Pós-Graduação em Ciência da Computação

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Uni-REPM SCS: A SAFETY MATURITY MODEL FOR REQUIREMENTS ENGINEERING PROCESS

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A Ph.D. Thesis presented to the Center of Informatics of Universidade Federal de Pernambuco in partial fulfillment of the requirements for the degree of Philosophy Doctor in Computer Science.

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I dedicate this work to God, to my parents Mário Vilela and Fátima Vilela, to my sister Francynne Vilela and to my fiancé Marcus Queiroz.

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ABSTRACT

Context: Software is an important part in safety-critical system (SCS) development since it is becoming a major source of hazards. Software has been responsible to implement innovative and complex functions and to send instructions to the hardware. Requirements-related hazards have been associated with many accidents and safety incidents. Requirements issues tend to be mitigated in companies with high processes maturity levels since they adopt good practices from software engineering in a systematic, consistent and proactive way. However, requirements engineers need systematic guidance to consider safety concerns early in the development process. **Objective**: This thesis investigates which safety practices/actions are suitable to be used in the Requirements Engineering process of SCS as well as to propose a safety maturity model to this area. **Method**: A set of empirical studies were used in this work. The data collection was done through systematic literature review and case studies. We followed the Design Science methodology to propose Uni-REPM SCS, a safety module for Unified Requirements Engineering Process Maturity Model (Uni-REPM), and the technology transfer framework to perform the safety module validation. Besides, comprehensive literature review was also conducted to provide background and support for the empirical studies. **Results**: The safety module has seven main processes, 14 sub-processes and 148 safety actions describing principles and practices that form the basis of safety processes maturity. Moreover, we describe its usage through a tool. We conducted a static validation with two practitioners and nine academic experts to evaluate its coverage, correctness, usefulness and applicability. Furthermore, we performed a dynamic validation with seven industry practitioners to evaluate the safety maturity level of seven industry projects. **Conclusions**: The validation indicates a good coverage of practices and good receptivity by the experts. Finally, the module can help companies in evaluating their current practices as well as offers a step-wise improvement strategy to reach higher maturity.

Key-words: Safety-critical systems. Requirements Engineering. Maturity Models. Uni-REPM. Safety Engineering.

RESUMO

Contexto: Software tem um papel importante no desenvolvimento de sistemas críticos visto que está se tornando uma fonte importante de perigos. Software tem sido responsável por implementar funcionalidades inovadoras e complexas e por enviar instruções ao hardware. Perigos relacionados a requisitos têm sido associados a muitos acidentes e incidentes de segurança. Os problemas de requisitos tendem a ser atenuados em organizações com altos níveis de maturidade de processos, pois elas adotam boas práticas da engenharia de software de forma sistemática, consistente e pró-ativa. Portanto, processos maduros contribuem para tornar o processo de desenvolvimento do sistema menos desafiador. No entanto, os engenheiros de requisitos precisam de orientação sistemática para considerar preocupações de segurança no início do processo de desenvolvimento. **Objetivo**: Esta tese investiga quais práticas/ações de segurança são adequadas para serem usadas no processo de engenharia de requisitos de sistemas críticos bem como propor um modelo de maturidade de segurança para esta área. **Método**: Um conjunto de estudos empíricos foi utilizado neste trabalho. A coleta de dados foi realizada por meio de revisão sistemática da literatura e estudos de caso. Nós seguimos a metodologia *Design Science* para propor o Uni-REPM SCS, um módulo de segurança para o *Unified Requirements Engineering Process Maturity Model (Uni-REPM)*. Nós adotamos o framework de transferência de tecnologia para realizar a validação do módulo de segurança. Além disso, uma revisão abrangente da literatura também foi realizada para fornecer referencial teórico e suporte para os estudos empíricos. **Resultados**: O módulo de segurança possui sete processos principais, 14 subprocessos e 148 ações de segurança que descrevem princípios e práticas que constituem a base da maturidade dos processos de segurança. Ademais, nós descrevemos seu uso por meio de uma ferramenta. Também realizamos uma avaliação estática com dois profissionais e nove especialistas da academia para avaliar sua cobertura, corretude, utilidade e aplicabilidade. Além disso, realizamos uma validação dinâmica com sete profissionais da indústria para avaliar o nível de maturidade de segurança de sete projetos industriais. **Conclusões**: O módulo pode ajudar as organizações na avaliação de suas atuais práticas de segurança no processo de RE, bem como oferecer uma estratégia de melhoria passo a passo para alcançar um nível mais alto de maturidade.

Palavras-chaves: Sistemas Críticos. Engenharia de Requisitos. Modelos de Maturidade. Uni-REPM. Engenharia de Segurança.

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LIST OF ABBREVIATIONS AND ACRONYMS

CMMI	Capability Maturity Model Integration
IIPS	Infusion Insulin Pump
MDREPM	Market-Driven Requirements Engineering Process Maturity Model
MPA	Main process area
RE	Requirements Engineering
REGPG	Requirements Engineering Good Practice Guide
REPM	Requirement Engineering Process Maturity Model
SCS	Safety-Critical Systems
SLR	Systematic Literature Review
SPA	Sub-process area
SPICE	Software Process Improvement and Capability Determination
Uni-REPM	Unified Requirements Engineering Process Maturity Model

CONTENTS

1 INTRODUCTION

In this chapter, we characterize the context of this work, the main motivations and rationale. Then, we present the objectives and research questions. Furthermore, we describe the research methodology and present an overview of the proposal of this thesis. Finally, the thesis structure is defined.

1.1 CONTEXT

Safety-Critical Systems (SCS) can be defined as a set of hardware, software, process, data and people whose failure could result in accidents that may cause damage to the environment, financial losses, injury to people or loss of lives (LEVESON, 2011).

These systems are used in a variety of domains, for example medical, transportation, electrical, automotive, space, nuclear energy, defense and many of them have safety-related implications. Software has becoming an important aspect in the system development process since significant changes have occurred in the types and context of systems built today (LEVESON, 2011). These systems are even more complex, their development involve many suppliers, and software is used to mitigate hardware issues for example. Hence, some challenges arose to be handled by Requirements Engineering (RE):

- Fast pace of technological change (LUTZ, 2000) (LEVESON, 2011) with constant evolution of frameworks and libraries that leads to changes in system requirements;
- Ability to learn from experience (LEVESON, 2011) which includes the improvement of system development processes and avoiding the re-utilization of incomplete or inconsistent requirements;
- Changing nature of accidents (LUTZ, 2000) (LEVESON, 2011) that are caused by requirements-related problems and not due to the implementation or component failure;
- New types of hazards (LUTZ, 2000) (LEVESON, 2011) (HATCLIFF et al., 2014) that are derived from requirements-related issues;
- Increasing complexity and coupling (LEVESON, 1995) (PERNSTÅL et al., 2015) (HATCLIFF et al., 2014) requiring more sophisticated RE approaches;
- Decreasing tolerance for single accidents (LEVESON, 2011) (HATCLIFF et al., 2014) which leads to extensive requirements analysis and validation procedures;
- Difficulty in selecting priorities and making trade-offs (LUTZ, 2000) (LEVESON, 2011) (PERNSTÅL et al., 2015) among functional and non-functional requirements;

- More complex relationships between humans and automation (LUTZ, 2000) (LEVESON, 2011) demanding the specification and analysis of human-interaction concerns;
- Changing regulatory and public views of safety (LEVESON, 2011) (HATCLIFF et al., 2014) where the standards are frequently evolving;
- Developing software for SCS is usually more expensive than non-safety-critical systems (ZOUGHBI; BRIAND; LABICHE, 2011) (SCHEDL; WINKELBAUER, 2008a) considering the need of extensive requirements specification, analysis, validation and certification processes.

Currently, software has been used to implement and/or control an increasing number of traditional as well as innovative functions and to handle functions that were controlled by humans (PANARONI et al., 2008). In this changing from hardware-driven to software-driven approach, the literature reports that software has collaborated to deaths and injuries in many safety incidents and safety-related catastrophes (LEVESON, 2011) (LUTZ, 2000) (GUILLERM; DEMMOU; SADOU, 2010) (SIMPSON; STOKER, 2002).

Hazardous situations, i.e. situations that can lead to accidents, can occur in a SCS in two forms (KAINDL; POPP; RANEBURGER, 2015): 1) the system causes a hazard (such as brake failure that cause a car collision); or 2) the system is exposed to a hazard (for example, a strong magnetic field that interfere in the control system).

There are many cases in the literature, e.g., (i) the computer-controlled radiation therapy machine called Therac-25 that overdosed six people (LEVESON, 1995); (ii) the crash of a Turkish Airline DC-10 resulting in 346 deaths (LEVESON, 1995); (iii) the Milstar satellite that was placed in an incorrect and unusable low elliptical final orbit, as opposed to the intended geosynchronous orbit (LEVESON, 2011); (iv) Bacterial Contamination of a Public Water Supply that resulted in half of the people in the town of 4800 that became ill and seven died (LEVESON, 2011); (v) the loss of the Mars Climate Orbiter spacecraft (LUTZ, 2000); and many others where inadequate or misunderstood requirements have been recognized as the major cause (not coding or implementation) (LUTZ, 2000) of a significant proportion of accidents (SIMPSON; STOKER, 2002) and safety-related catastrophes (LEVESON, 2002a).

In this context, software is becoming a major source of risks and hazards since it can give wrong instructions to system hardware, through actuators, that can lead to accidents and hurt people (PANARONI et al., 2008). Moreover, several studies have identified problems with the RE process for SCS (COX; NIAZI; VERNER, 2009)(AHMAD et al., 2015)(SOLEMON; SAHIBUDDIN; GHANI, 2008)(FIRESMITH, 2006a).

Considering the relevance of maintaining high confidence in safety-critical software (GRAYDON; HOLLOWAY, 2015), it is claimed in academia and industry that safety concerns should be addressed early in the system lifecycle (LEVESON, 2011)(PANARONI et al., 2008). Therefore, engineers must plan and specify SCS carefully, requiring more sophisticated RE approaches (LEVESON, 2011).

Nevertheless, requirements engineers traditionally are not familiar with system safety analysis processes which are usually performed by safety engineers. One reason is the gap that exists among the traditional development processes, methodologies, notations and tools used in safety engineering (SCHOLZ; THRAMBOULIDIS, 2013)(STANDARDIZATION, 2011c)(SEI, 2007). This gap makes the safety analysis process by the requirements engineers a hard and challenging activity (SCHOLZ; THRAMBOULIDIS, 2013). Among the implications of the insufficient guidance, we can cite (LEVESON, 2011): safety activities are isolated from RE and developers responsible for constructing the system; engineers face significant safety subjects just after it is too late or too costly to make significant changes; obstacles during the system certification.

Safety-related activities can create risks to acquisition cost and schedule performance if not managed and performed with discipline. These risks arise from a variety of causes including: lack of training, inability to provide guidance to acquirer project offices, insufficient consultation between acquirers and stakeholders, and a lack of understanding of safety requirements and safety engineering (SEI, 2007).

In addition to the consequences of lack of guidance, companies face some issues during system development such as (i) absence of systematization of available safety actions/practices (LAMI; FABBRINI; FUSANI, 2011a)(JOHANNESSEN; HALONEN; ÖRSMARK, 2011); (ii) need of integration among safety, RE and the broad context of product development, management and corporate strategy (MARTINS; GORSCHEK, 2016b)(LEVESON, 2011); (iii) lack of a model to guide them on how to apply their efforts systematically to achieve safety goals and to maintain continual improvements in safety implementation (LAMI; FABBRINI; FUSANI, 2011a)(JOHANNESSEN; HALONEN; ÖRSMARK, 2011), which can continually drive actions towards higher safety maturity levels; (iv) difficulties in establishing priorities to safety actions/practices to be followed (LAMI; FABBRINI; FUSANI, 2011a).

1.2 MOTIVATION AND RATIONALE

In order to ensure a safety progress, engineers should handle several features (e.g. organizational, technical, strategic) (SOLEMON; SAHIBUDDIN; GHANI, 2008) and this requires specialized processes, techniques, skills and experience (STANDARDIZATION, 2011c) (SEI, 2007). Aiming to unify the development process and give guidance to companies, some safety standards, such as ISO 61508 (STANDARDIZATION, 2011a) and ISO 2626-2 (STANDARDIZATION, 2011b), are available.

However, problems are described with standards usage (FUSANI; LAMI, 2014). For example, lack of management guidance (on how to interpret the standard and satisfy the requirements), conflicts among stakeholders views regarding the standard and issues related to conformance demonstration. Moreover, they have contributed to the development of systems historically depicted as mature or highly-evolved. This makes their implementation challenging for those companies starting to follow standards aiming to increase their systems safety (STANDARDIZATION, 2012a).

In this context, determining the capability or maturity of safety processes has been identified as necessary to have more technical results that can be used in a continuous process improvement (JOHANSSON; NEVALAINEN, 2012) (JOHANNESSEN; HALONEN; ÖRSMARK, 2011). The evaluation of safety processes is necessary since there specific practices to be adopted during the development of a SCS that are not covered by generic software maturity models. Improving the software process quality is a strategy adopted by many companies as a way to increase the confidence in the quality of the resulting software product (SOMMERVILLE, 2011)(LAMI; FABBRINI; FUSANI, 2011b).

In order to achieve such improvement, companies need methods to assess the strengths and weaknesses of their processes, and to develop strategies to mitigate the problems found (REIS; MATHIAS; OLIVEIRA, 2016). Additionally, they pursue well-structured and systematic processes to achieve their goals, with a set of resources or practices, resulting in a more mature organization or system.

Literature reports an increasing interest in maturity models (PÖPPELBUSS; RÖGLINGER, 2011) (REIS; MATHIAS; OLIVEIRA, 2016) to fill the gap of safety standards (PANARONI et al., 2008). A maturity model allows a company to determine its maturity level based on the performances of the companies' process areas or process capabilities (REIS; MATHIAS; OLIVEIRA, 2016) (NGAI et al., 2013).

Process capability is defined as a characterization of the ability of a process to achieve current or projected business goals (LAMI; FABBRINI; FUSANI, 2011b). Nevertheless, there is a risk that an organization that has been evaluated as adequately capable using a generic maturity model such as Capability Maturity Model Integration (CMMI) (TEAM, 2010) may have inadequate process capability for safety management and safety engineering (SEI, 2007).

Varkoi (2013) arguments that safety should be treated as a new process quality dimension. Although safety is usually considered as a characteristic of a product or system, the development process certainly can affect the safety of the product. Lawrence (1993) complements by emphasizing software life cycle to improve safety and reliability.

In this context, the development process is considered as one source of safety risks (VARKOI, 2013). The author also states that process assessment models can be developed to consider safety requirements and to address dependability including reliability issues. Hence, process-related safety refer to definition of important process attributes that contributes to develop safer products and systems.

Some safety maturity models have been proposed such as +SAFE-CMMI-DEV (SEI, 2007), and ISO 15504-10 (STANDARDIZATION, 2011c). However, these models are general (PEREIRA; SILVA, 2011), i.e. they cover the entire software development process, (such as software architecture, V & V among others), hence they have few RE-related practices compared with specific RE maturity models (GORSCHEK; SVAHNBERG; TEJLE, 2003).

The problems related to safety in RE, such as incomplete specifications, lack of systematic processes, definition of requirements impossible or expensive to implement, for example, have

a tendency of decreasing in higher maturity RE process (SVAHNBERG et al., 2015)(LEVESON, 2002a). Thus, companies should improve their RE process with the purpose of overcome the difficulties they face during the construction of SCS.

Handling safety concerns early in software development contributes to ensure that safety problems do not propagate through subsequent phases (SAEED; LEMOS; ANDERSON, 1995)(PERNSTÅL; FELDT; GORSCHEK, 2013a)(SECHSER, 2011). Furthermore, if changes in the system are stopped early, it is more likely to have the opportunity of mitigating errors and obtaining a stable software version (LEVESON, 2011)(GLINZ; FRICKER, 2015)(SECHSER, 2011).

Accordingly, the early consideration of safety issues in RE should be a top priority in the development of SCS since RE is essential for software quality (SHAKEEL et al., 2014)(HADDAD et al., 2016), and effectiveness of the software development process (SOLEMON; SAHIBUDDIN; GHANI, 2008).

Haddad et al. (2016) present a chronological summary with some research that highlight the importance of requirements in software development. The importance of early feedback has been demonstrated empirically from both an economic and a safety point of view (EASTERBROOK et al., 1996). In Table 1, we observe the need of proper requirements elicitation and a rigorous requirements engineering process to mitigate failures in the requirements process.

Moreover, high safety levels are typically better achieved by addressing safety from the beginning; not by trying to add protection components and additional complexities after the system has been developed (LEVESON, 2011)(HEIMDAHL, 2007). Mature organizations do their business in a systematic and proactive approach (KONTOGIANNIS; LEVA; BALFE, 2016a)(REIS; MATHIAS; OLIVEIRA, 2016). Empirical studies investigated the benefits of adopting a maturity model (ELLIS; BERRY, 2013) and reported that the most effective approach is software process improvement (SPI) (KHAN et al., 2018). The benefits include improved software product quality, improved productivity of developers, reduced project cycle time and cost, enhanced business growth, and improved customer satisfaction (CLARKE; O'CONNOR, 2012)(IVERSEN; NGWENYAMA, 2006)(STAPLES; NIAZI, 2008) (CHEVERS, 2017).

Ellis and Berry (2013) conducted a survey and compared the performance of independent organizations at different RDM (Requirements Definition and Management) maturity levels. They noticed that the average organization at a RDM maturity level outperforms the average organization at a lower RDM maturity level. They also found a correlation between an organization's return on assets (a measure of the organization's efficiency in turning assets into cash) and its RDM maturity.

Chevers (2017) conducted an online survey approach to gather data from Information Systems professionals. From the 69 answers received, they conclude several benefits of SPI programs such as improved software product quality, improved customer satisfaction, improved staff productivity, reduced development cost, and reduced project cycle time.

On the other hand, immature companies can and do produce good quality requirements documents, but they may not be able to do so consistently or when working to tight dead-

Table 1 – Chronological summary of research on the importance of requirements (adapted from Haddad et al. (2016)).

Year	Statement	Reference
1983	Correcting errors in the system can be up to 100 times more expensive than if the correction or prevention occurs during the phase involving the ER and the system implementation.	Boehm et al. (1983)
1992	Requirements-related defects accounts for 43% in a a system. 36% occurred due to problems in requirements translation, 5% cause by incomplete requirements, and 2% by documentation.	Sheldon et al. (1992)
1993	60% of critical system errors result from requirements failures.	Lutz (1993a)
1995	Clear Statement of Requirements is one of major reasons for a project to succeed according to 13% IT executive managers interviewed. They also say that factors that cause projects to be challenged include Incomplete Requirements & Specifications (12.8%), and Changing Requirements & Specifications (11.8%). Opinions about why projects are impaired and ultimately canceled ranked incomplete requirements as the top of the list (13.1%).	Group et al. (1995)
1995	"Early feedback is crucial to building safe software".	Leveson (1995)
1996	It is clear that in each case the study added value to the project by clarifying the requirements and identifying important errors very early in the lifecycle.	Easterbrook et al. (1996)
2002	A study pointed out that of the 268 problems encountered during software development, 50% are related to requirements.	Hall, Beecham and Rainer (2002)
2008	Among 40 and 60% of defects and failures in software are attributed to incorrect definition of requirements	Ellis and Berry (2013)
2011	"The serious problems that have happened with software have to do with requirements, not coding errors."	Leveson (2011)
2013	Understanding the company's business rules and correctly defining the scope of the project is critical to avoiding project failures, including forecasting changes in requirements throughout software development.	Manifesto (2013)

lines. Such companies lay emphasis on fixing problems right away and only obtain their results through the efforts of determined subjects, being informally known as firefighters, while deadlines and budgets are often exceeded, since the planning is not based on actual estimates (REIS; MATHIAS; OLIVEIRA, 2016).

Hence, a mature and practicable process contributes to reduce errors (SECHSER, 2011) from the beginning since the higher the maturity level of the company, the less frequent are the requirements problems (SOLEMON; SAHIBUDDIN; GHANI, 2009). Sadraei et al. (2007) indicate that in higher maturity levels there are less rework. Besides, if RE activities are performed quickly it could result in spending more time in performing later activities or even taking the project to failure. Furthermore, process improvement and assessment frameworks allow to transfer research results into practice (SVAHNBERG et al., 2013).

There are some RE assessment frameworks such as the REGPG (SAWYER; SOMMERVILLE; VILLER, 1997), Requirement Engineering Process Maturity Model (REPM) (GORSCHEK; SVAHNBERG; TEJLE, 2003), and Market-Driven Requirements Engineering Process Maturity Model

(MDREPM) (GORSCHEK et al., 2012), and others that allow organizations to evaluate the strengths and weaknesses regarding the RE process. However, they do not cover market-driven and bespoke RE practices in the same model (SVAHNBERG et al., 2015).

Therefore, the Unified Requirements Engineering Process Maturity Model (Uni-REPM) was proposed to fill this gap. It is a universal lightweight model to evaluate the maturity of a RE process structured in two views: Process Area and Maturity Level that covers both market-driven and bespoke (SVAHNBERG et al., 2015) practices and has been well accepted in companies. However, it does not consider the safety aspects required for the development of a SCS. Hence, it does not currently provide a sufficient basis for performing a process capability assessment of processes involved in the development of such systems or for its use in a safety-related context.

Systematic Literature Review (SLR)s about maturity models were conducted by Reis et al. (REIS; MATHIAS; OLIVEIRA, 2016) and Wendler (WENDLER, 2012). Besides, the integration of RE and safety was investigated in the SLR of by Martins and Gorschek (MARTINS; GORSCHEK, 2016a). Another SLR conducted by us (VILELA et al., 2017a) pointed out many types of contributions such as Approach, Framework, Method, Tool, Process, Model among others (see Figure 17) aiming to improve the integration between RE and safety analysis, however, no maturity model for safety was discovered. Therefore, we noticed a demand for a safety maturity model for the RE process.

1.3 OBJECTIVES

The industry challenges about the RE process of safety-critical systems mentioned previously motivated the investigation about how the quality of this process, with respect to the safety of such systems, can be improved.

The main goal of this thesis was defined using the template of Wieringa (2010):

Improve the quality of safety requirements engineering process *by* developing a safety module for Uni-REPM maturity model *which* is useful and suitable to domain-independent systems *in order to* increase the safety processes maturity levels and further develop safer systems.

It is important to note that to evaluate the usefulness of the proposal, we considered the opinion of domain experts if the proposal could be used to improve the requirements process of safety-critical systems.

In order to achieve this goal, we defined the following specific objectives:

- Contribute to the state-of-the-practice by defining a set of safety practices suitable to be used in the requirements engineering process of safety-critical systems.
- Define a safety maturity module for evaluating the maturity of safety processes during RE phase of the system development process compatible with Uni-REPM.

- Develop a tool to support the maturity evaluations.
- Investigate the maturity levels achieved by the companies when applying the proposed Uni-REPM safety module in different safety-critical domains.
- Explore the completeness, perceived usefulness, and ease of use of the proposed Uni-REPM safety module.

1.4 RESEARCH QUESTIONS

This work is motivated by the following Research Questions (RQs):

- RQ1: Which safety practices are suitable to be used in the requirements engineering process of safety-critical systems?

  To address this research question, we identified the safety practices to be adopted in the RE process. The identification demanded the analysis of multiple sources of information (see Section 3.3). The suitability of identified practices was evaluated in the static validation (Section 7.1) by eleven experts and in the dynamic validation (Section 7.2) by seven industry practitioners.

- RQ2: How to design a safety maturity module for the requirements engineering process of safety-critical systems?

  The design of the safety maturity module required the identification of features presented in maturity models (Section 2.3). We also considered the steps defined by the literature to propose maturity models (the traceability information about the steps is presented in Table 3). Finally, we considered such features as well as the twofold purpose of the Uni-REPM: Process Area view and a Maturity Level view.

- RQ3: How does the proposed safety maturity module compare with related solutions?

  We performed a comparison among our proposal and existing safety maturity models (+SAFE and ISO 15504-10). Accordingly, we identified similarities and differences with our work that have helped us to position our Uni-REPM SCS with respect to the related available solutions.

- RQ4: What is the effect of applying Uni-REPM safety module when it is instantiated in different safety-critical domains?

  We interviewed seven companies that work in distinct contexts: defense & aerospace, automotive, and industrial machinery to evaluate whether the evaluation results are diverse in different domains. All companies vary in relation to size (in number of employees and number of requirements in typical projects) and type of customers as presented in Section 7.2.

- RQ5: How is the perceived usefulness and ease of use of the Uni-REPM safety module?

  The usefulness and ease of use were evaluated in academia as well as in industry. To achieve this goal, we followed the technology transfer framework proposed by Gorschek et al. (2006). Accordingly, we performed a static validation (Section 7.1) and a dynamic validation (Section 7.2). These types of validation are based on the utility stakeholder opinion also used by important authors in the field such as (WIERINGA, 2010).

- RQ6: How to evaluate whether the module has a sufficient coverage of safety practices?

  To answer this research question, we performed a dynamic validation (Section 7.2) and we included question in the interview questionnaire (see Appendix F). In Section 7.2.7.3, we described the subjects answers regarding the coverage of the safety practices in Uni-REPM SCS (Question #16).

1.5 OVERVIEW OF THE PROPOSAL

This thesis proposes a safety maturity module for Uni-REPM, called Uni-REPM SCS. Companies can use it as a guide to assess and improve their current safety practices and processes. It is relevant to note that as the original Uni-REPM, the safety module is not purely prescriptive, but rather both the evaluation aspect and the improvement part of the model are context aware, i.e. companies can define based on the project context what is relevant for them to use, and what is not.

We used multiple information sources (see Section 5.1) to collect data and to define the practices to be included in a RE module for SCS, including two Systematic Literature Reviews (SLR) (MARTINS; GORSCHEK, 2016a)(VILELA et al., 2017a), one large interview study with companies (MARTINS; GORSCHEK, 2018), technical reports (MARTINS; GORSCHEK, 2016c), and an inventory and extraction from several safety standards.

The module follows the tree-structure of Uni-REPM where Main process area (MPA)s are the top nodes and the Actions are the bottom ones. Sub-process area (SPA)s allow to further granulate the MPAs into different subprocesses. Every Action is mapped to a certain maturity level spanning from 1 to 3. Further details about Uni-REPM structure is found at Section 2.4) and regarding Uni-REPM SCS at Section 5.2.

We evaluated the safety module in terms of coverage, correctness, usefulness, and applicability. This evaluation followed the technology transfer model (GORSCHEK et al., 2006) explained in Section 3.9. It consisted of a static evaluation and a dynamic validation. The former relied on the feedback of two practitioners and nine academic experts regarding the structure and safety practices presented in the module. The latter was conducted with seven practitioners from different companies located in three countries.

1.6 SUMMARY OF PUBLICATIONS

In this section, we list papers related to this thesis that were published in many venues.

- Journal Papers:

  1. VILELA, J., CASTRO, J., MARTINS, L. E. G., GORSCHEK, T. Safety Practices in Requirements Engineering: the uni-repm safety module.IEEE Transactions on Software Engineering, 2018, pp.1-32.
  2. VILELA, J., CASTRO, J., MARTINS, L. E. G., GORSCHEK, T. Integration between requirements engineering and safety analysis: A systematic literature review. Journal of Systems and Software, v. 125, 2017, pp. 68-92.

- Conference Papers:

  1. VILELA, J., CASTRO, J., MARTINS, L. E. G., GORSCHEK, T. Assessment of Safety Processes in Requirements Engineering. In: IEEE International Requirements Engineering Conference (RE), RE@Next Track, 2018, pp.358–363.
  2. VILELA, J., CASTRO, J., MARTINS, L. E. G., GORSCHEK, T. Safe-RE: safety requirements metamodel based on industry safety standards. In: Proceedings of the XXXII Brazilian Symposium on Software Engineering, Insightful Ideas & Emerging Results Track, pp. 196-201. ACM, 2018.
  3. VILELA, J., CASTRO, J., MARTINS, L. E. G., GORSCHEK, T. Specifying safety requirements with GORE languages. In: Proceedings of the 31st Brazilian Symposium on Software Engineering, Research Track, 2017, pp. 154–163.

- Workshop Papers:

  1. VILELA, J., CASTRO, J., MARTINS, L. E. G., GORSCHEK, T. Uni-REPM tool: Maturity Evaluation of Requirements Engineering Processes. In: Sessão de Ferramentas do Congresso Brasileiro de Software (CBSOFT), 2018, pp. 49-54.
  2. VILELA, J., CASTRO, J., MARTINS, L. E. G. Uni-REPM Safety Module: evaluating the maturity of safety processes in requirements engineering. In: VII Workshop de Teses e Dissertações do CBSoft (WTDSoft), 2017, pp. 91-99.

1.7 THESIS STRUCTURE

Table 2 presents the structure of this thesis, indicating how the chapters relate to the research questions.

Chapter 1 consists of this introduction about the context, motivation and rationale and the objectives of this research.

Table 2 – Thesis structure: chapters and research questions.

Topic	**Chapter**	**RQs**
Problem Investigation	Chapter 2: Background Chapter 4: Systematic Literature Review	RQ1
Solution Design	Chapter 3: Research Methodology Chapter 5: Module Chapter 6: Tool	RQ2, RQ3
Validation and Analysis of Results	Chapter7: Module validation Chapter 8: Discussion and Conclusions	RQ4, RQ5, RQ6

Chapter 2 summarizes the basic concepts of safety-critical systems, RE and maturity models. All these concepts are fundamental to understanding the nomenclature adopted and the research carried out. We also discuss related works.

Chapter 3 describes the research methodology followed to develop the Uni-REPM safety module.

Chapter 4 presents the protocol and results of a systematic literature review about the integration of requirements engineering and safety analysis.

Chapter 5 describes the module structure, contents, and usage.

Chapter 6 presents a web tool we developed to support the application of the safety module.

Chapter 7 discusses a static validation conducted with two practitioners and nine academic experts about the contents of the safety module. It also describes a dynamic validation conducted with seven practitioners from different companies to evaluate the safety module.

Chapter 8 discusses the results obtained in this thesis and makes some final considerations on the development of this work, as well as summarizes the main contributions, and limitations found. Finally, we indicate some future works that are required to improve our approach.

In the next chapter, we present the main concepts related to this thesis and discuss related works.

2 BACKGROUND

In this chapter, we define some concepts used in this work to ensure consistency throughout this thesis.

2.1 SAFETY-CRITICAL SYSTEMS

Safety-critical systems are composed of a set of hardware, software, process, data and people whose failure could result in accidents that cause damage to the environment, injury to people, and loss of lives (LEVESON, 2011). But, it may also involve other major losses, including mission, equipment, financial, and information losses (LEVESON, 2011)(MARTINS; GORSCHEK, 2016b)(LEVESON, 1995).

During the development of SCS, safety engineers typically review the requirements specifications in order to perform safety analysis to ensure that the hazardous situations were mitigated (MARTINS; GORSCHEK, 2016b). Such reviews are periodically repeated throughout the entire development process in order to align the safety analysis with requirements changes. As a major result of the safety analysis, safety engineers define many concepts such as, for example, accident, environmental condition, hazard, cause of hazard, safety requirement, and functional safety requirement.

Considering the need of integrate safety concerns in RE and a common nomenclature to improve the specification of SCS, we have proposed Safe-RE (VILELA et al., 2018a) which is not the safety module but this model can be used during safety requirements elicitation and documentation. It is a safety requirements model based on industry safety standards whose aim is to support the specification of safety-related concepts in the RE process. We describe some of these concepts using as an example an Infusion Insulin Pump (IIPS) (MARTINS et al., 2015)(MARTINS; OLIVEIRA, 2014a).

An insulin infusion pump is a medical device that simulates the functioning of the pancreas (SOMMERVILLE, 2011) being used for the treatment of patients with Diabetes Mellitus type 1 (DM1). An embedded safety-critical system collects information from a sensor and controls a pump that provides a controlled dose of insulin to the user (MARTINS; OLIVEIRA, 2014b). The system goal is to provide safe and effective treatment for people suffering from Diabetes Mellitus (DM1) and to enhance the long-term health of the patients. The prototype development of the IIP described in this section results from a partnership between Brazilian academia and the Brazilian companies DeltaLife and CNA Desenvolvimento.

A safety-critical system has **Safety Goals** which are high-level objectives related to achieving safety in the system. Such goals can be refined during the development process varying the level of abstraction (details). Examples of Safety Goals in the infusion insulin pump are:

- The system must be available to provide insulin when required;

- The system must perform reliably and provide the correct amount of insulin to control blood sugar level;
- Discuss safety with employees;
- Incorporate safety into system components.

Some **Accidents** can occur due to use of a SCS. They are defined as an undesired and unplanned (but not necessarily unexpected) event that results in (at least) a specified level of loss (LEVESON, 1995). This includes loss of human life or injury, property damage, environmental pollution, and so on (LEVESON, 2002b) (MEDIKONDA; PANCHUMARTHY, 2009). In the insulin pump, accidents can be *User receives incorrect treatment*, *User infection*, *Electrical Shock*, and *Environmental*.

A **Harm** can occur to **Assets** (People, Property, Environment, Service) of the system or to the **Mission**. A Harm can be of the following types:

- **Harm to People**: people in the system can be Human beings, roles played or organizations which can suffer with Death, Injury, Illness.
- **Harm to Property**: it can be Destruction, Damage, Corruption, Theft, Unauthorized Access or Unauthorized Disclosure. A Property has two attributes Property Type and Property Owner. A Property Type can be Tangible or Not Tangible and the Property Owner can be Private, Public or Commercial.
- **Harm to Environment**: it can be Destruction, Loss of Use or Damage.
- **Harm to Service**: it can be Corruption, Unauthorized Usage, Accidental Loss of Service, Denial of Service or Repudiation of Transaction.
- **Harm to Mission**: it compromises the satisfaction of some system goals.

The incorrect treatment can lead to deficient blood sugar levels (if there is too much insulin) or too high blood sugar (if too little insulin is present) (MARTINS; OLIVEIRA, 2014b). Low blood sugar can result in temporary brain malfunction and, in extreme cases, unconsciousness and death. On the other hand, high levels of blood sugar can cause fatigue in the short term, but, in the long term, cause damage to the eyes, kidneys and heart problems (SOMMERVILLE, 2011).

These consequences that can occur to the use of a SCS determine the **Safety integrity level**. It corresponds to a range of safety integrity values that represent the probability of a safety-related system accomplish the specified safety functional requirements under all the defined conditions within a stated period of time. IEC 61508 (STANDARDIZATION, 2011a) defines four levels (1-4) where the 4th level is the highest of safety integrity and 1st is the lowest. Accordingly, in case of the software in the IIP is not executed, or not correctly executed,

or whose anomalous behavior can cause or contribute to a system failure results in catastrophic consequences such as user insulin overdose/underdose, it has the **Safety integrity level** A (STANDARDIZATION, 2013).

Accidents are caused by a combination of **Hazard** and **Environmental conditions** (context). **Hazard** is a system state (MEDIKONDA; PANCHUMARTHY, 2009) or set of conditions that, together with a particular set of worst-case environmental conditions, will lead to an accident or some loss (LEVESON, 1995) (LEVESON, 2002b). Several hazards can occur in the IIP such as:

- Overdose: the user receives more insulin than required;
- Underdose: the user receives less insulin than required;
- Excessive thermal energy generation by the pump;
- Electrical shock: the pump transfers electric current to accessible surfaces during operation;
- Excessive electromagnetic emissions by the pump: affects the pump itself, another device (s) worn by the user, or other users and their devices;
- Excessive sound frequencies generated by the pump;
- User allergic reaction/rash to pump materials or insulin;
- Presence of sharp edges or scissor points;
- Excessive pump vibration;
- Unsafe disposal of the pump or pump components.

Environmental conditions consist of the set of factors including physical, cultural, demographic, economic, political, regulatory, or technological elements surrounding the system that could affect its safety (LEVESON, 2002b). For example, in the IIPS, examples of such conditions are:

- Valves in the delivery path are broken;
- Air pressure within the pump is much lower/higher than ambient air pressure;
- The Pump is positioned much higher than the infusion site, causing unintentional drug flow;
- Delivery path is damaged, creating a vent on the path that allows unintentional gravity flow;

- Large temperature changes causing a mismatch between drug reservoir volume change and insulin density change.

All **Hazard** have a **Cause of hazard** which is the reason that produces hazard as effect (SCHOLZ; THRAMBOULIDIS, 2013). It occurs due to environmental hazard, procedural hazard, interface hazard, human factor or system cause (SCHOLZ; THRAMBOULIDIS, 2013) (MEDIKONDA; PANCHUMARTHY, 2009). A *free flow* is one cause of the overdose hazard in the IIP.

Safety Requirements are also presented in the development of a SCS. They are typically of the form of a quality criterion (a system-specific statement about the existence of a sub-factor of safety) combined with a minimum or maximum required threshold along some quality measure. They directly specify how safe the system must be (MEDIKONDA; PANCHUMARTHY, 2009). In the IIPS, *the difference between the programmed infusion and the delivered infusion shall not be greater than 0.5% by hour*.

Functional Safety Requirements consist of the requirements to prevent or mitigate the effects of failures identified in safety analysis (MARTINS; GORSCHEK, 2016b). To mitigate the overdose hazard caused by free flow, *the system can monitor the insulin reservoir* in the IIPS.

2.2 REQUIREMENTS ENGINEERING

Requirements Engineering (RE) is the first stage of software development process (SOMMERVILLE, 2011) that address all of the activities involved in discovering, documenting, and maintaining a set of requirements for a software (KOTONYA; SOMMERVILLE, 1998).

The RE process is a design process with input and outputs (KOTONYA; SOMMERVILLE, 1998). The inputs of the RE process are: Existing system information (information about the functionality of the system to be replaced or that will interact with the proposed system), Stakeholder needs (descriptions of what the stakeholders require), Organisational standards (standards used in the organization regarding system development practice), Regulations (external regulations like safety standards), Domain Information (general information about the domain).

The outputs consists of Agreed requirements (description of system requirements understandable by stakeholders), System specification (detailed document containing system requirements) and System Models (a set of models which describes the system from different perspectives). The RE process, inputs and outputs are shown in Figure 1.

A structured set of activities compose the RE process that include requirements elicitation, requirements analysis and negotiation, requirements documentation, requirements validation, and requirements management as shown in Figure 2. According to Kotonya and Sommerville (1998), there are no distinct boundaries between the five activities. They also state that the activities are interleaved and conducted iteratively considering feedback from one activity from another.

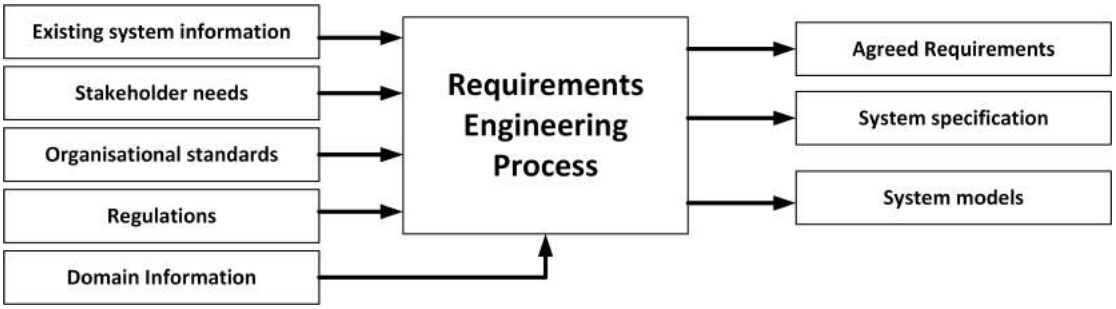

Figure 1 – Input and outputs of the RE process (adapted from (KOTONYA; SOMMERVILLE, 1998)).

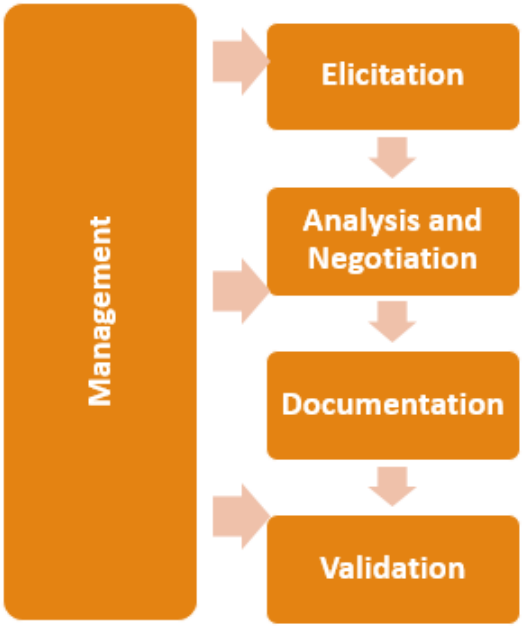

Figure 2 – Requirements Engineering Process (adapted from (KOTONYA; SOMMERVILLE, 1998)).

The activities of RE process Kotonya and Sommerville (1998) are explained in the next sections.

2.2.1 Requirements Elicitation

It corresponds to the stage of requirements acquisition from many stakeholders, artifacts, domain knowledge, and market studies. According to Kotonya and Sommerville (1998), a good elicitation process should include four critical activities (illustrated in Figure 3): Establish objectives, Understanding background, Organise knowledge, and Collect requirements.

2.2.2 Requirements Analysis and Negotiation

This phase comprehends activities aiming to discover problem with the system requirements and reach agreements on changes to satisfy all stakeholders. Hence, the elicited requirements

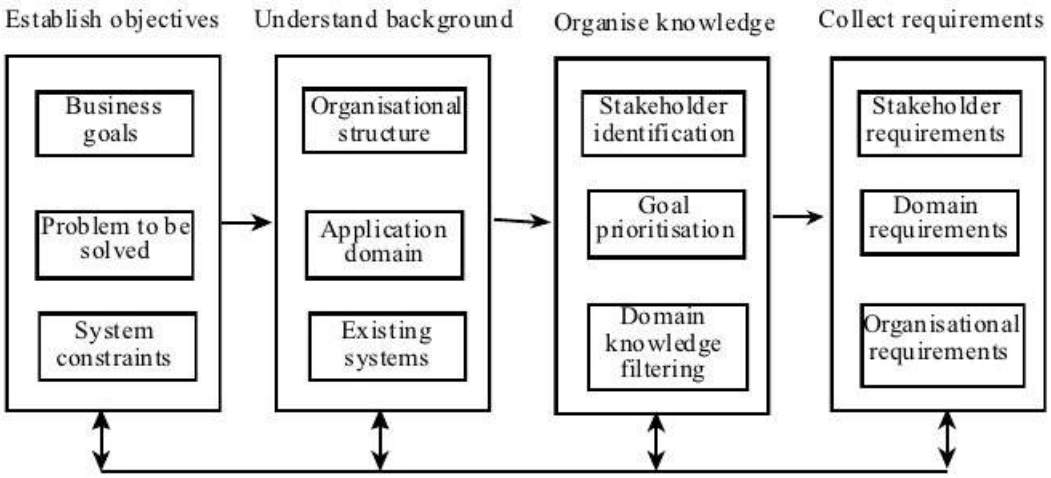

Figure 3 – A generic requirements elicitation process (adapted from (KOTONYA; SOMMERVILLE, 1998)).

are analyzed, prioritized, and negotiated. The result is a set of agreed requirements for the system.

Requirements analysis and negotiation is an expensive and time-consuming process because skilled and experienced people must spend time reading documents carefully and thinking about the implications of the statements in these documents.

2.2.3 Requirements Documentation

According to Kotonya and Sommerville (1998), the process of formulating, structuring and modeling requirements may be guided by a requirements method which is a systematic approach to documenting and analyzing system requirements. Associated with the method is usually a notation that provides a means for expressing the requirements.

It is important to record the collected and identified information in the requirements elicitation step appropriately. The agreed requirements are documented at an adequate level for stakeholders. To document requirements can be used natural language, formal models, and diagrams such as Unified Modeling Languages (UML), such as state diagrams, sequence diagrams, use case diagram and use-case specifications.

2.2.4 Requirements Validation

This phase is concerned with checking the requirements document for consistency, completeness, and accuracy. The requirements document which includes all system requirements and where known incompleteness and inconsistency has been removed. The inputs to the requirements validation process are listed in Figure 4.

The requirements document should be a complete version of the document, formatted and organized according to organizational standards. The organizational knowledge considers the implicit knowledge that is very important to the requirements document.

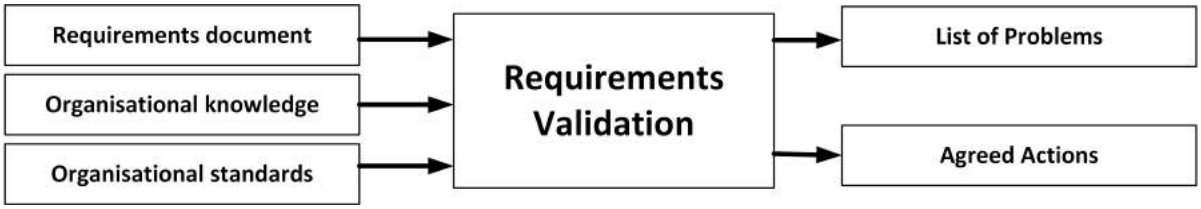

Figure 4 – Input and outputs of the Validation phase (adapted from (KOTONYA; SOMMERVILLE, 1998)).

As outputs, a list of reported problems is generated. Kotonya and Sommerville (1998) state that ideally, it should be organized according to the problem type: ambiguity, incompleteness, etc. As a consequence, it is generated a list of actions in response of the problems that have been agreed by those involve in the validation process.

2.2.5 Requirements Management

Requirements Management is an activity conducted in parallel of all the others cited above and it deals with changes of requirements to maintain requirements traceability. Kotonya and Sommerville (1998) cite that the main concerns of this phase are: managing changes to agreed requirements, managing the relationships among requirements, and managing the dependencies between the requirements document and other documents produced during the systems and software engineering process.

Changes to system requirements may be due to errors and misunderstandings in the RE process, design or implementation problems. In the next sections, we discuss basic characteristics and applications of maturity models and the contents of Uni-REPM.

2.3 MATURITY MODELS

Maturity can be classified as the state of being complete, perfect or ready (MARX; WORTMANN; MAYER, 2012)(REIS; MATHIAS; OLIVEIRA, 2016). Accordingly, this concept suggests an evolutionary progress from an initial to a desired stage (JOHANSSON; NEVALAINEN, 2012)(FRASER; MOULTRIE; GREGORY, 2002)(WILLIAMS, 2008)(WENDLER, 2012).

In software engineering, the notion of maturity is used by maturity models (MM) to assess the capabilities of a company (BECKER; KNACKSTEDT; PÖPPELBUSS, 2009)(BRUIN et al., 2005)(MARX; WORTMANN; MAYER, 2012).

According to Wendler (2012), a maturity model is *"a structured collection of elements that describe the characteristics of effective processes at different stages of development. It also suggests points of demarcation between stages and methods of transitioning from one stage to another".*

These models make it easy the assessment of organizations by outlining anticipated, typical, logical, and desired evolution paths (MARX; WORTMANN; MAYER, 2012). MM define best

actions/practices for software lifecycle processes, based on good engineering and process-management principles, and process-attribute sets for capability/maturity design aspects (WANGENHEIM et al., 2010b). Therefore, the objective in using MM is to detect and remove bad capabilities (PÖPPELBUSS; RÖGLINGER, 2011). Hence, the application of this concept is not limited to any particular domain (WENDLER, 2012).

Typically, maturity models:

- define capability areas, process areas or design objects (WILLIAMS, 2008)(JOHANSSON; NEVALAINEN, 2012)(BRUIN et al., 2005);
- consist of sequential maturity stages (JOHANSSON; NEVALAINEN, 2012)(WILLIAMS, 2008)(WENDLER, 2012);
- have a hierarchical progression from an initial to a desired stage (REIS; MATHIAS; OLIVEIRA, 2016)(FRASER; MOULTRIE; GREGORY, 2002) (WENDLER, 2012);
- involve a wide range of organizational activities and actions/practices (BRUIN et al., 2005)(WANGENHEIM et al., 2010b), (WENDLER, 2012);
- have an assessment instrument that can either be qualitative or quantitative (MARX; WORTMANN; MAYER, 2012)(FRASER; MOULTRIE; GREGORY, 2002).

In Figure 5, we illustrate the usage of a maturity model for continuous improvement. First, the company should evaluate its capabilities, then, define the projects with low maturity, prioritize them, plan the improvement (scope, responsible, risks, resources, and other variables), manage changes in people and company culture by implementing the improvement project, evaluate the results, and proceed with continuous improvement.

Figure 5 – Example of module use to continuous improvement (adapted from (PIGOSSO; ROZENFELD; MCALOONE, 2013)).

2.4 UNI-REPM

Uni-REPM is a universal lightweight model to evaluate the maturity of a RE process structured in two views: Process Area and Maturity Level (SVAHNBERG et al., 2015). The model hierarchy has three degrees of depth: MPA, SPA and Action.

- MPA: it is an element that corresponds to the requirements engineering main activities.
- Description: describes the purpose of the MPA.
- SPA: It is an element that group actions related to a particular area that, when implemented correctly, contributes to the achievement of the goals considered important for improvement in this area
- Description: describes the goals of the SPA.
- Actions: safety practices that are considered important to the SPA, to which it is associated, be achieved.
- Description: they are the description of a safety practice.
- Supporting action(s): it contains the list of actions related to the action in question, and reflects the high-level relationship between them.
- Example: it gives practitioners suggestions on proven techniques or supporting tools when performing the action.

Figure 6 shows the components of Uni-REPM and how its elements are related. It is important to understand its concepts:

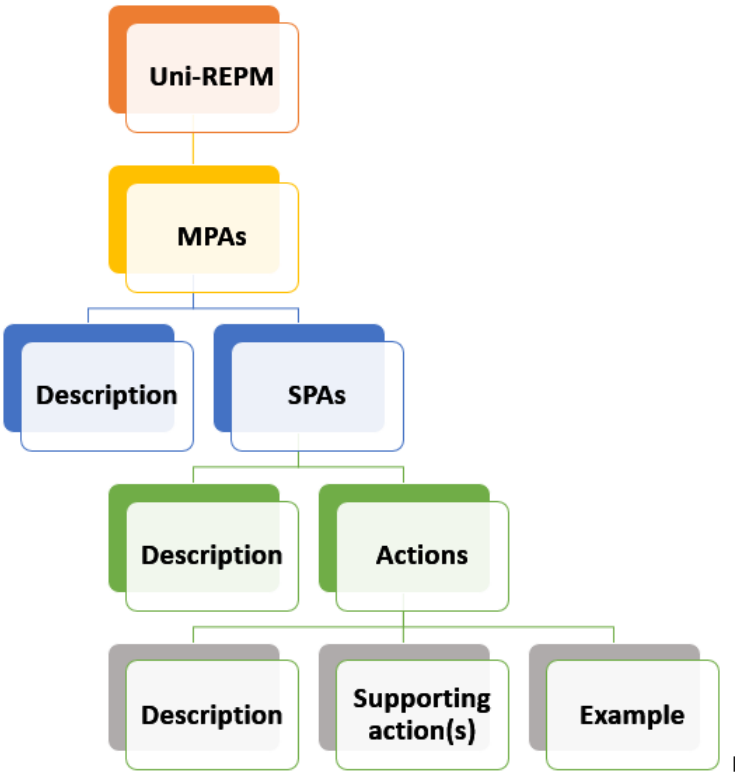

Figure 6 – Uni-REPM Components.

On the top level of the model, there are seven MPAs (Organizational Support, Requirements Management, Elicitation, Requirements Analysis, Release Planning, Documentation and Requirements Specification, and Requirements Validation) corresponding to RE main activities as presented in Figure 7.

Each MPA is further broken down into eighteen SPAs, which contributes to better understanding. At the bottom level, an Action denotes a certain activity that should be done or a certain item that should be present.

The Maturity Level establishes a certain level to each action (from 1 to 3, corresponding to "Basic", "Intermediate", and "Advanced" level) depending on the difficulty to implement the action, how essential it is for the RE process, and dependencies among actions.

The Uni-REPM has an assessment instrument in which the appraiser can mark one of three options: "Incomplete" (vital action performed partially or not at all in the RE process), "Complete" (action was completed in the RE process), and "Inapplicable" (action was not necessary or possible to be performed in the process).

Uni-REPM was designed with the ideas of being light-weight, and also a self-assessment and improvement tool. It can be used by professionals themselves acting as evaluators - making small improvements based on recent lessons learned. This has been used as traditional assessment tools, but also as a part of agile organizations (DINGSØYR et al., 2012) and a part

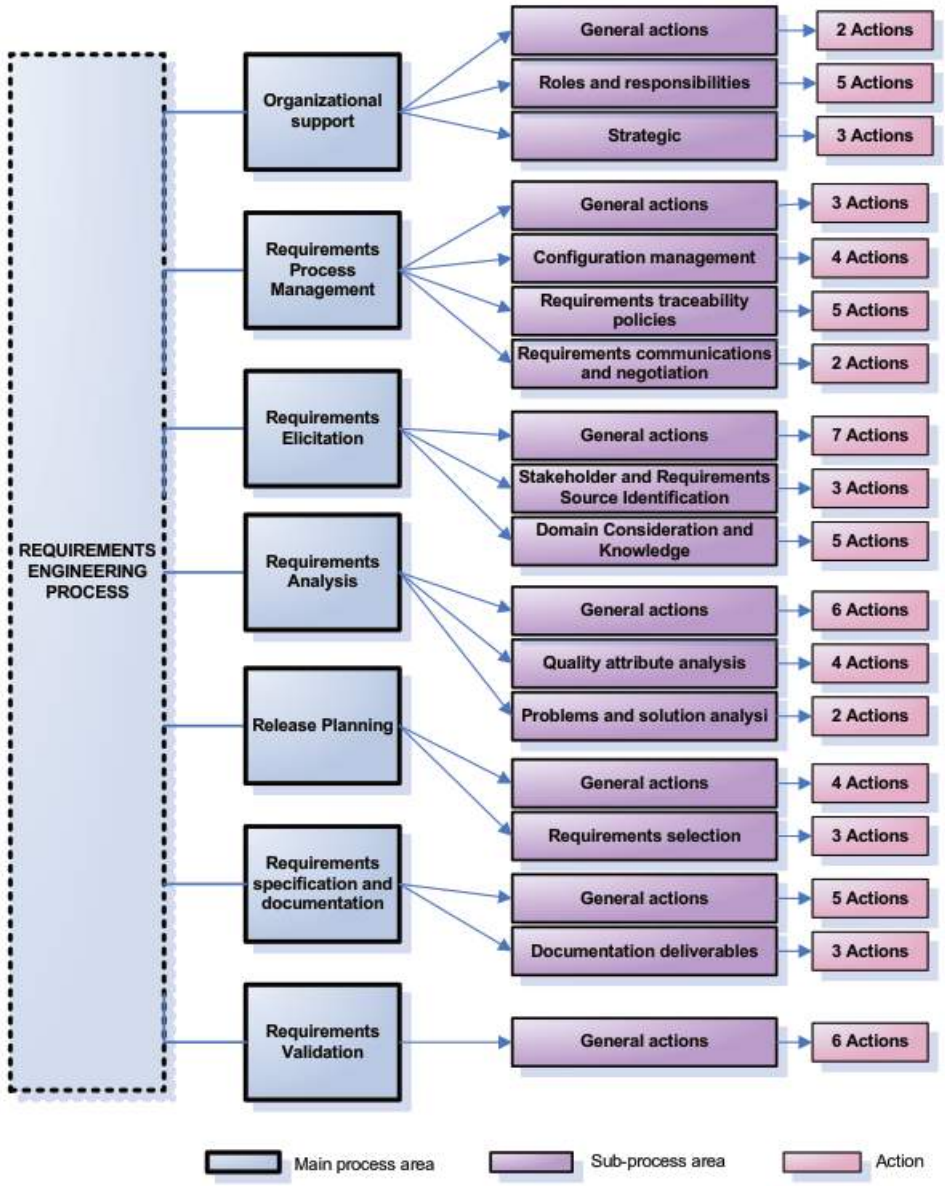

Figure 7 – Uni-REPM Model Structure (GORSCHECK, 2011).

of previous works on maturity models (SVAHNBERG et al., 2013).

An example of an action is presented in Figure 8. It presents the identifier of MPA (OS), SPA (OS.GP), and action (OS.GP.a1, OS.GP.a2). The names of MPA (Organizational Support), SPA (General Practices), and Action (Create a Product-wide Glossary of Terms, Train personnel in Requirements Management Process and Speciality) are also present in Figure 8. Finally, it also contains the maturity level of the actions.

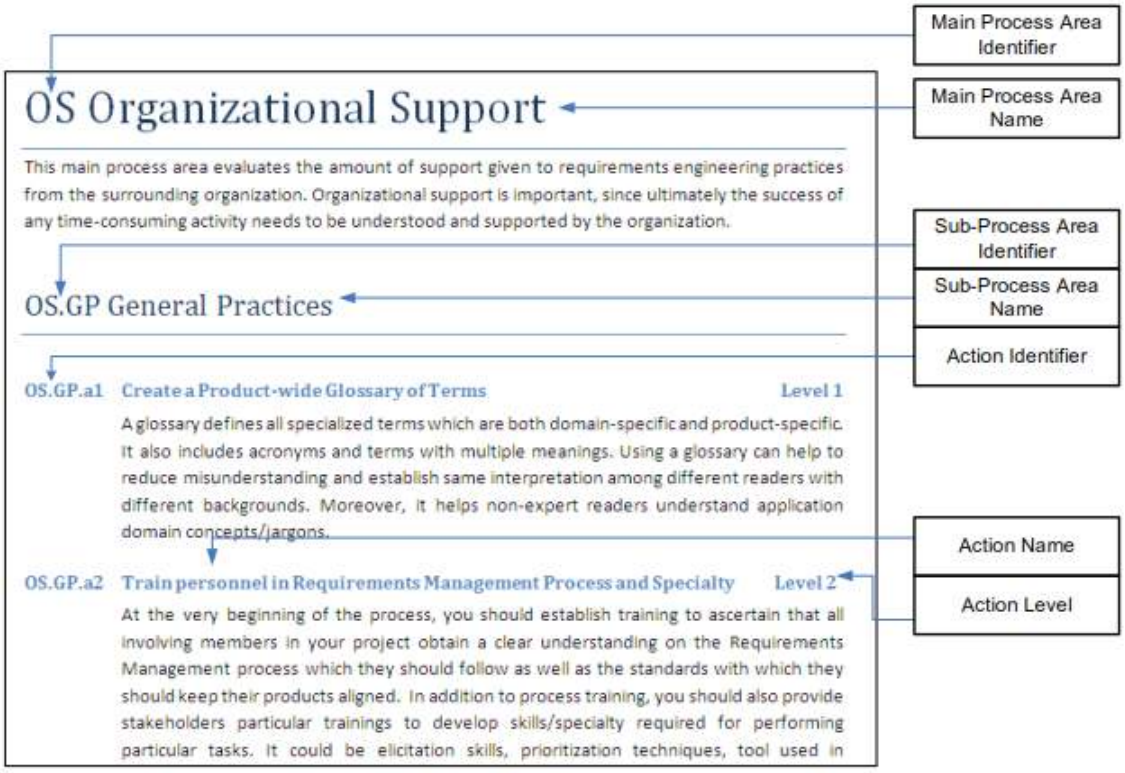

Figure 8 – Example of an action of Uni-REPM (SVAHNBERG et al., 2015).

2.5 RELATED WORK

Many software process capability/maturity models have been elaborated, expanded and modified over the past years. Accordingly, some SLRs about maturity models have been conducted (REIS; MATHIAS; OLIVEIRA, 2016) (WENDLER, 2012) (WANGENHEIM et al., 2010a) to investigate them.

The SLRs show that there is a clear trend to propose maturity models customized to specific domains, including customizations for small and medium companies, testing and quality assurance, security engineering, extreme programming, e-government, medical systems, aerospacial, telecommunications, software development among other domains (WANGENHEIM et al., 2010b).

The goal of this thesis is to propose a safety maturity model for the requirements engineering process. Although we did not direct related works, we have software maturity models, requirements engineering maturity models and safety maturity models discussed in the next sections.

2.5.1 Software maturity models

Generic software process improvement frameworks such as CMMI (TEAM, 2010), Software Process Improvement and Capability Determination (SPICE) (DORLING, 1993), have been proposed and adopted by companies. SPICE which includes the well-known ISO/IEC 15504

that was replaced by ISO 33000. Although they address RE in some extent, they do it shallowly since their scope is to cover all phases of development process having a larger scope than just RE (SVAHNBERG et al., 2015).

The above maturity models emphasize bespoke RE which is related to the development of a customized software system for a specific customer (GORSCHEK et al., 2012). Nevertheless, a company may be classified as advanced in a generic software maturity model, but may be immature in their safety processes.

2.5.2 RE maturity models

There are some RE assessment frameworks, for example, the Requirements Engineering Good Practice Guide (REGPG) (SAWYER; SOMMERVILLE; VILLER, 1997), REPM (GORSCHEK; SVAHNBERG; TEJLE, 2003), MDREPM (GORSCHEK et al., 2012) that allow organizations to evaluate the strengths and weaknesses (REIS; MATHIAS; OLIVEIRA, 2016) regarding the RE process.

The REGPG guide (SAWYER; SOMMERVILLE; VILLER, 1997) suggests a requirements maturity model based on 66 good requirements practices, where 36 are classified as basic, 21 as intermediate and 9 as advanced. The advanced practices are concerned with formal specification which is recommended for critical systems development. However, the model proposes only 9 practices for SCS being very succinct. Moreover, its implementation is very challenging for small/immature companies aiming to increase the safety of their systems.

The MDREPM model (GORSCHEK et al., 2012) is an evolution of REPM (GORSCHEK; SVAHNBERG; TEJLE, 2003) to consider market-driven practices. Market-driven RE is applicable to software companies that develop software to a determined market, which can be a combination of a number of known customers or, on another extreme, a mass market where customers cannot be clearly indicated (GORSCHEK et al., 2012).

However, REGPG, REPM, and MDREPM do not cover both market-driven and bespoke RE practices in the same maturity model as required by industry (SVAHNBERG et al., 2015). To fill this gap, the Uni-REPM (SVAHNBERG et al., 2015) was proposed. Nevertheless, it does not consider safety issues required for the development of a safety-critical system. Therefore, in this work, we propose Uni-REPM SCS which is a safety module for the Uni-REPM model.

2.5.3 Safety maturity models

Safety culture maturity models are available in literature (FLEMING, 2000)(FILHO; ANDRADE; MARINHO, 2010). Fleming (FLEMING, 2000) developed a model with the objective of helping organizations to identify the level of maturity of their safety culture. Filho, Andrade and Marinho (2010) proposed a framework to measure safety culture maturity in the Brazilian oil and gas companies based on the model of Hudson (HUDSON, 2001).

However, safety culture is a characteristic of groups and organizations that handle organizational collective practices to avoid accidents during the work in factories (FILHO; ANDRADE; MARINHO, 2010) and not about developing SCS.

Some safety maturity models have been developed, for example, +SAFE-CMMI-DEV (SEI, 2007) and ISO 15504-10 (STANDARDIZATION, 2011c). However, these models are too general (PEREIRA; SILVA, 2011), usually adopted by safety engineers, and do not consider the integration between safety and RE as well as the particularities of these two areas that are necessary to improve safety from the beginning of software development process. In Section 5.4, we analyze in details the similarities and differences among these models and the safety module.

