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Model-based Approach for the Automation and Acceleration of the CE-Conformity Process for Modular Production Systems: Future Requirements and Potentials

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Abstract

In the ultra-flexible factory, production machines reconfigure themselves ad-hoc depending on incoming production orders. Consequently, the IFF institute has developed a modular cyber-physical system (CPS) that consists of configurable robotic components. This paper is motivated by the need to reduce the effort and time associated with the CE conformity process for manufacturing systems with frequent reconfigurations, thus minimizing non-value adding machine downtime and increasing Overall Equipment Effectiveness (OEE). It presents an approach for an automated assistant system for the required risk assessment process using a database of previous CE conform system configurations and a reasoner that is able to verify the existence of a CE conform configuration that supersedes the hazards and risks of the new configuration. This allows the protective measures listed in the previous CE conform configuration to be reused, as well as a large part of the respective CE documentation.

Keywords

CE conformity process; human robot collaboration; safety; modular machines; reconfigurable manufacturing system; Industry 4.0; information model; cyber-physical systems, Matrix Fusion Factory

1. Introduction

Since the early 1980s the global manufacturing industry in general, and the European industry in particular, has had to cope with lower lot sizes, higher numbers of product variants and shorter product life cycles [1]. In response, new manufacturing concepts such as flexible, reconfigurable and changeable manufacturing systems (FMS, RMS and CMS) have emerged [2–4]. These manufacturing system concepts exploit the modularity of hardware and software, as well as model-based engineering, to rapidly adapt the manufacturing system to new product and production requirements. In recent years, the interconnectivity of manufacturing components, artificial intelligence, and digitalization have extended the concepts towards CPS that are able to semi-autonomously analyze product models, reason about the required production reconfiguration, and even partially reconfigure themselves [5–7]. Industry 4.0 has established itself as the common trademark for such systems. One example of such an Industry 4.0 system is the Matrix Fusion Factory (MFF) depicted in Figure 1. This outlines how temporary modular and mobile hardware and

software assemblies (classically referred to as machines) are composed. Humans and modular machines move and interact in the same workspace. Due to the constant adaptation of the production system to the orders, separated workspaces may not be beneficial and may have a negative impact on value-adding [8–10]. The modular assemblies, for example modular assembly I and II in Figure 1, consist of modules (a, a* to f*) with different functions and capabilities. Thus, the required capabilities can be generated flexibly by combining different modules. However, while autonomy, modularity, and flexibility enable manufacturing systems to be reconfigured and adapted more frequently, the logical conclusion of these enablers results in "previously unknown" manufacturing system configurations. These configurations, for which no CE markings have been issued, are potentially hazardous, considering the workspaces potentially shared by workers and machines. This makes CE marking and the corresponding risk/safety assessment the future bottleneck with regard to the frequent reconfiguration of manufacturing systems [11].

