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

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Abstract. To ensure safety, the machinery sector has to comply with the machinery directive. Recently, this directive has been not only revised to include requirements concerning other concerns e.g., safety-relevant cybersecurity and machine learning-based safety-relevant reliable self-evolving behaviour but also transformed into a regulation to avoid divergences in interpretation derived from transposition. To be able to seamlessly and continuously comply with the regulation by 2027, it is fundamental to establish a strategy for knowledge management, aimed at enabling traceability and variability management where chunks of conformity demonstration can be traced, included/excluded based on the machinery characteristics and ultimately queried in order to co-generate the technical evidence for compliance. Currently, no such strategy is available. In this paper, we contribute to the establishment of such a strategy. Specifically, we build our strategy on top of the notion of multi-concern assurance, variability modelling via feature diagrams, and ontology-based modelling. We illustrate our proposed strategy by considering the requirements for the risk management process for generic machineries, refined into sub-sector-specific requirements in the case of centrifugal pumps. We also briefly discuss about our findings and the relationship of our work with the SPI manifesto. Finally, we provide our concluding remarks and sketch future work.

Keywords: Machinery Directive · Machinery Regulation · Seamless and Continuous Compliance · Cyber Security Act · Cyber Resilience Act · Artificial Intelligence Act · EN 809:1998+A1 · Centrifugal pumps.

1 Introduction

Nowadays technological innovations such as increased connectivity via Internet of Things and usage of artificial intelligence for enabling self-evolving behaviour are being incorporated within machineries. These innovations have been progressively transforming traditional closed systems into open systems [23], i.e.,

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"systems whose boundaries, functions and structure change over time and are recognized and described differently from various points of view". The concept of liquid modernity [2], coined by Bauman Zygmunt to describe the condition of constant change in all aspects of human life (e.g., identities, relationships, education, and global economics) within contemporary society, is progressively influencing other spheres of human life including consumer products, which from solid are being transformed into liquid. Centrifugal pumps, for instance, are being transformed as well. The digitalisation process is increasingly making them connected and partly autonomous, e.g., in fault-diagnostics for predictive maintenance. These innovations call for new requirements to ensure safety of the machinery. To face such innovations, the machine directive has been revised and new requirements have been included concerning e.g., safety-relevant cybersecurity and machine learning-based safety-relevant reliable self-evolving behaviour. In addition, to avoid divergences in interpretation derived from transposition, the directive has been transformed into a regulation. As a consequence of this revision, the machinery sector needs to adapt to the upcoming regulation, expected to be published in the Official Journal by July 2023. Currently, no ready off-the-shelf solution is available to manage the knowledge concerning the needed multi-concern frame of reference. Hence, in this paper, we contribute to the establishment of such a solution, expected to be integrated within DevOps [24] practices integrated with processes for open dependability systems [23]. Specifically, we propose a knowledge management strategy for seamless and continuous compliance with the machinery directive and its upcoming revision on top of the notion of multi-concern assurance, variability modelling via feature diagrams, and ontology-based modelling. Our strategy partly contributes to the creation of a frame of reference [23], i.e., "set of conventions for the constructions, interpretation and use of documents describing a common understanding of and explicit agreements on a system, its purpose, objectives, environment, actual performance, life-cycle and changes thereof". We illustrate our proposed strategy by considering the requirements describing the risk management process for generic machineries, refined into sub-sector-specific process requirements in the case of centrifugal pumps. Our illustration is limited to a subset of hazard categories. We also provide our lessons learned.Then, we discuss the relationship of our work with the SPI manifesto. Finally, we provide our concluding remarks.

The rest of the paper is organised as follows. In Section 2, we provide essential background information. In Section 3, we propose our strategy. In Section 4, we illustrate our strategy. In Section 5, we discuss about our findings and we explain the synergy with the SPI Manifesto. In Section 6, we briefly discuss related work. Finally, in Section 7, we present our concluding remarks.

2 Background

In this section, we present essential background information on the context and problem space constituted of: the legislative and binding space, the increasingly binding space populated by standards and guidelines, machineries and sector-specific machineries such as pumps. All these spaces may include sector-independent or sector specific as well as sub-sector specific elements. The machinery sector for instance may be specialised (sub-sector) by considering specific machinery-types e.g., pumps. This section is not aimed at being exhaustive. Rather, the intention is to exemplify the problem by focusing on the machinery sector, pumps and related spaces in the context of risk-based driven machinery engineering and pump-specific machinery engineering focusing on risk management processes. This section also recalls essential information on the solution space aimed at contributing to the engineering of the knowledge captured by the different spaces. Specifically, Base Variability Resolution is recalled.

