DKE Deutsche Kommission
Elektrotechnik Elektronik Informationstechnik
im DIN und VDE

Deutsches Mitglied in IEC und CENELEC

VDE – DKE · Stresemannallee 15 · 60596 Frankfurt am Main

Sherman Eagles, Convener IEC 62A/JWG3

Alf Dolan, Convener IEC 62A/JWG1

CC: Hillary Wöhrle, Secretary ISO TC 210

CC: Chuck Sidebottom, Secretary IEC 62A

GESCHÄFTSSTELLE

Frankfurt am Main	2005-06-09
Telefon	+ 49 69 6308-277
E-Mail	klaus.neuder@vde.com

Discussionpaper on New Work Item Proposal "Networked PEMS"

Dear Sherman, dear Alf,

as a result of the Toronto meeting ISO TC 210/IEC 62A JWG 1 and JWG 3 in 2005-05-16 until 2005-05-19 please find attached a Working Document of the German National Mirror Committee on Software/PEMS related to a proposed New Work Item Proposal on "Networked PEMS".

Oliver Christ has presented the content of such a New Work Item Proposal within both Working Groups at the Toronto meeting in May 2005. Each Joint Working Group has decided that is a valuable source of information if each National Committee would be able to observe the content of this exisiting Working Document for information only.

We kindly ask the conveners of the two Joint Working Groups to distribute the attached Working Document on the IEC/ISO server of each Joint Working Group.

In case feedback will be received from different National Committees, wether this topic of "Networked PEMS" is of national interest, we kindly ask to identify one contact e.g. Sherman Eagles to collect this feedback.

Best regards,

Dr. Klaus Neuder

[Document reference]

WORKING DRAFT (WD)

	Project number Numéro de projet	
IEC/TC or SC: **62A or other committee** CEI/CE ou SC:	Date of circulation Date de diffusion	Closing date for voting (Voting mandatory for P-members) Date de clôture du vote (Vote obligatoire pour les membres (P))
Titre du CE/SC: Aspects généraux des équipments utilisés en pratique médicale	TC/SC Title: Common aspects of electrical medical equipment used in medical practice	
Secretary: USA Secrétaire:		
Also of interest to the following committees Intéresse également les comités suivants TC 62, SC 62A, TC 66, ISO/TC 210	Supersedes document Remplace le document	
Functions concerned Fonctions concernées ☒ Safety / Sécurité ☐ EMC / CEM ☐ Environment / Environnement ☐ Quality assurance / Assurance qualité		

CE DOCUMENT EST TOUJOURS À L'ÉTUDE ET SUSCEPTIBLE DE MODIFICATION. IL NE PEUT SERVIR DE RÉFÉRENCE.

LES RÉCIPIENDAIRES DU PRÉSENT DOCUMENT SONT INVITÉS À PRÉSENTER, AVEC LEURS OBSERVATIONS, LA NOTIFICATION DES DROITS DE PROPRIÉTÉ DONT ILS AURAIENT ÉVENTUELLEMENT CONNAISSANCE ET À FOURNIR UNE DOCUMENTATION EXPLICATIVE.

THIS DOCUMENT IS STILL UNDER STUDY AND SUBJECT TO CHANGE. IT SHOULD NOT BE USED FOR REFERENCE PURPOSES.

RECIPIENTS OF THIS DOCUMENT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

Titre :

Title : **- Medical Electrical Equipment - BASIC SAFETY, ESSENTIAL PERFORMANCE: responsibility for NETWORK/DATACOUPLING of ME EQUIPMENT/ME SYSTEM(s)**

Note d'introduction

Introductory note

This Working Draft was developed by German National Committee DKE UK 811.3
to be circulated with the NWIP as basic for further discussion

CONTENTS

Page

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

Medical Electrical Equipment BASIC SAFETY, ESSENTIAL PERFORMANCE: Responsibility for NETWORK/DATA COUPLING of ME EQUIPMENT/ME SYSTEM(s)

Foreword

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC XXX has been prepared by working group xy of subcommittee 62A: *Common aspects of electrical equipment used in medical practice*, of IEC technical committee 62: *Electrical equipment in medical practice.*

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

In this standard the following print types are used:

– Requirements and definitions: in roman type.
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance related to that item in Annex B.

The committee has decided that the contents of this publication will remain unchanged until _____. At this date, the publication will be

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

Annexes A to XXX of this International Standard are for information only.

