IEC Quality Assessment System, IECQ

Rules of Procedure –
Part 1: General Requirements for all IECQ Schemes
IECQ PUBLICATION

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Rules of Procedure –
Part 1: General Requirements for all IECQ Schemes
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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 related to the IECQ System management Basic Rules contained in publications (IEC CA 01 + IECQ 01-S), IEC Conformity Assessment Systems – Basic Rules (IEC CA 01) plus the IECQ Supplement (IECQ 01-S) and is a revision of the IECQ General requirements applicable to all IECQ Schemes concerning the issuing and maintenance of IECQ System Certificates, replacing IECQ QC 001002-3 which is hereby withdrawn.

This edition 3.1 is an administrative amendment to update the IECQ title. Edition 3.0 of IECQ 03-1 replaces edition 2.1 of IECQ 03-1. Main changes to this edition include:

- Alignment of the ISO 9001:2015 Clause references

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

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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 System provides 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.

These Rules of Procedure set out the application, assessment and surveillance process for organizations seeking to be assessed, certified and undergo ongoing surveillance under IECQ Certification Schemes by an IECQ CB. This Operational Document (OD) is to be used in conjunction with the IECQ System management Basic Rules contained in publications (IEC CA 01 + IECQ 01-S), IEC Conformity Assessment Systems – Basic Rules (IEC CA 01) plus the IECQ Supplement (IECQ 01-S) and the respective IECQ Certification Scheme Rules of Procedure.

While these Rules of Procedure contain general assessment and surveillance procedures for the certification of an organization, additional requirements beyond those covered here may apply for the respective IECQ Certification Schemes. Such additional requirements are detailed in the relevant Scheme’s Rules of Procedure, e.g. IECQ 03-4, IECQ 03-5, etc.

Further information concerning these procedures or any other aspect of the IECQ System and Scheme, may be obtained by contacting the IECQ Managing Secretary via E-mail.
Rules of Procedure –

Part 1: General Requirements for all IECQ Schemes

1 Scope

1.1 General

This publication contains the General Rules of Procedure for all Schemes of the IECQ System, hereinafter referred to as the "Rules".

These Rules relate to the IECQ System management Basic Rules as listed in the normative references Clause 2 below, (IEC CA 01 + IECQ 01-S).

This publication IECQ 03-1 shall be applicable in conjunction with the new format of IECQ Schemes rules and procedures as published, e.g. IECQ 03-4, IECQ 03-5 etc.

Permissible exclusions, as provided in ISO 9001, are not accepted within the IECQ Schemes and Programmes.

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 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 OD 010, Qualification Criteria for Assessors and Lead Assessors according to IECQ (third-party assessment) – General for all Schemes

ISO 9001, Quality management systems – Requirements

ISO 14001, Environmental management systems – Requirements with guidance for use

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

ISO/IEC 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements

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
3 Terms and Definitions

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

For the purpose of all IECQ Schemes the terms and definitions given in IEC CA 01, IECQ 01-S, IECQ 02 and the relevant IECQ 03-X Rules of Procedures along with the following apply.

3.1 IECQ Schemes
Schemes of the IECQ enable the independent conformity assessment of compliance to the requirements of particular standards and/or specifications.

3.2 IECQ Certification Body Certificate of Acceptance
a document issued under these Rules indicating that adequate confidence is provided that a duly identified Certification Body has been found to operate procedures that provide confidence that the IECQ activities undertaken comply with IECQ rules & requirements.

3.3 Designated Management Representative
a Designated Management Representative (DMR) is a person, acceptable to the IECQ Certification Body (CB), who is a member of the approved organization and who is responsible for liaison with the IECQ CB regarding the approval of that organization. That person is the focus of communication between the IECQ CB and the organization.

3.4 IECQ On-Line Certificate System (On-Line System)
an Internet based live Certificate system that provides for the preparation and issue of IECQ Certificates of Conformity or Approval by IECQ Certification Bodies (IECQ CBs). The IECQ operational document “IECQ OD 015” provides guidance for IECQ Certification Bodies concerning the IECQ On-Line Certificate System. The IECQ On-Line Certificate System can be found on the IECQ website: www.iecq.org

3.5 Applicant
an organization who applies to an IECQ Certification Body (CB) for an IECQ Scheme Certificate of Conformity or Approval.

3.6 full equivalent QMS standard
the standard covers all requirements of ISO 9001. Acceptable equivalent includes IATF 16949, AS 9100, International Railway Industry Standard (IRIS), and TL 9000.

3.7 QMS (Quality Manual / Policy)
This scheme requires an IECQ Quality Manual/Plan. "Equivalent" means the standard in question covers all requirements of ISO 9001 and where indicated an Acceptable equivalent includes although not limited to IATF 16949, AS 9100, International Railway Industry Standard (IRIS).

4 Governing of the IECQ Schemes

All IECQ Schemes will be governed by the IECQ Management Committee (IECQ MC). The responsibilities of the IECQ MC, in this respect, are defined in the IECQ System management Basic Rules.
This document, IECQ 03-1, sets out the common general rules and procedures for all IECQ Schemes and shall be read in conjunction with each IECQ Scheme specific rules and procedures document, e.g. IECQ 03-2, IECQ 03-3, IECQ 03-4, IECQ 03-5, IECQ 03-6, IECQ 03-7 and IECQ 03-8. IECQ Scheme general rules and procedures are supplemented by IECQ Operational Documents (ODs). These Operational Documents are available to all IECQ Member Bodies, IECQ CBs, and Applicants who have applied for an IECQ Certificate.

The Secretary shall be responsible for the issuing and maintenance of Operational Documents which generally fall under the following categories:

a) Document containing explanatory guidance;

b) Document containing rules and procedures that supplement those contained in e.g. IECQ 03-2, IECQ 03-3, IECQ 03-4, IECQ 03-5, IECQ 03-6, IECQ 03-7 and IECQ 03-8, which may include technical requirements.

The IECQ MC shall be kept informed on the currency of Operational Documents with IECQ MC approval required for Operational Documents that fall under category b) above.

