IEC Quality Assessment System for Electronic Components (IECQ System)

Rules of Prodecure –
Part 2-1: IECQ Approved Process Scheme, IECQ Approved Process – Distributor (IECQ AP-D)
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Part 2-1: IECQ Approved Process Scheme, IECQ Approved Process –
Distributor (IECQ AP-D)
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

RULES OF PROCEDURE –

Part 2-1: IECQ Approved Process Scheme
IECQ Approved Process – Distributor Certification (IECQ AP-D)

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).

IECQ 03-2-1 sets out the requirements for IECQ Approved Process – Distributor certification previously contained in IECQ 03-2 Ed 2.1 2013 section 5.4

– Distributors moved from IECQ 03-2 & IECQ 03-3 into its own Rule.
– 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
– IECQ 03-2-1 ed 1.1 – added missing IECQ rules reference to 10.4.

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

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<tr>
<th>Document</th>
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<td>IECQ WG10-011-CA</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

In support of the current operated scheme, IECQ 03-2 Approved Process, the following sections have been provided to highlight the particular requirements for IECQ Distributors and its implementation under this IECQ Approved Process Scheme of the IECQ System as IECQ Approved Process Certification.

Approved Process certification for Distributors is a method of certifying a complete process within the supply chain (validation of stock, revalidation, repacking). It extends the existing suite of IECQ certification concepts by adding the following principles as mandatory aspects of Approved Process for Distributors.

- The foundation of Approved Process for Distributors is a formal system for quality management within the organization. This requires that all employees are actively involved in the commitment to quality.
- The use of in process control methods and tools to demonstrate adequate control of processes and products. A programme shall be in operation at the initial certification to this programme;
- Continuous quality improvement strategy and its demonstration;
- Monitoring the overall operations associated with distribution.
- Procedural flexibility due to the certification being based on a company’s own assurance management system and market sector requirements;
- The acceptance of an organization’s operational documentation to provide a means for rapid certification or extension of certification.
RULES OF PROCEDURE –

Part 2-1: IECQ Approved Process Scheme
IECQ Approved Process – Distributor Certification (IECQ AP-D)

1 Scope

This International publication contains the Rules of Procedure of the Distributor Certification of the IECQ System, hereinafter referred to as the “Rules”, for the Approved Process – Distributor Certification (IECQ AP-D).

This IECQ Approved Process – Distributor Certification Rules of Procedure provides the requirements specific to this category of the Approved Process scheme and is to be used in conjunction with applicable IECQ System management Basic Rules (IEC CA 01, IECQ 01-S and IECQ 02), General Rules of Procedures (IECQ 03-1), Approved Process Rules of Procedure (IECQ 03-2) and Operating Documents Operational Documents (ODs) as listed in normative references Clause 2

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-D 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 03-2, IECQ Approved Process Scheme

IECQ 03-3, IECQ Approved Component Products, Related Materials & Assemblies Scheme

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 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 01-5, IECQ 01-2, IECQ 03-1 and the following apply

3.1 IECQ Approved Process Scheme – Distributors

Scheme of the IECQ enables the independent conformity assessment of an organization for the distribution of IECQ certified components within a declared scope and in accordance with this rules document. Compliant organizations are also known as IECQ AP Distributors.

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) for IECQ AP-D (Distributors) comply with IEC CA 01, IECQ 01-2, IECQ 01-2-1 and IECQ 03-3.

3.3 IECQ Quality Manual

The requirements of clause 9.2.3 of IECQ 03-1 apply.

3.4 IECQ SDoC

Supplier’s Declaration of Conformity in accordance with ISO/IEC 17050-1.

4 Governing of the IECQ Scheme

This document, IECQ 03-2-1, sets out the general rules and procedures of the IECQ Approved Process Scheme for Distributors. 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 – Distributors

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

This IECQ Approved Process Scheme provides the bases for the Distributor Certification and the means for distributors to obtain an IECQ Approved Process – Distributor Certificate that is intended to provide the international market with confidence that a process listed on the IECQ Approved Process – Distributor Certificate complies with the 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.

5.1 The IECQ Approved Process – Distributor Certification is bases its requirements for the conformity of the organization of a distributor on those of the ISO 9001, with the additional requirements in this document. This document shall be read in conjunction with ISO 9001.
5.2 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.

5.3 An organization may operate from more than one location (site) where: each site is capable of demonstrating that it complies with the requirements.

5.4 Where an IECQ AP Distributor is an integral part of the IECQ Approved Component (IECQ AC) supply chain and directly supporting IECQ AC manufactures in the controlled distribution of IECQ AC released product:

- An IECQ Distributor shall comply with the requirements of this publication in particular the detailed duties of the DMR in IECQ 03-1 Table 2.
- The IECQ AP Distributor Certification, where used in direct support of IECQ AC Scheme, shall be issued based on direct fulfilment of the Distributor related requirements of IECQ 03-1, IECQ 03-2, IECQ 03-2-1 and the Attestation of conformity provision IECQ 03-3 Annex B.

Alternatively, an IECQ AP Distributor may be an integral part of a supply chain of other IECQ scheme(s) other than IECQ AC Scheme.

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.

7 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 8.1.4 of IECQ 03-1 and the following as a minimum:

- Clear unambiguous detailed description of the Scope of Activity(ies), (process)
- An “Attached Schedule” to the IECQ Distributor Certificate, utilizing the IECQ Template, shall list the manufacturers who have authorized the distributor to stock, re-pack, release and distribute their approved components.
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 Distributor Certification may be applied to any distributor of electronic components, related assemblies or services. See 5 of IECQ 03-2 for Specialist Contractors.

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 manual relevant to the process of stockholding and distribution for which they are seeking IECQ Approved Process Certification against which it is intended to demonstrate compliance to these rules;
- IECQ Approved Process documented requirements and the resources available to meet the requirements of the process.

8.3 IECQ CB Assessment Team for IECQ Approved Process Assessments
The requirements of 8.3 of IECQ 03-2 apply

8.4 Extension of Scope for IECQ Approved Process certification
The requirements of 8.4 of IECQ 03-2 apply

8.5 Subcontracting in the IECQ Approved Process Scheme
The requirements of 8.5 of IECQ 03-2 apply

8.6 The Requirements of a quality manual
The requirements of 9.2.3 of IECQ 03-1 apply.

8.7 Identification of released lots
The requirements of 8.13.7 of IECQ 03-3 apply

8.8 Validity of release
The requirements of 8.13.2 of IECQ 03-3 apply.

9 Purchasing

In addition to the requirements of clause 9.2.3 Subclause 7.4.2 of IECQ 03-1:

Component distributors shall be authorized by one or more certified manufacturer to stock, re-pack, release and distribute their approved components. A distributor certified under the System is permitted to purchase released components from another certified distributor and deliver them provided that:
- the latter has purchased the components directly from an approved manufacturer, and
both distributors are authorized by the approved manufacturer to deliver the component.

10 Attestation of Conformity

The requirements of Annex B of IECQ 03-3 apply

10.1 General requirements for attestation of conformity

The requirements of Annex B of IECQ 03-3 apply

10.2 Marking of the Packaging

The requirements of Annex B of IECQ 03-3 apply

10.3 Mark of conformity (IECQ’s Mark of Conformity)

The requirements of Annex B of IECQ 03-3 apply

10.4 Supplier’s Declaration of Conformity (SDoC)

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 IECQ’s 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 specification or standard to which the component conforms. If required
   by the national rules, the national number of the 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 reparationed, 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 IECQ 03-3, 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.
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