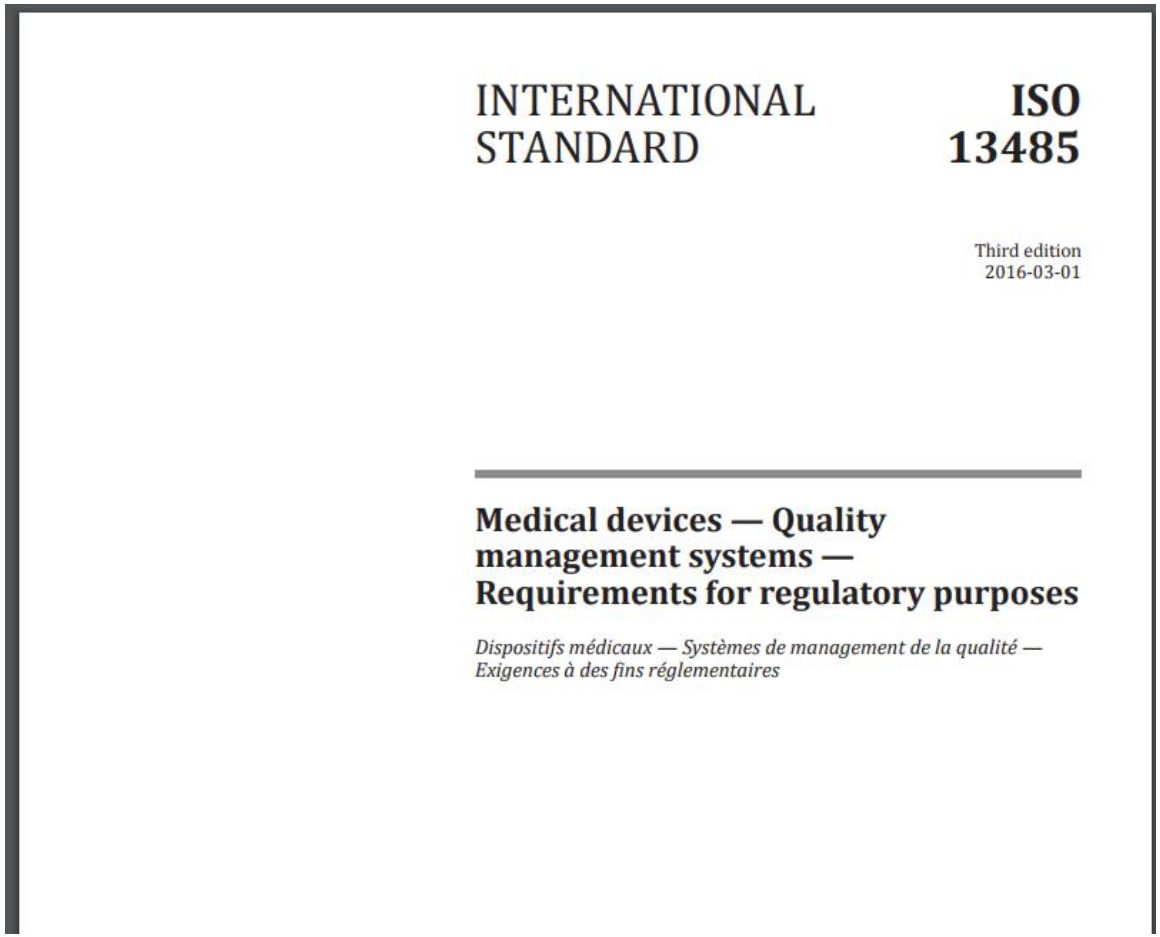
ISO 13485:2016

Scope of Stage 1 Audits



INTERNATIONAL STANDARD

ISO 13485

Third edition
2016-03-01

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

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Goals of Stage 1 Audit

- Audit the documentation system – *"Old Way"*
- Evaluate location & preparedness for Stage 2
- Review status & understanding of requirements
- Collect information on the scope
- Review allocation of resources and review details of Stage 2
- Provide a focus for planning the Stage 2
- Evaluate if internal audit & management review are planned, performed and fully implemented

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Why Risk-Based?