5 Principles of IECQ Schemes

IECQ Certificate of Conformity & Approval

5.1 An organization capable of demonstrating that it complies with the requirements shall be entitled to an IECQ Certificate in accordance with these IECQ Scheme General Rules of Procedure, the relevant IECQ Scheme Rules of Procedure and supporting IECQ Operational Documents.

5.2 An organization maybe covered by one certification for more than one location (site) where:

- each individual site shall be capable of demonstrating via annual on-site assessments that it complies with the requirements;
- an IECQ CB shall issue a certificate for each site, identified via the on-line system as an Additional Site certificate linked to the Parent/Master Certificate, in accordance with Annex D;
- the IECQ Scheme Certificate, scope of activity shall be clearly identified and relevant to the activity conducted at that location (site).

5.3 With justification, an organization may utilize one management system on multi-sites, for a definition of “one management system” see Annex D.

5.4 The IECQ Certificate may be issued for a specific area of operation of an organization, as clearly defined in the scope of activity.

5.5 An organization's right to use the IECQ Certificate is not transferable.

6 Confidentiality

All those participating in IECQ Schemes shall respect the confidentiality of any information that they obtain and take all reasonable steps to bind their staff and those working under contract to preserve that confidentiality. The effectiveness of such steps taken shall be evaluated as part of the IECQ assessment of the IECQ CB.

7 Organizational structure

7.1 General

The structure of the System, as defined in IEC CA 01, IECQ 01-S and IECQ 02 comprises

- IECQ Management Committee (IECQ MC)
• IECQ Conformity Assessment Bodies Committee (IECQ CABC)
• IECQ Schemes Administration (IECQ Secretariat)
• IECQ Certification Bodies (IECQ CB)
• Organization (Client)

7.2 Roles and responsibilities

7.2.1 General

The overall responsibility for the functioning of the whole IECQ System is vested in the IECQ MC. The composition roles and duties of the IECQ MC, CABC and Secretariat are defined in IEC CA 01, IECQ 01-S and IECQ 02.

7.2.2 IECQ Certification Bodies (IECQ CBs)

Only IECQ CBs that have been accepted to participate in the IECQ Schemes in accordance with IECQ 02 are permitted to issue IECQ Certificates.

The activities of an IECQ CB cover acceptance of applications seeking IECQ Certification, evaluation, surveillance and certification activities under the IECQ Schemes within their defined geographical areas, for which approval has been granted.

The IECQ CB is responsible for accepting applications, conducting assessments, issuing IECQ certification and the planning and conducting of ongoing surveillance activities in accordance with IECQ Scheme Rules of Procedure and supporting IECQ Operational Documents.

7.2.3 The Organization (Client/Applicant/Certificate Holder)

An Organization shall have the following responsibilities:

a) shall at all times comply with the requirements of the IECQ System and Scheme(s);

b) shall give the representatives of the IECQ CB access, during normal working hours, to the premises and/or sites in which work being performed within the scope of their certification is being carried out for the purpose of examining systems, processes, methods of test, and records. These access rights shall include, where necessary, any agreed visits needed to verify that the procedures for the termination of certification described below have been carried out. The organization shall facilitate any arrangement allowing the IECQ CB to conduct assessment at the supplier upon aspects of operations having influence on the scope of certification;

c) shall nominate a DMR, who shall be responsible for all matters in connection with the requirements of the IECQ Certificate as defined in Annex A;

d) shall upon the termination or suspension of an IECQ Certificate, immediately discontinue the use of the IECQ logo on all materials and refrain from making or implying any statement of IECQ certification or approval. No further release under IECQ can take place.

8 IECQ Certification

8.1 IECQ Certificate for an Organization (Client)

8.1.1 General

The definitive version of the IECQ Certificate is the English language version that appears on the IECQ On-Line Certificate System.

An IECQ CB may provide printed & signed copies of the definitive IECQ Certificate upon request, by utilising the “printable PDF” option in the IECQ On-Line Certificate System. These printed copies may be printed on any appropriate A4 quality paper stock.
An IECQ CB shall not develop or utilize any customized IECQ Certificate templates. The use of local language IECQ Certificates in conjunction with the definitive version is permissible in accordance with 8.1.5.

NOTE IECQ CBs shall consult IECQ OD 015 documents for guidance on generating Certificates in the IECQ On-Line Certificate System. The IECQ Secretariat is available to assist IECQ CBs in use of the on-line system.

8.1.2 Issue

An IECQ CB, on the basis of a satisfactory IECQ Compliance Report and IECQ Site Assessment Report, issues an IECQ Certificate certifying that the organization has developed and implemented procedures and processes which conform with the applicable requirements for IECQ scheme certification which is in accordance with the IECQ System management Basic Rules and these Rules of Procedure.

8.1.3 Layout

The IECQ MC shall decide on the layout and content of IECQ Certificates.

8.1.4 Contents

The IECQ Certificates shall contain at least the following information:

- Date of Issue
- Date of Expiry
- Original Issue Date (noting that it will be the same as the Issue Date for the first issue)
- Indication of the issue & status
- Clear unambiguous detailed description of the Scope of Activity
- The name and address of the organization
- The IECQ CB file reference number
- Name of the issuing IECQ CB
- The address of the IECQ CB – City/Town, State/Province, & Country
- Name of IECQ CB Authorized Person
- Signature of the IECQ CB Authorized Person – only on printed version

8.1.5 Local Language Translations

The definitive version of the IECQ Certificate is in English language. Local language translations of the IECQ Certificate are permissible under the following:

a) shall only use approved & issued IECQ language templates without any alteration;
b) the translated version shall be attached as a PDF document to the definitive internet based “On-Line” Certificate;
c) where such an IECQ local language template does not yet exist the relevant IECQ CB shall in coordination with the secretariat provide a translated template for approval by IECQ CABC;
d) all IEC, IECQ, IECQ HSPM & ECMP acronyms and full text meanings shall remain in the English language;
e) it is the issuing IECQ CB’s responsibility to ensure the local translated version of an issued Certificate is attached to the definitive on-line version and maintained accordingly.
9 IECQ Certification procedure

9.1 General

By submitting an application for an IECQ Certificate for any of the IECQ Schemes, the applicant agrees to comply with the IECQ Scheme Rules including surveillance requirements of the IECQ System, and any special surveillance visits that may be required.

