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Process Modeling for Requirements Engineering: A Medical System Case Study

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What is the URML?

The URML is a visual language for early systems engineering. It can, during requirements elicitation also capture:

- ❑Hazards, Threats and Mitigations
- ❑Product Line Variations
- ❑Goals and Goal Conflicts
- ❑Processes and use cases (treated differently)
- ❑Differentiation between different types of requirements including regulatory, functional and non-functional

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Application of the URML to a Medical Process

Prior applications of the URML have been to internal Siemens projects and could not published. For a general case study, a generic medical process was chosen. Medical processes in general are difficult to model as they:

- involve subjective decisions on the part of the participants (e.g. nurses, doctors, patients)
- can involve complex administrative procedures
- may have many potential hazards, and
- are subject to heavy regulation.

The Phlebotomy Process

Phlebotomy is a process whereby blood is collected from a patient's veins, arteries or capillaries.

- Venous blood is obtained through venipuncture using a needle and blood collection tube or syringe.

- Arterial blood is collected though arterial puncture using a syringe, and

- capillary blood is obtained through skin puncture with a lancet and collection into a micro-container

The Phlebotomy Process

Phlebotomy as a process and a profession are recorded as far back as 5th Century BC

A Phlebotomist hard at work in ancient Egypt

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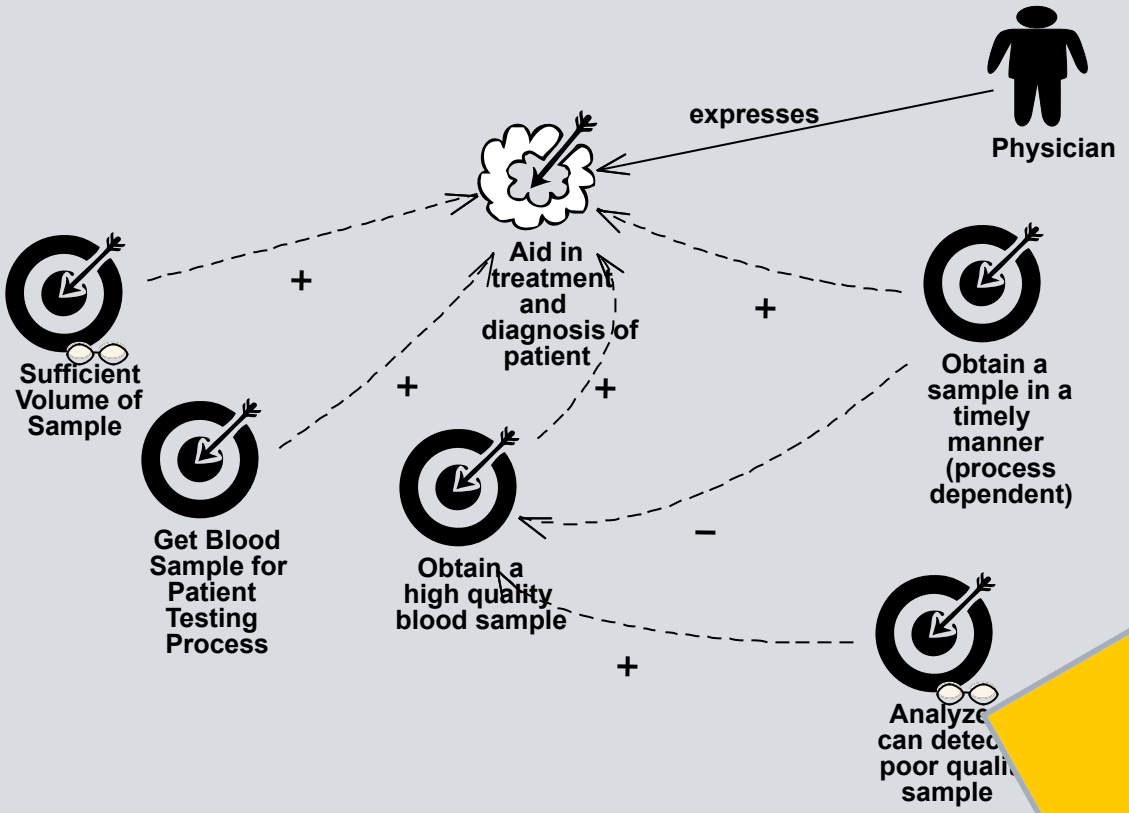
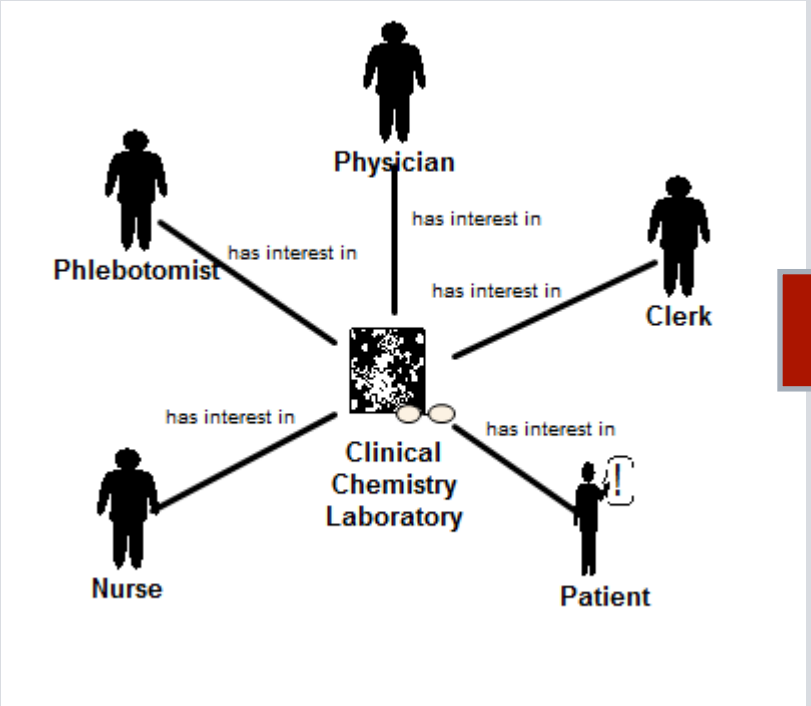
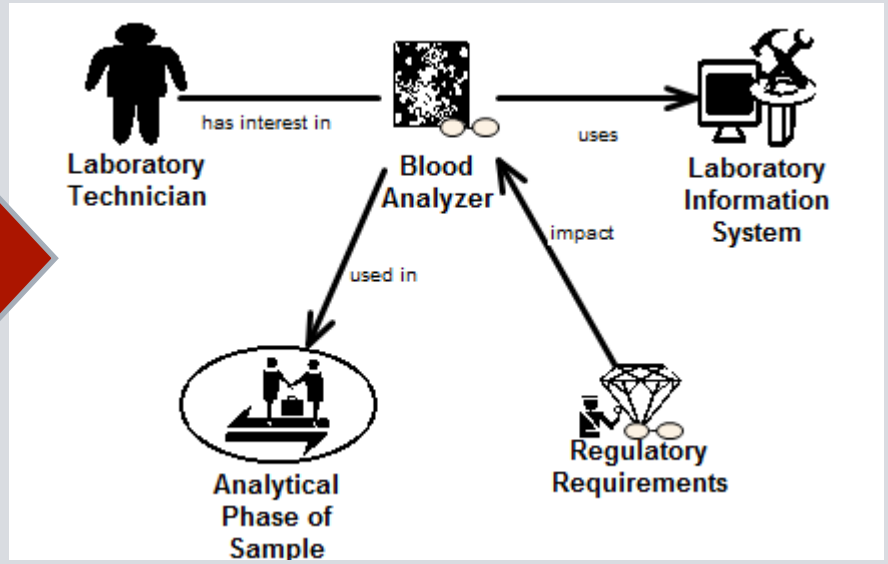
Goals of the Phlebotomy Process



Eyeglasses indicate an underlying diagram

Context and Process





External View

Internal View

Process Decomposition

Clinical Laboratory processes can be broken down into three phases:

- **pre-analytical process -** The pre-analytical phase begins with the order of the laboratory tests, sample collection, storage, transport, and sample preparation prior to entry into a laboratory analyzer.
- **The analytical process** - begins with entry of the sample into the analyzer and ends with the creation of the test result.
- **The post-analytical phase -** includes the quality check and release of the test results to the medical professional responsible for patient care and treatment.

