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Updated Proposal for a Guide for Quality Management Systems for PV Manufacturing: Supplemental Requirements to ISO 9001-2008

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Technical Report
NREL/TP-5J00-63742
March 2015

Contract No. DE-AC36-08GO28308

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Acronyms

ASQ	American Society for Quality
AIST	National Institute of Advanced Industrial Science and Technology
ESD	electrostatic discharge
FMEA	failure modes and effects analysis
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
JRC	Joint Research Centre
NREL	National Renewable Energy Laboratory
PFMEA	process failure modes and effects analysis
PV	photovoltaic
QA	quality assurance
QMS	quality management system
STC	standard test conditions
DMAIC	Define-Measure-Analyze-Improve-Control
PDCA	Plan-Do-Check-Act

Executive Summary

The goal of this Technical Specification is to provide a guideline for manufacturers of photovoltaic (PV) modules to produce modules that, once the design is proven to meet the quality and reliability requirements, replicate the design on an industrial scale without compromising its consistency with the requirements.

From 1996 to 2014, the PV industry grew by a factor of almost 500, resulting in annual PV module production of about 40 gigawatts (GW). With an annual investment in PV around $100 billion, the industry has become highly motivated to ensure quality of that investment, with special emphasis on the quality of the PV modules, because these are the most expensive parts of the system to replace and the extent of the modules' power output degradation in the field significantly impacts the return on investment.

The International PV Module Quality Assurance Task Force (PVQAT) was formed in 2011 to develop standards that can help customers quickly assess a PV product's ability to withstand regional stresses and to gain confidence that purchased PV products will be of consistent quality.

Reliability is neither defined, nor covered, by the existing International Electrotechnical Commission (IEC) standards. Module design qualification to those standards does not imply the PV module's reliability. Therefore, PVQAT set the goal to establish guidelines dealing with all relevant influences on the module, such as raw materials and components, process parameter sets and their control, reasonable test sequences, training of the staff, etc.

Task Group #1 of PVQAT has focused on the requirements of a quality management system (QMS) used to guide the manufacture of PV modules in maintaining module quality consistency. While ISO 9001 is used as an international standard for documenting QMSs, it addresses generic elements of a QMS and does not cover specific details of interest to the PV industry. Starting in the fall of 2011, Task Group #1 began to write a PV-specific supplement to ISO 9001 that would strengthen the QMS by incorporating known requirements for PV. An early draft of this supplement was accepted by IEC Technical Committee 82 (TC82) as a New Work Item Proposal. TC82 is currently preparing a Draft Technical Specification for vote (DTS) (IEC 62941 TS), and once the document is fully adopted through the standards process, it will become a Technical Specification that can be used by the community as the standard basis for audits of PV module manufacturers. The recent formation of IECRE (the IEC System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications) under IEC's Conformity Assessment Board will provide a direct vehicle for utilization of this Technical Specification as IECRE creates the capability to complete an inspection of a PV system and its constituent components to ensure that it was designed, installed, and operated correctly for the system design and local climate.

This report summarizes the recommendations identified by Task Group #1 and provides the community with a way to begin benefitting from the more robust QMSs, even before the standards process is completed. Community experience in implementing this draft standard will also provide essential feedback for the standardization process to help ensure that the adopted standard is optimally useful. In that context, the community is encouraged to use the contents of this report and to provide feedback to PVQAT and the IEC/ISO standards organizations. We are

interested in positive and negative experiences with the application of the recommendations herein.

Key requirements in the proposed standard include:

- Focus on the organization's control of the PV module's design to align the expected lifetime with its relationship to the organization's warranty. Warranty claims must be addressed by product and process design or by financial means
- Requirement to ensure the manufacturer has considered potential failure modes (e.g., through a Failure Modes and Effects Analysis, FMEA) and has taken steps to address those in the design, production, application and delivery process
- Requirement to obtain IEC product certification and implement an ongoing reliability test program that monitors PV modules' performance for compliance with standards and the stated design lifetime
- Requirement to improve product traceability through the entire supply chain to enact positive control of the product for recalls and warranty claims
- Design of a manufacturing process that will ensure conformance to the design intent for performance, lifetime, and warranty
- Special processes, such as control of solderability, electrostatic discharge (ESD) control, and assignment of PV module power rating.

