.13.2 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.

8.13.3 Quality conformance inspection

8.13.3.1 General

Quality conformance is established after carrying out tests demonstrating that the inspection lots (see 8.14) have achieved the quality prescribed in the specification. The organization 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 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 IECQ CB be sent to the organization in the IECQ member country. These samples shall be used for audit testing by the IECQ CB or by the organization on behalf of the IECQ CB, and the results of these audit tests compared with the results of the quality conformance inspection to validate the sentencing of each lot.

8.13.3.2 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.

8.13.3.3 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 IECQ Approved Component Certificate.

8.13.3.4 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.

8.13.3.5 Use of in-process testing

In-process testing may be substituted for the relevant test(s) of the quality conformance testing provided that the organization 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.

8.13.3.6 Test severity

An organization 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.

8.13.3.7 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 organization shall demonstrate to the IECQ CB that any alternative methods he uses will give results equivalent to those obtained by the specified method.

8.13.3.8 Measurement uncertainty

The limits prescribed in specifications are true values. When carrying out the specified tests the organization shall employ sufficient inset from the specified limits to cover the uncertainty of their measurement (see Annex C of IECQ 03-1).

8.13.4 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.

8.13.5 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 cancellation of IECQ Approved Component Certification (see 8.8).

8.13.6 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 8.13.3.2). 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.

8.13.7 Identification of released lots

Lots released by organizations or distributors shall be unambiguously identified by a Mark, or Supplier's Declaration of Conformity (SDoC), the affixing, or issue, of which is under the surveillance of the IECQ CB. This Mark, or SDoC, means that the components have been released in accordance with the requirements of the relevant detail specification (see Annex B).

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

Authorization to affix, or to issue, the Mark, or SDoC is suspended or cancelled if there is persistent non-conformity with the specification (see 8.8) or if the provisions of the Scheme are not observed.

While it is not permitted to release approved components prior to the issuing IECQ CB granting IECQ Approved Component Certification and issuing an IECQ Approved Component Certificate of Conformity to the organization, the organization may quote that it has certification pending provided that

- a) the Approved Component test report for the component(s) has been finalised and fully accepted by the issuing IECQ CB
- b) a draft certificate of conformity has been sighted by the organization
- c) the organization has submitted to the issuing IECQ CB a written request announcing their intention to quote that it has certification pending and that this request at the discretion of the IECQ CB has been accepted

- d) the organization shall not use the mark or issue SDoC's on components until it had been issued with an IECQ Approved Component Certificate of Conformity covering such components.

8.13.8 Switching rules for reduced inspection in Group C

8.13.8.1 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.

8.13.8.2 Switching rules

8.13.8.2.1 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 IECQ CB, 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.

8.13.8.2.2 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 IECQ CB, or identified by the IECQ CB.

8.13.8.2.3 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.

8.13.9 Customer returns and appropriate corrective action

An 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 organization's controlled store for release.

Where a manufacturing or test defect is confirmed, the organization shall follow the appropriate procedures as detailed under 8.9.

Organizations shall notify the IECQ CB 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 IECQ CB.

8.14 Inspection lots

8.14.1 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 organization 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 IECQ CB.

8.14.2 Structurally similar components

Structurally similar components are components produced by the same organization 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 IECQ Approved Component Certification and quality conformance inspection.

8.15 Specifications

Specifications used within the IECQ Scheme shall be either:

- an International IEC or ISO Standard; or
- a Component Specification complying with the requirements of Annex E.