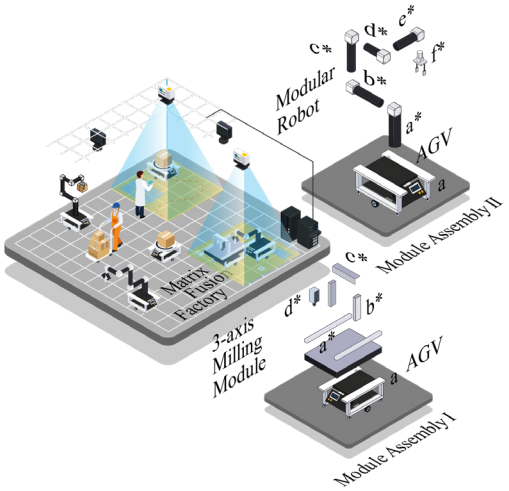


Figure 1: Concept of the Matrix Fusion Factory with modular, mobile machines

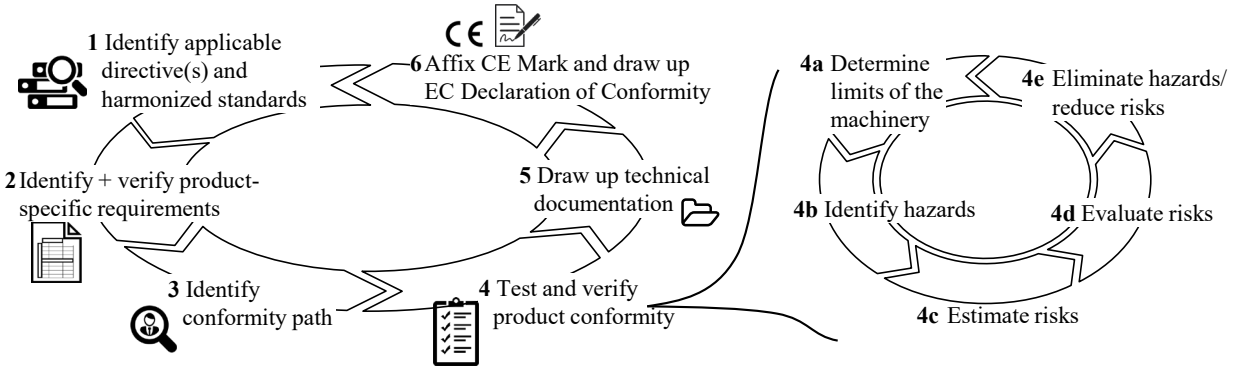
In the following sections, first the problem is presented in Section 2, followed by the current state-of-the-art approaches for risk assessment in Section 3. Section 4 presents the approach for speeding up/automating the conformity process, especially in terms of risk assessment. The approach is validated on a use case in Section 5. The results of the validation are discussed in Section 6 before an outlook on future research work in this field is given in Section 7.

1. Description of the problem

One of the questions that arises in the adaptable concept of the MFF is how to ensure regulatory safety demands. In conventional production, the manufacturer of a machine has to guarantee that their design meets the safety demands of the Machinery Directive 2006/42/EC [12], while the proprietor of the facility has to fulfil the requirements according to 2009/104/EG (minimum safety and health requirements for the use of work equipment by workers at work) [13] which demands the workplace conditions and surrounding conditions to be checked if they are still consistent with the intended use according to the machine manufacturer. If the machine manufacturer does not meet these requirements according to the Machinery Directive, they may be violating the law [14] and could lose their liability insurance coverage [15]. In general, the conformity process consists of the 6 steps listed in [16] and depicted in Figure 2.

While, in production scenarios, the machine manufacturer develops in the direction of a system proprietor [17], in the concept of the MFF the proprietor develops into a machine manufacturer and also potentially fulfils both roles. Therefore, the relevance of safety engineering will grow [18] in line with the fast adaptation of machines [19]. This means that a risk assessment must be conducted after each production system modification [20], resulting in a high effort for the proprietor because now the proprietor carries out tasks which would normally be performed during the design phase [20] by experienced health and occupational safety experts [21]. If, during the risk assessment, the modification is considered as being substantial, the machine is considered a new machine and the complete conformity process must be carried out [22].

Therefore, in order to apply the ultra-flexible production system - such as the MFF - in practice as well as reconfigurable manufacturing systems, the process of checking conformity must be supported in a more targeted and automated way [21].



1. Basically, for the products considered in this approach, the main directive will be the Machinery Directive. Besides the included Low Voltage Directive, other directives are likely to be included, e.g. the EMC Directive or possibly the RoHS Directive.
2. For the Machinery Directive, the essential health and safety requirements are included in Annex I of the Machinery Directive. Additionally, the relevant harmonized standards need to be derived.
3. It has to be determined whether a notified body has to be involved. For most machinery (except that mentioned in Annex IV), an assessment of conformity with internal checks is sufficient.
4. Consists of the risk assessment procedure and verification and tests of the derived measures e.g. according to the derived harmonized standards to prove conformity of the product.
5. All relevant documents as mentioned in Annex VII must be compiled and stored. This also includes technical, electrical and geometrical specifications.
6. Declaration of Conformity must be signed by an authorized representative of the manufacturer. Additionally, the CE Mark must be affixed to the product.

