Welcome to the webinar

What to expect in the next revision of IEC 62304

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Qualio

medicaldeviceHQ

Today’s agenda

01 Why IEC 62304 is changing — behind the scenes

02 What Edition 2 means for SaMD and AI companies

03 What will change, and how it impacts your organization

04 Qualio’s new tool for IEC 62304 conformity

05 Q&A

Qualio

Today’s hosts

Lola Furlong
Senior Quality Success Manager
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Qualio

medicaldeviceHQ

Medical device **training** from **ISO/IEC standards authors** and experts, with a **focus on practical application,** to help bring medical devices to the market in the most efficient way.

Topics:
Software Development, SaMD, Agile, Risk Management, Design Controls, Internal Auditing, Usability Engineering, Process Validation, etc.

Delivery options:

- Online
- Blended (online+live)
- Your company's own LMS platforms.

More information in post-webinar email

Qualio

Christian Kaestner

Background

- 25+ years of experience in medical devices.
- Experiences from software development, project management, quality management work, preparation of submissions and much more.

Standardisation work

- Active member of the IEC 62304 authoring team since 2013.
- Participated in the development of IEC 82304-1.
- Convener of IEC/TC62 ahG9: “The task of the group is to find consensus regarding the understanding of AI-related terms and concepts (e.g., ISO/IEC 22989-2) in IEC TC 62.”

Trainer at Medical Device HQ

- Software for medical device courses (IEC 62304, IEC 82304-1)
- Agile medical device software development

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Fine print, i.e. disclaimer

- This is **NOT** an official IEC presentation
- My perspective is one(1) of seventy-one (71) experts
- We are ~20 experts actively working on IEC62304 ed2
- It is not a one-man show; **it is a team effort!**

1. Why IEC 62304 is changing and what is happening behind the scenes

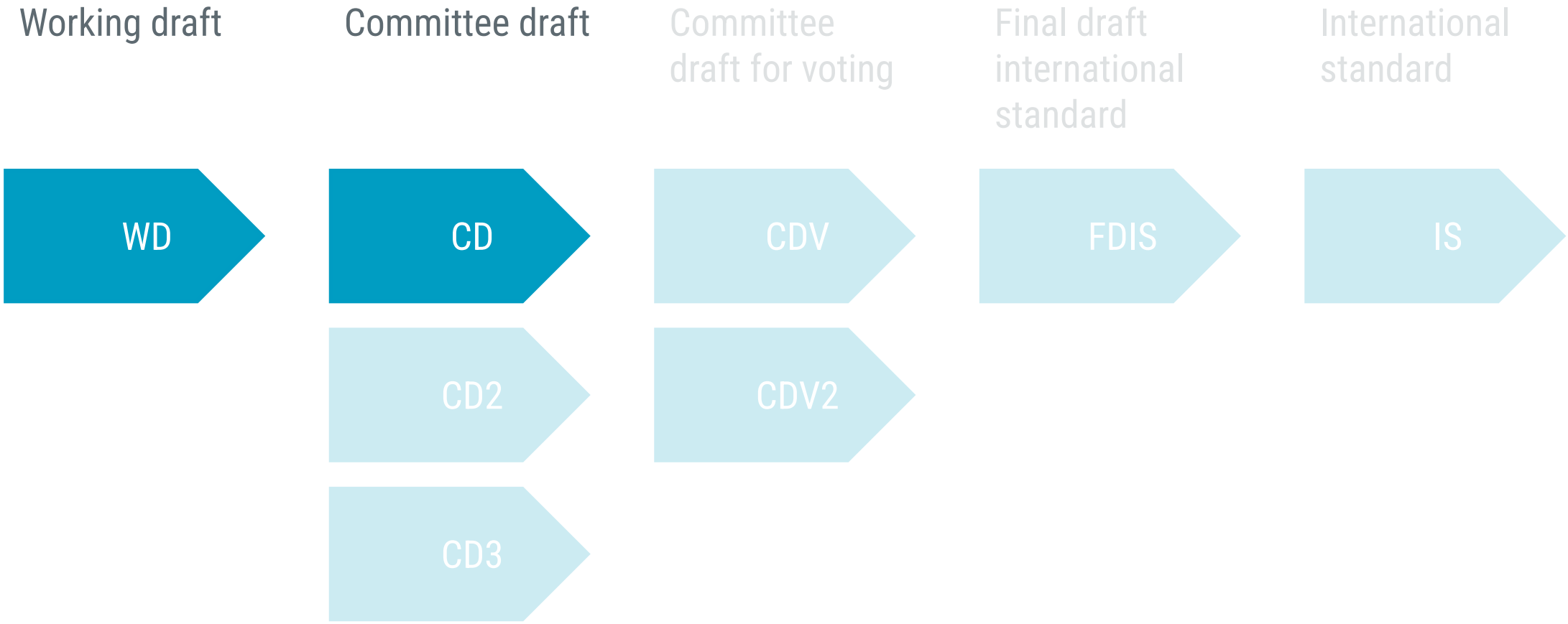
The IEC 62304 - future

- Edition 1
  - Regulatory needs
  - The work was initiated in the early 2000s
  - Published in 2006

- Amended 1, 2015
  - Legacy software
  - “Softening” software safety classification

- Edition 2 – current work
  - Scope change to “**health software**”
  - Simplification of software safety classification
  - Modernisation
  - ETA… 2028?

The process of revising a standard



The design specification

- Scope change from **medical device** to **health** software
- Three classes are replaced with two:
    - Level I ~ Class A
    - Level II ~ Class B and C
- Emphasis on product-level risk management
- No normative references to ISO 14971 or ISO 13485
- Legacy software should be moved to an annex
- Architectural planning for all levels
- Annexes are suggested to cover relations to other standards and technologies (security, cloud computing, AI, IMDRF)

62304 2nd Edition Change Rationales

Guides the changes implemented in CD1, examples:

- Risk classification criteria for process rigour level are changed
- New requirements for AI planning (when applicable)
- Clarification of supporting items to be controlled
- Communication planning
- Architectural design for all levels
- Revision and clarifications to the maintenance chapter

SC62A/MT49/N0166

62304 2nd Edition Change Rationales

Purpose

This document provides comment submission guidance and rationales for design decisions, and clause modifications (additive, removal, revision) made by IEC/SC 62A MT 49– Medical device software process.

NOTE: It is critical to fully read and follow the complete instructions provided to properly comment on the CD fragments for the comments to be accepted.

