

Letter to editor

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From Risk Reduction to Benefit–Risk: A Technical Appraisal of ISO 14971 (The Transition of 2007 to 2019 Edition)

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Abstract

ISO 14971 is the international standard that specifies terminology, principles, and a comprehensive process for risk management of medical devices. Risk management under this standard underpins every medical-device safety argument. The standard establishes a systematic framework for identifying hazards associated with medical devices, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls throughout the entire device life cycle. This letter offers a technical appraisal of the transition from ISO 14971:2007 to ISO 14971:2019, arguing that the third edition changes fewer requirements than specialists fear but shifts the epistemic centre of the standard more than they assume: risk acceptability is converted from a largely internal engineering judgement into an explicit, benefit-anchored and plan-governed decision. Five threads of the revision are examined: the formalisation of benefit and benefit–risk analysis with documented evidence; the sharpened hazard space through the defined term of reasonably foreseeable misuse; the rebuilt production and post-production loop (Clauses 9 and 10); the relocation of informative guidance to ISO/TR 24971:2020; and the resolution of the European harmonisation deviations through EN ISO 14971:2019+A11:2021.

Keywords ISO 14971, Risk Management, Medical Devices, Benefit–Risk Analysis, Post-Market Surveillance.

Dear Editor,

Risk management under ISO 14971 is the backbone of every medical-device safety argument: it supplies the hazards that design controls must retire, the acceptability criteria that verification evidence is judged against, and the residual-risk disclosure that reaches the clinical user. My central claim is that the transition from the second edition, ISO 14971:2007 [1], to the third and current edition, ISO 14971:2019 [2], changes fewer requirements than specialists fear, but changes the epistemic centre of the standard more than they assume: it converts risk ac-

ceptability from a largely internal engineering judgement into an explicit, benefit-anchored and plan-governed decision.

1. Formalisation of Benefit:

The most consequential substantive change is the formalisation of benefit. The 2007 edition used the term only in passing and left benefit–risk reasoning to a note-level discussion; the 2019 edition imports a formal definition of benefit from ISO/IEC Guide 63 [3], renames the activity benefit–risk analysis, and requires that when it is



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Table 1. Principal technical differences between ISO 14971:2007 and ISO 14971:2019.

Aspect	ISO 14971:2007	ISO 14971:2019
Structure	9 clauses; guidance in Annexes A to J	10 clauses; informative guidance moved to ISO/TR 24971:2020; 3 annexes retained
Benefit	Undefined; risk/benefit analysis as note-level escape valve	Benefit formally defined (Guide 63); benefit–risk analysis with documented evidence
Acceptability criteria	Criteria required, method for overall residual risk unspecified	Method and criteria for overall residual risk pre-committed in the risk management plan
Misuse	Mentioned, undefined	Reasonably foreseeable misuse defined; mandatory in hazard identification
Review and release	Risk management report (Clause 8)	Named risk management review before commercial release (Clause 9), documented in the report
Post-production	Single information clause	Structured Clause 10: collection system, active review, action, feedback to criteria
Terminology	Local definitions	Aligned with ISO/IEC Guide 63:2019 across the standards family
EU status	EN ISO 14971:2012 content deviations (Z-annexes)	EN ISO 14971:2019+A11:2021 harmonised under MDR; deviations resolved

invoked, either for an individual unacceptable risk or for the overall residual risk, the claimed benefits rest on documented evidence. This is not cosmetic. Under the 2007 text a manufacturer could treat benefit–risk analysis as an escape valve exercised at the end of risk control; under the 2019 text the criteria for overall residual-risk acceptability, including the method by which overall residual risk will be evaluated, must be defined in advance in the risk management plan (Clause 4.4) and the evaluation performed against that pre-committed method (Clause 8).

The revision thereby closes the quiet circularity of post hoc acceptability criteria, which in my experience was the most common audit finding under the old edition.

2. The Sharpened Hazard Space:

Second, the 2019 edition sharpens the boundary of the hazard space. Reasonably foreseeable misuse, previously a phrase inherited from other disciplines, is now a defined term that must be identified and documented alongside intended use in risk analysis (Clause 5.2), and the defini-

tions of harm, hazard and hazardous situation are harmonised with Guide 63 so that the same words carry the same meaning across ISO 14971, IEC 62304, IEC 62366-1 and the particular standards. For software-controlled devices this matters concretely: use errors and off-label operating sequences, precisely the territory of the user-interface failures that dominate software recall statistics, are pulled unambiguously inside the scope of hazard identification rather than being deferred to usability engineering alone.

3. The Rebuilt Life-Cycle Tail:

Third, the life-cycle tail of the process has been rebuilt. The single 2007 clause on production and post-production information became a structured Clause 10 with distinct requirements for establishing the information-collection system, for actively reviewing the collected information for relevance to safety, and for acting on it, including feeding the results back into the risk management file and re-examining the acceptability criteria themselves. Together with the new, explicitly named risk management review (Clause 9), which requires a documented review of the execution of the plan before commercial release, the 2019 edition converts what was often a passive complaint-handling appendix into a closed control loop. Readers running post-market surveillance under Regulation (EU) 2017/745 [4] will recognise deliberate convergence: the standard now speaks the regulation's language of proactive data collection rather than reactive vigilance.

4. Relocation of the Informative Material:

Fourth, and easily misread, is the relocation of the informative material. The 2019 edition retains only three annexes; the widely used guidance of the 2007 annexes, hazard exemplars, questions for identifying characteristics related to safety, risk-analysis techniques and the discussion of risk-acceptability frameworks, moved to the substantially expanded ISO/TR 24971:2020 [5]. The practical consequence is procedural rather than technical: quality-system procedures that cite '14971 Annex D' or reproduce its tables now point at a void, and the transition effort is dominated by re-referencing and by reconciling local templates with the reorganised guidance, not by new normative burden.

5. The European Harmonisation History:

Finally, the revision must be read against the European harmonisation history. The infamous content deviations of EN ISO 14971:2012, which asserted that all risks must be reduced as far as possible irrespective of economic considerations and cast doubt on using information for safety as a risk-control measure, were a property of the European foreword, not of the ISO text. EN ISO 14971:2019 as amended by A11:2021 [6] resolves that

episode: the Z-annexes now express the relationship to the MDR requirements without rewriting the standard. Two related subtleties survive into current practice and deserve the reader's attention. The 2019 edition still permits the manufacturer's policy to define risk acceptability, but European regulators expect reduction as far as possible without adversely affecting the benefit-risk ratio, so the policy must be written to satisfy the stricter envelope. And information for safety remains the last-priority risk-control option, with the 2019 text clarifying that users shall be informed of significant residual risks, while the question of how much risk-reduction credit such information may claim is answered conservatively in the accompanying guidance.

Table 1 condenses the comparison for reference.

Conclusion:

For specialists the transition checklist is short but pointed: rewrite the risk management plan to pre-commit the overall residual-risk method and criteria; define benefit claims and their evidence before they are needed; sweep procedures for orphaned annex references and re-anchor them in TR 24971; extend hazard identification templates to capture reasonably foreseeable misuse explicitly; and upgrade post-production procedures from complaint logging to an information-collection and review system whose outputs demonstrably re-enter the file. None of this alters the underlying discipline that risk controls must trace to hazards and tests to risk controls; all of it raises the standard of proof for the judgement that the remaining risk is worth taking. In an era in which software mediates ever more of device behaviour and post-market data arrives continuously, that shift of the third edition, from demonstrating that risk was reduced to demonstrating that residual risk is justified by evidence of benefit, is exactly the right one.

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