- 21 CFR 820 – 1 instance of the word “risk”
- ISO 9001:2008 – 3 instances of the word “risk”
- ISO 9001:2015 – 43 instances of the word “risk”
- ISO 13485:2003 – 4 instances of the word “risk”
- ISO 13485:2016 – 32 instances of the word “risk”

“13485 Plus” is a guidance document that was published by the Canadian Standards Association in February 2006. I have been recommending it over all other guidance documents for quality system implementation since 2010. It mentions the word “risk” 60 times.

http://shop.csa.ca/en/canada/quality-assurance-and-quality-management/plus-13485/invt/27023332006

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Annex A

- "Comparison of content between ISO 13485:2003 and ISO 13485:2016"
- Changes to almost every single clause, but overall structure is maintained
- Most changes are clarification
- Does not provide a side-by-side comparison table in Table A.1 as was provided in the DIS2 released in February 2015
- Annex B provides two comparison tables between ISO 13485:2016 and ISO 9001:2015, but italics text has been eliminated within the Standard to identify differences.

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Auditing ISO 13485:2016

- Develop a regulatory checklist for each of the 29 required processes
- Spread the pain by assigning a process owner to each process.
- Identify which procedures, forms and records are associated with each process.
- Develop a quality system plan for updating each process.
- Perform procedural audits 1st time.

Expert tip

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Clause 0.1 - General

- Introduction – "meet customer and applicable regulatory requirements *for safety and performance.*" Recommend adding language to Quality Policy during next management review.
- Documentation does not need to align with clause structure of the international standard (helpful for organization that want to maintain both ISO 13485 and ISO 9001 certification).

Note: *red italics font* indicates what's new.

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Clause 0.2 – Clarification of Concepts

- "As appropriate" is considered required if it is required for:
  - *"compliance with applicable regulatory requirements,*
  - *the organization to manage risks."*

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Clause 1 - Scope

- Application of Standard can be extended to suppliers and service providers.
- Non-applicability can be extended to Clauses 6 and 8 instead of just Clause 7.

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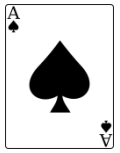
Exclusions / Non-Applicability

- Clause 7.3 remains the only clause that can be excluded
- Within Clauses 6, 7 and 8 the following might be not applicable:
  - 6.4 – Work environment (e.g., software products)
  - 7.5.2 – Cleanliness of product
  - 7.5.3 – Installation
  - 7.5.4 – Servicing
  - 7.5.5 – Sterile Devices
  - 7.5.6 – Process Validation
  - 7.5.7 – Sterilization Validation
  - 7.5.9.2 – Implantable Devices
  - 7.5.10 – Customer property
  - 7.6 – Calibration
  - 8.3.4 – Rework

Include justification for each area of non-applicability.



Caution: Many clauses remain applicable, because they must be controlled as an outsourced process.

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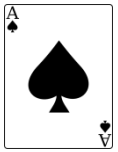
Clause 3 - Definitions

- 8 definitions in ISO 13485:2003
- 16 definitions in ISO 13485:201x (DIS2)
- 20 definitions in ISO 13485:2016
- Definitions no longer included:
  - Active implantable medical device
  - Active medical device
- New Definitions:
  - *Authorized representative*
  - *Clinical evaluation*
  - *Distributor*
  - *Importer*
  - *Life cycle*
  - *Manufacturer*
  - *Medical device family (not in DIS2)*
  - *Performance evaluation*
  - *Post market surveillance*
  - *Product (not in DIS2)*
  - *Purchased product (not in DIS2)*
  - *Risk (same as ISO 14971:2007, but different from ISO 9001:2015)*
  - *Risk management*
  - *Sterile barrier system (not in DIS2)*
- Expanded Definitions
  - *Complaint (added services)*
  - *Labeling (added advertising and marketing information)*
  - *Medical device (identifies possible definition differences)*

Consider using a glossary instead of definitions in each procedure.



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Clause 4

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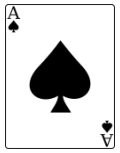
Clause 4 Changes

- *29 Required Procedures* instead of 19
- Clause 4.1 – Significant changes
- Clause 4.2.1. – expanded general requirements
- Clause 4.2.2 – no changes
- Clause 4.2.3 is new – *Medical device file*
- Clause 4.2.4 – minor addition to match QSR
- Clause 4.2.5 – no changes



Hopefully harmonization with MDD will be improved due to 4.2.3.

