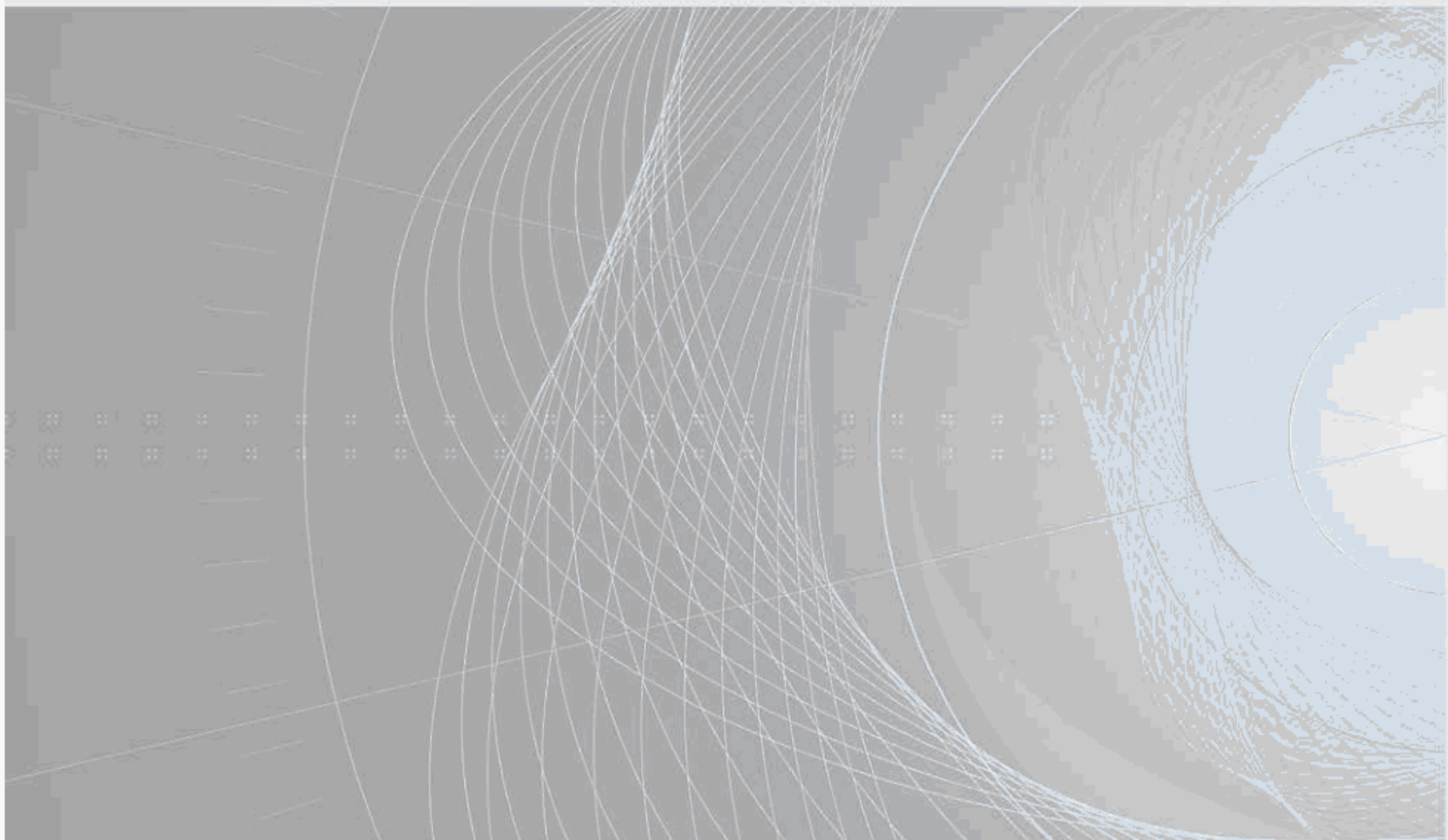
IEC TS 62941

Edition 1.0 2016-01

# TECHNICAL SPECIFICATION

## Terrestrial photovoltaic (PV) modules – Guidelines for increased confidence in PV module design qualification and type approval



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## Terrestrial photovoltaic (PV) modules – Guidelines for increased confidence in PV module design qualification and type approval

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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# TERRESTRIAL PHOTOVOLTAIC (PV) MODULES – GUIDELINES FOR INCREASED CONFIDENCE IN PV MODULE DESIGN QUALIFICATION AND TYPE APPROVAL

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Technical specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

IEC TS 62941, which is a technical specification, has been prepared by IEC technical committee 82: Solar photovoltaic energy systems.

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

| FDIS | Report on voting |
|---|---|
| 82/994/DTS | 82/1049/RVC |

Full information on the voting for the approval of this technical specification can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- Transformed into an International standard
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

# TERRESTRIAL PHOTOVOLTAIC (PV) MODULES – GUIDELINES FOR INCREASED CONFIDENCE IN PV MODULE DESIGN QUALIFICATION AND TYPE APPROVAL

## 1 Scope

This Technical Specification is applicable to sites manufacturing photovoltaic (PV) modules certified to IEC 61215 or IEC 61646 for design qualification and type approval. The design qualification and type approval of PV modules depend on appropriate methods for product and process design, as well as appropriate control of materials and processes used to manufacture the product. This technical specification lays out best practices for product design, manufacturing processes, and selection and control of materials used in the manufacture of PV modules that have met the requirements of IEC 61215, IEC 61646, or IEC 62108. These guidelines also form the basis for factory audit criteria of such sites by various certifying and auditory bodies.

