

1.2 Scope - Application

<p>The requirements of the international standard ISO9001-2008 are generic in order that they may be applied to all organisations, irrespective of their nature, size or product provided. Consequently, where the requirements of the standard are not applicable to the organisation and cannot therefore be applied, they may be considered for exclusion.</p> <p>Claims of conformity with the international standard ISO9001-2008, may only be made when all exclusions are limited to the requirements of Clause 7 of the standard. In addition, the exclusions shall not affect the organisation's ability or responsibility to provide products or services that comply with the customer's requirements and any statutory, legal or regulatory requirements.</p>	<p>INFORMATION REQUIRED</p> <p>Careful consideration is required in order to determine whether the Design clauses may be excluded. You should read the requirements of the standard and seek advice before making a decision. In many cases where an organisation considers that they are responsible for design, they may in fact not be required to include these clauses. For example, an irrigation installation company that 'designs' the layout of the pipes and determines the appropriate valves and pumps to meet the requirements of the system, may well be able to claim exemption. If, on the other hand, the company has designed and developed a device to detect and control water pressure variations in the system and offers this for sale, then it may be argued that they must comply with the requirements of clause 7.</p>
<p style="text-align: center;">EXAMPLE</p> <p>The organisation has no permissible exclusions as they apply to the organisation or its products under the requirements of the international standard ISO9001-2008.</p> <p>OR</p> <p>The organisation, due to the nature of the organisation and its products, has excluded section 7.3 Design and Development from the applicable requirements of the ISO9001 2008 standard. This exclusion does not affect the organisation's ability or responsibility to provide products or services that comply with the customer's requirements and any statutory, legal or regulatory requirements</p>	<p style="text-align: center;">YOUR INPUT</p>

7.3.5 Design and development verification

<p>The Standard requires.....</p> <p>evidence of procedures used to verify that the design and development outputs have met the design and development input requirements.</p>	<p>INFORMATION REQUIRED</p> <p>Your procedures.</p>
<p>EXAMPLE</p> <p>Reviews to verify that the design and development outputs have met the design and development input requirements are carried out by top management. The timing and frequency of the reviews may be determined by the Quality Manager or person in charge of the design project, at the start of the project or when necessary.</p> <p>Participants in the review process shall include top management, representatives from Sales, Finance, Operations and all functions that are associated with the design and development project.</p> <p>Each review is fully documented in the form of a report, citing the methodology and terms of reference used and any supporting data that was used in the review process, such as material specifications, test data, etc. The report may include details of any potential or actual problems that were identified proposed corrective action and the timing for this. The documentation is stored in accordance with the procedure 4.2.4 - Control of records</p>	<p>YOUR INPUT</p>

8.4 Analysis of data

<p>The Standard requires.....</p> <p>evidence to demonstrate the manner in which the organisation sources data and then uses it to determine the effectiveness of the Quality Management System and to identify opportunities for improvement.</p> <p>Analysis of the data will then be used to provide information relating to;</p> <ul style="list-style-type: none"> • customer satisfaction, • conformity to product requirements, • suppliers, • characteristics and trends of processes and products, including opportunities for preventive action. 	<p>INFORMATION REQUIRED</p> <p>What are the sources of information?</p> <p>Who correlates the data?</p> <p>What are the results from the evaluation of the data and how are they used?</p>
<p>EXAMPLE</p> <p>The organisation gathers data from various sources, including customer surveys, Corrective Action Required reports, inspection and test reports, supplier performance reports, sales and marketing reports etc.</p> <p>The data is correlated and the results used to identify trends. The trend data may indicate problems associated with processes, training, documentation, product specifications, suppliers, raw materials and many more.</p> <p>The results from the evaluation of the data and trends are used as a basis for changes and improvements to the Quality Management System.</p> <p>The results from the evaluation of the data may also be used :</p> <ul style="list-style-type: none"> • as input to management reviews • as input to decision processes for corrective and preventative actions • as inputs to assessing customer satisfaction • as evidence of conformance to customer requirements 	<p>YOUR INPUT</p>