9.2 Applicant

9.2.1 General

The organization shall have developed and implemented an ISO 9001 quality management system (QMS) or equivalent QMS.

Organizations that have already obtained certification from an ISO 9001 Certification Body that has current accreditation by an accreditation body that is a member of IAF (International Accreditation Forum) may not be required to be re-assessed to those requirements for their IECQ assessment where evidence exists that such requirements are duly met and where no Non-Conformances remain outstanding. Such organizations shall submit the most recent report and a copy of the registration Certificate detailing the scope of registration, covering a complete cycle of assessments (all elements of the standard assessed) to the IECQ CB for review. The IECQ CB shall determine which, if any, elements of the standard need to be assessed to achieve the IECQ certification applied for. QMS registrations awarded by unaccredited bodies shall not be taken into account for the purposes of IECQ certification.

Organizations not registered to ISO 9001 or equivalent QMS requirements shall comply with the requirements of the applicable standard. As a result, these organizations shall be required to undergo an assessment to the relevant requirements as part of the initial IECQ assessment, as well as subsequent surveillance assessments to these requirements.

9.2.2 Where ISO/IEC 17025 requirements apply

Organizations that have already obtained an ISO/IEC 17025 accreditation by a Body that is a member of ILAC (International Laboratory Accreditation Co-operation) may not be required to be re-assessed to those requirements for their IECQ assessment where evidence exists that such requirements are duly met and where no Non-Conformances remain outstanding. Such organizations shall submit the most recent report and a copy of the registration Certificate detailing the scope of registration, covering a complete cycle of assessments (all elements of the standard assessed) to the IECQ CB for review. The IECQ CB shall determine which, if any, elements of the standard need to be assessed to achieve the IECQ certification applied for. Laboratory registrations awarded by unaccredited bodies shall not be taken into account for the purposes of IECQ certification.

Organizations not accredited to ISO/IEC 17025, requirements shall comply with the requirements of the applicable standard, as they relate to the specific IECQ Scheme, e.g. Independent Test Laboratory. As a result, these organizations shall be required to undergo an assessment to the relevant requirements as part of the initial IECQ assessment, as well as subsequent surveillance assessments to these requirements.

9.2.3 IECQ Quality Management System requirements

This section sets out the IECQ Scheme(s) general requirements for an organization’s quality management system that relate to all IECQ Certification Schemes. Specific requirements for each IECQ Scheme are included in the Scheme’s specific Rules and Operational Documents, ODs.

This document needs to be read in conjunction with ISO 9001:2015.
The relevant provisions of ISO 9001:2015 shall be met. Implementation of this requirement means that ISO 9001 shall be applicable as far as relevant for the component(s) or the range(s) of activity, technology(ies), process(es) and/or technical service(s) concerned.

While an Organisation is required to comply with the requirements of ISO 9001 it is not a requirement that the company holds separate ISO 9001 certification.

In this Subclause, the numbering follows that of ISO 9001:2015. Where ISO 9001 Clauses are not specifically mentioned, the provisions of those Clauses apply without modification. Where the ISO 9001 Clauses are referenced, the additional requirements of the IECQ are given.

When referencing ISO 9001 it is the 2015 edition that is being referred to unless otherwise stated

ISO 9001:2015, Clause 4 Context of the organization

ISO 9001:2015, Clause 4.3 Determining the scope of the quality management system

The organisation shall ensure that the requirements of relevant IECQ Scheme are incorporated into its quality management system, including when considering specific customer needs

ISO 9001:2015, Clause 4.4 Quality management system and its processes

All the elements, requirements and provisions adopted by the organisation in order to ensure compliance of the component product or process with the specifications as listed on the IECQ Certificate and technical documentation shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of quality programs, plans, manuals and records.

ISO 9001:2015, Clause 5 Leadership

ISO 9001:2015, Clause 5.3 Organisational roles, responsibilities and authorities: Management representative.

In addition to the requirements of ISO 9001, Top Management shall appoint a Designated Management Representative (DMR), responsible for the formal contact point for the IECQ CB. The DMR shall be responsible for:

- all matters in connection with the requirements of the IECQ Certificate as defined in Annex A;
- the effective coordination of activities with respect to the design, manufacture and release of component parts or processes covered by IECQ Certification;
- the resolution of issues related to quality or compliance associated with items or processes covered by IECQ Certification;
- the authorization of initial approval and changes to any related drawings, where appropriate.

ISO 9001:2015, Clause 6 Planning

ISO 9001:2015, Clause 6.1 Actions to address risks and opportunities

The organization shall identify risks to the Processes that may result in non-conformity and apply appropriate measures to control such risks.

ISO 9001:2015, Clause 7 Support

The requirements of ISO 9001 apply along with the following:

ISO 9001:2015, Clause 7.2 Competence

The organization shall ensure that the competences for all personnel involved in the various stages of the Component product manufacture or provision of the process covered by IECQ Certification is appropriate and includes where relevant, the ability to:
a) identify, understand and apply the applicable specification(s);
b) conduct product design and development;
c) qualify and manage external provider(s);
d) qualify new materials;
e) conduct risk analysis on both internal and external provided processes, products, services or materials and the abilities of external providers on compliance control;
f) conduct testing and inspection of products / outputs;
g) communicate with customers and IECQ CB regarding conformity of the products;
h) prepare documented information according to this document and specifications.

EXAMPLE People having impact may include those concerned with manufacturing, inspection, testing, sales, supply management, calibration and control services and other services.

The organization shall maintain and retain documented information on these competences.

NOTE The competence could be collectively possessed by persons of the organization.

