## PRACTICAL FACT SHEET

ASD - 0109/0

Standards	ISO 9001: 2015	ISO 14001: 2015	45001: 2018	EN 9100: 2016
§	8.5.1	1	1	8.1.3

## Problème posé

What is meant by the term "product safety" in EN9100:2016?

In the Quality Management System, what are the devices to be considered in the framework of product safety?

## **Answer**

## Preamble:

The safety of people on board and overflown, the security of aircraft and airport facilities and the reduction of environmental damage are the 3 main strategic areas of regulations in the International Civil Aviation Organization (ICAO).

THE SAFETY CONCEPT (source ICAO - Guide doc 9859 edition 2006)

To understand what safety management is, it is necessary to look at what is meant by "safety".

- ». Depending on one's point of view, the concept of aviation security can take on different meanings, including:
  - a) zero accidents (or serious incidents), a point of view widely shared by travelers;
  - b) the absence of danger or risk, i.e. factors that cause or may cause damage;
  - c) the attitude of the staff when faced with dangerous acts and situations (reflecting a corporate culture that values safety);
  - d) the extent to which the risks inherent in aviation are "acceptable";
  - e) the hazard identification and risk management process;
  - f) the limitation of losses due to accidents (human losses, material losses and environmental damage).

It is desirable to eliminate accidents (and serious incidents) entirely, but a 100% safety rate is not an achievable goal. Despite all efforts to avoid failures and errors, they will always occur. No human activity or man-made system can be guaranteed to be absolutely safe, i.e. free of risk. The notion of safety is relative, the inherent risks being acceptable in a "safe" system.

Safety is increasingly viewed from a risk management perspective.



EN9100:2016 therefore leads as a definition to the management of product safety (3.4): "The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property".

EN9100:2016 requires "the organization shall plan, implement and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product".

Through the provisions implemented in the organization, they will be able to demonstrate their contribution to flight safety.

These provisions, in particular, must be found in the organization's Quality Management System, as well as:

- Consider product and personal safety in the requirements for products and services;
- Identification of special requirements associated with products and/or services;
- Hazard assessment and risk management of products and/or services (see 8.1.1);
- Management of obsolescence of materials, components, etc..;
- Identification of the risks related to the integration of the fortuitous and/or undesirable presence of foreign bodies in the product (Foreign Object Debris / Damage FOD);
- Awareness/training of people doing work under the control of the organization (including external providers) :
  - To the contribution to the conformity of the product or service;
  - To the contribution to the safety of the product;
  - The importance of ethical behaviour (see 7.3 and FP 110);
- Implementation of devices to prevent counterfeit coins (see 8.1.4);
- Implementation of actions to prevent human error (see 8.5.1 g);
- Treatment of root causes of nonconformities, including those related to human factors (see 10.2.1 b).
- Implementation of standard approaches:
  - Feedback; Lesson learned (see 7.1.6),
  - Monitors events that may affect safety via Civil Aviation regulatory bodies (ICAO, FAA, EASA, DGAC, OSAC etc.).

**Keyword(s):** Product safety; risk; hazard; human factors; error; awareness; FOD; product; service; nonconformity

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