Forward

This rationale document is intended to be utilized in partnership with (1) the IEC SC62A Design Specification for the second edition of IEC 62304 and (2) the committee draft of IEC SC 62A/MT49 62304. The design specification was developed and approved by National Committees and IEC SC62A to establish the scope of the revision of IEC 62304. The experts appointed to IEC SC62A/MT49 have developed the current Committee Draft within the bounds of this approved design specification. This rationale document was developed to accompany the committee draft in order to provide the national committees reviewing the committee draft additional context derived from MT49 discussions to address and resolve the requirements within the approved design specification. National experts are encouraged to utilize both the approved design specification and rationale document when considering their comments and feedback which would be submitted back to MT49 on the proposed committee draft. Please keep in mind this committee draft is not to be considered technically complete but has been provided to assist MT49 with refining the approach to develop a mature committee draft for vote (CDV). The editing team also experienced challenges with the OSD tool in updating the linked connections to specific referenced clauses/subclauses within other standards found in Annex C of this document. MT49 will work to resolve this before the CDV stage.

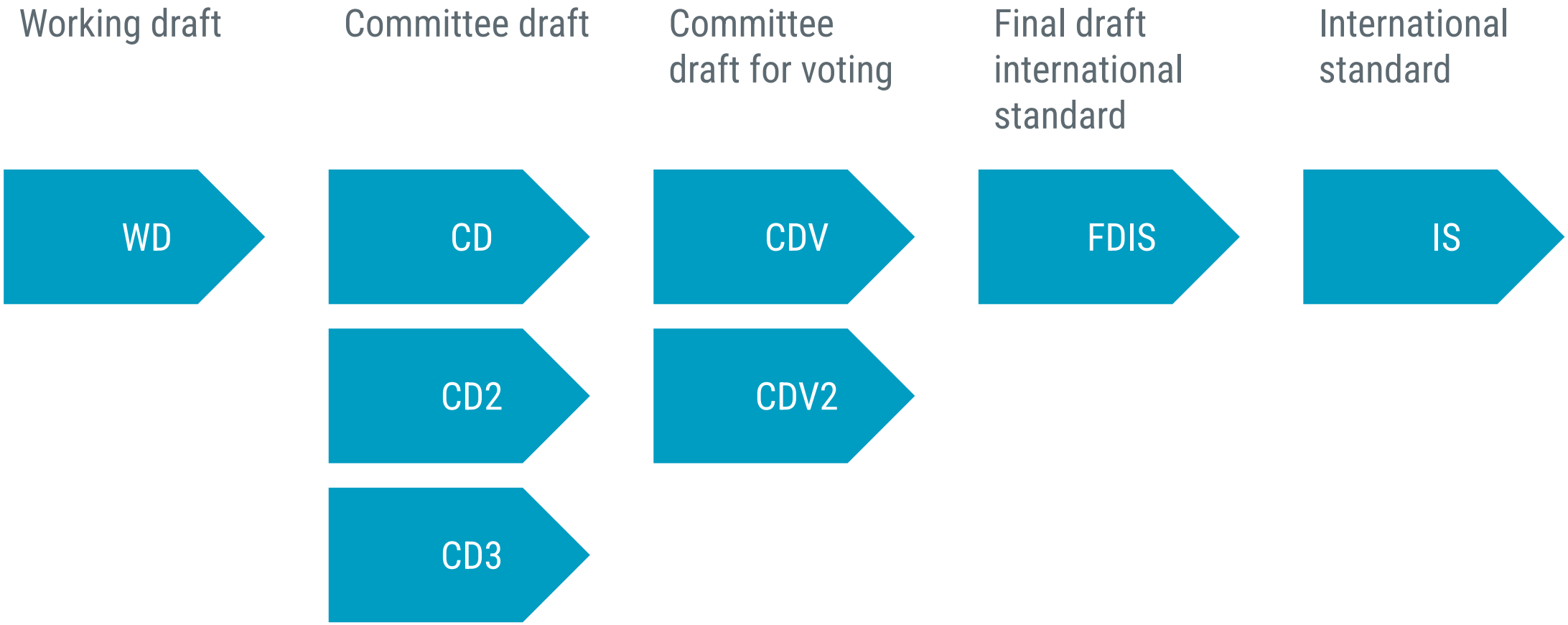
We welcome comments will be collected through the Online Standards Development (OSD) platform where possible. Commenters are requested to submit only high-level technical comments on the documents. Editorial comments will not be considered at this time. There are glitches in the OSD platform, e.g., one that prevents correct capitalization of defined terms when used in the beginning of a sentence, loss of pluralization, and change of alternate terms to the full term (e.g., MEE to medical electrical equipment). In addition, the content of the fragments is in a very early stage of development and many changes are likely to be implemented prior to a CDV ballot of each fragment.

Each comment will appear within the OSD platform when properly formatted. It is essential that each comment is correctly identified by subclause number (e.g., 5.3.2.2.2.). Line number and list items (e.g., a) i)) should be listed in the text of the comment itself to allow identification of the comment's exact location in OSD. Comments that are not properly referenced in the comment template are likely to be ignored as the references are difficult to trace to the proposed text.

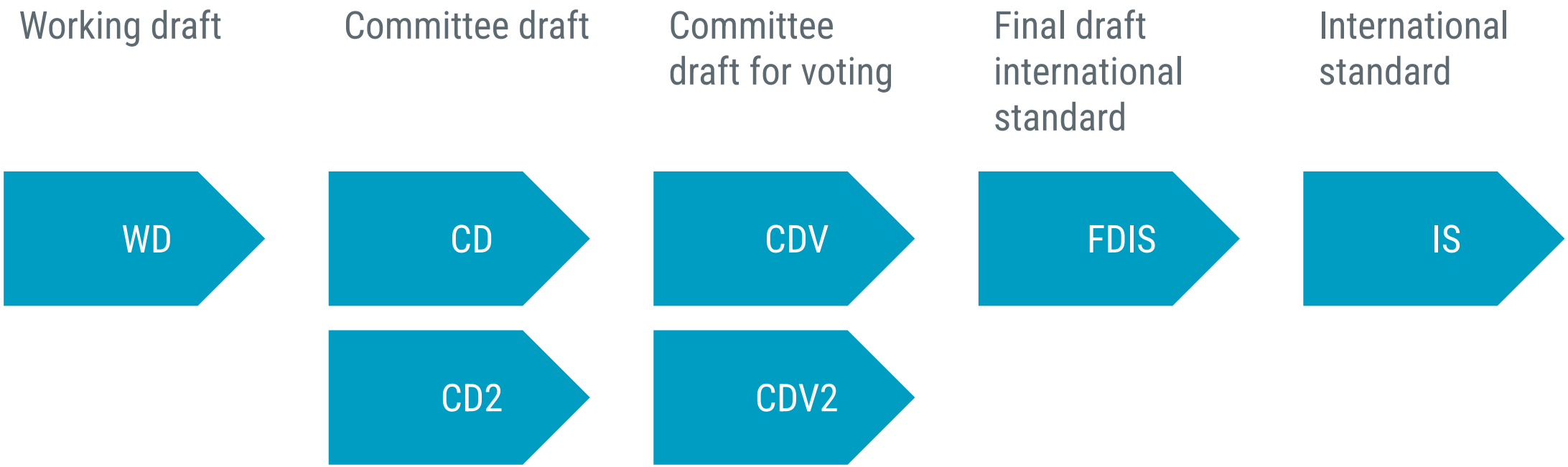
EXAMPLE:

- Green: the information in these cells is accepted (comment 1 is correctly formatted so that all of the relevant identifying information will be accepted into OSD.)

