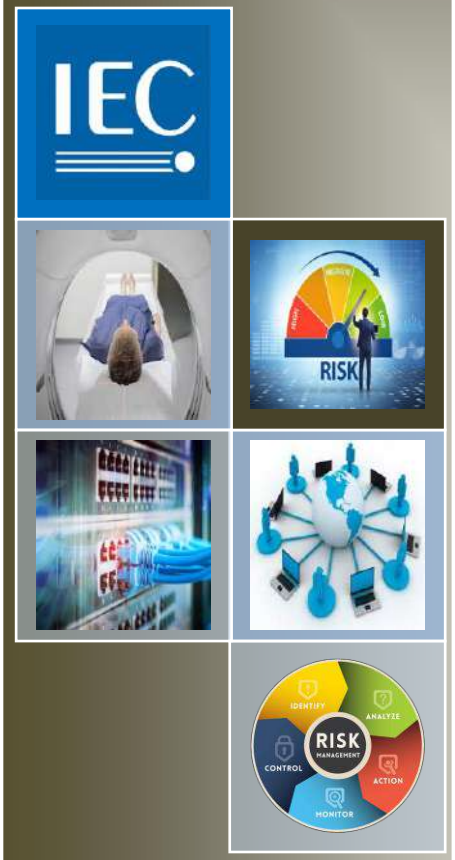
Deming Certification & Rating Pvt. Ltd.
Email: - info@demingcert.com
Contact: - 02502341257/9322728183
Website: - www.demingcert.com
No. 108, Mehta Chambers, Station Road, Novghar, Behind Tungareswar Sweet,
Vasai West, Thane District, Mumbai- 401202, Maharashtra, India



IEC 80001-1:2021 Risk Management for IT- networks incorporating medical devices

What is IEC 80001-1:2021 Risk management for IT-networks incorporating medical devices ?

IEC 80001-1:2021 Recognizing that medical devices are incorporated into IT-networks to achieve desirable benefits (for example, interoperability), defines the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security (the key properties). IEC 80001-1:2021 does not specify acceptable risk levels. IEC 80001-1:2021 applies after a medical device has been acquired by a responsible organization and is a candidate for incorporation into an IT-network. It applies throughout the life cycle of IT-networks incorporating medical devices. IEC 80001-1:2021 applies where there is no single medical device manufacturer assuming responsibility for addressing the key properties of the IT-network incorporating a medical device. IEC 80001-1:2021 applies to responsible organizations, medical device manufacturers and providers of other information technology for the purpose of risk management of an IT-network incorporating medical devices as specified by the responsible organization. It does not apply to personal use applications where the patient, operator and responsible organization are one and the same person.

Abstract

IEC 80001-1:2021 specifies general requirements for ORGANIZATIONS in the application of RISK MANAGEMENT before, during and after the connection of a HEALTH IT SYSTEM within a HEALTH IT INFRASTRUCTURE, by addressing the KEY PROPERTIES of SAFETY, EFFECTIVENESS and SECURITY whilst engaging appropriate stakeholders.
IEC 80001-1:2021 cancels and replaces the first edition published in 2010. This edition constitutes a technical revision.
This edition includes the following significant technical changes with respect to the previous edition:
a) structure changed to better align with ISO 31000;
b) establishment of requirements for an ORGANIZATION in the application of RISK MANAGEMENT;
c) communication of the value, intention and purpose of RISK MANAGEMENT through principles that support preservation of the KEY PROPERTIES during the implementation and use of connected HEALTH SOFTWARE and/or HEALTH IT

- **Contents**

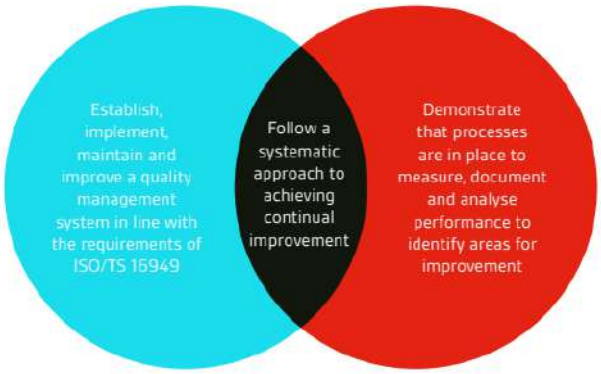
The IEC 80001-1:2021 will consist of following sections:

