IECQ
OPERATIONAL DOCUMENT

IEC Quality Assessment System, IECQ

Quality system requirements for manufacturers seeking IECQ LED Component Product Certificates of Conformity for Component Product(s) associated with LED lighting
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IECQ Operational Document 3802 –

Quality system requirements for manufacturers seeking
IECQ LED Component Products Certificates of Conformity for
Component Product(s) associated with LED lighting

FOREWORD

This Operational Document, OD 3802 sets out the quality system requirements for
manufacturers seeking IECQ LED Component Product Certificates of Conformity (CoC), for
Component Product(s) associated with LED lighting in accordance with the Rules and
Procedures, IECQ 03-8.

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

This editorial edition 2.1 of IECQ OD 3802 replaces edition 1 of IECQ OD 3802, effective from
its publication. This edition constitutes a non-technical revision, main changes to this edition
include:

– Alignment of the ISO 9001:2015 Clause references and IECQ 03-1
– Alignment of the IECQ Scheme name with IECQ 03-8
– Update Bibliography reference for IECQ Component/Product Specifications procedures

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INTRODUCTION

This operational document, OD 3802 sets out the IECQ System requirements for manufacturer’s quality system, relating to the production of Component Product for use in or in association with LED lighting.

This document shall be read in conjunction with ISO 9001:2015.

The purpose of this document is to embrace the “good manufacturing practices”.

The requirements contained in this document are in addition to the basic quality management system requirements of ISO 9001:2015. To assist in both the implementation of these requirements, they have been set out using the same structure and clause numbering of ISO 9001:2015 in order that manufacturers can simply add these requirements to their existing ISO 9001 quality management system.
IECQ Operational Document 3802 –

Quality system requirements for manufacturers seeking IECQ LED Component Product Certificates of Conformity for Component Product(s) associated with LED lighting

1 Scope

1.1 General

This document specifies particular requirements and guidance on the establishment and maintenance of a quality system to meet the requirements of the IECQ Scheme for LED Component Product. While based on the objectives of ISO 9001, it does not preclude the use of other quality systems that are compatible with the objectives of ISO 9001:2015, subject to the acceptance of the IECQ CB to which an application for IECQ LED Component Product Certification is made.

Therefore, when IECQ CBs assess the quality systems of manufacturers, this document shall be the basis of the initial assessment and subsequent surveillance visits.

The intention of this document is that quality management system requirements of the IECQ Scheme for LED Component Product are to be congruent with the elements of ISO 9001:2015.

1.2 Permissible exclusions

Permissible exclusions, as provided in ISO 9001, are not accepted within the IECQ Scheme for LED Component Product.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9001, Quality management systems – Requirements

IECQ 03-8, Rules of Procedure – Part 8: IECQ Scheme for LED Component Product

IECQ 03-1, Rules of Procedure – Part 1: General requirements for all IECQ Schemes

3 Terms and definitions

The definitions of IECQ 03-8, IECQ 03-1 and ISO 9001 apply, as do the following definitions:

3.1 contract
requirements forming an agreement between a manufacturer and a customer and transmitted by any appropriate means

3.2 customer complaint
any reported written or verbal allegation made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of Component Products covered by an IECQ LED Component Product Certificate.
3.3 schedule drawing
drawing listed in the IECQ CB’s internal files

3.4 Component Product(s)
an electronic device or module, range of electronic devices or modules, related materials, assemblies that are the subject of IECQ LED Component Product Certification. Component Product also includes items and devices that are not electronic but are used in conjunction with electronic devices to ensure their functionality, e.g., spacers, housings, mounting devices, sealing components, etc.

3.5 related drawing
drawing not listed in the IECQ Test Report, but used, for example for detailed manufacture of component parts

3.6 technical documentation
documentation that enables the conformity of the product with the requirements of the standard(s) to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and shall to that extent contain:

- a general type-description.
- design and manufacturing drawings and layouts of components, sub-assemblies, circuits diagrams, etc.
- descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product.
- a list of the standards and specifications referred to in the IECQ Test Report, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the standards.
- thermal and electrical ratings.
- optical ratings.
- results of design calculations made, examinations carried out, etc.
- test reports.

