

Joint Initiative Open Forum Session Software as Medical Devices

IEC 80001-1 & Medical Device Software Systems

October 10, 2010 | San Diego “America’s Finest City!”

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IEC 80001-1 Scope

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

Part 1: Roles, responsibilities and activities

Approved FDIS ~ publication 2010.11

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.**

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

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

IEC 80001-1 Key Properties

(in order of priority)

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

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

Note: ***ISO 14971 is focused on patient safety risk management ~ pre-market analysis***

IEC 80001-1: Additional Definitions

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:

[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]

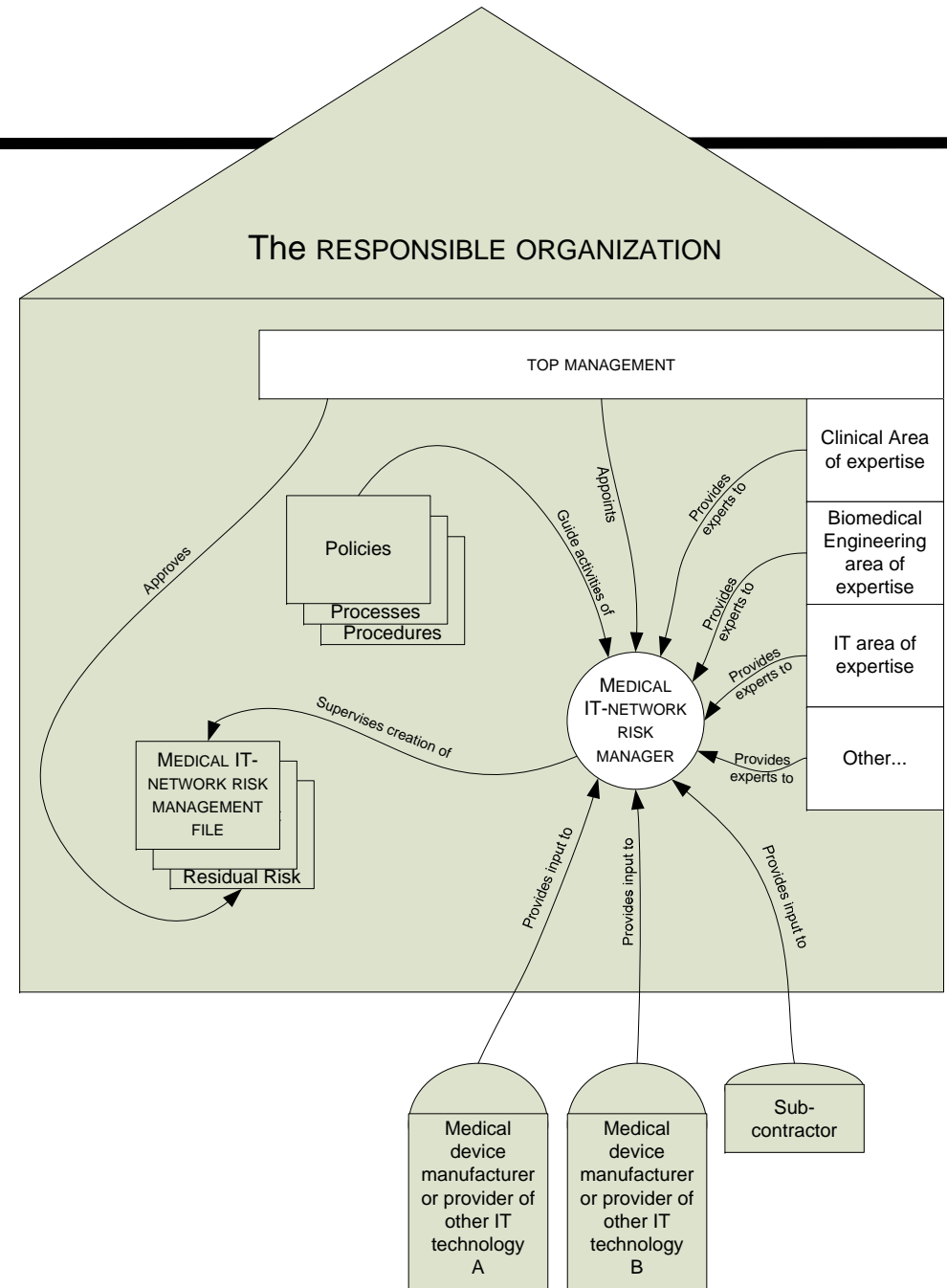
2.16

MEDICAL IT-NETWORK

an IT-NETWORK that incorporates at least one MEDICAL DEVICE

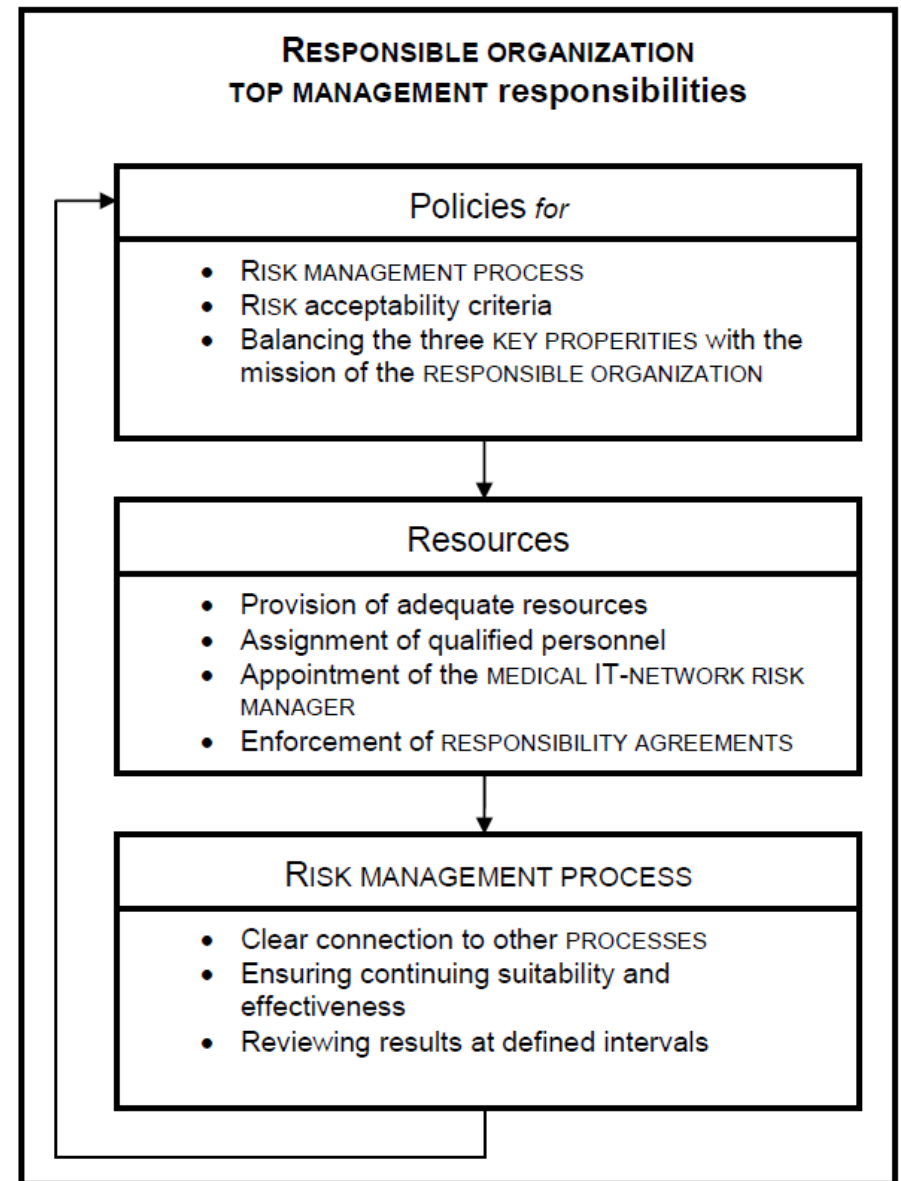
80001-1: Roles

Establishes a partnership framework both within the HDO, as well as with external technology & service providers.



