IECRE OD-405-2

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IECRE OPERATIONAL DOCUMENT

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

IECRE Quality System Requirements for PV Module Manufacturers –

Part 2: Audit Checklist

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECRE Operational Document 405-2 –

IECRE Certified Equipment Scheme –

IECRE Quality System Requirements for PV Module Manufacturers – Part 2: Audit Checklist

INTRODUCTION

This Operational Document, OD 405-2 provides an Audit Checklist when assessing a manufacturer's quality system for compliance with Part 1 of this Operational Document (OD).

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

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

– *Part 2: Audit Checklist*

– *Part 3: Requirements for PV Factory Auditors*

This Document needs to be read in conjunction with ISO 9001:201508 and IEC/TS 62941.

Document History

Date	Summary
2016-09-26	Edition 1.0
2020-05-04	Edition 2.0

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AUDIT CHECKLIST

NOTE: If manufacturer does not have a certified ISO 9001 Quality System, covering manufacturing of the product, all questions need to be answered. If the Manufacturer does have a certified ISO 9001Quality System, covering manufacturing of the product, skip questions without star marks may skippedstated as ISO 9001 applies, providing it is demonstrated by way of last ISO 9001 audit report that these questions have been successfully assessed.

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:
Section	Statement of requirement	ID#0	Star			
	The requirements of this guideline are defined with the assumption that the quality management system of the organization has already fulfilled the requirements of ISO9001 or equivalent quality management system	001	★	Does the QMS have a current ISO 9001 certification or equivalent?		
4 Documentation Requirements4.3 Control of documented Information						

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AÃAuditor Notes:
Section	Statement of requirement	ID#0	Star			
-	Records related to design, qualification, engineering changes, monitoring, and measurement of a manufacturing process 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.	41612	3-	Are 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 retained for at least the warranty period.Does the organization have a documented records control procedure? (Refer to the records control procedure or relevant formal documents.)		
				Are records related to meeting warranty conditions explicitly identified?		
				Are records related to design and development explicitly identified?		
	Records should also include Certificates of Conformity (CoC) and Certificates of Conformity Analysis (CoA) of key materials identified by the organization.	4-5-6	-8-9-	Are records of Certificates of Conformity (CoC) and Certificates of Analysis (CoA) of key materials identified by the organization In the design qualification?		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:	
Section	Statement of requirement	ID#0	Star				
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				Are records related to Engineering Changes explicitly identified?			
				Is there monitoring, and measurement of a manufacturing process (Identify specific processes) Includes Incoming QC COC/COA where applicable?			
				Is there monitoring, and measurement of a manufacturing products (Identify specific products) where applicable?			
				Are records related to Final Testing explicitly identified?			
				Are there Customer details on records where applicable?			
				Is ownership of records and storage locations identified by record type?			
		11		Test: Take sample record types from items 2 to 9 and verify robust implementation of the records management. Note: this is an example of the type of testing described at the beginning of the annex.			
4 Support5. Resource management							
4.1 Resources.25.1 Provision of resources for product warranty system							
4.1.1 Succession planning							

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AÃAuditor Notes:
Section	Statement of requirement	ID#0	Star			
-	The organization shall plan for succession for key functions that affect customer satisfaction, quality, reliability, safety, and performance.	401		Does the organization have a plan for succession for key functions that affect customer satisfaction, quality, reliability, safety and performance?		
4.1.2 Provision of resources for product warranty system						
5.1	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. For repairable products, the organization shall determine and include staffing and training of service personnel to do in-field service and adequately plan for maintaining spare part depots and service centres to assure the necessary quality of service for customers. -	4021 2	★ 13	Has the organization determined and provided 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?Does the organization provide resources needed to maintain the product warranty system?		
		403	★	For repairable products, has the organization determined and included staffing and training of service personnel to do in-field service and adequately plan for maintaining spare part depots and service centers to assure the necessary quality of service for customers?Are the resources assigned adequate for the organization to conduct failure		

IEC~~/TS~~ 62941 ~~Question ID~~		Question ID		Audit Question	~~Audit or Notes:~~ Y/N	~~AÃ~~Auditor Notes:
Section	Statement of requirement	ID#~~0~~	Star			
				~~analysis on all returned products and any appropriate follow-up actions such as adjustment to quality control plan or warranty recall?~~		
~~5.2 Succession planning~~ ~~-~~						
4.2 Monitoring and measuring resources						
4.2.1 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).	404		Are monitoring and measurement equipment characterized by measurement system analysis to understand gauge capabilities as referenced in the control plan?		
	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.	405		Has the organization controlled software so that it cannot be inadvertently changed from the version validated in 7.13? If software has been changed, has it been revalidated as per 7.13?		
	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	406	★	For monitoring and measurement equipment determined to be out of tolerance at the time of calibration, have corrective actions been taken to determine impact on product and		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AÃAuditor Notes:
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	documented per 4.3.			customer? Have the corrective actions been documented?		
-	The organization shall plan for succession for key functions that affect customer satisfaction, quality, reliability, safety, and performance.	15		Does the organization have a plan for succession for key functions that affect customer satisfaction, quality, reliability, safety and performance?		
4.2.2 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.	407	★	Does the control plan include a description of control of equipment (simulators) compliant to IEC 60904 series and IEC 60891?		
		408	★	Does the organization maintain records of compliance with IEC 60904 and IEC 60891?		
		409	★	Is the classification of each simulator shown on or near the simulator?		
	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 simulator manufacturer's data may be used to initially validate that the solar simulator meets the requirements of the organization.	410	★	Were the solar simulators initially qualified according to IEC 60904-9, including characterization of spectrum quality, uniformity of irradiance, and temporal instability of irradiance?		