2.5.4 Systematic literature reviews about safety-critical systems

Few SLRs about the development of SCS are found in the literature (VILELA et al., 2017a) (MARTINS; GORSCHEK, 2016a) (QUEIROZ; BRAGA, 2014) (NAIR et al., 2014). Queiroz and Braga (2014) conducted a SLR with the purpose of obtaining the state-of-the-art of the approaches, methods and methodologies whose goal was the combination of product line engineering and model-driven engineering for the development of safety-critical embedded systems. They also analyzed the existence of empirical studies on the use of these techniques in this type of development.

A SLR about safety evidence (the artifacts generated as indication that the developed system is safe) is presented in Nair et al. (2014). The main objective of their work is to synthesize the existing knowledge in the academic literature about safety evidence, concentrating on three facets: the information that constitutes evidence; structuring of evidence; and evidence assessment.

RE for SCS is the main investigation topic of a systematic literature review conducted by Martins and Gorschek (2016a). Their work investigated which approaches have been proposed to elicit, model, specify and validate safety requirements in the context of SCS, as well as to what extent such approaches have been validated in industrial settings. Moreover, they analyzed how the usability and usefulness of the reported approaches had been explored, and to what extent they enabled requirements communication among the development project/team actors in the SCS domain. Although they emphasize the need to further investigate the communication in the RE process among different parties when developing SCS, their work does not investigate deeply the collaboration of requirements and safety engineers. In fact, in this work, we restricted our search string to capture the results related to requirements communication.

Although above works explore several challenges related to the integration of RE and safety (LUTZ, 2000) (HEIMDAHL, 2007) (SIKORA; TENBERGEN; POHL, 2012) (HATCLIFF et al., 2014), little has been done to date to perform an extensive identification and mapping, in a comprehensive manner of the state-of-the-art on the integration between safety analysis and requirements engineering. Hence, to the best of our knowledge, the SLR conducted in this thesis (see Chapter 4 is the first with such specific focus.

2.6 FINAL CONSIDERATIONS

Developing a maturity model is a complex and hard task. When designing a model, the software engineer needs to deal with issues associated with: defining process areas and maturity stages, establishing the organizational activities and actions/practices and developing an assessment instrument.

This chapter described the main concepts required for the understanding of this thesis. We defined aspects of the safety-critical domain commonly used in safety analysis. In order to define the maturity model for which is proposed the safety module, we presented the UNI-REPM structure. Finally, we discussed related works. In the next chapter, we describe the research methodology followed to develop the Uni-REPM safety module.

3 METHODOLOGY

The maturity model development is an issue that should be treated as a design problem (WIERINGA, 2010) by some researchers (PÖPPELBUSS; RÖGLINGER, 2011) (REIS; MATHIAS; OLIVEIRA, 2016). This requires changes in the world and requests an analysis of actual or hypothetical stakeholder goals. Design problem is part of the design science methodology that defines that solutions must be iteratively proposed, refined, evaluated, and, if necessary, enhanced (BECKER; KNACKSTEDT; PÖPPELBUSS, 2009)(WIERINGA, 2010). Hence, following the recommendations of the literature, we also adopted this methodology to develop the safety module.

According to Wieringa (2010), design problems demand modifications in the world and claim an analysis of actual or hypothetical stakeholder goals. A solution is a design, and may exist a large number of distinct solutions that should be assessed by their utility with respect to the stakeholder goals, and there is no single best solution.

Solving a design problem in design science requires the interaction between an *artifact* and a problem *context* for producing *effects* (WIERINGA, 2010), as shown in Figure 9.

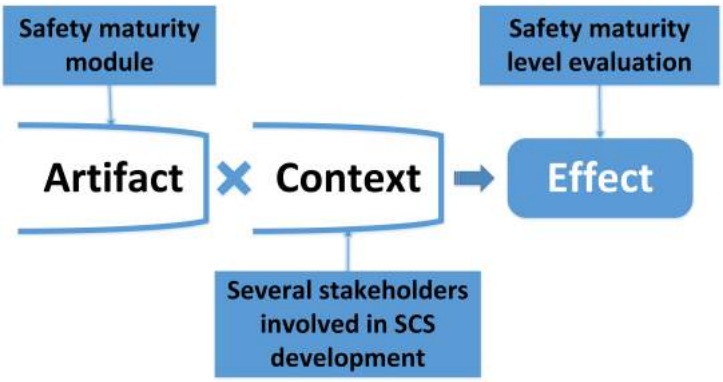

Figure 9 – Design science framework (adapted from Moraes (2014)).

In the context of this thesis, we defined the artifact, context and effects as follows:

- *Artifact*: safety maturity module;
- *Context*: Safety-Critical Systems and the several stakeholders, such as requirements engineering, safety analysts, quality engineering, testers among others involved in the development;
- *Effect*: evaluating the safety maturity level in the requirements engineering process of SCS projects.

Design problems are treated by following the design cycle that is decomposed into three tasks: problem investigation, treatment design, and treatment validation. Such cycle is part of a

larger one, called engineering cycle, in which the result of the former, i.e. a validated treatment, is transferred to the real world, used, and evaluated (WIERINGA, 2010). The engineering cycle is illustrated in Figure 10.

Figure 10 – The engineering design cycle (adapted from Wieringa (2010)).

Someone may question why not rather do e.g. a root-cause analysis of the actual "defects" (like mistakes, misunderstandings, wrong requirements, etc) to figure out what the root cause is and then invent a solution to fix it. To perform such analysis, the action research methodology (COUGHLAN; COGHLAN, 2002) should be used. Although action research and design science generate scientific knowledge by intentionally modifying a real setting and by carefully evaluating the result as well as both share an ability to adopt prototyping as an underlying approach, these features do not mean that these research approaches are the same (BASKERVILLE; PRIES-HEJE; VENABLE, 2009).

We adopted the design science research because the goal of this thesis is to propose a safety module for Uni-REPM maturity model to be used by several types of companies. Considering that the development of a maturity model is viewed as a design problem (PÖPPELBUSS; RÖGLINGER, 2011) (REIS; MATHIAS; OLIVEIRA, 2016), we followed a well-established methodology used by the literature to propose maturity models. Design science is used to develop new technologies for solving problems (BASKERVILLE; PRIES-HEJE; VENABLE, 2009). Accordingly, during the research is generated an artifact that represents a general solution to a class of problems shown to operate in some instances of that class of problems (BASKERVILLE; PRIES-HEJE; VENABLE, 2009). If the goal was to develop a solution for a specific company, the action research methodology could be used. Action research aims creating organizational changes in order to discover new knowledge to a specific situation. Design science, on the other hand, proposes the creation of an artifact in order to discover new knowledge applied in several contexts.

The steps of the methodology adopted to construct the Uni-REPM SCS is presented in Figure 11. This methodology was defined by considering the engineering design cycle (WIERINGA, 2010), the technology transfer framework (GORSCHEK et al., 2006) and by adapting methodologies for creating maturity models available in literature that inspired our model.

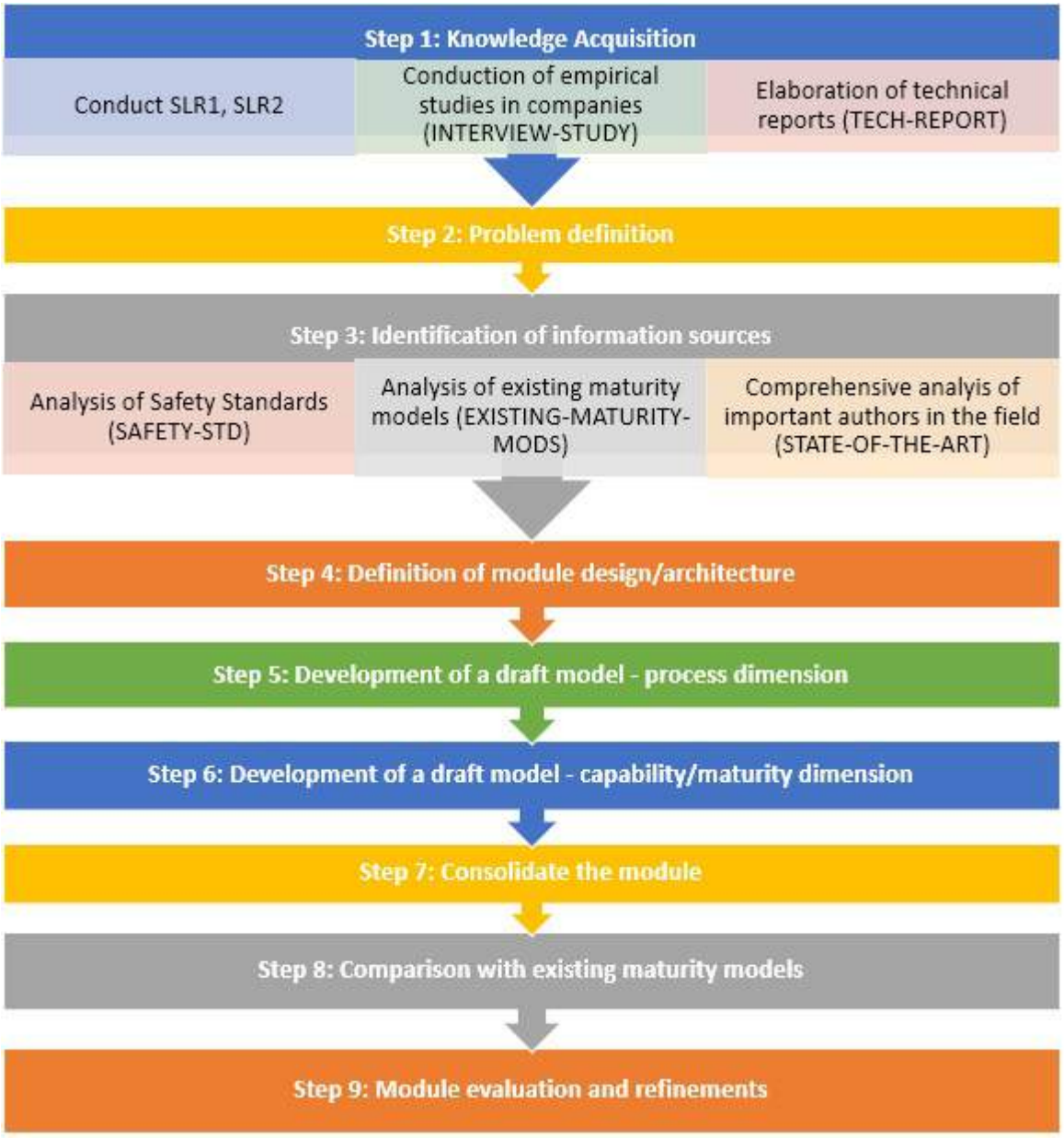

Figure 11 – Methodology for creating the Uni-REPM Safety module.

The basis of the methodology derived from Wangenheim et al. (2010b) that proposed a reference model for how to develop software process capability/maturity models (SPCMMs) that consists of five phases and 17 steps. We adopted this reference model because it relies on a survey with answers from 18 authors of previous SPCMMs.

The survey results of Wangenheim et al. (2010b) show a stronger presence of steps related to knowledge identification, specification, and refinement phases than to knowledge usage and evolution phases Wangenheim et al. (2010b).

We deleted/renamed steps, as needed, based on our experience/opinion, along the way considering the well-adopted engineering cycle from (WIERINGA, 2010) in several scientific studies and technology transfer framework (GORSCHEK et al., 2006). The latter was proposed through a partnership between academia and industry and it has been cited more than 244

times in Google scholar [1]. The traceability information regarding the steps of the methodology is presented in Table 3.

Table 3 – Traceability steps of adopted methodology.

Step	**Source/Inspiration**
Step 1: Knowledge Acquisition	Wangenheim et al. (2010b)
Step 2: Problem definition	Wangenheim et al. (2010b), Pöppelbuß and Röglinger (2011), Becker, Knackstedt and Pöppelbuß (2009), Bruin et al. (2005)
Step 3: Identification of information sources	Wangenheim et al. (2010b), Becker, Knackstedt and Pöppelbuß (2009)
Step 4: Definition of module design/architecture	Wangenheim et al. (2010b), Becker, Knackstedt and Pöppelbuß (2009), Bruin et al. (2005)
Step 5: Development of a draft model - process dimension	Wangenheim et al. (2010b), Bruin et al. (2005)
Step 6: Development of a draft model - capability/maturity dimension	Wangenheim et al. (2010b)
Step 7: Consolidate the module	Wangenheim et al. (2010b)
Step 8: Comparison with existing maturity models	Pöppelbuß and Röglinger (2011), Becker, Knackstedt and Pöppelbuß (2009)
Step 9: Module evaluation and refinements	Wangenheim et al. (2010b), Becker, Knackstedt and Pöppelbuß (2009), (WIERINGA, 2010), (GORSCHEK et al., 2006)

Each step of the adopted methodology is presented in the next sections.

3.1 KNOWLEDGE ACQUISITION

The first step consisted in understanding the phenomena that must be improved, the rationale, and prior knowledge. According to Wieringa (2010), there are many sources for prior knowledge (knowledge available prior to the project) such as scientific literature, technical literature, professional literature, and oral communication.

We used multiple sources to learn and collect data as to define what should be included in a RE module for SCS. Our first step was to investigate the literature regarding RE in safety-critical systems to become familiar with the domain, study the problem space, comprehend the concepts involved in the safety domain as well as to investigate the problems in the integration between RE and SCS.

We also analyzed the international quality standard ISO/IEC 25010 (STANDARDIZATION; COMMISSION, 2011) that is part of Systems and software Quality Requirements and Evaluation (SQuaRE) — System and software quality models. ISO/IEC 25010 cancels and replaces ISO/IEC 9126-1 (STANDARDIZATION; COMMISSION, 2004) and extends quality models to include computer systems, and quality in use from a system perspective.

[1] Date of search: October, 24th of 2018

3.2 PROBLEM DEFINITION

Nancy Leveson in 1986 brought the notion of "software safety" to the broader computer science community and laid the foundation for a research area rich with challenging problems (LEVESON, 1986). Nine years later, in 1995, she published the book *"Safeware: System Safety and Computers"* that became the reference about safety-critical systems area.

Then, Lutz (2000) in the journal Future of Software Engineering (FOSE) published *"Software engineering for safety: a roadmap"*. The paper provides a snapshot of six key areas in state-of-the-art software engineering for safety by defining concepts, citing techniques and tools (Hazard analysis, Safely requirements specification and analysis, Designing for safety Testing, Certification and standards, and Resources). She also discusses some directions for needed work:

- Further integration of informal and formal methods. This integration should consider the automatic translation of informal notations (descriptive notations most widely used by software developers) into lightweight formal methods. This challenge refers to automated analysis approaches that involve rapid, low-cost use of formal methods tailored to the immediate needs of a project. This usually means limited modeling, flexible use, building on existing products, highly selective scope, and forgoing the extended capabilities of theorem provers or model checkers.
- Constraints on safe product families and safe reuse. This topic highlights the need and challenges of performing safety analysis of product families.
- Testing and evaluation of safety-critical systems. The evaluation activities of those systems requires different types of tests: Requirements-based testing, Model consistency, Evaluation from multiple sources, and Virtual environments.
- Runtime Monitoring. Requirements and architectural analysis are needed for autonomous software and the system should be able to adapt itself considering the environmental conditions.
- Education. Few courses are currently offered in universities on the software engineering of safety. There is a need for courses in safety that build on prior education in fault tolerance, security, systems engineering, experimental techniques, and specific application domains.
- Collaboration with Related Fields. Problems in related fields such as RE whose solutions have potential benefits for safety are described.

Seven years later than the work of Lutz (2000), Heimdahl (2007) also published in the same periodic (FOSE) the paper *"Safety and software intensive systems: Challenges old and new"*. He stated that Lutz's challenges persisted valid and they have been only partially addressed

since then. Therefore, he did not revisit these challenges. He singled out 4 issues to be addressed in the following years:

- the nature of safety is continuing to be widely misunderstood and known system safety techniques are not applied. He argued that education and training of the software engineering professionals were necessary.
- the ability to demonstrate (certify) that safety requirements have been met is inadequate. Then he advocated a move towards evidence-based certification and some notion of safety-cases.
- the move towards various forms of model-based development with its increased reliance on tools rather than people in the software development process introduces new and poorly understood problems; (1) validation of the artifacts (models) forming the basis for tool intensive development, (2) assuring correctness of our automated tools, and (3) investigating the effect of replacing human activities with automated tools.
- incorrect data of data-driven safety-critical systems could have catastrophic and widespread consequences. Hence, techniques to assure the validity of the data are needed as well as to closely monitor the convergence of the critical control systems and large information systems.

Sikora, Tenbergen and Pohl (2012) in Requirements Engineering Journal conducted an industrial study to gain an in-depth understanding of practitioners' needs concerning RE research and method development. The study involved qualitative interviews as well as quantitative data collection by means of questionnaires.

The main results are related to five aspects of RE approaches: (1) the use of requirements models, (2) the support for high system complexity, (3) quality assurance for requirements, (4) the transition between RE and architecture design, (5) the interrelation of RE and safety engineering.

Hatcliff et al. (2014) in FOSE highlighted many problems related to the development of a safety-critical system: Certification of tools Developing foundational principles (still need of training), The nature of criteria in safety, Increasing automation in hazard analysis, Building competence to engineer software for safety critical systems and RE-related problems. Among the latter, they state that RE should facilitate the validation needed for assurance by third parties before deployment, many safety-critical systems developed today are built on (or derived from or modifications of) previous versions, the processes of system engineering, safety engineering, and software engineering are not well-integrated.

After the comprehensive investigation of the domain (STATE-OF-THE-ART[2]), considering the results of the SLR we performed (see Chapter 4) and based on the identified existing

[2] We adopted these codes to make explicit the information source category we are referring to during this thesis.

safety maturity models (EXISTING-MATURITY-MODS), we investigated the problem relevance (BECKER; KNACKSTEDT; PÖPPELBUSS, 2009), i.e. the gap that a maturity model can contribute to solve.

Therefore, we concluded that there was a need for proposing the Uni-REPM safety module according to the objectives and scope of our work.

3.3 IDENTIFICATION OF INFORMATION SOURCES

We performed a comprehensive literature review (STATE-OF-THE-ART) to identify and select the information sources for the safety actions/practices and the maturity module.

We relied on several works in RE and SCS to define the sources of information for the Uni-REPM Safety module:

1. SLRs conducted by Martins and Gorschek (2016b) (SLR1) and by us (VILELA et al., 2017a; VILELA et al., 2017b) (SLR2);

2. empirical studies (INTERVIEW-STUDY) with 11 companies (MARTINS; GORSCHEK, 2018) (MARTINS; GORSCHEK, 2017) and technical reports (TECH-REPORT) (MARTINS; GORSCHEK, 2016c);

3. safety standards (SAFETY-STD): ISO 61508, ISO 26262-6, ISO 9126, ISO 15998, ISO 15998-2, 20474-1, ECSS-E-HB-40A, ECSS-E-ST-40C, ISO 13849-1, ISO 13849-2, MIL-STD-882C, MIL-STD-882D, MIL-STD-882E, ISO 14639-1, ISO 14639-2;

4. existing maturity models (EXISTING-MATURITY-MODS): ISO 15504-10, +SAFE-CMMI-DEV;

5. comprehensive analyis of important authors in the field (STATE-OF-THE-ART) (LEVESON, 1995) (LEVESON, 2002b) (SCHEDL; WINKELBAUER, 2008b) (KIM; NAZIR; ØVERGÅRD, 2016) (KAZARAS; KIRYTOPOULOS, 2011) (BOSSE; MOGLES, 2013) (EKBERG et al., 2014a) (WHITEHEAD, 2007) (HALL; SILVA, 2008) (GRILL; BLAUHUT, 2008) (FIRESMITH, 2006b) (KONTOGIANNIS; LEVA; BALFE, 2016b) (PERNSTÅL; FELDT; GORSCHEK, 2013b) (SAWYER; SOMMERVILLE; VILLER, 1997) (LEVESON, 2011) (LAMI; BISCOGLIO; FALCINI, 2016).

Safety standards were analyzed considering that the practitioners highlighted the need and importance of following an adequate safety standard:

"*the certification process pushes us to define requirements with more details*" (MARTINS; GORSCHEK, 2018).

"*We have a set of international specific standards we have to follow to build the machines. We really need to identify what parts of the standards are applicable for the machinery we are designing (cutting, laminator, printing machine, and so on)*" (MARTINS; GORSCHEK, 2017).

"*the certification process improves the relationship with suppliers, because everyone must follow the same safety standards, which are used as artifacts of communicating between the company and its suppliers*" (MARTINS; GORSCHEK, 2018).

The list of information sources is presented in Section 5.1.

3.4 DEFINITION OF MODULE DESIGN/ARCHITECTURE

After the analysis of the information sources and data extraction, we established the design/architecture of the module (BECKER; KNACKSTEDT; PÖPPELBUSS, 2009). To decide whether we should have a new stand-alone maturity model or a module for an existing model, we analyzed existing maturity models with the problem definition. We concluded that we should adopt the enhancement of a well-established, adopted and a complete RE existing model as a design strategy.

Accordingly, we proposed a module following the structure of Uni-REPM. We opted to follow its structure since we are designing a safety module for a universal lightweight maturity model, capable of evaluating the maturity of RE process, that has been used and well accepted in some companies. This model is considered lightweight because it has a reduced number of RE practices compared to other maturity models and a reduced number of maturity levels, besides, it allows the requirements engineer evaluates himself a RE process in a couple of hours. Moreover, the SPAs (Sub Process Area) already present in the Uni-REPM cover the main process involved in the RE process (KOTONYA; SOMMERVILLE, 1998).

In the module definition process, existing safety maturity models (EXISTING-MATURITY-MODS) were used as a starting point for the design process because they already cover some RE aspects for the safety-critical domain. In this context, we identified the features that maturity models typically have.

Uni-REPM SCS follows the same hierarchical structure of multiple layers adopted by many maturity models (BRUIN et al., 2005)(FRASER; MOULTRIE; GREGORY, 2002) and Uni-REPM (SVAHNBERG et al., 2015) as well as the features listed in Section 2.3.

3.5 DEVELOPMENT OF A DRAFT MODEL - PROCESS DIMENSION

The next step consisted in the development of a draft module in the process dimension. Hence, we defined the 14 sub-processes areas of the module, their respective actions as well as how they would be connected to the Uni-REPM model.

After the comprehensive literature review performed and the safety standards analysis, we concluded that the proposed 14 SPAs represent the areas that should be addressed by SCS companies. They cover human factors, failure handling, safety knowledge management among others areas highlighted as critical by the safety standards and many authors, for example, we can cite Leveson (1995), Lutz (2000) and Hatcliff et al. (2014).

3.6 DEVELOPMENT OF A DRAFT MODEL - MATURITY DIMENSION

We updated the draft module considering the maturity dimension by assigning a fixed number of maturity levels for the actions already determined. We opted to maintain the Likert scale with three levels of Uni-REPM (Basic, Intermediate, Advanced), as adopted by other MM (SAWYER; SOMMERVILLE; VILLER, 1997)(WIEGERS, 2003), considering the difficulties that users have in interpreting among five options (JACKO, 2012) with very discrete differences as adopted in many maturity models.

Accordingly, we want users to be aware and can clearly distinct among the stages, reducing implications on module application and improving interpretation of stages (SVAHNBERG et al., 2015). This reduced number of maturity levels makes it easier for practitioners to understand the improvements in their RE processes by increasing the maturity level.

3.7 CONSOLIDATE THE MODULE

The last step was the consolidation of the module in a understandable way for the target group (PÖPPELBUSS; RÖGLINGER, 2011) by discussing it with the research group and refining the module several times.

3.8 COMPARISON WITH EXISTING MATURITY MODELS

We performed a comparison among existing maturity models in safety (EXISTING-MATURITY-MODS), whose results are described in Section 5.4. All maturity models analyzed cover the entire project lifecycle. Hence, they do not go into detail into any particular practice area, such as RE. Therefore, the maturity model we propose is more descriptive and detailed because it was designed specifically for safety in RE and contains a comprehensive assessment instrument. The other maturity models have safety practices for other areas like safety management and safety qualification.

Therefore, we used the knowledge obtained in steps 1-3 in Figure 11 to determine what characteristics a maturity model for safety in RE process should have.

3.9 MODULE EVALUATION AND REFINEMENTS

We adopted the technology transfer framework proposed by Gorschek et al. (2006) to perform the safety module validation. This model (GORSCHEK et al., 2006) (see Figure 12) was proposed through a partnership between academia and industry and it has been cited more than 244 times in Google scholar [3].

The seven steps of the technology transfer model are described below.

[3] Date of search: October, 24th of 2018

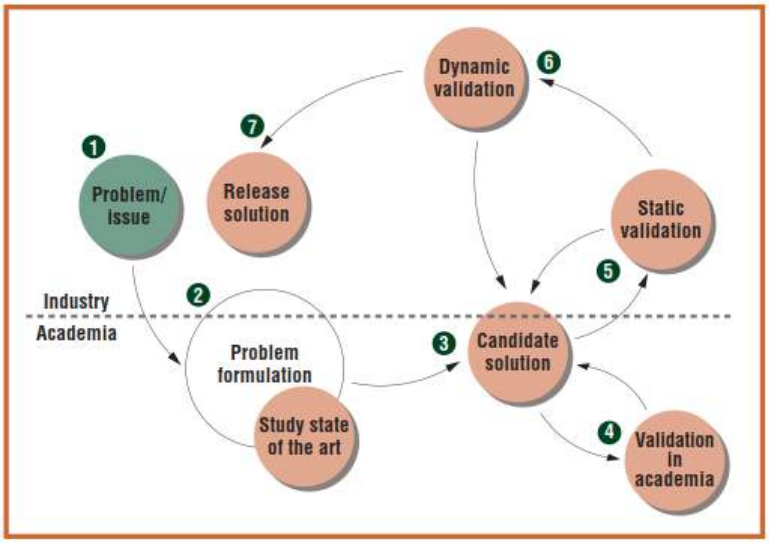

Figure 12 – Technology transfer model (GORSCHEK et al., 2006).

(1) Problem Issue: it corresponds to the identification of potential improvement areas based on industry needs, through process assessment and observation activities.

(2) Study the state of the art: in this step, it is formulated a research agenda using several assessments to find research topics, and formulate problem statements while studying the state of the art.

(3) Candidate solution: it involves the formulation of a candidate solution in cooperation with industry.

(4) Validation in academia: in this step, it should be performed a validation in academia (for example, through laboratory experiments).

(5) Static validation: it comprehends the conduction of a static validation (for example, interviews and seminars).

(6) Dynamic Validation: in this step, a dynamic validation (for example, pilot projects and controlled small tests) is performed.

(7) Release solution: it addresses the release of the solution step by step, while remaining open to smaller changes and additions.

In this step, we collected feedback regarding the contents of the module and its coverage of safety practices from eleven subjects (nine academic experts and two practitioners). The results of this validation are presented and discussed in Section 7.1.

A dynamic validation (See Section 7.2) was conducted with seven practitioners from different companies to evaluate the safety module in seven case studies.

Case study research is based on empirical software engineering methods and guidelines (WIERINGA, 2010) (SEAMAN, 1999). In order to conduct the investigation with practitioners, usually, a qualitative research approach is chosen. It involves semi structured interviews as the strategy to reach the goals of the study.

Qualitative researchers study phenomena in their natural settings, attempting to make sense of, or interpret, phenomena regarding the meanings people bring to them (MERRIAM; TISDELL, 2015).

Runeson and Höst (2009) proposed guidelines to investigate a contemporary phenomenon. There are five major process steps to go through in the case study research process (RUNESON; HÖST, 2009), as presented in Figure 13.

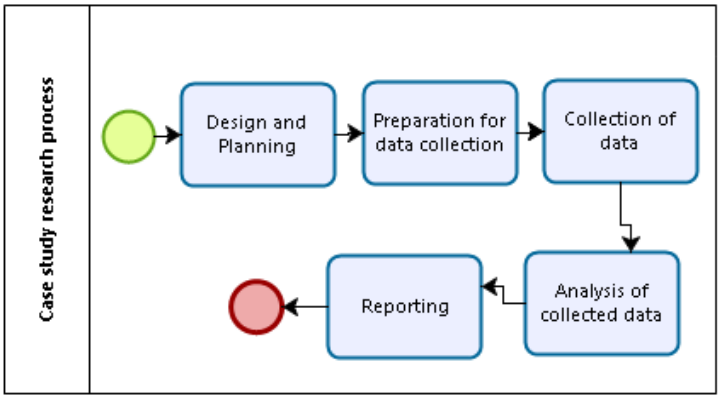

Figure 13 – Case study research process.

First, the objectives are established and the case study is planned (Step 1 - Design and Planning). Then, occurs the Preparation for data collection (Step 2) in which procedures and protocols for data collection are defined. The third step consists of Collection of data on the studied case. Later, qualitative/quantitative methods are used to obtain conclusions from the case study to perform the Analysis of collected data (Step 4). Finally, the documentation and dissemination of results is conducted (Step 5 - Reporting).

In the next chapter, we present the systematic literature review we conducted to analyze the integration between requirements engineering and safety analysis.

4 INTEGRATION BETWEEN REQUIREMENTS ENGINEERING AND SAFETY ANALYSIS: A SYSTEMATIC LITERATURE REVIEW

Motivated by the open issues highlighted by important authors in the safety area discussed in Section 3.2, we concluded that there was a need to investigate the existing approaches proposed to improve the integration between requirements engineering and safety analysis. In the next sections, we describe the planning and results of a systematic literature review we conducted to analyze this integration.

4.1 RESEARCH METHODOLOGY

The methodology to conduct the SLR (Figure 14) was based on the guidelines and the systematic review protocol template proposed by Kitchenham and Charters (2007).

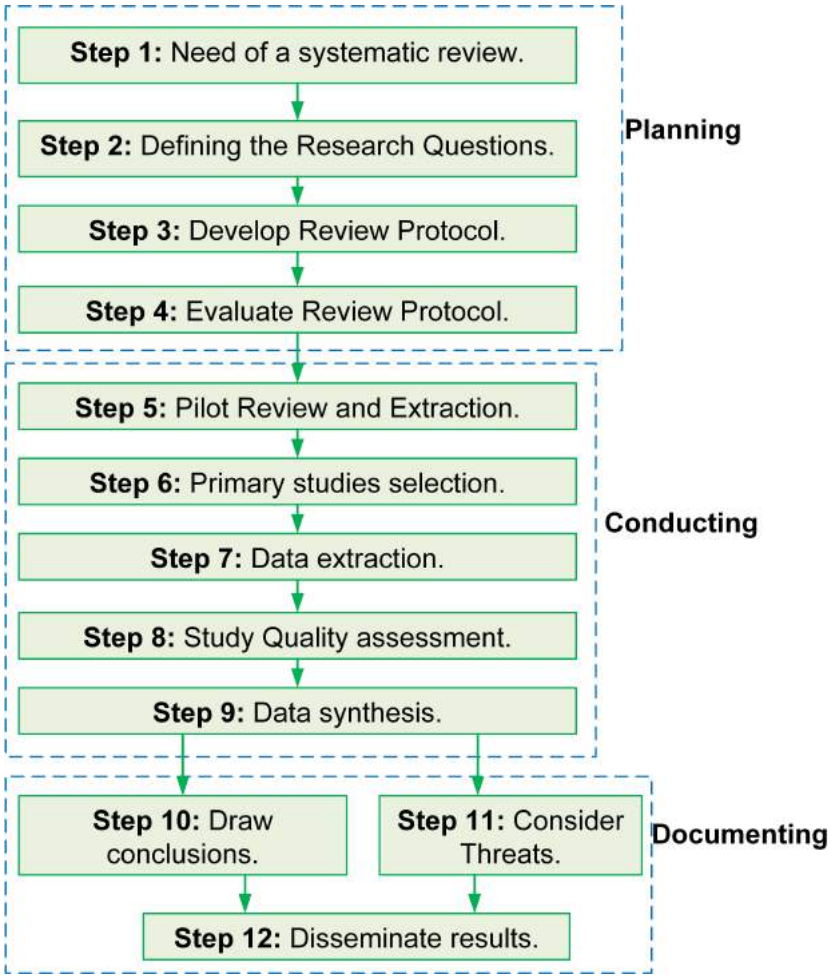

Figure 14 – Systematic review steps (adapted from (MARTINS; GORSCHEK, 2016a) and (KITCHENHAM; CHARTERS, 2007)).

According to the guidelines, the SLR process includes several activities, which can be grouped in three main phases: planning of the SLR, conducting the SLR and reporting the SLR.

Table 4 – Research questions and motivations.

Research Question	**Description and Motivation**
RQ1. What are the approaches proposed to improve the integration and communication between RE and safety engineering in the requirements engineering process of safety-critical systems?	The purpose of this question is to identify and analyze the approaches proposed to improve the integration and communication between RE and safety engineering. From the identification of these approaches, we want to investigate how the integration between these two areas has been performed and types of the approaches (methodologies, tools, techniques, maturity models, etc.)
RQ1.1. What activities can be performed by requirements engineers as a part of safety analysis in the approaches that integrate requirements and safety engineering?	This question intends to detect which activities (actions, tasks) are proposed by approaches that integrate requirements and safety engineering to be conducted requirements engineers during the safety analysis. The investigation of the activities is necessary to detect which ones we can include in a safety requirements engineering maturity model.
RQ1.2. What techniques can be used by requirements engineers during safety analysis in the approaches that integrate requirements and safety engineering?	This question aims to identify the techniques (systematic procedures, methods, formulas, routines by which a task is accomplished) can be used by requirements engineers in the the approaches that integrate requirements and safety engineering for performing the safety analysis of the systems. This information will be used to develop two conceptual models to classify the techniques used in hazard/safety analysis. Furthermore, the investigation of the techniques is necessary to detect which ones we can include in a safety requirements engineering maturity model.
RQ1.3. What data/information artifacts can be created by requirements engineers in the analysis and specification of SCS in the approaches that integrate requirements and safety engineering?	The aim of this question is to identify the various pieces of safety-related information (data, concepts, knowledge, facts) can be created by requirements engineers in the approaches that integrate requirements and safety engineering to document the safety concerns during the specification of SCS. The data/information obtained in this research question are used to develop two conceptual models regarding safety requirements classification. The conceptual models could be used during the safety analysis and to develop artifacts in the RE process.
RQ1.4. What are the tools used by the approaches that integrate requirements and safety engineering in safety analysis?	This question maps the Computer-Aided Software Engineering (CASE) tools used in the approaches that integrate requirements and safety engineering in the analysis of the safety requirements specifications of safety-critical systems. The identification of tools is necessary to improve the RE process, make the analysis more automatic, and the quality of analysis performed.
RQ1.5. What are the benefits of the approaches that integrate requirements and safety engineering identified in RQ1?	The purpose of this question is to analyze the benefits of the approaches (selected in RQ1) for integration and communication between RE and safety engineering extracted from the selected studies. The analysis of benefits is necessary to justify the need of integrating these two areas and the expected gains that could be achieved.
RQ2. What challenges/problems are identified in research literature relating to SCS and RE?	This question aims to identify works needed in this area. The identified issues could be used in future works ti address the problems faced in the RE process of SCS.

The SLR was motivated (Step 1, Figure 14) by the tighter integration of safety engineering concerns into the RE process desired by academia and industry as reported in many studies (LUTZ, 2000) (MARTINS; GORSCHEK, 2016a) (LEVESON, 2011) (HEIMDAHL, 2007) (SIKORA; TENBERGEN; POHL, 2012) (HATCLIFF et al., 2014). The gap that exists between the traditional development processes, methodologies, notations and tools and the ones used in safety engineering also contributes to the need of this SLR.

In order to determine if a SLR about integration and communication between RE and safety

engineering had already been performed, we searched the ACM, Springer, IEEE and Google Scholar digital libraries (performed in September, 2015). None of the retrieved studies were directly related to the objectives expressed in the research questions (Step 2, Defining Research Questions). In fact, few systematic literature reviews about the development of safety-critical systems are found in the literature.

We tested the string in 2018, however, we only found three new papers and we decided not to include them in this thesis.

4.1.1 Research questions

This systematic review's purpose is to analyze the approaches proposed to improve the integration and communication between RE and safety engineering as well as to understand which information regarding safety requirements should be specified by requirements engineers in order to reduce the gap between these two areas. Thus, we intend to answer the research questions described in Table 4.

4.1.2 Search Strategy

The search strategy included an automatic search, using a string validated by experts on the RE and safety-critical areas and a manual inclusion of papers well-known about requirements communication.

The development of our review protocol (Step 3, Figure 14) followed the PICOC (Population, Intervention, Comparison, Outcome, Context) criteria as suggested by Kitchenham and Charters (2007) as well as Petticrew and Roberts (2008):

- ***Population***: peer-reviewed publications reporting approaches to improve the integration and communication between RE and safety engineering;
- the aim of the ***intervention*** was to collect empirical evidence in relation to approaches proposed to improve the integration and communication among requirements and safety engineers during the development of SCS.
- ***Comparison***: it does not apply.
- ***Outcomes***: activities that should be performed by requirements engineering during safety analysis, the hazard/safety techniques they could use, the relationships between safety information that they should specify, the tools that can be used to support safety analysis as well as the benefits of the integration between RE and safety engineering. The activities, techniques and safety information should be performed, used or specified in the RE process. These activities and techniques have better results by RE and safety engineering working jointly.

- ***Context***: any context in which engineers in the RE process or safety analysis create or modify the specifications of safety-critical systems.

Moreover, the ***selected resources*** chosen were Science Direct, SpringerLink, ACM Digital Library, IEEE Xplore, Scopus, and Compendex; and the ***search method*** consisted of web search in digital libraries.

Our search string was specified considering the main terms of the phenomena under investigation (safety-critical systems, requirements engineering, safety requirements, and integration/communication).

We conducted pilot searches to refine the search string in an iterative way. We excluded keywords whose inclusion did not return additional papers in the automatic searches. After several iterations, we defined the following search string used to search within keywords, title, abstract and full text of the publications:

(1) *("safety critical system" OR "safety critical systems" OR "safety-critical system" OR "safety-critical systems") AND*

(2) *("requirements engineering" OR "requirements engineer" OR "requirements team" OR "requirements specification") AND*

(3) *("safety requirements" OR "safety engineering" OR "safety engineer" OR "safety team" OR "safety analysis" OR "safety specification") AND*

(4) *("communication" OR "integration" OR "interaction" OR "collaboration" OR "alignment" OR "understanding" OR "relationship" OR "share" OR "sharing" OR "combination" OR "interrelation" OR "interplay" OR "interdependency")*

Keywords related to safety-critical systems are presented in the first group of terms. The second one concerns to the requirements engineering, and the third group to the specification of safety requirements. Finally, the last group of terms are related to integration and communication. In this SLR, we want to collect information that should be shared by RE and safety engineering. Therefore, such information should be collected and specified early in the development process by requirements engineers to reduce the causes of accidents related to inadequate, incomplete or misunderstood requirements. If we had focused on words in the safety area, we would have extracted information that is beyond the scope and competence of requirements engineers, that is, more focused on tasks and competences of design engineers and safety engineers for example. Furthermore, we adapted the string for each search engine to consider their peculiarities.

We adopted the StArt (State of the Art through Systematic Reviews) tool (LAPES, 2014) to support the protocol definition and SLR conduction due to the positive results in the execution of SLRs reported in Hernandes et al. (2012).

4.1.3 Inclusion and exclusion criteria

The summarized inclusion and exclusion criteria are presented in Table 5. We were interested only in primary studies, published in any year until September 2015, that present some contribution on the requirements communication of safety-critical systems or relate requirements and safety or relate design and safety. Our protocol was validated (Step 4, Figure 14) by professionals of requirements engineering and safety-critical systems areas.

Table 5 – Inclusion/exclusion criteria.

#	**Inclusion Criterion**
1	Primary studies
2	Studies that address in the objectives the integration and communication between RE and safety engineering
3	Study published in any year until September 2015
4	Studies that relate Requirements and Safety
5	Studies that relate Design and Safety
#	**Exclusion Criterion**
1	Secondary studies
2	Short-papers ($\leq$ 3 pages)
3	Duplicated studies (only one copy of each study was included)
4	Non English written papers
5	Studies clearly irrelevant to the research, taking into account the research questions
6	Gray literature
7	Redundant paper of same authorship
8	Publications whose text was not available (through search engines or by contacting the authors)
9	Studies whose focus was not the integration and communication between RE and safety engineering or safety requirements specification (they addresses specific issues of safety-critical systems such as safety/hazard analysis, risk assessment/management, safety assurance or evidence, dependability/reliability, security, RE activities, traceability, software product lines, safety standards, design/architecture, human computer interaction concerns or human factors or operator behavior, robots development, and agile development)

4.1.4 Procedure for Studies Selection

Our procedure for studies selection, presented in Figure 15, consisted in four main steps. Besides the input and output of each step, this figure also shows two frames containing the exclusion criteria which were exclusively applied to the studies in Steps 3 and 4.

In Step 1, the studies were obtained from electronic databases using the search string. Springer returned 411 titles, IEEE Xplore 151, Science Direct 111, Scopus 159, Engineering Village (Compendex) 9 and ACM 193 search results. The search results (1034) were downloaded and were entered into and organized with the aid of StArt tool. Moreover, we included 3 papers manually.

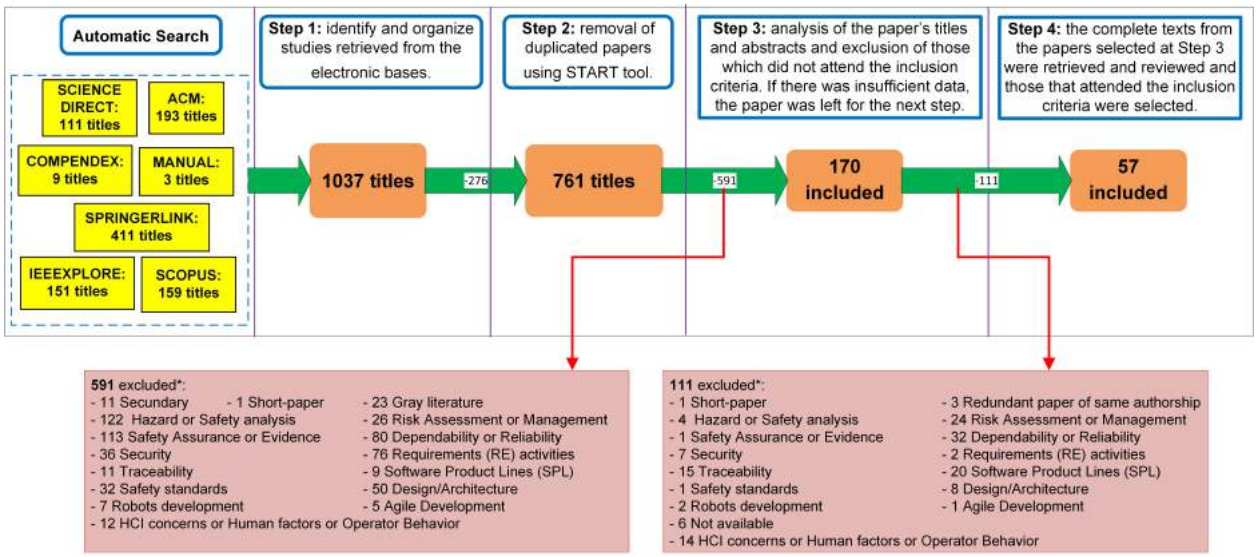

Figure 15 – Paper selection flowchart.

Out of 1037 search results, 761 were unique (step 2, Figure 15). Afterwards, reading the title and the abstract of the papers, we excluded 591 studies, based on the 9 exclusion criteria (step 3), as indicated on the left side of Figure 15. If there was insufficient data, the paper was left for the next step. After finishing the Step 3, 170 papers remained in the selection process.

After reading and analyzing 170 papers left for the full-text reading (step 4), we obtained 57 relevant papers (listed in appendix A). In this step, the papers were excluded according to the same 16 exclusion criteria (-111 papers) considered in the previous step, as also indicated in the right frame of Figure 15. Given that the systematic literature review results returned a great number of studies for extraction (57 papers), we limited the search procedures and we did not performed snowballing.

We excluded many studies from this SLR that address mainly hazard analysis, safety assurance, security or dependability. Hence, we selected papers that only propose the integration and communication between RE and safety engineering. The conduction of the SLR was performed by one person under supervision of senior researchers.

4.1.5 Data extraction and synthesis

We prepared digital forms to accurately record any information needed to answer the research questions. We extracted the data described in Table 6 from each of the 57 primary studies included in this systematic review. As well as the selection process, the data extraction was fully aided by the StArt tool.

During the synthesis phase, we normalized the terms describing the same phenomenon and we continued to use the most common term. We built four conceptual models using these terms: (1) the techniques that can be used by requirements engineers in the hazard analysis; (2) the techniques that can be used by requirements engineers in the safety analysis; (3) the

Table 6 – Extraction form

#	*Study Data*	*Description*	**Relevant RQ**
1	Study identifier	Unique id for the study	Study overview
2	Authors, Year, Title, Country		Study overview
3	Article source	ACM, Springer, IEEE, Science Direct, Scopus, El Compendex	Study overview
4	Type of article	Journal, conference, symposium, workshop, book chapter	Study overview
5	Application context	Industrial, academic, both	Study overview
6	Research Type (based on (WIERINGA et al., 2006)	Validation research, evaluation research, solution proposal, philosophical papers, experience papers	Study overview
7	Evaluation method (based on (EASTERBROOK et al., 2008))	Controlled experiment, case study, survey, ethnography, action research, illustrative scenario, not applicable	Study overview
8	Safety Activities	What activities can be performed by requirements engineers as a part of safety analysis in the approaches that integrate requirements and safety engineering?	RQ1.1
9	Safety Techniques	What techniques can be used by requirements engineers in safety analysis in the approaches that integrate requirements and safety engineering?	RQ1.2
10	Safety Information	What data/information artifacts should be created by requirements engineers in the analysis and specification of SCS in the approaches that integrate requirements and safety engineering?	RQ1.3
11	Safety Tools	What are the tools used by the approaches that integrate requirements and safety engineering in safety analysis?	RQ1.4
12	Benefits	What are the benefits of the approaches that integrate requirements and safety engineering identified in RQ1?	RQ1.5
13	Challenges/Problems issues	What challenges/problems are identified in research literature relating to SCS and RE?	RQ2

relationships between safety-related information that requirements engineers should specify; (4) a detailed set of information regarding the specification of hazards by requirements engineers.

According to Duarte et al. (2016), conceptual models are artifacts produced with the purpose of representing some part of reality. Hence, conceptual modeling allows the representation of entities (classes), their characteristics and their relationships. The authors also state that a class is a category assigned to the set of existing objects in the organization that are grouped according to their similarities.

4.1.6 Quality assessment

The quality assessment is critical in a SLR to investigate whether quality differences provide an explanation for differences in study results (KITCHENHAM; CHARTERS, 2007). Following the guidelines of Kitchenham and Charters (KITCHENHAM; CHARTERS, 2007), we considered that quality relates to the extent to which the study minimizes bias and maximizes internal and external validity.

The quality assessment (QA) of selected studies in both parts of our SLR was achieved by a scoring technique to evaluate the credibility, completeness and relevance of the selected studies. All papers were evaluated against a set of 20 quality criteria. The assessment instrument used

is presented in Table 7.

Table 7 – Study quality assessment criteria.

Questions	Eva	Val	Sol	Exp	Op
Q1. Is there a clear statement of the goals of the research (DERMEVAL et al., 2015)?	x	x	x	x	
Q2. Is the proposed technique clearly described (DERMEVAL et al., 2015)?			x		
Q3. Is there an adequate description of the context (industry, laboratory setting, products used and so on) in which the research was carried out (DERMEVAL et al., 2015)?	x	x			
Q4. Were treatments randomly allocated (KITCHENHAM; CHARTERS, 2007)?	x				
Q5. Is the sample representative of the population to which the results will generalise (KITCHENHAM; CHARTERS, 2007)?	x	x			
Q6. Was there any control group present with which the treatments can be compared, if applicable (TIWARI; GUPTA, 2015)?	x				
Q7. If there is a control group, are participants similar to the treatment group participants in terms of variables that may affect study outcomes (KITCHENHAM; CHARTERS, 2007)?	x				
Q8. Was the data analysis sufficiently rigorous (TIWARI; GUPTA, 2015)?	x	x			
Q9. Is there a discussion about the results of the study (DERMEVAL et al., 2015)?	x	x	x		
Q10. Are the limitations of this study explicitly discussed (DERMEVAL et al., 2015)?	x	x	x		
Q11. Are the lessons learned interesting (TIWARI; GUPTA, 2015)?				x	
Q12. Is the article relevant for practitioners (TIWARI; GUPTA, 2015)?	x	x	x	x	
Q13. Is there sufficient discussion of related work (TIWARI; GUPTA, 2015)? (Are competing techniques discussed and compared with the present technique?)	x	x	x		
Q14. Are the study participants or observational units adequately described (KITCHENHAM; CHARTERS, 2007)? For example, Software Engineering experience, type (student, practitioner, consultant), nationality, task experience and other relevant variables.	x	x			
Q15. What evidence is there of attention to ethical issues (KITCHENHAM; CHARTERS, 2007)?	x	x			
Q16. Is the study significantly increase the knowledge about integration and communication between RE and safety engineering research (TIWARI; GUPTA, 2015)?	x	x	x	x	
Q17. Is the stated position sound (WIERINGA et al., 2006)?					x
Q18. Is it likely to provoke discussion (WIERINGA et al., 2006)?					x
Q19. How well has diversity of perspective and context been explored (KITCHENHAM; CHARTERS, 2007)?					x
Q20. How clear are the assumptions/theoretical perspectives/values that have shaped the form and opinios described (KITCHENHAM; CHARTERS, 2007)?					x

Our primary studies were of different types, hence in order to assess their quality, we classified the 57 studies into five different categories - Evaluation Research Papers (EVA), Validation Research Papers (VAL), Solution Proposal Papers (SOL), Experience Papers (EXP), and Opinion Papers (OP). Then, we used a set of quality assessment questions for each category (see Table 7) as suggested by Kitchenham and Charters (2007), Tiwari and Gupta (2015), as well as Wieringa et al. (2006).

Each quality assessment question is judged against three possible answers: "Yes" (score = 1), "Partially" (score = 0.5) or "No" (score = 0). Consequently, the quality score for a particular study is computed by taking the sum of the scores of the answers to the questions

related to its research type. The quality scores of the selected studies are presented in Table 65 (see Appendix).

4.1.7 Threats to validity

We used the categorization of threats presented by Wohlin et al. (2000), which includes four types of validity threats, namely, conclusion, internal, construct, and external validity threats.

Construct validity: Construct validity is related to generalization of the result to the concept or theory behind the study execution (WOHLIN et al., 2000). Aiming to minimize threats of this nature, we used many synonyms for the main constructs in this review: "safety-critical systems", "requirements engineering", "safety requirements", and "communication". During the synthesis phase, we normalized the terms describing the same phenomenon and we continued to use the most common term (GASPARIC; JANES, 2016). We built four conceptual models using these terms: (1) the techniques that can be used by requirements engineers in the hazard analysis; (2) the techniques that can be used by requirements engineers in the safety analysis; (3) the relationships between safety-related information that requirements engineers should specify; (4) a detailed set of information regarding the specification of hazards by requirements engineers.

Internal validity threats are related to possible wrong conclusion about causal relationships between treatment and outcome (WOHLIN et al., 2000). The primary objective of conducting a SLR is to minimize internal validity threats in the research. We tried to mitigate threats due to personal bias on study understanding by conducting the selection process iteratively. Moreover, the first author is a PhD student in Requirements Engineering, and the other three authors are experienced researchers with expertise in Requirements Engineering, Software Engineering or Safety-Critical Systems.

External validity is concerned with establishing the generalizability of the SLR results, which is related to the degree to which the primary studies are representative for the review topic. In the case of a literature review, the external validity depends on the identified literature: if the identified literature is not externally valid, neither is the synthesis of its content (GASPARIC; JANES, 2016). By the choice of our exclusion criteria, we excluded gray literature papers. In order to mitigate external threats, our search process was defined after several trial searches and validated with the consensus of the authors.

Conclusion validity: The used methodology of Kitchenham and Charters (2007) already assumes that not all relevant primary studies that exist can be identified. To mitigate this threat, the research protocol was carefully designed and validated by the authors to minimize the risk of exclusion of relevant studies. Besides, we used many synonyms for the constructs of this SLR to improve high coverage of possibly important studies from automatic search. Furthermore, we did not conduct a complementary manual search since the main venues about requirements engineering and safety-critical systems are indexed by the search engines adopted in our protocol. Therefore, we only added 3 well-known studies (PERNSTÅL et al., 2015)

(FRICKER et al., 2010) (FRICKER; GORSCHEK; GLINZ, 2008) on requirements communication that were not captured by the search string. It is worth highlighting that we did not restrict the time period of published studies for this SLR aiming to obtain the maximum coverage possible. As mentioned in Section 2.5, for the best of our knowledge, this is the first SLR with a specific focus on integration and communication between RE and safety engineering.

4.2 RESULTS AND ANALYSIS

This section describes the results of our study; we discuss the answers of each research question separately. Our selection process resulted in 57 studies that met the inclusion criteria and we extracted the data following the extraction form described in Section 4.1.5. Before presenting the results and analysis for each research question, we depict the quality assessment results and give an overview of the general characteristics of the studies.

4.2.1 Quality assessment results

The quality assessment helped to increase the reliability of the conclusions obtained in this work and in ascertaining the credibility and coherent synthesis of results (DERMEVAL et al., 2015). We present the results of the quality assessment of the included studies in Appendix A according to the assessment questions described in Table 7. These 20 criteria provided a measure of the extent to which we could be confident that a particular selected study could make a valuable contribution to our review. The overall quality of the selected studies is reasonable since the mean of quality was 82.37%.

4.2.2 Overview of the Studies

The selected studies were published between 1994 and 2015. In Figure 16, we present the number of studies by year of publication. We can notice an increasing number of publications in the context of this review from 2007.

After analyzing the temporal view of the studies, we can conclude that the number of studies about integration and communication between RE and safety engineering is little through the years. Although the apparent increasing of the number of studies on this topic from 2007, this result corroborates with the statement that the integration of safety analysis and requirements engineering has been somewhat neglected (BROOMFIELD; CHUNG, 1997a).

We categorized the application context of the studies as *industrial*, *academic* or *both*. The studies that make explicit that they were performed in a real company or some authors works in the industry (we use their affiliations to obtain these information) we classified them as *industrial*. On the other hand, we classified the studies in *both* category, the studies conducted in/by industries or some authors are affiliated to the academia.

The results show that 27 studies (47%) belong to the *academic* context. 10 studies (17.54%) were conducted in *industrial* settings and 20 studies (35.09%) belong to the *both*

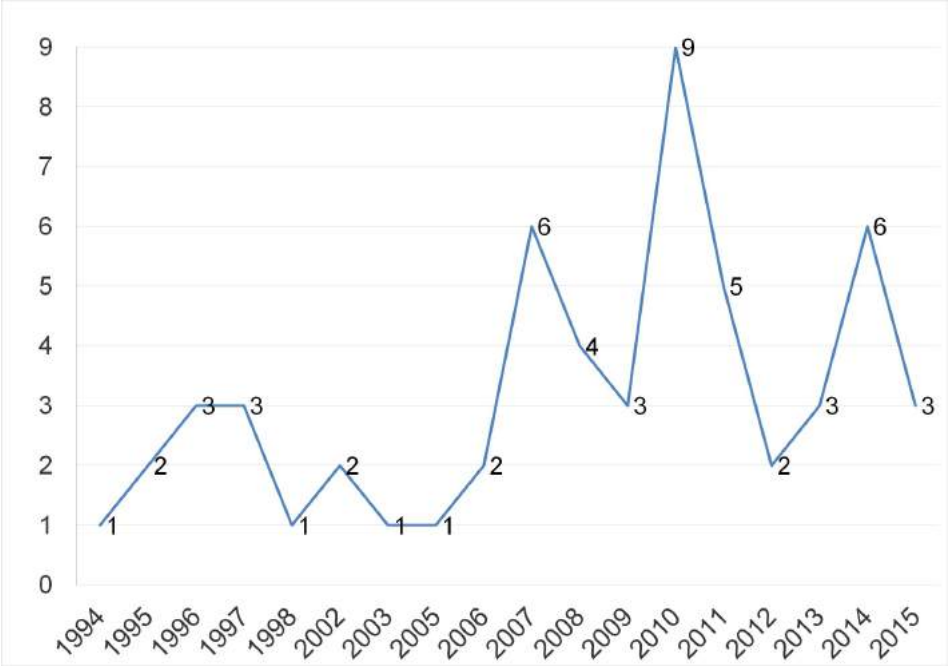

Figure 16 – Temporal view of the studies.

category. These results shows that more than half of the studies were classified as the industrial context. This may indicate that the studies are attempting to solve challenges faced by the industries. Besides, it also suggests that there is some approximation between industries and universities.

The selected studies were classified according to the applied research types defined by Wieringa et al. (2006), as can be seen in Table 8. The most adopted research type is *Solution Proposal* with 85.19% (46 studies) followed by *Evaluation Research* with 12.96% (7 studies), *Validation Research* with 7.41% (4 studies), and *Experience Papers* and *Opinion Papers* tied with 3.7% (2 studies) each. None of the selected studies belongs to *Philosophical Papers* category of research types. According to Wieringa et al. (2006), the difference between validation research and evaluation research is that in the first, techniques not yet implemented in practice are investigated, whereas in the second, techniques-in-practice are investigated.

We propose our classification of the evaluation method based on the categories (*controlled experiment, case study, survey, ethnography* and *action research*) defined by Easterbrook et al. (2008). In addition, we adopted two extra categories used in a previous work (DERMEVAL et al., 2015): *illustrative scenario* and *not applicable*. The first category is used to classify papers that only evaluate their contributions using small examples. The second extra category refers to the papers that do not contain any kind of evaluation method in the study.

Despite more than half of the selected studies were classified in the *industry context*, 84.21% of the studies were not evaluated empirically. 39 studies (68.42%) were evaluated only using small examples and 9 studies (15.79%) did not mention any kind of evaluation method or it does not apply since it is an opinion paper. Only 22.81% were evaluated empirically where

Table 8 – Research types of the selected studies.

Research Type	**Studies**	**Count**	**%**
Solution Proposal	(KAISER et al., 2010) (SAEED; LEMOS; ANDERSON, 1995) (DAVID; IDASIAK; KRATZ, 2010) (MOSTERT; SOLMS, 1994) (LUTZ, 1993b) (RATAN et al., 1996) (THRAMBOULIDIS; SCHOLZ, 2010) (BLACK; KOOPMAN, 2008) (NAVARRO et al., 2006)(KIM; CHUNG, 2005) (MANNERING; HALL; RAPANOTTI, 2008) (MEDIKONDA; PANCHUMARTHY, 2009) (WU; KELLY, 2007) (NEJATI et al., 2012) (MARTIN-GUILLEREZ et al., 2010) (LEVESON, 2002a) (HANSEN; RAVN; STAVRIDOU, 1998) (SCHOLZ; THRAMBOULIDIS, 2013) (MARKOVSKI; MORTEL-FRONCZAK, 2012) (BECKERS et al., 2013) (AROGUNDADE et al., 2012) (ARISS; XU; WONG, 2011) (GUIOCHET; MARTIN-GUILLEREZ; POWELL, 2010) (CHANDRASEKARAN et al., 2009) (BRIONES et al., 2007) (BROOMFIELD; CHUNG, 1997a) (GÓRSKI; WARDZIŃSKI, 1996) (DU; WANG; FENG, 2014) (ZOUGHBI; BRIAND; LABICHE, 2011) (JüRJENS, 2003) (SIMPSON; STOKER, 2002) (BIGGS; SAKAMOTO; KOTOKU, 2014) (LU; HALANG, 2007) (MUSTAFIZ; KIENZLE, 2009) (EKBERG et al., 2014b) (GUILLERM; DEMMOU; SADOU, 2010) (RAFEH, 2013) (CHEN et al., 2011) (TSCHüRTZ; SCHEDL, 2010) (ELLIOTT et al., 1995) (CROLL et al., 1997) (CANT et al., 2006) (MURALI; IRELAND; GROV, 2015) (PERNSTÅL et al., 2015) (FRICKER et al., 2010) (FRICKER; GORSCHEK; GLINZ, 2008)	46	85.19%
Evaluation Research	(MARTINS; OLIVEIRA, 2014b) (STÅLHANE; SINDRE, 2014) (STÅLHANE; SINDRE, 2007) (MUSTAFIZ; KIENZLE, 2009) (PAIGE et al., 2008) (JURKIEWICZ et al., 2015) (STÅLHANE; SINDRE; BOUSQUET, 2010)	7	12.96%
Validation Research	(NEJATI et al., 2012) (HATCLIFF et al., 2014) (PERNSTÅL et al., 2015) (FRICKER et al., 2010)	4	7.41%
Opinion Papers	(HEIMDAHL, 2007) (SIKORA; TENBERGEN; POHL, 2012)	2	3.7%
Experience Papers	(WILIKENS; MASERA; VALLERO, 1997) (SCHEDL; WINKELBAUER, 2008a)	2	3.7%

5 studies (8.77%) presented a controlled experiment and 8 studies (14.04%) adopted the case study strategy.

We noticed that there are few real experiments even though there is some empirical studies published on integration and communication between RE and safety engineering. In addition, we find that a lot of what is labelled as case study is really a proof of concept discussions related to simple examples. Hence, we classified them in the illustrative scenario category.

These findings reveal the need of applying the approaches in practice with real users in order to assess to what extent they contribute to integration and communication between RE and safety engineering. However, there are many difficulties faced when conducting controlled software engineering experiments in realistic environments that we are aware of. The absence of professionals as subjects in (software engineering) experiments is directly related to the high costs and large organizational effort spent in the conduction of such experiments as recognized by many authors, such as Basili, Selby and Hutchens (1986), Fenton (1993) as well as Sjoberg et al. (2002). In the next sections, we present and discuss the results of each research question.

4.2.3 RQ1: What are the approaches proposed to improve the integration and communication between RE and safety engineering in the requirements engineering process of safety-critical systems?

The purpose of this question is to identify and analyze the approaches proposed to improve integration and communication between RE and safety engineering. This research question was divided into five sub research questions (RQ1.1 to RQ1.5) aiming to analyze many aspects of the topic. In each one of these research questions, we provided a detailed discussion about our results. Our SLR returned 57 studies presented whose results will be discussed in Sections 4.2.4 to 4.2.8.

We analyzed the types of existing contributions based on the classification presented in the work of (PETERSEN et al., 2008) that includes the Approach, Framework, Method, Tool, Process, Model, Methodology, Template, Comparison, Metrics, Protocol, Checklist, Language, and Discussion categories (see Figure 17). It is important to note that we did not change the classification performed by the authors of the papers. For example, if the authors say the propose an approach but it is presented like a model or process, we counted the contribution as an approach. We only classified the ones where the authors did not present what is the contribution type.

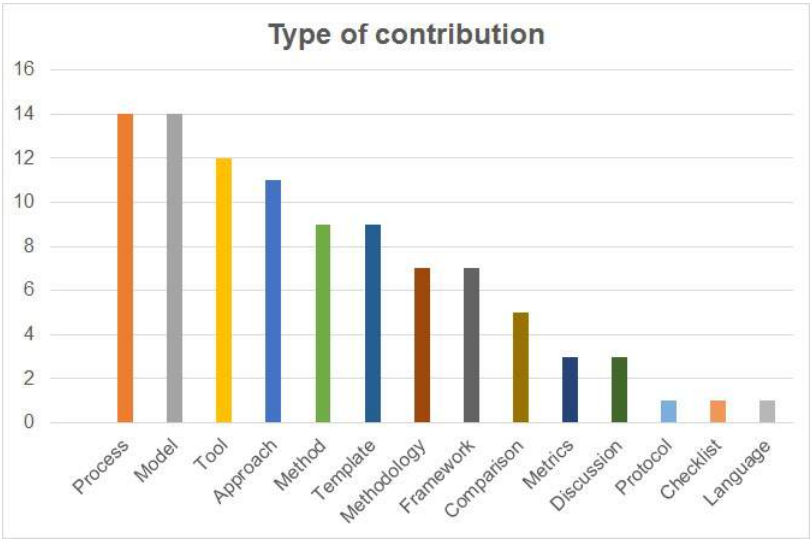

Figure 17 – Types of contributions on integration and communication between RE and safety engineering.

