PCB Quality System Overview

An Overview of the Basic Requirements of our Quality Management System

Standards and Regulations that apply to PCB

- **AS9100** Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations – ***The basic foundation of the PCB Quality Management System***.

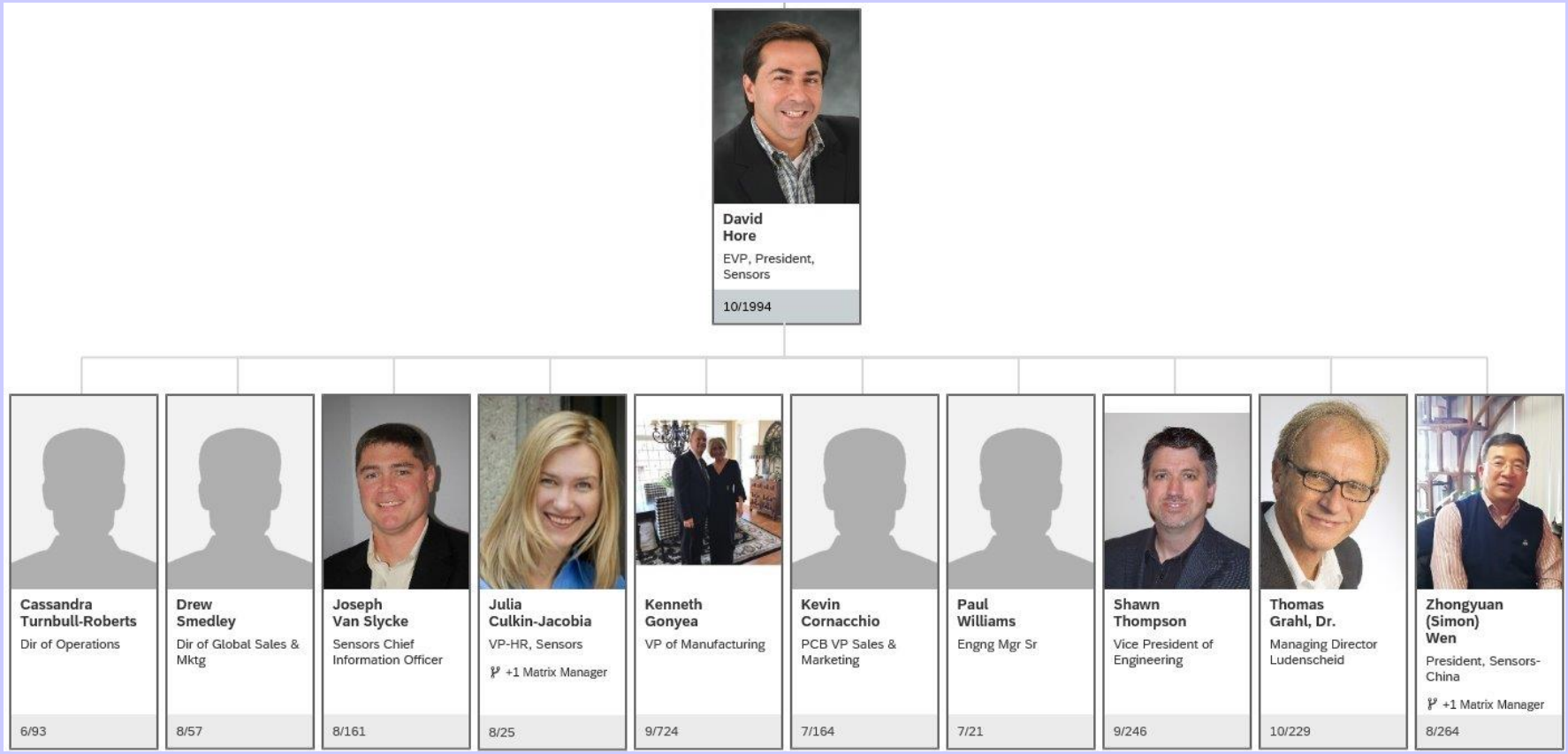
  What is AS9100? A Quality Management System standard designed to ensure a company consistently provides quality product for the aviation, space and defense industry.

  What is the purpose of AS9100? It outlines a set of requirements a company must adhere to and comply with in order to demonstrate its ability to meet customer requirements. Aims to enhance customer satisfaction through continual improvement of the quality system and the assurance of conformity to customer requirements.