IEC~~/TS~~ 62941 ~~Question ID~~		Question ID		Audit Question	~~Audit or Notes:~~ Y/N	~~AÃ~~Auditor Notes:	
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	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. When any critical change is found in measurement uncertainty, root cause analysis shall be made prior to ta	411	★	Has the uncertainty of the measurement been estimated according to ISO-IEC Guide 98-3 within the last year?			
		412	★	When any critical change is found in measurement uncertainty, has the root cause analysis been made prior to taking a corrective action?.			
		413	★	Is a procedure established for managing (use, storage and replacement) of secondary reference modules?			
	Solar simulators with a BBB 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 if it is indicated on the product literature						
	The organization shall retain all calibration documents including 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.	414	★	Does the organization retain all calibration documents including the reference device calibration certificate, or a report that can be traceable to international or national measurement standards?			
		415	★	Is this information traceable for each module manufactured and made available to customers upon			

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:
Section	Statement of requirement	ID#0	Star			
				request?		
4.3 Control of documented Information						
	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 at least the warranty period.	416		Are 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 retained for at least the warranty period.		
5 Operation6 Product realization						
6.1 General						
	The organization is required to implement a recognized basic QMS. In addition, the following requirements shall also apply.	16		Is there any recognized basic QMS implemented in the organization? Is it properly documented and maintained? Is ownership of QMS clearly defined and documented?		
5.16.2 Operational planning and control;Planning of product realization						
-	In planning product realization, the organization shall also determine the following, as appropriate:	5014 7 18	★ 19	In planning product realization, has the organization determined the following (as appropriate)?		
	a) Product certification requirements			a) Product certification requirements (NOTE: The product certification may depend on the application and geographies where the modules will		

IEC~~/TS~~ 62941 ~~Question ID~~		Question ID		Audit Question	~~Audit or Notes:~~ Y/N	~~AĀ~~Auditor Notes:
Section	Statement of requirement	ID#~~0~~	Star			
				be installed.)		
	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			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 (NOTE: The development and launch of new products should meet requirements of the product warranty as well as customers' needs.)		
	c) Recycling requirements at the end of the modules' lifetime	~~20~~ ~~21~~	~~22~~	c) Recycling requirements at the end of the modules' lifetime (NOTE1: The recycling requirements should comply with the geographies where the modules will be installed.) NOTE2: Until IEC or another international standard is established, the requirements of any applicable national and/or local code shall be met.)		
	d) Quality assurance and control measures to be applied to production to meet requirements of the applicable PV standards.			d) Assurance and control measures to be applied to production to meet requirements of the applicable PV standards.		
	e) ESD safe environmental area			e) ESD safe environmental area, as applicable		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AÃAuditor Notes:
Section	Statement of requirement	ID#0	Star			
	f) Packaging, storage and transportation requirements			f) Packaging, storage and transportation requirements		
	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 IEC/TS 62916 or as appropriate.	5022 3 24 25	★ 26 27 28	Has the organization identified the ESD sensitive materials and componentsIs an ESD safe environmental area determined at the raw material storage, processing, assembly areas, and all through packaging and shipping as defined in IEC/TS 62916 or as appropriate?		
		503	★	Is an ESD safe environmental area determined and maintained at the raw material storage, processing, assembly areas, and all through packaging and shipping?		
	ESD requirements should consider ANSI/ESD S20.20, or equivalent standards.	504		Are ESD requirements consider ANSI/ESD S20.20, or equivalent standards?		
	If ESD protection is sufficient, and it can be determined that the electrostatic potential of the work areas is low, it would not be necessary to create a designated 'ESD safe environmental area'.					

IEC~~/TS~~ 62941 ~~Question ID~~		Question ID		Audit Question	~~Audit or Notes:~~ Y/N	~~AĀ~~Auditor Notes:
Section	Statement of requirement	ID#~~0~~	Star			
	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.	505		Are customer requirements and references to related technical specifications, as applicable, 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.~~			~~Has a complete product life-cycle management process been defined, as appropriate?~~		
	NOTE: Since the geographies where the modules will be installed may not be identified when they are shipped, the organization is asked to pay best attention to the generic recycling requirements at the end of the modules' lifetime.~~The product certification may depend on the application and geographies where the modules will be installed.~~			~~Have the application and geographies where the modules will be installed been considered in designing the quality program?~~		
5.2 Requirements for products and services						
5.2.1 Customer communication						
	The organization shall also determine and implement effective arrangements for communicating with customers in relation to the following:	506	★	Has the organization determined and implemented effective arrangements for communicating with customers in relation to the		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AÃAuditor Notes:
Section	Statement of requirement	ID#0	Star			
				following?		
	a) Safety, workmanship warranty, output power warranty, and installation guidelines including electrical and mechanical installation instruction.			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 in the installed configuration			b) Application notes detailing specific attention and/or care need 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.			c) The definition of a warrantable defect or safety critical defect and the rules and/or process to manage stated defects?		
	d) Product recall notices.			d) Product recall notices?		
	NOTE “Information includes, but is not limited to, specifications, drawings, and other material, including “installation” manuals.					
5.2.26.3 Determining the requirements for products and services 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 or intended use conditions.	50730	★	Are product warranty workmanship and power degradation and its relationship to design lifetime under specified or intended use conditions determined and documented? Are documents maintained?		

