

# Technical Information Report

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

Application of risk  
management for IT-  
networks incorporating  
medical devices — Part 2-2:  
Guidance for the disclosure  
and communication of  
medical device security  
needs, risks and controls



# **Application of risk management for IT-networks incorporating medical devices — Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls**

Approved 20 August 2012 by  
**Association for the Advancement of Medical Instrumentation**

Approved 30 September 2012 by  
**American National Standards Institute, Inc.**

**Abstract:** Step-by-step guide to help in the application of risk management when creating or changing a medical IT-network.

**Keywords:** medical device, risk management, information technology, interoperability, IT-network

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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



<b>International designation</b>	<b>U.S. designation</b>	<b>Equivalency</b>
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 11663:2009	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

International designation	U.S. designation	Equivalency
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 TIR19218-1:2011	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

## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Information Technology Working Group

The adoption of IEC/TR 80001-2-2 as a new AAMI/IEC Technical Information Report was initiated by the AAMI Information Technology Working Group. U.S. cochair 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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Richard A. Schrenker, Massachusetts General Hospital
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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.

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

As indicated in the foreword to the main body of this document (page xi), 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 80001-2-2:2012 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 80001-2-2 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 80001-2-2 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.

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

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# INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

### Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls

#### FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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IEC 80001-2-2, which is a technical report, has been prepared 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/783/DTR	62A/807/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

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

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

**IMPORTANT – The 'color inside' logo on the cover page of this publication indicates that it contains colors which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a color printer.**

## INTRODUCTION

IEC 80001-1, which deals with the application of RISK MANAGEMENT to IT-networks incorporating medical devices, provides the roles, responsibilities and activities necessary for RISK MANAGEMENT. This technical report provides additional guidance in how SECURITY CAPABILITIES might be referenced (disclosed and discussed) in both the RISK MANAGEMENT PROCESS and stakeholder communications and agreements.

The informative set of common, high-level SECURITY CAPABILITIES presented here is intended to be the starting point for a security-centric discussion between vendor and purchaser or among a larger group of stakeholders involved in a MEDICAL DEVICE IT-NETWORK project. Scalability is possible across a range of different sized RESPONSIBLE ORGANIZATIONS as each evaluates RISK under the capabilities and decides what to include or not include according to its RISK tolerance and resource planning. This technical report might be used in the preparation of documentation designed to communicate product SECURITY CAPABILITIES and options. This documentation could be used by the RESPONSIBLE ORGANIZATION as input to their IEC 80001 PROCESS or to form the basis of RESPONSIBILITY AGREEMENTS among stakeholders. Other IEC-80001-1 technical reports will provide step-by-step guidance in the RISK MANAGEMENT PROCESS. Furthermore, the SECURITY CAPABILITIES encourage the disclosure of more detailed security controls – perhaps those specified in one or more security standards as followed by the RESPONSIBLE ORGANIZATION or the MEDICAL-DEVICE manufacturer (for example, ISO 27799:2008, ISO/IEC 27001:2005, ISO/IEC 27002:2005, ISO/IEC 27005:2011, the ISO 22600 series, the ISO 13606 series, and ISO/HL7 10781:2009, which covers the Electronic Health Record System Functional Model). This report remains agnostic as to the underlying controls framework; it only proposes a structure for the disclosure and communication among the RESPONSIBLE ORGANIZATION (here called the healthcare delivery organization – HDO), the MEDICAL DEVICE manufacturer (MDM) and the IT-vendor.

The capabilities outlined here comprise a disclosure set of controls which support the maintenance of confidentiality and the protection from malicious intrusion that might lead to compromises in integrity or system/data availability. Capabilities can be added to or further elaborated as the need arises. Controls are intended to protect both data and systems but special attention is given to the protection of both PRIVATE DATA and its subset called HEALTH DATA. Both of these special terms have been defined to carefully avoid any law-specific references (e.g., EC Sensitive Data or USA ePHI).





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

### **Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls**

#### **1 Scope**

This part of IEC 80001 creates a framework for the disclosure of security-related capabilities and RISKS necessary for managing the RISK in connecting MEDICAL DEVICES to IT-NETWORKS and for the security dialog that surrounds the IEC 80001-1 RISK MANAGEMENT of IT-NETWORK connection. This security report presents an informative set of common, high-level security-related capabilities useful in understanding the user needs, the type of security controls to be considered and the RISKS that lead to the controls. INTENDED USE and local factors determine which exact capabilities will be useful in the dialog about RISK.

The capability descriptions in this report are intended to supply:

- a) health delivery organizations (HDOs),
- b) MEDICAL DEVICE manufacturers (MDMs), and
- c) IT vendors

with a basis for discussing RISK and their respective roles and responsibilities toward its management. This discussion among the RISK partners serves as the basis for one or more RESPONSIBILITY AGREEMENTS as specified in IEC 80001-1.

The present report provides broad descriptions of the security-related capabilities with the intent that any particular device or use of a device will have to have at least one additional level of specification detail under each capability. This will often be site and application-specific and may invoke RISK and security controls standards as applicable.

At this introductory stage of IEC 80001-1 standardization, the SECURITY CAPABILITIES in this report provide a common, simple classification of security controls particularly suited to MEDICAL IT NETWORKS and the incorporated devices. The list is not intended to constitute or to support rigorous IT security standards-based controls and associated programs of certification and assurance such as might be found in other ISO standards (e.g., ISO/IEC 15408 with its Common Criteria for Information Technology Security Evaluation). The present report does not contain sufficient detail for exact specification of requirements in a request for proposal or product security disclosure sheet. However, the classification and structure can be used to organize such requirements with underlying detail sufficient for communication during the purchase and integration PROCESS for a MEDICAL DEVICE or IT equipment component. Again, this report is intended to act as a basis for discussion and agreement sufficient to initial integration project RISK MANAGEMENT. Additionally, security only exists in the context of the organizational security policies. Both:

- a) the security policies of the healthcare delivery organization (HDO), and

b) the product and services security policies of the MEDICAL DEVICE manufacturer (MDM)

are outside of the scope of this report. In addition, the Technical Report does not address clinical studies where there is a need for securing the selective disclosure of PRIVATE DATA or HEALTH DATA.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 80001-1:2010, *Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities*

## 3 Terms and definitions

### 3.1

#### DATA AND SYSTEMS SECURITY

operational state of a MEDICAL IT-NETWORK in which information assets (data and systems) are reasonably protected from degradation of confidentiality, integrity, and availability

[SOURCE: IEC 80001-1:2010, definition 2.5, modified — two notes integral to understanding the scope of the original definition have been deleted.]

### 3.2

#### EFFECTIVENESS

ability to produce the intended result for the patient and the RESPONSIBLE ORGANIZATION

[SOURCE: IEC 80001-1:2010, definition 2.6]

### 3.3

#### EVENT MANAGEMENT

PROCESS that ensures that all events that can or might negatively impact the operation of the IT-NETWORK are captured, assessed, and managed in a controlled manner

[SOURCE: IEC 80001-1:2010, definition 2.7]

### 3.4

#### HARM

physical injury or damage to the health of people, or damage to property or the environment, or reduction in EFFECTIVENESS, or breach of DATA AND SYSTEM SECURITY

[SOURCE: IEC 80001-1:2010, definition 2.8]

### 3.5

#### HAZARD

potential source of HARM

[SOURCE: IEC 80001-1:2010, definition 2.9]

**3.6****HAZARDOUS SITUATION**

circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: ISO 14971:2007, definition 2.4]

**3.7****HEALTH DATA**

PRIVATE DATA that indicates physical or mental health

Note 1 to entry: This generically defines PRIVATE DATA and its subset, HEALTH DATA, within this document to permit users of this document to adapt it easily to different privacy compliance laws and regulations. For example, in Europe, the requirements might be taken and references changed to "Personal Data" and "Sensitive Data"; in the USA, HEALTH DATA might be changed to "Protected Health Information (PHI)" while making adjustments to text as necessary.

**3.8****INTENDED USE****INTENDED PURPOSE**

use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the manufacturer

[SOURCE: IEC 80001-1:2010, definition 2.10]

**3.9****INTEROPERABILITY**

a property permitting diverse systems or components to work together for a specified purpose

[SOURCE: IEC 80001-1:2010, definition 2.11]

**3.10****IT-NETWORK****INFORMATION TECHNOLOGY NETWORK**

a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes

[SOURCE: IEC 80001-1:2010, definition 2.12, modified – the two notes to the original definition have not been retained.]

**3.11****KEY PROPERTIES**

three RISK managed characteristics (SAFETY, EFFECTIVENESS, and DATA AND SYSTEMS SECURITY) of MEDICAL IT-NETWORKS

[SOURCE: IEC 80001-1:2010, definition 2.13]

**3.12****MEDICAL DEVICE**

means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

- a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of MEDICAL DEVICES,
- providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Note 1 to entry: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some *in vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations.

Note 2 to entry: Products which may be considered to be MEDICAL DEVICES in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people;
- devices for the treatment/diagnosis of diseases and injuries in animals;
- accessories for MEDICAL DEVICES (see Note 3);
- disinfection substances;
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

Note 3 to entry: Accessories intended specifically by manufacturers to be used together with a 'parent' MEDICAL DEVICE to enable that MEDICAL DEVICE to achieve its INTENDED PURPOSE should be subject to the same GHTF procedures as apply to the MEDICAL DEVICE itself. For example, an accessory will be classified as though it is a MEDICAL DEVICE in its own right. This may result in the accessory having a different classification than the 'parent' device.

Note 4 to entry: Components to MEDICAL DEVICES are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a 'medical device'.

[SOURCE: IEC 80001-1:2010, definition 2.14]

### 3.13

#### **MEDICAL IT-NETWORK**

IT-NETWORK that incorporates at least one MEDICAL DEVICE

[SOURCE: IEC 80001-1:2010, definition 2.16]

### 3.14

#### **OPERATOR**

person handling equipment

[SOURCE: IEC 80001-1:2010, definition 2.18]

### 3.15

#### **PRIVATE DATA**

any information relating to an identified or identifiable person

### **3.16**

#### **PROCESS**

set of interrelated or interacting activities which transforms inputs into outputs

[SOURCE: IEC 80001-1:2010, definition 2.19]

### **3.17**

#### **RESIDUAL RISK**

RISK remaining after RISK CONTROL measures have been taken

[SOURCE: IEC 80001-1:2010, definition 2.20]

### **3.18**

#### **RESPONSIBILITY AGREEMENT**

one or more documents that together fully define the responsibilities of all relevant stakeholders

[SOURCE: IEC 80001-1:2010, definition 2.21, modified – a note to the original definition, containing examples, has not been retained.]

### **3.19**

#### **RESPONSIBLE ORGANIZATION**

entity accountable for the use and maintenance of a MEDICAL IT-NETWORK

Note 1 to entry: In this Technical Report, to avoid confusion associated with the notion of security responsibility, the RESPONSIBLE ORGANIZATION of IEC 80001-1 is given the name healthcare delivery organization (HDO).

[SOURCE: IEC 80001-1:2010, definition 2.22, modified — a note to the original definition, containing examples, has not been retained; a note to entry has been added.]

### **3.20**

#### **RISK**

combination of the probability of occurrence of HARM and the severity of that HARM

[SOURCE: IEC 80001-1:2010, definition 2.23]

### **3.21**

#### **RISK ANALYSIS**

systematic use of available information to identify HAZARDS and to estimate the RISK

[SOURCE: IEC 80001-1:2010, definition 2.24]

### **3.22**

#### **RISK ASSESSMENT**

overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[SOURCE: IEC 80001-1:2010, definition 2.25]

### **3.23**

#### **RISK CONTROL**

PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[SOURCE: IEC 80001-1:2010, definition 2.26]

### **3.24**

#### **RISK EVALUATION**

PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: IEC 80001-1:2010, definition 2.27]

### **3.25**

#### **RISK MANAGEMENT**

systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and monitoring RISK

[SOURCE: IEC 80001-1:2010, definition 2.28]

### **3.26**

#### **SAFETY**

freedom from unacceptable RISK of physical injury or damage to the health of people or damage to property or the environment

[SOURCE: IEC 80001-1:2010, definition 2.30]

### **3.27**

#### **SECURITY CAPABILITY**

broad category of technical, administrative or organizational controls to manage RISKS to confidentiality, integrity, availability and accountability of data and systems

### **3.28**

#### **VERIFICATION**

confirmation through provision of objective evidence that specified requirements have been fulfilled

[SOURCE: IEC 80001-1:2010, definition 2.32, modified – three notes to the original definition have not been retained.]

