NSAI
National Standards Authority of Ireland
Údarás Um Chaighdeáin Náisiúnta na hÉireann

National Standards Authority of Ireland
ISO 13485:2016 Transition Policy
July 11, 2016

ISO 13485:2016 was published on **March 1, 2016**. Clients certified to ISO 13485:**2003** have a transition period of three years from the date of publication within which to complete the transition to ISO 13485:2016.

IMPORTANT NOTE: For medical device clients who currently utilize quality management system certification to **EN ISO 13485:2012** in support of CE marking your medical devices with NSAI, ISO 13485:2016 has not yet been harmonized in Europe. Therefore, until ISO 13485:2016 has been officially recognized and harmonized within the European Union EN ISO 13485:2012 remains valid and unaffected.

Organizations currently certified to **ISO 13485:2003** are encouraged to take the following actions:

a. Identify organizational gaps which need to be addressed to meet new requirements
b. Develop an implementation plan
c. Provide appropriate training and awareness for all employees that have an impact on the effectiveness of the management system
d. Update the existing management system to meet the revised requirements and provide verification of effectiveness (internal audit of revised system).
e. Work with NSAI to arrange transition to the new standard.

The NSAI transition and implementation plan in relation to ISO 13485:2016 certifications is as follows:

New (Initial) ISO 13485 Certifications:

A. Companies seeking certification to ISO 13485 for the first time are encouraged to implement the ISO 13485:2016 version.

B. However, clients seeking certification in support of CE marking medical devices for sale in the European Union should continue to apply for EN ISO 13485:2012 until further notice. NSAI will publish additional guidance when/if the newest version of ISO 13485 has been formally harmonized and adopted for Europe.

C. Two years after publication of ISO 13485:2016, **(01 March 2018)**, all new (initial) client registrations issued by NSAI will be to ISO 13485:2016, unless registration to the EU Harmonized Standard version, EN ISO 13485:2012, is specifically requested by the client.

Existing ISO 13485:2003 Certifications:

NSAI has established our ISO 13485:2016 transition plan in accordance with the *Draft White Paper – ISO Transition Planning Guidance*, published by the International Standards Organization (ISO), dated 18 Nov 2015, and outlined below:

A. Until **01 March 2018** audits will continue to be conducted in accordance with ISO 13485:2003 unless otherwise directed by the client. After 01 March 2018, all audits conducted by NSAI will be to the ISO 13485:2016 version.

B. Effective **01 March 2018** (two years after publication of 2016 version), ISO 13485:2003 certificates will no longer be issued by NSAI.

C. Effective **01 March 2019** (three years after publication of 2016 version), all ISO 13485:2003 certificates will become invalid.

D. Effective **until** 01 March 2018 any new, modified or revised ISO 13485:2003 certificates issued by NSAI will have an expiry date not to exceed 01 March 2019.

For existing clients wishing to transition to ISO 13485:2016, the organization shall notify NSAI at least 90 days prior to their scheduled audit that they wish to transition. At that time you will be provided with a transition checklist to complete and submit with your amended Quality System Documentation for NSAI's review.

Conducting Transition Audits:

NSAI will conduct ISO 13485:2016 transition activities during a routine surveillance or recertification audit using audit durations outlined below. Additional audit time is required in order to ensure that all requirements are covered for both the existing ISO 13485:2003 and new ISO 13485:2016 standards.

For transition audits, NSAI will add the following time:

- ✓ + .5 day for the completion of an off-site QMS documentation review, plus
- ✓ + .5 day on-site for review of the implementation of the new requirements.

Please contact the Operations Manager if you have further questions about this transition.

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