IEC~~/TS~~ 62941 ~~Question ID~~		Question ID		Audit Question	~~Audit or Notes:~~ Y/N	~~AÃ~~Auditor Notes:
Section	Statement of requirement	ID#~~0~~	Star			
	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.	5083~~1~~	★ ~~32~~	Are requirements arising from all previous failure information, customer complaints, competitive analysis, supplier feedback and other internal inputs incorporated as requirements? Is traceability to these requirements maintained? Are those actions recorded? Are records maintained?		
	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 section 4.2.1 and 4.2.2~~6.9.2~~for proper control of solar simulators).	509	★	Is there an established method to specify nameplate power of a module with an allowed tolerance at standard test conditions per IEC 61215, IEC 61646 or IC 62108. Is this method defined in QMS documents?		
5.2.3~~6.4~~ Review of requirements related to ~~the~~ products and services						
	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.	5103~~3~~	★ ~~34~~	Are there records to show that all modified product, not covered by the retest guidelines as defined in IEC/TS 62915, is qualified to all related type designs? Are records maintained?		
		510-1	★	Are there records to show that the modified product is evaluated for impact on the warranty? Are records maintained?		
		510-2	★	Are above described actions defined and documented in QMS?		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:
Section	Statement of requirement	ID#0	Star			
5.2 Requirements for products and services						
5.2.16.5 Customer communication						
-	The organization shall also determine and implement effective arrangements for communicating with customers in relation to the following:	5063 7 38 39	★ 40 41	Has the organization determined and implemented communication requirements for:		
	a) Safety, workmanship warranty, output power warranty, and installation guidelines including electrical and mechanical installation instruction,			a) Safety, workmanship warranty, output power warranty, and installation guidelines including electrical and mechanical installation instruction?		
	b) Application notes detailing specific attention and care need to secure design lifetime of installed modules			b) Application notes detailing specific attention and/or care need 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 .			c) The definition of a warrantable defect or safety critical defect and the rules and/or process to manage stated defects?		
	d) Product recall notices. NOTE "Information includes, but is not limited to, specifications, drawings, and other material, including "installation" manuals.			d) Product recall notices?		

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IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:
Section	Statement of requirement	ID#0	Star			
5.2.46.6 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.	51142	★ 43	Are there processes and procedures in the QMS document for the organization to investigate, conduct risk analysis, and confirm the manufacturing feasibility at the necessary scale of the proposed products in the contract where applicable? Are the records maintained?		
	The organization shall manage the risks prior to manufacturing transfer.	512	★	Does the organization manage the risks prior to manufacturing transfer?		
	The organization shall confirm consistency of quality of the modules between before and after manufacturing transfer. The confirmation process and the results shall be documented and recorded.	513	★	Has the organization confirmed consistency of quality of the modules between before and after manufacturing transfer? Are the confirmation process and the results documented and recorded?		
5.36.7 Design and development of products and services						
5.3.16.7.1 Design and development planning						
	The organization shall include production processes in the design and development planning.	51444	★	Does the organization include production processes in the design and development planning?		
	The organization shall also determine:	51545		During the design and development planning, does the organization determine:		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:
Section	Statement of requirement	ID#0	Star			
	a) The responsibilities and authorities for a project design and development team,	46		a) The responsibilities and authorities for design and development?		
	b) The process to conduct design FMEAs as defined in IEC60812 or equivalent, reliability testing, design lifetime, and product specification generation, and	47		b) The process to conduct 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.	48		c) The requirements for process FMEAs as defined in IEC60812 or equivalent, specifications, layouts, control plan, and work instructions?		
5.3.26.7.2 Design and Development Inputs						
	The inputs shall also include the following:	51650	★	Does the organization's inputs relating to product requirements include:		
	a) Functional, performance, and safety requirements including design lifetime, power, maintainability durability, transportation, timing, and costs,	51 52 53	54 55	a) Functional /performance/safety /product lifetime/ power degradation requirements, including materials requirements defined in IEC 61730-1?		
	b) Identification of product, traceability, and packaging requirements,			b) Product identification, traceability and packaging requirements		
	c) Requirements for proper handling of product and components for ESD, and			c) Requirements for proper handling of product and component for ESD?		
	d) Lessons learned from previous designs.			d) Where applicable, information derived from previous similar designs including lessons learnt?		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:	
Section	Statement of requirement	ID#0	Star				
	NOTE: IEC 62759-1 defines transportation testing for designing packaging materials. The organization may consider application of IEC draft standard on transportation testing IEC 62759 when designing packaging materials.			Did the organization consider IEC 62759 or equivalent when designing packaging materials?			
5.3.3 Design and development controls							
	The organization shall include standard requirements from applicable IEC and national standards for validation of the design.	517	★	Has the organization included the standard requirements from applicable IEC and national standards as part of 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, future IEC/TS 62915, IEC 62108 or equivalent.	518	★	Have the performance testing activities including durability of prototype modules been monitored for timely completion and conformance requirements?			
		519	★	Has the performance testing conformed to a product and process approval procedure including a reliability test plan similar to applicable standards?			
		520	★	Is a reliability test plan consistent with the design lifetime?			
		522	★	Have the prototyped PV modules been tested according to IEC61215, IEC61646, IEC61730, IEC/TS62915 or equivalent?			

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:
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		521	★	Are the performance testing activities including durability of prototype modules consistent with the FMEA's results? Are the performance testing activities results recorded?		
	Validation of the design lifetime shall be confirmed with relevant internal data or published documents and recorded. The records shall be disclosed to the auditor if requested.	523	★	Has validation of the design lifetime been confirmed with relevant internal data or published documents and recorded?		
		524	★	Are the records disclosed to the auditor if requested?		
	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	525	★	Is product approval subsequent to the verification of the manufacturing process?		
		526	★	Is product and manufacturing process approval procedure applied to suppliers of key materials?		
	NOTE: IEC 61215 series do not intend to test long term reliability of PV modules.					
5.3.4 Design and Development Outputs						
	Design and development outputs shall also include the following:	527	★	Do the organization's design and development outputs include the following?		
	a) an instruction manual for safe and proper installation and use,			a) an installation manual for safe and proper installation use?		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:
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	b) DFMEAs as defined in IEC60812, or equivalent, which are to be updated during design reviews, and a related design qualification/verification and reliability test plan			b) DFMEAs 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?		
	c) 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.			c) characteristics of the product that are essential for its safe and proper use, including those which cannot be fully verified later by nondestructive methods and the designated means to control those characteristics for adequate product performance?		
5.3.5 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 IEC TS 62915.	528	★	Has the organization implemented a change management system for materials and processes and ensured all changes adhere to product requirements internal/ external qualifications and certification requirements such as IEC/TS62915?		
	Traceability of changes shall be documented and maintained in the organization's QMS.	529	★	Is the traceability of changes 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.	530	★	Are all design and development changes reviewed, risks identified and documented in the appropriate FMEA as defined in IEC60812 or equivalent?		

