

# Detailed Outline of Headings – ISO 13485:2016

## Foreword

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*\*These sub-heads are not in the Standard, but are descriptions of these untitled sub-clauses*

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- 8.3 Control of nonconforming product
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  - 8.3.4 Rework
- 8.4 Analysis of data
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**Annex A** (informative) **Comparison of content between ISO 13485:2003 and ISO 13485:2016**

**Annex B** (informative) **Correspondence between ISO 13485:2016 and ISO 9001:2015**

**Bibliography**

# ISO 9004:2009 (excerpt)

## 8.3.3 Internal audit

Internal audits are an effective tool for determining the levels of compliance of the organization's management system against given criteria, and provide valuable information for understanding, analyzing and continually improving the organization's performance. Audits should be conducted by people who are not involved in the activity being examined, in order to give an independent view on what is being performed.

Internal audits should assess the implementation and effectiveness of the management system. They can include auditing against more than one management system standard, such as ISO 9001 (quality management) and ISO 14001 (environmental management), as well as addressing specific requirements relating to customers, products, processes or specific issues.

To be effective, internal audits should be conducted in a consistent manner, by competent personnel, in accordance with an audit plan.

Internal auditing is an effective tool for identifying problems, risks, and nonconformities, as well as for monitoring progress in closing previously identified nonconformities (which should have been addressed through root cause analysis and the development and implementation of corrective and preventive action plans). Verification that the actions taken have been effective can be determined through an assessment of the improved ability of the organization to fulfil its objectives. Internal auditing can also be focused on the identification of good practices (that can be considered for use in other areas of the organization) as well as on improvement opportunities.

The outputs of internal audits provide a useful source of information for

- addressing problems and nonconformities,
- benchmarking,
- promoting good practices within the organization, and
- increasing understanding of the interactions between processes.

The results of internal audits are usually presented in the form of reports containing information on compliance against the given criteria, nonconformities, and improvement opportunities. Audit reports are also an essential input for management reviews. Top management should establish a process for the review of all internal audit reports, to identify trends that can require organization-wide corrective or preventive actions.

The organization should also take the results of other audits, such as second- and third-party audits, as feedback for corrective and preventive actions.

NOTE See ISO 19011 for further guidance on auditing.

The ISO 9004 Standard also contains an excellent Self-Assessment tool for reviewing the organization's activities and its performance in relation to its degree of maturity.

# ISO 9004:2009 (excerpt)

## 8.3.4 Self-assessment

Self-assessment is a comprehensive and systematic review of the organization's activities and its performance in relation to its degree of maturity (see Annex A).

Self-assessment should be used to determine the strengths and weaknesses of the organization in terms of its performance as well as its best practices, both at an overall level and at the level of its individual processes. Self-assessment can assist the organization to prioritize, plan and implement improvements and/or innovations, where necessary.

The results of self-assessments support

- continual improvement of the organization's overall performance,
- progress towards achieving and maintaining sustained success for the organization,
- innovation in the organization's processes, products, and structure, when appropriate,
- recognition of best practices, and
- the identification of further opportunities for improvement.

The results of self-assessments should be communicated to relevant people in the organization. They should be used to share understanding about the organization and its future direction. The results should be an input to management review.

NOTE 1 ISO 10014 provides a self-assessment tool directed specifically towards the financial and economic benefits of a quality management system for an organization.

NOTE 2 See Annex A for more information about self-assessment.