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Introduction: Motivation

From 1996 to 2014 the photovoltaic (PV) industry grew by a factor of almost 500, resulting in annual PV module production of about 40 gigawatts (GW). With an annual investment in PV of about $100 billion, the PV community has become highly motivated to ensure quality of that investment. Because PV module prices fell by a factor of about three between 2009 and 2012, manufacturers have been universally pressured to cut costs. There is some concern within the community that some manufacturers may be reducing costs by paying less attention to quality and reliability requirements. Even for the manufacturers who are conscientious, it is difficult to determine whether a PV module will have a lifetime that will meet the warranty (typically 25 years). For those who are less conscientious, the possibility of premature failure can be considered an unacceptable risk.

The International PV Module Quality Assurance Forum was held in July of 2011 in San Francisco, organized and sponsored by the National Institute of Advanced Industrial Science and Technology (AIST), the National Renewable Energy Laboratory (NREL), the European Commission Joint Research Centre (JRC), and the SEMI PV Group. About 160 individuals representing PV manufacturers, PV customers, test laboratories, and government organizations attended the Forum. The participants agreed that improved standards are needed to differentiate PV module durability in different climate zones and in various mounting configurations. In addition to the need for accelerated tests that match the intended use conditions, the participants highlighted the need to be able to communicate the strength of the quality management program used by the factory. Although factories use QMSs, there has been no simple way to differentiate a strong QMS from a weak one. The International PV Module Quality Assurance Task Force (PVQAT) was formed at the Forum to develop standards that can help customers quickly assess a PV product's ability to withstand regional stresses and to gain confidence that purchased PV products will be of consistent quality. Five task groups were formed to address the manufacturing consistency (Task Group #1) issues and need for accelerated tests (Task Groups #2–5). Since then, seven additional task groups have been formed to help discuss the communication of the testing results, as well as address other issues.

In 2014, IECRE was formed under IEC's Conformity Assessment Board to certify quality of renewable energy (RE) systems, including wind, PV, and marine systems. IECRE is committed to creating a standard method for verifying PV system quality. One critical piece of that method is the assurance of the consistent quality of the PV modules that are installed in the system.

With the targeted plan of implementation through IECRE, Task Group #1 of PVQAT has focused on the requirements of a QMS used to guide manufacture of PV modules. While ISO 9001 is used as a standard for documenting and implementing QMSs, it addresses generic elements of a QMS and does not touch on specific details of interest to the PV industry. Starting in the fall of 2011, Task Group #1 began to write a PV-specific supplement to ISO 9001 that would strengthen the QMS by incorporating known requirements for PV. This was accepted by IEC Technical Committee 82 (TC82) as a New Work Item Proposal in 2014 and a draft technical specification (DTS) for vote is being prepared for submission in spring 2015. Once the document is fully adopted through the standards process, it will become a Technical Specification (IEC 62941TS) that can be used by the community as the standard basis for audits of PV modules.

In the meantime, this report summarizes the work of Task Group #1 and provides the community with a mechanism to begin benefitting from more robust QMSs, even before the standards process is completed. Community experience gained by implementing this draft will also provide essential input into the standards process to help ensure that the adopted standard is optimally useful. In that context, the community is encouraged to use the contents of this report and to provide feedback to PVQAT and to IEC. We are interested in the positive and negative experiences with application of the recommendations herein.

This report is an update from a report published in 2013. It is intended to document the progress made in 2013, 2014, and early 2015.

Methodology

There have been a large number of participants in Task Group #1 (about 200). The participants have represented different continents, requiring optimization of the working method. A task leader was set as coordinator and four regional task groups were formed in Europe, the Americas, Japan, and China. International participation was encouraged, but the formation of regional teams allowed more convenient scheduling of meetings and, in some cases, aided in communication by allowing participants to speak in their native language. The four regional groups separated the various chapters and began to develop a set of suggested recommendations. Fig. 1 indicates an example of activities by regional groups when drafting the new proposal (the y-axis represents the percentage while the x-axis represents the section considered).