1. Introduction
2. Scope
3. Normative References
4. Terms and Definitions
5. Context of the organisation
6. Leadership
7. Planning
8. Support
9. Operation
10. Performance Evaluation
11. Improvement
12. Annex (informative): Guidance on the use of this International Standard

IEC TR 80001-1:2021 which is a technical report, gives guidance and practical techniques for responsible organizations, medical device manufacturers and providers of other information technology in the application of IEC 80001-1:2021 for the risk management of distributed alarm systems. This technical report applies to the transmission of alarm conditions between sources, integrator and communicators where at least one source is a medical device and at least one communication path utilizes a medical IT-network. This technical report provides recommendations for the integration, communication of responses and redirection (to another operator) of alarm conditions from one or more sources to ensure safety and effectiveness. Data and systems security is an important consideration for the risk management of distributed alarm systems.

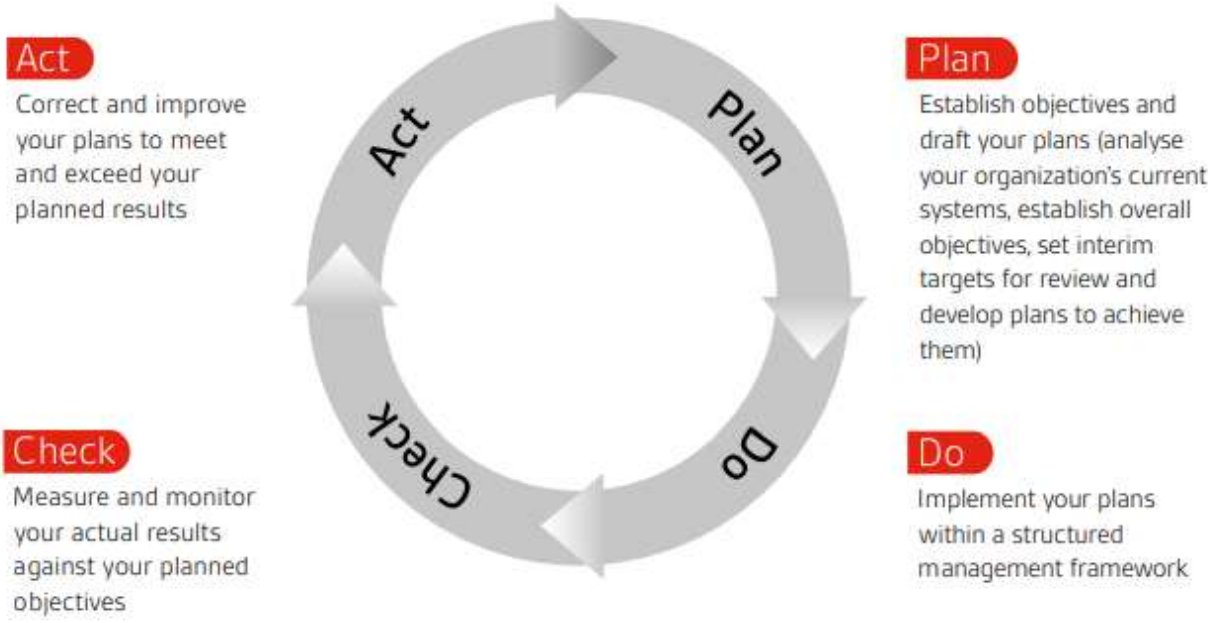
IEC TR 80001-1:2021 establishes a security case framework and provides guidance to health care delivery organizations (HDO) and medical device manufacturers (MDM) for identifying, developing, interpreting, updating and maintaining security cases for networked medical devices. Use of this part of 80001 is intended to be one of the possible means to bridge the gap between MDMs and HDOs in providing adequate information to support the HDOs risk management of IT-networks. This document leverages the requirements set out in IEC 80001-1:2021 for the development of assurance cases. It is not intended that this security case framework will replace a risk management strategy, rather, the intention is to complement risk management and in turn provide a greater level of assurance for a medical device by: - mapping specific risk management steps to each of the IEC TR 80001-1:2021 security capabilities, identifying associated threats and vulnerabilities and presenting them in the format of a security case with the inclusion of a re-useable security pattern; - providing guidance for the selection of appropriate security controls to establish security capabilities and presenting them as part of the security case pattern (IEC 80001-1:2021 provides examples of such security controls); - providing evidence to support the implementation of a security control, hence providing confidence in the establishment of each of the security capabilities. The purpose of developing the security case is to demonstrate confidence in the establishment of IEC TR 80001-1:2021 security capabilities. The quality of artifacts gathered and documented during the development of the security case is agreed and documented as part of a responsibility agreement between the relevant stakeholders. This document provides guidance for one such methodology, through the use of a specific security pattern, to develop and interpret security cases in a systematic manner.

