AAMI

Advancing Safety in Health Technology

AAMI Consensus Report

Guidance on the Application of ISO 14971 to

Artificial Intelligence and Machine Learning

AAMI CR34971:2022

Guidance on the application of ISO 14971 to artificial intelligence and machine learning

Approved July 2021 by
AAMI

Abstract: This document provides guidance and intends to serve as a companion to ANSI/AAMI/ISO 14971:2019 for those performing risk management for artificial intelligence (AI) or machine learning (ML) incorporating medical devices.

Keywords: machine learning, artificial intelligence, good machine learning practice, risk management

AAMI Consensus Report

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- While more robust data/information develops on emergent area;
- When variation in the development, implementation or use of a product or process exists;
- When existing standards or other documents require additional context/clarification.

A CR is not subject to the same formal process as a standard and while similar in nature to a technical information report (TIR), it is based on the collective knowledge and experience of a selected group of stakeholders and has not undergone the wider reviews of a TIR or standard. and offers an even greater response time.

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Comments on this consensus report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Rd, Suite 300, Arlington, VA 22203-1633.

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Committee representation

Association for the Advancement of Medical Instrumentation

Artificial Intelligence Committee

This consensus report (CR) was developed by a small task group of leadership and staff members under the auspices of the Association of the Advancement of Medical Instrumentation (AAMI) and the British Standards Institution (BSI).

The CR was then reviewed by the **AAMI Artificial Intelligence Committee** and the BSI CH/210/4, Risk analysis for Medical Devices and was balloted to the AAMI Artificial Intelligence Committee.

The Artificial Intelligence Committee had the following members in the development of this CR.

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NOTE Participation by federal agency representatives in the development of this document does not constitute endorsement by any government or any of its agencies.

Foreword

This consensus-driven document was proposed to be developed after the success of a white paper developed by the cooperation between the Association for the Advancement of Medical Instrumentation (AAMI) and the British Standards Institution (BSI). This is being developed to provide guidance on machine learning as it applies to ISO 14971:2019.

This document was developed as an AAMI Consensus Report (CR) but has also been provided to BSI for comments and input. BSI and AAMI plan to use this CR as the basis and publish it as a BSI British Standard and AAMI Technical Information Report (TIR). This document provides provisional content for the development of BSI 34971/AAMI TIR 34971.

As part of the consensus-driven process of the AAMI standards program, this document was circulated for comments to the AAMI Artificial Intelligence Committee and the BSI CH/210/4 Risk Analysis for Medical Devices. This document was also balloted for approval by the AAMI Artificial Intelligence Committee.

Suggestions for improving this Consensus Report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 900 North Glebe Road, Suite 300, Arlington, VA 22203-1633.

NOTE This foreword does not contain provisions of the AAMI CR34971, *Guidance on the application of ISO 14971 to artificial intelligence and machine learning* (AAMI CR34971:2022), but it does provide important information about the development and intended use of the document.

Introduction

Artificial Intelligence (AI) can be defined as the capability of a system to perform tasks or develop data processing systems that perform functions normally associated with human intelligence (adapted from ISO/IEC 2382:2015, Information technology – Vocabulary [3]).

Artificial Intelligence (AI) can bring benefits to healthcare – improved clinical outcomes, improved efficiencies, and improvement in the management of healthcare itself. However, the implementation of new technologies such as AI can also present risks that could jeopardize patient health and safety, increase inequalities and inefficiencies, undermine trust in healthcare, and adversely impact the management of healthcare.

A 2020 joint AAMI/BSI whitepaper [15] explored the safety and effectiveness of AI in medical devices and concluded that data-driven AI medical device systems or machine learning medical device systems - differed from traditional rules-based systems in three ways:

1) Learning—The systems can accumulate data to provide an elaboration that could have a positive impact on patient health in any term defined by the intended purpose of the medical device (in vitro or not) according to relevant regulations.

2) Autonomy—These systems have the potential to modify processes in outputs in response to their learning with reduced or even without clinician oversight.

3) Inexplicability[1]—Because of their sophisticated computational abilities, the intricate statistics involved, and the large, complex datasets involved, the rationale for outputs produced by such systems might not be easily understood by well-trained clinicians and other healthcare personnel, let alone by individuals without specialist knowledge [21].

Despite the sophistication and complicated methodologies employed, machine learning systems can introduce risks to safety by learning incorrectly, making wrong inferences, and then recommending or initiating actions that, instead of better outcomes, can lead to harm. The amplification of errors in an AI system has the potential to create large-scale harm to patients. Sometimes these systems detect correlations in data sets instead of causations, which can lead to incorrect conclusions. One well known example of correlation identification is an image recognition system that was trained to differentiate between photos of a wolf compared to photos of a husky dog. The wolf images used to train the system often had snow in the background, and the software picked up on this correlation, instead of detecting the differences in the animals themselves [21].