Figure 2: conformity process on the basis of [16,12]

2. State of the Art

The generic risk assessment process (RAP) is defined in ISO 12100 [23]. ISO 10218-1/2 [24] extends RAP by a list of common potential hazards encountered in human robot collaboration applications, while ISO/TS-15066 provides guidelines on the bio mechanical force and pressure limits arising from transient and quasi-static collisions [25]. In this paper, we group the various RAP techniques into three main categories:

1. Informal safety analysis techniques and conventional tool
2. Model-based and formal verification methods
3. Simulation/scenario-based methods

Informal methods are general-purpose techniques used to structure RAP. Examples of such techniques are HAZard and Operability studies (HAZOP) [26], checklists [27], Failure Mode and Effect Analysis (FMEA) [28], Failure Tree Analysis (FTA) [29], and Systems Theoretic Accident Model and Processes (STAMP) [30]. These rely solely on domain expertise and human reasoning, such as HAZOP entails brainstorming meetings by interdisciplinary teams to explore possible deviations from system design, system behavior and subsequent hazards. While the later mentioned methods can only be applied to areas which have been elaborated previously with much effort, informal methods can be applied to all type of risks and production scenarios. But the engineering judgement of the risk identification and the risk evaluation is usually done with reflection on a “mind internal” comparison to comparable situations or comparable machine structure. Therefore there is a potential of not identified risks as well as under- or overestimates of risks due to cognitive biases. [31,32]

Typical **model-based methods** derive hazards from system designs using rules and formal verification methods. [33] combines HAZOP and UML to systematically identify hazards in Human Robot Collaboration (HRC) applications. [34] introduces a rule-based system to automatically link certain Product Process Resource (PPR) properties to hazards and make recommendations for corresponding safety measures. SAFER-HRC is a formal verification method that guarantees the safety of the given HRC application [35].

[36] introduces a meta-model to automate a design space exploration which allows measuring impacts on design changes automatically. To increase automation in risk assessment [37] presents a model-based and software-assisted approach, performing hazard analysis at runtime on single components. While model-based methods can automatically identify hazards and formally verify the safety of an HRC application, they require rigorous formal models of the application – a highly work-intensive and knowledge-intensive task - and are only as complete or correct as the underlying model and verification rules.

Few **simulation-based methods** exist, inter alia, for identifying hazards [38] and the optimized placement of Rapid Response Mechanisms (RRM) [39] in HRC systems, for Automated Guided Vehicles (AGVs) in automated warehouses [40], or for cobots in domestic environments [41]. [40] combines a simulation-based approach with HAZOP, however with a focus on automated warehouses with AGVs. The authors simulate advanced sensors functionalities, such as depth cameras, which cannot be easily formulated by model-based and formal methods. Huck et al. [38] address hazard identification using optimization-based methods which search for risky human behavior that could lead to hazards. In a proof of concept, Huck et al. are able to identify hazards arising from unplanned transient contacts. However, the approach is not guaranteed to converge in a polynomial time. Furthermore, due to simplification of the human model in order to utilize a *branch&bound* algorithm, this approach can only be used to falsify specific safety configurations which are related to specific hazards. It is unable to guarantee safety because hazards may be overlooked.

Several contributions published in the production domain address an automation of single process steps in the CE conformity process for reconfigurable systems. Some work has been done on automating the identification of hazards associated with specific machine modules. Identification of hazards and evaluation of safety at system level still relies on expert knowledge "[originating] from a human integrator" [42]. [36,37,42]

The impact of modifying the configuration of modular machines - consisting of several single components – on the validity of safety configurations and subsequently the CE mark has not been addressed in detail. Specifically, the interactions between safety components and functional components being added or removed have not been in the focus of those publications.

In this publication the challenges of declaring CE conformity of modular machines are discussed. Following that, an approach for accelerating the declaration process is presented, considering current directives and standards. Consequently, all steps of the CE conformity process are considered - from single component up to system level - and their feasibility as well as degree of automation are discussed.