2.1 Machinery Directive

The Machinery Directive (MD) [8], Directive 2006/42/EC, is a European Union directive concerning machinery and certain parts of machinery. MD establishes a regulatory framework for placing machinery on the EU Market. MD has the dual aim of harmonising the Essential Health and Safety Requirements (EHSR) applicable to machinery on the basis of a high level of protection of health and safety, while ensuring the free circulation of machinery on the EU market. Manufacturers of products that fall under the scope of the MD, such as manufacturers of pumps, must issue a Declaration of Conformity (DoC) in order to sell their products in the EU. It shall be noted that the EHSR laid down are mandatory; however, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.

According to the MD, a machinery is defined as an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application. To comply with MD, the manufacturer has to compile a technical file, which shall comprise: a) a construction file and b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the MD. The construction file is expected to include:

- a general description of the machinery, the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery (full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements).
- the documentation on risk assessment demonstrating the procedure followed, including (i) a list of the essential health and safety requirements which apply to the machinery, (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery.
- the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

- any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
- a copy of the instructions for the machinery,
- where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
- where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,
- a copy of the EC declaration of conformity;

The MD provides a list of hazard categories (e.g., thermal hazards, electric hazards) that shall be considered when carrying out risk management, i.e., risk assessment and control.

For sake of clarity, it shall be pointed out that the EU publishes also guidance documents (see for instance, [10]) to guide users to the application of the MD.

2.2 Machinery Directive-related Harmonised Standards

To assist engineers when they are conducting management (i.e., risk assessment and risk control/reduction) on any type of machinery, EN ISO 12100 [26] has been developed. In addition, sub-sector specific standards have been developed. EN 809:1998+A1 [5] represents a sub-sector specific standard to provide means of conformity with the essential requirements of the MD in the context of liquid pumps. This standard pre-selects the main hazard categories that may affect liquid pumps and focuses on risk reduction. Hence this standard pre-assesses the risk. If a category is already fully covered by this standard, EN ISO 12100 does not need to be considered. Regarding thermal hazards, EN 809:1998+A1 shall be complemented with ISO 13732-1 [25]. This because EN 809:1998+A1 does not deal with means to reduce hazards from surface temperatures which derive from the temperature at which the pumped fluid is delivered to the pump inlet.

2.3 Machinery Regulation

Given a series of problems that emerged during the latest assessment of the MD, a revision proposal [13] was made circulate. The revision proposal addressed the MD-related problems. In addition, to avoid divergences in interpretation derived from transposition, proposed to transform the MD into a proper regulation. Hence, the draft global comprise, which is expected to be published by July 2023 as the machine regulation (MR) [15].

To comply with MR, the manufacturer has to provide the technical documentation, which shall include a set of evidential elements. In what follows, we recall a subset of those elements with the purpose of highlighting the potential for documentation reuse during the transition from Machine Directive to Machine Regulation. The recalled elements are taken from the MR text.

- (a) a complete description of the machinery or related product and of its intended use;

– (b) the documentation on risk assessment demonstrating the procedure carried out, including: (i) a list of the essential health and safety requirements that are applicable to the machinery or related product; (ii) the description of the protective measures implemented to meet each applicable essential health and safety requirement and, when appropriate, the indication of the residual risks associated with the machinery or related product;
– (d) design and manufacturing drawings and schemes of the machinery or related product and of its components, sub-assemblies and circuits;
– (e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the machinery or related product;
– (f) the references of the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied for the design and manufacture of the machinery or related product. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied.

For sake of clarity, it shall be pointed out that at the time being no harmonised standard is available yet. However, since some hazard categories (e.g., thermal hazards) remain the same, we can assume that the corresponding portion of the harmonised standards, valid for the MD, will remain valid also for the MR. It shall also be highlighted that the MR includes essential health and safety requirements in relation to corruption and that an explicit reference to the Cyber Security Act is present. In Article 17, it is stated: Machinery and related products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU) 2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof. Annex III, 1.1.9, states otherwise which requirements must be fulfilled.

