Technical Information Report

AAMI TIR115: 2026

Guidance for the appropriate use of public cloud computing to enable medical device functions

AAMI

Advancing Safety in Health Technology

Guidance for the appropriate use of public cloud computing to enable medical device functions

Approved 04 September 2026 by
AAMI

Abstract: The purpose of this document is to provide guidance to multiple stakeholders on the appropriate use of public cloud computing in support of the operation of regulated medical devices. Cloud service providers, medical device manufacturers, regulatory professionals, and regulators should be able to use this document to identify best practices that ensure the public cloud computing environment underlying medical devices works within the spirit and the letter of regulations designed to improve patient outcomes, while also being safe and effective.

This TIR supersedes AAMI CR510:2021; *Appropriate use of public cloud computing for quality systems and medical devices*.

Keywords: cloud technology, cloud computing, public cloud computing

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Committee representation

Association for the Advancement of Medical Instrumentation

Cloud Computing Working Group

This AAMI Technical Information Report (TIR) was developed and approved by the AAMI Cloud Computing Working Group.

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

Foreword

Medical device manufacturers have been utilizing cloud computing for several years, with largely positive results. Cloud computing has enabled clinicians and medical device companies to treat more patients and solve more clinical challenges.

The increasing use of cloud computing in the medical device industry brings new technical and business risks and challenges, including the management of medical device safety and effectiveness in an environment that is designed to change frequently (to ensure high quality, reliability, and security), change at different rates (i.e., a service level architecture where each module could change independent of another), and change outside the manufacturer's direct control (i.e., a third-party service provider of a public cloud environment). This creates a paradigm shift for safety and compliance. Manufacturers may have tried to mitigate these challenges by implementing their own cloud environment, but this approach requires significant resources, which is difficult for small manufacturers, and does not fully leverage the special expertise that a service provider may be able to provide to ensure the cloud environment is of sufficient quality. This has resulted in manufacturers avoiding the use of cloud computing, because of a lack of clarity and guidance on its safe, effective, and compliant use.

To address these challenges, a *Biomedical Instrumentation & Technology* (*BI&T*) journal article was developed ("Hey You, Get On the Cloud: Safe and Compliant Use of Cloud Computing with Medical Devices", AAMI *BI&T*, January/February 2021), followed by the article, Consensus Report (AAMI CR510:2021; *Appropriate use of public cloud computing for quality systems and medical devices*). This TIR, which supersedes AAMI CR510:2021, provides further recommendations on how to design, deploy, and maintain medical devices in a cloud environment, as well as guidance for building an effective relationship with cloud service providers. This TIR will provide recommendations for complying with international standards and U.S. Food and Drug Administration (FDA) regulations and guidance documents when using public cloud computing in the operation of medical device software.

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Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org

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Guidance for the appropriate use of public cloud computing to enable medical device functions

1 Scope

This document provides guidance to stakeholders on the use of public cloud computing in medical devices. Cloud technology providers, medical device manufacturers, regulatory professionals, and regulators alike should be able to refer to this document to identify known best practices for how to ensure that the cloud computing environment of any medical device system works both within the spirit and letter of regulations designed to ensure that medical devices improve patient outcomes, while also being safe and effective.

This report provides practical advice for medical device manufacturers that will continue to be relevant as cloud technologies evolve and improve over time.

1.1 In-scope and out-of-scope for this TIR

While the content in this TIR could be adapted for other purposes, e.g., private cloud, the scope of this TIR is specifically focused on the challenge of appropriately using public cloud computing to support the functions of a regulated medical device.

This TIR discusses general-purpose computing functions, such as operating systems, data storage, computing power, etc., that are managed by a public cloud service provider. However, management of privacy or cybersecurity concerns related to cloud-deployed medical devices are not discussed in detail but are within the scope of this TIR.

To further clarify the scope boundaries of this TIR, Annex E includes a detailed list of topics this Working Group determined to make out of scope for this TIR. That list can also provide future cloud-related topics to address in guidance or standards.

1.2 Unique benefits and risks for medical devices that operate in a cloud computing environment

Cloud computing's rapid growth is a story of the incredible power of economies of scale, and the ways that applying that economic principle to the provisioning of server-side computing has had tremendous benefits in terms of cost, reliability, security, agility, functionality, and scalability. Cloud computing has enabled the medical device industry to help more patients, clinicians, and caregivers by serving as a key platform for digital health technologies, providing solutions that allow clinicians and patients to interact at a distance, mobile medical applications that increase patient engagement or provide innovative therapeutic solutions, and the ability to store massive amounts of healthcare data for use in medical diagnostic models or patient monitoring.

Cloud computing also comes with a unique set of risks and considerations that medical device manufacturers should address to ensure the safe, effective, and compliant design, implementation, deployment, and maintenance of cloud based medical devices.

When compared to other major computing platforms, one of the key strengths of cloud environments is that changes and updates can be frequently, rapidly, and widely deployed. Changes may include, for example, the addition of more computing power in the form of additional servers or the regular adaptation of the environment to protect against emerging cybersecurity threats. Similarly, one of the key strengths of the public cloud environment is that organizations can leverage the experience and resources of a cloud service provider (CSP) without having to invest the resources to establish a similar internal infrastructure.

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