9 Acceptance of IECQ Certification Bodies (IECQ CB)

9.1 General

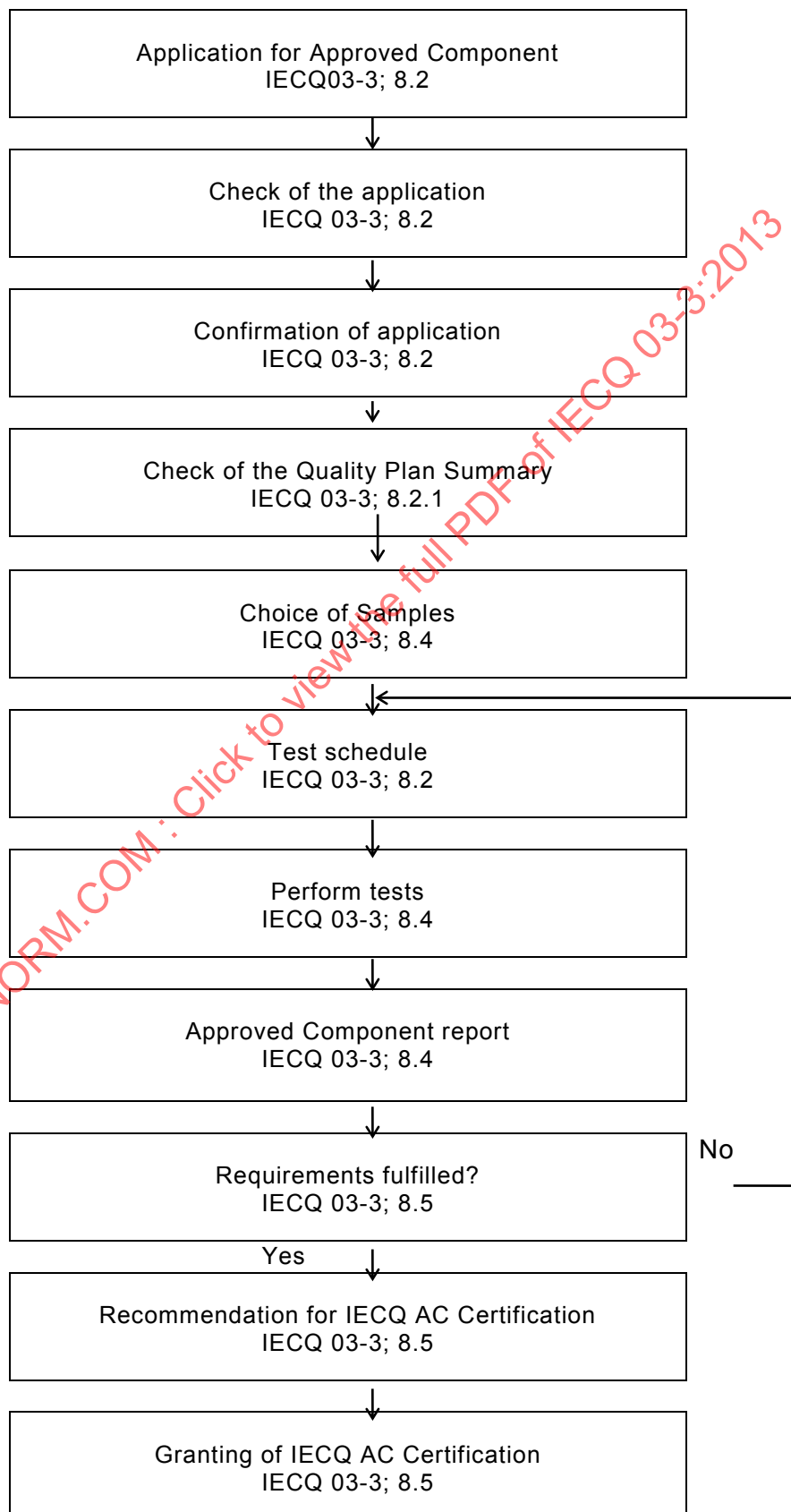
New IECQ CBs or existing IECQ CBs seeking to participate in the IECQ Approved Component Scheme shall comply with the general requirements of IECQ 02 along with the following additional requirements.

9.2 Specific requirements for IECQ Approved Component Scheme

IECQ CBs shall be assessed and approved by the IECQ for specific areas of competence.

Annex A (normative)

Flow-chart for the application of Approved Component (IECQ AC)



Annex B (normative)

Attestation of conformity

B.1 Introduction

An attestation of conformity shall be authenticated by the application of the IECQ's Mark of Conformity, or by the issue of a Supplier's Declaration of Conformity bearing the IECQ Logo along with the IECQ's Mark of Conformity and in accordance with ISO/IEC 17050-1, here after known/referred to as an SDoC.



IECQs' Mark of Conformity

Where the IECQs' Mark of Conformity is used it shall appear as shown preferably in Black.