Introduction

Medical locations (e,g, hospitals) are operating ME EQUIPMENT in a networked environment today. Originally, these networks were installed to optimize business economic and technical area. For this purpose, fast electronic data interchange was required.

Today, these networks are used additionally for exchange of medical data within a medical location or between medical locations, and/or from outside. This changes the original intend of the network dramatically, because now, BASIC SAFETY and ESSENTIAL PERFORMANCE have to be taken into consideration.

Initially, the use was only the exchange of laboratory data. Now there are large amounts of data transported over the networks, such as medical image data. There are further requests from the user to get "real time" solutions (e.g. control of devices during interventional surgery).

ME EQUIPMENT and ME SYSTEMS will sometimes be used together to create a system. It is very likely that this will happen even more frequent with the increasing use of computers to analyse clinical data and control medical treatment.

Connection of PEMS to a network or establishing any NETWORK/DATA COUPLING could result in additional / new RISKS to PATIENTS, OPERATORS or third parties.

Someone has to become responsible for ensuring that all separate ME EQUIPMENT work together satisfactorily combined as an integrated system; in other words, someone has to be responsible for designing the integration of NETWORK/DATA COUPLING systems.

From the viewpoint of a PEMS MANUFACTURER, any type of a NETWORK/DATA COUPLING is a source of additional causes for HAZARDS. In principle any NETWORK/DATA COUPLING that is outside the control of the PEMS MANUFACTURER should never be presumed to be 100 % reliable.

The evaluate more systematically the consequences for the PATIENT, it is may be useful to classify NETWORK/DATA COUPLING both by the direct consequences (harm) and by the reaction time. (where reaction time is the time delay between a NETWORK/DATA COUPLING failure and the onset of HARM to the PATIENT).

This standard provides a framework of responsibility sharing among different PEMS MANUFACTURERS, RESPONSIBLE ORGANIZATION and NETWORK MANUFACTURER to ensure a safe integration of different PEMS modalities within NETWORK/DATA COUPLING systems. This standard provides requirements for an RISK-MANAGEMENT NETWORK/DATA COUPLING PROCESS.

The RISK MANAGEMENT PROCESS is already very well addressed by the International Standard ISO 14971. Therefore IEC XXX makes use of this advantage and use major concepts and adopt these to the needs of NETWORK/DATA COUPLING systems.

Annex A provides rationale for the clauses of this standard. Annex B provides guidance on the provisions of this standard.

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;

– “establish” means to define, document, and implement; and

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT

BASIC SAFETY, ESSENTIAL PERFORMANCE:

Responsibility for NETWORK/DATACOUPLING

of ME EQUIPMENT/ME SYSTEM(s)

(Networked-PEMS)

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY, ESSENTIAL PERFORMANCE of, and responsibility for NETWORK/DATA COUPLING of ME EQUIPMENT and ME SYSTEM(s). This responsibility is usually outside of the control of a single PEMS MANUFACTURER. This International Standard is addressed to MANUFACTURERS as well as to the RESPONSIBLE ORGANIZATION.

To minimize RISK to PATIENTS, OPERATORS and / or third parties, this Standard provides detailed requirements to chapter 14.13 of IEC 60601-1 ed.3 and similar topics.

It applies to:

a) any means to transmit and/or receive information (network),

b) the NETWORK/DATA COUPLING of ME EQUIPMENT and ME SYSTEM(s) to other ME EQUIPMENT and / or ME SYSTEM(s),

c) the NETWORK/DATA COUPLING of ME EQUIPMENT and ME SYSTEM(s) to other equipment not being ME EQUIPMENT or ME SYSTEM(s),

d) (subsequent) changes of a), b) and c),

e) update and upgrade of ME EQUIPMENT and ME SYSTEM(s) as well as of other equipment not being ME EQUIPMENT or ME SYSTEM(s), connected to the NETWORK/DATA COUPLING,

f) safety related security issues within a), b), c), d) and e)

1.2 Object

The object of this Standard is to specify general requirements for the RISK MANAGEMENT of projects concerning the NETWORK/DATA COUPLING of ME EQUIPMENT/ME SYSTEMS. It defines responsibilities for PEMS MANUFACTURER(s), the RESPONSIBLE ORGANIZATION, and NETWORK/DATA COUPLING INTEGRATOR. This International Standard shall become part of a responsibility agreement (contract) among all parties of a NETWORK/DATA COUPLING project.

