

Technical Information Report

ANSI/AAMI/ IEC TIR80001- 2-4:2012

Application of risk
management for IT-
networks incorporating
medical devices — Part 2-4:
Application guidance —
General implementation
guidance for healthcare
delivery organizations

Application of risk management for IT-networks incorporating medical devices — Part 2-4: Application guidance — General implementation guidance for healthcare delivery organizations

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Association for the Advancement of Medical Instrumentation

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Abstract: This helps a RESPONSIBLE ORGANIZATION through the key decisions and steps required to establish a RISK MANAGEMENT framework, before the organization embarks on a detailed RISK ASSESSMENT of an individual instance of a MEDICAL IT-NETWORK. This Technical Report is addressed to all Healthcare Delivery Organizations. A Healthcare Delivery Organization includes hospitals, doctors' offices, community care homes and clinics. It identifies a series of decision points to steer the RESPONSIBLE ORGANIZATION through the process of understanding the MEDICAL IT-NETWORK context and identifying any organizational changes required before undertaking the RISK MANAGEMENT PROCESS identified in IEC 80001-1.

Keywords: HDO, IT-networks, risk management

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Contents

Page

Glossary of equivalent standards.....	v
Committee representation.....	vi
Background of AAMI adoption of IEC/TR 80001-2-4:2012.....	vii
FOREWORD	viii
INTRODUCTION	x
1 Scope	1
1.1 Purpose	1
1.2 HEALTHCARE DELIVERY ORGANIZATION.....	1
1.3 Field of application.....	1
1.4 Prerequisites.....	1
2 Normative references	2
3 Terms and definitions.....	2
4 RESPONSIBLE ORGANIZATION	7
4.1 TOP MANAGEMENT responsibilities	7
4.2 Small RESPONSIBLE ORGANIZATION – points to consider.....	7
4.3 Large RESPONSIBLE ORGANIZATION – points to consider	8
5 RISK MANAGEMENT implementation steps.....	8
5.1 Overview.....	8
5.2 Determine the clinical context within which the healthcare provision is made	9
5.3 Establish underlying RISK framework	9
5.4 Determining and understanding a MEDICAL IT-NETWORK	10
5.4.1 Performing a RISK ASSESSMENT	10
5.4.2 MEDICAL IT-NETWORK configuration	10
5.4.3 Development status of MEDICAL IT-NETWORK	13
5.4.4 Manufacturer identification	13
5.4.5 External IT and bio-medical engineering support.....	14
6 RESPONSIBILITY AGREEMENTS.....	14
Annex A (informative) MEDICAL IT-NETWORK configuration examples	15
Bibliography	20
 Figure A.1 – Standalone MEDICAL IT-NETWORK outside the scope of IEC 80001-1	16
Figure A.2 – Standalone MEDICAL IT-NETWORK	17
Figure A.3 – Collaborative MEDICAL IT-NETWORK.....	18
Figure A.4 – Centralized MEDICAL IT-NETWORK	19

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Information Technology Working Group

The adoption of IEC/TR 80001-2-4 as a new AAMI/IEC Technical Information Report was initiated by the AAMI Information Technology Working Group. U.S. cochairs of AAMI/SM/WG 02, William Hintz of Medtronic, Inc. and Richard Schrenker of Massachusetts General Hospital, played an active part in developing the IEC Technical Report.

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

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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.

Background of ANSI/AAMI adoption of IEC/TR 80001-2-4:2012

As indicated in the foreword to the main body of this document (page vii), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this technical report.

International technical report IEC/TR 80001-2-4:2012 was developed jointly by Sub-Committee IEC/SC 62A, Common aspects of electrical equipment used in medical practice and ISO/TC 215, Health informatics, to define the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security.

U.S. participation in this IEC SC is organized through the U.S. Technical Advisory Group for IEC/SC 62A administered by the Advanced Medical Technology Association (AdvaMed) on behalf of the American National Standards Institute. AAMI administers the International Secretariat for IEC/SC 62A on behalf of the United States, and U.S. experts made a considerable contribution to this International Technical Report.

AAMI encourages its committees to harmonize their work with International Standards in the area of risk management of information technology as it relates to medical devices. The AAMI Information Technology Working Group together with the U.S. Technical Advisory Group for IEC/SC 62A, reviewed IEC/TR 80001-2-4 to formulate the U.S. position and comments while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. As the U.S. Technical Advisory Group for IEC/SC 62A, AdvaMed granted AAMI permission to consider adoption of IEC/TR 80001-2-4 as a new AAMI Technical Information Report. Following AAMI procedures, the AAMI Information Technology Working Group voted to adopt the IEC technical report as written.

AAMI (and ANSI) have adopted other IEC and ISO documents. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

The concepts incorporated in this technical information report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

As used within the context of this document, "should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the technical information report. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Dr. Suite 301, Arlington, VA 22203-1633.

NOTE- Beginning with the IEC foreword on page x, this AAMI Technical Information Report is identical to IEC/TR 80001-2-4:2012.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

APPLICATION OF RISK MANAGEMENT FOR IT-NETWORKS INCORPORATING MEDICAL DEVICES –

Part 2-4: Application guidance – General implementation guidance for healthcare delivery organizations

FOREWORD

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IEC 80001-2-4, which is a technical report, has been prepared by a Joint Working Group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice and ISO technical committee 215: Health informatics.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/818/DTR	62A/835/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table. In ISO, the technical report has been approved by 15 P-members out of 16 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

Terms used throughout this technical report that have been defined in Clause 3 appear in SMALL CAPITALS.

A list of all parts of the IEC 80001 series, published under the general title *Application of risk management for IT-networks incorporating medical devices*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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