IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ System)

Rules of Procedure –
Part 2: IECQ Approved Process Scheme
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

Rules of Procedure –
Part 2: IECQ Approved Process Scheme

FOREWORD

This publication has been prepared by the IECQ Management Committee (IECQ MC) of the IEC Quality Assessment System for Electronic Components (IECQ).

This publication is directly related to the IECQ System management Basic Rules contained in publications (IEC CA 01 + IECQ 01-S), IEC Harmonised Basic Rules (IEC CA 01) plus the IECQ Supplement (IECQ 01-S).

This editorial edition 2.2 of IECQ 03-2 replaces the 2.1 edition IECQ 03-2. Main changes to this edition include:

- Includes align with the newly introduced IEC CA 01, IEC Harmonised Basic Rules Edition 2.0.
- Update all references to the former IECQ 01 document which is now replaced by combined documents known as IECQ System management Basic Rules (IEC CA 01 + IECQ 01-S), IEC Harmonised Basic Rules (IEC CA 01) plus the IECQ Supplement (IECQ 01-S)
- Update Normative references with IEC policy
- Extraction of Distributor Certification, requirements now contained in IECQ 03-2-1

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

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<tr>
<th>Document</th>
<th>Report on MC Consultation</th>
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<tr>
<td>IECQ WG10-005-CD</td>
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Full information on the approval by the IECQ MC of this publication can be found in the report indicated in the above table.
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 manufacturers 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 Process Certification may be applied to any process, which may affect conformity or compliance of electronic components, related assemblies or services. For example this may cover, but not limited to; product engineering, printed wiring board manufacture, electronic component manufacturing, printed circuit board assembly, Electro Static Discharge (ESD) controls or even supply chain management.

Additional the electronic components industry relies on, as a part of its manufacturing infrastructure, a supporting industry of organizations providing a wide range of specialized services, processing, and manufacture of piece parts and material.

The IECQ Approved Process Scheme permits such organizations to certify their specialized services or processes under the IECQ Approved Process Scheme. Manufacturers of finished electronic components shall seek certification to the IECQ Approved Component Scheme (IECQ 03-3) if they wish to qualify finished electronic components. However, such manufacturers may also seek certification for specific services or processes or for the manufacture of piece parts and material in accordance with the IECQ Approved Process Scheme. 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 supporting industry organizations are design bureaux, packagers, electroplaters, PCB mass laminators.
Rules of Procedure –
Part 2: IECQ Approved Process Scheme

1 Scope

This publication contains the Rules of Procedure of the Scheme of the IECQ System, hereinafter referred to as the "Rules", for the Approved Process Scheme. (IECQ Approved Process Scheme).

This IECQ Approved Process 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 (IEC CA 01 + IECQ 01-S), General Rules of Procedures (IECQ 03-1) and Operational Documents (OD) as listed in normative references Clause 2.

In the event of conflict between the provisions of these Rules of Procedure and any other requirements contained in referenced normative documents, the requirements of these Rules of Procedure shall apply.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. The IECQ Management Committee shall decide the timetable for the introduction of revised editions of the documents. For undated references, the latest edition of the referenced document (including any amendments) applies.

The IECQ System management Basic Rules and Procedures prescribed in the following documentation shall be used for the IECQ AP assessments where applicable.

IEC CA 01, IEC Conformity Assessment Systems – Basic Rules

IECQ 01-S, IECQ Supplement to Harmonized Basic Rules IEC CA 01

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

IECQ 03-1, General Requirements for all IECQ Schemes

IECQ 03-1-2, IECQ Approved Process – Distributor Certification (IECQ AP)

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 17025, General requirements for the competence of testing and calibration laboratories

ISO/IEC 17065, Conformity assessment – Requirements for bodies certifying products, processes and services

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 Process Scheme, the definitions contained in IEC CA 01, IECQ 01-S, IECQ 02, IECQ 03-1 and the following apply.

3.1 IECQ Approved Process Scheme

Scheme of the IECQ enables the independent conformity assessment of an organization for compliance with a defined specification within a given scope.

3.2 IECQ Approved Process Certificate

a Certificate issued under the IEC Quality Assessment System for Electronic Components (IECQ) recognizing that an organization has the resources and facilities necessary to assure that the specified process(es) comply with the stated specifications as listed on the Certificate.

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.

4 Governing of the IECQ Scheme

This document, IECQ 03-2, sets out the general rules and procedures of the IECQ Approved Process 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 Process Certificate.

5 Principles of the IECQ Approved Process Scheme

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

5.1 The IECQ Approved Process Scheme provides the means for organizations including manufacturers, distributors and specialist contractor to obtain an IECQ Approved Process Certificate that is intended to provide the international market with confidence that a process listed on the IECQ Approved Process Certificate comply with the technical specification(s) listed on the same Certificate by way of such organizations having implemented processes in accordance with the technical and quality system requirements of the IECQ Approved Process Scheme. This is ensured through independent conformity assessment and ongoing surveillance by an IECQ Certification Body (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 Process Scheme bases its requirements for the conformity of the organization of a manufacturer, distributor or specialist contractor (supplier) on those of the ISO 9001, with additional requirements specific to the Electronic Component Industry. This document needs to be read in conjunction with ISO 9001.