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	Qualification safety, compliance, and reliability tests shall be documented.	531	★	Are qualification, safety, compliance and reliability test results 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	532	★	Are the conditions of qualification, safety and reliability tests been defined by taking into consideration the specified condition required by IEC 61215, IEC 61646,IEC 61730, future IEC/TS 62915, 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.	533	★	Are there rules or regulations in the organization's QMS to prevent release of products to customers before applicable tests are verified?		
		534	★	If major changes occurred (form, fit and function), are there records of the certification and notification of the customers?		
5.3.66.7.3 **Manufacturing pProcess dDesign iInputs**						
	The organization shall identify, document, and review the manufacturing process design input requirements, including the following:	53556	★ 57	Does the organization identify, document and review the manufacturing process design input requirements, including:		
	a) Product design output data,			a) Product design output data?		
	b) Targets for productivity, process capability and cost,	58 59	60 61	b) Targets for productivity, process capability and cost?		
	c) Customers' requirements, if any, and			c) Customers requirements if any?		

IEC/TS 62941 Question ID		Question ID		Audit Question	Audit or Notes: Y/N	AĀAuditor Notes:	
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	d) Lessons learned from previous developments.			d) Experience 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.			Does the design consider error-proofing methods and statistical process control methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered?			
5.3.46.7.4 Design and Development Outputs							
6.7.4	-	62		Does the organization provide outputs of design and development in a form that enables verification against the design and development input and approved prior to release?			
	Design and development outputs shall also include the following:	52763	★	Do the organization's design and development outputs include the following?			
	a) Specify an instruction manual for safe and proper installation and use,	64		a) Specification of an installation manual for safe and proper installation use?			
	b) DFMEAs 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	65		b) 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?			

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	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.	66		c) Specify the characteristics of the product that are essential for its safe and proper use, including those which cannot be fully verified later by nondestructive methods and the designated means to control those characteristics for adequate product performance?		
5.3.76.7.5 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:	5367 67	—	Are the manufacturing process design output expressed in terms that can be verified against manufacturing process design input requirements and validated?		
		5367	★	Does the manufacturing process design output include data for quality, and reliability including the following:		
	a) Specifications and drawings,	68		a) Specifications and drawings		
	b) Manufacturing process flow chart/layout,	69 70 71 72 73 74	75 76 77 78 79	b) Manufacturing process flow chart/layout		
	c) Manufacturing process FMEAs as defined in IEC60812 or equivalent risk management			c) Manufacturing process FMEAs		

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	tool,					
	d) Control plan (see 5.5.27.12),			d) Control plan		
	e) Work instructions,			e) Work instructions		
	f) Process approval acceptance criteria,			f) Process approval acceptance criteria		
	g) An ESD protection plan,			g) An ESD protection plan		
	h) Error-proofing methods, as appropriate,			h) Error-proofing methods		
	i) Methods for product identification and traceability,			i) Methods for product identification and traceability		
	j) Methods of detection and feedback of product/manufacturing process nonconformities.			j) Methods of detection and feedback of product/manufacturing process nonconformities		
	k) Process for handling raw materials from the time of their receipt			k) Process for handling raw material from the time of their receipt		
	i) Process FMEAs (PFMEAs), or equivalent, shouldshall cover the process from material receipt to product delivery, and where appropriate, installation and maintenance.			i) Have the Manufacturing process FMEAs from material receipt to product delivery, and where appropriate, installation and maintenance been conducted as defined in IEC60812 or equivalent risk management tool?		
5.3.3 Design and development controls 6.7.6 Design and development validation						
		52691	★	Is product and manufacturing process approval procedure applied to suppliers of key materials?		
5.3.5 Design and development changes6.7.7 Control of design and development changes						

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6.7.7	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 IEC TS 62915.	52892	★	Has the organization implemented a change management system for materials and processes and ensured all changes adhere to product requirements internal/ external qualifications and certification requirements such as IEC/TS62915?		
		93		Has the organization defined internal/external qualifications and certification requirements such as IEC/TS62915?		
	Traceability of changes shall be documented and maintained in the organization's QMS.	52994	★	Is the traceability of changes 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.	95		Are all design and development changes evaluated for risks?		
		53096	★	Are all design and development changes reviewed, risks identified and documented in the appropriate FMEA as defined in IEC60812 or equivalent?		
	Qualification safety, compliance, and reliability tests shall be documented.	53197	★	Are qualification, safety, compliance and reliability test results documented?		

