DITTA Workshop
on Medical Software, Taipei on 03 November

Task Force FAQ EN 62304:2006

- activities and current status -

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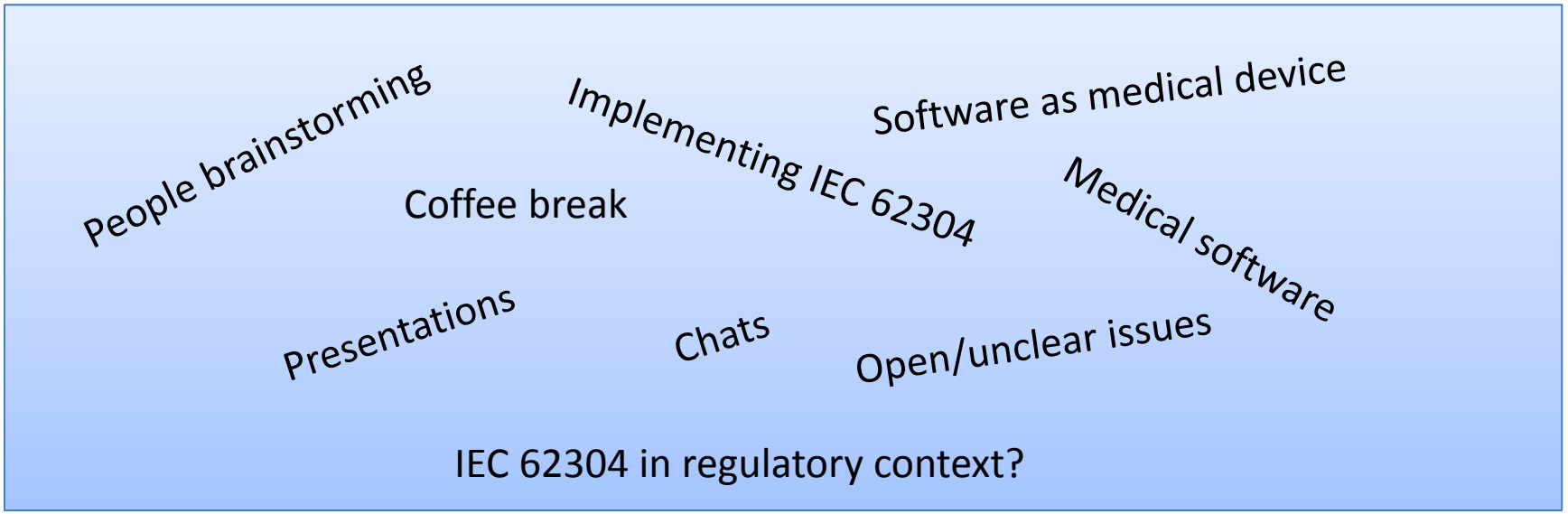
Overview

- How everything started...
- FAQ: Team-building and start-up
- Face2Face meetings
- FAQ: Table of contents
- FAQ: Examples
- Schedule and next steps

How everything started...

Feb. 2012 : VDE Symposium on IT-Networks in Berlin



Many people out there asking similar questions...

How can we help them?

