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INTERNATIONAL ELECTROTECHNICAL COMMISSION

TECHNICAL COMMITTEE Nº 62: ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE

SUBCOMMITTEE 62A; COMMON ASPECTS OF ELECTRICAL EQUIPMENT USED IN MEDICAL PRACTICE

Follow-up information regarding the revision of IEC 62304, *Health software – Software life cycle processes*

PowerPoint presentations from 2 and 4 October 2018 – share the status of document with National Committees

Please note that two webinars were held for the National Committees of IEC/SC 62A and the Member Bodies of ISO/TC 215, *Health informatics*, as well as the Member Bodies of ISO/TC 210, *Quality management and corresponding general aspects for medical devices*. These webinars explained the status of the IEC 62304 project.

It was noted that IEC 62304 will be circulated as a Committee Draft later this year. At that time, National Committees/Member Bodies will have a chance to submit comments. The webinars were held as part of the messaging campaign to alert the National Committee/Member Bodies of the planned action for IEC 62304.

The PowerPoint presentation used in the webinars are attached and distributed with this INF document.

IEC 62304 2nd Edition

Outline

- History of 2nd Edition
- What is changing in 2nd Edition
- Risk management and IEC 62304
- 2nd Edition Summary

IEC 62304

Foundation

- Quality system
- Risk Management
- Software engineering

2nd Ed

Currently in revision for CD3

Scope

Broadened scope to HEALTH SOFTWARE

Medical device software and Non-Medical Device Software are subsets of health software.

General Requirements

Quality system

Risk management (including Cybersecurity)

Usability

Software safety classification

Normative & Guidance

New requirements

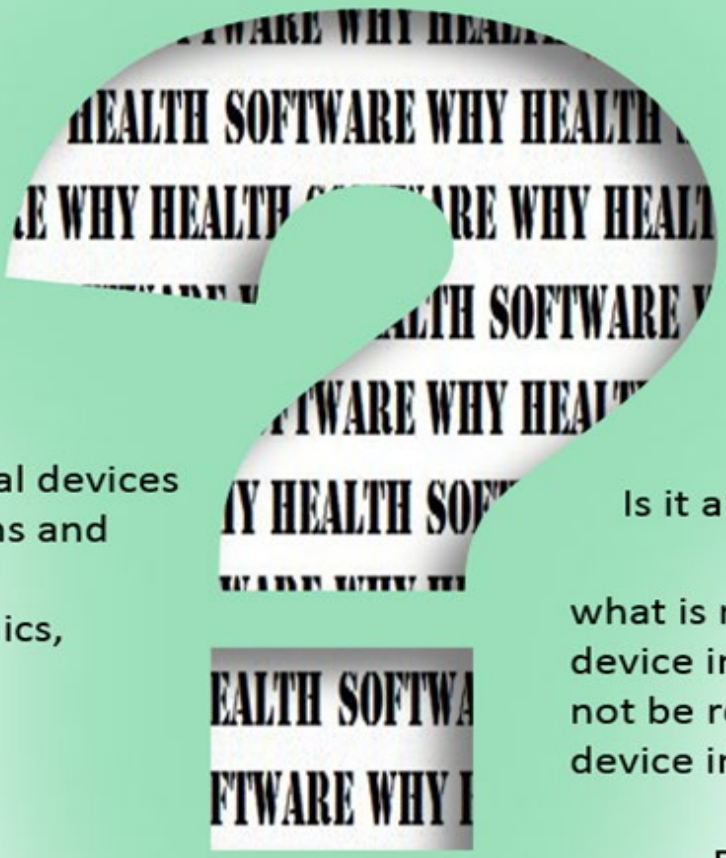
Clarifications & New Notes

IEC resolution: Shanghai 3 (IEC 62/877/RM)

SC 62A, having heard the report of the convener of JWG 3, and furthermore considering the comments by the National Committees on 1CD of IEC 62304 Ed 2, instructs JWG 3 to proceed as follows:

- To prepare Amendment 1 for IEC 62304 Ed 1 relating to Software Safety Classification and Legacy Software, etc.;
- To prepare a Technical Report based on Annex F of 1CD of IEC 62304 Ed 2, and to circulate the resulting document as a Draft Technical Report; and

To expand the scope of Ed 2 of IEC 62304 from "Medical Device Software" to "Health Software", with the understanding that "medical device software" is fully included in "health software".