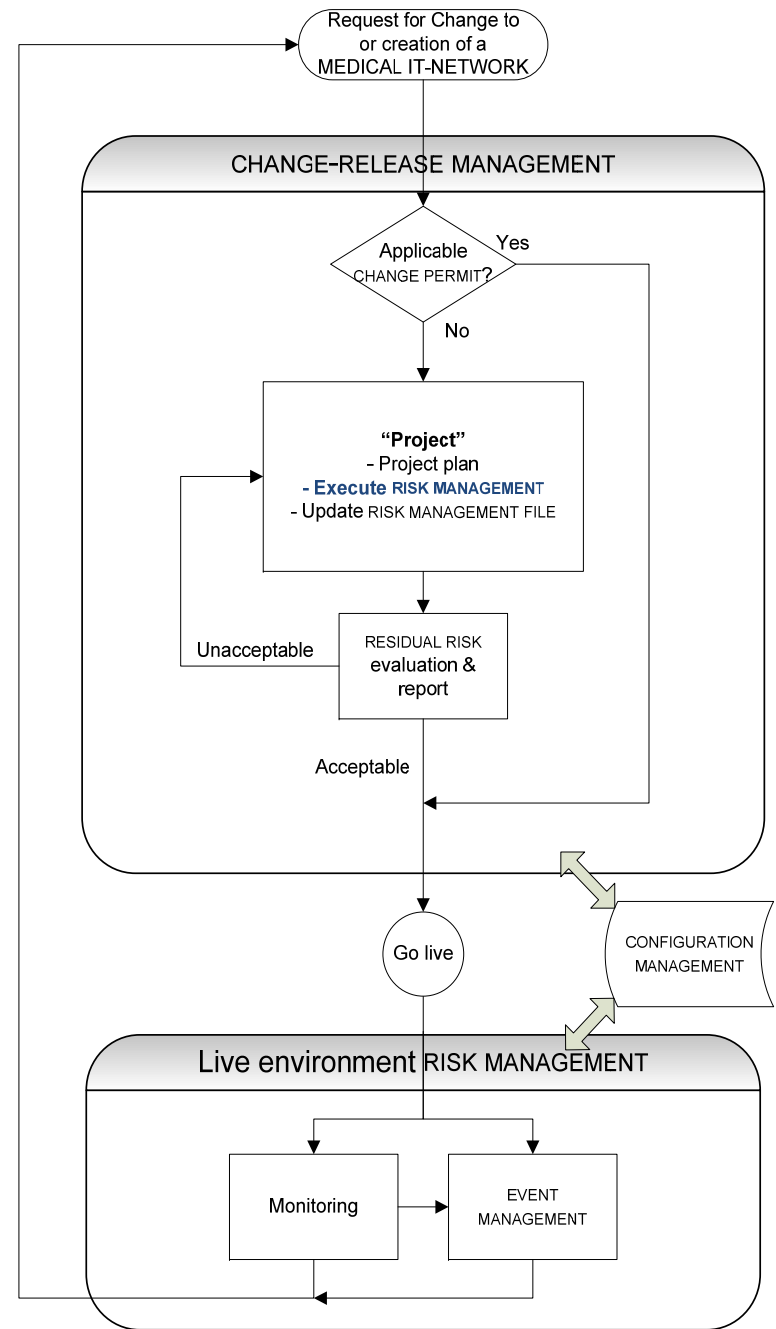
80001-1: Responsibilities

Responsibilities for each role are clearly specified



80001-1: Activities

Risk management activities and documentation are defined for the full life cycle of Medical IT-Networks



IEC 80001-1 & SAMD

- ☐ ***Establishes the basis for ensuring the safety, effectiveness and security of convergent networks***
- ☐ ***Applies to medical and non-medical devices ... including SAMD***
- ☐ ***Applies to post market systems ... only!***
- ☐ ***Adds no pre-market requirements for regulatory approval (references 60601-1 for pre-market requirements)***
- ☐ ***...***