The process of revising a standard



The process of revising a standard



This is where we are today

Working draft

Committee draft

~1500 comments

Each comment shall be responded to:

- Accepted
- Partially accepted
- Not accepted
- Noted
- Deferred

Comment example

Clause Title	Comment/Motivation	Proposal on Text	Proposed change
INTRODUCTION	ISO 13485 and ISO 14971 must remain normative standards for medical device software.	As the new, larger scope may include non-medical software, implementation of ISO 14971 for Risk Management or ISO 13485 for a Quality System can not be assumed. As a result, this document does neither normatively reference ISO 13485 nor ISO 14971.	ISO 13485 and ISO 14971 remain normative standards for medical device software throughout standard

Comment example

	Proposal on Text	Proposed change	ARLINGTON MEETING COMMENT COD	COMMENT NOTES	Working Group Action NOTES
normative	As the new, larger scope may include non-medical software, implementation of ISO 14971 for Risk Management or ISO 13485 for a Quality System can not be assumed. As a result, this document does neither normatively reference ISO 13485 nor ISO 14971.	ISO 13485 and ISO 14971 remain normative standards for medical device software throughout standard	4WG	ACCEPT IN PRINCIPLE: See row 447. /CK	TIED ROWS: 425; 427;428; 429; 433; 469; 67

Numbers (based on SWAG, Scientific Wild As Guess)

Three individuals spend an average of five minutes discussing the appropriate disposition, totalling **about 47 workdays**.

"Three experts can lose 47 workdays just arguing over commas"

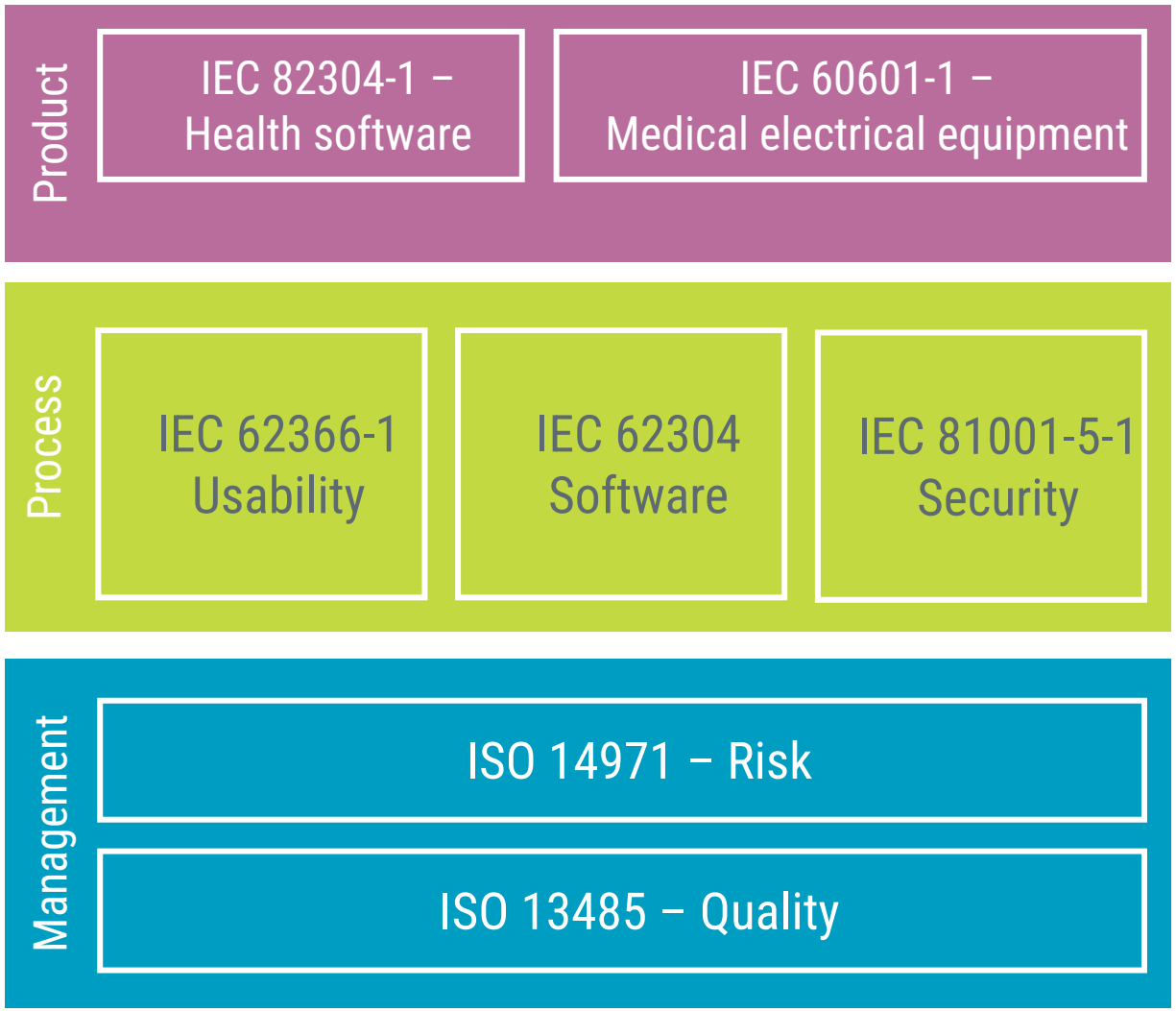
If 500 comments are accepted and require 10 minutes to implement, it will take one person approximately **10 workdays** to address them.

2. What Edition 2 means for SaMD and AI companies

IEC 62304 meets SaMD – don’t expect too much love!