3. CE Configuration

As specified in the description of the problem, the constant demand-driven modification of machinery results in significant work for the proprietor in order to guarantee compliance with the machine's standards and directives. During the conformity assessment procedure, the machine may not be productive, leading to downtime and lost added value (2006/42/EC). The presented approach includes a framework to help the proprietor with the conformity process and automate the respective steps. As a result, time-

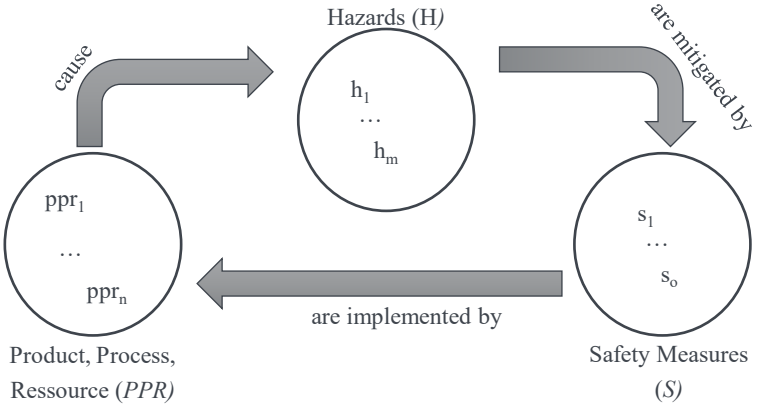


Figure 3: The PPRHS model extends the traditional PPR model by the hazards caused by the product, process or resource features of a workplace, as well as the mitigating safety measures that in turn are also implemented by PPR features.

consuming conformity assessment procedures can be avoided and downtime and costs for modular machinery minimized. The framework's contribution to Step 4 of the conformity process, which is depicted in Figure 2, is based on three core elements: 1) database of CE compliant configurations of machinery; 2) selection algorithm for identifying suitable machine configurations that meet process/product requirements, and 3) a reasoning algorithm that uses the PPRHS (**P**roduct, **P**rocess, **R**esource, **H**azard, **S**afety measure) model depicted in Figure 3, to determine whether a new configuration contains any unmitigated risks.

The used **database** contains a) the available machine modules for building modular machines, b) the CE compliant configurations of the used modules and their data. Furthermore, the saved data for each CE compliant configuration includes:

- machine-readable documentation of the configuration of machinery [43–45] (e. g. links between modules, geometrical, electrical wiring plans)
    - required capabilities of the configuration
    - available capabilities of the configuration
- standards used at the time of conducting CE compliancy (e. g. DIN EN ISO 10218-2:2012-06)
- family tree and timeline of configurations and sub-configurations used to modify the configuration
- risk assessment, including identified hazards and selected safety measures
- declaration of conformity

If a configuration is declared as being conform, the above-mentioned data is saved, thus extending the database. In general, modifications should only be implemented if they benefit value-adding (e.g. integration of necessary new capabilities or removal of obsolete ones).

To derive the required manufacturing capabilities from product and process requirements and to select configurations in the database which fulfil these requirements, a **selector algorithm** is used. The selector searches the database and compares the necessary derived capabilities with the available capabilities of the configurations in the database and outputs either a CE-compliant configurations that fulfils all requirements or a "best match". That best match is then further modified by the engineer in terms of **P**roduct, **P**rocess and **R**esource features to fulfils all requirements.

When a configuration is modified, risks and adequacy of safety measures must be verified, as:

- Existing hazards can become unmitigated (risk level increases) due to a modification/elimination of the PPR features implementing the corresponding safety measures.
- New but known hazards, i.e. safety measure is also known, may manifest due to a modified PPR features
- New unknown hazards, i.e. associated safety measure is not yet associated, may manifest due to new PPR features

A **reasoning algorithm** following formal rules and utilizing a simulation-based risk assessment procedure determines if the hazard increases and safety measures are sufficient.

This paper summarizes the framework's outcome for two different conformity process scenarios, outlined in Figure 4.

