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ISO 9001 Auditing Practices Group *Guidance on:*

Design and Development Process

1. Introduction

The objective of auditing the design and development process is to determine whether it is managed and controlled to enable products and services to meet their intended use and specified requirements.

It is necessary to note that for service organizations, the approach to design and development may be different from “traditional” manufacturing organizations (see the ISO 9001 Auditing Practices Group guidance document on “Service Organizations”).

Before discussing in detail the way in which the design and development process should be audited it is vital for the auditor to understand what is meant by the phrase “Design and development”. By misunderstanding this concept, many organizations have wrongly excluded this process from their quality management system.

ISO 9001 clause 8.3 refers only to design and development of **products and services**. In some organizations it can be beneficial, but not required, to apply the same methodology to design and development of **processes**.

Product and service design and development is the set of processes for transforming requirements for the products and services (for example specifications, statutory requirements and specific or implied customer requirements) into specified product/ service characteristics (“distinguishing features of the product”). ISO 9000 Clause 3.10.1 gives the following examples of characteristics:

- physical (e.g. mechanical, electrical, chemical or biological characteristics);
- sensory (e.g. related to smell, touch, taste, sight, hearing);
- behavioural (e.g. courtesy, honesty, veracity);
- temporal (e.g. punctuality, reliability, availability, continuity);

- ergonomic (e.g. physiological characteristic, or related to human safety);
- functional (e.g. maximum speed of an aircraft).

In order for to determine if the organization is in fact involved in design and development, auditors need to establish who is responsible for defining the characteristics of the product or service, together with how and when this is carried out. This may apply to original design or ongoing design changes.

Generally, the design and development process consists of the stages shown in Figure 1 below. Each stage has specific deliverables that cover both the commercial and technical aspects of design and development of a product or service. In some cases, organisations might be able to justify the exclusion of certain sub-clauses or individual requirements from their QMS, without necessarily excluding the entire clause. For an organisation with a long established and well validated product/service design, for example, the organisation might only need to ensure that design changes are managed in accordance with the requirements of clause 8.3. Auditors should verify that any claims of non-applicability are valid (see ISO 9001 Auditing Practices Group paper on “scope”).

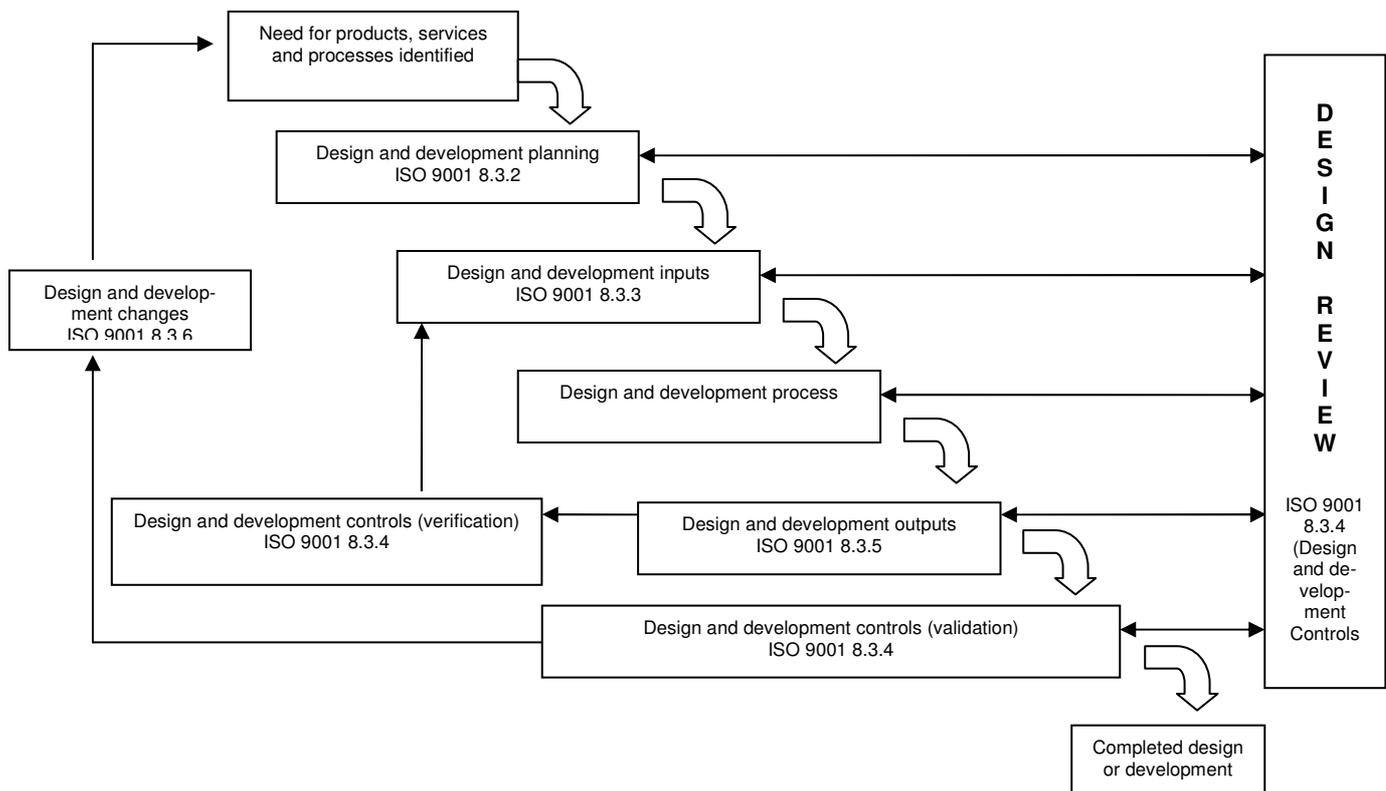


Figure 1 – Outline of the Design and Development Process

Auditors should establish what design and development projects have been, and are currently being, undertaken. Auditors should select a sufficient number of projects to be able to audit all stages of the design process.

Guidance for auditing the various stages of the design and development process is given below but it should be noted that it might not be possible to audit all stages for all the projects selected.

2. Auditing the need for design and development

The need for design and development comes from an organization's context and the application of risk based thinking. Auditors may also review that an organization has considered the following sources:

- customer requirements
- the organization's strategic intent;
- market intelligence and research;
- service reports;
- customer feedback;
- new or changed statutory and regulatory requirements;
- process changes;
- new technology;
- suppliers.

Auditors should evaluate whether the organization has in place, and performs, activities for the review of such needs. Auditors should review how the decision to proceed with design and development is taken, i.e. have risks and opportunities, including cost implications, been considered and have all relevant interested parties (internal or external) been consulted.

3. Auditing design and development planning

The following issues should be considered when auditing the planning function:

- what is the overall flow of the design planning process?
- how is it described?
- what resources and competencies are required?
- what part of the design will be outsourced?
- who is responsible and are the authorities defined?
- how are (internal and external) interfaces between various groups identified and managed?
- are the required verification, validation and review points defined?
- are the main milestones and timelines identified?
- is the implementation and effectiveness of the plan monitored?
- is the plan updated and communicated to all relevant functions as necessary?

4. Auditing design and development inputs

When auditing the design and development inputs, auditors should develop an understanding of how the organization identifies its own inputs based on:

- the organization's products, services and processes;
- financial, environmental, health and safety issues;
- the organization's risks and impacts;
- customer's requirements and expectations;
- statutory and regulatory requirements applicable to the product or service .

Auditors should evaluate the risks, the possible implications for customer satisfaction and issues that the organization may encounter if some relevant inputs are not considered.

5. Auditing design and development outputs

The design and development outputs should comply with the identified needs in order to ensure that the resulting product can fulfil its intended use. Outputs can include information relevant to the following:-

- marketing, sales and purchasing;
- production;
- quality assurance;
- information for service provision and maintenance of the product after delivery and, should be provided in a form that enables verification and validation activities to be performed.

Auditors should obtain evidence from the projects selected to confirm that:-

- information regarding the completion of design and development stages is available;
- the design and development process has been completed for the stage under review;
- design and development outputs have been confirmed

6. Auditing design and development controls

Design and development controls are aimed at providing assurance that the outputs of a design and development activities have met the input requirements for this activity, as outlined in Figure 2 below