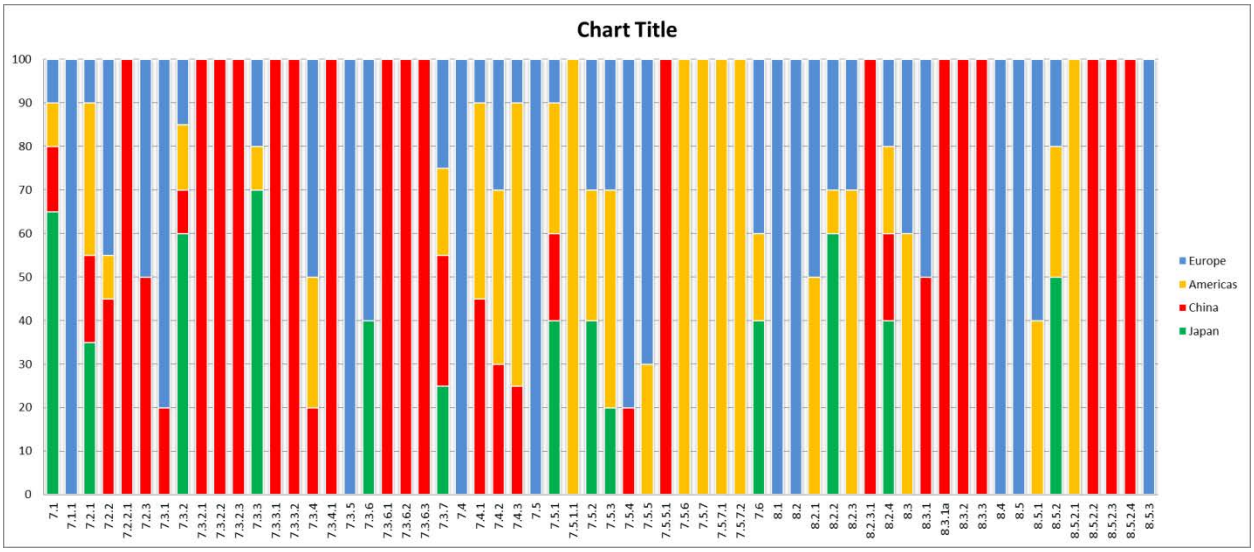

Fig. 1. Example of contribution of regions on chapters of the proposal

The four drafts were then merged to identify and resolve the differences. Each regional group leader was asked to participate, via online teleconference, in an alignment meeting by the coordinator. In 2014, the merged draft was submitted as a New Work Item Proposal to IEC TC82, and PVQAT continued to support the IEC TC82 committee's formal development of the standard.

The method for implementing the proposed QMS was discussed at length by both Task Group #1 and representatives of ISO and IEC to identify the "smoothest" way to introduce it into the community. Although this question has been quite controversial, in 2013 and 2014, there was convergence on the concept of forming IECRE under the IEC Conformity Assessment Board. IECRE is beginning to create a process that will provide a verification of PV system quality, including considerations for the design, installation, and operation. This report includes discussion of one small aspect of overall system quality: were the PV modules manufactured consistently with the intended quality?

This report is designed to help the reader understand the recommendations that are intended to eventually be approved by the participating countries of IEC TC82.

Recommendations to Supplement ISO 9001-2008

Goal of This Technical Specification

The goal of this Technical Specification is to provide a guideline for manufacturers of PV modules to produce modules that, once the design has proven to meet the quality and reliability requirements, replicate such design in an industrial scale without compromising its consistency with the requirements.

This Technical Specification is meant to be used in assessment audits of the PV module manufacturer's QMS, and to form a common basis for audits by various certifying bodies.

Such assessments should audit the entire set of materials, components, and processing.

The larger the diversity of products from a manufacturer, the more materials and material combinations must be controlled. All changes in the design, materials, or processes applied must be considered.

For the convenience of the reader, the relevant section numbers from ISO 9001-2008 are indicated. Note that no supplementary recommendations are proposed for many of the sections.