## **4 Use of SECURITY CAPABILITIES**

### **4.1 Structure of a SECURITY CAPABILITY entry**

The SECURITY CAPABILITIES clause below (Clause 5) itemizes the common SECURITY CAPABILITIES that can be included in a MEDICAL DEVICE or IT component. Four letter abbreviations are suggested for each capability as a convenience to reference and tabulation. Each section provides a broad view of a potentially applicable security control or PROCESS category. Each capability description contains:

- references to source material that informs the capability (i.e., applicable standards, policies and reference materials – here, the HDO and MDM should consider international security standards as well as applicable country-based standards such as the security elements present in NIST 800-39/53/66/... (US), NEN 7510 (NL), ASIP requirements (FR), Personal Information Protection Law & Guideline for Medical Information System Safety Management (JP), etc.);
- the fundamental security goal of the capability (i.e., requirement goal); and
- a statement of user (healthcare provider) need for the capability.

Often, the listed SECURITY CAPABILITIES form the basis for discussion among RESPONSIBILITY AGREEMENT participants. This discussion and eventual agreement(s) are intended to address features, roles, and responsibilities among stakeholders regarding security RISKS.

#### 4.2 Guidance for use of SECURITY CAPABILITIES in the RISK MANAGEMENT PROCESS

All SECURITY CAPABILITIES are potential security RISK CONTROL options. The selection of a security RISK CONTROL option follows after identifying the need for mitigation of a security RISK. See IEC/TR 80001-2-1:2012, for step-by-step details of the RISK MANAGEMENT PROCESS where the selection, implementation and VERIFICATION of RISK CONTROLS are performed from steps 6 through 8.

The SECURITY CAPABILITIES address security RISK CONTROL options as follows:

- The ‘requirement goal’ lists the potential security RISKS that can be addressed using that SECURITY CAPABILITY.
- The ‘user need’ section contains information on possible aspects that need to be considered when using this SECURITY CAPABILITY

It is essential that the reader understand that a specific security solution developed for a particular device in one use scenario might be inappropriate in another. The INTENDED USE of the MEDICAL DEVICE when incorporated into the MEDICAL IT-NETWORK informs the selection of which capabilities and at what level they should be supported. Sometimes this leads to important inclusion of SECURITY CAPABILITIES, for example, the use of user names and passwords on network-connected devices that contain patient data. Other times, the context of the INTENDED USE excludes a whole class of security controls; for example, a small, embedded software device like a SPO<sub>2</sub> monitor has little use for embedded security audit trails on the device itself. Security requirements applicable in the context of a specific INTENDED USE and in a specific environment should never be adopted without consideration of their potential impact on SAFETY and EFFECTIVENESS of the product.

#### 4.3 Relationship of ISO 14971-based RISK MANAGEMENT to IT security RISK MANAGEMENT

For information on applying security RISK MANAGEMENT at the organizational level see ISO/IEC 27001:2005, ISO/IEC 27002:2005, ISO/IEC 27799:2008. For the incorporation of a MEDICAL DEVICE onto an IT-NETWORK, some may choose to use ISO/IEC 27005:2011 for IT security RISK MANAGEMENT PROCESSES that can be adapted to complement the ISO 14971-based RISK MANAGEMENT PROCESS in IEC 80001-1:2010 (i.e., SAFETY, EFFECTIVENESS, and DATA AND SYSTEMS SECURITY). See the step-by-step technical report IEC/TR 80001-2-1:2012 for more detail on how to carry out RISK MANAGEMENT.

IEC 80001-1:2010 includes in the definition of HARM the KEY PROPERTIES of SAFETY, EFFECTIVENESS, and the breach of DATA AND SYSTEMS SECURITY. The HARM qualifying phrase “...breach of DATA AND SYSTEMS SECURITY” is equivalent to an executed exploit in the domain of IT security (e.g., cyber security). In the treatment of HAZARDS in IT security, a system vulnerability may lead to a breach event (via an exploit). In similar manner, a threat is anything that poses danger to DATA AND SYSTEMS SECURITY. This parallels a HAZARD as a potential source of HARM. Simply put, threats utilize vulnerabilities that can result in an exploit (known potential for HARM) or as noted in ISO/IEC 27005:2011, “Information security RISK is associated with the potential that threats will exploit vulnerabilities of an information asset or group of information assets and thereby cause HARM to an organization.”

This technical report uses security and RISK-related terms from both the IT and the traditional MEDICAL DEVICE (ISO 14971-based) RISK MANAGEMENT worlds. Table 1 can be used to relate both the IT security and ISO 14971-based terminology – it is inexact but aligns the concepts.

**Table 1 – Relationship of IT security and ISO 14971-based terminology**

IT security RISK MANAGEMENT	ISO 14971-based RISK MANAGEMENT
Vulnerability – recognized exposure that, in the presence of a threat, can lead to a reduction of data or systems information assurance	An attribute of a system that creates the potential for HARM (specifically to data and systems), i.e., a HAZARD arising from an attribute that is demonstrably exploitable (in IT terms).
Threat – something (either intentional or accidental) that can cause HARM to systems and organizations.	A circumstance or event that could lead to HARM, i.e., a HAZARD arising from a vulnerability plus the potentially activating circumstance or event (in IT, often involving a threat agent).
Exposure – situation that can cause HARM	HAZARDOUS SITUATION
Exploit (noun) – software or command(s) that breaches security  <i>Threat + Vulnerability + "activation" → HARM</i>	instance of HARM  <i>HAZARD+ HAZARDOUS SITUATION + "sequence of events" → HARM</i>
RISK – effect of uncertainty on objectives [ISO/IEC 27005:2011]	RISK – combination of the probability of occurrence of HARM and the severity of that HARM [ISO 14971:2007]
Countermeasures, safeguards, security controls	RISK CONTROL options (in IT, sometimes called mitigations in when rationalized by RISK ANALYSIS)
Compromise to confidentiality, integrity, or availability of systems or data (includes privacy breach)	HARM

## 5 SECURITY CAPABILITIES

### 5.1 Automatic logoff – ALOF

Applicable:	<b>Standard:</b> N/A
	<b>Policies:</b> Local HDO IT Policies
Reference material:	N/A
Requirement goal:	<p>Reduce the RISK of unauthorized access to HEALTH DATA from an unattended workspot.</p> <p>Prevent misuse by other users if a system or workspot is left idle for a period of time.</p>
User need:	<p>Unauthorized users are not able to access HEALTH DATA at an unattended workspot.</p> <p>Authorized user sessions need to automatically terminate or lock after a pre-set period of time. This reduces the RISK of unauthorized access to HEALTH DATA when an authorized user left the workspot without logging off or locking the display or room.</p> <p>Automatic log off needs to include a clearing of HEALTH DATA from all displays as appropriate.</p> <p>The local authorized IT administrator needs to be able to disable the function and set the expiration time (including screen saver)</p> <p>A screen saver with short inactivity time or manually enabled by a</p>



shortcut key might be an additional feature. This HEALTH DATA display clearing could be invoked when no key is pressed for some short period (e.g. 15 s to several minutes). This would not log out the user but would reduce RISK of casual viewing of information.

It is desirable that clinical users should not lose uncommitted work due to automatic logoff. Consider detailing characteristics under ALOF that distinguish between (a) logoff and (b) screen locking with resumption of session.

## 5.2 Audit controls – AUDT

Applicable:	<b>Profile:</b> IHE ATNA profile (Audit Trail and Node Authentication Integration Profile) IHE Radiology Technical Framework <b>Policies:</b> Local HDO IT Policies
Reference material:	NEMA: S&P Auditing
Requirement goal:	<p>Define harmonized approach towards reliably auditing who is doing what with HEALTH DATA, allowing HDO IT to monitor this using public frameworks, standards and technology.</p> <p>Our industry agreed upon and HDO IT strongly prefers IHE audit trail profile support.</p> <p>Audit goal (from IHE): To allow a security officer in an institution to audit activities, to assess compliance with a secure domain's policies, to detect instances of non-compliant behavior, and to facilitate detection of improper creation, access, modification and deletion of Protected Health Information (PHI).</p>
User need:	<p>Capability to record and examine system activity by creating audit trails on a device to track system and HEALTH DATA access, modification, or deletion.</p> <p>Support for use either as a stand-alone repository (logging audit files in its own file system) or, when configured as such, will send logged information to a separate, HDO-managed central repository.</p> <p>Audit creation and maintenance supported by appropriate audit review tools.</p> <p>Securing of audit data as appropriate (especially if they contain personal data themselves).</p> <p>Audit data that cannot be edited or deleted.</p> <p>Audit data likely contains personal data and/or HEALTH DATA and all processing (e.g., access, storage and transfer) should have appropriate controls.</p>

## 5.3 Authorization – AUTH

Applicable:	NOTE 1 Based on, but not to be confused with authenticating users.
	<b>Standard:</b> ANSI/INCITS 359-2004 Role-Based Access Control There are some frameworks that might prove useful here: IHE IT Infrastructure Technical Framework – Audit Trail and Node Authentication (ATNA) / Enterprise

User Authentication (EUA) / Cross-Enterprise User Assertion (XUA)

IETF: Transport Layer Security (TLS) 1.2 (RFC 5246)

ITU-T: Recommendation X.509. "Information technology - Open Systems Interconnection - The directory: Public-key and attribute certificate frameworks

**Policies:** Local HDO IT Policies

Reference material:

IHE White Paper – Access Control

IHE IT Infrastructure Technical Framework – Audit Trail and Node Authentication

ISO/TS 22600-1:2006 *Health informatics -- Privilege management and access control – Part 1: Overview and policy management*

ISO/TS 13606-4:2009 *Health informatics -- Electronic health record communication – Part 4: Security*

Requirement goal:

Following the principle of data minimization, provide control of access to HEALTH DATA and functions only as necessary to perform the tasks required by the HDO consistent with the INTENDED USE.

User need:

Avoiding unauthorized access to data and functions in order to (1) preserve system and data confidentiality, integrity and availability and (2) remain within permitted uses of data and systems.

As defined by the HDO's IT Policy and based on the authenticated individual user's identification, the authorization capability allows each user to only access approved data and only perform approved functions on the device.

Authorized users include HDO and service staff as defined by that policy.

MEDICAL DEVICES typically support a permissions-based system providing access to system functions and data appropriate to the role(s) of the individual in the HDO (role-based access control, RBAC). For example:

- OPERATORS can perform their assigned tasks using all appropriate device functions (e.g., monitor or scan patients).
- Quality staff (e.g., medical physicist) can engage in all appropriate quality and assurance testing activities.
- Service staff can access the system in a manner that supports their preventive maintenance, problem investigation, and problem elimination activities.

Authorization permits the HDO to effectively deliver healthcare while (1) maintaining system and data security and (2) following the principle of appropriate data access minimization. Authorization may be managed locally or enterprise-wide (e.g., via centralized directory).

NOTE 2 Where INTENDED USE does not permit the time necessary for logging onto and off of a device (e.g., high-throughput use), the local IT Policy can permit reduced authorization controls presuming adequacy of controlled and restricted physical access.

#### 5.4 Configuration of security features – CNFS

Applicable:	<b>Standard:</b> N/A
	<b>Policies:</b> Local HDO IT Policies
Reference material:	N/A
Requirement goal:	To allow the HDO to determine how to utilize the product SECURITY CAPABILITIES to meet their needs for policy and/or workflow.
User need:	The local authorized IT administrator needs to be able to select the use of the product SECURITY CAPABILITIES or not to use the product SECURITY CAPABILITIES. This can include aspects of privilege management interacting with SECURITY CAPABILITY control.