ISO 9001:2015, Clause 7.3 Awareness

The organization shall ensure that:

a) top management are aware of the implication of violation of compliance to the specification(s) and rules of the IECQ Certification Scheme(s);
b) persons doing work under the organization’s control are aware of the risks within their processes on compliance of the product and how they contribute to the achievement of the quality and compliance objectives.

ISO 9001:2015, Clause 7.5 Documented Information

The requirements of ISO 9001 apply along with the following:

ISO 9001:2015, Clause 7.5.1 General

The quality management system documentation requirements shall ensure that:

a) Specifications relating to the IECQ Certification are controlled and the IECQ CB responsible for issuing and maintaining the IECQ Certification is informed of critical changes.
b) Documented procedures shall ensure that amendment or changes to drawings and specifications relating to Component products or Processes that are covered by IECQ Certification are not implemented until approved by the IECQ CB that issued the IECQ Certificate;
c) The quality system shall ensure that no factor (type, characteristic, position etc.) covered by IECQ Certification and technical documentation (e.g. schedule drawings) is modified;
d) There shall be a documented system that refers all related drawings to the relevant schedule drawings;
e) For Component Products where there are common schedule drawings associated with more than one component part there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings;
f) For IECQ Approved Component Certificates, the manufacturer shall document which IECQ CB is responsible for each IECQ Certified Component Product;
g) Where equipment documents or manufacturer’s documents are passed to a third party, they shall be provided in a way that is not misleading.

ISO 9001:2015, Clause 7.5.2 Creating and updating

When creating and updating documented information, the organization shall take into consideration, the IECQ Certification requirements and the associated specification(s) regarding the procedures, content and format.
ISO 9001:2015, Clause 7.5.3 Control of documented information

Documented information that provides evidence of continued compliance of the Component product or Certified Process with the Specification shall be maintained and retained to demonstrate conformity of the component product or Process that is covered by an IECQ Certificate.

Documented information shall be maintained and retained for a minimum of one certification cycle (usually 3 years), unless otherwise required by contractual, statutory or legal requirements if applicable or a period not less than the periodic test frequency if this is longer, and access shall be made available to the IECQ CB upon request.

The term "Quality Records" includes documented information related to activities associated with the quality management system as well as to activities covered by IECQ certification.

For IECQ Approved Component Certification, as a minimum, the list of documented information requiring control and retention, as far as applicable, shall be:

- inspection and test data (per batch);
- Information relating to traceability;
- calibration data;
- supplier evaluation.

ISO 9001:2015, Clause 8 Operation

The requirements of ISO 9001 apply along with the following:

ISO 9001:2015, Clause 8.1 Operational planning and control

In planning product realization, the organization shall manage their quality planning.

ISO 9001:2015, Clause 8.3 Design and development of products and services

ISO 9001:2015, Clause 8.3.1 General

Where applicable, requirements for design control shall be implemented in accordance with the specific IECQ schemes rules of procedure e.g. Approved Process or Component Schemes.

ISO 9001:2015, Clause 8.3.2 Design and development planning

The requirements of ISO 9001 apply.

ISO 9001:2015, Clause 8.3.6 Design and development changes

Once an IECQ Certificate is issued covering a Component product or a Process, changes to that Component Product or Process shall not be made without the approval of the IECQ CB that issued the IECQ Certificate.

ISO 9001:2015, Clause 8.5 Production and service provision

ISO 9001:2015, Clause 8.5.1 Control of production and service provision

The requirements of ISO 9001 apply along with consideration of the following Note:

NOTE: Whilst servicing in the form of repair of discrete components are not permitted by the IECQ Rules of Procedure, the concept of "after sales service" is reinforced, that is to say, certified organizations are required to maintain close liaison with customers, to advise on usage applications and to analyse any problems experienced and to assist in the disposal of nonconforming items.

ISO 9001:2015, Clause 8.5.2 Identification and traceability
The organization shall identify the status of outputs with respect to monitoring and measurement requirements.

For IECQ Certified Component Products, the organization shall label / mark products in accordance with the specification.

The organization shall control the unique identification of the individual batches of IECQ Certified Component product and retain documented information. as defined by contractual, statutory or legal requirements to ensure traceability. This documented information shall include documentation and specifications covering materials, production and testing, test results and release data.

ISO 9001:2015, Clause 8.5.4 Preservation

The requirements of ISO 9001 apply along with those contained within the Specification covering the IECQ Certified Component Product or IECQ Certified Process.

The requirements of ISO 9001 apply to IECQ Schemes for both the finished Component product as well as to partly processed materials.

The organization shall preserve the outputs and products to ensure conformity to requirements which include the following:

a) the organization shall protect the characteristic of Component products;
b) the organization shall ensure the integrity of any labelling and identification used to specify the conformity of the Component products;
c) the organization shall ensure the integrity of Component products during handling, use and storage.
d) conforming and nonconforming materials and components products shall be segregated, clearly identified, and handled according to defined processes;
e) intermediate outputs or products are released correctly for production;
f) documented information related to the storage and the use of nonconforming Component products shall be retained.

NOTES:

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

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

2. Attention is drawn to requirements for integral and intimate packaging that may be given in the relevant technical specification.

ISO 9001:2015, Clause 8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that requirements for the IECQ Certified Component product or IECQ Certified Process have been met, and the documented information, identification, suppliers declaration of conformity (SDoC), labelling (where applicable) are attached correctly with the IECQ Certified Component product before release of products and services.

Release of conforming products shall be in accordance with the Manufacturer's specification as covered by the IECQ Certification.

ISO 9001:2015, Clause 8.7 Control of nonconforming product
The requirements of ISO 9001 apply along with the following:

**ISO 9001:2015, Clause 8.7.1** The organization shall identify nonconforming outputs / products, segregate them from conforming outputs / products and prevent them from unintended use or delivery.

Specimens found to be nonconforming during lot-by-lot testing shall be withdrawn from the lot and not delivered. Lots rejected in lot-by-lot testing may be re-submitted in accordance with the relevant sampling procedures, for example IEC 60410, and with the requirements prescribed in the relevant specification controlling the sampling procedure. No inspection lot, or part of it, shall be submitted more than twice-in total to the lot-by-lot testing unless specifically allowed by the relevant Component Products Specification.

