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Medical device software

Background

Software differs from other parts of medical devices. It is intangible, has a significant number of internal states which make it highly complex, and failures in software are systematic failures by definition. Dealing with these challenges requires different approaches (as compared to hardware) regarding the processes to be used during the development and the maintenance of software when software is used as stand-alone software or when it is part of a medical device.

The goal of the standard is to create a common framework for the software life cycle with regard to processes, activities, and tasks. These processes and tasks are necessary for the safe design and maintenance of medical device software. The documentation and the test efforts are scaled according to its criticality.

Which standards exist?

- EN 60601-1, 3rd edition (Medical electrical equipment – general requirements for basic safety and essential performance), clause 14
- EN 62304 (Medical device software – software life cycle processes)
- IEC 82304-1: Health software – Part 1: General requirements for product safety

What does IEC 62304 require?

The standard defines requirements for five processes. These requirements have to be implemented within the quality management system of the company.

1) Software development process
This process defines requirements to be followed during software development. It comprises the subprocesses software development planning, software requirements analysis, software architectural design, software detailed design, and software implementation. For each of these stages a corresponding test level has to be defined. The development effort (and related documentation) depends on the criticality of the software.

2) Software maintenance process
This process defines what has to be considered during the maintenance of the software.

3) Software risk management process
Risks related to software are sometimes different from those related to hardware. This chapter defines requirements on how to perform a risk analysis of the software. For risk management and software further guidance papers are available: AAMI TIR32:2004 and IEC/TR 80002-1 Ed. 1.0.

4) Software configuration management process
The software itself, the associated documentation, and the tools used (e.g. compilers, libraries) have to be subject to configuration management.

5) Software problem resolution process
Whenever software is changed after a certain time, the changes have to be documented and accepted, and the impact of the changes has to be analyzed (e.g. regarding documentation and tests already performed).

Apart from these five processes, the standard contains requirements regarding software classification and commercial software or software for which no adequate documentation exists.

Software safety classification: A safety class has to be assigned to each software system: C = serious injury or death possible; B = no serious injury possible; A = no injury possible. It is possible to break down a software system into components (items), each with its own safety class. In this context, a rationale for the individual safety classification is needed. The 2015 amendment to IEC 62304 clarifies some drawbacks of the former safety classification. Means external to the software which reduce the risk to an acceptable level may now be used in safety classification decisions.

Commercial software: The use and selection of commercially available software has to be considered carefully. Potential hazards resulting from commercial software (like operating systems, databases, and drivers) have to be evaluated. Since the quality of the development life cycle usually is unknown, software errors have to be assumed. Certain combinations of software with a higher safety classification and commercial software could be critical and need special consideration concerning the associated risks: a software system classified as C might not run safely on an off-the-shelf operating system for which no adequate verification and validation can be demonstrated.

Segregation: It is allowed to assign separate safety classifications to individual software items. In this connection, a rationale for the individual safety classification is needed. The rationale for the separate safety classification should include a consideration of the potential side effects of the software items on the safe operation of other software items, and demonstrate that there is sufficient segregation (a class A software item should not negatively influence software items of a higher safety class).

What does all this mean for you as a manufacturer?

The requirements of the standard have to be implemented within your quality management system. During product design, the challenges regarding software safety classification, commercial software, and segregation have to be addressed. The requirements have to be considered for all new or modified medical device software.

What does IEC 82304-1 require?

IEC 82304-1 focuses on stand-alone software but also includes medical health software which is not classified as a medical device. In contrast to the IEC 62304 it also contains requirements for validation and the information given to users (e.g. related to IT networks).

IEC 82304-1 did not reinvent the wheel: software development has to be done according to IEC 62304 and risk management according to ISO 14971 has to be applied as far as reasonable. The validation requirements cover the validation of use requirements (IEC 62366) and the independence of the validation team.

How can TÜV SÜD Product Service help you?

TÜV SÜD Product Service has a comprehensive service offer:

- Training regarding the requirements and challenges of the standard
- Gap analysis of existing processes and documentation regarding IEC 62304
- Functional Safety testing: Addressing the challenges of software safety classification, commercial software, and segregation with a Functional Safety assessment

Your contact partner at TÜV SÜD Product Service can provide further information.

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