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Edition 1.0 2012-07

TECHNICAL REPORT

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Application of risk management for IT-networks incorporating medical devices – Part 2-1: Step-by-step risk management of medical IT-networks – Practical applications and examples

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

Part 2-1: Step-by-step risk management of medical IT-networks – Practical applications and examples

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IEC 80001-2-1, which is a technical report, has been prepared by a Joint Working Group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62*:* Electrical equipment in medical practice and ISO technical committee 215: Health informatics.

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

Enquiry draft	Report on voting
62A/782/DTR	62A/803/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

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

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

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

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- replaced by a revised edition, or
- amended.

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INTRODUCTION

This technical report is a step-by-step guide to help in the application of RISK MANAGEMENT when creating or changing a MEDICAL IT-NETWORK. It provides easy to apply steps, examples, and information helping in the identification and control of RISKS. All relevant requirements in IEC 80001-1:2010 are addressed and links to other clauses and subclauses of IEC 80001-1 are addressed where appropriate (e.g. handover to release management and monitoring).

This technical report focuses on practical RISK MANAGEMENT. It is not intended to provide a full outline or explanation of all requirements that are satisfactorily covered by IEC 80001-1.

This step-by-step guidance follows a 10-step PROCESS that follows subclause 4.4 of IEC 80001-1:2010, which *specifically* addresses RISK ANALYSIS, RISK EVALUATION and RISK CONTROL. These activities are embedded within the full life cycle RISK MANAGEMENT PROCESS. They can never be the first step, as RISK MANAGEMENT follows the general PROCESS model which sets planning before any action.

For the purpose of this technical report, “prerequisites” as stated in subclause 1.3 are considered to be in place before execution of the 10 steps. Also, it is well understood that all steps outlined in this technical report should have been performed before any new MEDICAL IT-NETWORK can go live or before proceeding with a change to an existing MEDICAL IT-NETWORK. It is emphasized that subclause 4.5 of IEC 80001-1:2010 “CHANGE RELEASE MANAGEMENT and CONFIGURATION MANAGEMENT” explicitly includes and applies to new MEDICAL IT-NETWORKS, as well as changes to existing networks.

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This technical report will be useful to those responsible for or part of a team executing RISK MANAGEMENT when changing or creating (as the ultimate change) a MEDICAL IT-NETWORK. MEDICAL DEVICES in the context of IEC 80001 refer to those MEDICAL DEVICES that connect to a network.

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

Part 2-1: Step-by-step risk management of medical IT-networks – Practical applications and examples

1 Scope

This technical report provides step-by-step information to aid RESPONSIBLE ORGANIZATIONS in implementation of the RISK MANAGEMENT PROCESS required by IEC 80001-1. Specifically, it details the steps involved in executing subclause 4.4 of IEC 80001-1:2010 and provides guidance in the form of a study of RISK MANAGEMENT terms, RISK MANAGEMENT steps, an explanation of each step, step-by-step examples, templates, and lists of HAZARDS and causes to consider.

The steps outlined within this technical report are considered to be universally applicable. Application of these steps can be scaled as described within this document.

2 Normative references

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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.

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
CHANGE PERMIT
an outcome of the RISK MANAGEMENT PROCESS consisting of a document that allows a specified change or type of change without further RISK MANAGEMENT activities subject to specified constraints

[SOURCE: IEC 80001-1:2010, definition 2.3]

3.2
CHANGE RELEASE MANAGEMENT
PROCESS that ensures that all changes to the IT-NETWORK are assessed, approved, implemented and reviewed in a controlled manner and that changes are delivered, distributed, and tracked, leading to release of the change in a controlled manner with appropriate input and output with CONFIGURATION MANAGEMENT

[SOURCE: IEC 80001-1:2010, definition 2.2]

3.3
CONFIGURATION MANAGEMENT
PROCESS that ensures that configuration information of components and the IT-NETWORK are defined and maintained in an accurate and controlled manner, and provides a mechanism for identifying, controlling and tracking versions of the IT-NETWORK

[SOURCE: IEC 80001-1:2010, definition 2.4]

3.4
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 definition in the original document have been deleted.]

