Assurance Cases: A New Form of Requirements Traceability Matrix for Medical Devices

Fritz Eubanks, Ph.D., CRE
Melissa Masters
Advanced Engineering for Life Sciences
Battelle Memorial Institute
Columbus, OH

Agenda

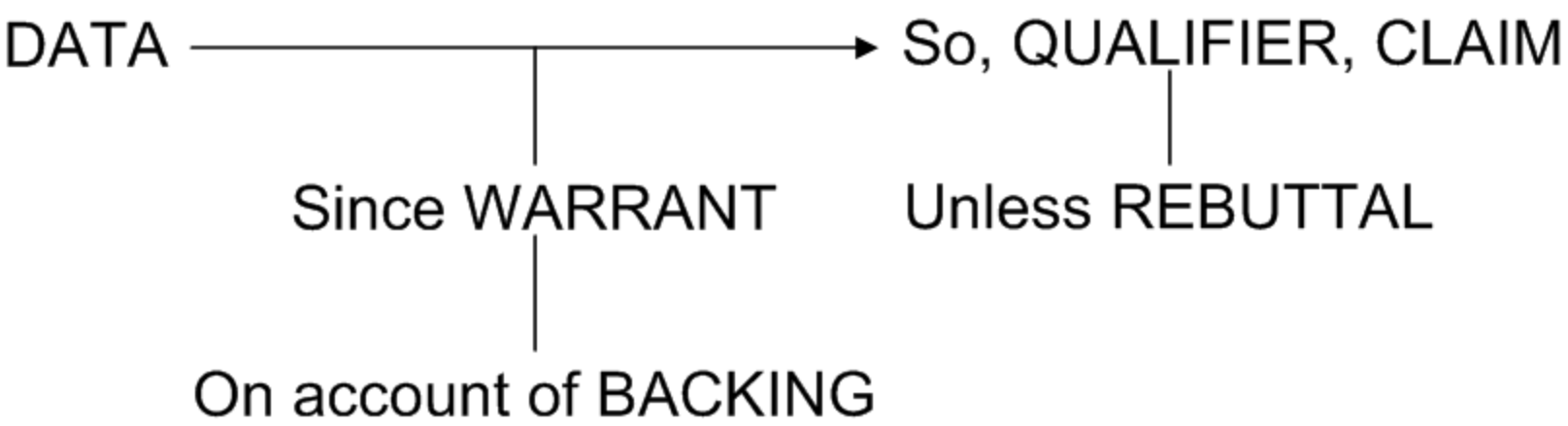
- Motivation
- Background
- Structure
- Challenges
- Laying the Groundwork
- References

Motivation

- Incidents from 2005 to 2009 (FDA 2010a)
  - 56,000 reports of adverse events
  - 87 Class II Infusion Pump Recalls
  - 14 Class I Recalls
- FDA begins initiative in April 2010 to improve Infusion Pumps (FDA 2010a)
  - Establish additional requirements
  - Proactively facilitate improvements
  - Increase user awareness
- One Additional Requirement: ASSURANCE CASE for the system (FDA 2010b)
  - Assurance Case: “Formal method for demonstrating the validity of a claim by providing a convincing argument together with supporting evidence. It is a way to structure arguments to help ensure that top-level claims are credible and supported.”

