

The Licensee's Responsibility for Process Validation

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Provide an understanding of how to review Process Validation Requirements whether addressed by:

- **API Specifications**
- **Industry Codes or Standards**
- **Licensee Requirements**

Establish a thought process by which to evaluate Processes Requiring Validation

- 1. Q1 / ISO 9001 Criteria Applying to Processes Requiring Validation**
- 2. Depth of Requirements**
- 3. Interaction of Codes & Standards with Product Specifications**
- 4. Processes Requiring Validation**
- 5. Codes & Standards**
- 6. Overview of Processes Requiring Validation**
- 7. Process Validation Where No Code or Standard is Specified**
- 8. Acceptable Practices to Document a Licensee's Vendor's Compliance with the Requirements**

Nondestructive Examination (NDE)

Process used to monitor and/or measure the result of production-related processes. (For the purpose of this presentation, it is considered to be a process that requires validation.)

Special Processes

Although some of the API Product Specifications still use the term “special processes”, for the purpose of this presentation, the term “Processes Requiring Validation” will apply.



Agenda Item 1

Q1 / ISO 9001 Criteria Applying to Processes Requiring Validation

Q1 - Clause 7.4.1.3

Supplier Provided Special Processes

“Where an organization chooses to outsource any special process, the organization shall require that the supplier comply with the requirements of 7.5.2, as applicable” (see 4.1).

ISO 9001 and Q1 Clause 4.1 General Requirements

“The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard”.

ISO 9001 and Q1 Clause 4.1 General Requirements

“The organization shall

- a) **Identify the processes needed** for the quality management system and their application throughout the organization (see 1.2),
- b) **Determine the sequence and interaction of these processes,**
- c) **Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,**
- d) Ensure the availability of resources and **information necessary to support the operation and monitoring of these processes,**
- e) **Monitor, measure and analyze these processes,** and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes”.

ISO 9001 and Q1 Clause 4.1 General Requirements

“These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.

Control of such outsourced processes shall be identified within the Quality Management System”.

ISO 9001 and Q1 Clause 7.5.2

Validation of Processes for Production and Service Provision

“The organization shall **validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement.** This includes **any processes where deficiencies become apparent only after the product is in use or the service has been delivered.**”

Validation shall demonstrate the ability of these processes to achieve planned results”.

ISO 9001 and Q1 Clause 7.5.2 Validation of Processes for Production and Service Provision

“The organization shall establish arrangements for these processes including, as applicable:

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel ,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation”.



Agenda Item 2

Depth of Requirements

The level of depth of requirements and/or implementation will greatly depend upon what quality management system and/or combination of systems the licensee has selected, for example:

- An API Product Specification License or Licenses (API Spec. Q1 is inherent) and/or,
- API Spec. Q1 / ISO TS 29001; and/or,
- ISO 9001

Depending upon the industry served by the Licensee, Quality Management System implementation **without** API Product Specification requirements will normally require less implementation. The level of implementation will depend upon:

- The licensee's level of understanding and sophistication
- The licensee's market place
- Whether or not the licensee's product is a regulated product

Quality management system implementation **with** API Product Specification requirements may or may not require more implementation. The level of implementation will depend upon:

- Whether or not the API Product Specification is silent regarding Processes Requiring Validation
- The complexity and/or criticality of the product

Some Product Specifications identify specific requirements for welding, NDE and heat treating, while others remain silent. Sometimes the requirements are identified as Product Specification text and sometimes the Product Specifications make reference to specific industry codes, standards, and/or specifications, for example:

2C Specification for Offshore Cranes

14.2 Welding Procedures

- “Pre-qualified procedures as defined in AWS D1.1 and AWS D14.3 are acceptable only for joining the materials using the consumables, joint configurations, and procedure limits specified therein”.
- “The welding of materials or use of procedures other than those defined by AWS specifications shall be qualified by testing a sample of the weld in accordance with a written procedure and tested in accordance with one of those standards listed in 14.1 above”.

4F Specification for Drilling and Well Servicing Structures

2.1.3 Equivalent Standards

- “Other nationally or internationally recognized standards may be used provided it can be shown that they **meet or exceed** the requirements of the reference standards herein”.

