

PRACTICAL FACT SHEET

ASD – 0105/3

Référentiel	ISO 9001 : 2015	ISO 14001 :2015	ISO 45001 :2018	EN9100 :2018
§				8.5.1.2

Issue raised:

How should chapter 8.5.1.2 "Validation and control of special processes" be addressed in a third party audit EN 9100: 2018?

Answer

Several elements are essential during the preparation of the audit and during its execution as described in § 8.5.1.2:

The list of special procedures defined by the body shall be provided for the preparation of the audit (see EN 9101:2018 - § 4.1.2.5 - Special procedures, 4.2.1b Audit planning; the special procedures present in the organization shall be mentioned in the audit plan.

Validation of special processes

The audit team must evaluate the validation of each process, as well as the measurement, monitoring and control of these processes. If these processes are qualified by external sources (Client, NADCAP...), the auditor may reference these elements in his report.

The documented process information must be reviewed for each special process audited; in particular the comparison between actual/counted results and the agreed arrangements (see 9100 paragraph 8.5.1). As a general rule, this part of the audit is carried out in the meeting room.

Surveillance of special processes ("shop floor" audit)

At the beginning of the audit or at the start of the special process audit, the audit team will select a sample of processes to be audited from those present in the organization. This list of audited processes should be transferred to the corresponding matrix or PEAR sheet.

The audit team must identify the process requirements, including customer requirements

For the selected process(es), the audit team must audit using the 5 M method:

- Follow-up of the skills of the operators / technicians implementing the special process (**Human**)
- monitoring of the environment required to implement the special process (**Environment**)
- monitoring of raw materials used in the implementation of the special process (**Materials**)
- the method(s) for implementing the special process (**Methods**)
- the monitoring and measuring equipments used (e.g. calibration, precision), monitoring of the means of production (**Equipment**)
- the method of recording results

If required by customers, traceability between the process (e.g. identification of the batch or its composition) and the resulting products must be verified.

Subcontracting of special processes

For special processes under treatment, the audit team must verify that the process of controlling the organization's external service providers addresses these points appropriately (§ 8.4). In addition, the audit team should review the use of customer-designated sources, if required (§ 8.4.1).

Note: Where an organization declares that special procedures are excluded from the scope of certification, the audit team should assess the rationale for this exclusion during the initial Stage 1 or other audit.

Keyword(s) : Special Processes, Production

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