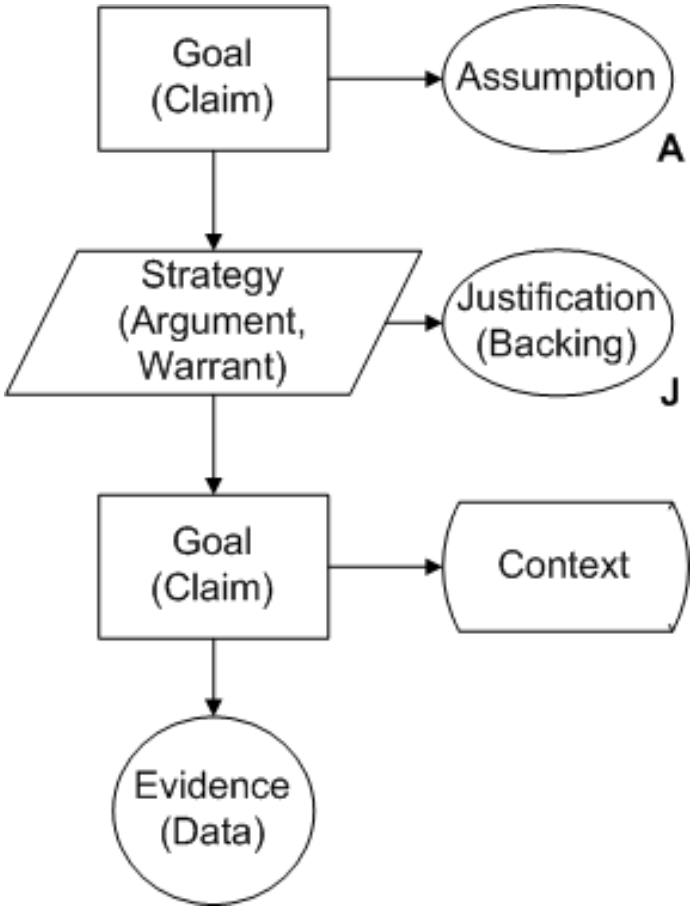
Background

- Assurance cases are arguments
  - Attempt to assure that a claim is valid based on verifiable data
- Toulmin model of argument structure

