

ISO/TR 80001-2-7:2015-04 (E)

Application of risk management for IT-networks incorporating medical devices -
Application guidance - Part 2-7: Guidance for Healthcare Delivery Organizations
(HDOs) on how to self-assess their conformance with IEC 80001-1

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Assessment Method	2
4.1 Prerequisites	2
4.2 Assessment Method Overview	2
4.3 Assessment Stages	3
4.3.1 Stage 1 -- Defining Assessment Scope	3
4.3.2 Stage 2 -- Stakeholder Involvement	3
4.3.3 Stage 3 -- Information Collection and Evaluation	3
4.3.4 Stage 4 -- Findings Report	3
4.3.5 Stage 5 -- Presentation of Findings	4
4.3.6 Stage 6 -- Improvement Plan (optional)	4
4.3.7 Stage 7 -- Follow-up Assessment (optional)	4
4.4 Process attribute rating scale	4
4.4.1 Rating of process attributes	4
4.4.2 Process attribute rating values	4
4.5 Capability Levels	5
4.6 Tailoring the Assessment Method	5
Annex A (informative) Assessment Method	7
Annex B (informative) Process Reference Model	38
Annex C (informative) Process Assessment Model	50
Annex D (informative) Abbreviations and Process Identifiers	100
Bibliography	102