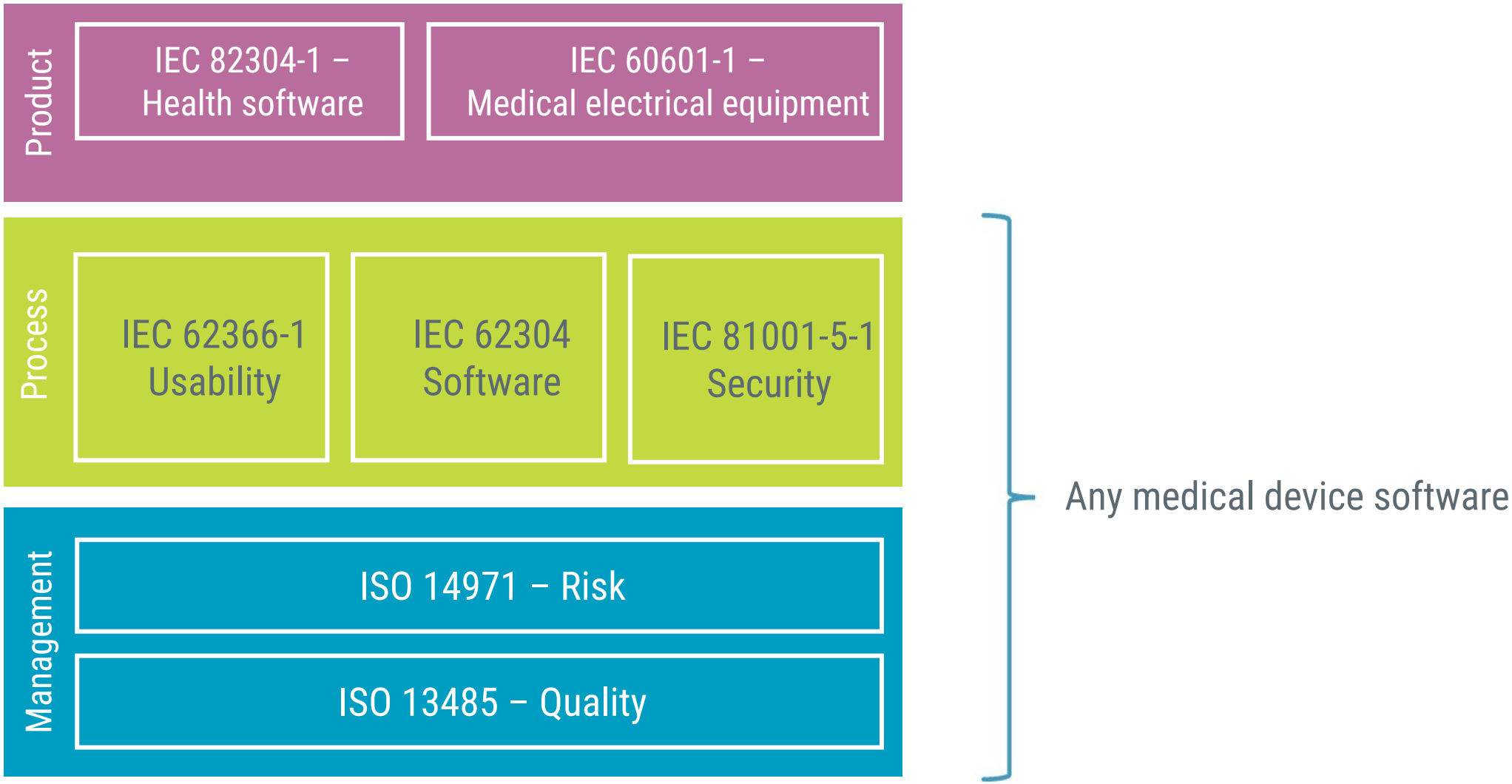
SaMD, SiMD, cloud or embedded—it is still medical device software, and IEC 62304 cares about **the process, not the acronym**.