Note that this analysis allows a study to be included in more than one category. The predominant contributions that we identified were *Process* and *Model*, followed by *Tool*, *Approach*, *Method*, and *Template*. These types of contributions show that there is a tendency of using common models among requirements, design and safety teams. This contribution was adopted by (WU; KELLY, 2007) (NEJATI et al., 2012) (MARKOVSKI; MORTEL-FRONCZAK, 2012) (AROGUNDADE et al., 2012) (ARISS; XU; WONG, 2011) (STÅLHANE; SINDRE, 2007) (EKBERG et

al., 2014b) (CHEN et al., 2011) (MURALI; IRELAND; GROV, 2015) to improve integration and communication between RE and safety engineering.

UML profiles were proposed by the works of Beckers et al. (2013), Zoughbi, Briand and Labiche (2011) as well as Lu and Halang (2007). The SysML language has been used by the works of Scholz and Thramboulidis (2013) as well as Biggs, Sakamoto and Kotoku (2014) as an approach to integrate safety engineering with an SysML-based development process.

An approach for safety management which can be used in different phases of software development before implementation and disposal phase is described in Rafeh (2013). In the proposed approach, safety begins from requirements as the infrastructure of design and continues through other phases of software production.

The shortcomings of the existing safety analysis techniques in software safety analysis were investigated by the works of Martins and Oliveira (2014b) as well as Du, Wang and Feng (2014). The former described a case study adopting a protocol to help requirements engineers to derive safety functional requirements from Fault Tree Analysis. The latter proposed a safety requirement elicitation technique combined with scenario to refine the system-level safety analysis into software behaviors in specific scenarios.

The variety of requirements specification languages motivated some works such as Stålhane and Sindre (2014) as well as Jurkiewicz et al. (2015) to perform experiments to identify which are the ones that best support non-experts in identifying hazards of safety-critical systems.

Finally, the work of Pernstål et al. (2015) presented a lightweight RE framework, demonstrated and evaluated its industrial applicability in response to the needs of a Swedish automotive company for improving specific problems in inter-departmental requirements coordination and communication in large-scale development of software-intensive systems.

We performed a rigor and relevance analysis of the approaches following the model proposed by Ivarsson and Gorschek (2011) for evaluating the rigor and industrial relevance of technology evaluations in software engineering. The results of rigor and relevance analysis of the approaches described in the selected studies are depicted in Figure 18.

The rigor is not the actual rigor of studies, e.g. use of a correct analysis method, that is considered in the model, but rather the extent to which aspects related to rigor are presented (IVARSSON; GORSCHEK, 2011). According to the model, the rigor is evaluated through three aspects: *Context described*, *Study design described*, and *Validity discussed*. All these aspects are scored with the same three score levels in a three point scale: 0 (weak), 0.5 (medium), and 1 (strong) description.

The relevance is evaluated by analyzing four aspects: *Subjects* that participated in the studies; (2) the *Context* in which the studies were performed; (3) the *Research Method* adopted in the studies; and (4) the *Scale* used in the studies evaluation. If the aspect contributes to industrial relevance it receives the score 1, otherwise, it receives 0. Therefore, the maximum value for rigor an approach can have is three, while relevance has a maximum of four (IVARSSON; GORSCHEK, 2011).

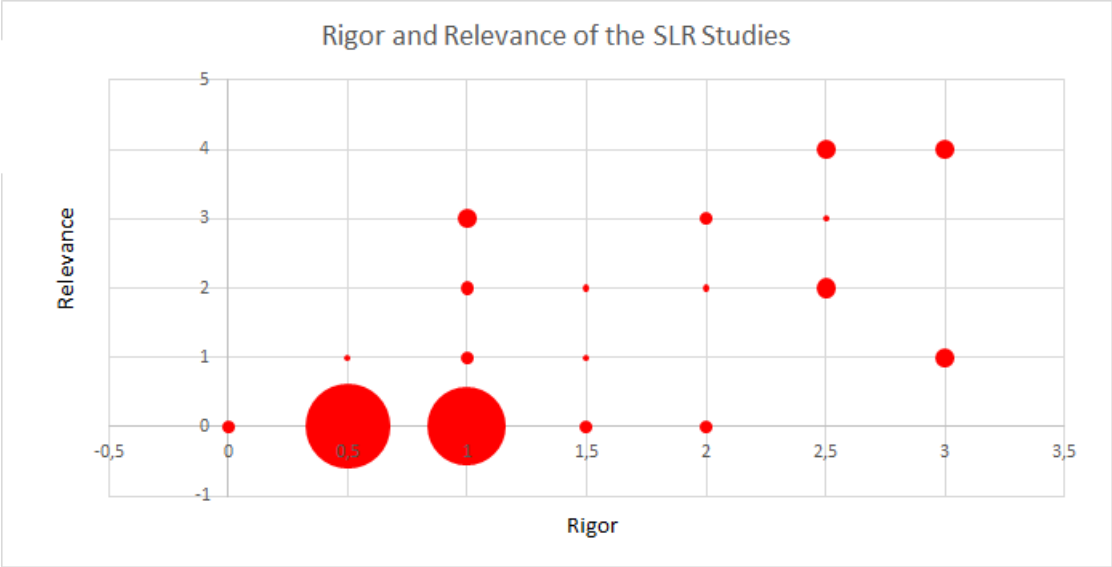

Figure 18 – Rigor and Relevance of the approaches.

Figure 18 shows that the majority of evaluations end up in the lower left quadrant of the bubble chart, indicating a lack of both rigor and relevance. Only 2 approaches have zero rigor and relevance, on the other hand, 13 studies (22.81%) have 0.5 rigor and 0 relevance. Moreover, 17 studies (29.82%) have 1 rigor and 0 relevance. This means that more than half of the studies (52.63%) of all approaches included in this review did not provide a description, or provided a weak one, of the context, study design or validity threats.

31 studies (54.39%) have 0 relevance. This means that they are examples of application of a proposal done by either students or researchers in academia in toy examples. This combination of low rigor and relevance is disappointing from a technology transfer perspective, as these evaluations have less potential for actually influencing practice (IVARSSON; GORSCHEK, 2011).

12 studies (21.05%) have the highest rigor (2.5 or 3) and relevance (3 or 4), but only three studies have the maximum rigor and relevance. These well classified studies proposed different types of contributions: framework, method, tool, process, model, template, comparison with other approaches, protocol or discussed challenges in the integration and communication between RE and safety engineering. All these papers were published in the last ten years (2006-2016) and classified as industrial or both (academic and industrial) context. Only 2 papers were written and published in the academic context. These results means that the year of publication might indicate that the quality of the studies changed over time and the relevance is affected by the affiliation of the researchers and the context in which the study is conducted. Furthermore, they also show that the levels of validation are increasing.

We present in Table 9 the average of each aspect regarding rigor (Context described (C), Study design described (SD), and Validity discussed (V)) and relevance (Context (CO), Research method (RM), User/Subject (U), and Scale (S)) per type of contribution. We also present the average of the sum of the aspects.

Table 9 – Average number of rigor and relevance per type of contribution.

	Rigor				Relevance				
Type	**C**	**SD**	**V**	**Sum - Rigor**	**CO**	**RM**	**U**	**S**	**Sum - Relevance**
Approach	0.36	0.23	0.50	1.09	0.18	0.09	0.09	0.00	0.36
Framework	0.64	0.36	0.64	1.64	0.29	0.29	0.29	0.29	1.14
Method	0.44	0.33	0.50	1.28	0.33	0.33	0.22	0.22	1.11
Tool	0.42	0.25	0.54	1.21	0.33	0.17	0.17	0.17	0.83
Process	0.61	0.39	0.50	1.50	0.50	0.29	0.50	0.43	1.71
Model	0.43	0.32	0.57	1.32	0.36	0.14	0.21	0.14	0.86
Methodology	0.36	0.07	0.57	1	0.14	0	0.14	0	0.29
Template	0.56	0.22	0.56	1.33	0.33	0.11	0.22	0.22	0.89
Comparison	1	1	0.90	2.90	1	1	0.40	0.40	2.80
Metrics	0.33	0	0.33	0.67	0.33	0	0.33	0.33	1
Protocol	1	1	0.5	2.5	1	1	1	1	4
Checklist	0.5	0	0.5	1	0	0	0	0	0
Language	0	0	0.5	0.5	0	0	0	0	0
Discussion	0.50	0.33	0.50	1.33	0.33	0.33	0.33	0.33	1.33

The results of Table 9 show that the studies that proposed *Metrics* and *Language* have the smallest number of rigor meaning that they are poor described. These papers discussed some limitations but they did not present the study design or research methodology adopted.

The types of contribution that have the worst relevance are *Approach*, *Methodology*, *Checklist* and *Language*. The scale of all papers in these categories do not contribute to relevance. This means that the evaluation is performed using applications of unrealistic size (down-scaled industrial) or toy examples.

4.2.4 RQ1.1: What activities can be performed by requirements engineers as a part of safety analysis in the approaches that integrate requirements and safety engineering?

This question intends to detect which activities can be conducted by requirements engineers during the safety analysis. In Table 10, we list the safety activities proposed by the selected studies that should have be conducted by RE and safety engineering working jointly to get better results during the development of safety-critical systems.

The results confirmed that there is no unified vocabulary among the approaches as well as they are not in compliance with safety standards. This lack of unified terminology hampers exchanging information between stakeholders contributing to a poor requirements analysis and specifications.

Several of these activities have the same purpose, for example *Safety analysis*, *Assessing Safety*, *Safety verification*, and *Safety Assessment*. Risk analysis is another activity with many variations: *Risk assessment*, *Risk identification*, *Risk evaluation*, and *Risk management*.

Many approaches do not explicitly mention which activities should be undertaken by requirements team or they generalize all activities as *Safety analysis*. Therefore, safety analysis is the activity reported in 37 studies (64.91%) as shown in Table 10.

Table 10 – Activities that should be performed in safety analysis.

Safety Activity	**Count**	**%**
Safety analysis	31	54.39%
Assessing Safety	2	3.51%
Safety verification	2	3.51%
Safety Assessment	2	3.51%
Hazard analysis	24	42.11%
Hazard Identification	6	10.53%
Risk analysis	9	15.79%
Risk assessment	5	8.77%
Risk identification	2	3.51%
Risk evaluation	1	1.75%
Risk management	1	1.75%
Dependability analysis	3	5.26%
Safety requirements specification	3	5.26%
The paper does not cite	3	5.26%
Reliability analysis	2	3.51%
Simulation	2	3.51%
Deviation analysis	2	3.51%
Verification of the completeness of requirements criteria	2	3.51%
Safety case generation	2	3.51%
Cause-consequence analysis	1	1.75%
Vulnerability analysis	1	1.75%
Robustness analysis	1	1.75%
Mode Confusion Analysis	1	1.75%
Human Error Analysis	1	1.75%
Timing and other analysis	1	1.75%
Operational Analysis	1	1.75%
Performance Monitoring	1	1.75%
Periodic Audits	1	1.75%
Incident and accident analysis	1	1.75%
Change Analysis	1	1.75%
Definition of System Level Requirements	1	1.75%
Definition of Safety Measures	1	1.75%
Definition of 1st Level System Architecture	1	1.75%
Refinement of Architecture	1	1.75%
System use modeling & task analysis	1	1.75%
Common cause, common mode and zonal analysis	1	1.75%

The second activity most referenced by the studies is the *Hazard analysis* that also has a variation *Hazard Identification*. This activity, cited in 30 studies (52.63%), consists in examining the system specification to identify potentially dangerous situations that may lead to an accident. When these situations are found, they should be adequately handled by specifying safety requirements (appropriate ways to eliminate or control the hazards).

Risk analysis is another activity well cited in the approaches (18 studies - 31.58%). This analysis comprises the evaluation of the risks, the likelihood of an injury or illness occurring, and the severity associated with the hazards.

Many activities were cited in the selected studies and we noticed that there is no consensus about which activities are essential in the development of a safety-critical system. The definition of the activities depends on the domain, culture and size of the company as well as the

knowledge and experience of the requirements and safety engineers. Moreover, few studies consider the guidelines and restrictions imposed by the safety standards.

4.2.5 RQ1.2: What techniques can be used by requirements engineers during safety analysis in the approaches that integrate requirements and safety engineering?

The safety analysis in the development of safety-critical systems requires the use of a technique to help finding the hazards of the system. Therefore, this question aims to identify what techniques that can be used by requirements engineers in the approaches for performing the hazard and safety analysis of the systems. These techniques are listed in the selected studies as having better results if RE and safety engineering work jointly. Accordingly, we did not investigate in this SLR the techniques for safety analysis that are used only by the safety engineering team.

The techniques obtained from the extracted data, the distribution of selected studies over the techniques including their count (i.e., the number of selected studies from each source), and the percentage of selected studies are presented in Table 11.

These techniques should be used in safety analysis to discover the hazards of a system, their causes and consequences. Such techniques can be classified according to the forms of logic and reasoning during the hazard analysis in Deductive (D), Inductive (I) or Both. The Table 11 also shows the General (G) category in which the techniques do not have the aim of discover hazards but another aspect of SCS. Besides the classification according to the type of hazard analysis, the techniques can be classified following the analytical styles that have two perspectives: qualitative and quantitative analysis.

In Figure 19, we present a conceptual model we created to classify the techniques used in the safety analysis but their main goal is not to discover hazards but some other aspect of SCS, for instance risk, safety criteria, usability of interface. On the other hand, the techniques used in the hazard analysis are listed in Figure 20.

The conceptual models of Figures 19 and 20 provide an intuitive and yet comprehensive way to present and summarize the techniques used in hazard/safety analysis. Furthermore, a conceptual model is an effective means for communicating the results in a more structured manner (NAIR et al., 2014). Experts in RE and safety engineering reviewed and provided feedback on the extracted safety techniques.

Some papers adopt techniques for safety analysis that their main objective is not discovering hazards but analyze other aspects of the SCS such as risk, safety criteria, usability of interface. Such techniques are exhibited in the conceptual model of Figure 19 and comprise *Mind storms and historical information*, *Preliminary controller task analysis (PTA)*, *Risk analysis (RA)*, *Interface analysis and human error analysis*, *Indirect Control Path Analysis (ICPA)*, *Safety Requirements/Criteria Analysis (SRCA)*, *Misuse cases (MUC)*, and *Scenario-based analysis*. They are cited 23 times in the selected studies corresponding to 15.75%. On the other hand,

Table 11 – Techniques that should be used in the safety analysis by RE and safety teams.

Technique	**Class.**	**Count**	**%**
Fault Tree Analysis (FTA)	D	18	31.58%
Preliminary Hazard Analysis (PHA)	I	18	31.58%
The paper does not cite		15	26.32%
HAZOPS (Hazard and Operability Studies)	Both	9	15.79%
Risk analysis (RA)	G	8	14.04%
Code hazard analysis (CoHA)	I	8	14.04%
System Hazard Analysis (SHA)	I	6	10.53%
Preliminary System Safety Assessment (PSSA)	I	6	10.53%
Deductive safety technique	D	5	8.77%
Failure Modes and Effects Analysis (FMEA)	I	5	8.77%
Misuse case (MUC)	G	5	8.77%
Guide-words	Both	5	8.77%
System safety analysis (SSA)	I	5	8.77%
Functional Hazard Analysis (FuHA)	I	4	7.02%
Inductive safety technique	I	4	7.02%
Scenario-based analysis	G	3	5.26%
Cause-consequence analysis (Cause-ConA)	Both	3	5.26%
Failure Modes Effects and Criticality Analysis (FMECA)	I	2	3.51%
Forward simulation (ForSim)	I	2	3.51%
Mind storms and historical information	G	2	3.51%
Interface analysis and human error analysis	G	2	3.51%
Deviation Analysis (DevA)	I	2	3.51%
Preliminary controller task analysis (PTA)	G	1	1.75%
Software Hazard Analysis (SwHA)	I	1	1.75%
Safety Requirements/Criteria Analysis (SRCA)	G	1	1.75%
Requirement Risk Assessment (RRAM)	D	1	1.75%
Risk Modes and Effect Analysis (RMEA)	I	1	1.75%
Event Tree Analysis (ETA)	I	1	1.75%
Indirect Control Path Analysis (ICPA)	G	1	1.75%
Preliminary Safety Analysis (PSA)	I	1	1.75%
Software safety design analysis (SSDA)	I	1	1.75%

15 studies (26.32%) did not cite any specific technique used in the safety analysis. They argue that this analysis should be conducted but they did not make any reference.

In the conceptual model of Figure 20, we list the techniques developed to perform hazard analysis classified in categories or analytical styles. They can be *Inductive (Forward)*, *Deductive (Backward)* or *Both*.

Inductive (forward) analysis is an approach for analyzing causal relations that starts with a set of particular facts and reasons to the more general. When employed for safety analysis, inductive analysis starts with a set of failure events and proceeds forward, seeking possible consequences (i.e. hazards) resulting from the events (SAEED; LEMOS; ANDERSON, 1995). This analytical style is cited 67 times (45.89%) in the studies.

The purpose of a forward search is to look at the effect on the system state of both (1) an initiating event and (2) later events that are not necessarily caused by the initiating event. In fact, causal independence is often assumed (LEVESON, 1995). Tracing an event forward can generate a large number of states, and the problem of determining all reachable states from

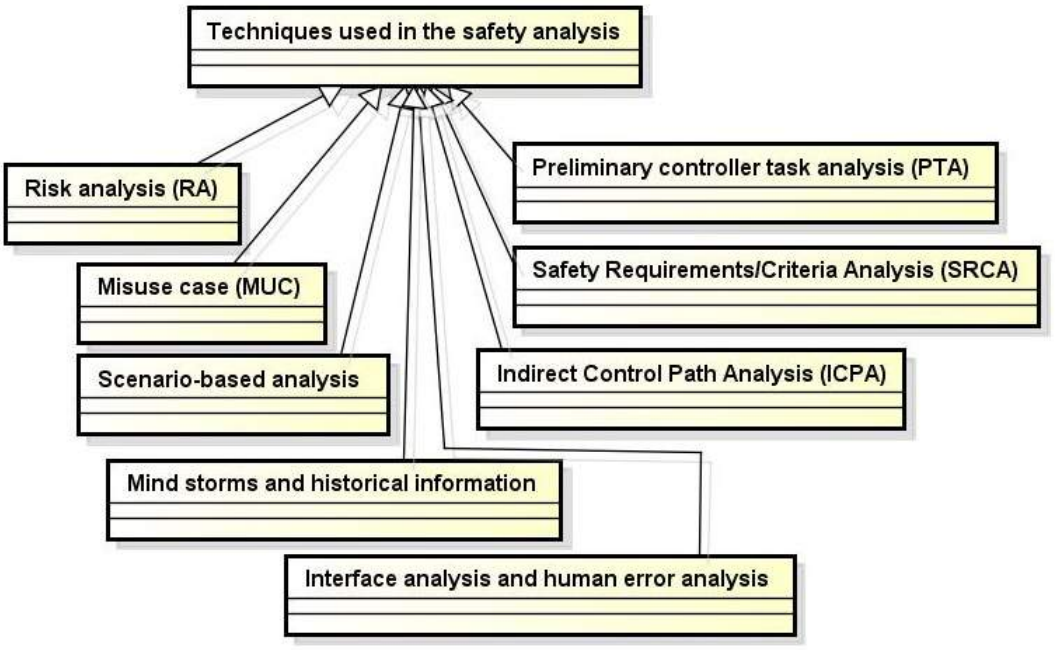

Figure 19 – Conceptual model of general techniques used in the safety analysis according to the selected studies.

an initial state may be unsolvable using a reasonable set of resources. For this reason, forward analysis is often limited to only a small set of temporally ordered events (LEVESON, 1995).

Deductive (backward) analysis is an approach for analyzing causal relations that starts with a general fact and reasons towards the more particular. When employed for safety analysis, deductive analysis starts with a hazard and proceeds backwards, seeking possible failures that can lead to the specific hazard (SAEED; LEMOS; ANDERSON, 1995). This analytical style is cited 24 times (16.44%) in the studies.

Backward search methods fit well with chain-of-event accident models, where the goal is to determine the paths (set of states or events in temporal ordering) that can lead to a particular hazard or accident. They are useful in accident investigations and in eliminating hazards by installing controls to eliminate predecessor events (LEVESON, 1995).

Furthermore, some techniques can be classified in *both* analytical styles. These techniques are cited 17 times (11.64%). Both inductive and deductive analysis can be employed during the safety analysis and the degree of application of one style of analysis versus the other varies according to the level of abstraction being considered and the representation technique (SAEED; LEMOS; ANDERSON, 1995).

The analytical styles can consider two perspectives: *qualitative analysis* and *quantitative analysis*. The *qualitative analysis* is conducted by examining the causal relations between events and states in sequences connecting failures of components to hazard states of the system (SAEED; LEMOS; ANDERSON, 1995). In the *quantitative* safety analysis, probabilities (or probability density functions) are assigned to the events in the chain and an overall likelihood of a loss is calculated (LEVESON, 2011).

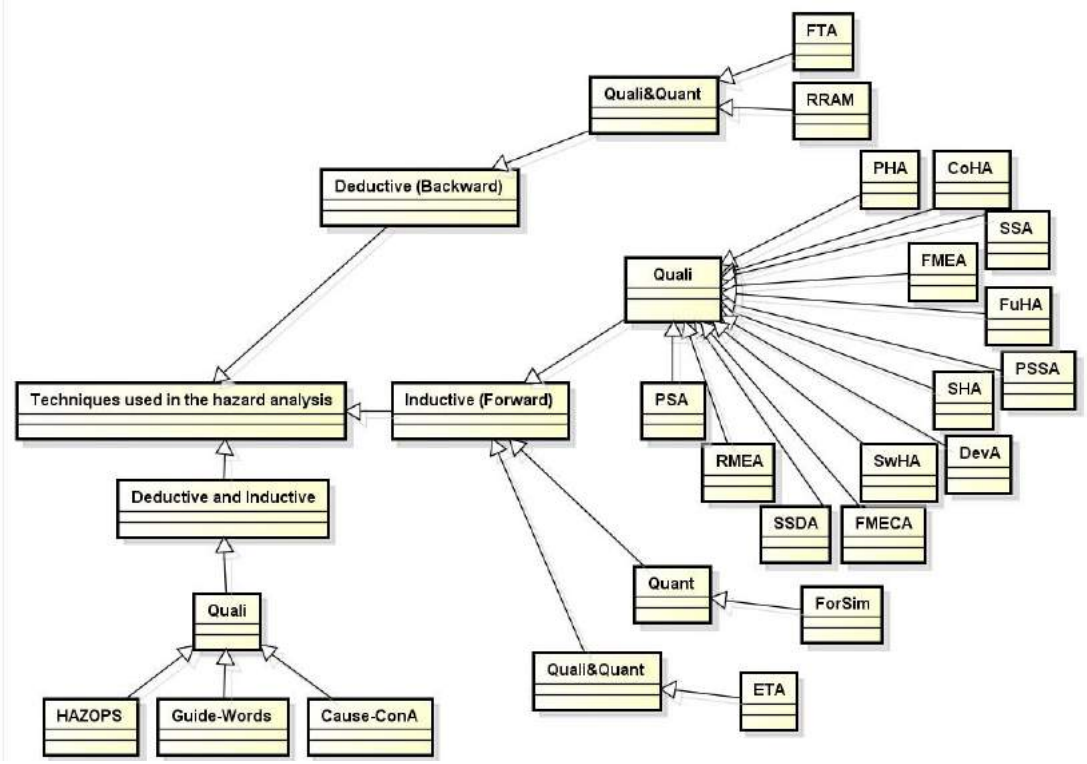

Figure 20 – Conceptual model of techniques used in the hazard analysis according to the selected studies.

The majority of the studies adopts the *qualitative analysis*. Such analysis is indicated at higher levels of abstraction, since the description of the requirements specifications is more general. Quantitative analysis is more appropriate at lower levels of abstraction, since the information on the elements of a requirements specification and their inter-relationships is more concrete and the stakeholders have a better understanding of the system's requirements.

4.2.6 RQ1.3: What data/information artifacts can be created by requirements engineers in the analysis and specification of SCS in the approaches that integrate requirements and safety engineering?

The aim of this question is to identify the various pieces of information used to define safety requirements in the specifications. The results of the conceptual analysis of the information extracted from the studies were used to develop conceptual models of safety-related information that are presented in Figures 21 and 22. The relationships among these information provide a structured representation of such concepts.

The safety information involved in safety analysis are the *Input, Hazard*, and *Output* (SAEED; LEMOS; ANDERSON, 1995) as presented in Figure 21. The safety analysis has as *Input* (SAEED; LEMOS; ANDERSON, 1995): *mission requirement*, *domain model*, *standard and guideline*, *requirements specification*, *safety integrity level* (LU; HALANG, 2007), *assumption* (KAISER et al., 2010) (NEJATI et al., 2012) (WILIKENS; MASERA; VALLERO, 1997), and *criteria*.

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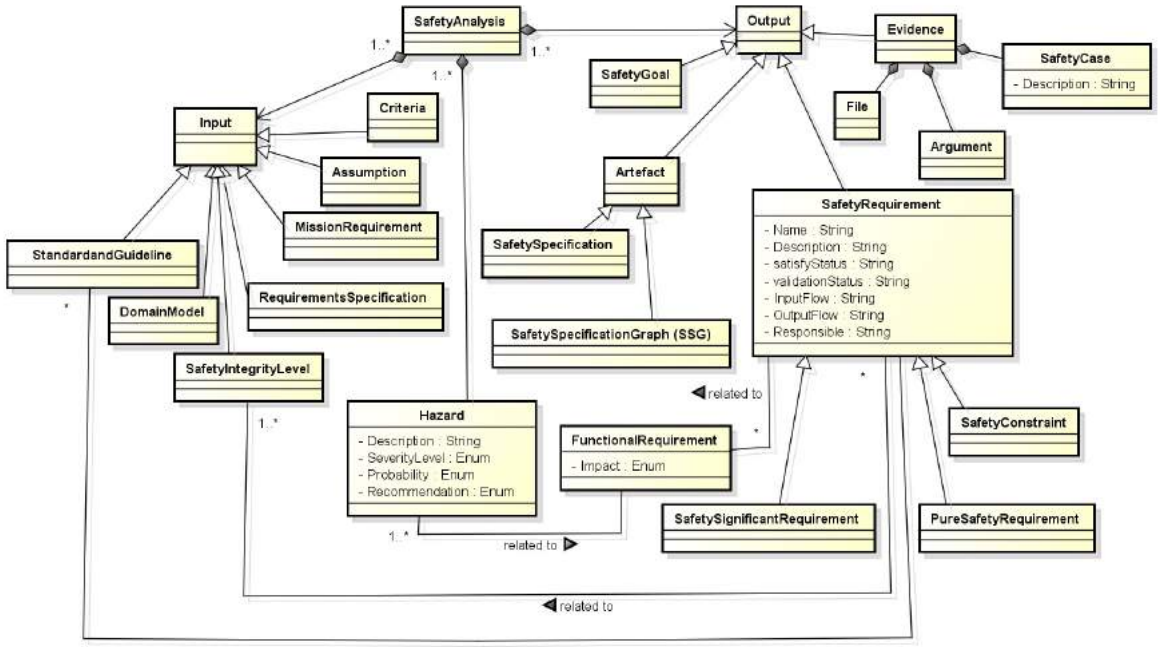

Figure 21 – Safety information conceptual models according to the selected studies.

The *Output* includes the *Safety Goal* as well as *Artifact* generated in the analysis, which can be *Safety Specification* or *Safety Specification Graph (SSG)* (SAEED; LEMOS; ANDERSON, 1995). The *SSG* is an information model to record the results of the requirements and safety analysis, and their interrelationships. *Evidence* (SAEED; LEMOS; ANDERSON, 1995) (ELLIOTT et al., 1995) is an output whose aim is to demonstrate that the *Hazard* was properly treated. The *Evidence* is composed by *File*, *Argument*, and *Safety Case* (LU; HALANG, 2007).

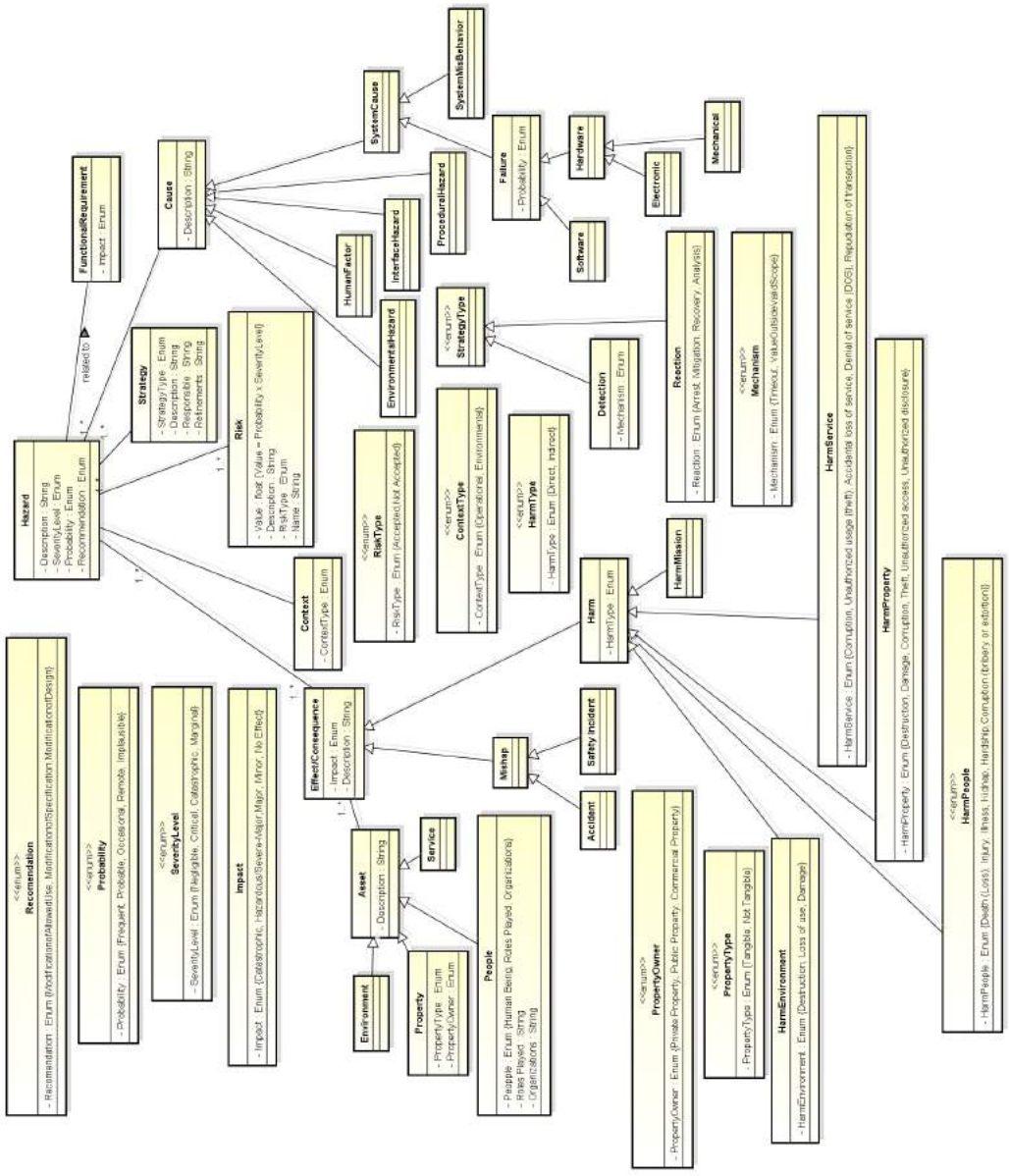

Figure 22 – Hazard information conceptual models according to the selected studies.

Safety Requirement, which constitutes another type of *Output* of safety analysis, is typically of the form of a quality criterion (a system-specific statement about the existence of a sub-factor of safety) combined with a minimum or maximum required threshold along some quality measure. It directly specifies how safe the system must be (MEDIKONDA; PANCHUMARTHY, 2009).

The *Safety Requirement* has the following attributes (WILIKENS; MASERA; VALLERO, 1997): *Name*, *Description*, *satisfyStatus*, *validationStatus*, *InputFlow*, *Outputflow*, and a *Responsible*. Moreover, it can be of three types (MEDIKONDA; PANCHUMARTHY, 2009): *Safety-significant requirement*, *Pure safety requirement*, and *Safety constraint* as shown in Figure 21.

Safety-significant requirement is a normal functional, data, interface, and non-safety quality requirement that is relevant to the achievement of the safety requirements. In other words, a *safety-significant requirement* can lead to hazards and accidents when not implemented correctly (MEDIKONDA; PANCHUMARTHY, 2009).

Pure safety requirement is a requirement that describe what actions and/or constraints should or should not be performed to maintain the system in a safe state (MEDIKONDA; PANCHUMARTHY, 2009). Finally, *Safety constraint* is an architecture or design constraint mandating the use of specific safety mechanism or safeguards (MEDIKONDA; PANCHUMARTHY, 2009). Moreover, *Safety Requirement* and *Hazard* are related to *Functional Requirement* (PAIGE et al., 2008).

Figure 22 depicts the information related to *Hazard*. It is a system state that might, under certain environmental or operational conditions (*Context* (WU; KELLY, 2007) (BIGGS; SAKAMOTO; KOTOKU, 2014)), lead to a *Mishap* or cause a *Harm* (MEDIKONDA; PANCHUMARTHY, 2009) (BIGGS; SAKAMOTO; KOTOKU, 2014).

Hazard has four attributes (see Figure 22): *Description* (BECKERS et al., 2013) (WILIKENS; MASERA; VALLERO, 1997), *Severity Level*, *Probability*, and *Recommendation* (THRAMBOULIDIS; SCHOLZ, 2010). The *Severity Level* (LEVESON, 1995) (THRAMBOULIDIS; SCHOLZ, 2010) can be *Catastrophic* (may cause death or system loss), *Critical* (may cause severe injury, severe occupational illness, or major system damage), *Marginal* (may cause minor injury, minor occupational illness or minor system damage), and *Negligible* (will not result in injury, occupational illness, or system damage).

The *Probability* of a hazard (WILIKENS; MASERA; VALLERO, 1997) can be *Frequent* (likely to occur frequently to an individual item, continuously experienced throughout the fleet or inventory); *Probable* (will occur several times during the life of an individual item, frequently throughout the fleet or inventory); *Occasional* (likely to occur sometime during the life of an individual item, several times throughout the fleet or inventory); *Remote* (unlikely to occur but possible during the life of an individual item; unlikely but reasonable expected to occur in a fleet or inventory); and *Implausible* (extremely unlikely to occur to an individual item; possible for a fleet or inventory).

Recommendation can be classified in the following categories (GUIOCHET; MARTIN-GUILLEREZ;

POWELL, 2010): *modification of allowed use*, *modification of the specification*, and *modification of the design* as depicted in Figure 22.

Risk is associated with *Hazard* and it is a combination of consequence (severity hazard) and likelihood of the hazard (risk = probability hazard x severity hazard) (THRAMBOULIDIS; SCHOLZ, 2010) (SIMPSON; STOKER, 2002).

Some strategies should be defined to minimize the consequence or probability of the hazard. A *Strategy* has the following attributes: *Strategy Type*, *Description*, *Responsible*, and *Refinement*.

The *Strategy Type* (KAISER et al., 2010) can be *Reaction* or *Detection* through mechanisms (*Timeout*, *Value outside of a valid scope*) (KIM; CHUNG, 2005). The strategy of *Reaction* can be *Arrest*, *Mitigation*, *Recovery*, and *Analysis*.

Hazard also has at least one *Cause* (THRAMBOULIDIS; SCHOLZ, 2010). It occurs due to *Environmental Hazard*, *Procedural Hazard*, *Interface Hazard*, *Human Factor* or *System Cause* (MEDIKONDA; PANCHUMARTHY, 2009). The last one can be *Failure* or *System MisBehavior* (SCHOLZ; THRAMBOULIDIS, 2013).

Failure is an event where a system or subsystem component does not exhibit the expected external behavior. *Failure* has a *Probability* (PAIGE et al., 2008) and it is related to *Hardware* (*Electronic* or *Mechanical*) or *Software* (MARTINS; OLIVEIRA, 2014b).

Hazard also has *Effect or consequence* in five levels of *Impact* (ZOUGHBI; BRIAND; LABICHE, 2011): *Catastrophic*, *Hazardous/Severe-Major*, *Major*, *Minor* or *No Effect*. This *Effect or consequence* can be a *Mishap* (MEDIKONDA; PANCHUMARTHY, 2009) or a *Harm*. *Mishap* can be a *Accident* (GÓRSKI; WARDZIŃSKI, 1996) or a *Safety Incident* (BROOMFIELD; CHUNG, 1997a).

An *Accident* is an undesired and unplanned (but not necessarily unexpected) event that results in (at least) a specified level of loss. On the other hand, a *Safety Incident* (BROOMFIELD; CHUNG, 1997a) is an event that involves no loss (or only minor loss) but with the potential for loss under different circumstances (MEDIKONDA; PANCHUMARTHY, 2009).

A *Harm* has a *Type* which occurs to (BIGGS; SAKAMOTO; KOTOKU, 2014) *People*, *Property*, *Environment* or *Service* (MUSTAFIZ; KIENZLE, 2009). Each type is an *Asset* of a system.

Harm to *People* (Human beings, roles played or organizations) can be *Death (Loss)*, *Injury* (GUIOCHET; MARTIN-GUILLEREZ; POWELL, 2010), *Illness*, *Kidnap*, *Hardship*, or *Corruption (bribery or extortion)*.

Harm to *Property* can be *Destruction*, *Damage*, *Corruption*, *Theft*, *Unauthorized access* or *Unauthorized disclosure*. A *Property* has two attributes *PropertyType* and *PropertyOwner*. A *PropertyType* can be *Tangible* or *Not Tangible* and the *PropertyOwner* can correspond to *Private Property*, *Public Property* or *Commercial Property*.

Harm to *Environment* can be *Destruction*, *Loss of Use* or *Damage*. Finally, *Harm* to *Service* can be *Corruption*, *Unauthorized usage (theft)*, *Accidental loss of service*, *Denial of service (DOS)* or *Repudiation of transaction*.

Terms related to system safety are not used consistently in the selected studies. Differences exist among countries and industries. The confusion is compounded by the use of the same terms, but with different definitions, by engineering, computer science and natural language (LEVESON, 1995).

To promote the effective integration of safety analysis and requirements analysis, a common formal basis should be provided for the results of these techniques (SIMPSON; STOKER, 2002). The conceptual models presented in our SLR provide a more solid background for requirements engineers during safety analysis at system level. Our goal is to create an agreed-upon vocabulary and semantic structure containing all the relevant concepts, their relations and axioms within safety domain for the purpose of exchanging information and facilitating reasoning.

With the conceptual models, presented in Figures 21 and 22, we aim to capture in particular information that is shared by RE and safety engineering. The structuring of concepts that belong to different areas is a challenging task since we have to consider the non-standardization of nomenclature, synonyms, redundancies and the relationships between the various pieces of information. Although we expect that the conceptual model can be refined and extended since we consider only the data extracted from the selected studies, we believe that the conceptual models can be used during the requirements elicitation process and preliminary safety analysis and contribute to a better integration and communication between RE and safety engineering.

Besides the communication among requirements and safety engineers, there is also the communication with certification authorities. The certification process of a system requires demonstrating that appropriate safety standard was followed during the development process.

Many standards require that a safety assessment be performed when developing or modifying a safety-critical system (ZOUGHBI; BRIAND; LABICHE, 2011). However, the differences among standards make it hard to translate evidence of compliance among them (HATCLIFF et al., 2014). In this context, the proposed conceptual models although did not considered the constraints proposed by the safety standards, they may help understanding and applying the safety standards and regulations since they provide the information that both engineering groups have to exchange for system safety analysis, during design and in the preparation of reports for certification. This common basis contributes to ensure that sufficient correct evidence has been collected to satisfy the relevant standards for certifying a system and thus improve the certification process (BIGGS; SAKAMOTO; KOTOKU, 2014) (HATCLIFF et al., 2014).

The conceptual models representing the safety-related information proposed in this SLR can contribute to researchers and practitioners to elicit (MAIDEN et al., 1999)(FIRESMITH, 2005), organize, and manage safety requirements. Moreover, conceptual models can be used in many purposes (FIRESMITH, 2005): training; improve communications through the use of common terms and concepts of the conceptual model and thereby improving the collaboration (UNTERKALMSTEINER; FELDT; GORSCHEK, 2014); verify requirements completeness in systems specification against the terms presented in the conceptual model (MAIDEN et al., 1999); structure the table of contents of the requirements specification related to safety requirements; as

a checklist for evaluating the safety-related requirements in a requirements repository; improve the traceability between the requirements and the safety-related information.

4.2.7 RQ1.4: What are the tools used by the approaches that integrate requirements and safety engineering in safety analysis?

This question maps the tools shared by requirements and safety engineers to develop the requirements specification of safety-critical systems. In Figure 23, we present the list of tools referenced in the approaches. The list is composed by the following tools: Sparx Systems Enterprise Architect, DOVE (Design Oriented Verification and Evaluation) tool, HIVE (Hierarchical Verification Environment) tool, Isabelle theorem prover, ISPRA-FTA, UWG3, Adelard's ASCE, Rodin platform, UM4PF, SafeSlice, Aralia Sim Tree, BPA DAS, KB3, Jagrif, Netica, AToM, ERRSYSL, APIS IQ-RM tool, Doors and tools developed by the approach (i.e. a proposed one).

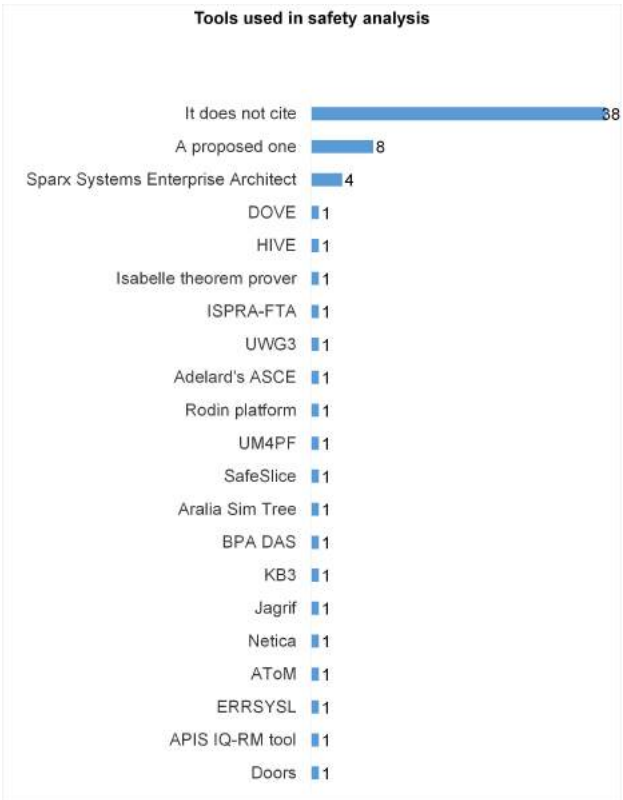

Figure 23 – Tools used in safety analysis.

The analysis of Figure 23 shows that 38 studies (66.67%) *did not cite* any tool support for the safety analysis. This outcome indicates the need of development of tools capable of integrating the requirements specification, safety analysis, and system management maintaining traceability links among all artifacts, models, and the information necessary for the development and certification of SCS.

The proposal of *new tools* is presented in 14.04% of the approaches (8 studies). It is too soon to affirm that there is a tendency in the academia and the market regarding to the development of tools for improving the safety analysis as required by the industry.

The lack of (commercial) tool support that would allow integrating requirements models in a seamless development process as well as the insufficient guidance, pointed by Sikora, Tenbergen and Pohl (2012), lead to uncertainty about how models should be used in the RE process.

The results about the tools cited in the selected studies demonstrate the absence of information on tools in the academic literature. Accordingly, we cannot draw conclusions about tool use with only the extracted information. One possible reason of these few number of tools can be the fact that regulatory agencies have been quite reluctant to qualify any tools for use on critical systems projects and they are actively debating how to address the issue (HEIMDAHL, 2007). In this context, Heimdahl (2007) complements stating that it is "highly unlikely that the researchers be able to provide the level of confidence necessary to trust a specific tool as a development tool in SCS development. Moreover, there are others aspects involved such as the tool evolution (maintenance, upgrades, and migration to new platforms)".

According to Hatcliff et al. (2014), researchers are not encouraged to engineer their tools to support certification (HEIMDAHL, 2007) (HATCLIFF et al., 2014). Moreover, the certification requirement vary significantly across safety standards for different domains. This requires tool vendors to develop different versions of their tool and qualification kits for each standard supported (HATCLIFF et al., 2014). Finally, another problem pointed out by Hatcliff et al. (2014) is that most of the tools are not standalone and rely on other tools and libraries that have their own independent life.

4.2.8 RQ1.5: What are the benefits of the approaches that integrate requirements and safety engineering identified in RQ1?

In Table 12, we present the benefits of the approaches for the integration and communication between requirements engineering and safety engineering from the extracted data of the selected studies.

The use of software in safety-critical systems, in particular in control systems, has increased to such an extent that failures in the software can impair system safety. In this context, analysis of software-related errors in computer based safety-critical systems have shown that mistakes made during the requirements analysis phase can easily introduce faults which subsequently lead to accidents (SAEED; LEMOS; ANDERSON, 1995).

A tendency we observed in the direction of decreasing the ambiguity and inconsistency of natural language specifications is to use common models for requirements specification and safety/hazard analysis shared by the requirements and safety engineers. This contributes partially to improve the process of exchanging information, increasing completeness, and correctness of the requirements specifications (FRICKER; GORSCHEK; GLINZ, 2008).

Table 12 – Benefits of the approaches for integration between RE and safety engineering.

Benefit	Count	%
B1: Reduction of errors in requirements specifications (increases quality).	25	43.86%
B2: It improves system safety.	17	29.82%
B3: It improves the analysis during overall system design.	8	14.04%
B4: Reduction of the software cost.	8	14.04%
B5: Models contributes to a precise (unambiguous) communication.	5	8.77%
B6: Bridge the existing gap between the disciplines and provide a framework for effective cooperation between experts.	4	7.02%
B7: Improves the traceability among requirements, design and safety requirements.	4	7.02%
B8: Better information presentation and increased information consistency.	3	5.26%
B9: Reduction of the workload on safety engineers.	3	5.26%
B10: Make appropriate design decisions and adaptation of the design to meet the safety requirements.	3	5.26%
B11: It contributes to have the same vocabulary.	3	5.26%
B12: Structuring the analysis in different steps on different levels.	3	5.26%
B13: Reduction of safety-related interface faults.	2	3.51%
B14: Reduction of the time in safety analysis.	2	3.51%
B15: It increases the confidence in the overall system development process.	2	3.51%
B16: Reduction of the number of iterations between system engineers and safety engineers.	1	1.75%
B17: It allows exhaustive and detailed user feedback and make possible to discover and then specify the complete system behavior.	1	1.75%

Addressing the safety concerns early in software development contributes to ensure that safety problems do not propagate through subsequent phases of development (SAEED; LEMOS; ANDERSON, 1995): the less time a misunderstanding has to unfold, the lower its impact (GLINZ; FRICKER, 2015). According to 17 approaches (29.82%), conducting the safety analysis in the requirements phase allows hazards to be identified and addressed early.

Identifying and assessing hazards is not enough to make a system safe; the information obtained in the hazard analysis needs to be used in the design (LEVESON, 1995) and implementation. In this context, some approaches aim to improve the integration between requirements and safety engineering by conducting the design and the safety analysis concurrently, thereby making it possible to let safety analysis results influence the system design. In order to do this, safety analysis and the system design may use the same system safety specification.

The late identification of problems in the safety specification leaves a number of potential risks that must be accounted for at huge cost at a later stage (MOSTERT; SOLMS, 1994). The cost is reduced since the hazards are discovered in the requirements phase where the cost of fixing an error is cheaper than in the later stages of the software development. Hence, safety must be designed into a system.

4.2.9 RQ2: What challenges/problems are identified in research literature relating to SCS and RE?

This question aims to identify works needed in this area. These challenges/problems were extracted from the selected studies and they are presented in Table 13.

Many studies presented their proposals, discussed some benefits but they did not explicitly

discussed challenges/problems in integration between requirements engineering and safety engineering as well as in requirements communication. This corresponds to 64.91% of the studies (37 studies).

The most cited challenges/problems are *Analysis of scalability of the technique about integration and communication between RE and safety engineering in real case studies (O1)* and *Conduction of more empirical studies about integration and communication between RE and safety engineering (O2)*. They were referenced in 4 studies (7.02%) each and are the consequence of the low number of proposals evaluated in the industrial context. These results show the need of applying the proposal in practice with real users in order to evaluate the extension of the contributions.

Develop safety analysis tools integrated with requirements specification (O3) is a concern mentioned in 3 studies (5.26%). Considering that 66.67% of the studies did not cite any kind of tool support (see Section 4.2.7), this outcome might indicate the need of development of tools capable of integrating the requirements specification, safety analysis, and system management maintaining traceability links among all artifacts, models, and the information necessary for the development and certification of SCS. This challenge about *Maintaining the traceability among (safety) requirements, architecture and implementation along with system development and evolution (O4)* is pointed out by 2 approaches (3.51%).

The above open issues may be useful in different contexts. For example, a newcomer (eg. new student research) will be able to identify new research opportunities and they can become the subject of new research projects.

Table 13 – Challenges/Problems in the integration and communication between RE and safety engineering.

Challenge/Problem	Studies	Count	%
The paper does not cite.		37	64.91%
O1: Analysis of scalability of the technique about integration and communication between RE and safety engineering in real case studies.	(RATAN et al., 1996)(BLACK; KOOPMAN, 2008) (NAVARRO et al., 2006)(STÅLHANE; SINDRE, 2014)	4	7.02%
O2: Conduction of more empirical studies about integration and communication between RE and safety engineering.	(SAEED; LEMOS; ANDERSON, 1995)(MARTINS; OLIVEIRA, 2014b) (MANNERING; HALL; RAPANOTTI, 2008)(STÅLHANE; SINDRE, 2014)	4	7.02%
O3: Develop safety analysis tools integrated with requirements specification.	(NAVARRO et al., 2006)(ARISS; XU; WONG, 2011)(JüRJENS, 2003)	3	5.26%
O4: Maintaining the traceability among (safety) requirements, architecture and implementation along with system development and evolution.	(KAISER et al., 2010)(CHEN et al., 2011)	2	3.51%
O5: Creation of formal guidelines to help requirements engineers to derive and communicate safety functional requirements from safety analysis.	(MARTINS; OLIVEIRA, 2014b)(BROOMFIELD; CHUNG, 1997a)	2	3.51%
O6: Integrate formal description techniques with safety requirements specifications.	(KIM; CHUNG, 2005)(MANNERING; HALL; RAPANOTTI, 2008)	2	3.51%
O7: Improve the completeness of requirements specification for safety analysis.	(SIKORA; TENBERGEN; POHL, 2012)(HATCLIFF et al., 2014)	2	3.51%
O8: Different standards in varying depth of compliance to be fulfilled can be bewildering to the stakeholders and a significant barrier to communication.	(SIKORA; TENBERGEN; POHL, 2012)(HATCLIFF et al., 2014)	2	3.51%
O9: Lack of experience of different stakeholders in safety engineering and the application domain (gaps in assumed knowledge, vocabulary and understanding) hampers exchanging information.	(HEIMDAHL, 2007)(HATCLIFF et al., 2014)	2	3.51%
O10: Requirements documentation tends to become large, ambiguous, inconsistent, and often lack clear structure affecting the process of exchanging information.	(HEIMDAHL, 2007)(HATCLIFF et al., 2014)	2	3.51%
O11: Decide and communicate which safety subgoals are “best”.	(BLACK; KOOPMAN, 2008)	1	1.75%
O12: Devise safety analysis techniques based on novel abstraction notions, that are appropriate for communication between application and software domains.	(SAEED; LEMOS; ANDERSON, 1995)	1	1.75%
O13: How safety checklists can be employed during the requirements phase to predict which factors in a particular system are likely to cause subsequent safety-related software errors.	(LUTZ, 1993b)	1	1.75%
O14: Extending safety concepts in UML diagrams to improve exchanging safety information.	(ZOUGHBI; BRIAND; LABICHE, 2011)	1	1.75%
O15: Evaluation of the time and cost of implementing an approach related to integration and communication between RE and safety engineering.	(MEDIKONDA; PANCHUMARTHY, 2009)	1	1.75%
O16: Adapt the integration and communication between RE and safety engineering proposal to the needs of any project size and of complexity.	(PAIGE et al., 2008)	1	1.75%
O17: Ensuring the correctness, completeness and consistency of safety requirements, analysis results and the subsequent design solutions contributing to a better communication process.	(CHEN et al., 2011)	1	1.75%
O18: Mastering, during design phase, the complexity of the combination of various technologies.	(HEIMDAHL, 2007)	1	1.75%
O19: Available safety analysis techniques are not adequate to establish explicit shared understanding among stakeholders and perform requirements validation and verification.	(HEIMDAHL, 2007)	1	1.75%
O20: Support for defining requirements across	(SIKORA; TENBERGEN; POHL,	1	1.75%

4.3 SUMMARY OF SYSTEMATIC LITERATURE REVIEW RESULTS

Our SLR draws on 57 studies, selected out of 1037, through a multistage process. A key feature of the review is that it does not restrict itself to a particular domain or safety standard. This broad scope in the search gives us deeper insights on the state-of-the-art about the content of the integration of RE and safety engineering.

The most important findings of this review and their implications for further research are as follows.

Non-standardization of nomenclature. There is a gap that exists between the traditional development processes, methodologies, notations and tools and the ones used in safety engineering. This gap makes the integration and communication between RE and safety engineering a difficult and challenging task. Hence, we believe a first step to this direction is the definition of a common nomenclature in order to satisfy system correctness and safety requirements and to provide a framework for effective cooperation between experts. Moreover, it is also necessary to look over safety standards to compare the nomenclature use in practice and what is required by the standards.

Need of improving the completeness of requirements specification for safety analysis. Providing the document details assists in getting complete and consistent documents. Absolute completeness may be unnecessary or uneconomical for many situations (GLINZ; FRICKER, 2015) (LEVESON, 1995). Hence, the requirements specification must simply be suitable to specify safe behavior in all circumstances in which the system is to operate (LEVESON, 1995). Therefore, RE approaches for SCS need to provide a significantly improved account of safety engineering concerns (SIKORA; TENBERGEN; POHL, 2012). We noticed that UML profiles and modeling languages have been used aiming to improve these specifications.

Compliance with safety standards. Different standards have to be fulfilled by the companies. Nevertheless, RE approaches do not provide explicit guidelines whether they comply with specific safety integrity levels or how the approach should be tailored to achieve compliance (SIKORA; TENBERGEN; POHL, 2012). Hence, standardization can be seen as a key coordination mechanism, enabling organizations to deal with inter dependencies in development work (PERNSTÅL et al., 2015).

Need of improving safety analysis techniques. Available safety analysis techniques are not adequate to establish explicit shared understanding among stakeholders and perform requirements validation and verification. Due to the implicit shared understanding in the system's specifications, too much information about the system is hidden. It might be useful to document which requirements and design decisions have not been documented in detail due to reliance on implicit shared understanding so that this information is not lost when the developed system evolves. Furthermore, it is necessary to improve the safety analysis techniques to handle with implicit shared understanding to allow the safety engineers to perform an adequate safety analysis.

Need of developing and maintaining traceability mechanisms for safety require-

ments specification. Consistency checking in large safety requirements specification demands different approaches than uncovering ambiguity or checking for testability (SIKORA; TENBERGEN; POHL, 2012). Furthermore, engineers consider tedious and error prone to deal with large bodies of natural language requirements. Since checking the consistency of the natural language requirements specification must be done manually by means of inspections, this leads to an enormous effort (SIKORA; TENBERGEN; POHL, 2012).

Need of integration tools. Many artifacts are generated by the requirements and safety teams during the development of SCS. The results of our SLR presented some tools that support safety analysis. Although 66.67% of the studies did not cite any kind of tool support, 27 tools were mentioned in the safety analysis. This outcome suggests the need of development of tools capable of integrating the requirements specification, safety analysis, and system management maintaining traceability links among all artifacts, models, and the information necessary for the development and certification of SCS.

Need of more integration between researchers and practitioners. The few number of real experiments on integration and communication between RE and safety engineering reveal the need of applying the approaches in practice with real users in order to assess to what extent they contribute to integration and communication between RE and safety engineering. This fact is corroborated by the rigor and industrial relevance we performed. The results of our analysis showed that more than half of the studies have 0 relevance meaning that they are examples of application of a proposal done by either students or researchers in academia in toy examples. Such results highlight the need of more integration between researchers and practitioners in order to improve the relevance of the research.

Communication format. The communication format most used by the included studies was *model-based collaboration* (42 papers) consisting of the use of models shared by different teams. The *Process support* was the second communication format most adopted by the approaches. It consists of collaborating through a predefined structure for the sequence of steps to be performed, the roles stakeholders must fulfill, and the artifacts that must be created. *Artifacts* (all documents that were not based on models) were adopted by 21 studies. In this communication format, several stakeholders contribute to the construct the artifacts, working to understand what each other has done, eliminate errors, and add their contributions. *Analysis tools* were adopted as a communication format by 19 studies. This category comprehends tools shared by stakeholders involved in the requirements specification and safety analysis as well as tools that support some kind of safety analysis. The *Face-to-face verbal communication*, used by 4 studies, includes meetings, informal conversations in hallways, doorways, and offices. The *Collaboration infrastructure* category comprises the technologies developed for the integration of software tools. Major forms of tool integration may be data integration, ensuring that tools can exchange data, and control integration, ensuring that tools are aware of the activities of other tools, and can take action based on that knowledge. Only three studies explicitly discussed this communication format. The last communication form adopted was *Awareness*

only explicitly used in two studies. It consists of providing information about the current activities of stakeholders.

Need of approaches to improve shared understanding. Many of challenges of requirements communication are related with the concept of shared understanding either explicit (interpreting explicit specifications, such as requirements, design documents, and manuals, in the same way by all group members) or implicit (common understanding of non-specified knowledge, assumptions, opinions, and values). The shared context provided by implicit shared understanding reduces the need for explicit communication and, at the same time, lowers the risk of misunderstandings. Shared understanding is important for efficient communication and for minimizing the risk of stakeholder dissatisfaction and rework in software projects. However, achieving a shared understanding among stakeholders and development team is not easy (GLINZ; FRICKER, 2015).

Adoption of new languages. *Textual requirements* is the dominant documentation style for requirements, but it does not imply that natural language is considered a satisfactory specification technique. Besides, many embedded systems practitioners are dissatisfied with using natural language for requirements specification. In this context, the *UML* language has been used in many academic and industrial works. A possible reason concluded through the selected studies is that the improvement of the requirements communication among engineers has been mainly a concern of requirements and software engineers, who are more familiar with UML. Furthermore, there is also the education concern. The engineers mostly learn UML during their education and to many of them, it now seems that the only design technique available is object oriented and the only design notation is the UML. Therefore, it is necessary to empirically investigate the ability of other languages to contribute to a better system specification.

Safety standards adoption. Different standards have to be fulfilled by the companies. The presence of so many standards, and the differences among standards, can be bewildering to anybody operating in the domain as well as a significant barrier to communication and in the education of new practitioners and researchers. In addition, RE approaches do not provide explicit guidelines whether they comply with specific safety integrity levels or how the approach should be tailored to achieve compliance. Finally, it is desirable to establish foundational principles that provide a common basis for software safety assurance across domains and applications. This common basis or an explicitly shared terminology reduces the probability of misunderstandings when concepts using this terminology are not specified or only coarsely specified (GLINZ; FRICKER, 2015).

Absence of tools to support the entire RE process and safety concerns. Many of the selected studies did not explicitly discuss how the tools support the communication throughout the RE activities (elicitation, analysis, specification, validation, management). This is a substantial issue for the requirements communication since tools can contribute to the requirements communication and mainly consider safety concerns to improve shared understanding.

4.4 FINAL CONSIDERATIONS

In this chapter, we presented the planning, conduction and analysis of the results obtained through a systematic literature review. The focus of the SLR was to investigate the integration of requirements engineering and safety analysis.

The results showed several types of contributions that includes Approach, Framework, Method, Tool, Process, Model, Methodology, Template, Comparison, Metrics, Protocol, Checklist, Language. However no maturity model that integrated RE and safety was found.

We also observed many benefits and open issues regarding the integration of these two areas. In the next chapter, e present the safety module for the Uni-REPM maturity model to handle safety concerns in the RE process.

5 UNI-REPM SCS: A SAFETY MODULE FOR UNI-REPM MATURITY MODEL

RE issues such as vague initial requirements, ambiguities in requirements specification, undefined requirements process, requirements growth, requirements traceability, and confusion among methods and tools (SVAHNBERG et al., 2013) (HALL; BEECHAM; RAINER, 2002) (JURISTO; MORENO; SILVA, 2002) (KAMSTIES; HÖRMANN; SCHLICH, 1998) have a huge impact in the quality of a system, especially in a safety-critical one.

In this context, it is claimed that the most cost-efficient place to fix many of the mentioned problems is in the RE phase (SVAHNBERG et al., 2013)(SOMMERVILLE, 2011)(LEFFINGWELL, 1997). Despite these issues, RE remains somehow a neglected area with respect to safety (SVAHNBERG et al., 2013)(HALL; BEECHAM; RAINER, 2002)(JURISTO; MORENO; SILVA, 2002)(NIKULA; SAJANIEMI; KÄLVIÄINEN, 2000).

Communication inside and between teams may be an alternative to reduce requirements-related problems during the development of a SCS. However, in such systems, we have multidisciplinary teams with large number of people involved. Accordingly, it is difficult to coordinate the interaction and communication among them. In this context, requirements problems are less frequent in organizations with high maturity levels (SOLEMON; SAHIBUDDIN; GHANI, 2009). Therefore, the Uni-REPM safety module aims to reduce issues in RE during SCS development by addressing safety actions/practices that should be covered in the RE process to reduce the gap between these areas. We considered a process as a set of activities performed to achieve some goal. In the next sections, we describe the sources of actions, module structure, its contents and how to use it to evaluate the maturity level of an organization.

5.1 SOURCES OF THE ACTIONS

The sources of the safety actions/practices of Uni-REPM module are presented in Table 14. Uni-REPM SCS is based on several sources listed in Table 14: SLRs (SLR1, SLR2), empirical studies (INTERVIEW-STUDY), technical reports (TECH-REPORT), safety standards (SAFETY-STD), existing maturity models (EXISTING-MATURITY-MODS), and comprehensive literature reviews (STATE-OF-THE-ART).

During the selection of safety actions/practices, we considered the definition of requirements practice of Davis and Zowghi (2006). They classify it as to be the use of a principle, tool, notation, and/or method in order to perform a requirements activity. When a practice reduces the cost of the development project or increases the quality of the resulting product, it is labeled as good requirements practice (DAVIS; ZOWGHI, 2006)(SOLEMON; SAHIBUDDIN; GHANI, 2009). In this context, we select safety practices capable of raising the likelihood that the right system will be built (DAVIS; ZOWGHI, 2006).

