A Safety Case Pattern for Model-Based Development Approach

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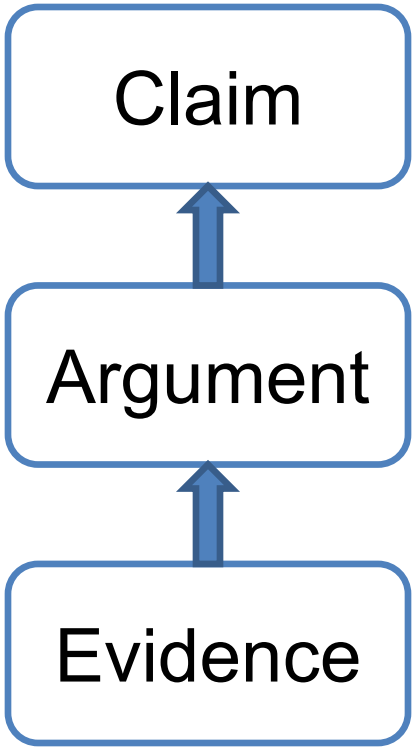
PENN RESEARCH IN EMBEDDED COMPUTING AND INTEGRATED SYSTEMS ENGINEERING

Motivation

- System assurance is a major issue in safety-critical applications
- Many safety-critical systems are reviewed and approved by regulators
- Domains:
  - Aerospace
  - Automobiles
  - Rail Systems
  - Energy (especially nuclear) systems
  - Medical systems
  - Weapons Systems

Assurance Cases

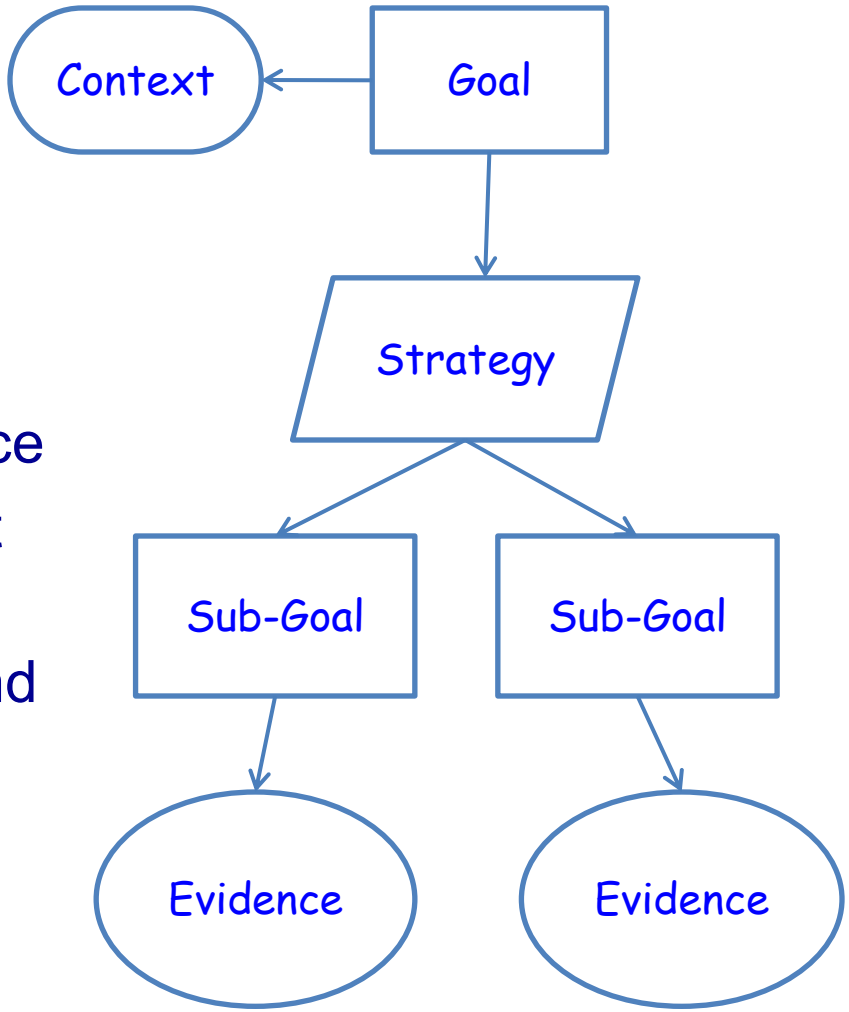
- An assurance case is a method for demonstrating the validity of a claim by providing a convincing argument together with supporting evidence.