#### 5.5 Cyber security product upgrades – CSUP

Applicable:	<b>Guideline:</b> OIS Guidelines for Security Vulnerability Reporting and Response V2.0 1 September 2004
	<b>Policies:</b> Local HDO IT Policies
Reference material:	NEMA SPC Patching off-the-shelf software used in medical information systems. October 2004.
Requirement goal:	Create a unified way of working. Installation / Upgrade of product security patches by on-site service staff, remote service staff, and possibly authorized HDO staff (downloadable patches).
User need:	<p>Installation of third party security patches on medical products as soon as possible in accordance with regulations requiring:</p> <ul style="list-style-type: none"> <li>• Highest priority is given to patches that address high-RISK vulnerabilities as judged by objective, authoritative, documented, MDM vulnerability RISK EVALUATION.</li> <li>• The medical product vendor and the healthcare provider are required to assure continued safe and effective clinical functionality of their products. Understanding of local MEDICAL DEVICE regulation (in general, MEDICAL DEVICES should not be patched or modified without explicit written instructions from the MDM).</li> <li>• Adequate testing has to be done to discover any unanticipated side effects of the patch on the medical product (performance or functionality) that might endanger a PATIENT.</li> <li>• User, especially HDO IT staff and HDO service, requires proactive information on assessed/validated patches.</li> </ul>

#### 5.6 HEALTH DATA de-identification – DIDT

Applicable:	<b>Standard:</b> NEMA DICOM Supplement 142: Clinical Trial De-identification Profiles.
	NEMA DICOM Supplement 55: Attribute Level Confidentiality (including De-identification) 5 Sept 2002.
	ISO 25237:2008, <i>Health Informatics – pseudonimization</i> ,

NOTE Pseudonimization and use of any manner of patient-identifying keys permit data to be re-identified and, as such, are not de-identification methods.

**Policies:** Local HDO IT Policies

Reference material:	Sweeney, L. 2002. <i>K-anonymity: a model for protecting privacy</i> . International Journal on Uncertainty, Fuzziness and Knowledge-based systems, 10(5), 557-570.
Requirement goal:	Ability of equipment (application software or additional tooling) to directly remove information that allows identification of PATIENT.  Data scrubbing prior to shipping back to factory; architecting to allow remote service without HEALTH DATA access/exposure; in-factory quarantine, labeling, and training.
User need:	Clinical user, service engineers and marketing need to be able to de-identify HEALTH DATA for various purposes not requiring PATIENT identity.

## 5.7 Data backup and disaster recovery – DTBK

Applicable:	<b>Standard:</b> N/A <b>Policies:</b> Local HDO IT Policies
Reference material:	ISO/IEC 20000-2:2012, Service continuity planning and testing
Requirement goal:	Assure that the healthcare provider can continue business after damage or destruction of data, hardware, or software.
User need:	Reasonable assurance that persistent system settings and persistent HEALTH DATA stored on products can be restored after a system failure or compromise so that business can be continued.

NOTE This requirement may not be appropriate for smaller, low-cost devices and may, in practice, rely on the ability to collect new, relevant data in the next acquisition cycle (e.g., short-duration heart rate data lost due to occasional wireless signal loss)

## 5.8 Emergency access – EMRG

Applicable:	<b>Standard:</b> N/A <b>Policies:</b> Local HDO IT Policies
Reference material:	NEMA SPC White paper: <i>Breakglass</i>
Requirement goal:	Ensure that access to protected HEALTH DATA is possible in case of an emergency situation requiring immediate access to stored HEALTH DATA.
User need:	During emergency situations, the clinical user needs to be able to access HEALTH DATA without personal user id and authentication (break-glass functionality).  Emergency access is to be detected, recorded and reported. Ideally including some manner of immediate notification to the system administrator or medical staff (in addition to audit record).  Emergency access needs to require and record self-attested user identification as entered (without authentication).  HDO can solve this through procedural approach using a specific user account or function of the system.

The administrator needs to be able to enable/disable any emergency functions provided by the product dependent on technical or procedural controls are required.

## 5.9 HEALTH DATA integrity and authenticity – IGAU

Applicable:	<b>Standard:</b> N/A.
	<b>Policies:</b> Local HDO IT Policies
Reference material:	NEMA Security and Privacy Auditing
Requirement goal:	Assure that HEALTH DATA has not been altered or destroyed in non-authorized manner and is from the originator. Assure integrity of HEALTH DATA.
User need:	User wants the assurance that HEALTH DATA is reliable and not tampered with.  Solutions are to include both fixed and also removable media.

## 5.10 Malware detection/protection – MLDP

Applicable:	<b>Standard:</b> N/A.
	<b>Policies:</b> Local HDO IT Policies
Quote from regulation:	Protection from malicious software (Addressable). Procedures for guarding against, detecting, and reporting malicious software.
Reference material:	NEMA Defending Medical Information Systems Against Malicious Software
Requirement Goal:	Product supports regulatory, HDO and user needs in ensuring an effective and uniform support for the prevention, detection and removal of malware. This is an essential step in a proper defense in depth approach to security.  Malware application software is updated, malware pattern data files kept current and operating systems and applications are patched in a timely fashion. Post-updating VERIFICATION testing of device operation for both continued INTENDED USE and SAFETY is often necessary to meet regulatory quality requirements.
User need:	HDOs need to detect traditional malware as well as unauthorized software that could interfere with proper operation of the device/system.

## 5.11 Node authentication – NAUT

Applicable:	<b>Profile:</b> IHE ATNA profile (Audit Trail and Node Authentication Integration Profile)
	<b>Policies:</b> NEMA/COCIR/JIRA Joint Security and Privacy Committee draft White Paper: <i>Management of Machine Authentication Certificates</i> , 10 February 2005  SANS Security Policy Project  Local HDO IT Policies

Reference material:	N/A
Requirement goal:	Authentication policies need to be flexible to adapt to local HDO IT policy. As necessary, use node authentication when communicating HEALTH DATA.
User need:	<p>Capability of managing cross-machine accounts on a modality to protect HEALTH DATA access.</p> <p>Support for stand-alone and central administration.</p> <p>Support for node authentication according industry standards.</p> <p>To detect and prevent entity falsification (provide non-repudiation).</p>

## 5.12 Person authentication – PAUT

Applicable:	<p><b>Profile:</b></p> <p>IHE ATNA profile (Audit Trail and Node Authentication Integration Profile)</p> <p>IHE PWP profile (Personal White Pages)</p> <p>IHE EUA (Enterprise User Authentication)</p> <p>IHE XUA (Cross-Enterprise User Assertion)</p> <p><b>Policies:</b></p> <p>SANS Security Policy Project</p> <p>Local HDO IT Policies</p>
Reference material:	N/A
Requirement goal:	<p>Authentication policies need to be flexible to adapt to HDO IT policy. This requirement as a logical place to require person authentication when providing access to HEALTH DATA.</p> <p>To control access to devices, network resources and HEALTH DATA and to generate non- repudiable audit trails. This feature should be able to identify unambiguously and with certainty the individual who is accessing the network, device or resource.</p> <p>NOTE This requirement is relaxed during “break-glass” operation. See capability “Emergency access.”</p>
User need:	<p>Creation and use of unique accounts for users and role based access control (RBAC,local and remote) for a network connected device to control and monitor network access and activity.</p> <p>Capability of managing accounts on a modality to protect HEALTH DATA access.</p> <p>Users might need to associate personal preferences with user accounts. This might help devices and systems used by multiple OPERATORS, departments or even multiple HDOs. Support for stand-alone and central administration.</p> <p>Single sign-on and same password on all workspots.</p> <p>To detect and prevent person falsification (provide non-repudiation).</p>

### 5.13 Physical locks on device – PLOK

Applicable:	<b>Standard:</b> N/A <b>Policies:</b> Local HDO IT Policies
Reference material:	none
Requirement goal:	Assure that unauthorized access does not compromise the system or data confidentiality, integrity and availability.
User need:	Reasonable assurance that HEALTH DATA stored on products or media is and stays secure in a manner proportionate to the sensitivity and volume of data records on the device.  Systems are reasonably free from tampering or component removal that might compromise integrity, confidentiality or availability. Tampering (including device removal) is detectable.

### 5.14 Third-party components in product lifecycle roadmaps – RDMP

Applicable:	<b>Standard:</b> N/A <b>Policies:</b> Local HDO IT Policies
Quote from regulation:	N/A
Reference material:	N/A
Requirement goal:	HDOs want an understanding of security throughout the full life cycle of a MEDICAL DEVICE.  MDM plans such that products are sustainable throughout their life cycle according internal quality systems and external regulations. Products provided with clear statement of expected life span.  Goal is to proactively manage impact of life cycle of components throughout a product's full life cycle. This commercial off-the-shelf or 3 <sup>rd</sup> party software includes operating systems, database systems, report generators, MIP components etc. (assumption is that existing PCP already manages hardware component obsolescence). 3 <sup>rd</sup> party includes here also internal suppliers of security vulnerable components with own life cycle and support programs.
User need:	HDO contracts, policy and regulations require that vendor maintain/support the system during product life.  Updates and upgrades are expected when platform components become obsolete.  HDOs and service provider show extreme care in irreversibly erasing HEALTH DATA prior to storage devices being decommissioned (discarded, reused, resold or recycled). Such activities should be logged and audited.  Sales and Service are well informed about security support offered per product during its life cycle.

### 5.15 System and application hardening – SAHD

Applicable:	<b>Standard:</b> N/A <b>Policies:</b> Local HDO IT Policies SANS Policy Project
Reference material:	SANS Information Security Reading Room (Step-by-step Guides) CIS Benchmarks and Security Tools
Requirement goal:	Adjust security controls on the MEDICAL DEVICE and/or software applications such that security is maximized (“hardened”) while maintaining INTENDED USE. Minimize attack vectors and overall attack surface area via port closing; service removal, etc.
User need:	<p>User requires a system that is stable and provides just those services specified and required according to its INTENDED USE with a minimum of maintenance activities.</p> <p>HDO IT requires systems connected to their network to be secure on delivery and hardened against misuse and attacks.</p> <p>It is desirable for the User to inform the MDM of suspected security breaches and perceived weaknesses in User equipment.</p>

### 5.16 Security guides – SGUD

Applicable:	<b>Standard:</b> N/A <b>Policies:</b> Local HDO IT Policies
Reference material:	Manufacture Disclosure Statement for Medical Device Security (MDS2)
Requirement goal:	Ensure that security guidance for OPERATORS and administrators of the system is available. Separate manuals for OPERATORS and administrators (including MDM sales and service) are desirable as they allow understanding of full administrative functions to be kept only by administrators.
User need:	<p>OPERATOR should be clearly informed about his responsibilities and secure way of working with the system.</p> <p>The administrator needs information about managing, customizing and monitoring the system (i.e. access control lists, audit logs, etc.).</p> <p>Administrator needs clear understanding of security capabilities to allow HEALTH DATA RISK ASSESSMENT per appropriate regulatory requirement.</p> <p>Sales and service also need information about the system’s SECURITY CAPABILITIES and secure way of working.</p> <p>It is desirable for the User to know how and when to inform the MDM of suspected security breaches and perceived weaknesses in User equipment.</p>



### 5.17 HEALTH DATA storage confidentiality – STCF

Applicable:	<b>Standard:</b> NEMA DICOM Part 15: Security and System Management Profiles NEMA DICOM Supplement 51: Media security NEMA DICOM Supplement 55: Attribute level confidentiality (including De-identification) 5 Sept 2002 (Final text) <b>Policies:</b> Local HDO IT Policies
Reference material:	Schneier B. 1996. Applied Cryptography, Second Edition. John Wiley & Sons, New York, NY.
Requirement goal:	MDM establishes technical controls to mitigate the potential for compromise to the integrity and confidentiality of HEALTH DATA stored on products or removable media.
User need:	Reasonable assurance that HEALTH DATA stored on products or media is and stays secure.  Encryption has to be considered for HEALTH DATA stored on MEDICAL DEVICES based on RISK ANALYSIS.  For HEALTH DATA stored on removable media, encryption might protect confidentiality/ integrity for clinical users but also MDM service and application engineers collecting clinical data.  A mechanism for encryption key management consistent with conventional use, service access, emergency “break-glass” access.  Encryption method and strength takes into consideration the volume (extent of record collection/aggregation) and sensitivity of data.

### 5.18 Transmission confidentiality – TXCF

Applicable:	<b>Profile:</b> IHE ATNA profile (Audit Trail and Node Authentication Integration Profile) <b>Policies:</b> Local HDO IT Policies
Reference material:	NEMA SPC Certificates white paper. NEMA DICOM Part 15: Security and System Management Profiles IETF: Transport Layer Security in Network Working Group RFC 5246 August 2008: The TLS Protocol Version 1.2 ITU-T: Recommendation X.509. “Information technology - Open Systems Interconnection - The directory: Public-key and attribute certificate frameworks”
Requirement goal:	DEVICE meets local laws, regulations and standards (e.g., USA HIPAA, EU 95/46/EC derived national laws) according to HDO needs to ensure the confidentiality of transmitted HEALTH DATA.
User need:	Assurance that HEALTH DATA confidentiality is maintained during transmission between authenticated nodes. This allows transport of HEALTH DATA over relatively open networks and/or environment where strong HDO IT policies for HEALTH DATA integrity and confidentiality are in use.