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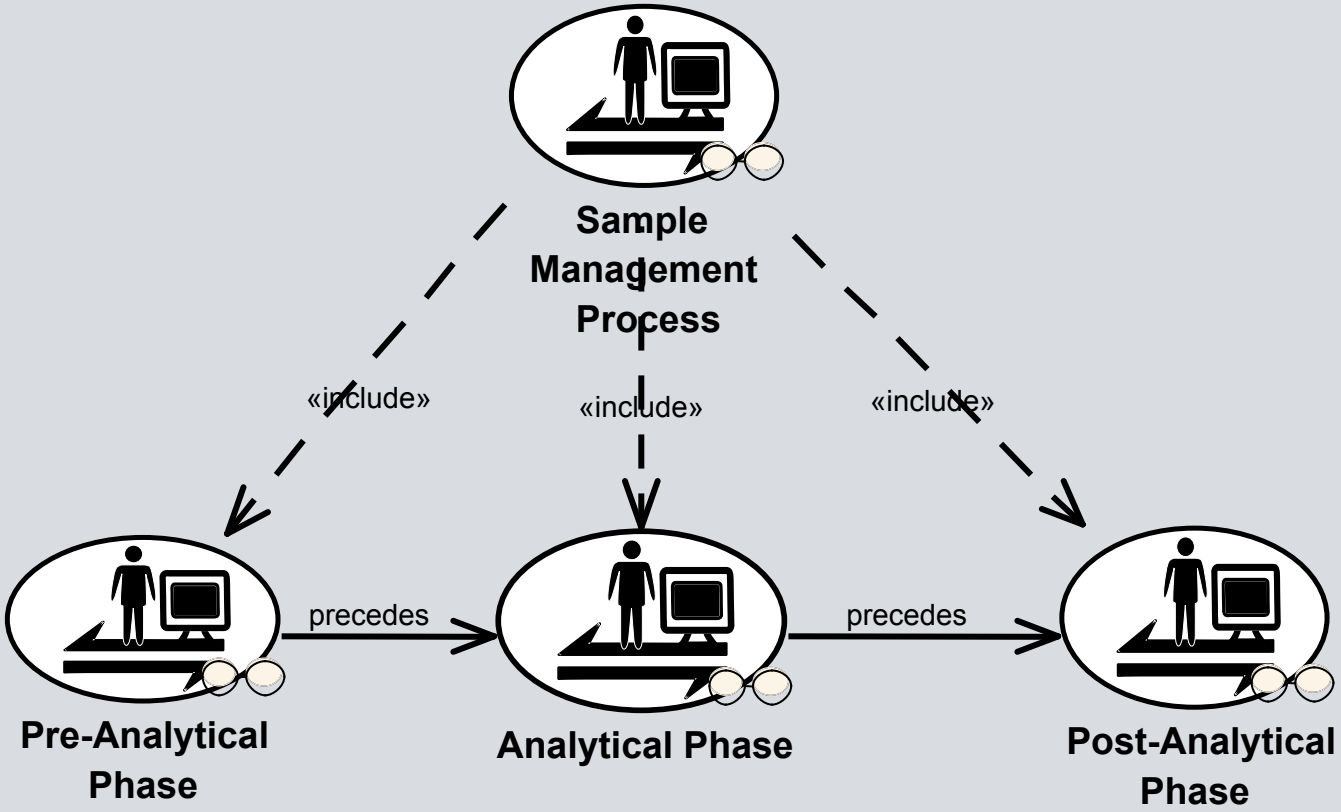
Three phases of the sample analysis process



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Pre-analytical phase

The pre-analytical process is greatly influenced by the interaction of patient care providers, patient and the phlebotomist . Due to these interactions and varied environments in which the phlebotomist performs his or her duty, it is an error prone (i.e. hazards) part of the total diagnostic process.

Unfortunately, errors in this phase often go undetected and can affect all downstream activities.