3.7 manufacturer’s documents
those documents required by a manufacturer when making an application for an IECQ Certificate (IECQ LED Component Product Certificate). For example, instructions, related drawings, data sheets and sales literature

4 Quality management system requirements

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.
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 the IECQ Scheme for LED Component Product are incorporated into its quality management system, including when considering specific customer needs.

One quality management system across multiple sites may be utilized providing it meets the requirements in accordance with IECQ 03-1, Annex D.

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 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.

The organisation shall create and maintain a summary of the quality management system in the form of a simplified process flowchart as a summary of its product quality plans that includes references to the manufacturing processes, test and assessment stages and any outsourcing of any critical processes performed during the manufacturing process.

ISO 9001:2015, Clause 5 Leadership

ISO 9001:2015, Clause 5.1 Leadership and commitment.

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 5.1.1 General

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 5.1.2 Customer focus

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 5.2 Quality policy

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 5.3 Organizational roles, responsibilities and authorities: Designated Management representative (DMR)

In addition to the requirements of ISO 9001:2015, Top Management shall appoint a Designated Management Representative (DMR), responsible for the formal contact point for the IECQ CB. The DMR shall have the defined responsibilities and authority for:

I. all matters in connection with the requirements of the IECQ Certificate as defined in IECQ 03-1 Annex A, IECQ 03-8 and IECQ OD 3802 Annex B.

II. the effective coordination of controls for quality and compliance of activities with respect to the design, manufacture, inspection, test and release of part-components, component products or processes covered by IECQ Scheme for LED Component Product Certification.

III. the resolution of issues related to quality or compliance associated to component product or processes covered by IECQ Scheme for LED Component Product Certification, including but not limited to suspending release and any required re-inspection due to delayed delivery of the component product.
IV. verification of the accuracy of certified records of released lots, signing the Supplier’s Declaration of Conformity (SDoC), maintaining records showing the relationship between a SDoC and the inspection lot to which it refers, and maintain a record of the application and use of the IECQ Mark of Conformity along with a register of seals or sealing materials bearing the IECQ Mark of Conformity.

V. the authorization of initial approval and changes to any related drawings, where appropriate and to immediately informing the IECQ CB that issued the certification.

VI. for notifying the IECQ CB immediately of any changes or failure in a periodic test to any certified LED Component Product.

ISO 9001:2015, Clause 6 Planning

The requirements of ISO 9001:2015 apply.

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 6.2 Quality objectives and planning to achieve them

The requirements of ISO 9001:2015 apply along with the following:

All the elements, requirements and provisions adopted by the manufacturer in order to ensure compliance of the component product 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.

For the purposes of the IECQ Scheme for LED Component Product the requirements set out in Annex A3 of this document shall apply and override those of ISO 9001:2015.

ISO 9001:2015, Clause 7 Support

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 7.1.1 General

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 7.1.2 People

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 7.1.3 Infrastructure

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 7.1.4 Environment for operation of processes

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 7.1.5 Monitoring and measuring resources

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 7.1.6 Organizational knowledge

The requirements of ISO 9001:2015 apply.

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:

I. identify, understand and apply the applicable specification(s).
II. conduct product design and development.
III. qualify and manage external provider(s).
IV. qualify new materials.
V. conduct risk analysis on both internal and external provided processes, products, services or materials and the abilities of external providers on compliance control.
VI. conduct testing and inspection of products / outputs.
VII. communicate with customers and IECQ CB regarding conformity of the products.
VIII. 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:

I. top management are aware of the implication of violation of compliance to the specification(s) and rules of the IECQ Scheme for LED Component Product.
II. 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 7.4 Communication.

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 7.5 Documented Information

The requirements of ISO 9001:2015 apply along with the following:

ISO 9001:2015, Clause 7.5.1 General

The quality management system documentation requirements shall ensure that:

I. 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.
II. 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.
III. 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.
IV. There shall be a documented system that refers all related drawings to the relevant schedule drawings.
V. 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.

