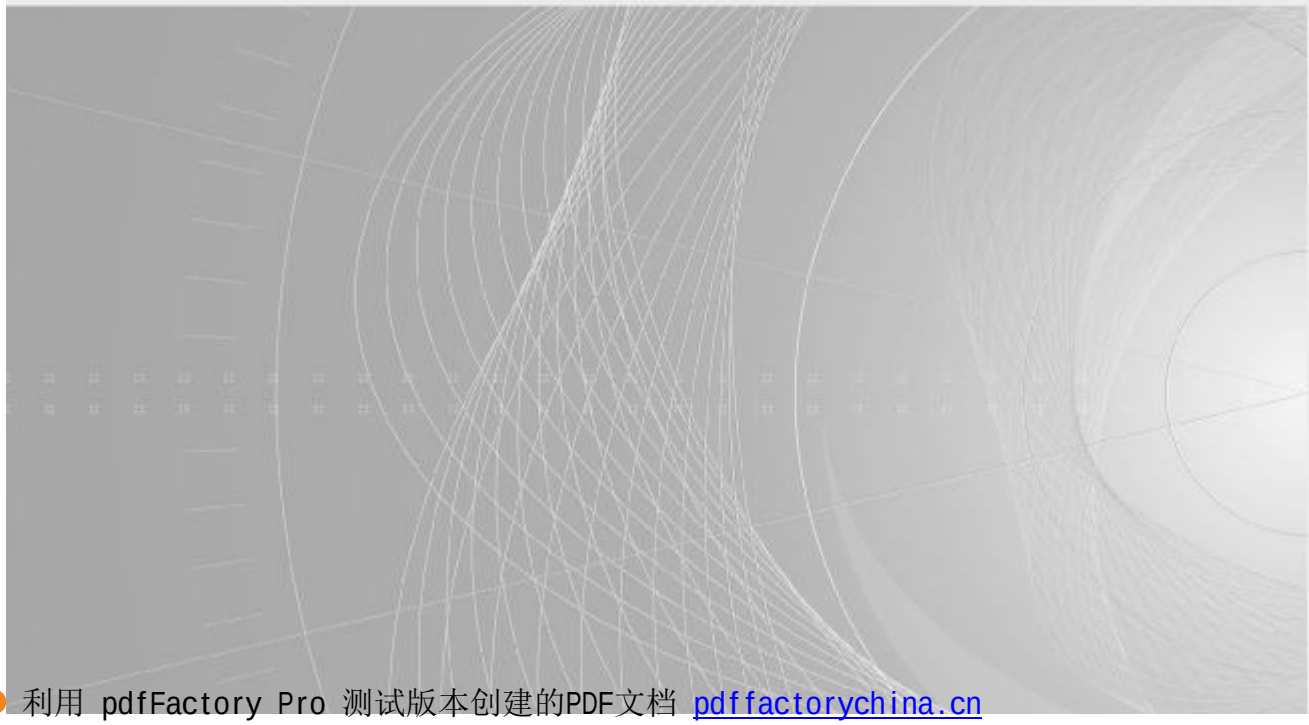
IECQ 03-6

Edition 2.0 2012-09

IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ System)

Rules of Procedure –
Part 6: IECQ ITL Scheme – Independent Testing Laboratory Assessment Program Requirements



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INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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

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

This second edition of IECQ 03-6 replaces the first edition IECQ 03-6. Main changes to the second edition include:

– Inclusion of requirements for organizations operating from more than one location (site),
– Inclusion of requirements for organisations utilizing one management system on multi-sites,

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

Document	Report on MC Consultation
IECQ MC/236/CA	MC/255A/R

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

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INTRODUCTION

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

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

The IECQ 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 sets out the application, assessment and surveillance process for independent testing laboratories seeking to be assessed, approved and undergo ongoing surveillance under the IECQ Independent Testing Laboratory (IECQ ITL) Approval Scheme by an IECQ CB.

The IECQ ITL Approval is available to independent testing laboratories intending to carry out tests in support of IECQ activities within the IECQ System. The approval covers the type of tests to be carried out, the component/product/material ranges/criteria to be tested and the facilities available, and exceeds the relevant requirements of ISO/IEC 17025.

