7.3 Design and development

### 7.3.1 Planning

* Determine all necessary design and development phases
* Determine the appropriate design review, verification and validation techniques
* Determine who has responsibility for design and development
* Determine the necessary authorities for design and development
* Maintain records

### 7.3.2 Input

* Determine functional and performance related characteristics
* Determine relevant statutory and regulatory requirements
* Determine relevant information from previous designs
* Determine other requirements that are essential to the product
* Maintain records

NB this relates to 7.2 Customer-related processes.

### 7.3.3 Output

The outputs must reconcile with the inputs:

* Determine whether the outputs meet the input requirements for design and development
* Determine whether the outputs provide suitable information for purchasing
* Ensure the outputs provide reference to product acceptance criteria
* Determine whether the outputs accurately specify essential characteristics
* Maintain records

The final drawing or specification should meet the input requirements. The outputs would also normally be used as the basis for purchasing and process control.

### 7.3.4 Review

At key stages of development the design should be reviewed to ensure that the inputs are met, and any technical problems identified and resolved.

* Determine whether the results conform to the specified requirements
* Identify any gaps in the design
* Propose and implement solutions to close gaps in the design
* Maintain records

### 7.3.5 Verification

* Determine whether the outputs meet the input requirements for the design
* Maintain records

### 7.3.6 Validation

* Ensure the product meets the specified requirements
* Undertake prototype testing
* Maintain records

### 7.3.7 Changes

Consider the impact of proposed changes, especially in terms of backwards compatibility and ensure control over design and development changes.

Design changes must be:

* Identified
* Recorded
* Reviewed
* Verified
* Validated
* Approved

Any design changes must be fed back through the entire design and development process, e.g. from 7.3.1 all the way through to 7.3.6, since any changes will impact these requirements.

### Exclusions

Some organisations do not undertake design and development activities.

If this is the case, you may exclude 7.3 from your quality management system so long as the excluded requirements do not:

* Affect the ability of the organisation to meet customer and regulatory requirements
* Affect the ability of the organisation to provide conforming products or services

### Should I document our design & development process?

It is not a mandatory requirement to document your design and development process. However, you should always look to adequately define and control any operational processes that directly impact upon product quality. Therefore, the implementation of a design and development procedure will be appropriate to most businesses where such activities are undertaken.

### How's best to document the design & development process?

Developing and implement a procedure for 7.3 that defines:

* The overall flow of design and planning activities
* The required responsibilities and authorities
* The criteria for design verification and validation
* Any design and development interfaces
* How design changes are controlled

### Measuring design & development effectiveness

This might be determined by ascertaining the level of control the organisation exerts over the process and whether information flows efficiently between each design and development phase.