



ISO Quality Management System

WHAT IS IT? WHAT IS IT NOT?

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ISO 9001

What it IS

- + A Quality Management Standard that is focused on:
 - Consistently providing products and services that meet customer and **applicable statutory and regulatory requirements.**
 - Facilitating opportunities to enhance customer satisfaction.
 - Addressing risks and opportunities associated with its context and objectives.
 - Demonstrating conformity to specified quality management system requirements.

Previous Reviews

SECY-03-0117

- + Reviewed ISO 9001-2000 against Appendix B
 - Noted less definitive requirements for:
 - Design controls
 - Software controls
 - Configuration control requirements and dispositioning of nonconforming items
 - Internal and external audits
 - Indoctrination, training, qualification and evaluation of personnel.

Previous Experience

SECY-03-0117

+ Conclusions

- Licensees could provide additional controls, where necessary, within their individual QA program, to procure safety-related items.
- The NRC staff would expect supplemental quality requirements be applied to ISO 9001-2000 QMS
- Noted the success of sector specific standards such as AS 9100.

+ Two revisions to ISO 9001 (2008 and 2015)

- 2015 introduced a risk-based approach, replacing the need for preventive action clauses by incorporating risk management directly into the planning process.

ISO 19443

Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)

- + Consensus standard developed by nuclear industry experts in collaboration with the IAEA.
- + Nuclear objectives include:
 - Enhanced nuclear safety culture.
 - Graded approach to quality.
 - Harmonization of requirements.
 - Combat of fraudulent items.

ISO 9001 / 19443

Can ISO standards be used to meet 10 CFR 50 Appendix B?

YES

- + An ISO requirement is to “meet customer and applicable statutory and regulatory requirements” (Clause 1, Scope).
- + A supplier providing ITNS products and services would need to address the applicable Appendix B requirements in their QMS.
- + It is expected that an ISO 9001 system meeting Appendix B requirements would look like an ISO 19443 system.

ISO 9001 / 19443

What it is NOT

- + It is not an Easy Button
 - There is a lot of communication that must take place between the buyer and the seller to ensure all of the required elements are provided.
- + Can an ISO 9001/19443 supplier be accepted based solely on the certificate?
 - NO
 - The certificate approves the quality management system only. As such it can simplify the approval process.
 - It does not approve the product or service that is provided.
 - The customer needs to be the subject matter expert in the item / service they are procuring.
 - As such, it is solely on the customer to ensure that the supplier can provide the items / services in accordance with the customer's applicable requirements.