ISO 9001:2015 – BACK TO BASICS - DESIGN

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Principal Assessor - QMS

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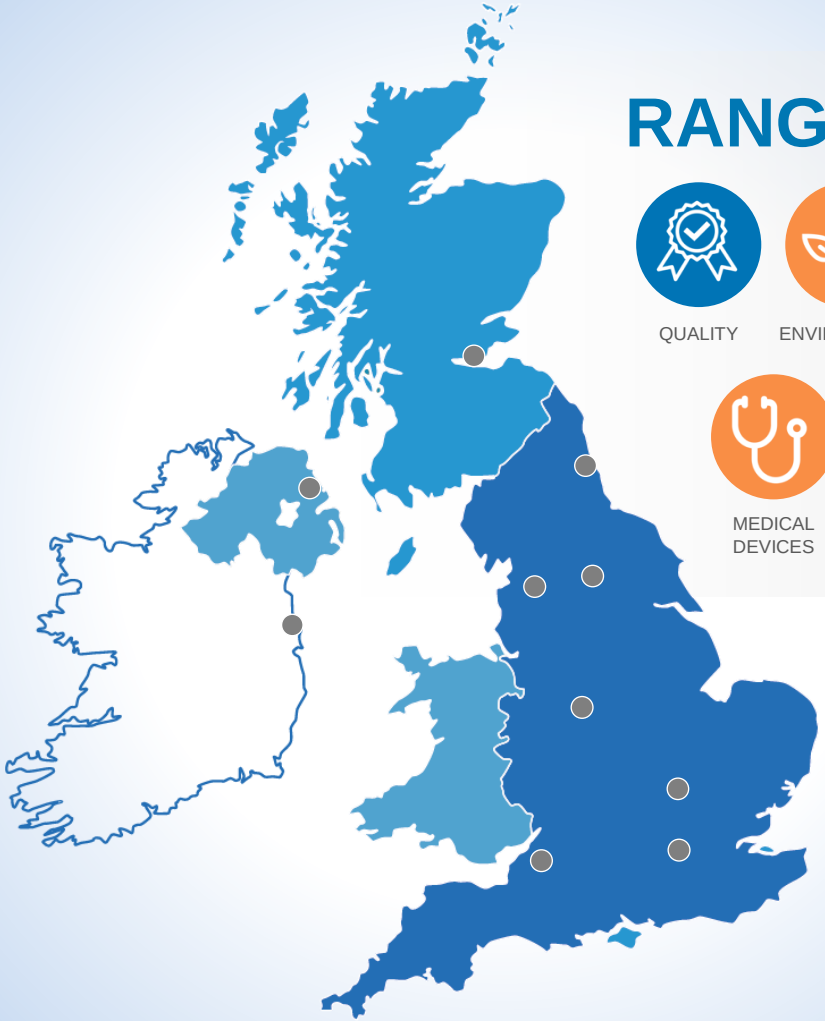

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YOUR PRESENTER

KEY INFO

- 60 minute webinar
- Questions in the chat box
- Q&A at the end
- Recording of webinar circulated shortly

Martin Graham

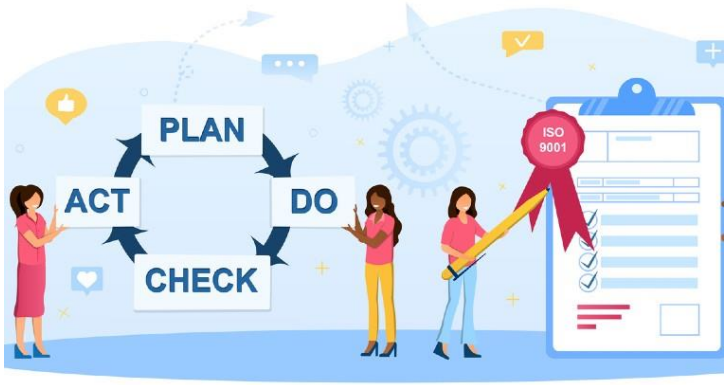
ISO 9001, ISO 14001, ISO 45001, ISO 50001, SSIP

NQA Principal Assessor for Quality

Martin is an experienced lead auditor, with 20 years' exposure to the certification industry covering sectors including retail, manufacturing and assembly, construction, engineering, testing, mechanical & electrical installations, transport logistics, communication, education and training providers. Having knowledge of managing each step of the certification process, he is well positioned to understand clients' needs and support them through the certification process.