See IEC/TR 80001-2-3:2012 for more information on RISK MANAGEMENT for wireless network systems.

### 5.19 Transmission integrity – TXIG

Applicable:	<b>Profile:</b>	IHE ATNA profile (Audit Trail and Node Authentication Integration Profile)
	<b>Policies:</b>	Local HDO IT Policies
Reference material:		NEMA SPC Certificates white paper NEMA DICOM Part 15: Security and System Management Profiles
Requirement goal:		Device protects the integrity of transmitted HEALTH DATA.
User need:		Assurance that integrity of HEALTH DATA is maintained during transmission. This allows transmission of HEALTH DATA over relatively open networks or environment where strong policies for HEALTH DATA integrity are in use.

## 6 Example of detailed specification under SECURITY CAPABILITY: Person authentication – PAUT

The previous “Security Capabilities” clause provided a description of the basic capability along with user need and source material. In actual use, a capability will be more detailed by the MDM in a security statement or the HDO in a request for product security information. The following is an example of a MDM’s disclosure under the “Person Authentication” capability. For the target MEDICAL DEVICE, the disclosure would indicate presence or absence of that SECURITY CAPABILITY.

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### PAUT: Person authentication

The term user is considered to refer to the caregiver and/or the network and security management roles in the healthcare delivery environment.

Requirement goal: Authentication policies need to be flexible to adapt to HDO IT policy. This requirement as a logical place to require person authentication when providing access to HEALTH DATA.

To control access to devices, network resources and HEALTH DATA and to generate non- repudiable audit trails. This feature should be able to identify unambiguously and with certainty the individual who is accessing the network, device or resource.

NOTE This requirement is relaxed during “break-glass” operation. See capability “Emergency access.”

User need: Creation and use of unique accounts for users and role-based access control (RBAC,local and remote) for a network connected device to control and monitor network access and activity.

Capability of managing accounts on a modality to protect HEALTH DATA access.

Users might need to associate personal preferences with user accounts. This might help devices and systems used by multiple OPERATORS, departments or even multiple HDOs. Support for stand-alone and central administration.

Single sign-on and same password on all workspots.

To detect and prevent person falsification (provide non-repudiation).

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PAUT.1 Product supports locally administered (on the device) User accounts operation. Capability for HDO IT and optionally the service engineer to manage the local User accounts.

- PAUT.2 Use of HDO central administration of User accounts according the IHE EUA profile.
- PAUT.3 Support for identifying multiple simultaneous users (e.g. OPERATOR + clinician) for role based access control.
- PAUT.4 Single sign-on for modalities with multiple workspots or single workspots running multiple applications.
- PAUT.5 Visible indication of who is the current user to make it easier to identify who is using the system, and determine if it is necessary to close the session.
- PAUT.6 Support fast user switching. By supporting this, signing off and on is not a time-consuming task.

## 7 References

This section describes the detail behind the abbreviated references used in the security capabilities clause above.

Reference Document	Title
CIS	The Center for Internet Security Benchmarks and Security Tools <a href="http://cisecurity.org/">http://cisecurity.org/</a>
DICOM	Digital Imaging and Communications in Medicine sponsored by NEMA  Standards:  NEMA DICOM Part 15: Security and System Management Profiles NEMA DICOM <i>Supplement 55: Attribute level confidentiality (including De-identification)</i> 5 Sept 2002 (Final text) NEMA DICOM <i>Supplement 51: Media security</i> NEMA DICOM <i>Supplement 142: Clinical Trial De-identification profiles</i>
IETF	The Internet Engineering Task Force  Papers:  Network Working Group RFC 5246 August 2008: <i>The TLS Protocol Version 1.2</i> : <a href="http://www.ietf.org/rfc/rfc5246.txt">http://www.ietf.org/rfc/rfc5246.txt</a>
IHE	Integrated Healthcare Enterprise: <a href="http://www.ihe.net/Technical_Framework/">http://www.ihe.net/Technical_Framework/</a>  Note on ATNA:  (see <a href="http://wiki.ihe.net/index.php?title=Audit_Trail_and_Node_Authentication">http://wiki.ihe.net/index.php?title=Audit_Trail_and_Node_Authentication</a> )  <i>Audit Trail and Node Authentication (ATNA) Integration Profile</i> is designed to support access control by limiting network access between nodes and limiting access to each node to authorized users (locally authenticated). It involves User Authentication, Connection Authentication, and Audit Trails. It supports actors including

Reference Document	Title
	<ul style="list-style-type: none"> <li>Secure Nodes,</li> <li>Audit Repository, and</li> <li>Time Server.</li> </ul> <p>The actions are to maintain time, authenticate nodes, and recording audit events. It is based upon standards established by the IETF IT Infrastructure Technical Framework including standards for Secure Communications, Audit Log Transport, Audit Log Message. Among these standards are RFC 5246, WS-I Basic Security Profile 1.1, RFC 5424, RFC 5425, RFC 5426, RFC 3164, RFC 3881, DICOM: Supplement 95 (ISO 12052  <a href="http://medical.nema.org/medical/dicom/final/sup95_ft.pdf">http://medical.nema.org/medical/dicom/final/sup95_ft.pdf</a>).</p>
Local HDO IT Policies	Policies created by our product user's organization specifying the acceptable use of information technology.
NEMA SPC	<p>Joint Security and Privacy Committee of NEMA/COCIR/JIRA:  <a href="http://www.medicalimaging.org/policy-and-positions/joint-security-and-privacy-committee-2/">http://www.medicalimaging.org/policy-and-positions/joint-security-and-privacy-committee-2/</a></p> <p>White papers:</p> <p>SPC Security and Privacy Auditing in Health Care Information Technology.</p> <p>SPC Break-Glass: An approach to granting emergency access to health care systems. December 2004.</p> <p>SPC Defending medical information systems against malicious software. December 2003. <i>SPC Patching off-the-shelf software used in medical information systems</i>, October 2004.</p> <p><i>SPC Remote Service Interface - Solution (A) - Version 2: IPSec over the Internet Using Digital Certificates</i>, December 2003.</p>
ITU	International Telecommunication Union Telecommunication Standardization Section (ITU-T) Recommendation X.509 (11/2008) ISO/IEC 9594-8:2008: <a href="http://www.itu.int/itu-t/recommendations/index.aspx?ser=X">http://www.itu.int/itu-t/recommendations/index.aspx?ser=X</a>
OIS	<p>Organization for Internet Safety <a href="http://www.oisafety.org/">http://www.oisafety.org/</a> publication:</p> <p><i>OIS Guidelines for Security Vulnerability Reporting and Response V2.0</i> 1 September 2004:  <a href="http://www.symantec.com/security/OIS_Guidelines%20for%20responsible%20disclosure.pdf">http://www.symantec.com/security/OIS_Guidelines%20for%20responsible%20disclosure.pdf</a></p>
SANS	<p>The SANS (SysAdmin, Audit, Network, Security) Institute:  <a href="http://www.sans.org">http://www.sans.org</a></p> <p>The SANS Security Policy Project – “...everything you need for rapid development and implementation of information security policies.”: <a href="http://www.sans.org/resources/policies/">http://www.sans.org/resources/policies/</a></p> <p>SANS Information <i>Security Reading Room</i>:  <a href="http://www.sans.org/reading_room/">http://www.sans.org/reading_room/</a></p>

Reference Document	Title
Schneier	Bruce Schneier. 1996. <i>Applied Cryptography: Protocols, Algorithms, and Source Code in C</i> , 2 <sup>nd</sup> Edition. J Wiley & Sons. N.B., if you use this book, please search the web for errata as there are some well-known errors present.
WEDI	<p>Workgroup for Electronic Data Interchange Security and Privacy Workgroup (SNIP)</p> <p>White papers:</p> <p>WEDI-SNIP Introduction to Security Final Rule Final Version – January 2004: (membership required) <a href="http://www.wedi.org">http://www.wedi.org</a></p> <p>WEDI-SNIP SECURITY: Audit Trail Clarification White Paper Version 5.0 November 7, 2003: (membership required) <a href="http://www.wedi.org">http://www.wedi.org</a></p>

## 8 Other resources

### 8.1 General

This clause contains some description and reference to standards and resources that also itemize the security capabilities of MEDICAL DEVICES or applications. The focus of each of these resources is slightly different and therefore they should be carefully applied according to their original context.

### 8.2 Manufacture disclosure statement for medical device security (MDS2)

Manufacture Disclosure Statement for Medical Device Security—developed by HIMSS to capture MEDICAL DEVICE SECURITY CAPABILITIES. This form is currently going through an international open consensus PROCESS under NEMA and HIMSS.

<http://www.himss.org/content/files/MDS2FormInstructions.pdf>

### 8.3 Application security questionnaire (ASQ)

Application Security Questionnaire—developed by HIMSS to capture Information System security and privacy capabilities.

[http://www.himss.org/asp/topics\\_FocusDynamic.asp?faid=212](http://www.himss.org/asp/topics_FocusDynamic.asp?faid=212)

### 8.4 The Certification Commission for Healthcare Information Technology (CCHIT)

The Certification Commission for Healthcare Information Technology or CCHIT is a recognized certification body (RCB) for electronic health records and their networks, and an independent, voluntary, private-sector initiative. It is our mission to accelerate the adoption of health information technology by creating an efficient, credible and sustainable certification program.

### 8.5 [http://www.cchit.org/get\\_certified](http://www.cchit.org/get_certified)HL7 Functional Electronic Health Record (EHR)

The goal of the EHR Work Group is to further the HL7 mission of designing standards to support the exchange of information for clinical decisions and treatments, and help lay the groundwork for nationwide INTEROPERABILITY by providing common language parameters that can be used in developing systems that support electronic records.

<http://www.hl7.org/ehr/>

## 8.6 Common criteria – ISO/IEC 15408

Common criteria – ISO/IEC 15408 (all parts) that would describe the capabilities of a system.

## 9 Standards and frameworks

The Bibliography contains a list of standards and frameworks referenced within this document. The following organizations are sources of additional information.

NSA	US National Security Agency NSA Security Configuration Guides <a href="http://www.nsa.gov/ia/mitigation_guidance/security_configuration_guides/index.shtml">http://www.nsa.gov/ia/mitigation_guidance/security_configuration_guides/index.shtml</a>
IETF	The Internet Engineering Task Force Papers: Network Working Group RFC 5246 August 2008: <i>The TLS Protocol Version 1.2</i> . <a href="http://www.ietf.org/rfc/rfc5246.txt">http://www.ietf.org/rfc/rfc5246.txt</a>
SANS	The SANS (SysAdmin, Audit, Network, Security) Institute: <a href="http://www.sans.org/">http://www.sans.org/</a> The SANS Security Policy Project – “...everything you need for rapid development and implementation of information security policies.” <a href="http://www.sans.org/resources/policies">http://www.sans.org/resources/policies</a> SANS Information <i>Security Reading Room</i> <a href="http://www.sans.org/rr/">http://www.sans.org/rr/</a> SANS security glossary <a href="http://www.sans.org/security-resources/glossary.php">http://www.sans.org/security-resources/glossary.php</a>
WEDI	Workgroup for Electronic Data Interchange Security and Privacy Workgroup (SNIP) White papers: WEDI-SNIP Introduction to Security Final Rule Final Version – January 2004: (membership required)  WEDI-SNIP SECURITY: Audit Trail Clarification White Paper Version 5.0 November 7, 2003: (membership required)
IHE	Integrated Healthcare Enterprise <a href="http://www.ihe.net/Technical_Framework/">http://www.ihe.net/Technical_Framework/</a> IHE ATNA profile (Audit Trail and Node Authentication Integration Profile) IHE EUA (Enterprise User Authentication) IHE RAD TF ( <i>Radiology Audit Trail</i> ) draft version for public comment.