4 Quality management system

4.1 General requirements

No supplementary requirements.

4.2 Documentation requirements

4.2.1 General

No supplementary requirements.

4.2.2 Quality manual

No supplementary requirements.

4.2.3 Control of documents

No supplementary requirements.

4.2.4 Control of records

Record retention

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.

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

5 Management responsibility

No supplementary requirements.

6 Resource management

6.1 Provision of resources

Product warranty system

The organization shall determine and provide the resources needed to maintain the product warranty system, including provision for 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.

Succession planning

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

6.2 Human resources

No supplementary requirements.

6.3 Infrastructure

No supplementary requirements.

6.4 Work environment

ESD safe environmental area

The organization shall identify the electrostatic discharge (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, packaging, and shipping.

> *NOTE: ESD requirement should consider ANSI/ESD S20.20, IEC/TS62916 or equivalent standard.*

7 Product realization

7.1 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, and

e) 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.

> *NOTE 1: 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.*
>
> *NOTE 2: The product certification may depend on the application and geographies where the modules will be installed.*
>
> *NOTE 3: The recycling requirements should comply with the geographies where the modules will be installed.*

7.2 Customer-related processes

7.2.1 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 and the measurement uncertainty at standard test conditions per IEC 61215, IEC 61646, or IEC 62108 (see section 7.5.1 and 7.6 for control of solar simulators).

7.2.2 Review of requirements related to the product

The organization shall ensure that all modified product not covered by the retest guidelines as defined in 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.

7.2.3 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 design lifetime of installed modules,

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.

7.3 Design and development

7.3.1 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 requirements for design FMEAs as defined in IEC60812 or equivalent, reliability testing, design lifetime, and product specification generation, and

c) The requirements for process FMEAs as defined in IEC60812 or equivalent, specifications, layouts, control plan, and work instructions.

7.3.2 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.

> *NOTE: The organization may consider application of the IEC draft standard on transportation testing IEC 62759 when designing packaging materials.*

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.

> *NOTE: 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.*

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 review where applicable.

The organization shall manage the risks prior to manufacturing transfer.

7.3.3 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 IEC60812, 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 nondestructive methods and the designated means to control those characteristics for adequate product performance.

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 IEC60812 or equivalent risk management tool,

d) Control plan (see 7.5.1),

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.

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

7.3.4 Design and development review

No supplementary requirements.

7.3.5 Design and development verification

No supplementary requirements.

7.3.6 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, IEC61646, IEC61730, IEC/TS 62915, or IEC 62108.

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.

NOTE: 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.

7.3.7 Control of design and development changes

The organization shall implement a change management system for materials and processes to ensure all changes adhere to defined internal and external qualification and certification requirements such as 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 IEC60812 or equivalent.

Qualification, safety and reliability tests shall be documented.

> *NOTE: The conditions of qualification, safety and reliability tests should be defined by taking into the consideration the specified condition required by IEC61215, IEC61646, IEC/TS62915, 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.

7.4 Purchasing

7.4.1 Purchasing process

Materials, components, and subassemblies that have a safety, performance, or reliability implication on the finished product and that are purchased from or prepared by suppliers 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, subassemblies 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; and
- 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.

NOTE: QMS requirements for key materials may include ISO 9001 compliance.

7.4.2 Purchasing information

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

7.4.3 Verification of purchased product

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, an out-of-control action plan (OCAP)) until supplier performance meets the purchase requirements.

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

7.5 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 products 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 and the measurement uncertainty of the power measurement on the label of the produced module and, if applicable, refer to the name of the PV institute that issued the reference device calibration certificate.

7.5.1 Control of production and service provision

Control plan

The organization shall establish control plans for all appropriate processes, subassemblies, 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 8.2) 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.

Control of solar simulators

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 test temperature of the module should be 25℃±2℃, and the module should be equilibrated enough that the variation between the cell junction and measurement point on the module is less than ±1℃.

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 datasheet.

Solar simulators that have been changed in a way that may affect the performance rating shall be requalified to IEC 60904-9 to ensure the original rating is maintained. In addition, each solar simulator used for performance rating shall be partially requalified 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. 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 and IEC 60904-7 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.

