PV QA Task Force 1

"Guideline for Integration of QA practices in the manufacturing process of PV Modules"

NREL 2/28/12

Observation

- The act of certifying a module or a module family is not meaningful unless it relates to the “Quality Systems requirements” and its ability to control the processes under which it is made so it is representative of the routine output.

Background

(the progress of “PV QA Guideline for Manufacturing Consistency”)

- In the “beginning” (after San Francisco)
  - “We stumbled in the wilderness for a while”
  - We accumulated samples and many suggestions of approaches to Quality systems, best practices, check lists, etc
  - PV QA Guideline for Manufacturing Consistency — (leader Ivan Sinicco) held on line meetings and created the four regions
- The Issue & the Survey
  - Issue = how to create Quality Systems / methods criteria that we all can ***harmoniously*** support
  - Ivan established a survey to gather opinions to determine how closely aligned the “group of *enthusiastic* volunteers” were.
  - Results showed that the key “ISO elements” were strongly supported.

The Issue & the Survey continued

- The clarity of the survey provided the direction to establish the "scope" of what we determined we would now focus on. The scales were "very important, neutral, not important, don't know" only the % of very important is shown here.
  - 1.42 Document Control 85.7%
  - 2.4.2.2 Quality Manual 85.7%
  - 3.4.2.3 Control of Documents 85.7%
  - 4.4.2.4 Control of Records 92.9%
  - 5.1.1 Management Commitment 84.6%
  - 2.5.2 Customer Focus 84.6%
  - 3.5.3 Quality Policy 84.6%
  - 4.5.4 Planning 69.1%
  - 5.5.5 Responsibility Authority & communication. 84.6%
  - 6.5.6 Management review 61.5%
  - 1.6.1 Provision of resources 30.8%
  - 2.6.2 Human Resources 14.3%
  - 4.7.3 Design & Development 83.3%
  - 5.7.4 Purchasing 50.0%
  - 6.7.5 Production & Service Provision 66.7%
  - 7.0 Control of monitoring 100.0%
  - 1.8.2 Monitoring & Measurement 100.0%
  - 2.8.3 Control of Nonconforming Product 92.9%
  - 3.8.4 Analysis of Data 85.7%

The Scope!

- *Design a guideline that could be used as base document for a new IEC standard or as a new ISO standard for PV. The guideline is focused on PV manufacturing processes and procedures aiming to insure manufacturing quality and the consistency of the produced photovoltaic modules to the warranties given by the producer. The ISO 9001-2008 standard is considered as starting point for drafting the guideline and an ISO-like structure must be reflected in the guideline.*
- *Each regional task group will focus initially on chapters 7 & 8 of the ISO9001-2008 standard.*

Where we are or “Progress to date”?

- Now that we have something “solid” to work on or from, we have begun to examine specific chapters that deal with the process of manufacturing in the ISO standard. Primarily chapters 6 & 7.
- In the following slides are our attempts at tracking and examples of the proposed changes to the standard that would primarily affect the Solar manufacturing activities.

ISO 9001:2000	PV Proposal	TS 16949:2000	DIS 13485	AS9100 Rev A
7.3.7 – Control of Design & Development Changes	Linda Merritt	Same as ISO	Same as ISO	• Adds customer and/or regulatory approval on changes
7.4 – Purchasing				
7.4.1 – Purchasing Process	**Paul Robusto**	**• Adds regulatory conformity •Adds Supplier Quality Management System development**	**• Requires a documented process**	**• Approved Supplier Control**
~~7.4.2 – Purchasing Information~~	~~Paul Robusto~~	~~Same as ISO~~	~~• Adds traceability requirement~~	~~• Adds more specific requirements including supplier notification of changes~~
7.4.3 – Verification of Purchased Product	Lisa Dwornik	• Specifies incoming product quality control and supplier monitoring	• Records of verification are required	• More stringent requirements for incoming quality control
7.5 – Production & Service Provision				
~~7.5.1 – Control of Production & Service Provision~~	~~Robin Kobren~~	~~• Requires control plans for all parts • Control plans are updated when changes occur • Adds PM & predictive maintenance~~	~~• Adds records keeping, sterile devices, cleanliness, installation & servicing~~	~~• Adds process control plans with in-process verification points • Control of production process changes & tools~~

