Overview of the Proposed PV Quality Management System

Task Group 1 - Govind Ramu
SunPower Corporation, San Jose, CA
About the presenter

- Director of Global Quality Management Systems, SunPower Corporation
- Has over 25 years of experience implementing quality management systems in various global locations from various industry sectors
- US TAG TC 176/SC2 participating member for ISO 9001:2015 standards
- Expert on IEC TC 82 WG 2- Solar photovoltaic energy systems- Modules- non concentrating
- A licensed professional engineer in the province of Ontario, Canada, mechanical engineering degree from Bangalore University, India
- An ASQ Fellow, holds six ASQ certifications: quality manager, quality engineer, Six Sigma Black Belt, quality auditor, software quality engineer and reliability engineer
- Registered QMS ISO 9001:2008 principal auditor from IRCA (UK)
- Has coauthored ASQ’s Certified Six Sigma Green Belt Handbook, one of the major contributing authors for The Lean Certification Handbook
- Served as an examiner in 2006, 2011, and 2012 for the California Awards for Performance Excellence (CAPE) and as an Examiner for the Malcolm Baldrige National Quality Award in 2010
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What customer needs?

Quality Management System = Business Management System

Source: Unknown
ISO 9001 Quality Management System Requirements

- Covers general and foundational quality management requirements applicable to any industry or service sectors
- Most widely used standard. Over 1 million organizations worldwide are registered to this standard
- Hundreds of registration bodies worldwide are accredited to issue certification for client organizations
- ISO 9001 is now a contractual requirement for many organizations worldwide, often prerequisite for bidding new tenders

ISO 9001 is implemented in various industries, countries worldwide
ISO 9001 Myth

**Perception:** ISO 9001 certification does not help improve quality of products and services. Only helps with consistent product/services.

**Fact:** There are 16 instances in the ISO 9001: 2008 requirements that call out improvement of product/service, process, effectiveness.

**Why this perception?**
Back in 1990s consultants and quality practitioners summarized ISO 9001 implementation in a nutshell for simplicity as:
“Say what you do, Do what you say”.

In the year 2000, ISO 9001 was significantly updated to change this perception. Customer focus, Improvement and effectiveness became a common theme throughout the standard.

ISO 9001 is more than just consistent product/services.
PDCA Cycle* - ISO 9001 framework

ISO 9001 requirements follow PDCA improvement model.

*Also popularly known as Deming Wheel/Cycle
Types of System audits

- **First party audit:** Organization use the standard to verify compliance. Also known as Internal quality systems audit.
- **Second party audit:** Organization use the standard to verify compliance of their suppliers.
- **Third party audit:** An independent organization (registrar) verify compliance to the standard to issue ISO 9001 certificate for a client.
- An accreditation body audits the registrars to verify their ability to issue ISO 9001 certificates.

Audit verify compliance to standard, organization’s QMS, and its effectiveness.
Certification Process

- **Stage 1 audit** - Registrar auditors verify compliance to the standard as a desk audit and review overall QMS framework

- **Stage 2 audit** - Registrar auditors verify compliance to the standard by auditing processes covered in the scope of registration

- Once certificate is issued, registrars conduct periodic surveillance audit annually, conduct recertification audit every 3 years

Due diligence all the way
Highlights of QMS requirements for PV Module Manufacturing - Task group 1
Task group 1 Participants

Govind Ramu
SunPower

Paul Norum
Amonix

Yoshihito Eguchi
Japan Electrical Safety and Environment Technology Laboratories (JET)

Wei Zhou
Trina Solar

Alex Mikonowicz
Powermark

Ivan Sinicco
Tokyo Electron

Sumanth Lokanath
First Solar

Masaaki Yamamichi
National Institute of Advanced Industrial Science and Technology (AIST)

Gunnar Brueggemann
Tokyo Electron

Sarah Kurtz
National Renewable Energy Laboratory

Partial group of Task group 1 participants
Why Industry specific standard?

- ISO 9001 Guidance notes: The extent of the quality management system documentation can differ from one organization to another due to the size of the organization and type of activities, the complexity of processes and their interactions, and the competence of personnel.

- However, organizations that are superficially implementing the QMS can unfortunately get certified due to:
  - Generic nature of requirements, inappropriate use of “Exclusion” clause
  - Lack of in-depth review by external auditors, auditor competency
  - Organization’s ability to prepare ahead of audit
  - Impress auditors with pockets of good practices and compliance

- Supplementing Industry requirements on top of the foundational ISO 9001 requirements provides organization specific expectations relevant to the industry.