The plan shall also contain elements for the following items:

a) Solar simulator maintained to have adequate* spatial uniformity, temporal consistency, and spectral accuracy (as determined by IEC 60904-9). *Adequate implies that the combination of all uncertainties (including uncertainty associated with the simulator classification) is within the uncertainty indicated on the module data sheet, and

b) 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.

7.5.2 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.

NOTE 1: These requirements are also applicable to key materials from suppliers.

NOTE 2: See IEC 61340-5-1 for guidance.

NOTE 3: Use of statistical process control is recommended for these processes.

NOTE 4: Software applications throughout the life cycle that are important to ensuring product quality, reliability, performance, or safety should be included.

NOTE 5: Software may include firmware.

7.5.3 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 the operation shall be recorded.

7.5.4 Customer property

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

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

7.5.5 Preservation of product

The packaging method of the PV module shall be tested as defined in IEC61759-1, 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.

7.6 Control of monitoring and measuring equipment

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. Records of actions shall be maintained (4.2.4).

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 include a statement on the tolerance and measurement uncertainty of the power measurement in the label of the produced module. 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.

> *NOTE: 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 tolerance indicated on the data sheet.*

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.

> *NOTE 1: The measurement uncertainty should be recorded on the nameplate.*
>
> *NOTE 2: Solar simulator manufacturer's data may be used to initially validate that the solar simulator meets the BBA or other requirement.*
>
> *NOTE 3: Multiple secondary reference modules may be needed because they could be damaged or during periods when one secondary reference is out for calibration.*

8 Measurement, analysis, and improvement

8.1 General

No supplementary requirements.

8.2 Monitoring and measurement

8.2.1 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.

The organization shall monitor the complaint log for recurring issues and escalate them 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 (4.2.4).

8.2.2 Internal audit

The organization shall periodically conduct process audits for all manufacturing processes to ensure compliance to work instructions, ESD controls, and the control plan.

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

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

8.2.3 Monitoring and measurement of processes

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 orders when nonconforming products are suspected to exceed specified limits. Records of such events shall be maintained (4.2.4).

8.2.4 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 irradiance and temperature).

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.

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 Sec. 8.5.2 and 8.5.3. 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 (4.2.4).

8.3 Control of nonconforming product

The 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 (4.2.4).

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.

8.4 Analysis of data

The analysis of data shall provide information relating to conformity to process and product requirements (see 8.4)

8.5 Improvement

8.5.1 Continual improvement

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

> *NOTE 1: The organization should identify, measure, and report quality metrics to drive continuous improvement.*
>
> *NOTE 2: The structured approach may include proven methodologies such as PDCA or DMAIC.*

8.5.2 (and 8.5.3) 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.

> *NOTE: The structured approach for root-cause analysis and corrective action may include proven methodologies such as why-why analysis and 8 Discipline.*

9 Proposed Implementation

For an interim period of time until this proposed program is standardized by IEC, the program can be used in internal audits of the PV manufacturer to assess robustness of its QMS. The program may also be used in factory inspections by test labs for IEC 61215/61646/62108 certification of the modules as a supplement to ISO 9001-2008. We encourage organizations to provide feedback to the IEC standards process to reflect their experiences.

When this program is published as an IEC standard, it will be a supplement to ISO 9001-2008 in factory inspections by test labs for IEC 61215/61646/62108 certification of the modules, to provide better assurance of quality management for the clients. This standard will also provide a common basis for audit findings from different agencies to be exchanged and acceptable, thereby reducing costs and increasing audit efficiency. We anticipate that this will be issued by the IEC as Technical Specification IEC 62941 in late 2015.

Consistent implementation of IEC 62941 will require appropriate training of inspectors and adherence to professional auditing procedures, such as those described in the IECEE operating

document 4004 (IECEE OD-4004). IECEE and IECRE will have oversight of implementation of IEC 62941 and will define appropriate rules, including a checklist (such as that found in IECEE OD-CB-FCS2008-Ed1.0); knowledge requirements for inspectors; and other guidelines for consistent implementation. It is anticipated that the knowledge requirements for inspectors implementing IEC 62941 will be more detailed and technical than is generally required. Additional information about auditing methods can be found in the ASQ publications found in the references section. An example of what the checklist may look like is included in Annex D.

