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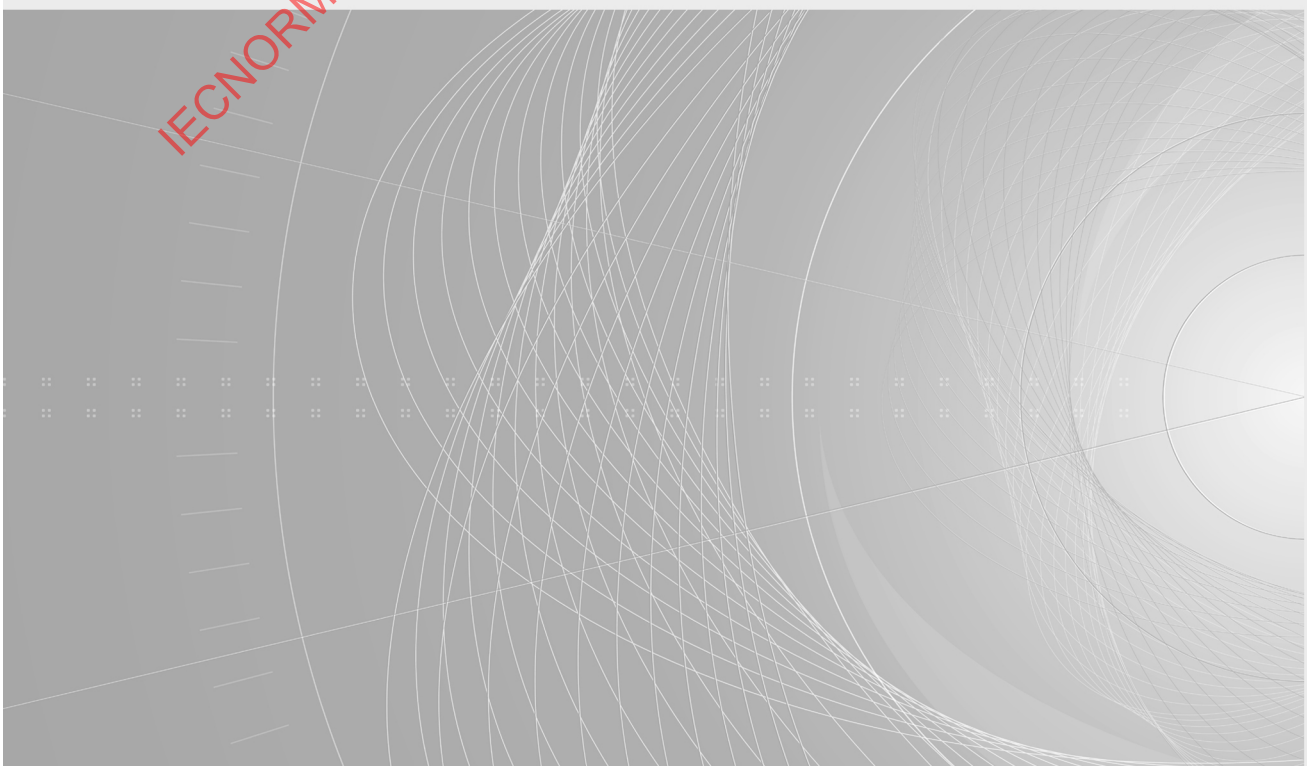
TECHNICAL SPECIFICATION

Photovoltaic systems – Guidelines for effective quality assurance of power conversion equipment



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PHOTOVOLTAIC SYSTEMS – GUIDELINES FOR EFFECTIVE QUALITY ASSURANCE OF POWER CONVERSION EQUIPMENT

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- the required support cannot be obtained for the publication of an International Standard, despite repeated efforts, or
- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

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

IEC TS 63157, which is a technical specification, has been prepared by IEC technical committee 82: Solar photovoltaic energy systems.

The text of this technical specification is based on the following documents:

Enquiry draft	Report on voting
82/1595/DTS	82/1625A/RVDTS

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

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

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

INTRODUCTION

The fundamentals of maintaining a quality assurance system are described in ISO 9001. The IEC Technical Committee 82 has supplemented ISO 9001 with additional technical details for guiding creation of quality assurance systems for the manufacture of photovoltaic (PV) modules (IEC TS 62941) and for installation of photovoltaic systems (IEC TS 63049).

Failures of PV systems are often reported to be caused by failures of the power conversion equipment, such as inverters and DC-DC converters. This document was developed to help the industry reduce those failures in a standardized and cost-effective way. It builds on ISO 9001 by adding technical details to be included in a quality assurance system. To facilitate the understanding of how ISO 9001 complements this document, the related ISO 9001 clause/subclause numbers are noted in square brackets as part of each heading as well as being tabulated in Annex A. A few references are also made to the IATF (International Automotive Task Force) 16949 *Quality Management Systems.*

PHOTOVOLTAIC SYSTEMS – GUIDELINES FOR EFFECTIVE QUALITY ASSURANCE OF POWER CONVERSION EQUIPMENT

1 Scope

This document lays out recommendations for best practices for product realization, safety, customer satisfaction, and stakeholders' relationship used in the manufacture of power conversion equipment (PCE).