FAQ: Team-building and start-up

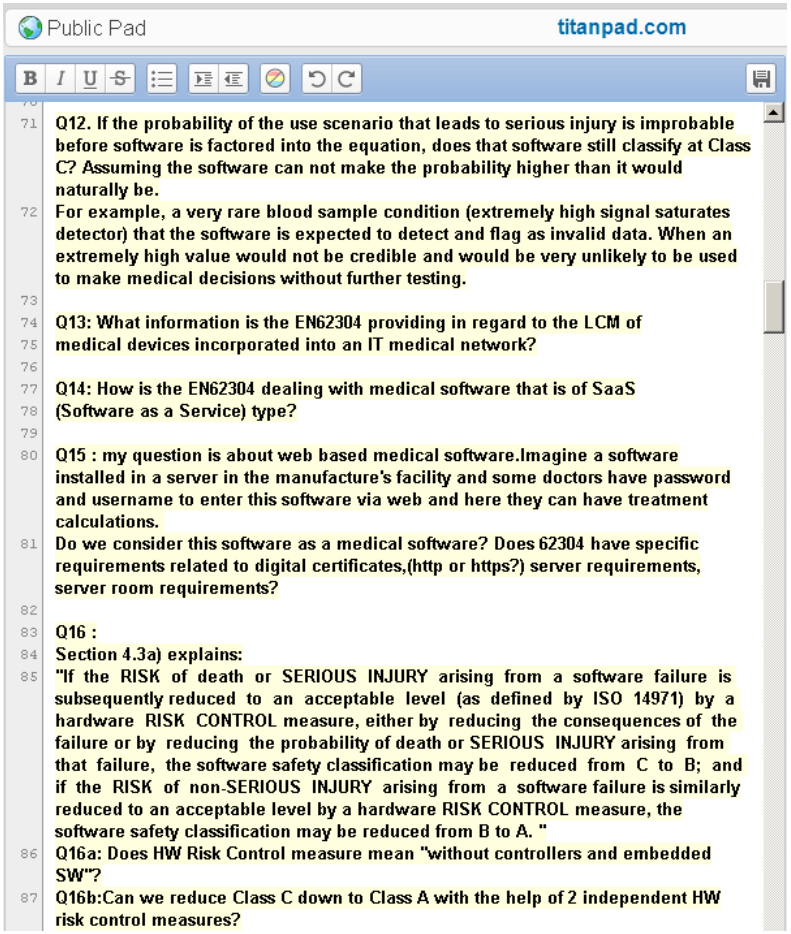
Call for questions:

- Announcement and invitation letter shared with:
  - NB-MED
  - industry associations in MD & SW : COCIR, Eucomed, EDMA, Eurom VI, AIPES, Euromcontact
  - CENELEC for posting on their website & publishing in their news
  - IEC SC 62A / ISO TC 210, the constituting committees for IEC 62304
  - LinkedIn forum on EU regulation
- Specific email address for incoming questions (FAQ62304@VDE.com)
- Time span for collecting questions: 14th – 31st of May 2012
- Initial number of questions submitted: 101

Face2Face working meetings

4th-5th July: first meeting

- Definition of time schedule
- Classification of questions into different categories (14 chapters)
- Weighting questions that fell into more than one category (*a* and *b*)
- Clustering of questions according to redundancy (and reformulating)



Classifying and weighting

Question	2. Scope and Conformity	3. How to place [software] products on the EU and other markets	4. SW Process	5. Risk Assessment / Risk Management	6. SW Classification after Risk Analysis	7. SW Development Plan	8. SW Requirements Specification	9. SW Architecture	10. SW Test Plan and Test Results	11. Traceability Matrix	12. Legacy	13. SOUP	14. Level of detail
1							a		b				
2		a											
3		a											
4											a		
5			b			a							
6					a								
7					a								
8					a								
9				a	b								
10					a								
11				a	b								
12				a	b								
13	a												
14	a												
15,1	a												
15,2							a						

Face2Face working meetings

20th-21st August: second meeting

- Re-definition of time schedule
- Merging redundant questions
- Reducing the number of categories (8 chapters)
- Discussing and answering; consensus building

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3		a											
4											a		
5			b			a							
6					a								
7					a								
8					a								
9				a	b								
10					a								
11				a	b								
12				a	b								
13	a												
14	a												
15,1	a												
15,2							a						

Condensing:
14 to 8 categories

Nr.		Question (original nr.)	1. Introduction	2. Scope of EN 62304	3. Placing on the market - regulatory considerations	4. Life-cycle processes	5. Risk assessment / Risk management	6. Classification and segregation	7. Specification, testing and tools	8. SOUP and legacy software
1	2.1.1	30		x						
2	2.1.2	14 15,1 25,1 32 33 47 51 85 101		x						
3	2.1.3	60 78		x						
4	2.1.4	13		x						
5	2.1.5	52		x						
6	2.1.6	71		x						
7	2.1.7	103		x						
8	2.1.8	25,2 74 106		x						

