Bulletin

Issue:	**MPD ISO 13485 and MDSAP transition Policy**
Date:	**Nov 10, 2016**
To:	**TUV USA / TUV NORD ISO 13485 Certified clients and Potential clients**
From:	**Bradley Chen**
Re:	**ISO 13485:2003 to ISO 13485:2016 / CMDCAS to MDSAP transition**

Dear Valued Customer:

On August 2, 2016 TUV USA, Inc. issued a bulletin regarding the ISO 13485 and MDSAP transition. At that time we committed to providing you with information regarding the new ISO 13485:2016 certificate issuance and the deadline for you to submit your transition plan(s) to TUV USA, Inc.

ISO 13485:2016

ISO 13485:2016 was published on March 01, 2016. The transition period from ISO 13485:2003 to the new 2016 version is three (3) years from the date of publication of the 2016 version of the standard.

Below is the transition policy of TUV USA, Inc.

New ISO 13485 Certifications (Initial Certification) requests

(i) First time or Initial Certification – Companies who do not have an existing ISO 13485 Certification and are seeking certification to it, are encouraged to implement the ISO 13485:2016 version

(ii) Starting from ***January 01, 2018*** – TUV USA, Inc. will issue ISO 13485:2016 Certificates to all "First time or Initial" Certification companies who successfully complete their audits

(iii) Companies seeking CE Marking for their Medical Devices for sale in the European Union may also apply for EN ISO 13485:2016

TUV USA, Inc., 215 Main Street, Salem, NH 03079 Phone: 603-870-8023 Fax: 603-870-8026 www.tuv-usa.com

Existing ISO 13485:2003 Certifications

(i) ***Before April 01, 2018 -*** TUV USA, Inc. will conduct the audit in accordance with ISO 13485:2003, unless the certified company is ready to be audited to the new version (ISO 13485:2016)

(ii) ***Starting April 01, 2018 and going forward*** – All ISO 13485 audits conducted by TUV USA, Inc. will be to the ISO 13485:2016 version

(iii) ***Starting April 01, 2018 and going forward*** – ISO 13485:2003 certificates will no longer be issued by TUV USA, Inc.

(iv) ***March 01, 2019*** – ISO 13485:2016 becomes effective (03 years after the publication of 2016 version of the standard)

(v) All new, modified or revised ISO 13485:2003 certificates issued by TUV USA, Inc. will have **expiration dates** as follows:

a. ISO 13485:2003 (under CMDCAS) valid until December 31, 2018
b. ISO 13485:2003 (under MDSAP) valid until December 31, 2018
c. ISO 13485:2003 Certificates valid until February 28, 2019

Medical Device Signal Audit Program (MDSAP)
In accordance with the direction received from Health Canada, all clients certified to ISO 13485:2003 (under CMDCAS) need to transition the CMDCAS Certificate to an MDSAP Certificate, ***latest December 31, 2018***.

New ISO 13485 Certifications (Initial Certification) under CMDCAS / MDSAP

(i) First time or Initial Certification – Companies who do not have an existing ISO 13485 Certification (under CMDCAS) and are seeking certification to it, are encouraged to implement the ISO 13485:2016 version and can request for CMDCAS until ***December 31, 2017***

(ii) All ISO 13485:2003 (under CMDCAS) Certificates will be ***valid until December 31, 2018*** (based on the direction / notification received from ***Health Canada*** – they ***will no longer accept the ISO 13485:2003 CMDCAS Certificate from January 01, 2019 going forward***)

(iii) ISO 13485:2016 (under MDSAP) certificate will have a normal three year validity

TUV USA, Inc., 215 Main Street, Salem, NH 03079 Phone: 603-870-8023 Fax: 603-870-8026 www.tuv-usa.com

Existing ISO 13485:2003 Certifications (under CMDCAS / MDSAP)

(i) ***April 01, 2017 ~ March 31, 2018*** – Any company with an existing ISO 13485:2003 (under CMDCAS) program can transition to ISO 13485:2016 (under CMDCAS). If you are ready to transition to ISO 13485:2016 (under MDSAP) please contact the TUV USA, Inc. corporate office

(ii) Companies with an existing ISO 13485:2003 Certification (under CMDCAS) seeking re-certification in 2017/2018 are encouraged to begin *planning for transition* to ISO 13485:2016 (under MDSAP) ***well in advance of March 31, 2018***