NOTE Some manufacturers use common components with common drawing numbers on more than one product. Some of these products may have different persons responsible for them. Therefore, if one product with a common component and drawing number is revised to meet a
need and the necessary supplementary certificate obtained, there needs to be a system for ensuring that any other certificates that call up such components are also subject to supplementary certification in order to avoid those products not being in compliance with their equipment documents.

VI. The manufacturer shall document which IECQ CB is responsible for each IECQ Certified Component Product.

VII. 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.

The manufacturer shall retain adequate quality records to demonstrate conformity of the component product.

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.

As a minimum, the list of documented information requiring control and retention, as far as applicable, shall be:

I. inspection and test data (per batch).
II. Information relating to traceability.
III. calibration data.
IV. supplier evaluation.

ISO 9001:2015, Clause 8 Operation

The requirements of ISO 9001:2015 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 according to the guidelines set out in Annex A3 of this document.

ISO 9001:2015, Clause 8.2 Determination of requirements for products and services

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 8.2.1 Customer communication

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 8.2.2 Determination of requirements relating to products and services

The requirements of ISO 9001:2015 apply.
ISO 9001:2015, Clause 8.2.3 Review of requirements relating to the products and services

The requirements of ISO 9001:2015 apply.

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 IECQ Scheme for LED Component Product rules of procedure.

ISO 9001:2015, Clause 8.3.2 Design and development planning

The requirements of ISO 9001:2015 apply along with the following:

The requirements as detailed in Annex A3 of this document shall be met.

ISO 9001:2015, Clause 8.3.3 Design and development Inputs

The requirements detailed in Annex A4 of this document replace those of ISO 9001:2015.

ISO 9001:2015, Clause 8.3.4 Design and development controls

The requirements detailed in Annex A4 of this document replace those of ISO 9001:2015.

ISO 9001:2015, Clause 8.3.5 Design and development outputs

The requirements detailed in Annex A4 of this document replace those of ISO 9001:2015.

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 8.4 Control of externally provided products and services

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 8.4.1 General

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 8.4.2 Type and extent of control of external provision

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 8.4.3 Information for external providers

The requirements of ISO 9001:2015 apply.

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 9001:2015 apply along with consideration of the following Note and for the purposes of production control the guidelines set out in Annex A4 of this document shall apply:
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 8.5.3 Property belonging to customers or external providers

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 8.5.4 Preservation

The requirements of ISO 9001:2015 apply along with the following:

The requirements of those contained within the Specification covering the IECQ Certified LED Component Product.

The requirements of ISO 9001:2015 apply to IECQ Scheme for LED Component Product 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:

I. the organization shall protect the characteristic of Component products.

II. the organization shall ensure the integrity of any labelling and identification used to specify the conformity of the Component products.

III. the organization shall ensure the integrity of Component products during handling, use and storage.

IV. conforming and nonconforming materials and components products shall be segregated, clearly identified, and handled according to defined processes.

V. intermediate outputs or products are released correctly for production.

VI. documented information related to the storage and the use of nonconforming Component products shall be retained.

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

I. anti-static precautions.

II. cleanliness.

III. health and safety aspects of chemicals and materials.

The Rules of Procedure for IECQ LED Component Product Certificates, IECQ 03-8 and the relevant specifications prescribe procedures for the unique identification of components and/or associated packaging.

If applicable, procedures for ensuring the validity of release are contained in the Rules of Procedure for IECQ Scheme for LED Component Product. Shelf life and revalidation requirements are detailed in the applicable specifications.

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

I. integral packaging, which is the case or body of the component itself.
II. intimate packaging, which is enveloping material which makes immediate contact with components, sub-assemblies or assemblies (sometimes referred to as "primary packaging"); and

III. 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 the relevant component or product specifications shall apply.

If the relevant component or product specifications require the control of humidity and other environmental factors, provisions to meet these requirements shall be made.