The object of this technical specification is to provide more confidence in the ongoing consistency of performance and reliability of certified PV modules. The requirements of this technical specification are defined with the assumption that the quality management system of the organization has already fulfilled the requirements of ISO 9001 or equivalent quality management system. By maintaining a manufacturing system in accordance with this guideline, PV modules are expected to maintain their performance as determined from the test sequences in IEC 61215, IEC 61646, or IEC 62108.

This technical specification is applicable to all PV modules independent of design and technology i.e. flat panel, concentrator photovoltaic (CPV). Quality controls for CPV and nonconventional flat-plate manufacturing will differ somewhat from those of more conventional designs; this technical specification has not considered these differences.

## 2 Normative references

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

IEC 60812, *Analysis techniques for system reliability –Procedure for failure mode and effects analysis (FMEA)*

IEC 60891, *Photovoltaic devices – Procedure for temperature and irradiance corrections to measured I-V characteristics*

IEC 60904-1, *Photovoltaic devices – Part 1: Measurement of photovoltaic current-voltage characteristics*

IEC 60904-2, *Photovoltaic devices – Part 2: Requirements for photovoltaic reference devices*

IEC 60904-3, *Photovoltaic devices – Part 3: Measurement principles for terrestrial photovoltaic (PV) solar devices with reference spectral irradiance data*

IEC 60904-4, *Photovoltaic devices – Part 4: Reference solar devices – Procedures for establishing calibration traceability*

IEC 60904-7, *Photovoltaic devices – Part 7: Computation of the spectral mismatch correction for measurements of photovoltaic devices*

IEC 60904-9, *Photovoltaic devices – Part 9: Solar simulator performance requirements*

IEC 61215, *Crystalline silicon terrestrial photovoltaic (PV) modules – Design qualification and type approval*

IEC 61646, *Thin-film terrestrial photovoltaic (PV) modules – Design qualification and type approval*

IEC 61730-1, *Photovoltaic (PV) module safety qualification – Part 1: Requirements for construction*

IEC 61730-2, *Photovoltaic (PV) module safety qualification – Part 2: Requirements for testing*

IEC TS 61836, *Solar photovoltaic energy systems – Terms, definitions and symbols*

IEC 61853-1, *Photovoltaic (PV) module performance testing and energy rating – Part 1: Irradiance and temperature performance measurements and power rating*

IEC 62108, *Concentrator photovoltaic (CPV) modules and assemblies – Design qualification and type approval*

IEC 62759-1, *Photovoltaic (PV) modules – Transportation testing – Part 1: Transportation and shipping of module package units*

IEC TS 62915, *Photovoltaic (PV) modules – Retesting for type approval, design and safety qualification*[1]

IEC TS 62916, *Bypass diode electrostatic discharge susceptibility testing for PV modules*[1]

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement*

## 3 Terms, definitions and acronyms

For the purposes of this document, the terms and definitions in ISO 9000:2005, IEC TS 61836 and the following apply.

**3.1**
**containment**
action taken to protect the customer from the effect of a situation. Containment may include correcting an existing situation or adding additional screening or retesting

**3.2**
**control plan**
documented description of the systems and processes required for controlling the product and process quality by addressing the key characteristics and engineering requirements

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1 To be published.

**3.3**
**customer**
end user, investor, installer who purchases modules from the organization

**3.4**
**design lifetime**
design target period during which PV modules are expected to safely satisfy the specified performance under the specified conditions

Note 1 to entry: Specified conditions include application of use, installation environment configurations and operation conditions of the PV module in use. The design target period is set considering changes in performance of PV modules due to aging degradation of parts and materials used in the stated environment.

**3.5**
**Design Failure Mode and Effects Analysis**
**DFMEA**
application of the Failure Mode and Effects Analysis (FMEA) method specifically to product/service

**3.6**
**define, measure, analyse, improve and control**
**DMAIC**
data-driven quality strategy for improving processes and an integral part of a Six Sigma quality initiative

**3.7**
**electrostatic discharge**
**ESD**
sudden flow of electricity between two electrically charged objects caused by contact, an electrical short, or dielectric breakdown

Note 1 to entry: Electrostatic discharge events are known to damage semiconductor devices such as diodes.

**3.8**
**Failure, Modes and Effects Analysis**
**FMEA**
document that defines the design, process, or solution with requirements and includes potential modes, causes and severity of effects of failure, along with an evaluation of the likelihood of their occurrence and ease of detection

Note 1 to entry: FMEA provides a mechanism to prioritize the risks and take appropriate mitigation steps.

**3.9**
**key materials**
materials that affect safety, reliability, or product performance of the PV module

Note 1 to entry: Key materials may include indirect materials. Those materials which are used during the manufacturing process of PV modules, but are not found in the end product. In most chemical processes, catalyzers are indirect materials.

