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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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 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 9001:2008 and IEC/TS 62941.

Document History

Date	Summary
2016-09-26	Edition 1.0

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 stated 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	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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	0	Does the QMS have a current ISO 9001 certification or equivalent?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	**Statement of requirement**			
4 Documentation Requirements				
	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.	1	Does the organization have a documented records control procedure? (Refer to the records control procedure or relevant formal documents.)	
		2	Are records related to meeting warranty conditions explicitly identified?	
		3	Are records related to design and development explicitly identified?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	Records should also include Certificates of Conformity (CoC) and Certificates of Conformity Analysis (CoA) of key materials identified by the organization.	4	Are records of Certificates of Conformity (CoC) and Certificates of Analysis (CoA) of key materials identified by the organization In the design qualification?	
		5	Are records related to Engineering Changes explicitly identified?	
		6	Is there monitoring, and measurement of a manufacturing process (Identify specific processes) Includes Incoming QC COC/COA where applicable?	
		7	Is there monitoring, and measurement of a manufacturing products (Identify specific products) where applicable?	
		8	Are records related to Final Testing explicitly identified?	
		9	Are there Customer details on records where applicable?	
		10	Is ownership of records and storage locations identified by record type?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
		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.	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	**Statement of requirement**			
5. Resource management				
5.1 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.	12	Does the organization provide resources needed to maintain the product warranty system?	
		13	Are the resources assigned adequate for the organization to conduct failure analysis on all returned products and any appropriate follow-up actions such as adjustment to quality control plan or warranty recall?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
		14	Are resources adequate for providing requested after-sales service?	
5.2 Succession planning				
	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?	
6 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?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
6.2 Planning of product realization				
	In planning product realization, the organization shall also determine the following, as appropriate:	17	In planning product realization, has the organization determined the following (as appropriate)?	
	a) Product certification requirements	18	a) Product certification requirements (NOTE: The product certification may depend on the application and geographies where the modules will 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	19	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.)	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	c) Recycling requirements at the end of the modules' lifetime	20	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.	21	d) Assurance and control measures to be applied to production to meet requirements of the applicable PV standards.	
	e) ESD safe environmental area	22	e) ESD safe environmental area, as applicable	
	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	23	Is 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?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	material storage, processing, assembly areas, and all through packaging and shipping as defined in IEC/TS 62916 or as appropriate.			
	f) Packaging, storage and transportation requirements	24	f) Packaging, storage and transportation requirements, as applicable.	
	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.	25	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	26	Has a complete product life-cycle management process been defined, as appropriate?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	the product warranty as well as customers' needs. A complete product life-cycle management process may be required.			
	The product certification may depend on the application and geographies where the modules will be installed.	27	Have the application and geographies where the modules will be installed been considered in designing the quality program?	
	The recycling requirements should comply with the geographies where the modules will be installed.	28	Do the recycling requirements comply with the geographies where the modules will be installed?	
	ESD requirement should consider ANSI/ESD S20.20, future IEC TS 62916 or equivalent standard	29	Does the ESD requirement consider ANSI/ESD S20.20, future IEC TS 62916 or an equivalent standard?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
6.3 Determination of requirements related to the product				
	The organization shall determine product warranty workmanship and power degradation and its relationship to design lifetime under specified or intended use conditions.	30	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?	
	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.	31	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?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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 6.9.2for proper control of solar simulators).	32	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?	
6.4 Review of requirements related to the product				
	The organization shall ensure that all modified product, not covered by the retest guidelines as defined in IEC/TS 62915, is qualified to all related type designs and that the modified product is evaluated for impact on the warranty.	33	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?	
		34	Are there records to show that the modified product is evaluated for impact on the warranty? Are records maintained?	
	The organization shall identify and document all limitations on product application.	35	Are all limitations on product application identified and documented?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	The organization shall identify critical areas for ESD control, where appropriate. ESD requirement should consider ANSI/ESD S20.20, future IEC TS 62916 or equivalent standard.	36	Where appropriate, are critical areas for ESD control identified? Does ESD requirement consider ANSI/ESD S20.20 or equivalent standard)	
