ISO Design Control

in plain English

by **Mickey Jawa, CEO, SatiStar Management Consulting**

Every organization that designs products and/or services must implement the requirements of Design Control that are part of the ISO9001 standard. The problem is that most companies don't use the same language as ISO. This paper will help you to address this language barrier and understand what ISO Design Control is all about.

A surprising number of organizations struggle with their implementation of the Design Control requirements that are part of the ISO9001 standard. The ISO standard simply doesn't describe its requirements in your language.

ISO Standard Requirements

Section 7.3 of the ISO9001:2000 standard has 7 sub-sections that describe the various components of Design Control activities. Each of these clauses must be addressed in your Quality Management System.

7.3.1 Design and development planning
The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

This clause requires you to pre-define how you'll manage the overall design process for any given design project. Even in organizations that custom-design one-of-a-kind products the basic steps that are followed are standardized.

7.3.2 Design and development inputs
Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

This clause requires you to fully determine and document all of the various needs that must be fulfilled by the design, including those that are explicitly and implicitly stated. These needs include those of your customer, legal, industry associations, internal requirements, as well as requirements that you'd add based on your previous experience.

7.3.3 Design and development outputs
The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

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The usual outputs of a design activity include drawings, specifications and instructions on how to make or provide the product or service. This clause also adds the requirements to check that the design outputs will meet all of the inputs already documented, will enable the subsequent organizational activities to proceed easily (including Purchasing, Manufacturing, Quality Control, etc.), how you'll know that the product or service is acceptable, and finally any information required to ensure that the product or service is used safely and properly by the end user.

7.3.4 Design and development review
At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

This clause requires you to pre-determine when you'll conduct reviews of any design project to ensure that it stays on track. It also requires you to define who will be involved in these reviews and how you'll document the results of the reviews and any actions needed to address identified issues.

7.3.5 Design and development verification
Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be

You'll need to check to ensure that what you've designed matches all of the input requirements. In order to do this, you'll need to figure out and document:

- What you'll be checking
- How you'll check it
- How you'll know whether or not the results you find are acceptable
- What you'll do if they're not.

You can have multiple verification stages during the evolution of your design project, including:

- checking the design output against the design inputs
- checking that the prototypes are being made as per the drawings and specifications
- checking that the product is being made or installed as per the drawings and specifications

7.3.6 Design and development validation
Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

Validation is different from Verification.

- Verification answers the questions – "Did we make it right?" "Did we build it the way we intended?"
- Validation answers the questions – "Did we make the right thing?" "Does it meet the use for which it was intended?"

You'll also have to figure out and document:

- What you'll be checking
- How you'll check it
- How you'll know whether or not the results you find are acceptable
- What you'll do if they're not.

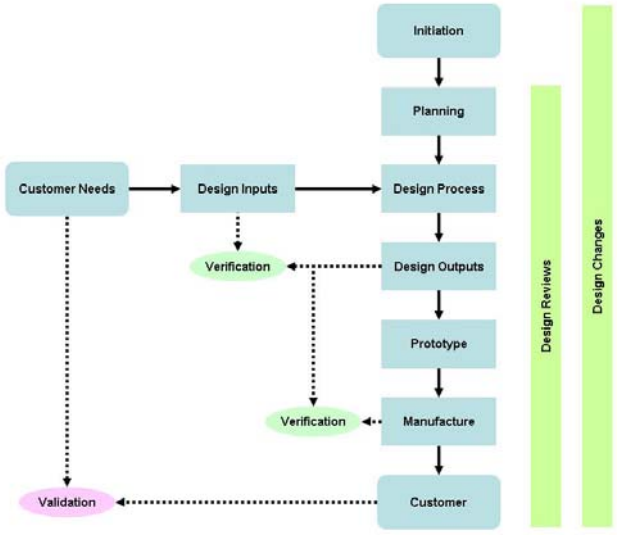
7.3.7 Control of design and development changes
Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

Despite our best effort at planning, stuff happens. This clause requires you to pre-define how you'll handle changes as they arise, including all of the requirements of Design Reviews, Verifications and Validation shown above. If you've already delivered a portion of the product or service, it also requires you to figure out and document what that means.

A Simple Conceptual Map

What the ISO9000 standard is missing is an overview of what Design Control entails. We have created a simple picture that is applicable to every type of organization that designs products and/or services.



This model depicts a typical design project from inception to completion.

An Example - Renovating Your Kitchen

Say you've decided to renovate the kitchen in your home. Let's see how the ISO9001 Design Control model applies:

- Project **Initiation** is basically a decision to go-ahead with the re-design of the kitchen – usually following a feasibility analysis that might include deciding whether or not this meets your budget and if this has made it to the top of your priority list.
- We then sit down and **Plan** out all of the phases of the project, including determining what, when, who, how, etc. It's at this stage that we decide that we're going to hire a professional kitchen designer and a general contractor to build it. We'll also need to establish how often we'll get together to **Review** overall progress.
- At this stage is usually when we figure out how we'll handle **Design Changes** that might originate from us, the designer, the contractor, the city inspector, etc.
- Now we determine and document the **Customer Needs** by asking them (you, your spouse, other family members).
- We then gather additional information from a variety of other sources (city and code requirements, contractor suggestions, supplier suggestions, kitchen design experts, magazines, library, etc.). This is added to our list of customer needs to create a detailed listing of all of the **Design Inputs** that must be met.
- Then the kitchen designer gets busy actually creating the design using their own **Design Process.**
- The **Design Outputs** of this stage are a set of conceptual and detailed drawings, specifications, material lists and prices, etc. These documents are **Verified** against the original list of Design Inputs and discrepancies are addressed. At this stage we also include the city permits department to verify the drawings and issue required permits.
- Our designer and contractor might even set up some mockups so that we can really get a feel for where we want the island installed. This would be the **Prototype** or Testing stage.
- Now they'll **Manufacture** our kitchen by assembling all of the components shown in the final design drawings and other documents. They'll **Verify** to ensure that what actually got built matches what was designed. The city inspector will also conduct his own verifications as needed at several stages of the manufacture.
- They're finally done, we take delivery and thoroughly check out our new kitchen. We're **Validating** that it meets all of our original needs.

Mickey Jawa is the CEO of SatiStar Management Consulting, and has over 25 years of experience in a wide range of industries. He has assisted companies worldwide in implementing Business Performance Improvement, especially in the area of cycle time reduction.

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