The IECQs' Mark of Conformity shall be used in the proportions shown and not distorted or stylised in any way. A minimum height of 10mm is recommended. It shall be legible at all times even if smaller than recommended.

The application of a IECQ's Mark of Conformity or the issue of an SDoC attests that the component(s) conform to the IECQ Approved Component Certification to which they have been produced.

B.2 General requirements for attestation of conformity

B.2.1 The information shall be intelligible to the customer and shall not be in coded form.

B.2.2 All forms of attestation shall be authorized by the Designated Management Representative (DMR) or the Approved Signatory and only for components being part of a released lot.

B.2.3 Arrangements for authenticating the attestation of conformity shall be controlled under secure conditions by the organisation and approved by the IECQ CB.

B.2.4 When a Mark of Conformity is being used; the DMR shall maintain a record of the application of the Mark.

B.3 Marking of the packaging

In addition to any marking of the components, the following information shall be marked on the labelling and/or packaging, including component reels or trays:

- a) the name of the organization to which IECQ AC certification has been granted;
- b) the name of the issuing IECQ CB;
- c) the inspection lot identification under which the components were released;
- d) the number of the detail specification or specification to which the component conforms. If required by the national rules, the national number of the detail specification may be added;

- e) that form of authentication which has been agreed with the IECQ CB;
- f) the component identification giving the full catalogue name and reference of the component allotted to it by the manufacturer.

B.4 Mark of conformity (IECQ's Mark of Conformity)

B.4.1 The Mark of Conformity as detailed above shall have information permitting the identification of

- a) the IECQ CB,
- b) the manufacturer's or the distributor's IECQ certification number relating to the product,
- c) the inspection lot,

placed close to the Mark of Conformity in the order given above.

NOTE Import regulations of some countries may require the country of origin to be marked.

B.4.2 The information given in a) to c) should normally allow the delivery lot to be traced to the manufacturer's test report. If this is not so, the necessary extra information shall be given on the package and/or on the component.

B.4.3 At the manufacturer's discretion and agreed by the IECQ CB, a smaller version of the Mark of Conformity accompanied only by the information in a) and c) may be used for the marking of individual components, provided that they are contained in a sealed package as described in B.4.4.

B.4.4 The Mark of Conformity shall be applied to an adhesive tape or to any other similar means of sealing the package. Component reels and tray are considered as forms of packaging. This is not compulsory if the individual components bear the Mark of Conformity. In the latter case, the Mark of Conformity shall be placed in the vicinity of the marking required by the relevant specification.

B.4.5 When sealed packages are used, the protection by the Mark of Conformity cannot be given if the order is less than the capacity of the smallest package for the corresponding component or, for part of the order, if this is not a multiple of the capacity of the smallest package.

B.4.6 Sealed packages may be opened by a distributor holding IECQ Approved Process Certification in order to re-distribute their contents in adequate packages of smaller unit capacity, the latter in turn being sealed with the Mark of Conformity by the distributor. This operation ensures that the components delivered come from an identifiable package which the distributor has opened on his premises, and that the operations that he has carried out on the components are as specified in IECQ 03-1, annex A, item 12).

B.4.7 The Mark of Conformity shall be affixed under the responsibility of the DMR and only on components from released lots or their packages or both.

B.4.8 The stamps or the sealing material bearing the Mark of Conformity shall be stored and used under secure conditions approved by the IECQ CB.

B.4.9 The DMR shall keep a register of seals or sealing material bearing the Mark of Conformity so that the IECQ CB may know where they are kept and how they are used.