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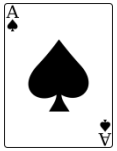
Clause 4.1 - General

- Clause 4.1.1 – addition of *regulatory requirements*
- Clause 4.1.2 – addition of *a risk-based approach*
- Clause 4.1.3 – reformat of 4.1 and *addition of records*



Add risk-based approach to all processes in your quality system documentation section of your quality manual (i.e., Clause 4.1.2). Tabular structure is ideal.

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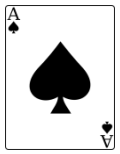
Clause 4.1 - General

- *Clause 4.1.4 – Changes to quality management system processes shall be:*
  - a) *"evaluated for their impact on the quality management system,*
  - b) *evaluated for their impact on medical devices produced under this quality management system,*
  - c) *controlled in accordance with the requirements of this International Standard and applicable regulatory requirements."*



Your quality plan for the change to ISO 13485:2016 must address this.

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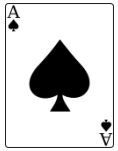
Clause 4.1 - General

- *Clause 4.1.5 – Controls for outsourced processes "shall include written quality agreements."*



Supplier quality management process must require a written quality agreement and controlled templates are recommended for each supplier type.

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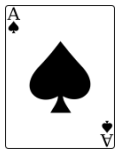
Clause 4.1 - General

- *Clause 4.1.6 – Validation of software used in quality system require procedures.*



I am asked if this is required frequently.
Now it's required.

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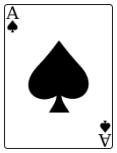
4.2.4 - Control of Documents

- This clause was 4.2.3.
- *Clause 4.2.4h) - prevent deterioration or loss of documents, and*



"Storage in fireproof cabinets may not be expected routinely in most locations, but controls to ensure integrity of records and protection from earthquake would be expected of some California manufacturers."

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Clause 5

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Clause 5 Changes

- Clause 5.1 – no change
- Clause 5.2 – added *regulatory requirements*
- Clause 5.3 – no change
- Clause 5.4.1 – added *regulatory requirements*
- Clause 5.4.2 – no change
- Clause 5.5.1 – no change
- Clause 5.5.2 – minor changes to wording
- Clause 5.5.3 – no change
- Clause 5.6.1 – added *documentation of interval*
- Clause 5.6.2 – added *complaint handling and reporting*
- Clause 5.6.3 – added *changes to address new and revised regulatory requirements*

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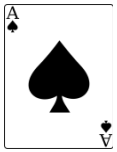
Management Review Inputs

Clause 5.6.2

a) Feedback
b) Complaint handling
c) Regulatory reporting
d) Audits
e) Monitoring & measurement of processes
f) Monitoring & measurement of product
g) Corrective actions
h) Preventive actions
i) Follow-up of actions from previous management reviews
j) Changes that could affect QMS
k) Recommendations for Improvement
l) New or revised regulatory requirements



I will be revising template and procedure again to reflect differences between DIS2 and Final version.

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Management Review Outputs

- Recommend documenting the next scheduled management review and a justification for changes (this was only in DIS2, but still recommended).
- Recommend documentation actions to address new and revised regulatory requirements as management review action items (this is a requirement).

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Clause 8 (just Stage 1)

Clause 8.2.2 is new – *Complaint handling*

Clause 8.2.3 is new – *Regulatory reporting*

Clause 8.2.4 – was Clause 8.2.2, but no change

Clause 8.5.2 / 8.5.3 – reorg and added *planning*

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Common Deficiencies in Complaint Handling Procedure

- Failure to:
  - Capture all complaints
  - Include time limits for investigation and reporting decisions
  - Extend the investigation to other potentially affected product
  - Document reason for no investigation
  - Document reason for no corrective action

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Reporting Regulations

- Canada Mandatory Problem Reporting
  - http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php
- Europe Vigilance Reporting
  - http://ec.europa.eu/DocsRoom/documents/15506/attachments/1/translations/en/renditions/native
- US Medical Device Reporting (21 CFR 803)
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM179471.pdf
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359566.pdf