All medical devices come with inherent risks. This also holds for medical devices using artificial intelligence (3.1) or machine learning (3.3). Manufacturers are required to demonstrate that their medical devices do not pose unacceptable risks, and that the benefits of their intended use outweigh the overall residual risk. ISO 14971:2019, *Medical devices — Application of risk management to medical devices*, details how manufacturers assess and mitigate potential risks in order to protect the health and safety of patients as well as data and system security. Additionally, IEC 80001-1:2010, *Application of risk management for IT-networks incorporating medical devices — Part 1: Roles, responsibilities and activities* addresses risks for IT-networks incorporating medical devices [11] and IEC/TR 80002-1:2009, *Medical device software — Part*

[1] "Explainability" is often used to refer to the technical details regarding how a ML system works, whereas "Interpretability" is used to refer to how predictable the system is – these are similar but different concepts which are appropriate for differing stakeholders. For example, a data scientist may be very interested in Explainability, but the end user may be more interested in Interpretability. https://www.kdnuggets.com/2018/12/machine-learning-explainability-interpretability-ai.html

1: Guidance on the application of ISO 14971 to medical device software [12] addresses software internal to the medical device that might support AI. These standards, and associated supporting guidance documents, provide the basis for risk management and the lifecycle process for all software that is regulated under medical device legislation.

To manage a risk, however, one has to be aware that the risk exists. With medical devices without AI, risk can be assessed from real-world experience with that technology. With AI-enabled medical devices, however, that experience is lacking, increasing the potential to fail to identify hazards, inequities, misunderstand the technology or the process, or underestimate the risk. Due to the nature of AI in itself, it may be more complex to identify risks and bias since the algorithmic decision pathways may be challenging to interpret.

One of the key findings of the 2020 AAMI/BSI whitepaper [15] was the need to develop "risk management guidance to assist in applying ISO 14971 to AI as a medical technology." ISO 14971 (also published as ANSI/AAMI/ISO 14971:2019 and BS EN ISO 14971:2019) is an International Standard that provides a process for managing the risk associated with medical devices. It has been recognized by medical device regulators and adopted as a national standard in countries across the world. This AAMI Consensus Report does not provide a new risk management process, nor does it expand the requirements of ISO 14971. Rather, it provides guidance to assist those who are applying ISO 14971 to regulated AI medical technologies.

There are many different algorithms that can support AI, including technologies such as decision trees, genetic algorithms, and neural nets. Often, when people are discussing AI, they are specifically talking about Machine Learning systems. Since Machine Learning (ML) systems are often more complicated and more opaque than other approaches, this report focuses on ML-related risks. Because of this potential for confusion, the remainder of this document will avoid the use of the terms "AI" and "AI-enabled" and use ML.

Guidance on the application of ISO 14971 to artificial intelligence and machine learning

1 Scope

1.1 This document provides guidance for applying an ISO 14971 risk management process when evaluating medical technology utilizing machine learning (ML). It is intended to apply to ML-enabled medical devices[2] throughout all phases of the product lifecycle.

1.2 This document is intended to be used in conjunction with ISO 14971. It does not modify the ISO 14971 risk management process—rather it provides information and guidance to inform the application of ISO 14971 to ML medical technology. A risk management process is further detailed in Annex A.

1.3 This document addresses the same types of risk that are addressed in ISO 14971 but focuses on risks that are elevated with or unique to ML medical devices. Because artificial intelligence (AI) and ML are software-driven, the unique or elevated risks are those around data management, feature extraction, algorithm training, evaluation, and cyber and information security. This document also provides examples and suggests strategies for eliminating or mitigating the associated risk.

1.4 Annex B of this standard provides additional clarification and examples of hazards, hazardous situations, and harms, as well as possible risk control strategies in a series of tables that correspond with ISO 14971: 2019, Tables C.1, C.2, and C.3.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions of this document. For dated references, only the cited edition applies. For undated references, the latest edition of the reference document (including any amendments) applies.

ISO 14971:2019, *Medical devices - Application of risk management to medical devices*

3 Terms and definitions

For the purpose of this document, the definitions in ISO 14971 and the following apply:

3.1
artificial intelligence
AI
capability of a system to perform tasks or develop data processing systems that perform functions normally associated with human intelligence

[Adapted from ISO/IEC 2382:2015, Information technology – Vocabulary].

[2] Also referred to as ML medical devices in this document.