**3.10**
**organization**
entity that supplies modules to the customer and that has responsibility for design, production, and after-service for the modules

Note 1 to entry: The organization may subcontract some of its responsibilities for design, production, and the after-sales service.

**3.11**
**out of box audit**
**pre-shipment audit**
is meant to simulate what a customer would experience when they open the packing box

Note 1 to entry: Usually the out-of box audit is carried out as follows: Samples of crates or packing boxes are taken from the delivery waiting for shipment and audited for compliance to packing, labeling instructions, documents along with the product, and finally the product itself. Product is verified for compliance to customer requirements including visual, dimension and functional. Non-conformances from these audits are escapes from the processes and outgoing inspection controls. These non-conformances are analyzed and fed back to improve the processes and controls to prevent recurrence.

**3.12**
**out of control action plan**
**OCAP**
supporting document to an SPC (Statistical Process Control) chart. An OCAP is typically presented as a flowchart that guides manufacturing floor employees' reactions to out-of-control situations. An OCAP consists of activators (which define out-of-control conditions); checkpoints (which are likely causes for the conditions); and terminators (which contain the action that should resolve the conditions). OCAPs should be dynamic and updated continually as and when new knowledge and information become available. A frequently occurring OCAP activator is an indication of a systemic issue in the process

**3.13**
**Plan, Do, Check, Act**
**PDCA**
four-step process for quality improvement

Note 1 to entry: In the first step (Plan), a way to affect improvement is developed. In the second step (Do), the plan is carried out, preferably on a small scale. In the third step (Check)), a study takes place between what was predicted and what was observed in the previous step. In the last step (Act), action is taken on the causal system to affect the desired change.

**3.14**
**performance warranty**
warranty provided by the party ensuring product liability to guarantee the specified performance of PV modules over the specified period and under the specified conditions

**3.15**
**Process Failure Modes and Effects Analysis**
**PFMEA**

**3.16**
**Product Life-Cycle Management**
**PLCM**
the process of managing the entire life cycle of a product from inception, through engineering design and manufacture, to service and disposal of manufactured products

**3.17**
**prototype**
early sample, model, or release of a product built to test a concept or process, but may not have been produced with the intended future processes

**3.18**
**Quality Management System**
**QMS**
formalized system that documents the structure, responsibilities, and procedures required to achieve effective quality management

**3.19**
**quality plan**
document, or several documents, that together specify quality standards, practices, resources, specifications, and the sequence of activities relevant to a particular product, service, project, or contract

**3.20**
**repeatability**
variation in measurements obtained when one measurement device is used several times by the same person to measure the same characteristic on the same product

**3.21**
**reproducibility**
variation in measurements made by different people using the same measuring device to measure the same characteristic on the same product

**3.22**
**statistical capability**
statistical measure of the inherent process variability of a given characteristic in comparison to the specification limits

**3.23**
**statistical process control**
**SPC**
application of statistical techniques to control and monitor process. It is used to determine the stability and predictability of a process

**3.24**
**supplier**
provider of materials to an organization building module manufacturing and assembly

## 4 Documentation requirements

Records related to design, qualification, engineering changes, monitoring, and measurement of manufacturing processes and products, final testing, and customer details that are necessary to secure the warranty condition and that are defined by the organization, shall be retained for a necessary period.

Records should also include Certificates of Conformity (CoC) and Certificates of Conformity Analysis (CoA) of key materials identified by the organization.

## 5 Resource management

### 5.1 Provision of resources for product warranty system

In addition to the basic QMS-required resource planning, the organization shall determine and provide the resources needed to maintain the product warranty system, including provision of after-sales service and for identifying cause of failure and any appropriate follow-up actions such as adjustment to quality control plan or warranty recall.

### 5.2 Succession planning

The organization shall plan for succession for key functions that affect customer satisfaction, quality, reliability, safety, and performance.

## 6 Product realization

### 6.1 General

The organization is required to implement a recognized basic QMS. In addition, the following requirements shall also apply.

### 6.2 Planning of product realization

In planning product realization, the organization shall also determine the following, as appropriate:

a) Product certification requirements.

b) Design lifetime aligned with the stated warranty under specific conditions and a documented method to ensure compliance to stated warranty by a combination of product reliability and after-sales services.

c) Recycling requirements at the end of the modules' lifetime.

d) Quality assurance and control measures to be applied to production to meet requirements of the applicable PV standards.

e) ESD safe environmental area.

   The organization shall identify the ESD sensitive materials and components and shall determine an ESD safe environmental area and maintain an ESD safe environment at the raw material storage, processing, assembly areas, and all through packaging and shipping as defined in future IEC TS 62916 or as appropriate.

f) Packaging, storage and transportation requirements.

Customer requirements and references to related technical specifications, as applicable, shall be included in the planning of product realization as a component of the quality plan.

With changing requirements from the market place and with emerging new technology in the PV industry, the development and launch of new products should meet requirements of the product warranty as well as customers' needs. A complete product life-cycle management process may be required.

The product certification may depend on the application and geographies where the modules will be installed.

The recycling requirements should comply with the geographies where the modules will be installed.