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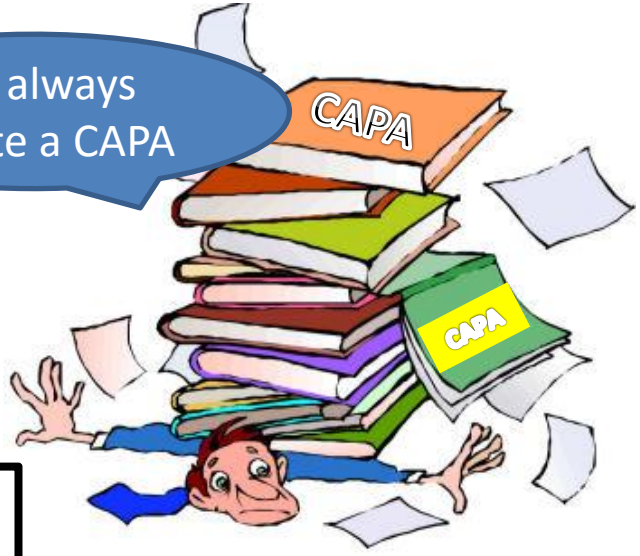
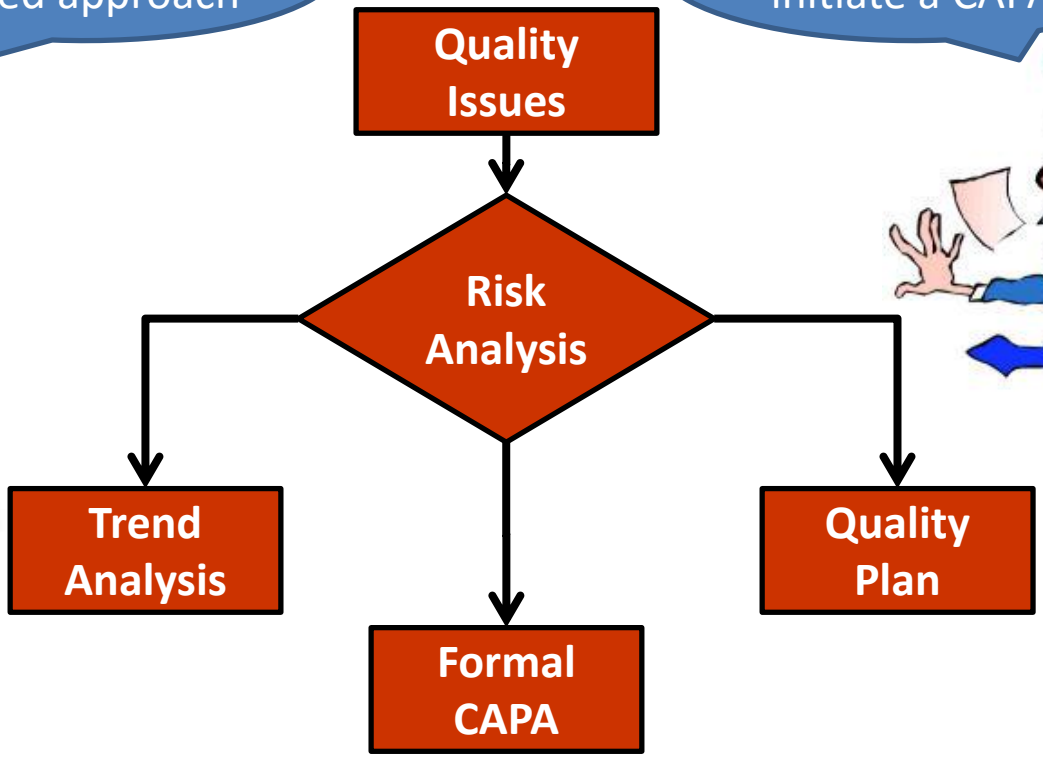
"Death by CAPA"

We use a risk-based approach



We always initiate a CAPA



http://medicaldeviceacademy.com/create-a-risk-based-capa-process/

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Corrective Action

Clause 8.5.2

- reviewing nonconformities (including customer complaints),
- determining the causes of nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
- *planning and documenting action needed*
- verification that corrective actions do not have adverse effects
- reviewing corrective action taken and its effectiveness
- recording of the results of any investigation and of action taken

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Preventive Action

Clause 8.5.3

- determining potential nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
- *planning and documenting action needed*
- verification that corrective actions do not have adverse effects
- reviewing corrective action taken and its effectiveness
- recording of the results of any investigation and of action taken

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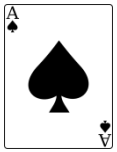
Key Elements of CAPA Forms