WHAT WILL BE DISCUSSED?

- What is design?
- What is development?
- Why so confusing?
- Does design apply?
- Design stages
- ‘Service’ design



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WHAT IS DESIGN?

WHAT IS DESIGN?

The definition of design is "*a plan or drawing produced to show the look and function or workings of a building, garment, or other object before it is made.*"

Simply put into context; if the organisation are creating something; be it tangible (product) or intangible (service), there will almost certainly be an element of design and or development.

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WHAT IS DEVELOPMENT?

WHAT IS DEVELOPMENT?

The definition of development is '*the process of developing or being developed*'.

An organisation provides an existing product or service, but needs to make changes to enhance the performance or to meet a customer's specific requirements - this is development.

You may visit an organisation that has an established process but they have needed to tweak it to achieve a different, or better result...development.

The internal combustion engine has been designed, but continues to be developed.

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WHY SO CONFUSING?

WHY SO CONFUSING…STILL?

Let’s go back 7 years…

The previous version of ISO 9001 specifically permitted the “exclusion” of certain clauses (including design), if they were not related to the client’s Quality Management System (QMS) scope.

ISO 9001: 2015 does not include this provision.

Instead of allowing specific exclusions it uses a more inclusive approach to scoping within clause 4.3, which states that: -

WHY SO CONFUSING…STILL?

“The organisation shall determine the boundaries and applicability of the quality management system to establish its scope.”

and that: -

WHY SO CONFUSING…STILL?

“The organisation shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.”

WHY SO CONFUSING…STILL?

The standard refers to design but in a specific way -

Clause 8.3.1 states that "*The organisation shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.*"

('subsequent' is not underlined in the standard, but it is an important word)

This reference to the design of products and services is an important one.

WHY SO CONFUSING…STILL?

Often in the past design has been considered to refer only to product design and exclusions were claimed on this basis, however in many instances, organisations did (and do) in fact carry-out design of processes and services to ensure the subsequent provision of products and services.

WHY SO CONFUSING…STILL?

With this change of emphasis on design within an organisation's Quality Management System, a claim that an organisation is not involved in design in any way is now less likely.

Therefore, certification body auditors (and clients) should be mindful when considering the boundaries of a client's QMS, taking account the design of their processes and services as well as products, so as to ensure that the organisation's activities relating to such design are fully understood and compliant.

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DOES DESIGN APPLY?

DOES DESIGN APPLY?

The 2015 edition replaced the concept of exclusion with applicability. In theory and by principle all requirements are applicable.

This means an organisation may choose to consider the entire applicability of the standard and not presenting any justification for non-applicability.

DOES DESIGN APPLY?

If the organisation are conducting any of the activities mentioned previously; then they cannot justify the non-applicability of '*Design and development of products and services*' in their management system.

An example of when this might be possible would be if the organisation are providing a product or service that is well-established or its design is fixed and requires no further amendments or development or is simply no undertaken by the organisation (e.g. they are manufacturing to a defined specification)

DOES DESIGN APPLY?

Example: the exclusion of Clause 8.3 from a management system by a client - their justification is that they were “making the product fit the customer’s requirements”.

They were modifying the characteristics of the product to meet the customer’s requirements for their intended application.

Whilst the product itself never actually changed, they were taking an existing formula and changing the specification in order to meet the client’s requirement - sound familiar?

DOES DESIGN APPLY?

That is development. It is important to remember that all design and development starts with an ‘input’ (more on this below) and just because that input comes from an external source, it doesn’t mean that the organisation are not responsible for the control of the design and development of products and services process.