References

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

IEC/TS 61836 Ed.2, Solar photovoltaic energy systems – Terms, definitions and symbols

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ISO 19011:2011, Guidelines for auditing management systems, http://www.iso.org/iso/catalogue_detail?csnumber=50675

ISO 9001-2008, Quality management systems – Requirements

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

ISO/TS16949, Quality management systems – Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations

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Annex A: Correspondence between ISO 9001:2008 and IEC 62941

(Informative)

ISO 9001: 2008	Section reference	Section reference	IEC 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	Document requirements (title only)
General	4.2.1		
Quality manual	4.2.2		
Control of documents	4.2.3		
Control of records	4.2.4	4.1	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		
Product realization (title only)	7	6	Product realization (title only)
Planning of product realization	7.1	6.1	Planning of product realization

Customer-related processes (title only)	7.2		
Determination of requirements related to the product	7.2.1	6.2	Determination of requirements related to the product
Review of requirements related to the product	7.2.2	6.3	Review of requirements related to the product
Customer communication	7.2.3	6.4	Customer communication
N/A		6.5	Organization manufacturing feasibility
Design and development (title only)	7.3	7	Design and development (title only)
Design and development planning	7.3.1	7.1	Design and development planning
Design and development inputs	7.3.2	7.2	Design and development inputs
N/A		7.3	Manufacturing process design inputs
Design and development outputs	7.3.3	7.4	Design and development outputs
N/A		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	7.6	Design and development validation
Control of design and development changes	7.3.7	7.7	Control of design and development changes
Purchasing (title only)	7.4		
Purchasing process	7.4.1	7.8	Purchasing process
Purchasing information	7.4.2	7.9	Purchasing information
Verification of purchased product	7.4.3	7.10	Verification of purchasing process
Production and service provision (title only)	7.5		
Control of production and service provision	7.5.1	7.11	Control of production and service provision
N/A		7.12	Control plan
Validation of processes for production and service provision	7.5.2	7.13	Validation of processes for production and service provisions
Identification and traceability	7.5.3	7.14	Identification and traceability
Customer property	7.5.4	7.15	Customer property
Preservation of product	7.5.5	7.16	Preservation of product
Control of monitoring and measuring equipment	7.6	7.17	Control of monitoring and measuring equipment
N/A		7.17.1	Control of performance rating (IV) measurement equipment
Measurement, analysis and improvement (title only)	8		
General	8.1		
Monitoring and measurement (title only)	8.2	8	Monitoring and measurement (title only)

Customer satisfaction	8.2.1	8.1	Customer satisfaction
Internal audit	8.2.2	8.5	Internal audit
Monitoring and measurement of processes	8.2.3	8.2	Monitoring and measurement of a manufacturing process
Monitoring and measurement of product	8.2.4	8.3	Monitoring and measurement of product
N/A		8.4	Ongoing product monitoring
N/A		8.6	Control of nonconforming product (title only)
Control of nonconforming product	8.3	8.6.1	Control of nonconforming product
Analysis of data	8.4	8.6.2	Analysis of data
Improvement (title only)	8.5		
Continual improvement	8.5.1	8.7	Continual improvement
Corrective action	8.5.2	8.8	Corrective and preventive action
Preventive action	8.5.3	8.8	Corrective and preventive action

Annex B: Related Standards

(Normative)

ANSI/ASQ Z1.4: 2008 - Sampling Procedures and Tables for Inspection by Attributes

ANSI/ASQ Z1.9:2008 - Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming

Failure Mode Effects Analysis- AIAG Publication

IEC60812 Ed.2.0: Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)

IEC 60891:2009, Photovoltaic devices – Procedure for temperature and irradiance corrections to measured I-V characteristics

IEC 60904-1:2006, Photovoltaic devices – Part 1: Measurement of photovoltaic current-voltage characteristics

