ISO 13485 3rd Edition

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QMS Certification Lead, Medical Devices

2 - ISO 9001:2015

3 - ISO 13485:2016

4 - Key Changes in ISO 13485:2016

5 - Potential Timings
What is the difference?

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>• The current International Standard</td>
<td>• The previous version of the European Harmonised Standard</td>
<td>• Changes within Foreword &amp; Annex Zs only</td>
</tr>
<tr>
<td></td>
<td>• Obsolete as of 30 August 2012</td>
<td>• <strong>No change</strong> to requirements (Normative Text)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Annex Z’s to provide greater clarity on applicability &amp; alignment with AIMDD, MDD &amp; IVDD</td>
</tr>
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</table>
### Relationship between Annex II of 93/42/EEC and clauses of ISO 13485

<table>
<thead>
<tr>
<th>Paragraph of Directive 93/42/EEC, Annex II</th>
<th>Clause(s) of EN ISO 13485</th>
<th>Comments/Qualifying remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 first sentence</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 1st indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 2nd indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 3rd indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 4th indent</td>
<td>4.1, 4.2</td>
<td>Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.</td>
</tr>
<tr>
<td>3.1 second sentence 5th indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 6th indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 7th indent</td>
<td></td>
<td>Not covered</td>
</tr>
</tbody>
</table>
| 3.2 first paragraph first sentence          |                           | Not covered. The application of EN ISO 13485 does not by itself assure the fulfillment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined,
ISO 9001:2015
New ISO Management Systems High Level Structure

- New and revised ISO MS Standards now using ISO Annex SL: A standard for standard writers

- Provides a 10 clause high-level structure and common text

- Standardises terminology for fundamental Management System requirements

- Follows the Plan → Do → Check → Act (PDCA) principle
New ISO 9001:2015

10 Clause Structure
The Future

ISO 9001  ISO 13485
ISO 13485:2016

Based on the Final Draft International Standard (FDIS) of 29 October 2015
ISO 13485:2016 – What’s New?

- What’s been put in?
- What’s come out?
- What’s the same?
ISO 13485:2016 – What’s New?

- Many additions
- Some new requirements
- Some expansion & clarification
- Increased clarity of interrelationship between clauses and requirements
## Regulatory Requirements

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“Regulatory requirements”</td>
<td>Appears 37 times</td>
</tr>
<tr>
<td>Appears 9 times</td>
<td></td>
</tr>
</tbody>
</table>
# Objectives and Scope

<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Objectives</strong></td>
<td>Facilitate harmonization</td>
<td>Facilitate global alignment</td>
</tr>
<tr>
<td><strong>Scope &amp; Role</strong></td>
<td>Organizations provide Medical devices and related services</td>
<td>Organizations can be involved in one or more stages of the life-cycle including the design and development, production, storage and distribution, installation, or servicing of a medical device and the design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product including quality management system-related services to such organizations.</td>
</tr>
</tbody>
</table>
## Definitions

**Clause 3**

<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Active implantable medical device</td>
<td>Advisory notice</td>
</tr>
<tr>
<td>Active medical device</td>
<td>Authorized representative</td>
</tr>
<tr>
<td>Advisory notice</td>
<td>Clinical evaluation</td>
</tr>
<tr>
<td>Customer complaint</td>
<td>Complaint</td>
</tr>
<tr>
<td>Implantable medical device</td>
<td>Distributor</td>
</tr>
<tr>
<td>Labelling</td>
<td>Implantable medical device</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Importer</td>
</tr>
<tr>
<td>Sterile medical device</td>
<td>Labelling</td>
</tr>
<tr>
<td></td>
<td>Life cycle</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
<tr>
<td></td>
<td>Medical device</td>
</tr>
<tr>
<td></td>
<td>Medical device family</td>
</tr>
<tr>
<td></td>
<td>Performance evaluation</td>
</tr>
<tr>
<td></td>
<td>Post market surveillance</td>
</tr>
<tr>
<td></td>
<td>Purchased product</td>
</tr>
<tr>
<td></td>
<td>Risk</td>
</tr>
<tr>
<td></td>
<td>Risk management</td>
</tr>
<tr>
<td></td>
<td>Sterile barrier system</td>
</tr>
<tr>
<td></td>
<td>Sterile medical device</td>
</tr>
</tbody>
</table>
Changes to Clause Numbering

• Due to the inclusion of several new clauses, several sub-clauses have been re-numbered.