This document captures key requirements customers would like to see completed to ensure high-quality products, specifically, that the products have the documented properties, including properties needed to give customer satisfaction with regard to the warranty.

The object of this document is to provide more confidence in the ongoing consistency of performance and reliability of certified power conversion equipment. The requirements of this document are defined with the assumption that the quality management system of the organization has already fulfilled the requirements of ISO 9001 or equivalent quality management system. These guidelines also form the basis for factory audit criteria of such sites by various certifying and auditory bodies.

This document covers manufacture of electronic power conversion equipment intended for use in terrestrial PV applications. The term PCE refers to equipment and components for electronic power conversion of electric power into another kind of electric power with respect to voltage, current and frequency. This document applies to PCE in both indoor and outdoor open-air climates as defined in IEC 60721-2-1 and IEC 60721-3-3. Such equipment may include, but is not limited to, DC-to-AC inverters, DC-to-DC converters and battery charge converters.

This document covers PCE that is used with PV arrays. The equipment may also be connected to other DC source or load circuits such as batteries. All parts of the PCE are included (*e.g.* connectors and software). This document may be used for accessories for use with PCE, except where more appropriate standards exist.

The object of this document is to define steps for providing assurance that:

- The customers' expectations are identified and the product is designed to meet those expectations,
- The performance characteristics and method of meeting the customers' expectations (*e.g.* efficiency) are identified,
- The specifications are either in conformance with the related standards or mentioned by the manufacturer on the data sheet or other product literature,
- The product has each of the properties described on the data sheet or other product literature, and
- The product has been designed and manufactured to retain those same properties after normal and reasonable environmental stresses experienced in the field (including worst-case typical temperatures, thermal cycling, corrosive conditions, over voltages/currents on DC and AC lines, transportation and installation, etc.) as well as survive stresses coming from the grid within the promise of the warranty.

To achieve these goals, this document requires:

- Analysis to identify potential failure modes and creation of a plan to prevent these during the time of the design lifetime,
- A documented change management control process to address raw material or manufacturing changes arising both internal and external to the organization,

- A documented supplier quality management process with integrated performance standards that uses continuous improvement to enhance overall product quality,
- A documented manufacturing process with workmanship standards that uses continuous improvement to enhance product quality,
- A documented manufacturing process that includes steps that identify when the process has gone out of control and high-level measures to follow to bring the process back in control as specified by an out-of-control action plan (OCAP). This includes measurements that ensure that the products have the defined properties including test results expected for certification, standards and warranty, and
- Testing of software to ensure that it works in the anticipated situations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60812, *Failure modes and effects analysis (FMEA and FMECA)*

IEC 61000-6-1:2016, *Electromagnetic compatibility (EMC) – Part 6-1: Generic standards – Immunity standard for residential, commercial and light-industrial environments*

IEC 61000-6-2:2016, *Electromagnetic compatibility (EMC) – Part 6-2: Generic standards – Immunity standard for industrial environments*

IEC 61000-6-3:2006, *Electromagnetic compatibility (EMC) – Part 6-3: Generic standards – Emission standard for residential, commercial and light-industrial environments*
IEC 61000-6-3:2006/AMD1:2010

IEC 61000-6-4:2018, *Electromagnetic compatibility (EMC) – Part 6-4: Generic standards – Emission standard for industrial environments*

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

IEC 61850-7-420:2009, *Communication networks and systems for power utility automation – Part 7-420: Basic communication structure – Distributed energy resources logical node*

IEC 62093, *Balance-of-system components for photovoltaic systems – Design qualification natural environments*

IEC 62109-1, *Safety of power converters for use in photovoltaic power systems – Part 1: General requirements*

IEC 62109-2, *Safety of power converters for use in photovoltaic power systems – Part 2: Particular requirements for inverters*

IEC 62443 (all parts), *Industrial communication networks – Network and system security*

IEC 62894:2014, *Photovoltaic inverters – Data sheet and name plate*

IEC 62920:2017, *Photovoltaic power generating systems – EMC requirements and test methods for power conversion equipment*

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

ISO 4180, *Packaging – Complete, filled transport packages – General rules for the compilation of performance test schedules*

ISO 9000:2015, *Quality management systems – Fundamentals and vocabulary'*

ISO 9001:2015, *Quality management systems – Requirements*

ISO 19011:2018, *Guidelines for auditing management systems*

IEEE 1547, *IEEE Standard for Interconnection and Interoperability of Distributed Energy Resources with Associated Electric Power Systems Interfaces*

