

Can AI Systems Be Recalled Like Medical Devices? A Regulatory Conundrum

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Published: November 22, 2022 | AI Diagnostics

DOI: [10.5281/zenodo.17997708](https://doi.org/10.5281/zenodo.17997708)

Abstract

The integration of Artificial Intelligence AI and Machine Learning ML into medical devices AIMDs is transforming healthcare, but it poses a profound challeng...

The integration of Artificial Intelligence (AI) and Machine Learning (ML) into medical devices (AIMDs) is transforming healthcare, but it poses a profound challenge to established regulatory frameworks, especially regarding product safety and **recall** mechanisms. The question of whether an AI system can be "recalled" like a traditional medical device is critical for patient safety, regulatory compliance, and the future of digital health.

The Traditional Recall Paradigm for Medical Devices

In the United States, the Food and Drug Administration (FDA) governs medical device recalls. A recall is the firm's removal or correction of a marketed device that violates FDA laws and poses a risk to health, typically triggered by a defect in manufacturing, design, or labeling [1].

The traditional recall process is well-defined: a defect is identified, the recall is classified (Class I, II, or III) based on the health hazard, and the firm must remove or correct the device. For physical devices, this involves retrieving units or issuing a software patch. This paradigm is built on the assumption of a **static product** whose core function does not change post-manufacture.

The Adaptive Challenge of AI/ML

AI/ML-enabled medical devices fundamentally challenge this static assumption. Many AIMDs, especially those with **adaptive algorithms**, learn and evolve from real-world data post-deployment. This continuous learning can lead to performance drift, bias amplification, or new, unforeseen errors—a phenomenon sometimes called "model decay" [2]. When an AI model's performance degrades or exhibits harmful bias, the issue is a functional failure in a constantly changing algorithm, not a physical manufacturing defect, making the traditional "recall" concept difficult to apply.

The Regulatory Shift: From Recall to Correction

Regulatory bodies are adapting by shifting the focus from a physical "recall" to a strategy of **"correction"** and **"algorithmic management."** The FDA, acknowledging the limitations of its traditional paradigm for adaptive AI, has proposed a new **Total Product Lifecycle (TPL)** approach [3].

Key elements of this new approach include: **Predetermined Change Control Plan (PCCP):** Manufacturers must submit a plan outlining the types of modifications they intend to make to the AI model (e.g., retraining with new data) and the methods they will use to manage and validate those changes. **Good Machine Learning Practice (GMLP):** A set of standards to ensure the quality, transparency, and reliability of the AI model throughout its lifecycle. **Real-World Performance Monitoring:** Continuous monitoring and evaluation of the AI's performance in clinical settings to detect drift or failure early.

When an AI system exhibits a safety issue, the action taken is often a **software correction**—a targeted update, patch, or retraining of the model—rather than a physical retrieval of the device. This correction must be managed under the TPL framework and, if it addresses a significant health risk, it is still reported as a recall event in the FDA's database, even if no physical device is returned [4].

The Future of Algorithmic Accountability

The challenge of recalling AI systems highlights a broader need for **algorithmic accountability**. The focus is moving from a single point-in-time regulatory clearance to continuous oversight of the algorithm's performance and the manufacturer's quality management system. This includes ensuring that the data used for retraining does not introduce new biases and that the model remains clinically valid across diverse patient populations.

The regulatory landscape is rapidly evolving to address these complexities. For more in-depth analysis on this topic, including the ethical implications of AI drift and the specific requirements for continuous validation, the resources at **www.rasitdinc.com** provide expert commentary and cutting-edge professional insight.

In conclusion, while the term "recall" is still used for regulatory reporting, the mechanism for AI systems is fundamentally different. It is not about retrieving a faulty product but about the continuous, controlled correction and management of a dynamic, learning algorithm to ensure patient safety and clinical efficacy. The success of AI in healthcare depends on transitioning from a static regulatory mindset to one of continuous algorithmic oversight.

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