(iii) Starting April 01, 2018 and going forward

a. TUV USA, Inc. will no longer conduct recertification audits under the CMDCAS program
b. MDSAP audit can be requested during the normal surveillance audit under the CMDCAS program cycle, but no certificate will be issued
c. Normal surveillance audit(s) will be held as scheduled if the company does not wish to transition to MDSAP

(iv) ***January 01, 2019*** – CMDCAS program will be terminated / will await for the final notification from Health Canada

---

Organizations with ISO 13485 Certifications are encouraged to take the following actions immediately:

(i) Develop a Quality Plan for the implementation of ISO 13485:2016 and if applicable, plan for transition from CMDCAS to the MDSAP program

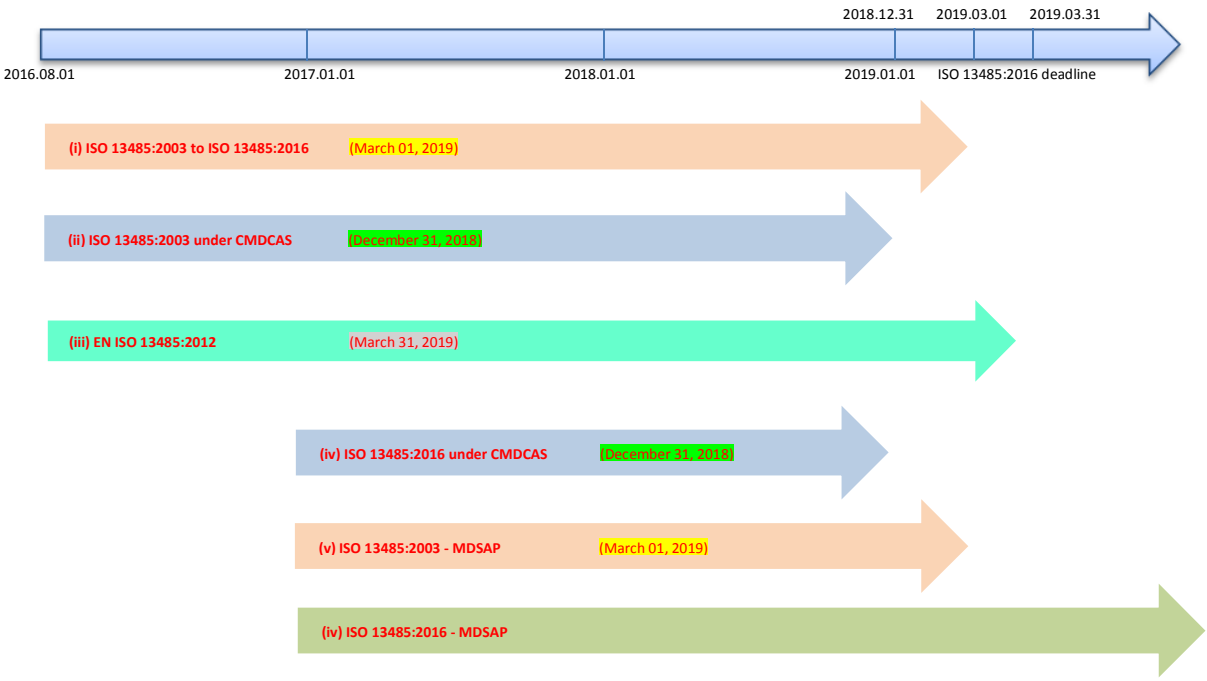
(ii) Identify organizational gaps, including training needs, to address and meet the new requirements of the ISO 13485:2016 and if applicable, the MDSAP Program

(iii) Update the existing Quality Management System to meet the new requirements and complete the internal audit and management review prior to the on-site audit by TUV USA, Inc.

(iv) Work with TUV USA, Inc. to complete your transition to the new ISO 13485:2016 and if applicable, to the MDSAP program. Organizations wishing to transition to the new requirements need to contact TUV USA office at least 120 days (4 months) prior to their scheduled transition audit.

TUV USA, Inc., 215 Main Street, Salem, NH 03079 Phone: 603-870-8023 Fax: 603-870-8026 www.tuv-usa.com

The following is the official deadline and transition time for both certification schemes:



If you have any questions, please feel free to contact the undersigned.

Thank you.

Bradley Chen
Director, Medical Products Div.
bchen@tuv-nord.com
Cell: (347)592-9872

Diana Sweeney
Project Manager
dsweeney@tuv-nord.com
(603)870-8023 Ext: 230