FCC Title 47 CFR Part 15, *Federal Communications Commission rules and regulations, Code of Federal Regulations, Title 47, Part 15*

IPC-9592B:2012, *Requirements for Power Conversion Devices for the Computer and Telecommunications Industries*

ANSI/ASQ Z1.4:2013, *Sampling procedures and tables for inspection by attributes*

ANSI/ASQ Z1.9:2013, *Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming*

ANSI/ESD S20.20-2014, *Protection of Electrical and Electronic Parts, Assemblies and Equipment (Excluding Electrically Initiated Explosive Devices)*

IATF 16949:2016, *Quality Management Systems*

3 Terms, definitions and acronyms

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
balance of system
BOS
parts of a PV system other than the PV array field, including switches, controls, meters, power conditioning equipment, PV array support structure, and electricity storage components, if any

3.2
containment
action taken to protect the customer from the effect of a situation. Containment may include correcting an existing situation or adding additional screening or retesting

Note 1 to entry: Containment may include correcting an existing situation or adding additional screening or retesting.

3.3
control plan
documented description of the systems and processes required for controlling the product and process quality by addressing the key characteristics and engineering requirements

3.4
cost of quality
cost of not creating a quality product or service, including the cost of reworking of product that is found to be outside of tolerance

Note 1 to entry: The cost of quality may include the cost of reworking of product that is found to be outside of tolerance.

3.5
critical item list
list of materials, components and software that have relatively high impact in determining product reliability

3.6
customer
all of the stakeholders and decision makers involved in the various stages of the system delivery process, and including the end user

3.7
design for assembly, manufacturing and testing
design technique for manufacturing ease of an assortment of parts to be assembled into the final product, focusing on minimizing the complexity of the manufacturing and assembly processes

3.8
design lifetime
design target period during which balance-of-system (BOS) components are expected to safely satisfy the specified performance under the specified conditions

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

3.9
define, measure, analyze, improve, and control
DMAIC
data-driven quality strategy for improving processes and an integral part of a Six Sigma quality initiative

3.10
electrostatic discharge
ESD
sudden flow of electricity between two electrically charged objects caused by contact, an electrical short, or dielectric breakdown

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

3.11
Failure Modes and Effects Analysis
FMEA
document that defines the design, process, or solution with requirements and includes potential modes, causes and severity of effects of failure, along with an evaluation of the likelihood of their occurrence and ease of detection.

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

3.12
key design characteristics
characteristics of the final product that are important to customer satisfaction

3.13
organization
entity that supplies product to the customer and that has responsibility for design, production, and after-service for the product

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

3.14
out of box audit
pre-shipment audit
simulation of what a customer would experience when they open the packing box

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

3.15
out of control action plan
OCAP
supporting document to an SPC (statistical process control) chart

Note 1 to entry: An OCAP is typically presented as a flowchart that guides manufacturing floor employees' reactions to out-of-control situations. An OCAP consists of activators (which define out-of-control conditions); checkpoints (which are likely causes for the conditions); and terminators (which contain the action that should resolve the conditions). OCAPs should be dynamic and updated continually as and when new knowledge and information become available. A frequently occurring OCAP activator is an indication of a systemic issue in the process.

3.16
Plan, Do, Check, Act
PDCA
four-step process for quality improvement. In the first step (Plan), a way to affect improvement is developed. In the second step (Do), the plan is carried out, preferably on a small scale. In the third step (Check), a study takes place between what was predicted and what was observed in the previous step. In the last step (Act), action is taken on the causal system to affect the desired change

3.17
performance warranty
warranty provided by the party ensuring product liability to guarantee the specified performance of the BOS components over the specified period and under the specified conditions

3.18
Process Failure Modes and Effects Analysis
PFMEA
quality engineering approach focussed on the manufacturing process

Note 1 to entry: PVMEA is to be compared to an FMEA, which is a reliability engineering approach focussed on usage of the product.

3.19
Product Life-Cycle Management
process of managing the entire life cycle of a product from inception, through engineering design and manufacture, to service and disposal of manufactured products

3.20
prototype
early sample, model, or release of a product built to test a concept or process, but may not have been produced with the intended future processes

3.21
Quality Management System
QMS
formalized system that documents the structure, responsibilities, and procedures required to achieve effective quality management

3.22
quality plan
document, or several documents, that together specify quality standards, practices, resources, specifications, and the sequence of activities relevant to a particular product, service, project, or contract

3.23
repeatability
variation in measurements obtained when one measurement device is used several times by the same person to measure the same characteristic on the same product

3.24
reproducibility
variation in measurements made by different people using the same measuring device to measure the same characteristic on the same product

3.25
statistical capability
statistical measure of the inherent process variability of a given characteristic in comparison to the specification limits

3.26
statistical process control
application of statistical techniques to control and monitor process

Note 1 to entry: It is used to determine the stability and predictability of a process.