2.4 MR-related Regulations

The upcoming Machine Regulation includes requirements that are related to cybersecurity and to the usage of artificial intelligence. Hence, even if not explicitly harmonised with the corresponding regulations, the MR is related to the Cyber Security Act [11], the Cyber Resilience Act (CRA) [14] and to Artificial Intelligence Act (AI Act) [12]. The published Cyber Security Act (CSA) defines the responsibility of EU Agency for cybersecurity (ENISA) and, within Article 51, it defines the security objectives in terms of the CIA triad, i.e., confidentiality, integrity and availability. These objectives are expected to be included within the EU cybersecurity certification schemes that shall be prepared by ENISA.

CRA is a recent proposal for legislation aimed at ensuring that digital connected products and associated services, placed on the EU market, are cybersecure by design and by default. CRA seeks to establish common cybersecurity rules. CRA provides essential requirements, which will be supported by horizontal and vertical / sectorial standards providing the necessary details for the concrete implementation. At the time being, however, it is unclear with which type of standard the CRA will be supported. In its current version, within article 10 (2), it is stated that manufacturers shall undertake an assessment of the cybersecurity risks associated with a product with digital elements and take the outcome of that assessment into account during the planning, design, development, production, delivery and maintenance phases of the product with digital elements with a view to minimising cybersecurity risks, preventing security incidents and minimising the impacts of such incidents, including in relation to the health and safety of users. Regarding vulnerability handling (risk management), within Annex 1, the proposal states that manufactures of the products with digital elements shall:

1. identify and document vulnerabilities and components contained in the product, including by drawing up a software bill of materials in a commonly used and machine-readable format covering at the very least the top-level dependencies of the product;
2. in relation to the risks posed to the products with digital elements, address and remediate vulnerabilities without delay, including by providing security updates.

Similar to the CSA, it shall be noted that where machinery products are products with digital elements within the meaning of the CRA and for which an EU declaration of conformity has been issued on the basis of the CRA, those products shall be deemed to be in conformity with the essential health and safety requirements set out in Annex III, Sections 1.1.9 and 1.2.175 to the Machinery Regulation proposal.

The Artificial Intelligence Act states in its Annex IV that the technical documentation for compliance shall also include a detailed description of the risk management system in accordance with Article 9, where a set of requirements are listed. It shall be noted that the members of the European Parliament (MEPs) have recently adopted the Parliament's negotiating position on the AI Act. The discussion with EU countries in the Council on the final form of the law is expected to take place as a next step.

2.5 Centrifugal Pumps

Centrifugal pumps are machinery for transporting fluids by the conversion of rotational kinetic energy to the hydrodynamic energy of the fluid flow. The rotational energy typically comes from an engine or electric motor. The fluid enters the pump impeller via the inlet along or near to the rotating axis and is accelerated by the impeller, flowing radially outward into a diffuser or volute chamber (casing), from which it exits (outlet). Nowadays, pumps can be remotely connected. Pumps can also include artificially intelligent components, used for instance for predictive maintenance. Grundfos is a leader pumps manufacturer. Centrifugal pumps are part of Grundfos pumps production and can be customised in multiple ways to meet specific requirements, e.g., the need of handling high temperature liquids, the need of ensuring predictive maintenance. In [6], a study was conducted to show that through cloud-side collaboration, real-time monitoring of the running status of centrifugal pumps and intelligent diagnosis of centrifugal pump faults might become possible, hence, enabling failure avoidance via a constant assessment of the reliability of the pump and allowing maintenance to be conducted only when necessary. Since this is an evolving research area, it is not excluded that on-the-air repair or machine-learning based self-healing reconfiguration might take place. Hence, Grundfos is interested in a multi-concern frame of reference as well as in managing its knowledge.

2.6 Multi-concern Assurance

The notion of Multi-concern Assurance was introduced in the context of the AMASS project [31, 32] to highlight that assurance of cyber physical systems cannot be limited to a single concern, e.g., safety assurance. Instead, multiple concerns shall be considered as well as their interplay and trade-offs. This necessity is even more true in the context of Industry 5.0, where cognitive cyber-physical systems are expected to play a major role in society.