1.3 Compliance

Compliance is determined by inspection of the documentation required by this Standard, especially the RISK MANAGEMENT FILE of the NETWORK/DATA COUPLING project and the responsibility agreement (contract).

NOTE 1 Where any requirements contain “as appropriate” and were not performed, documentation for the justification is necessary for this assessment.

2 * Normative references

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

ISO 14971:200X, *Medical devices – Risk management – Application of risk management to medical devices.*

IEC 60601-1:200X, *Medical electrical equipment – Part1: General requirements for basic safety and essential performance*

3 * Definitions

3.1
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, an equipment or an accessory and containing important information for the RESPONSIBLE ORGANIZATION, or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

3.2
ARCHITECTURE
organizational structure of a SYSTEM or component

[IEEE 610.12:1990]

3.3
***ESSENTIAL PERFORMANCE**
performance necessary to achieve freedom from unacceptable RISK.

3.4
***FUNCTIONAL CONNECTION**
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances.

NOTE Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

3.5
HARM
physical injury, damage, or both to the health of people or damage to property or to the environment

[ISO/IEC Guide 51:1999]

3.6
HAZARD
potential source of HARM

[ISO/IEC Guide 51:1999]

3.7
INTENDED USE/INTENDED PURPOSE
Use of a product, PROCESS or service in accordance with the specifications, instructions and information provided by the MANUFACTURER.

[ISO 14971: 2000]

3.8
MANUFACTURER
Natural or legal person with responsibility for the design, manufacture, packaging, marking or

ACCOMPANYING DOCUMENTS of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person himself or on his behalf by a third party.

[IEC 60601-1:200X]

3.9

MEDICAL DEVICE SOFTWARE

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

3.10

MEDICAL ELECTRICAL EQUIPMENT (hereinafter ME EQUIPMENT)

Electrical equipment:

1. provided with not more than one connection to a particular SUPPLY MAINS; and
2. intended by its MANUFACTURER to be used:

a) in the diagnosis, treatment, or monitoring of a PATIENT; and has an APPLIED PART or transfers energy to or from the PATIENT or detects such energy transfer to or from the PATIENT; or

b) for compensation or alleviation of disease, injury or disability

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. *in vitro* diagnostic equipment or the implantable parts of active implantable medical devices).

NOTE 3 This standard uses the term "electrical equipment" to mean ME EQUIPMENT or other electrical equipment.

NOTE 4 Electrical equipment that has originally been designed for a different purpose and is then assigned for use in diagnosis, treatment or monitoring of a PATIENT or for compensation or alleviation of disease, injury or disability can thereby be brought within this definition, if the other parts of the definition also apply

[IEC 60601-1:200X]

3.11

***MEDICAL ELECTRICAL SYSTEM** (hereinafter ME SYSTEM)

Combination, as specified by its MANUFACTURER, of items of equipment, at least one of which must be ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

[IEC 60601-1:200X]

3.12

NETWORK/DATA COUPLING INTEGRATOR (ND INTEGRATOR)

Person or organisation accountable for integrating ME EQUIPMENT/ME SYSTEMS into a NETWORK/DATA COUPLING .

3.13

***NETWORK/DATA COUPLING (ND)**

Any means to transmit and/or receive information to or from other equipment in accordance with the MANUFACTURER'S specifications.[1]

NOTE Network/data coupling as used in this Standard does not include transfer of information by humans

3.14

NETWORK/DATA COUPLING INTEGRATION RISK MANAGEMENT PLAN (ND RM-PLAN)

Starting document among different parties how to perform risk management activities required by this standard and assigning clearly defined responsibilities for each party.

184
185

186 **3.15**
187 **OPERATOR**
188 Person handling equipment.

189 **3.16**
190 **PATIENT**
191 Living being (person or animal) undergoing a medical, surgical or dental PROCEDURE

192 **3.17**
193 **PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)**
194 MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM containing one or more PROGRAMMABLE
195 ELECTRONIC SUBSYSTEM

196 **3.18**
197 **PROCESS**
198 a set of interrelated or interacting activities that transform inputs into outputs

199 NOTE The term "ACTIVITIES" covers use of resources.
200 [ISO 9000:2000]

201 **3.19**
202 **RESIDUAL RISK**
203 RISK remaining after protective measures have been taken.