In order to gain approval, independent testing laboratories must demonstrate that their organizations and facilities comply with IECQ requirements for the competence of staff and adequacy of testing facilities, and for performing their functions under the IECQ System. Account is taken of any existing and relevant accreditation.

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.

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RULES OF PROCEDURE – Part 6: IECQ ITL Scheme – Independent Testing Laboratory Assessment Program Requirements

1 Scope

This publication contains the Rules of Procedure of the Scheme of the IECQ, hereinafter referred to as the "Rules", for the Independent Testing Laboratory Scheme (IECQ ITL Scheme).

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

2 Normative references

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

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

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

IECQ OD 010, *Qualification Criteria for Assessors and Lead Assessors according to IECQ (third-party assessment)*

QC 001002-2, *IEC Quality Assessment System for Electronic Components (IECQ) – Rules of Procedure – Part 2: Documentation*

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

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

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

3 Terms and Definitions

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

For the purpose of all IECQ Schemes the terms and definitions given in IECQ 01 and the following apply.

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3.1
IECQ ITL Scheme
process of the IECQ System that provides for the independent conformity assessment of a testing laboratory (ITL) for compliance with ISO/IEC 17025 and IECQ Requirements within a given scope in support of IECQ activities

3.2
IECQ Certification Body (IECQ CB)
a body which has been accepted according to these Rules and which issues IECQ Certificates of Approval

4 Governing of the IECQ Schemes

This document, IECQ 03-6, sets out the Rules and Procedures for the IECQ ITL Scheme. These 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.

5 Principles of IECQ ITL Scheme

In addition to the requirements in Clause 5 of IECQ 03-1 the following applies.

IECQ ITL Certificate of Approval

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

5.1 An independent testing laboratory wishing to become an approved testing laboratory under the System in order to carry out tests on components within the System whom is capable of demonstrating that it complies with the requirements shall be entitled to an IECQ ITL Certificate in accordance with these Rules of Procedure, and supporting IECQ Operational Documents.

5.2 IECQ ITL scheme certificates of approval scope of activity; while multi site arrangements may exist with separately located ITL locations operating to a common management system, a separate certificate shall be issued for each site, with a clear description of the capability of that site being recorded on the certificate.

5.3 The IECQ Certificate may be issued for a specific area of operation of an independent testing laboratory, as clearly defined in the scope of activity.

5.4 An independent testing laboratory's right to use the IECQ Certificate is not transferable.

6 Roles and responsibilities

The Independent Testing Laboratory

An independent testing laboratory shall have the following responsibilities:

a) shall at all times comply with the requirements of the IECQ 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 independent testing laboratory 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;

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c) shall nominate a DMR, who shall be responsible for all matters in connection with the requirements of the IECQ Certificate as defined in IECQ 03-1 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.

7 IECQ ITL Approval Process

7.1 General

Clause 4 of IECQ 03-1 applies.

This document IECQ 03-6, sets out the general rules and procedures of the IECQ ITL Scheme. These general rules are supplemented by the Scheme's Operational Documents. These Operation Document are available to all IECQ Member Bodies, IECQ CBs, and Applicants who have applied for an IECQ ITL Certificate of Approval.

7.2 Technical competence

In addition to the requirements in Clause 9.2.2 of IECQ 03-1 the following applies.

This document shall be read in conjunction with ISO/IEC 17025.

The relevant provisions of ISO/IEC 17025 shall be met. Implementation of this requirement means that ISO/IEC 17025 shall be applicable as far as relevant for the component(s) or the range(s) of activity, technology(ies), process(es) and/or technical service(s) concerned.

In this Subclause, the numbering follows that of ISO/IEC 17025:2005. Where ISO/IEC 17025 Clauses are not specifically invoked, the provisions of those Clauses apply without modification. Where the ISO/IEC 17025 Clauses are referenced, the additional requirements of the IECQ are given.

4.1 (and 4.1.5 c & i) Organization

The Designated Management Representative (DMR), who may also be the 'Technical Manager' of the laboratory, provides a formal contact point for the IECQ CB to enable the resolution of issues related to quality. See Annex A and Table 2 of IECQ 03-1 for additional IECQ provisions related to the activities of the DMR, a position comparable to that of the 'Technical Manager' of the laboratory.