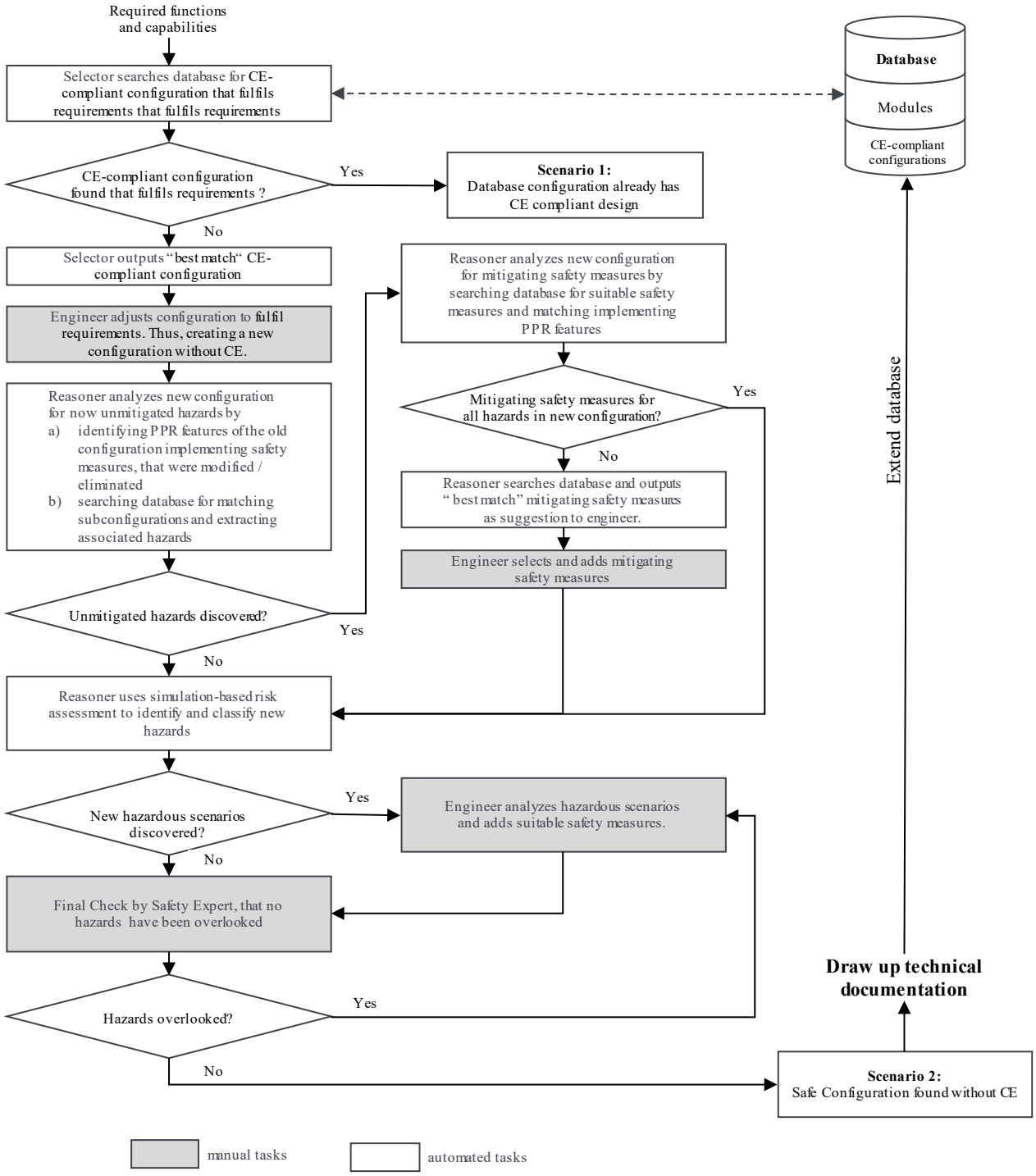


Figure 4: Outcome for different conformity process scenarios

Scenario 1: The selector finds one or more CE-compliant configurations in the database which fulfil all the requirements.

- These configurations can be reused as the "new" configuration. Since the new configuration, the configuration in the database, and the used standards are identical, the documentation of the database configuration can be reused for Step 5 of the conformity process.

Scenario 2: The configuration found is a modified configuration of a previous CE-compliant configuration (stored in database). In that case, a risk assessment procedure consisting of identifying hazards and selecting suitable safety measures is mandatory. To identify hazards the following four evaluation steps are conducted:

- In a first step, the reasoner analyzes whether hazards of the previous CE-compliant configuration become unmitigated due to elimination or modification of PPR features implementing safety measures. It should be noted that the elimination or modification of PPR features could also lead to the elimination or risk decrease of hazards.
- In a second step, the reasoner searches the database for matching sub-configurations and the reasoning algorithm uses the PPRHS model to evaluate adequacy of the safety measures and no increase in risk.
- In a third step, simulation-aided risk assessment (SARA) tool is used to identify potential new hazards that result from the "sum of all sub-configurations". The tool uses a digital twin of the machine and an adversarial human digital model to simulate different interaction behaviors in a physics simulation, where the human model is "trying to get hurt" and the physics engine is used to evaluate resulting collision forces and pressures.
- Since the rules and SARA tool used by the reasoner cannot claim completeness – they can only falsify safety; not verify it - a final check (step 4) is performed by a safety expert to make sure that no hazards are overlooked.

