

**Good morning
and
Welcome!**

4 QUALITY EDUCATION

9 INDUSTRY, INNOVATION AND INFRASTRUCTURE

11 SUSTAINABLE CITIES AND COMMUNITIES

Associate professor of dependable software systems

employed at



conducts research aligned with

plays role

DVA437 Safety Critical Systems Engineering-H24
OAI400 Functional Safety of Battery Management Systems (BMS)-H24

manages & teaches

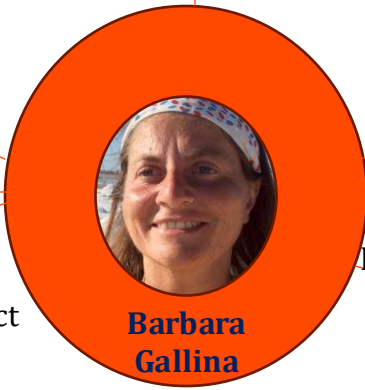
gives presentation on

Ontology-based representation for assurance and compliance

has e-mail address

barbara.gallina@mdu.se

runs research project



Collaborates within

#49-4DASafeOps - Standards, Assurance Case, Process, Product-Aware SafeOps - focus on variability management
#50-ET4CQPPAJ - Trace Evidence 4 Continuous Quality Product Process Assurance Justification - focus on traceability

has partner

Collaborates within



A graph-based knowledge representation!

**Assuming the underlying existence of:
an ontological underpinning
and reasoning engine**

it is Knowledge Graph!

- **What is a knowledge graph?**
- **What is an ontology?**
- **How can an ontology be developed?**
- **How can an ontology be represented?**

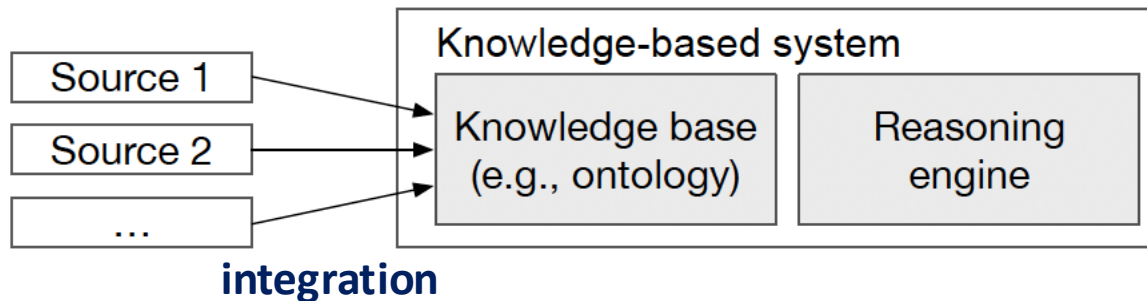
- **Why does all this matter for assurance and compliance?**

- **What is assurance?**
- **What is compliance?**

- **Pieces of solution towards the ontology-based representation for assurance and compliance**

What? Knowledge Graph

“A knowledge graph acquires and integrates information into an ontology and applies a reasoner to derive new knowledge.”



Lisa Ehlringer and Wolfram Wöß. *Towards a Definition of Knowledge Graphs*.

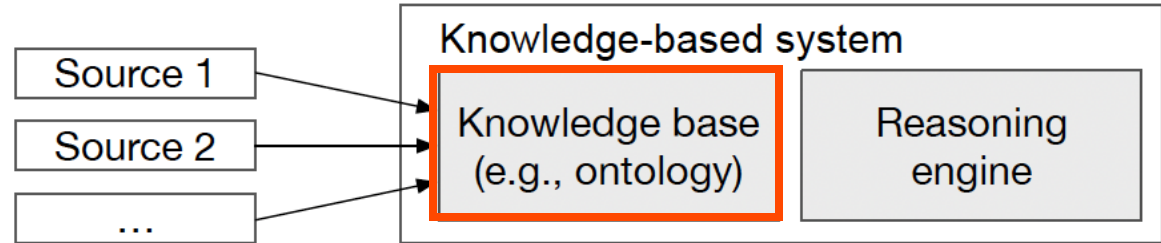
Joint Proceedings of the Posters and Demos Track of the 12th International Conference on Semantic Systems- SEMANTiCS2016 and the 1st International Workshop on Semantic Change & Evolving Semantics (SuCCESS'16) co-located with the 12th International Conference on Semantic Systems (SEMANTiCS 2016) Leipzig, Germany, September 12-15, 2016.

Do you know any knowledge graph?

The Semantic Web!

What? Ontology

An **ontology** is a formal description providing human users a shared understanding of a given domain



METHONTOLOGY: From Ontological Art Towards Ontological Engineering

Mariano Fernández, Asunción Gómez-Pérez, Natalia Juristo

Specification – purpose specification, *competency questions* (*)

Conceptualisation – terms distinguished from verbs

Formalisation – transform the conceptual model of the ontology into a formal model