Product-level vs IEC 62304

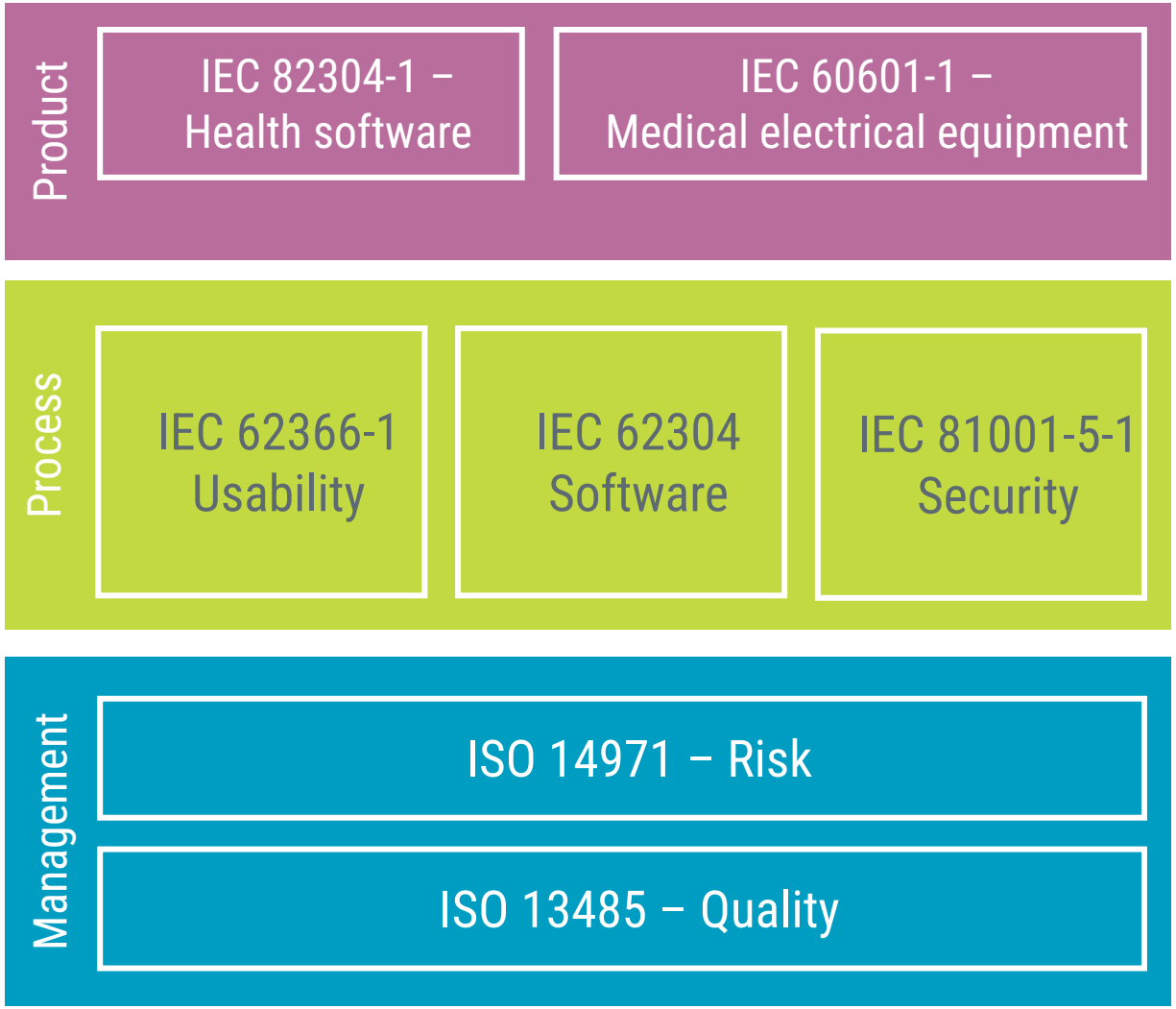


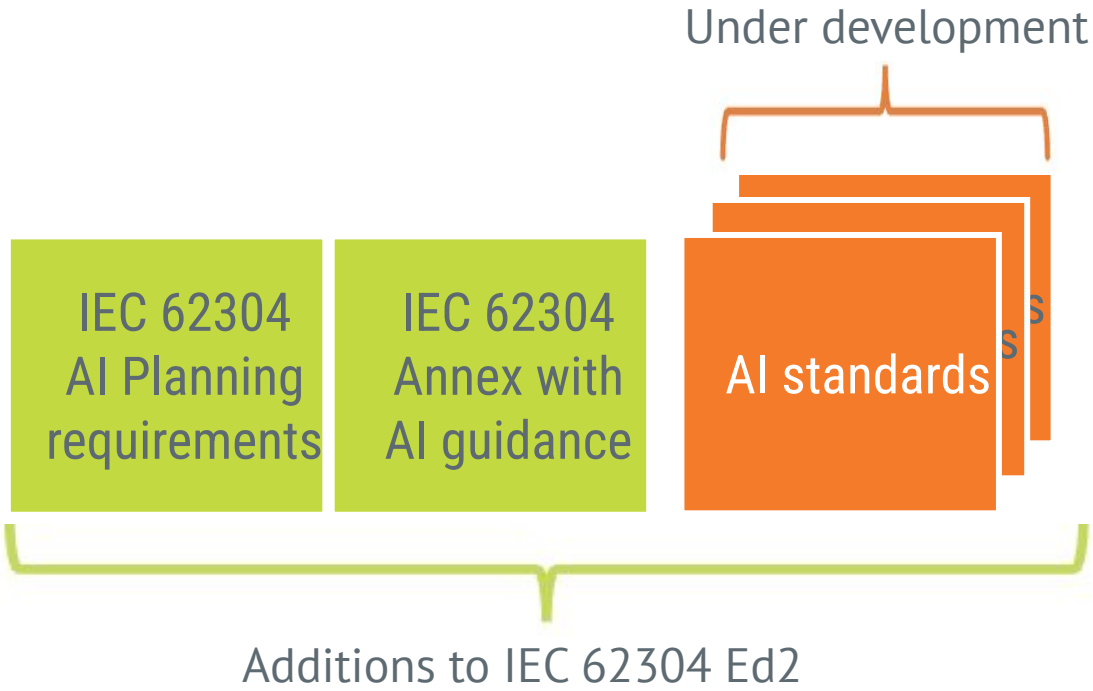
Whether a medical device software is SaMD or SiMD makes a difference at the product level.

Product-level vs IEC 62304

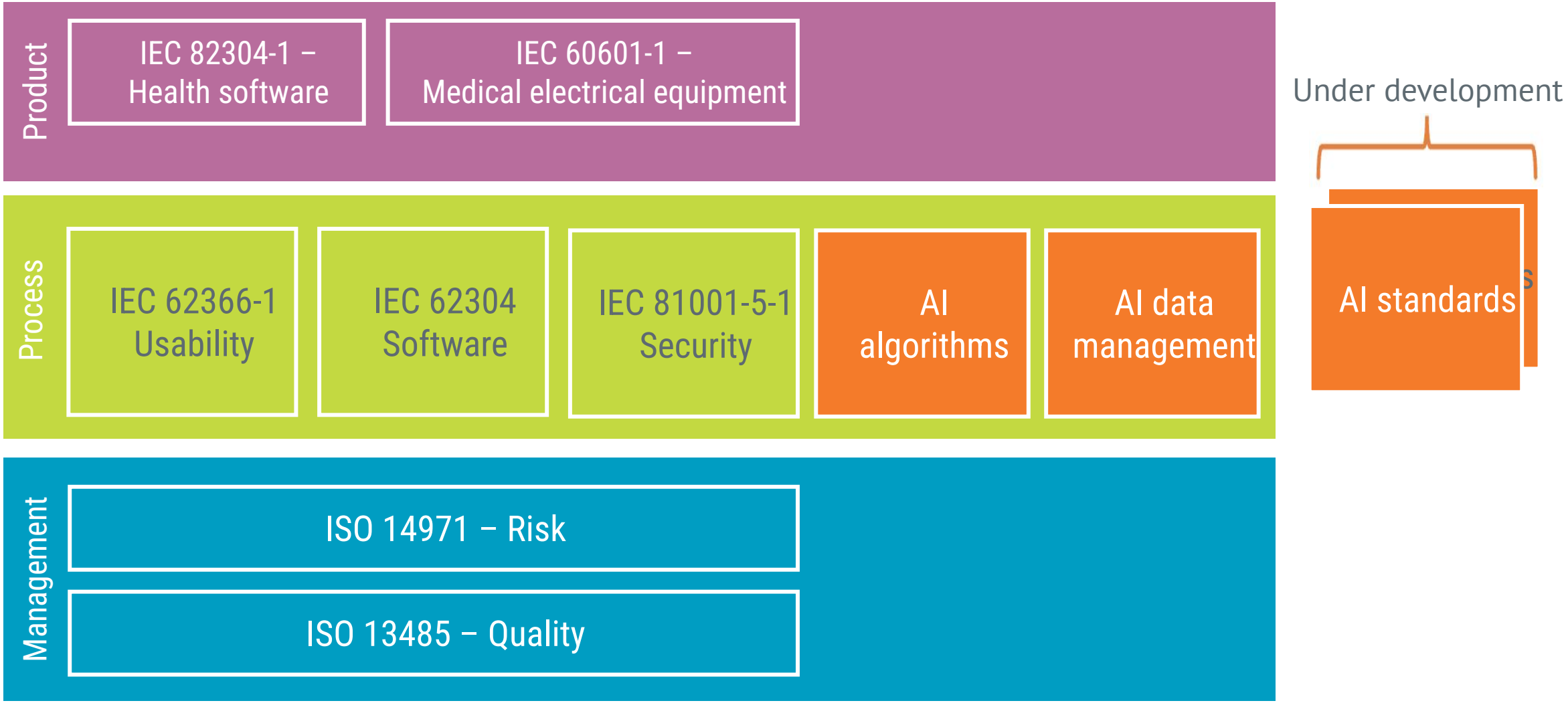


AI and IEC 62304





AI and IEC 62304



3. What will change –
and how it impacts your organization

Question

Has something changed to the software safety classification, and have the requirements (activities + documentation) related to the different classes been aligned with the documentation requirements in the FDA guideline "Content of Premarket Submissions for Device Software Functions”?

Answer:

- Yes, there are changes to the software safety classification.
- No, IEC 62304 is an international standard and is not aligned with any specific regulation or guidance.

Software safety classification (Class A, B, C)

Software process rigour level (Level I and II)

Process rigour level (PRL) - summary

Two key aspects determine if you can claim PRL I:

1. Very unlikely to contribute to the occurrence of harm; or
2. Negligible harm

Please note, the exact wording may change!

Question

Can I still reduce the safety classification by hardware measures?

