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Policy

PL–42

SNAS POLICY AND PROCEDURE ON THE ASSESSMENT OF CERTIFICATION BODIES CERTIFYING QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES ACCORDING TO STANDARD ISO 13485: 2016

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PURPOSE:

This document determines the SNAS policy and procedure on transition to the accreditation of certification bodies certifying quality management systems for medical devices according to ISO 13485:2016.

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1 POLICY

SNAS assesses the competence of certification bodies certifying the quality management systems for medical devices (QMS-MD) according to the requirements of the standard ISO/IEC 17021-1.

Revised version of standard ISO 13485: 2016 was published on March 2016.

SNAS in accordance with the resolution 2015 – 13 adopted on 29. IAF General Assembly (Resolution 2015 – 13 Agenda Item 10) on November 06, 2015, set the three-year transition period for implementation of the ISO 13485: 2016 which is ending on **March 01, 2019**. To this date, all accredited CBs, which meet the requirements of ISO/IEC 17021-1: 2015, have to demonstrate competence to perform certification QMS-MD according to standard ISO 13485: 2016. These requirements will be verified by SNAS during the planned or extraordinary assessment and in the case of their fulfilment, SNAS decides to issue the accreditation for certification QMS-MD according to standard ISO 13485: 2016.

2 ASSESSSMENT PROCEDURE AND TERMS

On the basis of the application for accreditation or reaccreditation SNAS will assess**,** the compliance with the requirements of ISO/IEC 17021-1: 2015 for performing of certification according to standard ISO 13485: 2016 from **March 01, 2017**.

CBs accredited for certification of QMS-MD according to standard EN ISO 13485: 2012 shall notify SNAS in written form **until June 30, 2017** at the latest, whether they have implemented in their management system the requirements for certification according to ISO 13485: 2016 or notify the date when they will implement these requirements; however, **no later than on February 28, 2018**. During planned assessment (surveillance) SNAS will verify the fulfilment of requirements for certification according to ISO 13485: 2016. CBs can also apply for an extraordinary assessment. All assessments for verification of implementation of the requirements for certification according to ISO 13485: 2016 shall be carried out until **October 19, 2018**, at the latest.

The CBs accredited for certification of QMS-MD must demonstrate the readiness for the certification according to the standard ISO 13485: 2016 within **December 21, 2018** and SNAS, will decide to issue the accreditation for QMS-MD certification according to ISO 13485: 2016 **no later than February 28, 2019**.

The findings from the assessments will be classified in accordance with the system published by SNAS and they must be resolved within a period according to the Act. No. 505/2009 Coll. on the accreditation of the conformity assessment bodies (including amendments to certain acts), as amended, but not later than two months after they were identified and recorded.

Notes: Certificates of accreditation issued during the transitional period will include two versions of the standard, i.e. EN ISO 13485: 2012 and ISO 13485: 2016. Certificates of accreditation issued for QMS-MD certification according to EN ISO 13485: 2012 will be canceled on February 28, 2019.
Certificates issued during the transitional period in accordance with EN ISO 13485: 2012 must be of limited validity only until the end of the transitional period, i.e. to March 01, 2019.

3 RELATED DOCUMENTS

ISO/IEC 17011: 2004 Conformity assessment. General requirements on the accreditation bodies accrediting the conformity assessment bodies
ISO/IEC 17021-1: 2015 Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements
ISO 13485: 2016 Medical devices. Quality management systems. Requirements for regulatory purposes
Act. No. 505/2009 Coll. on the accreditation of conformity assessment bodies (including amendments to certain acts), as amended