IEC 60904-2:2007, Photovoltaic devices – Part 2: Requirements for reference solar devices

IEC 60904-3:2008, Photovoltaic devices – Part 3: Measurement principles for terrestrial photovoltaic (PV) solar devices with reference spectral irradiance data

IEC 60904-4:2009, Photovoltaic devices – Part 4: Reference solar devices – Procedures for establishing calibration traceability

IEC 60904-7: Photovoltaic devices – Part 7: Computation of spectral mismatch error introduced in the testing of a photovoltaic device

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 61340-5-1 Ed.1.0: Part 5-1: Protection of electronic devices from electrostatic phenomena – General requirement

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

IEC 61730-1 Ed1.2 Consol. with am1&2 (2013-03) TC/SC 82 Photovoltaic (PV) module safety qualification - Part 1: Requirements for construction

IEC 61730-2 Ed1.1 Consol. with am1 (2012-11) TC/SC 82 Photovoltaic (PV) module safety qualification - Part 2: Requirements for testing

IEC61853-1 Ed1.0: Photovoltaic (PV) module performance testing and energy rating - Part 1: Irradiance and temperature performance measurements and power rating

IEC 62759-1 Ed.1.0: Transportation testing of photovoltaic (PV) modules – Part 1: Transportation and shipping of PV module stack

IEC/TS 61836 Ed.2.0: Solar photovoltaic energy systems – Terms, definitions and symbols

IEC/TS 62915 Ed.1.0: Photovoltaic (PV) Modules – Retesting for type approval, design and safety qualification

IEC/TS 62916 Ed.1.0: Bypass diode electrostatic discharge susceptibility testing

ISO 9001:2008 Quality management systems – Requirements

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

Annex C: Terms and Definitions for the PV Industry

(Informative)

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

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.

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.

Customer

End user, investor, or installer who purchases modules from the organization.

Design lifetime

Design target period during which PV modules are expected to safely satisfy the specified performance under the specified conditions.

> *Note 1: 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.*

DFMEA

DFMEA (Design Failure Mode and Effect Analysis) is the application of the Failure Mode and Effects Analysis (FMEA) method specifically to product/service.

DMAIC

DMAIC (define, measure, analyze, improve, and control). A data-driven quality strategy for improving processes and an integral part of a Six Sigma quality initiative.

ESD

ESD (electrostatic discharge) is the sudden flow of electricity between two electrically charged objects caused by contact, an electrical short, or dielectric breakdown. ESD events are known to damage semiconductor devices such as diodes.

FMEA

FMEA (Failure Modes and Effects Analysis) is a 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. The FMEA provides a mechanism to prioritize the risks and take appropriate mitigation steps.

Key materials

Those materials that affect safety, reliability, or product performance of the PV module. Key materials may include indirect materials.

Organization

Entity that supplies modules to the customer and that has responsibility for design, production, and after-service for the modules.

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

Out of Box Audit

Also referred to as a "pre-shipment" audit, it is meant to simulate what a customer would experience when he or she opens the packing box. 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. The product is verified for compliance to customer requirements, including visual, dimension, and functional requirements. Nonconformances from these audits are escapes from the processes and outgoing inspection controls. These nonconformances are analyzed and fed back to improve the processes and controls to prevent recurrence.

Out-of-control process

A process in which the statistical measure being evaluated is not in a state of statistical control. In other words, the variations among the observed sampling results cannot be attributed to a constant system of chance causes

PDCA

A four-step process for quality improvement (Plan, Do, Check, Act). 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.

Performance warranty

A 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.

PFMEA

Process Failure Modes and Effects Analysis.

PLCM

Product Life-Cycle Management. 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.

Prototype

An 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.

Quality Management System (QMS)

A formalized system that documents the structure, responsibilities, and procedures required to achieve effective quality management.

Quality plan

A document or set of documents that describe the standards, quality practices, resources, and processes pertinent to a specific product, service or project.

Repeatability

The 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.

Reproducibility

The variation in measurements made by different people using the same measuring device to measure the same characteristic on the same product.