FDA - Infusion Pump - Premarket Notification
[510(k)] Submissions DRAFT GUIDANCE, April 2010

Assurance Cases

- To construct an assurance case we need to:
  - make an explicit set of claims about the system
  - define the intended context
  - produce the supporting evidence
  - provide a set of arguments that link the claims to the evidence
  - make clear the assumptions and judgments underlying the arguments
- Safety case is a special kind:
  - Claims are limited to safety



Case Study: Infusion Pump

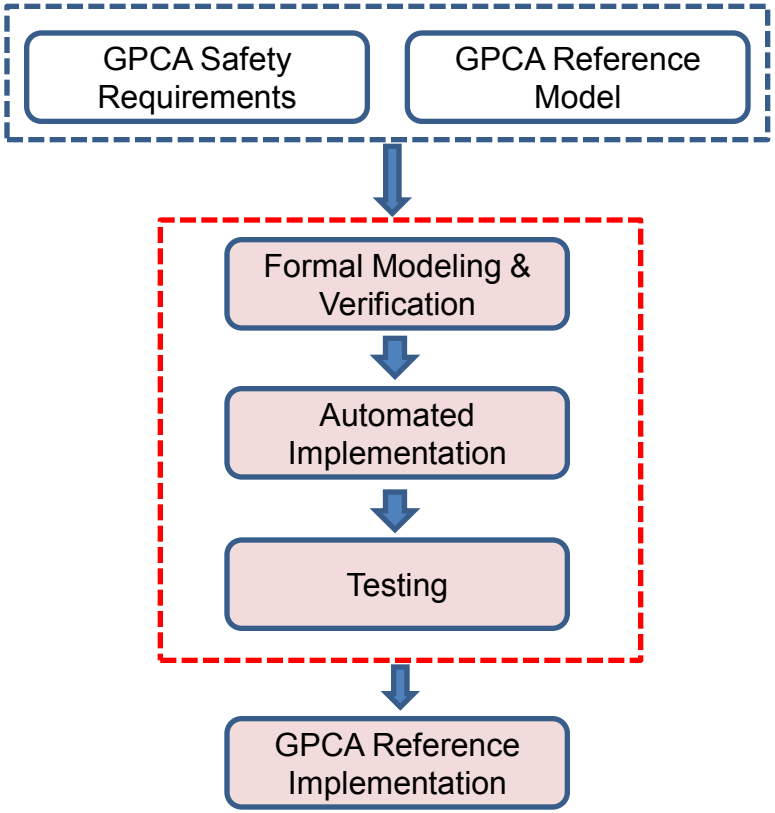
- Deceptively simple
  - 2005—2009: 56, 000 adverse event reports; 87 recalls
    - 1% deaths, 34% serious injuries

FDA, White Paper: Infusion Pump Improvement Initiative, April 2010.

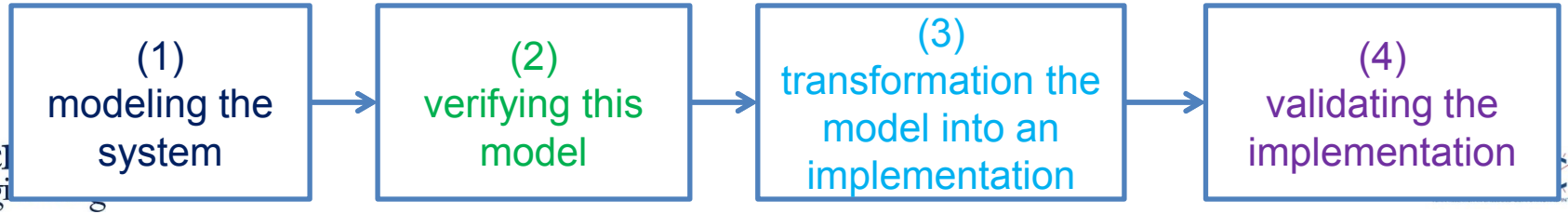
- Case study goals
  - Show how to do it right
    - Develop good requirements
    - Apply rigorous development
    - Explore assurance case construction
  - Provide guidance to manufacturers