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	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	53298	★	AreHave the conditions of qualification, safety and reliability tests been defined by taking into consideration the specified condition required by IEC 61215, IEC 61646,IEC 61730, future IEC/TS 62915, 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.	53399	★	Are there rules or regulations in the organization's QMS to prevent release of products to customers before applicable tests are verified?			
		534100	★	If major changes occurred (form, fit and function), are there records of the certification and notification of the customers?			
5.4. Control of externally provided processes, products and services 6.8 Purchasing							
5.4.1 General 6.8.1 Purchasing process							
6.8.1	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.	538101		Do 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 have a level of control adequate to ensure that the overall risks are minimal?Has the organization controlled the quality			

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				of materials, components and sub-assemblies adequately 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 to ensure that the components, sub-assemblies and assemblies completed by subcontractors meet the quality plans, including relevant safety and certification requirements.	5391 02 540 541		Has the organization defined a process for the supplier's notification of changes and ensured that the supplier maintains traceability of relevant changes?		
		5401 03 104 105	10 6 10 7	Are there any records of the supplier's notification of changes?		
		541		When a supplier provides a change notification, is a process defined to address this change notification?		
		542		Has the organization ensured that the components, sub-assemblies and assemblies met the quality plan's including relevant safety and certification requirements?		
		543		Are there records to ensure that the components, sub-assemblies and assemblies met the quality plan's relevant safety and certification		

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				requirements?		
	The organization shall complete the following actions to ensure their suppliers can meet product requirements by doing the following:	544		Has the organization completed the following actions to ensure their suppliers can meet the product requirements;		
	a) Set up a QMS	108 109	11 0	a) Has the supplier organization set up a QMS of the suppliers?		
	b) Evaluate the quality performance of key materials and audit the supplier of key materials on a regular basis,			b) Has the organization evaluated 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,			c) Have the suppliers ensured that the materials used in the product conform with material specifications provided by the organization?		
	d) Periodically carry out onsite audits to check that: tThe material produced is conformal with applicable organization or manufacturer specifications;	111 112 113 114	11 5 11 6 11 7	d) Has the organization carried out onsite audits to check that: Is theme m-Material produced conformal with applicable organization or manufacturer specifications?		
	e) tThe supplier has the capability to deliver the goods on time;			e)Does the supplier have the capability to deliver the goods on time?		

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	f) Et 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.			f) tThe 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?		
	ge) Urge the supplier to improve its quality performance if necessary, and			eg) If necessary, has the organization urged the supplier to improve its quality performance if necessary, ?		
	fh) Apply methods for incoming inspections and preparation of raw materials.			fh) ApplyHas the organization applied methods for incoming inspections and preparation of raw materials?		
6.8.26.8.2 Purchasing information						
6.8.2	Purchasing information shall also describe the requirements for materials/component traceability.	118 119	120	Is purchasing information documented and maintained in a manner as defined in QMS?		
				Does purchasing information describe the requirements for materials/component traceability?		
				Take a record of purchase information to check if it is conformant to this requirement.		

IEC~~/TS~~ 62941 ~~Question ID~~		Question ID		Audit Question	~~Audit or Notes:~~ Y/N	~~AĀ~~Auditor Notes:
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5.4.2 Type and extent of control ~~6.8.3 Verification of purchasing process~~						
~~6.8.3~~	The organization shall have a consistent process to assure the quality of key materials using an appropriate combination of the following methods:	5451~~21~~ ~~122~~ ~~123~~	★ ~~12 4~~ ~~12 5~~	Does the organization have a consistent process in QMS to assure the quality of key materials an appropriate combination of the following methods?		
	a) Receipt and review of certificate of conformance or analysis,			a) Receipt and review of certificate of conformance or analysis,		
	b) Evaluation of statistical data of purchased products and key materials			b) Evaluation of statistical data of purchased products and key materials		
	c) Receiving inspection or testing such as statistical sampling based on performance,			c) Receiving inspection or testing such as statistical sampling based on performance, [NOTE: Statistical sampling may be based on ANSI/ASQ Z1.4, Z1.9 or equivalent national standards.]		
	d) Product evaluation or material analysis by an independent laboratory or testing facility, and/or			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 history of product conformance to requirements.	~~126~~	~~12 7~~	e) Evidence of supplier inspections when the supplier has been delegated inspection authority based on history of product conformance to requirements.		

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	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.			f) Organization shall take appropriate steps (for example, out-of-control action plan (OCAP)) when a deficiency is identified until supplier performance meets the purchase requirements.		
5.4.3 Information on external providers						
	Purchasing information shall also describe the requirements for materials / component traceability.	546	★	Does purchasing information describe the requirements for materials / component traceability?		
5.5 6.9 Production and service provisions						
5.5.1 Control of production and service provision 6.9.1 Control of production and service provision						
6.9.1	The organization shall determine methods to monitor the performance and accuracy of the equipment used in the product realization process.	5471 28	12 9	Has the organization determined methods to monitor the performance and accuracy of the equipment used in the product realization process? Are the methods described in QMS?		
	The organization shall create definitions of product problems and determine rules and processes to minimize the impact of the problem.	548		Has the organization defined definitions of product problems and rules and processes to minimize the impact of the problem? Are the definitions described in QMS?		

IEC~~/TS~~ 62941 ~~Question ID~~		Question ID		Audit Question	~~Audit or Notes:~~ Y/N	~~AĀ~~Auditor Notes:
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	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.	5491~~30~~	~~131~~	Does the organization 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? Is this process defined and described in QMS?		
	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.	550		Does the organization provide technical support to customers on how to use the product, guide customers in trouble-shooting where applicable, and prevent any safety risks? Is this process defined and described in QMS?		
~~5.5.26.9.2 Control plan~~ ~~5.5.26.9.2 Control plan 6.9.26.9.2 Control~~	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 series or IEC 62108. In addition, the organization shall include on the datasheet, or other product literature:	551	★	Does the organization have a statement of the tolerance of the nominal power on the label of the produced module in accordance with IEC 61215 series or IEC 62108?		
		552	★	Does the organization include on the datasheet, or other product literature?		
		553	★	Does the organization include a statement of the tolerance of the nominal power on the label of the produced module in accordance with IEC 61215 series or IEC 62108?		

