The New ISO 13485:2015

Sue Spencer
2 – ISO 9001:2015 Update
3 - Future - ISO 13485:2015
4 - Key additions for ISO 13485:2015
5 - Potential Timings
EN ISO 13485:2012

• European harmonised standard for Medical Device Quality Management Systems
• Allows the presumption of conformity to Medical Directives - MDD, AIMD & IVD
• Published February 2012 & harmonised as of 30 August 2012

EN ISO 13485:2012 only applies to manufacturers placing devices on the market in Europe
What is the difference?

ISO 13485:2003
• The current International Standard

EN ISO 13485:2003
• The previous version of the European Harmonised Standard
• Obsolete as of 30 August 2012

EN ISO 13485:2012
• Changes within Foreword & Annex Zs only
  • No change to requirements (Normative Text)
• Annex Z’s to provide greater clarity on applicability & alignment with AIMDD, MDD & IVDD
Example

EN ISO 13485:2012
Annex ZB

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</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>1st indent</td>
<td></td>
<td></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>
<tr>
<td>3.2 first paragraph first sentence</td>
<td></td>
<td>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,</td>
</tr>
</tbody>
</table>
ISO 9001:2015
What’s next?

ISO 9001 Timeline


May 2014  | February 2015  | September 2016  | September 2017  | September 2018

FDIS 9000 & FDIS 9001 will be published 9th July 2015, with 2 month voting period, Straight YES/NO vote – no technical comments permitted

ISO 9001 will be published Late September 2015
QMS Structure

**PLAN**
- 4 Context of organization
  - Understanding of the organization and its context
  - Expectations of interested parties
  - Scope of management system
- 5 Leadership
  - Leadership and commitment
- 6 Planning
  - Quality policy
  - Roles, responsibilities, and authorities
  - Planning of changes
- 7 Support
  - Actions to address risk and opportunity
- 8 Operation
  - Resources
  - Competence
  - Awareness
  - Communication
  - Documented information

**DO**
- Operations of planning and control
- Determination of requirements for products and services
- Design and development of products and services
- Control of external provided products and services
- Production and service provision
- Release of products and services
- Control of nonconforming process outputs, products and services

**CHECK**
- Monitoring, measurement, analysis and evaluation
- Internal audit
- Management review

**ACT**
- Nonconformity and corrective action
- Continual improvement

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The Future?

ISO 9001

ISO 13485
ISO 13485:2015

3rd Edition – Based on Second Draft International Standard (DIS) of February 2015
ISO 9001 Revision Impact on ISO 13485:2015

• ISO 13485:2015 will follow the same current format as ISO 9001:2008 and will not align with the proposed ISO 9001:2015 (Annex SL – High Level Structure)
ISO 9001:2015 Main Changes

- The majority of the newer requirements follow a risk based approach
  - Risk analysis
  - Risk management
  - Uncertainty and the effect on actions
  - Risk management versus preventive action
- The numbering system is being changed from the existing structure (10 clauses)
- Designed to allow for greater flexibility with multiple quality management systems (QMS, EHS, etc).
- The diversion of ISO 9001 and ISO 13485 depends heavily on timing!!!!!

**NOTE:** ISO 13485:201x will not be aligned to the structure as defined by Annex SL High Level Structure. It will be aligned to the format of ISO 9001:2008, IAF has compiled a Transition Planning Guidance Document and BSI will be developing transition planning guidance for its clients.
ISO 13485:2015 – What’s New?

- Many additions
- Some new requirements
- Some expansion & clarification
- Increased clarity of interrelationship between clauses and requirements
# 1. New and Key Changes - Regulatory Requirements

