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BSI Standards Publication

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

Part 1: Requirements and risk analysis

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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

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Foreword

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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).

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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'.

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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.

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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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