6.5 Customer communication				
	The organization shall also determine and implement effective arrangements for communicating with customers in relation to the following:	37	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,	38	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	39	b) Application notes detailing specific attention and/or care need to secure design lifetime of installed modules?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	c) The definition of a warrantable defect or safety critical defect and the rules or process to manage stated defects and .	40	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.	41	d) Product recall notices?	
6.6 Organization manufacturing feasibility				
	The organization shall investigate, conduct risk analysis, confirm and document the manufacturing feasibility at the necessary scale of the proposed products in the contract where applicable.	42	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.	43	Does the organization manage the risks prior to manufacturing transfer?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
6.7 Design and development				
6.7.1 Design and development planning				
	The organization shall include production processes in the design and development planning.	44	Does the organization include production processes in the design and development planning?	
	The organization shall also determine:	45	During the design and development planning, does the organization determine:	
	a) The responsibilities and authorities for a project design and development team,	46	a) The responsibilities and authorities for design and development?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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?	
6.7.2 Design and Development Inputs				
6.7.2		49	Does the organization determine inputs relating to product requirements and maintain the related records?	
	The inputs shall also include the following:	50	Does the organization’s inputs relating to product requirements include:	
	a) Functional, performance, and safety requirements including design lifetime,	51	a) Functional /performance/safety /product lifetime/ power degradation requirements,	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	power, maintainability durability, transportation, timing, and costs,		including materials requirements defined in IEC 61730-1?	
	b) Identification of product, traceability, and packaging requirements,	52	b) Product identification, traceability and packaging requirements	
	c) Requirements for proper handling of product and components for ESD, and	53	c) Requirements for proper handling of product and component for ESD?	
	d) Lessons learned from previous designs.	54	d) Where applicable, information derived from previous similar designs including lessons learnt?	
	The organization may consider application of IEC draft standard on transportation testing IEC 62759 when designing packaging materials.	55	Did the organization consider IEC 62759 or equivalent when designing packaging materials?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
6.7.3 Manufacturing Process Design Inputs				
	The organization shall identify, document, and review the manufacturing process design input requirements, including the following:	56	Does the organization identify, document and review the manufacturing process design input requirements, including:	
	a) Product design output data,	57	a) Product design output data?	
	b) Targets for productivity, process capability and cost,	58	b) Targets for productivity, process capability and cost?	
	c) Customers' requirements, if any, and	59	c) Customers requirements if any?	
	d) Lessons learned from previous developments.	60	d) Experience from previous developments?	
	The manufacturing process design includes the use of error-proofing methods and statistical process control methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.	61	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?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
6.7.4 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:	63	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) 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?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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?	
6.7.5 Manufacturing process design outputs				
6. 7.5				
	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:	67	Does the manufacturing process design output include data for quality, and reliability including the following:	
	a) Specifications and drawings,	68	a) Specifications and drawings	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	b) Manufacturing process flow chart/layout,	69	b) Manufacturing process flow chart/layout	
	c) Manufacturing process FMEAs as defined in IEC60812 or equivalent risk management tool,	70	c) Manufacturing process FMEAs	
	d) Control plan (see 7.12),	71	d) Control plan	
	e) Work instructions,	72	e) Work instructions	
	f) Process approval acceptance criteria,	73	f) Process approval acceptance criteria	
	g) An ESD protection plan,	74	g) An ESD protection plan	
	h) Error-proofing methods, as appropriate,	75	h) Error-proofing methods	
	i) Methods for product identification and traceability,	76	i) Methods for product identification and traceability	
	j) Methods of detection and feedback of product/manufacturing process nonconformities.	77	j) Methods of detection and feedback of product/manufacturing process nonconformities	
	k) Process for handling raw materials from the time of their receipt	78	k) Processfor handling raw material from the time of their receipt	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	Process FMEAs (PFMEAs), or equivalent, shall cover the process from material receipt to product delivery, and where appropriate, installation and maintenance.	79	Have the Manufacturing process FMEAs been conducted as defined in IEC60812 or equivalent risk management tool?	
6.7.6 Design and development validation				
6.7.6	The organization shall include standard requirements from applicable IEC and national standards for validation of the design.	80	Has the organization included the standard requirements from applicable IEC and national standards as part of validation of the design?	
		81	Are design validation results and any necessary actions recorded?	
	Performance testing activities including durability of prototype modules shall be monitored for timely completion and conformance to requirements.	82	Have the performance testing activities including durability of prototype modules been monitored for timely completion and conformance requirements?	