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Regulatory appears <strong>16 times</strong></td>
<td><strong>80 times</strong> in new draft</td>
</tr>
<tr>
<td>1 Scope and application</td>
<td>4.1 OMS planning and outsourcing</td>
</tr>
<tr>
<td>4.2.1 Documentation</td>
<td>5.2 Customer focus</td>
</tr>
<tr>
<td>4.2.3 Document control</td>
<td>5.4.1 Quality objective</td>
</tr>
<tr>
<td>4.2.4 Record control</td>
<td>7.2.3.2 Communication with CA</td>
</tr>
<tr>
<td>5.1 Management commitment</td>
<td>7.3.3 Design inputs</td>
</tr>
<tr>
<td>5.3 Quality policy</td>
<td>7.3.5 design review</td>
</tr>
<tr>
<td>5.5.1 Responsibility &amp; Authority</td>
<td>7.3.6 Design verification</td>
</tr>
<tr>
<td>5.6 Management Review</td>
<td>7.3.7 Design Validation</td>
</tr>
<tr>
<td>6.1 Provision of resource</td>
<td>7.3.9 Design Change</td>
</tr>
<tr>
<td>6.2 Human resource</td>
<td>7.4.1 Supplier control</td>
</tr>
<tr>
<td>7.2 Customer related requirements</td>
<td>7.5.3 Identification and Traceability</td>
</tr>
<tr>
<td>7.3.2 Design input</td>
<td>8.2.1.2 Complaint handling</td>
</tr>
<tr>
<td>7.3.6 Design Validation</td>
<td>8.2.1.2.2 Reporting to regulatory authorities</td>
</tr>
<tr>
<td>8.1 Statistical technique</td>
<td>8.2.2 Internal audit</td>
</tr>
<tr>
<td>8.2.1 Customer feedback</td>
<td>8.3 Nonconforming products</td>
</tr>
<tr>
<td>8.5.1 Advisory notice and Reporting</td>
<td>8.5.2 Corrective action</td>
</tr>
</tbody>
</table>
## Objectives and scope

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>Objectives</strong></td>
<td>Facilitate harmonization</td>
</tr>
<tr>
<td><strong>Scope &amp; Role</strong></td>
<td>Organizations provide Medical devices and related services</td>
</tr>
<tr>
<td><strong>3.7 Definition</strong> (8→16)</td>
<td>Medical device</td>
</tr>
<tr>
<td></td>
<td>Implantable medical devices</td>
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<tr>
<td></td>
<td>Active implantable medical devices</td>
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<td>Sterile medical device</td>
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<td></td>
<td>Complaint</td>
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<td>Labelling</td>
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</tbody>
</table>
### 4 – Quality Management System

<table>
<thead>
<tr>
<th>Section</th>
<th>Topic</th>
<th>Details</th>
</tr>
</thead>
</table>
| 4.1     | General Requirements | + Document role(s) undertaken by organization under regulatory requirements  
+ Risk based approach for developing QMS processes  
+ For outsourced processes control based on risk and ability |
| 4.1.3 - 5 | General requirements | Records to meet regulatory requirements  
+ 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  
New note – defines areas |
| 4.2 | Documentation Requirements | + Detailed list of items (a-f) that can be included in a product or technical file to meet regulatory requirements |

New note – defines areas
# 5 – Management Responsibility

<table>
<thead>
<tr>
<th>5 General requirements</th>
<th>5.4.2 QMS planning</th>
<th>5.5.2 Management representative</th>
<th>5.6 Management review</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Regulatory requirements (throughout)</td>
<td>+ NOTE Quality objectives consistent with quality policy, action items to accomplish objectives, monitoring progress, and revision</td>
<td>Focus on documentation of the quality management system and the removal of customer requirements from bullet c)</td>
<td>+ Recorded rationale for frequency for management review + documented</td>
</tr>
<tr>
<td>+ Responsibilities &amp; authorities documented (5.5.1)</td>
<td></td>
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</tr>
</tbody>
</table>
6 – Resource Management

**6.2.1 Human resources – General**
- Personnel at all levels across product, process, regulatory requirements and QMS

**6.2.2 Competence, awareness & training**
- Maintain competency
- NOTE effectiveness methodology link to risk of work for which training provided

**6.3 Infrastructure**
- Product performance, documented procedures for production & controlled work env, Maintenance req. including intervals
- Records

**6.4 Work environment**
- Significant additional detail to clarify requirements
- 6.4.2 Particular requirements for sterile medical devices
7 – Product Realization

7.1 Planning of product realization
- Risk management
- Required planning for verification, validation, revalidation, monitoring, measurement, inspection, test activities, handling, storage, & traceability
- Software IEC/ISO 62304

7.2 Customer-related processes
- Regulatory requirement
- User training

7.2.3.2 Communication with regulatory authorities
- New clause
  - As appropriate, the organization shall communicate with regulatory authorities in accordance with planned arrangements.
## 7 – Product Realization (continued)

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3.1</td>
<td>Design &amp; development planning</td>
</tr>
<tr>
<td></td>
<td>+ Emphasis on planning, decision points, transfer activities, resources &amp; suitability</td>
</tr>
<tr>
<td>7.3.6 &amp; 7</td>
<td>Design &amp; development verification &amp; validation</td>
</tr>
<tr>
<td></td>
<td>+ Plan, method, criteria, sample size, &amp; device interfaces</td>
</tr>
<tr>
<td></td>
<td>+ Validation on production units or (documented) equivalents</td>
</tr>
<tr>
<td>7.3.8</td>
<td>Design &amp; development transfer</td>
</tr>
<tr>
<td></td>
<td>New Clause</td>
</tr>
<tr>
<td></td>
<td>+ Transfer plans for supplier, manufacturing, process, personnel, tools, environment, installation, etc</td>
</tr>
<tr>
<td>7.3.10</td>
<td>Design and development records</td>
</tr>
<tr>
<td></td>
<td>New Clause</td>
</tr>
<tr>
<td></td>
<td>+ Records shall be clearly identified and maintained in the design and development file...</td>
</tr>
</tbody>
</table>
7 – Product Realization (continued)

