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IEC 62304 Edition 2: Draft Changes for Medical Device Software

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Executive Summary

IEC 62304, the international standard for medical device software life-cycle processes, is undergoing a **major revision** (Edition 2). As of mid-2026 the revision was still at committee-draft stage: VDE reported in July 2026 that the next Committee Draft was expected in August 2026 (www.vde.com), and the Johner Institute reported that an FDIS is not expected until 2028, so publication may slip to 2029 (blog.johner-institute.com). Everything described below reflects draft proposals that may still change. This update reflects the rapidly evolving landscape of health software, including Software as a Medical Device (SaMD), digital health, and Artificial Intelligence (AI) applications. Key changes include a **simplified safety classification** system (reducing from three classes to two levels), an **expanded scope** covering all health software (not just formally regulated medical devices), new **AI/ML guidance** (an informative annex on AI-enabled health software in the July 2026 working draft), and an emphasis on **“harm”** (including property and environmental damage) in risk management, aligning with ISO 14971 (www.nsf.org). The update also clarifies processes by separating **development versus maintenance** activities, relocates legacy software requirements to an informative annex, and removes redundant Quality Management System (QMS) clauses, shifting general QMS obligations to ISO 13485.

These revisions aim to streamline compliance and better address modern technology: they remove ambiguity in classifying software based on risk (lfhregulatory.co.uk), introduce rigorous guidance for AI/ML software engineering (www.nsf.org) (lfhregulatory.co.uk), and acknowledge the broader healthcare context of software beyond traditional devices (www.nsf.org). For manufacturers, the transition will affect classification decisions, documentation effort, and development practices. For example, earlier drafts proposed dedicated **AI process planning** for AI-enabled software; the need is illustrated by data showing that **50%** of AI/ML medical device

recalls were attributed to device design or software design issues (pmc.ncbi.nlm.nih.gov). Moreover, the FDA's recent guidance replaces old "Levels of Concern" with "Basic vs Enhanced" risk categorizations, mirroring 62304's shift to two rigor levels (www.linkedin.com).

Implementation of Ed2 will require companies to **reevaluate risk management and quality processes**: migrating to the new classification (Level I/II), embedding AI/ML lifecycle controls, and integrating broader risk definitions. These changes have wide-ranging implications: streamlined class definitions will reduce documentation for low-risk software, but the inclusion of all health software and AI means many new products fall under 62304's umbrella. Case studies (e.g. AI diagnostic algorithms, surgical devices) underscore the need for this update. Looking forward, Edition 2 harmonizes with parallel standards (IEC 81001-5-1 on cybersecurity, ISO 14971:2019 on risk, ISO 13485:2016 on QMS) and sets the stage for safe innovation in digital health. The net result is a **more flexible yet rigorous framework** that emphasizes safety ("harm") and modern development practices (agile, AI) without sacrificing regulatory compliance (www.nsf.org) (lfhregulatory.co.uk).

Introduction

Since its original release in 2006 (with a major amendment in 2015), **IEC 62304** has served as the de facto global standard for medical device software life-cycle processes (www.linkedin.com). It imposes structured processes for planning, requirements analysis, architecture, design, implementation, verification, release, maintenance, configuration management, and problem resolution (www.linkedin.com). Critically, IEC 62304 requires all medical software to be classified into **three safety classes** (A, B, C) based on the severity of harm that could result from software failures (blog.johner-institute.com). Class C software (highest risk) demands the most rigorous documentation (detailed design, unit testing, etc.), whereas Class A (lowest risk) has minimal requirements (blog.johner-institute.com). This classification directly influences development effort: for example, only Class C requires a documented detailed design (Clause 5.4) and all software must undergo configuration management and problem resolution activities (blog.johner-institute.com).

For the EU MDR and IVDR, presumption of conformity through harmonised standards depends on publication of their references in the Official Journal of the European Union and extends to the requirements those standards cover (European Commission). FDA recognition record 13-79 identifies IEC 62304 Edition 1.1 (2015-06), comprising the 2006 edition and its 2015 amendment, for medical device software life-cycle processes. Its scope excludes validation and final release of the medical device, even when the device consists entirely of software (FDA recognition record). This recognition concerns the published edition, rather than the Edition 2 draft. In practice, auditors routinely check 62304-based documentation (software requirements, architecture, hazard analyses, etc.) for compliance. IEC 62304 establishes a common framework for medical device software life-cycle processes (FDA recognition record).