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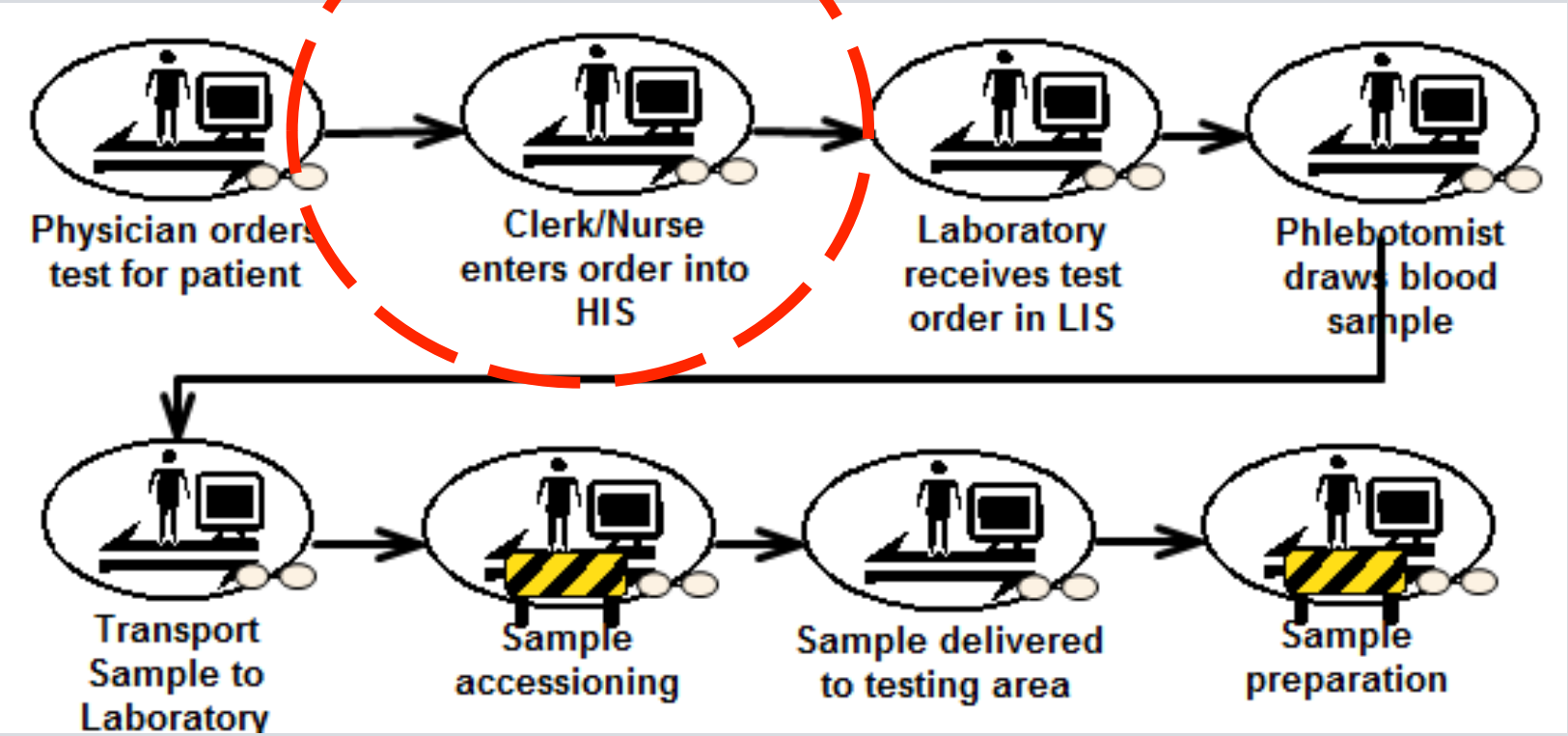
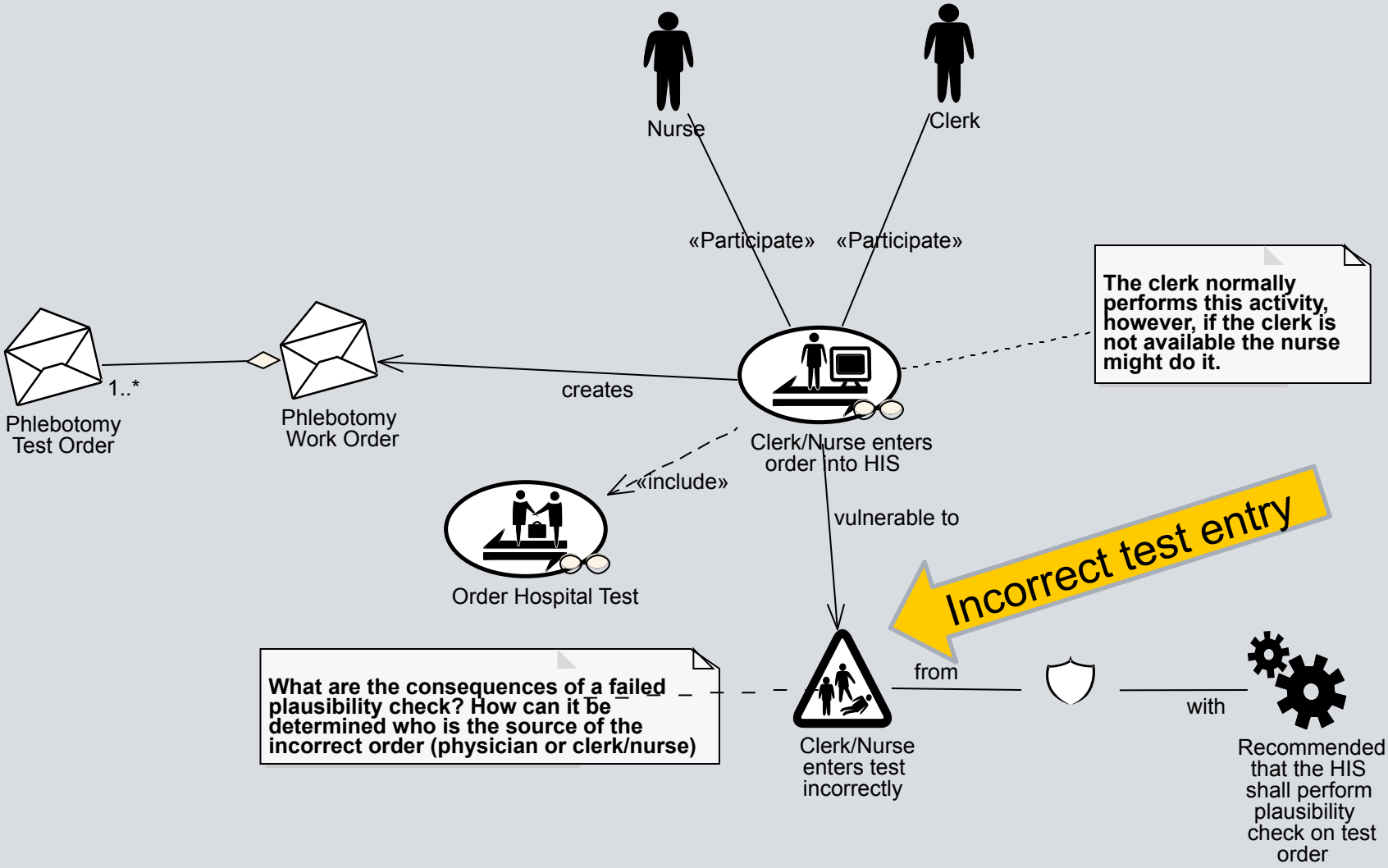
Pre-analytical phase