The long and short of it is that if the organisation “*uses resources to transform general input requirements for an object (tangible/intangible) into more detailed output requirements for the object*”, then they’re either designing or developing. (**Ref: ISO 9000:2015**)

DOES DESIGN APPLY?

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 organisations, the approach to design and development may be different from ‘traditional’ manufacturing organisations.

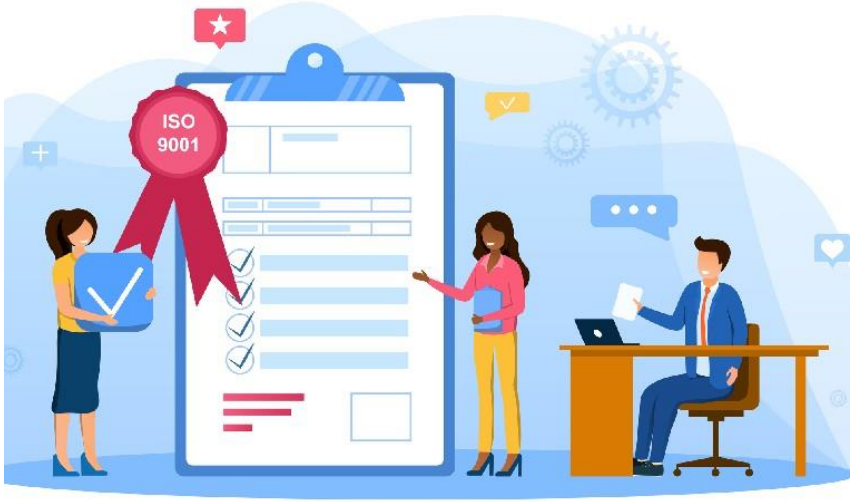
DOES DESIGN APPLY?

Before discussing in more detail the way in which the design and development process should be audited it is vital for the client and auditor to understand what is meant by the phrase ‘Design and development’.

By misunderstanding this concept, many organisations have wrongly excluded or claimed non-applicability of design from their quality management system.

DOES DESIGN APPLY?

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



DOES DESIGN APPLY?

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).

DOES DESIGN APPLY?

In order for to determine if the organisation 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.

DOES DESIGN APPLY?

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

DOES DESIGN APPLY?

A set of requirements or an entire clause cannot be considered non-applicable in the scope of the QMS (and the scope of the audit plan) only on the reason they are outsourced.

This occurs with some frequency with design and development, that may be totally or partially outsourced or made in collaboration with other organisations.

The organisation should ensure adequate and competent control over the outsourced activities or process and the auditor should not validate non-applicability of ISO 9001 Clause 8.3 requirements in this circumstance. Attention is drawn to the fact that not all requirements within 8.3 may be applicable

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DESIGN STAGES

DESIGN STAGES - PLANNING

Simply put, the organisation will have a plan on how they will do the design and development.

Good examples of this would be a design/development plan which demonstrates:

- ✓ The project timescales
- ✓ Deliverables
- ✓ Responsibilities of team/individuals
- ✓ Persons of authority for sign-off (internal, or external customer)
- ✓ Design reviews at relevant points in the project (e.g. start, confirmation of inputs, post verification, post validation, finish, etc.)
- ✓ Resources required throughout the project, communication with subsequent process owners
- ✓ Required controls throughout the project and intended use of the output.

DESIGN STAGES - INPUTS

There are many potential inputs to the process:

- Have the organisation confirmed the requirements from the customer (what do they want to achieve and what are their needs & expectations) and considered parameters & constraints? (e.g. materials, dimensions, functionality, life cycle, sustainability, etc.),
- Have statutory and regulatory requirements or codes of practice been considered (product and safety directives, building regulations, CDM, ACoPs, etc?
- Availability of information from previous designs (review of learnings - good/bad/potential improvements, etc.) which provide priceless data and knowledge to mitigate the risk and consequence of failure.

DESIGN STAGES - CONTROLS

A critical step in the process:

1) Has the organisation determined how results to be achieved are defined?