B.5 Supplier's Declaration of Conformity (SDoC)

A Supplier's Declaration of Conformity (SDoC) for use by organizations to which IECQ AC certification has been granted, shall be by a

- separate document (certificate style) or
- incorporated into the delivery documentation or
- incorporated into the product label attached to the component reels and trays (where the use of the Mark of Conformity shall be securely controlled, the method of control shall be approved by the IECQ CB.),

in either case it shall be in accordance with ISO/IEC 17050-1 and shall additionally contain the following information:

B.5.1 Manufacturers of Approved Components

- a) per ISO/IEC 17050-1, "the name and contact address of the issuer of the declaration of conformity", where the "Issuer" is the organization (manufacturer) to which IECQ AC certification has been granted;
- b) optional - the trade mark and/or symbol of the organization (manufacturer);
- c) the IECQ Logo with the IECQ AC Certificate Number to which the components have been produced, printed adjacent to it. Refer to IECQ 01A for usage of the IECQ Logo and IECQ's Mark of Conformity;
- d) the IECQs' Mark of Conformity;
- e) the date of declaration;
- f) the component identification giving the full catalogue name and reference of the component allotted to it by the organization (manufacturer);
- g) the organization's (manufacturer's) inspection lot identification under which the component was released. If the component has been re-inspected by the organization (for example, after long storage) the new inspection lot identification shall also be given;
- h) the number of the detail specification or standard to which the component conforms. If required by the national rules, the national number of the detail specification may be added;
- i) the statement of conformity as follows: "The components in this package have been released according to the above numbered detail specification or standard under the IECQ System in accordance with the rules of procedure of the IECQ Approved Component Scheme given in IECQ 03-3, under the supervision of IECQ CB(s)*."

* *the name of the IECQ CB who supervises the manufacturer.*

The DMR shall maintain records showing the relationship between a Declaration of Conformity and the inspection lot to which it refers. The DMR shall in accordance with ISO/IEC 17050-1 allot a unique reference number to each SDoC.

B.5.2 Subcontractors of Component Manufacturers holding an IECQ AP Certification (Specialist contractors)

- a) per ISO/IEC 17050-1, "the name and contact address of the issuer of the declaration of conformity", where the "Issuer" is the organization (Specialist contractor) to which IECQ AP certification has been granted;
- b) optional - the trade mark and/or symbol of the organization (Specialist contractor);
- c) the IECQ Logo with the IECQ AP Certificate Number to which the components have been produced, printed adjacent to it. Refer to IECQ 01A for usage of the IECQ Logo and IECQ's Mark of Conformity;
- d) the IECQs' Mark of Conformity;

- e) the date of declaration;
- f) the product identification; (* In the context of Specialist Contractors the term product is taken to include specialized services, materials, piece parts, and incomplete components)
- g) the organization's (Specialist Contractors) inspection lot identification under which the product was released;
- h) the number and revision of the Quality Plan Summary to which the product conforms;
- i) the statement of conformity as follows: "The process(es)/technical service(s) has(have) been provided according to the above numbered Quality Plan Summary under the IECQ System in accordance with the procedures given in document IECQ03-2 and IECQ03-3, under the supervision of IECQ CB(s)*."

** the name of the IECQ CB who supervises the Specialist contractor.*

The DMR shall maintain records showing the relationship between a Declaration of Conformity and the inspection lot to which it refers. The DMR shall in accordance with ISO/IEC 17050-1 allot a unique reference number to each SDoC.

B.5.3 Distributors of Approved Components

- a) per ISO/IEC 17050-1, "the name and contact address of the issuer of the declaration of conformity", where the "Issuer" is the organization (distributor) to which IECQ AP certification has been granted;
- b) optional - the trade mark and/or symbol of the organization (distributor);
- c) the IECQ Logo with the distributor's IECQ AP Certificate Number to which the components have been supplied, printed adjacent to it. Refer to IECQ 01A for usage of the IECQ Logo and IECQ's Mark of Conformity;
- d) the IECQs' Mark of Conformity;
- e) the name of the organization (manufacturer) who released the components under their IECQ AC certification and their IECQ AC Certificate Number;
- f) the component identification giving the full catalogue name and reference of the component allotted to it by the manufacturer, together with full catalogue name and reference, if any, allotted by the distributor;
- g) the manufacturer's inspection lot identification under which the component was released. If the component has been re-inspected while in the distributor's hands (for example, after long storage) the new inspection lot identification shall also be given;
- h) the number of the detail specification or standard to which the component conforms. If required by the national rules, the national number of the detail specification may be added;
- i) the statement of conformity as follows or appropriate statement of conformity as agreed between the IECQ CB and the Client: "The components in this package have been declared by the organization (manufacturer) as having released according to the above numbered specification or standard under the IECQ System, have been stored under suitable conditions and have not been used or modified or repaired, in accordance with the rules of procedure of the IECQ Approved Component Scheme given in IECQ 03-3, under the supervision of the IECQ CB(s) that issued the IECQ AC and AP Certifications as detailed above. These components are therefore released and delivered under the IECQ System."