US 21st Century Cures Act

Leveraging interoperability

Remote access

mobile health apps

Health IT safety

Wireless connections

digital health

Software is becoming increasingly important in healthcare

Remote management

"medical device" is a regulatory term

Exponential growth of medical devices (including consumer platforms and wearables running medical applications) in hospitals, clinics, medical offices, and homes

Is it a medical device or not?

what is regulated as a medical device in one geography may not be regulated as a medical device in another

Patient safety

FDASIA health IT report

IOM report: To Err is Human (2000)

Why expand to health software?

Key governance elements

Be aware of regulations and work to have the 2nd Edition remain recognized by regulators (harmonized, adopted, recognized);

Build upon IEC 62304 Ed 1.1 and be “backwards and forward compatible”; have the same rigor as to Class C software as in Ed1.1; provide a level playing field for all Health Software

Key governance elements

Function as a standard to be referenced by the following systems standards, and will thus have to be compatible on terms and definitions, and (normatively) referenced standards:

- IEC 60601-1 (must still be applicable to medical device software),
- IEC 82304-1; (Health software products)

Be developed to allow use as a non-referenced standard, i.e., be used as a "standalone" standard. For that purpose, 2nd Edition, should include all elements that normally come from referencing systems standards; this includes but is not limited to:

- General requirements security,
- Human factors/usability,
- Expand quality system, and
- Safety management/risk management;

Changes in the Introduction

Rationale for why security and usability were added to 2nd Edition general requirements:

- dependence on network connectivity
- integral to hospital workflows
- used more commonly in the home and outside of the hospital

The MANUFACTURER of HEALTH SOFTWARE is responsible for determining and complying with all appropriate SAFETY, SECURITY, environmental, health, and interference protection practices and all laws and regulations at all levels that are applicable.

Added / Updated Terms & Definitions from IEC Guide 51, IEC Guide 63 and ISO 14971 as appropriate

The following Terms/Definitions were added:

- Health Software,
- Intended use/Intended Purpose,
- Software Maintenance,
- Usability.

Terms and Definitions

Changes in General Requirements

The general requirements section has been updated to assure that edition 2.0 would meet the state of art of the use-environment and the way that health software is being used.

4.1 Quality System – CD3 will have no changes from Ed 1.1

4.2 Risk Management – Changes discussed

4.3 Usability – NEW! Changes discussed

4.4 Software Safety Classification – Changes in CD3 will be clarifications from Ed 1.1

4.5 Legacy Software – Changes discussed

DRAFT 2nd Edition IEC 62304 General requirements for Risk Management Clause 4.2

- **Health software** must have an established process for managing **risks (primarily to the people, equipment, and environment)**, and
  - Must be a methodology for identifying hazards, estimating and evaluating the associated risks, controlling the risks, and monitoring the effectiveness of the risk controls.

- **Health software** must have an established process for managing risks associated with **system security**
  - Must be a methodology for identifying vulnerabilities, estimating and evaluating the associated threats, controlling the threats, and monitoring the effectiveness of the security risk controls.

- **Health software** developer must demonstrate the use of usability engineering to identify and control **use-related risks (Clause 4.3)**

DRAFT 2nd Edition IEC 62304 Clause 4.2 and Clause 7 Risk management

Provide a consistent and appropriate approach to Risk Management for both Regulated Health Software and Non-regulated Health software.

Three options were discussed:

1. **Everyone use 14971**
2. **Require Risk Management without requiring a specific Risk Management Standard**
3. **If software can contribute to a hazardous situation, 14971 is required.**

DRAFT 2nd Edition IEC 62304 Clause 4.2 and Clause 7 Risk management

Both Regulated and Non-regulated Health Software use 14971

This option was not accepted

- **it was considered excessive to require 14971 (Medical Device Risk Management) for Non-Medical Device Health Software that does not contribute to a hazardous situation.**

DRAFT 2nd Edition IEC 62304 Clause 4.2 and Clause 7 Risk management

Require Risk Management without requiring a specific Risk Management Standard

This option was not accepted:

- There was concern that the claim of conformance to 62304 would be impacted as assessment of safety class, and action to take based on safety class would not be based on a consistent risk management approach and would impact the meaning of conformance to 62304.
- Health Software developers that are required to follow 60601-1 (Medical Electrical Standard) are required by that standard to follow 14971, meaning that most Medical Device companies would not have a level playing field with other Health Software companies if this option were accepted.
- Completing removing the adherence to 14971 requirement will adversely effect other linked standards.