In case an unmitigated or new hazards (see Figure 5) in any of the previous four steps is identified, three distinct cases can be distinguished:

- Case I: The PPR features causing those hazards can be identified as a sub-configuration in the database (common for results from step 1 and 2 of the hazard identification process), meaning that those hazards have been encountered before and suitable safety measures exist. It is then just a matter of identifying the PPR features implementing those safety measures in the configuration or adding them to the configuration if missing.
- Case II: The PPR features causing those hazards are similar but not an exact match to a sub-configuration in the database. The reasoner can output "best match" safety measures, but it is up to the engineer to evaluate, whether safety measure option is a) adequate or b) also requires modification.
- Case III: New unknown hazards (common for results from step 3 and 4 of the hazard identification process). In that case, the engineer needs to codify the underlying PPR features and suitable safety measures.

In Case I, the risk assessment procedure can be quickly passed. Further, the safety documentation which is already available can be largely reused in Step 5 of the conformity process. Case IIa requires more effort, but again a lot of the existing documentation can be reused, or the lacking documentation about the new mapping of hazards to safety measures can be simply added. In cases IIb and III, new previously unknown hazards are identified and no adequate safety measures exist. Thus, requiring a lot of the effort engineer, causing machine downtime and added human effort.

Therefore, if those cases can be avoided, which is one of the framework's core objectives, ultra-flexible production systems will be more efficient. To guarantee sufficient human safety, the risk must be reduced until it is within the limits defined by the standards. The documentation of this risk assessment is then added to the documentation of the machine. Furthermore, the new CE-compliant configuration extends the framework's database.

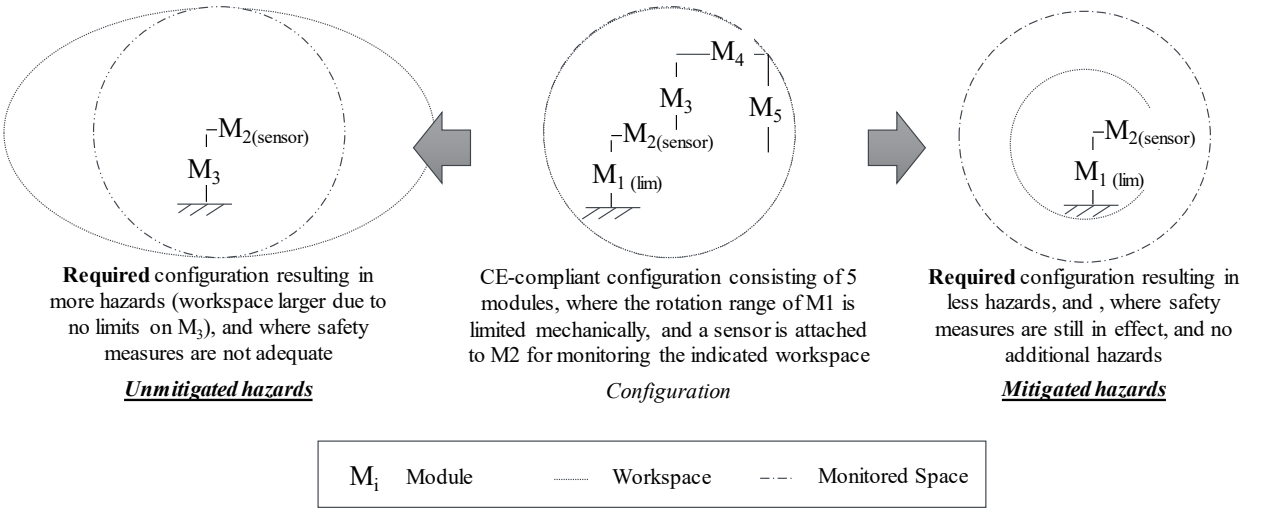


Figure 5: Examples of modifications of CE-compliant configuration (middle) resulting in reduced hazards / risk levels (right) or in unmitigated hazards / risks (left)