ESD requirement should consider ANSI/ESD S20.20, future IEC TS 62916 or equivalent standard.

### 6.3 Determination of requirements related to the product

The organization shall determine product warranty workmanship and power degradation and its relationship to design lifetime under specified and intended use conditions.

The organization shall incorporate requirements arising from applicable previous failure information, customer complaints, competitive analysis, supplier feedback, and other internal inputs. The organization shall maintain traceability to these requirements.

The organization shall establish a method for specifying the nameplate power of a module with an allowed tolerance at standard test conditions per IEC 61215, IEC 61646, or IEC 62108 (see 6.9.2 for proper control of solar simulators).

### 6.4 Review of requirements related to the product

The organization shall ensure that all modified product, not covered by the retest guidelines as defined in future IEC TS 62915, is qualified to all related type designs and that the modified product is evaluated for impact on the warranty.

The organization shall identify and document all limitations on product application.

The organization shall identify critical areas for ESD control, where appropriate.

ESD requirement should consider ANSI/ESD S20.20, future IEC TS 62916 or equivalent standard.

### 6.5 Customer communication

The organization shall also determine and implement effective arrangements for communicating with customers in relation to the following:

a) Safety, workmanship warranty, output power warranty and installation guidelines including electrical and mechanical installation instruction.

b) Application notes detailing specific attention and care needed to secure module design lifetime of the installed configuration.

c) The definition of a warrantable defect or safety critical defect and the rules or process to manage stated defects, and

d) Product recall notices.

NOTE "Information" includes, but is not limited to, specifications, drawings, and other material, including "installation" manuals.

### 6.6 Organization manufacturing feasibility

The organization shall investigate, conduct risk analysis, confirm and document the manufacturing feasibility at the necessary scale of the proposed products in the contract where applicable.

The organization shall manage the risks prior to manufacturing transfer.

### 6.7 Design and development

#### 6.7.1 Design and development planning

The organization shall include production processes in the design and development planning.

The organization shall also determine:

a) The responsibilities and authorities for a project design and development team.

b) The process to conduct design FMEAs as defined in IEC 60812 or equivalent, reliability testing, design lifetime, and product specification generation, and

c) The requirements for process FMEAs as defined in IEC 60812 or equivalent, specifications, layouts, control plan, and work instructions.

#### 6.7.2 Design and development inputs

The inputs shall also include the following:

a) Functional, performance, and safety requirements including design lifetime, power, maintainability, durability, transportation, timing, and costs, and including the materials requirements defined in IEC 61730-1.

b) Identification of product, traceability, and packaging requirements.

c) Requirements for proper handling of product and components for ESD, and

d) Lessons learned from previous designs.

The organization may consider application of IEC draft standard on transportation testing IEC 62759 when designing packaging materials.

### 6.7.3 Manufacturing process design inputs

The organization shall identify, document, and review the manufacturing process design input requirements, including the following:

a) Product design output data.

b) Targets for productivity, process capability and cost.

c) Customers' requirements, if any, and

d) Lessons learned from previous developments.

The manufacturing process design includes the use of error-proofing methods and statistical process control methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

### 6.7.4 Design and development outputs

Design and development outputs shall also include the following:

a) Specify an installation manual for safe and proper installation and use.

b) Include design FMEAs as defined in IEC 60812, or equivalent, which are to be updated during design reviews, and a related design qualification/verification and reliability test plan, and

c) Define characteristics of the product that cannot be fully verified later by non-destructive methods and the designated means to control those characteristics for adequate product performance.

### 6.7.5 Manufacturing process design outputs

The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include data for quality, and reliability including the following:

a) Specifications and drawings.

b) Manufacturing process flow chart/layout.

c) Manufacturing process FMEAs as defined in IEC 60812 or equivalent risk management tool.

d) Control plan (see 6.9.2).

e) Work instructions.

f) Process approval acceptance criteria.

g) An ESD protection plan.

h) Error-proofing methods, as appropriate.

i) Methods for product identification and traceability.

j) Methods for detection and feedback of product/manufacturing process nonconformities, and

k) Process for handling raw materials from the time of their receipt.

Process FMEAs (PFMEAs), or equivalent, should cover the process from material receipt to product delivery, and where appropriate, installation and maintenance.

### 6.7.6 Design and development validation

The organization shall include standard requirements from applicable IEC and national standards for validation of the design.

Performance testing activities including durability of prototype modules shall be monitored for timely completion and conformance to requirements. Performance testing shall conform to a product and process approval procedure including a reliability test plan similar to applicable standards. As a minimum, prototyped or pre-production PV modules shall be tested according to IEC 61215, IEC 61646, IEC 61730-1, IEC 61730-2, future IEC TS 62915, IEC 62108, or equivalent.

Although services may be outsourced, the organization shall be responsible for the qualification of subcontracted services, including ongoing technical oversight and confirmation of test results.

Product approval should be subsequent to the verification of the manufacturing process. This product and manufacturing process approval procedure should also be applied to suppliers of key materials.

### 6.7.7 Control of design and development changes

The organization shall implement a change management system for materials and processes and ensure all changes impacting form, fit and function adhere to product requirements and defined internal/external qualification and certification requirements such as future IEC TS 62915.

