

ISO 9001 - Design and Development:
Design Inputs (7.3.2)

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Many organizations struggle with understanding design inputs as specified by the ISO 9001:2008 standard in clause 7.3.2. As part of these requirements, the organization is required to ensure that *“inputs related to product requirements are identified and records maintained”*.

In order to clarify what design inputs are, we must understand that design and development is a process, which therefore requires us to first define what a process is. While there are a variety of different definitions related to this subject, one of the most illustrative definitions of a process is provided by Hammer & Champy (1993)[1]:

“a collection of activities that takes one or more kinds of input and creates an output that is of value to the customer.”

Personally, I like this definition of a process, as it’s simple, relatively straightforward and it usually minimizes the amount of further explanation required. While this definition is applicable to the ISO 9001:2008 standard in its entirety, when applied specifically to design and development, we can state that our design and development process (clause 7.3) is the manner in which we transform design inputs (clause 7.3.2) into design outputs (clause 7.3.3).

In clause 7.3.2, the ISO 9001:2008 standard identifies several types of design inputs that shall be determined by the organization, including:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Information derived from previous designs
- Other requirements essential for design and development

In some cases, particularly where design and development activities are performed on a made-to-order basis, the initial design inputs are established as part of an order provided by an external customer, specifying their needs and expectations. This order is reviewed as part of clause 7.2.2 of the ISO 9001:2008 standard (see Customer-related processes), and upon acceptance by the organization, the information provided becomes a primary, albeit not exclusive, source of design inputs for use by the organization.

Alternatively, design and development activities may be performed to create new products or to update existing products. In such cases, these activities are not initiated by an external order, but rather by a management directive or similar order of an internal nature, in order to meet an identified market, commercial or strategic needs identified by the organization. Similar to an order received from an external customer, such internal information also serves as a primary source of design inputs.

It is important to note here, that the list of design inputs specified in 7.3.2 is not all-inclusive; in fact, the fourth type of input identified by the standard is simply identified as “other requirements essential for

design and development". This is really a broad requirement for the organization to identify all other internal (organizational) and external (customer) inputs to ensure that all applicable needs, expectations and requirements are addressed. This could include, but would not be limited to, requirements specified by applicable codes, standards and specifications, supplier-provided information, competitive analysis, feedback from previous products, process performance data, etc., etc., etc.

Not only is the organization required to identify these inputs, it is also required to keep records relating to these inputs and to ensure that these inputs are formulated in a way that can be verified and validated. Inputs must also be reviewed by the organization prior to use, to ensure that the inputs are adequate and that there is sufficient information to carry out the assignment. Consideration must also be given to ensure that inputs are complete, unambiguous and not in conflict with each other.

**[1] Michael Hammer and James Champy (1993). Reengineering the Corporation: A Manifesto for Business Revolution, Harper Business*

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