3.27
supplier
provider of materials to an organization building product manufacturing and assembly

3.28
system delivery process
all stages of the system development beginning at concept and ending at site restoration

4 Documented information [7.5]

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

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

5 Planning [6.0]

5.1 Actions to address risks and opportunities [6.1]

5.1.1 Risk analysis [IATF 6.1.2.1]

The organization shall evaluate product risks and document in the appropriate FMEA as defined in IEC 60812 or equivalent. See 7.6.1. The organization shall include in its risk analysis, at a minimum, lessons learned from prior product recalls, product audits, product stress testing, field returns and repairs, complaints, scrap, and rework.

The organization shall retain documented information of the results of risk analysis and any preventive actions taken to address opportunities for improvement.

5.1.2 Preventive action [IATF 6.1.2.2]

The organization shall determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the severity of the potential issues.

The organization shall establish a process to lessen the impact of negative effects of risk including the following:

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) documented information of action taken,
e) reviewing the effectiveness of the preventive action taken,
f) utilizing lessons learned to prevent recurrence in similar processes.

5.2 Quality objectives and planning to achieve them [6.2 / IATF 6.2.2.1]

The organization shall ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.

This should include Cost of quality parameters. The parameters should be defined and quantified for particular equipment/device. This factor will provide further impetus to demonstrate that quality impacts the bottom line significantly.

The results of the organization's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

6 Support [7.0]

6.1 Resources [7.1]

6.1.1 People [7.1.2]

6.1.1.1 Provision of resources for commissioning

The organization shall provide resources for training workers to inspect all aspects of the system and to record any issues during commissioning.

6.1.1.2 Provision of resources for after sales services [IATF 10.2.5]

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.

6.1.1.3 Succession planning

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

6.1.1.4 Training of workers

Workers responsible for tasks that are critical for the specified operation of the PCE in either the short term or long term shall be appropriately trained and certified for performance of that task. These critical tasks (e.g. soldering and testing/verification) shall be identified as part of the risk assessment or determination of product requirements.

NOTE Examples of existing standards that may aid in establishing certification procedures include IPC-A-610E-2010, EIA/J-STD-001, and IPC/WHMA-A-620. Requirements are specified in the control plan as noted in 7.8.1.1.

6.1.2 Monitoring and measuring resources [7.1.5]

6.1.2.1 General

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

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

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

6.1.2.2 Control of performance measurement equipment

For the equipment used to measure critical performance metrics of the product, the organization shall maintain a control program. Records of compliance shall be maintained.

The organization shall retain all calibration certificates for electrical meters used for the rating or a report that can be traceable to international or national measurement standards. This information shall be traceable for each product manufactured and made available to customers upon request.

Electrical measuring devices 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.

Equipment accuracy and calibration shall be verified annually at a minimum, or more frequently if needed to maintain calibration.

During construction all equipment used should be calibrated including torque wrenches with torque marks clearly identified

6.1.3 Organizational knowledge [7.1.6]

The organization shall determine necessary knowledge gained from experience, lessons learned, success, failures, conferences, etc. and make this information available to the extent necessary including when addressing changing needs and trends.

6.2 Competence [7.2 / IATF 7.2.1 8.5.1e]

The organization shall establish and maintain a documented process(es) for identifying training needs including awareness and achieving competence of all personnel performing activities affecting conformity to product and process requirements including warranty and after-sales service. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements.

6.3 Awareness [7.3 / IATF 7.3.1]

The organization shall maintain documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with nonconforming product.

7 Operation [8.0]

7.1 General

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

7.2 Operational planning and control [8.1]

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

a) Product certification requirements.

b) Product properties that align with customers' expectations for performance including such factors as power conversion efficiency, defined DC input voltage window, output voltage and frequency within specifications, ability to control operating state on command or in response to changing conditions, availability, serviceability, reparability, ability to communicate current operating conditions through common data interfaces if part of product specification, and other properties described or referenced below.

c) 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.

d) Ability to tolerate typical variations within the operating environment.

e) Recycling requirements at the end of the product's lifetime.

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

g) Electrostatic discharge (ESD) safe environmental area

The organization shall identify the ESD sensitive materials and components and shall determine an ESD safe environmental area and maintain an ESD safe environment at the raw material storage, processing, assembly areas, and all through packaging and shipping.

NOTE A process similar to that defined in IEC 61000-4-2, ANSI/ESD S20.20, or as appropriate.

h) Packaging, storage and transportation requirements.

i) Requirements for ensuring quality assurance of components received from suppliers.

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

With changing requirements from the market place and with emerging new technology in the PV industry, the development and launch of new products should meet requirements of the product warranty as well as customers' needs. For products marketed to meet a local product life-cycle management requirement, related aspects of the device manufacturing are controlled.