2.1.4 Standards References

- “AWS D1.1, Structural Welding Code”

5D Specification for Drill Pipe

1.4 Special Processes

- “Special Processes are the final operations which are performed during pipe manufacturing that affect attribute compliance required in this document (except chemistry and dimensions).

The applicable special processes are **heat treatment**, **nondestructive testing**, and if applicable, **cold finishing**”.

6A Specification Wellhead and Christmas Tree Equipment

2 Normative References

- “ASME Boiler and Pressure Vessel Code: 1998, Section IX, Welding and Brazing Qualifications”



Agenda Item 3

Interaction of Codes and Standards with Product Specifications

The level of implementation may be greatly affected depending upon how the information about Processes Requiring Validation is addressed in a product specification; for example:

- Normative references
- Informative references
- Equivalent standards
- Year, edition or addenda of code, standard or specification



Agenda Item 4

Processes Requiring Validation

Traditional Processes Requiring Validation

- Heat Treating
- Welding
- **NDE**

Processes Requiring Validation, Depending Upon Organization or Industry (examples)

- Soldering
- Coating
- Painting
- **NDE**



Agenda Item 5

Codes & Standards

Note: Where a product standard does not provide the specific requirements, Q1 will provide guidance

1. Typical Welding Codes:

- ASME Section IX, Welding and Brazing Qualifications
- AWS D1.1, Structural Welding Code

2. Typical Codes and Standards Used for NDE:

- ASNT-TC-1A, Recommended Practice, Personnel Qualification and Certification in Nondestructive Test
- AWS D1.1, Structural Welding Code
- ASTM E709, Magnetic Particle Examination
- ASTM E165, Liquid Penetrant Examination

2. Typical Codes and Standards Used for NDE:

- Radiography
 - i. ASTM E94, Standard Recommended Practice for Radiographic Testing
 - ii. ASTM E142, Standard Method for Controlling Quality of Radiographic Testing
 - iii. ASTM E747, Controlling Quality of Radiographic Testing Using Wire Pentameters
 - iv. ASTM E1032, Radiographic Examination of Welds
- ASME Section V, Nondestructive Examination



Agenda Item 6

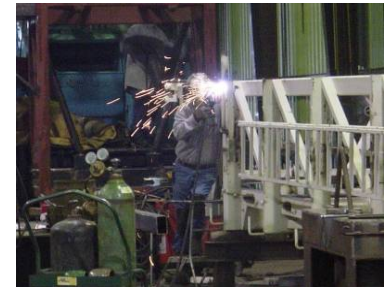
Overview of Processes Requiring Validation

1. Upsetting
2. Heat Treat – Quench, Temper, Stress Relieving
 - a. Batch
 - b. Continuous
3. Welding
 - a. GMAW – Gas Metal Arc Welding (Mig)
 - b. SMAW – Shielded Metal Arc Welding (Stick)
 - c. SAW – Submerged Arc Welding (Sub-Arc)



3. Welding

- d. TGAW – Tungsten Gas Arc Welding (Tig)
- e. FCAW – Flux Core Arc Welding (Flux Core)
- f. ERW – Electric Resistance Welding
- g. Friction Welding
- h. Brazing
- i. Hard Surfacing
- j. Hard Banding
- k. Soldering



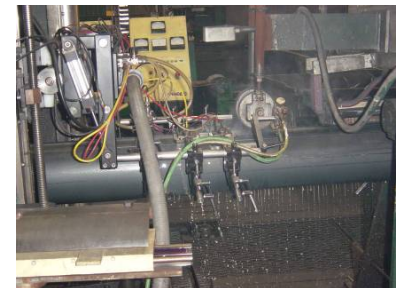
4. Cleaning & Coatings

- a. Blasting (e.g., grit, sand, beads)
- b. Painting
- c. Galvanizing
- d. Cadmium Plating
- e. Phosphating



5. NDE – Nondestructive Examination

- a. MT – Magnetic Testing
- b. PT – Liquid Penetrant Testing
- c. UT – Ultrasonic Testing
- d. RT – Radiographic Testing
- e. ET – Eddy Current Testing
- f. VT – Visual Testing





Agenda Item 7

Process Validation Where No Code or Standard is Specified

Consider the following:

