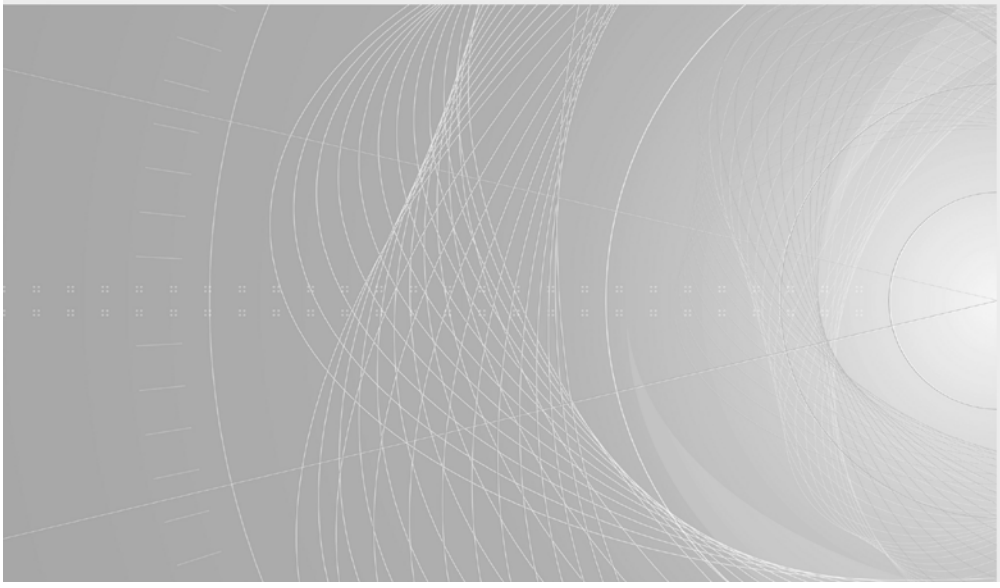
IECRE OD-405-1

Edition 2.0 2018-07-31**-**

IECRE
OPERATIONAL DOCUMENT

IEC System for Certification to Standards relating to Equipment for use in Renewable Energy applications (IECRE System)

IECRE Quality System Requirements for PV Module Manufacturers –
Part 1: Requirements for certification



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IECRE OPERATIONAL DOCUMENT

IEC System for Certification to Standards relating to Equipment for use in Renewable Energy applications (IECRE System)

IECRE Quality System Requirements for Manufacturers –

Part 1: Requirements for certification of a quality system for PV module manufacturing

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTRODUCTION

This Operational Document, OD 405-1, sets out the IECRE System requirements for manufacturer's quality system, relating to the production of certified PV modules.

OD 405, *IECRE Quality System Requirements for PV Module Manufacturers*, has now been published in three parts:

- *Part 1: Requirements for certification*
- *Part 2: Audit Checklist*
- *Part 3: Requirements for PV Factory Auditors*

This Document needs to be read in conjunction with ISO 9001:2015 and IEC/TS 62941.

The purpose of this Document is to embrace the "good manufacturing practices" which are appropriate to PV modules.

Document History

Date	Summary
2016-09-26	Edition 1.0
2018-07-31	Edition 2.0

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 IECRE Scheme. 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 an RECB. Therefore, when RECBs assess the quality systems of manufacturers, this document shall be the basis of the initial assessment and subsequent surveillance visits. ~~An application form for the RECB is included.~~

1.2 Permissible exclusions

The manufacturer may only exclude quality management system requirements within Clause 4, with the agreement of the RECB, provided that conformity of the product can still be demonstrated.

2 Normative references

This Document incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this Document only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

IEC/TS 62941 *Terrestrial photovoltaic (PV) modules - Guideline for increased confidence in PV module design qualification and type approval*

ISO/IEC 17025 *General Requirements for the Competence of Testing and Calibration Laboratories*

ISO 9001 *Quality management system – requirements*

IAF MD1:2007 *IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling*

3 Terms and definitions

The definitions of IECRE 01, IECRE 02 and ISO 9001 apply, as do the following definitions:

3.1 product

equipment, systems, devices, components and their combinations, as well as software and services as defined in 3.4.2 of ISO 9001.

3.2 Certification Body (RECB)

Organization that conducts conformity assessments and issues Certificate of Conformity (CoC) to PV systems. See 2.5 of ISO 17000.