Traceability of changes shall be documented and maintained in the organization's QMS.

All design and development changes shall be evaluated for risks and documented in the appropriate FMEA as defined in IEC 60812 or equivalent.

Qualification, safety, compliance, and reliability tests shall be documented.

The conditions of qualification, safety and reliability tests should be defined by taking into consideration the specified condition required by IEC 61215, IEC 61646, IEC 61730-1, IEC 61730-2, future IEC TS 62915, IEC 62108, or equivalent.

Such changes shall not be released to customers before applicable tests are verified to be satisfactory. Certification of the change may be necessary prior to release to a customer. If the change has impact to form, fit, function, safety, performance, or decrease in reliability of the product, notification to the appropriate customer is required.

## 6.8 Purchasing

### 6.8.1 Purchasing process

Materials, components, and sub-assemblies that have a safety, performance, or reliability implication on the finished product and that are purchased from or prepared by a supplier require a level of control adequate to ensure that the overall risks are minimal.

The organization shall define a process for the supplier's notification of changes and ensure that the supplier maintain traceability of relevant changes. It is the responsibility of the organization or the manufacturer to ensure that the components, sub-assemblies and assemblies completed by subcontractors meet the quality plans, including relevant safety and certification requirements.

The organization shall complete the following actions to ensure their suppliers can meet product requirements by doing the following:

a) Set up a QMS.

b) Evaluate the quality performance of key materials and audit the supplier of key materials on a regular basis.

c) Ensure that materials used in the product conform with material specifications provided by the organization.

d) Periodically carry out onsite audits to check that:

- the material produced is conformal with applicable organization or manufacturer specifications;
- the supplier has the capability to deliver the goods on time;
- the supplier maintains product quality consistently, notifies and seeks approval when there is any change of products, process, and manufacturing location, or significant process excursion that may affect form, fit, function, reliability, or performance.

e) Urge the supplier to improve its quality performance if necessary, and

f) Apply methods for incoming inspections and preparation of raw materials.

QMS requirements for key materials may include ISO 9001 compliance.

### 6.8.2 Purchasing information

Purchasing information shall also describe the requirements for materials/component traceability.

### 6.8.3 Verification of purchasing process

The organization shall have a consistent process to assure the quality of key materials using an appropriate combination of the following methods:

a) Receipt and review of certificate of conformance or analysis.

b) Evaluation of statistical data of purchased products and key materials.

c) Receiving inspection or testing such as statistical sampling based on performance.

d) Product evaluation or material analysis by an independent laboratory or testing facility.

e) Evidence of supplier inspections when the supplier has been delegated inspection authority based on the history of product conformance to requirements, and

f) When a deficiency is identified, the organization shall take appropriate steps (for example, out-of-control action plan (OCAP)) until supplier performance meets the purchase requirements.

Statistical sampling may be based on ANSI/ASQ Z1.4, Z1.9 or equivalent national standards.

## 6.9 Production and service provision

### 6.9.1 Control of production and service provision

The organization shall determine methods to monitor the performance and accuracy of the equipment used in the product realization process.

The organization shall create definitions of product problems and determine rules and processes to minimize the impact of the problem.

The organization shall inspect the product in-process in addition to performing a final inspection to ensure that the requirements of the product specification are met and defective product are prevented from release.

The organization shall provide technical support to customers on how to use the product, guide customers in trouble-shooting where applicable, and prevent any safety risks.

The organization shall include a statement of the tolerance of the nominal power on the label of the produced module in accordance with IEC 61215, IEC 61646 or IEC 61208. In addition, the organization shall include on the datasheet, or other product literature

a) a statement specifying if the measurement uncertainty is included within the specified nameplate tolerance in the module label or not,

b) if the uncertainty is not included, a statement specifying that the power measurement uncertainty is provided to the customer upon request.

### 6.9.2 Control plan

The organization shall establish control plans for all appropriate processes, sub-assemblies, components, and materials for the final product. Control plans shall

a) Be based on a risk analysis such as design or process FMEA outputs, or equivalent.

b) List the controls used for the manufacturing process control.

c) Include methods for monitoring of control exercised over special characteristics (see 7.2) defined by the organization.

d) Include customer required information, if any, and

e) Initiate a specific out of control action plan (OCAP) when a process becomes unstable or not statistically capable.

The organization shall review and update control plans when any change occurs that affects the product manufacturing process.

The organization shall periodically review control plans for effectiveness of the controls and take appropriate corrective actions.

The organization shall define and manage a process to disposition the affected product impacted by an out-of-specification process.

The organization shall maintain data records in a manner that allows detections of possible tendencies.

Specifically, the organization shall develop a control plan for all solar simulators used for performance rating. The control plan should be statistically based using reference modules. The simulator control plan shall have a documented out-of-control action plan for deviations. If multiple solar simulators are used, the control plan shall demonstrate how correlation between the solar simulators is maintained.

The organization shall develop a control plan for the measurement procedure that includes verifying control of the module temperature during the scan, placement of the module on the simulator, proper function of the simulator and data acquisition electronics, and verification and maintenance of low-resistance electrical connection to the module.