3.5
EFFECTIVENESS
ability to produce the intended result for the PATIENT and the RESPONSIBLE ORGANIZATION

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

3.6
ELECTROMAGNETIC INTERFERENCE
EMI
any electromagnetic phenomenon that may degrade the performance of a device, equipment, or system

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[SOURCE: IEC 60601-1-2:2007, definition 3.5, modified – the term has been changed, an abbreviation added and the note to the original definition removed.]

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3.7
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]

3.8
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 SYSTEMS SECURITY

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

3.9
HAZARD
potential source of HARM

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

3.10
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]

3.11
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.

[SOURCE: IEC 80001-2-2:2012, definition 3.7]

3.12
INTENDED USE
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]

3.13
INTEROPERABILITY
property permitting diverse systems or components to work together for a specified purpose

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

3.14
INFORMATION TECHNOLOGY
IT
technology (computer systems, networks, software) used to PROCESS, store, acquire and distribute information

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3.15
IT-NETWORK
INFORMATION TECHNOLOGY NETWORK
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.]

3.16
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]

3.17
LOCAL AREA NETWORK
LAN
computer network covering a small physical area, such as a home or office, or small group of buildings, such as a school or an airport

3.18
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a MEDICAL DEVICE, assembling a system, or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

[SOURCE: ISO 14971:2007, definition 2.8, modified – Note 1 to the original definition, which provides pertinent information, has not been retained.]

3.19
MEDICAL DEVICE
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.

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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.

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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 to entry);
- 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]

3.20
MEDICAL IT-NETWORK
IT-NETWORK that incorporates at least one MEDICAL DEVICE

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

3.21
MONITORING
on-going review of all RISK MANAGEMENT activities and RISK CONTROL options that were put in place to achieve acceptable RISK in the use of MEDICAL IT-NETWORK(S).

3.22
OPERATOR
person handling equipment

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

3.23
PATIENT
individual awaiting or under medical care and treatment

3.24
PROCESS
set of interrelated or interacting activities which transforms inputs into outputs

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

3.25
QUALITY OF SERVICE
QoS
the capability or means of providing differentiated levels of networking performance in terms of traffic engineering (packet delay, loss, jitter, bit rate) to different data flows.

3.26
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

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

3.27
RESPONSIBILITY AGREEMENT
one or more documents that together fully define the responsibilities of all relevant stakeholders

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

3.28
RESPONSIBLE ORGANIZATION
RO
entity accountable for the use and maintenance of a MEDICAL IT-NETWORK

[SOURCE: IEC 80001-1:2010, definition 2.22, modified – a note to the original definition, containg examples, has not been retained.]

3.29
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

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

3.30
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

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

3.31
RISK ASSESSMENT
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

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

3.32
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]

3.33
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]

3.34
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]

3.35
RISK MANAGEMENT FILE
set of records and other documents that are produced by RISK MANAGEMENT

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[SOURCE: IEC 80001-1:2010, definition 2.29]

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3.36
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]

3.37
TOP MANAGEMENT
person or group of people who direct(s) and control(s) the RESPONSIBLE ORGANIZATION accountable for a MEDICAL IT-NETWORK at the highest level

[SOURCE: IEC 80001-1:2010, definition 2.31]

3.38
UNINTENDED CONSEQUENCE
UC
unwanted and negative outcome of an event that results in one or more degraded KEY PROPERTIES

3.39
VERIFICATION
confirmation through provision of objective evidence that specified requirements have been fulfilled

Note 1 to entry: The term “verified” is used to designate the corresponding status.

Note 2 to entry: Confirmation can comprise activities such as:

– performing alternative calculations;
– comparing a new design specification with a similar proven design specification;
– undertaking tests and demonstrations; and