GPCA reference implementation

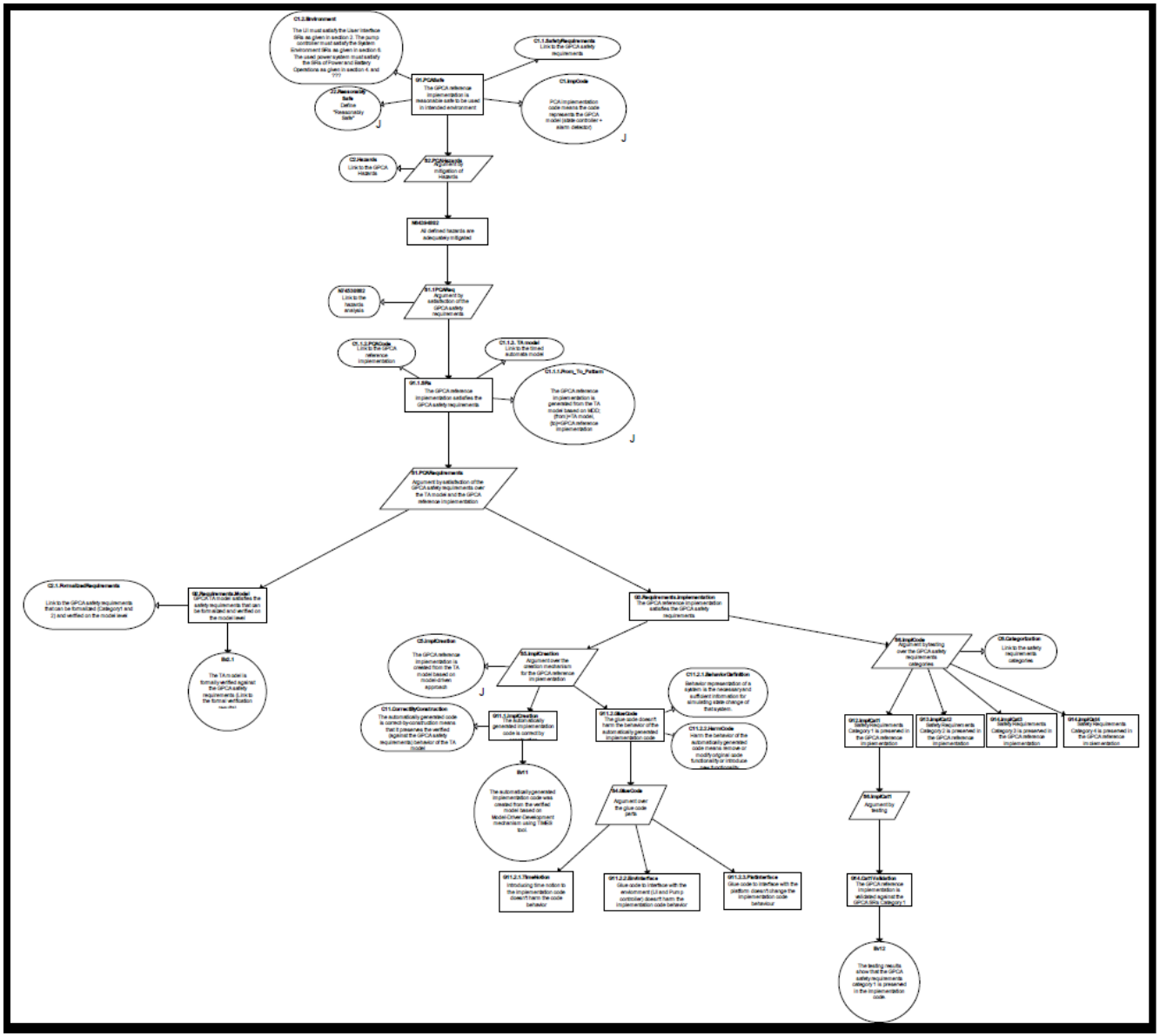
- FDA initiated
  - GPCA Safety Requirements
  - GPCA Reference Model (Simulink/Stateflow)
- Develop a GPCA reference implementation
- Construct a safety case for this implementation



