PRACTICAL FACT SHEET

ASD - 0100/1

Standard	ISO 9001 : 2015	ISO 14001 :2015	ISO 45001 :2018	EN9100 :2018
§				3

Issue raised:

What is the link between Special Requirements - Critical Elements and Key Features?

Answer

First, let's recall the definitions of each item:

Special requirements

"Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process.

Factors used in the determination of special requirements include product or process complexity, past experience and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by the organization to be at the limit of its technical or process capabilities."

Critical items

"Those items (e. g., functions, parts, software, characteristics, processes) having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed.

Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc."

Key characteristics;

"An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation."

The principle adopted by the organization must be that:

1st step: The organization, in the study phase of a call for tenders, a contract, an order must carry out a review of the requirements relating to the product and services (§8.2.3). The input data for this review of customer requirements are contracts, orders, technical specifications, plans, technical and logistical specifications, system quality requirements, etc. .... The organization will thus list or at least determine all customer requirements. The formalization of this list can be done for example with the help of a conformity matrix, specifications, etc. The formalization of this list can be done, for example, with the help of a conformity matrix, specifications, a form or by creating a file. This review should be carried out in coordination with the relevant functions of the organization. If the body finds that customer requirements cannot be met (conformity matrix, clause by clause etc.) or can only be partially met, the body shall negotiate mutually acceptable requirements with the customer.

2nd step: The organization will be able to highlight 2 types of requirements:
"**Standard**" requirements, i.e. requirements known by the organization, falling within its core business, falling within the ranges of products manufactured, falling within the technology present in the organization, within its technical capacity and that of its processes, in short, without any particular difficulty in meeting them,
"**Special**" requirements, i.e. not or not well known to the organization, not part of the organization's day-to-day operations. Special requirements include, for example, client-imposed performance requirements that are at the limit of the organization's industrial capability, or requirements determined by the organization to be at the limit of its technical or process capabilities.

Step 3: The organization integrates the special requirements into its risk management process (application § 8.1.1). As these requirements are "special", they will by definition be assessed as critical output of the risk analysis, hence the term "critical elements". These will have to be the subject of improvement actions, when possible, to reduce the level of risk of non-conformity of the product with these special requirements. These critical items must also be monitored and controlled by setting up adequate control stations. In case the special requirements or critical items are related to a subcontracting operation, they must be deployed to external service providers who must prove their control (e.g. measurement readings, test reports, etc.).

4th step: When these critical items (or characteristics) can evolve over time, during production or operation (example: color index of a led) or a production process at the limit of capability, it is the notion of key characteristics.
Certain critical iyems (functions, parts, software, characteristics, processes) will not be listed as key characteristics because no variation of these will be able to appear (ex: dimensional dimension...).

What is important to remember about the notion of key characteristics is that they affect the product and/or processes on 6 points:

- clutter,
- interchangeability,
- function,
- performance,
- service life,
- deliverability.

The aim is that these must be controlled, monitored and recorded; the implementation of control cards or at least monitoring with recording is necessary to monitor the variation of key characteristics. In case these key characteristics relate to a subcontracting operation, they must be deployed to external service providers who must prove that they have mastered these characteristics (e.g. measurement readings, test reports, ...).
A key characteristic can also be associated with manufacturing process parameters, and not only a product characteristic.

In summary :

- Not all client or organization-specific requirements are necessarily "special".
- Not all special requirements will necessarily remain "critical elements".
- Not all critical elements are necessarily "key characteristics".
- All the key characteristics are necessarily "critical elements".

Keyword(s): Risk, criticality, variation, special requirements

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