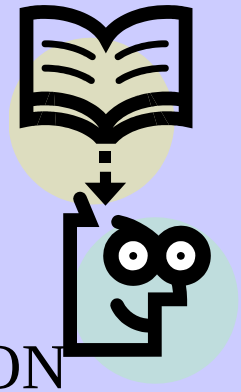
Standards and Regulations that apply to PCB (continued)

- **AS9100** Quality Systems Aerospace Model for Quality Assurance in Design, Development, Production, Installation and Servicing (Depew, NY and Halifax, NC locations).
- **ISO 9001** Quality Management System (Depew, NY; Halifax, NC; Provo, UT; Farmington Hills, MI; PCB Europe & Cary, NC locations)
- **ISO 17025** General requirements for the competence of testing and calibration laboratories (Depew, NY; Halifax, NC; Provo, UT; Farmington Hills, MI; & Cincinnati, OH)
- **ISO 10012** Measurement Management Systems – Requirements for measurement processes and measuring equipment
- **ANSI-Z540.3** General Requirements for Calibration Laboratories and Measuring and Test Equipment
- **IEC 80079-34** Application of a quality system for product intended for use in potentially explosive atmospheres.
- **10CFR21** Nuclear Regulatory Commission requirements for reporting defects and/or noncompliant delivered products which could create a possible safety hazard.

Senior Leadership Team



Everybody Must Know



Quality Policy

TOTAL CUSTOMER SATISFACTION

Mission Statement

"Helping You Make Better Measurements With Quality, Innovative Instruments."

Quality Management Representative

Depew Facility: Quality Assurance Manager - David Dulanski

Halifax Facility: Quality Manager - Brian Frys

Farmington Hills Facility: Quality Assurance Manager – Lance Pellens

Cary Facility: Quality Assurance Manager – Tim Stevens

Cincinnati Facility: Quality Assurance Manager – Lisa Moore

Provo Facility: Quality Assurance Manager – Thomi Barker

Quality System Documentation

1. **Quality System Manual (QSM) – Level I**: Provides an overview of the Quality Management System and conveys PCB's philosophy on Quality to our customer's.
2. **Quality Assurance Manual (QAM) – Level II**: Provides details of process operation and references level III supporting documents.
3. **Process Flow Charts** – Level III: Identifies the main business processes in PCB's quality system. Identifies roles, responsibilities and authorities within each process and links to other process flowcharts, User's Guides, and forms.
4. **User's Guides and Forms** – List specific tasks and requirements that are not able to be included in process flowcharts. *Process Procedures*
5. **Assembly Procedures** – define the build instructions necessary for product manufacture.

Document Control

QA01 Document & Data Control of TCS

QAM 7.5 Documented Information

Numbering Scheme

A two letter prefix denotes the department that initiated document.

CR – Crystals	**CS – Computer Services (IT)**	**DD- Drafting**
EA – Electronic Assembly	**EC – Electronic Calibration**	**EN – Engineering**
FA - Finance	**HC – Hermetic Connectors**	**IC – Inventory Control**
LC – Legal Compl.	**LG – Logistics**	**LT – Load & Torque**
MF – Micro Fabrication	**MS – Machine Shop**	**PD – Purchasing**
PE – Personnel (HR)	**PL – Planning**	**PS – Performance Spec**
QA – Quality Assurance	**QAM – Quality Assurance Manual**	**QC – Quality Control**
QSM – Quality Management System	**RA – Regulatory Affairs**	**SM – Sales & Marketing**
TA – Transducer Assembly	**TC – Transducer Calibration**	
AT – Acceptance Test	**IP – In Process (test)**	**OV – Output Verification (test)**

- **Process Flow Charts:** *QAM's follow ISO/AS*
  Contain 2 numbers after prefix.
  ex: QA01 Doc & Data Control of TCS, QA02 Management Responsibility.
- **Forms:**
  Contain 3 numbers after prefix.
  ex: DD002 ECO form, QA007 Extension Request, SM012 Quality Concern
- **User's Guides:** *Process Procedures*
  Contain 4 numbers after prefix.
  ex: QA1000 Document Administrators' User's Guide, QA1004 Auditors' User's Guide
- **Assembly Procedures**:
  1) Contain 4 number after prefix.
  ex: TA3115 ICP Strain Sensor Main Assembly
  2) 5 digit drawing number.
  ex: 32443 355M62+ Assembly Procedure

Document Control
(continued)

- **Document Administrators** – Control AS/TCS documentation: *Quality System Manual, Quality Assurance Manual Process Flowcharts, User's Guides and Forms*: QA002 Document Administrators List.
- **Engineering Change Order (ECO)** – Used for changes to drawings, specifications, BOM's, Assembly Procedures. Engineers and Drafting own process. DD02 ECO process map and DD002 ECO form.
- **Standards Library** – Contains copies of external documents such as specifications and standards. Example: ISO 9001, Military Standards and Specifications. Files are kept in the Quality Dept. List of standards in the library can be found at R:\Quality\Standards Library, Library Spreadsheet.
- **TCS Homepage** – http://mypcb/

Records Control

QA11 Records Control

QAM 7.5 Documented Information

A **Record** is:

a) A document that states results have been achieved.

b) Provides evidence of activities performed.

c) Demonstrates requirements have been met.