	Performance testing shall conform to a product and process approval procedure including a reliability test plan similar to applicable	83	Has the performance testing conformed to a product and process approval procedure including a reliability test plan similar to applicable standards?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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.	84	Is a reliability test plan consistent with the design lifetime?	
		85	Have the prototyped PV modules been tested according to IEC61215, IEC61646, IEC61730, IEC/TS62915 or equivalent?	
		86	Are the performance testing activities including durability of prototype modules consistent with the FMEA's results?	
		87	Are the performance testing activities results recorded?	
	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.	88	Has the organization done the qualification of subcontracted services including ongoing technical oversight and confirmation test results?	
		89	Are the qualification of subcontracted services results recorded?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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	90	Is product approval subsequent to the verification of the manufacturing process?	
		91	Is product and manufacturing process approval procedure applied to suppliers of key materials?	
6.7.7 Control of design and development changes				
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.	92	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?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	Traceability of changes shall be documented and maintained in the organization’s QMS.	94	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?	
		96	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.	97	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	98	Have 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?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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.	99	Are there rules or regulations in the organization's QMS to prevent release of products to customers before applicable tests are verified?	
		100	If major changes occurred (form, fit and function), are there records of the certification and notification of the customers?	
6.8 Purchasing				
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.	101	Has the organization controlled the quality of materials, components and sub-assemblies adequately to ensure that the overall risks are minimal?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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.	102	Has the organization defined a process for the supplier's notification of changes and ensured that the supplier maintains traceability of relevant changes?	
		103	Are there any records of the supplier's notification of changes?	
		104	When a supplier provides a change notification, is a process defined to address this change notification?	
		105	Has the organization ensured that the components, sub-assemblies and assemblies met the quality plan's including relevant safety and certification requirements?	
		106	Are there records to ensure that the components, sub-assemblies and assemblies met the quality plan's relevant safety and certification requirements?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	The organization shall complete the following actions to ensure their suppliers can meet product requirements by doing the following:	107	Has the organization completed the following actions to ensure their suppliers can meet the product requirements;	
	a) Set up a QMS	108	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,	109	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,	110	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:	111	d) Has the organization carried out onsite audits to check that:	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	The material produced is conformal with applicable organization or manufacturer specifications;	112	Is tme Material produced conformal with applicable organization or manufacturer specifications?	
	The supplier has the capability to deliver the goods on time;	113	Does the supplier have the capability to deliver the goods on time?	
	E 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.	114	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?	
		115	Are there audit records?	
	e) Urge the supplier to improve its quality performance if necessary, and	116	e) If necessary, has the organization urged the supplier to improve its quality performance?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	f) Apply methods for incoming inspections and preparation of raw materials.	117	f) Has the organization applied methods for incoming inspections and preparation of raw materials?	
6.8.2 Purchasing information				
6.8.2	Purchasing information shall also describe the requirements for materials/component traceability.	118	Is purchasing information documented and maintained in a manner as defined in QMS?	
		119	Does purchasing information describe the requirements for materials/component traceability?	
		120	Take a record of purchase information to check if it is conformant to this requirement.	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
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:	121	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,	122	a) Receipt and review of certificate of conformance or analysis,	
	b) Evaluation of statistical data of purchased products and key materials	123	b) Evaluation of statistical data of purchased products and key materials	
	c) Receiving inspection or testing such as statistical sampling based on performance,	124	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	125	d) Product evaluation or material analysis by an independent laboratory or testing facility,	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	e) Evidence of supplier inspections when the supplier has been delegated inspection authority based on history of product conformance to requirements.	126	e) Evidence of supplier inspections when the supplier has been delegated inspection authority based on history of product conformance to requirements.	
	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.	127	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.	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
6.9 Production and service provisions				
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.	128	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.	129	Has the organization defined definitions of product problems and rules andprocesses to minimize the impact of the problem? Are the definitions described in QMS?	