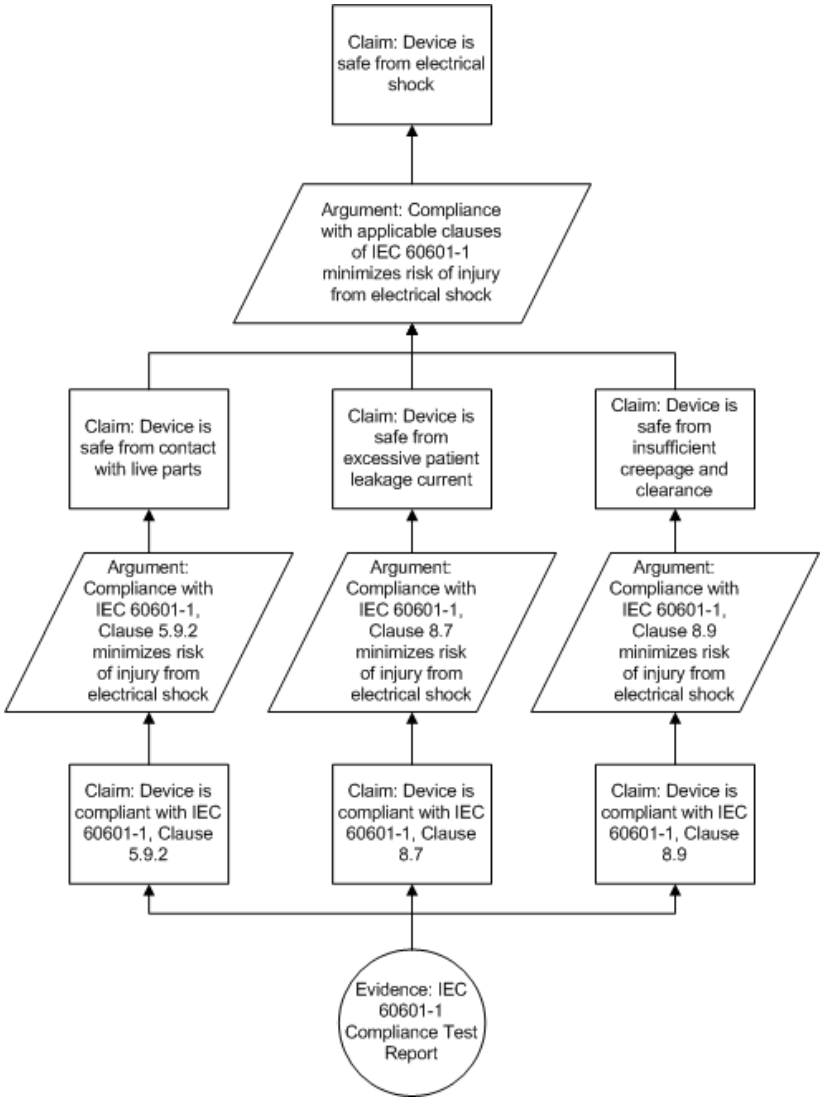


Background

- Kelly (1998) codifies structure and evaluation of safety case
  - Amalgamation of:
    - Goal Structuringing Notation (GSN)
    - Argumentation Logic
    - Traceability Matrices
    - Bayesian Belief Networks
    - Semantic Networks
- Weinstock (2009) extends GSN safety case to medical device
  - Generic Infusion Pump (GIP) example
- Chapman (2010) presents FDA's new infusion pump guidance