Visualization of potential problems



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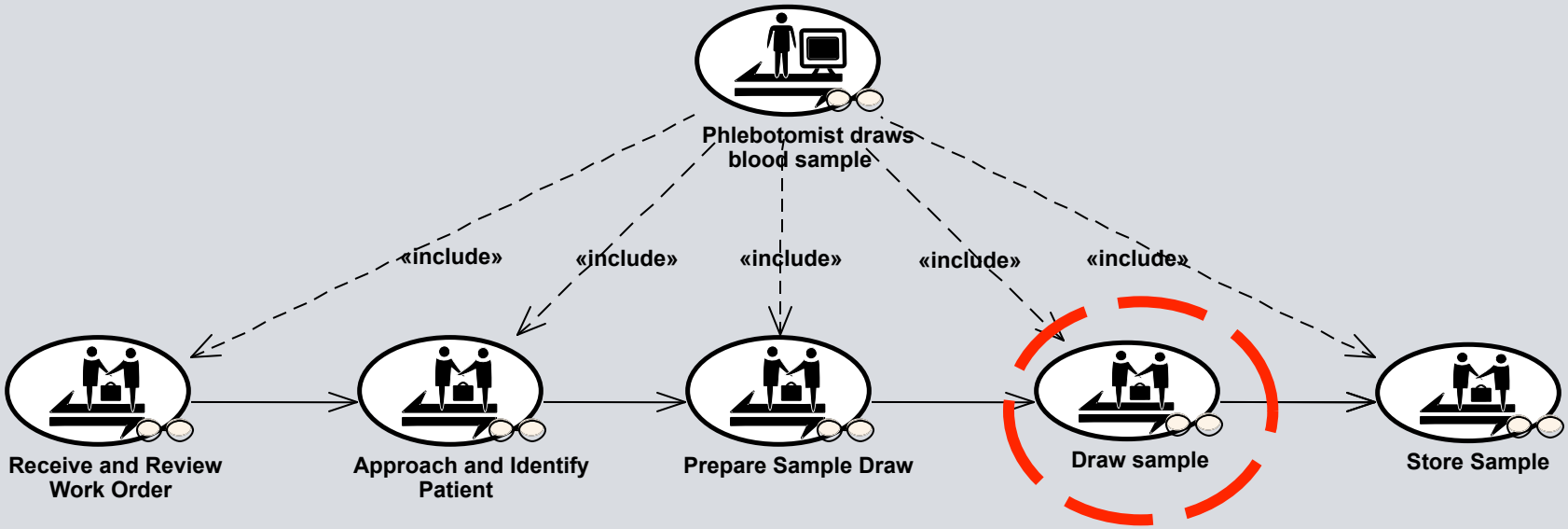
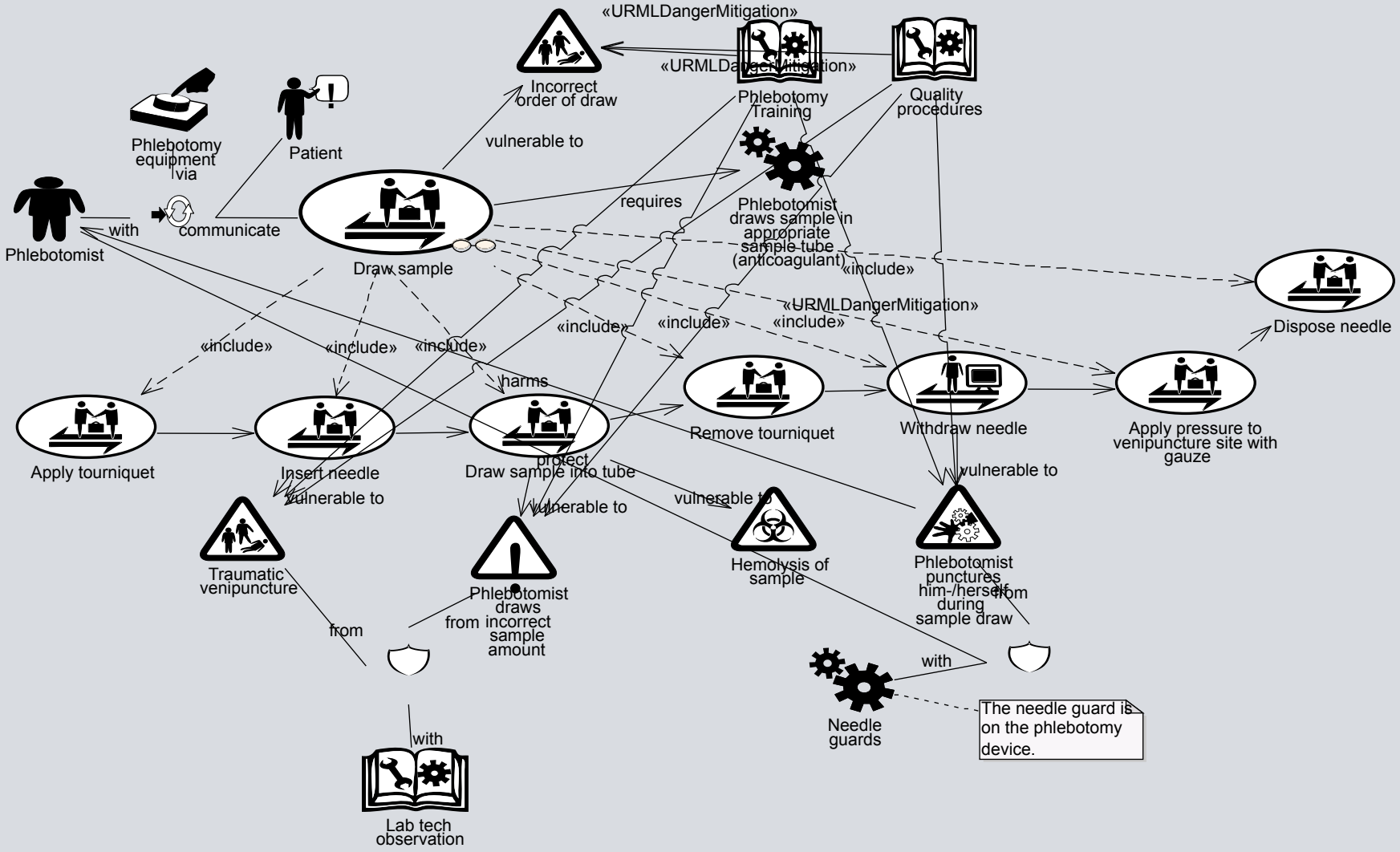
Processes around drawing a blood sample



Drawing a blood sample



Drawing a blood sample

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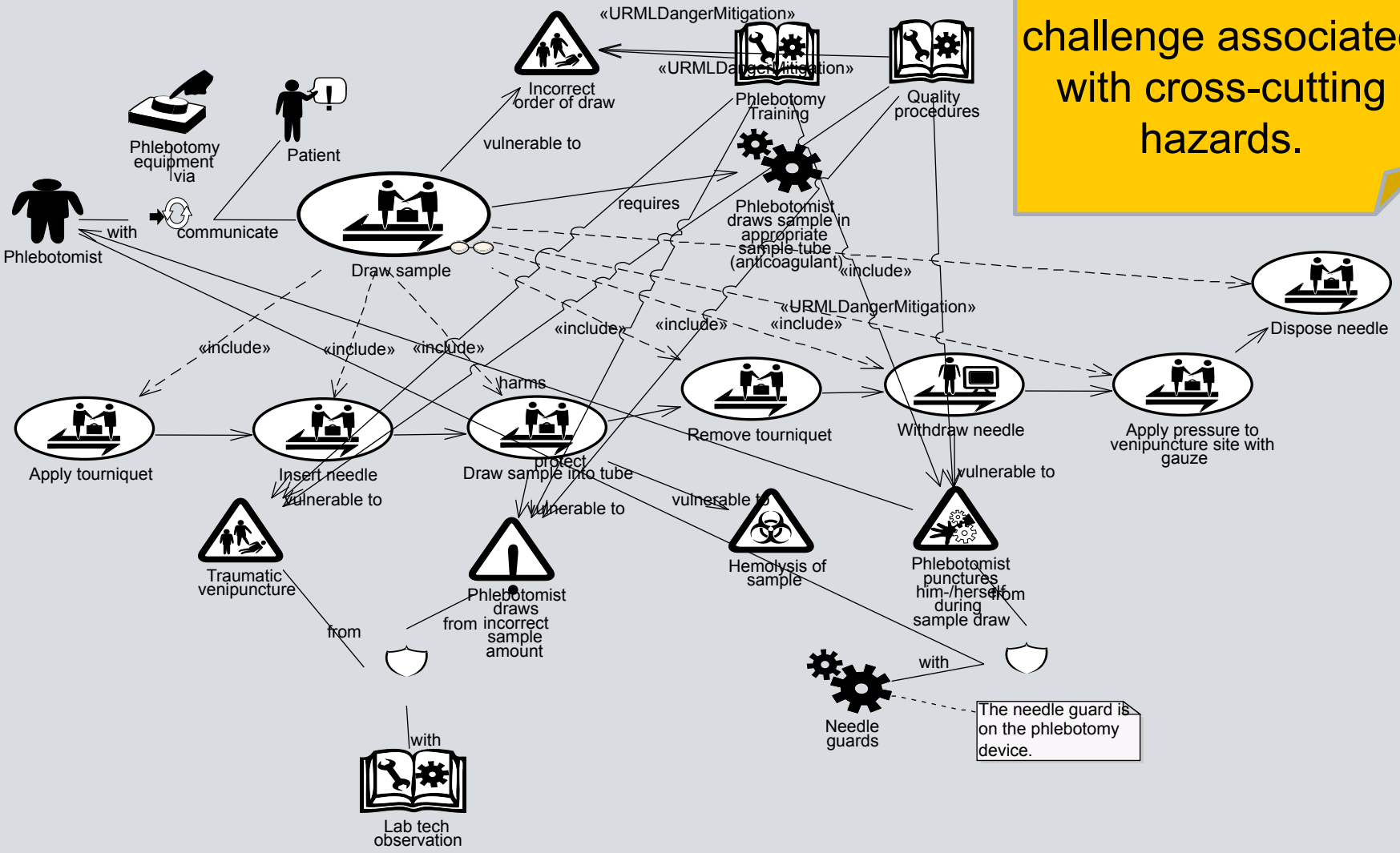
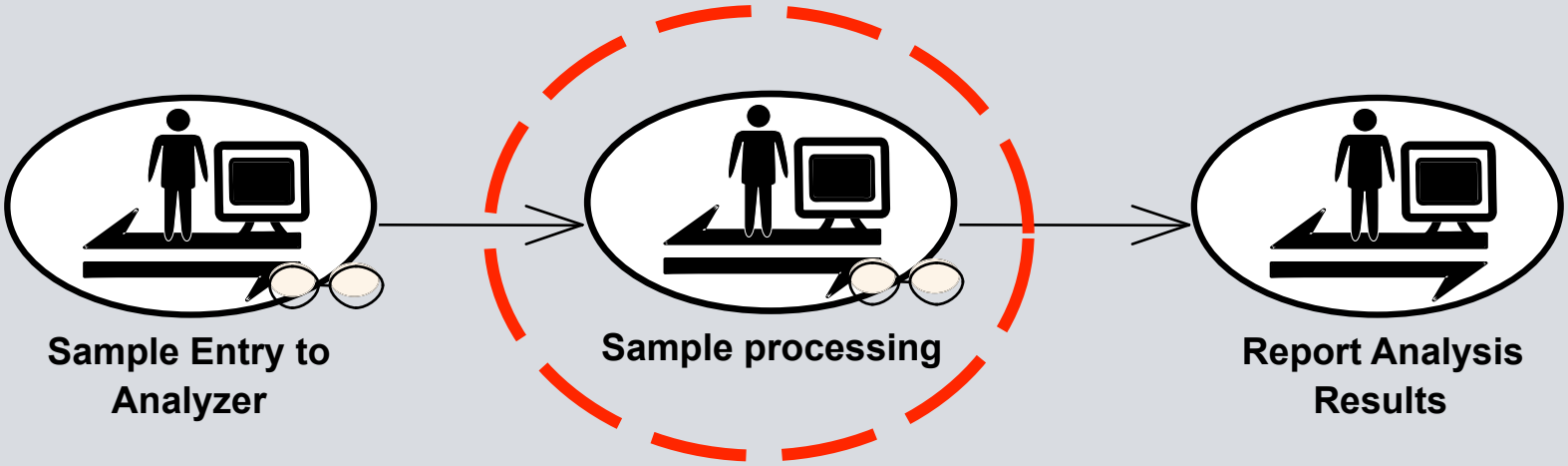
Here you can see the visualization challenge associated with cross-cutting hazards.



