

# Potential Advantages of Applying Assurance Case Modeling to Requirements Engineering for Interoperable Medical Device Systems\*

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## Abstract

This poster describes our initial work in applying assurance cases to the requirements engineering processes necessary in building interoperable medical device systems.

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## Overview

Habli and others have described the application of assurance case methods to support goal-oriented requirements engineering [3]. Atwood describes the application of goal-structuring notation (GSN) to make visible the domain knowledge and assumptions that support the validity of a specific requirement, noting the value of making this available for subsequent analysis on a requirement change or reuse across a system family [2].

Among the objectives of the CIMIT MD PnP Program is to develop one or more instances of systems that, using the same family of systems components and interfaces, satisfies the functional and non-functional needs of four distinct clinical scenarios [4] according to the criteria set forth in ASTM F2761-2009, Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model [1].

Our challenges include, on identifying requirements that at the clinical use level appear to span more than one use case, to assure that when the requirement and its derived specifications continue to satisfy the high level need throughout decomposition into technical requirements and specifications. Similarly, on changes to a requirement, the impact of the change needs to be assessed across the set of clinical scenarios to which it contributes.

Our plan to apply GSN covers the following. We include examples of traceable documentation and requirements decomposition and discussion of all points:

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- Documentation of traceability from clinical scenario through validation.
- Decomposition of requirements (goals) across key functional and non-functional properties (sub-goals).
- Determination whether sharing of the above with stakeholders spanning the clinical, technical, and management domains enable clearer communication, e.g., to support decision making.
- Analysis of how well the tools we are evaluating in the MD PnP Program cover the breadth of requirements posed by the full set of clinical scenarios.
- Capture and analysis of the cost of application of GSN to our work.

We are also in the process of implementing a requirements management database system and are considering mapping between the GSN and database model to identify potential added value in the combination, e.g. improvement to requirements conflict identification processes.

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### References

- 1 ASTM F2761-09(2013). Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model. <http://www.astm.org/Standards/F2761.htm>.
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