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

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

7.3 Customer communication [8.2.1]

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

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

b) Application notes detailing parameters and ranges of the designed-for operating environment and the specific attention and care needed to secure product design lifetime of the installed configuration, including any exclusions or preconditions.

c) Relevant 3rd-party qualifications and certification information.

d) The definition of cosmetic defects and associated product categories due to downgrade associated with cosmetic defects.

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

f) Recommended spare parts inventory, and

g) Product recall notices with appropriate report to the supervisory authorities based on the related law or regulations.

The identified design is summarized in a data sheet that clearly communicates to the customer using standard terminology such as described in IEC 62894. The data sheet should identify the relevant standards to which the component is in compliance

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

7.4 Determining the requirements for the product [8.2.2]

The organization shall determine product warranty requirement and its relationship to design lifetime under specified and intended use conditions, including temperature, humidity, dust, voltage (consistent with datasheet specification), conditions of the grid, and weather exposure for all components, as applicable. In addition, equipment interaction with flora, fauna, rodents and vermin in the application environment shall be given due consideration in the requirements of the product. The analysis of the use environment shall include transportation, storage and installation. The organization shall ensure that all products are qualified to all relevant performance and safety type tests.

The organization shall incorporate requirements arising from applicable previous failure information, customer complaints, competitive analysis, supplier feedback, stress testing results and other internal inputs. The organization shall maintain traceability to these requirements. The organization should periodically review requirements that arose from previous failures that are not relevant due to design changes that may have addressed those.

The organization shall establish a method for specifying the characteristics of PCE in accordance with IEC 62894, IEC 62109-2, or other specification, as applicable.

The organization shall include an evaluation of considerations related to cyber security including authentication of updated software, (IEC 62443 or other relevant standards may be used).

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

The organization shall identify critical areas for ESD control, where appropriate. ESD requirement should consider ANSI/ESD S20.20 or equivalent standard.

7.5 Review of the requirements for products [8.2.3]

7.5.1 General

The ISO 9001:2015, 8.2.3 review shall include review that the PCE can be configured to meet the specified grid frequency and voltage requirements and statutory and regulatory requirements related to requests by the grid operator to curtail or otherwise adjust interaction with the grid. The review shall include safety and any required safety certifications.

7.5.2 Organization manufacturing feasibility [IATF 8.2.3.1.3]

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

The organization shall manage the risks prior to manufacturing transfer.

7.6 Design and development [8.3]

7.6.1 Design and development planning [8.3.2]

The organization shall determine:

a) The responsibilities and authorities for a project design and development team, and relationship with the quality assurance team,

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

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

7.6.2 Design and development inputs [8.3.3]

The inputs shall also include the following:

a) Functional, performance, and safety requirements including design lifetime, power, maintainability, durability, transportation, timing, and costs, and including the materials requirements defined in IEC 62109-1 and any other product certifications.

b) The environmental and operational ranges and use profiles for the product.

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

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

e) Lessons learned from previous designs.

The organization may consider application of standards on transportation testing such as ISO 4180.

7.6.3 Design and development controls [8.3.4]

7.6.3.1 Design and development validation [IATF 8.3.4.2]

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

As a minimum, the design and development validation shall include testing according to IEC 62093, IEC 62109 series, or equivalent.

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

The organization shall develop and maintain (using emergent information) a Critical Item List (CIL) based on information gathered during the development process such as:

a) High risk items (criticality) identified by an FMEA,
b) Single point failures in reliability models,
c) Testing failures from design verification testing,
d) Field failures observed for prototypes and surrogate product,
e) Other design analysis including stress testing and derating,
f) Confirmation of patent clearance of design avoiding potential risks for delays related to infringing other party's industrial patents on safety and reliability, and
g) Critical outsourced components and raw materials.

Design and development validation shall include verification of the manufacturing process and verification of product and processes of suppliers of critical items, as appropriate. The organization is recommended to perform as part of its new product introduction process Design for Assembly, Manufacturability and Testability activities. This can also include design for ease of maintenance in the field.

Design and development shall include assessment of the maximum operating temperature using procedures from IEC 62109-1:2010, 4.3 or the equivalent, as appropriate and with the following modifications.

While IEC 62109 evaluates the safety, the intent of the temperature evaluation here is to identify appropriate component choice to gain confidence in successful operation (in addition to safe operation). Thus, temperatures are measured for all key components including transistors, circuit boards, circuit boards, input-output ports, power supplies, buffer supplies, power and electromagnetic interference (EMI) filter circuit (e.g. capacitors, inductors, resistors), high-power isolation switches, contactors and breakers. The maximum operating temperature is measured using the approaches in IEC 62109 with respect to all design specifications, such as the highest ambient temperature and highest enclosure or back-of-module temperature and also including external effects, such as heating from sunlight or nearby equipment.

Components shall be chosen using the measured maximum temperature of each component and best-practice guidelines for derating such as those presented in IPC-9592B, section 4 and Appendix A.