Analytical Phase of Process



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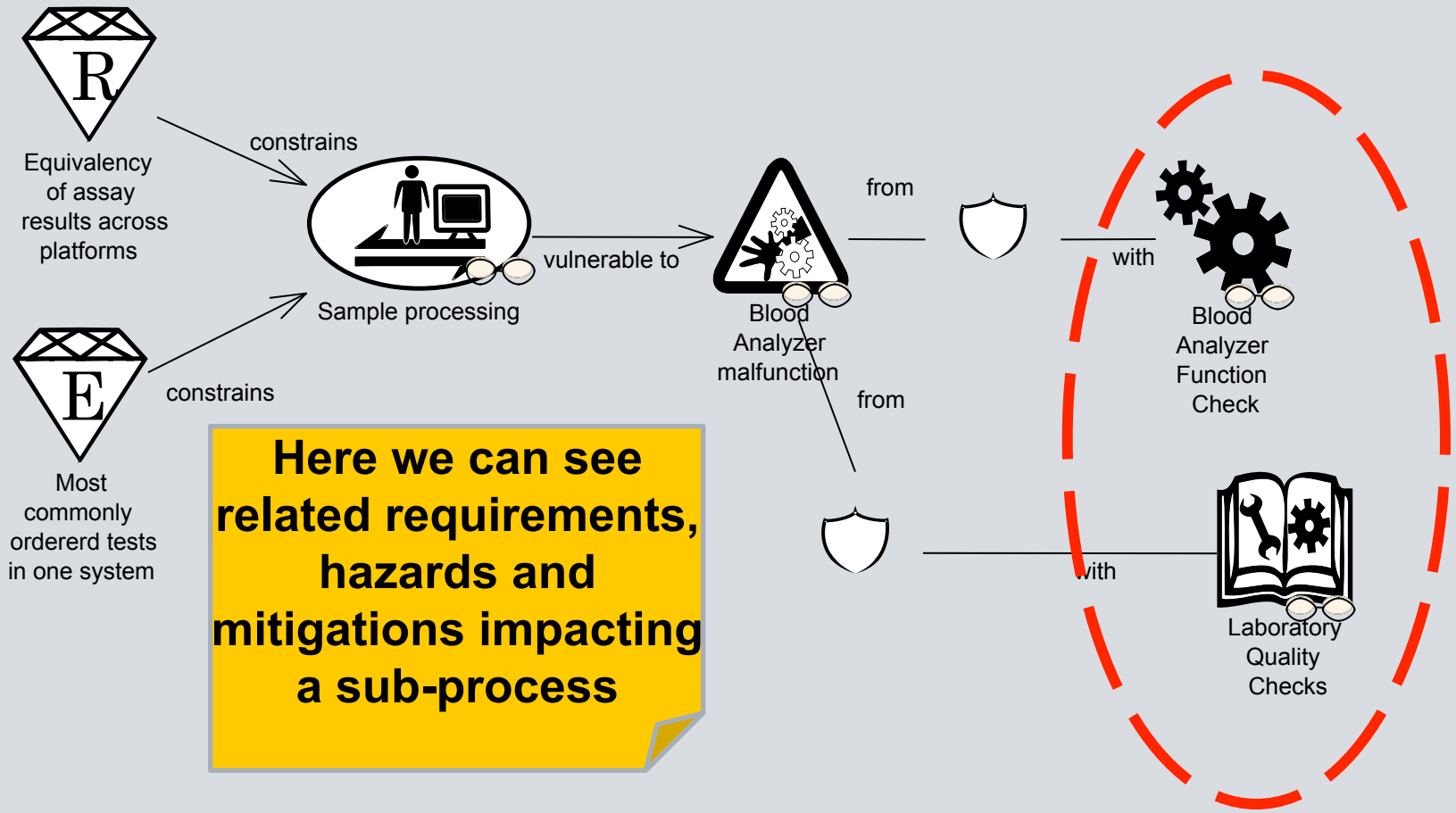
Sample Processing