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plan		554	★	Does the organization 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,			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 that power measurement uncertainty is provided to the customer upon request			b) if the uncertainty is not included, a statement specifying that that power measurement uncertainty is provided to the customer upon request		
5.5.2 Control plan6.9.2 Control plan						
6.9.2	The organization shall establish control plans for all appropriate processes, sub-assemblies, components, and materials for the final product. Control plans shall	5555513 2 133 134 135 136	★	Has the organization established control plans for all appropriate processes, sub-assemblies, components, and materials for the final product? Are the control plans described in QMS?		
		556556	★	Do the control plans meet the following requirements?		
	a) Be based on a risk analysis such as design or process FMEA outputs, or equivalent,			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,			b) List the controls used for the manufacturing process control,		

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	c) Include methods for monitoring of control exercised over special characteristics (see 7.2) defined by the organization,			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			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.			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	5575 57	★	Has the organization reviewed and updated control plans when any change occurs that affect the product manufacturing process?			
		5585 58	★ ★	Are there any record of the review and update of control plans ? Are the records maintained?			
	The organization shall periodically review control plans for effectiveness of the controls and take appropriate corrective actions	5595 59	★	Has the organization periodically reviewed 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.	5605 6014 1	★	Has the organization defined and managed a process to disposition the affected product impacted by an out-of-specification process? Is the process described in QMS?			

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	The organization shall maintain data records in a manner that allows detections of possible tendencies.	5615 61	★	Does the organization maintain data records in a manner that allows detections of possible tendencies? Is the process defined and maintained in MS?		
5.5.3 Control plan for the measurement procedure						
	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.	562	★	Has the organization developed 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 .	563	★	Is the variance of the temperature controlled?		
		564	★	Is the test temperature of the module controlled at 25 °C ± 2 °C, and the module equilibrated enough that the variation between the cell junction and measurement point on the module is less than 1 °C?		

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	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.	565	★	If the test temperature of the module falls outside the range of 25 °C ± 2 °C, or if the module is not equilibrated enough that the variation between the cell junction and measurement point on the module is less than 1 °C, does the control plan specify how to correct for these deviations so that the total uncertainty in within the range indicated on the product label, datasheet, or other product literature?		
	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.	566	★	Are IEC 60891 (temperature and irradiance correction) and IEC 60904-7 (spectral correction) been used to appropriately correct the current and voltage characteristics of a module under test?		
		567	★	Is IEC 61853-1 been used to determine the correction coefficients for irradiance and temperature effects on the measurement of the module?		
		568	★	Has the organization developed a plan to periodically revalidate the correction coefficients for a specific module type?		
	The plan shall also contain elements for the following items:	569	★	Does the plan contain elements for the following items?		

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	a) Solar simulator maintained to have adequate spatial uniformity, temporal consistency, and spectral accuracy (as determined by IEC 60904-9).			a) Solar simulators maintained to have adequate spatial uniformity, temporal consistency, and spectral accuracy (as determined by IEC 60904-9)?		
	b) The combination of all uncertainties (including uncertainty associated with the simulator classification) is within the uncertainty required by the organization.			b) The combination of all uncertainties (including uncertainty associated with the simulator classification) is within the uncertainty required by the organization rating		
	c) 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.			c) 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 to perform an adequate measurement.		
5.5.4 Control plan for all solar simulators used for performance rating						
	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 573	5705 7014 3	★	Has the organization developed a control plan for all solar simulators used for performance rating?		
		5715 71	★	Is the control plan statistically based using reference modules?		
		5725 72	★	Does the simulator control plan have a documented out-of-control action plan for deviations?		
		573	★ ★	If multiple solar simulators are used, does control plan shall demonstrate how correlation		

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				between the solar simulators is maintained?		
	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 any simulator characteristics required by the solar organization are maintained	574	★	Are solar simulators that have been changed in a way that may affect the performance rating shall re-qualified to IEC 60904-9 to ensure any simulator characteristics required by the organization are 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 once a year. If the minimum criteria for solar simulator quality is not met, this shall be twice per year.	575	★	Is each solar simulator used for performance rating partially re-qualified to IEC 60904-9 for uniformity of irradiance and temporal stability at a minimum of once a year?		
		576	★	If the minimum criteria for solar simulator quality is not met, is this re-qualification executed 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 may 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	577	★	Are secondary reference modules generated and certified by a recognized certification body for each specific module type, which can be traceable to international or national measurement standards.		
		578	★	Has the organization developed a control plan for the secondary reference and working reference modules to ensure no significant		

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	to ensure no significant change occurs that may affect the rating of the module.			change occurs that may affect the rating of the module?		
5.5.3 Control plan for the measurement procedure						
	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.	562144145146	★147148	Has the organization developed 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 .	563	★	Is Has the organization controlled the variance of the temperature controlled? Is the test temperature of the module controlled at 25 °C ± 2 °C, and the module equilibrated enough that the variation between the cell junction and measurement point on the module is less than 1 °C?		
		564	★	Is the test temperature of the module controlled at 25 °C ± 2 °C, and the module equilibrated enough that the variation between the cell junction and measurement point on the module is less than 1 °C?		

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	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.	565	★	If the test temperature of the module falls outside the range of 25 °C ± 2 °C, or if the module is not equilibrated enough that the variation between the cell junction and measurement point on the module is less than 1 °C, does the control plan specify how to correct for these deviations so that the total uncertainty in within the range indicated on the product label, datasheet, or other product literature?		
	cg) 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.	154		c)Have 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 to perform an adequate measurement.been maintained at a known, traceable calibration (per IEC 60904-4)?		
5.5.5 6.9.3 Validation of processes for production and services provisions						
6.9.3	The organization shall validate software used in the product, production and services provision. Software applications throughout the life cycle that are important to ensuring product quality, reliability, performance, or safety should be included. Software may include firmware. The organization shall define a certification	579 5791 55	★	Has the organization validated all software used in the product, production and services provision?		
		580 5811 56		Are software applications throughout the life cycle that are important to ensuring product quality, reliability, performance, or safety included in the		