Integration

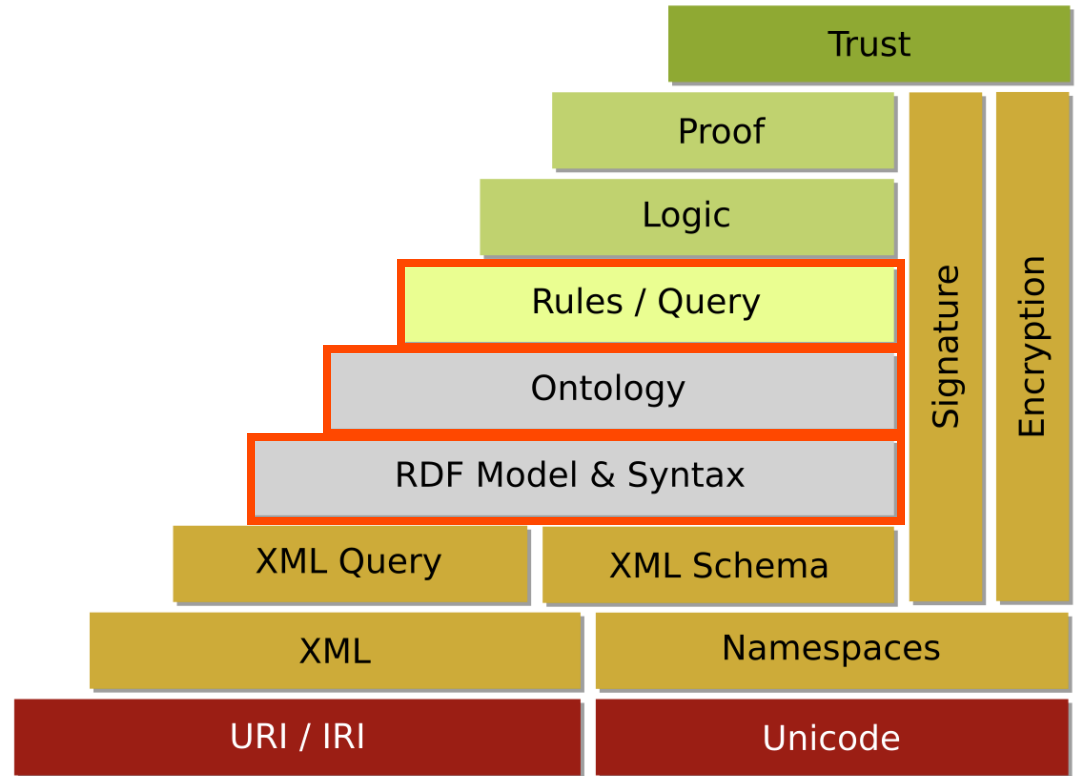
Implementation

Maintenance

(*) questions that the ontology must be able to answer

Competency questions capture the functional requirements of the ontology

What? Ontology representation



Source: <https://it.wikipedia.org/wiki/File:W3c-semantic-web-layers.svg>

What? RDF – Resource Description Framework

A standard for capturing triples

a simple language for writing statements about Web resources identified by URIs.

An RDF document is a set of RDF statements

An RDF statement expresses a relationship between two resources.

The **subject** and the **object** represent the two resources being related

The **predicate** represents the nature of their relationship

The relationship is phrased in a **directional way** (from subject to object) and is called in RDF a **property**.

We can visualize triples as a connected **graph**. Graphs consists of nodes and arcs.



Informal textual representation of the previous graph-based representation

Barbara Gallina
Barbara Gallina
Barbara Gallina
#49-4DASafeOps

plays role
gives presentation on
runs project
has partner

Associate Professor of Dependable Software Systems
Ontology-based representation for assurance and compliance
#49-4DASafeOps
Bosch

Source: <https://www.w3.org/TR/rdf11-primer/#section-data-model>

What? RDF –Resource Description Framework



RDF graphs can be textually specified. Different textual syntax can be used:

- Turtle
- RDF/XML
- etc.

What? OWL

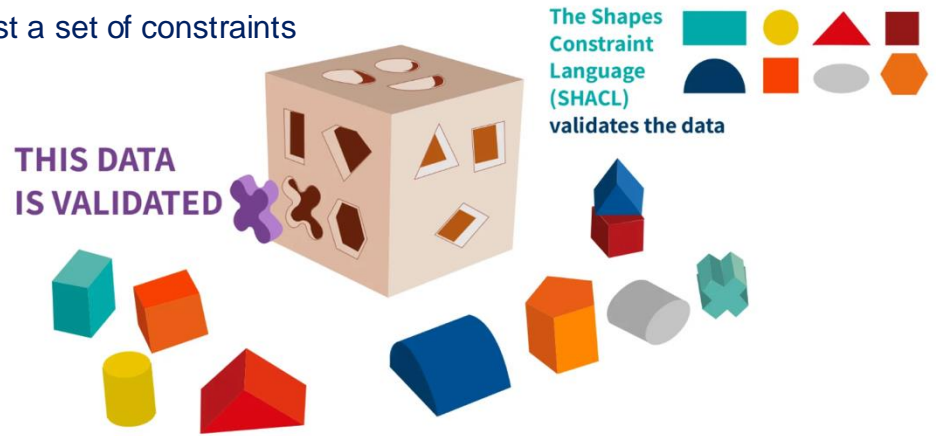
OWL-Web Ontology Language

Allows for the definition of the semantics of RDF statements.

The main building blocks of an OWL ontology are classes.

What? SHACL

A standard for a language for validating RDF graphs against a set of constraints



[source: <https://www.ontotext.com/knowledgehub/fundamentals/what-is-shacl/>]

SPARQL-SPARQL Protocol and RDF Query Language

A standard for querying the knowledge graphs, as well as constructing them

Query forms:

-**SELECT** - Returns all, or a subset of, the variables bound in a query pattern match

-**CONSTRUCT** -Returns an **RDF graph** constructed by substituting variables in a set of triple **templates**

