Change summary for ISO 11135:2014, Sterilization of health care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices

Approved 5 June 2016 by
Association for the Advancement of Medical Instrumentation

Abstract: Provides summary of differences between the new 2014 version and the 2007 version of ISO 11135. Provides end users with a quick reference when evaluating and implementing the 2014 version of ISO 11135 in their facilities.

Keywords: bioburden, endotoxin, guidance, load, parameter, product, qualification, requirement, specification

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633

Printed in the United States of America

ISBN 1–57020–614-7

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Association for the Advancement of Medical Instrumentation

AAMI Industrial Ethylene Oxide Sterilization Working Group

This Technical Information Report was developed by the AAMI Industrial Ethylene Oxide Sterilization Working Group. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

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Introduction: Need for this AAMI TIR

ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices* has now replaced the previous version of this standard, ISO 11135-1:2007, and it accompanying guidance document, ISO 11135-2:2008.

The purpose of this document is to provide a summary of differences between the new 2014 version and the 2007 version of this standard. The intent is to provide end users with a quick reference when evaluating and implementing the 2014 version of ISO 11135 in their facilities. The document has been created and reviewed by AAMI Working Group 1, Industrial Ethylene Oxide Sterilization. However, it should be noted that this document is a guidance summary only, and should not be considered a complete and definitive record of all changes. Final assessment of the changes, and possible impacts of these changes, is the responsibility of the end user.

The first column of the table references the clause in ISO 11135:2014, the second column provides a description of the change from the 2007 version to the 2014 version, and the 3rd column provides an opinion on the possible impact of the change.