However, the technology and regulatory environment have advanced significantly since 2015. Software development has shifted towards *cloud-based*, *connected*, and *AI/ML-enhanced* products, employing agile and DevOps practices (www.linkedin.com). Cybersecurity threats and supply-chain transparency (e.g. SBOMs) now compete equally with safety in importance (www.linkedin.com). Risk management itself has evolved: ISO 14971 defines "harm" to include damage to property or the environment, and FDA guidance replaced the older "levels of concern" with a simplified Basic/Enhanced scheme (www.nsf.org) (www.linkedin.com). In this

context, the IEC Technical Committee initiated a full **second edition (Ed2)** revision to modernize 62304. The Ed2 draft (still at committee-draft stage in 2026) incorporates extensive stakeholder feedback and aims to reconcile medical device practices with the broader domain of *health software*. As an earlier IntuitionLabs overview summarized, the revision reflects new hazards, norms, and technologies.

This report provides a **comprehensive analysis** of IEC 62304 Ed2: detailing what is changing, why it matters, and how medical device manufacturers should prepare. It draws on official committee documents, expert commentaries, and related research to break down the revised requirements. We cover the changes clause-by-clause, interpret them in practical terms, and discuss the implications for software development in 2026 and beyond. Case studies and data illustrate the motivation behind these updates, while tables compare old vs. new provisions. Our goal is to serve as an implementation guide: helping readers understand *"what's changing for medical device software"* and offering evidence-based advice to navigate the transition. All assertions are backed by credible sources (blog.johner-institute.com) (www.nsf.org) (lfhregulatory.co.uk) (pmc.ncbi.nlm.nih.gov).

Key Changes in IEC 62304 Edition 2

Expanded Scope: From "Device Software" to All Health Software

One of the most far-reaching changes in Ed2 is the expansion of scope. The original 62304 was explicitly limited to *medical device software* – that is, software that is a medical device or part of a medical device system. Edition 2 extends this to **all health software**, including wellness applications and IT systems that support healthcare (even if not classified as medical devices under some jurisdictions) (lfhregulatory.co.uk). In practice, this means that software-only health apps, clinical decision support tools, and even patient wellness software may need to follow 62304 processes if they make medical claims. The rationale is the convergence of healthcare and software: hybrid products often straddle regulations, so a unified standard simplifies global compliance. As the NSF Prosystem communiqué explains: "the draft of the second edition of IEC 62304 will extend the scope of the standard to include healthcare software" (www.nsf.org).

Implications: Companies developing software for health (beyond traditional devices) should now consider 62304. Quality and regulatory teams must map new product categories (e.g. hospital information systems with clinical functions, AI-driven diagnostic apps) into the standard's framework. This broadening also affects terminology in the standard, replacing "medical device software" with phrases like *"healthcare software"*. Importantly, this scope change does **not** eliminate 62304's relevance to conventional devices; rather it unifies "health software" processes. The Ed2 draft specifically cites as in-scope: software part of a device, embedded health hardware software, SaMD, "software-only products for health management or care delivery", and health software powered by AI/ML (www.nsf.org) (lfhregulatory.co.uk). Notably, the FDA and EU already regulate some "health software," so harmonized terminology will help manufacturers comply with both medical-device and broader digital health regulations.

Software Safety Classification (3 Classes → 2 Levels)

In Edition 1 (2006/2015), **software safety classification** was central: each software component and system was categorized as Class A, B, or C. These classes, defined by the *type of harm* after risk control, dictated development rigor (Table 1) (blog.johner-institute.com). For example, Class C (highest risk) requires documenting requirements, detailed design, unit testing, verification of each element, etc., whereas Class A still requires completion of its applicable lifecycle processes, activities and tasks, rather than only requirements and release documentation (IEC published-edition preview).