## **Annex A** (informative)

### **Sample scenario showing the exchange of security information**

#### **A.1 Introduction to the security characteristics scenario**

This annex contains documents shared in the first round of the exchange of security characteristics information between a hypothetical MEDICAL DEVICE manufacturer (MDM – The Widget Corporation) and a healthcare delivery organization (HDO – The New Town Hospital). The product under consideration is a DICOM Workstation called “FOOBAR 2.0”.

The MDM has received a request for IEC-80001 information on the FOOBAR 2.0 from the HDO. Section 2 contains the MDM’s initial communication about the SECURITY CAPABILITIES of the FOOBAR 2.0. This is followed by the HDO’s review of the security characteristics “offering” with their comments and additional questions.

This annex gives a simplified example of what the MDM of the FOOBAR would provide to a healthcare delivery organization who is contemplating the purchase or integration of the FOOBAR. It might be shared by the MDM under a non-disclosure agreement with the HDO or, perhaps, the MDM would publish the capabilities to their HDO Internet site. Either way, it is the first “offering” of information about the detailed SECURITY CAPABILITIES of a MEDICAL DEVICE under consideration. Likewise, the HDO’s reply is a first-response back to the MDM intended to identify areas of general agreement and understanding, issues that were not apparent in the document, and questions that need to be resolved in subsequent communications.

Of course, there is much more to a purchase, installation, and maintenance arrangement. As an overall context for this example of a simplified MEDICAL DEVICE purchase and later FOOBAR medical IT-NETWORK connection project, we outline some basic steps that might be followed during security RISK MANAGEMENT (see IEC 80001-1 for full details):

- a) The HDO requests or locates the MDM security characteristics summary (Section 2 below).
- b) The HDO examines the FOOBAR security characteristics report and responds in writing (Section 3 below).
- c) The HDO contacts the MDM and obtains answers to some details not present in the FOOBAR report.
- d) A decision is made by the HDO to complete a purchase and the MDM decides to accept the purchase pending some elements of the purchase to be worked out. The HDO uses the security input and dialog with the MDM to decide if this is a partner who will work in good faith.
- e) Various elements of project planning and execution are carried out including an explicit RESPONSIBILITY AGREEMENT with regard to RISK MANAGEMENT in the IT-NETWORK connection. The HDO and the MDM are clear about how various RISKS are managed. Some are managed intrinsically by the device security characteristics, some have to be mitigated by HDO security controls (technical and/or administrative). Preliminary estimates of RESIDUAL RISK are made. This step may be included in the purchase or may be preliminary to purchase.
- f) The HDO purchases the FOOBAR system and contracts for support for the connection/integration project.
- g) RISKS are analyzed and RESIDUAL RISK is surfaced and understood by the HDO and, where it is found acceptable in light of the benefits of the FOOBAR connection, the integration project is executed with the device connected to the HDO’s MEDICAL IT-NETWORK.
- h) The FOOBAR operates in a RISK managed manner as part of the HDO’s MEDICAL IT-NETWORK.



- i) Sustainable activities relating to emerging vulnerabilities, monitoring, EVENT MANAGEMENT are all put in place with necessary agreements with FOOBAR service providers.
- j) Decommissioning of storage devices and systems are considered in local procedures that contain requirements for data destruction, logging and auditing the decommissioning PROCESS.

NOTE This is a simple scenario with an agreement between two parties only. In real-life situations there may be other parties involved such as IT vendors, third-party integrators, etc. The actual steps will be decided on a case-by-case basis.

To be clear that these are sample pages from a hypothetical exchange, the security characteristics document from the manufacturer (MDM) has pages highlighted with a blue box border. The security characteristics document that contains the response from the hospital (HDO) back to the MDM has pages with an orange box border.

**Disclaimer:** *this scenario is provided without warranty, either expressed or implied, including, but not limited to, the implied warranties of merchantability, completeness and fitness for a particular purpose. The entire RISK as to the quality and performance of the provided information is with you.*

*The example describes a fictional device (FOOBAR 2.0) and is intended to provide a suggested way of beginning a security dialog between the MDM and the HDO.*

## A.2 Manufacturer (MDM) Security Characteristics Report – “The Offering”

The following pages are the FOOBAR 2.0 MDM’s statement of the security of the product arranged in a manner consistent with the advice of the IEC 80001-1 Security Technical Report (this document). This starts with an expression of interest by a healthcare deliver organization. The MDM responds with an email/letter and an attached FOOBAR 2.0 Security Characteristics Document.

Joan Kowalski, CISSP  
IT Security Officer  
New Town General Hospital

Dear Ms. Kowalski,

Thank you for your interest in the FOOBAR 2.0 DICOM PACS Workstation. We have received your signed non-disclosure agreement and please find attached for your records a copy signed by us.

You will also find attached the detailed security information about the FOOBAR 2.0 in a form consistent with IEC 80001-1 Security Technical Report. We always try to be clear and consistent in our communications with customer about security risk and I trust that this confidential document meets your needs.

Of course, security can be a highly complex issue when attaching a new medical device to a hospital IT-network. We look forward to working with you to resolve any questions or issues you see in considering our product for purchase and integration into your Medical IT-network.

Thank you for considering Widget Corporation’s products in your technology plans and we look forward to working with you this important purchase and the full integration of our product into your operational network.

Please let me know if you have any questions on our security capabilities and/or risks that might be present in this state-of-the-art product.

Best regards,  
Jose Armas  
FOOBAR Product Sales Manager,  
Widget Corporation

cc:

1. Doubly signed Non-disclosure Agreement dated May 1, 2010
2. FOOBAR 2.0 Security Characteristics Report (IEC80001-1)



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**FOOBAR 2.0 Security Characteristics Document per IEC 80001-1**  
**– MANUFACTURER'S OFFERING –**

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## **A. Brief Intended Purpose definition of the device FOOBAR 2.0**

The Advanced DICOM Viewing Station "FOOBAR 2.0" is connected to the DICOM network and enables its users to access DICOM 3.0 images and data outside the radiology department or imaging center in order to review these medical reports and medical images.

FOOBAR 2.0 is able to retrieve the medical data either from the dedicated remote archive present on the DICOM network or from a local hard drive.

Because of the internal storage capabilities, FOOBAR 2.0 is able to display the medical data even outside the boundaries of the DICOM network.

Security options are included in order to control access to medical imaging data, depending upon user privileges; access is logged in audit logs.

## **B. Detailed Specification of SECURITY CAPABILITIES**

In the security capabilities detailed below, each capability is tagged with the four-level-acronym of the SECURITY CAPABILITY. To assist in communication about specific characteristics under a SECURITY CAPABILITY, each is tagged with an identifier composed of the identifier and a two digit sequential number. This is intended to help in discussions and written communication about specific characteristics.

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**ALOF: Automatic logoff**

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**Goal:** Reduce the RISK of unauthorized access to HEALTH DATA from an unattended workspot. Prevent misuse by other users if a system or workspot is left idle for a period of time.

<b>Identifier</b>	<b>Capability</b>
/ALOF.01/	A screen-saver starts automatically 5 min after last keystroke / mouse movement operation.  <i><b>Remark:</b> the local authorized IT administrator can set the delay for this action and even disable the screen-saver.</i>
/ALOF.02/	The screen-saver clears all displayed HEALTH DATA from the screen.
/ALOF.03/	The screen-saver does not log-off the user / does not terminate the session.
/ALOF.04/	User has to log-in after occurrence of the screen-saver.
/ALOF.05/	The user-session terminates automatically 60 min after last keystroke / mouse movement / touchscreen operation.  <i><b>Remark:</b> the local authorized IT administrator can set the delay for this action and even disable the automatic log-off.</i>

### AUDT: Audit controls

**Goal:** Define harmonized approach towards reliably auditing who is doing what with HEALTH DATA, allowing HDO IT to monitor this using public frameworks, standards and technology.

Identifier	Capability
/AUDT.01/	Access, modification or deletion to any HEALTH DATA is recorded and stored on the dedicated remote DICOM archive.
/AUDT.02/	Download of HEALTH DATA (to the internal storage of the device) is recorded and stored on the dedicated remote DICOM archive.
/AUDT.03/	In case the device is used outside the boundaries of the DICOM network, access to any HEALTH DATA is stored on the internal storage of the device.
/AUDT.04/	After re-connecting the device back to the DICOM-Network, the audit-trails recorded on the internal storage of the device during offline-use are synchronized with the dedicated remote DICOM archive.
/AUDT.05/	Refers to /CNFS.01/: all changes to the SECURITY CAPABILITIES are included to the audit-trail of the device.

### CNFS: Configuration of security features

**Goal:** To allow the HDO to determine how to utilize the product SECURITY CAPABILITIES to meet their needs for policy and/or workflow.

Identifier	Capability
/CNFS.01/	The local authorized IT administrator can set / disable the available SECURITY CAPABILITIES of the device.
/CNFS.02/	Refers to /AUDT.05/: in case the local authorized IT administrator set / disables / changes the settings of the available SECURITY CAPABILITIES of the device, the action is logged in an audit-trail.

### DTBK: Data backup and disaster recovery

**Goal:** Assure that the healthcare provider can continue business after damage or destruction of data, hardware, or software.

Identifier	Capability
/DTBK.01/	FOOBAR 2.0 provides a back-up (built-in) to store the <u>system-settings</u> to an externally connected mass-storage-device (e.g. an USB-Stick).
/DTBK.02/	FOOBAR 2.0 provides a back-up (built-in) to store the <u>audit-trails</u> to an externally connected mass-storage-device (e.g. an USB-Stick).
/DTBK.03/	The audit-trails are encrypted accordingly in order to prevent loss of confidential information, contained in HEALTH DATA (like patient name, DOB, etc.).

Identifier	Capability
/DTBK.04/	Backup of locally stored HEALTH DATA can only be done back to the dedicated remote DICOM archive. <b>Rationale:</b> <i>this restrictive functionality is required in order to ensure that the HEALTH DATA remains consistent.</i>

### DIDT: HEALTH DATA de-identification

**Goal:** Ability of equipment (application software or additional tooling) to directly remove information that allows identification of PATIENT.

Identifier	Capability
/DIDT.01/	FOOBAR 2.0 does not support any means to directly remove information that allows identification of PATIENT.

### STCF: HEALTH DATA storage confidentiality

**Goal:** MANUFACTURER ensures that unauthorized access does not compromise the integrity and confidentiality of HEALTH DATA stored on products or removable media.

Identifier	Capability
/STCF.01/	HEALTH DATA, stored on the internal storage of FOOBAR 2.0 is encrypted. Used algorithm: AES (Rijndael), Encryption strength: 256 BIT. <b>Remark:</b> <i>this setting cannot be changed by local IT administrator.</i>
/STCF.02/	The secured / encrypted HEALTH DATA is accessible after successful boot only. See also /MLDP.04/.
/STCF.03/	Only the required HEALTH DATA is decrypted (required for the current interaction / usage / display). Currently not used HEALTH DATA remains encrypted.
/STCF.04/	Boot partition, operating system, temporary data on internal mass storage device, etc. is also encrypted. Used algorithm: AES (Rijndael), Encryption strength: 256 BIT. <b>Remark:</b> <i>this setting cannot be changed by local IT administrator.</i>
/STCF.05/	Accidental power-down of the system does not affect the encryption of the HEALTH DATA on the mass storage device. In no circumstance of operation is unencrypted HEALTH DATA present on the internal mass storage device.
/STCF.06/	Connection to the dedicated remote archive present on the DICOM network can be established via VPN.

### EMRG: Emergency access

**Goal:** Ensure that access to protected HEALTH DATA is possible in case of an emergency situation requiring immediate access to stored HEALTH DATA.

Identifier	Capability
/EMRG.01/	Break-glass functionality provided: even without <u>personal</u> user id and authentication clinical user can gather access to HEALTH DATA. <i><b>Remark:</b> remember that this functionality may be changed / disabled by local IT administrator.</i>
/EMRG.02/	Usage of the break-glass functionality /EMRG.01/ requires the usage of a <u>general</u> user id and authentication (in order to prevent patients or bystanders to access HEALTH DATA).
/EMRG.03/	Each use of the break-glass functionality /EMRG.01/ will be recorded in the audit-trail.
/EMRG.04/	Each use of the break-glass functionality /EMRG.01/ can be reported automatically to a defined user account, e.g. by means of e-mail.

### SGUD: Security guides

**Goal:** Ensure that security guidance for OPERATOR and administrator of the system and MANUFACTURER sales and service is available. Separate manuals are desirable as they allow understanding of full administrative functions to be kept only by administrators.

