



ISO/TS 11633-1

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

Second edition
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This second edition cancels and replaces the first edition (ISO/TS 11633-1:2019), which has been technically revised.

The main changes are as follows:

- complete revision to correspond to the latest editions of ISO/IEC 27001 and ISO/IEC 27002;
- revision of the clause structure;
- update of [Clause 3](#) and the Bibliography.

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Advancement of information and communications technology (ICT) has changed how networks are used in 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 sharing and exchange 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 remote maintenance services (RMS), it becomes possible to reduce down-time and lower costs for this maintenance activity.

While 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.