IEC/TS 62941		Question ID	Audit Question	Auditor Notes:
Section	Statement of requirement			
	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.	130	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.	131	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?	

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6.9.2 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	132	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?	
		133	Do the control plans meet the following requirements?	
	a) Be based on a risk analysis such as design or process FMEA outputs, or equivalent,	134	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,	135	b) List the controls used for the manufacturing process control,	
	c) Include methods for monitoring of control exercised over special characteristics (see 7.2) defined by the organization,	136	c) Include methods for monitoring of control exercised over special characteristics (see 7.2) defined by the organization,	

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	d) Include customer required information, if any, and	137	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.	138	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	139	Has the organization reviewed and updated control plans when any change occurs that affects the product manufacturing process? Are there any records 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	140	Has the organization periodically reviewed control plans for effectiveness of the controls and taken appropriate corrective actions?	

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	The organization shall define and manage a process to disposition the affected product impacted by an out-of-specification process.	141	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?	
	The organization shall maintain data records in a manner that allows detections of possible tendencies.	142	Does the organization maintain data records in a manner that allows detections of possible tendencies? Is the process defined and maintained in QMS?	
	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	143	Has the organization developed a control plan for all solar simulators used for performance rating? Is the control plan statistically based using reference modules? Does the simulator control plan have a documented out-of-control action plan for deviations? If multiple solar simulators are used, does the control plan demonstrate how correlation between the solar simulators is maintained?	

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	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.	144	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 .	145	Has the organization controlled the variance of the temperature? 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.	146	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?	
	Solar simulators that have been changed in a way that may affect the performance rating shall be re-qualified to IEC 60904-9 to ensure the original BBA or better rating is maintained. In addition, each solar simulator used for performance rating shall be partially re-qualified to IEC 60904-9 for uniformity of irradiance and temporal stability at a minimum of twice per year.	147	Have solar simulators that have been changed been re-qualified to IEC 60904-9 to ensure the original BBA or better rating is maintained? Has each solar simulator used for performance rating been partially re-qualified to IEC 60904-9 for uniformity of irradiance and temporal stability at a minimum of twice per year?	

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	Secondary reference modules shall be generated and certified by a recognized certification body for each specific module type, which can be traceable to international or national measurement standards. Working reference modules shall be created according to IEC60904-2 and IEC60904-4. 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.	148	Have secondary reference modules been generated and certified by a recognized certification body for each specific module type, with traceability to international or national measurement standards? Have working reference modules been created according to IEC60904-2 and IEC60904-4? Has the organization developed a control plan for the secondary reference and working reference modules to ensure no significant change occurs that may affect the rating of the module?	
	IEC 60891 (temperature and irradiance correction) and IEC 60904-7 (spectral correction) shall be used to appropriately correct the current and voltage characteristics of a module under test. IEC 61853-1 shall be used to determine the correction coefficients for	149	Have 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? Has IEC 61853-1 been used to determine the correction coefficients for irradiance and temperature effects on the measurement of the	

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	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.		module? Has the organization developed a plan to periodically revalidate the correction coefficients for a specific module type?	
	Solar simulator manufacturer's data may be used to initially validate that the solar simulator meets the BBA or better requirement.	150		
	Multiple secondary reference modules may be needed because they could be damaged or during periods when one secondary reference is out for calibration.	151	Have multiple secondary reference modules been acquired?	
	The plan shall also contain elements for the following items:	152		

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	f) Solar simulator maintained to have adequate spatial uniformity, temporal consistency, and spectral accuracy (as determined by IEC 60904-9). NOTE “adequate” implies that the combination of all uncertainties (including uncertainty associated with the simulator classification) is within the uncertainty indicated on the product label and literature.	153	Have all solar simulators been maintained to have adequate spatial uniformity, temporal consistency, and spectral accuracy (as determined by IEC 60904-9)?	
	g) Reference modules (as defined in IEC 60904-2) that are maintained at a known, traceable calibration (per IEC 60904-4) and that are similar to the product under test are used to perform an adequate measurement.	154	Have reference modules (as defined in IEC 60904-2) that are similar to the product under test been maintained at a known, traceable calibration (per IEC 60904-4)?	

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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.	155	Has the organization validated all software that could affect the quality of the product, including software used by suppliers of key materials?	
	The organization shall define a certification and periodic recertification process for qualified personnel.	156	Has the organization defined a certification and periodic recertification process for qualified personnel?	
	The organization shall determine parameter sets for the acceptance tolerance for the product.	157	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.	158	Has the organization validated the effectiveness of their ESD program?	
	These requirements are also applicable to key materials from suppliers. See IEC 61340-5-1 for guidance	159	Have these requirements been applied to key materials from suppliers?	

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	Use of statistical process control is recommended for these processes.	160	Has statistical process control or some other approach used that gives comparable results?	
	Software applications throughout the life cycle that are important to ensuring product quality, reliability, performance, or safety should be included. Software may include firmware.	161	Have software or firmware applications been used to ensure product quality, reliability, performance, and safety throughout the life cycle?	
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.	162	Has the organization documented changes to the product and the associated impact for previous and future deliveries?	
	The organization shall ensure traceability of the product, where appropriate, by			

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	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	Does the organization track product construction to the key raw materials and components used to the lot/batch level, including suppliers, date, 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	Does the organization track the specific machine and time of processing for each process step?	
		165	For manual process steps, does the organization track the operator who performed each step?	
6.9.5 Customer property				
6.9.5	The organization shall be responsible for protecting customer intellectual property for outsourced processes.	166	Does the organization protect customer intellectual property for outsourced processes?	

