Safety Assurance Cases: What the medical device industry is doing

Sherman Eagles
SoftwareCPR
seagles@softwarecpr.com
BECOMING AWARE
Early steps to awareness

- 2005 – EWICS TC7 medical device group begins working on safety case for hospital bed
- 2007 – EWICS safety case presented at SAFECOMP
- 2007 – AdvaMed meetings on safety cases with SEI and FDA
FDA begins to engage the industry

- 2008 – FDA workshop on assurance cases
- 2008 – AdvaMed software group workshop
- 2008 – AdvaMed software conference
- 2008-2009 FDA encourages some device manufacturers with new types of class III devices to use safety cases
- 2009 – FDA tries to get medical device manufacturers to pilot assurance cases for SOUP
FDA changes tactics

- 2010 – FDA issues draft infusion pump guidance with a requirement for a safety assurance case
- 2010 - The FDA 510(k) Working Group recommends that CDRH consider adopting the use of an “assurance case” framework for 510(k) submissions
A flurry of presentations

- FDA infusion pump initiative workshop
- AAMI webinar on assurance cases
- AAMI infusion pump summit
- AAMI/FDA International Standards Conference
EARLY ADOPTION
Struggling with what and how

- Assurance case – just a safety case? What about efficacy? What about substantial equivalence?
- Do we have to have a safety case for the entire system or just the new parts?
- Start with safety requirements or hazards?
- Organize by hazards or risks to health?
- What does the reviewer want to see?
- What nomenclature – GSN? CAE?
- What format? Graphical? Tabular?
Pat Baird and Erica Girard at Baxter began mapping safety case concepts and terms to ones that are more familiar to engineers, regulatory affairs staff and risk management practitioners at medical device manufacturers:

- Relationship to development
- Relationship to design controls
- Relationship to ISO 14971
Industry efforts – example case

- AdvaMed infusion pump working group started work on an example safety assurance case with the goal of creating a template
- Using the Generic Infusion Pump PCA project as the basis for the example
- Requesting review and feedback from FDA
Disclaimer:

The AdvaMed Infusion Pump Working Group has developed an assurance case template that illustrates approaches or elements a manufacturer may consider when developing assurance case reports for infusion pump submissions to FDA. We cannot guarantee that it covers all required aspects of an assurance case nor that it is correct in all aspects. The information and perspectives represented in this document are not intended to represent a standard and do not represent legal or compliance advice.
Overall structure - Flow-down from Intended Use all the way to Evidence

Device [its algorithm?] is acceptably safe to:
deliver _X_ fluids via _X_ routes in _X_ environments for _X_ patients, operated by _X_ users.

“The system is acceptably safe to prevent: . . .”

Over dose
Under dose
Delay
 Interruption
Air Embolism
Etc.
## Flow-down a High Level Argument (with Claims)

<table>
<thead>
<tr>
<th>G: The pump is acceptably safe to prevent...</th>
<th>S: By arguing over...</th>
<th>Ct: In the context of the following causes...</th>
<th>C: subclaim off context</th>
<th>subclaim off C</th>
<th>Diagram reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal</td>
<td>Argue over types of hazards...</td>
<td>Context</td>
<td>Goal</td>
<td>Subgoals of D</td>
<td>See Module</td>
</tr>
<tr>
<td>Overdose</td>
<td>Electrical Hazards</td>
<td>Properly trained users mitigates programming error</td>
<td>Incorrect programming has been mitigated by...</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Software Hazards</td>
<td>Keypad design causing programming errors is effectively mitigated</td>
<td></td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mechanical Hazards</td>
<td>Properly trained users mitigates programming error</td>
<td></td>
<td>1.4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use Hazards</td>
<td>Complexity of Interface mitigates programming error</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Slide presented by Pat Baird at AAMI/FDA ISC 23 March, 2011
Slide presented by Pat Baird at AAMI/FDA ISC 23 March, 2011
Industry efforts - guidance

- AAMI began work on a technical information report for guidance on safety assurance case reports
  - Task group under the infusion pump committee
- Goal is to have a draft early 2012
- Published TIR in early 2013
AAMI TIR sections

- Foreword
- Introduction
- General
- Regulatory Context
- Safety Case (SC) Discussion
- Lifecycle Management
- Documentation
- Confidence Case
AAMI TIR annexes

- Annex B: Assurance Cases & Predicate devices
- Annex C: Examples
- Annex D: Tool Selection
- Annex E: Legal Aspects of Safety Cases
- Annex F: Integration of Multiple Assurance Cases
- Annex G: Definitions
- Annex H: Bibliography
Industry efforts - training

- AAMI is working on development of a training course on safety assurance cases.
- 2 and ½ day course will be consistent with the TIR guidance and include hands-on exercises.
- First offering of the course will be in the D.C area on October 31 – November 2.
- Information and registration on AAMI web site: [http://www.aami.org/meetings/courses/safety.html](http://www.aami.org/meetings/courses/safety.html)
Training course topics

- Introduction to assurance cases
- Elements of an assurance case
- Establishing confidence in an assurance case
- Assurance cases in the product life cycle
- Assurance case formats and notations
- Creating a safety assurance case
- Integrating safety assurance cases and risk management
- Software considerations in safety assurance cases
- Reviewing a safety assurance case
- Maintaining a safety assurance case
- Tools for documenting safety assurance cases
- Relationship with harmonized EU standards for medical devices
- Integrating multiple safety assurance cases
Industry efforts - tools

- GessNet TurboAC - New web-based tool has been developed that integrates medical device risk management and safety assurance cases
  - Automatic synchronization of risk management file and safety assurance case through the product life cycle
  - Efficient method for hazard analysis, risk management and safety assurance case development
  - Automatic generation of assurance case from risk management file
  - Paper or electronic safety assurance case submission
  - www.gessnet.com
WHAT’S NEXT?
WHAT DO WE NEED TO GET TO BROAD ADOPTION?
Getting to broad adoption

- More guidance from FDA
- Consensus on best practice
- Align terminology and tools with existing medical device development processes and methods
- More training and easier access to training
More guidance from FDA

- Need feedback from FDA on what they like and don’t like
- Need to know what can be accepted as an assumption and what must be proved
  - What is part of compliance and what needs to be submitted for pre-market review?
- Need confidence that FDA reviewers are trained and reviewing assurance cases predictably
Consensus on best practice

- Need published examples of practical safety assurance cases for medical devices
- Need practical articles published in journals that medical device manufacturers use
- More presentations on adoption of assurance cases – what works and what is not working
- More presentations on case studies
Overcome uncertainty about future use

- FDA hasn’t published final infusion pump guidance yet
- After industry feedback on 510(k) recommendations, FDA decided to use their infusion pump experience as a pilot study to evaluate safety assurance cases in 510(k)s
- Although FDA is studying improvement initiatives for other device types (e.g. external defibrillators) they have not required safety assurance cases for any other devices

- Will FDA require safety assurance cases more widely? Many in industry will wait and see.
Thank You

Questions?