Statistical capability

A statistical measure of the inherent process variability of a given characteristic in comparison to the specification limits.

Statistical process control

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

Supplier

Provider of materials to an organization that is manufacturing and assembling PV modules.

Annex D: Example Checklist

This checklist and other notes are examples of guidelines that could facilitate consistent implementation of IEC 62941, and may be implemented by IECEE or IECRE, much like the checklist found within IECEE OD-CB-FCS2008-Ed1.0.

There are two objectives during an audit. One is to **verify compliance** of the organizational process documentation and records against the standards. The other is to **test** the controls for effectiveness. Although it is recommended to test controls for all applicable processes, understandably, due to time limitation on the ground, auditors should at the minimum test the controls for processes with potential significant risks to customers. Samples for testing the controls should be representative of variables in the process, i.e., operators, equipment, and materials. Audits should be conducted from all the shifts of the manufacturer operation. For manufacturing organizations with multiple site locations, audits should be done separately.

Audit sampling is NOT a statistical sampling. Often the number of samples is based on auditor discretion. Factors that influence the audit sample include 1) risk exposure to customer, 2) complexity of the process, 3) mix of manual and auto operations, 4) multiple handoff between departments and functions, and 5) multi-languages workforce. It is generally recommended to take limited samples and test thoroughly end to end on all applicable controls, rather than taking several samples and verifying partial controls. When testing controls, the auditor is determining if the current control(s) can detect an error or can prevent an error from happening, i.e., shipping defective products to a customer, sending incorrect information to a customer, etc.

Examples of use of testing controls during the audit process:

Samples of incoming key materials: test for supplier qualification, performance monitoring, applicable material changes, treatment of defective materials both incoming and in process.

Samples of measurement and test equipment: test for calibration validity, traceability to higher level standard, out of tolerance situation (if any), uncertainty measurements, adequacy of use, calibration interval recall.

Samples of records: test for retention and disposition, duration conflict with existing customer contracts, traceability to product/process step/supplier, ownership handover during employee turnover, back-up for disaster recovery.

Tables D1 and D2 describe the implementation of the example checklist.

Table D1. Columns used for recording the results of the audit when each question/item is asked.

Applicable (Yes/No)	Compliance (Yes/No)	Nonconformance (Yes/No)	Other outcome (Yes/No)	Objective Evidence, Finding Comments

Table D2. List of example audit questions in the form of a checklist, with cross referencing between ISO 9001 and IEC 62941. The questions in the column "Possibly redundant with ISO 9001" may be omitted if the question was asked as part of the ISO 9001 audit.

Item #	Question #	ISO 9001 cross reference	IEC 62941 cross reference	Audit question	Possibly redundant with ISO 9001?
1	1	N/A	Scope	Does the QMS have a current ISO 9001 certification or equivalent?	
2	2	4.2.4	4.1	Does the organization have a documented records control procedure?	✓
3	3			Records related to meeting warranty conditions explicitly identified? (the records control procedure or relevant formal documents)	
4				Design and development	
5				Design qualification	
6				Engineering change	
7				Monitoring, and measurement of a manufacturing process (Identify specific processes) Includes Incoming QC COC/COA where applicable	
8				Monitoring, and measurement of manufacturing products (Identify specific products) where applicable	
9				Final testing	
10	4			Customer details on records where applicable	
11	5			Records ownership and locations identified by record type?	✓
12	6			Record retention method/infrastructure robust enough to support the identification, storage, protection, retrieval, retention period? (e.g., Electronic vs. Hard copy, Disaster recovery planning, etc.)	
13	7			Does the organization also extend the record retention to suppliers of "key materials"?	
14	8	6.1	5.1	Does the organization provide resources needed to maintain the product warranty system?	
15	9			Are the resources assigned adequate for the organization to conduct failure analysis on all returned products?	
16	10			Are resources adequate for providing requested after-sales service?	
17	11	6.1	5.2	Does the organization have a plan for succession for key functions that affect customer satisfaction, quality, reliability, safety, and performance?	
18	12	7	6	Is there any recognized basic QMS implemented in the organization? Is it properly documented and maintained? Ownership of QMS?	