The principal requirements of the standard are illustrated below:



The next few pages of the guide takes you through the Plan-Do-Check-Act (PDCA) methodology, common in all ISO management systems and how DCS can help and support you on your ISO/TS 16949 journey.

Understanding the principles of continual improvement



10 Tips on making ISO/TS 16949 work for you

1. Top management commitment is vital for the system to be introduced successfully. Make sure senior managers are actively responsible, involved, approve resources and agree to the key processes.
2. Make sure your whole business and supply chain are committed to business improvement and engage them with a sound communications strategy.
3. Establish a competent and knowledgeable implementation team to deliver best results, sharing roles and responsibilities.
4. Review systems, policies, procedures and processes you have in place at the moment. Then compare them with what ISO/TS 16949 asks for. Get supply chain and stakeholder feedback on your current quality processes.
5. Adapt the basic principles of ISO/TS 16949 standard to your specific business objectives and environment.
6. Clearly lay out a well-communicated plan of activities and timescales. Make sure everyone understands them and their role in achieving them.
7. Consider using DCS's Entropy™ Software to manage your system which is configured to help you achieve sustained compliance with key ISO/TS 16949 requirements.
8. Train your staff to carry out internal audits, which can provide valuable feedback on potential audits and opportunities for improvement.
9. Encourage your supply chain to become certified to ISO/TS 16949 to benefit from a robust end to end system.
10. Regularly review your ISO/TS 16949 management system to make sure it remains appropriate, effective and delivered continual improvement.

How DCS supports you throughout the implementation of ISO/TS 16949

Speak to someone at DCS to help you understand the process If you are new to management systems then we know this may seem rather daunting at first. But don't worry – just pick up the phone to speak to one of our people. We can turn jargon into English and put you on the right track for success – simply call 02502341257/9322728183

Commit to best practice and start making excellence a habit

Once we have received your application, we will identify the best people to assist you on your journey – those that know your industry sector and will clearly understand your specific challenges. We also have some useful self-assessment tools to help you get started.

Engage your team and the rest of the organization

Success will depend on a team effort so get the backing of your organization by helping them understand how they can contribute to the system. Consider whether people have the necessary skills and if not equip them accordingly.

Get ahead with pre-assessment and identify potential loopholes

Many DCS clients like to get reassurance that they are on the right track before committing to the official stage 1 assessment. At your discretion, DCS will carry out an optional 'gap-analysis' or pre-assessment visit to help you identify any weaknesses or omissions prior to the formal assessment. Call our team on 02502341257/9322728183to book a pre-assessment

Celebrate the achievement of your official ISO/TS 16949

DCS will assess your management system in two stages. Our 'Stage 1' visit will involve the review of the system against the requirements of the standard. 'Stage 2' is simply a follow-up to check that you have corrected and progressed any issues raised in the first stage. Now is the time to celebrate your success.

Use your certificate to promote your business

Once certified, you'll be able to make your own mark by displaying the DCS Assurance Mark. It's a valuable marketing tool that you can use to promote your organization, differentiate you from your competitors and win new business.

Help for continuous improvement

DCS's support extends far beyond the issue of a certificate. Your certificate is valid for three years however our team will continue to work with you to ensure that your business remains compliant and you strive for continual improvement. If you are interested in additional scheme or integrating your system, DCS can help. Talk to your client manager or call our team on 02502341257/9322728183

We know ISO/TS 16949; DCS shaped the original standard.

DCS

• Shaped the original standard that is now ISO/TS 16949 and continues to lead the development of related standards
• Has the most highly trained and knowledgeable assessors
• Offers the widest range of support solutions in the market place
• Is the number one certification body in the UK, USA and Korea?
• Looks after more than 70,000 global clients
• Has an unrivalled International reputation for excellence