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

The requirements of ISO 9001:2015 apply along with the following:

The organization shall implement planned arrangements, at appropriate stages, to verify that requirements for the IECQ Certified Component product have been met, and the documented information, identification, supplier's 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 achieved by the DMR verifying the accuracy of certified records of released lots are in accordance with the IECQ LED Component Products Specification as covered by the IECQ LED Component Products Certification, and for the DMR to sign the individual Supplier’s Declaration of Conformity (SDoC).

ISO 9001:2015, Clause 8.7 Control of nonconforming product

The requirements of ISO 9001:2015 apply along with the following and the below sub-clauses:

The requirements detailed in Annex A and B of this document and those below apply.

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.

Repair is the making good of an approved Component Products that 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 Products, 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.

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

I. describes the nonconformity including but not limited to materials and processes.

II. describes relevant external providers and customers identified.

III. 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 requirements of ISO 9001:2015 apply along with the following:

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.

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 IECQ 03-1, Annex C.

ISO 9001:2015, Clause 9.1.2 Customer satisfaction

The requirements of ISO 9001:2015 apply.

ISO 9001:2015, Clause 9.1.3 Analysis and evaluation

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

ISO 9001:2015, Clause 9.2 Internal Audit

The requirements of ISO 9001:2015 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 LED Component Products.

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:

I. understanding of the specification.

II. understanding of the IECQ Schemes.
III. understanding the key risks with materials and processes to ensure compliance.
IV. understanding of the principles and limitations of the testing and measurement methods used by the organization.
V. 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 9001:2015 apply along with the following:
I. The maximum intervals between reviews shall not exceed 12 months.
II. Top management shall chair the review
III. 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 component products intended for use in LED lighting systems.

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:
I. any need for changes to the system to ensure ongoing compliance.
II. resource needs.
III. changes to the competence.
IV. 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 9001:2015 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.

For the purposes of the IECQ Scheme for LED Component Product the requirements set out in Annex A and B of this document shall apply and override those of ISO 9001:2015 where more onerous.

ISO 9001:2015, Clause 10.2 Nonconformity and corrective action

For the purposes of the IECQ Scheme for LED Component Product the requirements set out in Annex A and B of this document shall apply and override those of ISO 9001:2015.

ISO 9001:2015, Clause 10.3 Continual Improvement

This is not a requirement of the IECQ Scheme for LED Component Product.
Annexe A (normative)

Quality planning requirements for manufacturers of component parts for use or related to LED lighting

A.1 General

This annex sets out the requirements for manufacturers when developing and maintaining their quality management plans and planning for the purpose providing assurance that component parts used as part of an LED lighting system, assembly or module, will comply with specifications as declared by the component part manufacturer thereby providing confidence to both the supply chain and LED lighting market that LED lighting systems, incorporating IECQ Certified Component Products, will function and perform according to their intended design.

IECQ CBs performing assessments and auditing of manufacturers use this as part of the audit criteria, unless the manufacturer can demonstrate to the satisfaction of the IECQ CB alternative methods of control that provide an equivalent outcome.

One management system across multiple sites may be utilized providing it meets the requirements in accordance with IECQ 03-1, Annex D.

A.2 Application

The manufacturer seeking IECQ LED Component Product Certification submits its application to an IECQ approved Certification Body, IECQ CB as listed on the IECQ website: www.iecq.org.

In making its application the manufacturer is to supply a summary of its quality management system in the form of a simplified process flowchart as a summary of its product quality plans that includes references to the manufacturing processes, test and assessment stages and any outsourcing of any critical processes performed during the manufacturing process. This will assist the IECQ CB to gauge the scope of the assessment.

The application should inform:

- Details of the specifications/standards used as part of the Component Products Specification
- Clear detailed description/statement of location(s) the organization carries out all the processes, tests, measurements, etc. subsequent to and including the primary stage of manufacture
- The application shall also give the following details of the Component Products for which certification is sought:
  - type reference(s) for the component or range of components, assemblies, related materials, i.e., how the components and items are to be known/referred.
  - the nominal parameters and/or criteria (for example, rated voltage, rated current, rated luminous flux, efficacy (lm/W)).
  - other information or specific criteria, for example, materials and style.

