



National Accreditation Scheme

Transition Policy from MSZ EN ISO 13485:2012 to MSZ EN ISO 13485:2016

NAR-34

1st edition

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Introduction

The purpose of this policy is to describe how the accreditation system of the National Accreditation Authority (hereinafter referred to as NAH) and accredited certification bodies registered with NAH shift from MSZ EN ISO 13485:2012 to MSZ EN ISO 13485:2016.

1. International requirements

In IAF Resolution 2015-13, the International Organisation for Standardisation (ISO) stipulated a period of 3 years for transition from ISO 13485:2012 to ISO 13485:2016 from the publication date of the standard. According to the document, quality management system (QMS) certificates issued in accordance with ISO 13485:2003 (MSZ EN ISO 13485:2012) are valid for 3 years from the date of publication of ISO 13485:2016.

ISO 13485:2016 was published on 01 March 2016; accordingly, QMS certificates issued under ISO 13485:2003 (MSZ EN ISO 13485:2012) to medical device manufacturers remain valid until 28 February 2019. As from 01 March 2019, certificates issued under ISO 13485:2003 (MSZ EN ISO 13485:2012) will cease to be effective.

A certification body can prove compliance of its certification activities with MSZ EN ISO 13485:2016 within the scope of a scheduled accreditation procedure; annual surveillance visits; or unscheduled surveillance visits.

As from 01 March 2019, accredited certification bodies can only issue certificates under ISO 13485:2016 (MSZ EN ISO 13485:2016).

2. Rules of application

2.1.1 In order to ensure transition by accredited QMS certification bodies by the required deadline, NAH has determined the following deadlines for the planning of evaluation processes:

- Applications for accreditation and surveillance related to certification under MSZ EN ISO 13485:2016 will be admitted by NAH from 01 April 2016.
- Certification bodies can request assessment of compliance within the scope of unscheduled surveillance audits, which requests will be admitted by NAH between 01 October 2016 and 01 September 2018.
- Certification bodies have until 31 December 2017 to submit applications for accreditation and surveillance audits under MSZ EN ISO 13485:2012.
- As from 01 January 2018, NAH will only admit applications under MSZ EN ISO 13485:2016.
- As of 01 March 2019, NAH will withdraw accredited statuses proving compliance of certification activities with MSZ EN ISO 13485:2012 and granted earlier with a validity date falling after 01 March 2018.
- In the event of failure to meet the above deadlines, NAH will not be in a position to ensure that certification bodies fulfil MSZ EN ISO 13485:2016 accreditation requirements for QMS certification by the deadline set by IAF.

2.1.2 NAH will evaluate compliance of transition by way of document reviews, local visits and surveillance audits applied in combination.

2.2 The tasks of certification bodies for the transition period

For NAH to be able to plan a programme for accrediting transition to MSZ EN ISO 13485:2016 and thus to ensure that accredited transition processes and their conditions are in place and in line with certification bodies' plans, certification bodies must submit their schedules of transition to certification under MSZ EN ISO 13485:2016 to the NAH Office by 01 October 2016.

When putting together transition schedules, the following must be borne in mind:

- preparation of internal staff and auditors; competency evaluation; documented verification of preparedness;
- method to notify existing and future clients concerning the transition period and requirements;
- overview of auditing and certification activities over time and their scheduling;
- overview of the certification period and the transition cycle;
- time scheduling of certification decisions necessary for updating certificates.

3. Closing provisions

3.1 This policy is issued by NAH's General Director by way of General Director's Instruction No. 21/2016.

3.2 This General Director's Instruction will take effect as of 22 August 2016 and expire on 01 March 2019.

3.3 This General Director's Instruction will be deemed to be published by appearance on NAH's website (www.nah.gov.hu).