5.3 Under the surveillance plan for maintenance of certification, IECQ CBs issuing IECQ Approved Process Certificates shall conduct site assessments on a programme agreed between the IECQ CB and the Organization.
5.4 IECQ AP Distributors

Requirements for Distributors are contained in IECQ 03-2-1.

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 Process 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 Process 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, the IECQ CB shall be notified;

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

7 IECQ Approved Process Certification

7.1 IECQ Approved Process Certificate for an Organization

IECQ 03-1 applies except as follows:

7.1.1 IECQ Approved Process Certificate Contents

The IECQ Approved Process 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), (process and/or technical service including related technologies)
- For additional or specific criteria, if required to be publicly listed, shall be attached as an “Attached Schedule” to the IECQ Approved Process Certificate utilizing the IECQ Templates
- Clear unambiguous detailed reference to the relevant international accepted standard or specification against which the organization has demonstrated compliance, including Revision & Date of Revision shall be included in the “Scope of Activities” field

8 IECQ Approved Process Certification procedure

8.1 General

IECQ Approved Process assessments for compliance 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 Process Certification may be applied to any process which may affect conformity or compliance of electronic components, related assemblies or services. For
example this may cover, but not limited to; product engineering, printed wiring board manufacture, electronic component manufacturing, printed circuit board assembly, Electro Static Discharge (ESD) controls or even supply chain management. The organization shall demonstrate compliance of such processes to an internationally accepted standards or specification.

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

8.2.1 General

- The organizations Quality Plan Summary, relevant to the range of activity(ies), (process and/or technical service including related technologies) for which they are seeking IECQ Approved Process Certification in accordance with the relevant international accepted standard or specification against which it is intended to demonstrate compliance
- IECQ Approved Process documented requirements and the resources available to meet the requirements of the process

8.2.2 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), and/or technical service(s) for which they are seeking IECQ Approved Process Certificate. Where confidential processes or services are involved, the organization is only required to provide the information necessary for the IECQ Approved Process Certificate.

The IECQ CB shall not 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 Process Specification(s);

b) define in accordance with the international accepted standard or specification the process(es) or technical service(s) for which they are seeking certification;

   NOTE When required by the international accepted standard or specification, these statements shall take the form of a Process Specification.

c) state the design rules when required by the relevant international accepted standard or specification 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 IECQ Approved Process certification 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 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 identification and traceability;

j) define how modifications are notified (as applicable);

k) describe their training policy; and
I) describe their internal auditing procedure.

The relevant international accepted standard or specification shall give more detailed information concerning the description of process capability to be supplied by the organization.

### 8.3 IECQ CB Assessment Team for IECQ Approved Process Assessments

The IECQ CB assessment team for IECQ Approved Process assessments shall be comprised as follows:

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

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 led by a qualified IECQ CB Lead Assessor with expertise and competence in the IECQ Approved Process Scheme and the technology under assessment with responsibility for assuring all elements of the assessment plan are covered including IECQ requirements, applicable IECQ Approved Process processes.

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

### 8.4 Extension of Scope for IECQ Approved Process Certification

On application, an organization’s IECQ Approved Process certification shall be extended as described in an undated Quality Plan Summary in accordance with the relevant international accepted standard or specification, when the IECQ CB, responsible for issuing the IECQ Approved Process Certificate, has determined that the extension meets the requirements of this scheme.

### 8.5 Subcontracting in the IECQ Approved Process Scheme

#### 8.5.1 The approved organization shall not subcontract operations which are covered by the scope of their IECQ Approved Process Certification, as defined in their Quality Plan Summary and the relevant PAS or with any internationally accepted standard or specification.

The organization may subcontract operations outside the scope of their IECQ Approved Process Certification to non-approved organizations, 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 Scheme and nominated specification.

#### 8.5.2 The organization, when applying for IECQ Approved Process Certification, shall state whether any individual operations of their process(es) and/or services are subcontracted and shall identify these operations.

#### 8.5.3 When the conditions of 0 apply, the application for IECQ Approved Process Certification shall contain:
• details of the division of individual operations between the organization and the subcontractor; and

• details of the arrangements 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 subcontractor; and in particular
  o the procedures for the assessment of quality of the subcontracted operations; and
  o details of the means whereby changes to the agreed arrangements are communicated to the IECQ CB.

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

The IECQ CB of the organization seeking IECQ Approved Process 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 Certification Body (IECQ CB) shall confirm that the details contained in the application for IECQ Approved Process Certification satisfy the requirements of the Scheme.

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 Products, Related Materials & Assemblies Scheme shall comply with the general requirements of IECQ 02 along with the following additional requirements.

9.2 Specific requirements for IECQ Approved Process Scheme

IECQ CBs shall be assessed and approved by the IECQ for specific areas of competence, e.g. ESD.