

# TECHNICAL REPORT



**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**

WITHDRAWN

IEC TR 80001-2-1:2012

<https://standards.iteh.ai/cou/standards/iec/cb1dc6f4-ed7e-4f94-9358-dc01d97a9dfc/iec-tr-80001-2-1-2012>



**THIS PUBLICATION IS COPYRIGHT PROTECTED**  
**Copyright © 2012 IEC, Geneva, Switzerland**

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.  
If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

### About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

### About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

#### Useful links:

IEC publications search - [www.iec.ch/searchpub](http://www.iec.ch/searchpub)

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,...).

It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.

Electropedia - [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [csc@iec.ch](mailto:csc@iec.ch).

IEC TR 80001-2-1:2012

<https://standards.iteh.ai/catalog/standards/iec/cb34c6f4-ed7e-4f94-9358-dc01d97a9dfc/iec-tr-80001-2-1-2012>

## TECHNICAL REPORT



**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**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

PRICE CODE **XB**

ICS 11.040.01; 35.240.80

ISBN 978-2-83220-201-2

**Warning! Make sure that you obtained this publication from an authorized distributor.**

## CONTENTS

FOREWORD.....	5
INTRODUCTION.....	7
1 Scope.....	8
2 Normative references .....	8
3 Terms and definitions .....	8
4 Prerequisites .....	14
5 Study of terms used in RISK MANAGEMENT.....	14
5.1 Overview .....	14
5.2 HAZARDS.....	15
5.3 HAZARDOUS SITUATIONS .....	15
5.4 Foreseeable sequences of events and causes.....	16
5.5 UNINTENDED CONSEQUENCE .....	16
5.6 RISK CONTROL measures (mitigations).....	17
5.7 Degrees of RISK.....	17
5.8 Checking wording.....	18
6 The steps .....	18
6.1 Overview of the steps.....	18
6.2 A basic example using the 10 steps.....	19
6.2.1 General.....	19
6.2.2 Initial RISK – Steps 1 – 5 (Figure 2).....	19
6.2.3 RISK CONTROL and final RISK – Steps 6 – 10 (Figure 3) .....	20
7 IEC 80001-1:2010, Clause 4.4: Step by step .....	23
7.1 General.....	23
7.2 Application of Subclause 4.4.1: Document all RISK MANAGEMENT elements .....	23
7.3 Note about RISK EVALUATION .....	23
7.4 The 10-step PROCESS .....	23
7.4.1 STEP 1: Identify HAZARDS and HAZARDOUS SITUATIONS.....	23
7.4.2 STEP 2: Identify causes and resulting HAZARDOUS SITUATIONS.....	24
7.4.3 STEP 3: Determine UNINTENDED CONSEQUENCES and estimate the potential severities .....	25
7.4.4 STEP 4: Estimate the probability of UNINTENDED CONSEQUENCE .....	25
7.4.5 STEP 5: Evaluate RISK.....	26
7.4.6 STEP 6: Identify and document proposed RISK CONTROL measures and re-evaluate RISK (return to Step 3) .....	27
7.4.7 STEP 7: Implement RISK CONTROL measures.....	28
7.4.8 STEP 8: Verify RISK CONTROL measures.....	29
7.4.9 STEP 9: Evaluate any new RISKS arising from RISK CONTROL.....	30
7.5 The steps and their relationship to IEC 80001-1 and ISO 14971 .....	30
8 Practical examples .....	31
8.1 General.....	31
8.2 Example 1: Wireless PATIENT monitoring during PATIENT transport .....	32
8.2.1 Full description of context.....	32
8.2.2 Description of network under analysis.....	32
8.2.3 The 10 Steps.....	32
8.3 Example 2: Remote ICU / Distance medicine.....	35