4.2 Quality System

The Quality Manual or supporting documentation shall include any mandatory requirements for IECQ schemes. For guidance, see ISO 10013, *Guidelines for developing Quality Manuals*.

4.5 Subcontracting of tests and calibrations

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

- the required service is not available from any approved independent testing laboratory within the System;
- the approved independent testing laboratory demonstrates to the IECQ CB that other approved independent testing laboratories known to be operating in the relevant area of technology are unable to undertake the specified testing. When invoking these provisions, the approved independent testing laboratory shall produce a document which describes the surveillance arrangements by which it can be ensured that the testing to be carried out shall comply with the specification. Where possible the nominated testing laboratory shall be approved to ISO/IEC 17025 by a nationally recognized laboratory accreditation body. The document shall define how the nominated testing laboratory;

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- ensures that its relevant staff possesses the necessary competence and its relevant facilities are completely adequate for the purpose of the subcontracted testing;
- proposes to operate the subcontracted testing; and
- ensures that it has an adequate System for the calibration of its relevant measurement and test equipment and can provided adequate traceability to national standards.

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

4.12 Control of records

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

5.4 Test and calibration methods and method validation

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

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

5.5 Equipment

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

5.8 Handling of test and calibration items

Product identification and traceability are specified requirements of the IECQ in accordance with the relevant IECQ Scheme rules of procedure. Where relevant, particular requirements are given in specifications for the following:

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

5.10.3 Test reports

Guidance for the determination of the uncertainty of measurement in accordance with ISO 10012-1 are given in IECQ 03-1, Annex C. Acceptance criteria shall be defined in the applicable specification. Where applicable, a regional or internationally recognized specification shall be used for parts per million (ppm) Systems, Assessed Process Average, etc.

7.3 Application

An organization may make an application for an IECQ ITL Certificate to any IECQ CB that has been accepted for this purpose by IECQ MC.

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

- accurately identify the intended scope of activity for which certification is sought;
- the type(s) of tests it wishes to carry out on components under the System;

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- the location of the testing laboratory (laboratories), or part thereof, for which approval is sought. A separate application shall be submitted for each location; and
- that it has prepared the required documentation as a basis for the appraisal by the IECQ CB and has available the resources to meet the requirements of the System.

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

a) Quality Manual
b) Management Review Procedure
c) Internal Assessment Procedure;
d) Corrective/Preventive Action Procedure
e) Registration report(s) covering all Clauses of ISO/IEC 17025 accreditation report (if required)

The documentation may be provided in paper form or electronic format. If electronic format is used, it shall be provided in a commonly used file format as determined by the IECQ MC, e.g. PDF or TIF.

7.4 Assessment of IECQ Applicant's Site(s)

In addition to the requirements 9.4 of IECQ 03-1 the following applies.

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 these Rules of Procedures.

The IECQ CB shall assess the conformity of the Applicants Site(s) quality system and IECQ ITL Scheme related procedures and processes for compliance with the requirements. This shall include but not be limited to

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

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

The IECQ CB shall issue a finalised Site Assessment Report (SAR), only when full conformity with the IECQ Scheme requirements has been established. Where an IECQ SAR format exists for a specific Scheme this shall be used, where not available then the IECQ CB shall issue such a report in accordance with their Quality Management System and accreditation requirements.

The basis of all assessments is to seek evidence of compliance with requirements with the approach to assessment being that decisions shall be either "comply" or "does not comply".

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 ITL 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.

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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 nonconformities 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. It is permissible for the team to provide a brief or hand written report prior to leaving the site, however the formal draft or if appropriate finalised assessment report shall be issued not later than 4 weeks after the site visit.

7.5 Completion (Granting of the IECQ Certificate)

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

An IECQ Certificate is granted only if the organization evaluated meets all the applicable IECQ ITL scheme requirements for the intended scope of activity that is sort, as stated by the organization in their application, see 7.3. 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 finalised SAR to the applicant;

b) where requested by the applicant, issue a printed & signed copy of the definitive IECQ Certificate in accordance with IECQ 03-1.

7.6 Surveillance

In addition to the requirements of 9.8 IECQ 03-1 the following applies.

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/IEC 17025 accreditation by an accredited body.

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