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

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Application de la gestion des risques aux réseaux des technologies de l'information contenant des dispositifs médicaux – Partie 1: Fonctions, responsabilités et activités

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

Part 1: Roles, responsibilities and activities

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It is published as a double logo standard.

The text of this standard is based on the following documents:

FDIS	Report on voting
62A/703/FDIS	62A/718/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 17 P-members out of 18 having cast a vote.

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

Terms defined in Clause 2 of this standard are printed in SMALL CAPITALS.

For the purposes of this standard:

- “shall” means that compliance with a requirement is mandatory for compliance with this standard;
- “should” means that compliance with a requirement is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement; and
- “establish” means to define, document, and implement.

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INTRODUCTION

An increasing number of MEDICAL DEVICEs are designed to exchange information electronically with other equipment in the user environment, including other MEDICAL DEVICES. Such information is frequently exchanged through an information technology network (IT-NETWORK) that also transfers data of a more general nature.

At the same time, IT-NETWORKS are becoming increasingly vital to the clinical environment and are now required to carry increasingly diverse traffic, ranging from life-critical patient data requiring immediate delivery and response, to general corporate operations data and to email containing potential malicious content (e.g. viruses).

For many jurisdictions, design and production of MEDICAL DEVICES is subject to regulation, and to standards recognized by the regulators. Traditionally, regulators direct their attention to MEDICAL DEVICE manufacturers, by requiring design features and by requiring a documented PROCESS for design and manufacturing. MEDICAL DEVICES cannot be placed on the market in these jurisdictions without evidence that those requirements have been met.

The use of the MEDICAL DEVICES by clinical staff is also subject to regulation. Members of clinical staff have to be appropriately trained and qualified, and are increasingly subject to defined PROCESSES designed to protect patients from unacceptable RISK.

In contrast, the incorporation of MEDICAL DEVICES into IT-NETWORKS in the clinical environment is a less regulated area. IEC 60601-1:2005 [1][1)] requires MEDICAL DEVICE manufacturers to include some information in ACCOMPANYING DOCUMENTS if the MEDICAL DEVICE is intended to be connected to an IT-NETWORK. Standards are also in place covering common information technology activities including planning, design and maintenance of IT-NETWORKS, for instance ISO 20000-1:2005 [9]. However, until the publication of this standard, no standard addressed how MEDICAL DEVICES can be connected to IT-NETWORKS, including general-purpose IT-NETWORKS, to achieve INTEROPERABILITY without compromising the organization and delivery of health care in terms of SAFETY, EFFECTIVENESS, and DATA AND SYSTEM SECURITY.

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There remain a number of potential problems associated with the incorporation of MEDICAL DEVICES into IT-NETWORKS, including:

– lack of consideration for RISK from use of IT-NETWORKS during evaluation of clinical RISK;

– lack of support from manufacturers of MEDICAL DEVICES for the incorporation of their products into IT-NETWORKS, (e.g. the unavailability or inadequacy of information provided by the manufacturer to the OPERATOR of the IT-NETWORK);

– incorrect operation or degraded performance (e.g. incompatibility or improper configuration) resulting from combining MEDICAL DEVICES and other equipment on the same IT-NETWORK;

– incorrect operation resulting from combining MEDICAL DEVICE SOFTWARE and other software applications (e.g. open email systems or computer games) in the same IT-NETWORK;

– lack of security controls on many MEDICAL DEVICES; and

– the conflict between the need for strict change control of MEDICAL DEVICES and the need for rapid response to the threat of cyberattack.

When these problems manifest themselves, unintended consequences frequently follow.

This standard is addressed to RESPONSIBLE ORGANIZATIONS, to manufacturers of MEDICAL DEVICES, and to providers of other information technology.

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1) Numbers in square brackets refer to the Bibliography.

This standard adopts the following principles as a basis for its normative and informative sections:

– The incorporation or removal of a MEDICAL DEVICE or other components in an IT-NETWORK is a task which requires design of the action; this might be out of the control of the manufacturer of the MEDICAL DEVICE.

– RISK MANAGEMENT should be used before the incorporation of a MEDICAL DEVICE into an IT-NETWORK takes place, and for any changes during the entire life cycle of the resulting MEDICAL IT-NETWORK, to avoid unacceptable RISKS, including possible RISK to patients, resulting from the incorporation of the MEDICAL DEVICE into the IT-NETWORK. Many things are part of a RISK decision, such as liability, cost, or impact on mission. These should be considered in determining acceptable RISK in addition to the requirements described in this standard.

– Aspects of removal, maintenance, change or modification of equipment, items or components should be addressed adequately in addition to the incorporation of MEDICAL DEVICES.