* Summarized from Elsmar Cove Forum poster "howste" - posted on June 19, 2003

ISO 9001:2000	PV Proposal	TS 16949:2000	DIS 13485	AS9100 Rev A
~~7.2 – Customer-related Processes~~	~~Linda & Stacey – 1st Draft~~	–	–	
~~7.2.1 – Determination of requirements related to the product~~	~~Linda & Stacey – 1st Draft~~	~~• Adds notes for post-delivery, activities & compliance to environmental requirements~~ ~~• Customer-designed special characteristics~~	~~Same as ISO~~	~~Same as ISO~~
~~7.2.2 – Review of requirements related to the product~~	~~Linda & Stacey – 1st Draft~~	~~• Adds requirement of customer review to waive a formal review~~ ~~•Requires documentation of manufacturing feasibility in contract review~~	~~• Requires documentation~~	~~• Risks have to be evaluated~~
~~7.2.3 – Customer Communication~~	~~Linda & Stacey – 1st Draft~~	~~• Adds more specifics for ability to communicate via CAD & electronic data exchange~~	~~• Adds advisory notice~~	~~Same as ISO~~
7.3 – Design & Development		• Adds a note that it includes manufacturing process design & focuses on prevention rather than detection		
7.3.1 – Design & Development Planning	**Paul Norum**	**• Adds a multi-disciplinary approach**	**• Planning must be documented and updated**	**• Splits design into tasks and requires responsible people identified**

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~~7.3.2 – Design & Development Inputs~~	~~Paul Robusto~~	~~• Adds more specific design inputs including knowledge gained from previous design~~ ~~• Adds design of manufacturing process~~ ~~• Adds special characteristics~~	~~• Adds requirement for approval~~	~~Same as ISO~~
7.3.3 – Design & Development Outputs	Lisa Dwornik	• Adds design FMEA • Adds process FMEA for manufacturing process	• Requires records	• Requires Design Package
~~7.3.4 – Design & Development Review~~	~~Robin Kobren~~	~~• Requires monitoring with measurements at design stages~~	~~Same as ISO~~	~~• Introduces authorization to progress to the next stage~~
~~7.3.5 – Design & Development Verification~~	~~Paul Norum~~	~~Same as ISO~~	~~Same as ISO~~	~~• Adds note to specify possible methods of verification~~
7.3.6 – Design & Development Validation	Stacey Rassas	• Adds specifics of prototype program and approval process	• Validation must be completed before delivering product • Adds clinical evaluations	• Adds notes defining validation • Adds documentation requirement •Defines test plan

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8.3 – Control of Nonconforming Product	Stacey Rassas	• Adds reworked product • Customer waiver	• Only allows release of nonconforming product that meet regulatory requirements • Document rework procedure	• Customers must approve use-as-is or repair • Notification of nonconforming product
8.4 – Analysis of Data	Linda Merritt	• Trends in quality compared against goals	• Requires documented procedures and records	Same as ISO
8.5 – Improvement				
8.5.1 – Continual Improvement	**Robin Kobren**	**• Continual improvement of the organization** **• Reduction of manufacturing variation**	**• Advisory notes for medical devices** **• Records of customer complaints**	**Same as ISO**
~~8.5.2 – Corrective Action~~	~~Paul Robusto~~	~~• Requires process for problem solving~~ ~~• Error proofing~~ ~~• Rejects product test/analyzed~~	~~• Records~~	~~• Flow down corrective action to suppliers~~
8.5.3 – Preventive Action	Lisa Dwornik	Same as ISO	• Records • Review preventive action and it effectiveness	Same as ISO

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8 – Measuring, Analysis & Improvement				
8.1 – General	**Paul Norum**	**• Identification of statistical tools • Knowledge of basic statistical concepts**	**• Exchanges "maintain" for continually improvement**	**• Adds note on where statistics can be used.**
8.2 – Monitoring and Measurement				
8.2.1 – Customer Satisfaction	Paul Robusto	• Specifies measures for customer satisfaction	• Requires documentation of customer feedback system	Same as ISO
8.2.2 – Internal Audit	Lisa Dwornik	• Adds QMS, manufacturing process and product audits • Adds requirement for Internal Auditor qualification	Same as ISO	• Requires appropriate tools and techniques be developed for Internal Audits • Adds contract and/or regulatory audits
8.2.3 – Monitoring & Measurement of Processes	Robin Kobren	• Requires process capability studies • More detail on control plans • Requires out of control action plans	Same as ISO	• Specifies process for nonconformities
8.2.4 – Monitoring & Measurement of Product	Paul Norum	• Requires input inspection and functional testing • Adds requirements for appearance items	• Documentation required • Implantable devices	• Requires statistically valid sampling plans • Positive recall system • Inspection documents •First Article required

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Example of “Solar required updates”

- **7.4 Purchasing**
-
- **7.4.1 Purchasing process**
- The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
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- Materials, components, and sub-assemblies which have a safety implication on the finished product and which are purchased from or prepared by an outside supplier, require higher levels of control and shall be verified as complying with designated specifications.
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- The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements. Organizations. which must comply with technical specification, drawings, etc. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).
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- *Note: It is the responsibility of the organization to ensure that sub-assemblies and assemblies completed by subcontractors meet the quality plans and relevant safety requirements. To ensure this, subcontracted assembly and production services must meet all requirements of paragraph 7.4 purchasing and the subparagraphs that comprise it.*


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The issues

- Who wants what?
- Who will pay?
- Who will warrant the value, the performance


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