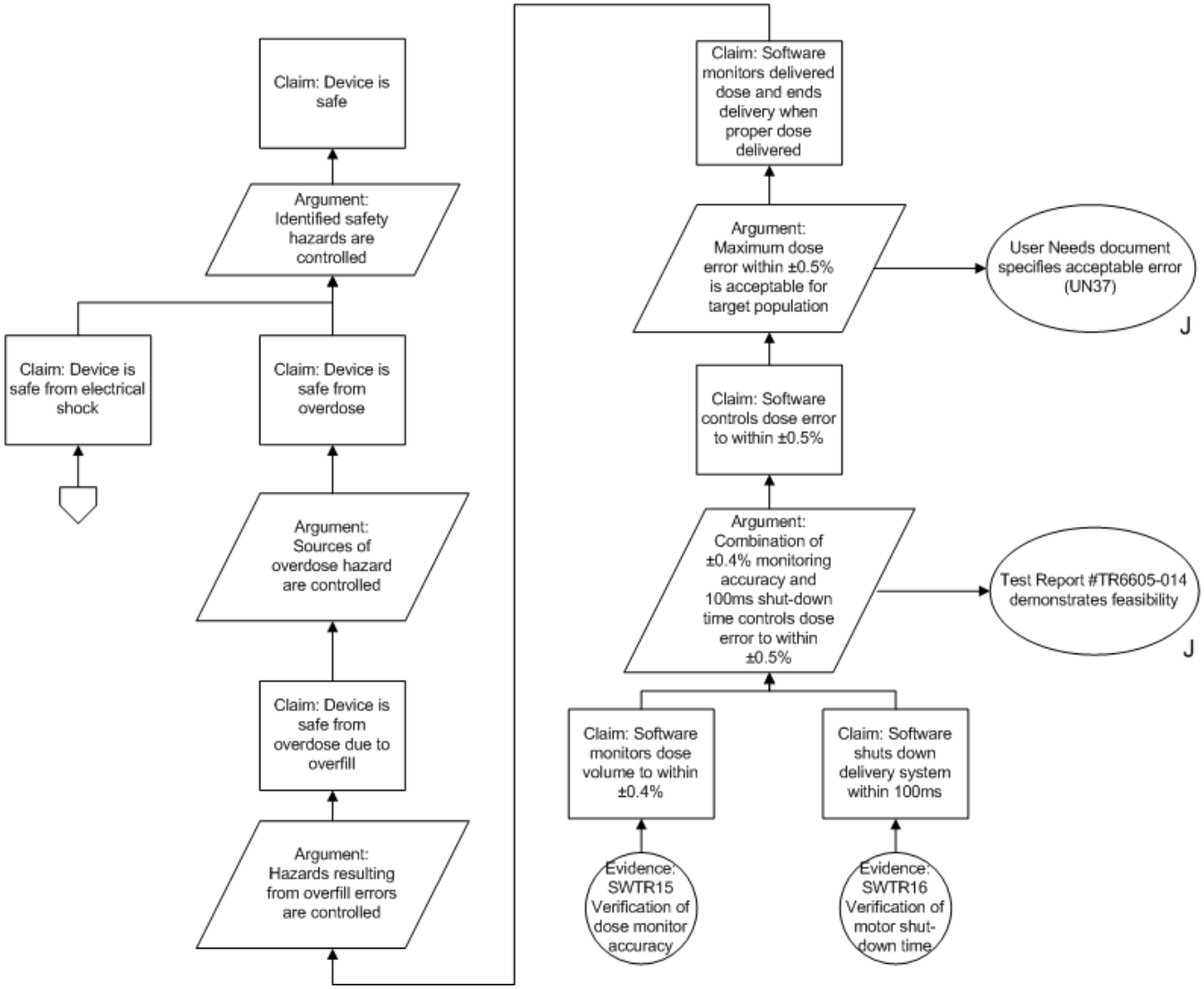
Safety Case Structure



Safety Trace Matrix Structure

Hazard	Cause	Required Risk Control	In-links at depth 1	In-links at depth 2	In-links at depth 3	In-links at depth 4
2 Overdose	2.1 Device is overfilled	2.1.1 D: Software monitors delivered dose and ends delivery when proper dose delivered [HA107	PR35 The device shall deliver the target dose volume to within ±0.5%	SRS86 The device shall monitor the delivered drug volume with an accuracy of ±0.4%. SRS87 The device shall terminate drug delivery within 100ms of reaching the target volume.	SWTP191 Verify delivered volume is within ±0.4% of reported volume SWTP202 Verify piston velocity is 0 mm/sec within 100ms of receiving shut-down signal from motor controller	SWTR15 Verification of dose monitor accuracy SWTR16 Verification of motor shut-down time

“Translated” Safety Case



Manufacturer's Challenge

- Capturing arguments, justifications, assumptions
  - "Write it down!? Isn't it obvious?"
- Integration into existing processes and tools?
  - DOORS-to-Visio
  - SysML
- Deployment of new tools?
  - Adelard ASCE
  - CET GSNCaseMaker
  - Atego GSN modeler
- Level of detail required

Regulator's Challenge

- Providing manufacturers with: (Weinstock, 2009)
  - A process definition that includes
    - How much evidence is enough
    - How the evidence is used
    - Evidence ownership (may contain trade secrets)
    - How to submit both the assurance case and the evidence supporting it
  - Assurance of fair evaluation of submissions by manufacturers that use assurance cases vs. those that do not
    - Forced adoption may create industry backlash

Laying the Groundwork

- Guidance for Industry and FDA Staff: Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions (Draft Guidance, April 23, 2010)
- Public Meetings with FDA, Industry and the public
- Presentations of Richard Chapman, FDA
  - Establishing regulatory expectations
- Presentations of Pat Baird, Baxter
  - AdvaMed Assurance Case Template
  - AAMI Working Group to write Assurance Case TIR
- ISO 15026-2: Systems and software assurance – Part 2: Assurance Case

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- Toulmin, S. E. 1958. The Uses of Argument. Cambridge University Press, London.
- Kelly, T. P. 1998. Arguing Safety – A Systematic Approach to Managing Safety Cases. Doctoral thesis, University of York, UK.
- Weinstock, C. and J. Goodenough. 2009. "Towards an Assurance Case Practice for Medical Devices," Carnegie Mellon University Technical Note CMU/SEI-2009-TN-018.
- Chapman, R. 2010. "Assurance Cases for External Infusion Pumps," downloaded from http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM219685.pdf
- FDA. April 2010a. Infusion Pump Improvement Initiative
- FDA. April 2010b. Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions.