Technical Information Report

ANSI/AAMI/ IEC TIR80001-2-3:2012

Application of risk management for IT-networks incorporating medical devices — Part 2-3: Guidance for wireless networks

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An ANSI Technical Report prepared by AAMI ANSI/AAMI/IEC TIR80001-2-3:2012

Application of risk management for IT-networks incorporating medical devices — Part 2-3: Guidance for wireless networks

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Association for the Advancement of Medical Instrumentation

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American National Standards Institute, Inc.

Abstract: Supports the Healthcare Delivery Organizations (HDO) in the risk management of medical IT-networks that incorporate one or more wireless links.

Keywords: medical device, risk management, information technology, interoperability, wireless networks

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 IEC 60601-1:2005/A1:2012 IEC Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005/(R)2012 ANSI/AAMI ES60601-1:2005/A1:2012 ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012 (amdt) ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012	Major technical variations A1 identical C1 identical to Corrigendum 1 & 2 A2 applies to AAMI, only
IEC 60601-1-11:2010	ANSI/AAMI HA60601-1-11:2011	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007/(R)2012	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2012	ANSI/AAMI/IEC 60601-2-16:2012	Identical
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-25:2011	ANSI/AAMI/IEC 60601-2-25:2011	Identical
IEC 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
IEC 60601-2-47:2012	ANSI/AAMI/IEC 60601-2-47:2012	Identical
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 61289:2011	ANSI/AAMI/IEC TIR61289:2011	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC 62366:2007	ANSI/AAMI/IEC 62366:2007	Identical
IEC 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	Identical
IEC/TR 80001-2-1:2012	ANSI/AAMI/IEC 80001-2-1:2012	Identical
IEC/TR 80001-2-2:2012	ANSI/AAMI/IEC 80001-2-2:2012	Identical
IEC/TR 80001-2-3:2012	ANSI/AAMI/IEC 80001-2-3:2012	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009 and Amendment 1:2012	ANSI/AAMI/ISO 7199:2009 and Amendment 1:2012	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical

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International designation	U.S. designation	Equivalency
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008/(R)2012	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2012	ANSI/AAMI/ISO 10993-12:2012	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006/(R)2011	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2012	ANSI/AAMI/ISO 11137-2:2012	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007/(R)2012	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007/(R)2012	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007/(R)2012	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11658:2012	ANSI/AAMI/ISO 11658:2012	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11633:2009	Identical
ISO 11737-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO/TS 12417:2011	ANSI/AAMI/ISO TIR12417:2011	Identical
ISO 13022:2012	ANSI/AAMI/ISO 13022:2012	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008/(R)2011	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical

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ISO 13408-7:2012	ANSI/AAMI/ISO 13408-7:2012	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 13958:2009	ANSI/AAMI/ISO 13958:2009	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959:2009	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	Identical
ISO 14160:2011	ANSI/AAMI/ISO 14160:2011	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007/(R)2010	Identical
ISO 15223-1:2012	ANSI/AAMI/ISO 15223-1:2012	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009 and A2:2012	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006/(R)2010	Identical
ISO/TS 19218-1:2011	ANSI/AAMI/ISO TIR19218:2011	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO/TR 22442-4:2010	ANSI/AAMI/ISO TIR22442-4:2010	Identical
ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
ISO/TS 23810:2012	ANSI/AAMI/ISO TIR23810:2012	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 25539-3:2011	ANSI/AAMI/ISO 25539-3:2011	Identical
ISO 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27185:2012	ANSI/AAMI/ISO 27185:2012	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

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Association for the Advancement of Medical Instrumentation

Information Technology Committee

The adoption of IEC/TR 80001-2-3 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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Background of ANSI/AAMI adoption of IEC/TR 80001-2-3:2012

As indicated in the foreword to the main body of this document (page xii), 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 80001-2-3:2012 was developed jointly by Subcommittee 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 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 80001-2-3 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 80001-2-3 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 xii, this AAMI Technical Information Report is identical to IEC/TR 80001-2-3:2012.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 2-3: Guidance for wireless networks

FOREWORD

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IEC 80001-2-3, 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.

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

Enquiry draft	Report on voting
62A/784/DTR	62A/804/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.

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.

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

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

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INTRODUCTION

0.1 Background

Wireless communications has been a key technology enabling the connectivity of MEDICAL DEVICES for decades. Early examples of the use of wireless technologies and MEDICAL DEVICES include ambulatory cardiac monitoring systems in hospitals and telemetry systems used by paramedics over wide area wireless networks. While these solutions were based on proprietary technology, the advent of off-the-shelf standards-based approaches has resulted in increasingly ubiquitous wireless communications systems both indoors and outdoors. These provide and enable compelling and varied use cases for connection between MEDICAL DEVICES and information systems. Wireless technology has great benefits; however, as with any technology, certain RISKS are introduced that can affect the three KEY PROPERTIES of SAFETY, EFFECTIVENESS, and DATA AND SYSTEMS SECURITY. This document will review the challenges associated with wireless technologies and provide guidance regarding the safe, effective, and secure use of MEDICAL DEVICES on a wireless MEDICAL IT-NETWORK. This is done in a framework that follows the RISK MANAGEMENT PROCESS as defined by the IEC 80001-1 standard.

The targeted audience for this technical report is the HDO IT department, biomedical and clinical engineering departments, risk managers, and the people responsible for design and operation of the wireless IT network.

For the purposes of this technical report, “should” is used to indicate that amongst several possibilities to meet a requirement, one is recommended as being particularly suitable without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required. This term is not to be interpreted as indicating requirement.

0.2 Organization of the technical report

This technical report is divided into five main clauses, a bibliography and two annexes. Clause 4 provides an overview of a wireless MEDICAL IT-NETWORK and reviews varying types of wireless technologies and their applicability to healthcare. The next three clauses focus on the high level steps involved with understanding and defining the networking performance characteristics, requirements and associated RISK CONTROL measures regarding the creation a MEDICAL IT-NETWORK, namely:

a) planning and design;

b) deployment and implementation; and

c) operational management.

Clause 8 provides general RISK CONTROL measures that might be applicable to an HDO's unique MEDICAL IT-NETWORK. Finally, a bibliography is included that lists references for further exploration. Annex A offers a table that suggests a mapping between MEDICAL DEVICE data types and associated networking QUALITY OF SERVICE priorities. Annex B is a checklist questionnaire for assistance in performing a RISK ANALYSIS.

0.3 Clinical functionality and use case

One of the fundamental concepts that this technical report emphasizes is that MEDICAL DEVICES have networking characteristics that are similar to other types of general purpose devices and applications; yet the repercussions of not properly designing and managing the network to ensure the SERVICE LEVEL AGREEMENT of the MEDICAL DEVICES could negatively impact clinical functionality. This can lead to erroneous diagnostics and/or missed treatment that can ultimately affect patient health outcome. In this technical report, clinical functionality and the clinical use case are interchangeable; they are a reference to the means by which a clinician (nurse, physician, etc.) performs their clinical duties across the wireless network, and includes the

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component of patient care and SAFETY. These are components in the overall context as it is referred to in the step-by-step technical report, IEC 80001-2-1, and this information is required for a complete RISK ANALYSIS. A typical example is a nurse who is remotely monitoring a patient from the nursing central station using a patient monitor at the bedside that is wirelessly connected to the network. The clinical functionality is the remote monitoring of a patient's health.

0.4 Wireless guidance and RISK MANAGEMENT

The wireless link between a patient and the remote clinician is now a component of the clinical functionality and may impact the KEY PROPERTIES of SAFETY and DATA AND SYSTEMS SECURITY. While the benefits of wireless access are well known and documented, typically the wireless link between a MEDICAL DEVICE and a clinician is more likely, or has a higher probability, of experiencing a loss of connectivity versus that of a wired connection. This is a motivation behind the creation and focus of this technical report.