• This presentation covers changes to content, not every sub-clause re-number.

• In order to work with the MDSAP program of determining levels of non-conformance grading, the clauses and sub-clauses required formatting

* See GHTF Document SG3 N19
## 4 – Quality Management System

### 4.1 - 2 General Requirements
- + Document role(s) undertaken by organization under regulatory requirements
- + Risk based approach to control QMS processes

### 4.1.3 - 5 General requirements
- Records to meet regulatory requirements.
- Change control
- For outsourced processes control based on risk and ability

### 4.1.6 General Requirements
- + Requirement to validate the computer software used for QMS prior to initial use & after changes

### 4.2 Documentation Requirements
- Medical Device File
- + Detailed list of items (a-f) that shall be included to meet regulatory requirements
5 – Management Responsibility

5
General requirements

5.5.1
Responsibility & Authority

Top mgmt shall DOCUMENT the interrelation of all personnel who....

5.5.2
Management representative

Focus on documentation of the quality management system and the removal of customer requirements from bullet c)

5.6
Management review

Procedures required, document planned intervals

+ More bullet points for inputs, new bullet for outputs
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.2</td>
<td>Human resources</td>
<td>Shall document the processes for establishing competence, providing training, and ensuring awareness.</td>
</tr>
<tr>
<td>6.2</td>
<td>Human resources</td>
<td>+ Maintain competency  + NOTE effectiveness methodology link to risk of work for which training provided</td>
</tr>
<tr>
<td>6.3</td>
<td>Infrastructure</td>
<td>+ Prevent product mix up, ensure orderly handling; Maintenance of equipment applies to production, control of work env, monitor and measurement.</td>
</tr>
</tbody>
</table>
6.4 – Work environment and contamination control

6.4.1 Work environment

Additional reference - + NOTE
For information see for example ISO 14644 and ISO 14698 series.

6.4.2 Contamination control

For sterile medical devices, the organization shall document requirements for control of contamination with micro-organisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.
# 7 – Product Realization

## 7.1 Planning of product realization

- Documented processes for risk management
- Required planning for verification, validation, monitoring, measurement, inspection, test activities, handling, storage, distribution, & traceability

## 7.2.1 Determination of product requirements

- Any user training needed to ensure specified performance and safe use of the product

## 7.2.2 Review of product requirements

- Applicable regulatory requirements are met
- Any user training identified in accordance with 7.2.1 is available or planned to be available...

## 7.2.3 Communication

The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements
## 7 – Product Realization (continued)

<table>
<thead>
<tr>
<th>7.3.2</th>
<th>Design &amp; development planning</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>List of items to document:</td>
</tr>
<tr>
<td></td>
<td>+ Traceability of outputs to inputs</td>
</tr>
<tr>
<td></td>
<td>+ Competence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.3.3 - 5</th>
<th>D &amp; D Inputs, outputs, review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inputs + Usability and the ability to verify/validate</td>
<td></td>
</tr>
<tr>
<td>Outputs + Shall be in a form suitable for verification against inputs</td>
<td></td>
</tr>
<tr>
<td>Review + Record requirements</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.3.6 &amp; 7</th>
<th>Design &amp; development V/V</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirement to document: the V/V plan, the methods of V/V, criteria for acceptance, rationale for sample sizes. Connections and interfaces</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.3.6 &amp; 7</th>
<th>Design &amp; development V/V</th>
</tr>
</thead>
<tbody>
<tr>
<td>V/V of device interfaces. All validation activity must be conducted on representative product or documented equivalent devices</td>
<td></td>
</tr>
</tbody>
</table>
7.3.8 Design & development transfer

New Clause
Procedures required

7.3.9 Design and development changes

Was 7.3.7 – Includes greater detail regarding the control of changes, risk management

7.3.10 Design and development files

New Clause
+ Shall maintain a D&D file for each medical device type or family. This file shall include or reference records generated to demonstrate conformity to the requirements for D&D and records for D&D changes
7 – Product Realization (continued)

7.4.1 Purchasing

Criteria for evaluation and selection of suppliers includes performance and risk. Supplier performance monitoring as part of re-evaluation process.

7.4.2 Purchasing information

+ Purchasing information to include, as applicable product specifications. Suppliers to agree to prior notification of changes.

7.4.3 Verification of purchased product

+ Extent of verification based on risk/supplier evaluation and link to change control.
7.5.1 Control of production & service provision

Production and service provisions must be monitored and controlled as well as planned and carried out to ensure product conforms to specifications.