– The manufacturer of the MEDICAL DEVICE is responsible for RISK MANAGEMENT of the MEDICAL DEVICE during the design, implementation, and manufacturing of the MEDICAL DEVICE. This standard does not cover the RISK MANAGEMENT PROCESS for the MEDICAL DEVICE.

– The manufacturer of a MEDICAL DEVICE intended to be incorporated into an IT-NETWORK might need to provide information about the MEDICAL DEVICE that is necessary to allow the RESPONSIBLE ORGANIZATION to manage RISK according to this standard. This information can include, as part of the ACCOMPANYING DOCUMENTS, instructions specifically addressed to the person who incorporates a MEDICAL DEVICE into an IT-NETWORK.

– Such ACCOMPANYING DOCUMENTS should convey instructions about how to incorporate the MEDICAL DEVICE into the IT-NETWORK, how the MEDICAL DEVICE transfers information over the IT-NETWORK, and the minimum IT-NETWORK characteristics necessary to enable the INTENDED USE of the MEDICAL DEVICE when it is incorporated into the IT-NETWORK. The ACCOMPANYING DOCUMENTS should warn of possible hazardous situations associated with failure or disruptions of the IT-NETWORK, and the misuse of the IT-NETWORK connection or of the information that is transferred over the IT-NETWORK.

– RESPONSIBILITY AGREEMENTS can establish roles and responsibilities among those engaged in the incorporation of a MEDICAL DEVICE into an IT-NETWORK, all aspects of the life cycle of the resulting MEDICAL IT-NETWORK and all activities that form part of that life cycle.

– The RESPONSIBLE ORGANIZATION is required to appoint people to certain roles defined in this standard. This standard defines the responsibilities of those roles. The most important of those roles is the MEDICAL IT-NETWORK RISK MANAGER. This role can be assigned to someone within the RESPONSIBLE ORGANIZATION or to an external contractor.

– The MEDICAL IT-NETWORK RISK MANAGER is responsible for ensuring that RISK MANAGEMENT is included during the PROCESSES of:

  - planning and design of new incorporations of MEDICAL DEVICES or changes to such incorporations;
  - putting the MEDICAL IT-NETWORK into use and the consequent use of the MEDICAL IT-NETWORK; and
  - CHANGE-RELEASE MANAGEMENT and change management of the IT-NETWORK during the IT-NETWORK'S entire life cycle.

– RISK MANAGEMENT should be applied to address the following KEY PROPERTIES appropriate for the IT-NETWORK incorporating a MEDICAL DEVICE:

  - SAFETY (freedom from unacceptable RISK of physical injury or damage to the health of people or damage to property or the environment);
  - EFFECTIVENESS (ability to produce the intended result for the patient and the RESPONSIBLE ORGANIZATION); and

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

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

Part 1: Roles, responsibilities and activities

1 Scope

Recognizing that MEDICAL DEVICES are incorporated into IT-NETWORKS to achieve desirable benefits (for example, INTEROPERABILITY), this international standard defines 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 (the KEY PROPERTIES). This international standard does not specify acceptable RISK levels.

NOTE 1 The RISK MANAGEMENT activities described in this standard are derived from those in ISO 14971 [4]. The relationship between ISO 14971 and this standard is described in Annex A.

This standard applies after a MEDICAL DEVICE has been acquired by a RESPONSIBLE ORGANIZATION and is a candidate for incorporation into an IT-NETWORK.

NOTE 2 This standard does not cover pre-market RISK MANAGEMENT.

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This standard applies throughout the life cycle of IT-NETWORKS incorporating MEDICAL DEVICES.

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NOTE 3 The life cycle management activities described in this standard are very similar to those of ISO/IEC 20000-2 [10]. The relationship between ISO/IEC 20000-2 and this standard is described in Annex D.

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This standard applies where there is no single MEDICAL DEVICE manufacturer assuming responsibility for addressing the KEY PROPERTIES of the IT-NETWORK incorporating a MEDICAL DEVICE.

NOTE 4 If a single manufacturer specifies a complete MEDICAL DEVICE that includes a network, the installation or assembly of the MEDICAL DEVICE according to the manufacturer's ACCOMPANYING DOCUMENTS is not subject to the provisions of this standard regardless of who installs or assembles the MEDICAL DEVICE.

NOTE 5 If a single manufacturer specifies a complete MEDICAL DEVICE that includes a network, additions to that MEDICAL DEVICE or modification of the configuration of that MEDICAL DEVICE, other than as specified by the manufacturer, is subject to the provisions of this standard.

This standard applies to RESPONSIBLE ORGANIZATIONS, MEDICAL DEVICE manufacturers and providers of other information technology for the purpose of RISK MANAGEMENT of an IT-NETWORK incorporating MEDICAL DEVICES as specified by the RESPONSIBLE ORGANIZATION.

