TECHNICAL REPORT

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Guidance on transition periods for standards developed by ISO/TC 84 — Devices for administration of medicinal products and catheters

Directives relatives aux périodes de transition concernant les normes développées par l'ISO/TC 84 — Dispositifs d'administration de produits médicinaux et cathéters

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

Introduction

This Technical Report outlines an ISO/TC 84 recommended transition period for newly published standards. It describes the recommended plan and the rationale for transitioning from "old versions" or "outdated" standards, which have been updated or replaced by new ISO/TC 84 standards. It addresses the concepts of "Grandfathering" and "Transition Periods" relative to compliance requirements with new standards.

When new International Standards are issued, the standard is valid from the date of publication. When new versions of existing International Standards are issued, the new standard is valid from the date of publication and the previous version of the standard is withdrawn. In certain cases, the previous version can still be valid for a certain period of time.

As a new standard does not specify any transition period, this report provides guidance on code of conduct in relation to implementing standards in manufacturing medical devices covered by ISO/TC 84 standards.

New or revised standards might influence both development of new products or need for changes of marketed devices. Both issues are addressed in this report.

The intent of the transition period is to allow a reasonable amount of time for the development of the resources and test method/validation and documentation time to meet the new requirements and to fulfil the entire approval process.

The transition period also includes sufficient time for the manufacturer to work with a Notified Body (and in turn, Competent Authorities) to approve this change.

NOTE There can be legal or regulatory requirements that take precedence over the recommendations in this Technical Report.

Guidance on transition periods for standards developed by ISO/TC 84 — Devices for administration of medicinal products and catheters

1 Scope

This Technical Report outlines the recommended transition plans for all the TC 84 standards:

— Needle-based Injection systems [ISO 11608 (all parts)];

— Sharps Injury Protection (ISO 23908);

— Sharps Containers (ISO 23907),

— Aerosol Drug Delivery Devices (ISO 20072);

— Needle-free injection systems (ISO 21649);

— Syringes [ISO 7886 (all parts), ISO 8537, ISO 9626];

— Needles (ISO 6009, ISO 7864);

— Intravascular Catheters and Ports [ISO 10555 (all parts), ISO 11070].

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
grandfathering
acceptance of no need for changes to a marketed device that has exhibited no safety or performance issues, without meeting the latest version of an ISO/TC 84 standard

2.2
transition period
timeframe from the date of publication of a new ISO/TC 84 standard to when a manufacturer should no longer claim compliance with a previous version of the standard when marketing a new device or a device with a significant design change

2.3
significant design change
modification of the product, which either modifies essential performance and/or introduces new risks that need to be assessed

3 Recommendations for implementing ISO/TC 84 standards

3.1 Marketed devices (Grandfathering)

A marketed device does not need to meet the requirements of a new or revised ISO/TC 84 standard. This is referred to as the “grandfather” clause, or “grandfathered” devices.

In cases where:

a) sufficient post-market safety and quality data exist and demonstrate that performance of the devices is acceptable in relation to the issues addressed in the new standards, and

b) a risk assessment is updated at least annually showing no need for further risk control (see ISO 14971:2007, definition 2.19),

the grandfathering concept applies.

In cases where significant design changes to the marketed product are made, the grandfathering concept should not be applied and it is recommended that a design verification is performed in accordance with the latest version of the ISO/TC 84 standard.

3.2 Non-marketed devices

It is recommended that non-marketed devices are designed to meet the requirements of the latest edition of the applicable ISO/TC 84 standards. However, this will not be possible in all cases and it is recommended that new-marketed devices comply with the new standard no later than three years after its publication. Beyond that point, a Notified Body or regulator should not accept a manufacturer's desire to release new products referring to the previous version of the applicable ISO/TC 84 standard.

3.3 Rationale for the transition period

The rationale for this transition period is to enable:

— a marketed device, which may not meet the latest version of applicable ISO/TC 84 standards, to nonetheless stay on the market, as long as the conditions in 3.1 are met;

— non-marketed devices to be released to the market without fulfilling the requirements of newly published ISO/TC 84 standards.

Bibliography

[1] ISO 6009, *Hypodermic needles for single use — Colour coding for identification*

[2] ISO 7864, *Sterile hypodermic needles for single use*

[3] ISO 7886 (all parts), *Sterile hypodermic syringes for single use*

[4] ISO 8537, *Sterile single-use syringes, with or without needle, for insulin*

[5] ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

[6] ISO 10555 (all parts), *Intravascular catheters — Sterile and single-use catheters*

[7] ISO 11070, *Sterile single-use intravascular introducers, dilators and guidewires*

[8] ISO 11608 (all parts), *Needle-based injection systems for medical use — Requirements and test methods*

[9] ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

[10] ISO 20072, *Aerosol drug delivery device design verification — Requirements and test methods*

[11] ISO 21649, *Needle-free injectors for medical use — Requirements and test methods*

[12] ISO 23907, *Sharps injury protection — Requirements and test methods — Sharps containers*

[13] ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*