The organization shall evaluate the uncertainties of the temperature measurements and shall account for design margins based on stringent operating conditions that the PCE's will be subjected to in the field.

The organization shall include protective derating based on the temperature of the critical components, cabinet and operating temperatures.

Based on the intended use, the operating voltage/current range and relevant utilization factors shall be determined for each component. The maximum electrical stress conditions (including voltage, current, and/or power, as is relevant to each component) are compared with the specifications for each key electrical component (such as transistors, capacitors, etc.). The designed/measured voltage or other electrical stress should be consistent with best-practice derating guidelines such as those described in IPC-9592B:2012, section 4 and Appendix A.

The organization shall evaluate the uncertainties of the bias condition measurements and shall account for design margins based on stringent operating conditions that the PCE's will be subjected to in the field.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

Additionally:

- Highly accelerated lifetime testing (HALT) or Highly Accelerated Stress Screen (HASS) testing of critical boards/component subassemblies shall be used for identifying products' possible points of failure and steps taken to address the identified deficiencies.
- Failure limited/Time limited Reliability Demonstration Tests (RDT) shall be used to identify possible issues with critical subassemblies such as liquid-cooled cooling systems.
- System level testing shall be used to identify problems that are missed with component-level tests. Typically, this is achieved by using completed PV systems into which the newly manufactured PCE is installed to verify system-level performance.

7.6.4 Design and development outputs [8.3.5]

Design and development outputs shall also include the following:

a) A manual for safe and proper installation, operation, maintenance, and dismantling (instruction for use),

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,

c) Process FMEAs as defined in IEC 60812, or equivalent, which are to be updated during design reviews, and a related incoming material and manufacturing quality control plan,

d) Final bill of material including material/component designation, brief description, identified source/s of supply, predicted/expected failure rates, and method for confirming quality of incoming materials and components, and

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

The PCE display panel should have the ability to indicate the exact cause when the PCE internal components fail.

When possible, the product should be designed to be quickly serviced for anticipated failure mechanisms.

Product or internal components replacement should be possible even after long-term operation.

All software features shall be reviewed with regard to potential safety risks and device functionality.

7.6.5 Design and development changes [8.3.6]

The organization shall implement a change management system for materials and processes and ensure all changes impacting form, fit and function are controlled and adhere to product requirements and defined internal/external qualification and certification requirements.

Recertification shall be completed for changes related to anti-islanding performance and for major changes in design. When a judgement of whether recertification is required, the decision shall be made by the certifying organization.

The approval and traceability of changes shall be documented and maintained in the organization's QMS.

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

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

The conditions of qualification, safety and reliability tests should be defined by taking into consideration the specified condition required by IEC 62093, IEC 62109-1, and IEC 62109-2, or equivalent.

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

7.6.6 Manufacturing process design inputs [IATF 8.3.3.2]

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

a) Product design output data.
b) Targets for productivity, process capability and cost.
c) Customers' requirements, if any.
d) Lessons learned from previous developments, and
e) Opportunities to utilize lean manufacturing.

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.

7.6.7 Manufacturing process design outputs [IATF 8.3.5.2 8.5.1a]

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

a) Specifications and drawings.
b) Manufacturing process flow chart/layout.
c) Manufacturing process FMEAs as defined in IEC 60812 or equivalent risk management tool.
d) Control plan (see 7.8.1.1).
e) Work instructions.
f) Process approval acceptance criteria.
g) An ESD protection plan.
h) Error-proofing methods, as appropriate.
i) Methods for product identification and traceability.
j) Methods for detection and feedback of product/manufacturing process nonconformities.
k) Safety programs to protect workers during manufacturing and associated posted metrics.
l) Process for handling raw materials from the time of their receipt, and
m) Supplier control.

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

The organization shall also document the key characteristics of the product.

The statement of key characteristics shall include specification of the environmental range over which these properties are retained as well as the corresponding measurement tolerances.

This list shall include as a minimum:

Key properties on nameplate and data sheet such as (as applicable):

- Electrical parameters from IEC 62894:2014, 4.4;
- Operating performance from IEC 62894:2014, 4.5.

Safety requirements associated with compliance to IEC 62109 series and any other relevant safety requirements.

Grid-interaction requirements as defined and certified to local code such as to IEEE 1547 or other relevant local codes and remotely controlled by communication standards like IEC 61850-7-420 or others. These may include requirements for protective functions such as interface protection and anti-islanding.

EMC requirements:

– Compliance with EMI standards so that the product neither emits electromagnetic radiation that disturbs function of nearby electronic devices, nor is it susceptible to common sources of electromagnetic radiation, for example, IEC 62920 and IEC 61000-6-1, IEC 61000-6-2, IEC 61000-6-3, IEC 61000-6-4, IEEE 1547 and FCC Title 47 CFR Part 15.