-**ASK** - Returns a boolean indicating whether a query pattern matches or not

-**DESCRIBE** -Returns an **RDF graph** that describes the resources found

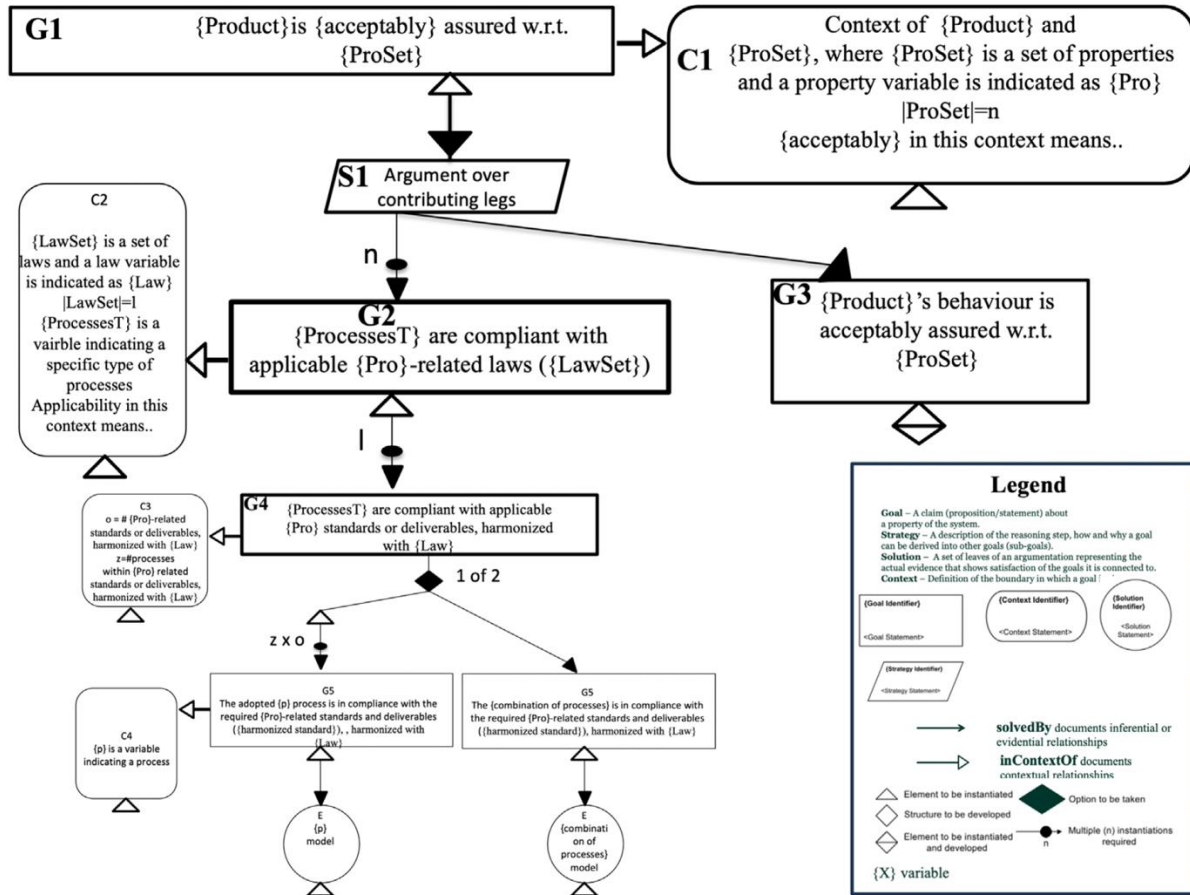
**Why does all of this matter for assurance
and compliance?**

Assurance “grounds for justified confidence that a claim has been or will be achieved”

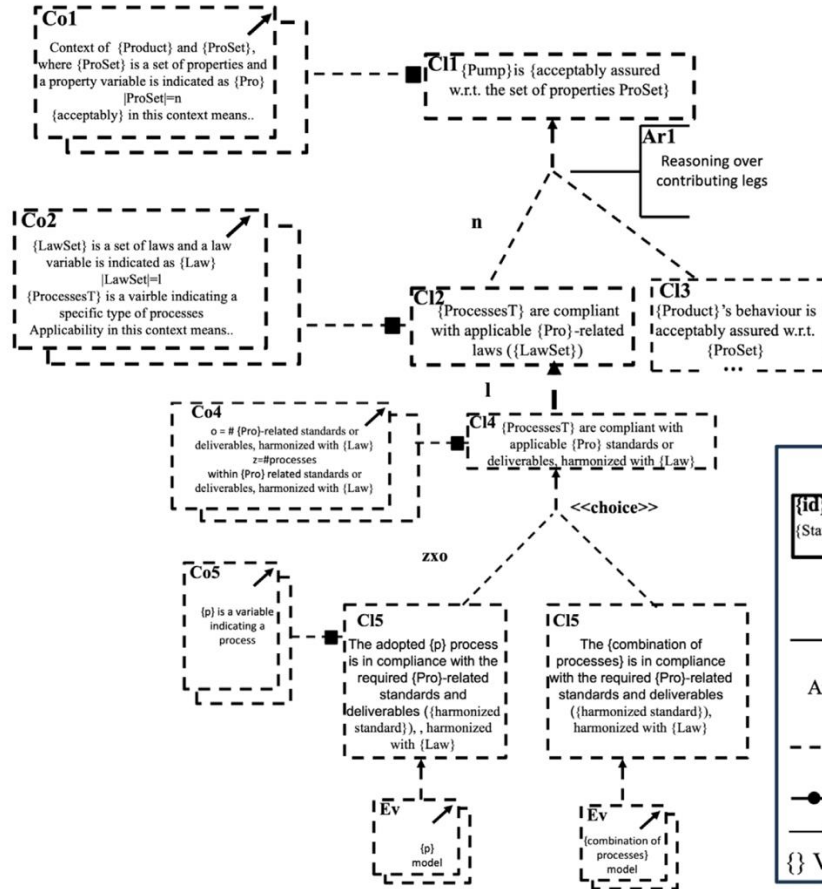
[ISO/IEC JTC 1/SC 7, ISO/IEC 15026: Systems and software engineering — Systems and software assurance, Part 1: Concepts and vocabulary (2019)]

Multiconcern assurance means grounds for justified confidence that multi-concern claims have been or will be achieved, as well as arguments that those claims about multi-concerns are justified by the evidence about the system

GSN pattern proposal



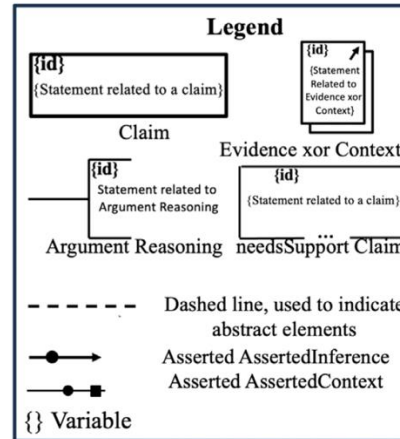
What? Assurance



SACM pattern proposal

Are you instead **text-inclined?**

The information could be rendered in structured prose!



