4.1 Understanding the organization and its context
Who are we?
What processes is our system comprised of?
Which processes are internal and which external?

4.2 Understanding the needs and expectations of interested parties
What are the needs and expectations of interested parties?
Who are interested parties?
4.4.1 The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;
b) determine the sequence and interaction of these processes;
c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
d) determine the resources needed for these processes and ensure their availability;
e) assign the responsibilities and authorities for these processes;
f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
h) improve the processes and the quality management system.

4.4.2 Requirements about documented information
The organization determines the extent of documented information on processes, depending on factors such as process complexity or employee competence. ISO 9001:2015 no longer requires certified organizations to maintain an up-to-date quality manual, however the documentation requirement is still part of the standard. It is still necessary to document, maintain and preserve relevant information.
Sales process can be comprised of:
• Marketing activities,
• Sales management,
• Customer relationship management,
• Sales literature and tools,
• Distribution channels.

See ISO 9001:2015, clause 8.2 Requirements for products and services for details.
Design and development process can be comprised of:
• Research (What to design?)
• Design (preliminary and final design) Output is a finished set of drawings that govern how to build a physical prototype.
• Design analysis for verifying performance of design solution.
• Testing pre-production prototypes.
• Hazard analysis to identify any potential safety issues that may be presented by the product.
• Preparing production process and product release to production.

See ISO 9001:2015, clause 8.3 Design and development of products and services for details.
Purchasing process can be comprised of:
• Discover potential suppliers,
• Evaluate potential suppliers,
• Select suppliers,
• Develop suppliers,
• Manage supplier relationships.

See ISO 9001:2015, clause 8.4 Control of externally provided processes, products and services for details.
The organization shall produce or provide services under controlled conditions. Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:
   the activities to be performed; (what is being done)
   the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities to verify that the acceptance criteria for products and services, have been met;

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities.

See ISO 9001:2015, clause 8.5 Production and service provision for details.
See ISO 9001:2015, clause 8.6 Release of products and services for details.
The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession.

Verification of conformity after correction.

See ISO 9001:2015, clause 8.7 Control of nonconforming outputs for details.
See ISO 9001:2015, clause 7.1.3 Infrastructure for details.
See ISO 9001:2015, clause 4.2 Understanding the needs and expectations of interested parties and 5.1.2 Customer focus for details.
Strategic planning determines the entire long term direction of your organization. Operational planning is the day-by-day and month by month planning for what your organization is doing. Each process owner should know what organization is expecting of his/hers process, what to measure and how and when to report to top management. The two forms of planning must be aligned and synchronized.
Top management shall provide resources for operation of processes.
Controlling costs and especially quality costs is a very useful way to show the efficiency and effectiveness of quality management system and it provides valuable data about possible quality problems that needs to be addressed with improvement project. For quality improvement projects estimation should be made about annual cost of present problem or situation, annual savings potential of new situation (or problem elimination) and costs to implement the improvements and return on investment for the project.
QA function is coordinating activities needed for assuring quality and is reporting directly to top management.
This is how processes are connected by inputs and outputs in a QMS.
Example of documenting sequence and interaction of processes. Each line connecting processes is numbered. On the next slide a table is shown with description of information or material products transferred from one process to another.
# 4.4 QMS Example cont.

<table>
<thead>
<tr>
<th>Nr.</th>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Market requirements</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Business plan, Quality policy, quality objectives</td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>Proposals, Contracts</td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>Design and development support to sales and marketing</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Customer requirements</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Product</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Product inspection and test documentation</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Production documentation, purchase orders</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Purchased products, prototypes from vendors</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Tested prototypes and documentation</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Customer satisfaction data</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Reporting of quality related information (nonconformities statistics, status of corrective actions, management review reports, audit reports, risk reports (FMEA, FTA, ...))</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Quality related information from processes</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Accounting information from processes</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Accounting reports</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Customer requirements, project change requests</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Project deliverables</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Project progress reports</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>Human, financial and IT resources</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Information about quality and accounting</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Project management information (tasks, schedules, deliverables)</td>
<td></td>
</tr>
</tbody>
</table>