Identifier	Capability
/SGUD.01/	Security guidance for OPERATOR is included in the instructions for use of FOOBAR 2.0. See chapter 13.
/SGUD.02/	Security guidance for administrator is included in the technical information of FOOBAR 2.0. See chapter 17.

### IGAU: HEALTH DATA integrity and authenticity

**Goal:** Assure that HEALTH DATA has not been altered or destroyed in non-authorized manner and is from the originator. Assure integrity of HEALTH DATA.

Identifier	Capability
/IGAU.01/	HEALTH DATA, stored on the mass storage of FOOBAR 2.0 in order to display the medical data outside the boundaries of the DICOM network, is secured by adequate checksum (SHA1) in order to assure integrity of data.
/IGAU.02/	Backup-capabilities are provided. See chapter DTBK: Data backup and disaster recovery

### MLDP: Malware detection/protection

**Goal:** Product supports regulatory, HDO and user needs in ensuring an effective and uniform support for the prevention, detection and removal of malware. This is an essential step in a proper defense in depth approach to security.

Identifier	Capability
/MLDP.01/	All unnecessary network-ports of FOOBAR 2.0 are closed. <i><b>Remark 01:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details. See /SGUD.02/.</i> <i><b>Remark 02:</b> this capability cannot be changed by local IT-administrator.</i>
/MLDP.02/	The operating-system on the boot-device of FOOBAR 2.0 is protected against authorized / unauthorized changes. After re-boot, the system is back in the initial state. <i><b>Remark:</b> this capability cannot be changed by local IT-administrator.</i>
/MLDP.03/	All relevant files are secured by adequate checksum (SHA1) and checked during boot-sequence. In case of error detection, system does not start but displays an error message. <i><b>Remark:</b> this capability cannot be changed by local IT-administrator.</i>
/MLDP.04/	The secured / encrypted HEALTH DATA is accessible after successful boot only. See also /STCF.01/. <i><b>Remark:</b> this capability cannot be changed by local IT-administrator.</i>

### PAUT: Person authentication

**Goal:** Authentication policies need to be flexible to adapt to HDO IT policy. This requirement as a logical place to require person authentication when communicating HEALTH DATA.

Identifier	Capability
/PAUT.01/	FOOBAR 2.0 supports local and global management of accounts. <i><b>Remark:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details.</i>
/PAUT.02/	FOOBAR 2.0 supports withdrawal of accounts. <i><b>Remark:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details.</i>
/PAUT.03	FOOBAR 2.0 supports fast user switching. By supporting this, signing off and on is not a time-consuming task.

### PLOK: Physical locks on device

**Goal:** Assure that unauthorized access does not compromise the integrity and confidentiality of HEALTH DATA stored on products or removable media.

Identifier	Capability
/PLOK.01/	Because of the chosen encryption, FOOBAR 2.0 does not require physical lock-outs.

### CSUP: Cyber security Product upgrades

**Goal:** Create a unified way of working. Installation / Upgrade of product security patches by on-site service staff, remote service staff, and possibly authorized HDO staff (downloadable patches).

Identifier	Capability
/CSUP.01/	We herewith confirm that internal procedures for market surveillance are in place in order to determine current threads, concerning cyber security. In case patches are necessary, technical support can be addressed. <i><b>Remark:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details.</i>
/CSUP.02/	Based on the internal design of the device, we (the manufacturer) do not allow the HDO to install any unauthorized patches.

### RDMP: 3rd party components in product lifecycle roadmaps

**Goal:** Manufacturer plans such that products are sustainable throughout their life cycle according to internal quality systems and external regulations.

Identifier	Capability
/RDMP.01/	We herewith confirm that we maintain/support the system during estimated product life. In case maintenance / repair / patches are necessary, technical support can be addressed. <i><b>Remark:</b> refer to the technical information of FOOBAR 2.0 (chapter 42) for further details.</i>

## SAHD: System and application hardening

**Goal:** Minimize attack vectors and surface area via port closing; service removal, etc.

Identifier	Capability
/SAHD.01/	All capabilities to ensure that a system that is stable and provides just those services specified and required according to its INTENDED USE with a minimum of maintenance activities and to allow healthcare providers / HDOs to connect FOOBAR 2.0 to their network are addressed in chapter MLDP: Malware detection/protection in <i>the technical information of FOOBAR 2.0 (chapter 38)</i> .

## AUTH: Authorization

**Goal:** Provide access to MEDICAL DEVICE data and functions only as necessary to perform the tasks required by the HDO consistent with the INTENDED USE of the device.

Identifier	Capability
/AUTH.01/	Despite the administrative functions listed below, only personnel authorized by us (the manufacturer) have access to service functions and capabilities. Besides administrative tasks, allowed in the technical documentation, we do not allow further repair by unauthorized personnel. <b>Remark:</b> refer to the technical information of FOOBAR 2.0 for further details.
/AUTH.02/	So-called Administrator logins are provided with FOOBAR 2.0 for <ul style="list-style-type: none"> <li>– general server administration;</li> <li>– installation of updates/fixes;</li> <li>– adding more FOOBAR clients;</li> <li>– master user administration;</li> <li>– backup operations.</li> </ul>
/AUTH.03/	So-called Master User logins are pre-configured and can be added to <ul style="list-style-type: none"> <li>– fix/join reports/patient data;</li> <li>– recover lost reports;</li> <li>– general user administration;</li> <li>– edit and maintain general FOOBAR application configuration.</li> </ul>

### TXDF: Transmission confidentiality

**Goal:** MANUFACTURER demonstrates that its equipment meets multiple national standards or regulations (USA HIPAA, EU 95/46/EC, HBP 517, etc.) according to HDO needs to ensure the confidentiality of transmitted HEALTH DATA.

Identifier	Capability
/TXDF.01/	See /STCF.06/: connection to the dedicated remote archive present on the DICOM network can be established via VPN.  <b>Remark:</b> refer to the technical information of FOOBAR 2.0 (chapter 33) for further details.
/TXDF.02/	Upon request: we (the manufacturer) will provide certificates to demonstrate compliance with applicable national regulation. As these certificates vary, depending on the country, please contact technical service for further details.

### TXIG: Transmission integrity

**Goal:** Device protects the integrity of transmitted HEALTH DATA

Identifier	Capability
/TXIG.01/	See /STCF.06/: connection to the dedicated remote archive present on the DICOM network can be established via VPN.  This capability assures that integrity of HEALTH DATA is maintained during transmission and allows FOOBAR 2.0 transmission of HEALTH DATA over relatively open networks or environment where strong policies for HEALTH DATA integrity are in use.  <b>Remark:</b> refer to the technical information of FOOBAR 2.0 (chapter 33) for further details.



### A.3 HDO's reply to the MDM Security Characteristics Report – “The Response”

The following pages are the New Town Hospital's (HDO) response to the FOOBAR 2.0 Widget Corporation (MDM) statement of the SECURITY CAPABILITIES of the product (given in Section 3). Overall New Town is pleased with the security information as presented but there a few things missing and a few questions to be resolved before the New Town Security Officer can give a “proceed” message to the purchasing committee. The New Town Hospital's Security Officer responds with an annotated (right-most column added – in blue) FOOBAR 2.0 Security Characteristics Document. The response is started with an email/letter.

**Jose Armas**

FOOBAR Product Sales Manager,  
Widget Corporation

Dear Mr. Armas,

Thank you for your detailed response to my request for security information on Widget Corporation's FOOBAR 2.0 DICOM PACS Workstation. We find your IEC 80001-1 based document highly informative and a good start to our purchase and installation project prior to connecting the PACS Workstation to New Town Hospital's Medical IT-network

Although I appreciate your attempts at clarity and risk transparency, I have some comments and questions. I have taken the liberty of adding a column to your document and placing my comments to the right of your description of the security characteristics. Where I found a security feature lacking, I have added a row in the appropriate section. Further, where I recognized the security capability and where it seemed likely to meet our needs, my comment reads “Acknowledged.” Although not yet ready to “Accept” at this early date, I thought it useful to use this term so we could focus on other, more important issues, in our first discussion.

Once you have reviewed the attached document, I suggest that we have a teleconference to resolve items that can easily be clarified by telephone. If New Town Hospital Radiology and Purchasing decide to go forward with the purchase of your equipment and installation, we will have ample opportunity to further detail the security risks and mitigations in the integration project planning and implementation.

My office will contact you regarding the follow-up phone discussion.

Sincerely, Joan Kowalski, CISSP  
IT Security Officer  
New Town General Hospital

Cc: New Town Hospital Response to FOOBAR 2.0 Security Characteristics Report (IEC80001-1)

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**FOOBAR 2.0 security characteristics**  
**– New Town Hospital RESPONSE to Proposal from Widget Corporation –**

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The example contains a first reaction of a fictional health delivery organization New Town General Hospital. This HDO is considering the purchase of several FOOBAR 2.0 devices. This document section describes reaction/questions/issues on the security statement of the manufacturer of the FOOBAR 2.0 MEDICAL DEVICE.

### **A. Short description of the hospital**

The New Town General Hospital consists of multi-medical disciplines. Additional technical staff positions support the clinicians in the fields of privacy and security. The FOOBAR workstation will be placed into the Pulmonary Intensive Care Unit for use by Pulmonologists and Radiology consultants.

### **B. Short description of the network**

The network is divided into a general network and special network segments for medical products.

System and network administration is done by a local team of well-trained network administrators. A training program on medical product judicial aspects exists.

### **C. Short description of security aspects**

The network security strategy relies on a mixed protection and sensor strategy.

Certain network areas are protected by security equipment to prevent infections by malicious software. The whole network is monitored by sensor networks which reports malware infections exceeding a threshold level.

Please note that the text in **BLACK** in Section 4 below was provided by Widget Corporation for their FOOBAR 2.0 device. The text comments in *BLUE* below are the response by New Town Hospital's security staff.

### **D. Detailed Specification of SECURITY CAPABILITIES**

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**ALOF: Automatic logoff**

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**Goal:** Reduce the RISK of unauthorized access to HEALTH DATA from an unattended workspots. Prevent misuse by other users if a system or workspot is left idle for a period of time.

Identifier	Capability	HDO Comments/needs
/ALOF.01/	A screen-saver starts automatically 5 minutes after last keystroke / mouse movement operation. <b>Remark:</b> the local authorized IT administrator can set the delay for this action and even disable the screen-saver.	<i>acknowledged by HDO</i>  <i>desirable would be a longer time period since diagnostics has pauses with inactivity</i>
/ALOF.02/	The screen-saver clears all displayed HEALTH DATA from the screen.	<i>acknowledged by HDO</i>
/ALOF.03/	The screen-saver does not log-off the user / does not terminate the session.	<i>acknowledged by HDO</i>
/ALOF.04/	User has to log-in after occurrence of the screen-saver.	<i>acknowledged by HDO</i>
/ALOF.05/	The user-session terminates automatically 60 minutes after last keystroke / mouse movement / touchscreen operation. <b>Remark:</b> the local authorized IT administrator can set the delay for this action and even disable the automatic log-off.	<i>acknowledged by HDO</i>
		<i>additional: a master account would be desirable to override a user account and log in a screen-saved box</i>

### AUDT: Audit controls

**Goal:** Define harmonized approach towards reliably auditing who is doing what with HEALTH DATA, allowing HDO IT to monitor this using public frameworks, standards and technology.

Identifier	Capability	HDO Comments/needs
/AUDT.01/	Access, modification or deletion to any HEALTH DATA is recorded and stored on the dedicated remote DICOM archive.	<i>Feature not needed in this application.</i>
/AUDT.02/	Download of HEALTH DATA (to the internal storage of the device) is recorded and stored on the dedicated remote DICOM archive.	<i>Feature not needed in this application.</i>
/AUDT.03/	In case the device is used outside the boundaries of the DICOM network, access to any HEALTH DATA is stored on the internal storage of the device.	<i>Feature not needed in this application.</i>

Identifier	Capability	HDO Comments/needs
/AUDT.04/	After re-connecting the device back to the DICOM-Network, the audit-trails recorded on the internal storage of the device during offline-use are synchronized with the dedicated remote DICOM archive.	<i>Feature not needed in this application.</i>
/AUDT.05/	Refers to /CNFS.01/: all changes to the SECURITY CAPABILITIES are included to the audit-trail of the device.	<i>Feature not needed in this application.</i>

### CNFS: Configuration of security features

**Goal:** To allow the HDO to determine how to utilize the product SECURITY CAPABILITIES to meet their needs for policy and/or workflow.