FAQ: Table of contents

1. Introduction
2. Scope of EN 62304 (13 questions)
3. Placing software as medical device on the market (8 questions)
4. Life-cycle processes (15 questions)
5. Risk assessment and risk management (6 questions)
6. Classification and segregation (13 questions)
7. Specifications, testing and tools (11 questions)
8. SOUP and legacy software (5 questions)

FAQ: Examples I

Is EN 62304 alone sufficient to fulfill the Essential Requirements of the Medical Device Directive for a Standalone SW product?

Answer:

No. Compliance with EN 62304 does not provide a presumption of conformity with all aspects of the essential requirements of Annex I of the Medical Device Directive. One single standard cannot cover all essential requirements, as EN 63204 for instance doesn't cover usability issues, clinical evaluation or the final validation of the software product. Therefore, other standards and procedures need to be considered to show complete fulfillment of all applicable essential requirements. (If harmonized standards are not applied, there's the necessity of the manufacturer to justify and make explicit the selected equivalent alternative methods)

What kind of review process should be applied on Requirement, Design and Test Specs at the end of each iteration when updated versions are available? Is there any formal sign off needed?

Answer:

The manufacturer has freedom to define the review and approval process. EN 62304 however requires that these processes are appropriate to the scope, magnitude and software safety classification of the Software system to be developed. Especially change requests require formal approval. ISO 14971 requires documents related to the Risk Management to be maintained. In addition, the quality system ISO 13485 also requires control of documents.

See for example clauses 5.1.8, 5.2.6, 5.5.2, 6.2.4, 8.2.1, 9.4, annex B and table C.3

FAQ: Examples II

If software development is an outsourced activity, what is expected from the Notified Body as evidence, that the service supplier's software development process is in compliance with IEC 62304 ?

Answer :

The NB expects the manufacturer to be in control of the service supplier. For compliance with 62304, the service supplier must have the processes in place and have produced all the documents required by 62304 for those processes that have been outsourced. For example, if the code development and unit testing have been outsourced, the service supplier should provide evidence of those activities, the manufacturer must do the remaining activities, such as risk management and integration, etc.

What are the expectations of the Notified Bodies in regard to 62304 Compliance?

Answer :

Compliance to EN 62304 gives the presumption of conformity with some of the essential requirements of the Directive. If the standard is not applied, the manufacturer has to provide other objective evidence that the software is in conformance with the corresponding essential requirements. Although the application of the standard is voluntary, it represents the current state of the art and as such gives a good guidance for manufacturers to demonstrate conformity

FAQ: Examples III

Is IEC 62304 accepted/required in other regions/countries regulatory approval process ?

Answer :

It is very likely that there is similar acceptance of IEC 62304 in other countries, for example it is recognized by the FDA under recognition number 13-8 and has been translated into an identical Chinese standard YY/T 0664. It needs to be clarified for other markets.

Software development uses tools/objects found in shared open sources (forums) where verification is unlikely. Does this standard set precedence for control of such open source tools?

Answer :

The standard also applies to open source code. If you take the code it follows the requirements of a SOUP. If you make changes to the code, then you must consider it as a software item that you developed yourself. The level of control depends on the safety class of the code.

Work c‘tnd

- 19.09 - 21.09.2012 : JWG3 meeting in Erlangen:
  - Presentation of activities and status
  - Nomination of 3-4 volunteers for Review
  - Discussion on CD1 relevant questions

- 24.09 - 25.09.2012 : JWG7 meeting in Vienna - activities and status

- 21.09. - 31.10.2012 : JWG 3 Review
- 11.10. - 30.11.2012 : NBRG Review
- 1.12. - year‘s end : Incorporate feedback and document update
- early 2013 : Publication

……. Keep you Updated !

Courtesy : The Team

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