DRAFT 2nd Edition IEC 62304 Clause 4.2 and Clause 7 Risk management

If software can contribute to a hazardous situation, 14971 is required.

This option was accepted:

- Removed the focus on Regulated versus Non-regulated and instead focuses on if the software can contribute to a hazardous situation.
- A *software safety class for Health Software shall be determined prior to start of software development ACTIVITIES. Class C requirements shall apply until a software safety class is assigned.
- If the Health Software can contribute to a hazardous situation, 14971 is required.

Usability

Definition of Usability

Characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment

[SOURCE: IEC 62366-1:2015, 3.16, modified – Note 1 to entry has been deleted.]

4.3 USABILITY engineering

The MANUFACTURER of HEALTH SOFTWARE shall demonstrate use of USABILITY engineering to identify and control use-related RISKS of HEALTH SOFTWARE.

NOTE 1 Demonstration of this requirement can be by the use of IEC 62366-1 [5].

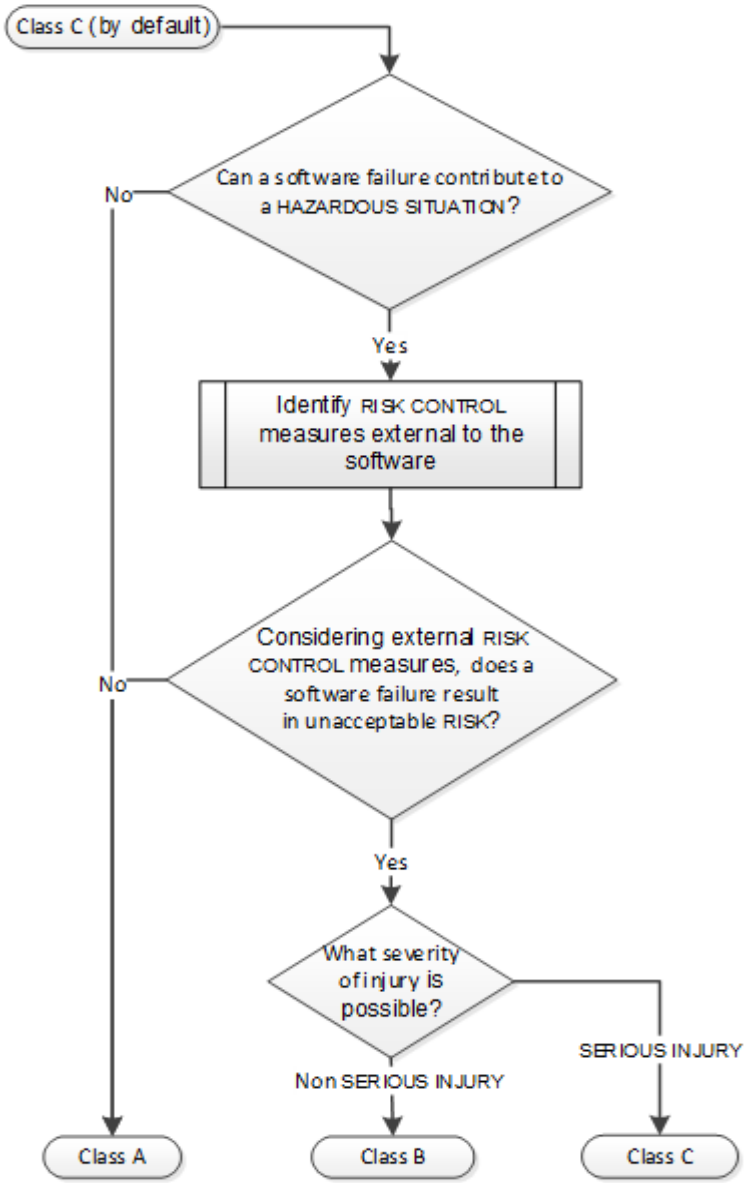
NOTE 2 See also 5.2.2 list item f).