A.3 Requirements for the content of manufacturer’s product quality plans (process manual)

The product quality plan(s) shall, either directly or by reference to the organization’s internal documents as appropriate,
a) state compliance with the minimum requirements given in the Component Products specification(s);
b) provide a process and test flow chart of the component(s) for which IECQ Scheme for LED Component Product Certification is sought.
c) list the manufacturing facilities and the inspection, measuring and test equipment relevant to the range of Component Product(s) for which they are seeking certification.
d) list or make reference to the specifications for the raw material, piece parts, incorporated components and/or part-finished components used as applicable.
e) list or make reference to the specifications for the inspection to be carried out during the production of the Component Product(s).
f) define its procedures for testing, identification and traceability.
g) define how changes to the Component Products are handled in accordance with IECQ OD 3801.
h) define its procedures for ESD control where applicable.

A.4 Ensuring conformity

A.4.1 General

The organization has the responsibility to ensure that all Component(s) Product(s), related materials and or assemblies produced under their IECQ Scheme for LED Component Product Certification is in conformity with the stated specification(s). Failure to do so could lead to suspension or cancellation of the IECQ LED Component Product Certificate.

A.4.2 Documented procedures

The manufacturers shall implement and maintain document procedures to address:

a) In the event of failure during a lot-by-lot test or periodic test
b) Changes or modifications
c) Outsourcing of critical processes
d) Release of certified Component Products including the unique identification of lots

A.5 Specifications

Specifications used within the IECQ Scheme for LED Component Product shall be either:

- an IEC or ISO International Standard; or
- a Component Specification complying with the requirements of IECQ 03-8, Annex A.
Annexe B
(informative)

Guidance for manufacturers

B.0 Information

This annex provides guidance to manufacturers on critical aspects of their quality system as it relates to the production of Component Products which is one approach that may be used.

B.1 Guidance for procedure in the event of failure in a periodic test

B.1.1 Where a sample fails to satisfy the requirements of a periodic test the DMR (Designated Management Representative) (or, where applicable, the local DMR) would immediately

- suspend further releases under the Mark, or Certificate of Conformity of the Component Products in question.
- initiate an investigation to determine the reasons for failure; and
- report the situation to the IECQ CB.

B.1.2 The DMR (or, where applicable, the local DMR) would maintain this suspension until the investigation has been concluded and the IECQ CB has been informed of the results. The DMR (or, where applicable, the local DMR) would then proceed according to the appropriate conditions in B.1.3, B.1.4 or B.1.5 below.

B.1.3 If the failure is concluded to have been due solely to an error in test procedure,

a) release under the Mark, or Certificate of Conformity should be resumed immediately; and
b) the correct test procedure would be applied to a sample drawn from the first available inspection lot. If the sample fails the corrected test, action would be taken as in B.1.1.

B.1.4 If the failure is concluded to be due to an identified manufacturing fault, which can immediately be corrected,

a) release under the Mark, or Certificate, of Conformity of corrected lots would be resumed immediately.
b) the test would be repeated on the first available corrected lot; and
c) if the result of the repeated test is unsatisfactory, the procedure defined in B.1.5 or B.1.6 would be applied as appropriate.

B.1.5 If the failure is concluded to be due to an identified manufacturing fault, which cannot be corrected immediately, but defective components can be detected and rejected by an appropriate eliminating test acceptable to the DMR (or, where applicable, the local DMR),

a) release under the Mark, or Certificate, of Conformity of accepted components would be resumed immediately; and
b) elimination before submission for acceptance would be continued until the necessary steps to correct the manufacturing fault have been taken, and until satisfactory results for the periodic test in question have been obtained on a sample from the first available lot presented for inspection after correction.
B.1.6 If the failure is concluded to be due to an identified manufacturing fault, which cannot be corrected immediately, and defective components cannot be removed by the application of an eliminating test, the IECQ CB would normally take action to suspend the IECQ LED Component Product Certificate and withdraw the right to use the Mark, or Certificate of Conformity for the Component Product in question. IECQ LED Component Product Certificate and the right to use the Mark, or Certificate of Conformity would be reinstated when the organization was able to demonstrate, by the successful submission of a sample from a production lot to the periodic test, that the manufacturing fault has been eliminated.

