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CONTENTS

1 Scope ........................................................................................................................................ 4
  1.1 General .......................................................................................................................... 4
  1.2 Permissible exclusions ............................................................................................... 4

2 Normative references ............................................................................................................. 4

3 Terms and definitions ........................................................................................................... 4
  3.1 product ....................................................................................................................... 4
  3.2 Certification Body (RECB) ....................................................................................... 4

4 Quality management system requirements ........................................................................... 4
  4.1 General requirements ............................................................................................... 4
  4.2 Audit Process ............................................................................................................. 4
  4.3 Audit Sampling and Audit time ............................................................................... 5
  4.4 Auditor selection ....................................................................................................... 5
  4.5 Stages of audit ....................................................................................................... 5

5 Certification Body .............................................................................................................. 6
  5.1 Certification Body Responsibilities ........................................................................... 6

6 PV Factory Auditor ............................................................................................................. 6
  6.1 Roles and Requirements for PV Factory Auditor ....................................................... 6
  6.2 PV Factory Auditor’s scope ..................................................................................... 6
  6.3 Application, Qualifications, and registration of PV Factory Auditors ................. 7
  6.4 Maintenance of auditor qualification ..................................................................... 8

7 Pass/Fail criteria of IEC 62941 .......................................................................................... 8
  7.1 Responsibility of the client organization ................................................................. 8
  7.2 Pass/Fail criteria ....................................................................................................... 8

8 Expiration of the certificate, Surveillance Audit, and Re-Audit ......................................... 9
  8.1 Expiration of the certificate, .................................................................................. 9
  8.2 Surveillance Audits ............................................................................................... 9
  8.3 Re-Audits .............................................................................................................. 9

Annex A – PV Factory Auditor Qualifications Table ................................................................ 10
Annex B – PV Factory Audit Log (informative) ...................................................................... 11
Annex C – PV Factory Auditor CPD Log (informative) .......................................................... 12
Bibliography ......................................................................................................................... 13
IECRE Operational Document 405-1 –

IECRE Certified Equipment Scheme –

IECRE Quality System Requirements for PV Module Manufacturers – Part 1:
Requirements for certification of a quality system for PV module manufacturing

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 two 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

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<tr>
<td>2016-09-26</td>
<td>Edition 1.0</td>
</tr>
<tr>
<td>2018-07-31</td>
<td>Edition 2.0</td>
</tr>
<tr>
<td>2020-xx-xx</td>
<td>Edition 3.0</td>
</tr>
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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.

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 is 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. To avoid possible low value added cost, audit may cover only questions with star marks listed in OD-405-2 for the client certified to ISO 9001. If the client is not certified to ISO 9001, audit shall cover all the questions listed in OD-405-2.

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 17021-2:2015.

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 MD1:2018, Surveillance and Recertification audits should be sampled based on the formula provided in section 65.2.3 of IAF MD 1:2018. Selection criteria should also take into consideration guidelines provided in section 65.1.4 of IAF MD1:2018.

4.3.2 Audit time

The minimum baseline time requirements for initial and re-certification audits is 2.0 man-days (+/-1.0 man-days) 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 man-day 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, unless there is specific documented agreement between the client and the CB.

4.3.1.2 The 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 Annex A – PV Factory Auditor Qualifications Table 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

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 Stage 1: Some of the objectives of the Stage 1 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;

4.5.2.1 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.

4.5.2.3 Stage 2:
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.

4.5.3.1 The purpose of the 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 17021-1:2015 sections 9.3.1.2 and 9.3.1.3.

5 Certification Body

5.1 Certification Body Responsibilities
Overall responsibility for qualification and registration of the PV Factory Auditors and Trainees rests with the RECB.

6 PV Factory Auditor

6.1 Roles and Requirements for PV Factory Auditor
The PV Factory Auditor is responsible for carrying out initial certification audits of factories as well as routine surveillances (both pre-certification and post-certification) in accordance with the appropriate international standards, documented requirements, rules, guidelines, and procedures. The PV Factory Auditor must successfully meet the requirements, which include, but are not limited to:

- Satisfy the IECRE MB qualification process defined in section 3.2.1 in order to be authorized as PV Factory Auditor.
- Meet the minimum qualification requirements as per section 3 of this document.
- Successfully pass the supervision and training as per section 4 of this document. The term PV Factory Auditor, used throughout this document, is applicable for an IECRE PV Factory Auditor registered by the IECRE secretariat only.

