Overview of the Proposed PV Quality Management System

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About the Presenter

- Director of Global Quality Management Systems, SunPower Corp.
- More than 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
  - 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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ISO 9001 Quality Management System Requirements

- More than 25 years of evolution since its inception in 1987.
- Covers general and foundational quality management requirements applicable to any industry or service sectors
- ISO 9001 is now a contractual requirement for many organizations worldwide, often prerequisite for bidding new tenders

ISO 9001 is implemented in over million organizations worldwide
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 quality systems.
- **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
Why Industry specific standard?

- Generic nature of ISO 9001 requirements
- Inconsistent use of “Exclusion” clause from ISO 9001 users
- No requirements to apply specific proven controls (FMEA, Control Plan, SPC, Mistake proofing, etc.)
- Requirements not addressing PV industry specific expectations

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.

Best Practices from industries:
- Telecom - Metrics submission and reporting (Double blind process)
- Supply Chain Practices in Aerospace
- Production Part Approval Process (PPAP) in Automotive.

Other industry sectors are very successful in development and deployment of standards
Highlighted the need 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.
PV QMS Key requirements

- PV module’s design to align the expected lifetime
- Product realization that includes appropriate certification, qualification, including both type approval and safety testing
- Product traceability through the entire supply and delivery chain
- Ongoing, periodic monitoring program to ensure consistency of aspects of manufacturing
- Special Process controls
- Power rating tolerance
- Resource Management
- Closed loop learning from field information
- Supplier Management
- Manufacturing and testing
- Process auditing
- Use Statistical methods, sampling
PV QMS Requirements

• 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
PV QMS – Power Rating

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

• Controls:
  – Determine parameter sets for the acceptance tolerance
  – Determine measurement uncertainty
PV QMS Requirements - Traceability

- 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, process conditions, equipment
- Traceable to operators (manual processes)
- Reworked/repai red products
PV QMS Requirement – Design controls

• 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, periodic testing, Long term outdoor testing, etc.
  – Lessons learned
  – Closed loop learning
Design at the Source: **Factor of 10 Thumb Rule**

The cost of addressing reliability issues increases tenfold as you move through the development process.
PV QMS Requirements - Certification

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

• Controls:
  – Design FMEA/ Risk assessment
  – Internal/external testing and qualification
  – Certification
  – Warranty modeling
  – Customer return FA
PV QMS Requirements - Reliability

• An ongoing, periodic monitoring program to ensure consistency of aspects of manufacturing that may affect safety, performance, and reliability

• Controls:
  – Control Plan
  – Statistically adequate sampling
  – Reliability Monitoring Program (RMP)
PV QMS – Special Processes

- Special processes such as control of solder connections
- Control of processes for ESD protection
- ESD- Electrostatic Discharge (ESD) safe environment at the raw material storage, processing, assembly areas, as appropriate
- Controls:
  - Process qualification, critical controls identification, operator qualifications
  - Software validation
  - ESD Program audit
PV QMS – Resource Management

- 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
- **Controls:**
  - Product warranty database management system
  - Technical support resources
  - Succession planning, periodic review
PV QMS Requirements

- Previous failure information incorporated into the requirements of the QMS
- **Controls:**
  - Failure information database management
  - Closed loop learning
  - Updated DFMEA, Design Review
PV QMS Requirements – manufacturing and testing

- 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 PVQMS- Product- Process- System Audits

System Audit (E.g. ISO 9001)

Process Audit (PV QMS)

Product Audit (PV QMS)
PV QMS

• 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 based thinking-leveraged with leadership managing risks when making organizational decisions. (adding good foundation)

- Knowledge Management (aligns with closed loop learning in PV QMS)

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

(Standard currently at draft stage. Standard expected by Sep 2015)
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Thank You

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Appendix
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” (Similar to PPAP from Automotive industry)

- PV QMS transition to PV IMS “Integrated Management system” to include Environmental, occupation health and safety requirements for PV manufacturing

- Graded approach to PVQMS 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)