Compliance “meeting all the organization’s compliance obligations”

[ISO 37301:2021 Compliance management systems — Requirements with guidance for use]

Compliance obligations - “ requirements that an organization mandatorily has to comply with as well as those that an organization voluntarily chooses to comply with. ”

[ISO 37301:2021 Compliance management systems — Requirements with guidance for use]

I

(Legislative acts)

Machinery Regulation

REGULATIONS

REGULATION (EU) 2023/1230 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 14 June 2023

on machinery and **repealing Directive 2006/42/EC** of the European Parliament and of the Council
and Council Directive 73/361/EEC

(Text with EEA relevance)

- On 17 October 2024, the Regulation **on horizontal cybersecurity requirements** for products with digital elements and amending Regulation (EU) 2019/1020 entered into force.
- On 25 July 2024, the Directive on corporate **sustainability** due diligence (Directive 2024/1760) entered into force.
- On 17 August, 2023, Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning **batteries and waste batteries** has entered into force.
- On 1 August, 2024, The AI Act - Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down **harmonised rules on artificial intelligence** has entered into force.
- Product Liability Act ...

When is it necessary to care about assurance and compliance?

...continuously...

Typical *Kaizen* PDCA cycle

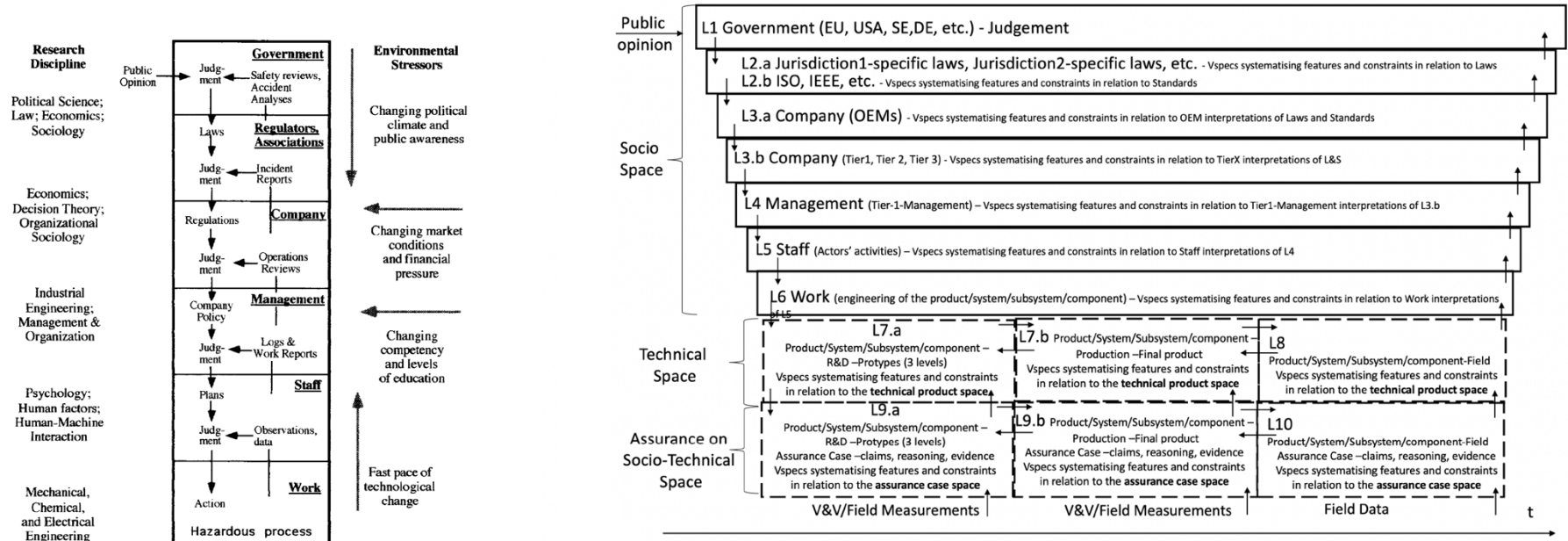
Change for the better
Continuous improvement



Claims + Evidence
Claims + Argument + Evidence

Vision: Knowledge graph capturing the socio-technical system

[Gallina et al.2024a]



J. Rasmussen, "Risk management in a dynamic society: a modelling problem," *Safety Science*, vol. 27, no. 2, pp. 183–213, 1997.

J. Rasmussen and I. Svedung, *Proactive Risk Management in a Dynamic Society*. Swedish Rescue Services Agency, 2000.

B. Gallina, Peter Munk, Markus Schweizer.

An Extension of the Rasmussen Socio-technical System for Continuous Safety Assurance.

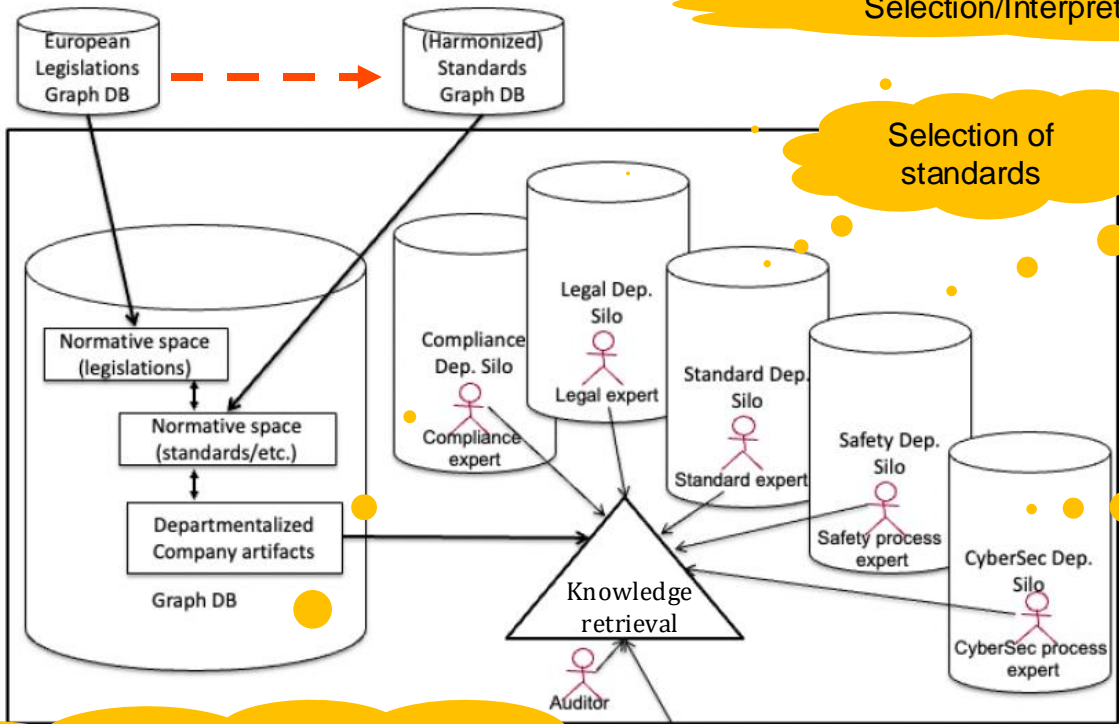
Proceedings of 8th International Workshop on Critical Automotive Applications: Robustness & Safety (CARS), Leuven, Belgium, April 8th, 2024. Soon available at HAL archives ouvertes.fr