Model-Based Development of GPCA Reference Implementation



The PCA Safety Case



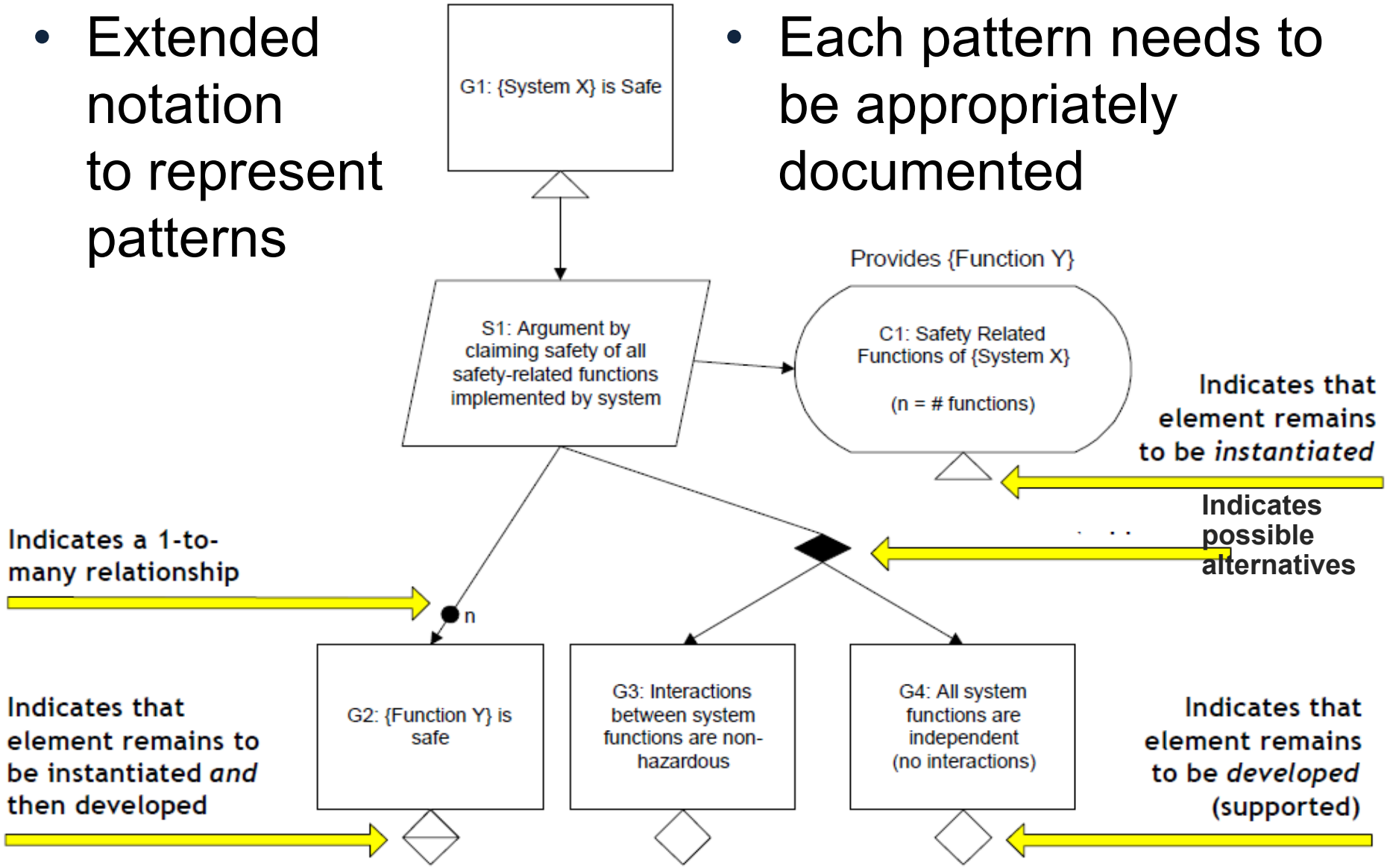
Safety Case Patterns

- Defined to capture successful (i.e., convincing, sound, etc.) arguments.
- Whenever a pattern is appropriate to a new safety case then it is instantiated within it.
- Therefore, safety case patterns allow reusing successful arguments among different safety cases.