If an approved distributor repacks released components, he shall mark the final packaging in accordance with B3, including his own identification.

The DMR shall maintain records showing the relationship between a SDoC and the inspection lot to which it refers. The DMR may, if he wishes, allot a reference number to the SDoC.

Annex C (normative)

IECQ Qualification Approval (QA)

C.1 Introduction

Qualification Approval is part of the IECQ previously operated schemes now integrated into the IECQ 03-3 Approved Components scheme. In support of the previously operated scheme Qualification Approval and its maintenance for existing clients this annex has been provided. The use of this Annex C is only available to existing clients, which already hold current Qualification Approval Certificates. The previously operated scheme Qualification Approval 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 as prescribed by Annex E of this document for use within the IECQ System.

C.2 QA Procedure

C.2.1 Eligibility

The client shall already hold certification under the previously operated scheme as an organization that has been granted Manufacturer's Approval (MA) in accordance with the requirements of IECQ 03-1 including, as appropriate, those of ISO 9001 and, additionally, the requirements of this clause.

The client shall additionally already hold Qualification Approval under the previously operated scheme.

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 Annex E of this document) is carried out by one or more manufacturers approved in accordance with the previously operated scheme requirements of QC 001002-3 clause 2 and under the direct supervision of the relevant Designated Management Representative (DMR) or local DMR.

NOTE The Manufacturers Approval along with the Qualification Approval certificates are currently being phased out – product certificates will then stand alone in accordance with the IECQ Approved Components scheme. Clients are therefore encouraged to transfer their Approvals across to Certifications under the IECQ AC Scheme.

C.2.2 Application for IECQ Qualification Approval (QA)

C.2.2.1 For organizations that hold QA approval under the previously operated scheme they may apply in the normal way for any additional product ranges.