B. Gallina, T. Young Olesen, E. Parajdi, and M. Aarup.

A Knowledge Management Strategy for Seamless Compliance with the Machinery Regulation.

30th European & Asian Systems, Software & Service Process Improvement & Innovation (EuroSPI), Communications in Computer and Information Science (CCIS), vol. 1890, Springer Cham, pp. 220-234, DOI: 10.1007/978-3-031-42307-9_17, Grenoble, France, August 30.-September 1. 2023.

Vision: Knowledge Engineering within Highly Regulated Companies



Selection/Interpretation of laws

Selection of standards

Safety Risk Assessment and control

Security Risk Assessment and control

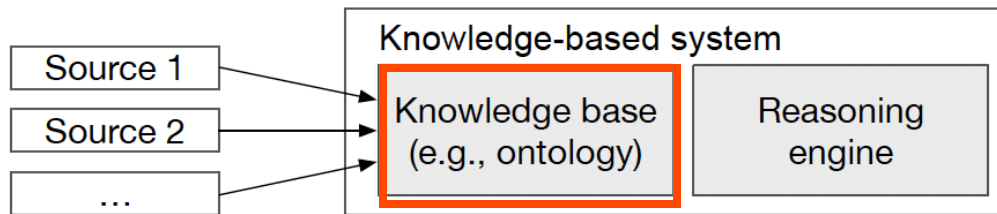
Sustainability Risk Assessment and control

Evidence Management; Evidence Tracing with the purpose of showing fulfillment of the legal requirements; Variability management with the purpose of reusing as well as managing the impact of changes

- **Capturing conceptually connected heterogeneous information in order to:**
 - **guarantee seamless traceability,**
 - **enable semi-automated multi-concern assurance argumentation**
 - **streamline auditing / regulatory compliance demonstration**
- **Braking the silos by connecting people with heterogeneous background or competence**
- **On demand-Knowledge Retrieval**
- **Flexible evolution**

Let's reconsider how knowledge graphs fit into the picture

Law-related knowledge
Standards-related knowledge
...



Pumps product line and corresponding regulations [ET4CQPPA]

The physical world meets the digital world

- Transforming the pump to a digital pump using IoT connectivity, AI and sensing capabilities

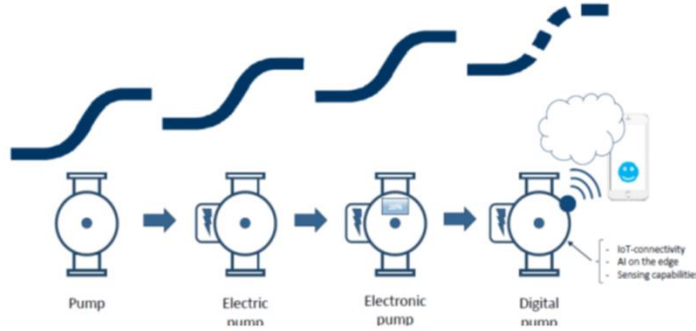


Image source: Grundfos

[<https://iot.telenor.com/iot-case/grundfos/>]



EN 809:1998 + A1:2009

Pumps and pump units for liquids -
Common safety requirements

ISO 12100: 2010 -Safety of machinery-

General principles for design —
Risk assessment and risk reduction

Machine Directive
2006/42/EC

Machine Regulation

Cybersecurity Act
Cyber Resilience Act



Artificial Intelligence Act
Trustworthy AI Guidelines

Pieces of solution towards the ontology-based representation

- > ● PumpsCompliance:layer0_Problem_Space_Thing (4)
- > ● PumpsCompliance:layer1_Legislation_Thing (21)
- > ● PumpsCompliance:layer2_Standardization_Thing (14)
- > ● PumpsCompliance:layer3_Company_level_Thing (14)
- > ● PumpsCompliance:layer4_SystemProductThing (2)

A layered ontology-based representation of the socio-technical system – Legislation layer

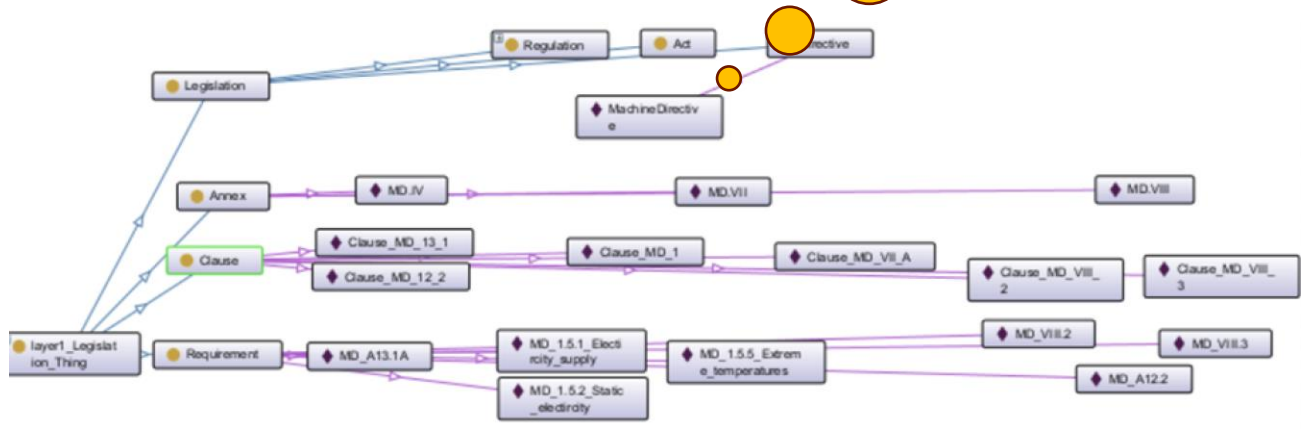
[Gallina et al.2024c]