B.1.7 If the failure cannot be attributed with certainty to a specific error in test procedure or to an identified manufacturing fault, samples from subsequent lots shall then be subjected to all tests of the periodic test in which the failure occurred, on a lot-by-lot basis, and these lots may be released if these samples pass the test successfully.

Except where otherwise specified in the Component Products Specification, normal periodic testing shall be resumed when two successive lots have successfully passed the tests in question, or as otherwise specified in the Component Products Specification.

B.1.8 If the requirements of above are not fulfilled within a reasonable period of time, IECQ LED Component Product Certificate would be re-examined and may be cancelled by the IECQ CB.

B1.9 If the duration of the periodic test in question exceeds three months and if special conditions would be appropriate to the particular type of component and the nature or extent of the failure, the relevant specification would prescribe any special procedure to be followed.

B.2 Changes (modifications)

In addition to the general requirements of IECQ 03-1, Clause 9.9 the following would be recommended.

The organization would report to the IECQ CB any changes likely to affect the validity of the IECQ LED Component Product Certificate (for example changes to materials used and/or the processes involved).

The IECQ CB would usually decide whether it is necessary to repeat all or some of the tests or assessments. The relevant standard/specification may give more detailed information.

B.3 Outsourcing of critical processes

B.3.1 The primary stage and/or subsequent stages may be carried out by companies who hold IECQ Certification covering their process to IECQ 03-2 (IECQ Approved Process) or, under certain conditions, outsource critical processes (see B.3.4).

B.3.2 The organization would only outsource critical process operations, which are covered by the scope of their IECQ LED Component Product Certification, for which the quality plan summary details the methods of control used.

B.3.3 Standards or Component Product Specifications may

- either forbid these outsourced critical processes on technical grounds; or
- where it is considered necessary, include any special requirements, for example for specified successive stages to be performed by the same manufacturer; or
- permit the outsourcing of critical processes unreservedly.

Such restrictions do not apply to companies holding IECQ Approved Process Certification.
B.3.4 When outsourcing of critical processes is undertaken the DMR must be able to demonstrate to the IECQ CB that the process(es) concerned is (are)
• performed in a manner which satisfies the appropriate requirements of the relevant quality plans and Component Product Specification or standard, where such exists; or
• carried out satisfactorily.

B.3.5 To verify the satisfactory conduct of outsourced critical process operations in accordance with B.3.4, the manufacturer would ensure that the IECQ LED Component Product testing and quality conformance testing will be performed under their control in an approved laboratory located in an IECQ member country, or exceptionally in accordance with B.3.7.

B.3.6 The organization, when applying for IECQ LED Component Product Certification, shall state whether any individual operations of their process(es) are carried out by IECQ AP certified outsourcing suppliers in accordance with B.3.1 or are outsourced in accordance with B.3.4 and would identify these operations.

B.3.7 If outsourcing suppliers not approved within the IECQ System are used, the organization would describe the method of control of all the outsourced stages or operations.

B.3.8 When the conditions of B.3.6 apply, the application for IECQ LED Component Product Certification would contain:
• details of the division of individual operations between the organization and the contractor(s) or subcontractor(s) as per B.3.6; and
• details of the arrangements that need to be agreed with the IECQ CB for the approval of the quality of outsourced operations. These details should take into account the transfer of products or services between the organization and the contractor/suppliers; and in particular
  o the procedures for the assessment of quality of the outsourced operations; and
  o details of the means whereby changes to the agreed arrangements are communicated to the IECQ CB.

