

Special Process Validation and Control Methods

- I. Purpose: Define Special Processes at API Technologies including validation and control requirements.

- II. Scope: Processes where the resulting output cannot be verified by subsequent monitoring or measurement, these processes shall include the following as applicable:
 - a. Definition of criteria for review & approval of the processes
 - b. Determination of conditions to maintain approval
 - c. Approval of facilities and equipment
 - d. Qualification of operators
 - e. Use of specific methods and procedures to implement and monitor the processes
 - f. Requirements for documented information to be retained

- III. Required Information :
 - a. Internal
 - i. Method for review and monitoring of process
 - ii. Qualification of Operator
 - iii. Qualification of Facility, Equipment and Process
 - b. Supplier
 - i. Method for review and monitoring of process
 - ii. Qualification of Operator
 - iii. Qualification of Facility, Equipment and Process

- IV. Special Process Qualification:
 - a. API Technologies will define a qualification methodology for each special process, operator, facility and equipment.
 - b. For equipment in operation prior to the implementation of this document, operating instructions and prior historical preventative maintenance will constitute qualification for the equipment. The special process qualification may require additional testing (i.e. endurance, thermal shock, power handling, metallurgical analysis)
 - c. Any outside suppliers / contractors will not change special process parameters (including facility & equipment) without notification and approval of API Technologies.

Process	API Process	Supplier Process	Supplier Approval
Solder	X		In accordance with QMS060B
Weld	X	X	
Braze	X		
Paint	X	X	
Plating	X	X	
Potting	X		
Conformal Coat	X	X	
X-Ray Inspection	X	X	

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V. Approval of Process and Monitoring

API will define the monitoring criteria by special process. Examples of process and monitoring controls are listed below but are not limited to the following:

i. Material Controls:

1. Material Certificate of Conformance (C of C)
2. Raw material lot number for traceability
3. Key material properties (i.e. viscosity, hardness, cleanliness, purity, chemical composition, shelf life, expiration date)

ii. Process Controls:

1. Process documents and records (in accordance with defined procedure)
2. Process parameters in accordance with work instructions

iii. Equipment Controls:

1. Equipment asset number
2. Equipment calibration
3. Equipment preventive maintenance
4. Equipment settings in accordance with work instructions

iv. Test and Validation Records

1. Equipment asset number
2. Equipment calibration record
3. Process output data
4. Applicable qualification records for process and operator
5. Record retention per QMS 160A

v. Process control and monitor requirements *examples* as defined below:

Process	API Process Controls and Monitors [Examples]
Solder	Material controls for solder, flux / pull test
Weld	Equipment controls / weld coupon
Braze	Equipment controls / 1 st piece inspection
Paint	Material controls for paint, equipment controls / adhesion tape test, visual inspection to acceptance criteria and/or comparative paint sample to “gold” standard
Plating	Material controls for chemicals, bath temperatures, pH, equipment controls/ plating thickness, solderability
Potting	Material controls for potting compounds, equipment controls/ durometer, electrical test, visual inspection to acceptance criteria
Conformal Coat	Material controls for coating, visual inspection to acceptance criteria
X-Ray Inspection	Equipment controls / penetrometer evaluation

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- VI. Qualification of Operators
- a. API will provide verification protocols for training and validation of the operator qualification process
 - b. Operator qualification requirement *examples* are defined below:

Process	API Operator Qualification Test [examples]
Solder	Peer training/pull test/visual/SEM validation
Weld	Peer training, initial weld coupon - revalidation yearly – all alloys produced
Braze	Peer training, visual inspection
Paint	Adhesion tape test/ visual inspection to acceptance criteria and/or comparative paint sample to “gold” standard
Plating	Training Lot - Plating thickness, solderability
Potting	Peer training, Durometer, electrical test, visual
Conformal Coat	UV light, visual qualification to acceptance criteria
X-Ray	Peer training /Penetrometer evaluation

- VII. Supplier Requirements:
- a. Supplier to meet API requirements for special process monitoring and qualification in accordance with AT35-3027
 - b. Shipment validation, documentation, and data in accordance with purchase order clauses and requirements
 - c. Supplier may choose to do alternate qualification, guidelines including:
 - i. Operators are certified to Industry/Agency special process standards, or internal training programs
 - ii. Operator is qualified to API approved supplier program
 - iii. Process and Equipment are qualified
 - iv. A requalification process must be used if process is shut down for maintenance, move or out of tolerance conditions

VIII. Process Monitoring Details:

Location Key: FV = Fairview, SC = State College, MX = Mexico, ML = Marlborough
DE = Delmar, PH = Philadelphia

Welding (Tig) Process Monitoring SC

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	039-10094	KBM router
Asset Control	Model / Serial	SAM	SAM
Asset Location Control	Production Layout	Floor Plan	N/A
Calibration	Schedule	SAM	SAM
Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	Product requirement	039-10094	N/A
Process Check	Visual Weld Inspection	039-10094	KBM router

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Laser Weld Process Monitoring ML

