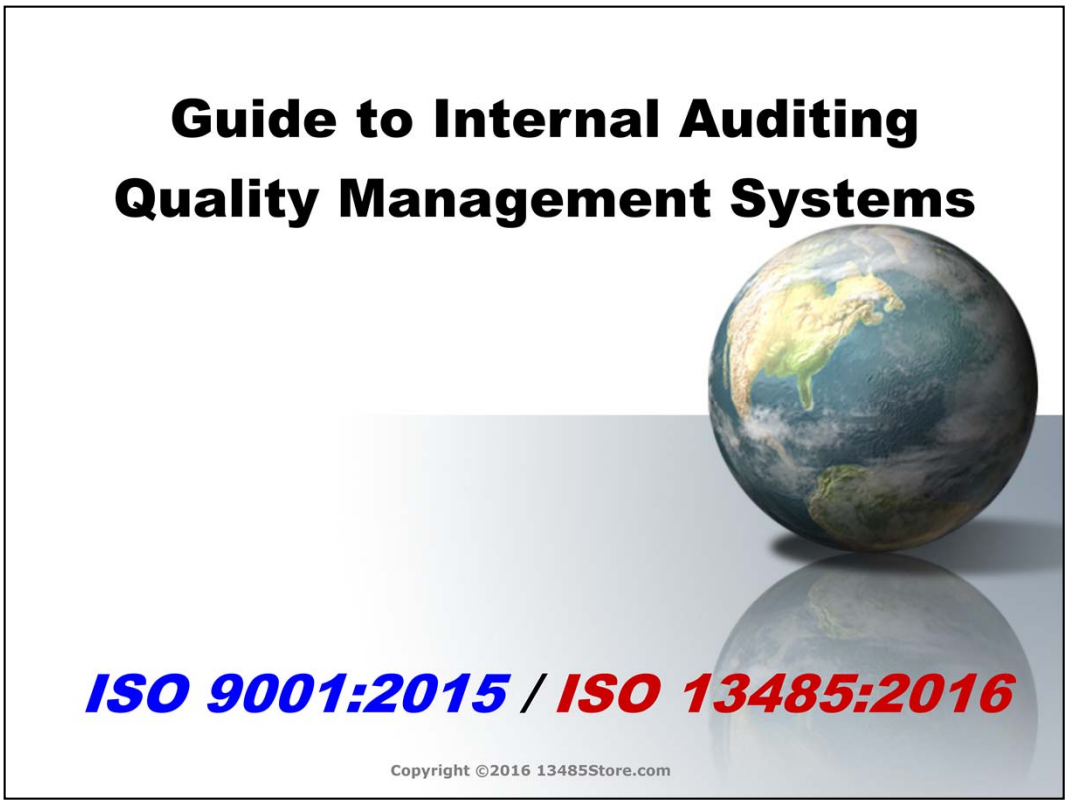

Clause 9.2.2 of ISO 9001 and clause 8.2.4 of ISO 13485 for medical devices require that organizations conduct internal audits of the QMS.

Introduction: Why are you here?

- To learn more about Quality Systems
- To be able to evaluate your own area and make improvements.
- To understand the audit process
- To be able to participate in the audit process

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If you have been involved with internal auditing of other management systems such as ISO 9001, you will find this guide to be familiar.

Why Audit?

International Standards follow ***Plan-Do-Check-Act***:

- **Plan -** Establish the objectives and processes needed to deliver the QMS results
- **Do -** Implement the QMS processes
- **Check -** Check the processes against the policy, objectives, targets, regulations, and report on the results. (**Auditing**)
- **Act -** Take actions to improve the QMS.

P-D-C-A is a well recognized “Continual Improvement” cycle

Why Audit?

Internal auditing is one of the most challenging requirements of ISO standards.

Audit are necessary and need to be done to take advantage of the possible benefits.

.. Audits are the Key to Improvement ..

Internal audits are the key to improvement ..

Internal audits add value to the organization.