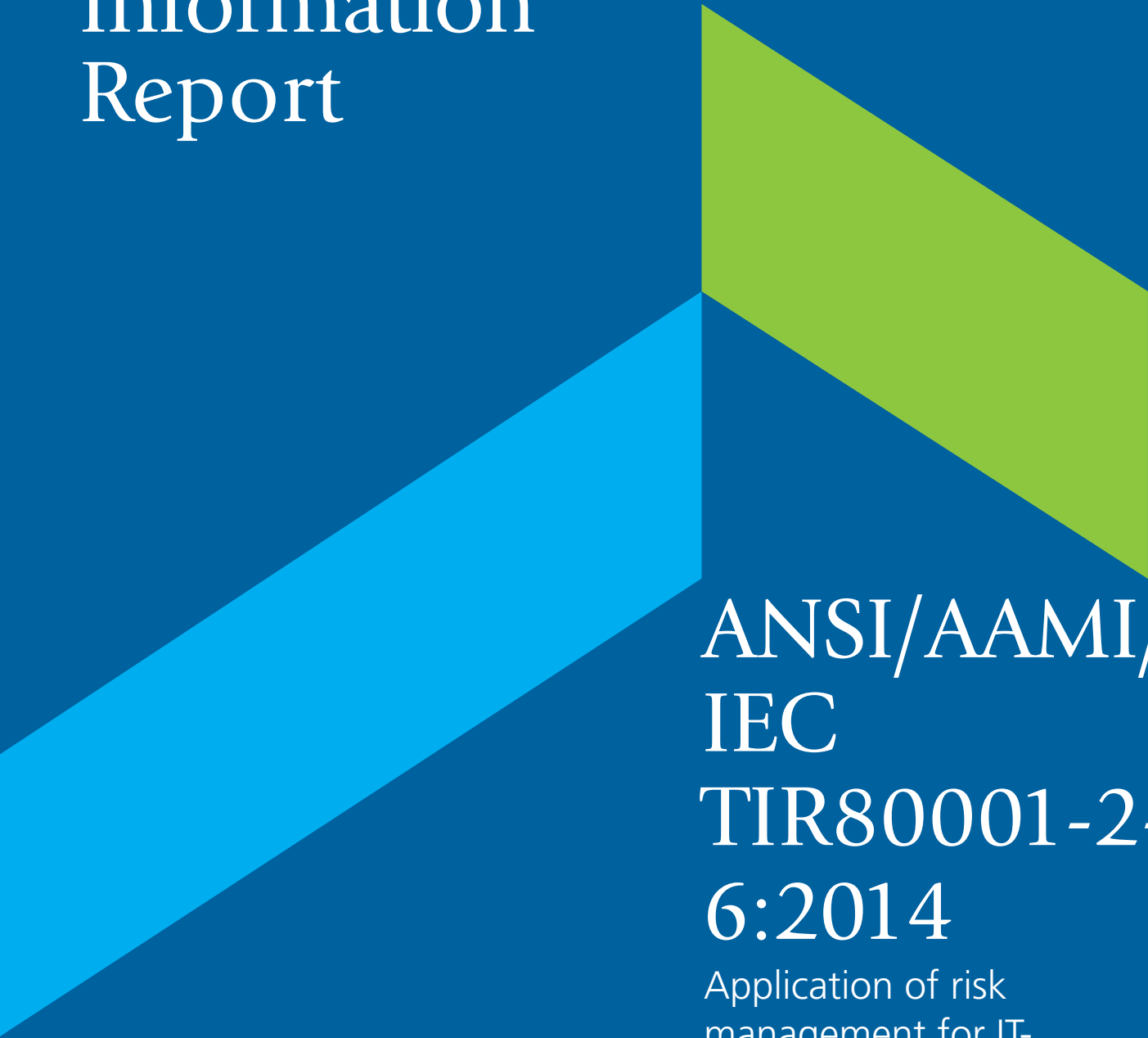


Technical Information Report



ANSI/AAMI/ IEC TIR80001-2- 6:2014

Application of risk
management for IT-
networks incorporating
medical — Application
guidance —
Part 2-6: Guidance for
responsibility agreements

Application of risk management for IT-networks incorporating medical — Application guidance — Part 2-6: Guidance for responsibility agreements

Approved 10 December 2014 by
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Abstract: Provides guidance for stakeholders on implementing RESPONSIBILITY AGREEMENTS to establish the roles and responsibilities among the stakeholders engaged in the incorporation of a MEDICAL DEVICE into an IT-NETWORK in order to support compliance to ANSI/AAMI/IEC 80001-1. The goal of the RESPONSIBILITY AGREEMENT is that these roles and responsibilities should cover the complete lifecycle of the resulting MEDICAL IT-NETWORK.

Keywords: Responsibility Agreements. IT-network, MEDICAL DEVICES, RESPONSIBLE ORGANIZATIONS, IT suppliers, MEDICAL DEVICE manufacturers

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Glossary of equivalent standards

International Standards or Technical Reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI/SM/WG 02, Information Technology Networks Working Group

The adoption of the ISO 80001-2-6 as a new AAMI/ISO Technical Information Report was initiated by the AAMI Information Technology Working Group.

Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, **the AAMI Information Technology Networks Working Group** had the following members:

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