- > ● PumpsCompliance:layer0_Problem_Space_Thing (4)
- > ● PumpsCompliance:layer1_Legislation_Thing (21)
- > ● PumpsCompliance:layer2_Standardization_Thing (14)
- > ● PumpsCompliance:layer3_Company_level_Thing (14)
- > ● PumpsCompliance:layer4_SystemProductThing (2)

Formalisation after specification, conceptualisation

A legislation has a preamble, which in turns is constituted by

- a set of citations
- a set of recitals
- a set of articles
- a set of annexes

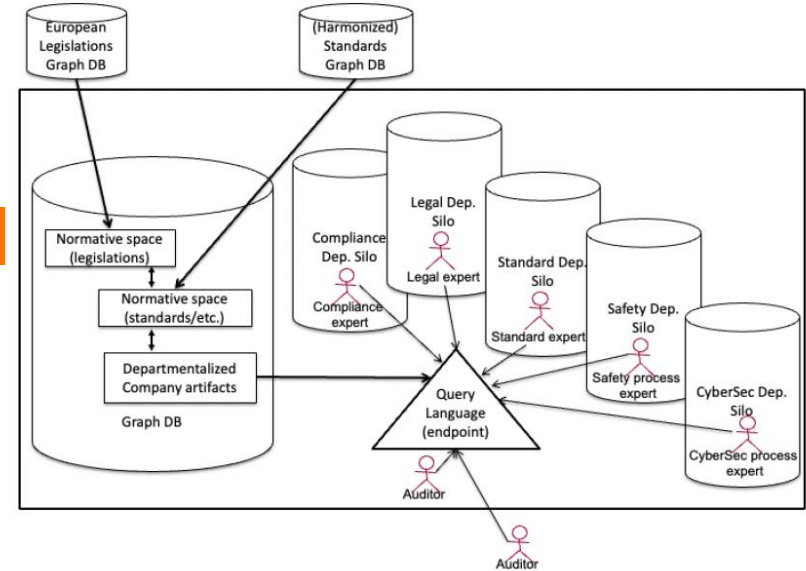


A layered ontology-based representation of the socio-technical system – Legislation layer

[Gallina et al.2024c]

Which are the safety-related legislations?

- > PumpsCompliance:layer0_Problem_Space_Thing (4)
- > PumpsCompliance:layer1_Legislation_Thing (21)
- > PumpsCompliance:layer2_Standardization_Thing (14)
- > PumpsCompliance:layer3_Company_level_Thing (14)
- > PumpsCompliance:layer4_SystemProductThing (2)



Imports Instances Inheritance Domain Relevant Properties Error Log SPARQL SPARQL Text Search

Query Editor Query Library

```
SELECT ?Legislation
WHERE {
  ?Legislation PumpsCompliance:SubjectsOfApproval ?Subject .
  ?Legislation a ?L .
  ?L rdfs:subClassOf* PumpsCompliance:Legislation .
  Filter (?Subject = PumpsCompliance:FunctionalSafety)
}
```

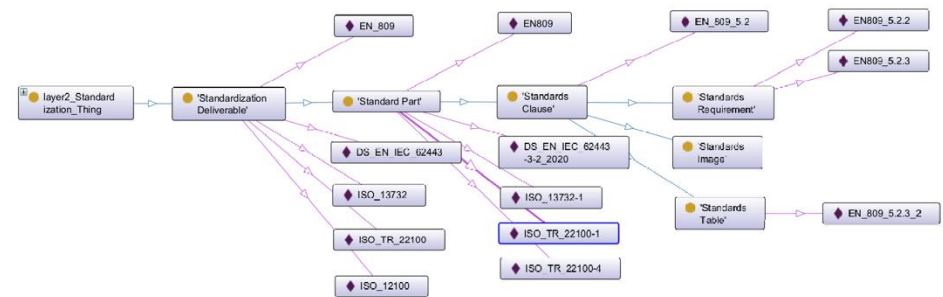
[Legislation]

- ◆ PumpsCompliance:MachineDirective
- ◆ PumpsCompliance:MachinearyRegulation

[Gallina et al.2024c]

- > ● PumpsCompliance:layer0_Problem_Space_Thing (4)
- > ● PumpsCompliance:layer1_Legislation_Thing (21)
- > ● PumpsCompliance:layer2_Standardization_Thing (14)
- > ● PumpsCompliance:layer3_Company_level_Thing (14)
- > ● PumpsCompliance:layer4_SystemProductThing (2)

- a set of parts. Each part in turns is constituted by:
 - set of clauses, Each clause in turns is constituted by:
 - * set of requirements
 - * set of images
 - * set of tables
 - a set of associated standards
 - a set of associated legislations

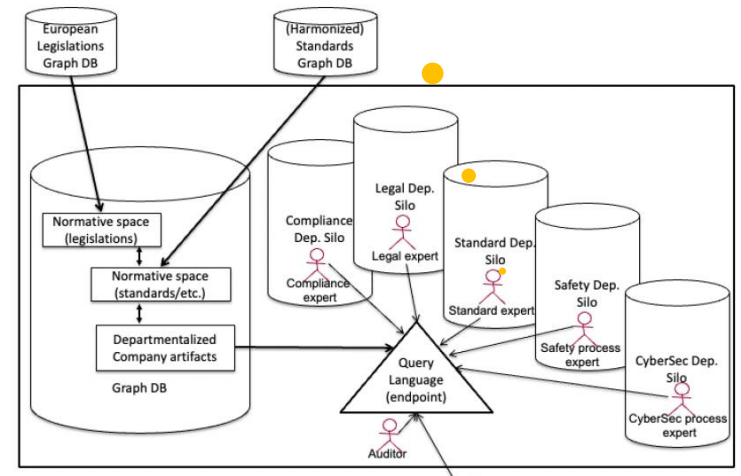


A layered ontology-based representation of the socio-technical system – Standardization layer

[Gallina et al.2024c]

Which are the safety-related standards?