Table 14 – Source of actions.

Type	Reference	Actions	#actions
STATE-OF-THE-ART	(LEVESON, 1995)	13,14,16,19,20,23,25,41,43,44,52,53, 54,55,56,57,62,65,69,71,75,76,77,80, 81,82,86,87,91,94,95,108,133,145	32
	(SAWYER; SOMMERVILLE; VILLER, 1997)	3,13,16,18,22,27,28,31,32,34,37,42,43,58, 65,75,114,118,132,137,138,139,140,142	24
	Kontogiannis, Leva and Balfe (2016b)	7,8,19,24,51,90,95,98,107,108,109, 111,114,133	14
	(LEVESON, 2011)	7,8,17,30,37,38,58,68,85,87,138,144	12
	(LAMI; BISCOGLIO; FALCINI, 2016)	5,66,147,148	4
	(WHITEHEAD, 2007)	134,135,137	3
	(FIRESMITH, 2006b)	35,36,37	3
	(SCHEDL; WINKELBAUER, 2008b)	25,77,94	3
	(KAZARAS; KIRYTOPOULOS, 2011)	37,38	2
	(KIM; NAZIR; ØVERGÅRD, 2016)	37,38	2
	(LEVESON, 2002b)	10,16	2
	(GRILL; BLAUHUT, 2008)	9	1
	(EKBERG et al., 2014a)	106	1
	(PERNSTÅL; FELDT; GORSCHEK, 2013b)	5	1
	(HALL; SILVA, 2008)	8	1
SAFETY-STD	(STANDARDIZATION, 2011a)	18,21,24,28,37,39,46,59,61,62,63,64,67,72, 78,90,92,93,95,102,104,105,110,112,118, 119,120,122,123, 124,125,126,127,143	34
	(STANDARDIZATION, 2013)	4,11,12,45,49,60,66,70,73,100,101,103,104, 128,129,140,146,147	18
	(AMERICA, 1993)	19,32,45,57,58,62,77,79,84,85,87,90,95, 96,98,131	17
	(STANDARDIZATION, 2012b)	31,32,39,47,48,89	6
	(AMERICA, 2012)	29,32,33,70,90	5
	(STANDARDIZATION, 2015)	4,11,15,39,141	5
	(STANDARDIZATION, 2009)	74,146,147,149	4
	(STANDARDIZATION, 2012a)	107,109,111	3
	(AMERICA, 2000)	69,84	2
	(STANDARDIZATION, 2012c)	50,62	2
	(STANDARDIZATION, 2011b)	67	1
	(STANDARDIZATION, 2008a)	88	1
	(STANDARDIZATION, 2014)	109	1
INTERVIEW-STUDY	(MARTINS; GORSCHEK, 2018)	2,6,9,25,26,31,32,34,42,67,70,84,86,105, 106,107,113,114,115,124,130	21
EXISTING-MATURITY-MODS	(SEI, 2007)	1,25,28,31,32,33,39,56,58,77,83,85,94,59, 95,120,124,133,135	19
	(INSTITUTE, 2001a)	1,2,3,5,61,62,66,74,76,85,93,96,98,99, 118,121,127	17
	(STANDARDIZATION, 2008b)	7,8,9,10,11,12	6
	(STANDARDIZATION, 2011c)	93,123	2
	(INSTITUTE, 2001b)	76,99	2

5.2 MODULE OVERALL STRUCTURE

The Uni-REPM SCS is a safety module for the existing Uni-REPM maturity model. It is a well-established, adopted and a complete RE existing model as a design strategy. The safety module follows the components of Uni-REPM illustrated in Figure 24.

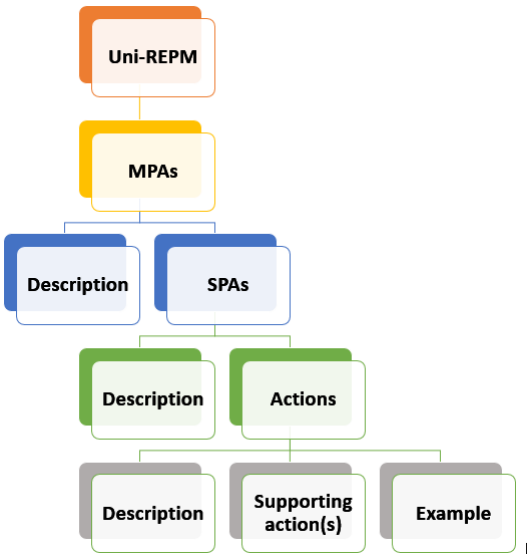

Figure 24 – Components of Uni-REPM.

We opted to follow Uni-REPM structure since we are designing a safety module for a universal lightweight maturity model, capable of evaluating the maturity of RE process, that has been used and well accepted in some companies. Moreover, the SPAs already present in the Uni-REPM cover the main process involved in the RE process (KOTONYA; SOMMERVILLE, 1998).

Aiming to maintain compability with Uni-REPM, the safety module follow its dual-view-approach: Process Area view and Maturity Level view. Accordingly, we proposed a module following the structure of Uni-REPM.

The process area view allows to visualize the hierarchy of processes that consist the model and faster discover actions/practices of the same group. The maturity level view, on the other hand, defines sets of practices that compose a consistent and coherent RE process, and where the practices in one level supports each other as well as the more advanced practices on the next level (SVAHNBERG et al., 2015).

5.2.1 Process area view

The safety module follows the same hierarchy of Uni-REPM that defines three levels: Main process area (MPA), Sub-process area (SPA) and Action. Since we want to integrate safety in the RE process, we maintained the seven MPAs of Uni-REPM that were defined considering well-adopted processes such as Kotonya and Sommerville (KOTONYA; SOMMERVILLE, 1998). The MPAs of Uni-REPM, which are the same for Uni-REPM SCS, are described below:

1. *Organizational Support (OS)*: assesses the quantity of support provided to RE practices from the surrounding organizations.
2. *Requirements Process Management (PM)*: contains activities to manage, control requirements change as well as to assure that the process is being followed.
3. *Requirements Elicitation (RE)*: it handles actions for discovering and understanding the necessities and desires of costumers in order to communicate them to others stakeholders.
4. *Requirements Analysis (RA)*: contains activities to detect errors, create a detailed view of requirements as well as to esteem information needed in later activities of RE process.
5. *Release Planning (RP)*: comprises important actions to define the optimal set of requirements for a certain release in order to accomplish defined/estimated time and cost goals.
6. *Documentation and Requirements Specification (DS)*: addresses how a company structures the requirements and other information collected during elicitation into consistent, accessible and reviewable documents.
7. *Requirements validation (RV)*: includes checking the requirements against defined quality standards and the real needs of the several stakeholders. Its aim is to assure that the documented requirements are complete, correct, consistent, and unambiguous.

The 14 safety new sub-process areas of Uni-REPM SCS and the related main process areas are listed below. The descriptions of the SPAs are presented in Table 15.

- *Organizational Support (OS)*: Safety Knowledge Management (SKM), Safety Tool support (STO), General Safety Management (GSM), Safety Planning (SP).
- *Requirements Process Management (PM)*: Safety Configuration Management (SCM), Safety Communication (SCO), Safety Traceability (ST).
- *Requirements Elicitation (RE)*: Supplier Management (SM).
- *Requirements Analysis (RA)*: Preliminary Safety Analysis (PSA), Failure Handling (FH).
- *Release Planning (RP)*: Safety Certification (SC).
- *Documentation and Requirements Specification (DS)*: Human Factors (HF), Safety Documentation (SDO).
- *Requirements validation (RV)*: Safety Validation and Verification (SVV).

The SPAs were proposed after a comprehensive literature review and the safety standards analysis. We concluded that they represent the areas that should be addressed by SCS companies. They cover human factors, failure handling, safety knowledge management among other areas highlighted as critical by the safety standards and many authors, for example, we can cite Leveson (1995), Lutz (2000) and Hatcliff et al. (2014).

Table 15 – Overview of new functional safety sub-processes, i.e. extensions, to UNI-REPM.

UNI-REPM MPA	**New safety sub-process area**	**Description**
1. Organizational Support (OS)	Safety Knowledge Management (SKM)	It provides transparency in the development process by making sure that projects and the company have the required knowledge and skills to accomplish project and organizational objectives.
	Safety Tool support (STO)	It is responsible for facilitate the appropriate execution of the corresponding tasks and manage all safety-related information that should be created, recorded and properly visualized.
	General Safety Management (GSM)	It covers project safety management activities related to planning, monitoring, and controlling the project.
	Safety Planning (SP)	It provides the safety practices and establishes a safety culture in the company.
2. Requirements Process Management (PM)	Safety Configuration Management (SCM)	It addresses the control of content, versions, changes, distribution of safety data, proper management of system artifacts and information important to the organization at several levels of granularity.
	Safety Communication (SCO)	It aims to improve the safety communication sub-process by establishing actions related to many safety terms, methods, process to support the safety analysis and assurance processes.
	Safety Traceability (ST)	It handles the traceability among artifacts helping to determine that the requirements affected by the changes have been completely addressed.
3. Requirements Elicitation (RE)	Supplier Management (SM)	It is responsible for managing the acquisition of products and services from suppliers external to the project for which shall exist a formal agreement.
4. Requirements Analysis (RA)	Preliminary Safety Analysis (PSA)	It addresses the realization of a preliminary safety analysis to avoid wasting effort in next phases of system development.
	Failure Handling (FH)	It handles failures in system components that can lead to hazardous situations, addition of redundancy as well as protection mechanisms.
5. Release Planning (RP)	Safety Certification (SC)	It has actions related to system certification.
6. Documentation and Requirements Specification (DS)	Human Factors (HF)	It handles issues regarding system's users and operators that can lead to hazards and shall be considered during the RE stage of safety-critical system development.
	Safety Documentation (SDO)	It has practices to record all information related to system's safety produced in RE phase.
7. Requirements Validation (RV)	Safety Validation and Verification (SVV)	It contains actions to requirements validation and the definition of strategies to the verification of requirements aiming to obtain requirements clearly understood and agreed by the relevant stakeholders.

Sub-process area (SPA) contains closely related actions, which help to achieve a bigger goal. The unique identifier assigned to each SPA is composed of the MPA identifier to which the SPA attaches and its abbreviation. For example, "OS.SKM" represents a sub-process area called "Safety Knowledge Management (SKM)" which resides under MPA "Organizational Support".

Figure 25 presents the Safety module and its relationship with Uni-REPM. The module extends the Uni-REPM model by adding 14 new SPAs highlighted through dashed lines. The existing process artifacts were not altered and none were removed.

At the low-level of module structure, we have "actions" that represent a specific good practice. By performing the action, the organization can improve their process and gain certain benefits (SVAHNBERG et al., 2015).

In the safety module, actions also follow the same format assigned to sub-processes to define their unique identifiers and also used to define safety extensions (JOHANNESSEN; HALONEN; ÖRSMARK, 2011). Actions are identified by the MPA/SPA under which they reside, followed by an "a" which stands for "action" and their position in the group. For example, action "*OS.SP.a1 Develop an integrated system safety program plan*" of Figure 26 means the first action under MPA "*Organizational Support*" and SPA "*Safety Planning*".

Besides the action identifier, every action has a description to explain what should be performed and can have recommendations (SVAHNBERG et al., 2015) that provide suggestions on well-adopted techniques or supporting tools to practitioners implement an action. It can also can have supporting actions that define links to other actions which will benefit the practitioners if they are implemented together. The complete description of 148 actions of Uni-REPM SCS following the structure of Figure 26 can be found in Appendix B. The online software tool developed to conduct RE/Safety evaluations using Uni-REPM and the safety module is described in Chapter 6.

The dependencies among the main process areas of Uni-REPM and the subprocess areas of the safety module are illustrated in Figure 27. They represent that to achieve the safety practices some RE practices (represented by the MPAs) are necessary as well as the relationships with other safety practices. From these figure, we can observe that the Safety Certification (SC) is the SPA that most depends of other components.

In the next sections, we describe each MPA and SPA and the traceability information of all actions. This information is presented so that the reader may locate the sources of individual actions in the module.

5.2.2 RE - Requirements Elicitation

Elicitation is the process of discovering, understanding, anticipating and forecasting the needs and wants of the potential stakeholders in order to convey this information to the system developers. The potential stakeholders can include customers, end-users and other people who have the stake in the system development. In the process, the application domain and

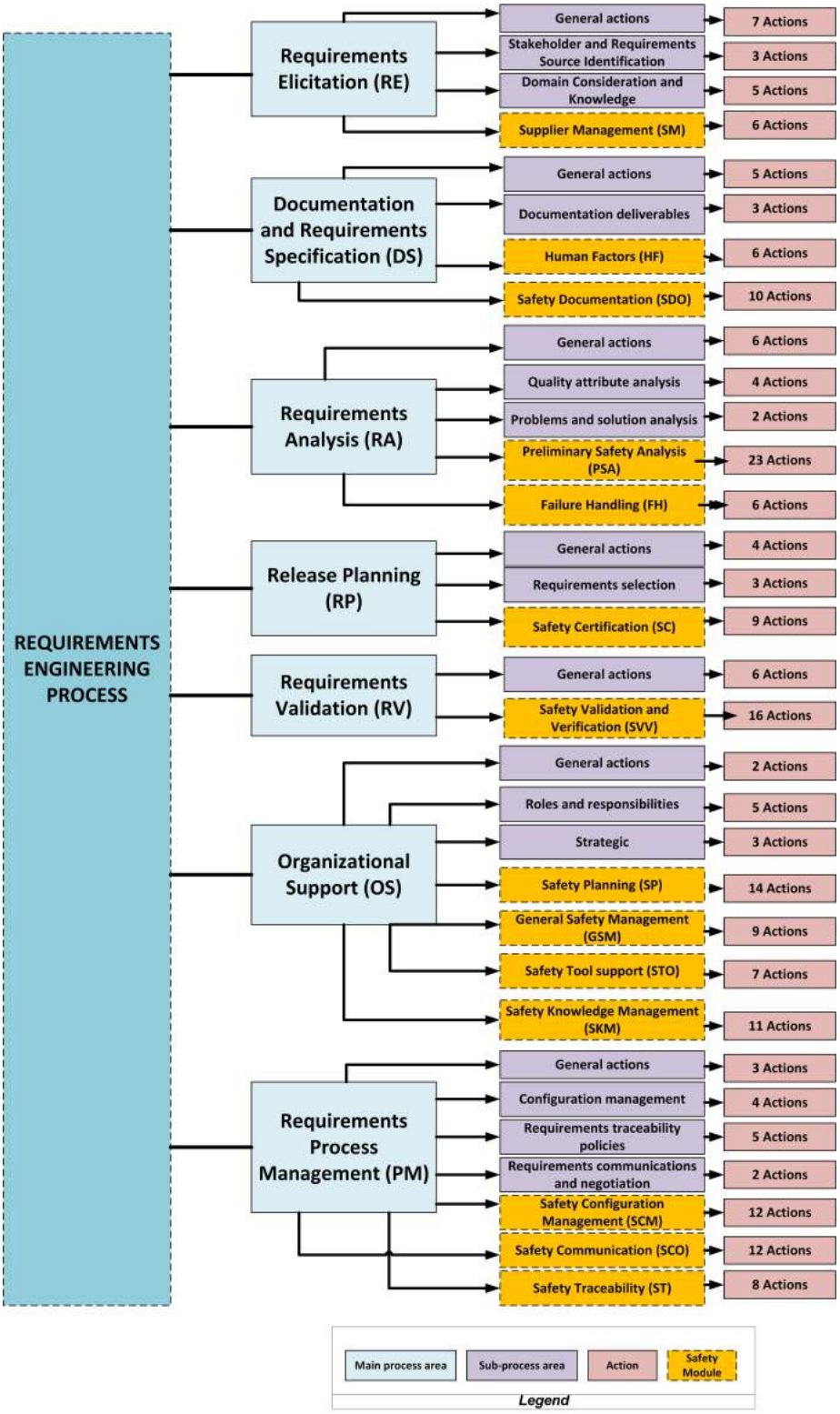

Figure 25 – Safety module and its relationship with Uni-REPM (VILELA et al., 2018b).

organizational knowledge are necessary among other things.

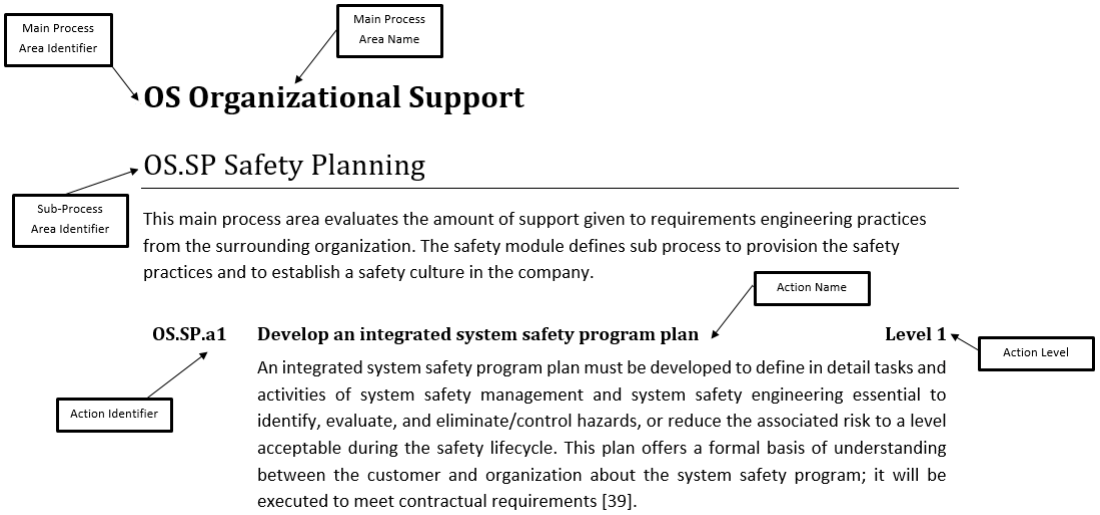

Figure 26 – Example of an Uni-REPM Safety module action.

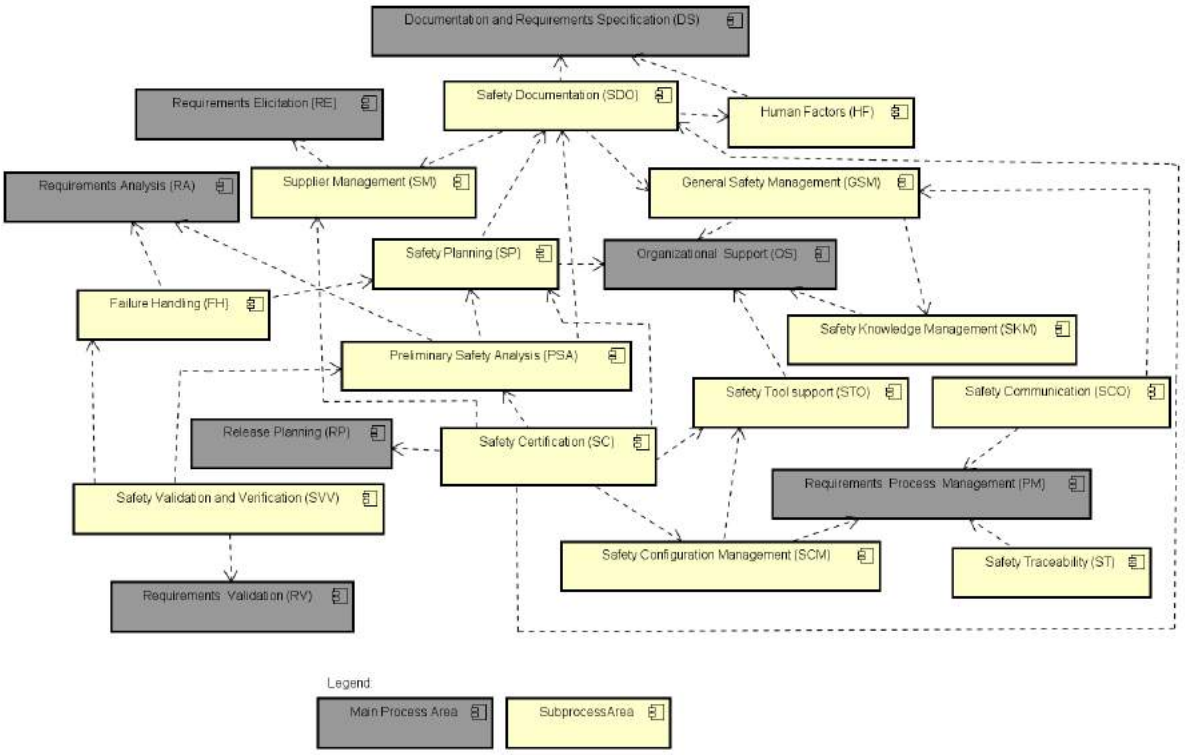

Figure 27 – Dependencies among the MPAs of Uni-REPM and the SPAs of the safety module.

5.2.2.1 RE.SM - Supplier Management

The development of safety-critical systems usually requires a combination of internal software and third-party systems. Therefore, in the Requirements Engineering phase, it is necessary to elicit and specify the requirements that suppliers must satisfy.

Suppliers correspond to internal or external organizations that develop, manufacture, or support products being developed or maintained that will be delivered to other companies or

final customers. Suppliers include in-house vendors (i.e., organizations within a company but which are external to the project), fabrication capabilities and laboratories, and commercial vendors (INSTITUTE, 2001b).

The Supplier Management sub-process is responsible to manage the acquisition of products and services from suppliers external to the project for which shall exist a formal agreement. The traceability information of the actions of this sub-process are presented in Table 16.

Table 16 – SPA: Supplier Management.

#	ID	Refs
	RE	Requirements Elicitation
	RE.SM	Supplier Management
1	RE.SM.a1	(INSTITUTE, 2001a; SEI, 2007)
2	RE.SM.a2	(MARTINS; GORSCHEK, 2018; INSTITUTE, 2001a)
3	RE.SM.a3	(INSTITUTE, 2001a; SAWYER; SOMMERVILLE; VILLER, 1997)
4	RE.SM.a4	(STANDARDIZATION, 2015; STANDARDIZATION, 2013)
5	RE.SM.a5	(PERNSTÅL; FELDT; GORSCHEK, 2013b; LAMI; BISCOGLIO; FALCINI, 2016; INSTITUTE, 2001a)
6	RE.SM.a6	(MARTINS; GORSCHEK, 2018)

5.2.3 DS - Documentation and Requirements Specification

Documentation and Requirements specification deals with how a company organizes requirements and other knowledge gathered during requirements engineering process into consistent, accessible and reviewable documents. In the safety module, the management of human factors and the documentation of safety issues are the main concern of the sub-process added to this process. The safety documentation contains the product's detailed functional and safety requirements.

5.2.3.1 DS.HF - Human Factors

Human factors have a significant importance in safety standards since many hazardous situations are caused by system's users and operator due to lack of training or unfamiliarity with the operator mental models. Although, the main goals of human-computer interaction are not primarily for safety but to make recommendations and application of technical guidelines (EDWARDS, 2017), the human factors shall be considered during the Requirements Engineering stage of safety-critical system development. The traceability information of the actions of this sub-process are presented in Table 17.

5.2.3.2 DS.SDO - Safety Documentation

Many artifacts are generated during the development of a safety-critical system that are used throughout the development to construct safety cases or documents with certification purposes. Accordingly, all information related to system's safety produced in the Requirements

Table 17 – SPA: Human Factors

#	ID	Refs
	DS	Documentation and Requirements Specification
	DS.HF	Human Factors
7	DS.HF.a1	(STANDARDIZATION, 2008b; LEVESON, 2011; KONTOGIANNIS; LEVA; BALFE, 2016b)
8	DS.HF.a2	(HALL; SILVA, 2008; STANDARDIZATION, 2008b; LEVESON, 2011; KONTOGIANNIS; LEVA; BALFE, 2016b)
9	DS.HF.a3	(GRILL; BLAUHUT, 2008; STANDARDIZATION, 2008b; MARTINS; GORSCHEK, 2018)
10	DS.HF.a4	(LEVESON, 2002b; STANDARDIZATION, 2008b)
11	DS.HF.a5	(STANDARDIZATION, 2015; STANDARDIZATION, 2008b; STANDARDIZATION, 2013)
12	DS.HF.a6	(STANDARDIZATION, 2008b; STANDARDIZATION, 2013)

Engineering phase must be recorded. This activity can also be done together with members from other phases that will use the information later. The traceability information of the actions of this sub-process are presented in Table 18.

Table 18 – SPA: Safety Documentation.

#	ID	Refs
	DS.SDO	Safety Documentation
13	DS.SDO.a1	(LEVESON, 1995; SAWYER; SOMMERVILLE; VILLER, 1997)
14	DS.SDO.a2	(LEVESON, 1995)
15	DS.SDO.a3	(STANDARDIZATION, 2015)
16	DS.SDO.a4	(LEVESON, 1995; LEVESON, 2002b; SAWYER; SOMMERVILLE; VILLER, 1997)
17	DS.SDO.a5	(LEVESON, 2011)
18	DS.SDO.a6	(SAWYER; SOMMERVILLE; VILLER, 1997; STANDARDIZATION, 2011a)
19	DS.SDO.a7	(LEVESON, 1995; KONTOGIANNIS; LEVA; BALFE, 2016b; AMERICA, 1993)
20	DS.SDO.a8	(LEVESON, 1995)
21	DS.SDO.a9	(STANDARDIZATION, 2011a)
22	DS.SDO.a10	(SAWYER; SOMMERVILLE; VILLER, 1997)

5.2.4 RA - Requirements Analysis

Safety requirements gathered from different sources need to be analyzed to detect incomplete or incorrect ones as well as to estimate necessary information for later activities (e.g. risk, priorities). It is also necessary to conduct a preliminary safety analysis and failure handling to dismiss avoiding wasting effort in next phases of system development.

5.2.4.1 RA.PSA - Preliminary Safety Analysis

Conducting safety analysis early in the development process contributes to improve system quality and detect hazards and related information in the beginning of Requirements Engi-

neering phase. The traceability information of the actions of this sub-process are presented in Table 19.

Table 19 – SPA: Preliminary Safety Analysis.

#	ID	Refs
	RA	Requirements Analysis
	RA.PSA	Preliminary Safety Analysis
23	RA.PSA.a1	(LEVESON, 1995)
24	RA.PSA.a2	(KONTOGIANNIS; LEVA; BALFE, 2016b; STANDARDIZATION, 2011a)
25	RA.PSA.a3	(SCHEDL; WINKELBAUER, 2008b; MARTINS; GORSCHEK, 2018; LEVESON, 1995; SEI, 2007)
26	RA.PSA.a4	(MARTINS; GORSCHEK, 2018)
27	RA.PSA.a5	(SAWYER; SOMMERVILLE; VILLER, 1997)
28	RA.PSA.a6	(SEI, 2007; SAWYER; SOMMERVILLE; VILLER, 1997; STANDARDIZATION, 2011a)
29	RA.PSA.a7	(AMERICA, 2012)
30	RA.PSA.a8	(LEVESON, 2011)
31	RA.PSA.a9	(STANDARDIZATION, 2012b; MARTINS; GORSCHEK, 2018; SEI, 2007; SAWYER; SOMMERVILLE; VILLER, 1997)
32	RA.PSA.a10	(AMERICA, 2012; STANDARDIZATION, 2012b; MARTINS; GORSCHEK, 2018; AMERICA, 1993; SEI, 2007; SAWYER; SOMMERVILLE; VILLER, 1997)
33	RA.PSA.a11	(AMERICA, 2012; SEI, 2007)
34	RA.PSA.a12	(MARTINS; GORSCHEK, 2018)
35	RA.PSA.a13	(FIRESMITH, 2006b)
36	RA.PSA.a14	(FIRESMITH, 2006b)
37	RA.PSA.a15	(KIM; NAZIR; ØVERGÅRD, 2016; KAZARAS; KIRYTOPOULOS, 2011; FIRESMITH, 2006b; LEVESON, 2011; SAWYER; SOMMERVILLE; VILLER, 1997; STANDARDIZATION, 2011a)
38	RA.PSA.a16	(KIM; NAZIR; ØVERGÅRD, 2016; KAZARAS; KIRYTOPOULOS, 2011; LEVESON, 2011)
39	RA.PSA.a17	(STANDARDIZATION, 2015; STANDARDIZATION, 2012b; SEI, 2007; STANDARDIZATION, 2011a)
40	RA.PSA.a18	
41	RA.PSA.a19	(LEVESON, 1995)
42	RA.PSA.a20	(MARTINS; GORSCHEK, 2018; SAWYER; SOMMERVILLE; VILLER, 1997)
43	RA.PSA.a21	(LEVESON, 1995; SAWYER; SOMMERVILLE; VILLER, 1997)
44	RA.PSA.a22	(LEVESON, 1995)
45	RA.PSA.a23	(AMERICA, 1993; STANDARDIZATION, 2013)

5.2.4.2 RA.FH - Failure Handling

Hazardous situations can be originated due to failures in system components that are hard to discover by either analysis or test. This difficult can originate the release of systems allowing uncommon hazards. Hence, it is important to specify and manage these faults. The safety module has a sub process to handle such failures. The traceability information of the actions of this sub-process are presented in Table 20.

Table 20 – SPA: Failure Handling.

#	ID	Refs
	RA.FH	Failure Handling
46	RA.FH.a1	(STANDARDIZATION, 2011a)
47	RA.FH.a2	(STANDARDIZATION, 2012b)
48	RA.FH.a3	(STANDARDIZATION, 2012b)
49	RA.FH.a4	(STANDARDIZATION, 2013)
50	RA.FH.a5	(STANDARDIZATION, 2012c)
51	RA.FH.a6	(KONTOGIANNIS; LEVA; BALFE, 2016b)

5.2.5 RP - Release Planning

Release planning consists in determining the optimal set of requirements for a certain release to be implemented at a defined/estimated time and cost to achieve some goals. A careful release planning is necessary to avoid risky situations, fail to achieve planned goals or miss the time-to-market. Besides the sub processes and actions already present in UNI-REPM, the module defines a new one related to system certification.

5.2.5.1 RP.SC - Safety Certification

Considering that many safety-critical systems should be certified by regulatory authorities, the Safety Certification sub process area handles certification issues early in the development process. The traceability information of the actions of this sub-process are presented in Table 21.

Table 21 – SPA: Safety Certification.

#	ID	Refs
	RP	Release Planning
	RP.SC	Safety Certification
52	RP.SC.a1	(LEVESON, 1995)
53	RP.SC.a2	(LEVESON, 1995)
54	RP.SC.a3	(LEVESON, 1995)
55	RP.SC.a4	(LEVESON, 1995)
56	RP.SC.a5	(LEVESON, 1995; SEI, 2007)
57	RP.SC.a6	(AMERICA, 1993; LEVESON, 1995)
58	RP.SC.a7	(LEVESON, 2011; AMERICA, 1993; SEI, 2007; SAWYER; SOMMERVILLE; VILLER, 1997)
59	RP.SC.a8	(SEI, 2007; STANDARDIZATION, 2011a)
60	RP.SC.a9	(STANDARDIZATION, 2013)

5.2.6 RV - Requirements Validation

Requirements validation includes the inspection of the produced documents against defined safety and quality standards and the needs of stakeholders. In the safety module, a sub process

to plan the verification and validation activities was added since they often run concurrently and may use portions of the same environment.

5.2.6.1 RV.SVV - Safety Validation and Verification

In the Safety Validation and Verification (V&V) there are actions to validation of the requirements and the definition of strategies to the verification of safety requirements. V&V activities should be available early in the development process so that the safety requirements are clearly understood and agreed by the relevant stakeholders. The traceability information of the actions of this sub-process are presented in Table 22.

Table 22 – SPA: Safety Validation and Verification.

#	ID	Refs
	RV	Requirements Validation
	RV.SVV	Safety Validation and Verification
61	RV.SVV.a1	(INSTITUTE, 2001a; STANDARDIZATION, 2011a)
62	RV.SVV.a2	(STANDARDIZATION, 2012c; INSTITUTE, 2001a; AMERICA, 1993; LEVESON, 1995; STANDARDIZATION, 2011a)
63	RV.SVV.a3	(STANDARDIZATION, 2011a)
64	RV.SVV.a4	(STANDARDIZATION, 2011a)
65	RV.SVV.a5	(LEVESON, 1995; SAWYER; SOMMERVILLE; VILLER, 1997)
66	RV.SVV.a6	(LAMI; BISCOGLIO; FALCINI, 2016; INSTITUTE, 2001a; STANDARDIZATION, 2013)
67	RV.SVV.a7	(STANDARDIZATION, 2011b; MARTINS; GORSCHEK, 2018; AMERICA, 1993; STANDARDIZATION, 2013)
68	RV.SVV.a8	(LEVESON, 2011)
69	RV.SVV.a9	(AMERICA, 2000; LEVESON, 1995)
70	RV.SVV.a10	(AMERICA, 2012; MARTINS; GORSCHEK, 2018)
71	RV.SVV.a11	(LEVESON, 1995)
72	RV.SVV.a12	(STANDARDIZATION, 2011a)
73	RV.SVV.a13	(STANDARDIZATION, 2013)
74	RV.SVV.a14	(STANDARDIZATION, 2009; INSTITUTE, 2001a)
75	RV.SVV.a15	(LEVESON, 1995; SAWYER; SOMMERVILLE; VILLER, 1997)
76	RV.SVV.a16	(INSTITUTE, 2001b; INSTITUTE, 2001a; LEVESON, 1995)

5.2.7 OS - Organizational Support

This main process area evaluates the amount of support given to requirements engineering practices from the surrounding organization. Organizational support is important, since ultimately the success of any time-consuming activity needs to be understood and supported by the organization. This main process area is aimed to enable organizational support, but also make the importance of requirements engineering clear to the development organization at large. The safety module added three new areas: Safety Planning, General Safety Management, Safety Tool Support, Safety Knowledge Management.

5.2.7.1 OS.SP - Safety Planning

This main process area evaluates the amount of support given to requirements engineering practices from the surrounding organization. The safety module defines sub process to provision the safety practices and to establish a safety culture in the company. The traceability information of the actions of this sub-process are presented in Table 23.

Table 23 – SPA: Safety Planning.

#	ID	Refs
	OS.SP	Safety Planning
77	OS.SP.a1	(SCHEDL; WINKELBAUER, 2008b; LEVESON, 1995; SEI, 2007)
78	OS.SP.a2	(STANDARDIZATION, 2011a)
79	OS.SP.a3	(AMERICA, 1993)
80	OS.SP.a4	(LEVESON, 1995)
81	OS.SP.a5	(LEVESON, 1995)
82	OS.SP.a6	(LEVESON, 1995)
83	OS.SP.a7	(SEI, 2007)
84	OS.SP.a8	(AMERICA, 2000; MARTINS; GORSCHEK, 2018; AMERICA, 1993)
85	OS.SP.a9	(LEVESON, 2011; INSTITUTE, 2001a; AMERICA, 1993; SEI, 2007)
86	OS.SP.a10	(MARTINS; GORSCHEK, 2018; LEVESON, 1995)
87	OS.SP.a11	(LEVESON, 2011; AMERICA, 1993; LEVESON, 1995)
88	OS.SP.a12	(STANDARDIZATION, 2008a)
89	OS.SP.a13	(STANDARDIZATION, 2012b)
90	OS.SP.a14	(AMERICA, 2012; KONTOGIANNIS; LEVA; BALFE, 2016b; AMERICA, 1993; STANDARDIZATION, 2011a)

5.2.7.2 OS.GSM - General Safety Management

The general safety management sub process covers the project safety management activities related to planning, monitoring, and controlling the project. The traceability information of the actions of this sub-process are presented in Table 24.

5.2.7.3 OS.STO - Safety Tool support

The Requirements Engineering process is better conducted when supported by adequate tools. In order to be able to facilitate the appropriate execution of the corresponding tasks and manage all safety-related information that should be created, recorded and properly visualized, the module has a sub process to handle these issues. The traceability information of the actions of this sub-process are presented in Table 25.

5.2.7.4 OS.SKM - Safety Knowledge Management

The Safety Knowledge Management sub process area provides transparency in the development process by making sure that projects and the company have the required knowledge and skills

Table 24 – SPA: General Safety Management.

#	ID	Refs
	OS	Organizational Support
	OS.GSM	General Safety Management
91	OS.GSM.a1	(LEVESON, 1995)
92	OS.GSM.a2	(STANDARDIZATION, 2011a)
93	OS.GSM.a3	(STANDARDIZATION, 2011c)(INSTITUTE, 2001a)(STANDARDIZATION, 2011a)
94	OS.GSM.a4	(SCHEDL; WINKELBAUER, 2008b)(LEVESON, 1995)(SEI, 2007)
95	OS.GSM.a5	(KONTOGIANNIS; LEVA; BALFE, 2016b)(AMERICA, 1993)(LEVESON, 1995)(SEI, 2007; STANDARDIZATION, 2011a)
96	OS.GSM.a6	(INSTITUTE, 2001a)(AMERICA, 1993)
97	OS.GSM.a7	Proposed in this work
98	OS.GSM.a8	(KONTOGIANNIS; LEVA; BALFE, 2016b)(INSTITUTE, 2001a)(AMERICA, 1993)
99	OS.GSM.a9	(INSTITUTE, 2001b)(INSTITUTE, 2001a)

Table 25 – SPA: Safety Tool support.

#	ID	Refs
	OS.STO	Safety Tool support
100	OS.STO.a1	(STANDARDIZATION, 2013)
101	OS.STO.a2	(STANDARDIZATION, 2013)
102	OS.STO.a3	(STANDARDIZATION, 2011a)
103	OS.STO.a4	(STANDARDIZATION, 2013)
104	OS.STO.a5	(STANDARDIZATION, 2013)(STANDARDIZATION, 2011a)
105	OS.STO.a6	(MARTINS; GORSCHEK, 2018)(STANDARDIZATION, 2011a)
106	OS.STO.a7	(EKBERG et al., 2014a)(MARTINS; GORSCHEK, 2018)

to accomplish project and organizational objectives. The goal is to guarantee the effective application of project resources (people, knowledge and skill) against the organization's needs. The traceability information of the actions of this sub-process are presented in Table 26.

5.2.8 PM - Requirements Process Management

The requirements process management covers all the activities to manage and control requirements change as well as to ensure the creation, control, and evolution of the processes, as well as coherence among team members. The safety module added three new areas: Safety Configuration Management, Safety Communication, and Safety Traceability.

5.2.8.1 PM.SCM - Safety Configuration Management

The safety configuration management addresses the control of content, versions, changes, distribution of safety data, proper management of system artifacts and information important to the organization at several levels of granularity. Examples of artifacts that may be placed under configuration management include plans, process descriptions, safety requirements, models, system specification, system data files, and system technical publications among other infor-

Table 26 – SPA: Safety Knowledge Management.

#	ID	Refs
	OS.SKM	Safety Knowledge Management
107	OS.SKM.a1	(STANDARDIZATION, 2012a)(KONTOGIANNIS; LEVA; BALFE, 2016b)(MARTINS; GORSCHEK, 2018)
108	OS.SKM.a2	(KONTOGIANNIS; LEVA; BALFE, 2016b)(LEVESON, 1995)
109	OS.SKM.a3	(STANDARDIZATION, 2014; STANDARDIZATION, 2012a; KONTOGIANNIS; LEVA; BALFE, 2016b)
110	OS.SKM.a4	(STANDARDIZATION, 2011a)
111	OS.SKM.a5	(STANDARDIZATION, 2012a)(KONTOGIANNIS; LEVA; BALFE, 2016b)
112	OS.SKM.a6	(STANDARDIZATION, 2011a)
113	OS.SKM.a7	(MARTINS; GORSCHEK, 2018)
114	OS.SKM.a8	(KONTOGIANNIS; LEVA; BALFE, 2016b)LuizTSE(SAWYER; SOMMERVILLE; VILLER, 1997)
115	OS.SKM.a9	(MARTINS; GORSCHEK, 2018)
116	OS.SKM.a10	Proposed in this work
117	OS.SKM.a11	Proposed in this work

mation (INSTITUTE, 2001b). The traceability information of the actions of this sub-process are presented in Table 27.

Table 27 – SPA: Safety Configuration Management

#	ID	Refs
	PM	Requirements Process Management
	PM.SCM	Safety Configuration Management
118	PM.SCM.a1	(INSTITUTE, 2001a; SAWYER; SOMMERVILLE; VILLER, 1997; STANDARDIZATION, 2011a)
119	PM.SCM.a2	(STANDARDIZATION, 2011a)
120	PM.SCM.a3	(SEI, 2007; STANDARDIZATION, 2011a)
121	PM.SCM.a4	(INSTITUTE, 2001a)
122	PM.SCM.a5	(STANDARDIZATION, 2011a)
123	PM.SCM.a6	(STANDARDIZATION, 2011c; STANDARDIZATION, 2011a)
124	PM.SCM.a7	(MARTINS; GORSCHEK, 2018; SEI, 2007; STANDARDIZATION, 2011a)
125	PM.SCM.a8	(STANDARDIZATION, 2011a)
126	PM.SCM.a9	(STANDARDIZATION, 2011a)
127	PM.SCM.a10	(INSTITUTE, 2001a; STANDARDIZATION, 2011a)
128	PM.SCM.a11	(STANDARDIZATION, 2013)
129	PM.SCM.a12	(STANDARDIZATION, 2013)

5.2.8.2 PM.SCO - Safety Communication

The safety analysis and assurance processes requires knowledge of many safety terms, methods, and processes from requirements engineers. However, they generally are unfamiliar with all such information. Aiming to minimize this problem, the safety module add actions to improve the safety communication sub process. The traceability information of the actions of this sub-process are presented in Table 28.

Table 28 – SPA: Safety Communication.

#	ID	Refs
	PM.SCO	Safety Communication
130	PM.SCO.a1	(MARTINS; GORSCHEK, 2018)
131	PM.SCO.a2	(AMERICA, 1993)
132	PM.SCO.a3	(SAWYER; SOMMERVILLE; VILLER, 1997)
133	PM.SCO.a4	(KONTOGIANNIS; LEVA; BALFE, 2016b; LEVESON, 1995; SEI, 2007)
134	PM.SCO.a5	(WHITEHEAD, 2007)
135	PM.SCO.a6	(WHITEHEAD, 2007; SEI, 2007)
136	PM.SCO.a7	Proposed in this work
137	PM.SCO.a8	(WHITEHEAD, 2007; SAWYER; SOMMERVILLE; VILLER, 1997)
138	PM.SCO.a9	(LEVESON, 2011; SAWYER; SOMMERVILLE; VILLER, 1997)
139	PM.SCO.a10	(SAWYER; SOMMERVILLE; VILLER, 1997)
140	PM.SCO.a11	(STANDARDIZATION, 2013; SAWYER; SOMMERVILLE; VILLER, 1997)
141	PM.SCO.a12	(STANDARDIZATION, 2015)

5.2.8.3 PM.ST - Safety Traceability

Changes in requirements will probably occur during the system development. Therefore, it is necessary to ensure consistency among system artifacts. This sub process area of safety module handles the traceability among artifacts helping to determine that the requirements affected by the changes have been completely addressed. The traceability information of the actions of this sub-process are presented in Table 29.

Table 29 – SPA: Safety Traceability.

#	ID	Refs
	PM.ST	Safety Traceability
142	PM.ST.a1	(SAWYER; SOMMERVILLE; VILLER, 1997)
143	PM.ST.a2	(STANDARDIZATION, 2011a)
144	PM.ST.a3	(LEVESON, 2011)
145	PM.ST.a4	(LEVESON, 1995)
146	PM.ST.a5	(STANDARDIZATION, 2009; STANDARDIZATION, 2013)
147	PM.ST.a6	(LAMI; BISCOGLIO; FALCINI, 2016; STANDARDIZATION, 2009; STANDARDIZATION, 2013)
148	PM.ST.a7	(LAMI; BISCOGLIO; FALCINI, 2016)
149	PM.ST.a8	(STANDARDIZATION, 2009)

All actions of the Uni-REPM Safety module, their identifier and maturity level are presented in Table 30, Table 31, Table 32, Table 33. In these tables, the actions are grouped according to the subprocess areas.

5.2.9 Maturity Level view

Following the structure of Uni-REPM Svahnberg et al. (2015), the safety module, the Maturity Level View is developed by assigning a level to each action in a likert scale from 1 to 3,

Table 30 – Uni-REPM Safety module overview - part 1.

#	ID	Description	Level
	RE	Requirements Elicitation	
	RE.SM	Supplier Management	
1	RE.SM.a1	Establish and maintain formal agreements among organization and suppliers	3
2	RE.SM.a2	Identify and document the products to be acquired	1
3	RE.SM.a3	Select suppliers and record rationale	1
4	RE.SM.a4	Specify all external systems and safety-related software	2
5	RE.SM.a5	Establish and maintain detailed system integration procedures for the external systems and safety-related software	2
6	RE.SM.a6	Define the safety standards that suppliers must follow	2
	DS	Documentation and Requirements Specification	
	DS.HF	Human Factors	
7	DS.HF.a1	Construct models about the way of work of the operator	1
8	DS.HF.a2	Document human factors design and analysis	1
9	DS.HF.a3	Evaluate prototypes, requirements and technical Human Machine Interface restrictions	2
10	DS.HF.a4	Model and evaluate operator tasks and component black-box behavior	2
11	DS.HF.a5	Define interfaces considering ergonomic principles	2
12	DS.HF.a6	Specify Human Machine Interface requirements	1
	DS.SDO	Safety Documentation	
13	DS.SDO.a1	Record safety decisions and rationale	1
14	DS.SDO.a2	Ensure that safety requirements are incorporated into system and subsystem specifications, including human-machine interface requirements	2
15	DS.SDO.a3	Document all lifecycle and modification activities	2
16	DS.SDO.a4	Develop and document training, operational and software user manuals	1
17	DS.SDO.a5	Document System Limitations	1
18	DS.SDO.a6	Provide an operation manual	2
19	DS.SDO.a7	Document lessons learned	3
20	DS.SDO.a8	Ensure that safety-related information is incorporated into user and maintenance documents	1
21	DS.SDO.a9	Maintain hazard and risk analysis results for the system throughout the overall safety lifecycle	2
22	DS.SDO.a10	Include a summary of safety requirements	2
	RA	Requirements Analysis	
	RA.PSA	Preliminary Safety Analysis	
23	RA.PSA.a1	Identify and document safety-critical computer software components and units	2
24	RA.PSA.a2	Simulate the process	2
25	RA.PSA.a3	Identify and document system hazards	1
26	RA.PSA.a4	Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)	1
27	RA.PSA.a5	Specify the type of initiating events that need to be considered	2
28	RA.PSA.a6	Obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.)	1
29	RA.PSA.a7	Identify and document hazardous materials	1
30	RA.PSA.a8	Identify and document consequences of hazards, severity categories and affected assets	1
31	RA.PSA.a9	Conduct risk estimation	1
32	RA.PSA.a10	Conduct risk evaluation for each identified hazard	2
33	RA.PSA.a11	Identify and document risk mitigation procedures for each identified hazard	1
34	RA.PSA.a12	Collect safety requirements from multiple viewpoints	2
35	RA.PSA.a13	Identify and document pure safety requirements	1
36	RA.PSA.a14	Identify and document safety-significant requirements and safety integrity levels	2

Table 31 – Uni-REPM Safety module overview - part 2.

#	ID	Description	Level
37	RA.PSA.a15	Identify and document safety constraints and how they could be violated	2
38	RA.PSA.a16	Identify and document possible control flaws and inadequate control actions	2
39	RA.PSA.a17	Identify and document safety functional requirements	1
40	RA.PSA.a18	Identify and document operational requirements	1
41	RA.PSA.a19	Perform and document the feasibility evaluation of safety functional requirements	2
42	RA.PSA.a20	Prioritize hazards and safety requirements	1
43	RA.PSA.a21	Document verification requirements, possible human-machine interface problems, and operating support requirements	2
44	RA.PSA.a22	Perform interface analysis, including interfaces within subsystems (such as between safety-critical and non-safety-critical software components)	3
45	RA.PSA.a23	Consolidate preliminary system safety technical specification	2
	RA.FH	Failure Handling	
46	RA.FH.a1	Define requirements to minimize systematic faults	2
47	RA.FH.a2	Specify Fault-detection procedures	2
48	RA.FH.a3	Specify Restart-up procedures	1
49	RA.FH.a4	Document the system behavioral model	1
50	RA.FH.a5	Identify and document Common-cause failures (CCF) and how to prevent them	1
51	RA.FH.a6	Perform reliability and system performance analysis	2
	RP	Release Planning	
	RP.SC	Safety Certification	
52	RP.SC.a1	Conduct safety audits	2
53	RP.SC.a2	Demonstrate the preliminary safety integrity level achieved by the system	2
54	RP.SC.a3	Evaluate the threat to society from the hazards that cannot be eliminated or avoided	1
55	RP.SC.a4	Construct preliminary safety and hazard reports	1
56	RP.SC.a5	Construct preliminary safety cases	2
57	RP.SC.a6	Demonstrate preliminary compliance with safety standards	2
58	RP.SC.a7	Ensure that the hazard report is updated with embedded links to the resolution of each hazard, such as safety functional requirements, safety constraints, operational requirements, and system limitations	2
59	RP.SC.a8	Document the division of responsibility for system certification and compliance with safety standards during safety planning	1
60	RP.SC.a9	Specify a maintenance plan	1
	RV	Requirements Validation	
	RV.SVV	Safety Validation and Verification	
61	RV.SVV.a1	Define the safety validation plan for software aspects of system safety	2
62	RV.SVV.a2	Define the safety verification plan	1
63	RV.SVV.a3	Define the technical strategy for the validation of external systems and safety-related software	2
64	RV.SVV.a4	Define pass/fail criteria for accomplishing software validation and verification	1
65	RV.SVV.a5	Develop safety test plans, test descriptions, test procedures, and validation and verification safety requirements	1
66	RV.SVV.a6	Define and maintain a software integration test plan	2
67	RV.SVV.a7	Validate safety-related software aspects	1
68	RV.SVV.a8	Ensure that there is no potentially hazardous control actions	1
69	RV.SVV.a9	Perform safety evaluation and verification at the system and subsystem levels	1
70	RV.SVV.a10	Conduct joint reviews (company and customer)	1
71	RV.SVV.a11	Ensure that the stakeholders understand software-related system safety requirements and constraints	2
72	RV.SVV.a12	Document discrepancies between expected and actual results	1
73	RV.SVV.a13	Verify the behavioral model 3	
74	RV.SVV.a14	Ensure that software requirements and software interface specification are consistent	2
75	RV.SVV.a15	Perform safety inspections	1
76	RV.SVV.a16	Identify and fix inconsistencies safety requirements specification	2

corresponding to "Basic", "Intermediate", and "Advanced" level where 3 represents the highest level of maturity.

These different levels of maturity are specified according to the difficulty to implement the action, how essential it is for the RE process, and dependencies among actions (SVAHNBERG et al., 2015).

The maturity levels of safety module are:

1. 0 (Incipient): The evaluated requirements engineering process does not satisfy all safety actions from basic level. Accordingly, the project does not receive any maturity level.

2. 1 (Basic): The aim of this level is to achieve a rudimentary repeatable safety requirements engineering process. The process in this level is defined and followed. Basic usability and interface aspects are considered, basic safety-related information is incorporated into system artifacts, responsibility, accountability and authority are identified, a lifecycle for projects artifacts is defined, and it also contains initial practices to establish a safety culture in the company. Moreover, in this level, preliminary safety and hazard reports as well as a maintenance plan are constructed, the system behavioral model and restart-up procedures are specified, and a preliminary safety analysis is performed. Initial project monitoring and take corrective actions are implemented and a common nomenclature is established. In this level there is no activity performed to collect and analyze data/feedback for future improvement of the process.

3. 2 (Intermediate): in this level, the process is more rigorous because it involves various perspectives and is led by product strategies/goals. Operator task models are evaluated, ergonomic principles are considered. Lifecycle and modification activities, system development methodology, competence requirements, safety policy and safety goals are clearly defined and documented. Safety manual is elaborated, hazard and risk analysis results are maintained throughout the overall safety lifecycle, the hazards auditing and log file as well as working groups and structures are established, safety experience on similar systems are considered, and tools are used to support the processes. The preliminary level of safety achieved by the system and preliminary compliance with safety standards are demonstrated, safety audits are conducted and initial traceability mechanisms are considered in system artifacts. Also considered are requirements for the avoidance of systematic faults and fault-detection procedures. Moreover, external systems and safety-related software concerns as well as system integration procedures are handled, and communication among stakeholders is also considered.

4. 3 (Advanced): it denotes the most mature process. The improvements in the process are shown in the advanced way of documenting lessons learned, sharing knowledge in the organization, specifying the general safety control structure, formal agreements among organization and suppliers are established and maintained. Moreover, formal communi-

cation channels among different organizational levels and common safety information system for system specification and safety analysis are used.

It is important to note that Uni-REPM SCS is not intended to be used as part of a product assessment. While safety standards require the definition of safety integrity level of the system under development to set requirements for the project and the system, the module provides a way to evaluate the capability of safety-related processes as well as a scheme for their improvement.

Therefore, the maturity level achieved is not related with the safety integrity level the project has to fulfill. Accordingly, an evaluation based on safety maturity models, such as Uni-REPM SCS, +SAFE or ISO 15504-10, is not analogous to a functional safety assessment. Hence, using a maturity model does not provide any guarantee of compliance with any safety standard.

Moreover, Uni-REPM SCS does not prescribe any specific technique, method or tool. Its goal is to consider the process (the "what") and it does not require the adoption of any specific technique or method (the "how").

These different levels of maturity were specified according to the difficulty to implement the action, how essential it is for the RE process, dependencies among actions, the frequency they appear in different information sources as well as the ability to optimize the safety processes considering our experience and the results of literature reviews and safety standards.

This view shows the actions from all process areas which the organization should implement in order to achieve a specific maturity level.

5.2.10 Examples of definition of actions

The definition of the actions considered the sources of information listed in Table 14. The different sources and their terminologies were reconciled by reading the full description of the action and adopting the most common term. For example, the description of action *OS.SP.Develop an integrated system safety program plan* is presented in Figure 26. This action was identified through both SAFETY-STD (AMERICA, 1993), EXISTING-MATURITY-MODS (SEI, 2007), and STATE-OF-THE-ART (SCHEDL; WINKELBAUER, 2008b)(LEVESON, 1995).

In the SAFETY-STD source, the MIL-STD-882C (AMERICA, 1993) requires the development of a System Safety Program Plan (SSPP) that should specify in detail activities required to identify, evaluate, and eliminate/control hazards, or reduce the associated risk to an acceptable level.

+SAFE (SEI, 2007) of EXISTING-MATURITY-MODS category declares that elements of the plan for performing the safety engineering process are part of the safety plan that may take on various formats according to the requirements of regulatory agencies.

Studies in the STATE-OF-THE-ART also address the need of conducting a proper safety planning. Schedl and Winkelbauer (2008b) say that the process related to customer require-

ments have to be assessed and resources planning should be performed and detailed in a System Safety Plan. Leveson (1995) also states that in the early stage of system development, the system safety program plan should be developed.

Another example of an action is #95 (see Table 24) *"Identify and document responsibility, accountability and authority"* that was inspired in SAFETY-STD, EXISTING-MATURITY-MODS, STATE-OF-THE-ART.

In the SAFETY-STD category, the IEC 61508 safety standard (STANDARDIZATION, 2011a) requires that a company developing an electrical/electronic/programmable electronic safety-related system must designate one or more persons to assume responsibility for safety activities. In the same way, the MIL-STD-882C (AMERICA, 1993) defines that a safety plan should depict the responsibility and authority of safety team, other contractor organizational elements involved in the system safety effort, subcontractors, and system safety groups.

EXISTING-MATURITY-MODS also requires evident specification of responsibility. +SAFE SEI (2007) demands the definition of who or what should be assigned responsibility and authority for performing the processes, developing the work products, and providing the services of the safety management process.

Responsibility and authority are also a concern reported in STATE-OF-THE-ART. Leveson (LEVESON, 1995) determines in her proposal of elements in a safeware program that a safety policy should include a well-defined assertion of responsibilities, authority, accountability, and scope of activities. Finally, Kontogiannis et al. (KONTOGIANNIS; LEVA; BALFE, 2016a) states that risk management should be comprehensive and clear about accountability.

In the next sections, we explain some examples of how we grouped the actions in sub-process areas of Uni-REPM SCS.

5.2.11 Examples of definition of SPAs

5.2.11.1 SPA: Safety Knowledge Management (SKM)

The SKM sub-process provides transparency in the development process by making sure that projects and the company have the required knowledge and skills to accomplish project and organizational objectives. The definition of this SPA was inspired in the presence of safety practices related with knowledge sharing in an organization as described in the works of the SAFETY-STD, INTERVIEW-STUDY, STATE-OF-THE-ART categories.

In the SAFETY-STD, for example, we noticed the need of an infrastructure to share knowledge (OS.SKM.a1) in (STANDARDIZATION, 2012a), control access mechanisms to the safety information system (OS.SKM.a3) in (STANDARDIZATION, 2014)(STANDARDIZATION, 2012a), and maintain employees' competence information (OS.SKM.a4) (STANDARDIZATION, 2011a).

In the INTERVIEW-STUDY (MARTINS; GORSCHEK, 2018), the practitioners highlighted the need to define and maintain a strategy for reuse (OS.SKM.a7), reuse the stored knowledge (OS.SKM.a8), and document the use of stored knowledge (OS.SKM.a9). On the other

hand, the development of a safety information system to share knowledge in the organization (OS.SKM.a2) is emphasized by (KONTOGIANNIS; LEVA; BALFE, 2016b)(LEVESON, 1995) in the STATE-OF-THE-ART.

Finally, we propose two actions: *OS.SKM.a10 Notify users about problems, new versions and exclusions of artifacts in use*, and *OS.SKM.a11 Manage assets*.

5.2.11.2 SPA: Safety Tool support (STO)

This sub-process is responsible for facilitating the proper execution of the corresponding tasks and manage all safety-related information that should be created, recorded and properly visualized. We included this SPA in the module considering some SAFETY-STD request, for example, the specification of the reasons for the selection of the off-line support tools (OS.STO.a2) (STANDARDIZATION, 2013), the assessment of such tools that can directly or indirectly contribute to the executable code of the safety related system (OS.STO.a3) (STANDARDIZATION, 2011a), the use of tools with support to cross reference and maintain the traceability among safety information in the software specification (OS.STO.a5) (STANDARDIZATION, 2013; STANDARDIZATION, 2011a).

In the INTERVIEW-STUDY (MARTINS; GORSCHEK, 2018) and STATE-OF-THE-ART (EKBERG et al., 2014a), the requirement of defining and using tools to support the safety process and workflow management (OS.STO.a7) is presented.

5.2.11.3 SPA: General Safety Management (GSM)

GSM covers project safety management activities related to planning, monitoring, and controlling the project. We defined this SPA considering the practices presented in works of STATE-OF-THE-ART, SAFETY-STD, and EXISTING-MATURITY-MODS categories.

The works of STATE-OF-THE-ART cite, for example, the identification and documentation of the system development methodology (OS.GSM.a1) (LEVESON, 1995), responsibility, accountability and authority (OS.GSM.a5) (KONTOGIANNIS; LEVA; BALFE, 2016b)(LEVESON, 1995) as well as setting safety policy and defining safety goals (OS.GSM.a4) (SCHEDL; WINKELBAUER, 2008b)(LEVESON, 1995).

SAFETY-STD (STANDARDIZATION, 2011a)(AMERICA, 1993) and EXISTING-MATURITY-MODS (STANDARDIZATION, 2011c)(INSTITUTE, 2001a) require the identification and documentation of safety lifecycle for the system development (OS.GSM.a), the competence requirements for the safety activities (OS.GSM.a3), and defining system safety program milestones and relate these to major program milestones, program element responsibility, and required inputs and outputs.

5.2.11.4 SPA: Safety Planning (SP)

This is one of the most important SPA in the module since it provides the safety practices and establishes a safety culture in the company. The development of a SCS requires a careful planning and safety analysis (described in next section). Therefore, the SP was proposed considering the actions in SAFETY-STD, EXISTING-MATURITY-MODS, STATE-OF-THE-ART, and INTERVIEW-STUDY.

Several actions are cited in different categories such as develop an integrated system safety program plan (OS.SP.a1) which is presented in the STATE-OF-THE-ART (SCHEDL; WINKELBAUER, 2008b)(LEVESON, 1995) and EXISTING-MATURITY-MODS (SEI, 2007). Moreover, the identification of certification requirements for software, safety or warning devices or other special safety feature (OS.SP.a8) is presented in the INTERVIEW-STUDY (MARTINS; GORSCHEK, 2018) as well as in SAFETY-STD (AMERICA, 2000)(AMERICA, 1993).

Finally, the identification and documentation of the hazard analysis to be performed; the analytical techniques (qualitative or quantitative) to be used; and depth within the system at which each analytical technique will be used (e.g., system level, subsystem level, component level) (OS.SP.a14) is required in SAFETY-STD (AMERICA, 2012)(AMERICA, 1993; STANDARDIZATION, 2011a) and STATE-OF-THE-ART (KONTOGIANNIS; LEVA; BALFE, 2016b).

5.2.11.5 SPA: Preliminary Safety Analysis (PSA)

The PSA is the sub-process with more actions in the module since we grouped all actions related to performing a preliminary safety analysis. Someone may argue that some actions may be in other SPA like elicitation for example. We agree that they may be included in such SPA, but we argue that the elicitation and analysis are generally done in parallel.

Furthermore, PSA is usually performed when some system functionalities are already elicited and documented, i.e. using a preliminary system specification as a basis. Therefore, we opted to classify all practices of safety analysis only in this group aiming to improve understandability of the module.

This SPA has practices from SAFETY-STD such as conduct risk evaluation for each identified hazard (RA.PSA.a10) (AMERICA, 2012)(STANDARDIZATION, 2012b)(AMERICA, 1993), EXISTING-MATURITY-MODS like identify and document safety functional requirements (RA.PSA.a17) (STANDARDIZATION, 2015)(STANDARDIZATION, 2012b)(SEI, 2007; STANDARDIZATION, 2011a), STATE-OF-THE-ART such as identify and document safety constraints and how they could be violated (RA.PSA.a15) (KIM; NAZIR; ØVERGÅRD, 2016)(KAZARAS; KIRYTOPOULOS, 2011)(FIRESMITH, 2006b)(LEVESON, 2011)(SAWYER; SOMMERVILLE; VILLER, 1997), and INTERVIEW-STUDY like identify and document system hazards (RA.PSA.a3) (MARTINS; GORSCHEK, 2018).

Table 32 – Uni-REPM Safety module overview - part 3.