The configured machine still has to be approved (conducted manually) in order to avoid modification errors, such as wrongly-attached wires, sensors or the omission of electrical grounding. The construction must correspond to the CE-compliant design in the database. If more than one configuration is available after the database search, the found configurations are prioritized according to multi-criterial objectives, such as time, cost, or associated risks. Reusing configurations in the database enables Steps 4 to 6 in the conformity process to be accomplished quickly, thus minimizing machine downtime.

It should also be noted that the CE-conform configurations in the database can only be employed if the relevant standards are still valid. Otherwise, their CE marking can be used by the reasoner as a valid option before it is updated according to current standards during reconfiguration.

4. Use Case

Using the modular, mobile machines (see Figure 6) designed by IFF, the presented framework are applied to an example of a scenario. In this scenario a CPS, represented by a mobile modular machine consisting of a modular robot, an automated guided vehicle (AGV), and its respective power supply, is assigned an assembly task. This CPS was digitally modeled and visualized in Unity Engine and is continuously updated regarding the current configuration. This game engine allows to integrate 3D models, scripting and several relevant technologies, like communication network protocols. Using Unity Engine and physics engines, like MuJoCo, it is possible to simulate CPS and their physical properties, including collisions and mechanical behavior according to the current configuration [46–48]. The assembled product is expected to be delivered to a specific location in the factory. The transport time is used to assemble the product. At this stage, the robot is in a 3-axis configuration. However, the production engineer discovers that the robot is unable to fulfil the planned assembly task in its current configuration.

After an iterative process, the worker derives that the minimal required configuration to achieve the task needs the integration of three additional modules. He or she modifies the robot accordingly. Following the procedures detailed in Section 3, the machine's current configuration must comply with ISO 10218-2 [24]. IFF is considered as the machine's integrator and is accordingly responsible for compliance with the Machinery Directive as well as with the specific robot standard [24]. On conducting a database search using the framework presented, neither a configuration nor sub-configuration fulfilling the requirements can be found. It cannot be proven that the new configuration poses a lower risk than the old. Additional safety measures are required and a "classical" CE process is performed. The resulting documentation and the declaration of CE conformity is then stored depending on the time and location, and the production engineer

is then permitted to affix the CE marking. Following the procedure described, the modification process is complete and the CE-conform modular machine is now able to start its assembly task. Further, the new configuration is stored in the described database. When the scheduled task is finished, the worker removes one of the modules again because it is needed for another robot. Utilizing the framework presented in Section 3, it can be determined that the configuration is a subclass of a CE compliant configuration with the same safety measures and no additional hazards identified (see Figure 5). Consequently, it can be proven that the new configuration poses no higher risk than the preceding configuration. Thus, the safety measures are considered to be adequate. The configuration only has to be approved and the technical documentation added.

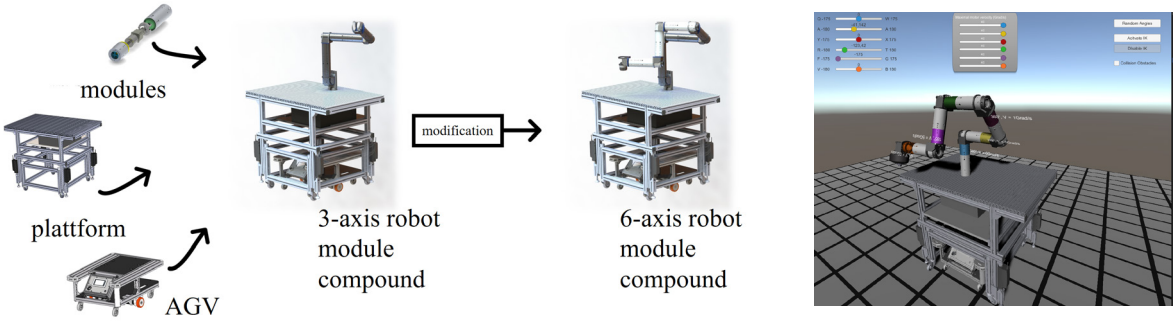


Figure 6: Modification of a machine consisting of different modules (left) and its digital representation (right) in Unity Engine

Later, the worker needs the robot to accomplish a different task. Using the framework once again, an already CE compliant design suitable for the task can be found. The configuration therefore only has to be approved and the appropriate technical documentation compiled.