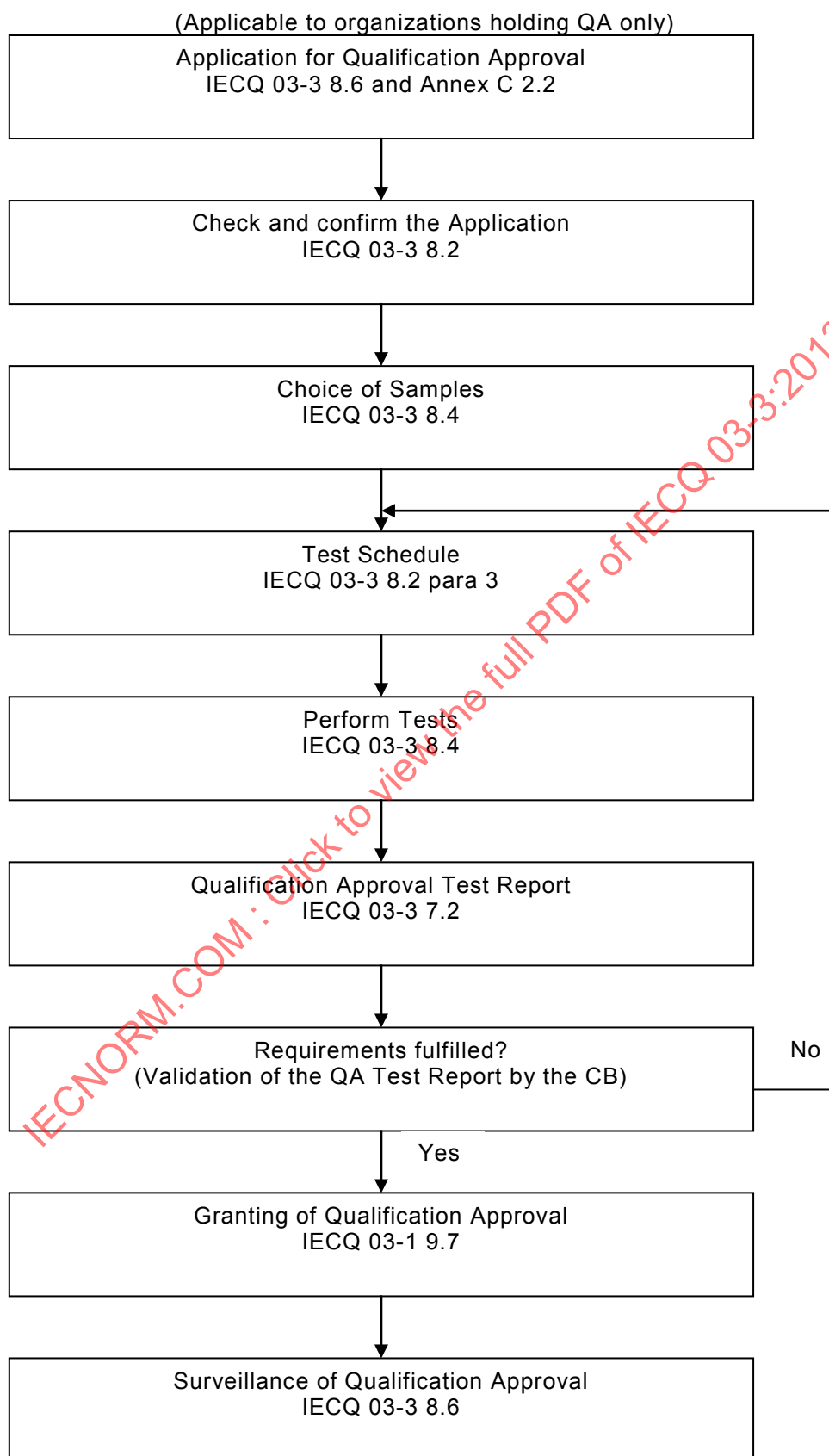
C.2.2.2 The references made to "Quality Plan Summary (Process Manual)" for organizations holding QA under the previously operated scheme, may be substituted by the Quality Manual reference if no separate quality plan is available for a given product.

C.2.2.3 Organizations new to the IECQ scheme must use the "IECQ Approved Component" scheme as covered in the main body of this document.

C.2.3 Transfer from IECQ Qualification Approval to IECQ Approved Component Certification

C.2.3.1 The organization shall construct and be assessed to a "Quality Plan Summary (Process Manual)" in accordance with "IECQ Approved Component" scheme as covered in the main body of this document.

C.3 Flowchart for IECQ Qualification Approval (QA)



Annex D (normative)

IECQ Approved Component – Capability Certification (IECQ AC-C)

D.1 Introduction

Capability Approval is part of the previously operated schemes now incorporated in the IECQ 03-3 Approved Components scheme as IECQ Approved Component – Capability Certification. This Capability Certification (IECQ AC-C) procedure shall be used only when provided for in relevant specifications or standards (see D.8.9 of this document for use in IECQ Capability Certification).

D.2 Normative references

No additional Normative references.

D.3 Terms and Definitions

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

D.3.1 Capability Approval

A term used to describe one of the approval types of the previously operated schemes, now IECQ Approved Component – Capability Certification.

D.3.2 IECQ AC – Capability Certification (IECQ AC-C)

A certification granted to an organization (manufacturer) when it has been established that their capability for manufacturing processes and quality control methods (including design aspects as applicable) covering a specific component technology, fulfils the requirements of the relevant specification or standard.

NOTE In the previously operated schemes this would be a (generic specification).

D.3.3 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 specification or standard.

D.3.4 Capability Manual

The Capability Manual is an expanded version of the Quality Plan Summary (Process Manual) as detailed in this document. For Capability Certification under the IECQ Approved Component Scheme, this document, in addition to the requirements of 8.2.1 of this document the form and content of a Capability Manual is detailed in D.7.2.

NOTE For maintenance of Capability Approvals already issued under the previously operated schemes the form and content as detailed in D.7.2 only, may apply.

D.3.5 Incorporated components

Incorporated components are components that form the constituent parts of a larger, more complex, electronic component.

D.3.6 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.