When nonconforming outputs are detected after delivery, the organization shall inform customers or notify legal authorities according to legal or customer requirements. Nonconforming products shall be traced and withdrawn from the customer or recalled from the market under request.

External provider(s) associated with the nonconforming outputs shall be identified and informed of the nonconformity to ensure corrective measures are taken.

**ISO 9001:2015, Clause 8.7.2** The organization shall retain documented information that:

a) describes the nonconformity including but not limited to materials and processes;

b) describes relevant external providers and customers identified;

c) describes the actions taken;

**ISO 9001:2015, Clause 9 Performance evaluation**

**ISO 9001:2015, Clause 9.1 Monitoring, measurement, analysis and evaluation**

**ISO 9001:2015, Clause 9.1.1 General**

The use of statistical process control (SPC) is optional for monitoring and measurement of processes.

Product final inspection and testing requirements shall be as defined in the relevant specification. A list of authorized signatories shall be maintained.

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

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

Acceptance criteria shall be as defined in the specification that is covered by IECQ Certification.

The methods used for monitoring, measurement, analysis and evaluation shall ensure valid results.

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

**ISO 9001:2015, Clause 9.1.3 Analysis and evaluation**

Unless specified in the specific IECQ Scheme rules, this requirement of ISO 9001 does not apply.
ISO 9001:2015, Clause 9.2 Internal Audit

The requirements of ISO 9001 apply along with the following:

The organization shall conduct internal audits at planned intervals to provide information on whether the system conforms to the specification and its own requirements and is effectively implemented and maintained.

The audit programme shall be planned, established, implemented and maintained in consideration of the importance of the processes concerned, changes affecting the organization, and the results of previous audits in respect of IECQ Certified Component Products or IECQ Certified Processes.

The frequency with which the processes are audited shall not be less than that of the QMS and at least annually.

Auditors performing the internal audit shall demonstrate knowledge, as well as the ability to apply this knowledge during the internal audit, in the following areas, at a minimum:

a) understanding of the specification;
b) understanding of the IECQ Schemes;
c) understanding the key risks with materials and processes to ensure compliance;
d) understanding of the principles and limitations of the testing and measurement methods used by the organization;
e) understanding of the testing and measurement results obtained by the organization.

Documented information of how this competence is acquired and assessed shall be retained.

ISO 9001:2015, Clause 9.3 Management review

ISO 9001:2015, Clause 9.3.1 General

The requirements of ISO 9001 apply along with the following:

a) The maximum intervals between reviews shall not exceed 12 months.
b) Top management shall chair the review
c) The DMR shall participate in the review

ISO 9001:2015, Clause 9.3.2 Management review inputs

The review shall include the overall effectiveness of the quality management system with respect to IECQ Certified Component Products and IECQ Certified Processes.

NOTE Results of audits should include both internal audits and those conducted by other parties.

ISO 9001:2015, Clause 9.3.3 Management review outputs

The outputs of management review shall include decisions and actions related to:

a) any need for changes to the system to ensure ongoing compliance;
b) resource needs;
c) changes to the competence;
d) changes to the testing, monitoring and measurement equipment.

The results of management review shall be retained as documented information as evidence.

ISO 9001:2015, Clause 10 Improvement

ISO 9001:2015, Clause 10.1 General
The requirements of ISO 9001 apply along with the following:

Repair is defined as the making good of an IECQ Certified Component Product that has been damaged or has become defective after its release. Repair in this instance is not permitted.

**ISO 9001:2015, Clause 10.2 Nonconformity and corrective action**

For the purposes of the IECQ Approved Component Scheme, the requirements of ISO 9001 apply when determining the cause of any non-conformity.

### 9.3 Application

Applications for IECQ Certificates of Conformity are made to any IECQ CB approved in the system for the activity concerned. The application submitted by the applicant shall indicate as a minimum the following:

- accurately identify the intended scope of activity for which certification is applied for;
- the full details of the location(s) where the organization conducts its activities;

The organization seeking approval shall submit or make available the following documentation (non-exhaustive) for review by the assessment team:

- Quality Manual;
- Management Review Procedure;
- Internal Assessment Procedure;
- Corrective/Improvement Action Procedure;
- Registration report(s) covering all Clauses of ISO 9001 or equivalent QMS and/or ISO/IEC 17025 accreditation report (if required).

The documentation may be provided in paper form or electronic format. The electronic format shall be provided in a commonly used file format e.g. PDF.

### 9.4 Assessment Team for IECQ Assessments

The assessment team for IECQ assessments shall be determined by the IECQ CB in accordance with the specific IECQ Scheme rules.

### 9.5 Examination

The IECQ CB assessment team shall conduct a Stage 1 examination of the documentation to verify its compliance with the applicable requirements.

The IECQ CB shall notify the organization if there are any issues that need to be resolved.

The examination of documentation forms part of the assessment and may be conducted either on- or off-site. If conducted off-site due justification shall be documented.

Major non-conformances issued in this stage shall be corrected and the corrective action(s) accepted by the IECQ CB prior to scheduling the on-site assessment. Minor non-conformances may be cleared during the on-site assessment. In all cases the IECQ CB shall verify the non-conformance corrective actions.

Upon satisfactory review of the documentation an assessment plan shall be developed and the assessment shall be scheduled.
9.6 Assessment of IECQ Applicant’s Site(s)

The assessment shall be conducted in accordance with the assessment plan defined by the assessment team and supplied to the Applicant prior to the audit, the requirements of the applicable IECQ Scheme and these Rules of Procedures.

The IECQ CB shall assess the conformity of the Applicants Site(s) quality system and associated IECQ Scheme related procedures and processes for compliance with the relevant IECQ Scheme requirements.

The IECQ CB shall issue a finalized Site Assessment Report (SAR), only when full conformity with the IECQ Scheme requirements has been established. The IECQ CB may use its own reporting system, which incorporates as a minimum the IECQ SAR requirements, where one exists for a specific Scheme, in accordance with their Quality Management System and accreditation requirements.