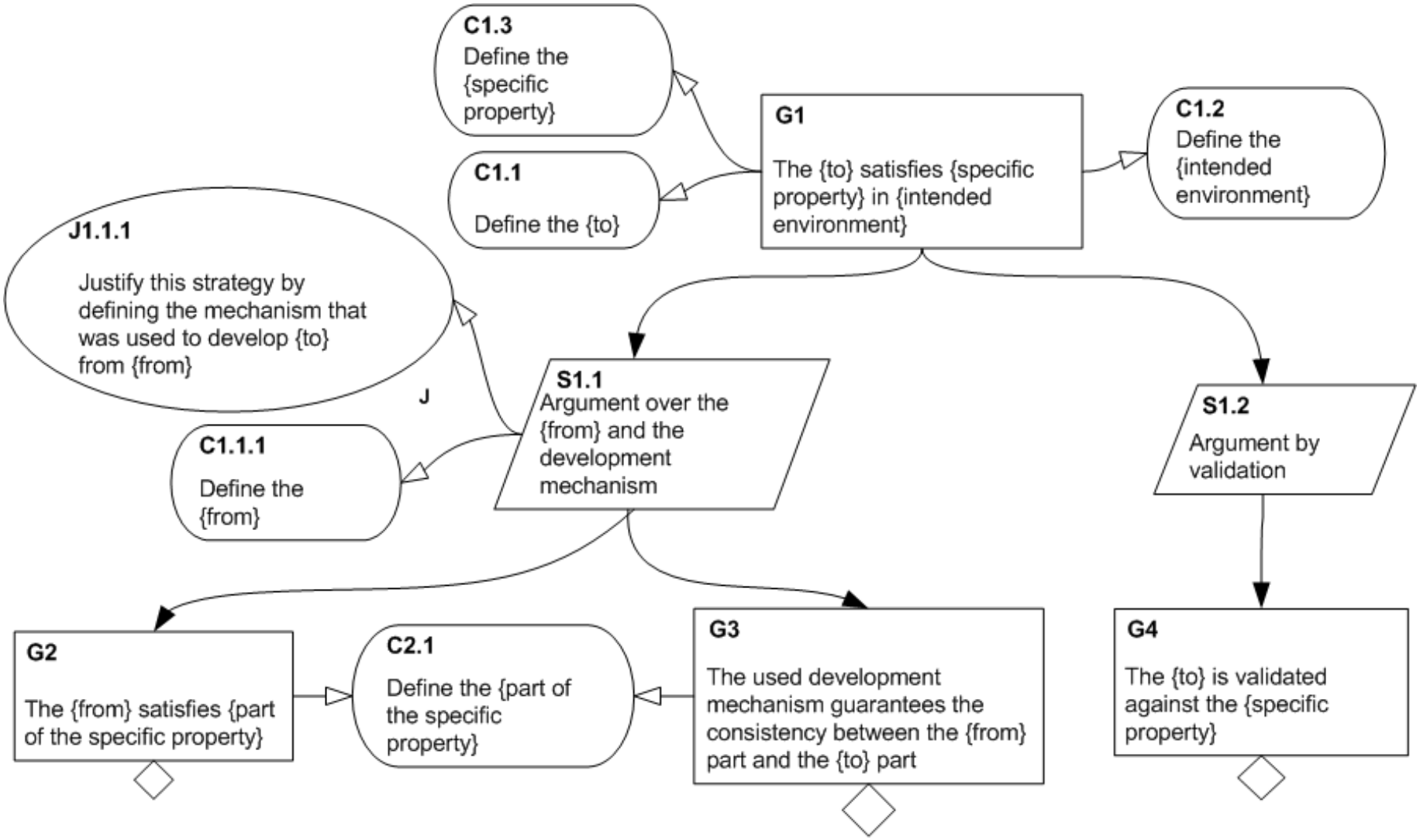
Tim Kelly, University of York, 1998

Safety Case Patterns -- Notation

