
**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 médicaux et cathéters*

Sample Document

get full document from standards.iteh.ai



Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Terms and definitions	1
3 Recommendations for implementing ISO/TC 84 standards	1
3.1 Marketed devices (Grandfathering)	1
3.2 Non-marketed devices	2
3.3 Rationale for the transition period	2
Bibliography	3

Sample Document

get full document from standards.iteh.ai

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*.

get full document from standards.iteh.ai

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.

get full document from standards.iteh.ai