Edition 2 **simplifies this structure**. The three classes are replaced by **two "software process rigor levels"**: *Level I* (low risk) and *Level II* (high risk) (www.nsf.org) (lfhregulatory.co.uk). Essentially, Level I subsumes Class A, and Level II covers what were Classes B and C, as NSF summarized: "Level I essentially replaces software safety class A, and Level II replaces software safety classes B and C" (www.nsf.org). The stated motivation is to reduce ambiguity in classification. By collapsing B and C, Ed2 removes a "gray area" between "no serious injury" vs. "serious injury possible," speeding decisions on classification.

Feature	IEC 62304:2006/2015 (Ed 1)	IEC 62304 Ed 2 Draft (2026)
Scope	Medical device software only	All health software and medical device SW (www.nsf.org)
Classification	Three classes (A, B, C) by harm severity (blog.johner-institute.com)	Two levels (Level I, Level II) (www.nsf.org)
Risk Criteria	"Harm to persons" emphasis (www.nsf.org)	Focus on *"harm"* (includes property/environment) (www.nsf.org)
Maintenance/Updates	Separate development (Clause 5) and maintenance (Clause 6) processes (IEC published-edition preview)	Proposed clarification of the existing processes and their interaction (IEC design specification)
Registry of References	References ISO 14971 (normative), ISO 13485	Still aligns with ISO 14971 (updated terms) and ISO 13485 (QMS handled outside)
AI/ML Provisions	None	Draft AI guidance (informative annex on AI-enabled health software in the July 2026 working draft) (www.nsf.org) (lfhregulatory.co.uk)
Legacy Software	Normative requirements for legacy compliance	Moved to informative annex (guidance only) (lfhregulatory.co.uk)
QMS Requirements	QMS requirements in subclause 4.1	Design specification proposes removing subclause 4.1, with other Clause 4 provisions modified or relocated (IEC design specification)
Documentation Effort	Varies by class (A minimal, C maximal) (blog.johner-institute.com)	Effort based on two levels (streamlined assessment)

Discussion (Classification): The move to two levels should be easier for manufacturers. Companies that previously had Class B vs. C systems will now simply treat them as "high-risk (Level II)" and document commensurately. Auditors will still expect thorough documentation for Level II software (drawing from former B/C requirements) but the delineation is clearer. LFH Regulatory notes that such simplification *"helps*

streamline risk management" and reduces "ambiguity in classification decisions" (www.nsf.org) (lfhregulatory.co.uk). Risk considers both the probability of harm occurring and its severity (Health Canada glossary).

Risk Management Emphasis – *"Harm", Not Just "Hazardous Situations"*

IEC 62304 has always required integration with risk management (ISO 14971). Under Ed1, ISO 14971 was a normative reference: manufacturers had to perform a hazard analysis and tie software actions to harm mitigation. However, the terminology was tied to "hazardous situations" leading to "harm to persons." Edition 2 aligns with the latest ISO 14971 language by using the broader concept of **"harm"**. Specifically, the updated draft **emphasizes "harm" instead of "harm to patients, operators, or other persons"** (www.nsf.org). This change deliberately includes potential **damage to property or the environment** as harms, consistent with the ISO 14971 definition of harm. For example, an environmental control system failure might cause property damage (water/mold damage) even if no person is injured; Ed2 explicitly considers such scenarios as harm. A hazardous situation remains distinct from harm: it concerns exposure to hazards, whereas harm concerns injury or damage (Health Canada glossary).

In addition, Ed2 **revises how risk management is presented**. The draft places *risk management at the product/system level rather than embedding it solely in the software process*. The software-specific Risk Management Plan from Ed1 may be de-emphasized, with risk treated as a separate lifecycle aligned to product hazards. The exact architecture of the new clauses is still under review, but sources indicate that companies will align their 62304 risk tasks closely with their ISO 14971 processes.

A related change is in the classification/risk interplay: the two-level classification is coupled with *simplified risk categorization*. The standard now requires clarifying **whether the software contributes to a hazardous situation at all**, and if so, applying appropriate mitigations (lfhregulatory.co.uk). The new level scheme explicitly **"helps streamline risk management"**. IEC's design specification proposes Level II for software that implements a risk control measure (IEC design specification). These clarifications aim to ensure engineers **"can more easily assess whether their software poses any risks to patient safety and determine the necessary mitigations"** (lfhregulatory.co.uk). In short, risk decisions hinge on *harm potential* and appropriate controls, rather than complex sub-class distinctions.

AI and Machine Learning Provisions

A landmark addition in Ed2 is explicit coverage of **AI, machine learning (ML), and deep learning** within medical software. Whereas the 2015 edition of 62304 contained no AI guidance, the 2025 draft described **AI process planning** with an AI development lifecycle (AIDL) for software that incorporates AI/ML; in the July 2026 working draft this material sits in an informative annex on AI-enabled health software, offering guidance rather than binding, auditable requirements (www.vde.com) (www.nsf.org). This is consistent with global trends: IMDRF and FDA have signaled that AI/ML medical devices require special scrutiny.

In the July 2026 working draft described by VDE, the AI annex is informative and introduces no new mandatory requirements. Teams can use it to inform planning discussions about AI development; it does not itself mandate an AI development lifecycle, dataset-validation procedure or retraining strategy (VDE draft analysis).

Why does this matter? The industry has seen numerous AI-related device issues. A recent study found that **50% of AI/ML-enabled device recalls** in the US (since 1997) were due to design or development problems (pmc.ncbi.nlm.nih.gov). In a JAMA Health Forum analysis of 950 AI-enabled devices, recalled devices with *no reported clinical validation* averaged 3.4 recall events (vs. 1.9 with retrospective and 2.0 with prospective validation), and absence of reported clinical validation was associated with higher odds of recall (odds ratio 2.8) (pmc.ncbi.nlm.nih.gov). These data underscore the need for disciplined AI engineering. By addressing AI explicitly, Ed2 encourages manufacturers to integrate *"Good Machine Learning Practice"* (GMLP) concepts into 62304 compliance. Model drift, dataset version control and post-market performance are topics teams can consider when planning AI development; the draft's informative AI annex does not itself impose mandatory controls (VDE draft analysis).

Practically, development teams should update their software development plans to include AI process roles (data scientists), additional verification activities (e.g. algorithm validation), and continuous monitoring plans. In the July 2026 working draft the AI material is informative (guidance), not mandatory, so treat it as good practice rather than a certification requirement. Use the proposed informative AI annex as a planning aid, and assess each applicable regulatory requirement separately. The annex introduces no new mandatory requirements (VDE draft analysis); FDA's recognition of the published IEC 62304 edition excludes medical-device validation and final release (FDA recognition record).

Development vs. Maintenance Distinction

The published Edition 1.1 already distinguishes software development (Clause 5) from software maintenance (Clause 6); these are existing processes, rather than a distinction first introduced by Edition 2 (IEC published-edition preview). The revision should be described as proposed clarification of that existing framework.

A "maintenance" label alone does not justify reduced verification or documentation. Assess a change's effects and the applicable published requirements before determining its implementation and testing scope. The published edition defines compliance by implementation of the processes, activities and tasks applicable to the software safety class (IEC published-edition preview).

Legacy Software (Subclause 4.4)

The published Edition 1.1 places legacy-software provisions in subclause **4.4**, rather than Clause 10 (IEC published-edition preview). IEC's design specification proposes moving these provisions to an informative annex and changing requirements to guidance (IEC design specification).

That proposal does not establish a general permission to bring marketed devices only partially into compliance. Assess present compliance against the applicable published requirements, including subclause 4.4, and document any planned response to draft guidance separately (IEC published-edition preview).

Removal of QMS General Requirements (Clause 4)

The IEC design specification proposes removing **subclause 4.1**, rather than all of Clause 4. It separately proposes modifications to risk management (4.2) and software process rigor (4.3), and relocation of legacy-software provisions (4.4) (IEC design specification).

The broader health-software scope should not be read as a universal ISO 13485 requirement for every developer. VDE explains that some health software is outside medical-device regulation and describes quality and risk management at product level. Assess the product's applicable quality and risk-management obligations separately (VDE draft analysis).

Implementation Considerations and Process Changes

Having outlined the edits to IEC 62304, we now examine how development teams should implement these changes in practice. The transition to Edition 2 will require a **thorough gap analysis** of existing processes, documentation, and tools. Key implementation areas include:

- **Revised Safety Classification:** Keep present conformity claims tied to the applicable published edition and assess the proposed two-level scheme separately. In IEC's published design specification for Edition 2, proposed Level I depends on a product/system preliminary risk analysis finding that the software cannot contribute to a hazardous situation; software implementing a risk control measure is Level II. These are provisional proposal criteria, rather than a "minimal harm" threshold (IEC design specification).
- **Risk Management Alignment:** Preserve hazards, event sequences, hazardous situations, harms, probabilities, severities and the links to risk control measures as distinct elements of the risk analysis. Do not replace "hazardous situation" with "harm": FDA's risk-management training documents the situation, possible harm, severity, probability and possible controls separately (FDA risk-management training). Broader harm terminology includes damage to property or the environment; it does not erase the exposure circumstances that precede harm (Health Canada glossary).
- **AI/ML Development:** If your product uses AI/ML, create an AI development life-cycle process. This means adding roles (ML engineers), additional planning documents (data requirements, algorithm selection justification), and enhanced verification (e.g., performance testing on retrospective and prospective data). For example, a diagnostic AI should have documented phases: data collection, model training, validation, transfer to production, and continuous monitoring. Validation should include both software verification (code quality) and clinical validation (model performance against a reference standard). Although the current draft presents AI content as guidance, it is prudent to treat these activities like other verification tasks: include them in test plans and design reviews. Companies should also consider utilizing related guidances (FDA's Good ML Practice, IMDRF's AI recommendations) as input to satisfy the 62304 AI clauses.

- **Maintenance Procedures:** Document an impact and risk assessment for each change to determine the applicable development activities, design documentation, verification and validation, including regression testing. IEC's Edition 2 design specification proposes appropriate Clause 5 activities within the plan for each maintenance type (IEC design specification). For devices subject to FDA's 510(k) framework, assess and document whether the change requires a new submission (FDA software-change guidance). Use the assessment to define the work in change-control templates and team training.
- **Documentation and Traceability:** Ensure documentation structure reflects the new levels. For Level II software, continue rigorous documentation (requirements specs, design docs, test reports). For Level I, some documents (like detailed design) may no longer be mandated. However, best practice dictates maintaining essential traceability even for low-risk software. The standard will likely still require a Historian documenting all anomalies and changes (Cl.8) due to risk considerations. Review architecture and requirements docs to align with any Ed2 clause renumbering or wording changes. IEC's design specification proposes removing subclause 4.1, rather than all of Clause 4. Keep any document changes provisional, and assess applicable product-level QMS obligations separately (IEC design specification).
- **Legacy Software Analysis:** For marketed products, assess legacy-software compliance under the applicable published requirements. Edition 1.1 addresses legacy software in subclause 4.4. The proposal to move those provisions to informative guidance is a draft change, rather than permission to substitute unrestricted engineering judgment for current compliance requirements (IEC published-edition preview; IEC design specification).
- **Training and QMS Updates:** Educate project and quality teams on all changes. Since 62304 is often used in internal audits, updating internal audit checklists and training materials is essential. Update the QMS such that 62304 process documents refer to ISO 13485 for general quality requirements and highlight the changes in 62304 Ed2. Management review agendas might track Ed2 transition readiness as the draft matures. Since regulators may expect compliance within a few years of publication (which the Johner Institute does not expect before 2028–2029), aim to complete the transition plan early.
- **Regulatory Submissions:** For products in development, note that IEC 62304:2006+A1:2015 will remain the state of the art until Ed2 is formally published and harmonized. However, being proactive by designing with Ed2 in mind (especially for new devices) can pay off. Declare in submissions any planned migration approach. If submitting a 510(k) or CE filing in the Ed2 era, be prepared to justify how your processes satisfy the upcoming requirements (e.g. "our software classification aligns with IEC 62304 Ed2 rigor levels"). Conformity can only be declared to a published edition (for FDA, a recognized one), so a draft cannot replace IEC 62304:2006+A1:2015 in a submission. Similarly, the EU's MDR transitional grace (until 2027/2028 for legacy MDD devices) gives some runway to adopt the new standard, but notified bodies will likely encourage early alignment.

Data Analysis and Evidence

To understand the practical impact of Ed2's changes, we examine empirical data and expert findings relevant to software risk. While IEC 62304 itself is prescriptive, real-world case studies illustrate why the revisions are timely.

AI/ML Device Recalls: A 2025 review of AI/ML-enabled medical device recalls provides a cautionary tale (pmc.ncbi.nlm.nih.gov). Analyzing over 27 years of FDA data, researchers found that AI/ML devices (of which 878 had been cleared by early 2024) had a disproportionate share of recalls with design-related root causes. In particular, *50% of AI device recalls* were attributed to design or software process faults (vs. 22% across all 510(k) devices) (pmc.ncbi.nlm.nih.gov). This underpins the Ed2 focus on AI: **uncontrolled algorithms and inadequate development controls can directly lead to harm**. A separate JAMA Health Forum study found that recalls were more frequent among devices with no reported clinical validation (pmc.ncbi.nlm.nih.gov). Indeed, recalled devices without reported clinical validation averaged 3.4 recall events, versus 1.9 with retrospective and 2.0 with prospective validation (pmc.ncbi.nlm.nih.gov). Furthermore, absence of reported clinical validation was independently associated with recall (odds ratio 2.8) (pmc.ncbi.nlm.nih.gov). These statistics underscore that Ed2's AI provisions and rigorous validation steps are evidence-based moves to reduce post-market failures.

Cybersecurity and Software Supply Chain: Data on cybersecurity incidents in devices show an increasing need for secure lifecycles. FDA's February 2026 final guidance, Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions, supersedes its June 27, 2025 final guidance. Since IEC 81001-5-1 (cybersecurity) already complements IEC 62304, companies should prepare to align risk management activities (e.g. hazard analysis will consider malicious cyber scenarios). We lack space for a detailed analysis of cybersecurity, but note that security risk management under IEC 81001-5-1 complements 62304's safety focus.

Software Updates and Agile Development: For devices subject to FDA's 510(k) framework, manufacturers must assess software changes to determine whether a new 510(k) is required and obtain any required clearance before marketing the modified device (FDA 510(k) requirements). FDA's 2017 software-change guidance explains that changes that could significantly affect safety or effectiveness require a new 510(k), even when routine verification and validation succeed (FDA software-change guidance). While Ed2 is not explicitly an "agile standard," it is clearly being drafted in the context of such practices. 62304 Ed2 does not forbid agile methods; in fact, its emphasis on evidence and risk aligns with AAMI TIR45 (agile in MedTech) (www.linkedin.com). Thus, when implementing Ed2, firms should ensure their CI/CD pipelines and documentation (e.g. user stories, automated tests) map to the required outputs (traceable requirements, verification records). The Ed2 draft's streamlined classes and maintenance process will support agile cycles by reducing unnecessary gates for low-risk software updates.

Case Studies and Real-World Examples

Example 1: AI Diagnostic Software

Consider a hypothetical SaMD that uses a deep learning model to analyze radiology images. Its team could use the proposed informative AI annex to structure discussions about training data, model performance, monitoring and retraining. These are illustrative planning topics, rather than mandatory AI development lifecycle or dataset-testing requirements created by Edition 2. VDE's July 2026 account explicitly describes the annex as informative, with no new mandatory requirements (VDE draft analysis).

The study classified clinical validation status from public FDA summaries (pmc.ncbi.nlm.nih.gov). These categories describe reported validation, rather than proving that manufacturers omitted testing. The findings do not establish that following Edition 1 alone caused inadequate clinical testing or a subsequent regulatory action.

Example 2: Connected Infusion Pump (Cybersecurity and Updates)

Consider a hypothetical connected infusion pump receiving a cybersecurity patch. The manufacturer would document an impact and risk assessment, including effects on other functions, to determine the necessary requirements and design-documentation updates, verification and validation, and regression-test scope (FDA software-change guidance). IEC's Edition 2 design specification proposes appropriate Clause 5 development activities for each maintenance type (IEC design specification). The assessment would determine the necessary work for this patch; calling it a fix would not establish that reduced design documentation or testing only core infusion functions is adequate. For a device subject to FDA's 510(k) framework, the manufacturer would also assess whether a new submission is needed.

Example 3: Surgical Navigation System (AI-enhanced)

As a hypothetical planning exercise, a team could review how an AI upgrade to a surgical navigation system affects its verification plans, clinical evaluation and change control.

Implications and Future Directions

The shift to IEC 62304 Edition 2 has broad implications for the medical technology ecosystem:

- **Regulatory Alignment:** Evaluate FDA recognition and EU harmonisation separately. FDA record 13-79 identifies IEC 62304 Edition 1.1 (2015-06); its scope excludes medical-device validation and final release (FDA recognition record). Under the MDR and IVDR, presumption of conformity through harmonised standards depends on Official Journal publication and applies to the requirements those standards cover (European Commission). Do not infer Edition 2 recognition, an adoption timetable or a transition obligation from a draft.
- **Quality and Process Integration:** Ed2 removes some redundancy (Clause 4) and shifts QMS focus to ISO 13485. Companies should, therefore, revisit their QMS documentation, making sure 62304 processes are nested in ISO 13485. Audit trails in QMS should link to both standards. The clearer

separation of development vs maintenance also suggests updating QA procedures: maintenance releases may get a faster review cycle, but still under QMS change control.

- **Industry Adaptation:** Smaller companies (start-ups in digital health, AI) may struggle with the new requirements. Expanding scope means more developers must adopt medical-grade processes. However, Ed2's goal is not to create more burden as much as to clarify it. For instance, with fewer classification levels, documentation for low-risk software may decrease, saving effort. The legacy software annex being informative can reduce retrofit costs. Consultants note that manufacturers should start "familiarizing themselves with the draft changes" now, indicating a transition period. In fact, standards generally take ~2-3 years to be fully adopted by regulators after publication (8foldgovernance.com), so companies have some runway.
- **Synergy with Other Standards:** Ed2 does not stand alone. It is used alongside **IEC 81001-5-1** (health software security), **IEC 62366-1** (usability), and ISO 14971:2019; the use of "harm" follows ISO 14971. Software teams may also draw on ISO/IEC 27001 for information security and on companion guidance such as IEC/TR 80002-1 (applying ISO 14971 to medical device software). The emphasis on AI in 62304 complements IMDRF's Good Machine Learning Practice guiding principles, as both aim to embed algorithmic safety in product lifecycles.
- **Continuous Improvement and Updates:** No standard is final. Edition 2 is unlikely to be the last word. Future work could address rapid software updates (digital thread), cybersecurity requirements (maybe baselined in Ed3 with IEC 81001-5-1), cloud-based software delivery, and possibly software-of-unknown-provenance (SOUP) policies for open source. For now, edition 2 provides a platform: after publication, user feedback and identified gaps may inspire technical reports or an Ed3 with even broader scope (e.g. internet medical devices, add-ons to consumer health). The community should treat Ed2 as a living document foundation.

Conclusion

IEC 62304 Edition 2 is poised to **transform medical device software development**. By reducing software classes to two levels, expanding scope to encompass all healthcare software, and incorporating AI/ML lifecycle planning, it reconciles the standard with modern digital health realities. Critically, the updated emphasis on *"harm"*, broader risk views, and abandoned QMS redundancy make the standard more aligned with current regulations (ISO 14971:2019, FDA guidances) and less bureaucratic. Early analysis of AI-related recalls and regulatory surveys reveals the need for these changes: absence of reported clinical validation was associated with more recalls per device in the JAMA Health Forum study (pmc.ncbi.nlm.nih.gov). Edition 2's new requirements and clarifications aim to prevent such issues by ensuring robust processes are in place before software reaches patients.

For industry, the path forward is clear: **prepare now**. Companies should inventory their software assets, classify them under the new scheme, and update their software development plans to address AI and maintenance as per Ed2. Regulatory submissions and QMS documentation will need updates, and processes (agile pipelines, test frameworks) should map to the revised standard's outputs. Although adoption will take

time, the transition offers benefits – streamlined documentation for low-risk software, better risk alignment, and a standard that explicitly legitimizes best practices (AI validation, cyber-security integration) without adding arbitrary hurdles.

In sum, IEC 62304 Ed2 reflects two decades of learning in medical software. It **provides a modern, risk-oriented framework**, extending the 62304 *"engine"* to power the next generation of safe, effective digital health products. As one advisory notes, manufacturers should begin aligning practices with the draft changes immediately. Treat preparation for the draft as part of compliance planning. Assess applicable regulatory requirements separately: even the FDA-recognized published IEC 62304 edition excludes validation and final release of the medical device (FDA recognition record).

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