204 [ISO 14971: 2000]

205 **3.20**
206 **RESPONSIBLE ORGANIZATION**
207 Entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM
208
209 NOTE 1 The accountable entity can be, for example, a hospital, a private clinician or a lay person. In home use
210 applications, the PATIENT, OPERATOR and RESPONSIBLE OR GANIZATION can be one and the same person.
211
212 NOTE 2 Education and training is included in "use."
213

214 **3.21**
215 **RESPONSIBLE ORGANIZATION FOR NETWORKED/DATA COUPLED ME SYSTEM (MEDICAL IT)**
216 Person / organization accountable for the implementation, use and maintenance of NETWORKED /DATACOUPLED ME
217 SYSTEM.

218 **3.22**
219 **RISK**
220 combination of the probability of occurrence of HARM and the severity of that HARM

221 [ISO/IEC Guide 51:1999]

222 **3.23**
223 **RISK ANALYSIS**
224 systematic use of available information to identify HAZARDS and to estimate the RISK

225 [ISO/IEC Guide 51:1999]

226 **3.24**
227 **RISK CONTROL**
228 PROCESS in which decisions are made and RISKS are reduced to, or maintained within, specified
229 levels

230 [ISO 14971:2000]

3.25
RISK EVALUATION
Judgement, on the basis of RISK ANALYSIS, of whether a RISK which is acceptable has been achieved in a given context based on the current values of society.

[ISO 14971:2000]

3.26
RISK MANAGEMENT
systematic application of management policies, procedures, and practices to the TASKS of analyzing, evaluating, and controlling RISK

[ISO 14971:2000]

3.27
RISK MANAGEMENT FILE
set of records and other documents, not necessarily contiguous, that are produced by a RISK MANAGEMENT PROCESS

[ISO 14971:2000]

3.28
SECURITY
protection of information and data so that unauthorized people or SYSTEMS cannot read or modify them and so that authorized persons or SYSTEMS are not denied access to them

[ISO/IEC 12207:1995]

3.29
SERIOUS INJURY
injury or illness that:

a) is life threatening,
b) results in permanent impairment of a body function or permanent damage to a body structure, or
c) necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

NOTE Permanent impairment means an irreversible impairment or damage to a body structure or function excluding trivial impairment or damage.

3.30
VERIFICATION
confirmation through provision of objective evidence that specified requirements have been fulfilled

NOTE 1 "Verified" is used to designate the corresponding status.

[ISO 9000:2000]

NOTE 2 In design and development, VERIFICATION concerns the PROCESS of examining the result of a given ACTIVITY to determine conformity with the stated requirement for that ACTIVITY.

4 * General requirements

4.1 Identification of responsible parties

In accordance with this Standard it is required that each NETWORK/DATA COUPLING integration project will be performed under a framework of clearly defined responsibilities. Within the framework of this Standard the following parties are distinguished:

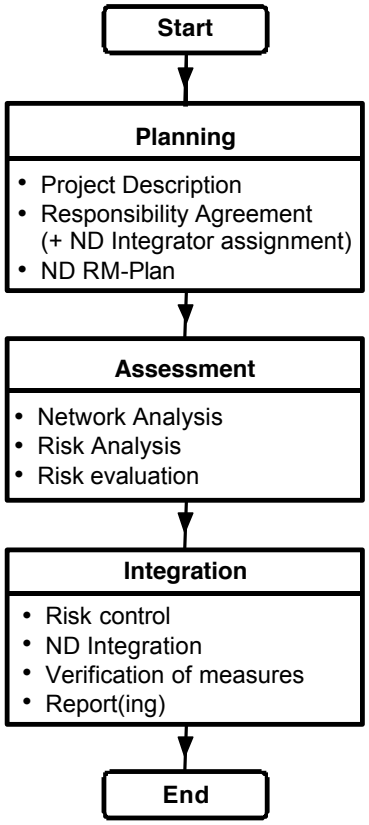
- PEMS-MANUFACTURER(s)
    - (e.g. represented by a project manager)

- RESPONSIBLE ORGANISATION (including)
    - o RESPONSIBLE ORGANIZATION FOR NETWORKED/DATA COUPLED ME SYSTEM (Medical IT)
    - o IT Department (without Medical IT) (General IT)
- NETWORK/DATA COUPLING INTEGRATOR (ND INTEGRATOR)

Note 1: Detailed requirements on the responsibility of each party see clause XXX.

4.2 Overview of NETWORK/DATA COUPLING PROCESS

If the criteria of clause 5.1 are met, the RESPONSIBLE ORGANIZATION shall initiate the NETWORK/DATA COUPLING PROCESS, comprising of three major activities:



<small_figure_workflow_20050419-1300.doc>

Figure 1 – Overview of the NETWORK/DATA COUPLING PROCESS

Note 1: For detailed requirements see clause XXX.