	# ID	Description	Level
	OS	Organizational Support	
	OS.SP	Safety Planning	
77	OS.SP.a1	Develop an integrated system safety program plan	1
78	OS.SP.a2	Define and document requirements for periodic functional safety audits	2
79	OS.SP.a3	Define and document the interface between system safety and all other applicable safety disciplines	1
80	OS.SP.a4	Define the scope of safety analysis	1
81	OS.SP.a5	Establish the hazards auditing and log file	2
82	OS.SP.a6	Establish working groups and structures	2
83	OS.SP.a7	Define and document the regulations and safety standards to be followed	2
84	OS.SP.a8	Identify any certification requirements for software, safety or warning devices or other special safety feature	1
85	OS.SP.a9	Define and document requirements completeness criteria and safety criteria	2
86	OS.SP.a10	Review safety experience on similar systems	2
87	OS.SP.a11	Specify the general safety control structure	3
88	OS.SP.a12	Specify operating conditions of the machine and installation conditions of the electronic parts	1
89	OS.SP.a13	Determine the required performance level	1
90	OS.SP.a14	Identify and document the hazard analysis to be performed; the analytical techniques (qualitative or quantitative) to be used; and depth within the system that each analytical technique will be used (e.g., system level, subsystem level, component level)	1
	OS.GSM	General Safety Management	
91	OS.GSM.a1	Identify and document the system development methodology	2
92	OS.GSM.a2	Identify and document safety lifecycle for the system development	1
93	OS.GSM.a3	Identify and document competence requirements for the safety activities	2
94	OS.GSM.a4	Set safety policy and define safety goals	2
95	OS.GSM.a5	Identify and document responsibility, accountability and authority	1
96	OS.GSM.a6	Define system safety program milestones and relate these to major program milestones, program element responsibility, and required inputs and outputs	1
97	OS.GSM.a7	Use of indicators on engineering documentation to assess the product properties and the development progress	2
98	OS.GSM.a8	Prepare progress reports in a period of time defined by the project	2
99	OS.GSM.a9	Monitor project and take corrective actions	1
	OS.STO	Safety Tool support	
100	OS.STO.a1	Use of verification and validation tools	2
101	OS.STO.a2	Specify justifications for the selection of non-safety-related support tools	2
102	OS.STO.a3	Assess non-safety-related support tools which can directly or indirectly contribute to the executable code of the safety related system	2
103	OS.STO.a4	Record information of the tools in the baseline	1
104	OS.STO.a5	Use of tools with support to cross reference and maintain the traceability among safety information in the software specification	2
105	OS.STO.a6	Make use of specification tools	2
106	OS.STO.a7	Define and use tools to support the safety process and workflow management	3
	OS.SKM	Safety Knowledge Management	
107	OS.SKM.a1	Establish and maintain an infrastructure to share knowledge	2
108	OS.SKM.a2	Develop a safety information system to share knowledge in the organization	3
109	OS.SKM.a3	Define control access mechanisms to the safety information system	2
110	OS.SKM.a4	Maintain employees competence information	2
111	OS.SKM.a5	Document a strategy to manage the knowledge	3
112	OS.SKM.a6	Define a lifecycle for projects artifacts	1
113	OS.SKM.a7	Define and maintain a strategy for reuse	2
114	OS.SKM.a8	Reuse the stored artifacts and knowledge	2
115	OS.SKM.a9	Document that stored artifacts and knowledge are being used in the project	3
116	OS.SKM.a10	Notify users about problems, new versions and exclusions of artifacts in use	2
117	OS.SKM.a11	Manage assets	2

Table 33 – Uni-REPM Safety module overview - part 4.

#	ID	Description	Level
	PM	Requirements Process Management	
	PM.SCM	Safety Configuration Management	
118	PM.SCM.a1	Maintain with unique identification all safety configuration items	1
119	PM.SCM.a2	Define and document change-control procedures	2
120	PM.SCM.a3	Define and document safety configuration items to be included in the baseline	2
121	PM.SCM.a4	Document configuration status, release status, the justification (taking account of the impact analysis) for and approval of all modifications, and the details of the modification	2
122	PM.SCM.a5	Document the release of safety-related software	2
123	PM.SCM.a6	Perform safety impact analysis on changes	1
124	PM.SCM.a7	Specify and follow the template for software modification request	2
125	PM.SCM.a8	Document the procedures for starting modifications in the systems, and to obtain approval and authority for these modifications	1
126	PM.SCM.a9	Maintain and make available the software configuration management log	2
127	PM.SCM.a10	Create all deliverable documents according to the rules defined in the Configuration Management Plan	1
128	PM.SCM.a11	Upload all documents on the safety information system	3
	PM.SCO	Safety Communication	
129	PM.SCO.a1	Establish formal communication channels among different organizational levels	3
130	PM.SCO.a2	Define a method of exchanging safety information with the suppliers	2
131	PM.SCO.a3	Establish a common nomenclature	1
132	PM.SCO.a4	Train people continuously in system engineering and safety techniques (education)	2
133	PM.SCO.a5	Use of a common safety information system for system specification and safety analysis	3
134	PM.SCO.a6	Keep stakeholders updated regarding the progress of all safety-related activities	2
135	PM.SCO.a7	Construct a repository of common hazards	2
136	PM.SCO.a8	Define and follow templates for system artifacts	2
137	PM.SCO.a9	Document how conflicts will be resolved	2
138	PM.SCO.a10	Identify, record and resolve conflicts	1
139	PM.SCO.a11	Produce all the deliverables documents based on the official document templates	2
140	PM.SCO.a12	Make available safety-related software specification to every person involved in the lifecycle	2
	PM.ST	Safety Traceability	
141	PM.ST.a1	Define and maintain traceability policies	2
142	PM.ST.a2	Define and maintain bi-directional traceability between the system safety requirements and the software safety requirements	2
143	PM.ST.a3	Define and maintain bi-directional traceability between the safety requirements and the perceived safety needs	2
144	PM.ST.a4	Link and maintain bi-directional between environmental assumptions and the parts of the hazard analysis based on the assumption	2
145	PM.ST.a5	Define and maintain bi-directional traceability between system and subsystem verification results and system specification	1
146	PM.ST.a6	Define and maintain bi-directional traceability between validation results and system specification	1
147	PM.ST.a7	Define and maintain bi-directional traceability among system hazards into components	2
148	PM.ST.a8	Justify reasons for not traced software requirements	2

5.3 MODULE USAGE

The Uni-REPM Safety module aims to assess the safety maturity in the RE process; hence, it can be used by people who are involved in RE process, deeply understand it and are in charge of process improvement in general.

Examples of users are:

- Requirements Engineer
- Safety Engineer
- Software Engineer
- Quality assurance engineer
- Project manager
- Product manager

Since we designed a module for an existing maturity model, aiming to maintain compatibility with Uni-REPM, the safety maturity evaluation is performed using an assessment instrument. The instrument consists of questions, available in the tool (see Chapter 6) after sign in, grouped according to the MPA and SPA.

The instrument has a query to evaluate each safety action in which the evaluator can select one of three options:

1. "Incomplete" (IC) - the action was deemed vital but was done partially or not at all in this RE process.
2. "Complete" (C) - the action was done in this RE process.
3. "Inapplicable" (IA) - the action was not necessary or possible to be done in the process.

Safety-critical systems are developed in several domains by companies with different sizes, infrastructure and maturity. Hence, some organizations may not benefit from implementing all the actions in the module or some actions are deemed unnecessary to be done in particular situations of organizations.

For example, in small systems, prototypes may be not useful since the system can be very simple. In this case, the action "*OS.SKM.a4 Evaluate prototypes, requirements and technical UI restrictions (Basic Level)*" might not be useful for some companies. If we consider it as "Incomplete", the process may not reach the Basic level because not all actions in this level are fulfilled. This is even more unfair if all other actions in higher maturity levels are completed.

Accordingly, safety processes of the companies should not be "devalued" if they do not perform a certain non-essential action (in their point of view). In order to consider situations

like these, the option "Inapplicable" is provided. In this way, the module fits more real process and the evaluation result is less distorted.

Therefore, in some cases, the organization may find some actions only applicable in one of the settings. Whether an action is "Inapplicable" or not is solely based on the judgment of the project evaluator. Reasons for marking the action with this option should be considered carefully to avoid accidentally skipping an important action. Moreover, lack of time, resource or unawareness cannot be used as a reason to mark an action as being "Inapplicable".

The assessment instrument is implemented in an online software tool aiming to facilitate and automate the evaluation process. The tool, whose features are described in Chapter 6, is available at <http://www.cin.ufpe.br/~ler/unirepm>. The tool supports the evaluation of the entire Uni-REPM (requirements and safety module) and it has three types of user: (1) external evaluator - this user can insert companies, projects and perform Safety/RE evaluations; (2) internal evaluator - this user only can insert projects to the company he/she belongs and perform Safety/RE evaluations; (3) admin - besides the functionalities of external evaluators, this user can manage users and different versions of RE/Safety models.

In Figure 28, we present an example of the Uni-REPM SCS assessment instrument. The Action ID in the checklist links the question(s) to the associated action in the model. This helps the users in case they need to locate the item for further information or clarification.

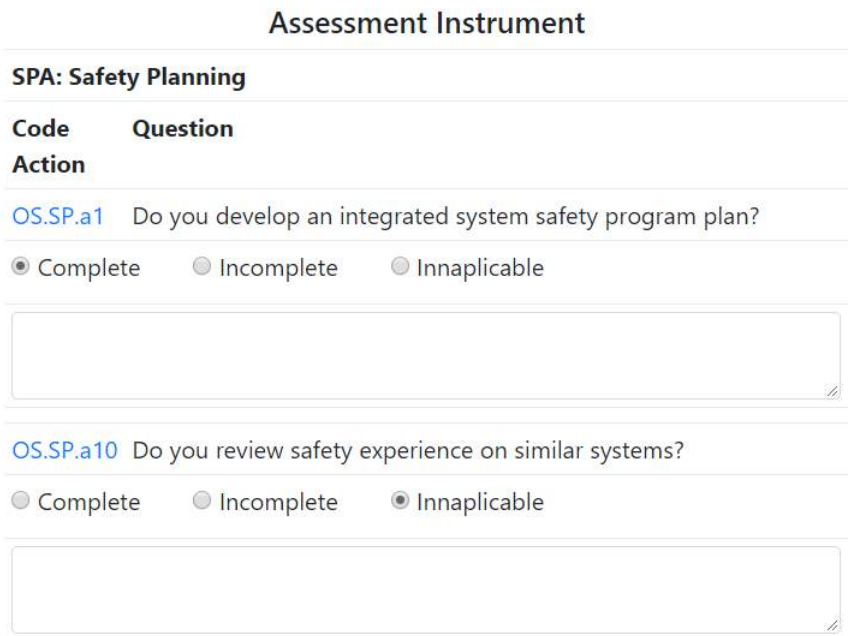

Figure 28 – Partial view of Uni-REPM SCS assessment instrument.

After answering all questions present in the assessment instrument, the tool determines and presents the evaluation results. To define the maturity level, the tool consider that: (1) for each SPA, all actions at a certain level must be Completed (or Inapplicable) in order to the MPA achieve such level; (2) for the whole process, all actions at a certain level must be Completed (or Inapplicable) to the process achieve such level.

There are special cases where a SPA does not have actions at a certain level: (1) if the SPA does not have advanced actions, the maximum level possible is intermediate; (2) if the SPA does not have basic actions and the company completed at least one action at the intermediate level, it is classified as Basic, otherwise, the company is not classified as Basic and remains in the level Incipient. The same principles are applied to MPAs and, consequently, to determine the maturity of the entire project.

The evaluators should perform a careful analysis about the reasons that contribute to an action to be marked as incomplete, as they indicate which activities should be considered for process improvement efforts (SVAHNBERG et al., 2015).

An example of evaluation results of SPA *"Safety Planning"* is described in Figure 29. The assessment results can be presented graphically, as for example in Figure 30. These results do not correspond to real data, it is just presented with illustration purposes. Such representation provides a better view, allowing the organization to benchmark their maturity and to monitor their development. The tool were designed to evaluate projects of the companies. However, if an evaluator wants to assess the entire company, he/she can create a project that represents the whole company and proceed the evaluation normally.

SPA: Safety Planning

Level	Completed actions	Incomplete actions	Inapplicable actions	Complete + Inapplicable Actions	Total actions
Basic	7	0	0	7	7
Intermediate	5	0	1	6	6
Advanced	0	1	0	0	1
SPA Level achieved: Intermediate					

Figure 29 – Assessment results of SPA "Safety Planning".

In Figure 30, the blue line presents actions which were *Complete* in the SPA "Safety Planning" in the RE process illustrated in this example. In this case, 7 actions in the Basic Level were *Complete*, 5 actions in Intermediate level and 0 actions in the Advanced level. The purple line presents *Complete* actions together with *Inapplicable*.

The distance between the blue line and the purple line is called the module lag, which represents the number of *Inapplicable* actions. Hence, the module lag is important as it indicates to what extent the module works for a specific company and the context of that company. In Figure 30, the module lag (i.e. the absolute numerical limit) is fairly small with only 1 *Inapplicable* action. This means a high applicability of the module.

Figure 30 – Example of a graphical presentation of assessment results of SPA "Safety Planning".

Besides, in Figure 30, the green line presents the total actions that should be completed in *"Safety Planning"* SPA. For example, at Advanced level, there is 1 action that should be finished. The difference between the purple and green lines is important because it denotes the improvement area of the process. It shows how many additional actions should be conducted to achieve a certain level of maturity.

Overall, the graph of Figure 30 denotes that, in this SPA, the process has not done all the actions at Advanced level. Hence, the SPA received Intermediate Level. In order to reach the Advanced level, 1 more action has to be done. Similar work can be done with other SPAs to achieve the result for the whole process.

It is important to highlight that the graphical presentation of Figure 30 does not include cumulative action counts. It only shows the total number of actions and the number of completed + inapplicable actions by maturity level. So, even if the company complete all actions of higher levels, for example intermediate level, but did not complete the actions of basic level, the company does not achieve the basic level, remaining at level Incipient.

5.4 COMPARISON WITH RELATED SOLUTIONS

Maturity models that explicitly address safety in RE process could not be identified. Instead, we found only two safety maturity models that address RE and safety engineering as separate fields. In Tables 34 and 35, we present a comparison among them.

The Uni-REPM Safety module differs from existing safety maturity models such as +SAFE-CMMI-DEV (SEI, 2007), and ISO 15504-10 (STANDARDIZATION, 2011c) in terms of purpose, scope, intended usage and number of practices.

+SAFE-CMMI-DEV, developed in 2007, is an extension to CMMI for Development (CMMI-DEV) developed for standalone use, i.e. it is not intended to be embedded in a CMMI model,

but can be modified to support different safety standards. It covers two process areas that have Generic Goals, Specific Goals and Specific Practices: Safety Management and Safety Engineering (JOHANNESSEN; HALONEN; ÖRSMARK, 2011).

The Generic Goals of *Safety Management* are Achieve Specific Goals (1 practice), Institutionalize a Managed Process (10 practices), Institutionalize a Defined Process (2 practices), Institutionalize a Quantitatively Managed Process (2 practices), and *Institutionalize an Optimizing Process* (2 practices). Specific Goals include Develop Safety Plans (4 practices), Monitor Safety Incidents (1 practice), and Manage Safety-Related Suppliers (2 practices).

The Safety Engineering process area has the same five Generic Goals (and their practices) of Safety Management. Its Specific Goals are Identify Hazards, Accidents, and Sources of Hazards (2 practices), Analyze Hazards and Perform Risk Assessments (1 practices), Define and Maintain Safety Requirements (3 practices), Design for Safety (3 practices), and Support Safety Acceptance (4 practices).

ISO/IEC 15504-10 (STANDARDIZATION, 2011c), developed in 2011 as a standalone document, was conceived to be used in conjunction with ISO/IEC 15504-5 (An exemplar Process Assessment Model) and/or ISO/IEC TR 15504-6 (An exemplar system life cycle process assessment model) process assessment models by experienced assessors with minimal support from safety domain experts (LAMI; FABBRINI; FUSANI, 2011c).

The structure of ISO/IEC 15504-10 has the same process areas of +SAFE-CMMI-DEV. However, the number of practices is higher. *Safety Management* has 10 base practices, *Safety Engineering* has 11 practices. Moreover, it has one more process than +SAFE-CMMI-DEV: *Safety Qualification* (JOHANNESSEN; HALONEN; ÖRSMARK, 2011) with 5 practices. Finally, it claims that the defined processes are consistent with five different safety standards: IEC 61508, +SAFE-CMMI-DEV, ISO 26262, IEC 60880, UK MoD Def Stan 00-56.

None of the models are intended to be used as part of a product assessment. While safety standards require the definition of safety integrity level of the system under development to set requirements for the project and the system, the maturity models provide a way to evaluate the capability of safety-related processes as well as a scheme for their improvement (LAMI; FABBRINI; FUSANI, 2011c). Hence, the maturity level achieved is not related with the safety integrity level the project has to fulfill. Accordingly, an evaluation based on any of these models is not analogous to a functional safety assessment (SEI, 2007).

Besides, standards do not have the feature of making possible for practitioners and a company to state "*this specific practice is not relevant for us*". Safety maturity models do, and thus, the model applicability to a real industrial context is better. Therefore, we share the view of +SAFE-CMMI-DEV and ISO 15504-10 that there is no relationship between safety integrity levels and maturity levels.

Another common feature of the maturity models is that they do not prescribe any specific technique, method or tool. Their goal is to consider the process (the "what") and not require the adoption of any specific technique or method (the "how") (LAMI; FABBRINI; FUSANI, 2011c).

+SAFE-CMMI-DEV and ISO/IEC 15504-10 cover the entire project lifecycle. Hence, they do not go into detail into any particular practice area, such as RE. In introduction section, we discuss presenting references which show that requirements problems have been associated with many accidents and safety incidents. The need of integrating safety and RE teams has been well discussed by very seminal papers in SCS area, and now a consensus in academia and industry is being established that addressing safety concerns early in software development contributes to ensuring that safety problems do not propagate through subsequent phases. Furthermore, the early consideration of safety concerns in RE should be a top priority in the development of SCS since RE is essential for software quality, and the effectiveness of the software development process. Moreover, high safety levels are typically best achieved by addressing safety from the beginning; not by trying to add protection components and additional complexities after system has been developed. Accordingly, such requirements issues tend to be mitigated in companies with high process maturity levels since they do their business in a systematic, consistent and proactive approach.

Uni-REPM SCS proposes 148 safety actions while +SAFE-CMMI-DEV has 20 in which 13 actions have a correspondence with our model; and ISO/IEC 15504-10 has 26 actions being 16 present in Uni-REPM SCS. The other actions involve later stages of system development that are not the scope of our model. These demonstrate that Uni-REPM SCS has a good coverage of safety practices when compared with related solutions.

Therefore, the maturity model we propose is more descriptive and detailed as stated by the practitioners in the static validation (Section 7.1) and in the dynamic validation (Section 7.2). It was designed specifically for safety in RE and contains a comprehensive assessment instrument considering the total number of safety practices 148 against 20 (+SAFE) and 26 (ISO 15504-10).

Table 34 – Comparison among Uni-REPM SCS, +Safe-CMMI-DEV, and ISO 15504-10 (part 1).

	Uni-REPM SCS	**+SAFE-CMMI-DEV**	**ISO 15504-10**
Year	2017	2007	2011
Motivation for creating the model	In order to ensure a well-ordered safety progress, engineers should handle several features (e.g. organizational, technical, strategic). Thus, companies should improve their RE process with the purpose of overcome the difficulties they face during the construction of SCS. Requirements engineers need systematic guidance to consider safety concerns early in the development process.	The extension was developed because the Australian Defense Materiel Organization recognized that CMMI is a generically structured framework that requires amplification for specialized areas of engineering such as safety engineering. Developing safety-critical products requires specialized processes, techniques, skills, and experience within an organization.	ISO/IEC 15504 process assessment models for systems and software do not currently provide a sufficient basis for performing a process capability assessment of processes with respect to the development of complex safety-related systems. Developing safety-related systems requires specialized processes, techniques, skills and experience. Process amplifications are needed in the area of safety management, safety engineering and the safety qualification.
Full Available to download	Yes	Yes	No
Independent of any domain-specific standard	Yes	Yes	Yes
Intended usage	RE phase	System lifecycle	System lifecycle
Independent of safety integrity level	Yes	Yes	Yes
Goals of the model	It aims to reduce issues in RE during SCS development by addressing safety actions/practices that should be covered in the RE process to reduce the gap between these areas.	Its purpose is to extend CMMI to provide an explicit, specific framework for functional safety with respect to developing complex safety-critical products.	It presents these amplifications (a safety extension) as three process descriptions to provide additional life-cycle verification activities related to the methods and techniques selected relevant to safety requirements adopted and tailoring guidance for users intending to use the safety extension as part of a process assessment.
Number of levels	3 (Basic, Intermediate, Advanced)	5 (Initial, Managed, Defined, Quantitatively Managed, Optimizing)	5 (Initial, Managed, Defined, Quantitatively Managed, Optimizing)
Lowest maturity level	It contains actions of primitive but repeatable RE process. Although the actions are basic, the RE process in this level is defined and followed.	The processes are usually ad hoc and chaotic. The organization usually does not provide a stable environment to support processes. Maturity level 1 companies are characterized by a tendency to over commit, abandon their processes in a time of crisis, and be unable to repeat their successes.	The process achieves the objectives in some way and generates the expected work products.
Highest maturity level	It is the most mature RE process that cover predefined and structured procedures as well as pays adequate attention to future processes and work products.	An organization focuses on continually improving process performance through incremental and innovative process and technological improvements. The organization's quality and pro-	The process, in addition to being executed, managed, defined and executed within quantitative limits, can be continuously improved.

Table 35 – Comparison among Uni-REPM SCS, +Safe-CMMI-DEV, and ISO 15504-10 (part 2).

	Uni-REPM SCS	**+SAFE-CMMI-DEV**	**ISO 15504-10**
Evaluated Capabilities	Safety Knowledge Management; Safety Tool support; General Safety Management; Safety Planning (SP); Safety Configuration Management; Safety Communication; Safety Traceability; Supplier Management; Preliminary Safety Analysis; Failure Handling; Safety Certification; Human Factors; Safety Documentation; Safety Validation and Verification	Safety Management; Safety Engineering	Safety Management process; Safety Engineering process; Safety Qualification process
Total Number of practices	148	53 being 20 (safety-related)	26
Number of practices in common with Uni-REPM SCS	-	13	16
Strengths	It is a very detailed maturity model because it was designed specifically for safety in RE and contains a comprehensive assessment instrument.	It covers the entire project lifecycle. This extension was developed for standalone use. It is not intended to be embedded in a CMMI model.	It covers the entire project lifecycle.
Weakness	It covers only the activities of RE process.	It contains material that is fully redundant with CMMI to support its standalone use. It is too general, usually adopted by safety engineers, and do not consider the integration between safety and RE as well as the particularities of these two areas that are necessary to improve safety.	As well as +Safe, ISO 15504-10, it does not go into detail into any particular practice area from the beginning of software development process.
Safety standards considered	ISO 61508; ECSS-E-HB-40A; MIL-STD-882C; ISO/TS 15998-2; MIL-STD-882E; ISO 13849-1; ECSS-E-ST-40C; ISO 14639-1; MIL-STD-882D; ISO 13849-2; ISO 26262-6; ISO 15998; ISO/TR 14639-2	It is intended to be consistent with the Australian Defence Standard, Safety Engineering in the Procurement of Defence Systems, and is intended to be consistent with the principles of other contemporary safety standards (e.g., IEC's Safety of Machinery—Functional Safety of Safety-Related Electrical, Electronic and Programmable Electronic Control Systems; U.S. military standard, System Safety Program Requirements; the U.K. Defence Standard, Safety Management Requirements for Defence Systems, Part 1, Issues 2 and 3; and domain-specific safety standards wherever feasible).	It claims that the defined processes are consistent with the five different safety standards: IEC 61508, +SAFE, IEC 60880, UK MoD Def Stan 00-56, and ISO 26262.

5.5 FINAL CONSIDERATIONS

RE problems during the development of SCS may be reduced in higher mature processes. Accordingly, we propose a safety module for the Uni-REPM maturity model to handle safety concerns in the RE process. The safety module proposed in this thesis breaks down RE practices and actions and balances them for the SCS development which is an activity that has not done before. Hence, it brings RE knowledge into sync with many traditional safety standards that often omit details about RE.

In this chapter, we described the structure, contents and usage of the Uni-REPM Safety module. The module consists of seven main process areas, 14 sub-process areas and 148 actions. These action are classified in a maturity level in a Likert scale (1-Basic, 2-Intermediate, 3-Advanced).

Besides, we compared the module with the only two existing safety maturity models found. In the next chapter, we describe the web tool we developed to support the assessments using the Uni-REPM and its safety module.

6 SUPPORT TOOL

This chapter describes the Uni-REPM Tool that supports the Uni-REPM (Universal Requirements Engineering Process Maturity Model) as well as its safety module.

Uni-REPM tool can be used by practitioners who are involved in software development, such as requirements, safety, software or quality assurance engineers as well as project and product managers. An overview of the solution is presented in Figure 31.

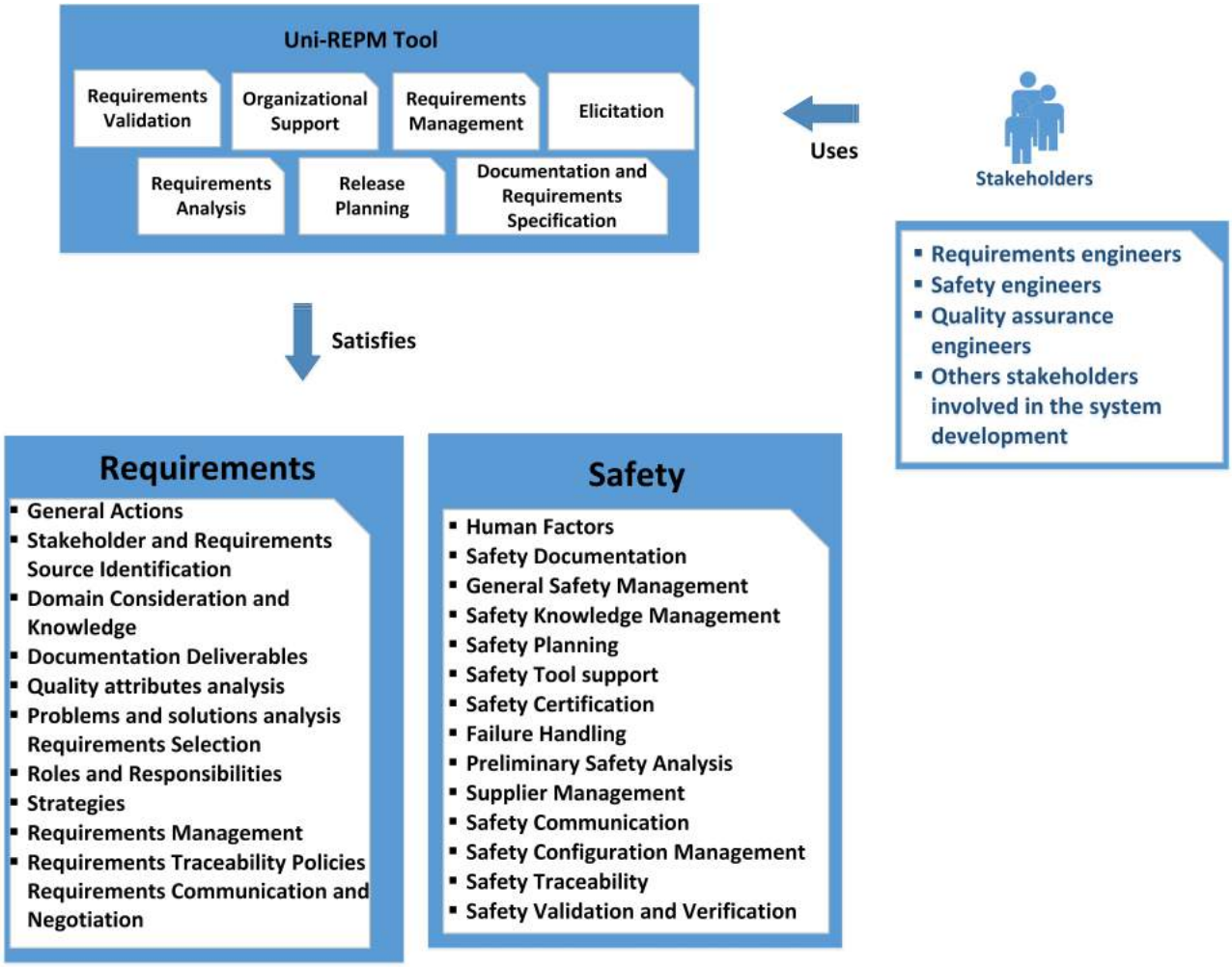

Figure 31 – Tool overview.

The tool was developed following the waterfall software development process model (SOMMERVILLE, 2011). We chose this methodology since we had well-defined requirements, mainly derived from the literature review. Accordingly, requirement changing was not a risk to handle. Hence, there was no need of following an iterative and incremental approach like an agile methodology. Moreover, we needed the complete system to develop the assessments with practitioners.

According to Sommerville (2011), the waterfall model takes the fundamental process activ-

ities of specification, development, validation, and evolution and represents them as separate process phases.

6.1 REQUIREMENTS DEFINITION

6.1.1 Use Case Diagram

In order to describe the functionalities of our proposed tool, we performed a use case modeling. Figure 32 describes the general actions that can be done by each user type when using our tool.

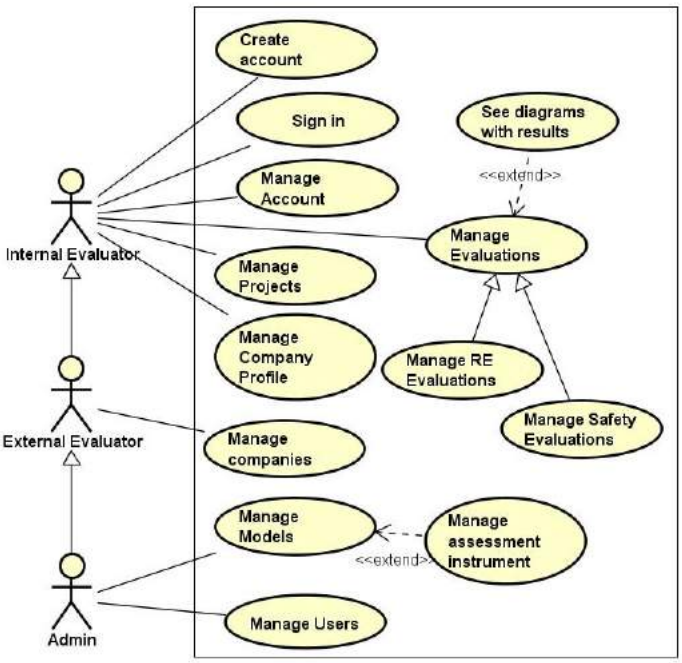

Figure 32 – Use Case Diagram of the Uni-REPM tool.

The tool supports three types of user: (1) external evaluator - this user can insert companies, projects and perform Safety/RE evaluations; (2) internal evaluator - this user only can insert projects to the company he/she belongs and perform Safety/RE evaluations; (3) admin - besides the functionalities of external evaluators, this user can manage users and different versions of RE/Safety models.

It is important to note that the tool was developed only to support the evaluation activity. Functionalities reported to planning the evaluations like defining the evaluation schedule, scheduling interviews, conducting interviews, collecting data, among others are not part of the scope of the tool as adopted by other tools in the literature (LIBÓRIO, 2014).

Please refer to Appendix C for the description of each use case stated in Figure 32. Finally, the use cases are directly related to the functional requirements described in the next section.

6.1.2 Functional and Non-Functional Requirements

After the Use case diagram elaboration, we identified the system's functional and non-functional requirements. To facilitate the search and reference of requirements throughout this thesis will be adopted a convention for each type of requirement. The functional requirements will be represented in [FRxx] format and non-functional requirements in [NFRxx] format, where "FR" and "NFR" are the acronyms for each type and "xx" represents the requirement number.

The requirements were classified as:

- Essential: It is the requirement indispensable to the system's operation. This type of requirement must be implemented, otherwise the project will lose its usefulness.
- Important: Without this requirement, the system is still capable of being used. However, such use occurs unsatisfactorily by the customer.
- Desirable: This type of requirement can be implemented in later versions of the system, since even without its implementation the system fulfills its basic functionalities.

The non-functional requirements as well as functional requirements are presented in Table 36 and Table 37 respectively.

Table 36 – Uni-REPM tool non-functional requirements.

Code	**Description**	**Priority**
NRF01	The system must allow users to sign in.	Essential
NRF02	Compatilibty: The system must execute in the following browsers: Google Chrome, Internet Explorer, Mozilla Firefox.	Important
NRF03	The system must be developed using the PHP language.	Essential
NRF04	The system must use the MySQL database.	Essential
NRF05	The system must be a web application.	Essential
NFR06	The projects and assessment shall only be accessible by owner if owner is logged in.	Essential
NFR07	The admin user can access all assessments of all users.	Essential
NFR08	The system shall validate user input for required input to prevent empty data.	Essential
NFR09	Persistence: It is necessary that the data generated by users are stored for later use.	Essential

Table 37 – Uni-REPM tool functional requirements.

Code	Description	Priority
	Projects	
RF01	An authorized user shall be able to add new projects.	Essential
RF02	An authorized user shall be able to open the details of projects that he/she inserted.	Essential
RF03	An authorized user shall be able to update details of projects that he/she inserted.	Essential
RF04	An authorized user shall be able to remove project that he/she inserted.	Essential
	RE and Safety Assessments	
RF05	An authorized user shall be able to add new assessments of projects that he/she inserted.	Essential
RF06	An authorized user shall be able to modify assessments of projects that he/she inserted.	Essential
RF07	An authorized user shall be able to restore assessments of projects that he/she inserted.	Essential
RF08	An authorized user shall not be able to delete assessments of projects that he/she inserted.	Essential
RF09	An authorized system must keep history of assessments to monitor progress on improving processes.	Essential
RF10	An authorized system must support recurring appraisals of the same project.	Essential
RF11	An authorized system must generate graphical and tabular assessment results.	Essential
RF12	An authorized system should automatically determine the maturity level.	Essential
	Companies	
RF13	An authorized user shall be able to add new companies.	Essential
RF14	An authorized user shall be able to open details of companies that he/she inserted.	Essential
RF15	An authorized user shall be able to update details of companies that he/she inserted.	Essential
RF16	An authorized user shall be able to remove companies that he/she inserted.	Essential
	Users	
RF17	An authorized user shall be able to add new users.	Essential
RF18	An authorized user shall be able to open details of users.	Essential
RF19	An authorized user shall be able to update details of users.	Essential
RF20	An authorized user shall be able to remove users.	Essential
RF21	An authorized user shall be able to remove users.	Essential
RF22	The user shall be able to change his/her profile details and password.	Essential
	Reports	
RF23	Partial or total reports must be generated at any time of the evaluation.	Important
RF24	The system shall be able to export the results of an assessment as Portable Document Format file (.PDF).	Desirable
RF25	The system shall be able to export the answers and comments of an assessment as Portable Document Format file (.PDF).	Desirable
RF26	The system shall be able to export assessment history as Portable Document Format file (.PDF).	Desirable

6.2 SYSTEM AND SOFTWARE DESIGN

In order to implement our tool, we sketched the user interface design using paper prototyping before mapping it into real website.

6.2.1 Software Architecture

We implemented a client-server architecture shown in the deployment diagram of Figure 33. The major components of this model are (SOMMERVILLE, 2011): a set of servers that offer services to other components; a set of clients that call on the services offered by servers; and a network that allows the clients to access these services. In this architecture, services and servers can be changed without affecting other parts of the system.

The user's computer runs software called the client and it interacts with another software known as the server located at a remote computer. The client is a web browser where the user accesses the tool website and performs a HTTP (Hypertext Transfer Protocol) request to the server using a form. The server runs the script PHP (Hypertext Preprocessor), a server-side language, and it passes the request to the PHP interpreter.

The interpreter then processes the PHP code, it accesses the MySQL database, system's files or email server if necessary, and it generates a dynamic HTML output. This is sent to the server which in turn redirects it to the client. The browser is not aware of the functioning of the server. It just receives the HTML code, which it appropriately formats and displays on your computer.

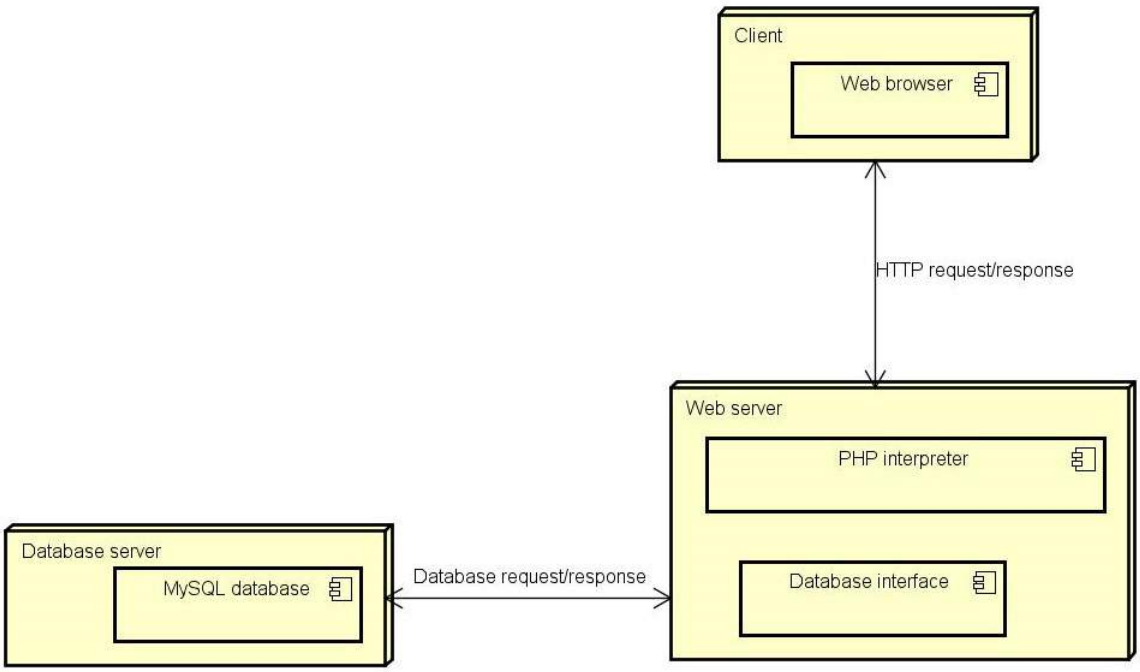

Figure 33 – Tool Architecture.

6.2.2 Database Logical Model

At the design phase, eleven tables were identified, as shown in the database logical model presented in Figure 34. This model allows to include all entities and relationships among

them and to specify all attributes and primary keys for each entity are specified. In the Uni-REPM tool model, a project (table project) belongs to a company (table company), it has an owner (table projectowner associated with an user - table user)) who added in the database and it can have many evaluations (table projectevaluation). These evaluations have a type (table evaluationtype) which can be a requirements or safety evaluation resulting in a maturity level (table maturitylevel). This level is defined considering the assessment instrument that consists of questions (table question), answer (table evaluationanswer) that has a type (table answertype). Finally, the tool manages the models (table model), the associated main process areas (table mpa), subprocess areas (table spa), actions (table action), and supporting actions.

6.2.3 Behavioral View

Statecharts (HAREL, 1987) extend conventional state-transition diagrams with essentially three elements, dealing, respectively, with the notions of hierarchy, concurrency and communication (VILELA; CASTRO; PIMENTEL, 2016).

Figure 35 shows the statechart developed to represent the high-level states and transitions of Uni-REPM tool. After the user access the uni-repm website, he/she can click on register and save his/her data or click on cancel or back. Then, he/she can login, if successful, the system verifies its permission, defines it in the php session and open the initial page.

The system displays the option available according to the user permission. The functionalities perfomed by the three types of users are found at Figure 32.

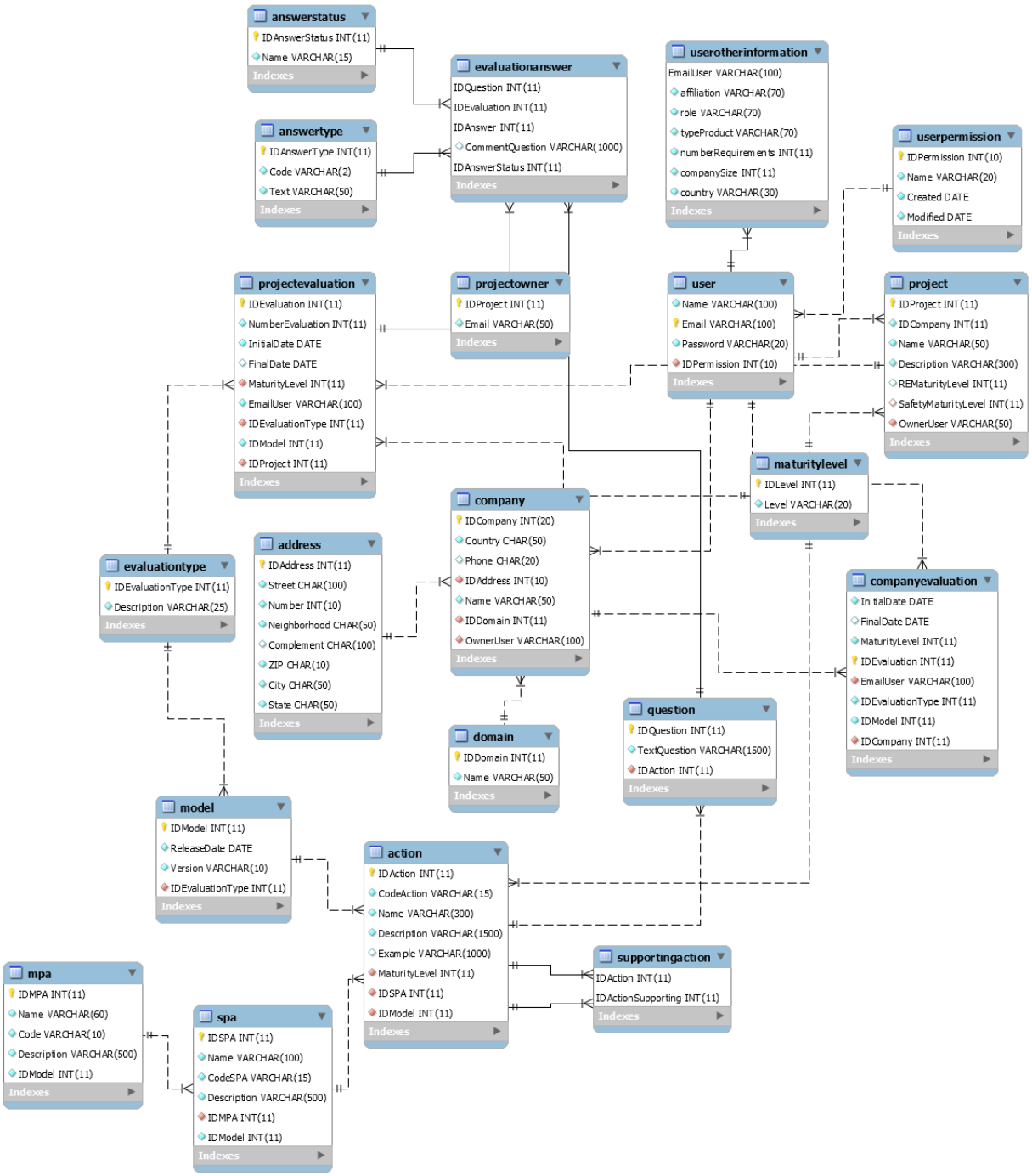

Figure 34 – Database Logical Model of Uni-REPM tool.

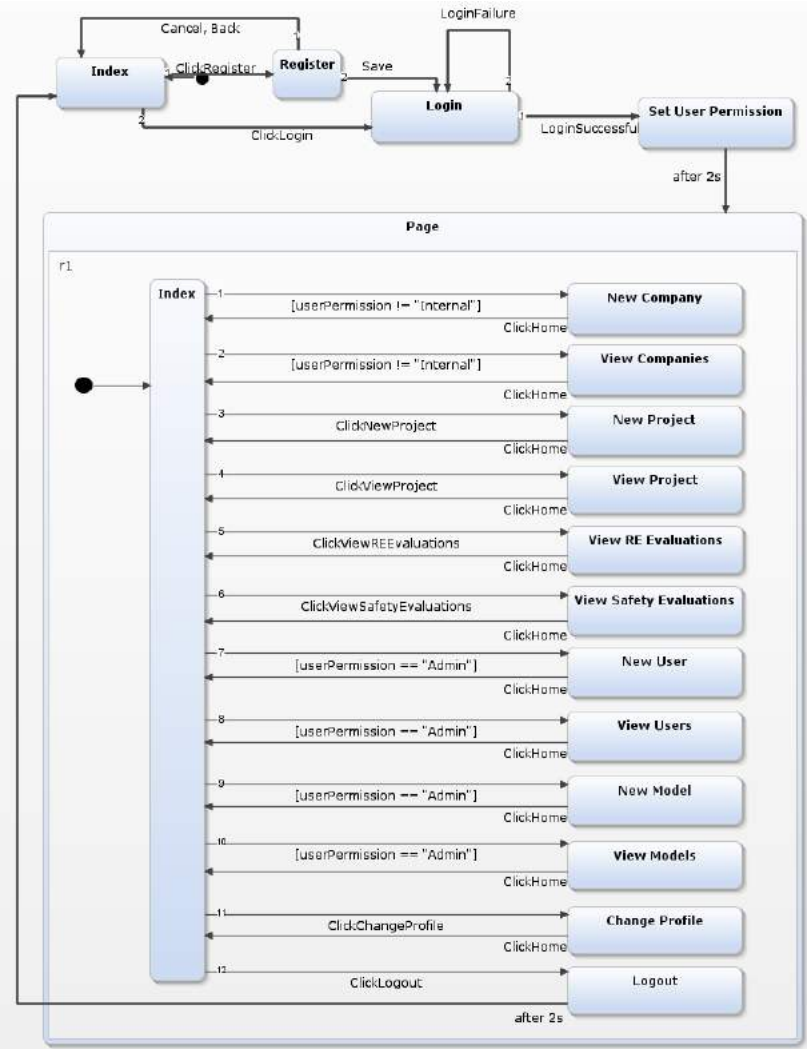

Figure 35 – Statechart of Uni-REPM tool.

6.3 IMPLEMENTATION AND TEST

The Uni-REPM web-based tool was coded in PHP (GROUP, 2018) as back-end programming language, JavaScript (KANTOR, 2018) as front-end programming language, and HTML as Hypertext Markup Language. The main libraries used in the tool were: Bootstrap (MIT, 2018), Sweetalert (EDWARDS, 2018), and Google Charts (GOOGLE, 2018). All the data is stored in a MySQL database (ORACLE, 2018).

In the last decades, several techniques for software Validation and Verification (V & V) have emerged. The V & V technique chosen to be used in this work was functional test, also known as black-box test, since it evaluates the external behavior of the software component, without considering its code (DELAMARO; JINO; MALDONADO, 2017). In this technique, implementation details are not considered and the system is tested from the user's point of view.

The criteria we used to perform functional test in Uni-REPM were equivalence class partitioning and Boundary Value Analysis for being the ones most adopted in this type of test (DELAMARO; JINO; MALDONADO, 2017).

Equivalence class partitioning is a testing criterion that splits the input of a software unit into partitions of equivalent data from which test cases can be derived (DELAMARO; JINO; MALDONADO, 2017).

The Boundary Value Analysis is a software testing criterion in which tests are designed to verify the boundary values in a range. The case tests are derived from the equivalence class partitioning criterion (DELAMARO; JINO; MALDONADO, 2017).

In the next section, we present an overview of how to use the Uni-REPM tool.

6.3.1 Using Uni-REPM Tool

The main goal of Uni-REPM Tool is to provide users with a web-based questionnaire to evaluate the maturity of their RE and/or safety-critical projects. For the organization of these processes and practices within the tool, a structure in sections, according to Figure 36 is provided. Each MPA has related SPAs presented as subsections. When selecting one SPA, the system presents all the questions related to the selected SPA. The questions that are part of the assessment questionnaire are described at: <http://www.cin.ufpe.br/~ler/unirepm>.

From the structure shown in Figure 36, the evaluator can insert information about each practice evaluated, informing whether it "Incomplete", "Complete" or "Inapplicable" as well as insert additional comments on the action. The Action ID in the checklist, for example DS.DD.a1, links the question (s) to the associated action in the model. This helps the users in case they need to locate the item for further information or clarification.

After answering all questions present in assessment instrument, the tool determines and presents the evaluation results. Based on the information provided by the evaluator, the system enables the extraction of information such as the maturity level reached in each SPA and MPA, and a summary of the answers to all questions as well as graphical visualization of maturity

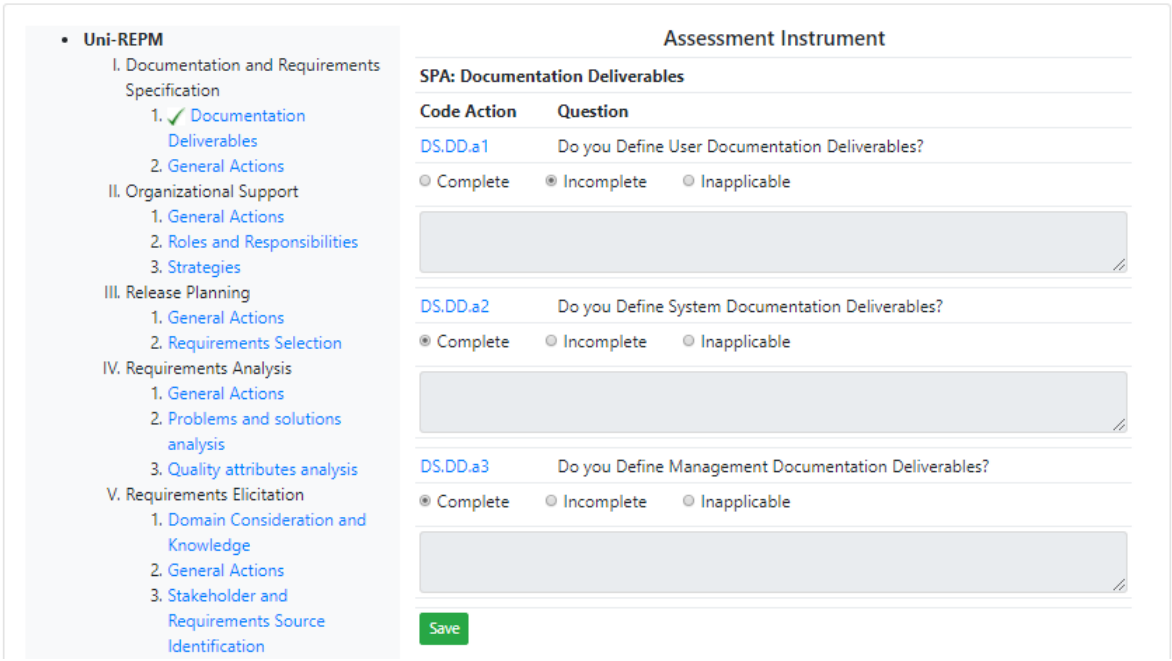

Figure 36 – Partial view of Uni-REPM assessment instrument structure.

level.

In order to provide the assessment, some functionalities were needed to be developed, such as registration of users, questions, options of answers, MPA, SPA, and actions. Moreover, there is the possibility to create new versions of the model using the tool (available only to admin users), which can support different companies' profiles.

The link (for tool demo) can be found at <https://youtu.be/nvZCdUmA61U>.

6.4 INTEGRATION AND SYSTEM TESTING

The Uni-REPM Tool was evaluated by potential users. Section 7.2 presents the validation carried out from the point of view of industry practitioners.

The evaluation of the tool usability was based on the PSSUQ (The Post-Study System Usability Questionnaire) (LEWIS, 1995). This method provides a 19-item questionnaire, with administration and scoring instructions, that were used in usability measurement at IBM.

The PSSUQ analyzes the system usability through four factors (overall satisfaction, system usefulness, information quality and interface quality) from the answers obtained from the evaluation questionnaire. Although it has 19 questions, we used only five closed-ended questions (presented below) that we consider the most important and one open question to subjects express their opinion. We made this choice due to the time constraints of the practitioners.

Accordingly, The practitioners filled in a questionnaire form which evaluates the tool from the aspects below:

"I could effectively complete a safety evaluation using this software tool."

( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

"I felt comfortable using this software tool."

( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

"I believe I could become productive quickly using this software tool."

( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

"This software tool has all the functions and capabilities I expect it to have."

( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

"Overall, I am satisfied with how easy it is to use this software tool."

( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

If you have further comments about the software tool, please state below.

The answers of the respondents (please Section 7.2.8 for the full description of the results) show that the tool has usability level considered good or very good by most of them.

6.5 OPERATION AND MAINTAINANCE

6.5.1 Version Control System

In order to keep trace of changes made in the source code after its release, we defined a configuration management plan using the bit bucket version control system [1]. We created a private repository which only is accessible by ourselves and pushed any changes to the repository. This will ensure that we always have a backup on the server and can freely to make any changes as long as we committed latest code to the server.

In our repository there are branches, which are *master branch* (permanent branch that reflects a production-ready state), *deploy branches* (temporary branches that can be created to implement and test changes) and *tags* (used to identify snapshot of baselines or releases). The repository structure is presented in Figure 37.

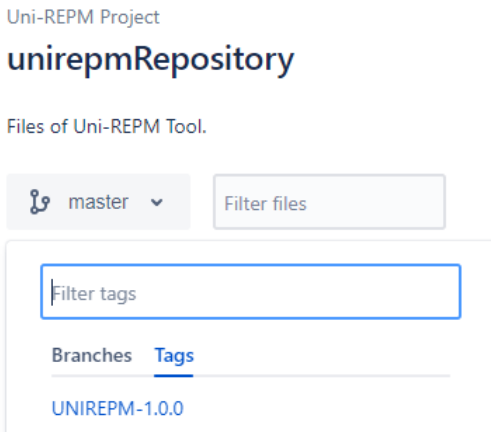

Figure 37 – Uni-REPM tool repository.

[1] https://bitbucket.org/

6.6 FUTURE IMPROVEMENT ROADMAP

As a closure for this project, we had planned a roadmap for future improvement of this tool. The following features are not included in our project, but it will be helpful to be added to overcome the limitations of this tool. To improve this tool, we may add other functionalities such as:

- **Collaboration Features**: literature reports that experienced users tend to use collaborative tool in their requirement specification process. This suggested that in the industry, requirement specification process are most likely conducted by few persons. Hence, we propose to allow multiple users assessing the same project.
- **Support adding/editing evidence**: documents that support the completion of practices (evidences) may be upload or edited in the tool to increase the reliability of answers. This will allow to store the evidences that the action is in fact complete and not only rely on respondent answers.
- **Calculate the average of assessments**: the tool may keep history of assessments and calculate an average of assessment performed previously.
- **Sending reports by email**: the tool may allow adding a set of emails to be notified each time evaluation results are submitted to the tool. This would make communication between the assessment team faster and more agile, where all stakeholders would have real-time knowledge of data submissions to the tool (LIBÓRIO, 2014).
- **Export evaluations**: besides having the option to export the results in PDF format, the tool could provide means of construction customized reports. Accordingly, the user could choose what data would be displayed, the form of display (source, positioning, etc.), as well as characterize the report according to the evaluated organization, for example.

6.7 FINAL CONSIDERATIONS

The Uni-REPM tool provides an interactive environment for evaluating the maturity of RE processes of software development organizations. Uni-REPM SCS is crossing boundaries considering its goal of integrating the RE and safety areas increasing its impact in academia and industry.

In general, the interviewees considered the proposed tool useful and easy to conduct assessments. Future work will concentrate on adding new features to the tool, such as new kinds of visualization and reports such as the evaluations history. We are also looking to new organizations to perform new evaluations and collect feedback from practitioners about the tool usability.

In the next chapter, we describe the static validation performed to evaluate the completeness and usefulness of Uni-REPM SCS.

7 MODULE VALIDATION

In this chapter, we describe the planning and results of the validation we performed to validate Uni-REPM SCS. We adopted the concept of validation of Wieringa et al. (2006) that defines validation research as the investigation by a thorough ad methodologically sound research setup of the properties of a novel solution proposal that has not yet been implemented in RE practice. The solution may have been proposed by the author or by someone else. Furthermore, we are following the framework of technology transfer of Gorschek et al. (2006) that also adopts the term validation for a candidate solution.

Aiming to validate Uni-REPM SCS and ensure that the model quality is suitable for companies to pilot, we performed a static validation following the technology transfer framework described in Section 3.9. After we formulated the candidate solution, which was the version 0.1 of UniREPM SCS, we conducted a static validation (Section 7.1). This type of validation proposes collecting experts' opinion in order to analyze whether the knowledge in literature was reasonably transferred and presented in the model (NGUYEN, 2010).

Conducting the static validation made possible to improve the candidate solution by generating the version 0.2 and preparing it for the next step - dynamic validation (GORSCHEK et al., 2006) described in Section 7.2.

7.1 STATIC VALIDATION

The static validation provides an early feedback that helps to identify potential problems without using industry resources (NGUYEN, 2010). Hence, it is possible to improve the candidate solution and prepare it for the next step - dynamic validation (GORSCHEK et al., 2006).

7.1.1 Static validation design

We conducted the validation considering the aspects listed below. We decided to use these aspects since they already have been used in the literature (NGUYEN, 2010) and we considered them sufficient to evaluate a candidate solution to a industry problem (GORSCHEK et al., 2006).

- Coverage: to make sure the module presents the necessary safety practices and to detect others that might not be captured in the sources of information used to propose the module.
- Correctness: to ensure the names and maturity levels of the proposed practices are correctly presented.
- Usefulness and Applicability: to collect the experts opinion about the module application in industrial settings and to what extent.

Considering the aspects above, the validation design was guided by the research questions below:

RQ1: Does Uni-REPM SCS have a sufficient coverage of safety practices?

RQ2: To what extent is Uni-REPM SCS suitable for companies, in terms of its correctness, usefulness and applicability?

RQ3: What improvements can be done to Uni-REPM SCS based on the findings from RQ1 and RQ2?

To answer these research questions, we interviewed two industry practitioners and conducted a survey with nine domain experts that work in academia and have partnerships with industry. The subjects provided their opinion about the SPAs, actions, and their maturity levels to validate its accuracy and adequacy.

The interviews were conducted in face-to-face meetings and the survey consisted in contacting domain experts using self-administered questionnaires sent by email. All subjects answered the same profile and module evaluation questionnaires and received a copy of Uni-REPM SCS full description. The artifacts used are presented in Appendix E.

We adopted the self-administered questionnaire survey strategy because the subjects could spend their most convenient time to analyze the module and answer the module evaluation questionnaire. Besides, we collected subjects background aiming to better contextualize the feedback received. These questions aimed to extract information about their knowledge and experience in the area as well as to help to draw a better view about them.

The subjects were selected using random sampling after a previous analysis of their profile. We considered their research interest in SCS, embedded systems and RE, their experience in these areas, and if they have publications in these areas. We searched for experts from many sources (publications, personal recommendation) and contacted them through emails. After four months, 11 out of 137 experts contacted accepted to participate and returned their feedback.

7.1.2 Subjects Profile

Eleven experts participated in this validation. Considering their affiliation, they are from four countries: Brazil (eight experts), Norway, Poland, and South Korea with one subject each. The majority of them has PhD (eight subjects) and three have Master degree. In order to easily refer to their comments, an ID that consisted of S# was assigned to each experts.

They have experience in academia, industry (working or with partnership), research institute, and spin-off company as presented in Table 38. We have mainly academics participating in this static validation as required by the technology transfer model (GORSCHEK et al., 2006) that defines that we should formulate a candidate solution, evaluate it in academia and improve it before using/validating in industry. Although the subjects are mainly academics, many of them have previous industrial experience and also work actively with industry collaborators in the field. Considering that they have such experience, we asked them about the module

usefulness and if they would adopt it to get preliminary insights.

Table 38 – Time of experience - by type and with safety-critical systems (years).

	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	Mean
Academia		8	9	15	16	16	7	2	6	10	7	8.73
Industry	8	15							7	2	7	3.55
Research Institute	6		3		31							3.64
Spin-off company				3								0.27
Industry - Partnership						10						0.91
Experience in safety-critical systems	12	15	6	NI	6	16	7	2	6	6	1	7

Besides, the time of experience with safety-critical systems is relevant (7 years average) which can increase our confidence in their opinion. It is important to highlight that Subject #4 did not inform (NI) the time of experience with SCS, but he/she does have experience as safety case editor.

The subjects have experience with different domains (see Figure 38) and several roles (see Table 39) which contributed to analyze the coverage of practices and to have indications of its applicability in different domains.

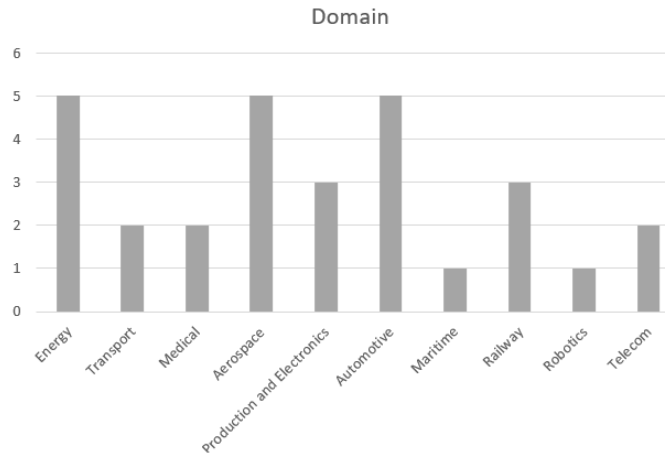

Figure 38 – Domain of experience.

Observing the need of certification by regulatory entities of the developed systems, we also questioned the subjects experience with safety standards which is depicted in Table 40. Except for two subjects, all of them have experience with standards. Subject #6 stated that "*I never get caught up in the rules during the developments. I have always been concerned with the problem itself and the rules of application, not development.*"

Questions about maturity models were also considered. First, we asked if the experts had already followed a maturity model (Figure 39). The majority did not follow as already expected since they are mostly from academia, and two subjects (S2 and S11) had followed.

Table 39 – Experience - Roles.

	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	%
Requirements engineer		x	x	x				x	x		x	54.55
Designer (architecture and detailed design)	x	x						x				27.27
Developer/programmer	x				x	x			x		x	45.45
Tester				x							9.09	
Safety analyst/expert (internal to the company)		x	x	x	x			x				45.45
Independent assessor (consultant or external to the company)		x										9.09
Project leader or manager	x		x		x	x			x		x	45.45
Researcher	x		x	x	x	x	x	x		x	x	81.82
Teacher (Professor, lecturer etc.)		x	x	x	x	x	x		x	x	x	81.82
System engineer					x	x		x	x			36.36

Table 40 – Experience with safety standards.

	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11
DO-178		x	x							x	
EN 50126			x					x			
EN 50128			x								
EN 50129			x								
FDA's guidelines for infusion pumps				x							
ISO 14971				x							
ISO 26262			x		x			x		x	
IEC 60601	x			x							
IEC 61508			x	x	x					x	
ISO/IEC 62279								x			
ISO 62304		x									
MIL-STD-498		x							x		
MIL-STD-882		x						x			
MIL-STD-2167									x		
None						x	x			x	

It is important to note that subject S2 is one of the two practitioners interviewed and this expert had followed the CMMI (TEAM, 2010) maturity model. S11 had used CMMI and MPS.BR (SANTOS et al., 2012) maturity models previously in other companies. In case they have followed, we asked if the expert prefers a generic maturity model or a specific maturity model. S2 answered "*I prefer a specific maturity model to avoid conflicts of interpretation*".

S11 said : "*Maturity models serve as guides for customizing processes and selecting prac-*

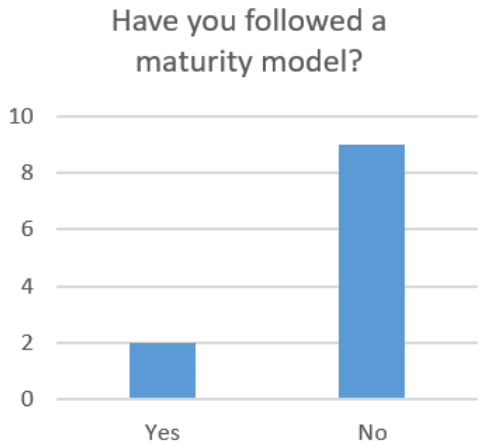

Figure 39 – Results of the question whether subjects had already followed a maturity model.

tices. One problem with the most popular models (MPS.Br and CMMI) is because they are generic in nature. This makes them extensive, and this is reflected in the need for a great deal of effort to study and evaluate what should really be incorporated into each organization. More specific maturity models can provide a leaner and more cohesive set of recommendations and practices suggestion."

These statements corroborate the literature (SEI, 2007) (STANDARDIZATION, 2011c) about the need of a specific maturity model for SCS. Regarding their opinion of the importance of such models, shown in Figure 40, the great majority (81.82%) considered them important, one expert did not answer and only one considered it unimportant.

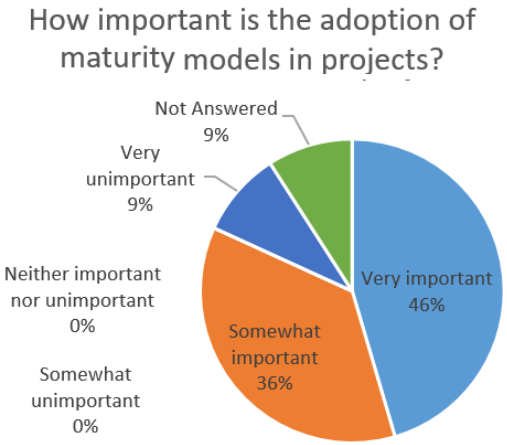

Figure 40 – Opinion of subjects about the importance of maturity models.

7.1.3 Results from module validation

After collecting the subjects background, the module evaluation questions aimed to uncover improvement areas in terms of coverage, correctness, usefulness and applicability. They were

about the sub-process areas, the coverage of practices, the maturity levels assigned and subjects opinion about the module.

The first element we asked the experts was their opinion about the safety processes (or focus areas), presented in the module, they consider important and should be considered in RE process. Table 41 shows these results.

Table 41 – Opinion of the experts about the SPAS of Uni-REPM SCS.

SPA	Don't know (%)	Not Needed (%)	Desirable (%)	Essential (%)
Safety Knowledge Management			63.64	36.36
Safety Tool support	9.09	9.09	54.55	27.27
General Safety Management		9.09	18.18	72.73
Safety Planning		18.18	36.36	45.45
Safety Configuration Management	9.09	18.18	18.18	54.55
Safety Communication			54.55	45.45
Safety Traceability	9.09		36.36	54.55
Supplier Management	18.18	9.09	63.64	9.09
Preliminary Safety Analysis	9.09		36.36	54.55
Failure Handling	9.09		9.09	81.82
Safety Certification	18.18	18.18	45.45	18.18
Human Factors			27.27	72.73
Safety Documentation			45.45	54.55
Safety Validation and Verification			18.18	81.82

The results based on the opinion of 11 experts demonstrate that all SPAs in Uni-REPM SCS are considered desirable or essential by the majority of experts. This indicates that the reviews we performed and sources of information used are updated and reflect current industry needs.

The subjects reported if they think that other safety-related process are also important for the development of a safety-critical system. The changes we performed (response actions) due to the experts feedback presented below are discussed in Section 7.1.4.

S1: *The existing usability needs to be considered in the development of a new critical system. The change in the way of using the system can generate failures.*

S5:*Environment description – safety is always a relationship between a system and its environment.*

S6: *Durability tests - a fully functional and bug-free prototype can fail in a short time due to poor component quality or wrong handling in the welding process, for example.*

S8: *The proposed module supports reliability based safety engineering along with system thinking for safety critical systems but still some process are missing while generating inade-*

quate control actions in Requirements Analysis.

S10: *Since safety standards in both aerospace (DO-178C and SAE ARP 4754A) and automotive (ISO 26262) domains recommend or mandate the development of an Assurance/Safety Case (Kelly, 2003) as a requirement for certification of a safety-critical system, The Safety Assurance process should be considered during the development of a given safety-critical system to obtain certification credits. An Assurance Case is a clear, comprehensive, and justifiable argument supported by a body of evidence that a system is acceptably safe to operate in a particular context.*

S11: *No, the process relationship is already comprehensive.*

The easiness of understand the SPAs in the module in experts opinion is presented in Figure 41. We observed that great majority (72.73%) agree that the SPAs are easy to understand. This was a concern we have when defining the SPAs since we wanted to adopt the terms that are in fact used in the SCS domain. This may be an indication that such goal was achieved.

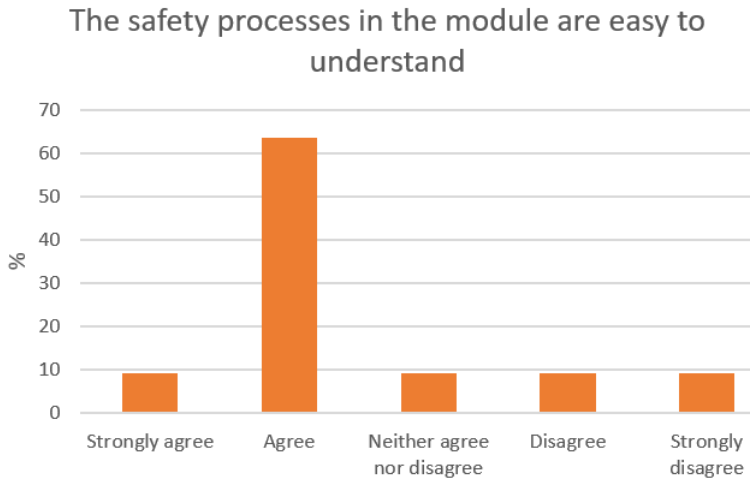

Figure 41 – Opinion of subjects whether the SPAs are easy to understand.

The experts classified the practices using the following scale: "Don't know", "Not Needed", "Desirable", and "Essential". The number of practices indicated by the experts in each category are listed in Table 42.

All experts, including the industry practitioners interviewed, considered the great majority of safety practices of the module are desirable or essential. The exceptions were S4 that did not answer this question and S6 that opted to not answer once he/she said that "*I do not have practical experience to answer this question*".

We asked the subjects whether there are actions important for RE process of safety-critical systems that are missing in the module. Our response actions to their answers, described below, are discussed in Section 7.1.4.

S1: *Verification of existing products.*

S3: *For assessing the completeness of the module, safety standards could be checked. For example, some prescribe traceability between requirements and code.*

Table 42 – Opinion about the practices.

Subject	Not Answered	Don't know	Not Needed	Desirable	Essential
S1	0	10	1	62	75
S2	0	0	0	24	124
S3	0	0	0	62	86
S4	148	0	0	0	0
S5	0	0	14	41	93
S6	0	10	23	65	50
S7	0	146	0	0	2
S8	1	0	11	80	56
S9	4	18	8	69	49
S10	0	0	2	24	122
S11	0	12	0	70	66

S4: *Security analysis - it is hard to find a domain/application where those 2 topics wouldn't interrelated. Here, the main focus is: can safety be compromised by malicious actions.*

S5: *Formal communication is mentioned several (3) times in the document. However IMHO, the informal communication in a project is more important, mainly because it is much more frequent.*

S8: *In my view, all the processes are well reflected in proposed module.*

S9: *It would be interesting to define a set of basic requirements that should be verified in each new software version (shakedown). There is a compromise between cost and coverage so there is a minimum test for releasing a new version.*

The easiness of understanding the actions in the module in experts opinion is presented in Figure 42. We noticed that the actions were considered as easy to understand by almost 70% of the subjects. We believe that the understanding of actions across domains is not compromised since we provide explanations for each action and examples. This is an important result since most of them analyzed the actions considering only their names and not the description.

The maturity level we defined to each action was also evaluated by the subjects. The number of changes proposed by them is presented in Table 43. Excepting S4, S5, S8, and S11 there was a tendency in the experts to reduce the maturity level we proposed to the actions. This occurred mostly with the two practitioners (S1 and S2) that during the interviews constantly repeated that the actions are the common procedure and are required by safety standards. Nevertheless, we observed a tendency of academic experts in proposing to increase the maturity level. It is important to highlight that the total number of changes is higher than 148 once many suggestions referred to the same action by different subjects.

During the analysis of subjects opinions, we observed some conflicting suggestions for the same action (increase and decrease). The number of actions in conflict per SPA is listed in Table 44. The number of conflicts was low, only 29 actions in a total of 148. We did not

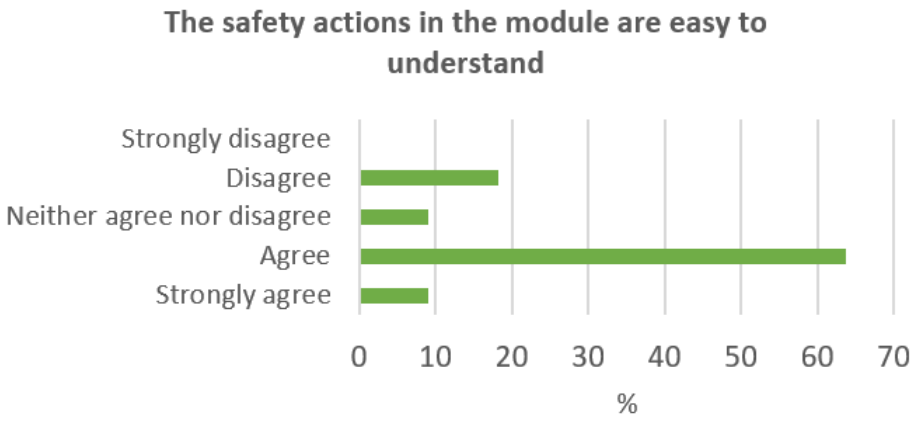

Figure 42 – Opinion of subjects whether the actions are easy to understand.

Table 43 – Suggestions about the maturity level of the practices.

Subject	Proposes to increase the maturity level	Proposes to decrease the maturity level	Total number of changes
S1	1	17	18
S2	0	15	15
S3	11	37	50
S4	30	28	58
S5	40	9	50
S6	0	0	0
S7	0	2	2
S8	34	6	41
S9	1	0	1
S10	26	5	31
S11	0	0	0
Total	143	119	262

believe that there were misunderstandings during the interpretation of an action, however, this may be occurred due to the differences in subjects experiences.

To answer RQ2, a query about the extent they believe the safety module will help requirements engineers to perform safety-related activities or tasks in the project (Figure 43) and whether they would adopt the module (Figure 44) was made to the experts.

We observed that they consider the contribution of Uni-REPM SCS significant to industry and they would adopt it case they would work in industry. Considering that the majority of experts are from academia, we have many answers of inapplicable.

7.1.4 Response Actions and Model Improvements

The feedback results were analyzed, response actions were decided and the model was refined and improved (RQ3).

Table 44 – Number of actions in conflict based on subjects opinion per SPA.

SPA	# actions with conflicts
Safety Knowledge Management	3
Safety Tool support	0
General Safety Management	1
Safety Planning	1
Safety Configuration Management	2
Safety Communication	0
Safety Traceability	3
Supplier Management	0
Preliminary Safety Analysis	10
Failure Handling	0
Safety Certification	0
Human Factors	0
Safety Documentation	2
Safety Validation and Verification	7
Total	29

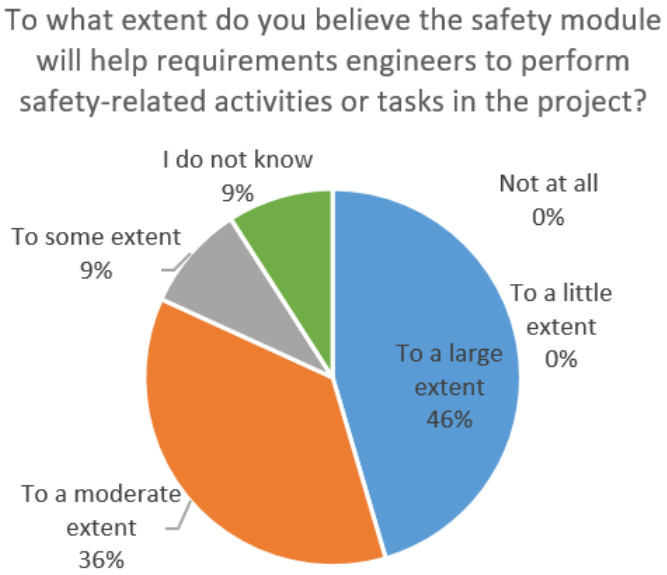

Figure 43 – Opinion of subjects about the usefulness of Uni-REPM SCS.

7.1.4.1 Regarding new SPAs

We discarded the following suggestions to add new SPAs because they are already covered by the safety module:

- usability needs (S1) - there is no need to add a new SPA specific to the issues because they are already addressed in the Human Factors SPA;

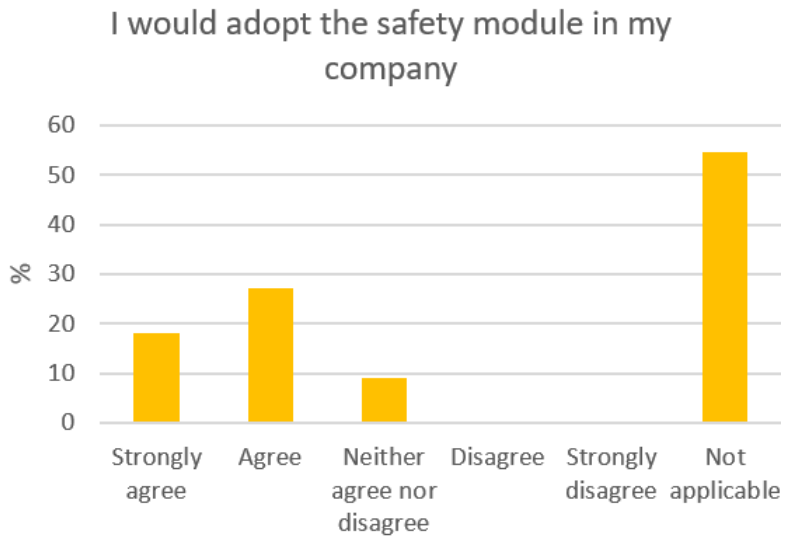

Figure 44 – Opinion of subjects about the adoption of Uni-REPM SCS.

- environment description (S5) - there is no need to add a new SPA to handle this because preliminary safety analysis, failure handling, and safety planning SPAs have already practices related to this comment;
- durability tests (S6) - the subjects stated that a fully functional and bug-free prototype can fail in a short time due to poor component quality or wrong handling in the welding process, for example. However, the required performance level, which considers this quality, is an action that is already presented in the safety planning SPA;
- inadequate control actions (S8) - according to the subject some processes are missing while generating inadequate control actions. However, the safety module already has actions in the preliminary safety analysis SPA to model the safety control structure which handles this type of actions.
- safety assurance (S10) - the module already has the safety certification and safety planning SPAs that contain practices related to safety cases.

The subjects did not considered that the SPAs are insufficient or deficient for usability needs or environment description since they did not propose to add new actions. The comments are related to separate these issues in specific SPAs.

7.1.4.2 Regarding new actions

We discarded two suggestions to add actions that are: traceability between requirements and code (S3) - we are concerned with RE phase and code is produced in later stages; and informal communications (S5) - because it is a practice already performed in any project and generally SCS projects are large and involve several stakeholders that it would be impossible to manage

informally. In a project that formal communication are not necessary, the company can mark it as inapplicable.

Some comments were left as future work considering the estimated resource and time taken to implement them. They are: verification of existing products (S1); security analysis (S4) that although is out of Uni-REPM SCS scope it is related with safety; and requirements for shakedown testing (S9) which basically refers to the fast/high-level testing that is performed to an application after it has been migrated or deployed to a given environment to assure that is up and running without major glitches, which means that is ready for being tested.

Finally, according to S8: *In my view, all the processes are well reflected in proposed module*. Considering the experts comments about the actions, we believe that the module has a good coverage of safety practices. These results contribute to increase our confidence in its coverage (RQ1). This aspect was analyzed again in the dynamic validation with seven companies (described in Section 7.2).

7.1.4.3 Regarding the maturity level of actions

Considering the goal of the model and the knowledge acquired in the several sources of information used, we tried to accommodate as much feedback as possible. As a result, 98 out of 120 suggestions to change the maturity level of practices were implemented. The others were discarded as discussed in the previous sections. In Table 45, we show the number of implemented changes in the maturity levels of actions by SPA.

The criteria adopted to decide if we should implement the suggestion were:

- unanimity: all subjects, that proposed changing the action, suggested the same maturity level. For example, we assigned the maturity level 3 for an action, and all suggestions were changing to level 2. Accordingly, we changed it for level 2.
- majority: the majority of subjects, that proposed changing the action, suggested the same maturity level. Considering the same example that we assigned the maturity level 3 for an action. If the majority of suggestions were changing to level 2, we changed it for level 2.
- agree: the suggestion was made by only one expert, but we agree. For example, only one subject suggested changing the maturity of a level 2 action for level 1, we changed it for level 1 if we agree and if the subject is an industry practitioner.
- disagree: we did not implement because we disagree with the subject. For example, only one subject suggested changing the maturity of a level 2 action for level 1. However, the other 10 did not propose any change) and we did not change it for level 1 if we disagree and if the subject is from academia.

In case of conflicts, i.e different experts suggested different maturity levels, we discussed which expert suggestion made more sense to us and we decided what response action we

Table 45 – Implemented changes in maturity levels by SPA.

SPA	# of actions	# of suggested changes			# of implemented changes		
		Increase	Decrease	Total	Increase	Decrease	Total
Safety Knowledge Management	11	1	8	9	1	8	9
Safety Tool support	7	-	4	4	-	4	4
General Safety Management	9	4	2	6	3	2	5
Safety Planning	14	6	2	8	3	2	5
Safety Configuration Management	12	3	7	11	3	6	10
Safety Communication	12	6	3	10	5	3	9
Safety Traceability	8	-	8	8	-	8	8
Supplier Management	6	4	2	6	4	2	6
Preliminary Safety Analysis	22	19	2	21	3	2	12
Failure Handling	6	3	2	5	3	2	5
Safety Certification	9	5	2	7	2	2	4
Human Factors	6	2	2	4	1	2	3
Safety Documentation	10	5	4	9	4	4	8
Safety Validation and Verification	16	5	7	12	4	6	10
Total	148	63	55	120	43	53	98
%		42.57	37.16	81.08	68.25	96.36	81.67

would adopt. This action was necessary because we had conflicts among the suggestions made from the two practitioners and from the nine academic experts. We opted to proceed like this planning to evaluate this latter in the dynamic validation. Furthermore, during the case studies, there were no comments regarding the maturity levels assigned. This is an issue we intend to evaluate later with larger samples in future studies.

7.2 DYNAMIC VALIDATION

In the static validation, we obtained (VILELA et al., 2018b) an early feedback to help to identify potential problems without using industry resources (NGUYEN, 2010). Hence, it was possible to improve the candidate solution and prepare it for the next step - dynamic validation (GORSCHEK et al., 2006) described in this section.

The dynamic validation relied on the conduction of case studies (described in Section 3.9). The phenomenon investigated was the application of Uni-REPM SCS, within its real-life context (maturity evaluation of the companies). We detail the activities conducted in each step of the case study process in the next sections.

7.2.1 Design and Planning

In this stage, the case study protocol was elaborated. We conducted the validation considering the following aspects (NGUYEN, 2010):

- Coverage: to make sure the module presents the necessary safety practices and to detect others that might not be captured in the sources of information used to propose the module.
- Usefulness and Applicability: to collect the experts opinion about the module application in industrial settings and to what extent.

Considering the aspects above, the validation design was guided by the research questions below:

RQ1: Which safety maturity level is achieved by the requirements engineering processes of the investigated software development companies?

RQ2: Does Uni-REPM SCS have a sufficient coverage of safety practices?

RQ3: What is the effect of applying Uni-REPM SCS when it is instantiated in different safety-critical domains?

RQ4: What is the level of acceptance of Uni-REPM SCS by practitioners?

RQ5: What improvements can be done to Uni-REPM SCS based on the findings?

The goal of this study is presented in Table 46.

Table 46 – Research General Purpose.

Analyze	the safety processes of companies that develop safety-critical systems.
With the purpose of	investigate the maturity level of their projects.
In the point of view of	Project Managers, Technical and Project Leaders, Technical Cordinators, Software Engineers.
In the context of view	safety-critical systems development.

According to Yin (2003), the case may in general be virtually anything which is a "*contemporary phenomenon in its real-life context*". In this work, we have seven separate holistic cases since our context is considered being the seven companies from three different countries that work with the safety-critical systems development. Each case has an unit of analysis which is the project that each practitioner chose to evaluate using Uni-REPM SCS. This design is illustrated in Figure 45.

We adopted the strategy of previous works (MARTINS; GORSCHEK, 2017)(SVENSSON et al., 2012) where the sampling strategy was a combination of convenience sampling (SVENSSON et al., 2012) and variation sampling. The former means that the nearest and most convenient persons were selected as subjects, using our industrial collaboration network.

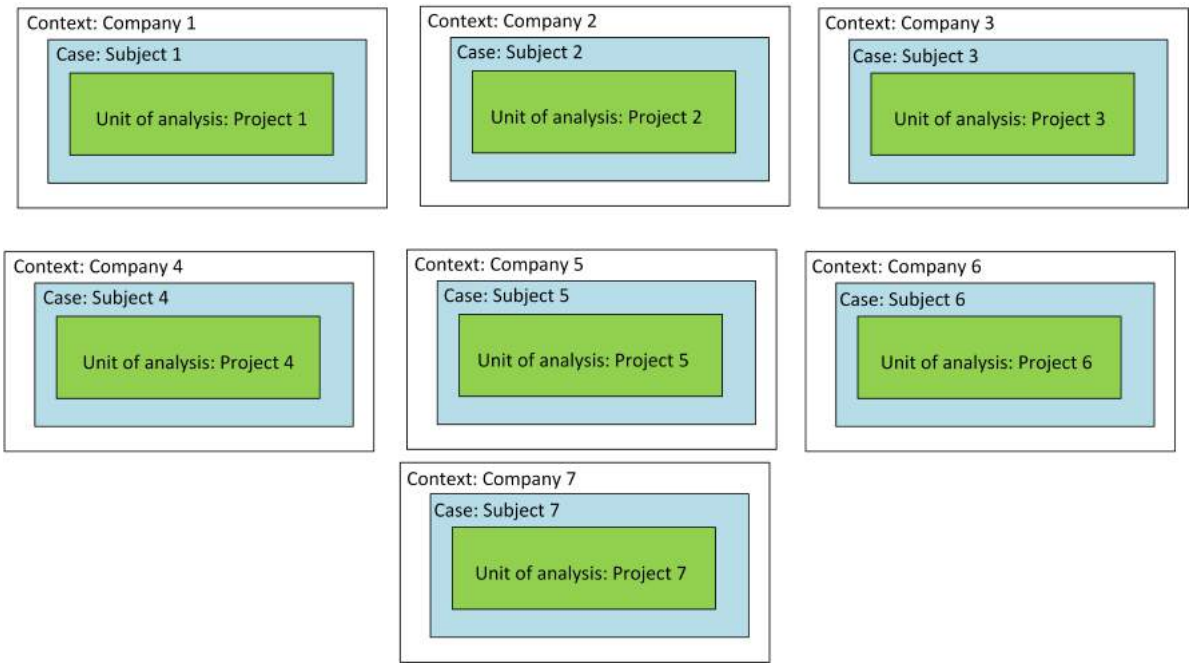

Figure 45 – Case Study Design.

The latter refer to selection of companies in different domains. The companies were contacted to participate in our study, and from those who accepted, we asked them to indicate the subjects to participate.

The companies acts in the following domains: defense & aerospace, automotive, and industrial machinery. All companies vary in relation to size (in number of employees and number of requirements in typical projects) and type of customers. For confidentiality reasons we cannot show more details about the companies, according to the recommendations from Ivarsson and Gorschek (IVARSSON; GORSCHEK, 2009).

Therefore, we conducted seven case studies at different companies with seven practitioners with different jobs, time of experience and company domain. The practitioners profiles are described in Section 7.2.4.1.

7.2.2 Ethical Considerations

In software engineering, case studies often include dealing with confidential information in an organization (RUNESON; HÖST, 2009). In this work, before the study, the participants were informed about the objectives, purpose of the empirical study, procedures used in the empirical study, i.e. a short description of what the participant should do during the study and what steps the researcher will carry out during these activities. In the first contact, we also provided a list of costs (spending some time in a interview) as well as a list of benefits for the participants. Confidentiality of the information and anonymity of the participants were also informed. Clarification and informed consent were performed verbally.

7.2.3 Preparation for data collection

We adopted semi-structured interviews as a first degree data collection technique. It means that the researcher is in direct contact with the subjects and collect data in real time. According to Runeson and Höst (2009), first degree methods are mostly more expensive to apply than second or third degree methods, since they require significant effort both from the researcher and the subjects. However, it allows the researcher controls to a large extent exactly what data is collected, how it is collected, in what form the data is collected, which the context is etc. The tools used in the process of data collection and analysis are described in Table 47.

Table 47 – Tools used in the case study.

Activity	**Tool**
Data collection	Audio record, Uni-REPM tool, Text editors.
Data transcription	Text editors and Audio Tool
Data analysis	Text editors and spreadsheets.

In this step, we also developed the questionnaire (presented in Appendix F) used to collect feedback about the module and the tool whose results are described in Section 7.2.4.

7.2.3.1 Data Collection

Due to the qualitative nature of the case studies, we followed the recommendations of Runeson and Höst (2009) to select subjects based on differences instead of trying to replicate similarities. This means that we selected subjects with different roles, personalities, etc. to the interviews. Hence, this work consists of seven holistic case studies because the unit of analysis in each one is a software development project of a specific organization.

The interviews were conducted by two researchers between January and October of 2018. Each participant was contacted to schedule the interview, respecting the availability of each professional. Three interviews were conducted at the company facility, but outside the participants workspace, in a reserved room, with only the presence of the researcher and the interviewee. This ensured secrecy and provided more reassurance to the interviewees. Four interviews were conducted from distance using communication software due to the impossibility of performing them in person.

The negotiated interview duration was two hours, however, the researcher and interviewee would determine the pace of the interview. The researcher did not rush the interview and allowed sufficient time for the interviewee to express his/her opinion effectively (NIAZI; WILSON; ZOWGHI, 2005).

The interview session was divided into a number of phases. At the beginning of the interview, the researcher presented the objectives of the interview and the case study, explained how the data from the interview would be used, the confidentiality policy and voluntary participa-

tion. The informed consent was verbally exposed and the audios of the face-to-face interviews were recorded. Only after verbal authorization to record the recording interviews was initiated. However, there were no denials.

In the beginning of the study, we also did a brief explanation/presentation about the SCS module. The presentation lasted 15 minutes approximately and it contained ten slides. Then, a set of introductory questions were asked about the subjects profile (see Section 7.1.2). The questions were relatively simple to answer.

After the introduction, we asked the subject to evaluate himself/herself the maturity level of the selected project using the Uni-REPM tool, which take up the largest part of the interview. Each interview varied from 90 to 150 minutes in which each safety practice of Uni-REPM SCS was answered by the subjects. The module assessment instrument is detailed with 148 actions[1] and in the Appendix B.

When answering the questions, the subjects may encounter one of the following situations:

- The action was deemed vital but was performed partially or not at all in this RE process. It should be marked as "Incomplete" (IC).

- The action was completed in this RE process. It should be marked as "Complete" (C).

- The action was not necessary or possible to be performed in the process. It should be marked as "Inapplicable" (IA).

After evaluating the maturity level, we asked the subjects to answer the questions related to the feedback about the module and tool.

7.2.3.2 Analysis of collected data

We combined qualitative methods of data analysis (SEAMAN, 1999) with some charts to close-ended questions. To analyze the audios record, we used an audio tool. The analysis was complemented using word processors and spreadsheet tools.

The analysis process was performed based on a set of answers obtained from the seven interviewees (all answers were considered during the analysis process). They answered the open-ended and close-ended questions, which were associated to one or more Research Questions (RQs) of this case study. Table 48 shows the association between the dynamic validation RQs and the open-ended and close-ended questions of interview questionnaire of Appendix F. The interviewees did not have access to the RQs, but only to the questions available in the questionnaire (available in Appendix F).

7.2.3.3 Reporting

The results obtained from the case studies are described in Section 7.2.4.

[1] The complete module description and assessment instrument can be found at project website: <http://www.cin.ufpe.br/~ler/unirepm>

Table 48 – Association among dynamic validation RQs and open-ended and close-ended questions of interview questionnaire of Appendix F.

RQs	Open-ended questions	Close-ended questions
RQ1		
RQ2	16	
RQ3	4, 13	14, 15
RQ4	19, 25	17, 18, 20-24
RQ5	19, 21	

7.2.4 Results of dynamic validation

In this section, we present the analysis of the results. The subsections are following the case study organization: information about practitioners profile and projects details, the evaluation results as well as feedback about the module and the tool. Finally, we discuss response actions and model improvements.

7.2.4.1 Practitioners Profile

We collected information about the interviewees in order to better understand their experiences and their feedback. Seven subjects participated in this evaluation. In order to easily refer to experts comments, an ID that consisted of S#D (Subject + number + D - Dynamic) was assigned to each subject. We adopted the S#D to distinguish from S# of static validation (Section 7.1).

The seven interviewees are from three countries and they have an average of 11 years of experience in the development of safety-critical systems as presented in Table 49. Their profile contributes to increase our confidence in their opinion.

We asked the subjects about the company practices. Mostly are established in the market for more than 40 years (see Figure 46). Moreover, they act in different domains and have several employees in the company/business unit they work as shown in Table 50.

Another point of investigation was if the organization currently use some maturity model and the level it is classified. All companies do not follow any maturity model. S3D highlighted the cost associated with well-known maturity models:

"Cost of maintaining certificate over time." (S3D)

Although the company of S1D does not follow a maturity model, the practitioner reported the benefits of adopting one:

"Not specifically about safety but in general using maturity models could be useful for the company in many perspectives such as improving internal processes and communications. Also to make the development artifacts and deployment more efficient." (S1D)

Subject S7D reported that they do not follow a maturity model but the company adopts the

Table 49 – Position and time of experience of the Practitioners.

#	**Position/job scope**	**Time of experience in SCS**	**Specific area(s) the job focus on**	**Country**
S1D	Business analyst, application engineer, safety solution owner	5 years in industry and 5 years in research	Making tool support for ISO 26262, FMEA and FTA	Sweden
S2D	Supports our customers with their applications	20 years	Programming fail safe systems	Sweden
S3D	Head of strategy	More than 10 years	Weapons and flight	Sweden
S4D	System/Certification engineer	More than 10 years	Aeronautical/Space (mechanical and avionics systems)	Brazil
S5D	Integration Engineer	12 Years	Integration of on board equipments in space payloads and sounding rockets	Brazil
S6D	Software Engineering Manager	10 years	Embedded Systems and software	Brazil
S7D	Senior Software Design Development	More than 6 years	Aerospace field	Germany
	Average: 11 years			

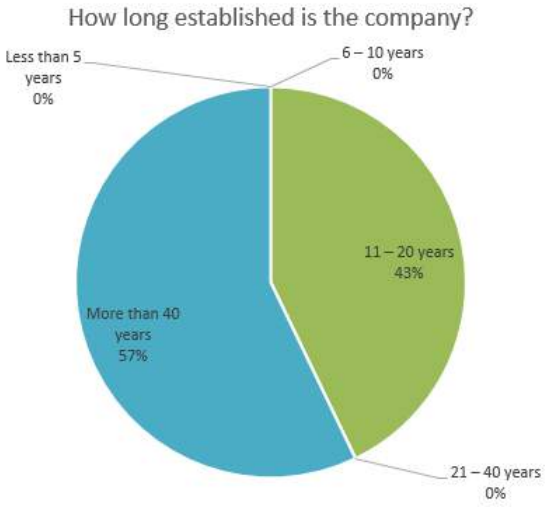

Figure 46 – Time that the company is established in the market.

V-Model (MATHUR; MALIK, 2010) once they develop software level A (according to DO-178B). This practitioner highlighted that they face problems with software development process: *"The mainly problem is the missing information or not documentation of the lessons learned".*

7.2.5 Projects Details

In the case study, we asked the subjects to select a project that they already worked to evaluate its maturity. In order to achieve better conclusions, some details of these projects were needed. The answers regarding the product being developed and the project details are presented in Table 51 and 52. We replaced the name of the platform and the aircraft to "ABC" to maintain

Table 50 – Domain and number of employees in the company/business unit.

#	**Industry domain**	**Number of employees in company or business unit**
S1D	IT but they support customers in automotive industry	20
S2D	Industrial machinery	350000
S3D	Defense & Aerospace	500
S4D	Aerospace	Around 900
S5D	Aerospace	650
S6D	Aerospace	18000
S7D	Aerospace	More than 17000

the interviewee and the company anonymous.

Table 51 – Product developed in the project.

#	**What is the project about? What is the product?**
S1D	"The project is about creating a solution for managing development data according to ISO 26262."
S2D	"Machine and machine lines for different kind of industry."
S3D	"Naval (gun) fire control."
S4D	"Avionics systems modernization installed in the ABC aircraft."
S5D	"Rocket events sequencer."
S6D	"New transport aircraft development."
S7D	"Air transport. Mainly the products are engines or FCC (Flight Control Computer)."

S7D reported an important issue faced by the company regarding the safety process. He/she said: *"The safety process is so complicated and there are a lot of open points that we can interpret differently. It's really hard to follow always the same process to generate the artifacts. Should have a way to not became easy, but less complicated regarding the interpretation and what the artifacts are needed."* This difficulty, reported by the subjects, about following the same process for all projects (since they have different scopes, teams sizes, domains and time of experience of the employees) contributes to the maturity model proposal since we define what to do and not how to do it.

7.2.6 Evaluation Results

We analyzed the maturity level of the organizations considering the structure of Uni-REPM: project, MPA and SPA. The results described in Table 53 show that all organizations skip

Table 52 – Project Details.

S#D	**How many man-hours for the project? (how many people involved in the project? How long does it last?)**
S1D	"More than 1500 hours by 4-5 people so far spread on 4 years that work directly with this project. This project is also supported by the general development of the ABC platform as well. Those numbers are not included in this figure. The project continues to evolve and includes an increasing number of customers and users."
S2D	"Around 1000 man hours (8 for me), usually around five people."
S3D	"25000 man hours, 15 people, 1 year."
S4D	"For the certification process, more than 20 people was involved and the process was finished in 2017 (initiated in 2009)."
S5D	"Approximately 10000h (worked) during 2 years and 20 people involved."
S6D	"10 years, 800 employees involved."
S7D	"We support the development team with tools to certification, like SCADE and MATLAB. The team is really volatile, but at most we have 10 engineers."

important steps during RE and all obtained level Incipient, i.e. none of the seven investigated companies satisfied all the actions of level 1 (Basic).

Table 53 – Maturity level of the projects.

Company	**Domain**	**Project maturity level**
1	Automotive	Incipient
2	Industrial machinery	Incipient
3	Defense & Aerospace	Incipient
4	Aerospace	Incipient
5	Aerospace	Incipient
6	Aerospace	Incipient
7	Aerospace	Incipient

Figure 47 shows the total number of safety actions performed by each project/company in its current process per MPAs, according to the Uni-REPM SCS, namely: Requirements Elicitation (RE), Documentation and Requirements Specification (DS), Requirements Analysis (RA), Release Planning (RP), Requirements Validation (RV), Organizational Support (OS), and Requirements Process Management (PM). In the X axis are arranged MPAs, in the Y axis is the amount of safety practices performed by MPA, and the number of complete practices by project is represented by colors according to the legend of the chart.

We noticed that Requirements Validation (RV) is completely satisfied by projects 1, 4, and 5; Requirements Analysis by projects 2 and 3; Release Planning (RP) by projects 2, 3 and 4; Documentation and Requirements Specification by project 5. Requirements Elicitation (RE) is the one MPA that the great majority of projects (five out of seven) performs all safety

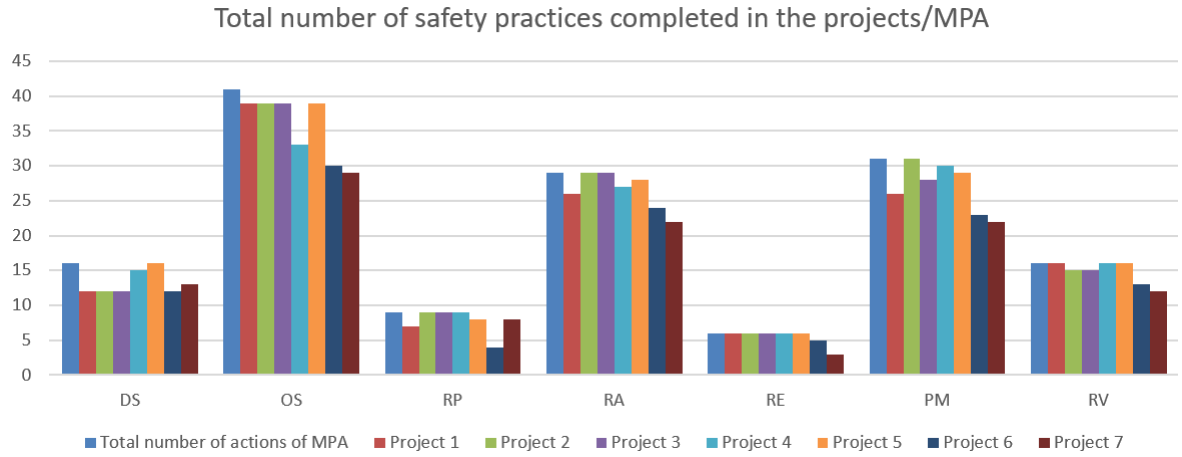

Figure 47 – Comparison of the total number of actions of all MPAs of the current process of each project/company.

practices.

Considering Documentation and Requirements Specification (DS) and Organizational Support (OS), we observed that 4 out 7 companies perform the same number of practices. It is important to note that in this chart we do not consider the maturity level of practices (this analysis is performed later from Table 56 to Table 62), just the total number. Finally, project 2 satisfies the higher number of safety actions (141 out of 148).

Table 54 shows a summary of the assessments results of each company regarding to the seven MPAs of Uni-REPM SCS. From the analysis of this table, we can notice that although the evaluated RE processes of the projects were classified as level Incipient in Table 53, some MPAs were classified as Intermediate or even as Advanced level. This occurs because some basic safety practices were not satisfied by the companies, consequently, they did not achieve the Basic Level for the entire project. These results also mean that all parts of the model are used by some of the companies.

We also performed the same comparison of SPAs on each project. Figure 48 shows the total number of satisfied safety actions in SPA by each project/company. In the X axis are arranged SPAs, in the Y axis is the amount of safety practices performed by SPA, and the number of complete practices by project is represented by colors according to the legend of the chart. The SPAs of Uni-REPM SCS are listed in Chapter 5.

From these results we concluded that Failure Handling is the SPA with higher coverage (6 out of 7 projects). Besides, project 2 has the same number of actions as the other projects or higher, and Project 7 usually perform worse than the other projects. Table 55 shows a summary of the assessments results of each company regarding the 14 subprocess areas of Uni-REPM SCS (see Table 15).

Tables 56 to 62 show the total number of safety practices at each maturity level proposed by Uni-REPM and the percentage of complete actions by each company per SPA and level.

Table 54 – Maturity level of the MPAs.

MPA	Project 1	Project 2	Project 3	Project 4	Project 5	Project 6	Project 7
Requirements Elicitation	Advanced	Advanced	Advanced	Advanced	Advanced	Incipient	Incipient
Documentation and Requirements Specification	Advanced	Incipient	Advanced	Intermediate	Advanced	Incipient	Incipient
Requirements Analysis	Advanced	Incipient	Advanced	Incipient	Incipient	Incipient	Incipient
Release Planning	Intermediate	Basic	Intermediate	Intermediate	Incipient	Incipient	Basic
Requirements Validation	Incipient	Advanced	Incipient	Advanced	Advanced	Incipient	Incipient
Organizational Support	Incipient	Incipient	Incipient	Incipient	Incipient	Incipient	Incipient
Requirements Process Management	Incipient	Incipient	Advanced	Incipient	Incipient	Incipient	Incipient

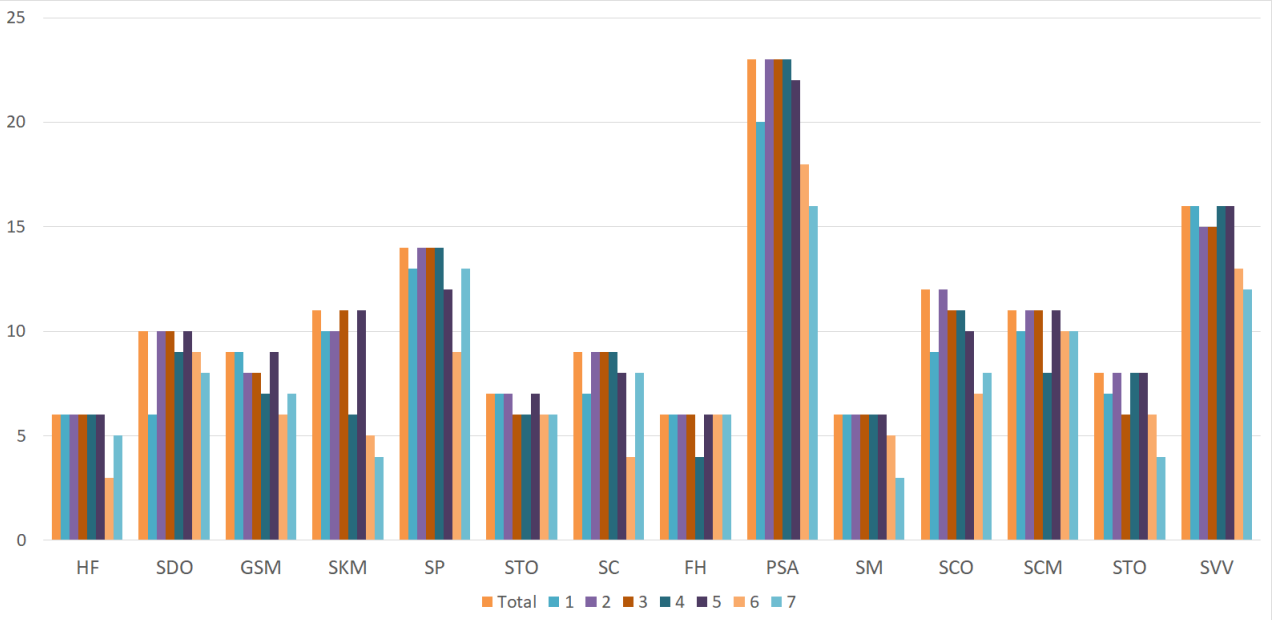

Figure 48 – Comparison of the total number of actions of each SPA of the current process of each project/company.

7.2.7 Feedback about the module

Considering the practitioners busy schedule, the feedback questionnaire was sent to them by email. We received the answers of six out of seven practitioner (S6 did not send the questionnaire). We sent reminders, but one practitioner did not return. Therefore, the feedback and percentages were calculated considering six answers.

Table 55 – Maturity level of the SPAs per project.

MPA	SPA	1	2	3	4	5	6	7
RE	Supplier Management	Advanced	Advanced	Advanced	Advanced	Advanced	Incipient	Incipient
DS	Human Factors	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Incipient	Incipient
	Safety Documentation	Advanced	Incipient	Advanced	Intermediate	Advanced	Intermediate	Incipient
RA	Preliminary Safety Analysis	Advanced	Incipient	Advanced	Advanced	Incipient	Incipient	Incipient
	Failure Handling	Intermediate	Intermediate	Intermediate	Incipient	Intermediate	Intermediate	Intermediate
RP	Safety Certification	Intermediate	Basic	Intermediate	Intermediate	Incipient	Incipient	Basic
RV	Safety Validation and Verification	Incipient	Advanced	Incipient	Advanced	Advanced	Incipient	Incipient
OS	Safety Planning	Advanced	Incipient	Advanced	Advanced	Incipient	Incipient	Incipient
	General Safety Management	Basic	Intermediate	Basic	Basic	Intermediate	Incipient	Incipient
	Safety Tool support	Incipient	Advanced	Advanced	Incipient	Advanced	Intermediate	Intermediate
	Safety Knowledge Management	Advanced	Intermediate	Incipient	Incipient	Advanced	Incipient	Incipient
PM	Safety Configuration Management	Advanced	Incipient	Advanced	Advanced	Advanced	Intermediate	Incipient
	Safety Communication	Incipient	Incipient	Advanced	Incipient	Incipient	Incipient	Incipient
	Safety Traceability	Basic	Basic	Intermediate	Intermediate	Intermediate	Basic	Incipient

Table 56 – Complete actions by level in Requirements Elicitation MPA.

MPA: Requirements Elicitation								
		1	2	3	4	5	6	7
Level	# Total	% Complete						
SPA: Supplier Management								
Basic	2	100	100	100	100	100	100	50
Intermediate	3	100	100	100	100	100	66.67	33.33
Advanced	1	100	100	100	100	100	100	100

7.2.7.1 Terminology

We asked the subjects if they are familiar with the terminology used in the Uni-REPM SCS. We observed that they understand mostly of the terminology and where actions needed some clarifications they put an observation in the tool as described in Section 7.5.1. Their answers were:

"Working with ISO 26262 I am familiar with most of the concepts discussed by UNI-REPM. Although sometimes another terminology was more familiar for me. I have made a note in my answers in these cases where I found something ambiguous." (S1D)

"Mostly." (S2D)

"Terminology is not hard to understand. " (S3D)

Table 57 – Complete actions by level in Documentation and Requirements Specification MPA.

MPA: Documentation and Requirements Specification								
		1	2	3	4	5	6	7
Level	#Total	% Complete						
SPA: Human Factors								
Basic	3	100	100	100	100	100	33.33	66.67
Intermediate	3	100	100	100	100	100	66.67	100
Advanced	0							
SPA: Safety Documentation								
Basic	4	50	100	100	100	100	100	100
Intermediate	5	60	100	100	100	100	100	80
Advanced	1	100	100	0	0	0	0	0

Table 58 – Complete actions by level in Requirements Analysis MPA.

MPA: Requirements Analysis								
		1	2	3	4	5	6	7
Level	# Total	% Complete						
SPA: Preliminary Safety Analysis								
Basic	11	81.81	100	100	100	100	90.91	63.64
Intermediate	11	90.91	100	100	100	90.91	63.64	72.73
Advanced	1	100	100	100	100	100	100	100
SPA: Failure Handling								
Basic	3	100	100	100	66.67	100	100	100
Intermediate	3	100	100	100	66.67	100	100	100
Advanced	0							

Table 59 – Complete actions by level in Release Planning MPA.

MPA: Release Planning								
		1	2	3	4	5	6	7
Level	# Total	% Complete						
SPA: Safety Certification								
Basic	4	100	100	100	100	75	50	100
Intermediate	5	60	100	100	100	100	40	80
Advanced	0							

"The terminology is quite simple to understand . " (S5D)

"All the terms are in the scope of our projects. Maybe because we work with software level A, for aerospace. " (S7D)

Practitioner S4D confirmed that he/she is familiar with the terminology used in the Uni-REPM safety module, but reported that found hard to understand the term "computer-aided":

Table 60 – Complete actions by level in Requirements Validation MPA.

MPA: Requirements Validation								
		1	2	3	4	5	6	7
Level	# Total	% Complete						
SPA: Safety Validation and Verification								
Basic	9	100	88.89	100	100	100	77.78	77.78
Intermediate	6	100	100	83.33	100	100	83.33	83.33
Advanced	1	100	100	100	100	100	100	0

Table 61 – Complete actions by level in Organizational Support MPA.

MPA: Organizational Support								
		1	2	3	4	5	6	7
Level	# Total	% Complete						
SPA: Safety Planning								
Basic	7	85.71	100	100	100	85.71	85.71	100
Intermediate	6	100	100	100	100	100	50	83.33
Advanced	1	100	100	100	100	0	0	100
SPA: General Safety Management								
Basic	4	100	100	100	100	100	50	75
Intermediate	5	100	80	80	60	100	80	80
Advanced	0	0						
SPA: Safety Tool support								
Basic	1	100	100	100	100	100	100	100
Intermediate	5	100	100	100	80	100	100	100
Advanced	1	100	100	100	0	0	0	0
SPA: Safety Knowledge Management								
Basic	1	100	100	100	100	100	100	0
Intermediate	7	100	85.71	100	71.43	100	57.14	42.86
Advanced	3	66.67	100	100	0	0	0	33.33

"Yes. "computer-aided"" (S4D)

7.2.7.2 Comprehension

The easiness of understand the SPAs in the module in practitioners opinion is presented in Figure 49.

We observed that great majority (83.3%) agree or strongly agree that the SPAs are easy to understand. This was a concern we have when defining the SPAs since we wanted to adopt the terms that are in fact used in the SCS domain. This may be an indication that such goal was achieved.

The easiness of understanding of the actions in the module in experts opinion is presented

Table 62 – Complete actions by level in Requirements Process Management MPA.

MPA: Requirements Process Management								
		1	2	3	4	5	6	7
Level	# Total	% Complete						
SPA: Safety Configuration Management								
Basic	4	100	100	100	100	100	100	75
Intermediate	6	83.3	100	100	100	100	100	100
Advanced	1	100	100	100	100	100	0	100
SPA: Safety Communication								
Basic	2	50	100	100	100	50	100	50
Intermediate	8	75	100	87.5	87.5	87.5	62.5	62.5
Advanced	2	100	100	100	100	100	0	100
SPA: Safety Traceability								
Basic	2	100	100	100	100	100	100	50
Intermediate	6	83.33	100	66.67	100	100	66.67	50
Advanced	0	0						

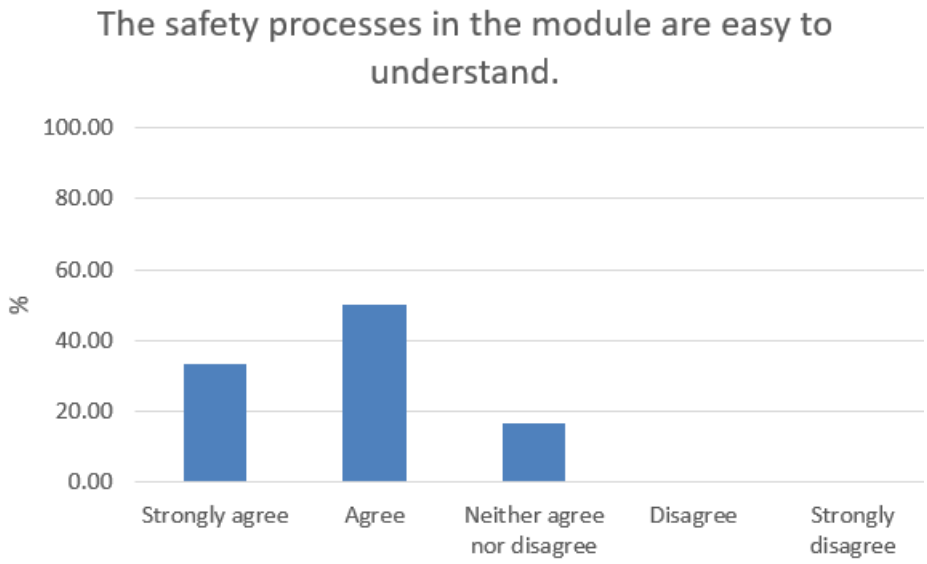

Figure 49 – Practitioners' opinion whether the SPAs are easy to understand.

in Figure 50.

We noticed that the actions were considered as easy to understand by 83.3% of subjects. We believe that the understanding of actions across domains is not compromised since the subjects work in different domains. Besides, we provide explanations for each action and examples.

7.2.7.3 Module coverage

Aiming to evaluate the module coverage, we asked the practitioners whether they perform any additional action(s) that is (are) not covered in the model. We observed that they did not

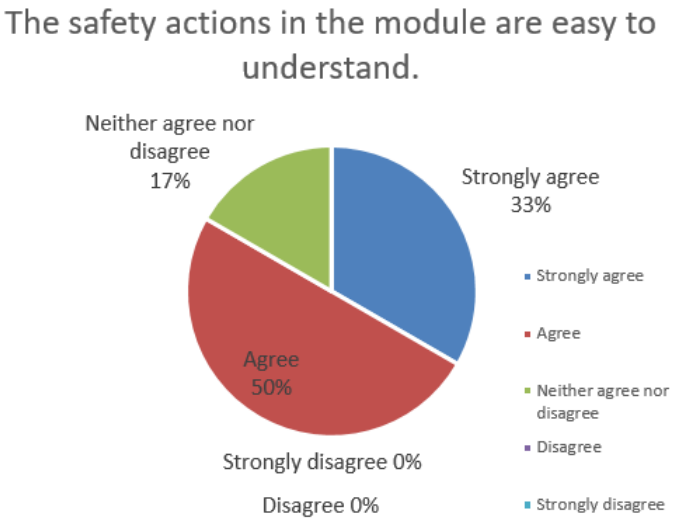

Figure 50 – Opinion of practitioners whether the actions are easy to understand.

report any action:

"I answered the questionnaire from the perspective of one of our customers working with ISO 26262. There are more parts to ISO 26262 than were covered by Uni-REPM but your model captures the heart of the ISO 26262 requirements. It also provides concrete actions for companies to develop their safety process further in case they do not already follow a safety framework or if they have not a mature safety process." (S1D)

"I read the included help texts". (S2D)

"No." (S3D)

"No." (S4D)

"No, we perform less actions compared with the model proposes." (S6D)

"No." (S7D)

It is important to note that S5 did not send the questionnaire.

7.2.7.4 Usefulness

To answer RQ4, we query the experts about the extent they believe the safety module will help requirements engineers to perform safety-related activities or tasks in the project (Figure 51).

We also asked whether they would adopt Uni-REPM SCS in their companies. The results are shown in Figure 52. S5D commented that decision of adoption is up to managers, but he/she strongly recommends:

"If I could chose to adopt the safety module I would. Although it is not up to me. I will strongly recommend."

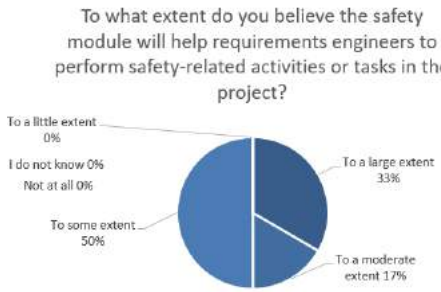

Figure 51 – Opinion about the usefulness of Uni-REPM SCS.

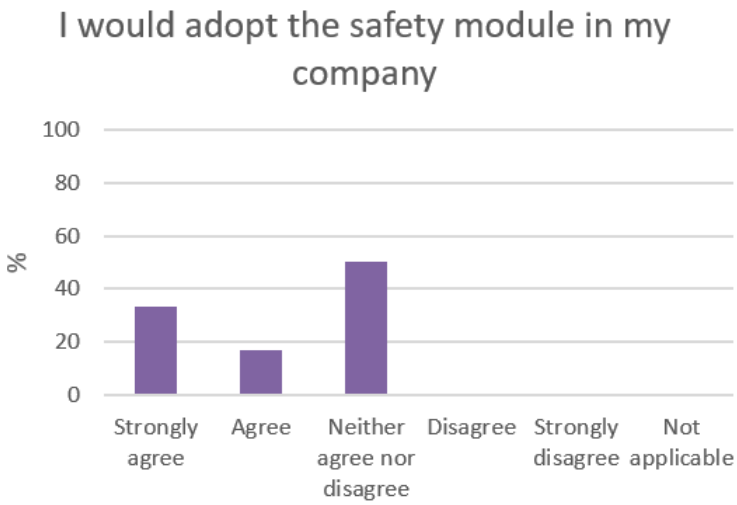

Figure 52 – Opinion of Practitioners whether they would adopt Uni-REPM SCS.

7.2.7.5 Safety practices that company could improve

Practitioners S2D and S3D from industrial machinery and defense & aerospace domains, respectively, commented that some practices could be better performed by the company as listed in Table 63.

Table 63 – Safety practices to improve in the safety module.

	Action	**Question**	**Comment**
S1D	RA.PSA.a3	Do you identify and document system hazards?	"*Room for improvements on our side.* "
	PM.SCO.a7	Do you construct a repository of common hazards?	"*Room for improvements.* "
	PM.SCO.a9	Do you document how conflicts will be resolved?	"*It could be, perhaps, better documented.* "
	PM.SCM.a9	Do you maintain and make available the software configuration management log?	"*Could perhaps be a little better handle but usually only as comment in the program.* "
S3D	OS.SKM.a5	Do you document a strategy to manage the knowledge?	*"Could definitely be improved, maybe with a safety information system. The usual solution is consultants.*"

7.2.8 Feedback about the support tool

The evaluation of the tool usability was based on the PSSUQ (The Post-Study System Usability Questionnaire) (LEWIS, 1995). This method provides a 19-item questionnaire, with administration and scoring instructions, that were used in usability measurement at IBM.

After the practitioners finished the safety evaluation using the Uni-REPM tool [2], they rated the system with the PSSUQ. These data allowed us to obtain feedback regarding the easy of use of tool that support the module.

The PSSUQ analyzes the system usability through four factors (overall satisfaction, system usefulness, information quality and interface quality) from the answers obtained from the evaluation questionnaire. Although it has 19 questions, we used only five closed-ended questions (see Table 64) that we consider the most important and one open question to subjects express their opinion. We made this choice due to the time constraints of the practitioners.

Table 64 – Questions used to evaluate the usability of Uni-REPM tool.

Question	**Options**
I could effectively complete a safety evaluation using this software tool.	( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree
I felt comfortable using this software tool.	( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree
I believe I could become productive quickly using this software tool.	( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree
This software tool has all the functions and capabilities I expect it to have.	( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree
Overall, I am satisfied with how easy it is to use this software tool.	( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

The ability of performing a safety evaluation using the tool was asked. The results are presented in Figure 53. One subject strongly agreed that he/she could effectively perform an evaluation, four subjects agreed and one subject marked neither agree or disagree. During the conduction of the first case study, we detected a problem with one of the libraries used making the tool not usable in the internet explorer navigator. We fixed this problem and now the tool supports Google Chrome (we tested on version 70.0.3538.102), Mozilla Firefox (60.3.0) and Internet Explorer (11.345.17134.0).

Their experience using the tool was evaluated by the sentence *I felt comfortable using this software tool.* In Figure 54, we see that three strongly agreed, two agreed and the third did not agree or disagree.

In Figure 55, one subject strongly agreed with the sentence *I believe I could become productive quickly using this software tool*, four agreed and one did not agree or disagree.

This software tool has all the functions and capabilities I expect it to have was the opinion of four subjects and two did not agree or disagree in Figure 56. The tool is not collaborative

[2] <http://www.cin.ufpe.br/~ler/unirepm>

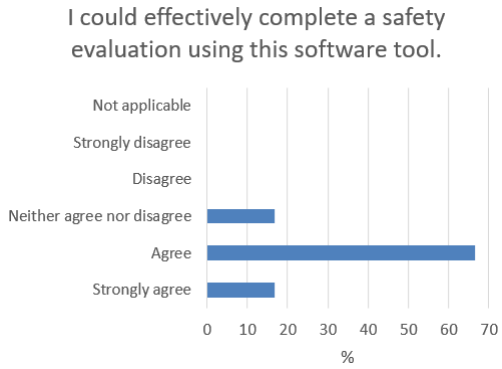

Figure 53 – Opinion of subjects if they could effectively complete a safety evaluation using the Uni-REPM tool.

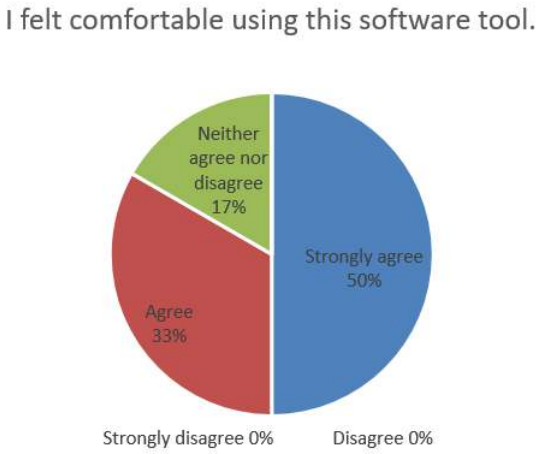

Figure 54 – Opinion of subjects if they felt comfortable using the tool.

Figure 55 – Opinion of subjects if could become productive quickly using the Uni-REPM tool.

yet, but we intend to add collaborative features as discussed in Section 6.6.

Two subjects strongly agreed that they were *satisfied with how easy it is to use this software tool*, three agreed and one did not agree or disagree.

Question #25 was an open-ended question to subjects provide further comments about

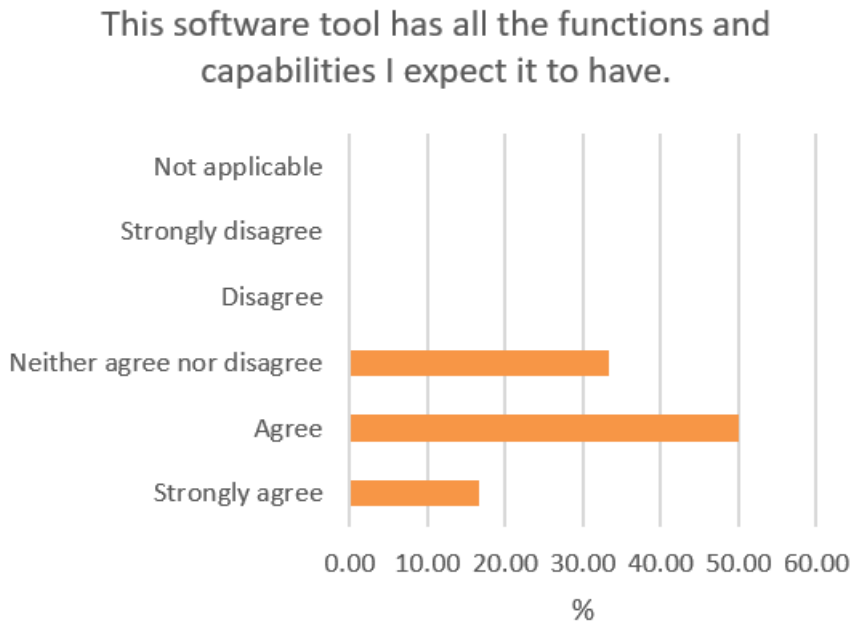

Figure 56 – Opinion of subjects if the tool has all the functions and capabilities they expected it to have.