7.5.2 Cleanliness & contamination control

Similar to 2003 requirements.

7.5.3 Installation activities

Similar to 2003 requirements.

7.5.4 Servicing activities

Servicing activity records must be analyzed to determine if the issue is a complaint or must be utilized as an improvement input.

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7 – Product Realization (continued)
### 7 – Product Realization (continued)

#### 7.5.6 Validation of processes for production and service provision

- Validate processes for production & service provision where output cannot be or is not verified
- Use appropriate statistical techniques and rationale for sample sizes, approval of changes, and validation of software after any changes, risk based

#### 7.5.8 Identification

- UDI where required by national or regional regulations
- Requirement for procedures for separation of returned products from conforming product

#### 7.5.7 Validation of sterilization and sterile barriers

- Documented procedures required for validation of sterilization and sterile barriers
- Validation required prior to implementation
- Document results and conclusion
<table>
<thead>
<tr>
<th>7.5.9 Traceability</th>
<th>7.5.10 Customer property</th>
<th>7.5.11 Preservation of product</th>
<th>7.6 Control of monitoring and measuring equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar to 2003 version</td>
<td>Consistent with 7.5.4 of current document</td>
<td>Specific reference to packaging and shipping containers</td>
<td>Requirements for the validation of the application of computer software used for monitoring and measurement requirements are now within this clause. Risk based approach required.</td>
</tr>
</tbody>
</table>

+ Distribution is specified
8 – Measurement, Analysis and Improvement

8.2
Monitoring and measurement

+ Feedback procedures, input to risk management and improvement process. Clause strengthened.

8.2.2 and 8.2.3
Complaint handling & Reporting to regulatory authorities

New Clauses

Requires procedures for timely complaint handling, investigation, regulatory notification and more

Procedures for reporting to regulatory authorities regarding complaints are required
8 – Measurement, Analysis and Improvement

8.2.6 Monitoring and measurement of product

+ Test equipment shall be identified as appropriate

8.3 Control of non conforming product

+ NC product shall be considered for corrective action following investigation (or documented justification for lack of investigation)
+ 8.3.1 - 4 New clauses for nonconforming product before delivery, after delivery and rework

8.5.2 & 8.5.3 Corrective & Preventive action

Verifying that the corrective or preventive action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of product
Areas of Increased Emphasis

- Regulatory Requirements
- Risk Management
- Validation, Verification & Design Transfer
- Outsourced Processes & Supplier Control
- Feedback

ISO 13485 3rd Edition

Improved linkage of clauses
ISO 13485:2016 Annexes

Annex A
• Comparison of content between ISO 13485:2003 and ISO 13485:2016

Annex B
• Comparison of content between ISO 13485:2016 and ISO 9001 9001:2015

European Annexes ZA (AIMD), ZB (MDD) and ZC (IVD)
• Identifies relationship between the European Standard (EN ISO 13485:2016?) and Conformity Assessment Requirements of the respective EU Medical Device Directives via each conformity assessment route for each directive
Potential Timings
EN ISO 13485:2016 – Possible Timings

FDIS Published for 2 month vote under the Vienna Agreement
Straight Yes / No Vote with no technical comments permitted

End of 2 month vote period
If positive vote outcome proceeds to publication

ISO 13485:2016 published with 3 year transition period
No new ISO 13485:2003 certificates in final year of transition

European Harmonization? EN ISO 13485:2016??

End of 3 year transition

29 October 2015
29 December 2015
March 2016
March – June 2016
March – June 2019
Global Picture

• ISO 9001 and ISO 13485 Revisions

• MDSAP Pilot - US, Canada, Brazil, Australia (& in 2016 Japan with Europe watching carefully)

• Japanese Requirement (J PMD Act)

• New MDR / IVDR
Thank you

<table>
<thead>
<tr>
<th>Name:</th>
<th>Stewart Brain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td>QMS Certification Lead – Medical Devices</td>
</tr>
<tr>
<td>Address:</td>
<td>BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, UK</td>
</tr>
<tr>
<td>Mobile:</td>
<td>+44 (0)7768 387325</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:stewart.brain@bsigroup.com">stewart.brain@bsigroup.com</a></td>
</tr>
<tr>
<td>Links:</td>
<td><a href="http://medicaldevices.bsigroup.com/">http://medicaldevices.bsigroup.com/</a></td>
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