2.7 Variability management via Base Variability Resolution

Base Variability Resolution (BVR) is a metamodel [22] for modelling (VSpec model), resolve (Resolution model) the variability at abstract level, i.e., without referring to the exact nature of the variability with respect to the base model and to realise (Realisation model) a new configuraration of the base model. In this paper, we limit out attention to the VSpec model. VSpec permits users to model the variability in a feature diagram-like fashion, i.e., via a tree structure, where vertices are called Vnodes and arcs (connecting Vnodes) represent implicit logical constraints on their resolutions. In what follows, we recall the BVR modelling elements used in this paper. For a complete introduction of BVR, the reader may refer to [22]. *Root (feature)* represents the starting node of the tree-structure. It is depicted with a rounded rectangle. *Choice (feature)* represents a yes/no decision. It is depicted with a rounded rectangle. *Constraint*, given in BCL (Basic Constraint Language), is a logical formula or expression over VSpecs used to restrict the allowed resolutions. It is depicted with a parallelogram with the textual constraints written inside. The parallelogram is linked to a VSpec, representing the context of the constraint. If not linked, it is interpreted as global constraint. *Group* dictates the number of choice resolutions, e.g., 1..1, which refers to *xor* in which exactly one of the child features must be selected; 1..N, refers to *or* in which at least one of the child features must be selected. The group is depicted with a triangle plus the textual notation representing the multiplicity. *ChoiceOccurrence* is depicted via a choice symbol enriched by textual notation to indicate the type. *A dashed link between choices* indicates that the child choice is not implied by its parent. *A solid link between choices* indicates that the child choice is implied by its parent.

The cognitive effectiveness of BVR has been assessed by Bernhard et al. [3], based on Moody's principles [28]. Despite some cognitive weaknesses revealed by the assessment, from a semantically transparent relationships perspective, the BVR inherent support for tree-like structures is cognitively effective in representing the semantics of the relationships. Hence, we believe that feature diagram-like representations can be intuitive and can represent a helpful modelling means for establishing a multi-concern frame of reference. BVR was extensively used within and beyond the AMASS project to enable intra-domain, cross-domain and cross-concern reuse [27] as well as co-engineering of mono-concern risk-based processes, specifically in the space [16], medical [21] and automotive domain [4].

3 Knowledge Management Strategy

As seen in the background section, legislations, harmonised standards, and guidance provide requirements that contribute to constraining the engineering of the process-focused artefacts. We see that requirements are refined from high-level process-focused requirements, provided within legislations and guidance to the legislations application, to technically specialised requirements at generic machinery-level (provided by harmonised standards at generic machinery level) down to sub-sector-specific machinery (e.g., requirements provided at liquid pump-level). At each level, we have sets: sets of partly overlapping legislations, sets of partly overlapping standards, etc. Given these sets of overlapping elements, a product line approach constituted of the traditional two-phase engineering process can be adopted (as depicted in Fig. 1). First, the process-focused domain is engineered and then the process-focused artefacts based on the constraints imposed by the domain are engineered.

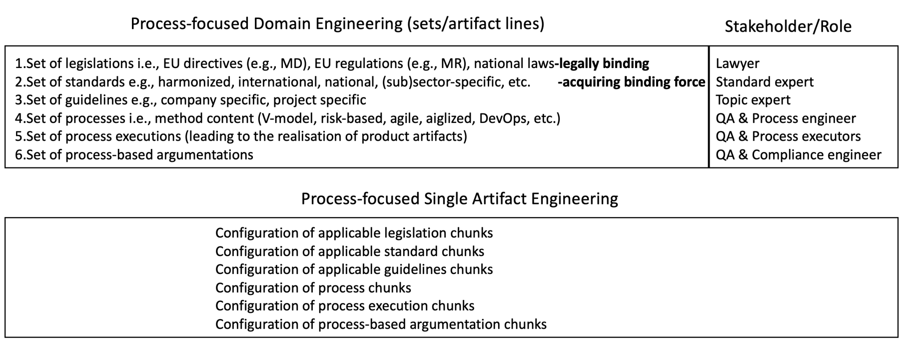

Fig. 1. Process-focused Domain and Artifact Engineering.

This high-level product line-oriented approach can be translated into BVR-given feature diagrams in order to provide an intuitive representation.Once the intuitive representation is understood and shared by all stakeholders/roles, in our strategy, as depicted in Fig. 2, an ontology-based representation is expected to be adopted in order to enable the querying the knowledge graphs and the co-generation of the technical documentation.