Because the definitions of HAZARD, HAZARDOUS SITUATIONS, HARM and causes are use case specific to each HDO, this document should be used in conjunction with both the IEC 80001-1 and IEC/TR 80001-2-1 at a minimum.

Figure 1 provides an overview of the RISK MANAGEMENT aspect of this technical report. The column of boxes on the left of the figure is an overview (for this technical report's purpose) of the 10 steps of RISK MANAGEMENT as defined in the IEC/TR 80001-2-1. The center boxes show the steps of the RISK MANAGEMENT PROCESS that this technical report is focused on. They are the following in terms of the RISK MANAGEMENT PROCESS:

– The cause is an event that can turn a HAZARD into a HAZARDOUS SITUATION. Examples of causes in a wireless network are RF interference, wireless network misconfiguration, or networking device failure.

– A HAZARD associated in the context of wireless connectivity is the loss or impairment of connectivity in a medical system. This disruption in connectivity can negatively impact the ability of a MEDICAL DEVICE or clinical system to perform its intended function.

– A HAZARDOUS SITUATION is a circumstance in which the MEDICAL DEVICE or clinical functionality is exposed to a HAZARD. For example, a clinician is monitoring a patient at the nursing station (clinical functionality is remote monitoring). If RF interference *causes* the wireless network to be disabled (loss of connectivity is the HAZARD), then the patient is no longer being remotely monitored (HAZARDOUS SITUATION).

– The RISK CONTROL measures as used in this technical report are the steps taken to reduce the probability of the occurrence of a HAZARDOUS SITUATION (referred to as P1 in IEC/TR 80001-2-1), or the steps taken to reduce the probability of HARM once the HAZARDOUS SITUATION has occurred (referred to as P2 in IEC/TR 80001-2-1). A P1 RISK CONTROL measure example might be RF redundancy or networking change control procedures. A P2 RISK CONTROL measure example might be the sequence of actions that a nurse would take if notified that the connectivity is lost between a patient monitor and central station.

The majority of this technical report focuses on the design and RISK CONTROL measures associated with wireless technologies. However, and this is another motivation for engaging with the clinicians early in the planning phase, the role of the clinicians in mitigating against patient HARM should be clearly reviewed. In the example used in the bulleted steps above, the clinician might have a documented procedure to follow during network outages; when the network experiences loss of connectivity the clinician can follow a procedure where they need to attend to the patient directly.