Answer:
Yes, it is still accepted to consider “external risk control measures”. 😀

Question

Will the requirement that the probability of occurrence of software events cannot be estimated and must be set at 100% still exist in the next version? And do you still support the interpretation (which Christian presented in another course on IEC 62304) that this probability of occurrence CAN be reduced with risk control measures?

Answer:

For the **process rigour level** determination, it is rephrased to say that the probability of **defects** is 100%, but the likelihood of ***failures*** can be lower if justified.

Question

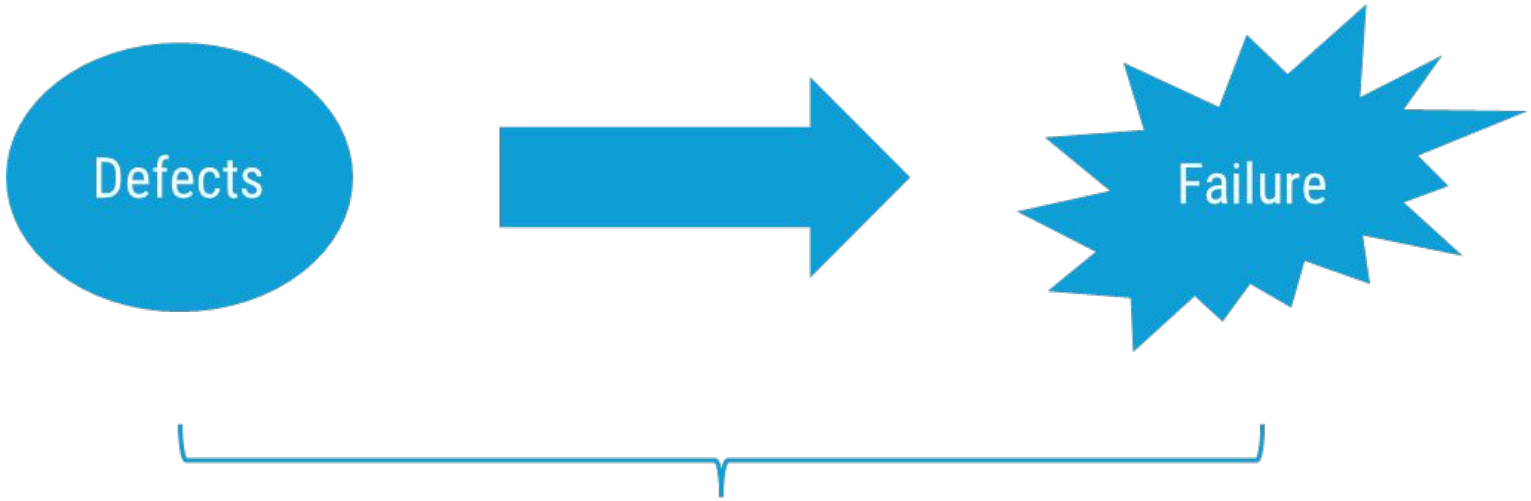
Will the requirement that the probability of occurrence of software events cannot be estimated and must be set at 100% still exist in the next version? And do you still support the interpretation (which Christian presented in another course on IEC 62304) that this probability of occurrence CAN be reduced with risk control measures?

Answer:

For the **process rigour level** determination, it is rephrased to say that the probability of **defects** is 100%, but the likelihood of ***failures*** can be lower if justified.

Defects vs failures

Software is likely to contain defects; therefore, the worst-case scenario assumes the probability of **defects** is 100%.



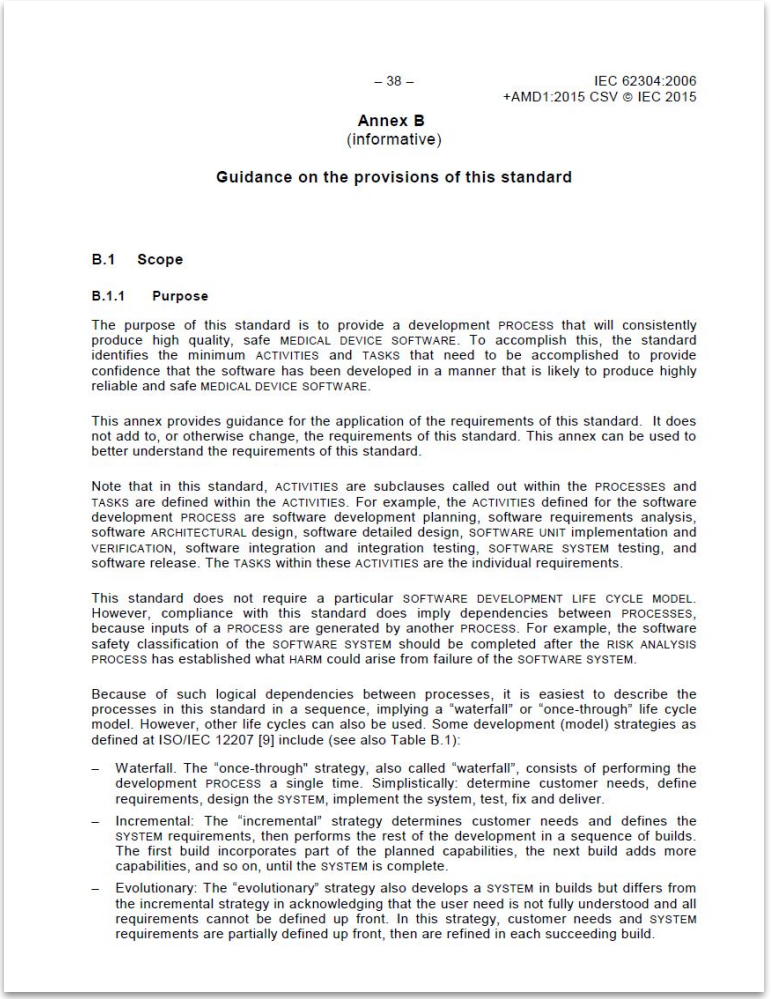
The probability of defects manifesting themselves as ***failures*** is referred to as P1. (Po=P1xP2)

If P1 cannot be quantified, it should be assumed to have the highest probability level.

Is it complicated?

Much effort is currently being put into the annex about:

- Worst Case
- Unlikely
- Negligible harm



Annex B
(informative)

Guidance on the provisions of this standard

B.1 Scope

B.1.1 Purpose

The purpose of this standard is to provide a development PROCESS that will consistently produce high quality, safe MEDICAL DEVICE SOFTWARE. To accomplish this, the standard identifies the minimum ACTIVITIES and TASKS that need to be accomplished to provide confidence that the software has been developed in a manner that is likely to produce highly reliable and safe MEDICAL DEVICE SOFTWARE.

This annex provides guidance for the application of the requirements of this standard. It does not add to, or otherwise change, the requirements of this standard. This annex can be used to better understand the requirements of this standard.