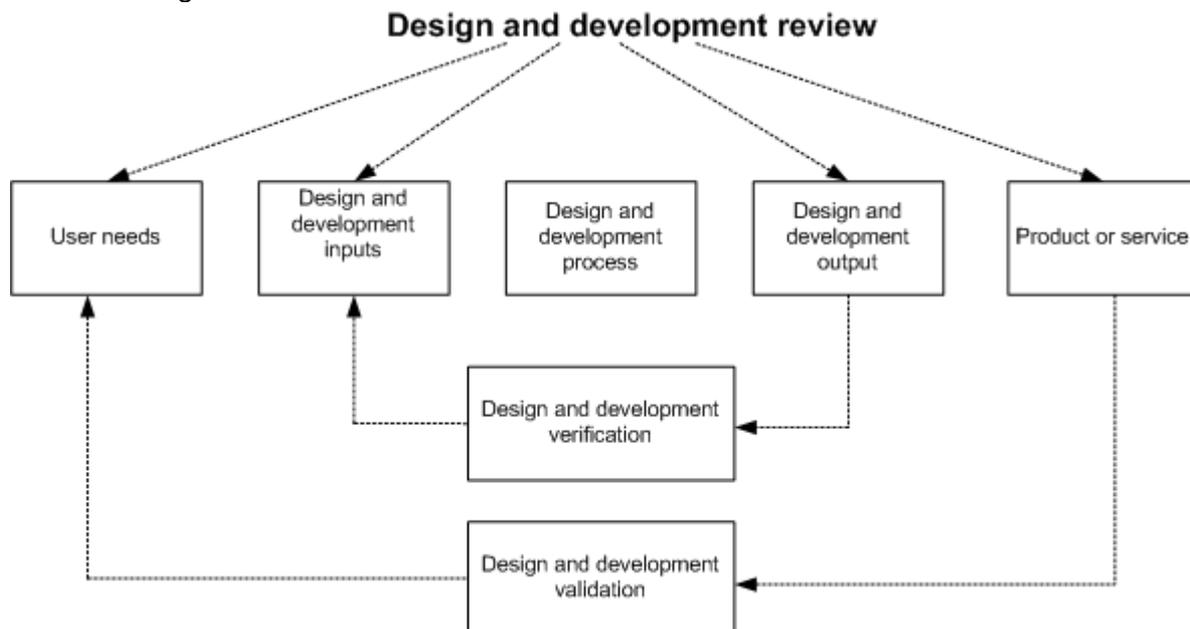


Figure 2

6.1. Auditing the design reviews

Auditors should verify that the overall design and development process is controlled in accordance with the organization's original plan, that it is being reviewed and that the design and development reviews take place at appropriate planned stages.

The following issues should be considered by auditors when examining the review process:

- do reviews occur at planned stages throughout the design process?
- are the reviews carried out in a systematic way involving representatives of the functions concerned with the stage(s) being reviewed?
- have all original and any new inputs been considered ?
- are the original outputs still relevant or have revised outputs been identified?
- have revised inputs and outputs been reviewed and approved by those with the relevant responsibility and authority (including the customer where appropriate)?
- does the output demonstrate the suitability, adequacy and effectiveness of the designed product or service?
- are the relevant design objectives being achieved?
- are there adequate records of reviews?

6.2. Auditing design and development verification

Design and development verification is aimed at providing assurance that the outputs of a design and development activity have met the input requirements for this activity.

Verification can comprise activities such as:

- performing alternative calculations;
- comparing a new design specification with a similar proven design specification;
- undertaking demonstrations including prototypes, simulations or tests; and,
- reviewing documents prior to issue.

Auditors should determine that the design and development verification activities should provide confidence that:

- required verifications are planned and that verification is performed as appropriate during the design and development process;
- the completed design or development is acceptable and the results are consistent with and traceable to the initial requirements;
- the completed design or development is the result of implementation of a proper sequence of events, inputs, outputs, interfaces, logic flow, allocation of timing, etc;
- the design or development provides safety, security, and compliance with other requirements and design inputs;
- evidence is available to demonstrate that the verification results and any further actions have been recorded and confirmed when actions are completed.

Auditors should determine that only verified design and development outputs have been submitted to the next stage, as appropriate.

6.3. Auditing design and development validation

Design and development validation is the confirmation by examination, and the provision of evidence, that the particular requirements for specific intended use are fulfilled. In other words, is the validation process capable of checking that the final product and/or service will meet, or does meet, the customer's needs when it is in use ?

Validation methods should be specified as part of the design and development planning process, although these could be modified during the realization of design and development.

For many products and services, validation is relatively simple process. An example could be a new design of office furniture, which could be validated by the testing of prototypes, followed by testing of initial samples of the finished product.

However, in many other situations, design validation will be more complex. For example, the products or components used in electric or electronic systems may have to comply with several performance requirements established by other system design organizations. In such a situation, design validation can only be completed by obtaining information about the performance of the products or components (preferably formal test results) from such system design organizations or by users of the products or components.

Another example of a difficult situation is when design validation is performed by the client or some other external organization (e.g. for the confirmation of architectural and engineering designs).

In such complex situations, the organization will need to seek agreement with the relevant external parties as to how design validation will be performed and the results communicated to and shared with it. In such a situation, provision should be incorporated into the organization's design and development planning for completing design validation in this manner.

Auditors should ensure that:

- there are records to confirm that the validations have been carried out;
- the validation was carried out in accordance with the planned arrangements for validation;
- the validation indicates that the resulting product or service is capable of meeting the requirements of the specification;
- wherever practical, the validation has been carried out prior to delivery or implementation; and that,
- there are records of any actions necessary to correct non-compliance with the design and development inputs and the reasons for these deviations.

Where validation cannot be carried out prior to delivery or implementation, auditors should ensure that these activities are carried out at the earliest opportunity, such as when commissioning a complex plant or factory, and that this is communicated to the client. Auditors should determine that only validated design and development outputs have been submitted for customer use.

7. Auditing design and development changes

Design and development changes made during the design process need to be controlled. Auditors should consider the following:

- are the sources and requests for changes properly identified and communicated?
- is the impact of any change evaluated?
- is any additional design proving or testing undertaken where appropriate?
- are the effects of the changes on products (or constituent parts) and services already delivered evaluated?

- has appropriate approval been given before a change is implemented (this could include statutory or regulatory approval or approval by the client)?
- are the changes fully documented and do records include information regarding any necessary additional actions?

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: *Introduction to the ISO 9001 Auditing Practices Group*

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsigroup.com.

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

www.iaf.nu
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