

# PRACTICAL FACT SHEET

ASD – 0108/1

Standard	EN 9100 : 2018		
§	8.5.1.3		

## Issue raised:

How to apply the requirements of § 8.5.1.3 "Production process verification" (1st article) in engineering companies?

## Answer:

### 1. First of all, a reminder:

EN 9100 :2010 stated :

*"The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).*

EN 9100 :2018 has kept the above requirement to the letter, with the exception of a non-impact word in a list of examples manufacturing processes instead of production processes.

On the other hand, we note that this unchanged requirement is now framed by 2 new requirements that give full meaning to the whole of this paragraph.

*"The organization shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.*

*NOTE These activities can include risk assessments, capacity studies, capability studies and control plans".*

*"The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are able to produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results (e. g., engineering changes, production process changes, tooling changes)".*

*NOTE This activity can be referred to as First Article Inspection (FAI)".*

*The organization shall retain documented information on the results of production process verification.*

### 2. How to apply the requirements of § 8.5.1.3 "Production process verification" (1st article) in engineering companies?

We propose to look at the 3 cases which seem to us to cover engineering activities:

**1st case:** when the "product or service" is the deliverable of the "design and development" process with reference to the EN9100 § 8.3 requirements:

→ In this case, § 8.5 may be declared not applicable.

**2nd case:** when the "product or service" is unique and is manufactured only once (non-recurring) by reference to the requirements EN9100 § 8.5:

- In this case, § 8.5.1.3 can be declared partially not applicable i.e. not applicable for the requirement "review first article", since this requirement to use an article representative of the first production only makes sense if there is going to be a second or even third production.

**3rd case:** when the "product" produced by the engineering company is an output of a production process and it will not be unique, § 8.5.1.3 is applicable and should meet the elements below:

- The organization shall demonstrate the existence of production process verification activities, e.g. a product or service realization process validated internally or by the customer (e.g. in the form of a Product Quality Assurance Plan, a work flow, a flow chart, a user manual, etc ...). This process of product or service realization must formally show the different steps of realization and verification of the product
- The organization must use a first conforming deliverable, made in "serial conditions" (\*), to carry out the above mentioned validation, internal or customer validation. This point is essential in order to confirm that the product realization process is capable.
- The organization shall maintain documented information on the results of production process audits .

This third case also covers the setting up of catalogs of contractual services (units of work) and service platforms that generate recurring products or services (chargeable to § 8.5 if the organization declares them not to be design activities § 8.3). Examples: calculations, plans, measurements/tests, etc. carried out periodically. There may also be production or test activities, carried out by engineering companies and in this case, in general, the ISP is the customer's ISP because it is under the customer's process and procedure.

(\*) means together with the Human, means, methods, environment, measures, materials used in the production after 1st item of the product

**Keyword(s):** process, validation, 1<sup>st</sup> article

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