4 Quality management system requirements

4.1 General requirements

4.1.1 Refer to IEC/TS 62941 for applicable requirements to be covered in the audit.

4.1.2 Refer to OD 405-2 for Audit Checklist to be used when conducting an audit.

4.1.3 Refer to OD 405-3 for Requirements for PV Plant Inspectors and PV Factory Auditors.

4.2 Audit Process

4.2.1 The audit process shall encompass audit planning, audit execution, reporting, surveillance and maintenance of the certification. The process shall include handling complaints and feedback regarding the audit process.

4.2.2 The Certification Body shall ensure that:

i) Only competent audit team members that meet qualification and experience requirements are assigned to Factory audits.

ii) Audit plans cover all areas and activities applicable to the standard/ specification covered by the scope of the audit.

iii) The audit shall be managed by a team leader, competent in at least one of the audited standards/specifications.

iv) Sufficient time is allocated to accomplish a complete and effective audit of the organization's management system covered by the scope of the audit and as estimated in section 4.3.2.

4.2.3 Audit reports shall be prepared and documented in a manner as specified in PV-OMC OD-408-3. Each finding raised in a report shall be traceable to the applicable standard(s)/specification(s).

NOTE: The typical process flow for the audit and certification process is outlined in figure E.1 of ISO/IEC 17021:2015.

4.3 Audit Sampling and Audit time

4.3.1 Audit Sampling: If an organization has multiple manufacturing sites in different geographic locations, the initial certification audit shall be required for all the site locations. If eligible as per section 3 of IAF MD1:20017, Surveillance and Recertification audits should be sampled based on the formula provided in section 5.2.3 of IAF MD 1:2007. Selection criteria should also take into consideration guidelines provided in section 5.1.4 of IAF MD1:2007.

4.3.2 Audit time

~~To determine the audit time, the Certification Body shall:~~

~~calculate the required audit time by the relevant application documents and/or scheme rules for each standard.~~

~~Calculate the starting point "T" for the duration of the audit.~~

~~Adjust the starting point figure by taking into account factors that may increase or reduce the time required for the audit.~~

The minimum baseline time requirements for initial and re-certification audits is 2.0 mandays (+/- 1.0 mandays) for the per manufacturing site of the auditee. Prolongation of these time periods can be decided upon during audit execution. The minimum baseline time requirement for surveillance audits is 1 manday per manufacturing site of the auditee.

The baseline time requirement can be adjusted by taking into account factors that may increase or reduce the time required for the audit.

The factors for reduction shall include but are not limited to:

i) Design responsibility of the organization

ii) Extent of manual processes

iii) The complexity of the audit

iv) Maturity of the management systems (consideration for surveillance)

The RECB shall inform the client that the duration of the audit based on the declared level of the organization's management system may be subject to adjustment on the basis of confirming the level of complexity at stage one and subsequent audits.

4.3.1.1 Adjustment of the audit time shall not exceed 20% from the baseline time requirement~~starting point "T"~~, unless there is specific documented agreement between the client and the CB.

4.3.1.2 The ~~starting point figure~~ baseline time requirement and justification for increase or reduction shall be documented.

NOTE: The Advanced Surveillance and Recertification Procedures (ASRP) as per IAF MD3:2008 may place greater (but not total) reliance on the organization's internal audit and management review processes.

4.4 Auditor selection

4.4.1 Please refer to the Operational document (OD-405-3) on PV Inspector and Factory auditor qualification and certification requirements. Additional information is available from ISO/IEC 17021 Part 3: Competence requirements for auditing and certification of quality management systems [Technical Specification].

4.5 Stages of audit

4.5.1 Stage 1 is required for the initial certification and significant scope extension to the existing certification. (e.g., Addition of design, new product technology, etc.). Stage 1 is not required for adding new site locations as long as the management systems from the existing registered sites are applied.

4.5.1.1 Stage1: Some of the objectives are

a) review the client's management system documented information;

b) determine the preparedness for *stage 2;*

c) obtain necessary information regarding the scope of the management system, including:

- the client's site(s);
- processes and equipment used;
- levels of controls established (particularly in case of multisite clients);
- applicable statutory and regulatory requirements;

4.5.2 Evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2.

4.5.2.1 The stage 1 may take place at the site(s) of the client. CB shall decide if this can be effectively carried out as a desk audit or a remote audit.

4.5.3 Stage 2:

The purpose of stage 2 is to evaluate the implementation, including effectiveness, of the client's management system.