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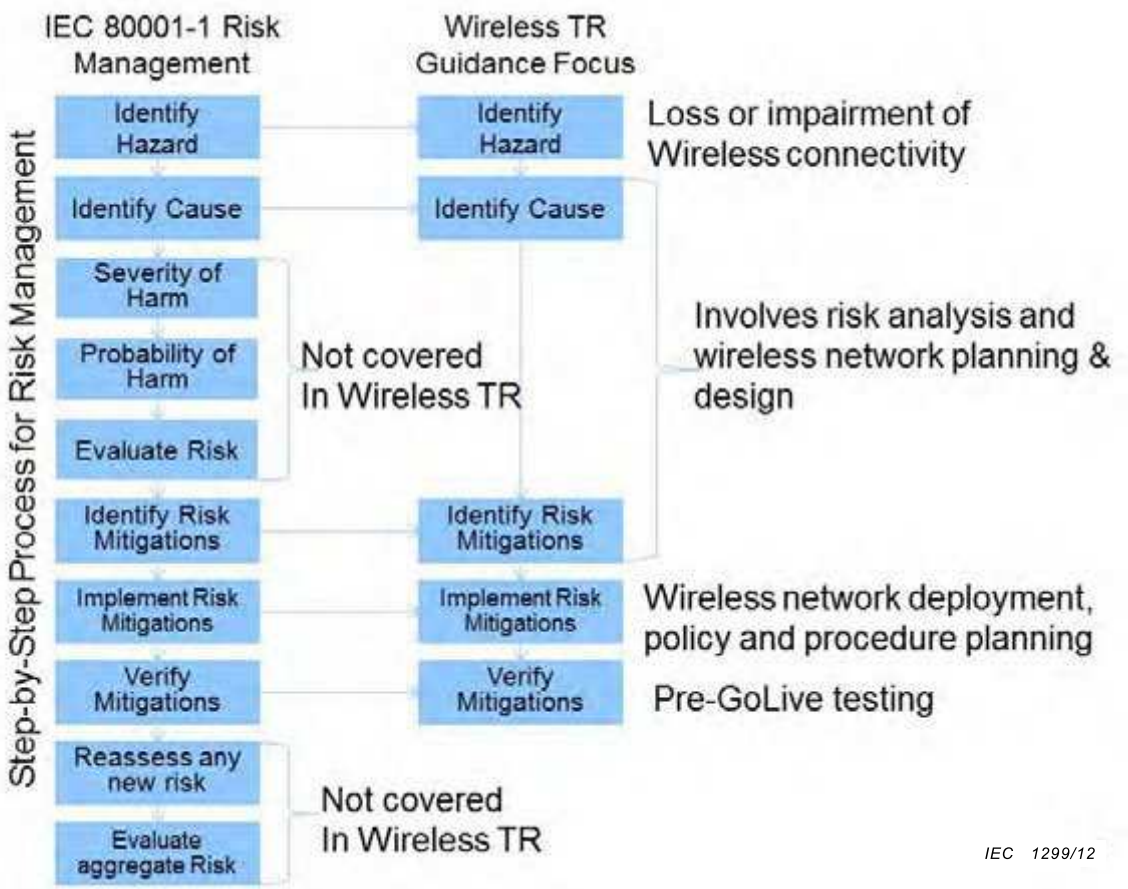


Figure 1 – Focus of technical report

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

Part 2-3: Guidance for wireless networks

1 Scope and object

1.1 Scope

This part of IEC 80001 supports the HDO in the RISK MANAGEMENT of MEDICAL IT-NETWORKS that incorporate one or more wireless links. The report provides technical background concerning wireless technology and examples of HAZARDS to be considered when wireless technology is used in MEDICAL IT-NETWORKS and suggests RISK CONTROL measures to reduce the probability of UNINTENDED CONSEQUENCES.

1.2 Objective

This Technical Report, as part of IEC 80001, considers the use of wirelessly networked MEDICAL DEVICES on a MEDICAL IT-NETWORK and offers practical techniques to address the unique RISK MANAGEMENT requirements of operating wirelessly enabled MEDICAL DEVICES in a safe, secure and effective manner.

This technical report is focused on wireless technologies from an agnostic viewpoint; however, there are particular wireless technologies that are predominant in HDOs (e.g. 802.11) and are discussed in more detail. Where appropriate, these differences are pointed out and discussed. In addition, while it does not focus on a single wireless technology, it is assumed that the attached wired infrastructure is an Ethernet-based IP network.

It is not the intent of this document to propose a regimented step-by-step PROCESS for implementing a wireless MEDICAL IT-NETWORK or mitigating the RISK associated with a particular wireless technology. There are many reasons which conspire against such an effort and chief among them are:

– There are many different wireless technologies available, each with their PHY, MAC and upper layer characteristics with varying degrees of control available to the HDO.
– Many wireless technologies are in an evolving stage of development and are still subject to frequent and significant changes.
– HDOs, depending on their needs, might utilize varying combinations of wireless technologies to meet their particular requirements. Each technology should require its own independent RISK ANALYSIS and RISK CONTROL measures that should be reviewed systemically (aggregate RISKS ANALYSIS).
– Each HDO will have their own unique clinical use cases and network topologies and will perform their own unique RISK ANALYSIS and management that will differ from other HDOs.

Instead, this technical report acknowledges a generalized or high level approach relative to a step-by-step PROCESS review that both inherently and intentionally considers HAZARDS, the causes leading to HAZARDOUS SITUATIONS, and RISK CONTROL measures. The general approach that this technical report follows is the following:

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