

European Workshop On Industrial Computer Systems
Technical Committee 7:
Reliability, Safety And Security



3rd Medical Devices Workshop

Newcastle (UK)
September 25, 2005

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MeD Workshops

- ◆ 1st: Gatwick, July 2003
 - networked systems; home care systems; soup
 - emerging standard on software (not IEC 61508)
 - TC7 focus on management of operational risks
- ◆ 2nd: September 2005
 - set of standards, incl. ISO 14971, IEC 62304, IEC 60601 revision, not covering all...
 - pending Gatwick issues: networked systems, home care systems
 - emerging problems include: system integration, safety cases for MeD, software update & recertification



MeD Workshops

- ◆ 3rd: Newcastle (UK), September 2008
 - focus on building arguments for claims of safe use of medical systems: safety/trust/assurance cases
 - examples regard networked systems; system integration; home care systems, soup
 - TC7 focus on management of operational risks in throughout the lifecycle of medical systems



Problem Statement

- ◆ active medical devices become more complex, more dependent on programmable electrical/electronic (PE) subsystems, and are more often linked into a network of medical systems
- ◆ regulation provides limited control of operational risks
- ◆ processes with operational risks are 'owned' by users in health care or at home



Workshop Purpose [1]

- ◆ **Information exchange** on state-of-the-art issues on Assurance Cases for Medical Devices, and their potential to address problem areas such as:
 - facilitation of communication between different stakeholders,
 - the integration of evidence from different manufacturers in multi-vendor systems
 - the integration of devices by the healthcare service provider or in home care setting



Workshop Purpose [2]

- ◆ **Identification and discussion on problematic topics**, including different views in EU and USA
- ◆ **Issues** for the MeD Subgroup + follow-up

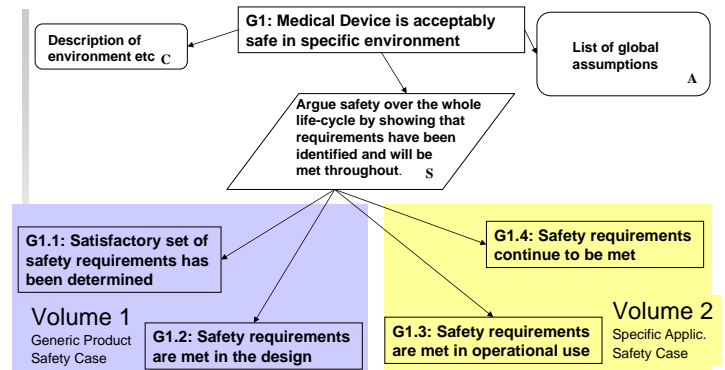


Topics for discussion

- ◆ Scope of what are we talking about: devices and systems, real-time, on-the-spot, remote and off-line (e.g. in laboratory) applications, radiation systems, imaging (diagnostic and archive) systems, home and self-care systems, implants, robots, devices of different classes (I, IIa, IIb, III)
- ◆ Regulation: what is/is not regulated?
- ◆ What safety/trust/assurance cases do
- ◆ Risks and management of operational risks related to the use of medical systems in use context
- ◆ Assurance cases in health care
- ◆ Networked (including multi-sited) systems
- ◆ Home/self care systems
- ◆ Informational hazards => actuation => patient safety risks



Top-Level Argument MeD SC



Programme Outline

Schedule:

- ◆ **09:00 - 12:30 Round I:** information exchange
- ◆ **12:30 - 13:30: Lunch**
- ◆ **13:30 - 15:30 Round II:** Discussions organised per topic (in groups, followed by plenary)
15:30-15:45 Tea Break (or during Round III)
- ◆ **15:45 - 17:00 Round III:** group summaries & concluding discussion
- ◆ **17:00: closure of this workshop**



Presentations Round 1

Schedule:

- ◆ **09:20 - 12:30**
 - Udo Voges - Progress and open issues in Standards
 - Richard Hawkins- Benefits of assurance cases for the medical device industry
 - Patty Krantz - Possible uses of assurance cases in the US medical device industry
 - Paul Hopkins - Integration of safety and security considerations in remote monitoring environments
 - David Embrey - Integration of human factors considerations into assurance cases for medical devices
 - Matthew Cooke - A clinician's perspective to improving the safety of medical devices
 - Janusz Gorski - The trust or safety case
 - Lukasz Cyra - Assurance cases for distributed healthcare scenarios
 - Nick Chozos - Dependency aspects of a department safety case



Membership

- About 30 members listed
 - **affiliations** (assessors, industry, academia, research)
 - **countries** (DE, UK, NL, AT, PL, US, Japan)
 - **active** (about 50%)
- MeD Subgroup meetings: 3 / year
 - **information collection**
 - **standards, certification, examples**
 - **dissemination and review of the above**
 - **briefing papers**
 - Risk Management of Medical Systems
 - Safety Cases for Medical Devices



MeD Subgroup - Contacts

- Liaisons are being sought with industry, licensing bodies and other committees working in the domain of medical devices

Further information:

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