- Provide Enough Room
- Date Initiated
- Include a Cross-Reference
- CAPA Source
- Description of Issue
- Investigator Assigned & Target Due Date
- Investigation of Problem
- Containment
- Correction(s)
- Investigation of Root Cause
- Corrective Action Plan & Target Due Date
- Preventive Action Plan & Target Due Date
- Actions Implemented
- Plan for Verification of Effectiveness
- Effectiveness Verification
- Signature & Closure Date

"15 Tips for Creating an Effective CAPA Form"
http://medicaldeviceacademy.com/15-tips-for-creating-an-effective-capa-form/



FRM-009, CAPA Report
(sold with CAPA Procedure)
http://medicaldeviceacademy.com/corrective-preventive-action-capa-procedureform/

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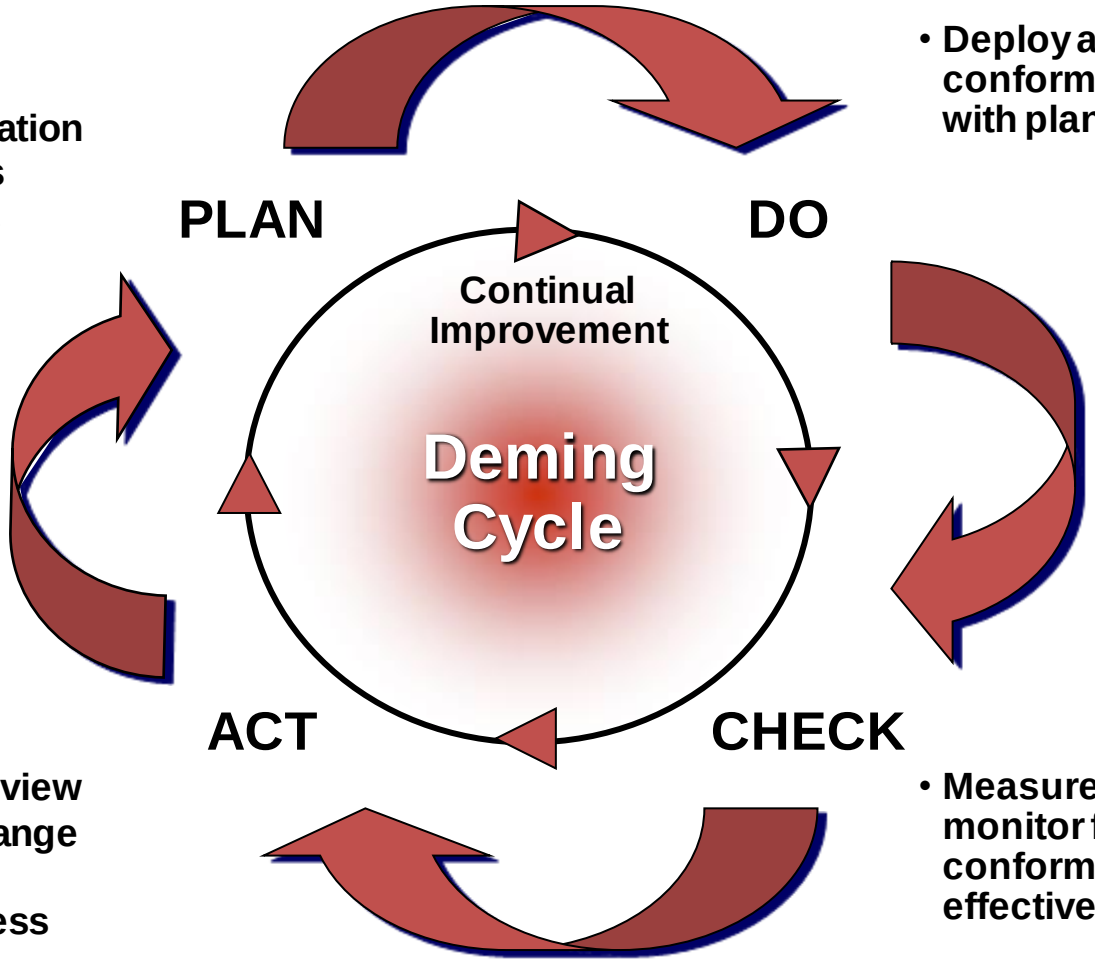
Plan-Do-Celebrate-Check-Act

- Activities
- Controls
- Documentation
- Resources
- Objectives



- Deploy and conform with plan

- Analyze/review
- Decide/change
- Improve effectiveness

- Measure and monitor for conformity and effectiveness

Celebrate!

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Q & A

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