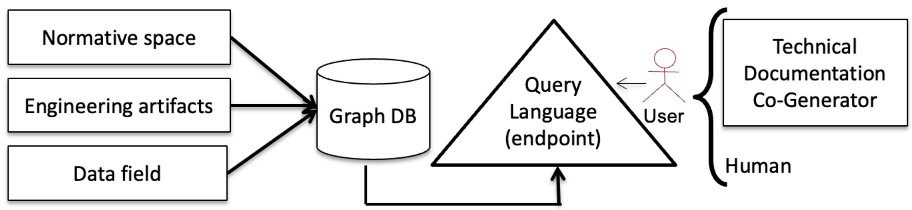

Fig. 2. Ontology-based Continuous Compliance Strategy.

It shall be noted that at each level, different stakeholders with different expertise play a role. Often these stakeholders work in silos. Hence, a common frame of reference would be beneficial to expose them to the interfaces.

4 Exemplification of the Strategy

In this section, we partly exemplify our knowledge management strategy. Specifically, we limit the exemplification to the BVR representation and we represent part of the knowledge contained within the legislations, standards, etc, related to the generic machinery and partly to the liquid pumps. The process-focused information is strictly dependent on the characteristics and type of the machinery. Hence, as depicted in Fig. 3, we need also to model the space of possibilities that interests us.

At Grundfos, and in the context of our research project, the focus is on the specialisation of machinery with respect to the pump-type, which then may further be specialised (e.g., electric, electronic, digital) to distinguish the products within the product line and the need of conformity based on e.g., the presence/absence of digital elements enabling connectivity, evolutionary behaviour, etc. However, in this paper, we do not provide details regarding the technical pump system since our attention is limited to process-focused artefacts. The Multi-concern Machinery Compliance Line, which results by considering all legislations considered in the background, is depicted in Fig. 4.

This figure shall be further refined to take into consideration the development of the individual features representing the technical evidence as a block (e.g., technical file (TE) for the machine directive (MD)) but also as reusable pieces of evidence when MR overlaps with MD or with the other regulations.

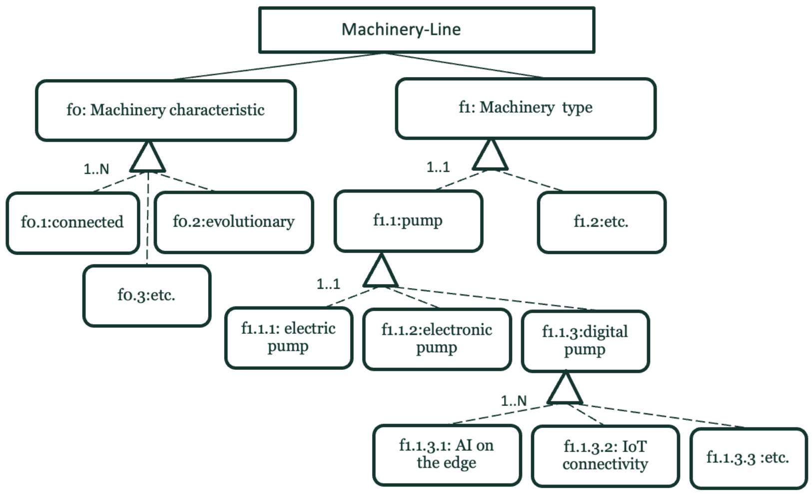

Fig. 3. Machinery Characteristics.

From a technical documentation perspective, Annex VII of the MD largely overlaps with Annex IV of the MR. At a first glance, this large overlap may remain hidden, given the different way that these pieces of documentation are expected to be packaged. MD and MR, however ,do not only differ in the way they require to structure the technical documentation but also in the way safety is interpreted. MR expects manufacturers to embrace a larger categories of risks while conducting their risk assessment.

If MD is in focus and if the pump is neither connected nor evolutionary, the technical documentation to be considered is limited to the technical file (TF), as depicted in Fig. 5. It shall be pointed out that Fig. 5 constitutes the resolution (inclusion/exclusion) of features from the Multi-concern Machinery Compliance Line. The root of Fig. 5 corresponds to the expansion of feature f2.1.1 of Fig. 4 based on the evidential elements, which were listed in Section 2.1.

5 Discussion and Synergy with the SPI Manifesto

In Section 4, we provided a preliminary but timely illustration of our strategy. A more complex implementation/illustration is expected to be developed iteratively and incrementally along with the understanding of the upcoming regulations. Regarding the synergy with the SPI Manifesto [29], which targets software. Our strategy is not limited to software, it embraces organisational knowledge management in general and, in the context of this paper, it focuses on knowledge management in relation to commonalities and variabilities among risk management processes described within the machinery directive/regulation and further refined by harmonised standards and company-specific guidelines.