4.5.3.1 In determining the interval between stage 1 and stage 2, consideration shall be given to the needs of the client to resolve areas of concern identified during stage 1. The client shall be informed that the results of stage 1 may lead to postponement or cancellation of the certification process. The stage 2 shall take place at the site(s) of the client.

See additional details in ISO/IEC 17021:2015 sections 9.3.1.2 and 9.3.1.3.

5 Pass/Fail criteria of IEC TS 62941

5.1 The client organization shall demonstrate their ability to consistently provide product and services that meets customer and applicable statutory and regulatory requirements, and shall incorporate requirements for the continual improvement of the effectiveness of the QMS. (See ISO 9001:2015 section 1).

5.2 The following Pass/Fail criteria shall be applied in the audit.

v) No major nonconformity shall be found in the audit. Certification shall not be issued until satisfactory corrective action response and an onsite follow up verification by the audit team.

vi) If any minor nonconformity is found, as defined in ISO/IEC 17021 clause 9.1.15 (c), certification shall not be issued until satisfactory correction of the situation, and its desktop verification, corrective action response by the lead auditor. Corrective action shall be verified in the subsequent surveillance audit.

NOTE: Major and minor nonconformance are defined below; originally taken from ISO/IEC 17021:2015.

5.2.1.1 Major nonconformity

nonconformity that affects the capability of the management system to achieve the intended results

NOTE 1 to entry: Nonconformities could be classified as major in the following circumstances:

- if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;
- a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

5.2.1.2 Minor nonconformity

nonconformity that does not affect the capability of the management system to achieve the intended results.

For Certification decision, please refer to section 9.5 of ISO/IEC 17021:2015. *Guidelines for maintaining certifications* are outlined in section 9.6 of ISO/IEC 17021:2015.

6 Expiration of the certificate, Surveillance Audit, and Re-Audit.

6.1 Expiration of the certificate,

The certificate expires in three year after its issu~~n~~ance date. Surveillance audit is mandatory to maintain effectiveness of the certificate within this period.

6.2 Surveillance Audits

Surveillance Audits must be conducted at least annually, and no later than 12 months after the previous Audit. Surveillance Audits shall cover aspects of the organization's quality management system at the discretion of the nominated auditor. A report shall be produced identifying any areas requiring Corrective Actions.

The RECB in charge of the assessment and the certification, can extend above mentioned 12 months period up to 18 months based on the results of the assessment. In such a case, RECB shall notify its decision to the Executive Secretary for approval.

6.3 Re-Audits

Organizations shall be subject to a Re-Audit at the end of every three-year certification cycle. A Re-Audit shall be required prior to the expiry date of the organization's existing certificate, in accordance with RECB requirements. Three-months prior to the Re-Audit due date a new proposal and contract shall be created, covering the next three year cycle. Failure to submit for a Re-Audit prior to the expiry date of the existing certificate shall result in a period during which the organization's certification shall be deemed to have expired and therefore continuous certification cannot be shown on subsequent certificates.

~~**6.3.1.1 7 General information**~~

~~**6.3.1.2**~~

~~**6.3.1.3 The following application shall be completed by the candidate RECB and shall be submitted by the Member Body in which the candidate resides. The Member Body shall ensure that the application package, as noted below, is complete.**~~

~~**6.3.1.4**~~

~~**6.3.1.5 NOTE: Incomplete applications will not be processed until full documentation has been received.**~~

~~**6.3.1.6 NOTE: Once this application is accepted and approved by the Secretariat, it shall be noted that additional documentation will be required to establish the assessment team and to facilitate the assessment, e.g. test reports, results of proficiency testing, accreditation reports, internal quality management documentation, etc.**~~

~~**6.3.1.7 Applicant RECB shall provide the information in the table below:**~~

~~**6.3.1.8**~~

~~Legal Entity Name:~~	~~Click here to enter text.~~

~~**Address:**~~	~~**Click here to enter text.**~~
~~**Contact person:**~~	~~**Click here to enter text.**~~
~~**E-mail:**~~	~~**Click here to enter text.**~~
~~**Tel.:**~~	~~**Click here to enter text.**~~
~~**Fax:**~~	~~**Click here to enter text.**~~
~~**Website:**~~	~~**Click here to enter text.**~~

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IEC CA 01 *IEC Conformity Assessment Systems –Basic Rules*

IECRE 01-S *IECRE Supplement to IEC CA 01*

IECRE 02 *System Rules of Procedure*

IECRE 04 *PV-OMC Rules of Procedure*

ISO/IEC 17020 *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17065 *Conformity assessment – Requirements for bodies certifying products, processes and services*

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