Technical Information Report

AAMI TIR105: 2020

Risk management guidance for combination products

AAMI
Advancing Safety in Health Technology

Risk management guidance for combination products

Approved 10 September 2020 by
AAMI

Abstract: This technical information report provides recommendations and processes to assist manufacturers of combination products in identifying hazards associated with the combination product, assessing associated risks, selecting options for controlling these risks, and monitoring the effectiveness of the implemented controls.

Keywords: combination products, risk management

AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All 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.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-770-9

Contents

Tables

Figures

Committee representation

Association for the Advancement of Medical Instrumentation

Combination Products Committee

This technical information report (TIR) was developed by the AAMI Combination Products Committee. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Combination Products Committee** had the following members:

Cochairs:
Jon Cammack
John Weiner

Members:
Kent Abrahamson, AbbVie
Ed Bills, ELB Consulting
Steve Binion, PhD MBA
Melissa Burns, FDA/OCP
Jon Cammack, Nevakar, Inc.
Stephanie Del Paine, Cook Research Inc
Gordon Ely, LexaMed Ltd.
Bryant Foster, Research Collective
Sunny Gill, Combination Product Partners
Richard Hall, Eli Lilly & Company
Byron Hayes, WL Gore & Associates Inc
Steven Hertz, FDA/CDER
Stephen Holcroft, Johnson & Johnson
Marcia Howard, Consumer Healthcare Products Association
Erin Keith, FDA/CDRH
Mark Leahey, Medical Device Manufacturers Association
Lee Leichter, P/L Biomedical
Rich Levy, PhD, PDA
Kathleen Miller, Amgen
Jim Niederecker, Abbott Laboratories
Andrea Ruth, ALR Consulting
Michael Schousboe, Novo Nordisk
Mutahar Shamsi, Deloitte
Lana Shiu, Amgen Inc
Dave Sterry, Clinical and Laboratory Standards Institute (CLSI)
Ashland Sutherland, Design Science Consulting
Deborah Thomas, Sanofi
Nicole Trudel, FDA/CBER
John Weiner, FDA/OCP

Alternates:
Jonathan Amaya-Hodges, Biogen
Stan Mastrangelo, ELB Consulting
Thomas Feldsien, Abbvie
Dhaval Gaglani, FDA/CDER
Kalub Hahne, Cook Research Inc
Reade Harpham, Priority Designs Inc.
Christina Laskar, Sanofi-Aventis
Sara Waxberg McNew, Design Science Consulting
Thinh Nguyen, FDA/OCP
Nancy Regulski, Johnson & Johnson-Skillman
Christine Schumard-Sauer, Abbott Laboratories
Melissa Torres, FDA/CDRH

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