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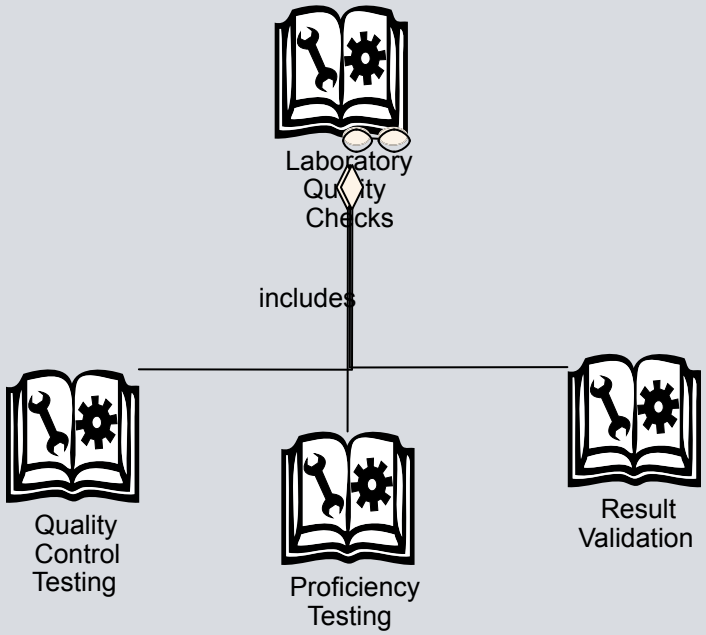
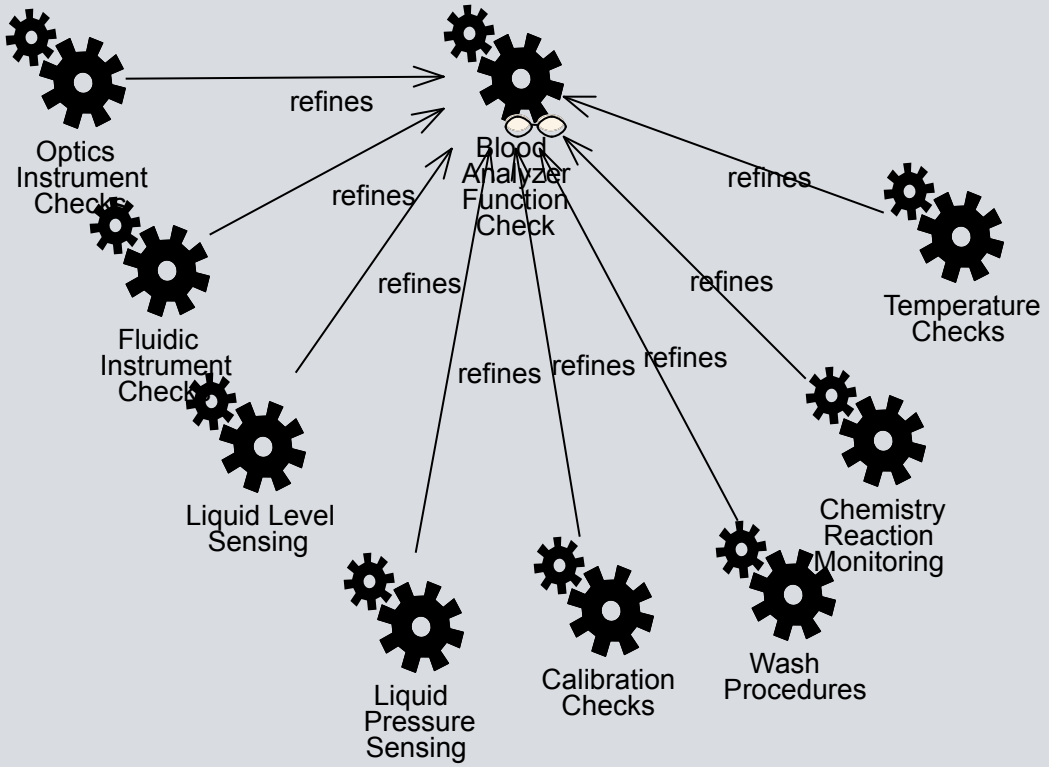
Procedural and requirement mitigations captured during elicitation

Sample processing is vulnerable to instrument malfunction. This can be mitigated technically by instrument function checks or non-technically by quality checks in the laboratory



Procedural Mitigations



Mitigating Requirements

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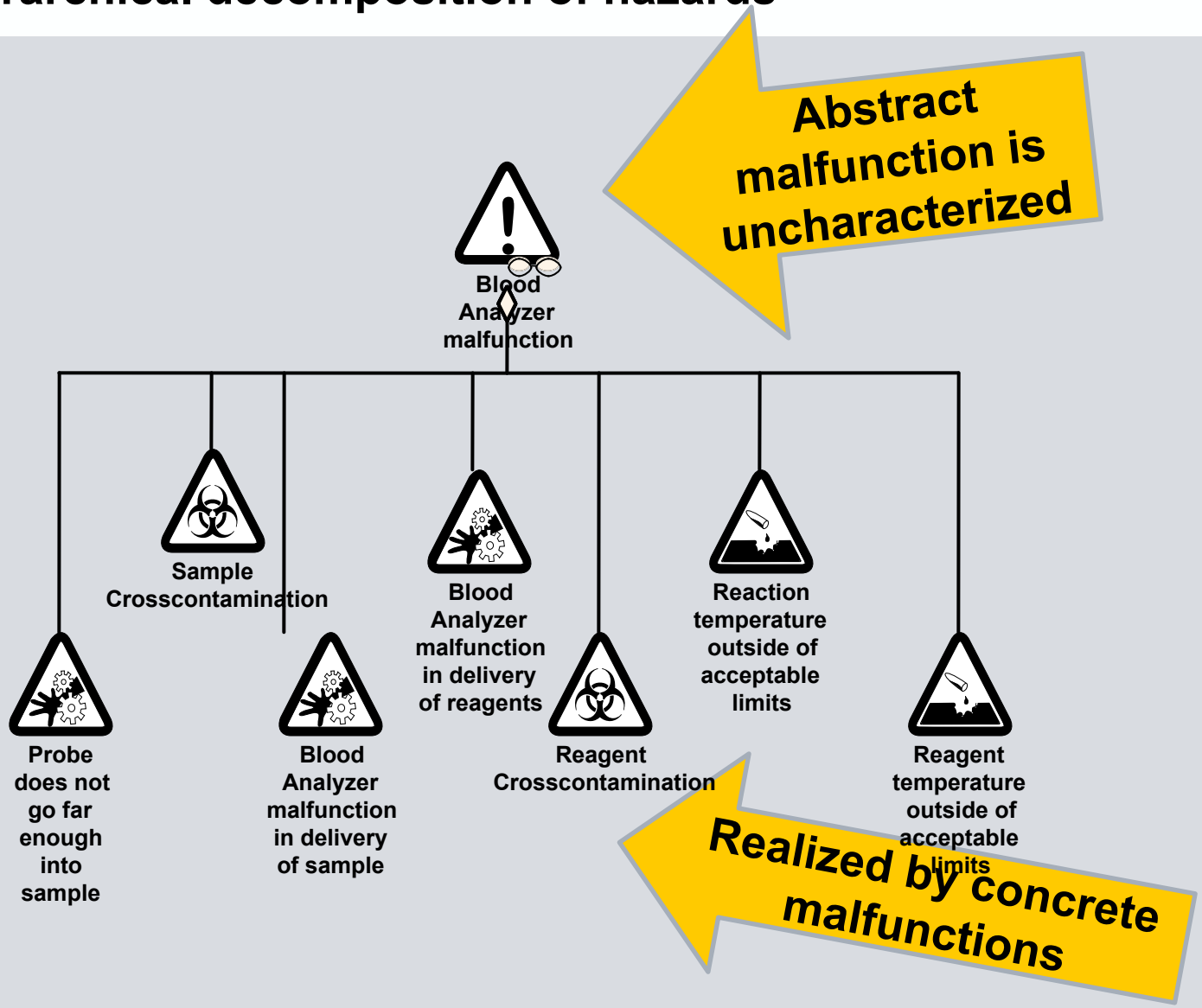
Hierarchical decomposition of hazards