The variance of temperature shall be controlled. To minimize the uncertainty, the test temperature of the module should be 25 °C ± 2 °C, and the module should be equilibrated enough that the variation between the cell junction and measurement point on the module is less than 1 °C .

If the test temperature is outside of the recommended range, a correction is made for test temperature and the deviation from test conditions coupled with the uncertainty in temperature coefficient shall not cause the total uncertainty of the measurement to exceed the uncertainty indicated on the product label, datasheet, or other product literature.

Solar simulators that have been changed in a way that may affect the performance rating shall be re-qualified to IEC 60904-9 to ensure the original BBA or better rating is maintained. In addition, each solar simulator used for performance rating shall be partially re-qualified to IEC 60904-9 for uniformity of irradiance and temporal stability at a minimum of twice per year.

Secondary reference modules shall be generated and certified by a recognized certification body for each specific module type, which can be traceable to international or national measurement standards. Working reference modules shall be created according to IEC 60904-2 and IEC 60904-4. The organization shall develop a control plan for the secondary reference and working reference modules to ensure no significant change occurs that may affect the rating of the module.

IEC 60891 (temperature and irradiance correction) and IEC 60904-7 (spectral correction) shall be used to appropriately correct the current and voltage characteristics of a module under test. IEC 61853-1 shall be used to determine the correction coefficients for irradiance and temperature effects on the measurement of the module. The organization shall develop a plan to periodically revalidate the correction coefficients for a specific module type.

Solar simulator manufacturer's data may be used to initially validate that the solar simulator meets the BBA or better requirement.

Multiple secondary reference modules may be needed because they could be damaged or during periods when one secondary reference is out for calibration.

The plan shall also contain elements for the following items:

f) Solar simulator maintained to have adequate spatial uniformity, temporal consistency, and spectral accuracy (as determined by IEC 60904-9).

NOTE "adequate" implies that the combination of all uncertainties (including uncertainty associated with the simulator classification) is within the uncertainty indicated on the product label and literature.

g) Reference modules (as defined in IEC 60904-2) that are maintained at a known, traceable calibration (per IEC 60904-4) and that are similar to the product under test are used to perform an adequate measurement.

### 6.9.3 Validation of processes for production and services provisions

The organization shall validate software used in the product, production and services provision.

The organization shall define a certification and periodic recertification process for qualified personnel.

The organization shall determine parameter sets for the acceptance tolerance for the product.

The organization shall validate the effectiveness of its ESD program, as required.

These requirements are also applicable to key materials from suppliers.

See IEC 61340-5-1 for guidance.

Use of statistical process control is recommended for these processes.

Software applications throughout the life cycle that are important to ensuring product quality, reliability, performance, or safety should be included.

Software may include firmware.

### 6.9.4 Identification and traceability

The organization shall document traceability of changes to the product and impact from those changes for previous and future product deliveries.

The organization shall ensure traceability of the product, where appropriate, by

a) Tracking product construction to the constituent key raw materials and components used to the lot/batch level that are traceable back to suppliers, dates, and locations of manufacture, and,

b) Tracking the product through each process step to the specific machine and time of processing. For manual process steps, traceability to the operator performing operation shall be recorded.

### 6.9.5 Customer property

The organization shall be responsible for protecting customer intellectual property for outsourced processes.

If required, the control methods of customer property should be approved by the customer.

### 6.9.6 Preservation of product

The packaging method of the PV module shall be tested as defined in IEC 62759-1 or equivalent and validated to meet customer requirements and ensure that the product can be transported to customer sites properly. Product traceability information should be easily identified from the outside of the packaging.

The organization shall also ensure the preservation of potential nonconforming products and key materials under material review until disposition as not fit for use.

The organization shall use an inventory management system to ensure stock rotation.

## 6.10 Control of monitoring and measuring equipment

### 6.10.1 General

Monitoring and measurement equipment referenced in the control plan shall be characterized by measurement system analysis to understand gauge capabilities (repeatability and reproducibility).

Software shall be considered an integral part of monitoring and measuring equipment and shall be appropriately controlled and validated. For changes that affect configuration, including software, the organization shall revalidate monitoring and measurement equipment.

For monitoring and measurement equipment determined to be out of tolerance at the time of calibration, corrective actions shall be taken to determine impact to the product and documented per Clause 4.

### 6.10.2 Control of performance rating (IV) measurement equipment

For the equipment used to measure the power performance of the module, the organization shall maintain a control program compliant to IEC 60891 and IEC 60904 series of standards. Records of compliance shall be maintained.

The organization shall retain all calibration certificates including the name of the PV institute that issued the reference device calibration certificate or a report that can be traceable to international or national measurement standards. This information shall be traceable for each module manufactured and made available to customers upon request.

Solar simulators shall be initially qualified according to IEC 60904-9 and shall include characterization of spectrum quality, uniformity of irradiance, and temporal instability of irradiance.

Solar simulators with a BBA rating or better are suggested for performance rating of modules, but the simulator requirement may vary with the solar cell technology, the geometry of the module, the match between the reference module and the test modules, and the power measurement uncertainty indicated on the product literature.