4.3 * RISK MANAGEMENT for NETWORK/DATA COUPLING

Connection of PEMS to a network or establishing any NETWORK/DATA COUPLING could result in additional / new RISKS to PATIENTS, OPERATORS or third parties. For PEMS a complete RISK MANAGEMENT PROCESS is already required by ISO 14971 and IEC 60601-1 (3rd editon), but for NON-ME EQUIPMENT (e.g. network components, general purpose IT-equipment) RISK MANAGEMENT is not required. In order to address hazards associated with the NETWORK/DATA COUPLING of ME EQUIPMENT/ME SYSTEM with NON-ME EQUIPMENT additional RISK MANAGEMENT activities are necessary.

The RESPONSIBLE ORGANIZATION shall establish, document and maintain a process for identifying these HAZARDS, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls.

Note 1: Subsequent changes to the NETWORK/DATA COUPLING could introduce new RISKS and require additional analyses.

The ND INTEGRATOR shall address HAZARDS that are likely to arise from NETWORK/DATA COUPLING and ensure that the RESIDUAL RISKS of the individual PEMS are maintained.

4.4 Network classification

In order to ensure PATIENT SAFETY, it is necessary to classify the network used for NETWORK/DATA COUPLING. Criteria for the classification are consequences (harm) for the patient if medical data are incorrect or not available at a required point in time.

This Standard defines the following network safety classification:

Class A: Patient vital data; real-time

Class B: Patient data prior to report (report); non-real time;
only one defined gateway to class C network

Class C: Non-critical medical data; reported medical data (incl. archive data)

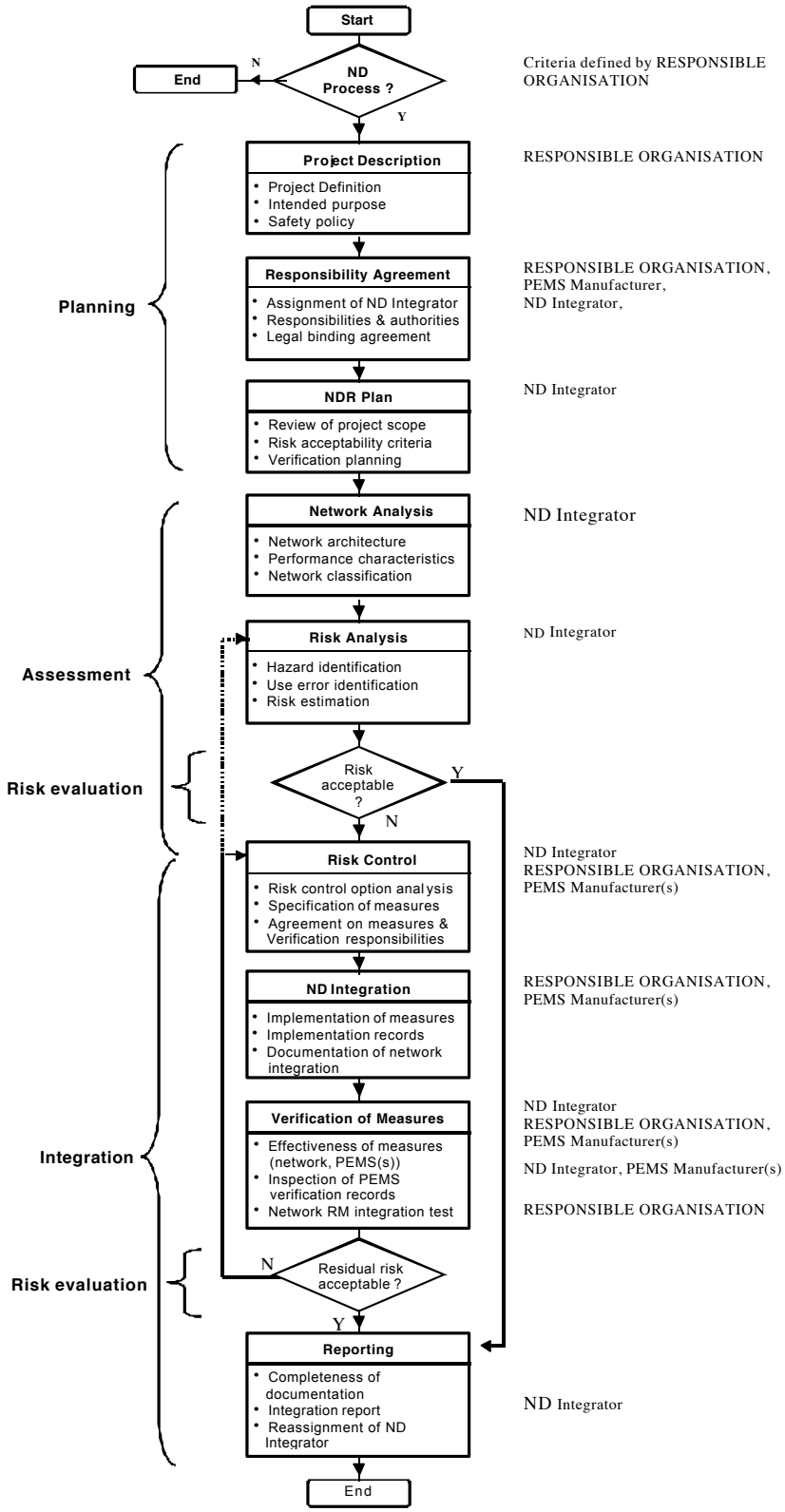
Each PEMS MANUFACTURER shall specify the characteristics of the NETWORK/DATA COUPLING necessary for the PEMS to achieve its INTENDED USE/INTENDED PURPOSE including the required network classification (A,B,C).