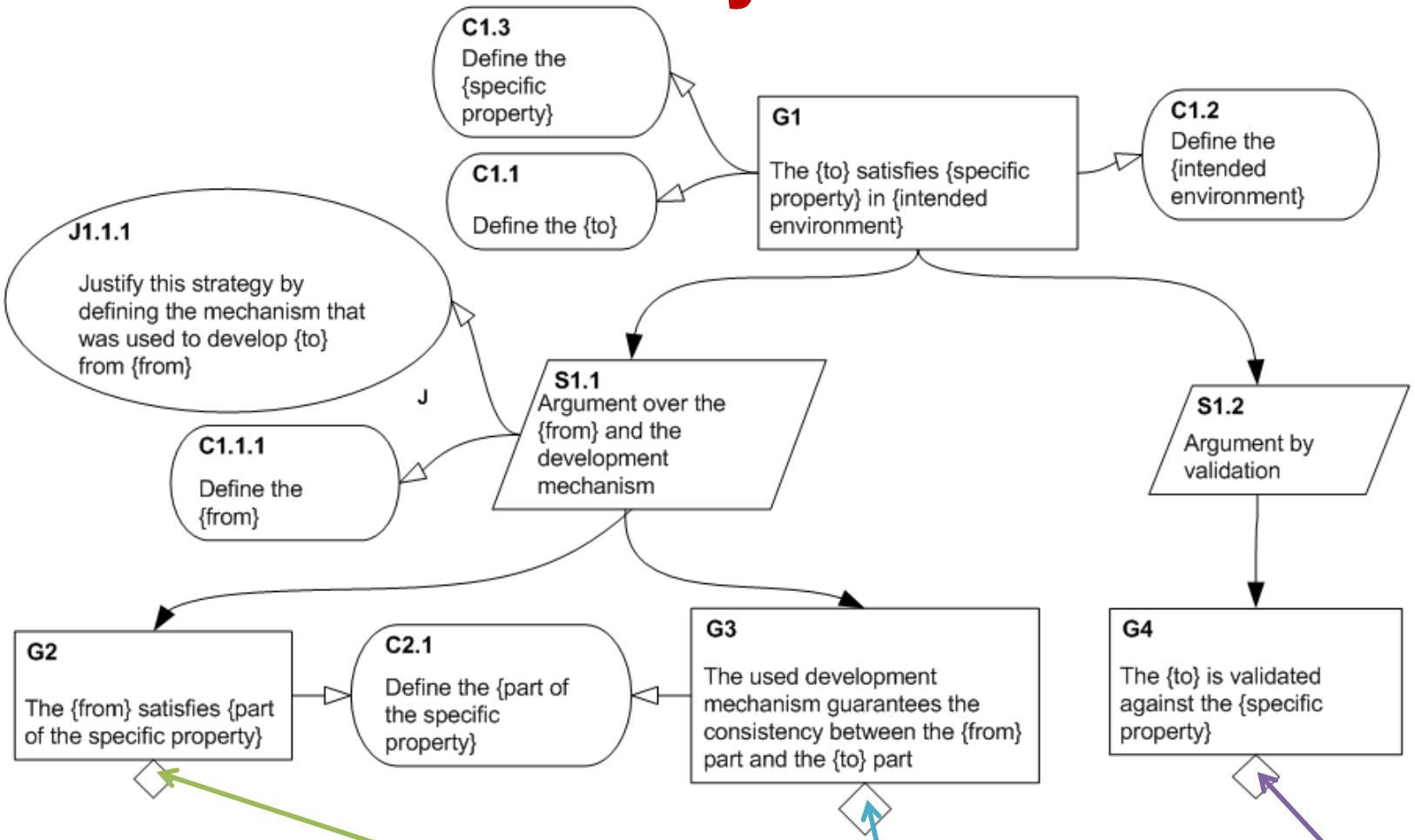
- Extended notation to represent patterns
- Each pattern needs to be appropriately documented