5. Discussion of results

The presented framework proposes an approach to minimize downtime by speeding up and automating the respective conformity assessment procedures.

The analysis in this paper is limited to machines falling under the machinery directive (2006/42/EC), excluding the machinery listed in Annex 4 of the directive. Due to this limitation, the only applicable directive identified is the machinery directive excluding Annex 4, i.e. excluding machines requiring conformity assessment by a notified body. Accordingly, this publication only considers machines where the conformity process requires a self-declaration.

Steps 1, 2, 3 and 5 in the CE marking process can already be automated with database software which output the respective applicable harmonized standards, including the requirements of the machinery directive. Step 4 includes the database search and case distinction into three scenarios.

Scenario 1 can be fully automated. The degree of process automation in Scenario 2 depends on the completeness of the reasoning algorithm's rules for determining that there is no increased risk and that safety measures are sufficient. Gaps identified in the rule system can be filled by adding more rules (which would result in the common problem of keeping rule-based systems up to date) or by integrating additional tools, e.g. simulation models, which can be used to falsify safety measures. While this concept will never yield a 100 percent guarantee, it could be argued that the results obtained with it will approach and surpass the results of the human safety expert.

Scenario 2 and 3 require a conformity assessment procedure which not only involves human effort for Steps 4 to 6 but also causes machine downtime. However, as the framework matures and is filled with more CE compliant configurations, Scenario 3 Case IIb and Case III in scenario 2 become less and less likely. Applied

to production systems and “self-extending” networks around the globe, cases like Scenario 3 could become insignificant and the conformity process almost fully automatable. However, going forward, one challenge will be the necessary processing power, depending on the number of modules and configuration possibilities (framework scale up).

As the frequency of system modification increases, the proportion of modification-time = downtime = lost added value in today’s machine lifecycle will increase, resulting in decreasing OEE. At best, the framework aims at eliminating the time required for the conformity process, which is considered part of modification time.

Related to machines that are modified within minutes to hours and extrapolated to hundreds of machines in a production system, the use of this framework could save considerable modification time that could be used for manufacturing. In addition, the framework evaluates whether a conformity assessment procedure is required and offers the additional criterion of whether the modification will add value.

6. Outlook

Ongoing activities at IPA and IFF are filling the gaps in the rule-based system by restructuring the guidelines, as well as further **integrating a simulation-based risk assessment module**, which uses a digital twin of the machine configuration and erroneous human behavior to attempt to falsify safety measures. Furthermore, to **quantify the achieved time savings**, the framework will be benchmarked using standardized use cases that reflect the typical reconfiguration scenario of the future factory. Hence, the definition of such benchmark use cases is a challenge within itself.

Another research avenue being pursued is connecting the framework to the digital safety shadow of machines. Like the digital process shadow, the **digital safety shadow** primarily gathers safety-related data over time and contextualizes these data into usable information. Such information could be used to quantify risk frequency and probabilities in order to either verify or reassess the risks associated with an HRC application. For example, the information on how often a worker enters a designated hazard area could be used to confirm the risk frequency of the hazard in the risk assessment. If the risk frequency is much higher, additional safety measures will be required; if it is much lower, safety measures can be relaxed and the flexibility of the application increased.

Another point to be examined in the future is the fact that currently no additional specific formal qualification of the CE declarant is required for the declaration of CE conformity. This raises the question of how a person without specific training can assess hazards. Taking into account typical definitions of competence in production technology [49–52], the analysis of the situation can only be done by including and estimating hazards of already known systems. An estimation via similarities of known systems and the abstraction to common features represent a form of modelling. In this context, the question is whether and if so, how human abstraction and modelling can be transferred to a decision support approach to further accelerate and improve decision making.

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