ANSI/AAMI/ISO 13408-6:2005
Aseptic processing of health care products — Part 6: Isolator systems

Amendment 1

Developed by
Association for the Advancement of Medical Instrumentation

Approved 11 March 2013 by:
American National Standards Institute, Inc.

Abstract: Updates references, modifies a number of definitions and informative notes, introduces new requirements, and updates the Bibliography.

Keywords: sterilization, aseptic, isolator

Documents
Document Sharing Hub

Full document details: ANSI AAMI ISO 13408-6-2005 A1-2013

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at www.aami.org.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

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

© 2013 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-525-1067.

Printed in the United States of America

ISBN 1-57020-331-8

Documents
Document Sharing Hub

Full document details: ANSI AAMI ISO 13408-6-2005 A1-2013

Contents

Page

Committee representation ..... **iv**
Background on AAMI adoption of ISO 13408-1:2008 Amd 1 ..... **vi**
Foreword ..... **vii**
Amendment **1**

Documents
Document Sharing Hub

Full document details: ANSI AAMI ISO 13408-6-2005 A1-2013

Committee representation

Association for the Advancement of Medical Instrumentation

Sterilization Standards Committee

This AAMI Standard was developed by the AAMI Aseptic Processing Working Group, under the auspices of the AAMI Sterilization Standards Committee.

At the time this document was published, the **AAMI Aseptic Processing Working Group** had the following members:

Cochairs:
Thomas J. Arista, FDA/CDRH
Robert P Tomaselli, Johnson & Johnson

Members:
Thomas J. Arista, FDA/CDRH
Charles Cogdill, Covidien
Steven J. Elliot, NAMSA
Kimbrell Darnell, CR Bard
Susan Elwell, Medtronic Inc. WHQ Campus
Gordon M. Ely, WuXi AppTec Inc
Rosanna Fardo, RN BSN CIC CHSP, Department of Veterans Affairs
Robert Fry, Baxter Healthcare Corporation
Naomi Gamm, St Jude Medical Inc.
Deborah A. Havlik, Hospira Worldwide Inc.
Rachel Hill, CareFusion
Roland C. Kippenhan, Medivators Inc.
James P. Kulla, BS MS, LexaMed Ltd
Carol M. Lampe, JM Hansen & Associates
Daniel S. Larrimore, Alcon Laboratories Inc.
Christine Loshbaugh, Edwards LifeSciences
Lisa N. Macdonald, Becton Dickinson & Company
Tonya M. Morris, BS, Nelson Laboratories Inc.
Janet M. Prust, 3M Healthcare
Manuel Saavedra, Jr., Kimberly-Clark Corporation
David SIlor, Zimmer Inc.
Robert P Tomaselli, Johnson & Johnson

Alternates:
David J. Brodersen, Covidien
Trabue D. Bryans, WuXi AppTec Inc.
Jonathan Bull, Becton Dickinson & Company
Alyce Dobie, Bausch & Lomb
David A. Dominguez, CareFusion
Joyce M. Hansen, Johnson & Johnson
Suzanne Leung, 3M Healthcare
Jeff Martin, Alcon Laboratories Inc.
Elaine S. Mayhall, PhD, FDA/CDRH
Terry Mistalski, Medivators Inc.
Emily Mitzel, MS, Nelson Laboratories Inc.
Robert R. Reich, BS MS, LexaMed Ltd
Tyrone S Rouse, Kimberly-Clark Corporation
Mike Sadowski, Baxter Healthcare Corporation
Dennis L. Wildes, St Jude Medical Inc.
Cheryl Work, Becton Dickinson & Company

NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

Cochairs:
Victoria M. Hitchins, PhD, FDA/CDRH
Michael H. Scholla, Ph.D., Dupont Protection Technologies

Documents Document Sharing Hub
Full document details: ANSI AAMI ISO 13408-6-2005 A1-2013