Identifier	Capability	HDO Comments/needs
/CNFS.01/	The local authorized IT administrator can set / disable the available SECURITY CAPABILITIES of the device.	<i>HDO acknowledges</i>
/CNFS.02/	Refers to /AUDT.05/: in case the local authorized IT administrator set / disables / changes the settings of the available SECURITY CAPABILITIES of the device, the action is logged in an audit-trail.	<i>HDO acknowledges</i>
		<i>HDO misses an important security feature (e.g., port blocking). An investment plan is created to calculate the costs for additional equipment which compensates these deficiencies.</i>

### DTBK: Data backup and disaster recovery

**Goal:** Assure that the healthcare provider can continue business after damage or destruction of data, hardware, or software.

Identifier	Capability	HDO Comments/needs
/DTBK.01/	FOOBAR 2.0 provides a back-up (built-in) to store the <u>system-settings</u> to an externally connected mass-storage-device (e.g. a USB-stick).	<i>Feature not needed in this application.</i>

Identifier	Capability	HDO Comments/needs
/DTBK.02/	FOOBAR 2.0 provides a back-up (built-in) to store the <u>audit-trails</u> to an externally connected mass-storage-device (e.g. a USB-stick).	<i>Feature not needed in this application.</i>
/DTBK.03/	The audit-trails are encrypted accordingly in order to prevent loss of confidential information, contained in HEALTH DATA (like patient name, DOB, etc.).	<i>Feature not needed in this application.</i>
/DTBK.04/	Backup of locally stored HEALTH DATA can only be done back to the dedicated remote DICOM archive. <b>Rationale:</b> <i>this restrictive functionality is required in order to ensure that the HEALTH DATA remains consistent.</i>	<i>Feature not needed in this application.</i>

#### DIDT: HEALTH DATA de-identification

**Goal:** Ability of equipment (application software or additional tooling) to directly remove information that allows identification of PATIENT.

Identifier	Capability	HDO Comments/needs
/DIDT.01/	FOOBAR 2.0 does not support any means to directly remove information that allows identification of PATIENT.	<i>HDO acknowledges</i>  <b>Note to HDO Purchasing:</b> <i>This device capability prevents use in research and teaching</i>
		<i>HDO needs to receive from the MDM an exact specification of all data put into the DICOM 3.0 files. This is essential to write its own file format manipulators (e.g., deidentification, transfer to research archive).</i>

### STCF: HEALTH DATA storage confidentiality

**Goal:** Manufacturer ensures that unauthorized access does not compromise the integrity and confidentiality of HEALTH DATA stored on products or removable media.

Identifier	Capability	HDO Comments/needs
/STCF.01/	HEALTH DATA, stored on the internal storage of FOOBAR 2.0 is encrypted. Used algorithm: AES (Rijndael), Encryption strength: 256 BIT.  <b>Remark:</b> this setting cannot be changed by local IT administrator.	<i>HDO needs more information of the key generation PROCESS.</i>  <i>When the key generation is done by the manufacturer, a PROCESS must exist that makes a separation of those parties that generate the key and those doing a hardware support case, to prevent legal privacy issues when a defect harddrive is returned to the manufacturer to get a replacement device. How is key management done?</i>
/STCF.02/	The secured / encrypted HEALTH DATA is accessible after successful boot only. See also /MLDP.04/.	<i>HDO acknowledges</i>  <i>During reboot, does the device require a special password (other than user logon) to proceed to operational state?</i>
/STCF.03/	Only the required HEALTH DATA is decrypted (required for the current interaction / usage / display). Currently not used HEALTH DATA remains encrypted.	<i>HDO acknowledges</i>
/STCF.04/	Boot partition, operating system, temporary data on internal mass storage device, etc. is also encrypted. Used algorithm: AES (Rijndael), Encryption strength: 256 BIT.  <b>Remark:</b> this setting cannot be changed by local IT administrator.	<i>HDO acknowledges</i>
/STCF.05/	Accidental power-down of the system does not affect the encryption of the HEALTH DATA on the mass storage device. In no circumstance of operation is unencrypted HEALTH DATA present on the internal mass storage device.	<i>HDO acknowledges</i>
/STCF.06/	Connection to the dedicated remote archive present on the DICOM network can be established via VPN.	<i>HDO acknowledges</i>

### EMRG: Emergency access

**Goal:** Ensure that access to protected HEALTH DATA is possible in case of an emergency situation requiring immediate access to stored HEALTH DATA.

Identifier	Capability	HDO Comments/needs
/EMRG.01/	Break-glass functionality provided: even without <u>personal</u> user id and authentication clinical user can gather access to HEALTH DATA.  <i><b>Remark:</b> remember that this functionality may be changed / disabled by local IT administrator.</i>	<i>HDO acknowledges</i>
/EMRG.02/	Usage of the break-glass functionality /EMRG.01/ requires the usage of a <u>general</u> user id and authentication (in order to prevent patients or bystanders to access HEALTH DATA).	<i>HDO acknowledges</i>
/EMRG.03/	Each use of the break-glass functionality /EMRG.01/ will be recorded in the audit-trail.	<i>HDO acknowledges</i>
/EMRG.04/	Each use of the break-glass functionality /EMRG.01/ can be reported automatically to a defined user account, e.g. by means of e-mail.	<i>HDO acknowledges</i>

### SGUD: Security guides

**Goal:** Ensure that security guidance for OPERATOR and administrator of the system and MANUFACTURER sales and service is available. Separate manuals are desirable as they allow understanding of full administrative functions to be kept only by administrators.

Identifier	Capability	HDO Comments/needs
/SGUD.01/	Security guidance for OPERATOR is included in the instructions for use of FOOBAR 2.0. See chapter 13.	<i>HDO acknowledges</i>
/SGUD.02/	Security guidance for administrator is included in the technical information of FOOBAR 2.0. See chapter 17.	<i>HDO acknowledges</i>

### IGAU: HEALTH DATA integrity and authenticity

**Goal:** Assure that HEALTH DATA has not been altered or destroyed in nonauthorized manner and is from the originator. Assure integrity of HEALTH DATA.

Identifier	Capability	HDO Comments/needs
/IGAU.01/	HEALTH DATA, stored on the mass storage of FOOBAR 2.0 in order to display the medical data outside the boundaries of the DICOM network, is secured by adequate checksum (SHA1) in order to assure integrity of data.	<i>HDO knows of weaknesses of SHA1 algorithm and needs a policy statement how manufacturer reacts on cryptographic security issues.</i>
/IGAU.02/	Backup-capabilities are provided. See chapter DTBK: Data backup and disaster recovery	<i>HDO acknowledges</i>

### MLDP: Malware detection/protection

**Goal:** Product supports regulatory, HDO and user needs in ensuring an effective and uniform support for the prevention, detection and removal of malware. This is an essential step in a proper defense in-depth approach to security.

Identifier	Capability	HDO Comments/needs
/MLDP.01/	All unnecessary network-ports of FOOBAR 2.0 are closed.  <i><b>Remark 01:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details. See /SGUD.02/.</i>  <i><b>Remark 02:</b> this capability cannot be changed by local IT-administrator.</i>	<i>HDO acknowledges</i>
/MLDP.02/	The operating-system on the boot-device of FOOBAR 2.0 is protected against authorized / unauthorized changes. After re-boot, the system is back in the initial state.  <i><b>Remark:</b> this capability cannot be changed by local IT-administrator.</i>	<i>HDO needs a statement from the manufacturer how malicious run time modifications are detected.</i>
/MLDP.03/	All relevant files are secured by adequate checksum (SHA1) and checked during boot-sequence. In case of error detection, system does not start but displays an error message.  <i><b>Remark:</b> this capability cannot be changed by local IT-administrator.</i>	<i>HDO acknowledges</i>
/MLDP.04/	The secured / encrypted HEALTH DATA is accessible after successful boot only. See also /STCF.01/.  <i><b>Remark:</b> this capability cannot be changed by local IT-administrator.</i>	<i>HDO acknowledges</i>



### PAUT: Person authentication

**Goal:** Authentication policies need to be flexible to adapt to HDO IT policy. This requirement as a logical place to require person authentication when communicating HEALTH DATA.

Identifier	Capability	HDO Comments/needs
/PAUT.01/	FOOBAR 2.0 supports local and global management of accounts. <b>Remark:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details.	<i>HDO needs exact specification of connection to central authentication structures (e.g., PKI, IEEE 802.1X).</i>  <i>NOTE Please provide Guidance Documents ASAP.</i>
/PAUT.02/	FOOBAR 2.0 supports withdrawal of accounts. <b>Remark:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details.	<i>Can this be done remotely or does the IT Administrator have to be at the FOOBAR device?</i>
/PAUT.03	FOOBAR 2.0 supports fast user switching. By supporting this, signing off and on is not a time-consuming task.	<i>HDO acknowledges</i>

### PLOK: Physical locks on device

**Goal:** Assure that unauthorized access does not compromise the integrity and confidentiality of HEALTH DATA stored on products or removable media.

Identifier	Capability	HDO Comments/needs
/PLOK.01/	Because of the chosen encryption, FOOBAR 2.0 does not require physical lock-outs.	<i>HDO acknowledges</i>
		<i>HDO asks if keyboard is protected or an illegal key-logger device can easily be attached between the keyboard and cabinet.</i>
		<i>Does the computer cabinet use a lock? Can disk drives be easily removed or replaced?</i>

## CSUP: Cyber security Product upgrades

**Goal:** Create a unified way of working. Installation / Upgrade of product security patches by on-site service staff, remote service staff, and possibly authorized HDO staff (downloadable patches).

Identifier	Capability	HDO Comments/needs
/CSUP.01/	<p>We herewith confirm that internal procedures for market surveillance are in place in order to determine current threads, concerning cyber security. In case patches are necessary, technical support can be addressed.</p> <p><b>Remark:</b> refer to the security guidance for administrator in the technical information of FOOBAR 2.0 (chapter 17) for further details.</p>	<p><i>HDO needs more information:</i></p> <ol style="list-style-type: none"> <li><i>1. PROCESS must exist and be disclosed how relevant security and stability upgrades are distinguished from irrelevant ones.</i></li> <li><i>2. PROCESS must exist and be disclosed which criteria must be fulfilled that cyber security actions are worth a CAPA-message.</i></li> <li><i>3. PROCESS must exist and be disclosed, about delay between announcement from the operating system manufacturer and reaction from the MEDICAL DEVICE manufacturer.</i></li> <li><i>4. PROCESS must exist and be disclosed how cyber security threats are announced to the HDO.</i></li> </ol>
/CSUP.02/	Based on the internal design of the device, we (the manufacturer) do not allow the HDO to install any unauthorized patches.	<i>HDO acknowledges and adds a statement to the RESPONSIBILITY AGREEMENT that manufacturer is fully responsible for HARM to patients because of missing approval of critical patches.</i>

### RDMP: 3rd party components in product lifecycle roadmaps

**Goal:** Manufacturer plans such that products are sustainable throughout their life cycle according to internal quality systems and external regulations.

Identifier	Capability	HDO Comments/needs
/RDMP.01/	<p>We herewith confirm that we maintain/support the system during estimated product life. In case maintenance / repair / patches are necessary, technical support can be addressed.</p> <p><b>Remark:</b> refer to the technical information of FOOBAR 2.0 (chapter 42) for further details.</p>	<p><i>A PROCESS must exist and be disclosed how HDO will be informed of end of life dates of critical components. We must know when security upgrades are no longer possible.</i></p>

### SAHD: System and application hardening

**Goal:** Minimize attack vectors and surface area via port closing; service removal, etc.

Identifier	Capability	HDO Comments/needs
/SAHD.01/	<p>All capabilities to ensure that a system that is stable and provides just those services specified and required according to its INTENDED USE with a minimum of maintenance activities and to allow healthcare providers / HDOs to connect FOOBAR 2.0 to their network are addressed in chapter MLDP: Malware detection/ protection in the technical information of FOOBAR 2.0 (chapter 38).</p>	<p><i>HDO acknowledges</i></p>

## AUTH: Authorization

**Goal:** Provide access to MEDICAL DEVICE data and functions only as necessary to perform the tasks required by the HDO consistent with the INTENDED USE of the device.