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6.9.6 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.	167	Is the packaging method for the PV module tested as defined in IEC 61759-1 or equivalent?	
		168	Has the packaging been validated to meet customer requirements including that product is properly transported to customer sites?	
		169	Has the packaging been validated to meet customer requirements including delivery site storage conditions until product use/installation?	
		170	Is 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.	171	Does the organization ensure the preservation of potential nonconforming products and key materials under material review until disposition as not fit for use?	

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	The organization shall use an inventory management system to ensure stock rotation.	172	Does the organization use an inventory management system to ensure stock rotation?	
6.10 Control of monitoring and measuring equipment				
6.10.1 General				
6.10.1	Monitoring and measurement equipment referenced in the control plan shall be characterized by measurement system analysis to understand gauge capabilities (Repeatability and Reproducibility).	173	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	174	Has the organization controlled software so that it cannot be inadvertently changed from the version validated in 7.13?	
		175	If software has been changed, has it been revalidated as per 7.13?	

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	shall revalidate monitoring and measurement equipment.	176	Does the organization revalidate monitoring and measurement equipment after hardware reconfiguration?	
	For monitoring and measurement equipment determined to be out of tolerance at the time of calibration, corrective actions must be taken to determine impact to the product and documented per clause 4.	177	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, both in process and previously shipped, and customer?	
		178	For monitoring and measurement equipment determined to be out of tolerance at the time of calibration, has documentation been completed as per clause 4?	
6.10.2Control of performance rating (I-V) measurement equipment				
6.10.2	For the equipment used to measure the power performance of the module, the organization shall maintain a control program	179	Does the control plan include a description of control of equipment (simulators) compliant to IEC 60904 series and IEC 60891?	

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	compliant to IEC 60891 and IEC 60904 series of standards. Records of compliance shall be maintained.	180	Does the organization maintain records of compliance with IEC 60904 and IEC 60891?	
	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.	181	Has the organization retained 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? Is this information traceable for each module manufactured? Does the organization make this information available to customers upon request?	
		182	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.	183	Were the solar simulators initially qualified according to IEC 60904-9, including characterization of spectrum quality, uniformity of irradiance, and temporal instability of irradiance?	

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	Solar simulators with a BBA rating or better are suggested for performance rating of modules, but the simulator requirement may vary with the solar cell technology, the geometry of the module, the match between the reference module and the test modules, and the power measurement uncertainty indicated on the product literature.	184	Does the uncertainty indicated in the product literature take into account any uncertainties associated with the solar cell technology, the geometry of the module, the match between the reference module and the test modules?	
		185	Is a procedure established for managing (use, storage and replacement) of secondary reference modules?	

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7. Monitoring and measurement				
7.1 Customer satisfaction				
7.1	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.	186	Does the organization log customer complaints in a controlled manner?	
		187	Have the organization taken necessary corrections and corrective actions without undue delay and communicated to the customer, where appropriate?	
	Organization shall monitor the complaint log for recurring issues and escalate to management, as appropriate.	188	Does the organization monitor the complaint log for recurring issues and escalate to management, as appropriate?	

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	The organization shall send quality alert internal communications to all affected manufacturing locations upon discovery of new failures and defects.	189	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 clause 4.	190	Upon discovery of new failures and defects, have records of internal communications to all affected manufacturing locations been maintained?	
7.2 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	191	Has the organization performed process studies on all new manufacturing processes (including assembly or sequencing) to verify process capability?	
		192	Has the organization used the process studies to provide input for process control?	

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	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:	193	Are the results of the studies documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions?	
		194	Do these documents include objectives for manufacturing process capability, equipment availability and acceptance criteria?	
		195	Does the manufacturing process and tool capability or performance meet the customer's approval requirements or organization targeted level?	
		196	Does the organization ensure that the control plan and process flow diagram are implemented, including adherence to the specified?	
	a) Measurement techniques,	197	Measurement techniques	

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	b) Sampling plans,	198	Sampling plans	
	c) Acceptance criteria,	199	Acceptance criteria	
	d) Preventive maintenance, and	200	Preventive maintenance	
	e) Reaction plans when acceptance criteria are not met.	201	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.	202	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.	203	Does the organization record significant process events, such as a tool change or machine downtime and repair?	