- > ● PumpsCompliance:layer0_Problem_Space_Thing (4)
- > ● PumpsCompliance:layer1_Legislation_Thing (21)
- > ● **PumpsCompliance:layer2_Standardization_Thing (14)**
- > ● PumpsCompliance:layer3_Company_level_Thing (14)
- > ● PumpsCompliance:layer4_SystemProductThing (2)



Imports | Instances | Inheritance | Domain | Relevant Properties | Error Log | SPARQL | SPARQL | Text Search | Targets | SHACL Validation

Query Editor | Query Library

```
SELECT ?Standard
WHERE {
  ?Standard PumpsCompliance:SubjectsOfApproval ?Subject .
  ?Standard a PumpsCompliance:StandardizationDeliverable .
  Filter (?Subject = PumpsCompliance:FunctionalSafety)
}
```

[Standard]

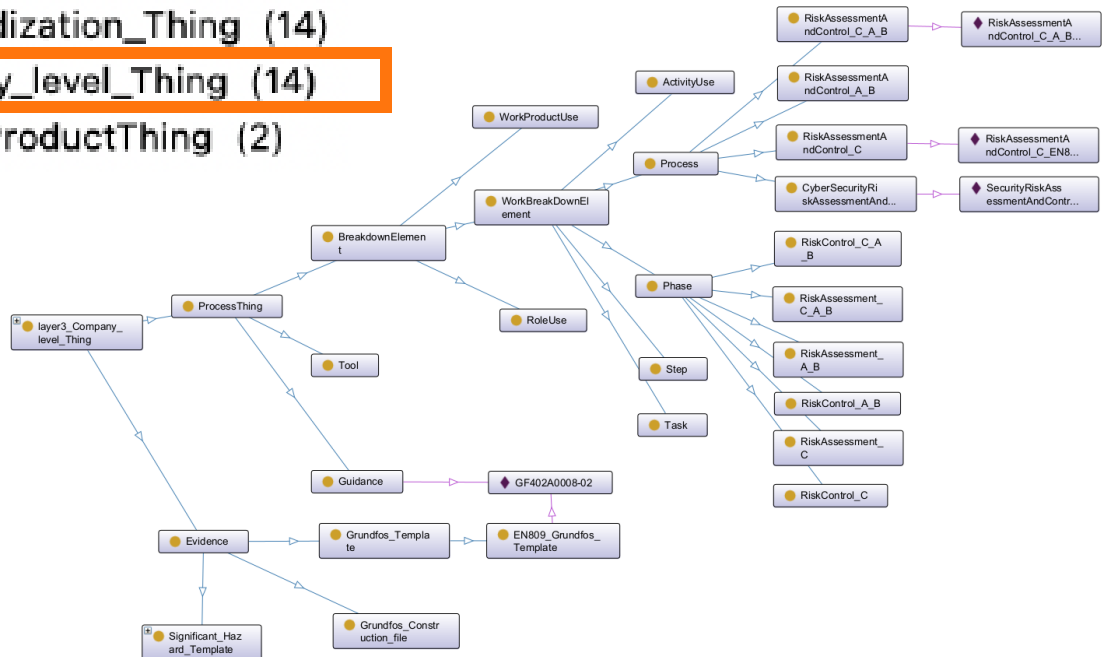
- ◆ PumpsCompliance:EN_809
- ◆ PumpsCompliance:ISO_12100
- ◆ PumpsCompliance:ISO_TR_22100

A layered ontology-based representation of the socio-technical system – Company layer

[Gallina et al.2024c]

- > ● PumpsCompliance:layer0_Problem_Space_Thing (4)
- > ● PumpsCompliance:layer1_Legislation_Thing (21)
- > ● PumpsCompliance:layer2_Standardization_Thing (14)
- > ● PumpsCompliance:layer3_Company_level_Thing (14)
- > ● PumpsCompliance:layer4_SystemProductThing (2)

- a set of phases, where each phase in turn is constituted by:
 - a set of activities, where each activity in turn is constituted by:
 - * a set of tasks, where each task in turn is constituted by:
 - a set of steps, where each step in turn is constituted by:
 - a set of roles
 - a set of tools
 - a set of work products in input
 - a set of work products in output
 - a set of guidelines/templates

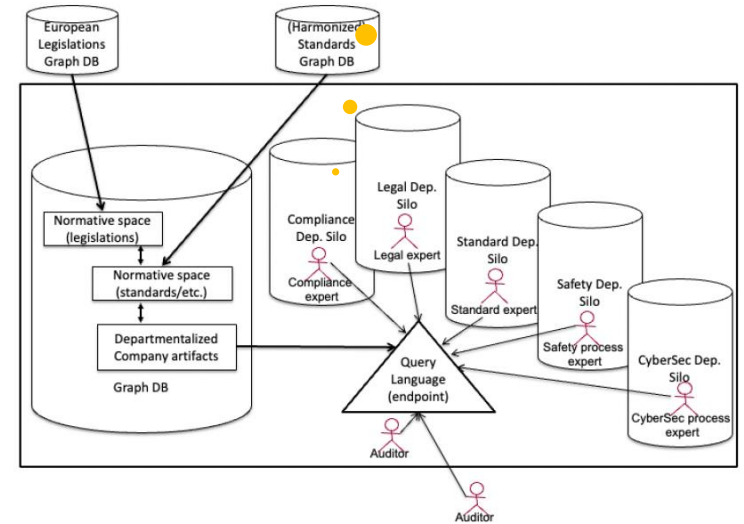


A layered ontology-based representation of the socio-technical system – Company layer

[Gallina et al.2024c]

Which is the process model overview adopted for developing pump CR-1?