ISO 9001 alone may not be adequate to address industry specific requirements.
Industry specific QMS standards
Started from mid 1990s

- TS 16949- Automotive
- AS9100- Aerospace
- ISO 13485- Biomedical
- TL 9000- Telecommunication

Service sectors are also developing QMS standards to address specific requirements.

Some interesting standards currently under development:

- Guidelines for the application of ISO 9001:2008 in local government
- Requirements for the application of ISO 9001:2008 for electoral organizations at all levels of government

Other industry sectors are very successful in development and deployment of standards
Highly to strengthen the QM program used by the PV module manufacturer, conclusion was to adopt the two primary goals and form the five Task Groups. The International PV Module Quality Assurance Task Force was formed – 5 Task groups formed, Task Group 1 - Responsible for PV QMS. Task Group #1 began to write a PV-specific version of ISO 9001 supplementary requirements. National Committees of IEC TC82 WG2 as the New Work Item Proposal 82/800/NP.
9001 vs PV QMS

ISO 9001 QMS requirement

• Inputs relating to product requirements shall be determined and shall include functional and performance requirements
• The organization shall determine requirements specified by the customer, including the requirements for delivery and post-delivery activities (Warranty)

PV QMS Requirement

• Focus on the organization’s control of the PV module’s design to align the expected lifetime with its relationship to the organization’s warranty
• Controls:
  – Design FMEA
  – Reliability testing
  – Lessons learned
Design at the Source: 
Factor of 10 thumb rule

The cost of addressing reliability issues increases tenfold as you move through the development process.

Concept Phase
$x\times10$

Design Phase
$x\times100$

Development Phase
$x\times1000$

Manufacture Phase
$x\times10000$

Field Support Phase

"... and we can save 700 lira by not taking soil tests."
9001 Vs PV QMS

ISO 9001 QMS requirement
• Inputs relating to product requirements shall be determined and shall include applicable statutory and regulatory requirements

PV QMS Requirement
• A product realization that includes appropriate certification (e.g. IEC qualification, including both type approval and safety testing), a design lifetime that enables compliance with warranty, and recycling provisions

• Controls:
  – Internal/external qualification
  – Certification
  – Design FMEA/ Risk assessment
9001 Vs PV QMS

ISO 9001 QMS requirement
• Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.

PV QMS Requirement
• Requirement to improve product traceability through the entire supply and delivery chain to enact positive control of the product for recalls and warranty claims.
• Controls:
  – constituent key materials and components
  – lot/batch level
  – Traceable to supplier, date, Mfg. location
  – Traceable to Internal processes
  – Reworked/repai red products
9001 Vs PV QMS

**ISO 9001 QMS requirement**
• The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.
• This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

**PV QMS Requirement**
• An ongoing, periodic monitoring program to ensure consistency of aspects of manufacturing that may affect safety, performance, and reliability.
• **Controls:**
  – Reliability Monitoring Program (RMP)
9001 Vs PV QMS

ISO 9001 QMS requirement

• The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement

• The analysis of data shall provide information relating to conformity to product requirements

PV QMS Requirement

• Special processes such as control of solder connections

• Control of processes for ESD protection

• Assignment of PV module power rating with allowed tolerance including measurement uncertainty

• Controls:
  – Software validation
  – ESD Program effectiveness
  – determine parameter sets for the acceptance tolerance
  – Determine measurement uncertainty.
9001 Vs PV QMS

ISO 9001 QMS requirement
• The organization shall determine and provide the resources needed to enhance customer satisfaction by meeting customer requirements
• No requirement on Succession planning for key functions
• The organization shall determine and manage the work environment needed to achieve conformity to product requirements

PV QMS Requirement
• Resources needed to maintain the product warranty system, product reliability measurements, provision of after-sales service
• Succession planning for key functions that affect customer, quality reliability, safety and performance
• ESD- Electrostatic Discharge (ESD) safe environment at the raw material storage, processing, assembly areas, as appropriate
9001 Vs PV QMS

ISO 9001 QMS requirement

• Inputs relating to product requirements shall be determined. These inputs shall include where applicable, information derived from previous similar designs.

PV QMS Requirement

• Previous failure information incorporated into the requirements of the QMS

• Controls:
  – Failure information database management
  – Design Review
ISO 9001 QMS requirement

- The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established.
- The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

PV QMS Requirement

- A method for selection of vendors that can provide quality materials or products
- Receiving inspection and/or testing such as statistical sampling based on performance.
- Ensure that the supplier maintains product quality consistently, and will notify and seek approval when there is any change of products, process, manufacturing location or significant process excursion that may affect form, fit, function, reliability or performance.
- Controls:
  - Periodic supplier audits.
  - Performance monitoring.
  - Traceability requirements.
ISO 9001 QMS requirement

- The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process.
- The organization shall review the requirements related to the organization’s ability to meet the defined requirements.
- The organization shall plan under controlled conditions shall include the availability and use of monitoring and measuring equipment.