The basis of all assessments is to seek evidence of compliance with requirements. The approach to assessment being that decisions shall be either “comply”, “does not comply” or “not applicable”. Selection / use of “not applicable” shall be justified in the report.

During an assessment, it is permissible and encouraged for the assessment team to review areas of potential non-compliance with the organization. As part of this review, it is appropriate to discuss options for obtaining compliance.

It is possible that during an assessment it becomes clear to the assessment team that the organization being assessed is not prepared for an IECQ Scheme assessment. With the agreement of the organization being assessed, the assessment team is empowered to change the session to a pre-assessment session for the remainder of the authorized time. All other terms of the agreement between the IECQ CB and the organization being assessed remain the same.

At the completion of the assessment, and generally prior to leaving the site, the assessment team shall provide the DMR with an assessment report, including the team's findings and any action requests generated during the evaluation which itemize non-conformities uncovered during the assessment. Where the assessment team identify areas where a review of a particular aspect would provide benefit these are identified in the observations, except where excluded by a specific IECQ Scheme. It is permissible for the team to provide a brief or handwritten report prior to leaving the site, however the formal draft or if appropriate finalized assessment report shall be issued not later than 4 weeks after the site visit.

9.7 Completion (Granting of Certification)

Following the assessment, the relevant assessment information, including a Draft copy of the relevant IECQ Scheme Certificate, shall be reviewed by the IECQ CB for a certification decision, in accordance with IECQ Operational Documents. The certification decision shall be notified to the applicant along with a copy of the Draft IECQ Certificate for their review and acceptance.

Certification is granted only if the organization evaluated meets all the applicable IECQ scheme requirements for the intended scope of activity for which certification is applied for, as stated by the organization in their application, see 9.3. The organization shall respond directly to the IECQ CB regarding any non-conformities determined during the assessment. If the non-conformities are not satisfactorily resolved, the IECQ CB shall provide an explanation of the reasons for rejection. If necessary, arrangements shall be made for a follow-up assessment.

Upon satisfactory completion of the work, the IECQ CB shall:

a) issue the finalized SAR to the applicant;

b) where requested by the applicant, issue a printed & signed copy of the definitive IECQ Certificate in accordance with 8.1.
9.8  Surveillance

9.8.1  General

Certification shall be maintained through a programme of periodic surveillance assessments conducted by the IECQ CB that issued the IECQ certification, during which relevant quality system and associated relevant IECQ Scheme procedures and processes are audited to ensure continued compliance with the requirements.

The surveillance assessments shall include on-site assessments at all the organization’s certified location(s), except where alternate assessment arrangements are allowed for in the scheme specific rules. Each separate Certificate held by the organization will require a surveillance assessment.

Note: An example of where alternate assessment arrangements are allowed under scheme specific rules is in IECQ 03-4 subclause 4.6 that currently allows surveillance via a combination of on-site and electronic communications assessments.

There shall be no unannounced on-site assessments.

The frequency of such surveillance, inspection, assessment and testing shall be determined by the IECQ CB; they shall not be greater than annually (12 Months apart). Such frequency shall take into account whether the organization holds current ISO 9001 certification/registration by an accredited Certification body.

9.8.2  Special Surveillance

A special surveillance visit shall be conducted by the IECQ CB in situations where:

- an organization has relocated;
- an organization has been taken over or acquired by another organization which may have resulted in changes to personnel, management and/or management system procedures;
- an organization changes it’s DMR; The IECQ CB will determine if a special surveillance visit is to be conducted when an organization changes it’s DMR.
- the IECQ CB has just cause for concern regarding an organization’s continued compliance with the relevant IECQ Schemes requirements.

The IECQ CB will determine if a special surveillance visit is to be conducted when an organization changes it’s DMR.

9.9  Changes

If the IECQ Certified Organization wishes to make any significant changes in the application of the IECQ Scheme requirements or processes controlled by the IECQ Scheme requirements that may compromise the IECQ Certification, the DMR shall notify the applicable IECQ CB in advance.

9.10  Ensuring conformity

The IECQ Certified Organization has the responsibility to ensure that all IECQ Scheme activities as detailed in their scope of activity are conducted in accordance with IECQ Scheme requirements. The IECQ Certified Organization shall ensure that the IEC IECQ logo is not subjected to misuse or misrepresentation. Such misuse or misrepresentation could lead to suspension or withdrawal of the Organization’s IECQ Certificate.
9.11 Documentation retained

In placing an application with an IECQ CB, the Organization authorizes the IECQ CB to keep, for future reference, photographs and technical documentation of the Organization. Such reference material shall be confidential.

9.12 Renewal of the Certificate of Conformity (Recertification)

IECQ Certificates shall be renewed at least once every three years, unless the termination rights provided for in the IECQ Basic Rules and Rules of Procedure are exercised. If an organization does not intend to renew its certification, it shall notify the IECQ CB in writing of its intentions not less than 60 days prior to its renewal date.

Renewal of the IECQ Certification / Approval at the three-year interval shall be on the condition of a successful recertification audit and that all scheduled surveillance assessments have been successfully completed.

A recertification audit shall be planned and conducted to evaluate the continued fulfilment of all the requirements of the relevant IECQ Scheme. The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the implemented processes and procedures to the IECQ Scheme requirements as a whole, and its continued relevance and applicability for the scope of certification.

Recertification audit activities may need to have a detailed document review (stage 1 audit) in situations where there have been significant changes to the management system or implemented processes and procedures, the client, or the context in which the management system or the implemented processes and procedures are operating (e.g. changes to legislation).

All sites covered by the IECQ Certification / Approval shall be assessed.

Note see ISO/IEC 17021 “Recertification” for further guidance.

