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SOFTWARE FAILURES IN RADIOLOGY DEVICES: TWENTY YEARS OF U.S. FDA MEDICAL DEVICE RECALLS, 2005-2025

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Abstract: Software is now part of most medical devices, and its errors can harm patients. This study uses the public openFDA database, which lists 20,576 U.S. medical device recall events initiated in 2005-2025, to ask how often recalls are caused by software in radiology compared with other medical specialties, and whether this has changed as artificial intelligence has entered radiology. Among recall events with a determined root cause, software was the cause of 38.1% of radiology recalls in 2005-2011, 47.9% in 2012-2018 and 40.0% in 2019-2025, against 6.0%, 9.4% and 11.4% for other devices. Radiology accounted for 16.9% of these recalls but 49.6% of software recalls. The results support the author's expectation that software fails more often in radiology, but not her expectation that the spread of artificial intelligence would increase software recalls: the FDA authorized 1,013 AI-enabled radiology devices in 2019-2025, against 82 before, while the software share of radiology recalls did not rise (28.9-44.6% a year in 2019-2025) and the gap with other specialties narrowed.

Keywords: medical devices, software, recalls, radiology, FDA, artificial intelligence

1. Introduction

Modern medical devices depend on software: scanners reconstruct images with it, treatment planning systems calculate radiation doses with it, and more and more devices contain algorithms based on artificial intelligence. When a device is found to be faulty, the manufacturer recalls it, and in the United States the Food and Drug Administration (FDA) records the recall and its root cause. An analysis of recalls from 2005 to 2011, based on public and internal databases, found that "19.4% of medical device recalls are related to software" [1].

Radiology is a natural place to look at software failures, because its devices handle large images and complex calculations and because it is the specialty where artificial intelligence is most common: of the 1,614 AI-enabled devices on the FDA list, 1,230 (76.2%) belong to radiology [3]. This study uses twenty years of FDA recall records to compare radiology with other specialties and to see whether software recalls in radiology have risen recently.

2. Hypothesis

Before the analysis, the author proposed (12 October 2026) that software errors in radiology are most often caused by complex programs for processing medical images, which affect the accuracy of diagnosis and treatment, and by the heavy load that modern scanners, producing thousands of images per examination, place on networks and memory. She expected that as more artificial intelligence enters medicine, such recalls would become more frequent, because AI

systems can make errors when images are distorted by small artefacts, patient movement or poor quality (original in Russian).

3. Data and methods

The data are the openFDA device recall file (export of 27 October 2026) [2]. It contains one record per recalled product; records that share a recall event number were combined into one recall event, giving 20,576 events initiated in 2005-2025 from 54,280 product records. Events were assigned to the year in which they were initiated. An event was counted as software-related if its FDA root-cause category contains the word "software" (Software design, Software design change, Software change control, Software manufacturing/software deployment, Software design (manufacturing process) and Software in the use environment); all records of an event carry the same root cause. An event was counted as radiology if any of its products has the medical specialty Radiology in the openFDA record, and as another specialty if its products have a different known specialty; 1,536 events with no or unknown specialty were left out of both groups. Events whose root cause is still recorded as "Under Investigation by firm" (148 in radiology and 1,905 in other specialties, most of them recent) have no determined cause yet and were left out of the shares. Shares were compared for three seven-year periods and by year.

To describe the spread of artificial intelligence, the FDA list of AI-enabled medical devices (CSV, downloaded on 30 October 2026, decisions up to 06/29/2026) was used, counting authorizations by year whose lead review panel is Radiology [3].

4. Results

Software is a much more frequent cause of recalls in radiology than elsewhere (Table 1). In 2005-2011, 369 of 969 radiology recall events with a determined cause (38.1%) were caused by software, against 6.0% of events in other specialties. The share in radiology was 47.9% in 2012-2018 and 40.0% in 2019-2025, while in other specialties it rose from 6.0% to 11.4%, so the difference between them narrowed from 6.4 times to 3.5 times. Over the whole period radiology accounted for 16.9% of recall events with a determined cause but 49.6% of software-related events (1,222 of 2,463).