Usability engineering was added to Annex B

IEC 62304 Software safety class

Simplified

Intent and approach remain the same as in AMD1

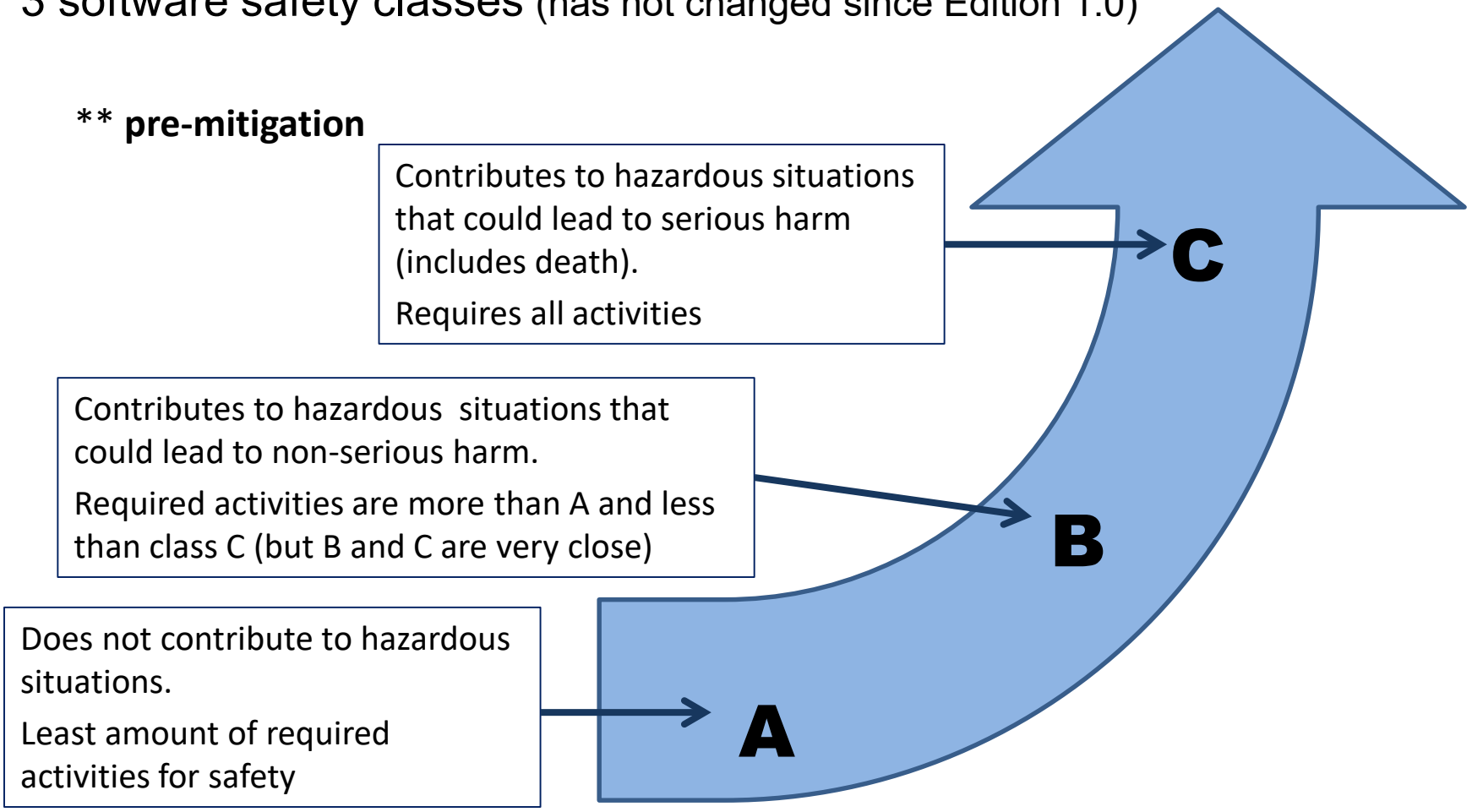


***One acceptable method of determining Software safety class is through the use of a FMEA (Failure mode and effects analysis).**

IEC 62304 Software safety class

3 software safety classes (has not changed since Edition 1.0)

** **pre-mitigation**



Software safety classification determines what are minimum required activities and tasks

Legacy Software

LEGACY SOFTWARE is HEALTH SOFTWARE which was legally placed on the market and is still marketed today but for which there is insufficient objective evidence that it was developed in compliance with the current version of this standard.