Power measurement with solar simulators and the methodology used for performance rating shall have an initial estimate of the uncertainty according to ISO/IEC Guide 98-3. The uncertainty analysis shall be re-evaluated at least annually.

# 7 Monitoring and measurement

## 7.1 Customer satisfaction

The organization shall manage customer complaints in a controlled manner, log the issues, and take corrective and preventive actions, as appropriate. The organization shall ensure that any necessary corrections and corrective actions are taken without undue delay and communicated to the customer, where appropriate.

Organization shall monitor the complaint log for recurring issues and escalate to management, as appropriate.

The organization shall send quality alert internal communications to all affected manufacturing locations upon discovery of new failures and defects.

Records of such alerts shall be maintained in accordance with Clause 4.

## 7.2 Monitoring and measurement of a manufacturing process

The organization shall perform process studies on all new manufacturing processes (including assembly or sequencing) to verify process capability and to provide additional input for process control. The results of process and tool capability studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for manufacturing process capability, equipment availability, as well as acceptance criteria.

The organization shall maintain manufacturing process and tool capability or performance as specified by the customer part approval process requirements or organization targeted level. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified:

a) Measurement techniques.

b) Sampling plans.

c) Acceptance criteria.

d) Preventive maintenance, and

e) Reaction plans when acceptance criteria are not met.

The organization shall use appropriate statistical tools and statistically significant sample sizes to make decisions that affect quality of process and products at all stages of the life cycle.

Significant process events, such as a tool change or machine repair, shall be recorded.

The organization shall initiate an out-of-control action plan from the control plan for characteristics that are either not statistical capability or are unstable. These plans shall include the containment of product and 100 % inspection, as appropriate. A corrective action plan shall then be completed by the organization, indicating specific timing and assigned

responsibilities to ensure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer when so required.

The organization shall maintain records of effective dates of process changes through a change management system. A quality management representative of the QMS shall be empowered to issue stop-work or stop-ship when nonconforming products are suspected to exceed specified limits. Records of such events shall be maintained (see Clause 4).

### 7.3 Monitoring and measurement of product

Measurement of module performance before shipment shall be to a recognized standard such as IEC 60904-1 using a defined reference spectrum such as the AM1.5 Global Spectrum defined in IEC 60904-3.

Control of measurement conditions shall minimize the need for correction to STC, and correction for any deviations from STC according to IEC 60904-7 (correction for spectrum) and IEC 60891 (correction for temperature and irradiance).

Tests performed on 100 % of the products for validation of performance and safety shall be carried out at the final stage of production, and no further operations except cleaning, labeling, and packaging may be carried out after these tests.

Monitoring and measurement of product shall include studies of the performance during the expected design lifetime of the product.

### 7.4 Ongoing product monitoring

The organization shall define an ongoing/periodic reliability monitoring/production monitoring program that uses appropriate tests for the known failure mechanisms of the product. The tests shall be conducted on the samples that are selected by the internal sampling procedure.

Discovery of failures from these activities shall follow 7.8. Corrective action to address the root cause shall be taken and documented for any failures.

Records of the results of any ongoing/periodic reliability testing/production monitoring program activities and any necessary actions arising from such activities shall be maintained (see Clause 4).

### 7.5 Internal audit

The organization shall periodically conduct process audits for all manufacturing processes (including assembly or sequencing) to ensure compliance to work instructions, ESD controls, and control plan.

The organization shall also periodically conduct outgoing quality audits and out-of-box audits to ensure conformance to product quality requirements.

Internal audits should be implemented based on ISO 19011:2011 or equivalent national standard.

### 7.6 Control of nonconforming product

#### 7.6.1 Control of nonconforming product

Organization shall conduct a systematic material review to disposition nonconforming products and constituent raw materials. Product with unidentified or suspect status shall be identified as potentially nonconforming product and subjected to a systematic review process.

Customers shall, where appropriate, be informed promptly in the event that nonconforming product has been shipped without customer approval. Records of customer notifications, where appropriate, shall be maintained (see Clause 4).

The organization shall, where appropriate, obtain a customer concession or a deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

### 7.6.2 Analysis of data

The analysis of data shall provide information relating to conformity to process and product requirements (see 7.3)

## 7.7 Continual improvement

The organization shall deploy continual improvement through a structured approach and demonstrate that results are sustained.

The organization should identify, measure, and report quality metrics to drive continuous improvement.

The structured approach may include proven methodologies such as PDCA or DMAIC.

## 7.8 Corrective and preventive action

The organization shall use a structured approach to conduct root-cause analysis and corrective action.

The organization shall share lessons learned from the corrective action across all manufacturing locations and affected functions and suppliers, as appropriate, to prevent recurrence.

Structured approach for root-cause analysis and corrective action may include proven methodologies such as why-why analysis and “8 Discipline” method (also called “Eight Disciplines Problem Solving” method).