7.4 Purchasing

7.4.1.1 Supplier approval
7.4.1.2 Monitoring of suppliers
7.4.1.3 Supplier documentation
+ Criteria for selection, evaluation / re-evaluation consistent with risk

7.4.2 Purchasing information
+ Purchasing information to include, where possible, suppliers agree to notify changes

7.4.3 Verification of purchased product
+ Extent of verification commensurate with risks and result of evaluation and re-evaluation
# 7 – Product Realization (continued)

## 7.5.2 Validation of processes for production & service provision

- Validate processes for production & service provision where output cannot be or is not verified
- Documented validation plans & procedures, including procedures for validation of sterilization & packaging processes

## 7.5.3 Identification & traceability

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

## 7.5.4 Customer Property

**NOTE**

Customer property can include intellectual property or confidential health information.

## 7.5.5 Preservation of product

- NOTE Sterile barrier systems of sterile medical devices are a constituent part of a medical device.
- Distribution is specified
8 – Measurement, Analysis and Improvement

8.2 Monitoring and measurement

+ Feedback procedures, input to risk management

8.2.1.2.1 Complaint Handling

New Clause

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

8.2.1.2.2 Reporting

New Clause

+ requires procedures and records for reporting to regulatory authorities
8 – Measurement, Analysis and Improvement

8.3
Control of nonconforming product

+ NC product shall be considered for corrective action

8.3.1 - 4 New clauses for nonconforming product before delivery, after delivery and rework

8.5.2 & 8.5.3
Corrective & Preventive action

+ New bullets regarding
1) Impact on CA with regard to safety and performance
2) Timely manner PA
3) Impact to QMS and regulatory requirements for PA
Areas of Increased Emphasis

ISO 13485 3rd Edition

Regulatory Requirements

Risk Management

Validation, Verification & Design Transfer

Outsourced Processes & Supplier Control

Feedback

Improved linkage of clauses
Potential Timings
## EN ISO 13485:201X – History

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2014</td>
<td>ISOTC 210 WG1 Meeting – Review DIS comments. Decision to issue 2nd DIS.</td>
</tr>
<tr>
<td>Dec 2014</td>
<td>Consolidate comments review and prepare 2nd DIS</td>
</tr>
<tr>
<td>January 2015</td>
<td>Finalize 2nd DIS text, submit to CEN/CENELEC for translation, required for parallel vote ISO/CEN</td>
</tr>
<tr>
<td>February 2015</td>
<td>Issue 2nd DIS for 2 month vote &amp; parallel vote under the Vienna Agreement I</td>
</tr>
<tr>
<td>June 2015</td>
<td>Working Group meeting, in Denver 2nd week June to review DIS2 comments approx 860 in total</td>
</tr>
<tr>
<td>May 2015</td>
<td>May 2015 Consolidate comments in preparation for meeting</td>
</tr>
<tr>
<td></td>
<td>NOTE: A 3 month vote actually occurred.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Voting ISO +ve CEN –ve Should not have any impact on the progress under the Vienna Agreement for both versions ie ISO &amp; EN</td>
</tr>
<tr>
<td>June 2015 – forward</td>
<td>Next options include;</td>
</tr>
<tr>
<td></td>
<td>• WG met in Denver &amp; completed review of all comments. Text for a draft FDIS was agreed.</td>
</tr>
<tr>
<td></td>
<td>WG will meet in late August for editorial correction and review of text and prepare FDIS for publication by ISO</td>
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<td>Publication late 2015/early 2016 tbc</td>
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• WG met in Denver & completed review of all comments. Text for a draft FDIS was agreed.
• WG will meet in late August for editorial correction and review of text and prepare FDIS for publication by ISO
• Publication FDIS late 2015/early 2016 tbc
Bigger Global Picture

• ISO 9001 and ISO 13485 Revisions
• Medical Device Directive Updates
• IVD Directive Updates
• AIMD Directive Updates
• Japanese Requirement Updates (November 2014)
• MDSAP (US, Canada, Brazil, Australia with the EU and Japan watching carefully)
Questions?
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