Technical Information Report

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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

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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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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 or 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.

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Clause from 11135:2014	Description of the Change	Rationale and Potential Impact
SECTION 1 - Scope		
General	Combined all requirements and guidance into a single document, guidance is found in Annexes C and D.	Better clarification of guidance to each specific clause of the requirements and less conflict in guidance.
General	Added specific information that is applicable to EO sterilization in Health care facilities.	For HCF that are required to follow ISO 11135 it provides more detail of how to meet the requirements or the intent of the requirement.
1.1 Inclusions	Specifies requirements for both industrial and health care facility settings.	Provides more clarification for health care facility settings.
1.1 Note 1	Describes similarities and major differences between industrial and health care facility settings.	Provides more clarification for health care facility settings.
1.1 Note 2	Describes primary functions of industrial and health care facility settings.	None.
1.1 Note 3	Sterilization of medical devices from virgin material. Reusable medical devices and new devices in health care settings – provides information on additional challenges.	Provides more information for health care facility settings.
1.1 Note 4	Benefits of EO gas and its mixtures.	None.
1.1 Note 5	Clarifies that the standard provides guidance and requirements that can be applied to health care products.	None.