The European Association
Medical Devices - Notified Bodies

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Team-NB Position Paper

Team NB position statement on the requirements for the EU MDR/IVDR Notified Body Partners under the Technical Cooperation Program on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports (TCP III)

Executive Summary

This document gives a common position of TCP III interested EU Notified Bodies. It addresses how audit time reduction could be reconciled with the legal obligations for EU Notified Bodies as stipulated in the EU Medical Devices Regulations. In addition, it proposes how training requirements for EU Notified Body auditors qualified for auditing TCP III related aspects could be fulfilled and which input from TFDA would be required in order to implement these training requirements adequately.

Background

Both the EU and Taiwan have aligned their medical device quality management system (QMS) regulatory requirements to ISO 13485[1]. The TCP III program allows for the exchange of medical device QMS regulatory audit reports between EU notified bodies designated according MDR[2] and/or IVDR[3], and the Taiwan Food and Drug Administration (TFDA) authorised medical device QMS auditing organisations. (The exchange of reports is done through manufacturer, and not directly between notified bodies and TFDA authorised auditing organisations). In order to get its report to be accepted by TFDA authorised auditing organisations, the

1 PD CEN/TR 17223:2008 Guidance on the relationship between EN ISO 13485: 2016 (Medical devices – Quality management systems – Requirements for regulatory purposes) and European Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation (shows how the EU requirements align to EN ISO 13485). A cross/reference between TFDA medical device GMP regulation and ISO 13485 is currently not yet available, and the adjustment of regulations to ISO 13485:2016 is currently in progress.

2 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

3 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

notified body must become an EU Notified Body Partner under the Technical Cooperation Program TCP III established by TFDA [4].

Among others, the following two requirements must be met by an EU Notified Body Partner:

1. TFDA would expect that EU Notified Body Partners accept audit reports issued by the TFDA recognised auditing organisations to Taiwanese manufacturers when planning their ISO 13485 assessments, and reduce the time and cost of audits (sixth paragraph of Section 1, point b of Section 3, and point 3 of Section 5 of TCP III). Having a procedure to meet this expectation is part of TCP III program requirements for EU Notified Body Partners (item 11.2 in the Annex of TCP III).
2. The EU Notified Body Partners' auditors must be trained on the TCP III requirements prior to becoming authorised to perform audits under the TCP III program (point 5 of Section 5 of TCP III). Having a procedure for such training is also part of TCP III program requirements for EU Notified Body Partners (item 11.3 in the Annex of TCP III Program).

In its responses to notified bodies' applications for initial recognition as EU Partner Notified Body under the TCP III program, the TFDA determined in multiple instances that procedures to address these requirements were lacking detail.

The purpose of this Team NB position statement is to address both requirements in a uniform way, respecting the legal obligations for notified bodies in the current EU regulatory framework.

1. EU Notified Body Partner's procedure on reducing the time and cost of audits based on audit reports issued by TFDA recognised auditing organisations to Taiwanese manufacturers when planning their ISO 13485 assessments

The requirements of notified bodies' conformity assessment activities are set out in Annex VII of MDR/IVDR, while EN ISO 13485 is used as additional audit criteria. When determining the audit time for the assessment against requirements of EN ISO 13485, notified bodies are obliged to apply methods defined in the International Accreditation Forum Mandatory Documents (IAF MD 5 and IAF MD 9)[5] and, by way of being members of Team NB, also the Team NB Code of Conduct[6], and are limited to the criteria defined in these documents.

Based on these methods, notified bodies may choose to utilise the following provisions for reducing the time and cost of audits based on the acceptance of audits reports issued by TFDA authorised auditing organisations:

- If an audit report issued by TFDA authorised auditing organisations is submitted by a manufacturer located in Taiwan to a notified body, who is EU Notified Body Partner under TCP III, this audit report

[4] Technical Cooperation Programme on Exchange of Medical Device Quality Management System Regulation and ISO 13485 Audit Reports between EU MDR/IVDR Notified Body Partners and R.O.C. TFDA Authorized Medical Device QMS Auditing Organizations, Version 3, November, 2019.

[5] IAF MD 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems, and IAF MD 9:2017 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485).

[6] Code of Conduct for Notified Bodies under Directives 90/385/EEC, 93/42/EEC, 98/79/EC, EU 2017/745 and EU 2017/746 "Improving implementation of the European CE certification of medical devices through the harmonization of Notified Bodies", Version: 4.0, October 2019.

must be reviewed and taken into consideration by the notified body when determining the time and cost of its assessment to EN ISO 13485. Based on discussions with TFDA AAO, it is reasonable to expect that such an audit report is:

- sufficiently recent (not older than 1 year from the date of audit)[7];
- written in the English language[8];
- assessing the conformity of manufacturer's QMS against clauses of the current revision of ISO 13485[9].

- Before taking the decision to reduce the time and cost of its audits, the notified body shall confirm, after reviewing the manufacturer's application for assessment to EN ISO 13485 including the audit report issued by TFDA authorised auditing organisations, that there are no indications of:
  - the manufacturer's organisation and QMS not being in good standing;
  - major nonconformities requiring on-site verification;
  - multiple nonconformities indicating lack of operative controls;
  - negative compliance history;
  - negative trends;
  - counterfeit product, fraudulent activity or threat to public health;
  - any other factors allowing to conclude that the manufacturer may be lacking the capability to comply with the QMS requirements.
- When taking the decision to reduce the time and cost of its audits based on the audit report issued by TFDA recognised auditing organisations, the EU Notified Body Partner shall apply a reduction factor of up to 15% for the reason of "client preparedness for certification" in accordance with the section "Minimum Time for Notified Body assessment" of Team NB Code of Conduct and Annex D of IAF MD 9.

2. Procedure for training auditors on TCP III program requirements

Taking into account that notified body auditors assigned to TCP III audits are already meeting the qualification requirements to perform audits against EN ISO 13485 and/or MDR/IVDR, the EU Notified Body Partners must ensure that they are also trained on TCP III requirements, and their knowledge is kept current or updated as necessary.

After the initial training on TCP III requirements has been provided to them by TFDA, the EU Notified Body Partners will become responsible to provide this training to their auditors.

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[7] While TFDA AAO audits are only performed once in three years, it is recognised, that the notified bodies framework requires audits to be performed on an annual base.

[8] The TFDA is currently planning to create a mechanism for manufacturers to request audit reports in English for use under TCP III.

[9] See footnote 1.

The EU Notified Body Partners may choose to utilise the following provisions when establishing their TCP III training and qualification program:

- Prior to becoming authorised to perform TCP III audits, an auditor shall receive the initial training on TCP III requirements with the content corresponding to the initial training on TCP III provided by TFDA, covering at least the following aspects:
    - Introduction to TCP III
    - General background on the TFDA medical device regulatory requirements
    - Information to be covered in TCP III audit reports
- When planning its on-going training programme for auditors authorised to perform TCP III audits, the EU Notified Body Partner shall ensure that it covers the following aspects, on an annual basis (as necessary):
    - Update on the TCP III and TFDA medical device regulatory requirements, based on any input from TFDA (as necessary)
    - Update on any actions resulting from review of TCP III audit reports (as necessary)

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