The PCA Safety Case – Safety Pattern

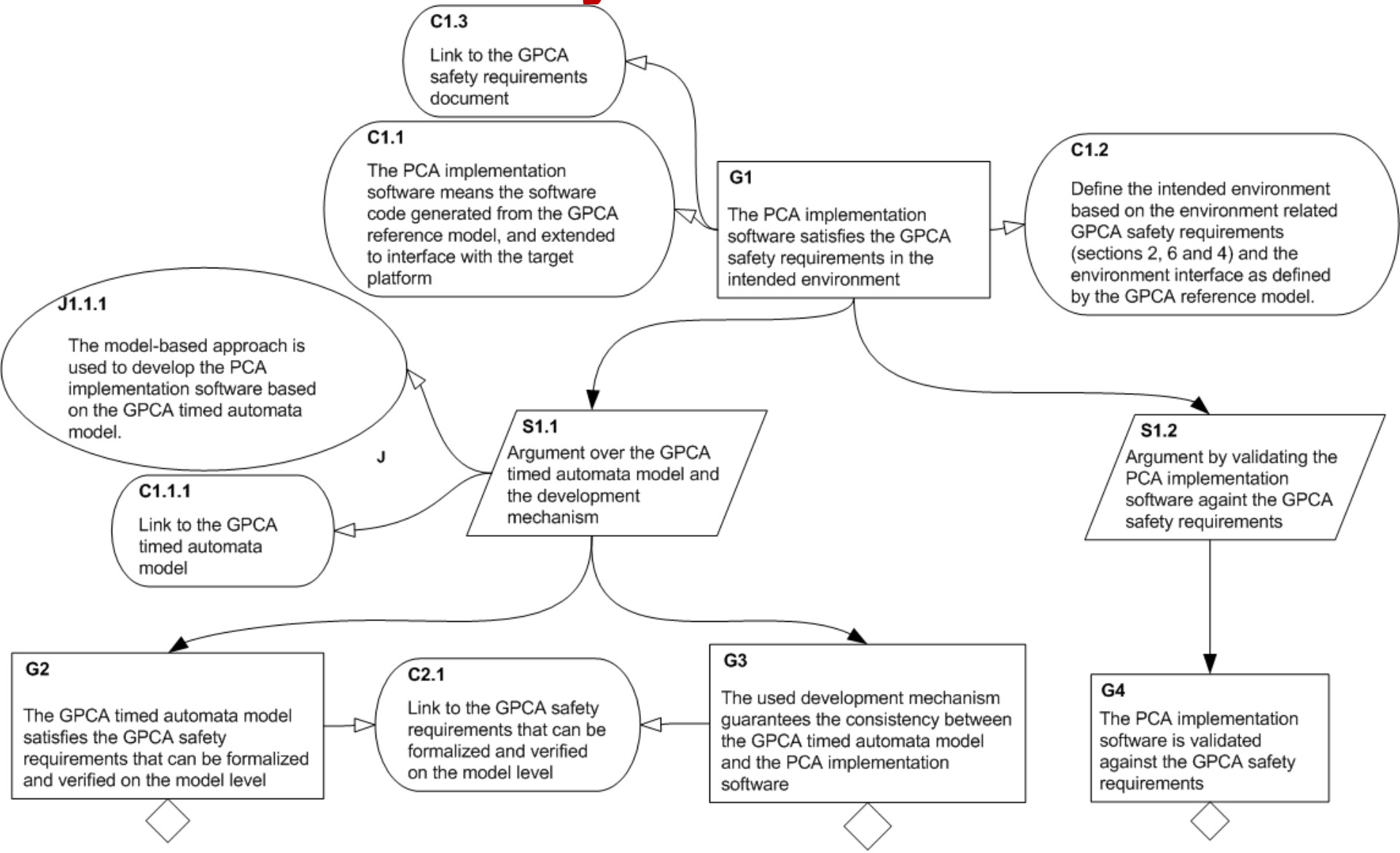


Mapping the Model-Based Approach to the Safety Pattern



(1) modeling the system → (2) verifying this model → (3) transformation the model into an implementation → (4) validating the implementation

The PCA Safety Case – Instantiation



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Conclusion

- The main contribution of this paper is to define a safety case pattern
- This pattern is appropriate to be instantiated when implementations are developed using model-based approaches

Questions?