2) I.e., what are the project deliverables, how will they be achieved and how will they be measured (acceptance criteria)?

3) Have reviews been conducted throughout the project as mentioned above at relevant points in order to meet the input requirements?

DESIGN STAGES - 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.

Has the product/service as designed/developed as intended in relation to the input requirements, this can be reviewed through different types of testing (e.g. prototype, proof, demonstration, inspection, analysis or acceptance).

DESIGN STAGES - 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?

Has the product/service been designed/developed that it fulfils the requirements of its intended use, most likely reviewed once the deliverables have been achieved. For example: testing under operating conditions, in order validate that the product/service meets the customer's requirements and covers all outputs, including potential risks of use. Conducting reviews post verification and validation in order to iron out any potential issues - these are all critical requirements of design and development controls and must be documented in some form.

DESIGN STAGES - VALIDATION

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.

DESIGN STAGES - OUTPUTS

Has the organisation met the input requirements (achieved the intended results), can they move forward in the project using the outputs, have they confirmed any necessary equipment for measuring and/or testing and the acceptance criteria?

Typical examples of such outputs include:

- Conceptual designs
- Technical/engineering drawings
- Product specifications
- Manufacturing instructions
- Bill of materials
- Information for purchasing and other subsequent processes.

DESIGN STAGES - CHANGES

Have the organisation established a formal process for controlling design and development changes; throughout the project and during reviews, how have changes been documented, the results of design and development reviews communicated.

How are changes authorised (think about the persons of authority, as above), how can most up-to date revisions be identified and mitigate the risk of using superseded versions?

Examples of this include:

- Version/revision/authorisation control on drawings
- A design/drawing register
- Engineering change notes, etc

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SERVICE DESIGN

SERVICE DESIGN

- An organisation may not design a product
- But they may design a service
- Design will then apply

SERVICE DESIGN

According to ISO 9000 a Service is the output of an organisation with at least one activity necessarily performed between the organisation and the customer.

The provision of a service can involve, for example, the following:

- An activity performed on a customer-supplied tangible product (e.g. a car to be repaired);
- An activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
- The delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- The creation of ambience for the customer (e.g. in hotels and restaurants)

SERVICE DESIGN

Most organisations also have an element of service in their products.

This may range from almost 100% service (in the case of a law firm, for example), to a relatively small service component in the case of a manufacturing organisation providing, for example, an after-sales service.

SERVICE DESIGN

ISO 9001 requires: "*the organisation shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services*".

'Exclusions' of the requirements of ISO 9001 are no longer possible; however, organisations might determine that these requirements are not applicable in the scope of their management system.

For determining their applicability, an organisation will have to ensure that the requirements on design and development do not affect its ability or responsibility to **ensure the conformity of its services and the enhancement of customer satisfaction**.

SERVICE DESIGN

When an organisation makes a claim for non-applicability of this requirement, auditors need to see documented objective evidence that the following two conditions are both fulfilled:

1) The requirement cannot be applied
2) By not applying the requirement there is no effect on the organisation's ability or responsibility to ensure the conformity of its services and the enhancement of customer satisfaction.

Only if these can be proven, should an auditor accept the non-applicability.

SERVICE DESIGN

It is quite common for organisations to consider primarily their products when addressing the requirements for Design and Development. The design and development of a service often is not carried out in technical ‘design departments’ but under a title such as ‘Business model development’; however, the relevant requirements still apply. Auditors should identify carefully the organisation’s unit in which the design and development of services is carried out.

The auditor should also examine whether the organisation has an effective design and development process that sufficiently defines the characteristics of its service, and of its service delivery processes, that are needed to meet customer needs and expectations.

SERVICE DESIGN

The requirements of ISO 9001 apply to the design and development of products and services.

It is not mandatory to apply these requirements to the design and development of the processes involved in the provision of such products or services.

The organisation may decide to extend the applicability of this requirement to the design and development of processes.

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Q&A

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TAKE THE NEXT STEP

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THANK YOU

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