

IEC/TR 80001-2-1:2012-07 (E)

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

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

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