9.13 Suspension or Cancellation (withdrawal)

An IECQ Certificate shall be suspended or cancelled by the issuing IECQ CB if:

- there is non-payment of outstanding fees;
- it has been issued in error;
- the holder requests cancellation;
- it is used in a misleading way, the IECQ Certificate shall be suspended with the possibility of cancellation if the Organization fails to take corrective action in this respect within 2 weeks of being requested to do so by the issuing IECQ CB;
- the IECQ Certified Organization no longer complies with the IECQ Scheme requirements; or
- the IECQ Organization’s quality system, associated procedures or processes no longer provide adequate confidence that their scope of activities can be conducted in accordance with IECQ Scheme requirements.

If the causes that may justify a CB to consider the cancellation of the IECQ Certificate are temporary, and it is demonstrated that the causes may be remedied after a brief delay (normally not exceeding one month), then an IECQ Certificate shall be suspended by the issuing IECQ CB as opposed to being cancelled.

The cancellation of an IECQ certificate by a CB is considered as a permanent change of status and shall not be reinstated, unless provided for in subsequent IECQ 03-x rules of procedure relating to a specific IECQ scheme.
The IECQ CB shall give due notice to the IECQ Certificated Organization of such suspension or cancellation and shall give the reason(s).

When an IECQ Certificate is suspended or when it has been cancelled, the Organization shall no longer describe their organization, as "IECQ Certified", nor shall they use the IECQ logo or marks of conformity related to the IECQ AC scheme.

The IECQ CB shall ensure that all suspensions and cancellations of IECQ Certificates are recorded in the IECQ On-line Certificate System in accordance with IECQ OD 015.

9.14 Reinstatement of IECQ Certificates

A Suspended IECQ Certificate shall only be reinstated once all causes have been resolved in full and that the issuing IECQ CB is adequately confident that the organization's scope of activities can be conducted in accordance with IECQ System / Scheme requirements.

The IECQ CB shall ensure that all reinstatements of suspensions of IECQ Certificates are recorded in the IECQ On-line Certificate System in accordance with IECQ OD 015.

9.15 Notification of cancellation

When an IECQ Certificate has been cancelled, the issuing IECQ CB shall notify the IECQ Secretary as soon as possible. Cancellation of IECQ Certificates is recorded on-line in accordance with IECQ OD 015.

9.16 Compliance with rules

The applicant shall follow the rules of procedure of the IECQ CB and shall confirm readiness to comply with all the relevant provisions regarding, for example, on-site assessment visits and payment of fees.

9.17 Appeals

Should an IECQ Certified Organization or applicant be refused the issuing of an IECQ Certificate or be the subject of suspension or cancellation of an IECQ Certificate and disagree with this decision they may lodge an appeal to the IECQ Board of Appeals only after lodging a formal appeal through the IECQ CB's own appeal procedures.

Applications for IECQ appeals are made in accordance with IEC CA 01 and IECQ 01-S.

9.18 Transfer of Certificate of Conformity

Should there be a desire for an IECQ Certificate holder company to transfer their IECQ Certificate from their Certificate issuing IECQ Certification Body to another IECQ Certification Body, the following shall apply.

- Formal application shall be submitted by the applicant to the newly selected IECQ Certification Body in accordance with 9.2 & 9.3
- The IECQ Certification Body receiving the application shall obtain a full copy of the latest IECQ surveillance assessment report from the customer and conduct a formal technical review, ensuring there are no outstanding NCRs
- Where the technical review of the latest surveillance assessment report confirmed no outstanding NCRs then a new Certificate maybe issued covering the scope of activity & site(s) listed in the assessment report without the need for a site visit
Note the new Certificate shall line up with the time frame of the previous issued Certificate for the next surveillance visit & expiration date, i.e. as a minimum the “Original Issue” and “Expiration” dates shall match that of the previous held IECQ Certification.

- Where at the end of the technical review of the latest surveillance assessment report NCRs are revealed, these shall be closed prior to the issuing of a new Certificate. This may require a site visit depending on the severity of the NCRs
- Once the application has been completed and a new Certificate has been issued the customer shall formally notify the original Certificate issuing IECQ Certification Body that annual surveillance is no longer required and that they wish to cancel their Certificate
- The IECQ Certificate Body shall immediately send a cancellation request including complete details and effective date to the IECQ Secretariat

10 Acceptance of IECQ Certification Bodies (IECQ CB)

General

New IECQ CBs or existing IECQ CBs seeking to participate in the IECQ Scheme(s) shall comply with the general requirements of IECQ 02 along with any additional requirements in the individual scheme rules & procedures.
Annex A
(normative)

Requirements for Designated Management Representative (DMR)

A.1 The organization's Designated Management Representative (DMR) and, if applicable, the organization's Local DMR shall be acceptable to the IECQ CB as both technically and administratively competent for the purposes of the System.

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

A.2 In addition to being responsible for maintaining liaison with the IECQ CB, the DMR shall have defined authority for ensuring that the organization complies with the requirements of the System. The DMR's duties, associated with requirements of the System, are summarized in Table 1. When applicable, these duties may be delegated to the Local DMR at a remote site to which approval has been extended, however they shall report to the organization's DMR for these matters.
Table 1 – Summary of Designated Management Representative’s duties

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

ITL* = Independent Testing Laboratory
Annex B
(normative)

Evaluation of Suppliers

a) The evaluation shall be made by one or more of the following methods:
   • the supplier has third party quality system certification to the appropriate standard and scope issued by an accredited body which can demonstrate that it operates in compliance with ISO/IEC 17021. This can be achieved by an accredited certification;
   • a documented evaluation which provides objective evidence that the supplier can provide product, process or service that are fit for purpose;
   • a documented site assessment to ensure that all relevant controls are available, documented, understood and effective.

   NOTE The evaluation should take the following into account:
   • criticality of the product, process or service;
   • degree of difficulty, or variability in the manufacturing process;
   • location of the supplier and hence the effectiveness of communications;
   • does the supplier, in turn, sub-contract the product, process or service.

b) Suppliers providing calibration services shall be evaluated on their ability to meet stated requirements.

c) Where the specification for supplied components, materials, processes & assemblies cannot be verified at a later or final stage, then the evaluation shall include initial and periodic site assessments at the supplier’s premises to ensure relevant controls are available, documented, understood and effective.

d) Suppliers not used for a period exceeding one year shall be re-evaluated prior to the placing of the contract.