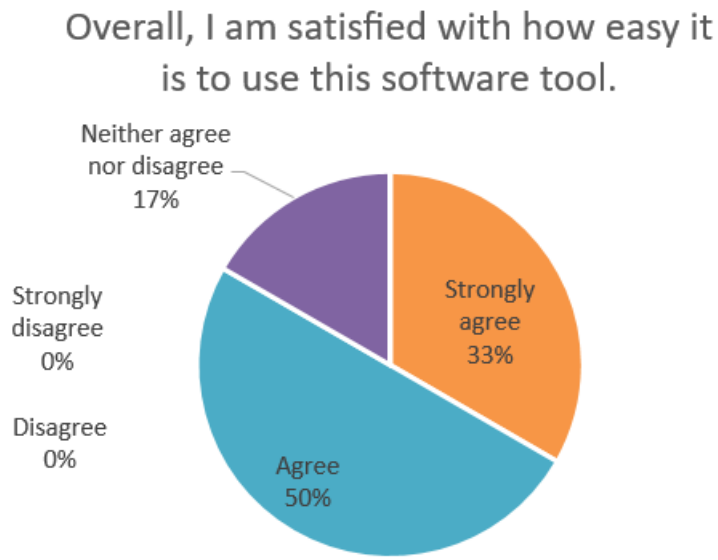

Figure 57 – Opinion of subjects if they are satisfied with how easy it is to use the tool.

the software tool. The practitioners answers were:

"More understanding of the actions and concrete recommendations for the next step would be appreciated although I am not sure how feasible this is in a generic case." (S1D)

"I could not use it with Internet Explorer, I had to use Firefox." (S2D)

"Many questions are "Yes/No" questions, but in practice it is not a black and white but rather a gray scale over how well the ambition is in the area. What if there was a scale from "Well implemented" to "Badly implemented" and a separate box for N/A? It's often not "Complete" but also not completely "Incomplete"." (S3D)

"I work in several areas of the project, and during almost all the entire lifecycle. Although in most companies this is not true. In order to answer all the questions, it is needed a team, or the software tool be used by several members of the team and correctly designated to them." (S5D)

"For sure, it's not an easy topic. The tool is really efficient but many projects we don't need all the formalities. I believe the final result should take in account the percentage of applications. I don't think its a good idea evaluate as ZERO if the project is missing only one step." (S7D)

Some feedback we received from these practitioners using the tool were:

"*... we have to realize what we don't do today and, perhaps, this one (action) is good and we have to be better...*" (S1D)

"*...the ideas...in this tool can help... perhaps to think in some improvement...in a context...*" (S2D)

"*...Can we use the mapping from the safety standards? .. We can get support of your work in mapping the standard to the questions.*" (S3D)

7.3 SAFETY MATURITY LEVEL ACHIEVED BY INVESTIGATED SOFTWARE DEVELOPMENT COMPANIES

In Section 7.2.6, we presented that the interviews results showed that the RE processes of the projects of the analyzed companies did not achieve any maturity level considering the Uni-REPM SCS maturity assessment framework. We also analyzed which main process areas have the largest and smallest number of activities carried out in the companies current process.

In order to verify how close or distant the companies are to reach a level of maturity, a latency analysis by maturity level was performed. Through this analysis, it is possible to verify how many safety actions will be necessary for the maturity at each of the Uni-REPM SCS levels. The latency charts by the current process level are presented from Figure 58 to Figure 64. These process latency charts, by level, consider all MPAs (Main Process Area) of the respective level.

The latency of project 1 (Figure 58) shows that out of 57 proposed actions at the basic level, the company carries out in its current process 51 actions; at the intermediate level, from the 79 actions proposed by Uni-REPM SCS, the company performs 70; and in the advanced level, out of the 12 actions, the company performs 11.

For the company achieve the basic level maturity, it needs to insert in its process 6 actions; to be considered with intermediate level maturity, it needs 9 more actions; and the advanced level maturity can be achieved with the inclusion of one more action.

The Project 2, whose latency is illustrated in Figure 59, also did not reach any maturity level of the Uni-REPM SCS, with 56 out of 57 actions in basic level, 77 actions out of 79 in intermediate level and 12 out of 12 in advanced level. This was the project that had the best level of maturity with lower latency.

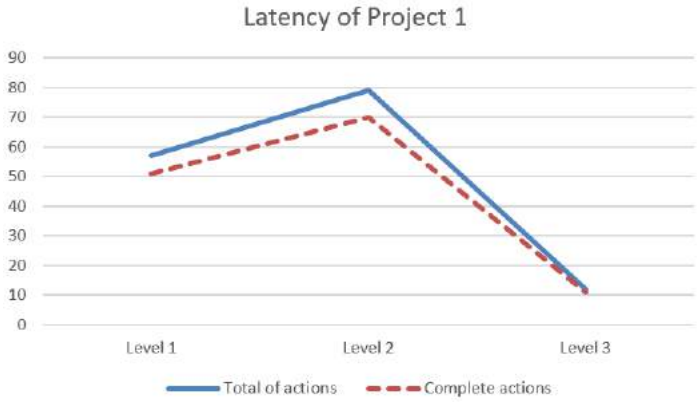

Figure 58 – Latency by maturity level of project 1.

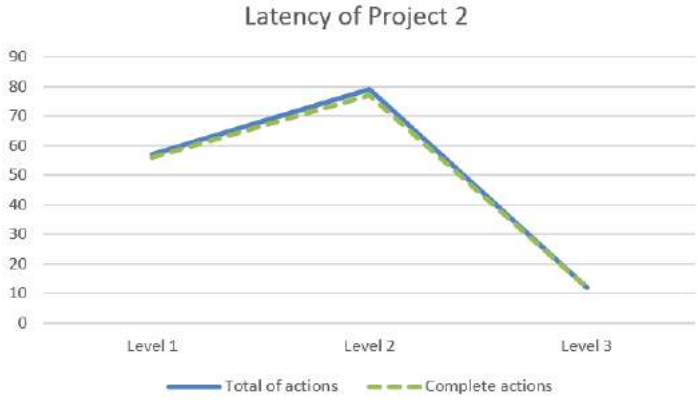

Figure 59 – Latency by maturity level of project 2.

Likewise, Figure 60 shows that project 3 also did not reach any maturity level of the Uni-REPM SCS, with 56 actions out of 57 in basic level, 74 actions out of 79 in intermediate level and 12 out of 12 in advanced level.

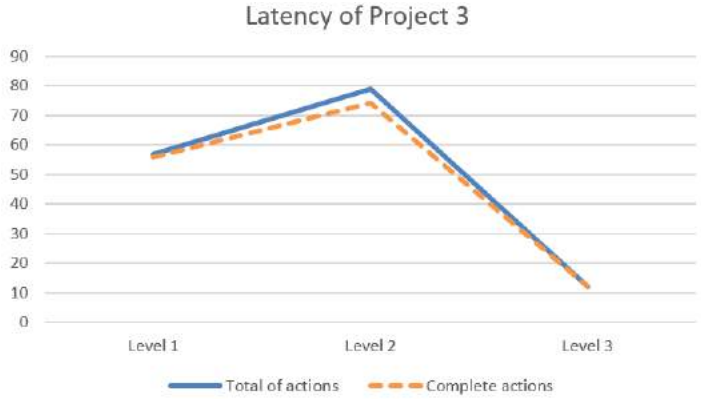

Figure 60 – Latency by maturity level of project 3.

The latency of project 4 (Figure 61) shows that out of 57 proposed actions at the basic level, the company carries out in its current process 56 actions; at the intermediate level, from

the 79 actions proposed by Uni-REPM SCS, the company performs 72; and in the advanced level, out of the 12 actions, the company performs 8.

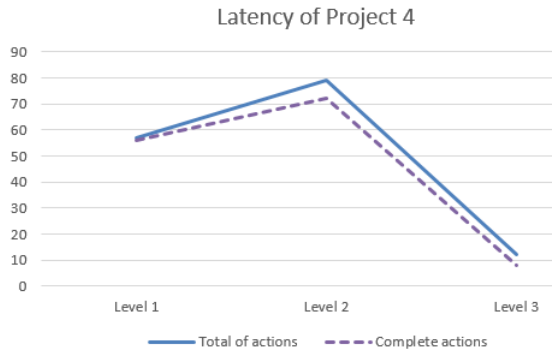

Figure 61 – Latency by maturity level of project 4.

Figure 63 presents the latency of project 5. The company performs 54 out of 57 actions in basic level, 77 actions out of 79 in intermediate level and 6 out of 12 in advanced level.

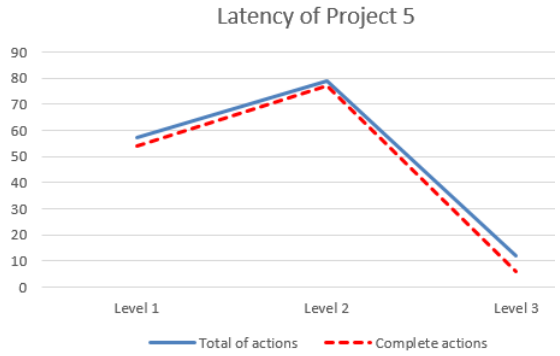

Figure 62 – Latency by maturity level of project 5.

The Project 6, whose latency is illustrated in Figure 63, also did not reach any maturity level of the Uni-REPM SCS, with 47 out of 57 actions in basic level, 57 actions out of 79 in intermediate level and 3 out of 12 in advanced level.

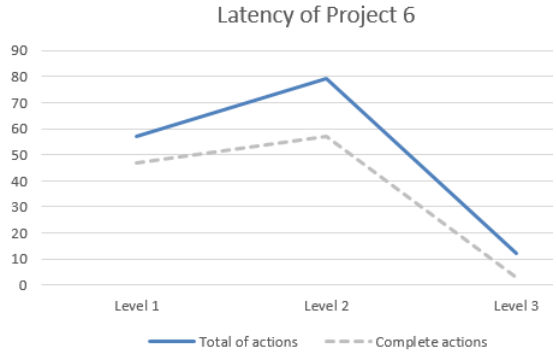

Figure 63 – Latency by maturity level of project 6.

Likewise, Figure 64 shows that project 3 also did not reach any maturity level of the Uni-REPM SCS, with 44 actions out of 57 in basic level, 59 actions out of 79 in intermediate level and 7 out of 12 in advanced level.

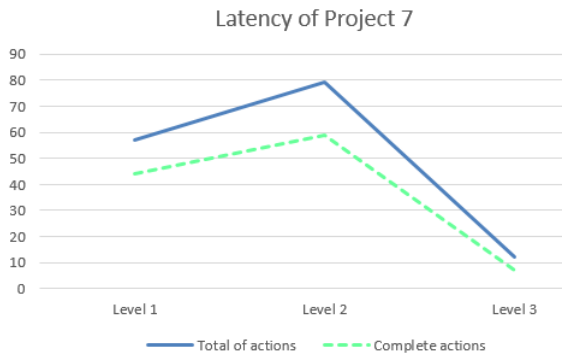

Figure 64 – Latency by maturity level of project 7.

This form of presentation, through the latency graphs, provides an overview of the current processes in relation to Uni-REPM SCS. We noticed that companies are really close to complete all actions proposed by the safety module.

7.4 ANALYSIS OF THE SAFETY MODULE APPLICABILITY

Another view of analysis of the safety module applicability consisted of the investigation of the model lag. This concept used by Uni-REPM (SVAHNBERG et al., 2013) means the number of actions deemed "inapplicable". This analysis allows to verify if we have a high number of actions that practitioners considered not necessary in their context. According to the authors, if an action does not suit a particular company, this is simply viewed as a deficiency of the model itself - a lag between the prescribed and the needed practices.

A summary of the module lag is presented in Table 65 along with the domain of each project, the maturity level achieved, and the list of actions marked as inapplicable by the practitioner. The model lag is presented in per cent along with the number of actions for each project. The highest lag occurred in project #2 with 10 out of 148 actions that corresponds to 6.8% of the total number of actions. This means the module has a good applicability and that the proposed safety actions are in fact used by the SCS companies.

Table 65 – Module lag summary.

Company	Domain	Maturity level	Lag	Inapplicable Action(s)
1	Automotive	Incipient	0	
2	Industrial machinery	Incipient	10/148 (6.8%)	DS.HF.a3 Do you evaluate prototypes, requirements and technical UI restrictions? DS.HF.a4 Do you model and evaluate operator tasks and component black-box behavior? DS.SDO.a7 Do you document lessons learned? OS.GSM.a7 Do you make use of indicators on engineering documentation to assess the product properties and the development progress? OS.GSM.a8 Do you prepare progress reports in a period of time defined by the project? OS.SKM.a11 Do you manage assets? OS.SKM.a3 Do you define control access mechanisms to the safety information system? OS.STO.a3 Do you assess offline support tools which can directly or indirectly contribute to the executable code of the safety related system? OS.STO.a5 Do you use of tools with support to cross reference and maintain the traceability among safety information in the software specification? RP.SC.a3 Do you evaluate the threat to society from the hazards that cannot be eliminated or avoided?
3	Defense & Aerospace	Incipient	3/148 (2%)	PM.SCM.a9 Do you maintain and make available the software configuration management log? PM.SCM.a11 Do you upload all documents on the safety information system? PM.ST.a8 Do you justify reasons for not traced software requirements?
4	Aerospace	Incipient	9/148 (6.1%)	DS.HF.a4 Do you model and evaluate operator tasks and component black-box behavior? OS.GSM.a4 Do you set safety policy and define safety goals? OS.GSM.a8 Do you prepare progress reports in a period of time defined by the project? OS.STO.a2 Do you specify justifications for the selection of the offline support tools? OS.STO.a3 Do you assess offline support tools which can directly or indirectly contribute to the executable code of the safety related system? OS.STO.a6 Do you use of computer-aided specification tools? RA.FH.a1 Do you define requirements for the avoidance of systematic faults? RA.PSA.a15 Do you identify and document safety constraints and how they could be violated? PM.ST.a8 Do you justify reasons for not traced software requirements?
5	Aerospace	Incipient	0	
6	Aerospace	Incipient	4/148 (2.7%)	DS.HF.a5 Do you define interfaces considering ergonomic principles? DS.SDO.a4 Do you develop and document training, operational and software user manuals? DS.SDO.a6 Do you provide a safety manual? RV.SVV.a6 Do you define and maintain a software integration test plan?
7	Aerospace	Incipient	1/148 (0.7%)	OS.SP.a3 Do you define and document the interface between system safety and all other applicable safety disciplines?

7.5 IMPROVEMENTS PERFORMED BASED ON THE FINDINGS

Considering the practitioners comments during the interviews and their feedback in the open-ended questions #19 and #21, response actions were decided and the model was refined and improved. We discuss them in the next subsections.

7.5.1 Comprehension

During the interviews, the practitioners suggested the rewriting of some questions to make them more clear. Ten suggestions, described in Table 66, were made being 5 from S1, 2 from S2 and 3 from S3. We agreed with them, and we have changed these questions. The updated safety module description presented in Appendix B.

7.5.2 Regarding new actions

Considering the practitioners comments about the actions, we believe that the module has a good coverage of safety practices. These results contribute to increase our confidence in its coverage (RQ2). Such results are aligned with our previous study with nine academic experts and two practitioners in the static validation (see Section 7.1). Since the practitioners did not report any additional action (s) or suggested remove any action, we maintained the 148 actions.

7.5.3 Regarding new answer options and new evaluation format

S3 suggested adding new answer options:

"Many questions are "Yes/No" questions, but in practice it is not a black and white but rather a gray scale over how well the ambition is in the area. What if there was a scale from "Well implemented" to "Badly implemented" and a separate box for N/A? It's often not "Complete" but also not completely "Incomplete"." (S3)

We agree with the practitioner that, in some cases, an action is partially incomplete. Hence, we are discussing the possibility and viability of implementing this new scale in a future version of Uni-REPM SCS.

S7 suggested changing the evaluation format:

"I believe the final result should take in account the percentage of applications. I don't think its a good idea evaluate as ZERO if the project is missing only one step." (S7)

We understand that this may be seen as not fair, if a company performs all actions of a MPA or SPA and does not just one basic action, in this current version of Uni-REPM, it was classified as Zero Level. However, considering this suggestion, we change Zero level to Incipient level. Changing the evaluation format for ranges in each maturity level requires a lot of effort and changes. We are discussing the feasibility of this changing and how we can implement it in a future version of the module.

Table 66 – Suggestions for changing actions.

Subject	Action	Question	Comment
S1	OS.SP.a4	Do you delineate the scope of safety analysis?	"*I was not familiar with the word delineate. Maybe you can use another word?*"
	RP.SC.a2	Do you demonstrate the preliminary level of safety achieved by the system?	"*Maybe the question can be clarified a bit. An example would be good.*"
	RA.PSA.a21	Do you identify and document analysis and verification requirements, possible safety-interface problems, including the human-machine interface, and operating support requirements?	"*Perhaps the question should be more clear and specific.*"
	PM.SCM.a8	Do you document the procedures for initiating modifications to the safety-related systems, and to obtain approval and authority for modifications?	"*Please clarify and rephrase the question.*"
	RV.SVV.a14	Do you ensure that software requirements and interface specification are consistent?	"*Please clarify what kind of interface you are referring to.*"
S2	PM.SCM.a10	Do you appoint all deliverable documents according to the rules defined in the Configuration Management Plan?	''*Bad wording.*"
	PM.SCM.a2	Do you define and document change-control procedures?	"*Should be better specified.*"
S3	OS.SKM.a7	Do you define and maintain a strategy for reuse?	"*Perhaps to divide this question into one general level and one specific level.*"
	OS.SKM.a8	Do you reuse the stored knowledge?	"*This question should be better specified.*"
	OS.SKM.a9	Do you document the use of stored knowledge?	"*This question should be better specified.*"
S4	DS.HF.a1	Do you construct operator task models?	"*Suggestion: change the action to "way of work of the operator" to not give rise to the interpretation that is a tool (model)*"
	DS.SDO.a6	Do you provide a safety manual?	"*Suggestion: change to system operation manual."*
	OS.STO.a2	Do you specify justifications for the selection of the offline support tools?	"*Remove the term "offline"* "
	OS.STO.a3	Do you assess offline support tools which can directly or indirectly contribute to the executable code of the safety related system?	
	OS.STO.a6	Do you use of computer-aided specification tools?	"*Note: I am not familiar with the term "computer-aided". Not applicable within a certification process. More suitable for development.*"
	RA.FH.a1	Do you define requirements for the avoidance of systematic faults?	"*Note: Change from "avoid" to "minimize."* "
S5	PM.SCM.a1	Do you maintain accurately and with unique identification all safety configuration items and safety information (hazards, safety requirements, risks, etc.) ?	"*Improve the text a bit (make it more direct)*"
S7	DS.HF.a3	Do you evaluate prototypes, requirements and technical UI restrictions?	"*We are used to call UI as HMI (Human Machine Interface).*"
	OS.SP.a13	Do you determine the required performance level?	"*Question should be more clear.*"

7.6 VALIDITY THREATS

7.6.1 Static Validation

Our experience confirmed that planning, preparing and executing validations require extensive effort (NGUYEN, 2010). Six months were needed to elaborate a careful design of the static validation to ensure that nothing important was missing and no error would be made; selecting

and contacting experts; and analyzing the results.

The aim of the static validation was to identify possible improvements that can be done to the Uni-REPM SCS. With the help and feedback from two practitioners and nine experts from academia coming from various countries with diversified expertise, significant improvement in the module were performed. With this validation, we evaluated all aspects of the module structure (SPAs, actions and maturity levels).

The module was analyzed in terms of correctness, coverage, usefulness, and applicability. The majority of the suggestions were regarding the maturity levels of actions. We addressed 98 of 120 suggestions and a revised version of the module was generated and it is available at <http://www.cin.ufpe.br/~ler/unirepm>. We did not perform follow-up interviews with the subjects nor different set of experts to obtain feedback about this revised version. We plan to perform this in future studies.

We acknowledge that there is some subjectivity in deciding which actions would be included in the module and the maturity level assigned. However, this is an issue of any proposed maturity model. Well-adopted maturity models such as ISO 15504, CMMI, and MPS.BR and bodies of knowledge such as PMBOK just state that their set of practices reflects current industry best practices. Furthermore, they are frequently updated and new practices/actions are added or removed in each release. Thus, maturity models should be seen as constantly evolving – just like all models of this type.

We believe that domain-dependent safety maturity models are not feasible since safety-critical systems share many practices as present in different safety-standards. Related solutions such as ISO 15504-10, +Safe-CMMI are domain-independent as well. If a practice is not applicable in a particular context, the evaluator can mark it as Inapplicable. This "feature" is built into the framework of this model. Moreover, the improved model was fairly complete as there were no suggestions about adding new actions. According to the experts opinions, the actions in the model are applicable in real settings. Therefore, our research questions were answered and our goal to validate the module was successfully achieved.

The fact we had more academic experts than practitioners in the static validation may be a threat to validity. In our opinion, this is not a major threat since the framework of technology transfer states that the first validation in a candidate solution should be performed in academia. Therefore, in our vision, having two practitioners is a benefit for this validation and not a threat.

Finally, the purpose of this model is to present good practices that give an organization ideas to improvement. However, it is the organization responsibility to decide whether the recommended practices are indeed beneficial and suitable and when to implement them. We observed in our interview with one of the practitioners that the actions that most attracted him/her were those of the subprocesses "Safety Tool support" and "Safety Traceability". The reasons were that the company does not yet use a support tool for requirements engineering or safety analysis; and they do almost nothing in terms of traceability. Therefore, we noticed that

they have learned these practices after participating of Uni-REPM SCS' validation process.

7.6.2 Dynamic Validation

Case studies do not generate the same results of controlled experiments like the possibility of testing causal relationships, but they provide deeper understanding of the phenomena under study in its real context (WOHLIN et al., 2012). This critique were addressed by applying proper research methodology practices and accepting that knowledge is not only statistical significance (FLYVBJERG, 2006)(WOHLIN et al., 2012).

It is important to consider the validity of the case study from the beginning. To achieve this, we chose a classification scheme to discuss the validity threats which is also used by Runeson and Höst (2009) and Yin (2003) that it is similar to what is usually used in controlled experiments in software engineering (WOHLIN et al., 2012). This classification distinguishes among four aspects of the validity discussed below.

Construct validity: it is concerned with the extent to which the study setting reflects the construct under study that include the potential problem of evaluation apprehension, among others. In our study, threats were mitigated by the anonymity of the participants, as well as the guarantee that all information obtained during the interviews would be used only by the researchers.

Internal validity: threats in this type are related to the possibility of uncontrolled factors influencing the results obtained. Therefore, in the evaluation, we did not perform a previous training on how to use the module and the tool. The knowledge of each participant in Uni-REPM SCS could have been decisive in their evaluation. Therefore, to mitigate this threat, it was ensured that the selected participants did not know the maturity model. Moreover, to ensure that the results represent the reality, we interviewed team members with different roles in each study. According to Niazi, Wilson and Zowghi (2005), the variety in company type, size, nature of business, age, type of applications and other aspects can limit sample bias. Therefore, the collection of data from different companies and the rigor used in the execution of the case studies and analysis process contributes to reinforce the internal validity. We tested the module by using the tool at the same time due to the availability of the practitioners. This can be a threat to validity, hence, in future works, we intend to perform separately tests for the module and for the tool to verify if we have the same acceptance for the tool and the module as we obtained in the seven case studies presented in this thesis.

External validity: it is concerned with the extent to which the research findings can be applied or used in contexts different from those in which the study was conducted. To mitigate threats of this type, we detailed the research method so that other researchers can use the procedures to produce similar and comparable studies. Moreover, we sampled the participants to achieve maximum variation since this would provide richer data. Furthermore, the generalization in the statistical sense (from a random sample for the population) is not possible in qualitative research. This occurs because cases are selected purposely because the researcher

wants to understand the facts in depth and not find out what is usually true for many cases. Therefore, the qualitative results are generalizable to the theoretical propositions and not to the populations or universes. Our study has achieved results that are compatible with other studies that evaluate the maturity level of organizations. For example, Haddad et al. (2016) presents the evaluation of 20 companies in Brazil using Uni-REPM and none of the companies achieved some maturity level.

Reliability: it is related to the extent to which the research findings can be replicated by the same or other researchers. We believe that following the same procedures, data collection techniques and conditions will result in similar data if the same set of projects were selected to evaluation. Hence, the results of other studies may lead to similar or identical theoretical explanations. To reduce threats in replications of the study all material used in the case studies is available in this thesis. Therefore, other researchers may also replicate the assessment.

7.7 FINAL CONSIDERATIONS

This chapter described the planning and results of a static validation that we conducted with 11 subjects (two practitioners and nine academic experts). We evaluated the Uni-REPM SCS considering its coverage of safety practices; correctness of the proposed maturity levels; usefulness and applicability by collecting the experts opinion about the module application in industrial settings and to what extent.

We also described seven case studies that we conducted to evaluate the maturity level of safety processes in requirements engineering. It presented seven holistic cases studies with companies of defense & aerospace, automotive, and industrial machinery. The practitioners evaluate the RE process of seven projects and provide feedback about the safety module regarding its coverage and usefulness and applicability and about the tool developed to support the Uni-REPM. In the next chapter, we discuss the results obtained in this thesis.

8 DISCUSSIONS AND CONCLUSIONS

Investigations into the causes of accidents suggest that more rigour is required in setting the requirements and specification of safety-related systems. In this context, safety engineering is effective when it participates in and provides input to the RE process and to the system design. The main objective of the SLR we conducted (Chapter 4) was to synthesize the existing knowledge about the integration between RE and safety engineering. Different aspects of such integration was analyzed such as activities, hazard/safety techniques, relationships between safety information, tools to support safety analysis as well as the benefits of the integration.

When developing SCS, RE activities and processes are critical to avoid the introduction of defects and misunderstandings among engineers and developers (LEVESON, 2011) (FIRESMITH, 2004) (PERNSTÅL et al., 2015). An elaborated RE approach is crucial in order to meet time, cost, and quality goals in safety-critical systems development (SIKORA; TENBERGEN; POHL, 2012)(HATCLIFF et al., 2014). Therefore, the integration between RE and safety engineering is desired by academia and industry (LEVESON, 2011) (LUTZ, 2000) (MARTINS; GORSCHEK, 2016a) (HEIMDAHL, 2007) (SIKORA; TENBERGEN; POHL, 2012) (HATCLIFF et al., 2014).

However, requirements engineers, traditionally, are not well familiar with system safety analysis processes which are usually performed by safety engineers. One reason is the gap that exists among the traditional development processes, methodologies, notations and tools used in safety engineering (SCHOLZ; THRAMBOULIDIS, 2013)(STANDARDIZATION, 2011c)(SEI, 2007).

Furthermore, according to Leveson (1995), for practical reasons, training a software engineer in system safety may be more successful than training a safety engineer in software engineering. This work is a step in this direction to reduce the gap between RE and safety engineering. Accordingly, requirements engineers need systematic guidance to consider the safety concerns early in the development process of a safety-critical system.

In this context, determining the capability or maturity of safety processes has been identified as necessary to have more technical results that can be used in a continuous process improvement (JOHANSSON; NEVALAINEN, 2012) (JOHANNESSEN; HALONEN; ÖRSMARK, 2011). Improving the software process quality is a strategy adopted by many companies as a way to increase the confidence in the quality of the resulting software product (SOMMERVILLE, 2011) (LAMI; FABBRINI; FUSANI, 2011b).

In order to achieve such improvement, companies need methods to assess the strengths and weaknesses of their processes, and to develop strategies to mitigate the problems found (REIS; MATHIAS; OLIVEIRA, 2016).

The goal of this research is to *Improve* the quality of safety requirements engineering process *by* developing a safety module for Uni-REPM maturity model *that* is useful and suitable to domain-independent systems *in order to* help to increase safety processes maturity

levels and further develop safer systems.

In this thesis, we propose a Safety Module (described in Chapter 5), which consists in an enhancement of the Uni-REPM maturity model. The module has seven main processes, 14 sub-processes and 148 safety actions describing principles and practices that form the basis of safety processes maturity.

In Chapter 7, we presented the design and results of a static validation conducted with two practitioners and nine academic experts to evaluate the module usefulness, correctness and completeness. Seven case studies we conducted to evaluate the maturity level of safety processes in requirements engineering were also described. It presented seven holistic cases studies with companies of defense & aerospace, automotive, and industrial machinery.

In next sections, we discuss the contributions of this thesis by reflecting on the results and describe how we addressed the research questions presented in Section 1.4.

8.1 RQ1: WHICH SAFETY PRACTICES/ACTIONS ARE SUITABLE TO BE USED IN THE REQUIREMENTS ENGINEERING PROCESS OF SAFETY-CRITICAL SYSTEMS?

The module construction process started with the investigation of literature available about RE in SCS. Accordingly, we performed a SLR (VILELA et al., 2017a) and analyzed others found in the literature (MARTINS; GORSCHEK, 2016b) to investigate the problem domain, learn the concepts involved as well as to explore the problems in the integration of these RE and safety (SLR1, SLR2).

With this investigation, we have gained the necessary knowledge to be able to select the information sources of the safety practices proposed in this Uni-REPM Safety module. The sources, see Table 14, comprised well-known authors of the field (STATE-OF-THE-ART), international standards (SAFETY-STD), existing maturity models (EXISTING-MATURITY-MODS), and empirical studies (INTERVIEW-STUDY, TECH-REPORT). Hence, we chose sources from academia and industry.

We have selected 148 safety practices capable of raising the likelihood that the right system will be built (DAVIS; ZOWGHI, 2006). The practices are presented in Table 30, Table 31, Table 32, Table 33.

During the selection of safety actions/practices, we considered the definition of requirements practice of Davis and Zowghi (2006). They classify requirements practices as the adoption of a principle, tool, notation, and/or method in order to perform a RE activity. When a practice reduces the cost of the development project or increases the quality of the resulting product, it is labeled as good requirements practice (DAVIS; ZOWGHI, 2006)(SOLEMON; SAHIBUDDIN; GHANI, 2009).

The practices were evaluated in the static validation by two practitioners and nine academic experts (Section 7.1); and in the dynamic validation by practitioners of seven companies (Section 7.2).

8.2 RQ2: HOW TO DESIGN A SAFETY MATURITY MODEL FOR THE REQUIREMENTS ENGINEERING PROCESS OF SAFETY-CRITICAL SYSTEMS?

To define the architectural structure of our module, we have identified a set of requirements and characteristics presented in maturity models, described in Section 2.3. Accordingly, we considered such characteristics as well as the twofold purpose of the Uni-REPM: Process Area view and a Maturity Level view.

The process area view allows to visualize the hierarchy of processes that consists the model and to facilitate the discovery of practices of the same group. The maturity level view, on the other hand, defines sets of practices that compose a consistent and coherent RE process, and where the practices in one level supports each other as well as the more advanced practices on the next level (SVAHNBERG et al., 2015).

The safety practices (RQ1) were organized in sub-process areas to separate activities that belong to the same group. We did not performed any change in the seven (Requirements Elicitation, Documentation and Requirements Specification, Requirements Analysis, Release Planning, Requirements validation, Organizational Support, and Requirements Process Management) main process areas of the Uni-REPM that were defined considering well-adopted RE processes.

From the list of safety actions/practices previously elicited, we group them in fourteen sub-process areas (Safety Planning - SP, Supplier Management - SM, Preliminary Safety Analysis - PSA, Failure Handling - FH, Safety Validation and Verification - SVV, Safety Certification - SC, General Safety Management - GSM, Safety Configuration Management - SCM, Safety Communication - SCO, Human Factors - HF, Safety Tool support - STO, Safety Documentation - SDO, Safety Traceability - ST, Safety Knowledge Management - SKM).

In the Maturity Level View, we assigned a level ("Basic", "Intermediate", and "Advanced") to each action considering the difficulty to implement the action, how essential it is for the RE process, and dependencies among them (SVAHNBERG et al., 2015).

Our module has 148 safety actions to be adopted in the RE process. These actions should be used as a guide in the development process. Hence, the module is focused on what to do instead of how to do. It can not be considered as a process itself, as this would be very difficult to propose one because of the many different contexts in several organizations from different application domains where it would be applied. This focus provides flexibility for different organizations to use established "in-house" procedures or processes.

For example, we say that hazards, safety requirements, accidents, risks, and other concepts must be documented as defined in Section 2.1. However, it is out of the module scope to prescribe which technique the company should use to elicit these information, the safety analysis method it will adopt, as for example FTA (BROOMFIELD; CHUNG, 1997b), HAZOP (KLETZ, 1997), STAMP (LEVESON, 2011), etc.; or how the company will document (natural language, model-based, which language etc).

Therefore, by proposing a comprehensive set of safety practices, our aim is to provide clear

guidance addressing some critics that maturity models do not look deeply enough into all organizational practices (SOLEMON; SAHIBUDDIN; GHANI, 2009).

8.3 RQ3: HOW DOES THE PROPOSED SAFETY MATURITY MODULE COMPARE WITH RELATED SOLUTIONS?

In Section 2.5, we have discussed the body of knowledge with respect to maturity models and we present a comprehensive comparison among Uni-REPM SCS, + SAFE and ISO 15504-10 in Section 5.4. Therefore, we identified similarities, and differences with our work that have helped us to position our Uni-REPM SCS with respect to the related available solutions.

Hence, it is out of scope with the module to provide evidence of meeting regulatory requirements/standards. First, some of them have domain-specific requirements that are not covered by our proposal. There are several works of safety evidence, traceability and certification in the literature. Our aim is to improve the development process by addressing many safety practices early in the development process, i.e. adopt practices in Requirements Engineering phase, instead of handling in later stages of software development. Since they will be handled in the beginning, many artifacts and evidence will be produced and documented when satisfying the practices in the module. This is an indirect contribution.

Independently of domain, companies can and do develop successful systems without maturity models. However, literature reports (SOMMERVILLE, 2011)(REIS; MATHIAS; OLIVEIRA, 2016) that deadlines and budgets are routinely exceeded, resources are wasted, and there are a lot of rework. For very large systems that include separate subsystems such as SCS, developed by teams who may be working in different locations, an important factor that affects product quality is the software process. The major problems with large projects are integration, project management, and communication (SOMMERVILLE, 2011). There is usually a mix of abilities and experience in the team members and, because the development process usually takes place over a number of years, the development team is volatile. It may change completely over the lifetime of the project.

Accordingly, our goal in proposing this maturity model is to contribute to a company to evaluate its strengths and weaknesses, to develop improvement plans when compared to other organizations standards and best practices. The maturity model we propose is more detailed than others, and useful because it was designed specifically for SCS and contains a comprehensive assessment instrument. This model can be used to help an organization defining what to improve or implement next in order to make their processes more efficient.

8.4 RQ4: WHAT IS THE EFFECT OF APPLYING UNI-REPM SAFETY MODULE WHEN IT IS INSTANTIATED IN DIFFERENT SAFETY-CRITICAL DOMAINS?

In order to evaluate whether the results are diverse in different domains, we interviewed seven companies from three countries that work in distinct contexts: defense & aerospace, automo-

tive, and industrial machinery. All companies vary in relation to size (in number of employees and number of requirements in typical projects) as listed in Table 67 and type of customers.

Table 67 – Number of employees and number of requirements in typical projects of the investigated companies.

	Number of employees	**Number of requirements in typical projects**
Company 1	20	∼2000
Company 2	∼4000	∼300
Company 3	∼14500	∼1000
Company 4	∼900	∼50
Company 5	∼650	∼27
Company 6	∼18000	Not informed
Company 7	∼17000	Not informed

We did a comparison about the number of complete actions by maturity level per company. These results, described in Table 68, show: from 57 actions of basic level, companies perform an average of 52 with a standard deviation of 4.86; from 79 actions of intermediate level, companies satisfy 69.43 with 8.22 of standard deviation; and, from 12 actions of advanced level, two companies perform all of them, but in general they perform an average of 8.43 with a standard deviation of 3.41.

Therefore, we tend to conclude that the domain does not have a significant influence in the maturity level achieved by the companies. Moreover, the size of companies appears not influence either. The latter is a result somewhat expected, that despite the number of employees the systems should be certified by regulatory entities.

We also analyzed whether the practitioners understand the terminology used by the safety module in Section 7.2.7.1 as well as the comprehension of SPAs and safety actions in Section 7.2.7.2. We observed that great majority (83.33%) in Figure 41 agree that the SPAs are easy to understand. Besides, we noticed that the actions were considered as easy to understand by the subjects (Figure 42). Therefore, we believe that the understanding of actions across domains is not compromised since the subjects work in different domains. Besides, we provide explanations for each action and examples in the tool.

Table 68 – Number of complete actions by maturity level.

	Domain	Level 1	Level 2	Level 3
Project 1	Automotive	51	70	11
Project 2	Industrial machinery	56	77	12
Project 3	Defense & Aerospace	56	74	12
Project 4	Aerospace	56	72	8
Project 5	Aerospace	54	77	6
Project 6	Aerospace	47	57	3
Project 7	Aerospace	44	59	7
Total of actions		57	79	12
Average		52	69.43	8.43
Standard Deviation		4.86	8.22	3.41

8.5 RQ5: HOW IS THE PERCEIVED USEFULNESS AND EASE OF USE OF THE UNI-REPM SAFETY MODULE?

The validation and evaluation of Uni-REPM SCS occured in academia as well as in industry in order to prepare it for widespread industry use. To achieve this goal, we followed the technology transfer framework proposed by Gorschek et al. (2006) explained in Section 3.9. Accordingly, we performed a static validation (Section 7.1) and a dynamic validation (Section 7.2).

In the literature, there are many argumentation that maturity models describe "what activities to implement" instead of "how to implement" these activities. However, subject S1 commented that Uni-REPM SCS has an adequate level:

"...It also provides concrete actions for companies to develop their safety process further in case they do not already follow a safety framework or if they have not a mature safety process." (S1)

In the static validation, the usefulness and applicability were evaluated through the experts opinion about the extent they believe the safety module will help requirements engineers to perform safety-related activities or tasks in the project (Figure 43) and whether they would adopt the module (Figure 44). We observed that they consider the contribution of Uni-REPM SCS significant to industry and they would adopt it case they would work in industry.

We included a question (#17) in the questionnaire of the dynamic validation (Appendix F) about the extent they believe the safety module will help requirements engineers to perform safety-related activities or tasks in the project. 33% said it can contribute to a large extent, 17% to a moderate extent and 50% said some extent as shown in Figure 43.

In question #19, we asked if they would adopt the safety module in the company. 33.33% strongly agreed, 16.67% agreed and 50% did not agree or disagree. We believe it is necessary to conduct more case studies to understand these answers. Probably, they did not see yet the benefits of maturity models and process improvements initiatives. On the other hand, they

perform the great majority of safety practices presented in Uni-REPM SCS.

Questions #20-25 of the questionnaire aim to collect their feedback about the Uni-REPM tool we developed. These questions were used to evaluate the tool usability considering the PSSUQ (LEWIS, 1995).

The PSSUQ analyzes the system usability through four factors (overall satisfaction, system usefulness, information quality and interface quality) from the answers obtained from the evaluation questionnaire. The results, described in Section 7.2.8, showed that the tool has good usability.

8.6 RQ6: HOW TO EVALUATE WHETHER THE MODULE HAS A SUFFICIENT COVERAGE OF SAFETY PRACTICES?

To answer this research question, we included question #16 in the interview questionnaire (see Appendix F) of dynamic validation (Section 7.2). In Section 7.2.7.3, we described the subjects answers regarding the coverage of the safety practices in Uni-REPM SCS (Question #16). The practitioners reported that they do not perform any additional action(s) that is (are) not covered in the model. Therefore, we tend to conclude that the safety module has a sufficient coverage.

In the next sections, we describe some conclusions from the case studies.

8.7 SUMMARY OF FINDINGS

Subjects reported some practices that the company need to better document or highlighted some problems in their processes that they should have to perform better as presented in Table 69.

The needs of improvements reported by four practitioners in their RE processes belong to six out of seven main process areas, except Requirements Validation. The main process area that had more space to improve was Requirements Analysis with three comments.

Regarding subprocess areas, the one that need more improvements according to the feedback of the practitioners was Preliminary Safety Analysis with three comments being two from the same subject (S2D).

The need of improving system development methodology adopted by the company was reported by S3D when we asked:

Do you identify and document the system development methodology? which is the action OS.GSM.a1.

Subject S3D said:

"*Different for different parts of the system, which is a problem.*" (S3D)

We observed that there is need of involving more the customer in the system development process when S2D answered the question:

Table 69 – Safety practices that need to be more documented according to the practitioners in their RE processes.

Subject	Action	Question	Comment
S1D	PM.SCO.a9	Do you document how conflicts will be resolved?	*"Sometimes no. If the artifacts are released then the conflict resolution is more clear but if you mean the conflicts during the development and assessment then the answer is varied in different group."*
S2D	RE.SM.a3	Do you select suppliers and record rationale?	"*Perhaps not record rationale.* "
	PM.SCO.a10	Do you identify, record and resolve conflicts?	"*Only resolve the conflicts. Not record them.* "
	RP.SC.a2	Do you demonstrate the preliminary level of safety achieved by the system?	"*Not done for the software today, only for hardware.* "
	RA.PSA.a10	Do you conduct risk evaluation for each identified hazard?	"*But only for the major hazards. Not for all hazards.* "
	RA.PSA.a11	Do you identify and document risk mitigation procedures for each identified hazard?	"*But only for the major hazards. Not for all hazards.* "
S3D	OS.GSM.a8	Do you prepare progress reports in a period of time defined by the project?	*"Progress reports are done periodically depends on the activity."*
S7D	DS.SDO.a7	Do you document lessons learned?	"*We only talk about it.*"
	OS.GSM.a9	Do you monitor project and take corrective actions?	*"Should work better if the lessons learned ware documented."*
	OS.STO.a7	Do you define and use tools to support the safety process and workflow management?	*"Just to support the safety process."*
	RA.PSA.a6	Do you obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.)?	*"Not all of this examples."*
	RE.SM.a4	Do you specify all external systems and safety-related software?	*"Not the safety-related software."*
	PM.SCO.a3	Do you establish a common nomenclature?	*"Sometimes the nomenclature from the suppliers are not following our standard."*

Do you conduct joint reviews (company and customer)? which corresponds to the action RV.SVV.a10:

"*End customer not always involved.*" (S2D)

Subject S1D reported in action RA.PSA.a2 whose question is:

Do you simulate the process?

"*There is tool support but we don't have a one click simulation.*"

An infrastructure to share knowledge is necessary to manage any project, but this is more important when developing SCS since the projects usually take years to be delivered and employees may leave the company. In Table 70, we present some comments of the practitioners.

8.7.1 Summary of assessments

With the seven assessments conducted we may conclude the following:

- All organizations did not achieve any maturity level. This means they are skipping impor-

Table 70 – Infrastructure to share knowledge.

Subject	Action	Question	Comment
S2	OS.SKM.a1	Do you establish and maintain an infrastructure to share knowledge?	*"Informal information sharing, meetings but no formal way."*
S3	OS.SKM.a1	Do you establish and maintain an infrastructure to share knowledge?	*"No specific tools are used. "*
	OS.SKM.a2	Do you develop a safety information system to share knowledge in the organization?	*"No presence of centralised tools or repositories for Safety information."*
	OS.SKM.a5	Do you document a strategy to manage the knowledge?	*"Could definitely be improved, maybe with a safety information system. The usual solution is consultants."*
	OS.SKM.a3	Do you define control access mechanisms to the safety information system?	*"Access to the analysis are company classified i.e. availability if access is allowed. However no safety information system is present."*

tant safety practices at requirements engineering phase when developing safety-critical systems.

- Companies perform the great majority of safety practices presented in Uni-REPM SCS.
- The Uni-REPM SCS has a sufficient coverage of safety practices since the practitioners reported that they do not perform any additional action(s) that is (are) not covered in the model.
- From the latency analysis, we could conclude that the domain did not have a significant influence in the maturity level achieved by the companies. Furthermore, the size of companies did not influence either.
- The SPAs and actions presented in Uni-REPM SCS are easy to understand. Therefore, we believe that the understanding of actions across domains is not compromised.
- All experts said that Uni-REPM SCS can contribute to some extent the requirements engineers to perform safety-related activities or tasks in the project.
- The tool has a good usability.
- Subjects suggested to change only 22 actions to make them more clear. Uni-REPM SCS has 148 actions, hence, this corresponds to 14.86%. Accordingly, we can say that our goal of making the model understandable regardless the domain was achieved.

In the next sections, we discuss some contributions of this thesis.

8.8 CONTRIBUTIONS

Companies with high maturity levels tend to reduce requirements issues and make the system development process less challenging. Although maturity models are not "silver bullets",

they may be used for several purposes providing useful benefits (WENDLER, 2012)(BECKER; KNACKSTEDT; PÖPPELBUSS, 2009)(SVAHNBERG et al., 2015).

8.8.1 Benefits to academia

For researchers, we hope that the safety module offers a comprehensive summary of state of the art, by providing the identification and systematization of existing safety practices being a knowledge base.

8.8.2 Benefits to industry

For industry practitioners, the module may provide a process evaluation model of safety concerns targeted at the RE process. Accordingly, it may guide requirements and safety engineers to develop SCS with high quality by providing a very practical structure with which to assess their maturity and reduce RE issues in the process.

8.8.3 Evaluation regarding specific concerns

Uni-REPM SCS addresses the problem space by identifying relevant safety actions and detailed factors that determine maturity of companies that develop SCS. Being structured in MPAs and SPAs, the module gives the potential to evaluate the maturity of whole RE process, but also specific areas in order to address the needs of several stakeholders.

8.8.4 Module could be used as a diagnostic tool

The module enables the determination of the current state ("as-is") of companies processes. The determination of company *status quo* allows a better decision-making processs since it contributes to instruct managers regarding their current processes and service' status (REIS; MATHIAS; OLIVEIRA, 2016). Besides, such evaluation enables the elaboration of a roadmap for improving the domain position from 'as-is' (where they are) to what they should do (the state 'to-be') (BRUIN et al., 2005).

8.8.5 Availability of assessment instrument

The safety module has an instrument to evaluate the maturity that is important for SCS development. It consists in a checklist allowing to provide a reminder of what to look for and reduce the chances of forgetting some safety action (COX; NIAZI; VERNER, 2009). The instrument is fully supported by online software tool. Besides, the subjects of the static validation agree that the safety practices/questions are easy to understand.

8.8.6 Tool Support

We designed and implement a software tool to support the usage of Uni-REPM and the safety module available at <http://www.cin.ufpe.br/~ler/unirepm>. The main features of the tool were discussed in Section 6. The tool has three types of users that can perform RE/Safety evaluations and all maturity levels achieved (SPA, MPA, and at project level) are calculated automatically. This tool support helps reducing time and effort in assessing the maturity.

8.8.7 Determination of organization weakness

The module allows the analysis of work processes rather than the analysis of isolated safety-critical activities. Therefore, the maturity evaluation should reveal areas of weakness (KONTOGIANNIS; LEVA; BALFE, 2016a; REIS; MATHIAS; OLIVEIRA, 2016). For example, an important area or activity (e.g. requirements management) may be conducted in *ad-hoc* way, with few good safety actions, or left to 'individual' discretion. This indicates an area where improvement efforts may be focused in order to achieve substantial improvement considering that the benefits of high maturity levels increase in larger and more complex systems (SAWYER; SOMMERVILLE; VILLER, 1997).

8.8.8 Using the module to continuous improvement

Maturity models may be defined as artifacts which allow to minimize the challenges of determining a company *status quo* of its capabilities and give directions for continuous improvement (BRUIN et al., 2005; PIGOSSO; ROZENFELD; MCALOONE, 2013).

The Uni-REPM Safety maturity module guides the development by outlining an evolution from a basic maturity level (level 1), to a balanced maturity level (level 2), and a comprehensive maturity level (level 3). Hence, the module may be used as reference frame to implement a systematic and well-directed approach (WENDLER, 2012) offering a continuous improvement culture that affects all levels in the organization (KONTOGIANNIS; LEVA; BALFE, 2016a). This contributes to ensure a certain quality, avoid errors, and assess organizations own capabilities on a comparable basis.

8.8.9 Module could be used in different types of companies

We adopted the definition of Leveson (1995) which a SCS consists of a set of hardware and software. Accordingly, several non-SCS can be combined to create a system that becomes a SCS like self-driving cars. Hence, if the system had a hardware controlled by software, the safety module could be used in its development. Therefore, we argue that the module will work for companies and domains not traditionally under the same regulations as SCS companies if the developed system follows this definition.

It is important to note that it is not necessary to implement all safety actions to have a repeatable RE process (SAWYER; SOMMERVILLE; VILLER, 1997). Furthermore, some practices

may not be appropriate for an organization and need never be implemented. Accordingly, the company should mark them as inapplicable during the maturity evaluation, making the safety module appropriate for organizations of different types, sizes, market, or geographical localization.

8.8.10 Validation

The static validation we performed with the help of two practitioners and nine academic experts provided to us valuable contributions to our model and an improved version was elaborated and it is already available. The improved version was used for dynamic validation, i.e. to evaluate the maturity of seven projects from different companies, domains and countries.

The careful designs of the validations performed contributed to collect relevant feedback, to assure that the model was of good quality and usable before its release. Despite this careful design and potential benefits, we highlight some limitations of this proposal.

8.9 MODULE LIMITATIONS

(1) Improve actions' descriptions: a follow-up investigation to be conducted could be determine how the companies implement the safety practices, collect which tools, techniques and methods they use to satisfy the practices.

(2) Some subjectivity in deciding which actions would be included in the module and the maturity level assigned. This is always an issue when developing maturity models, to mitigate some threats, we have performed a static and a dynamic validation in the safety module.

(3) Conduct Studies with more companies. We performed seven case studies with companies of three companies, more case studies are required in other countries and in different domains.

(4) Answer options: S3 suggested adding new answer options: "Many questions are "Yes/No" questions, but in practice it is not a black and white but rather a gray scale over how well the ambition is in the area. What if there was a scale from "Well implemented" to "Badly implemented" and a separate box for N/A? It's often not "Complete" but also not completely "Incomplete"." (S3) This is a significant change in the evaluation instrument that we need to deeply discuss it in the research group.

(5) Evaluation format: S7 suggested changing the evaluation format: "I believe the final result should take in account the percentage of applications. I don't think its a good idea evaluate as ZERO if the project is missing only one step." (S7) This is also a significant change in the evaluation instrument that we need to deeply discuss it in the research group.

In the next section, we suggest further research regarding maturity models for safety-critical systems.

8.10 FURTHER RESEARCH

This work has generated some research directions that should be explored in future efforts:

[(1)] Which are the contextual factors that influence the maturity level of an organization? A study involving before/after assessments of organizations that engaged in safety processes improvement projects will enable the analysis of contextual factors that influence the maturity level of an organization. Among these factors, there can be the size of the organization, culture, domain or coordination form, which influence the weighting of certain components or factors determining maturity (FITTERER; ROHNER, 2010). Hence future research will also need to be directed towards the identification of such context factors.

[(2)] What is the module impact in the safety processes considering before/after assessments of companies? Considering that maturity evaluations can be a competitive advantage (JUGDEV; THOMAS, 2002), a subsequent study could be the investigation of the impact of adopting the safety module in the projects success rates. Hence, a throughout analysis of in which extent maturity evaluations can help companies to improve in a long term.

[(3)] Can practitioners reconcile the actions in the module with what they already need to do in order to comply with mandatory standards in their application domain? Further research could be conducted to investigate if are there any conflicts among the module and the standards/existing company practices. The initial validation performed with the seven practitioners did not reveal any conflict so far. However, more case studies are necessary to make substantial conclusions.

[(4)] Which are the benefits of using the safety module in the developed system? Uni-REPM SCS offers an initial paradigm with which to evaluate organizations and their safety capabilities (JUGDEV; THOMAS, 2002). Further research could be conducted to evaluate in what extent the safety assessment contributed to the quality of the development system. Aspects, for example, system development time, number of errors, changes due to requirements problems could be evaluated.

[(5)] What is the core set of activities to be performed by requirements engineers in safety analysis? In the SLR we conducted (Chapter 4) we analyzed the activities that can be performed by requirements engineers as a part of safety analysis in the approaches that integrate requirements and safety engineering. We found more than 26 activities (see Section 4.2.4), hence, future studies should investigate which of these

activities should be conducted by requirements engineers. However, a trade-off must be established in order to not overwhelming them and still get benefits in the system development.

[(6)] How to evaluate the implicit shared understanding in the safety analysis techniques? From the results of SLR, we observed that implicit shared understanding may be a problem in the development of a SCS (see Section 4.2.9). In the system's specifications, too much information about the system is hidden and many information is lost when the developed system evolves. Accordingly, usually, during safety analysis, the evaluator does not have information and further research could evaluate how to detect whether relevant information is missing and which is the granularity level adequate to document this implicit shared understanding.

[(7)] In what extent are the tools used in the requirements specification capable of improving integration and communication between RE and safety engineering and safety analysis? The SLR results showed that 66.67% of the studies did not cite any kind of tool support (see Section 4.2.7). Therefore, a follow up study could focus on the analysis of the extent the existing tools used in the requirements specification are capable of improving integration and communication in these two areas.

[(8)]How to measure the costs and benefits of improving the integration and communication between RE and safety engineering in safety-critical systems? The benefits reported by the literature regarding the integration these two areas is listed in Section 4.2.8. Despite we have collected some potential benefits, further research could be evaluate empirically such benefits as well as the costs of such integration.

[(9)] Post-Mortem analysis Conduct the safety maturity assessment of ended projects and correlate the maturity levels with the quality of the developed system.

We intend to address such questions in future works.

8.11 FINAL CONSIDERATIONS

The Uni-REPM Safety module presented in this thesis has provided an initial insight into improving the requirements/safety engineering integration through maturity management. This chapter presented the answer to our research questions, the main contributions. Moreover, we indicate some future works that can be conducted to improve our approach.

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APPENDIX A – QUALITY ASSESSMENT OF THE ACCEPTED PAPERS IN THE SLR

This chapter presents the list of accepted papers in the systematic literature review and their quality scores (described in Chapter 4). We adopted the numerical citation style to improve table presentation since the name of author/year presentation does not fit in the table making difficult readability.

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The quality scores of these papers are presented in Figure 65 and Figure 66.

ID	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Total Score	Qual.	Citations
(Kaiser et al., 2010)	1	1							0.5	0.5		1	0			1					5	71.4%	6
(Saeed et al., 1995)	1	1							0.5	0.5		1	0			1					5	71.4%	14
(David et al., 2010)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	78
(Mostert and von Solms, 1994)	1	1							0.5	0.5		1	0			1					5	71.4%	9
(Lutz, 1993)	1	1							0.5	0.5		1	1			1					6.0	85.7%	151
(Ratan et al., 1996)	1	1							0.5	0.5		1	0			1					5	71.4%	24
(Thramboulidis and Scholz, 2010)	1	1							0.5	0.5		1	1			1					6.0	85.7%	17
(Black and Koopman, 2008)	1	1							1	0.5		1	1			1					6.5	92.9%	2
(Navarro et al., 2006)	1	1							0.5	0.5		1	1			1					6.0	85.7%	3
(Galvao Martins and De Oliveira, 2014)	1		1	0	1	0	1	1	1	0.5		1	1	1	0.5	1					11	78.57%	4
(Kim and Chung, 2005)	1	1							0.5	0.5		1	0			1					5	71.4%	14
(Mannering et al., 2008)	1	1							1	0.5		1	1			1					6.5	92.9%	16
(Medikonda and Panchumarthy, 2009)	1	1							0.5	0.5		1	0			1					5	71.4%	10
(Wu and Kelly, 2007)	1	1							1	0.5		1	1			1					6.5	92.9%	12
(Nejati et al., 2012)	1	1	1		1			1	1	1		1	1	1	0.5	1					11.5	95.83%	26
(Martin-Guillerez et al., 2010)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	21
(Leveson, 2002)	1	1							0	0.5		1	0			1					4.5	64.3%	12
(Stålhane and Sindre, 2014)	1		1	1	0	1	1	1	1	1		1	1	1	0.5	0.5					12	85.71%	0
(Hansen et al., 1998)	1	1							0.5	0.5		1	1			1					6.0	85.7%	137
(Scholz and Thramboulidis, 2013)	1	1							0.5	0.5		1	1			1					6.0	85.7%	1
(Markovski and van de Mortel-Fronczak, 2012)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	0
(Beckers et al., 2013)	1	1							0.5	0.5		1	1			1					6.0	85.7%	5
(Arogundade et al., 2012)	1	1							0.5	0.5		1	1			1					6.0	85.7%	1
(El Ariss et al., 2011)	1	1							0.5	0.5		1	1			1					6.0	85.7%	22
(Guiochet et al., 2010)	1	1							0.5	0.5		1	1			1					6.0	85.7%	20

Figure 65 – List of papers included in the review along with their quality scores and number of citations.

ID	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Total Score	Qual.	Citations
(Chandrasekaran et al., 2009)	1	1							0.5	0.5		1	0			1					5	71.4%	1
(Briones et al., 2007)	1	1							1	0.5		1	1			1					6.5	92.9%.	4
(Broomfield and Chung, 1997)	1	1							0.5	0.5		1	0			1					5	71.4%	14
(Górski and Wardziński, 1996)	1	1							0.5	0		1	0			1					4.5	64.3%	16
(Du et al., 2014)	1	1							0.5	0		1	0			1					4.5	64.3%	1
(Zoughbi et al., 2011)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	29
(Jrjens, 2003)	1	1							0.5	0.5		1	1			1					6.0	85.7%	52
(Simpson and Stoker, 2002)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%.	0
(Biggs et al., 2016)	1	1							1	1		1	1			1					7	100%	3
(Lu and Halang, 2007)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	18
(Ståhane and Sindre, 2007)	1		1	1	0	1	1	1	1	1		1	1	1	0.5	0.5					12	85.71%	22
(Mustafiz and Kienzle, 2009)	1	1	1		0.5			0.5	1	0.5		1	1	1	0	1					9.5	79.17%	17
(Ekberg et al., 2014)	1	1							0.5	0		1	0			1					4.5	64.3%	0
(Wilikens et al., 1997)	1										1	1				0.5					3.5	87.5%	4
(Paige et al., 2008)	1		1	0	1	0	1	0.5	1	0		1	1	1	0	1					9.5	67.86%	8
(Guillerm et al., 2010)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	8
(Schedl and Winkelbauer, 2008)	1										0.5	1				0.5					3	75%	1
(Rafeh, 2013)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	3
(Chen et al., 2011)	1	1							0.5	0.5		1	1			1					6.0	85.7%	3
(Tschrtz and Schedl, 2010)	1	1							0.5	0.5		1	0			1					5	71.4%	1
(Elliott et al., 1995)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	3
(Croll et al., 1997)	1	1							0.5	0.5		1	0.5			1					5.5	78.6%	6
(Cant et al., 2006)	1	1							1	0.5		1	0			1					5.5	78.6%	3
(Jurkiewicz et al., 2015)	1		1	1	1	1	1	1	1	1		1	1	1	0.5	1					13.5	96.43%	4
(Ståhane et al., 2010)	1		1	1	0	1	1	1	1	1		1	1	1	0.5	0.5					12	85.71%	10
(Murali et al., 2015)	1	1							1	1		1	1			1					7	100%	0
(Pernstål et al., 2015)	1	1	1		1			1	1	1		1	1	1	0.5	1					11.5	95.83%	0
(Fricker et al., 2010)	1	1	1		1			0.5	1	1		1	1	0.5	0.5	1					10.5	87.5%	52
(Fricker et al., 2008)	1	1							1	1		1	1			1					7	100%	24
(Heimdahl, 2007)																	1	1	1	1	4	100%	44
(Sikora et al., 2012)	1	1	1		1			1	1	1		1	1	1	0.5	1					10.5	95.45%	34
(Hatcliff et al., 2014)																	1	1	1	1	4	100%	12
Average																						82.37%	17.58

Figure 66 – List of papers included in the review along with their quality scores and number of citations - part 2.

APPENDIX B – UNI-REPM SAFETY MODULE – COMPLETE DESCRIPTION

This appendix presents the full description of all 148 actions of Uni-REPM SCS.

UNI-REPM Safety Module – Actions Description

Part I. Description of actions

RE Requirements Elicitation

Elicitation is the process of discovering, understanding, anticipating and forecasting the needs and wants of the potential stakeholders in order to convey this information to the system developers. The potential stakeholders can include customers, end-users and other people who have the stake in the system development. In the process, the application domain and organizational knowledge are necessary among other things.

RE.SM Supplier Management

The development of safety-critical systems usually requires a combination of internal software and third-party systems. Therefore, in the Requirements Engineering phase, it is necessary to elicit and specify the requirements that suppliers must satisfy.

Suppliers correspond to internal or external organizations that develop, manufacture, or support products being developed or maintained that will be delivered to other companies or final customers. Suppliers include in-house vendors (i.e., organizations within a company but which are external to the project), fabrication capabilities and laboratories, and commercial vendors [28].

The *Supplier Management* sub-process is responsible to manage the acquisition of products and services from suppliers external to the project for which shall exist a formal agreement. The actions of this sub-process are described below.

RE.SM.a1 **Establish and maintain formal agreements among organization and suppliers** **Level 3**

Formal agreements among organization and suppliers must be established and maintained. A formal agreement is a document legally valid that describe terms and conditions, a list of deliverables, a schedule, budget, and other relevant information.

Supporting action(s)

- RE.SM.a3 Select suppliers and record rationale

RE.SM.a2 **Identify and document the products to be acquired** **Level 1**

The determination of what products or components will be purchased should be based on an analysis of the needs of the project. This analysis begins in the elicitation phase, continues during the design level, ending when the company decides to buy the product.

RE.SM.a3 Select suppliers and record rationale Level 1

The selection of suppliers and its rationale, for example, advantages and disadvantages, should be recorded. The list of products to be acquired can provide a direction for such selection.

Supporting action(s)

- RE.SM.a2 Identify and document the products to be acquired

RE.SM.a4 Specify all external systems and safety-related software Level 2

The characteristics of all external systems (e.g. data bus, computer, ground interface, communication protocol, the concurrency and real-time model) that interact with the system as well as safety-related software used to implement functions intended to achieve or maintain a safe state in a safety-critical system must be properly documented.

Supporting action(s)

- RE.SM.a2 Identify and document the products to be acquired

RE.SM.a5 Establish and maintain detailed system integration procedures for the external systems and safety-related software Level 2

Detailed system integration procedures, for example the number of iterations to be performed and details of the expected tests and other types of information, for the components of external systems and safety-related software must be established and maintained.

Supporting action(s)

- RE.SM.a4 Specify all external systems and safety-related software

RE.SM.a6 Define the safety standards that suppliers must follow Level 2

The safety standards to be followed by suppliers must be defined and properly specified. This information will be necessary during the construction of safety cases and certification process of the system being developed.

Supporting action(s)

- RE.SM.a1 Establish and maintain formal agreements among organization and suppliers

DS Documentation and Requirements Specification

Documentation and Requirements specification deals with how a company organizes requirements and other knowledge gathered during requirements engineering process into consistent, accessible and reviewable documents. In the safety module, the management of human factors and the documentation of safety issues are the main concern of the sub-process added to this process. The safety documentation contains the product's detailed functional and safety requirements.

DS.HF Human Factors

Human factors have a significant importance in safety standards since many hazardous situations are caused by system's users and operator due lack of training or unfamiliarity with the operator mental

models. Although, the main goals of human-computer interaction are not primarily for safety but to make recommendations and application of technical guidelines [29], the human factors shall be considered during the Requirements Engineering stage of safety-critical system development.

DS.HF.a1 Construct models about the way of work of the operator **Level 1**

Operator's task models regarding the way of work of the operator impact fundamental dimensions of system usage such as workload, situation awareness, performance, stress, and tiredness, etc. Therefore, such models must be adequately constructed. The representation of such models using visual task-modeling language allows integrated simulation and analysis of the entire system, including human – computer interactions.

DS.HF.a2 Document human factors design and analysis **Level 1**

Developing safety-critical systems requires integrating human factors into the basic Requirements Engineering process, which in turn has important implications for system requirements. The human factors design and analysis should be performed to ensure that the system is designed for the user, regardless the type of user. This analysis should consider the comfort of the users, fit the human body and their cognitive abilities and the system's functionalities. The results of such analysis should be documented.

DS.HF.a3 Evaluate prototypes, requirements and technical Human Machine Interface restrictions **Level 2**

When the first version of system specification is available or whenever occurs changes on it, the prototypes, requirements and technical **Human Machine Interface** restrictions should be evaluated with the user. This evaluation, which can be with user in labs or using questionnaires, should consider the system specification. If problems in prototypes, in requirements or in **Human Machine Interface** are identified, new human factors requirements must be specified.