8.3.1	Full description of context.....	35
8.3.2	Description of network under analysis.....	35
8.3.3	The 10 Steps.....	35
8.4	Example 3: Post Anaesthesia Care Unit (PACU).....	38
8.4.1	Full description of context.....	38
8.4.2	Description of network under analysis.....	38
8.4.3	The 10 Steps.....	39
8.5	Example 4: Ultrasound –Operating system (OS) vulnerability.....	44
8.5.1	Full description of context.....	44
8.5.2	Description of network under analysis.....	44
8.5.3	The 10 Steps.....	44
Annex A (informative)	Common HAZARDS, HAZARDOUS SITUATIONS, and causes to consider in MEDICAL IT-NETWORKS.....	48
Annex B (informative)	List of questions to consider when identifying HAZARDS of the MEDICAL IT-NETWORK.....	52
Annex C (informative)	Layers of MEDICAL IT-NETWORKS where errors can be found.....	53
Annex D (informative)	Probability, severity, and RISK acceptability scales used in the examples in this technical report.....	56
Annex E (informative)	MONITORING RISK mitigation effectiveness.....	59
Annex F (informative)	RISK ANALYZING small changes in a MEDICAL IT-NETWORK.....	62
Annex G (informative)	Example of Change Window Form.....	63
Annex H (informative)	Template for examples.....	64
Bibliography	.....	66
Figure 1 – Basic flow of concepts from HAZARD to HAZARDOUS SITUATION to UNINTENDED CONSEQUENCE.....		15
Figure 2 – Steps 1 – 5: HAZARD identification through RISK EVALUATION.....		20
Figure 3 – Steps 6 – 10: RISK CONTROL measures through overall RESIDUAL RISK.....		21
Figure 4 – Sample summary RISK ASSESSMENT register format.....		22
Figure 5 – Relation of cause to HARM.....		26
Figure 6 – Schematic of the post anaesthesia care unit (PACU).....		39
Figure 7 – Example of the use of colour coding cables.....		42
Figure 8 – Sample summary RISK ASSESSMENT register for the PACU example.....		43
Figure D.1 – Application of STEPs 5 and 6 with 3 levels of RISK acceptability.....		58
Figure F.1 – Overview of RISK ANALYZING small changes in a MEDICAL IT-NETWORK.....		62
Table 1 – Relationship of KEY PROPERTIES, SAFETY, EFFECTIVENESS and DATA AND SYSTEMS SECURITY with associated UNINTENDED CONSEQUENCE as used in this technical report.....		17
Table 2 – Methods for checking accurate and appropriate wording of causes, HAZARDOUS SITUATIONS, and UNINTENDED CONSEQUENCES.....		18
Table 3 – Relationship between this technical report, IEC 80001-1:2010 and ISO 14971:2007.....		31
Table A.1 – HAZARDS related to potential required network characteristics.....		50
Table A.2 – Relationship between HAZARDS, foreseeable sequences, and causes.....		50
Table A.3 – Relationship between HAZARDS, causes, foreseeable sequences, and HAZARDOUS SITUATIONS.....		51

Table C.1 – Layers of an MEDICAL IT-NETWORK ..... 53

Table C.2 – Example of the layers of an MEDICAL IT-NETWORK ..... 55

Table D.1 – Probability scales used in the examples in this technical report ..... 56

Table D.2 – Severity scales ..... 56

Table D.3 – Risk level matrix ..... 57

Withdrawing

iTech Standards  
(<https://standards.iteh.ai>)  
Document Preview

IEC TR 80001-2-1:2012

<https://standards.iteh.ai/cou/standards/iec/cb3dc6f4-ed7e-4f94-9358-dc01d97a9dfc/iec-tr-80001-2-1-2012>

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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**

## 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.
- 2) The formal decisions or agreements of 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 IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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

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

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

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



## 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.

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.

IEC TR 80001-2-1:2012

<https://standards.iteh.ai/catalog/standards/iec/cb3dc6f4-ed7e-4f94-9358-dc01d97a9dfc/iec-tr-80001-2-1-2012>

# 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

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

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

[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.]

### 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

**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.

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 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

[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

[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, containing 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