This standard does not apply to personal use applications where the patient, OPERATOR and RESPONSIBLE ORGANIZATION are one and the same person.

NOTE 6 In cases where a MEDICAL DEVICE is used at home under the supervision or instruction of the provider, that provider is deemed to be the RESPONSIBLE ORGANIZATION. Personal use where the patient acquires and uses a MEDICAL DEVICE without the supervision or instruction of a provider is out of scope of this standard.

This standard does not address regulatory or legal requirements.

2 Terms and definitions

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

2.1
ACCOMPANYING DOCUMENT
a document accompanying a MEDICAL DEVICE or an accessory and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding SAFETY

NOTE Adapted from IEC 60601-1:2005, definition 3.4.

2.2
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

NOTE Adapted from ISO/IEC 20000-1:2005, Subclauses 9.2 (change management) and 10.1 (release management).

2.3
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

2.4
CONFIGURATION MANAGEMENT
a 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

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NOTE Adapted from ISO/IEC 20000-1:2005, Subclause 9.1.

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2.5
DATA AND SYSTEMS SECURITY
an operational state of a MEDICAL IT-NETWORK in which information assets (data and systems) are reasonably protected from degradation of confidentiality, integrity, and availability

NOTE 1 Security, when mentioned in this standard, should be taken to include DATA AND SYSTEMS SECURITY.

NOTE 2 DATA AND SYSTEMS SECURITY is assured through a framework of policy, guidance, infrastructure, and services designed to protect information assets and the systems that acquire, transmit, store, and use information in pursuit of the organization's mission.

2.6
EFFECTIVENESS
ability to produce the intended result for the patient and the RESPONSIBLE ORGANIZATION

2.7
EVENT MANAGEMENT
a 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

NOTE Adapted from ISO/IEC 20000-1:2005, Subclauses 8.2 (incident management) and 8.3 (problem management).

2.8
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 SYSTEM SECURITY

NOTE Adapted from ISO 14971:2007, definition 2.2.

2.9
HAZARD
potential source of HARM

[ISO 14971:2007, definition 2.3]

2.10
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

[ISO 14971: 2007, definition 2.5]

2.11
INTEROPERABILITY
a property permitting diverse systems or components to work together for a specified purpose

2.12
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

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NOTE 1 Adapted from IEC 61907:2009, definition 3.1.1.

NOTE 2 The scope of the MEDICAL IT-NETWORK in this standard is defined by the RESPONSIBLE ORGANIZATION based on where the MEDICAL DEVICES in the MEDICAL IT-NETWORK are located and the defined use of the network. It can contain IT infrastructure, home health and non-clinical contexts. See also 4.3.3.

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2.13
KEY PROPERTIES
three risk managed characteristics (SAFETY, EFFECTIVENESS, and DATA AND SYSTEMS SECURITY) of MEDICAL IT-NETWORKS

2.14
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 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 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 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 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'.

[GHTF SG1/N29R16:2005]

2.15
MEDICAL DEVICE SOFTWARE
software system that has been developed for the purpose of being incorporated into the MEDICAL DEVICE or that is intended for use as a MEDICAL DEVICE in its own right

[IEC 62304:2006, definition 3.12, modified]

2.16
MEDICAL IT-NETWORK
an IT-NETWORK that incorporates at least one MEDICAL DEVICE

2.17
MEDICAL IT-NETWORK RISK MANAGER
person accountable for RISK MANAGEMENT of a MEDICAL IT-NETWORK

2.18
OPERATOR
person handling equipment

[IEC 60601-1:2005, definition 3.73]

2.19
PROCESS
set of interrelated or interacting activities which transforms inputs into outputs

[ISO 14971:2007, definition 2.13]

NOTE The term "activities" covers use of resources.

2.20
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

[ISO 14971:2007, definition 2.15]

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2.21
RESPONSIBILITY AGREEMENT
one or more documents that together fully define the responsibilities of all relevant stakeholders

NOTE This agreement can be a legal document, e.g. a contract.

2.22
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL IT-NETWORK

NOTE 1 The accountable entity can be, for example, a hospital, a private clinician or a telehealth organization.

NOTE 2 Adapted from IEC 60601-1:2005 definition 3.101.

2.23
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

[ISO 14971:2007, definition 2.16]

2.24
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

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[ISO 14971:2007, definition 2.17]

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2.25
RISK ASSESSMENT
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

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[ISO/IEC Guide 51:1999, definition 3.12]

2.26
RISK CONTROL
PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[ISO 14971:2007, definition 2.19]

2.27
RISK EVALUATION
PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[ISO 14971:2007, definition 2.21]

2.28
RISK MANAGEMENT
systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and monitoring RISK

[ISO 14971:2007, definition 2.22]

2.29
RISK MANAGEMENT FILE
set of records and other documents that are produced by RISK MANAGEMENT