Our strategy is specifically related to the SPI-principle Create a learning organisation. Our strategy is also related to the SPI-principle Ensure all parties understand and agree on process, since by managing knowledge related to risk assessment processes in a traceable and systematic manner, we contribute to ensuring that all parties understand and agree on the processes.

6 Related Work

In the law community, Chiara [7] provides an informal (textual) and brief discussion about the interplay between the CRA and the MR. However, no technical solution for managing the knowledge is envisioned. In the knowledge management community, an important number of works proposes knowledge management strategies. However, few of them, mainly stemming from the intersecting computational law community, focus on compliance via ontology-based solutions. Robaldo et al. [30], for instance, conduct experiments to compare semantic web-based technologies for automating the compliance. To the best of our knowledge, our work represents a novelty with respect to 1) the technical solution and the case considered. From a technical solution perspective, no approach so far has proposed a two-phase strategy. Even though it shall be stated that this work is connected to another ongoing and unpublished work conducted by the first author in the context of a sibling national project [1], where the two-phase strategy is also explored but within a broader scope. This work also borrows the general idea of creating ontologies for compliance purposes from Gallina et al. [18, 17, 20, 19], where ontology-based representation of automotive standards were proposed for compliance purposes as well as for automated generation of safety cases. From a case perspective, no research so far has been conducted to elaborate a knowledge management strategy targeting the multi-concern frame of reference for seamless and continuous compliance with the machinery directive/regulation.

7 Conclusion and Future Work

In this paper, we have presented our knowledge management strategy for enabling seamless and continuous compliance with the machinery directive and its upcoming revision. We have also applied it to the sub-sector populated by centrifugal pumps, focusing on risk management processes. Given, the space limits, we have largely simplified the case. Hence, in future, we plan to consider more complex cases in order to investigate the scalability and efficiency of our strategy. We also intend to translate BVR representations into ontology-based representations. Finally, we plan to continue digging into the same sector and sub-sector as well as exploring other sub-sectors to be able to reuse sub-sector independent modelling chunks.

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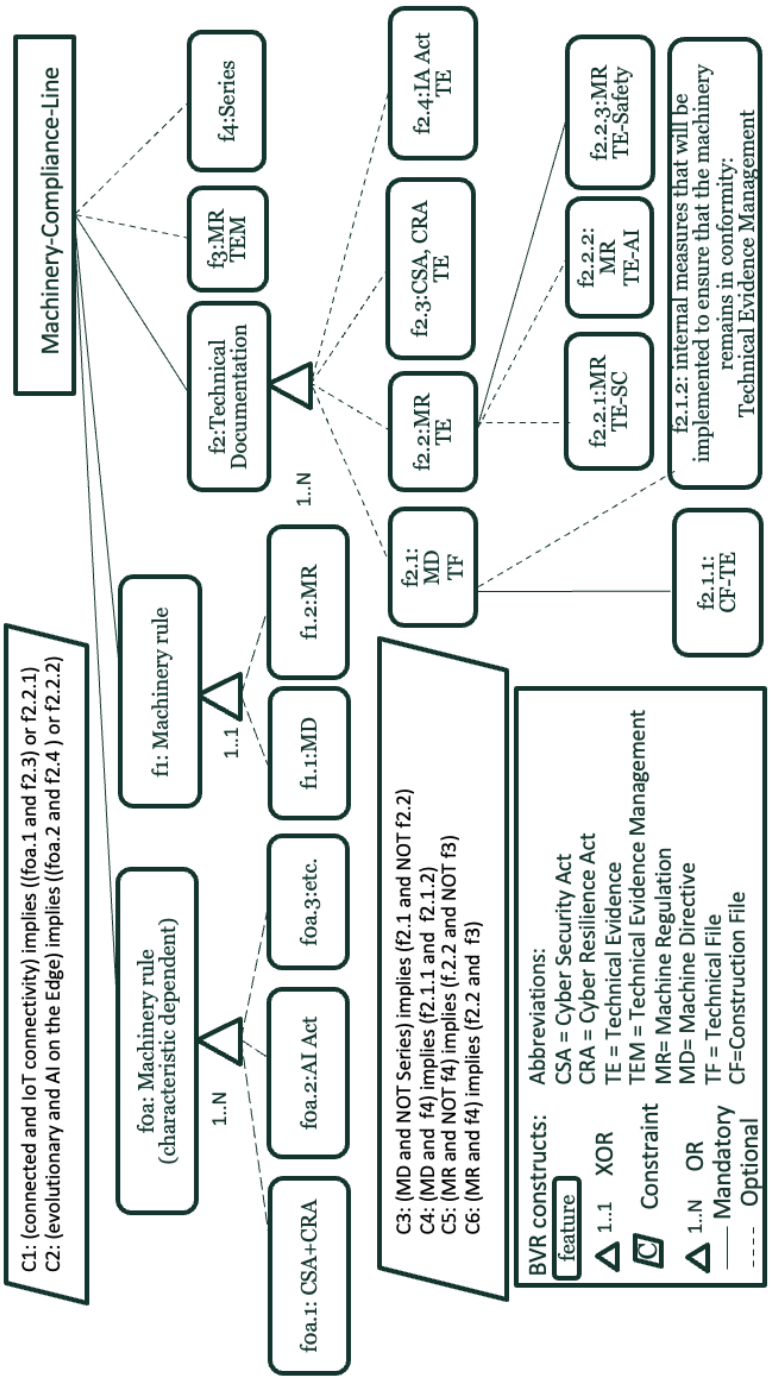