PV QMS Requirement

- Routine tests on 100% of product to ensure consistency of initial quality.
- Manufacturing feasibility at the necessary scale, including risk analysis.
- Control plan for solar simulators and how they are used in the performance rating of modules.

Controls:
- Process FMEA
- Control Plan
- Measurement System Analysis – uncertainty calculations
9001 Vs PV QMS- Product- Process- System audits

- Product Audit (PV QMS)
- Process Audit (PV QMS)
- System Audit (E.g. ISO 9001)
Cost of Poor Quality (COPQ)

Visible Costs
- Rework / Re-grade
- Yield
- Gross Margin Erosion
- Lost sales / opportunities
- Late delivery
- Expediting costs
- Excess inventory
- Long cycle times

Hidden Costs
- Lost Customer Loyalty
- Degraded Brand Image
- Excessive Material Orders/Planning
- Engineering change orders
- Reacks / Scrap
- Time value of money
- More Set-ups
- Working Capital allocations
- RMA

COPQ ranges 15-20% of total cost! Hidden costs can be up to 4 times the visible costs!
9001 Vs PV QMS

**ISO 9001 QMS requirement**
- The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system
- The organization shall apply suitable methods for monitoring of processes
- The organization shall continually improve the effectiveness of the quality management system through the use of analysis of data, corrective and preventive actions

**PV QMS Requirement**
- Use appropriate statistical tools and statistically significant sample sizes to make decisions that affect quality of process and products at all stages of the lifecycle
- Use of error proofing, Statistical process Control, control plan, Failure mode effects analysis, and 8 Discipline methodology to build PV modules with consistent quality and reliability
- Controls:
  - Process FMEA
  - Poke Yoke
  - Control Plan
  - SPC
  - 8D methodology
What is next in ISO 9001 (2015)?

- Standard becoming more generic to cater all industry types including service sector. Mandatory documentation requirements for some process go away (Even more so why we need PV Industry specific QMS!)

- Risk management-leveraged with leadership managing risks when making organizational decisions. (adding good foundation)

- Specific requirements for adopting the process approach*. (adding good foundation)

(Standard currently at the Committee draft stage. Draft standard expected by April 2014)
PV QMS future Possibilities (Brainstorm ideas)

- PV design, manufacturing and service metrics periodic submission to a vetted third party for analysis and publication of Best in class, top decile, median values (with anonymity - double blind process) for industry benchmarking
- PV QMS extended to suppliers of “key materials”
- PV QMS transition to PV IMS “Integrated Management system” to include Environmental, occupation health and safety requirements for PV manufacturing
- Graded approach to PV QMS audit outcome based on maturity levels. Audits go beyond compliance
- Exchange of epidemic failure information by PV technology
- Benchmark QMS practices with other well established industry sectors (e.g. Automotive, Telecom, Aerospace)
Appendix
References, Bibliography & Acknowledgements

- **References:**
  - ISO 9001:2008 Quality Management System requirements
  - 82/800/NP- Guideline for increased confidence in PV module design qualification and type approval

- **Bibliography:**
  - ISO 19011:2011 Guidelines for auditing management systems
  - Tip of the iceberg- Quality Progress article, May 2001

- **Acknowledgement:**
  - Ms. Sarah Kurtz, Reliability Group Manager, Principal Scientist, PhD, National Renewable Energy Laboratory, Golden, CO 80401
  - Task Group 1 International team members
  - SunPower Corporation, San Jose, CA USA Quality, Reliability & Management
BACK UP SLIDES
Nuggets in the ISO 9001 notes (Items gets pushed to notes during standards review)

- Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements.
- The extent of the quality management system documentation can differ from one organization to another due to the size of the organization and type of activities, the complexity of processes and their interactions, and the competence of personnel.
- Conformity to product requirements can be affected directly or indirectly by personnel performing any task.
- Design and development review, verification and validation have distinct purposes.
- Customer property can include intellectual property and personal data.
- Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.
- In some industry sectors, configuration management is a means by which identification and traceability are maintained.
*Process Approach

Systems / Processes

Inputs
- Supplier
- Machines
- People
- Material
- Environment

Outputs
- Product or Service
- End-user

Methods