Identifier	Capability	HDO Comments/needs
/AUTH.01/	<p>Despite the administrative functions listed below, only personnel authorized by us (the manufacturer) have access to service functions and capabilities. Besides administrative tasks, allowed in the technical documentation, we do not allow further repair by unauthorized personnel.</p> <p><b>Remark:</b> refer to the technical information of FOOBAR 2.0 for further details.</p>	<i>Statement will be accepted in the RESPONSIBILITY AGREEMENT.</i>
/AUTH.02/	<p>So-called Administrator logins are provided with FOOBAR 2.0 for</p> <ul style="list-style-type: none"> <li>– general server administration;</li> <li>– installation of updates/fixes;</li> <li>– adding more FOOBAR clients;</li> <li>– master user administration;</li> <li>– backup operations.</li> </ul>	
/AUTH.03/	<p>So-called Master User logins are pre-configured and can be added to</p> <ul style="list-style-type: none"> <li>– fix/join reports/patient data;</li> <li>– recover lost reports ;</li> <li>– general user administration;</li> <li>– edit and maintain general FOOBAR application configuration.</li> </ul>	

### TXDF: Transmission confidentiality

**Goal:** MANUFACTURER demonstrates that its equipment meets multiple national standards or regulations (USA HIPAA, EU 95/46/EC, HBP 517, etc.) according to HDO needs to ensure the confidentiality of transmitted HEALTH DATA.

Identifier	Capability	HDO Comments/needs
/TXDF.01/	See /STCF.06/: connection to the dedicated remote archive present on the DICOM network can be established via VPN.  <b>Remark:</b> refer to the technical information of FOOBAR 2.0 (chapter 33) for further details.	<i>HDO requires a statement of the specific VPN compatibility to determine the true INTEROPERABILITY with HDO existing VPNs.</i>
/TXDF.02/	Upon request: we (the manufacturer) will provide certificates to demonstrate compliance with applicable national regulation. As these certificates vary, depending on the country, please contact technical service for further details.	<i>HDO acknowledges and will decide on the required compliance certifications prior to purchase.</i>

### TXIG: Transmission integrity

**Goal:** Device protects the integrity of transmitted HEALTH DATA

Identifier	Capability	HDO Comments/needs
/TXIG.01/	See /STCF.06/: connection to the dedicated remote archive present on the DICOM network can be established via VPN.  This capability assures that integrity of HEALTH DATA is maintained during transmission and allows FOOBAR 2.0 transmission of HEALTH DATA over relatively open networks or environment where strong policies for HEALTH DATA integrity are in use.  <b>Remark:</b> refer to the technical information of FOOBAR 2.0 (chapter 33) for further details.	<i>HDO acknowledges.</i>

### Additional security needs of New Town Hospital

*None specified at this time but New Town Hospital reserves the right to introduce additional needs as we develop our dialog about this product.*

## **Annex B**

(informative)

### **Examples of regional specification on a few SECURITY CAPABILITIES**

The following are a few examples of capabilities adapted for regional use in the USA. This is illustrative only and is not intended as complete or as final guidance for USA use.

**PAUT: Person authentication**

Applicable:	<b>Profile:</b> IHE ATNA profile (Audit Trail and Node Authentication) IHE PWP profile (Personal White Pages) IHE EUA (Enterprise User Authentication) IHE XUA (Cross-Enterprise User Assertion) <b>Policies:</b> SANS Security Policy Project Local HDO IT Policies
Source Requirement	HIPAA Security Rule <sup>1</sup> ), § 164.312. (a)(1) <i>Standard: Access control. Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).</i>
Reference material:	2 (i) Unique user identification (Required). Assign a unique name and/or number for identifying and tracking user identity. NIST SP 800-53 v3 AC3: Access Enforcement—access enforcement mechanisms are employed by organizations to control access between users and objects
Dependence:	AUDT, NAUT
Requirement goal:	Authentication policies need to be flexible to adapt to HDO IT policy. This requirement as a logical place to require person authentication when communicating Protected Health Data (PHI).
User need:	Users might need the capability of creating and using unique accounts for users and role based access control (RBAC, local and remote) for a network connected device to control and monitor network access and activity. Capability of managing accounts on a modality to protect Protected Health Data (PHI) access. Users might need to associate personal preferences with user accounts. This might help devices and systems used by multiple OPERATORS, departments or even multiple HDOs. Support for stand-alone and central administration. Single sign-on and same password on all workspots. Support for node authentication according industry standards. To detect and prevent person/entity falsification (provide non-repudiation).

<sup>1</sup>) Department of Health and Human Services, Office of the Secretary, 45 CFR, Parts 160, 162, and 164 Health Insurance Reform; Security Standards; Final Rule, February 20, 2003

**NAUT: Node authentication**

Applicable:	<b>Profile:</b> IHE ATNA profile (Audit Trail and Node Authentication) IHE EUA (Enterprise User Authentication) IHE XUA (Cross-Enterprise User Assertion)  <b>Policies:</b> NEMA/COCIR/JIRA Joint Security and Privacy Committee draft White Paper: <i>Management of Machine Authentication Certificates</i> , 10 February 2005 SANS Security Policy Project Local HDO IT Policies
Source Requirement	HIPAA Security Rule, § 164.312 Technical safeguards. (a)(1) <i>Standard: Access control. Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).</i>
Reference material:	NIST SP 800-53 v3  AC3: Access Enforcement—access enforcement mechanisms are employed by organizations to control access between users and objects
Dependence:	AUDT, PAUT
Requirement goal:	Authentication policies need to be flexible to adapt to HDO IT policy. This requirement as a logical place to require node authentication when communicating Protected Health Data (PHI).
User need:	Capability of managing machine-to-machine access between a modality and a workstation or PACS system to protect Protected Health Data (PHI) access.  Single sign-on and same password on all workspots. Support for node authentication according industry standards.  To detect and prevent person/entity falsification (provide non-repudiation).

**ALOF: Automatic logoff**

Applicable:	<b>Standard:</b> N/A  <b>Policies:</b> Local HDO IT Policies
Source Requirement:	HIPAA Security Rule, § 164.312 Technical safeguards – (a)(1) <i>Standard: Access control. Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).</i>  (2)(iii) (iii) Automatic logoff (Addressable). Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.  NIST 800-53, Rev 3 – Supplemental Guidance: A session lock is a temporary action taken when a user stops work and moves away from the immediate physical vicinity of the information system but does not want to log out because of the temporary nature of the absence. AC-11 SESSION LOCK: Control: The information system:



Reference material:	<p>a. Prevents further access to the system by initiating a session lock after [Assignment: organization-defined time period] of inactivity or upon receiving a request from a user; and</p> <p>b. Retains the session lock until the user re-establishes access using established identification and authentication procedures.</p>
Dependence:	N/A
Requirement goal:	<p>AUDT</p> <p>Reduce the RISK of unauthorized access to Protected Health Data (PHI) from an unattended workspots.</p> <p>Prevent misuse by other users if a system or workspot is left idle for a period of time.</p>
User need:	<p>Unauthorized users are not able to access Protected Health Data (PHI) at an unattended workspot.</p> <p>Authorized user sessions need to automatically terminate or lock after a preset period of time. This reduces the RISK of unauthorized access to Protected Health Data (PHI) when an authorized user left the workspot without logging off or locking the display or room.</p> <p>Automatic log off needs to include a clearing of Protected Health Data (PHI) from all displays as appropriate.</p> <p>The local authorized IT administrator needs to be able to disable the function and set the expiration time (including screen saver)</p> <p>Screen saver with short inactivity time or manually enforced by key shortcut might be additional feature. This Protected Health Data (PHI) display clearing could be invoked when no key is pressed for some short period (e.g. 15 seconds to several minutes). This would not log out the user but would reduce RISK of casual viewing of information.</p> <p>Clinical users cannot lose uncommitted work due to automatic logoff.</p>

## Annex C (informative)

### SECURITY CAPABILITY mapping to C-I-A-A

Table C.1 provides a sample mapping by a hypothetical HDO of the degree to which each of the listed SECURITY CAPABILITIES addresses the concepts of security (confidentiality, integrity, availability, and accountability) and supports their organizational policies. It supports IT professionals to understand the contributions of the respective SECURITY CAPABILITIES to security.

A "2" means that the Capability strongly supports a policy Concept. A blank indicates that it is relatively neutral and a -1 means that the capability actually detracts from the policy Concept (e.g., having Automatic logoff actually lessens availability).

**Table C.1 – Sample mapping by a hypothetical HDO**

<b>Capabilities:</b>	<b>Concepts:</b>	Confidentiality	Integrity	Availability	Accountability
<b>ALOF:</b> Automatic logoff		2	2	-1	
<b>AUDT:</b> Audit controls		1	1		1
<b>AUTH:</b> Authorization		2	2	-1	1
<b>CNFS:</b> Configuration of security features		1	1	1	1
<b>CSUP:</b> Cyber security Product upgrades		1	1	1	
<b>DTBK:</b> Data backup and disaster recovery			1	2	
<b>EMRG:</b> Emergency access				2	-1
<b>DIDT:</b> HEALTH DATA de-identification		2			
<b>IGAU:</b> HEALTH DATA integrity and authenticity			2		2
<b>STCF:</b> HEALTH DATA storage confidentiality		2			
<b>MLDP:</b> Malware detection/protection		1	1	1	
<b>NAUT:</b> Node authentication		1			1
<b>PAUT:</b> Person authentication		1			2
<b>PLOK:</b> Physical locks on device		1	1	1	
<b>SGUD:</b> Security guides		1	1	1	1
<b>SAHD:</b> System and application hardening		1	1	1	
<b>RDMP:</b> Third party components in product lifecycle roadmaps					
<b>TXDF:</b> Transmission confidentiality		2			
<b>TXIG:</b> Transmission integrity			2		

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### Standards

IEC 60300-3-9:1995, *Dependability management – Part 3-9: Application guide – Risk analysis of technological systems*<sup>1)</sup>

IEC 60601-1-6:2006, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

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ISO/IEC 20000-1:2011, *Information technology – Service management – Part 1: Service management system requirements*

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ISO/IEC 27002:2005, *Information technology. Security techniques. Code of practice for information security management*

ISO/IEC 27005:2011, *Information technology – Security techniques – Information security risk management*

ISO 13485:2003, *Quality management systems – Requirements for regulatory purposes*

ISO/TS 13606-4:2009, *Health informatics – Electronic health record communication – Part 4: Security*

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<sup>1)</sup> Replaced by IEC/ISO 31010:2009, *Risk management - Risk assessment techniques*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

ISO/TS 25238:2007, *Health informatics – Classification of safety risks from health software*

ISO 27799:2008, *Health informatics – Information security management in health using ISO/IEC 27002*

ISO/TR 27809:2007, *Health informatics – Measures for ensuring patient safety of health software*

IEEE 610.12:1990, *IEEE Standard Glossary of Software Engineering Terminology*

### **Additional frameworks**

ASIP requirements      *FR l'Agence des Systèmes d'Information Partagés de Santé (ASIP Santé) [ASIP Santé, the shared healthcare information systems agency <http://esante.gouv.fr/en>] creating conditions to comply with Law No. 2002-303 of 4 March 2002 on patients' rights and quality care system*

DICOM      *Digital Imaging and Communications in Medicine (DICOM)  
National Electrical Manufacturers Association.  
<http://medical.nema.org/dicom/>*

Japan Law/Guidance      *JP Act on the Protection of Personal Information (PFD)  
[http://www.caa.go.jp/seikatsu/kojin/index\\_en.html](http://www.caa.go.jp/seikatsu/kojin/index_en.html) and Guideline for Medical Information System Safety Management  
<http://www.mhlw.go.jp/shingi/2010/02/s0202-4.html> (Japanese only),  
Ministry of Health, Labor and Welfare, Japan*

NEMA/COCIR/JIRA      *Joint Security and Privacy Committee. See tutorials and white papers at <http://www.medicalimaging.org/policy-and-positions/joint-security-and-privacy-committee-2/>*

NEN 7510      *NL Netherlands Normalisatie-instituut Standard Medische informatica - Informatiebeveiliging in de zorg – Algemeen [Health Informatics - Information Security in the Healthcare Sector – General] <http://www.nen.nl/web/Normshop/Norm/NEN-75102004-nl.htm>*

NIST 800 series      *US National Institute of Standards and Technology Special Publications series on Computer Security  
<http://csrc.nist.gov/publications/PubsSPs.html>*