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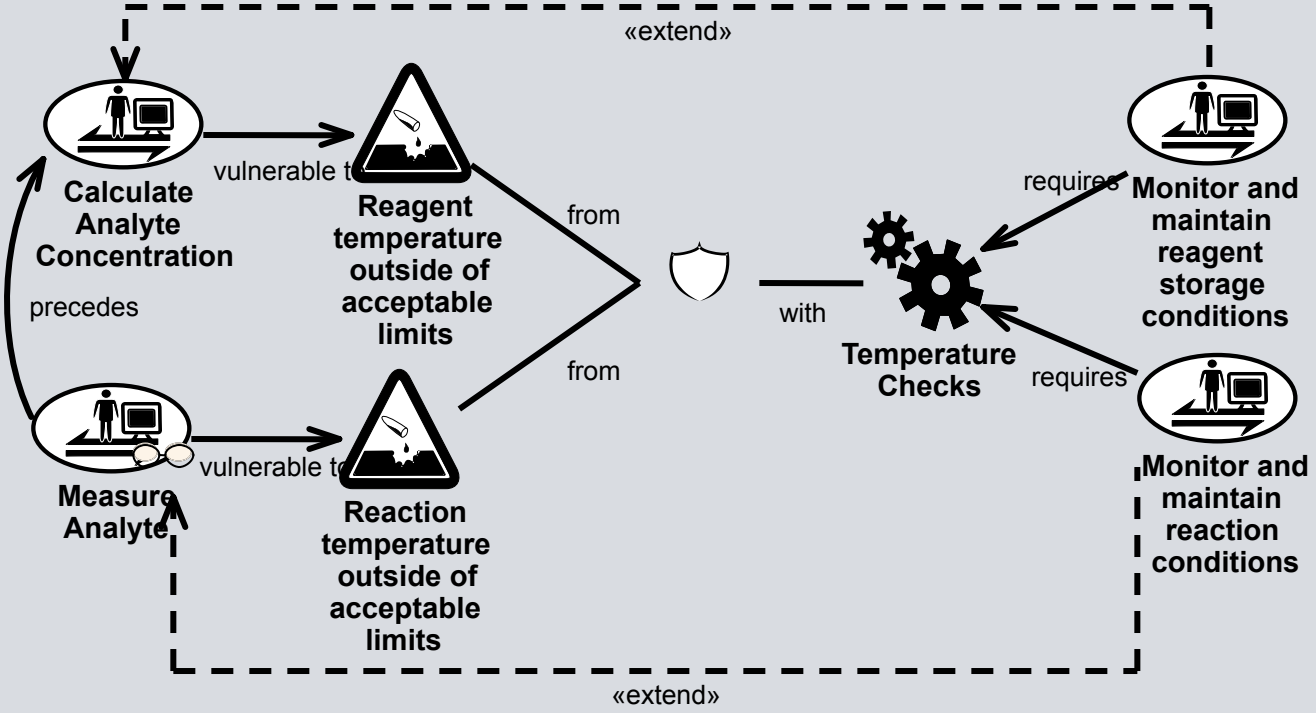
Multiple Process Mitigation

We can show sub-processes that are vulnerable to **dangers related to wrong temperature**. Both can be technically mitigated by the requirement to have temperature sensors in the analyzer. A diagram can also show that there might be a future requirement for multiple sensors, as they are needed by different use cases



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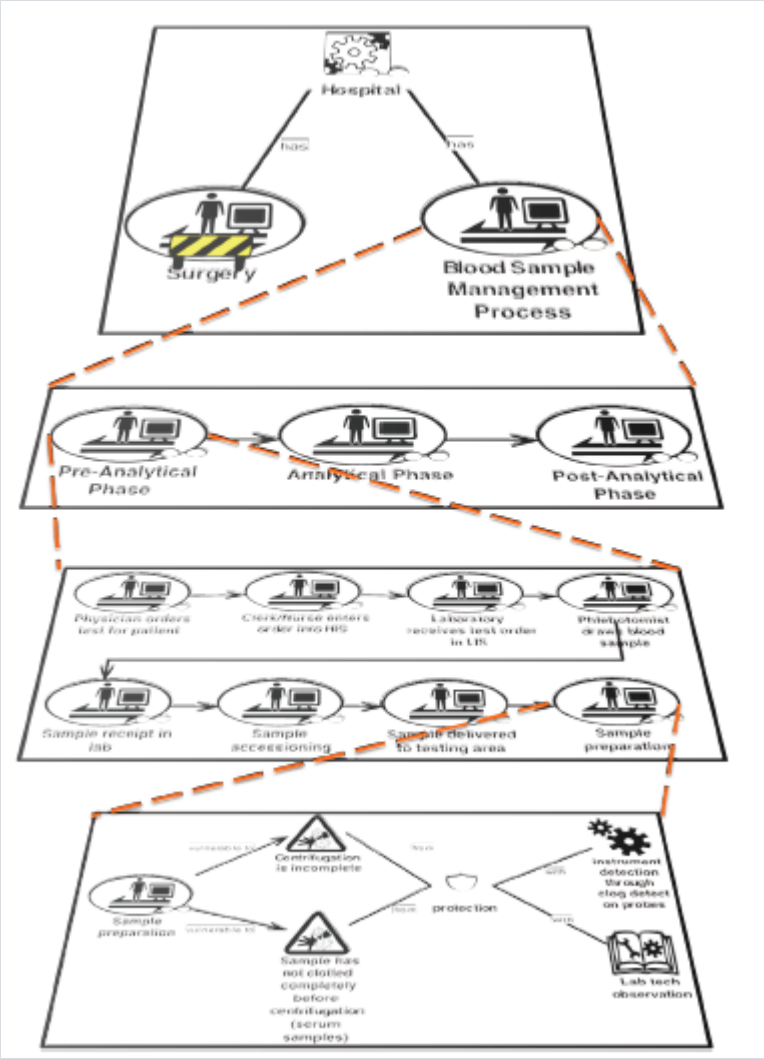
Hierarchical decomposition of use cases

Hazards and mitigations are first class concepts, captured as they are encountered