   NOTE "re-evaluation" means to treat the supplier as a new supplier and therefore 9.2.3 Subclause 7.4.1 b) is applicable.

e) Requirements 9.2.3 Subclause 7.4.1 b) and Annex B d) are not mandatory for products, processes or services where the manufacturer fully verifies each item for conformance.

f) The on-going ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year.

NOTES
1 "review" is a process by which the manufacturer demonstrates the ongoing suitability of their suppliers e.g. receiving inspection report analysis.
2 The terms "re-evaluation" and "review" are different and should not be mixed.
IECQ policy on uncertainty of measurement and inset limits

C.1 Objective

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

The purpose of this Annex is to define mandatory IECQ policy on the calculation of measurement uncertainty and in setting limits to ensure uniform implementation of the rules of IECQ. The special case of outset limits is also covered.

C.2 Definitions

C.2.1 uncertainty of measurement
a statement of the limits of the range within which the true value of the measurement is expected to lie in relation to the recorded result with a defined confidence level

C.2.2 measuring equipment
all of the instruments which are necessary in order to carry out a measurement. The definition makes it clear that items such as cables, connectors, handlers, handler cards or other fixtures used in conjunction with a measurement indicating instrument are subject to the requirements of this policy

C.2.3 inset limits
tightened limits resulting from an allowance applied to the specified limits of a parameter to take into account all influence quantities on the indication of a measuring instrument so as to ensure that out of limit devices are not accepted due to measurement errors

C.2.4 outset limits
relaxed limits resulting from an allowance applied to the specified limits of a parameter to take into account all influence quantities on the indication of a measuring instrument so as to ensure that in limit devices are not rejected due to measurement errors

C.3 Calculation of measurement uncertainty

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

1) identification of possible error contributions;
2) quantifying the size of each listed contribution;
3) calculating the total uncertainty of measurement.
C.4 Policy

C.4.1 A measurement uncertainty value shall be calculated for each performance requirement which is related to IECQ Approved Process, IECQ Approved Component / Products or Related Materials, screening, lot-by-lot and periodic tests as defined by the specifications of the IECQ System.

C.4.2 Each measurement uncertainty value shall be used to apply an inset, of at least this value, to the relevant specification limits as defined in C.4.1.

C.4.3 This inset shall be applied in accordance with C.5.2 for manufacturers and C.5.3 for CBs.

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

C.5 Calculation of inset and outset Limits

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

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

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

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

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

C.6 Examples

Setting “inset limits” and “outset limits”

C.6.1 Example 1: Resistor Measurement

<table>
<thead>
<tr>
<th>Specified resistance value:</th>
<th>100 ohms ± 10% = 90 ohms to 110 ohms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertainty of measurement calculated to be:</td>
<td>±1.2% = ±1.08 ohms and ±1.32 ohms</td>
</tr>
<tr>
<td>Inset Limits:</td>
<td>91.08 ohms to 108.68 ohms</td>
</tr>
<tr>
<td>Outset Limits:</td>
<td>88.92 ohms to 111.32 ohms</td>
</tr>
</tbody>
</table>
C.6.2 Example 2: Resistor Measurement

Initial measurement: 105,0 ohms
Specified resistance value: \( \leq 0,5 \% = \pm 0,53 \text{ ohms} \)
Uncertainty of measurement calculated to be: \( \pm 0,1 \% = \pm 0,10 \text{ and } \pm 0,11 \text{ ohms} \)
Inset Limits: 104,57 ohms to 105,42 ohms
Outset Limits: 104,37 ohms to 105,64 ohms

C.6.3 Example 3: Transistor Measurement (gain)

Specified limits: \( 60 \leq h_{21E} \geq 80 \)
Uncertainty of measurement calculated to be: 5
Inset Limits: 65 to 75
Outset Limits: 55 to 85

C.6.4 Example 4: Comparison between initial and final measurement results

Initial measurement: 102,05 \( \mu \text{F} \)
Specified tolerance: Variation @ 1 \%
Uncertainty of measurement calculated to be: 0,1 \%
Inset Limits: 101,13 \( \mu \text{F} \) to 102,97 \( \mu \text{F} \)
Outset Limits: 100,93 \( \mu \text{F} \) to 103,17 \( \mu \text{F} \)

C.7 References (Information only)

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

Standard ECMA–181, *Uncertainty of measurement as applied to type approval of products* (issued by ECMA TC 12).
Annex D
(normative)

Definition of “one management system”

One management system on multi-sites comprises:

- one set of management system procedures throughout all locations;
- one ultimately responsible DMR;
- central control of internal audit program, investigation of root causes, and deployment of corrective/preventive actions; and
- central management review;
- central management of complaint handling.

NOTE 1  Each location could have its own local management representative for local operation, but there should be an ultimate DMR responsible for the compliance of the entire system.

NOTE 2  Similarly for internal audit and management reviews. Due to geographical separation or travelling restrictions (e.g. visa issue), internal audits or management review could be performed locally but the ultimate DMR should be well aware of the results and the corrective/preventive actions are deployed throughout the entire system.

One management system with multi-site requirements includes:

- all locations involved are subject to the same set of requirements or specifications;
- the sites together form one complete homogeneous production stream if the sites are located in different countries/areas; and
- these sites together form one application/registration.

NOTE 1  One complete production stream means that although each location individually may be responsible for one or more processes (e.g. sales, R&D, moulding, painting, PCB assembly, etc), all locations must be put together to complete the final product.

NOTE 2  Example "same set of requirements or specifications", For IECQ HSPM Scheme this would mean "same set of HS requirements."

Treatment of multi-sites:

- all locations will be assessed to all clauses annually, no sampling allowed;
- each location must have its own Certificate of Conformity;
- the scope of activity for each site shall clearly be identified on each site certificate; and
- the IECQ scope is identical on all Certificates of Conformity.

Master site is regarded as the head office of the organisation where the management system is controlled and shall be identified at all times.