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**Health informatics — Information  
security management for remote  
maintenance of medical devices and  
medical information systems —**

**Part 1:  
Requirements and risk analysis**

*Informatique de santé — Management de la sécurité de l'information  
pour la maintenance à distance des dispositifs médicaux et des  
systèmes d'information médicale —*

*Partie 1: Exigences et analyse du risque*

ISO/TS 11633-1:2019

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Published in Switzerland

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This first edition cancels and replaces ISO/TR 11633-1:2009, which has been technically revised. The main changes compared to the previous edition are as follows:

- complete revision to correspond to the latest editions of the reference standards, ISO/IEC 27001 and ISO/IEC 27002;
- addition of use case 'remote monitoring'.

A list of all parts in the ISO 11633 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

The advancement and spread of technology in the information and communication technology field, and the infrastructure based on them, have brought many changes in how technology and networks are used in modern society. Similarly, in healthcare, information systems which were once closed in each healthcare facility (HCF) are now connected to the outside by networks and are progressing to the point of being able to facilitate mutual use of health information accumulated in these information systems. Such information and communication networks are spreading not only in between HCFs but also between HCFs and vendors of medical devices and healthcare information systems. Maintenance of such systems is paramount to keeping them up-to-date. By practicing so-called 'remote maintenance services', it becomes possible to reduce down-time and lower costs for this maintenance activity.

Whilst there are benefits to remote maintenance, such remote connections with external organizations also expose HCFs and vendors to risks regarding confidentiality, integrity and availability of information and systems; risks which previously received scant consideration.

Although normal remote maintenance is generally done on a contract basis, in the case of medical devices, risk assessment is commonly a legal prerequisite. Therefore, it is necessary to implement appropriate risk assessment where remote maintenance is provided in any healthcare context. The risk assessment examples provided in ISO/TR 11633-2 provide support for HCFs and RMS providers to implement risk assessment effectively.

By implementing the risk assessment process and employing controls referencing ISO/TR 11633-2, HCFs owners and RMS providers will be able to obtain the following benefits:

- Risk assessment can result in improved efficiency. If the risk assessment document created through the use of ISO/TR 11633-2 does not fully conform to ISO/IEC 27001, it can be used in part in a risk assessment of an incompatible area, thus reducing the risk assessment effort required.
- Documented validity of the RMS security countermeasures in place will be available to third parties.

If providing RMS to two or more sites, the provider can apply countermeasures consistently and effectively.

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# Health informatics — Information security management for remote maintenance of medical devices and medical information systems —

## Part 1: Requirements and risk analysis

### 1 Scope

This document focuses on remote maintenance services (RMS) for information systems in healthcare facilities (HCFs) as provided by vendors of medical devices and health information systems.

This document specifies the risk assessment necessary to protect remote maintenance activities, taking into consideration the special characteristics of the healthcare field such as patient safety, regulations and privacy protections.

This document provides practical examples of risk analysis to protect both the HCF and RMS provider information assets in a safe and efficient (i.e. economical) manner. These assets are primarily the information system itself and personal health data held in the information system.

### 2 Normative references

There are no normative references in this document.

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 3.1

##### **asset**

anything that has value to the organization

[SOURCE: ISO/IEC 21827:2008, 3.4]

Note 1 to entry: In the context of health information security, information assets include

- a) health information,
- b) technical information (credentials, passwords, calibration data, etc.),
- c) non-health information (e.g. financials, administrative, legal, human resources, etc.),
- d) IT services,
- e) hardware,
- f) software,
- g) communications facilities,

- h) media,
- i) IT facilities, and
- j) medical devices that record or report data.

### 3.2 availability

property of being accessible and usable upon demand by an authorized entity

[SOURCE: ISO/IEC 21547:2010, 3.2.7]

### 3.3 confidentiality

property that information is not made available or disclosed to unauthorized individuals, entities, or processes

[SOURCE: ISO/IEC 21827:2008, 3.13]

### 3.4 information security

preservation of *confidentiality* (3.3), integrity and *availability* (3.2) of information

Note 1 to entry: Other properties, particularly accountability of users, but also authenticity, non-repudiation, and reliability are often mentioned as aspects of information security but could be considered as derived from the three core properties in the definition.

### 3.5 risk

effect of uncertainty on objectives

Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both, and can address, create or result in opportunities and threats.

Note 2 to entry: Objectives can have different aspects and categories, and can be applied at different levels.

Note 3 to entry: Risk is usually expressed in terms of risk sources, potential events, their consequences and their likelihood.

[SOURCE: ISO/IEC 31000:2018, 3.1]

### 3.6 risk assessment

overall process of risk identification, risk analysis, and risk evaluation

[SOURCE: ISO/TS 13131:2014, 3.5.4]

### 3.7 threat

potential cause of an unwanted incident, which may result in harm to a system or organization

## 4 An outline of RMS security of medical devices and medical information systems

### 4.1 Contents of RMS security of medical devices and medical information systems

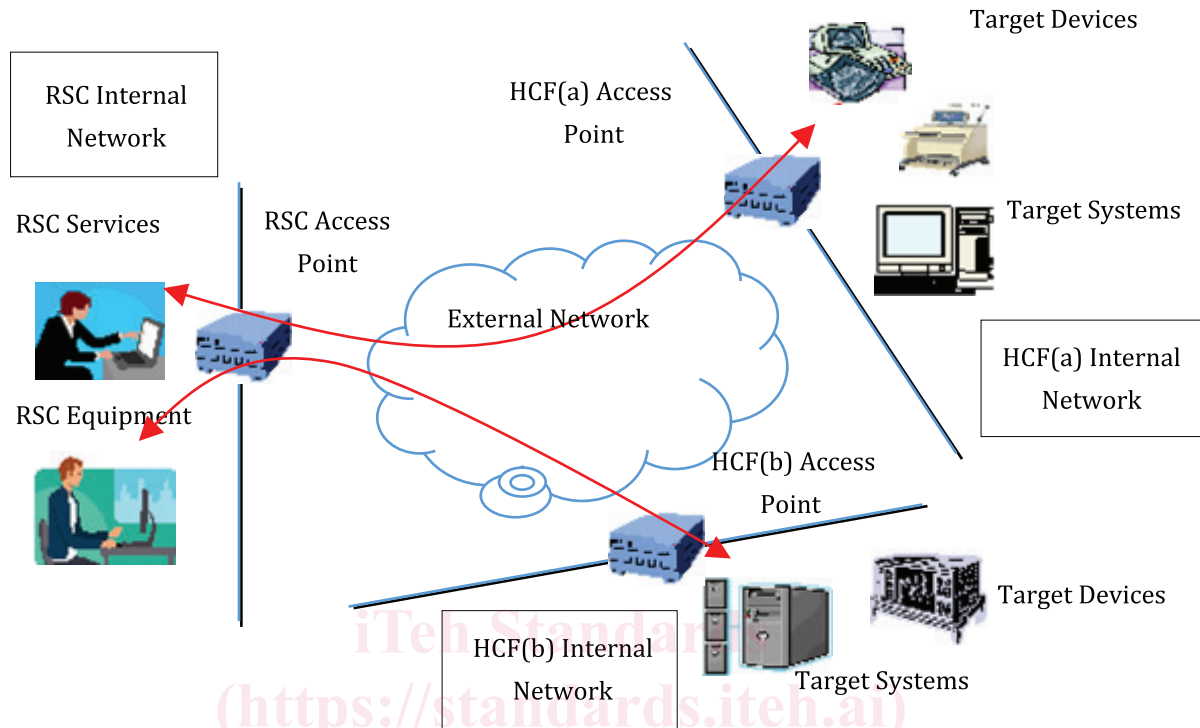
#### 4.1.1 General

The following architectural configuration is assumed in this document (Figure 1):

- target device;
- internal network within a HCF;



- external network connecting a HCF and remote service centre (RSC);
- internal network within a RSC;
- equipment and services in the RSC.



**Figure 1 — Assumed RMS architecture**

This document introduces the potential types of RMSs and provides options for appropriate security controls to be considered in the risk analysis phase.

Use cases of RMSs are provided in [Annex A](#).

The types of RMS and technical security measures related to each type are explained in [4.1.2](#) and [4.1.3](#).

#### 4.1.2 RMS using a public switched telephone network

Where a HCF sets up a machine for dial-up server function, the machine connects with a public switched telephone network via modem and waits for access from a RSC remote connection. Telecommunications equipment that offer these functions such as dial-up routers are in widespread use.

In the use of the public switched telephone network, telecommunication lines have the following features:

- a one-to-one communication pathway between a HCF and the RSC can be secured;
- tapping is difficult because a public switched telephone network is fully-digitalized.

Using these features, security can be maintained by the following technical measures:

- determination of caller number — use of call back certification function or caller ID specification certification function;
- user certification — use of one-time password and encryption of password; and
- review of communication audit logs to detect illegal access attempts to a HCF.

#### 4.1.3 RMS using the Internet

A device using an Internet connection with an externally accessible IP address is placed at the HCF. The RSC prepares the Internet connection environment and connects itself to the HCF through the Internet.

This subclause specifies the technologies for communication and user authentication between a HCF and a RSC using the Internet for connection. This is the same as a typical Internet connection and not a one-to-one communication like the public switched telephone network.

Examples of security control are shown below:

- using firewall(s);
- using tools such as anti-virus software;
- communication using VPN for encryption of the communication path; and
- use of a variety of user authentication methods such as one-time passwords, multi-factor authentication and digital certificates

### 4.2 Security requirement of RMS of medical devices and medical information systems

#### 4.2.1 General

The RMS security requirements can be classified into three categories: measures, contracts and protection measures.

#### 4.2.2 Security measures in RMS operation

Regulations and legislation commonly drive specific requirements on how to operate a system securely and protect the privacy of personal information. Examples are shown below:

- those concerning the RSC operator;
- measures for excluding unauthorized operations;
- requirements for when RSC remote terminals are increased or relocated; and
- requirements for access from mobile terminals.

#### 4.2.3 Contracts between HCF and RSC including 3rd parties

The following can be used to prepare for security incidents:

- requirements for responsibility demarcation between a HCF and a RSC;
- establishment of contracts between a HCF and a RSC, including requirements for confidentiality, integrity and availability of information.

#### 4.2.4 Protection of personal information

There might be provisions that impose obligations on a HCF for the protection of personal health information. As remote services provide an interface with a health information system which potentially contains personal health information, the RMS provider shall incorporate security measures to protect personal information.

There are various means for providing security measures in a RMS. Each RMS provider maintains security by using these mean, taking into account the relevant provisions.