6.1.1 PV Factory Auditor Trainee
The PV Factory Auditor Trainee is engaged in job specific training and is in the process of completion of the qualification process. The PV Factory Auditor Trainee is entitled to carry out an audit, whilst under supervision of a PV Factory Auditor or Lead auditor. Under such supervision, PV Factory Auditor Trainees are permitted to conduct initial certification audits as well as routine surveillances (both pre-certification and post-certification) in accordance with the appropriate international standards, documented requirements, rules, guidelines and procedures. See Annex A for details.

6.2 PV Factory Auditor’s scope
The PV Factory Auditor’s scope covers one or more IECRE categories within the Certification Body (RECB) scope (for example, IEC 61215 and IEC 61730).
6.3 Application, Qualifications, and registration of PV Factory Auditors

The application shall be submitted to the RECB accompanied by the documentation as far as applicable. The RECB shall endorse the candidate based upon review of the credentials and past experience. The following application shall be completed by the candidate Factory Auditor and shall be submitted to the RECB for determination of acceptance.

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

Applicant shall provide the information in the table below:

<table>
<thead>
<tr>
<th>Name:</th>
<th>Click here to enter text.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>E-mail:</td>
<td>Click here to enter text.</td>
</tr>
<tr>
<td>Tel.:</td>
<td>Click here to enter text.</td>
</tr>
</tbody>
</table>

6.3.1 Initial training of PV Factory Auditors

Each applicant shall be trained in the following content:

a) ISO/IEC 17024 and 17021 (relevant clauses) e.g.:
   - Technical Requirements
   - Quality System
   - Personnel

b) Inspection Methods and Procedures e.g.:
   - Product review according to product certification documents
   - Handling Inspection Samples
   - Records
   - Inspection Reports and Inspection Certificates

c) Requirements for surveillance sample testing and test results evaluation as needed during the performance of PV Factory Auditor in the applicable product categories.

d) Familiarity with the IEC 61215 series, the IEC 61730 series, and all other standards listed in normative references of IEC 62941.

6.3.2 Documentation of completion of qualification requirements for auditors

The requirements identified in Annex A to all grades of PV Factory Auditors. Evidence of audit experience shall be verified by the audited client (e.g. by authorized signature on the audit report or supporting letter), and shall include confirmation of the audit duration, audit objective, and role played in the audit (e.g. principal auditor, lead auditor or audit team member).

The following application shall be completed by the candidate Factory Auditor and shall be submitted to the RECB for determination of acceptance.

<table>
<thead>
<tr>
<th>Application criteria</th>
<th>Documentation / Confirmation provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Educational background</td>
<td>Indication of degree or certification.</td>
</tr>
<tr>
<td>2. General Work Experience</td>
<td>Listing of relevant work experience.</td>
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<tr>
<td>3. Solar PV specific work experience</td>
<td>Listing of relevant solar work experience.</td>
</tr>
<tr>
<td>4. Auditor training</td>
<td>Listing of training classes attended as per Annex C</td>
</tr>
<tr>
<td>5. Auditing experience</td>
<td>Listing of audit experience with customer signatures as per Annex B</td>
</tr>
</tbody>
</table>

NOTE: Time required for follow-up on corrective actions related to audit findings should not be counted toward the "Auditing experience".
In addition, voluntary collaborations with international PV committees will be taken into consideration as eligible experience. Evidence of this collaboration shall be provided and assessed by the corresponding RECB.

6.4 Maintenance of auditor qualification

The RECB is responsible to carry out annual training and supervision programs that cover but are not limited to:

6.4.1 Review of auditor performance

The RECB shall review auditors’ performance regularly based upon:

a) Audit reports on a sampling basis by the certification body technical manager.
b) Feedback from manufacturers (audit clients)
c) Feedback from other certification bodies (for contract auditors)
d) Feedback from Team lead auditor (where applicable)

The review cycle shall be conducted annually

Performance related improvement is addressed through additional training, closer supervision and mentoring by experienced auditors as decided by the RECB.

NOTE: Validation of the CB/IB’s management of auditors is part of the Peer Assessment process.

6.4.2 Auditor certification renewal

Auditors shall accumulate the audit experience and submit every three years for renewal to the RECB for continuation of the grades or to request of upgraded status. Proof of continual professional development (CPD) totaling 45 hours should be submitted as an additional evidence during the three year renewal. These 45 hours may be accumulated at any point during the three year cycle. This CPD can be acquired through attending formal training on Quality Management systems, technical training relevant to PV Solar systems, attending PV solar conference, seminar, volunteering for PV Solar standards development, etc.