Other product functions that may be included as key:

– Display functionality – as described in the operating instructions, if available,
– User-interface functionality including communications band width, for example – (ethernet, wireless communications), as appropriate,
– Software functionality.

7.7 Control of externally provided processes, products and services [8.4]

7.7.1 General [8.4.1]

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.

The organization shall define processes for the supplier's notification of changes, ensure that the suppliers maintain traceability of relevant changes and the organization maintains traceability of those changes in its final products. 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.

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

a) Set up a QMS.
b) Evaluate the quality performance related to critical items (identified in 7.6.3.1) and audit the suppliers of critical items on a regular basis.

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

d) Periodically carry out onsite audits to check that:

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

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

f) Ensure that training and validation for effectiveness of training is taking place, and

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

QMS requirements for critical items may include ISO 9001 compliance.

7.7.2 Type and extent of control [8.4.2]

The organization shall have a consistent process to assure the quality of critical items and components defined in 7.6.3. and control of key design characteristics defined in 7.6.7 using an appropriate combination of the following methods:

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

b) Evaluation of statistical data of purchased products and critical items.

c) Evaluation of data collected during manufacturing.

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

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

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

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

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

7.7.3 Information for external providers [8.4.3]

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

7.8 Production and service provision [8.5]

7.8.1 Control of production and service provision [8.5.1] including (f)

7.8.1.1 Control plan [IATF 8.5.1.1]

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

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

b) List the controls used for the manufacturing process control. Identify relevant metrics to be tracked at each work station.

c) Include methods for monitoring of control exercised over special characteristics defined by the organization such as illustrating defect rates and areas with improvement.

d) Include customer required information, if any.

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

f) Identify and include areas of inspection using QC checklists prior to continuing through next steps in production.

g) Develop a final quality control checklist to identify issues prior to testing.

h) Identify provisions for use of specific tools/equipment used and requiring calibration.

i) Identify required incoming inspections of parts and equipment from outside (3rd party) suppliers.

j) Identify training records that are needed to assure quality control.

k) Identify methods for validation of effectiveness of training.

l) Identify written work instructions available on the work floor, including visual aids.

m) Identify measurement and calibrated tools and fixtures on which to maintain calibration "due" labels or equivalent system.

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

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

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

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

For determination of extent of products' failure in production period or serial number, tracking of production record is used to provide the reason for the extent of product recall reported to the customer. The organization shall define items of tracking record in the production and incoming component/material.

Examples of information the organization may choose to track:

- Statistical records of defects/failures found in manufacturing process and final inspection
- Records of incoming material or components (also refer to 7.7.2)
- Periodic authorized calibration or self-checking record of measuring instruments
- Name of individual performing the task in work stations
- Potting material injection check list including two-liquid mixture type for solidification
- Screw tightening torque or painting check list for structural construction
- Shipping set points and their test records for utility-interaction protection level and delay time before disconnection
- Installed software name and identification of utility interaction functions that are specific for countries or regions
- Any change information of line configuration and operation method for improvement or trouble shooting
- Any manufacturing line trouble issues happened and actions taken including pass/fail threshold change

The organization shall develop a control plan for all measurement devices used for key measurements and tests (see 7.8.1.).

7.8.1.2 Monitoring of product and processes during manufacturing and providing for service [8.5.1(c)(f)]

The organization shall determine methods to monitor the performance and functionality of the equipment used in the product realization process with focus on the key characteristics identified in 7.6.7. These measurements and tests are completed on a statistically capable fraction of manufactured product or components in order to provide the customer with confidence that the product meets these key design specifications, including anticipated lifetime. Measurement of product performance before shipment shall be consistent with the accuracy promised to the customer. The organization shall determine parameter sets for the acceptance tolerance for the product.

The statistical sample methods shall be disclosed.

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

The organization shall inspect the product in-process in addition to performing a final inspection to ensure that the requirements of the product specification are met and defective product are prevented from release. Tests performed on 100 % of the products for validation of 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.

The following tests shall be performed on 100% of products:

- Surface mount technology (SMT) on printed circuit boards (PCB) shall undergo AOI (AOI =Automatic Optic Inspection, to ensure existence of correct components and their position), where applicable.
- Post manual-insertion (MI) workmanship of boards shall also undergo quality inspection.
- PCB washing or the use of appropriate no-clean solder pastes shall be part of production flow to avoid dendrite growth.
- Product parametric testing shall be performed (In Circuit Test – ICT), where applicable.
- Hi-pot testing (also known as high voltage test) shall be performed to identify sites that could short or arc in the future.
- Conformal coating coverage is checked

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.

Burn-in, if used, shall be disclosed along with the details.

a) Validation of processes for production and services provisions

The organization shall validate software used in the servicing of product. Software updates shall be tested on all product models before updating the software or firmware. The process for authorization of release of software updates shall be defined. Additionally, the process shall be specified by which, before completing an upgrade, a PCE in the field authenticates the source and identifies that the software has been authorized for release. The review of the software release shall also consider whether the software update affects the PCE function, requiring a design recertification and whether the update may affect compliance with the local grid 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.