- The process and appropriate equipment have been identified to meet the intended outcome for the product or product constituent(s) (7.1)
- Monitoring & measuring equipment have been identified and calibrated and the calibration is current (7.4)
- A sequence, operating parameters and acceptance criteria have been established for the process (7.5)
- Materials and consumables needed to perform the process have been identified (7.1)
- Materials and consumables have been verified by qualified personnel (7.4.3)
- Operator training specifically in the process has been performed or verified (6.2)

Consider the following:

- Subsequent verification of operator competence through inspection, test or other means (e.g., a hydrostatic test, bend test, etc.) has been performed (6.2)
- Inspections, tests or other methods have been established to confirm the process is operating as planned (8.2.4)
- Monitoring and measurement personnel training specifically in the methods used has been performed or verified (6.2)
- Subsequent verification of monitoring and measurement personnel competence has been performed (6.2)
- Records are generated to document all of the above (4.2.4)
- All of the above steps have been considered for revision or revisions have been made if any change of the intended product or product constituent outcome, process parameters and/or acceptance criteria has been made (7.1, 4.2.3)

Methodologies used for monitoring & measuring processes:

- Upsetting
 - a. Visual examination
 - b. Dimensional inspection
 - c. Mechanical testing

- Heat Treatment
 - a. Visual examination (e.g., straightness, warpage, cracking)
 - b. Mechanical testing (e.g., hardness, tensile testing, charpy impact testing)

- Welding
 - a. Visual examination
 - b. Dimensional inspection
 - c. Mechanical testing (e.g., bend test, tensile testing, charpy impact testing)
 - d. NDE (e.g., radiography)

Methodologies used for monitoring & measuring processes:

- Cleaning & Coatings
 - a. Visual examination of cleanliness
 - b. Anchor profile verification for blasting
 - c. Coating continuity checks (e.g., holiday testing)
 - d. Coating adherence tests (e.g., pull-off tester, adhesion tester)
 - e. Coating thickness measurement (e.g., dry film thickness gage)

Considerations for verifying NDE processes:

1. Personnel are “certified” to a known practice (e.g., ASNT-TC-1A)
 - a. For each NDE methodology
 - b. Levels of proficiency have been established (e.g., Level 1, II or III)
 - c. Proficiency is determined by examination and by a practical demonstration (for Level I and II) for a specified period of time)
 - d. Re-certification is performed
 - e. Level III (depending upon the year of the standard) may be:
 - i. Through national examination
 - ii. Through appointment

Considerations for verifying NDE processes:

- f. Criteria for eye examinations have been established, such as:
 - i. Near distance acuity (Jaeger J1 or J2) – at a 12 inch distance
 - ii. Color contrast determination – usually red/green

Considerations for verifying NDE processes:

2. Procedures are available:
 - a. The actual process has been “qualified”
 - b. Procedures are current
 - c. Procedures are signed by a Level III
3. Consumable “quality” levels have been established, for example:
 - a. Low sulfur and/or chloride content
4. Equipment have been calibrated
 - a. Use of known standards



Agenda Item 8

Acceptable Practices to Document a Licensee's Vendor's Compliance with the Requirements

Although ISO 9001 does not address a clause 7.4.1.3, has the Licensee demonstrated due diligence?

The criteria specified by Q1/ISO 9001 clause 7.5.2 **MUST** be demonstrated:

1. Vendor audit, if so:
 - a. A simple vendor questionnaire may be unacceptable
 - b. The audit must be performed by a qualified auditor
 - c. The audit checklist cannot be a generic ISO 9001/Q1 checklist, it must include specific information related to the information discussed herein

2. Maintenance of records is satisfactory providing they include:
 - a. Personnel qualifications
 - i. Welder
 - ii. NDE
 - b. A current eye examination for NDE personnel
 - c. Certificates of Calibration for equipment used to perform NDE, welding, etc.
 - d. Availability of the procedures used
 - e. Results of monitoring (acceptable or rejected) and approval thereof
 - f. Traceability to the procedure or code, standard or specification used, including revision level
 - g. Identification of the acceptance criteria

Final Thought:

Do not become complacent; the requirements for Processes Requiring Validation will change from licensee to licensee. No two will be the same.

THANK YOU



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