

IECQ PUBLICATION

IEC Quality Assessment System for Electronic Components (IECQ System)

Rules of Procedure –

Part 1: General Requirements for all IECQ Schemes

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

Rules of Procedure –

Part 1: General Requirements for all IECQ Schemes

FOREWORD

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

This publication is related to Publication IECQ 01 containing the Basic Rules of the IECQ System and is a revision of the IECQ General requirements applicable to all IECQ Schemes and is considered a revision in-part of IECQ QC 001002-3 concerning the issuing and maintenance of IECQ System Certificates.

This second edition of IECQ 03-1 replaces the first edition IECQ 03-1. Main changes to the second edition include:

- Inclusion into the General requirements for all IECQ Schemes – requirements for organizations operating from more than one location (site),
- Inclusion into the General requirements for all IECQ Schemes – requirements for organisations utilizing one management system on multi-sites,
- Clarification on the use of IECQ Site Assessment Reports,
- Clarification on the Renewal of the Certificate of Conformity (Recertification),
- Clarification on the use of Suspension and Cancellation (Withdrawal),
- Inclusion into the General requirements for all IECQ Schemes – requirements for the Reinstatement of IECQ Certification,
- Clarification on Transfer of Certificate of Conformity,
- Update of Table 2,
- Inclusion into the General requirements for all IECQ Schemes – Annex D (normative) Definition of “one management system”
- Requested changes from WG4

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

Document	Report on MC Consultation
IECQ MC/231A/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.

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 OD is to be used in conjunction with the IECQ Basic Rules, IECQ 01 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 03-5

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 1: General Requirements for all IECQ Schemes

1 Scope

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

These Rules relate to the Basic Rules of the IECQ System, as given in Publication IECQ 01.

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.

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)*

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, *Conformity assessment – Requirements for bodies providing audit and certification of management systems*

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

ISO/IEC 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, IECQ 02 and 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 <http://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

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 Basic Rules of the IECQ System, Publication IECQ 01.

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 and IECQ 03-6. 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 and IECQ 03-6, 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 IECQ 01 comprises

- Management Committee (MC)
- Conformity Assessment Bodies Committee (CABC)
- IECQ Schemes Administration (Secretariat)
- Certification Bodies (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 MC. The composition roles and duties of the IECQ MC, CABC and Secretariat are defined in IECQ 01.

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 Basic Rules IECQ 01 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, 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) requirements for an organization's quality management system.

This document needs to be read in conjunction with ISO 9001.

The relevant provisions of ISO 9001 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.

In this Subclause, the numbering follows that of ISO 9001:2008. Where ISO 9001 Clauses are not specifically invoked, the provisions of those Clauses apply without modification. Where the ISO 9001 Clauses are referenced, the additional requirements of the IECQ are given.

4.1 General requirements

This document specifies particular requirements and guidance on the establishment and maintenance of a quality system to meet the requirements of the IECQ System. It does not preclude the use of other quality systems that are compatible with the objectives of ISO 9001, subject to the acceptance of an IECQ CB.

Therefore, IECQ CB assesses the quality systems of organizations with respect to this document. This document shall be the basis of the initial assessment and subsequent surveillance visits.

4.2.2 Quality manual

Exclusions that are permitted under Clause 7 of ISO 9001:2008 are restricted under the IECQ, dependent on the approval required. Details are given in Table 1 of this Clause.

4.2.4 Control of records

The term "Quality Records" includes records related to activities associated with the System as well as to activities covered by approvals against the requirements of ISO 9001. These 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.

5.5.2 Management representative

The Designated Management Representative (DMR) is the formal contact point for the IECQ CB. The DMR facilitates the resolution of issues related to quality. See Annex A and Table 2 of this document for additional IECQ provisions.

7.2 (and 5.2) Customer-related processes (and customer focus)

The purchaser's (customer's) requirements, as reflected in the contract, shall refer to the relevant System documents or Customer Detail Specifications where these exist. They may, alternatively, refer to appropriate regional or internationally recognized publications. The organization shall establish and maintain documented procedures for contract review and for the coordination of these activities.

7.3.1 (and 7.1) Design and development planning (and planning of product realization)

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

7.3.6 (and 7.1) Design and development validation (and planning of product realization)

The requirements of the Approved Process or Component Schemes embrace the requirements of Clause 7.3.6 of ISO 9001:2008 for design validation.

7.4 Purchasing – Exclusions not permitted in IECQ

7.4.1 Purchasing process

- a) While manufacture, test and final inspection may be sub-contracted, the responsibility for ensuring conformance with components, materials, processes & assemblies covered by a defined specification shall not be sub-contracted.
- b) Suppliers providing a component, materials, process, or service that can affect the component or products compliance with the a defined specification shall only be selected after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements. See Annex B for guidance.

7.4.2 Purchasing information

Purchasing data may be prepared jointly with the subcontractor and shall be clearly defined technically (for example, in a Customer Detail Specification) in order to ensure the quality of purchased products and services.

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.

7.4.3 Verification of purchased product

The System requires the supplier to verify the satisfactory maintenance quality control procedures performed by their subcontractor.

7.5.1 Control of production and service provision – Exclusion not permitted in IECQ

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

7.5.3 Identification and traceability – Exclusion not permitted in IECQ

The organization shall establish procedures and maintain records for identifying individual batches of product for a minimum period (from the date of product release) of two years, or a longer period as defined by contractual, statutory or legal requirements. These records shall include documentation and specifications covering materials, production and testing, test results and release data.

Further technologically-specific requirements shall be given in the relevant Generic Specification or Process Assessment Schedule. Reference shall be made to appropriate marking requirements.

Release of conforming products shall be in accordance with the System requirements for Certificates of Approval and Attestation of Conformity.