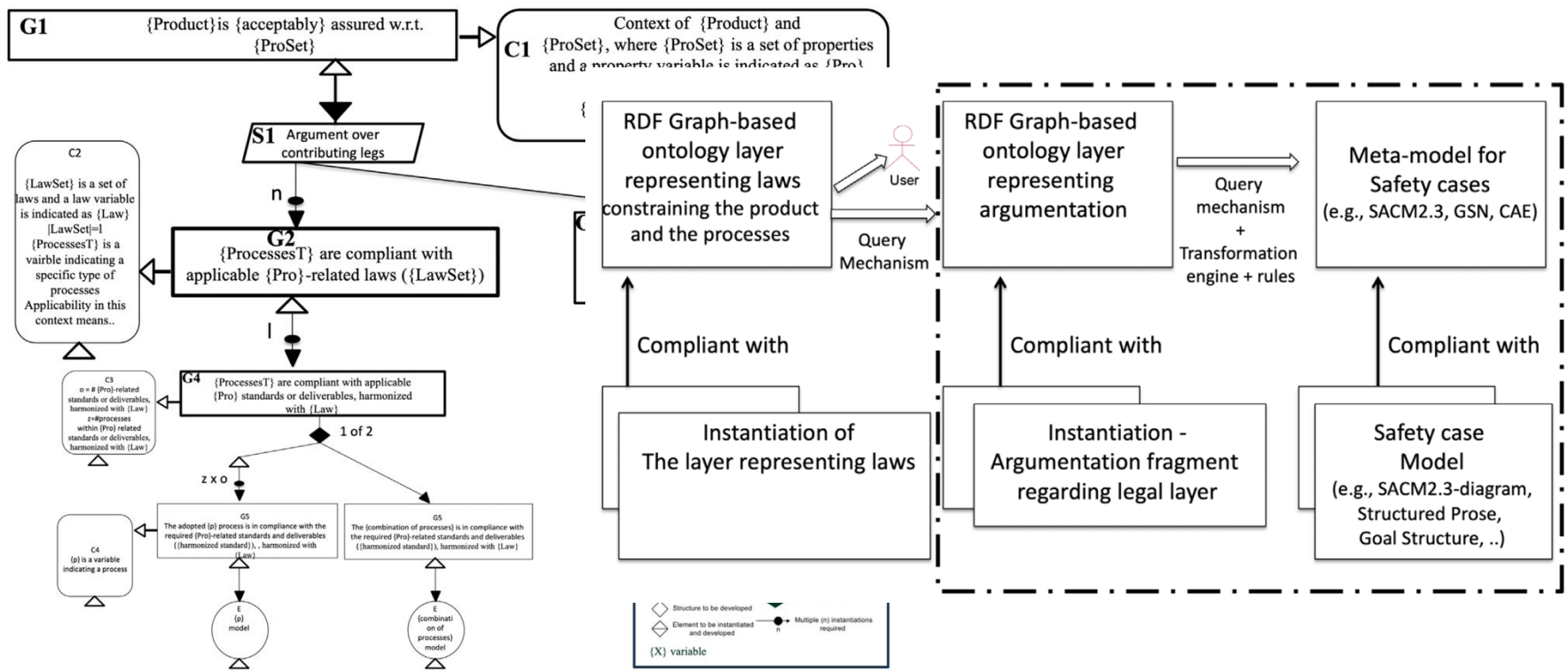
- > ● PumpsCompliance:layer0_Problem_Space_Thing (4)
- > ● PumpsCompliance:layer1_Legislation_Thing (21)
- > ● PumpsCompliance:layer2_Standardization_Thing (14)
- > ● PumpsCompliance:layer3 Company level Thing (14)
- > ● PumpsCompliance:layer4_SystemProductThing (2)



```
Imports | Instances | Inheritance | Domain | Relevant Properties | Error Log | SPARQL | SPARQL | SPARQL | Text Search | Targets | SHACL Validation |  
Query Editor | Query Library |  
[pump] | PMO | https://grundfos.sharepoint.com/i:/r/sites/Project50-ET4CQPPA/Shared%20Documents/General/ProcessModelOverview.p...  
◆ PumpsCompliance:Pump_CR_1 |  
SELECT ?pump ?PMO  
WHERE {  
  ?pumpclass rdfs:subClassOf* PumpsCompliance:PumpDriveSystem .  
  ?pump a ?pumpclass .  
  ?pump PumpsCompliance:AssociatedSetOfProcesses ?process .  
  ?process PumpsCompliance:ProcessModelOverview ?PMO  
}
```

Automated generation of multi-concern assurance argumentation

[Gallina et al.2024c]



- More complex case study in cooperation with stakeholders
- Tooling

- [Gallina et al.2024a] B. Gallina, P. Munk, M. Schweizer. An Extension of the Rasmussen Socio-technical System for Continuous Safety Assurance. Proceedings of 8th International Workshop on Critical Automotive Applications: Robustness & Safety (CARS), Leuven, Belgium, April 8th, 2024. HAL archives ouvertes.fr, <hal-04558510>
- [Gallina et al.2024b] B. Gallina, H. Dibowski, M. Schweizer. An Ontology-based Representation for Shaping Product Evolution in Regulated Industries. 21st International Conference on Software and Systems Reuse (ICSR-2024), Lecture Notes in Computer Science, vol 14614. Springer, Cham. DOI: 10.1007/978-3-031-66459-5_6, Limassol, Cyprus, June 19-20, 2024.
- [Gallina et al.2024c] B. Gallina, G. L. Steierhoffer, T. Young Olesen, E. Parajdi, M. Aarup. Towards an ontology for process compliance with the (machinery) legislations. Journal of Software Evolution and Process (JSEP). 2024; e2728. DOI; 10.1002/smr.2728

Hope it was interesting!
Thank you very much for your attention!

#49-4DASafeOps – Standards, Assurance Case, Process, Product-Aware SafeOps – focus on variability management
#50-ET4CQPPAJ – Trace Evidence 4 Continuous Quality Product Process Assurance Justification – focus on traceability

Software Center 

barbara.gallina@mdu.se