QA1041 Maintenance & Protection of Hardcopy Records

- Records must remain legible, readily identifiable and retrievable.
- Hardcopy Records must be stored in a suitable environment to protect and prevent damage or deterioration and in a manner to prevent loss.

Document Revision Index– Identifies where records are stored, how long they're kept and how they are dispositioned.

Records Control

QAM 7.5 Documented Information

QA1044 Records Control Policy

- When making a change to a record, a single-line cross-out is required along with one of the following four methods of employee identification.
  a) Printed name, and the date the cross-out was made,
  b) A controlled stamp that contains both the employee's number and initials, and the date the cross-out was made (e.g CTP),
  c) Any controlled stamp that is traceable to the employee (e.g. assigned stamps controlled through processes QA14 and MS02), and the date the cross-out was made.
  d) Employee number and also their initials, and the date the cross-out was made.

- No erasable (i.e.: pencil) or water soluble (i.e.: non-permanent marker) medium is allowed on records. Also, no white-out, correction tape, or similar cover-up material is allowed.

- Ink is the only acceptable form used to record evidence on a hardcopy record (preferably blue or black ink with the color red used for indicating a revision).

Management Responsibility

<u>Policy Deployment</u>
Primal Metrics

1. **Shipments - % of goal**
2. **Delivery to Promise** – on time delivery
3. **Quality at the Customer** – PPM (Parts Per Million): defective units returned
4. **Scrap & Rework** – % of Sales

Human Resources

QAM 7.2 – 7.4 Competence, Awareness & Communication

Training Committee

QA001 Training Committee members

Training Methods

1. On-The-Job
2. Instructor led/Classroom Training
3. Department Review
4. Self-training through LMS

- **All personnel must be aware of how their job functions contribute to achieving the organizations goals.**
- Department Supervisors are responsible for ensuring that all personnel in their department or group understand the quality policy, mission statement and how their job affects quality.

Nonconforming Material Control

TA01 Nonconforming Material Control – Manufacturing Center

Each manufacturing area must have an identified "Scrap" container.

WIP and Finished Goods:

- **Must be identified with a TA081 In-Process Nonconforming Material Report unless it is reworked immediately at the Technician's workstation.**

- **Nonconforming Product shall be segregated and placed into a location labeled: "Nonconforming Product Hold Area".**

TA081 In-Process Non-Conforming Material Report

PCB PIEZOTRONICS

TA081 In-Process Non-Conforming Material Report

Where applicable place a copy of the serialization/calibration sheet from the original job or print out a new TA098 serialization sheet.

SECTION 1: Description Of Nonconformance: (This section to be completed by Initiator.)

PART #:_____ QUANTITY:____ WORK ORDER/LOT/JOB #:_____

LAST OPERATION:_____ INITIATOR-Print Name:_____ DATE INITIATED:_____

REASON CODE:_____ SYMBOL / SERIAL #: _____

PROGRAM PRODUCT? ☐Yes /☐No (Code ENG5555-04)

ATEX PRODUCT? ☐Yes /☐No (Code ENG5555-02, -03)

ITAR PRODUCT? ☐Yes /☐No (Code ENG5555-05)

EXPORT CONTROLLED INFORMATION PART? (Code ENG5555-07) ☐Yes /☐No

DESCRIPTION OF NON-CONFORMANCE: _____

SECTION 2: Disposition:

☐Use "As Is" Print Name (Engineer): _____ Reason:_____

☐Rework/Salvage ☐Scrap ☐Re-grade/customer approved by concession (Copy of SM011 required to be stored with router).

☐Corrective Action required (use document QA020) Record Corrective Action Number:_____

Containment Decision:

☐Yes – Initiate MDR or MRR, verify all facilities per TA05 instructions.
If yes, confirm completed containment report filed @ R:\Quality\Containment Sheets.
☐ No containment required - record reason: _____

Material Disposition: (Department supervisor and/or engineer responsible for accurate completion of this section.)

QUANTITY:_____ NAME: (Print Name)_____ DATE:_____

Material Review Board Record: (For Program or ITAR or Export Controlled Information product only, the following four printed names are required per QA018.)
(For ATEX product, only obtain Printed Name of Engineering approval authority per EN048

Production _____ Quality Assurance _____

Sales _____ Engineering _____

SECTION 3:SCRAP ITEMS - DESTRUCTION INSTRUCTIONS: (Engineer to complete this section.)