They are an integral part of the model

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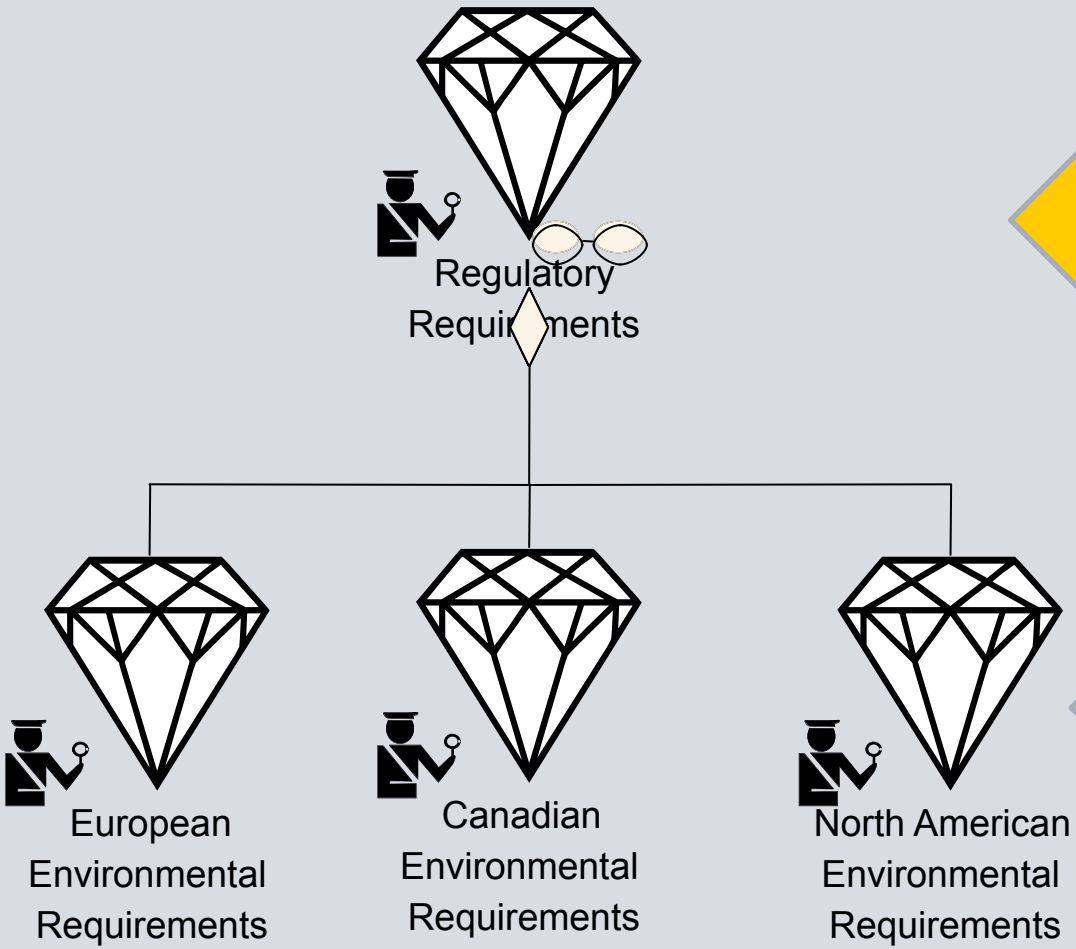
Regulatory Codes can be analyzed and decomposed



Regulatory requirements can be captured during elicitation.

They can be modeled as first class concepts.

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What a medical expert liked about the URML

- The URML allows requirements elicitation to follow the natural flow for the application domain being studied
- Process steps are examined in the context of the environment- including external influences such as regulations and organizational structure
- Risks and Hazards are captured at the time of elicitation- including “unspoken” requirements and user errors
- The ability to move up or down in the model hierarchy when detailed discussions were ongoing in one area of the model was very useful.

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Areas for improvement for medical processes

- The URML needs an online guide so that different modelers can work on different sections of a complex model.
- Have 1 or 2 modelers set up the model skeleton for consistency
- Regulatory requirements impact many sections of a healthcare system model, the treatment of regulatory elements needs to be further explored

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Some general thoughts from the Domain Expert

"->I found the URML to follow my natural way of thinking of processes, workflow and environment in the hospital. Many times when eliciting requirements, analysts try to force a system design structure, which leaves a lot of unspoken needs.

->It was very easy to define hazards when modeling the process steps. User related hazards and mitigations were elicited in context.

-> Regulatory impacts are another useful piece, & many of the regulatory req. can be reusable from project to project."

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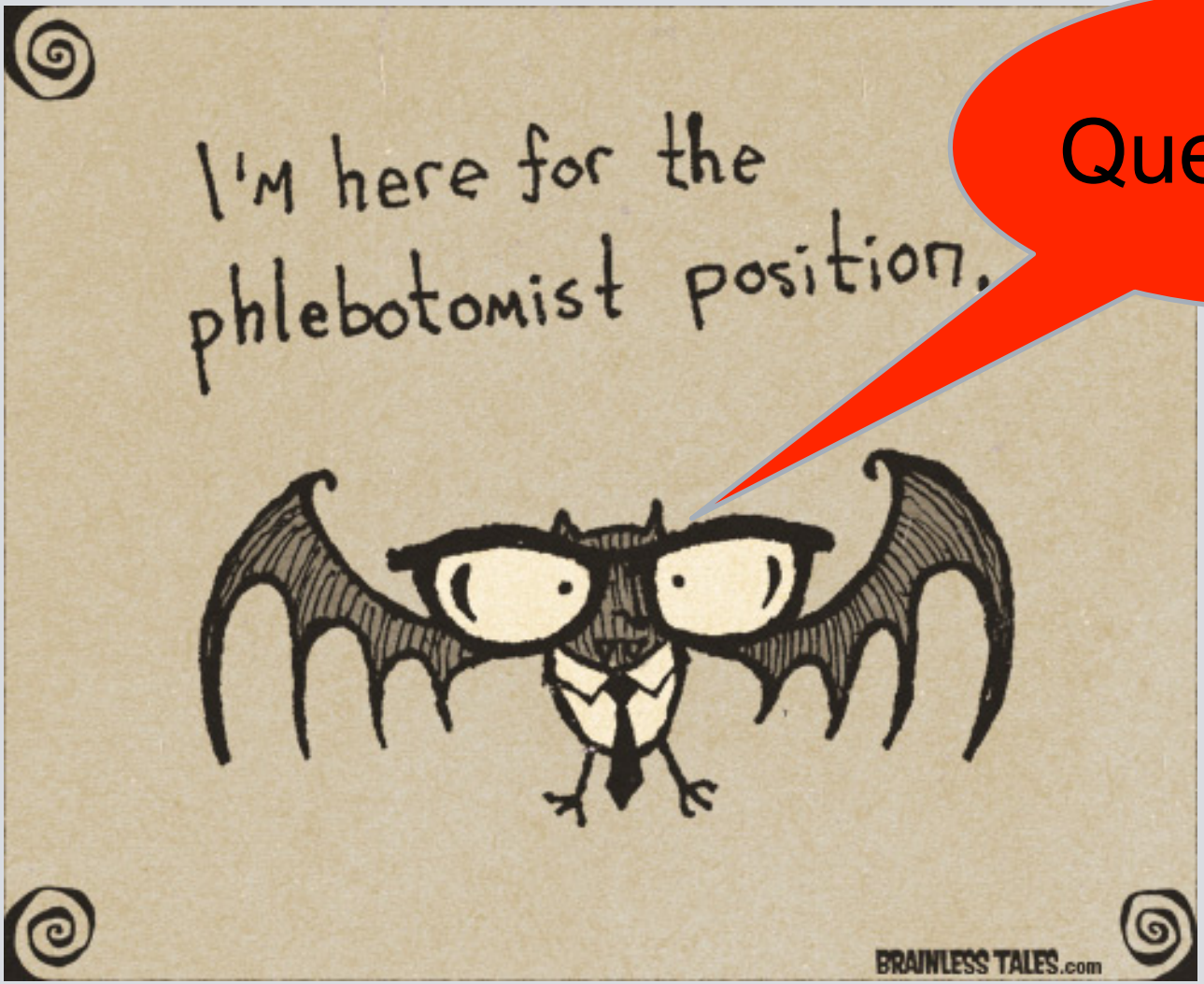
Areas for future research

- How much regulatory information should be included in an analysis model?
- The relationship of internal and external processes and use cases needs to be formalized/clarified
- Above and beyond the connectivity rules provided by the URML meta-model, construction and validation rules are needed
- When adding hazards and mitigations to a medical model, the complexity increases rapidly, e.g. a hazard cross-cutting many processes. How best to show that?
- How to integrate the analysis and design space, while still keeping a wall between them for review purposes?



Questions?