7.5.5 (and 8.3) Preservation of product (and control of nonconforming product) – Exclusion not permitted in IECQ

Customer (purchaser) supplied product is material (e.g. raw or partly processed materials, piece-parts, software, testing or production equipment) owned by the customer (purchaser) and which is necessary to complete the product in accordance with the contract. The organization shall accept responsibility for prevention from damage, identification, maintenance, handling, use and storage of the customer (purchaser) supplied product.

Where relevant, particular requirements are given in particular specifications for the following:

- anti-static precautions,
- cleanliness,
- health and safety aspects of chemicals and materials.

The requirements of ISO 9001 are applied by the System not only to the finished product, but also to partly-processed materials.

The Rule of Procedure for Certificates of Approval and Attestation of Conformity, and the relevant specifications prescribe procedures for the date-coding of components and/or associated packaging. Procedures for ensuring the validity of release are contained in the Rules of Procedure for Approved Process or Component Schemes. Shelf life and revalidation requirements are detailed in the applicable specifications.

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").

Requirements for integral and intimate packaging are given in the relevant technical specification. For the protection of electrostatically sensitive devices (ESDs), the requirements of generic specifications shall apply.

The relevant technical specifications may require the control of humidity and other environmental factors.

8.2.3 Monitoring and measurement of processes

The use of statistical process control (SPC) is optional in most System approvals.

8.2.4 Monitoring and measurement of 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 relevant specification. Where applicable, a regional or internationally recognized specification shall be used for parts per million (ppm) Systems, Assessed Process Average, etc.

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 of this Clause.

8.3 Control of nonconforming product

Repair is the making good of an approved component which has been damaged or has become defective after release, and is not permitted under the Rules of Procedure.

Rework is the rectification of processing errors, prior to the release of the component, by means not differing from those used in the current process or the rework processes to an agreed procedure as permitted by the relevant specification.

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 generic, sectional or blank detail specification. In circumstances where a responsible specification authority finds it necessary to make such allowances, the conditions governing further re-submission of rejected lots shall be specified in the relevant specification in such a manner that the reasons for allowing such further re-submissions are clear and unambiguous.

9.3 Application

Applications for IECQ Certificates 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:

- 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 9001 or equivalent QMS and/or 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 e.g. PDF or TIF.

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-conformance's 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.

9.5.1 Exclusions

ISO 9001 permits organizations to claim exclusions to the requirements contained within ISO 9001 Clause 7. This document incorporates the requirements of ISO 9001, but exclusions are only permitted in accordance with Table 1 provided that they are justified to the IECQ CB in the organization's Quality Manual.

NOTE Individual IECQ Scheme Rules of Procedure may further limit the allowable exclusions.

Table 1 – IECQ Permitted ISO 9001 Exclusions

ISO 9001:2008 Clause ...		Manufacturing	Distributing	Special Process	Avionics OEM
7.1	Planning of product realization	N	N	N	N
7.2.1	Determination of requirements relating to the product	N	N	N	N
7.2.2	Review of requirements relating to the product	N	N	N	N
7.2.3	Customer communication	N	N	N	N
7.3	Design and development	Y	Y	Y	Y
7.4.1	Purchasing process	N	N	N	N
7.4.2	Purchasing Information	N	N	N	N
7.4.3	Verification of purchased product	N	N	N	N
7.5.1	Control of production and service provision	N	N	N	N
7.5.2	Validation of processes for production and service provision	Y	Y	Y	Y
7.5.3	Identification and traceability	N	N	N	N
7.5.4	Customer property	Y	Y	N	Y
7.5.5	Preservation of product	N	N	N	N
7.6	Control of monitoring and measuring devices	N	Y	N	Y
Y May exclude with justification					
N May not exclude					

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 hand written 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 its 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 its 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 of 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 assessment.

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 IECQ 01.

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 2. 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.

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Table 2 – Summary of Designated Management Representative's duties

Approved Process						The designated Management Representative (DMR) shall have defined responsibilities for:	
Approved Component							
Distributor							
ITL ^a							
HSPM							
ECMP							
P	C	D	I	H	E	ensuring compliance with the requirements of the Scheme	1
P	C	D		H	E	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
			I			the correct testing of components received by the testing laboratory	3
P	C	D		H	E	investigating cases of returned non-conforming product(s)	4
P	C	D		H	E	the quality of the component(s), part-processed component(s), piece part(s) or material for which the validity of release has expired	5
		D				re-submission of components to the manufacturer or to an approved testing laboratory if the period of validity of release has expired	6
P	C	D	I	H	E	maintaining liaison with the IECQ CB	7
		D				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
		D				the maintenance of the identity of lots held in stock and their relation to the manufacturer's attestation of conformity	9
P	C		I	H	E	ensuring that the results of inspection tests are recorded and for holding them at the disposal of the IECQ CB	10
P	C	D		H	E	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. NOTE Mark not applicable to HSPM & ECMP Schemes	11
		D				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
P	C		I	H	E	ensuring the availability of inspection and test schedules for the use of inspection staff	13
P	C	D	I	H	E	the competence and continuing effectiveness of inspection staff	14
P	C	D	I	H	E	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
P	C					ensuring that applicable specifications issued by the company comply with the relevant blank detail specification/PAS/TAS	16
P	C			H	E	the compliance with the relevant specification of all piece parts and materials obtained from subcontractors, suppliers and specialist contractors	17
P	C	D	I	H	E	the maintenance of records, including records of internal audits, to demonstrate the effectiveness of the inspection organization	18
			I			the confidentiality of test results which shall not be disclosed to other individuals or organizations without the written permission of the customer	19
P	C	D	I	H	E	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
ITL ^a = 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 Guide 62. 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.