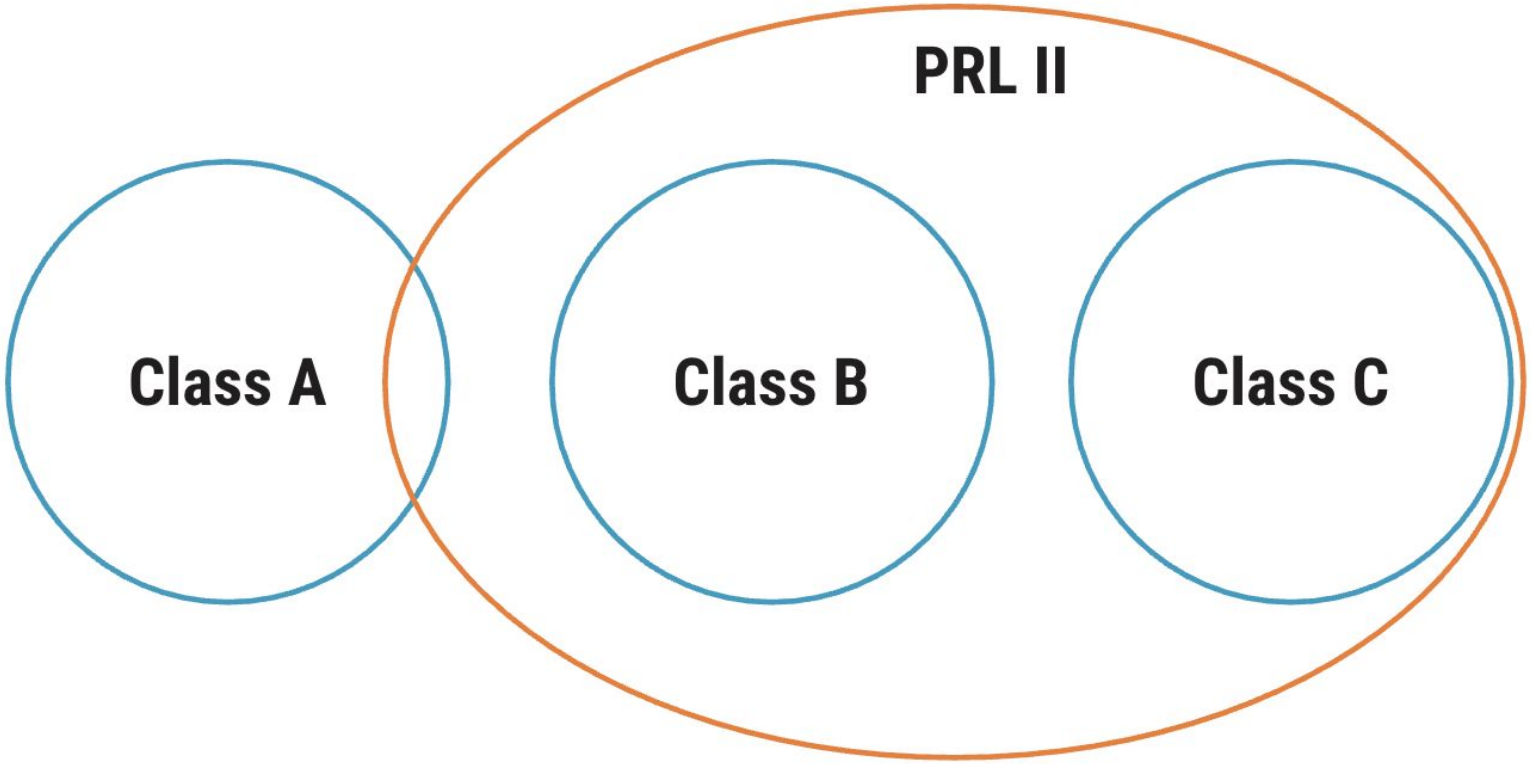
Note that in this standard, ACTIVITIES are subclauses called out within the PROCESSES and TASKS are defined within the ACTIVITIES. For example, the ACTIVITIES defined for the software development PROCESS are software development planning, software requirements analysis, software ARCHITECTURAL design, software detailed design, SOFTWARE UNIT implementation and VERIFICATION, software integration and integration testing, SOFTWARE SYSTEM testing, and software release. The TASKS within these ACTIVITIES are the individual requirements.

This standard does not require a particular SOFTWARE DEVELOPMENT LIFE CYCLE MODEL. However, compliance with this standard does imply dependencies between PROCESSES, because inputs of a PROCESS are generated by another PROCESS. For example, the software safety classification of the SOFTWARE SYSTEM should be completed after the RISK ANALYSIS PROCESS has established what HARM could arise from failure of the SOFTWARE SYSTEM.

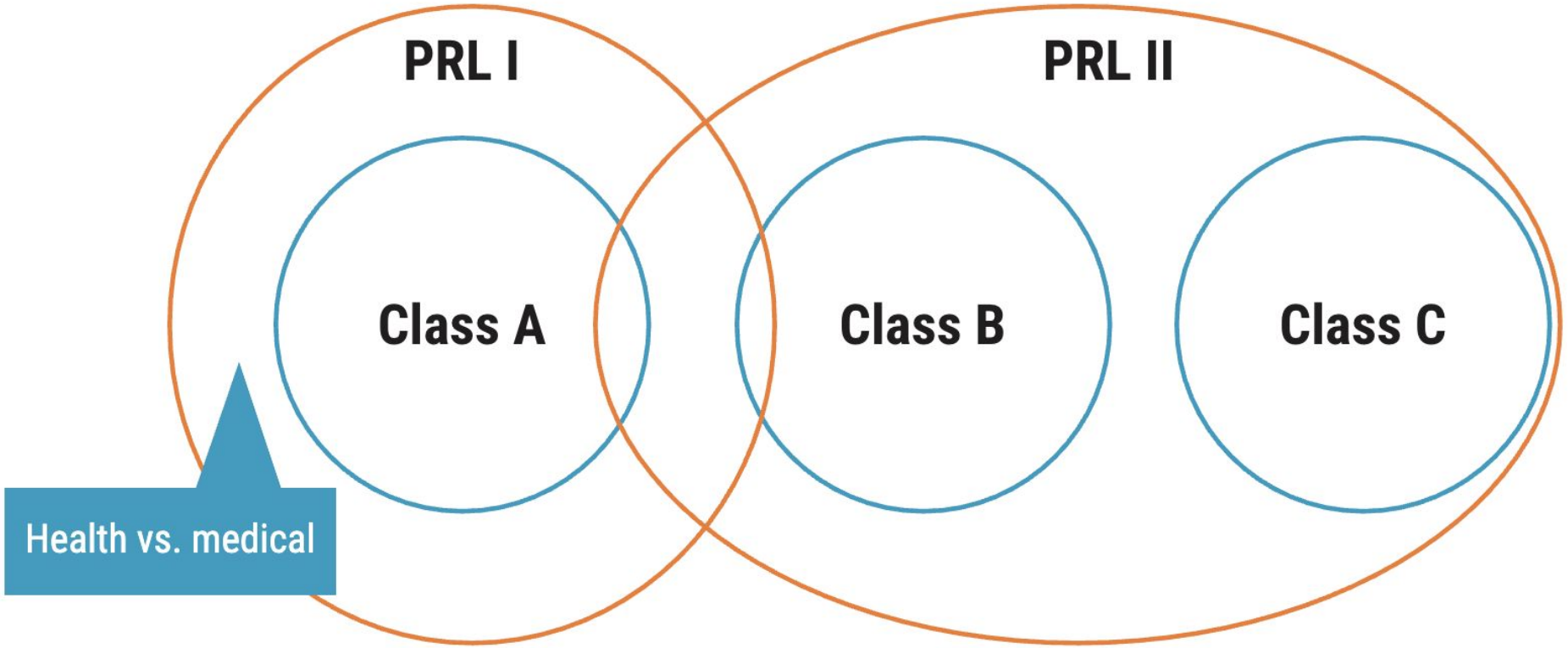
Because of such logical dependencies between processes, it is easiest to describe the processes in this standard in a sequence, implying a "waterfall" or "once-through" life cycle model. However, other life cycles can also be used. Some development (model) strategies as defined at ISO/IEC 12207 [9] include (see also Table B.1):

