

PRACTICAL FACT SHEET

ASD - 0102/1

Standard	ISO 9001 : 2015	ISO 14001 :2015	ISO 45001 :2018	EN9100 :2018
§				7.1.2

Issue raised:

How and to what does the "management of risks related to operational activities" in EN 9100: 2018 apply?

Answer

The EN 9100 standard in its 2018 version introduces requirements on the management of risks related to operational activities. These requirements are mainly cited in article 8 and in particular in chapter 8.1.1. This first point is important because it shows that this paragraph on risk management is now transverse in the entire realization of the product and/or service (Article 8).

It should be noted that ISO 9001: 2015, and therefore EN 9100: 2018 introduces another chapter on risk management (§ 6.1) relating to the identification of risks and opportunities in the face of internal and external challenges and stakeholder requirements.

Note 1 of § 8.1.1 of EN 9100 clearly defines the difference between these 2 chapters.

How does it apply?

EN 9100 answers this question by planning, implementing and CONTROLLING a risk management process. Of course, the term "process" does not mean that the representation of the process approach in the organization must necessarily show a risk management process. The term "process" in EN 9100: 2018 on this paragraph simply defines that a methodology must be found in the organization to deal with risk management (note that a documented procedure is not mandatory either), but respecting the following points :

- Assignment of responsibilities for managing risks related to operational activities
- Definition of risk criteria and level of acceptance
- Risk identification, assessment (not rating), and communication
- Identification, implementation and management of reduction actions for risks above the defined acceptance criteria
- Acceptance of residual risks after implementation of reduction actions

Mastering a risk management process means that it does not stop as long as the organization delivers products and/or services to its customers.

What does it apply to?

The management of risks related to operational activities is applicable to the products developed and/or manufactured by the organization, and by cause and effect to almost the entire organization (processes, procedures, registrations, training, etc ...). The purpose of these risk analyses remains focused on meeting customer and regulatory requirements as well as meeting delivery deadlines.

Risk management should be applied as a minimum:

- Project management (project within the organization) (§ 8.1)
- A review of product requirements (§ 8.2.2)
- The development of new products (§ 8.3)
- Possibly to the control of activity transfers (which can be managed in project management) (§ 8.1) - see practical rule n°101
- The purchasing process when selecting and using suppliers (§8.4)
- Production and control (§ 8.5 and 8.6)

Among the good practices observed, the realization of a complete or simplified FMEA (Failure Modes and Effects Analysis).

Concerning more specifically the management of risks at suppliers, the EN 9100: 2016 standard clearly indicates that this risk analysis must start when selecting a new supplier and be maintained throughout the contractual relationship with the latter. The risk analysis ends when the organization decides to reject the supplier and therefore no longer work with it.

Keyword(s): Risk management, establishment, implementation, maintenance, evaluation

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