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	IT 38-0184	KBM router
Asset Control	Model / Serial	SAM	SAM
Asset Location Control	Production Layout	Floor Plan	N/A
Calibration	Schedule	SAM	SAM
Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	Product requirement	Equip/Process doc	N/A
Process Check	Visual Weld Inspection	Equip/Process doc	KBM router

Brazing Process Monitoring SC

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	039-10119	KBM router
Asset Control	Model / Serial	SAM	SAM
Asset Location Control	Production Layout	Floor Plan	N/A
Calibration	Schedule	SAM	SAM
Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	Product requirement	039-10119	N/A
Process Check	Visual Braze Inspection	039-10119	KBM router

Soldering Process Monitoring FV, SC, ML

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	FV: QMS Doc's, MT's, SC: Purchase Specs	N/A
Shelf Life Control	Expiration date	FV: IT38-0184 SC: Doc's	KBM
Reflow Ovens	Model / Serial	SAM	SAM
Reflow Oven Calibration	Schedule	SAM	SAM
Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	Defined Recipe	FV: OMS Doc's, SC: WS Doc's	FV: SPC Charts SC: SMP Profile Form
Process Check	Solder Joint Visual Inspection	FV: OMS Doc's, Sales Dwg SC: WS Doc's	FV: BOM SC: Traveler

Special Process Validation and Control Methods

Painting Process Monitoring MX

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	QMS Doc's, MT's	KBM
Shelf Life Control	Expiration date	IT38-0184	KBM
Asset Control	Model / Serial	SAM	SAM
Asset Location Control	Production Layout	Floor Plan	N/A
Calibration	Schedule	SAM	SAM
Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	Equipment Doc	OT 34-0749	N/A
Process Check	Adhesion Test	IT 38-0546	34-1091 Logsheet

Plating Process Monitoring SC

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	Purchase Spec WS-56-0014	KBM
Shelf Life Control	Expiration date	Purchase Spec WS-56-0014	KBM
Pot Life Control (EN only)	Bath Life	Plating Analytical Doc WS-54-0061-2	Plating Logsheet
Plating Equip't Control	Model / Serial	SAM	SAM
Plating Equip't Location Control	Production Layout	Floor Plan	N/A
Calibration	Schedule	SAM	SAM
Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	Defined Conditions	Work Instructions	N/A
Process Check	Chemistry checks	Plating Analytical Doc WS-54-0061-2	Plating Log sheets
Process Check	Thickness coupons	XRF WS 31-0439	Traveler
Process Check	Solderability test	WS 55-0168-1	Traveler

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Potting Process Monitoring FV, SC

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	FV: QMS Doc's, MT's SC: Purchase Specs	N/A
Shelf Life Control	Expiration date	FV: IT38-0184 SC: Doc's	KBM
Potting Robots Control	Model / Serial	SAM	SAM
Cure Oven (where applicable) Calibration	Schedule	SAM	SAM
Potting Robots Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	Defined Recipes	FV: OMS Docs SC: Work Instruction	FV: BOM sign off SC: PN Cure Log
Process Check	Post cure visual inspection	FV: OMS Doc's, Sales Dwg SC: WS Doc's	FV: BOM SC: Traveler

Conformal Coating Process Monitoring FV

Attribute	Detail	Process Document	Record
Material Control	PN Traceability	FV: QMS Doc's, MT's	N/A
Shelf Life Control	Expiration date	FV: IT38-0184	KBM
Process Check	Viscosity Test	MT Docs, traveler	Log Sheet

➤ X-Ray Process Monitoring FV

Attribute	Detail	Process Document	Record
Asset Control	Model / Serial	SAM	SAM
Asset Location Control	Production Layout	Floor Plan	N/A
Calibration	Schedule	SAM	SAM
Preventative Maintenance	Schedule	SAM	SAM
Equipment Settings	X-Ray Imaging	➤ OT 34-0649, OT 34-0736	N/A
Process Check	X-Ray Penetrometer	IT 38-0004	Test Plan
Equipment Function	Radiation Badge	AT 35-2017	UKG

Special Process Validation and Control Methods

I. Operator / Process / Equipment Qualification:

Weld (Tig) Qualification SC

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen - initial weld coupon - revalidation yearly – all alloys produced /Optical or Metallurgical Inspection -	039-10094	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR

Weld (Laser) Qualification ML

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG/Historical training record	UKG
Operator / Process	Qualification Specimen- initial weld coupon - revalidation yearly/ Inspection	1 st Piece	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR

Brazing Qualification SC

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen/ Optical Inspection	1 st Piece	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR

Solder Process Qualification FV, SC, MX

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen (First Article unit)	Test Plan	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR

Painting Process Qualification MX

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen (Adhesion test)	IT 38-0615	N/A

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Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR
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Plating Process Qualification SC

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen	WS docs	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR

Potting Process Qualification FV

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen (First Article unit)	Test Plan	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR

Conformal Coat Process Qualification FV

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen (Black light unit)	Test Plan	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR

X-Ray Process Qualification FV

Attribute	Detail	Document	Record
Operator	Skills Training Record	UKG	UKG
Operator / Process	Qualification Specimen	Test Plan	N/A
Process / Equipment	Qualification Test Plan (for new processes)	N/A	EAR