– Waterfall. The "once-through" strategy, also called "waterfall", consists of performing the development PROCESS a single time. Simplistically: determine customer needs, define requirements, design the SYSTEM, implement the system, test, fix and deliver.
– Incremental: The "incremental" strategy determines customer needs and defines the SYSTEM requirements, then performs the rest of the development in a sequence of builds. The first build incorporates part of the planned capabilities, the next build adds more capabilities, and so on, until the SYSTEM is complete.
– Evolutionary: The "evolutionary" strategy also develops a SYSTEM in builds but differs from the incremental strategy in acknowledging that the user need is not fully understood and all requirements cannot be defined up front. In this strategy, customer needs and SYSTEM requirements are partially defined up front, then are refined in each succeeding build.

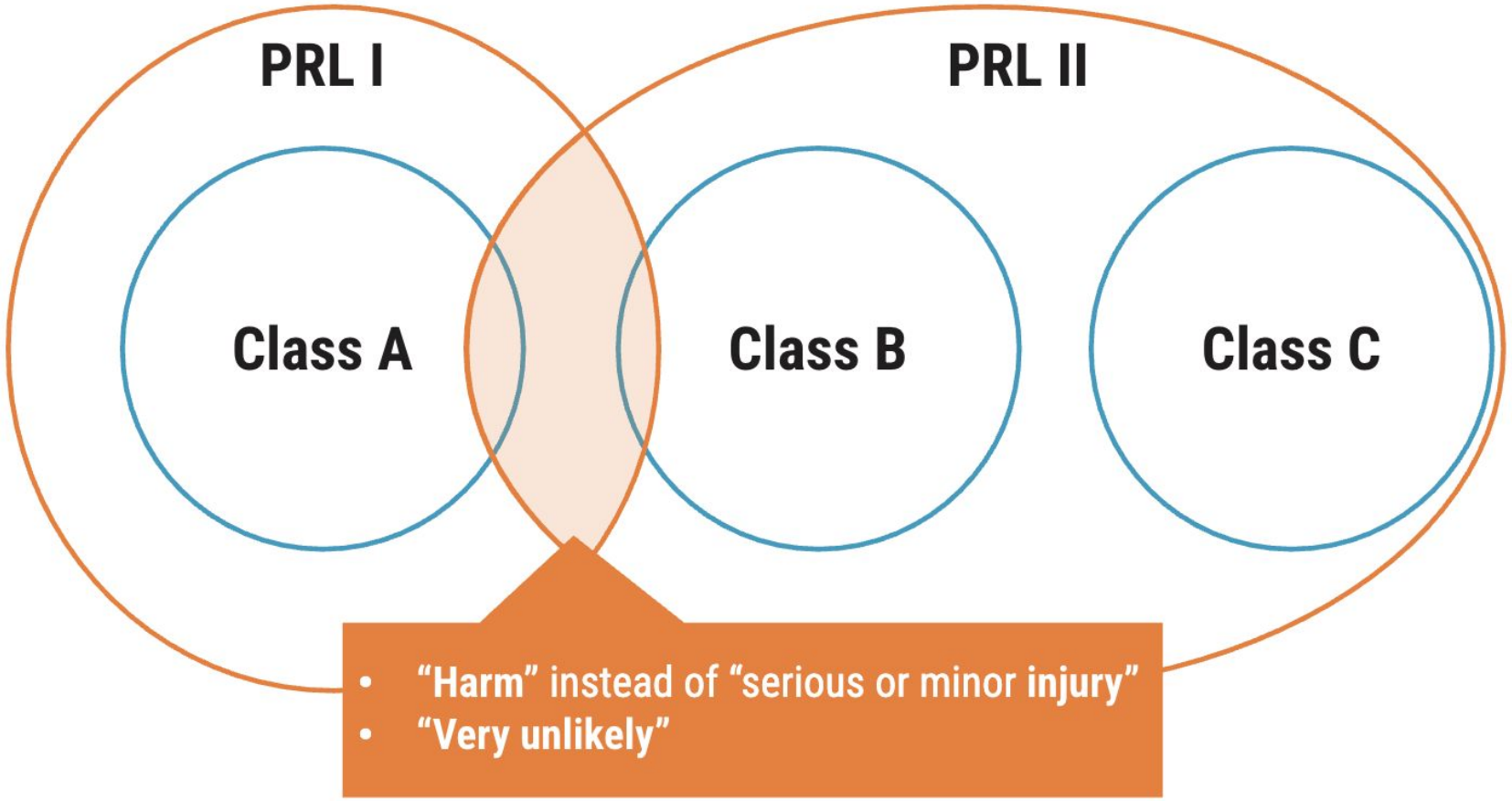
Your current classification may change



Your current classification may change



Your current classification may change



Question

Will there be a transition period, and is that period expected to be recognised globally by regulators?

Answer:

Depends on regions and regulations, but I would expect a transition period of a couple of years. (3 years?)

The bar will rise (for both levels)

- Documenting methods for verification (Level I, II)
- Static code review (Level II)
- Architectural requirements (Level I, II)
- Document the level of independence (Level I, II)

4. Qualio’s new tool for IEC 62304 conformity

Qualio

Q&A

Disclaimer:

The standard is still in the making,

there are no absolute answers at this stage.

Q&A

If we run out of time, I will share my responses to the remaining IEC 62304 Edition 2 questions on LinkedIn.

I'd be happy to continue the conversation, so let's connect on LinkedIn! I look forward to our discussions!

LinkedIn

https://www.linkedin.com/in/christiankaestner/

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Thank you!