The RESPONSIBLE ORGANIZATION shall assign to each network where ME EQUIPMENT/ME SYSTEM is integrated into - a network classification (A, B, or C). This shall take into account the possible effects on the PATIENT, OPERATOR, or third parties resulting from a HAZARD to which the NETWORK/DATA COUPLING of ME EQUIPMENT / ME SYSTEMS can contribute.

NOTE: If the risk arising from the hazard is reduced to an acceptable level by an external risk control measure, the classification scheme may take this into account.

The RESPONSIBLE ORGANIZATION shall record the network classification assigned to each network where ME EQUIPMENT/ME SYSTEM is integrated into in the RISK MANAGEMENT FILE.

328 **5 NETWORK/DATA COUPLING PROCESS**



329

330 **Figure 2 – Detailed Workflow of the NETWORK/DATA COUPLING PROCESS**

5.1 Initiation of a network/data coupling process

The RESPONSIBLE ORGANIZATION shall establish and maintain records for each network classification (A,B and C) which criteria (activities) shall initiate a formal NETWORK/DATA COUPLING PROCESS prior to implementation of network modifications. This record shall be part of the RISK MANAGEMENT FILE.

In accordance with IEC 60601-1 3rd ed. the criteria shall be based on the RISK for PATIENT, OPERATOR and/or third parties and shall consider the following aspects related to NETWORK/DATA COUPLING:

- new installation of or changes into an existing NETWORK/DATA COUPLING configuration
- connection of additional items to the NETWORK/DATA COUPLING
- disconnecting items from the NETWORK/DATA COUPLING
- update of equipment connected to the NETWORK/DATA COUPLING
- upgrade of equipment connected to the NETWORK/DATA COUPLING
- others

If one or more of the documented criteria are fulfilled a NETWORK/DATA COUPLING PROCESS shall be initiated.

NOTE: e.g. Replacement of identical network components does not require a formal ND Process.

Compliance is checked by inspection of appropriate documents.

5.2 Planning

5.2.1 Project Description

The following topics have to be considered:

a) Functionality of the PEMS after network integration (Integrated System Intended Use)
b) Different Intended Use(s) of each network/data coupling PEMS
c) Specifications and performance of all ME EQUIPMENT
d) The information flow in and around the system
e) Reason for PEMS integration into a network
f) Necessary Client/Server components
g) Physical and logical network topologies (where the PEMS shall be integrated into including their specifications)
h) Responsibly for each effected network
i) Actual latest status of the existing network installation
j) Proposed requirements specification for the integration project
k) Required specification and performance of other network components
l) Constraints on the extendibility of the existing network

5.2.2 Responsibility Agreement

TBD: Agreement of the NETWORK/DATA COUPLING INTEGRATOR, the RESPONSIBLE ORGANISATION and all involved PEMS MANUFACTURERS

5.2.3 NETWORK/DATA COUPLING risk management plan (ND RM-Plan)

RISK MANAGEMENT activities for NETWORK/DATA COUPLING of ME EQUIPMENT/ ME SYSTEM shall be planned. The RESPONSIBLE ORGANIZATION shall establish and document a ND RM-PLAN. The ND RM-PLAN shall be part of the RISK MANAGEMENT FILE.