For "Program" or "ITAR" or "Export Controlled Information" items, engineering to record instructions to render item unusable and unrecognizable:_____

Engineer: (Print Name): _____ DATE:_____

SECTION 3A: SCRAP DESTRUCTION VERIFICATION: (Shall be completed within 30 days of disposition decision – see section

2.) Scrap mutilation to render product unusable and unrecognizable has been verified as effectively completed:

Completed By: (Print Name)_____ DATE:_____

Nonconforming Material Control

TA02 Scrap Process – Manufacturing Center

- **Disposition and Disposition Authority (Section 2) must be recorded on the TA081**
- **Only a Supervisor, Manager or an Engineer can fill out Section 2.**
- **“Program” product that is scrapped must be rendered physically unusable (i.e.: crush in vise, cut in half).**
- **Scrap quantities are recorded in Syteline.**

Nonconforming Material Control

TA03 Rework Process – Manufacturing Center
QAM 8.7 Control of Nonconforming Outputs

- **Disposition and Disposition Authority must be recorded on the TA081(Section 2)**
- **Rework instructions are recorded on the TA081(Section 4)**
- **Section 4 can not be completed unless section 2 has been completed**
- **A copy of the original router, a rework router and, if applicable, the serialization sheet must accompany the TA081**
- **All rework product must be re-inspected and have evidence recorded on the TA081**

Nonconforming Material Control

QA06 Control of Supplied Nonconforming Material

- Purchased product found to be nonconforming is brought to the attention of the Quality Engineer so that an MRR can be generated.

Control of Nonconforming Product

Customer Nonconforming Product

Customer Returns

- Nonconforming material sold to a customer is returned using the RMA process (SM09).
- Products returned for potential quality issues (e.g. workmanship, design issues, etc.) are forwarded to Quality Assurance for a Failure Analysis. Quality related issues are documented in Syteline on the "PCB QC Customer CAR" form and assigned to the appropriate employee for preventive action.

Improvement

QAM 10 - Improvement

- **A Quality Concern <u>may</u> be generated in the event of a customer complaint or when a customer would normally complain** (dissatisfied customer, shipping problem, product warranty problem, order entry error, etc.)

- **A Quality Concern <u>must</u> be generated by any employee who becomes aware of a defect in a delivered product or service** (required by 10CFR21).

Control of Electrostatic Discharge (ESD)

- **Wrist and Foot Straps**

1. Wrist straps must be worn and plugged into grounds when in ESD control areas and working with product. Foot straps can be worn when wrist straps are not practical. Foot straps are not to be worn in the Machine Shop or outside of the building.
2. Wrist straps and foot straps are monitored twice daily and recorded on the Wrist and Heel Strap Log (TA079), unless plugged into a continuous monitoring station.

- **Work Stations**

1. Static generating materials must be kept off ESD work mats and benches (e.g. plastic bottles, boxes or bags, coffee cups and paper products and/or food wrappers of any kind).
2. Sweaters and jackets cannot be hung on the backs of workstation chairs.
3. Food is prohibited in any ESD designated area.

Control of Electrostatic Discharge (ESD)

- **Storage and Handling**

1. ESD sensitive parts are to be stored in ESD safe containers, (e.g. transport boxes with their covers installed correctly, Faraday cages) capped with protective connector covers or in ESD protected bags.
2. The ESD protection should only be removed at grounded workstations while using wrist straps.

Review

- **Quality Policy** – Total Customer Satisfaction
- **Mission Statement** – Helping you make better measurements with quality innovative instruments
- **ISO Management Representative**
- **Quality System** – Basis is **AS9100**, also ISO9001, ISO17025, ANSIZ540.3, ISO 10012 and IEC 80079-34.
- **4 Types of Documentation** – 1) Quality System Manual, 2) QAM's with Process Flowcharts, 3) User's Guide (Instructions) and Forms and 4) Assembly Procedures.
- **Document Control** – Document Administrators
- **Record –** Must be legible and accurate! Shows results achieved, activities performed, requirements have been met. Controlled by Document Revision Index.
- **Training** – Authorized Trainers, OJT, Formal Classroom setting, Outlook
- **Nonconforming product** – MDR, In-Process Nonconforming Material report, Quality Concern, MRR and CAR.
- **Quality Concern** – Must be used to report a defective product delivered to the customer and is our internal corrective action system.
- **Primal Metrics** – Shipments, On-time Delivery, Quality at the Customer and Scrap & Rework.
- **Know how your job affects Quality.**