# Annex A
(informative)

## Correspondence between ISO 9001:2008 and IEC TS 62941

| ISO 9001:2008 | Clause/subclause | Clause/subclause | IEC TS 62941 |
|---|---|---|---|
| Scope | 1 | 1 | Scope |
| Normative references | 2 | 2 | Normative references |
| Terms and definitions | 3 | 3 | Terms and definitions |
| Quality Management System (title only) | 4 | | |
| General requirements | 4.1 | | |
| Document requirements (title only) | 4.2 | 4 | Documentation requirements (title only) |
| General | 4.2.1 | | |
| Quality manual | 4.2.2 | | |
| Control of documents | 4.2.3 | | |
| Control of records | 4.2.4 | 4 | Record retention |
| Management responsibility (title only) | 5 | | |
| Management commitment | 5.1 | | |
| Customer focus | 5.2 | | |
| Quality policy | 5.3 | | |
| Planning (title only) | 5.4 | | |
| Quality objectives | 5.4.1 | | |
| Quality management system planning | 5.4.2 | | |
| Responsibility, authority, and communication (title only) | 5.5 | | |
| Responsibility and authority | 5.5.1 | | |
| Management representative | 5.5.2 | | |
| Internal communication | 5.5.3 | | |
| Management review (title only) | 5.6 | | |
| General | 5.6.1 | | |
| Review input | 5.6.2 | | |
| Review output | 5.6.3 | | |
| Resource management (title only) | 6 | 5 | Resource management (title only) |
| Provision of resources | 6.1 | | |
| N/A | | 5.1 | Provision of resources for product warranty system |
| N/A | | 5.2 | Succession planning |
| Human resources (title only) | 6.2 | | |
| General | 6.2.1 | | |
| Competence, training and awareness | 6.2.2 | | |
| Infrastructure | 6.3 | | |
| Work environment | 6.4 | | |

| ISO 9001:2008 | Clause/subclause | Clause/subclause | IEC TS 62941 |
|---|---|---|---|
| Product realization (title only) | 7 | 6 | Product realization (title only) |
| Planning of product realization | 7.1 | 6.2 | Planning of product realization |
| Customer-related processes (title only) | 7.2 | | |
| Determination of requirements related to the product | 7.2.1 | 6.3 | Determination of requirements related to the product |
| Review of requirements related to the product | 7.2.2 | 6.4 | Review of requirements related to the product |
| Customer communication | 7.2.3 | 6.5 | Customer communication |
| N/A | | 6.6 | Organization manufacturing feasibility |
| Design and development (title only) | 7.3 | 6.7 | Design and development (title only) |
| Design and development planning | 7.3.1 | 6.7.1 | Design and development planning |
| Design and development inputs | 7.3.2 | 6.7.2 | Design and development inputs |
| N/A | | 6.7.3 | Manufacturing process design inputs |
| Design and development outputs | 7.3.3 | 6.7.4 | Design and development outputs |
| N/A | | 6.7.5 | Manufacturing process design outputs |
| Design and development review | 7.3.4 | | |
| Design and development verification | 7.3.5 | | |
| Design and development validation | 7.3.6 | 6.7.6 | Design and development validation |
| Control of design and development changes | 7.3.7 | 6.7.7 | Control of design and development changes |
| Purchasing (title only) | 7.4 | | |
| Purchasing process | 7.4.1 | 6.8.1 | Purchasing process |
| Purchasing information | 7.4.2 | 6.8.2 | Purchasing information |
| Verification of purchased product | 7.4.3 | 6.8.3 | Verification of purchasing process |
| Production and service provision (title only) | 7.5 | | |
| Control of production and service provision | 7.5.1 | 6.9.1 | Control of production and service provision |
| N/A | | 6.9.2 | Control plan |
| Validation of processes for production and service provision | 7.5.2 | 6.9.3 | Validation of processes for production and services provisions |
| Identification and traceability | 7.5.3 | 6.9.4 | Identification and traceability |
| Customer property | 7.5.4 | 6.9.5 | Customer property |
| Preservation of product | 7.5.5 | 6.9.6 | Preservation of product |
| Control of monitoring and measuring equipment | 7.6 | 6.10 | Control of monitoring and measuring equipment |
| N/A | | 6.10.2 | Control of performance rating (IV) measurement equipment |
| Measurement, analysis and improvement (title only) | 8 | | |
| General | 8.1 | | |
| Monitoring and measurement | 8.2 | 7 | Monitoring and measurement (title |

| ISO 9001:2008 | Clause/subclause | Clause/subclause | IEC TS 62941 |
|---|---|---|---|
| (title only) | | | only) |
| Customer satisfaction | 8.2.1 | 7.1 | Customer satisfaction |
| Internal audit | 8.2.2 | 7.5 | Internal audit |
| Monitoring and measurement of processes | 8.2.3 | 7.2 | Monitoring and measurement of a manufacturing process |
| Monitoring and measurement of product | 8.2.4 | 7.3 | Monitoring and measurement of product |
| N/A | | 7.4 | Ongoing product monitoring |
| N/A | | 7.6 | Control of nonconforming product (title only) |
| Control of nonconforming product | 8.3 | 7.6.1 | Control of nonconforming product |
| Analysis of data | 8.4 | 7.6.2 | Analysis of data |
| Improvement (title only) | 8.5 | | |
| Continual improvement | 8.5.1 | 7.7 | Continual improvement |
| Corrective action | 8.5.2 | 7.8 | Corrective and preventive action |
| Preventive action | 8.5.3 | 7.8 | Corrective and preventive action |

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