For NETWORK/DATA COUPLING project the ND RM-PLAN shall include at least the following:

a) The scope of the planned NETWORK/DATA COUPLING activities, identifying and describing all equipment (ME EQUIPMENT/ ME SYSTEM as well as NON-ME EQUIPMENT) including the network environment into which all equipment shall be integrated;

b) assignment of responsibilities and authorities (reference to the responsibility agreement);

c) requirements for review of risk management activities;

d) criteria for risk acceptability, based on the RESPONSIBLE ORGANIZATION'S policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated;

e) verification activities; and

f) specification of minimum set of documents required for the NETWORK/DATA COUPLING project

NOTE 1 Refer to Annex xxx for guidance on developing an ND RM-PLAN.

NOTE 2 The criteria for risk acceptability are essential for the ultimate effectiveness of the risk management process.

If the ND RM-PLAN changes during the time of the NETWORK/DATA COUPLING project a record of the changes shall be maintained in the risk management file.

Compliance is checked by inspection of the risk management file.

5.3 Assessment

5.3.1 Network Analysis

5.3.2 Risk Analysis

5.3.3 Risk Evaluation

5.4 Integration

5.4.1 Risk Control

Risk control measures may either be implemented

- in a ME equipment or other network component
- by the ND integration
- or by any combination of both types.

Where a risk control measure is implemented in a ME equipment or other network component their specifications shall be changed accordingly.

The ND Integrator shall both clearly address to the corresponding responsible party and control the implementation of each risk control measure.

5.4.2 ND Integration

5.4.3 Verification of Measures

(a) Risk control measures implemented by change of a ME equipment or other network component:

- Change of specification shall be verified against specification of risk control measure defined in the risk management file

- Evidence of implementation of the change and -where possible outside the specific ndi- its effectiveness shall be provided by the manufacturer of the ME equipment/other network component

(b) Risk control measures provided by the ND integration:

- Implementation and effectiveness of each risk control measure as defined in the risk management file shall be verified.

(c) Where a combination of measures has been defined for risk control effectiveness of the combination shall be verified. Implementation of each measure is verified according to a) or b)

(d) Basic safety and essential performance provided by the network/data coupling integration shall be verified.

5.4.4 Risk Evaluation

TBD

5.4.5 Reporting

TBD

6 NETWORK/DATA COUPLING Roles and Responsibilities

6.1 RESPONSIBLE ORGANIZATION

The RESPONSIBLE ORGANIZATION decides:

– what equipment to purchase;
– what equipment is integrated into a system;
– how the NETWORK/DATA COUPLING system is used.

Obviously a RESPONSIBLE ORGANISATION can employ a MANUFACTURER to integrate their system. In this case the whole system can become a medical electrical system and it will be the MANUFACTURER'S responsibility to provide a correctly integrated system. In this case the system could be separately regulated.

6.2 RESPONSIBLE ORGANIZATION FOR NETWORKED/DATA COUPLED ME SYSTEM (MEDICAL-IT)

TBD

6.3 PEMS MANUFACTURER(S)

TBD

6.4 NETWORK/DATA COUPLING INTEGRATOR (ND INTEGRATOR)

ME EQUIPMENT may be designed by the MANUFACTURER to work with other ME EQUIPMENT, however, it will often be the case that the separate ME EQUIPMENT will not have been designed to work with each other. The responsibility of an individual MANUFACTURER is limited to provide the required information related to his equipment.

Therefore, the task of a ND INTEGRATOR is the provision of solutions for NETWORK/DATA COUPLING to ensure safe operation of all PEMS.

Ultimately, the responsibility for the integrated system belongs to the RESPONSIBLE ORGANISATION. The role of a ND INTEGRATOR may be performed by the RESPONSIBLE ORGANIZATION itself or it may be assigned to a third-party (ME manufacturer, independent expert).

It is recognized that the ND INTEGRATOR often has to comply with a wide range of different regulatory requirements.

6.4.1 Skills and Qualification

In order to perform his function, the ND INTEGRATOR needs the following know-how and knowledge:

a) Technical engineering degree (or equivalent)
b) Experience within Medical Engineering of pems
c) Specific IT network and client/server know-how (related to the integration task)
d) Practical experience with network/data coupling projects
e) Regulatory expertise
f) Quality and risk management experience
g) Documentation skills
h) Communication and moderation experience

Compliance is checked by inspection of education and training records.

