

ISO 9001:2015 Differences

1. Process Approach is used

ISO 9001:2015 DIS expects organizations to apply a process approach when planning, implementing and developing their QMS.

ISO 9001:2008 promoted the adoption of process approach, while ISO in 9001:2015 DIS this is a requirement.

ISO 9001:2008 (4.1 Quality Management System - General Requirements) required organizations to establish, document, implement and maintain a quality management system and improve its effectiveness.

ISO 9001:2015 DIS (4.4 Quality Management System and **its Processes**) requires organizations to establish, implement and maintain and continually improve a quality management system, **including the processes needed and their interactions**.

2. Quality Manual Not Required

Requirements in ISO 9001:2008

Clause 4.1 (Quality management system – General requirements) of ISO 9001:2008 requires:

“The organization shall establish, document, implement and maintain a quality management system”

In addition clause 4.2.1 (Documentation requirements – General) of ISO 9001:2008 requires organizations to have a Quality Manual as a part of documentation.

Clause 4.2.2 (Quality manual) provides the details on what should be included in the Quality Manual.

Requirements in ISO 9001:2015 DIS

Clause 4.4 (Quality management system and its processes) of ISO 9001:2015 DIS requires:

"The organization shall establish, implement, maintain and continually improve a quality management system"

3. No Mandatory Procedure

Requirements in ISO 9001:2008

The current version of ISO 9001 (which is ISO 9001:2008) requires organizations to have "documented procedures" for the following six activities:

[4.2.3 Control of documents](#)

[4.2.4 Control of records](#)

[8.2.2 Internal audit](#)

[8.3 Control of nonconforming product](#)

[8.5.2 Corrective action](#)

[8.5.3 Preventive action](#)

These are minimum required procedures and the organization may have more documents for their Quality Management System to function effectively.

Requirements in ISO 9001:2015 DIS

ISO 9001:2015 Draft International Standard (DIS) does not suggest any specific procedure to be developed. ISO has left that open for organizations to decide based on the context of the organization.

This gives more flexibility to the organization to decide.

4. No Management Representative

Requirement in ISO 9001:2008

Earlier ISO 9001:2000 required the organization to appoint a Management Representative.

9001-2015

When ISO 9001:2008 was released it added the requirement that [Management Representative](#) should be a member of the organization management.

[Requirement in ISO 9001:2015 DIS](#)

ISO 9001:2015 Draft International Standard (DIS) assigned the role of management Representative to the top management of the organization and does not require a person to be specifically assigned as a Management Representative.

In new version of ISO 9001, top management will be required to fulfill the responsibilities earlier assigned to a Management Representative.

5. Records and Documents become Documented Information

ISO 9001 standard from the first issue onwards has been using the terms document and record. The difference between these has been confusing to some people.

Requirements in ISO 9001:2008

Records and documents are covered in two separate clauses in ISO 9001:2008.

Clause 4.2.3 covers Control of Documents

Clause 4.2.4 covers Control of Records

ISO 9000:2005 defines documents and records as follows:

Document: information and its supporting medium

Record: document stating results achieved or providing evidence of activities performed

Requirements in ISO 9001:2015 DIS

ISO 9001:2015 Draft International Standard (DIS) proposes to replace the term "document" and "record" by "documented information".

Example:

- ISO 9001:2008

Clause 8.2.2 of ISO 9001:2008 requires organization to:

- Establish a documented procedure to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
- Records of the audits and their results shall be maintained.

- ISO 9001:2015 Draft International Standard (DIS)

Clause 9.2 of ISO 9001:2015 DIS requires organizations to:

- Retain documented information as evidence of the implementation of the audit program and the audit results.

6. No Preventive Action

Requirement in ISO 9001:2008

In the existing standard ISO 9001:2008 organizations are required to determine action to eliminate the causes of “potential nonconformities” in order to prevent their occurrence.

Requirement in ISO 9001:2015 DIS

In the ISO 9001:2015 Draft International Standard (DIS) this requirement has not been included.

Explanation for removing this clause

- A Formal quality management system acts as a preventive tool.
- Requires organizations to adopt risk driven approach to preventive actions.
- The new version of ISO 9001 requires organizations to :
 - assess the issues which affect organization’s ability to achieve its goals (intended outcomes).
 - determine risks and opportunities

7. From Product to Product and Services

Requirement in ISO 9001:2008

In Terms and definitions (Section 3), it is stated that wherever the term "product" occurs, it can also mean "service".

Requirements in ISO 9001:2015 DIS

The term "product" has been explicitly been replaced with "products and services" in the DIS.

8. Risk Based Thinking – New element