Fig. 4. Multi-concern Machinery Compliance Line.

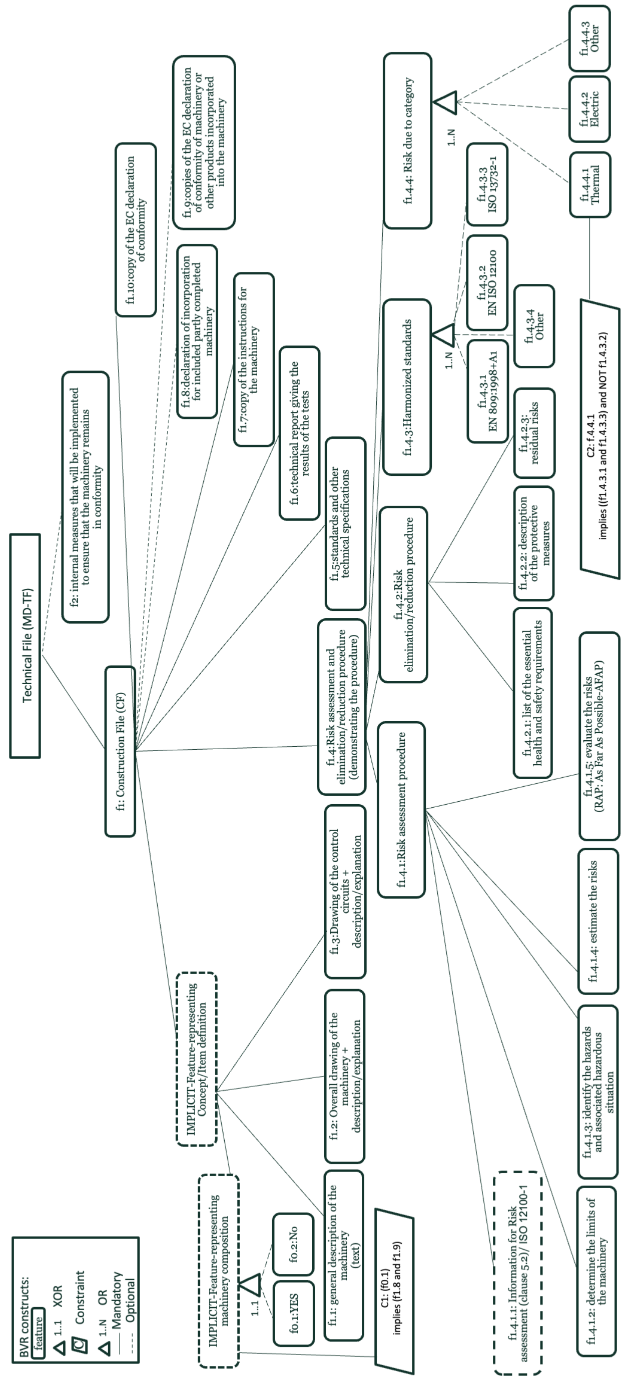

Fig. 5. Machinery Directive Technical File.