6.4.3 Promotion or disqualification of auditors

The RECB can nominate promotion of the PV Factory Auditors from auditor trainee based on review of the auditor performance in section 4.2. Auditors shall be disqualified if there is a continued poor performance or unacceptable behavior – violation of auditor ethics, unprofessional conduct.

PV Factory auditors are responsible to maintaining and upgrading their auditor grades by keeping their auditor qualifications and audit experience updated in an audit log as shown in Annex B.

57 Pass/Fail criteria of IEC TS 62941

7.1 Responsibility of the client organization

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).

7.2 Pass/Fail criteria

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

i) 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.

ii) If any minor nonconformity is found, as defined in ISO/IEC 17021-1 clause 9.1.15, 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 17021-1:2015.

5.1.1.1.7.2.1.1.5.2.1.1. 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.

5.1.1.2 Minor nonconformity

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


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

6.8.1 Expiration of the certificate,
The certificate expires in three year after its issuance date. Surveillance audit is mandatory to maintain effectiveness of the certificate within this period.

6.8.2 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.

6.8.3 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.
Annex A– PV Factory Auditor Qualifications Table

<table>
<thead>
<tr>
<th>Auditor Grade</th>
<th>Educational Background</th>
<th>General Work Experience</th>
<th>Solar PV specific work experience*</th>
<th>Auditor Training Experience</th>
<th>Auditing Experience</th>
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</thead>
<tbody>
<tr>
<td>Auditor Trainee</td>
<td>Either a University degree / College diploma in the relevant discipline (e.g., Electrotechnical, mechanical, chemical, etc.) or certified / licensed master craftsman, technician or engineer in the relevant technical working field.</td>
<td>4 Years, or equivalent</td>
<td>2 Years, or equivalent</td>
<td>Attended a lead assessor/auditor training on ISO 9001 approved by a accreditation board from IAF. Or, Attended auditor training or a training on IEC 62941 requirements interpretation</td>
<td>None</td>
</tr>
<tr>
<td>Auditor</td>
<td>Same as above</td>
<td>4 Years, or equivalent</td>
<td>2 Years, or equivalent</td>
<td>Same as above</td>
<td>4 Full Management Systems audit, all elements of audit cycle, 20 days of which 15 on site</td>
</tr>
</tbody>
</table>

- Manufacturing or downstream PV module experience acceptable.
- PV Module manufacturing experience preferable.

NOTE: IAF (International Accreditation Forum) http://iaf.nu/
# Annex B – PV Factory Audit Log (informative)

<table>
<thead>
<tr>
<th>Audit Number</th>
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<td>(DD/MM/YY)</td>
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<tr>
<td>STATE: Start and finish dates of the audit on site</td>
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</tr>
<tr>
<td>Total Duration of Audit in days</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STATE: Number of days of your involvement (including off-site time)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit Days spent on site</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>STATE: Duration of your on-site days</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

## Contact details of the company audited (auditee)

- **PROVIDE:**
  - Auditee contact name
  - Complete address
  - Telephone/fax number
  - E-mail address

## Role in audit

## Total Number in Audit Team (including yourself)

## Audit standard (e.g. ISO 9001:2015)

- **STATE:** Full Reference including date of standard

## Type of audit

- (Surveillance; Second party; Third party)

## Contact details of the company that employed you

- **PROVIDE:**
  - Company name
  - Complete address
  - Contact Name
  - Position within Organization
  - Contact telephone number
  - Email address

## Declaration of competence

(This person declares that the audit was conducted adequately and professionally and that the presented information is accurate)

- **PROVIDE:**
  - Name
  - Position
  - Auditor certification number: (if applicable)
  - Contact telephone / fax number
  - Email address
  - Signature
# Annex C – PV Factory Auditor CPD Log (informative)

<table>
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<th>3</th>
<th>Etc.</th>
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<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>STATE:</strong> Start and finish dates of the training</td>
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<td></td>
<td></td>
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<tr>
<td><strong>Professional development hours</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
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<td><strong>Training origination OR Volunteering organization</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PROVIDE:</strong> Training attendance sheet, conference badge, or letter from volunteering organizations signed by the chair of the interest group.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

________________________
Bibliography

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