D.3.7 Repair

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

D.4 Governing of the IECQ Scheme

No additional requirements.

D.5 Principles of the IECQ AC – Capability Certification

D.5.1 IECQ AC – Capability Certification

Subclause 5 applies except as follows:

A component is eligible for IECQ AC-C in accordance with the Scheme if the manufacturing process, commencing not later than that manufacturing operation which is called the "primary stage" (see Annex E of this document) is carried out by one or more manufacturers approved in accordance with the requirements of IECQ 03-1 9.2.3 and under the direct supervision of the relevant Designated Management Representative (DMR) or local DMR.

D.5.2 In support of the previously operated scheme (CA);

Organizations that hold Capability Approval (CA) under the previously operated scheme and fulfil a) and b), are eligible to apply in the normal way for any additional product ranges.

- a) The client must already hold certification under the previously operated scheme as a manufacturer who has been granted manufacturer's approval in accordance with the requirements of IECQ 03-1 including, as appropriate, those of ISO 9001 and, additionally, the requirements of this clause.
- b) The client shall already hold Capability Approval (CA) under the previously operated scheme.

NOTE The Manufacturers Approval along with the Capability Approval certificates are currently being phased out – product certificates will then stand alone in accordance with the IECQ Approved Components scheme. Clients are therefore encouraged to transfer their Approvals across to Certifications under the IECQ AC Scheme.

D.6 Organization structure

The Organization (Client/Applicant/Certificate Holder).

D.6.1 Management responsibility

An organization shall have the responsibilities, specified in Subclause 7.2.3 of IECQ 03-1 and the following:

D.7 IECQ AC Certification, Documentation Requirements

D.7.1.1 IECQ AC – Capability Certificate Content

The IECQ Approved Component – Capability Certificate as registered in the IECQ On-Line Certificate System shall have the listed content as detailed in Subclause 7.1 of this document and the following as a minimum:

- The organization's reference number for the Capability Manual, or other documentation defining the limits of the capability, on which the approval is based;
- Clear unambiguous general description for the technology or component to be covered by the IECQ AC-C Certification shall be provided in the "Scope of Activity(ies)" field on the certificate;
- Clear unambiguous detailed abstract of the description of the capability (see D.8.3), shall be attached as an "Attached Schedule" to the certificate utilizing the IECQ Templates.

D.7.2 Requirements for the form and content of a Capability Manual

D.7.2.1 General Requirements

D.7.2.1.1 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 1 (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.

The Capability Manual shall be raised in issue when a change is made. There shall be a means for recording that amendments have been incorporated and a means for summarizing the nature or purpose of the amendments.

D.7.2.1.2 Introductory pages

These shall include the following:

- Title page: "Capability Manual": " - - - The technology and specification to be noted here - - ". Document identity, date and Issue, manufacturer's name, telephone, fax numbers etc. Authorization by the DMR and a space for countersignature by the CB.
- Distribution list
- Amendment record (including amendment details)
- Contents list (sections as defined by the Table D.1 below)

Table D.1

Section	Title
1	Scope of Capability Certification
2	Technology/range of components
3	Subcontracting
4	Limits of capability
5	Description of capability
6	Manufacturer to customer interface
7	Design rules
8	Materials list

9	Manufacture
10	Procedure in the event of CQC or product failure
11	Test programme for IECQ AC-C
12	Maintenance of IECQ AC-C
13	Modifications to the IECQ AC-C
14	Test methods and inspection
15	Register of product specifications covered by the IECQ AC-C

D.7.2.2 Scope of Capability Approval (CA)

This section shall include

- a) a summary of those products covered by the relevant specification or standard for which capability is claimed,
- b) the organization's policy for dealing with other electronic components which form an integral part of the finished component (see NOTE to D.7.2.9.2),
- c) claims additional to those prescribed in the specification,
- d) assessment levels (where appropriate), and
- e) screening levels (where appropriate).

D.7.2.3 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 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.

D.7.2.4 Subcontracting

In this section the organization 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 D.8.2.1 apply.

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

D.7.2.5 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 organization exploits the limits defined in the relevant specification (for example generic or sectional) or standard and will be the basis against which the capability is to be assessed.

