ISO/TC 210/WG 1
Application of quality systems to medical devices

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**wg1N233 Draft White Paper - ISO Transition Planning Guidance for ISO 13485:2016**

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| Replaces: | N 224 |
| Document type: | Other committee document |
| Date of document: | 2015-11-18 |
| Expected action: | INFO |
| Background: | Enclosed is the final transition white paper that includes the edits suggested from the UK and Seattle meeting of WG1. |
| Committee URL: | http://isotc.iso.org/livelink/livelink/open/tc210wg1 |

# ISO/TC 210/WG 1 N233

November 2015

**INTERNATIONAL ORGANIZATION FOR STANDARDIZATION**
**ISO/TC 210/WG 1, APPLICATION OF QUALITY SYSTEMS TO MEDICAL DEVICES**

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## ISO Transition Planning Guidance for ISO 13485:2016

**(position paper)**

*Secretariat Note:* This document will be considered at the 16-20 November 2015 meeting of ISO/TC 210/WG 1 in the USA. If you have comments please submit them to the Secretariat by 1 October 2015.

Convener of ISO/TC 210/WG 1:

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# 1.0 PURPOSE

The purpose of this document is to provide recommendations for transition to the application of ISO 13485:2016 globally. This document is intended for current users of ISO 13485:2003 (Ref. 1), those who are intending to use ISO 13485:2016, as well as other interested parties. These parties include, but are not limited to, medical device manufacturers, accreditation bodies, certification bodies, registrars, regulatory authorities responsible for implementation and surveillance of medical device regulatory requirements that will include the use of ISO 13485:2016, and international and national standards bodies.

# 2.0 INTRODUCTION

ISO 13485 was developed by ISO TC 210, *Quality management and corresponding general aspects for medical devices*, to provide particular requirements for organizations that provide medical devices.

ISO 13485:2003 is being used in regulatory schemes worldwide for meeting regulatory requirements for medical devices. For example, it has been:

- Incorporated by reference in the Canadian Medical Devices Regulations.
- Recognized by Australia as satisfying the quality management system requirements of the Australian conformity assessment procedures.
- Harmonized within the Japanese QMS Ordinance for medical devices.
- Adopted as a European standard and harmonized under the medical devices directives. This was most recently confirmed with the publication of EN ISO 13485:2012 that is identical to ISO 13485:2003 with the revision of the European Foreword and Annexes ZA, ZB and ZC.
- Incorporated into the Medical Device Single Audit Program (MDSAP).

ISO 9001:2015 was published in September, 2015. TC 176 has approved a transition plan (Ref. 2) which includes a three year transition period with the withdrawal of ISO 9001:2008 in October, 2018. The recommendations for ISO 13485 transition have been developed taking into consideration the approaches described in Reference 2.

# 3.0 EXPLANATION OF THE REVISION PERIODS

The revision for ISO 13485 can be divided into the pre-publication period and the transition period.

### 3.1 Pre-publication period

The pre-publication period includes the following development stages of ISO 13485:

- CD: Committee Draft (completed)
- DIS: Draft International Standard (completed)
- FDIS: Final Draft International Standard (completed—29 Oct 2015)

During the pre-publication period, accredited certification should continue to be issued to ISO 13485:2003. Draft documents may not be used for accredited certification. Accredited certification should also continue to be issued to national or regional editions

of the 2003 versions of ISO 13485. These national or regional editions may have later published dates (e.g., EN ISO 13485:2012).

### 3.2 Transition period

During the transition (co-existence) period, ISO 13485:2016 will co-exist with ISO 13485:2003. The estimated time of publication of ISO 13485:2016 is early 2016.

Due to the changes required, it is recommended that users have three years in which to update their quality management systems to meet the requirements of ISO 13485:2016. For example, if the final standard is published in January, 2016, the transition period will last until February, 2019, at which point the 2003 version will be withdrawn.

## 4.0 TRANSITION GUIDANCE FOR USER GROUPS

### 4.1 Pre-publication period

Manufacturers may prepare but should not adopt ISO 13485:2016 based on information contained in draft documents (e.g., ISO FDIS 13485:2016).

Manufacturers that have started the preparation for implementing ISO 13485:2016 based on the draft documents, should carefully check the differences between the final, published version and the draft documents to address any differences.

An accredited certification based on draft documents is not permitted. Organizations should be aware of how ISO 13485:2016 may be utilized in different regulatory jurisdictions. Guidance on this issue should be sought from the appropriate regulatory bodies.

### 4.2 Co-existence period

This phase concerns the co-existence of the availability of accredited certification to ISO 13485:2003 and ISO 13485:2016. It is recommended to ISO TC 210 that this phase last for three years, during which time users will have to update their quality management systems to meet the requirements of ISO 13485:2016 to an accredited certificate.It is recommended that the users of ISO 13485:2003 work with their certification bodies or registrars to schedule an upgrade audit at a convenient time within the transition period.

It is recommended that:

- Two years after the publication of ISO 13485:2016 all accredited certifications issued (new certifications or re-certifications) will be to ISO 13485:2016.
- Three years after publication by ISO of ISO 13485:2016, any existing certification issued to ISO 13485:2003 will not be valid.

## REFERENCES


1. ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes
2. ISO TC 176/SC2 Document N1278, September 2015 Implementation Guidance for ISO 9001:2015