B.3.9 Before tests are carried out by laboratories not approved under the IECQ System, the organization would take all reasonable steps to ensure that the required service is not available from any approved independent testing laboratory within the IECQ System.

The organization would demonstrate to the IECQ CB that IECQ Approved Independent Testing Laboratories known to be operating in the relevant area of technology are unable to undertake the specified testing.

Where testing laboratories not approved within the IECQ System carries out tests, the organization would include in their quality plans (process manual) or produce a document that describes the surveillance arrangements by which they shall ensure that the testing to be carried out shall comply with the specification or standard. Where possible, the nominated testing laboratory would hold accreditation to ISO/IEC 17025 by a body that is a member of ILAC (International Laboratory Accreditation Co-operation). The document would define how the nominated testing laboratory
• ensures that its relevant staff possesses the necessary competence and its relevant test facilities are completely adequate for the purpose.
• proposes to operate the test; and
• ensures that it has an adequate system for the calibration of its relevant measurement and test equipment and can provide adequate traceability to national standards.

In establishing the degree of surveillance necessary, account would be taken of any current accreditations, approvals and/or registrations held by the nominated testing laboratory.
Prior to permitting testing, the organization would demonstrate to the IECQ CB that his proposed surveillance arrangements comply with the specification.

The organization would demonstrate to the IECQ CB by any suitable means that the quality and compliance of the final component will not be adversely affected by the use of these outsourced arrangements.

The IECQ CB of the organization seeking IECQ LED Certification shall ensure that the specialist contractor’s DMR is able to verify the satisfactory maintenance of the quality control procedures performed by their outsourced supplier.

IECQ CB would confirm that the details contained in the application for IECQ LED Component Product Certification satisfy the requirements of the Scheme.

The procedures given in this subclause would be applied separately to any subsequent programme of testing, including those carried out for periodic testing for the maintenance of a certification.

B.4 Release for delivery and validity of release

B.4.1 General

Quality conformance inspection and periodic testing requirements for components are given, either directly or by reference, in LED Component Product Specifications.

B.4.2 Validity of release

A release for delivery is valid for five years unless a shorter period is specified in the LED Component Product Specification. The relevant specification would prescribe the tests, which would be repeated in order to revalidate the release.

B.5 Quality conformance inspection

B.5.1 General

Quality conformance is established after carrying out tests demonstrating that the inspection lots have achieved the quality prescribed in the specification. The organization would carry out these tests or arrange to have them carried out in a laboratory approved under the IECQ System. The Component Product Specification would prescribe those tests, which have to be performed. The acceptability of the lot is determined by the requirements of the specification.

B.5.2 Lot-by-lot tests

Lot-by-lot tests would be carried out on each inspection lot. These tests may be divided into two groups:

- Group A, covering visual and dimensional inspection of the components and the principal characteristics of the components (initial measurements)
- Group B, covering additional important characteristics

Each group may be divided into two or more subgroups.

B.5.3 Periodic tests

Periodic tests would be carried out at fixed intervals on samples taken from lots, which have already satisfied the lot-by-lot tests.
B.5.4 Destructive tests

Specimens, which have been subjected to destructive tests, would not be included in lots to be delivered. Specimens subjected to non-destructive tests may be included in lots to be delivered provided they satisfy the specified tests.

B.5.5 Use of in-process testing

In-process testing may be substituted for the relevant test(s) of the quality conformance testing provided that the organization demonstrates that the in-process testing is such that the corresponding requirements of the specification would have been met at the final stage of inspection.

B.5.6 Test severity

An organization may carry out any test at a greater severity than that specified, but the component after testing would satisfy the limits prescribed in the specification.

B.5.7 Alternative test methods

The test and measurement methods given in the relevant LED Component Product Specification are intended to unify test and measurement procedures. They are not necessarily the only methods, which can be used except when specifically designated as referee or reference methods. The organization would demonstrate to the IECQ CB that any alternative methods he uses will give results equivalent to those obtained by the specified method.