The factors that 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 D.7.2.12.1

D.7.2.6 Description of the capability

The description of the capability (see D.8.3) is a written declaration by the organization identifying the scope and limits of his IECQ AC-C. It shall be written in accordance with the requirements given in the specification (for example generic or sectional) or standard, 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."

D.7.2.7 Manufacturer to customer interface

In this section the organization 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 their 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.

D.7.2.8 Design rules, (when required, see D.8.3)

In this section the organization should state their design rules and indicate their routine, which may be presented as a flow chart (see 8.2.1 of this document), 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 organization'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 IECQ AC-C 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.

D.7.2.9 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 IECQ AC-C. 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.

D.7.2.9.1 Raw materials

- a) the specification references against which they are purchased
- b) incoming goods inspection document references

D.7.2.9.2 Components/piece parts

- c) the specification references against which they are purchased
- d) 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 D.8.15.

D.7.2.10 Manufacture

D.7.2.10.1 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).

D.7.2.10.2 Process flow chart

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.

D.7.2.10.3 Rework policy (see D.8.13.1)

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.

D.7.2.11 Procedure in the event of CQC or product failure

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

- a) D.8.4.1 in respect of the failure of CQCs during the demonstration and verification of capability,

- b) D.8.4.2 in respect of failure of CQCs during maintenance of IECQ AC-C, and
- c) D.8.4.3 in respect of persistent non-conformity with the specification
- d) Particular attention shall be paid to the need for
- e) a procedure for a clear analysis of the cause of failure in the case of a), b) and c) above,
- f) the suspension of release under the Mark, or Certificate, of Conformity in the case of a), b) and c) above, and
- g) the timely reporting to the IECQ CB of the failures and the corrective actions.

D.7.2.12 Test programme for IECQ AC-C

D.7.2.12.1 CQC detail specifications

The Capability Manual shall include or reference a detail specification for each CQC, in accordance with D.8.11.

The CQCs, together with the processes and limits, which they assess, should be listed. This list may conveniently be displayed in matrix form (see D.9.0 of this Annex).

NOTE The limits of a organization's IECQ AC-C 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.

D.7.2.12.2 Total CQC test programme

The total CQC test programme to meet the requirements of D.8.4.1 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.

D.7.2.13 Maintenance of IECQ AC-C

The organization shall outline his approach to maintenance of IECQ AC-C, together with the means by which they intend 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 organization shall state his programme for maintenance that 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 IECQ AC-C 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.

D.7.2.14 Modifications to the IECQ AC-C

The manufacturer shall declare his procedures for controlling modifications to his established capability. This shall include his responsibility for notifying and agreeing with the CB 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 certification. This section shall also detail the procedures for amending the Capability Manual and the description of the capability as appropriate.

D.7.2.15 Test methods and inspection

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

D.7.2.15.1 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.

D.7.2.15.2 Screening

Use of screening procedures appropriate to the technology.

D.7.2.15.3 Quality conformance inspection

Tests performed as a mandatory requirement for quality conformance inspection.

D.7.2.15.4 Reliability testing

Procedures for determining product reliability.

D.7.2.16 Register of product specifications covered by the IECQ AC-C

The Capability Manual shall include a reference to a register of customer detail and standard catalogue item specifications covered by the organization's IECQ AC-C.

D.8 IECQ AC Capability Certification procedure

D.8.1 General

IECQ AC-C assessments of an organization are based on the requirements of ISO 9001 and requirements within this document.

D.8.2 Application

Application for IECQ Approved Component – Capability Certification (IECQ AC-C).

D.8.2.1 When an approved organization wishes to obtain IECQ AC-C, they shall submit an application in writing to the IECQ CB. In this application they shall state the scope of the proposed IECQ AC-C, preferably in the form of a first draft of the information required under D.8.3, and clearly defining the range of technologies and/or the range of components they wish to manufacture in accordance with the stated specification (for example generic and/or sectional) or standard.

They shall also state

- a) that they carry 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 companies approved within the IECQ System, some of whom may be located in other countries (see D.8.15.2), or by distributors acting in another role (see IECQ 03-2), or
- c) that defined stages are subcontracted in accordance with 8.12.4 and 8.12.5 of this document, or