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	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.	204	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?	
		205	Does the out-of-control action plan include containment of product and 100% inspection, as appropriate?	
		206	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?	
		207	Were out-of-control plans reviewed with and approved by the customer when required?	

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	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)	208	Does the organization maintain records of effective dates of process changes through a change management system?	
		209	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?	
		210	Are records of identification of suspected nonconforming products and the associated stop-work or stop-ship orders maintained?	

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7.3 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.	211	Is the module performance measured before shipment according to a recognized standard such as IEC 60904-series?	
		212	Is the module performance measurement referenced to a defined reference spectrum such as the AM1.5 Global Spectrum defined in IEC 60904-3?	
	Control of measurement conditions shall minimize the need for correction to STC, and correction for any deviations from STC according to IEC 60904-7 (correction for spectrum) and IEC 60891 (correction for temperature and irradiance).	213	Is the module performance measurement done under controlled conditions so as to minimize needed corrections?	
		214	Is the module performance measurement corrected for deviations from standard test conditions according to IEC 60904-7 or IEC 60891?	

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	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.	215	Are tests performed on 100% of product for validation of performance and safety carried out at the final stage of production, 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.	216	Does the company study performance during the expected design lifetime of the product?	
7.4 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.	217	Has the organization defined an ongoing/periodic reliability monitoring/production monitoring program that uses appropriate tests for the known failure mechanisms of the product?	
		218	Is this ongoing product monitoring program conducted on the samples that are selected by the internal sampling procedure?	

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	Discovery of failures from these activities shall follow 7.8. Corrective action to address the root cause shall be taken and documented for any failures.	219	When failures are discovered as part of this ongoing monitoring program, is Sec. 7.8 followed?	
		220	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 Clause 4).	221	Are results of the ongoing/periodic reliability testing/production monitoring program activities and any necessary actions recorded?	
7.5 Internal audit				
	The organization shall periodically conduct process audits for all manufacturing processes (including assembly or sequencing) to ensure compliance to work instructions, ESD controls, and control plan..	222	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?	

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	The organization shall also periodically conduct outgoing quality audits and out-of-box audits to ensure conformance to product quality requirements. Internal audits should be implemented based on ISO 19011:2011 or equivalent national standard.	223	Does the organization also periodically conduct outgoing quality audits and out-of-box audits to ensure conformance to product quality requirements? Are the internal audits implemented using ISO 19011:2011 or equivalent national standard?	
		224	Does the organization take appropriate corrective actions and improvement measures for issues identified in the audits?	
7.6 Control of nonconforming product				
7.6.1 Control of nonconforming product				
	The organization shall conduct a systematic material review to disposition nonconforming products and constituent raw materials. Product with unidentified or	225	Does the organization conduct a systematic material review to disposition nonconforming products and constituent raw materials?	

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	suspect status shall be identified as potentially nonconforming product and subjected to a systematic review process.	226	If product is identified to have unidentified or suspect status, is it subjected to a systematic review process?	
	Customers shall, where appropriate, be informed promptly in the event that nonconforming product has been shipped without customer approval. Records of customer notifications, where appropriate, shall be maintained (see Clause 4).	227	If nonconforming product is found to have been shipped to a customer, was the customer informed promptly, if appropriate?	
		228	Has the organization maintained records of notifications to customers regarding nonconforming product shipped to them?	
	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.	229	Has the organization obtained 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?	

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7.6.2 Analysis of data				
	The analysis of data shall provide information relating to conformity to process and product requirements (see 7.3)	230	Does the organization use analysis of data collected to assess conformity to process and product requirements as described in 7.3?	
7.7 Continual improvement				
	The organization shall deploy continual improvement through a structured approach and demonstrate that results are sustained. The organization should identify, measure, and report quality metrics to drive continuous improvement The structured approach may include proven methodologies such as PDCA or DMAIC.	231	Does the organization deploy continual improvement through a structured approach (such as PDCA or DMAIC)?	
		232	Does the organization demonstrate that the positive results (using appropriate metrics) of the continuous improvement are sustained?	
		233	Does the organization identify, measure, and report quality metrics to drive continuous improvement?	

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7.8 Corrective and preventive action				
	The organization shall use a structured approach to conduct root-cause analysis and corrective action.	234	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.	235	Does the organization share lessons learned from corrective action across all manufacturing locations and affected functions and suppliers, as appropriate, to prevent recurrence?	
	Structured approach for root-cause analysis and corrective action may include proven methodologies such as why-why analysis and “8 Discipline” method (also called “Eight Disciplines Problem Solving” method).			

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