B.5.8 Measurement uncertainty

The limits prescribed in specifications are true values. When carrying out the specified tests the organization would employ sufficient inset from the specified limits to cover the uncertainty of their measurement.

B.5.9 Non-conforming components in lot-by-lot tests

Specimens found non-conforming during lot-by-lot testing would be withdrawn from the lot and not delivered. Lots rejected in lot-by-lot tests may be resubmitted in accordance with the requirements prescribed in the relevant specification.

B.5.10 Non-conformances in periodic tests

The DMR would keep records of non-conformances observed in samples subjected to periodic tests where the repetition of such non-conformances may lead to the suspension or cancellation of IECQ LED Component Product Certification.

B.5.11 Release or rejection of lots

Except when otherwise prescribed in the relevant specification, the lots would be released or rejected on the basis of the lot-by-lot tests (see B.5.2). The failure of the sample submitted to one of the periodic tests would entail the rejection of the lot from which the sample came unless release has already taken place due to the length of the test.

B.5.12 Identification of released lots

Lots released by organizations or distributors would be unambiguously identified by a Mark, or Supplier’s Declaration of Conformity (SDoC), the affixing, or issue, of which is under the surveillance of the IECQ CB. This Mark, or SDoC, means that the components have been released in accordance with the requirements of the relevant specification.
Only components approved against a Component Product Specification or registered within the System may receive the Mark, or Certificate of Conformity.

Authorization to affix, or to issue, the Mark, or SDoC is suspended or cancelled if there is persistent non-conformity with the specification or if the provisions of the Scheme are not observed.

While it is not permitted to release approved components prior to the issuing IECQ CB granting IECQ LED Component Product Certification and issuing an IECQ LED Component Product Certificate to the organization, the organization may quote that it has certification pending provided that

a) the LED Component test report for the component(s) has been finalized and fully accepted by the issuing IECQ CB.

b) a draft Certificate of Conformity has been sighted by the organization.

c) the organization has submitted to the issuing IECQ CB a written request announcing their intention to quote that it has certification pending and that this request at the discretion of the IECQ CB has been accepted.

c) the organization would not use the mark or issue SDoC’s on components until it had been issued with an IECQ Approved Component Certificate of Conformity covering such components.

B.6 Customer returns and appropriate corrective action

A component returned for non-technical reasons, provided that the package is unopened and undamaged, and its original labelling is intact, may be returned to the organization’s-controlled store for release.

Where a manufacturing or test defect is confirmed, the organization would notify the IECQ CB responsible for issuing the IECQ LED Component Product Certificate.

Organizations would notify the IECQ CB every six months of non-conformities on components released under the Scheme. Notification would be given in writing and may be presented during a surveillance/audit visit, or otherwise as agreed with the IECQ CB.

B.7 Inspection lots

B.7.1 Formation of inspection lots

An inspection lot may be formed by the aggregation of several production lots provided that

a) the production lots are manufactured under essentially the same conditions (materials, processes, machines, personnel, etc.); and

b) quality control and inspection during manufacture is performed to the extent necessary, in accordance with directives established by the appropriate departments of the organization in consultation with the DMR; and

c) the results of this inspection indicate for each production lot that the quality of materials and processing is maintained within the limits necessary for the production of components satisfying the requirements of the specification; and

d) the period over which production lots may be aggregated into one inspection lot should normally not exceed one week and shall not exceed one month unless permitted by the relevant specification.

The programme for the aggregation of production lots into inspection lots would be determined by the DMR and would be submitted for approval to the IECQ CB.
Bibliography

ISO 10005, *Quality management systems – Guidelines for quality plans*

ISO 10006, *Quality management systems – Guidelines for quality management in projects*

ISO 19011, *Guidelines for auditing management systems*

IEC 61340-5-1, *Electrostatics – Part 5-1: Protection of electronic devices from electrostatic phenomena – General requirements*

IECQ OD 3803, *Procedures for the development, publication and maintenance of IECQ Component/Product Specifications used within the IECQ Scheme for LED Component Product*