

TECHNICAL REPORT



**Application of risk management for IT-networks incorporating medical devices –
Part 2-4: Application guidance – General implementation guidance for healthcare
delivery organizations**

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IT-NETWORKS INCORPORATING MEDICAL DEVICES –****Part 2-4: Application guidance – General implementation guidance
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FOREWORD

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IEC 80001-2-4, 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:

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62A/818/DTR	62A/835/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. In ISO, the technical report has been approved by 15 P-members out of 16 having cast a vote.

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.

A list of all parts of the IEC 80001 series, published under the general title *Application of risk management for IT-networks incorporating medical devices*, can be found on the IEC website.

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

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INTRODUCTION

This technical report is a guide to help a HEALTHCARE DELIVERY ORGANIZATION (see 1.2) fulfilling its obligations as a RESPONSIBLE ORGANIZATION in the application of IEC 80001-1, in conjunction with other technical reports in this series. Specifically, this guide helps the HEALTHCARE DELIVERY ORGANIZATION assess the impact of the standard on the organization and establish a series of business as usual PROCESSES to manage RISK in the creation, maintenance and upkeep of its MEDICAL IT-NETWORKS. Whilst this document is aimed solely at HEALTHCARE DELIVERY ORGANIZATIONS, the term RESPONSIBLE ORGANIZATION is used throughout this document to ensure consistency with IEC 80001-1. In this respect the two terms are synonymous.

This technical report will be useful to those responsible for establishing an IEC 80001-1 compliant RISK MANAGEMENT framework within a RESPONSIBLE ORGANIZATION that is expecting to establish one or more MEDICAL IT-NETWORKS. In particular, the RISK MANAGEMENT framework should address the KEY PROPERTIES – SAFETY, DATA AND SYSTEM SECURITY and EFFECTIVENESS – as defined in IEC 80001-1. The purpose of the framework is to ensure that the potential problems associated with the incorporation of MEDICAL DEVICES into IT-NETWORKS, identified in IEC 80001-1, are avoided.

Defining and implementing the RISK MANAGEMENT framework and the business change that can result, will require the RESPONSIBLE ORGANIZATION to draw upon a range of skills from within the organization, managerial, clinical and technical. Where such skills are not available within the RESPONSIBLE ORGANIZATION, consideration should be given to collaboration with similar organizations or through experts in the field. It is important that the RESPONSIBLE ORGANIZATION be able to draw upon expertise with respect to appropriate standards and their corresponding technical reports.

In establishing a RISK MANAGEMENT framework, a RESPONSIBLE ORGANIZATION will need to take account of:

- the size and capabilities of the organization;
- the extent of its IT operations and the complexity of its current infrastructure and systems; and
- the cost of implementing IEC 80001-1.

It is expected that some of the above factors, for example size of IT operations and complexity of the networks, will be proportionate to the size of the organization. It is important that the framework itself does not create patient RISK by placing unnecessary demands on clinical staff, yet at the same time this workload should not introduce avoidable new RISKS when implementing a new technology.

In taking a RESPONSIBLE ORGANIZATION through the key decisions and steps required to successfully establish a RISK MANAGEMENT framework for MEDICAL IT-NETWORKS this document refers to small and large organizations. These are subjective terms, for which no precise measures are given, though:

- a small organization could be a doctor's practice with:
 - a few clinicians, or
 - with many clinicians, a consolidated IT function and a highly centralised governance structure
- a large organization could be:
 - a multi-hospital conglomerate, or
 - an organisation with distributed clinics and a mixture of in-house and outsourced clinical and IT governance.

Small organisations may also find the guidance identified under large organisation relevant.

The RISK MANAGEMENT framework developed by a RESPONSIBLE ORGANIZATION following the guidance in this technical report needs to fit into the formal management systems that are