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

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

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

These requirements are also applicable to critical items from suppliers.

Use of statistical process control is recommended for these processes.

b) Ongoing reliability monitoring

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

When failures from these activities are observed the implications shall be analysed. Appropriate corrective action to address the root cause shall be taken when the analysis identifies that the product may not meet customer expectations.

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).

The durability of the product should be assessed including:

- Retention of full functionality after aging in the relevant use environment including consideration of altitude and electromagnetic interference. Full functionality should include acceptably low emission of electromagnetic signals.
- Product resistance to grid stresses (e.g. voltage transients).

These may be partially confirmed using tests such as those defined in IEC 62109 and IEC 62093, but the tests may vary from what is in standardized test sequences based on the organization's experience with field returns and observed failure modes.

7.8.2 Identification and traceability [8.5.2]

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

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

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

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

7.8.3 Property protection [8.5.3]

7.8.3.1 Property belonging to the organization

The organization's intellectual property may be protected during external party reviews through non-disclosure agreements aided by on-site visual review of proprietary documents without physical or electronic exchange of sensitive documents.

7.8.3.2 Property belonging to customers or external providers

If required, the organization's methods for controlling customer property can be audited by the customer to ensure the customer's confidence in these.

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

7.8.4 Preservation [8.5.4]

The packaging method of the product shall be tested and validated to meet customer requirements and ensure that the product can be transported to customer sites properly. Product traceability information should be easily identified from the outside of the packaging.

The recyclability of the packaging should be considered in the context of recycling facilities in the target market.

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

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

7.8.5 Post-delivery activities [8.5.5]

7.8.5.1 Feedback of information from service [IATF 8.5.5.1]

The organization shall ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

The intent of communicating "service concerns" is to ensure that the organization is aware of nonconforming product(s) and material(s) that may be identified at the customer location or in the field.

"Service concerns" should include the results of field failure test analysis, where applicable.

7.8.5.2 Service agreement with customer [IATF 8.5.5.2]

When there is a service agreement with the customer, the organization shall:

- verify that the relevant service centers comply with applicable requirements
- verify the effectiveness of any special purpose tools or measurement equipment
- ensure that all service personnel are trained in applicable requirements

7.8.5.3 Spare parts component and quantity recommendation

By attaining feedback information on failed and replaced components and their quantity in the field, the organization shall recommend or revise annual spare parts list for continuous operation of the product.

7.8.6 Control of changes [8.5.6 / IATF 8.5.6.1]

The organization shall have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, shall be assessed.

The organization shall:

a) define verification and validation activities to ensure compliance with customer requirements,

b) validate changes before implementation,

c) document the evidence of related risk analysis,

d) define who has the authority and responsibility for final approval of changes that affect form, fit, function, reliability, or performance, and

e) retain records of verification and validation.

Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.

When required by the customer by contract, the organization shall:

f) notify the customer of any planned product realization changes after the most recent product approval,

g) obtain documented approval, prior to implementation of the change,

h) complete additional verification or identification requirements, such as production trial run and new product validation.

7.9 Release of products and services [8.6 / IATF 8.6.1]

7.9.1 General

The organization shall ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan.

The organization shall ensure that the planned arrangements for initial release of products and services encompass product or service approval.

The organization shall ensure that product or service approval is accomplished after changes following initial release.

7.9.2 Statutory and regulatory conformity [IATF 8.6.5]

Prior to release of externally provided products into its production flow, the organization shall confirm and be able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, certification, qualification, and other requirements in the countries where they are manufactured and in the customer-identified countries and jurisdictions of destination, if provided.

7.9.3 Acceptance criteria [IATF 8.6.6]

Acceptance criteria shall be defined by the organization and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects.

7.10 Control of nonconforming outputs [8.7]

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

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

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

8 Performance evaluation [9.0]

8.1 Monitoring, measurement, analysis and evaluation [9.1]

8.1.1 Monitoring and measurement of a manufacturing process [IATF 9.1.1.1]

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 with focus on the key design characteristics identified in 7.6.7. 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's part-approval criteria or organization-targeted level. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified:

a) Measurement techniques.

b) Sampling plans.

c) Acceptance criteria.

d) Preventive maintenance, and

e) Reaction plans when acceptance criteria are not met.

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

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

The organization shall initiate an out-of-control action plan from the control plan for characteristics that are either not statistically capable or are unstable. These plans shall include the containment of product and 100 % inspection, as appropriate. A corrective action plan shall then be completed by the organization, indicating specific timing and assigned responsibilities to ensure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer when so required.

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

8.1.2 Customer satisfaction [9.1.2]

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.