	~~and periodic recertification process for qualified personnel.~~			validation?		
	The organization shall define a certification and periodic recertification process for qualified personnel	581	★	Has the organization developed and consistently applied a certification and periodic recertification process for qualified personnel?		
	The organization shall determine parameter sets for the acceptance tolerance for the product.	582 ~~5821~~ ~~57~~	★	Has the organization determined parameter sets for the acceptance tolerance for the product?		
	The organization shall validate the effectiveness of their ESD program, as required~~.~~	583 ~~5831~~ ~~58~~		Has the organization validated the effectiveness of their ESD program?		
	Use of statistical process control is recommended for these processes.	~~160~~				
	NOTE: See IEC 61340-5-1 for Protection of electronic devices from electrostatic phenomena - General requirements					
	~~Software applications throughout the life cycle that are important to ensuring product quality, reliability, performance, or safety should be included.~~ ~~Software may include firmware.~~	~~5801~~ ~~61~~				
5.5.6 ~~6.9.4~~ Identification and traceability						
~~6.9.4~~	The organization shall document traceability of changes to the product and impact from those changes for previous and future product deliveries.	584 ~~162~~	★	Has the organization 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	585	★	Does the organization 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,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,	163		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,			
	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.164	165		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.b)Does the organization Ttracking the specific machine and time of processing for each process step?			
	In case batch processing is deployed in some process steps, tracking granularity may be limited to machine groups, time zones, and operator team.			c) For manual process steps, does the organization traceablityk to the operator who performing ed each step? Shall e recorded			
5.5.76.9.5 Customer property							
6.9.5	The organization shall be responsible for protecting customer intellectual property, if any, for outsourced processes.	586 166		Does the organization protect customer intellectual property for outsourced processes?			
.	If required, the control methods of customer property should be approved by the customer	587		Has the control methods of customer property been approved by the customer, if required?			

6.9.6 **5.5.86.9.6 Preservation of product**						
6.9.6	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.	588 588 167 168 169	★	Is the packaging method for the PV module tested as defined in IEC 61759-1 or equivalent?		
		589 589	★	Has the packaging been validated to meet customer requirements including that product is properly transported to customer sites?		
		590 590		Is the product traceability information 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.	591 591	★	Does the organization 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.	592 592 172		Does the organization shall use an inventory management system to ensure stock rotation?		
5.5.9 Post-delivery activities						
5.5.9.1 General						
	The organization shall organize warranty service system to securely implement the warranty.	593	★	Has the organization organized warranty service system to securely implement the warranty?		
	The organization may subcontract its responsibility for the above-mentioned warranty services to third parties.	594	★	Does the organization notify installers of the PV modules of precautions for use and/or installation, if necessary, so that the requirements for the warranty may be met?		

5.5.9.2 Notification of items concerning reliability							
	The organization shall notify installers of the PV modules of precautions for use and/or installation, if necessary, so that the requirements for the warranty may be met.	595	★	Does the organization notify installers of the PV modules of precautions for use and/or installation, if necessary, so that the requirements for the warranty may be met?			
5.5.9.3 Disclosure of contents of the warranty							
	The organization shall disclose contents of the warranty to the purchasers of PV modules, including warranty conditions pertaining to it and matters necessary for after-sales services specified in the warranty.	596	★	Does the organization disclose contents of the warranty to the purchasers of PV modules, including warranty conditions pertaining to it and matters necessary for after-sales services specified in the warranty?			
5.5.9.4 Acceptance of consultation requests							
	The operational rules and/ or systems shall be defined for acceptance of consultation requests from purchasers when some problems occur, diagnosis to identify the problem, compensation after it was identified, measures for preventing the recurrence.	597	★	Do the operational rules and/ or systems define for acceptance of consultation requests from purchasers when some problems occur, diagnosis to identify the problem, compensation after it was identified, measures for preventing the recurrence?			
	The organization shall define rules to specify actions to be taken in case of occurrence of severe troubles.	598 ★ ~~175~~ ~~176~~ ★~~1~~ ~~78~~ ★ ★ ★ ★~~1~~ ~~82~~ ★	~~19~~ ~~0~~ ~~19~~ ~~4~~ ~~19~~ ~~5~~ ~~19~~ ~~6~~ ★ ~~20~~ ~~1~~ ~~20~~ ~~2~~	Has the organization defined rules to specify actions to be taken in case of occurrence of severe troubles?			

		★★★★	20 7 20 8 20 9 21 0 ★			
5.6 Control of nonconforming outputs						
	Organization shall conduct a systematic material review to disposition processes including rework, reuse, and recycle of the 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.	599		Does organization conduct a systematic material review to disposition processes including rework, reuse, and recycle of the nonconforming products and constituent raw materials?		
		5991		Is product with unidentified or suspect status 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 4.3).	5992		Are customers I, where appropriate, informed promptly in the event that nonconforming product has been shipped without customer approval? Are records of customer notifications, where appropriate, maintained? (see 4.3).		
	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.	5993		Does the organization, 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?			
	~~The organization shall send quality alert internal communications to all affected manufacturing locations upon discovery of new failures and defects.~~			~~Does the organization 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 4.3clause 4.~~			~~Are records of such alerts maintained in accordance with 4.3Upon discovery of new failures and defects, have records of internal communications to all affected manufacturing locations been maintained?~~			
6 Performance evaluation							
6.1 Monitoring, measurement, analysis and evaluation							
6.1.1 Monitoring and measurement of a manufacturing process							
~~7.2~~	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~~	601		Has the organization performed process studies on all new manufacturing processes (including assembly or sequencing) to verify process capability and to provide additional input for process control?			
		602		Are the results of the studies documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions?			
		603		Do these documents include objectives for manufacturing process capability, equipment availability and acceptance criteria?			