6.4.2 Disclosure of requirements specification and integration project description

The Information necessary for a complete project description may not be fully available to an individual MANUFACTURER. For that reason each individual MANUFACTURER can not carry out separately from other parties NETWORK/DATA COUPLING integration activities. In any case the NETWORK/DATA COUPLING INTEGRATOR has to be a single entity (e.g. individual expert or team from one organisation) that has the overall responsibility. This overall responsibility can not be shared between different parties.

The ND INTEGRATOR shall:

- Plan the integration of any ME EQUIPMENT or ME SYSTEM and non-medical equipment in accordance with the instructions provided by the various MANUFACTURERS;

- Perform RISK MANAGEMENT on the NETWORK/DATA COUPLING system; and

- Pass on any MANUFACTURER's instructions to the responsible organisation where these are required for the safe operation of the integrated system. These instructions should include warnings about the hazards of any change of configuration.

- Negotiate a decision with all project parties on the overall architecture.

- Negotiate with the PROJECT LEADERS and MEDICAL IT relevant risk control measures (e.g. design modification of existing PEMS(s) and/or measures included within the network) as well as identification of Control Points (including detailed parameters to monitor) for the safe operation of the network in normal use.

- Coordinate the implementation of all risk control measures

- Ensure existence of verification records/documents related to implementation and effectiveness of each risk control measure.

- Provide a complete set of the ND Integration documentation including all verification documents, list of all additional risk control measures and Control Points as well as an formal Integration (summary) Report to the RESPONSIBLE ORGANISATION.

7 Documentation

7.1 NETWORK/DATA COUPLING Documentation (Input)

The RESPONSIBLE ORGANIZATION shall provide network ARCHITECTURE documentation for the interfaces between the PEMS and all NETWORK COMPONENTS (both software and hardware) related to:

a) Physical network configuration

b) Logical network configuration

c) Applied standards and conformance statements

d) Client / server structure

e) Network security, reliability and data integrity

f) Network communication requirements for each PEMS

7.2 REQUIRED DOCUMENTATION (Output)

The NETWORK/DATA COUPLING INTEGRATOR shall include or reference in the ND RM-PLAN information about the documents to be established during the NETWORK/DATA COUPLING project related to ensure safety and essential performance for NETWORK/DATA COUPLING of all ME EQUIPMENT and ME SYSTEM(s) such as:

- Project Description
    - o Approved Requirement Specification
    - o Finally agreed Network Architecture (Physical and Logical network topologies)
- Responsibility Agreement
    - o Description of the NETWORK/DATA COUPLING project
    - o Description of contributing parties and their role and responsibility in this NETWORK/DATA COUPLING project
- Risk Management File for the NETWORK/DATA COUPLING, including
    - o ND RM-PLAN
    - o Risk Analysis
    - o List of additional Risk Control measures to be included:

517 ▪ Risk Control measures for individual PEMS

518 ▪ Risk Control for existing Network/other Network components

519 ▪ Critical Control Points to monitor specific parameters (of the network)

520 ▪ Administrative Measures (addressed to the RESPONSIBLE ORGANIZATION)

521 ▪ Standard operating procedures for clinical workflow

522 ▪ Training for OPERATORs

523 ▪ Additions to accompanying documents of individual PEMS

524 o Integration Report

Annex A
(informative)
Rationale for the requirements of this standard

Rationale for the clauses of this standard is provided in this annex.

A.1 Rationale

TBD

Annex B
(informative)
Guidance for drafting a Responsibility Agreement

B.1 Scope

TBD

Annex C
(informative)
Guidance on developing an ND RM -PLAN

C.1 General

TBD

Bibliography

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems.* Amendment 1 (1999)

IEC 61508:1998, Functional safety of electrical/electronic/programmable electronic safety-related systems.

IEEE 610.12:1990, IEEE standard glossary of software engineering terminology.

ISO/IEC 90003:2003, Software and system engineering – Guidelines for the application of ISO 9001:2000 to computer software.

ISO 9000:2000, Quality management systems – Fundamentals and vocabulary.

ISO 9001:2000, Quality management systems – Requirements

ISO/IEC 12207:1995, Information technology – Software life-cycle processes.

ISO/IEC 9126-1:2001, Software engineering — Product quality — Part 1: Quality model.