Table 1. Software-related FDA medical device recall events, radiology and other specialties [2]. *Events with a determined root cause

Period	Radiology events*	of them software	Software share, %	Other events*	of them software	Software share, %
2005-2011	969	369	38.1	4,656	278	6.0
2012-2018	1,212	580	47.9	5,644	528	9.4
2019-2025	682	273	40.0	3,824	435	11.4

Over the same years artificial intelligence spread quickly in radiology: the FDA authorized 82 AI-enabled radiology devices up to the end of 2018 and 1,013 in 2019-2025, from 51 in 2019 to 254 in 2025 [3]. Software recalls in radiology did not rise with it (Table 2). The software share of radiology recall events was between 42.1% and 44.6% in 2019-2022, lower in 2023 (33.0%) and 2024 (28.9%), and 42.4% in 2025; the number of software-related radiology events was 22-51 a year. In other specialties the share was 10.1% in 2019 and 14.7% in 2025. In 2023-2025 about a fifth of radiology events still had no determined cause, so the shares for these years may change.

Table 2. Radiology recall events, software share and AI-enabled radiology devices authorized by year, 2019-2025 [2, 3]

Year	2019	2020	2021	2022	2023	2024	2025
Radiology events with determined cause	112	112	121	74	88	76	99
of them software	48	48	51	33	29	22	42
Software share, radiology, %	42.9	42.9	42.1	44.6	33.0	28.9	42.4

Software share, other, %	10.1	11.0	12.5	9.4	11.4	10.6	14.7
Radiology events under investigation	6	10	14	9	27	19	23
AI radiology devices authorized [3]	51	99	110	138	178	183	254

5. Discussion

The first part of the hypothesis is supported: in every period software caused recalls in radiology 3.5 to 6.4 times more often than in other specialties, and about half of all software-related recalls came from radiology, which is consistent with the complexity of imaging and treatment-planning software. The second part is not supported by these data: while the number of AI-enabled radiology devices authorized each year grew about fivefold, the software share of radiology recalls did not rise and the yearly number of software recalls did not grow. What changed is that software recalls became more common in other specialties, as software spread to other devices.

When she saw these results, the author suggested (25 October 2026) three explanations: AI systems are checked carefully before use, so many errors are corrected in advance; software in general and quality control have improved; and not all radiology programs use AI, so it is wrong to claim that its spread increases the overall number of software errors (original in Russian). These recall data cannot separate AI devices from other radiology devices, so they cannot test these explanations; they show only that the growth of AI in radiology has not been accompanied by more software recalls so far.

The overall share of software-related recalls here, 11.5% of events with a determined cause in 2005-2011, is lower than the 19.4% found for the same years in [1]. The two studies classify recalls differently: this one counts only events whose recorded FDA root cause is a software category, while [1] used public and internal databases and examined the causes of recalls in more detail, and the two may count different units. Limitations. The root cause is recorded by the FDA and may be classified differently over time; the medical specialty comes from the device classification and is missing for some events; recent recalls may still be updated, and many recent ones are still under investigation; AI devices are counted when authorized, not by how many are in use; and the databases cover only the United States.

6. Conclusion

Across twenty years of FDA recalls, software has caused about two-fifths of radiology recalls with a known cause, several times more often than for other devices, and radiology accounts for about half of all software recalls. In the years when artificial intelligence spread in radiology, the software share of its recalls did not rise, while it grew slowly in other specialties.

Data availability

The openFDA recall data and the FDA list of AI-enabled devices are public [2, 3]. The analysis script and the yearly tables are available from the author on request.

Author contributions and use of AI tools

The author chose the research direction, proposed the hypothesis quoted in Section 2 before the analysis, found the earlier study [1] and proposed the explanations discussed in Section 5. The data were analysed and the text was drafted by her mentor with the help of a generative AI assistant (Claude, Anthropic). Every number was computed by the analysis script from the FDA data.

Conflicts of interest

The author declares no conflicts of interest. No funding was received for this study.

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