The New ISO 13485 – Will You Be Ready?

Bill Enos
Microbiology Team Leader – Americas
BSI Medical Devices
2 – ISO 9001:2015 Update
3 - Future - ISO 13485:201X
4 - Key additions for ISO 13485:201X
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

<table>
<thead>
<tr>
<th>ESO (1)</th>
<th>Reference and title of the standard or other document containing the requirements for regulatory purposes (ISO 13485:2003)</th>
<th>Date expired</th>
<th>Date published</th>
</tr>
</thead>
</table>

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**EN ISO 13485:2012 only applies to manufacturers placing devices on the market in Europe**

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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</td>
</tr>
</tbody>
</table>

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ISO 9001:2015
Current ISO 9001:2015 Timeline

2013

May 2013 CD
(Committee Draft)

2014

May 2014 DIS
(Draft International Standard)

February 2015 FDIS
(Final Draft International Standard)

2015

September 2015
Published International Standard
The Future?

ISO 9001

ISO 13485
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!!!!!
ISO 13485:201X

3rd Edition – Based on Draft International Standard (DIS) of February 2014
ISO 13485:201X – What’s New?

- Many additions
- Some new requirements
- Some expansion & clarification
- Increased clarity of interrelationship between clauses and requirements
ISO 13485:201X
DISCLAIMER!!!!!!!

THE FOLLOWING INFORMATION IS PRELIMINARY AND NOT CONSIDERED A FINAL DRAFT.

THE ITEMS OUTLINED HERE ARE CURRENT PROPOSED CHANGES.

THE LAST MEETING VOTE DISAPPROVED THE REVISIONS AS A WHOLE.
## 4 – Quality Management System

### 4.1 General Requirements

- Document role(s) undertaken by organization under regulatory requirements
- Risk based approach for developing QMS processes

### 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-z) that can be included in a product or technical file to meet regulatory requirements
## 5 – Management Responsibility

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 General requirements</td>
<td>+ Regulatory requirements (throughout) + Responsibilities &amp; authorities documented (5.5.1)</td>
</tr>
<tr>
<td>5.4.2 QMS planning</td>
<td>+ NOTE Quality objectives consistent with quality policy, action items to accomplish objectives, monitoring progress, and revision</td>
</tr>
<tr>
<td>5.5.2 Management representative</td>
<td>+ NOTE on management rep to include liaison with external parties, including regulatory authorities</td>
</tr>
<tr>
<td>5.6 Management review</td>
<td>+ Recorded rationale for frequency for management review + documented Improvement needed for new or revised regulatory requirements</td>
</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 & work env, 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
+ Records
+ Required planning for verification, validation, revalidation, monitoring, measurement, inspection, test activities, handling, storage, & traceability

7.2 Customer-related processes
+ Regulatory requirement
+ User training
+ Methods for protecting confidential health information

7.2.3.2 Communication with regulatory authorities
New clause
+ Document arrangements, product information, enquiries, complaints, advisory notices
7 – Product Realization (continued)

7.3.1 Design & development planning

- Emphasis on planning, decision points, transfer activities, resources & suitability

7.3.5 & 6 Design & development verification & validation

- Plan, method, criteria, sample size, & device interfaces
- Validation on production units or (documented) equivalents

7.3.7 Design & development transfer

- New Clause
- Transfer plans for supplier, manufacturing, process, personnel, tools, environment, installation, etc

7.3.9 Design and development records

- New Clause
- Records shall be clearly identified and maintained in the design and development file...
  (list items a-j)
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

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### 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

#### 7.5.5 Preservation of product

- Detailed requirements on device packaging & shipping
- Validation of packaging
- Particular requirements for sterile devices
8 – Measurement, Analysis and Improvement

8.2 Monitoring and measurement
- Feedback procedures, input to risk management, statistical evaluation using statistical tools for input to CAPA

8.2.4 Monitoring and measurement of product
- Identify test equipment used to perform measurement (as well as person)

8.3 Control of nonconforming product
- Determine need to investigate, escalation to CA
- 8.3.2 - 5 New clauses for nonconforming product after delivery and rework

8.5.2 & 8.5.3 Corrective & Preventive action
- Review of product and process data
- Link to CAPA, Risk Management & Management Review
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
Potential Timings
EN ISO 13485:201X – Potential Timings

February 2014
• Draft International Standard (DIS) published, then 5 month vote (disapproved as we saw previously)

September 2014
• ISOTC 210 WG1 Meeting – Review of comments on DIS and Proceed to 2nd DIS or Final Draft International Standard (FDIS)

November 2014
• DIS and 2 month vote (then FDIS and vote) or Final Draft International Standard (FDIS) published, then 2 month vote

April – June 2015
• ISO 13485 3rd Edition?

July 2015 – July 2018
• 3 Year Transition Period
Note on ISO 9001 Revision Impact on ISO 13485:201X – Potential Timings

- If timelines on previous slide hold the standard will retain ISO 9001:2008 format as 2003 version
- BUT, any deviation in timelines will mean further delay to ISO 13485:201X as would then need to follow Annex SL (High Level Standard) Format per ISO 9001 next revision
  - This will require a re-write of the standard
  - Likely publication in 2017 if that happens
DISCLAIMER!!!!!!

- There is currently a meeting being held in Stockholm the week of 8 September
- A new vote could:
  - Move this to a second DIS for review
  - Move this to an FDIS (probably unlikely considering the number of comments)
Transition Period

• It is anticipated that there will be a 3 year transition period
• Transition periods begin when the new version takes effect.
• At this time, it is unknown when that will be
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)
Thank you

<table>
<thead>
<tr>
<th>Name:</th>
<th>Bill Enos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title:</td>
<td>Microbiology Team Leader, Americas</td>
</tr>
<tr>
<td>Address:</td>
<td>BSI America, 12950 Worldgate Drive, Suite 800, Herndon VA 20170</td>
</tr>
<tr>
<td>Telephone:</td>
<td>800-862-4977</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:Bill.enos@bsigroup.com">Bill.enos@bsigroup.com</a></td>
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<tr>
<td>Links:</td>
<td><a href="http://www.bsigroup.com">www.bsigroup.com</a></td>
</tr>
</tbody>
</table>
Questions?
bsi. ...making excellence a habit™
Enhanced Certification
What is “Enhanced Certification”? 

- It is the process of continued improvement across a number of market segments
- It is not limited to Assessment or CE Marking
- BSI looks at continued education regarding market changes, QMS improvement tools and access to better resources in addition to Assessment and CE Marking services
Continued QMS Improvement

• Via a software tool that gives you;
  • *Speed*
    • Pull up any and all findings, actions and dashboards quickly
    • View your dashboard anytime, anywhere!
  • *Visibility*
    • See the status of open actions by location, department or person(s) responsible
  • *Flexibility*
    • *Tailor the tool to your needs*
    • *Let the system work for you... not you working for your system*
• Action Manager is the one stop solution for you and your quality team
Dashboard View