	~~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:~~					
	The organization shall maintain manufacturing process and tool capability or performance as specified by the customer part approval process requirements or organization-targeted level.	604		Does 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:	605	★	Does the organization ensure that the control plan and process flow diagram are implemented, including adherence to the specified?:		
	a) Measurement techniques,			a) Measurement techniques		
	b) Sampling plans,			b) Sampling plans		
	c) Acceptance criteria,			c) Acceptance criteria		
	d) Preventive maintenance, and			d) Preventive maintenance		
	e) Reaction plans when acceptance criteria are not met.			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.	606		Does the organization 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.	607		Does the organization record significant process events, such as a tool change or machine downtime and repair?		
	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.	608		Does the organization initiate an out-of-control action plan from the control plan for characteristics that are either not statistical capability or are unstable?		
		609		Does the out-of-control action plan include containment of product and 100% inspection, as appropriate?		
		610		For out-of-control events has the organization completed a corrective action plan that included specific timing and assigned responsibilities to ensure the process became stable and capable?		
		611		Were out-of-control plans reviewed with and approved by the customer when 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 specific limits. Records of such events shall be maintained (see clause 4)	612		Does the organization maintain records of effective dates of process changes through a change management system?		
		613	★	Is a quality management representative of the QMS empowered to issue stop-work or stop-ship when nonconforming products are suspected to exceed specific limits?		
		★ 614	★	Are records of identification of suspected nonconforming products and the associated stop-work or stop-ship orders maintained?		

6.1.2 Monitoring and measurement of product						
7.3	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.	1212 2216 15	★ ★ 226 228 ★	Is the module performance measured before shipment according to a recognized standard such as IEC 60904 series using reference 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).	616	★	Does control of measurement conditions minimize the need for correction to STC, according to IEC 60904-7 (correction for spectrum) and IEC 60891 (correction for temperature and irradiance)?Is the module performance measurement done under controlled conditions so as to minimize needed corrections? Is the module performance measurement corrected for deviations from standard test conditions according to IEC 60904-7 or IEC 60891?		
	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 that do not affect performance and safety should be carried out after these tests. cleaning, labeling, and packaging may be carried out after these tests.	617	★	Are tests performed on 100% of product for validation of performance and safety carried out at the final stage of production, and no further operations except those that do not affect performance and safety carried out after these tests?with no further operations performed except cleaning, labeling, and packaging?		
	Monitoring and measurement of product shall include studies of the performance during the expected design lifetime of the product.	618	★	Does monitoring and measurement of product include the company studies ofy performance during the expected design lifetime of the product?		

6.1.3 Ongoing product monitoring						
7.4	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.	619		Has the organization defined an ongoing/periodic reliability monitoring/production monitoring program that uses appropriate tests for the known failure mechanisms of the product?		
		620		Are the tests ~~Is this ongoing product monitoring program~~ conducted on the samples that are selected by the internal sampling procedure?		
	Discovery of failures from these activities shall follow 7.~~8~~1 to address the root cause.. Corrective action to address the root cause shall be taken and documented for any failures.	621		Does discovery of failures from these activities shall follow 7.1 to address the root cause?~~When failures are discovered as part of this ongoing monitoring program, is Sec. 7.8 followed?~~		
		622		Is corrective action taken and documented for any failures?~~When failures are discovered, is the root cause addressed and documented?~~		
	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 4.3~~Clause~~ 4).	623	★	Are results of the ongoing/periodic reliability testing/production monitoring program activities and any necessary actions recorded?		
6.2 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	624		Has the organization managed customer complaints in a controlled manner,logged the issues, and take corrective and preventive actions, as appropriate?		

	and corrective actions are taken without undue delay and communicated to the customer, where appropriate.	625		Has the organization taken any necessary corrections and corrective actions to customer complaints without undue delay?		
		626		Has the organization communicated to the customer, where appropriate?		
	Organization shall monitor the complaint log for recurring issues and escalate to management, as appropriate.	627		Does the organization 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.	628		Hass the organization sent 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 4.3.	629		Are records of such alerts maintained in accordance with 4.3		
6.3 Analysis and evaluation						
-	The analysis of data shall provide information relating to conformity to process and product requirements (see 5.3.4 and 5.3.7)	630	★	Does the organization use analysis of data collected to assess conformity to process and product requirements (see 5.3.4 and 5.3.7).?		
6.4 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..	631	★	Does the organization 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	632		~~Does the organization also periodically conduct outgoing quality audits and out of box audits to ensure conformance to product quality requirements?~~ Has ~~Are~~ the internal audits implemented using		

	based on ISO 19011:2011 or equivalent national standard.			ISO 19011:2011 or equivalent national standard?		
- - - - -	~~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.~~			~~Does the organization conduct a systematic material review to disposition process including rework, reuse, and recycle of the nonconforming products and constituent raw materials?~~		
				~~If product is identified to have unidentified or suspect status, is it identified as nonconforming product and subjected to a systematic review process?~~		
7 Improvement						
7.1 Corrective and preventive action						
-	The organization shall use a structured approach to conduct root-cause analysis and corrective action.	701		Does the organization use a structured approach (such as a why-why analysis and 8 Discipline) 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.	702		Does the organization share lessons learned from corrective action across all manufacturing locations and affected functions and suppliers, as appropriate, to prevent recurrence?		
	NOTE: some examples of proven methodologies used for s~~S~~tructured approach, for root-cause analysis and corrective action are~~may include proven methodologies such as~~ why-why analysis and “8 Discipline” method (also called “Eight Disciplines Problem Solving” method).					

7.2 Continual improvement						
	The organization shall deploy continual improvement through a structured approach and demonstrate that results are sustained.	703		Does the organization 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	704		Does the organization identify, measure, and report quality metrics to drive continuous improvement?		
	The structured approach may include proven methodologies such as PDCA or DMAIC.					

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