Clause 4.5 will be modified in CD3 to clarify the requirements

The MANUFACTURER of LEGACY SOFTWARE may consider this software compliant upon meeting the requirements given in 4.1 (quality system), 4.2 (risk management), 4.4 (software safety classification), and 4.5 (legacy software).

Risk management activities shall also consider security and usability

(…along with assessing feedback and post-production information and …)

Changes to the LEGACY SOFTWARE shall be performed in accordance with this document (the standard).

62304 2nd Ed changes within processes

5.1 Planning

- Moved 5.1.12 Identification & avoidance of common software defects moved into Clause 7 Software Risk Management Process (**7.1.2 Potential causes of contribution to hazardous situations**)

5.2 Software requirements analysis

- **Security capabilities** to be considered in the software and resolved into security requirements
  (**see IEC TR 80001-2-8** *Application of risk management for IT-networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2)*

62304 2nd Ed other changes

Annex B

Guidance

- B.4.2 Guidance on risk management including cybersecurity risk management
- B.4.4 Clarify guidance on software safety classification
- B.5.2 Guidance on security requirements
- B.9 Clarify guidance on problem resolution process interaction with configuration management and change requests

Annex C

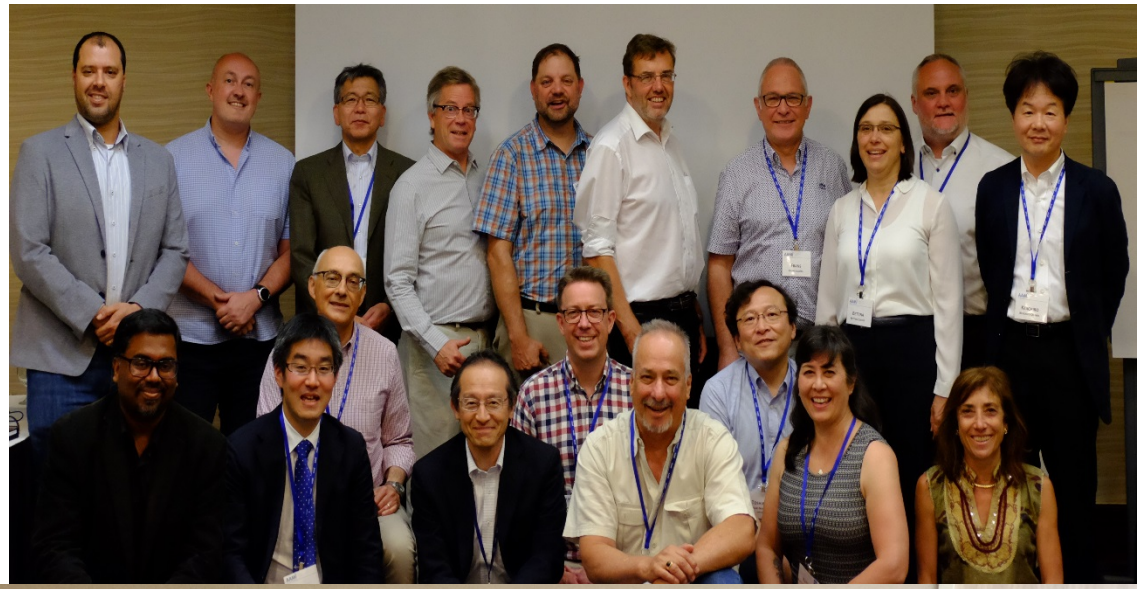
Relationship with other standards

- Added a table of 13 useful security standards
- New section on relationship with Active Implantable product safety standards (EN 45502-x and ISO 14708-x)

Advantages of 2nd Edition changes

- **Provides a level playing field for all Health Software.**
- **Provides Non-Regulated Health Software with a Life-cycle standard to follow for software, and provides a path to regulated health software.**
- **Modified to provide additional clarity where needed.**
- **Added more notes.**
- **Added more content to Annexes.**

We'd like to thank the team members of IEC/SC62A – ISO/TC215 - 62304 2nd Edition workgroup for all their hard work without which this new edition would not be possible



THANK YOU!

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