Supporting action(s)

- DS.HF.a1 Construct models about the way of work of the operator
- DS.HF.a2 Document human factors design and analysis

DS.HF.a4 Model and evaluate operator tasks and component black-box behavior **Level 2**

The component black-box behavior describe the inputs and outputs of each component and their relationships only in terms of externally visible behavior. Black-box behavioral specifications as well as operator tasks can be used to maintain the system and to specify and validate changes before the actual development of the system.

Supporting action(s)

- DS.HF.a1 Construct models about the way of work of the operator

DS.HF.a5 **Define interfaces considering ergonomic principles** **Level 2**

The interfaces of the safety-critical system should consider ergonomic principles to ensure that the system, including the safety-related parts, is easy to use, and so that the operator is not tempted to act in a hazardous manner.

Supporting action(s)

- DS.HF.a6 Specify Human Machine Interface requirements

DS.HF.a6 **Specify Human Machine Interface requirements** **Level 1**

The Human-Machine Interfaces specify the connection between user and system. Designing a good interface is a challenging Requirements Engineering task since the construction of a well-operable, user-friendly and ergonomic interface presumes great expertise. The human machine interface requirements, including all elements that a user will touch, see, hear, or use to perform safety control functions and receive feedback on those actions, should be described. These requirements allow providing details about the controls by which a user operates the system.

DS.SDO Safety Documentation

Many artifacts are generated during the development of a safety-critical system that are used throughout the development to construct safety cases or documents with certification purposes. Accordingly, all information related to system's safety produced in Requirements Engineering phase must be recorded. This activity can also be done together with members from other phases that will use the information later.

DS.SDO.a1 **Record safety decisions and rationale** **Level 1**

Safety analysis encompasses trade-offs and decision making to provide safety to the system. Therefore, all safety decisions and rationale for them must be documented and included in the safety requirements specification for later analysis and certification.

Supporting action(s)

- DS.SDO.a9 Maintain hazard and risk analysis results for the system throughout the overall safety lifecycle

DS.SDO.a2 **Ensure that safety requirements are incorporated into system and subsystem specifications, including human-machine interface requirements** **Level 2**

The safety requirements defined to mitigate the hazards should be traced to (sub) systems and components to improve safety communication and to construct the safety cases.

Supporting action(s)

- DS.HF.a6 Specify Human Machine Interface requirements

DS.SDO.a3 **Document all lifecycle and modification activities** **Level 2**

The company should define a software and safety lifecycle and record the activities and modification occurred in each of the lifecycle.

Supporting action(s)

- OS.GSM.a2 Identify and document safety lifecycle for the system development

DS.SDO.a4 **Develop and document training, operational and software user manuals** **Level 1**

Training, operational and software user manuals must be developed and properly maintained. These manuals will be updated and improved in the next stages of system development.

DS.SDO.a5 **Document System Limitations** **Level 1**

Sometimes not all hazards and risks are possible or viable to be eliminated or controlled, so, the system is released with limitations (accepted risks). Limitations can be associated, for example, with basic functional requirements, environment assumptions, hazards or hazard causal factors, problems encountered or tradeoffs made during Requirements Engineering. Such limitations should be recorded with links to the pertinent portions of the hazard analysis along with an explanation of why they could not be eliminated or adequately controlled. The limitations are used by management and stakeholders to determine whether the system is adequately safe to use; and, hence, affect both acceptance and system certification.

Supporting action(s)

- DS.SDO.a1 Record safety decisions and rationale
- DS.SDO.a9 Maintain hazard and risk analysis results for the system throughout the overall safety lifecycle

DS.SDO.a6 **Provide an operation manual** **Level 2**

A safety manual describing the functions as well as the inputs and outputs interfaces of an external element must be provided. The manual also should contain the identification of the hardware and/or software configuration of the compliant element to enable configuration management of safety-related system. Moreover, it is also necessary to relate constraints on the use of the element and/or assumptions on which analysis of the behavior or failure rates of the item are based. Such manual may be derived from the supplier's own documentation and records, or may be created or supplemented by the company. If available, reverse engineering can be used.

Supporting action(s)

- RE.SM.a1 Establish and maintain formal agreements among organization and suppliers
- RE.SM.a4 Specify all external systems and safety-related software
- RE.SM.a5 Establish and maintain detailed system integration procedures for the external systems and safety-related software
- RE.SM.a6 Define the safety standards that suppliers must follow

DS.SDO.a7

Document lessons learned **Level 3**

Many times the company develops new versions of existing systems with new functionalities or constructs new systems but in the same area. In this context, a better safety analysis can be conducted by collecting information from previous projects. Hence, the company should document lessons learned to prevent or mitigate risks already identified.

Supporting action(s)

- DS.SDO.a1 Record safety decisions and rationale

DS.SDO.a8

Ensure that safety-related information is incorporated into user and maintenance documents **Level 1**

Safety-related information must be included into user and maintenance documents as long as they are produced. Moreover, periodic reviews should be conducted to ensure that such information were incorporated.

Supporting action(s)

- DS.SDO.a1 Record safety decisions and rationale
- DS.SDO.a9 Maintain hazard and risk analysis results for the system throughout the overall safety lifecycle

DS.SDO.a9

Maintain hazard and risk analysis results for the system throughout the overall safety lifecycle **Level 2**

The results of hazard and risk analysis must be maintained throughout the overall safety lifecycle, from the Requirements Engineering phase to the disposal phase.

DS.SDO.a10

Include a summary of safety requirements **Level 2**

To improve the communication among stakeholders a summary of safety requirements with their associated page numbers in the document must be produced and maintained.

Supporting action(s)

- DS.SDO.a9 Maintain hazard and risk analysis results for the system throughout the overall safety lifecycle

RA Requirements Analysis

Requirements gathered from different sources need to be analyzed to detect incomplete or incorrect ones as well as to estimate necessary information for later activities (e.g. risk, priorities…). It is also necessary to conduct a preliminary safety analysis and failure handling to dismiss avoiding wasting effort in next phases of system development.

RA.PSA Preliminary Safety Analysis

Conducting safety analysis early in the development process contributes to improve system quality and detect hazards and related information in the beginning of Requirements Engineering phase.

RA.PSA.a1 **Identify and document safety-critical computer software components and units** **Level 2**

Improving system safety requires the identification of safety-critical computer software components and units that demand special attention. Safety engineers and the quality assurance staff will be responsible to monitoring of the strategies to reduce hazardous situations associated with these elements.

RA.PSA.a2 **Simulate the process** **Level 2**

Better safety analysis can be performed by simulating the process related to the system. The process simulation enable modeling complex tasks providing a representative environment to elaborate and test hypotheses. The system can also be simulated by analyzing its inputs and outputs, anticipated occurrences as well as undesired conditions requiring system action.

RA.PSA.a3 **Identify and document system hazards** **Level 1**

The identification of hazards should be identified using appropriate methods and tools for the type of system and be properly recorded.

Possible documents/sources to be consulted or analyzed to achieve this task may be:

- system specification;
- lessons learned;
- pertinent standards and regulations;
- safety design checklists;
- safety related interface considerations among various elements of the system;
- environmental constraints;
- facilities;
- real property installed equipment;
- support equipment and training;
- safety-related equipment
- safeguards; and
- possible malfunctions to the system, subsystems, or software.

Supporting action(s)

- DS.SDO.a7 Document lessons learned
- OS.SP.a14 Identify and document the hazard analysis to be performed; the analytical techniques (qualitative or quantitative) to be used; and depth within the system that each analytical technique will be used (e.g., system level, subsystem level, component level)

RA.PSA.a4 **Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)** **Level 1**

Besides system hazards, a safety-critical system can suffer from hazards, hazardous situations or harmful events due to interaction with other equipment or systems (installed or to be installed). Therefore, it is necessary perform the analysis related to this information.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards

RA.PSA.a5 Specify the type of initiating events that need to be considered Level 2

Hazards generally are initiated by some event. Hence, the type of these event must be considered during safety analysis.

Example of events may be:

- component failures
- procedural faults
- human error; and
- dependent failure mechanisms that can cause hazardous events.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards
- RA.PSA.a4 Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)

RA.PSA.a6 Obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.) Level 1

Once hazards are identified, the next step is to specify details about them. Some information are required during the construction of safety cases and certification of the system.

Example of data that should be recorded are [33]:

- cause of hazard
- probability
- severity
- duration
- intensity
- toxicity
- exposure limit
- mechanical force
- explosive conditions
- reactivity
- flammability etc.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards
- RA.PSA.a4 Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)

RA.PSA.a7 Identify and document hazardous materials Level 1

Some safety-critical systems, specially the medical ones, can be constructed using materials that can cause allergic reactions. Therefore, it is necessary to specify any item or substance that, due to its chemical, physical, toxicological, or biological nature, could cause harm to people, equipment, or the environment. Moreover, this information should be present in system specification and available to potential users.

RA.PSA.a8 Identify and document consequences of hazards, severity categories and affected assets — Level 1

When a hazardous situation occurs, it may result in consequences for people and environment. Accordingly, the types of such consequences, for example incident and accident, should recorded.

The severity categories may be specified following the classification of safety standards. The MIL-STD-882D [32] for example define four categories:

- Catastrophic
- Critical
- Marginal
- Negligible

Moreover, the affected assets should also be specified.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards
- RA.PSA.a4 Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)
- RA.PSA.a6 Obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.)

RA.PSA.a9 Conduct risk estimation — Level 1

After the identification of hazards, a risk analysis should be conducted. It involves the risk estimation and risk evaluation. Risk estimation corresponds to the identification of risks presented by hazards, barrier failures and human errors and their quantification.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards
- RA.PSA.a4 Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)
- RA.PSA.a6 Obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.)

RA.PSA.a10 Conduct risk evaluation for each identified hazard — Level 2

The risk evaluation addresses decision making about the risk level and its priority during the mitigation specification phase through the application of the criteria developed when the context was established.

The ISO 15998 [33] safety standard recommends the use of risk assessment methodologies such as presented in ISO 14121-1 or IEC 61508-5.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards
- RA.PSA.a4 Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)
- RA.PSA.a6 Obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.)

RA.PSA.a11 Identify and document risk mitigation procedures for each identified hazard — Level 1

Risk mitigation procedures should be defined to handle the hazards and reduce the risks previously identified. Examples of procedures are prevention, detection, reaction, and adaptation.

Supporting action(s)

- RA.PSA.a9 Conduct risk estimation
- RA.PSA.a10 Conduct risk evaluation for each identified hazard

RA.PSA.a12 Collect safety requirements from multiple viewpoints — Level 2

The development of safety-critical system requires multidisciplinary teams (computer science, medical, electrical, mechanical, among others) that have different backgrounds and expertise. Accordingly, better safety analysis will be achieved if safety requirements were collected from multiple viewpoints.

The safety requirements can be of different types [34]: pure safety requirements, safety-significant requirements, and safety functional requirements.

Supporting action(s)

- OS.SP.a3 Define and document the interface between system safety and all other applicable safety disciplines
- RA.PSA.a13 Identify and document pure safety requirements
- RA.PSA.a14 Identify and document safety-significant requirements and safety integrity levels
- RA.PSA.a15 Identify and document safety constraints and how they could be violated

- RA.PSA.a16 Identify and document possible control flaws and inadequate control actions
- RA.PSA.a17 Identify and document safety functional requirements
- RA.PSA.a18 Identify and document operational requirements

RA.PSA.a13 Identify and document pure safety requirements — Level 1

Pure safety requirements should be identified and specified. These requirements are a kind of quality requirement.

Example

"The system shall not cause more than 3 amount of accidental harm per year."

RA.PSA.a14 Identify and document safety-significant requirements and safety integrity levels — Level 2

Sometimes, some requirements are not originally defined to mitigate some hazard, but they can have significant safety ramifications. They are non-safety primary mission requirements and due to their relationship with safety, they should be identified and documented**.**

Safety-significant requirements can be identified based on hazard analysis results and sources of such requirements can be [34]:

- Functional Requirements
- Data Requirements
- Interface Requirements
- Non-safety Quality Requirements
- Constraints

Safety-significant requirements are classified according to the safety integrity level (SIL) which corresponds to a range of safety integrity values representing a category of required safety. In IEC 61508, SIL can be in a range of 1-4 where level 4 has the highest level of safety integrity and level 1 has the lowest.

Example(s)

Requirements for controlling elevator doors.
Requirements to control insulin infusion.

RA.PSA.a15 Identify and document safety constraints and how they could be violated — Level 2

The safety requirements specification may have safety constraints that are engineering decisions that have been chosen to be mandated as a requirement intended to ensure a minimum level of safety. Therefore, any safety-related or relevant constraints between the hardware and the software should be identified and documented.

Example of sources of safety constraints are [34]:

- Architecture constraints
- Design constraints
- Implementation (e.g., coding) constraints
- Testing constraints

Moreover, it is necessary to conduct an analysis about how the safety constraints of a system could be violated and add mechanisms to enforce them.

Supporting action(s)

- RA.PSA.a16 Identify and document possible control flaws and inadequate control actions

RA.PSA.a16 Identify and document possible control flaws and inadequate control actions — Level 2

Following control theory principles, the system must be analyzed to identify possible control flaws and inadequate control actions. Inadequate control actions can be hazardous in four ways [35]:

- A control action required for safety is not provided;
- An unsafe control action is provided;
- A potentially safe control action is provided too late, or out of sequence;
- A correct action is stopped too soon.

RA.PSA.a17 Identify and document safety functional requirements — Level 1

Safety functional requirements are functions to be implemented in a safety-critical system that is intended to achieve or maintain a safe state for the system, in respect of a specific hazardous situation. These requirements should be identified and properly specified.

Example

- Emergency core coolant system for nuclear power plant

RA.PSA.a18 Identify and document operational requirements — Level 1

Operational requirements, which are the basis for system requirements, of a safety-critical system should be identified and recorded. These requirements describes how to run the system.

Example

- Logging, startup/shutdown controls, monitoring, resource consumption, backup, availability among others.

RA.PSA.a19 Perform and document the feasibility evaluation of safety functional requirements — Level 2

Occasionally, the safety functional requirements defined are not viable or impossible to implement. Therefore, stakeholders should conduct a feasibility evaluation of such

requirements. In such analysis trade-offs are performed aiming to achieve a best combination of viability, safety and cost. Sometimes, the definition of new safety functional requirements are necessary.

Supporting action(s)

- RA.PSA.a17 Identify and document safety functional requirements
- RA.PSA.a20 Prioritize hazards and safety requirements

RA.PSA.a20 Prioritize hazards and safety requirements — Level 1

Hazards in a system have different levels of severity and consequences. The lack of prioritization can severely limit the Requirements Engineering process, and the success of the project, because such activities helps to identify critical requirements and contributes to the decision making process [36]. Therefore, some hazards should have high priority and more resources allocated to mitigate them. In this step, hazards and safety requirements are prioritized and the results recorded.

Supporting action(s)

- RA.PSA.a8 Identify and document consequences of hazards, severity categories and affected assets
- RA.PSA.a17 Identify and document safety functional requirements

RA.PSA.a21 Document verification requirements, possible human-machine interface problems, and operating support requirements — Level 2

In this step, analysis and verification requirements, possible safety-interface problems, including the human-machine interface, and operating support requirements should be defined. The specification of such requirements in the Requirements Engineering process is necessary to avoid defining a hazard that may be implemented correctly but whose test is impossible or very costly [37].

RA.PSA.a22 Perform interface analysis, including interfaces within subsystems (such as between safety-critical and non-safety-critical software components) — Level 3

In this step, the hazard analysis should be reviewed and updated to consider problems with hardware-software and their interfaces.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards
- RA.PSA.a4 Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)

RA.PSA.a23 Consolidate preliminary system safety technical specification — Level 2

In this step, it is necessary to ensure that the results of all analysis conducted and the information identified are consolidated in a preliminary system safety technical specification.

RA.FH Failure Handling

Hazardous situations can be originated due to failures in system components that are hard to discover by either analysis or test. This difficult can originate the release of systems allowing uncommon hazards. Hence, it is important to specify and manage these faults. The safety module has a sub process to handle such failures.

RA.FH.a1 **Define requirements to minimize systematic faults** **Level 2**

Systematic faults can happen in the system due to their complexity. In this step, an analysis should be conducted to define requirements for the avoidance or control of those faults. The definition of such requirements depend on the expertise of the requirements engineer and judgment from practical experience gained in industry.

Supporting action(s)

- RA.FH.a2 Specify Fault-detection procedures
- RA.FH.a3 Specify Restart-up procedures

RA.FH.a2 **Specify Fault-detection procedures** **Level 2**

To avoid hazards and maintain a safe state in the system, it is important to monitor a system, identifying when a fault has occurred, and presenting its type and location. This early detection of a fault contributes to avoid systematic faults and providing time to the system to recover from the fault.

RA.FH.a3 **Specify Restart-up procedures** **Level 1**

Sometimes, hazards can be eliminated by taking restart-up procedures. This step of the safety module concerns to the specification of such automatic procedures.

RA.FH.a4 **Document the system behavioral model** **Level 1**

The specification of the system behavioral model allows to verifying early its behavior against the one expected. This analysis contributes to detect early the errors and inconsistencies in the system specification as well as to anticipate the correct behavior of the system.

RA.FH.a5 **Identify and document Common-cause failures (CCF) and how to prevent them** **Level 1**

Some failures may have a shared cause and its repeatability is known. Such failures are called Common-cause failures (CCF) and due to the presence of many electronic parts in the system, they should be identified and documented.

RA.FH.a6 Perform reliability and system performance analysis Level 2

The time to failure as well as to repair some component impact in system recovery and avoidance of hazardous situations. Accordingly, reliability and system performance analysis should be conducted and its results recorded.

Supporting action(s)

- OS.SP.a13 Determine the required performance level

RP Release planning

Release planning consists in determining the optimal set of requirements for a certain release to be implemented at a defined/estimated time and cost to achieve some goals. A careful release planning is necessary to avoid risky situations, fail to achieve planned goals or miss the time-to-market. Besides the sub processes and actions already present in UNI-REPM, the module defines a new one related to system certification.

RP.SC Safety Certification

Considering that many safety-critical systems should be certified by regulatory authorities, the Safety Certification sub process area handles certification issues early in the development process.

RP.SC.a1 Conduct safety audits Level 2

Safety audits should be conducted to examine whether the requirements are being achieved and the desired level of safety is preserved. This step should be a periodic activity during the Requirements Engineering process as well as the next stages of system development.

Supporting action(s)

- OS.SP.a2 Define and document requirements for periodic functional safety audits

RP.SC.a2 Demonstrate the preliminary safety integrity level achieved by the system Level 2

From the results of safety audits is possible to demonstrate the preliminary level of safety achieved by the system. The level should be compared against the one desired and can be improved still in Requirements Engineering process or in the next stages of development.

Example of safety integrity level are:

- IEC 61508 defines four levels (1-4) where the 4th level is the highest of safety integrity and 1st is the lowest.
- ECSS-E-HB-40A defines the following categories of software criticality: category A, B, C, D.

Supporting action(s)

- RP.SC.a1 Conduct safety audits
- OS.SP.a7 Define and document the regulations and safety standards to be followed

RP.SC.a3 Evaluate the threat to society from the hazards that cannot be eliminated or avoided **Level 1**

Stakeholders should be aware of the risks caused by hazards that cannot be eliminated or avoided and are present in the system. Hence, the threats to society should be evaluated and properly documented.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards
- RA.PSA.a4 Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)
- RA.PSA.a6 Obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.)
- RA.PSA.a9 Conduct risk estimation
- RA.PSA.a10 Conduct risk evaluation for each identified hazard

RP.SC.a4 Construct preliminary safety and hazard reports **Level 1**

During the development of safety-critical systems results in many iterations of hazard analysis, that generates a lot of safety and hazard reports. In Requirements Engineering phase, a preliminary version of such documents should be constructed and updated during system lifecycle.

RP.SC.a5 Construct preliminary safety cases **Level 2**

At the end of Requirements Engineering stage, all information gathered during safety and hazard analysis should be used to construct preliminary safety cases.

Supporting action(s)

- RA.PSA.a3 Identify and document system hazards

RP.SC.a6 Demonstrate preliminary compliance with safety standards **Level 2**

The safety level achieved at Requirements Engineering phase should be used to demonstrate preliminary compliance with safety standards. The demonstration may be performed by developing a document describing the safety requirements, listing the safety standards and system specifications containing requirements to be satisfy by suppliers among other relevant information.

Supporting action(s)

- RP.SC.a2 Demonstrate the preliminary safety integrity level achieved by the system
- DS.SDO.a10 Include a summary of safety requirements

- RE.SM.a6 Define the safety standards that suppliers must follow
- OS.SP.a8 Identify any certification requirements for software, safety or warning devices or other special safety feature

RP.SC.a7 Ensure that the hazard report is updated with embedded links to the resolution of each hazard, such as safety functional requirements, safety constraints, operational requirements, and system limitations **Level 2**

The information about hazards should be easy to find to improve the communication among stakeholders and the traceability in the development process. Accordingly, safety functional requirements, safety constraints, operational requirements, and system limitations should be inserted in the hazard report and periodically updated.

Supporting action(s)

- RP.SC.a4 Construct preliminary safety and hazard reports
- PM.SCM.a1 Maintain with unique identification all safety configuration items
- OS.STO.a5 Use of tools with support to cross reference and maintain the traceability among safety information in the software specification

RP.SC.a8 Document the division of responsibility for system certification and compliance with safety standards during safety planning **Level 1**

Division of responsibility is necessary in the development of safety-critical systems especially in large and complex projects. This division of activities among personnel should be documented during safety planning and include the specification of people responsible for system certification and to demonstrate compliance with safety standards.

Supporting action(s)

- OS.SP.a7 Define and document the regulations and safety standards to be followed

RP.SC.a9 Specify a maintenance plan **Level 1**

A maintenance plan is necessary to release of a safety-critical system. This plan should describe the development and testing activities required to be undertaken on each new release of software including the obsolescence of development equipment, test environments and software among other relevant information.

RV Requirements Validation

Requirements validation includes the inspection of the produced documents against defined safety and quality standards and the needs of stakeholders. In the safety module, a sub process to plan the verification and validation activities was added since they often run concurrently and may use portions of the same environment.

RV.SVV Safety Validation and Verification

In the Safety Validation and Verification (V&V) there are actions to validation of the requirements and the definition of strategies to the verification of requirements. V&V activities should be available early in the development process so that the safety requirements are clearly understood and agreed by the relevant stakeholders.

RV.SVV.a1 Define the safety validation plan for software aspects of system safety **Level 2**

The objective of this action is to define a safety validation plan for software aspects of system safety. This plan should contain [38]:

- details of when the validation will be conducted;
- details of personnel responsible for performing the validation;
- identification of the relevant modes of system operation such as preparation for use including setting and adjustment, startup, automatic, manual, re-setting, shut down, maintenance, and uncommon conditions;
- identification of the safety-significant software which needs to be validated;
- the technical strategy for the validation;
- the required environment in which the validation activities will be performed;
- the pass/fail criteria;
- the policies and procedures for evaluating the results of the validation, particularly failures.

Supporting action(s)

- RA.SVV.a3 Define the technical strategy for the validation of external systems and safety-related software
- RA.SVV.a4 Define pass/fail criteria for accomplishing software validation and verification

RV.SVV.a2 Define the safety verification plan **Level 1**

The demonstration that safety will be properly achieved encompasses the definition of a safety verification plan. This plan comprises planning inspection, testing, analyses, and demonstration activities and should describe the following information [28][39][40]:

- methods of verification (for example, inspections, peer reviews, audits, walkthroughs, analyses, simulations, testing, and demonstrations);
- support tools, test equipment and software, simulations, prototypes, and facilities;
- safety test specifications;
- required outcome of the tests for compliance;
- chronology of the tests.

Supporting action(s)

- RV.SVV.a5 Develop safety test plans, test descriptions, test procedures, and validation and verification safety requirements.
- RA.PSA.a21 Document verification requirements, possible human-machine interface problems, and operating support requirements

RV.SVV.a3 Define the technical strategy for the validation of external systems and safety-related software **Level 2**

A technical strategy for the validation (for example analytical methods, statistical tests etc.) should be defined and the rationale for choosing it recorded. The strategy should include [38]:

- choice of manual or automated techniques or both;
- choice of static or dynamic techniques or both;
- choice of analytical or statistical techniques or both;
- choice of acceptance criteria based on objective factors or expert judgment or both.

RV.SVV.a4 Define pass/fail criteria for accomplishing software validation and verification **Level 1**

A part of safety V&V activities consists in defining pass/fail criteria for accomplishing them. The criteria should address [38]:

- the required input signals with their sequences and their values;
- the anticipated output signals with their sequences and their values;
- other acceptance criteria, for example memory usage, timing and value tolerances.

RV.SVV.a5 Develop safety test plans, test descriptions, test procedures, and validation and verification safety requirements **Level 1**

The goal of this step is to define and document preliminary versions of safety test plans, test descriptions, test procedures, and validation and verification of safety requirements. The definition of such documents and requirements to be used in V&V activities aims to ensure that no hazards are introduced by test procedures [37]. Therefore, this should be careful planned and begin early in the development process.

Supporting action(s)

- RA.PSA.a21 Document verification requirements, possible human-machine interface problems, and operating support requirements

RV.SVV.a6 Define and maintain a software integration test plan **Level 2**

Since there are many systems and subsystems as well as third-party software and equipment communicating with the safety-critical system it is necessary to define and maintain a software integration test plan. A successful integration strategy should use a combination of techniques, depending on the complexity of components [28].

Some factors to be considered during the elaboration of this plan are availability of the product components, test equipment, procedures, integration environment, and personnel skills [28].

RV.SVV.a7 Validate safety-related software aspects **Level 1**

The safety-related software aspects described in the safety validation plan should be validated and the results documented.

Supporting action(s)

- RV.SVV.a1 Define the safety validation plan for software aspects of system safety

RV.SVV.a8 Ensure that there is no potentially hazardous control actions **Level 1**

The aim of this step is to analyze whether the safety control actions provided in the system design previously defined there is no potential for inadequate control, leading to a hazard.

Supporting action(s)

- RA.PSA.a16 Identify and document possible control flaws and inadequate control actions

RV.SVV.a9 Perform safety evaluation and verification at the system and subsystem levels **Level 1**

The safety evaluation and verification of the safety-critical system should be performed at system and subsystem levels to ensure that there is no hazardous situation remains in the system.

Supporting action(s)

- RA.PSA.a21 Document verification requirements, possible human-machine interface problems, and operating support requirements

RV.SVV.a10 Conduct joint reviews (company and customer) **Level 1**

The validation and verification of the system should be performed in meeting with company and customer together. Conducting non-jointly reviews rises the risk to find late disagreements among stakeholders on the product capability or quality, causing substantial reengineering and increasing its cost and time to develop [41].

RV.SVV.a11 Ensure that the stakeholders understand software-related system safety requirements and constraints **Level 2**

Stakeholders involved in the development of a safety-critical system, particularly Requirements engineers, should understand the software-related system safety requirements and constraints in order to produce better system specification. These requirements should not be merely included in the specification, it is necessary to properly and clearly specify them in details. This will contribute to avoid that developers or other stakeholders involuntarily disable or override system safety features or implement the functionalities erroneously [30].

RV.SVV.a12 Document discrepancies between expected and actual results Level 1

Any discrepancies between expected and obtained results of V&V should be documented. It is also necessary to record the analysis made of such discrepancies such as the decisions taken about continuing the validation, the change requests and the return to an earlier part of system development [38].

Supporting action(s)

- RV.SVV.a7 Validate safety-related software aspects

RV.SVV.a13 Verify the behavioral model Level 3

The verification of system behavior should use the system behavioral model defined previously aiming to ensure the correctness of the system or detect errors and inconsistencies in the system specification.

Supporting action(s)

- RA.FH.a4 Document the system behavioral model

RV.SVV.a14 Ensure that software requirements and software interface specification are consistent Level 2

The objective of this action is to analyze whether the software requirements and software interface specification are compatible and they do not have contradictory issues. The non-consistent parts should be documented and corrected.

RV.SVV.a15 Perform safety inspections Level 1

Stakeholders should implement controls and to inspect the Requirements Engineering process and operations in order to discover and correct any additional hazards [30].

RV.SVV.a16 Identify and fix inconsistencies in safety requirements specification Level 2

The safety requirements specification should be examined in order to find inconsistencies that must be recorded and solved. The documentation of such inconsistencies should include the sources, conditions, rationales, as well as corrective action requirements and actions.

Supporting action(s)

- RV.SVV.a12 Document discrepancies between expected and actual results
- RV.SVV.a13 Verify the behavioral model

OS Organizational Support

This main process area evaluates the amount of support given to requirements engineering practices from the surrounding organization. Organizational support is important, since ultimately the success of any time-consuming activity needs to be understood and supported by the organization. This main

process area is aimed to enable organizational support, but also make the importance of requirements engineering clear to the development organization at large. The safety module added three new areas: Safety Planning, General Safety Management, Safety Tool Support, Safety Knowledge Management.

OS.SP Safety Planning

This main process area evaluates the amount of support given to requirements engineering practices from the surrounding organization. The safety module defines sub process to provision the safety practices and to establish a safety culture in the company.

OS.SP.a1 Develop an integrated system safety program plan **Level 1**

An integrated system safety program plan must be developed to define in detail tasks and activities of system safety management and system safety engineering essential to identify, evaluate, and eliminate/control hazards, or reduce the associated risk to a level acceptable during the safety lifecycle. This plan offers a formal basis of understanding between the customer and organization about the system safety program; it will be executed to meet contractual requirements [39].

OS.SP.a2 Define and document requirements for periodic functional safety audits **Level 2**

Periodic functional safety audits should be performed during safety lifecycle. Accordingly, it is necessary to define and document requirements for such audits. The requirements should include [38]:

- assumptions, limitations, hazard analysis results, constraints and safety decisions;
- the frequency of the functional safety audits;
- the level of independence of those carrying out the audits;
- the necessary documentation and follow-up activities.

OS.SP.a3 Define and document the interface between system safety and all other applicable safety disciplines **Level 1**

Considering that there are many disciplines involved in the development of a safety-critical system, the interface between system safety and other safety disciplines such as nuclear, range, explosive, chemical, biological, among others should be defined and recorded.

OS.SP.a4 Define the scope of safety analysis **Level 1**

At the very beginning of Requirements Engineering process, the scope and objectives of safety analysis should be defined. This includes an analysis of system boundaries, assumptions to be considered as well as data/information sources and documents to be consulted.

OS.SP.a5 Establish the hazards auditing and log file **Level 2**

The template for the hazards auditing and log file should be created. This file will be periodically updated and should contain corrective actions, waivers, and verification efforts [30].

OS.SP.a6 Establish working groups and structures **Level 2**

In complex systems, special organizational structures such as the definition of working groups that are necessary but do not already exist must be established at this step.

OS.SP.a7 Define and document the regulations and safety standards to be followed **Level 2**

The regulations and safety standards to be followed should be defined and documented. Compliance with such standards is necessary for the certification and release of many safety-critical systems.

OS.SP.a8 Identify any certification requirements for software, safety or warning devices or other special safety feature **Level 1**

The certification requirements for software, safety or warning devices or other special safety features should be identified and documented in this step.

Safety features or devices are define to protect the system when it is not possible to eliminate the hazard. Warning devices, on the other hand, are used to alert personnel to the particular hazard if safety devices do not adequately lower the risk of the hazard. These certification requirements will be used to demonstrate the level of safety achieved by the system and compliance with safety standards.

OS.SP.a9 Define and document requirements completeness criteria and safety criteria **Level 2**

Ensuring completeness in a system is a challenging task. A system must not be complete in the mathematical sense, but rather in the sense of a lack of ambiguity. Accordingly, the system specification may be sufficiently complete with respect to safety without being absolutely complete: it just have to achieve the safe behavior in all circumstances in which the system operates [30]. In this step, criteria for requirements completeness and safety should be defined.

OS.SP.a10 Review safety experience on similar systems **Level 2**

Lessons learned and safety experience on similar systems of the stakeholders should be reviewed, including mishap/incident hazard tracking logs (if accessible), among other information to identify possible sources of hazards and their risks.

Supporting action(s)

- DS.SDO.a7 Document lessons learned

OS.SP.a11 Specify the general safety control structure **Level 3**

Safety-critical systems can be described as hierarchical structures, where each level imposes constraints on the activity of the level beneath it [30]. Such structures describe control processes that should enforce the safety constraints for which the control process is responsible. The determination of a safety control structure is

important for safety analysis since accidents occur when these processes provide inadequate control and the safety constraints are violated in the behavior of the lower-level components.

For details about how to elaborate the safety control structure, please see [30].

OS.SP.a12 Specify operating conditions of the machine and installation conditions of the electronic parts **Level 1**

Some operating conditions of the machine and installation conditions of the electronic parts as well as other environmental conditions should be specified by the company. This specification may include:

- Environment temperature and humidity
- Degree of protection
- Electromagnetic compatibility
- Mechanical vibration and shock
- Emergency stop function

OS.SP.a13 Determine the required performance level **Level 1**

The performance level that should be satisfied by the system in order to achieve the required risk reduction for each safety requirements should be determined and recorded. This performance level will be used in the reliability analysis of the system.

OS.SP.a14 Identify and document the hazard analysis to be performed; the analytical techniques (qualitative or quantitative) to be used; and depth within the system that each analytical technique will be used (e.g., system level, subsystem level, component level) **Level 1**

The techniques to be used in hazard analysis should be identified. The techniques are classified as qualitative or quantitative. Qualitative analysis concerns with examining the causal relations between events and states in sequences connecting failures of components to hazard states of the system [43]. In the quantitative safety analysis, probabilities (or probability density functions) are assigned to the events in the chain and an overall likelihood of a loss is calculated [30].

The choice of such techniques depend on [31][38] their goals and limitations (i.e., the level of uncertainty, possible unexpected outcomes, assumptions, team knowledge, system complexity, the application sector and its accepted good practices, legal and safety regulatory requirements; and the availability of accurate data upon which the hazard and risk analysis is to be based.

Moreover, the depth within the system that each analytical technique will be used should be specified. The level can be associated for example with [39]: the system, subsystem, components, software, hazardous materials, personnel, ground support equipment, non-developmental items, facilities, and their interrelationship in the logistic support, training, maintenance, operational environments.

OS.GSM General Safety Management

The general safety management sub process covers the project safety management activities related to planning, monitoring, and controlling the project.

OS.GSM.a1 Identify and document the system development methodology Level 2

The system development methodology should be defined and properly documented. There are different types of process models to develop software such as traditional methodologies (waterfall model), agile methodologies (XP, Scrum, FDD e Crystal), evolutionary (incremental, prototyping, spiral), and emergent methodologies (based on reuse, components) among others. The company should choose the one that most fit the project goals and needs of organization.

OS.GSM.a2 Identify and document safety lifecycle for the system development Level 1

A safety lifecycle should be defined by the company and followed during system development.

Example

- Initial concept, design, implementation, operation and maintenance, and disposal [38].

OS.GSM.a3 Identify and document competence requirements for the safety activities Level 2

The competence requirements for the safety activities during the project should be determined. These requirements depends on the knowledge and skills of the employees available to support the development of the project [38]. A two-dimensional matrix with the competences along one-axis and project activities along the other axis may be a suitable format for achieving this identification [38].

Some factors impacts the definition of the competence requirements [38]:

- responsibilities
- level of supervision required
- potential consequences in the event of failure of systems
- novelty of the design
- previous experience and its relevance to the specific duties to be performed and the technology being employed
- type of competence appropriate to the circumstances
- safety engineering knowledge appropriate to the technology
- knowledge of the legal and safety standards
- relevance of qualifications to specific activities to be performed.

Supporting action(s)

- OS.SKM.a4 Maintain employees' competence information

OS.GSM.a4 Set safety policy and define safety goals Level 2

Safety Policy, which correspond to strategic decision that establishes a safety goal [34], should be defined. The description of such information may include the

relationships of safety to other organizational goals and provide the scope for the discretion, initiative, and judgment in deciding what should be done in specific situations [37].

OS.GSM.a5 Identify and document responsibility, accountability and authority **Level 1**

Responsibility, accountability and authority for which activity to be performed during development should be assigned and documented.

Supporting action(s)

- OS.SKM.a4 Maintain employees' competence information

OS.GSM.a6 Define system safety program milestones and relate these to major program milestones, program element responsibility, and required inputs and outputs **Level 1**

A schedule of system safety activities including required inputs and outputs, start and completion dates that support the Requirements Engineering process should be determined. This schedule will contain the system safety program milestones and the relationships to major program milestones, program element responsibility.

Supporting action(s)

- OS.GSM.a5 Identify and document responsibility, accountability and authority

OS.GSM.a7 Make use of indicators on engineering documentation to assess the product properties and the development progress **Level 2**

Indicators about the percentage of requirements allocation, implement, verification, and about the engineering documentation to assess the product properties and the development progress should be identified and recorded.

OS.GSM.a8 Prepare progress reports in a period of time defined by the project **Level 2**

Progress reports are the basis for monitoring activities, communicating status, and taking corrective action. Progress is defined by comparing actual work product and task attributes, effort, cost, and schedule to the plan at prescribed milestones or control levels within the project schedule or work breakdown structure [28]. The elaboration of these reports in a period of time defined by the project allows taking corrective actions early.

The progress reports may describe the implementation status of recommended mitigation measures [44], hazard status among other information.

Supporting action(s)

- OS.GSM.a7 Make use of indicators on engineering documentation to assess the product properties and the development progress

OS.GSM.a9 Monitor project and take corrective actions **Level 1**

The defined indicators and the progress reports should be used to monitor the project and take corrective actions when progress varies significantly from that planned. Corrective action may include [28]:

- changing the process(es), changing the plan, or both;
- adjusting resources, including people, tools, and other resources;
- negotiating changes to the established commitments;
- changing the requirements and standards that have to be satisfied;
- finishing the project if necessary.

Supporting action(s)

- OS.GSM.a8 Progress reports should be prepared in a period of time defined by the project

OS.STO Safety Tool support

The Requirements Engineering process is better conducted when supported by adequate tools. In order to be able to facilitate the appropriate execution of the corresponding tasks and manage all safety-related information that should be created, recorded and properly visualized, the module has a sub process to handle these issues.

OS.STO.a1 Make use of verification and validation tools **Level 2**

Tools to be used during the verification and validation such as static code analyzers, test coverage monitors, theorem proving assistants, and simulators should be determined and their use documented.

OS.STO.a2 Specify justifications for the selection of non-safety-related support tools **Level 2**

The software tools that supports a phase of the software development lifecycle and that cannot directly influence the safety-related system during its run time must be specified. These tools can be of three types [38]:

1. the ones that generates no outputs which can directly or indirectly contribute to the executable code (including data) of the safety related system, for example, text editors or a requirements or design support tool with no automatic code generation capabilities; configuration control tools;
2. tools that supports the test or verification of the design or executable code, where errors in the tool can fail to reveal defects but cannot directly create errors in the executable software such as test harness generators, test coverage measurement tools; and static analysis tools;
3. the ones that generate outputs which can directly or indirectly contribute to the executable code of the safety related system. Examples of these types may be an optimizing compiler or a compiler that incorporates an executable run-time package into the executable code.

OS.STO.a3 Assess non-safety-related support tools which can directly or indirectly contribute to the executable code of the safety related system **Level 2**

The non-safety-related support tools selected previously should be evaluated to determine the level of reliance that can be provided by the tools, and their potential failure mechanisms that may affect the executable software. In case of identifying

such mechanisms, they must be documented and suitable mitigation procedures must be carried out.

Supporting action(s)

- OS.STO.a2 Specify justifications for the selection of non-safety-related support tools

OS.STO.a4 Record information of the tools in the baseline **Level 1**

Information about the tools (such as version, installation and execution requirements, name of vendor) used in each baseline must be recorded.

OS.STO.a5 Make use of tools with support to cross reference and maintain the traceability among safety information in the software specification **Level 2**

Cross referencing is fundamental for establish and maintain traceability among safety information in the software specification. Therefore, it is necessary to select and use tools that supports this feature.

Supporting action(s)

- OS.STO.a6 Make use of specification tools

OS.STO.a6 Make use of specification tools **Level 2**

The use of specification tools contributes for developing high-quality systems since methods for the development of systems together with automated mechanisms can be provided. Such tools facilitates the development, reduce the probability of introducing errors in the system through the use of syntax checks, and other functionalities.

OS.STO.a7 Define and use tools to support the safety process and workflow management **Level 3**

Project management activities can be facilitated using tools to support the safety process and workflow management. Accordingly, the tools that will be used by the project should be defined and documented.

OS.SKM Safety Knowledge Management

The Safety Knowledge Management sub process area provides transparency in the development process by make sure that projects and the company have the required knowledge and skills to accomplish project and organizational objectives. The goal is to guarantee the effective application of project resources (people, knowledge and skill) against the organization's needs.

OS.SKM.a1 Establish and maintain an infrastructure to share knowledge **Level 2**

Collecting and disseminating knowledge about safety concerns across organizational levels can improve safety practices [31]. To achieve this, it is necessary to establish and maintain an infrastructure to support the system capable of sharing knowledge.

OS.SKM.a2 Develop a safety information system to share knowledge in the organization **Level 3**

A safety information system capable of maintain the organization knowledge into a single database contributes to better integration of documents, and teams. Among the benefits a safety information system are a more efficient analysis of tasks and hazards, better transfer of data with subsequent methods of risk quantification, and better monitoring of safety measures [31].

Supporting action(s)

- OS.SKM.a1 Establish and maintain an infrastructure to share knowledge

OS.SKM.a3 Define control access mechanisms to the safety information system **Level 2**

Control access mechanisms to the safety information system should be implemented to enable stakeholders locate and consume only the data adequate for their roles.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization

OS.SKM.a4 Maintain employees' competence information **Level 2**

The competence, i.e. skills, previous training, technical knowledge, experience and qualifications of company employees should be maintained in the safety information system. This information will be used to identify and document competence requirements for the safety activities, allocate people in teams and responsibility.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization

OS.SKM.a5 Document a strategy to manage the knowledge **Level 3**

The strategy to manage the knowledge such as procedures to insert information in the system, personnel responsible for such activity, periodicity of updates must be defined and document.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization

OS.SKM.a6 Define a lifecycle for projects artifacts **Level 1**

A lifecycle of project artifacts describing the possible states in which an artifact can be located should be defined and documented.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization

OS.SKM.a7 Define and maintain a strategy for reuse **Level 2**

The data stored in the safety information system should be reused at system and component levels to reduce time of development, costs and develop better systems. A strategy for reuse should be defined describing in details the procedures for conducting such activity.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization

OS.SKM.a8 Reuse the stored artifacts and knowledge **Level 2**

The reuse strategy defined must be followed and the stored knowledge should be reused.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization
- OS.SKM.a7 Define and maintain a strategy for reuse

OS.SKM.a9 Document that stored artifacts and knowledge are being used in the project **Level 3**

The use of artifacts in a given moment should be documented to improve the communication among stakeholders. The registration that an artifact is being used allows notifying users about problems, new versions and exclusions of artifacts in use.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization

OS.SKM.a10 Notify users about problems, new versions and exclusions of artifacts in use **Level 2**

The safety information system should notify the users about problems, updates and exclusions that many occur with artifacts in use.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization
- OS.SKM.a9 Document that stored artifacts and knowledge are being used in the project

OS.SKM.a11 Manage assets **Level 2**

The assets of the organization and the system, for example people, property, environment or service should be documented and managed.

Supporting action(s)

- OS.SKM.a2 Develop a safety information system to share knowledge in the organization

PM Requirements Process Management

The requirements process management covers all the activities to manage and control requirements change as well as to ensure the creation, control, and evolution of the processes, as well as coherence among team members. The safety module added three new areas: Safety Configuration Management, Safety Communication, and Safety Traceability.

PM.SCM Safety Configuration Management

The safety configuration management addresses the control of content, versions, changes, distribution of safety data, proper management of system artifacts and information important to the organization at several levels of granularity. Examples of artifacts that may be placed under configuration management include plans, process descriptions, safety requirements, models, system specification, system data files, and system technical publications among other information [28].

PM.SCM.a1 **Maintain with unique identification all safety configuration items** **Level 1**

The safety configuration items (artifacts) and safety information, such as hazards, safety requirements, risks, among others, required to achieve the safety integrity requirements of the safety-related system should be maintained accurately and with unique identification. A configuration item is an element designated for configuration management, which may consist of multiple related work products.

Supporting action(s)

- OS.STO.a5 Use of tools with support to cross reference and maintain the traceability among safety information in the software specification

PM.SCM.a2 **Define and document change-control procedures** **Level 2**

Change-control procedures that regulate changes to hardware and software maintained by the project and the strategy to control these changes that will be adopted must be defined and recorded.

PM.SCM.a3 **Define and document safety configuration items to be included in the baseline** **Level 2**

The safety configuration items that will be included in the baseline should be defined and documented. Examples of criteria for selecting such items may be artifacts/information used by two or more groups, the ones that are expected to change over time either because of errors or change of requirements, dependent on each other and a change in one mandates a change in others and the ones critical for the project [28].

Supporting action(s)

- PM.SCM.a1 Maintain with unique identification all safety configuration items

PM.SCM.a4 **Document configuration status, release status, the justification (taking account of the impact analysis) for and approval of all modifications, and the details of the modification** **Level 2**

The configuration status, release status, the justification (taking account of the impact analysis) for an approval of all modifications, and the details of the modification should be recorded.

Supporting action(s)

- PM.SCM.a6 Perform safety impact analysis on changes

PM.SCM.a5 Document the release of safety-related software Level 2

The release of safety-related software, changes in the agreements with the suppliers, and other relevant information should be documented.

PM.SCM.a6 Perform safety impact analysis on changes Level 1

Change request may occur at any phase of the software safety lifecycle regarding artifacts or information specified earlier in the safety lifecycle. In this case, an impact analysis must be conducted to determine [38][45]: (1) which software modules are impacted; and (2) which earlier safety lifecycle activities shall be repeated.

Supporting action(s)

- PM.SCM.a7 Specify and follow the template for software modification request

PM.SCM.a7 Specify and follow the template for software modification request Level 2

A template for software modification request should be defined by the configuration management area and followed by all stakeholders of the organization.

PM.SCM.a8 Document the procedures for starting modifications in the systems, and to obtain approval and authority for these modifications Level 1

The procedures for initiating modifications to the safety-related systems, and to obtain approval and authority for modifications should be determined and recorded.

Supporting action(s)

- PM.SCM.a7 Specify and follow the template for software modification request

PM.SCM.a9 Maintain and make available the software configuration management log Level 2

A log with all commands executed in the artifacts, such as insertion, exclusion and update, must be maintained. This log must be accessible by all authorized stakeholder so they can be aware of all changes in such artifacts.

Supporting action(s)

- PM.SCM.a1 Maintain with unique identification all safety configuration items

PM.SCM.a10 Create all deliverable documents according to the rules defined in the Configuration Management Plan Level 1

A standard for naming the deliverable documents established in the configuration management plan should be followed.

Supporting action(s)

- PM.SCM.a1 Maintain with unique identification all safety configuration items

PM.SCM.a11 Upload all documents on the safety information system **Level 3**

The safety information system must be used to manage all documents produced during the development process.

PM.SCO Safety Communication

The safety analysis and assurance processes requires knowledge of many safety terms, methods, process from requirements engineers. However, they generally are unfamiliar with all such information. Aiming to minimize this problem, the safety module add actions to improve the safety communication sub process.

PM.SCO.a1 Establish formal communication channels among different organizational levels **Level 3**

Formal communication channels (for example email, face-to-face, meeting, collaboration infrastructure) among different organizational levels are also necessary to maintain continuous communication with internal stakeholders, including comprehensive reporting of safety performance.

Supporting action(s)

- OS.GSM.a8 Progress reports should be prepared in a period of time defined by the project

PM.SCO.a2 Define a method of exchanging safety information with the suppliers **Level 2**

Exchanging safety information with the suppliers is fundamental for the development of safety-critical systems. Therefore, adequate method for communication with suppliers must be defined.

PM.SCO.a3 Establish a common nomenclature **Level 1**

Common nomenclature is of paramount importance for specifying safety to avoid misunderstandings, redundancies and errors in system specification. Hence, the company should define a glossary and adopt at all levels of organization.

PM.SCO.a4 Train people continuously in system engineering and safety techniques (education) **Level 2**

Stakeholders should be trained continuously about methods, techniques, terms of system engineering and safety techniques to improve the safety analysis and the Requirements Engineering process.

PM.SCO.a5 Make use of a common safety information system for system specification and safety analysis **Level 3**

The safety information should be shared with the purpose of specifying the system and conducting safety analysis. The use of a common system improves the communication among personnel improving the system safety.

PM.SCO.a6 Keep stakeholders updated regarding the progress of all safety-related activities **Level 2**

Stakeholders must be aware of the status of system development process. In order to achieve this, progress reports should be elaborated and published.

Supporting action(s)

- PM.SCO.a1 Establish formal communication channels among different organizational levels

PM.SCO.a7 Construct a repository of common hazards **Level 2**

A repository listing the common hazards can reduce the time spent in safety analysis contributing to a better analysis. Accordingly, such repository should be constructed and maintained.

PM.SCO.a8 Define and follow templates for system artifacts **Level 2**

Templates are important to optimize the specification, provide stakeholders with acquaintance about the artifacts and processes adopted by the company. Hence, templates for system artifacts must be established and followed.

PM.SCO.a9 Document how conflicts will be resolved **Level 2**

Misunderstandings and conflicts among safety goals or mission goals and safety goals for example may occur during system specification. Therefore, procedures to solve such conflicts must be established.

PM.SCO.a10 Identify, record and resolve conflicts **Level 1**

When conflicts are identified, they should be recorded and solved following the procedures defined previously.

Supporting action(s)

- PM.SCO.a9 Document how conflicts will be resolved

PM.SCO.a11 Produce all the deliverables documents based on the official document templates **Level 2**

All deliverables documents should be produced according the templates defined by the company.

Supporting action(s)

- PM.SCO.a8 Define and follow templates for system artifacts

PM.SCO.a12 Make available safety-related software specification to every person involved in the lifecycle **Level 2**

The personnel involved in the system lifecycle must be able to visualize to the safety-related software specification with control access.

PM.ST Safety Traceability

Changes in requirements will probably occur during the system development. Therefore, it is necessary to ensure consistency among system artifacts. This sub process area of safety module handles the traceability among artifacts helping to determine that the requirements affected by the changes have been completely addressed.

PM.ST.a1 **Define and maintain traceability policies** **Level 2**

Traceability policies to be followed during the development process must be elaborated.

PM.ST.a2 **Define and maintain bi-directional traceability between the system safety requirements and the software safety requirements** **Level 2**

The safety-critical system is composed not only by software, hence, bi-directional traceability between the system safety requirements and the software safety requirements must be defined and maintained.

Supporting action(s)

- PM.ST.a1 Define and maintain traceability policies

PM.ST.a3 **Define and maintain bi-directional traceability between the safety requirements and the perceived safety needs** **Level 2**

The relationships between the safety requirements and the perceived safety needs must be identified and maintained. If such relationships will be possible to determine which safety requirements satisfy some safety needs and vice-versa.

Supporting action(s)

- PM.ST.a1 Define and maintain traceability policies

PM.ST.a4 **Link and maintain bi-directional traceability between environmental assumptions and the parts of the hazard analysis based on the assumption** **Level 2**

Environmental assumptions play an important role in safety analysis since their occurrence assumed by the requirements engineer may compromise the system safety. Hence, the links between the environmental assumptions and the parts of the hazard analysis based on the assumption must be properly maintained.

Supporting action(s)

- PM.ST.a1 Define and maintain traceability policies

PM.ST.a5 **Define and maintain bi-directional traceability between system and subsystem verification results and system specification** **Level 1**

Bi-directional traceability between system and subsystem verification results and system specification must be established and maintained.

Supporting action(s)

- PM.ST.a1 Define and maintain traceability policies

PM.ST.a6 **Define and maintain bi-directional traceability between validation results and system specification** **Level 1**

The relationships between the validation results and system specification must be established.

Supporting action(s)

- PM.ST.a1 Define and maintain traceability policies

PM.ST.a7 **Define and maintain bi-directional traceability among system hazards into components** **Level 2**

The back and forth traceability between system hazards and its components must be defined and maintained.

Supporting action(s)

- PM.ST.a1 Define and maintain traceability policies

PM.ST.a8 **Justify reasons for not traced software requirements** **Level 2**

The software requirements that are not traced must be documented and the reasons for such decision must be recorded.

Part II. Glossary

Accident: an undesired and unplanned (but not necessarily unexpected) event that results in (at least) a specified level of loss (including loss of human life or injury, property damage, environmental pollution, and so on). In an insulin infusion pump, an accident can be *incorrect treatment received by the patient*.

Environmental conditions: the state of the environment. The set of factors including physical, cultural, demographic, economic, political, regulatory, or technological elements surrounding the system that could affect its safety. For example, in an insulin infusion pump, an environmental condition can be *obstruction in the delivery path*.

Harm: physical injury or damage to the health of people or damage to property or the environment.

Hazard: system state or set of conditions that, together with a particular set of worst-case environmental conditions, will lead to an accident (loss). One hazard in an insulin infusion pump can be an *insulin overdose.*

Pure safety requirements: are typically of the form of a quality criterion (a system-specific statement about the existence of a sub-factor of safety) combined with a minimum or maximum required threshold along some quality measure. They directly specify how safe the system must be. In an insulin infusion pump, *the difference between the programmed infusion and the delivered infusion shall not be greater than 0.5%*.

Safety-significant requirements: non-safety primary mission requirements, i. e. requirements that are not originally defined to mitigate some hazard, but they can have significant safety ramifications.

Safety functional requirements: Safety functional requirements are functions to be implemented in a safety-critical system that is intended to achieve or maintain a safe state for the system, in respect of a specific hazardous situation.

Safety Constraints: engineering decisions that have been chosen to be mandated as a requirement intended to ensure a minimum level of safety. Therefore, any safety-related or relevant constraints between the hardware and the software should be identified and documented.

Systematic faults: faults produced by human error during system development and operation that will always appear when the necessary environmental conditions occur.

Risk: combination of the probability of occurrence of a harm and its severity.

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APPENDIX C – USE CASE DESCRIPTIONS

This appendix contains the Use Case Descriptions of Uni-REPM tool.

Name	[UC01] Create Account
Brief Description	The Create Account use case allows the User to create a login and become a Registered User.
Actor(s)	Guest
Flow of Events	
Basic Flow	
This use case starts when the User clicks on the option “Register” from the index page. 1. The User enters the required information values and requests that the system saves the entered values. 2. The system validates the entered information. *3.* The information is stored in the User’s account. The system notifies the User that the account has been created. *4.* The use case ends.	
Alternate Flows	
Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the account creation. At which point, the processing is discontinued, the user account remains unchanged, and the user is notified that the account management request has been cancelled.
Step 2: User does not provide the required information	If during Create Account, the system determines that the User did not provided all required fields, the following occurs: a) The system shows which information were not provided and prompts the User to re-enter the information. b) Step 1 is executed.
Pre-Conditions	
Title	
None	
Post-Conditions	
Title	**Description**
Success	The User entered data is stored in the user account. Confirmation message is displayed in the system.
The user account was not created	The User entered invalid data or chose to cancel the account creation request. In either case, no account will be created.
Extension Points	
None	

Name	[UC02] Sign in
Brief Description	The Sign in use case allows a Registered User to login in and perform evaluations.
Actor(s)	Internal Evaluator, External Evaluator, Administrator
Flow of Events	
Basic Flow	

This use case starts when the User accesses the sign in feature of the system.

1. The user selects the option Sign In.
2. The system prompts the User for his/her email and password.
3. The User enters his/her username and password.
4. The system validates the entered information, making sure that the entered username and password are valid for one user account in the system, and that the required password is entered for the entered username.
5. The User is signed in. The system displays a message indicating that the user is signed in.
6. The use case ends.

Alternate Flows

Title	Description
Step 2: User Forgot User Name/Password	If the User forgot his/her user name or password: 2 (a) The System will prompt the user to provide his/her email. 2 (b) The user enters the email. 2 (c) If the email is entered correctly, a new password is emailed to the email address provided.
Step 4: User Fails Authentication	If the User entered an invalid username and/or password, the following occurs: a) The system informs the User that the combination of email and password is incorrect and the system prompts the User to re-enter the valid information. b) Step 2 is executed.

Pre-Conditions

Title
The user must be registered.

Post-Conditions

Title	Description
Success	The User is authenticated and the system displays all features available for the role the user is associated with as defined in his/her user account.
User not signed in	This can occur because the User repeatedly entered invalid sign in information. The User is not authenticated and remains in the Anonymous User role.

Name	[UC03] Manage Account
Brief Description	The Manage Account use case allows the User to update the User Account Information maintained in the User's account.
Actor(s)	Registered User
Flow of Events	
Basic Flow	

This use case starts when the User accesses the option *Change Profile* that enables him/her to update the information that is maintained in the User's account. 1. The system displays information currently stored for the User. 2. The User enters the desired information values and requests that the system saves the entered values. 3. The system validates the entered information. *4.* The values for the information are stored in the User's account. The system notifies the User that the account has been updated. *5.* The use case ends.
Alternate Flows

Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the account update/deactivation. At which point, the processing is discontinued, the user account remains unchanged.
Step 3: User Enters Invalid User Account Information	If during Modify Account, the system determines that the User did not provided all required fields, the following occurs: a) The system shows which information were not provided and prompts the User to re-enter the information. b) Step 1 is executed.

Pre-Conditions
Title
The User must be signed in before the User can edit or deactivate his/her account.
Post-Conditions

Title	**Description**
Success	The User entered data is stored in the user account.
The user account was not updated	The User entered invalid data or chose to cancel the account management request. In either case, there is no change to the user account.

Extension Points
None

Name	Manage Projects
Brief Description	The Manage Projects use case allows the User to add, edit, view and delete projects.
Actor(s)	Registered User
Flow of Events	
Basic Flow	

This use case starts when the User accesses the option *Projects* that enables him/her to manage information regarding the projects he/she is allowed to manage.

1. The use case starts when the User needs to maintain (add, update, view or delete) projects.
2. According to the operation desired by the User, one of the sub flows is executed:
3. If the customer wants to add a project, the Add project sub flow is executed.
4. If the customer wants to edit a project, the Edit project sub flow runs.
5. If the customer wants to delete a project, the Delete project sub flow is executed.
6. If the customer wants to view all project he/she has previously stored, the View projects sub flow is executed.
7. The use case ends.

Alternate Flows

Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the request. At which point, the processing is discontinued, the user account remains unchanged.
Step 3: Add project	a) This sub flow starts when the User requests to Add a project; b) The system prompts the Project information. c) The User enters the information requested. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the project has been created. f) Step 7 is executed.
Step 4: Edit project	a) This sub flow starts when the User requests to Edit a project; b) The system displays the Project information. c) The User updates the project information. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the project has been updated. f) Step 7 is executed.
Step 5: Delete project	a) This sub flow starts when the User requests to Delete a project; b) The system requests a confirmation of exclusion. c) The User confirms the request. *d)* The system deletes the project and all evaluations performed on this project and notifies the User that the project has been deleted. e) Step 7 is executed.
Step 6: View project	a) This sub flow starts when the User requests to View a project; *b)* The system shows the project information. c) Step 7 is executed.

Pre-Conditions

Title
The User must be signed in before the User can select any of the options.

Post-Conditions

Title	**Description**

Success	The project entered data is stored.
The project was not added or updated	The User entered invalid data or chose to cancel the project management request. In either case, there is no change in the information stored.
Extension Points	
None	

Name	[UC04] Manage Company Profile
Brief Description	The Manage Company Profile use case allows the User to edit and view information regarding its company.
Actor(s)	Internal Evaluator
Flow of Events	
Basic Flow	
This use case starts when the User accesses the option *Company Profile* that enables him/her to manage information regarding his/her own company. 1. The use case starts when the User needs to maintain (edit, view) Company Profile. 2. According to the operation desired by the User, one of the sub flows is executed: 3. If the customer wants to edit a company, the Edit Company Profile sub flow runs. *4.* If the customer wants to view the Company Profile, the View company sub flow is executed. *5.* The use case ends.	
Alternate Flows	
Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the request. At which point, the processing is discontinued, the user account remains unchanged.
Step 4: Edit Company	a) This sub flow starts when the User requests to Edit the company; b) The system displays the company information. c) The User updates the company information. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the company has been updated. f) Step 5 is executed.
Step 6: View Company	a) This sub flow starts when the User requests to view a company; *b)* The system shows the company information. c) Step 5 is executed.
Pre-Conditions	
Title	
The User must be signed in before the User can select any of the options.	
Post-Conditions	
Title	**Description**
Success	The Company entered data is stored.

The company was not added or updated	The User entered invalid data or chose to cancel the company management request. In either case, there is no change in the information stored.
Extension Points	
None	

Name	[UC05] Manage Companies
Brief Description	The Manage Companies use case allows the User to add, edit, view and delete companies.
Actor(s)	External Evaluator, Administrator
Flow of Events	
Basic Flow	
This use case starts when the User accesses the option *Companies* that enables him/her to manage information regarding the companies he/she is allowed to manage. 6. The use case starts when the User needs to maintain (add, update, view or delete) companies. 7. According to the operation desired by the User, one of the sub flows is executed: 8. If the customer wants to add a company, the Add company sub flow is executed. 9. If the customer wants to edit a company, the Edit company sub flow runs. *10.* If the customer wants to delete a company, the Delete company sub flow is executed. *11.* If the customer wants to view all companies he/she has previously stored, the View companies sub flow is executed. *12.* The use case ends.	
Alternate Flows	
Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the request. At which point, the processing is discontinued, the user account remains unchanged.
Step 3: Add Company	a) This sub flow starts when the User requests to Add a company; b) The system prompts the Company information. c) The User enters the information requested. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the company has been created. f) Step 7 is executed.
Step 4: Edit Company	g) This sub flow starts when the User requests to Edit a company; h) The system displays the company information. i) The User updates the company information. j) The system validates the entered information. *k)* The information is stored in the User's account. The system notifies the User that the company has been updated. l) Step 7 is executed.
Step 5: Delete Company	a) This sub flow starts when the User requests to Delete a company;

	b) The system requests a confirmation of exclusion. c) The User confirms the request. *d)* The system deletes the company and all projects and evaluations performed on this company and notifies the User that the company has been deleted. e) Step 7 is executed.
Step 6: View Companies	d) This sub flow starts when the User requests to view a company; *e)* The system shows the company information. f) Step 7 is executed.
Pre-Conditions	
Title	
The User must be signed in before the User can select any of the options.	
Post-Conditions	
Title	**Description**
Success	The Company entered data is stored.
The company was not added or updated	The User entered invalid data or chose to cancel the company management request. In either case, there is no change in the information stored.
Extension Points	
None	

Name	[UC06] Manage models
Brief Description	The Manage models use case allows the User to add, edit, view and delete models.
Actor(s)	Administrator
Flow of Events	
Basic Flow	
This use case starts when the User accesses the option *Models* that enables him/her to manage information regarding the models. 1. The use case starts when the User needs to maintain (add, update, view or delete) models. 2. According to the operation desired by the User, one of the sub flows is executed: 3. If the customer wants to add a model, the Add company sub flow is executed. 4. If the customer wants to edit a model, the Edit company sub flow runs. *5.* If the customer wants to delete a model, the Delete company sub flow is executed. *6.* If the customer wants to view all models stored, the View models sub flow is executed. *7.* The use case ends.	
Alternate Flows	
Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the request. At which point, the processing is discontinued, the user account remains unchanged.
Step 3: Add model	a) This sub flow starts when the User requests to Add a company;

	b) The system prompts the Company information. c) The User enters the information requested. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the company has been created. f) Step 7 is executed.
Step 4: Edit model	m) This sub flow starts when the User requests to Edit a company; n) The system displays the company information. o) The User updates the company information. p) The system validates the entered information. *q)* The information is stored in the User's account. The system notifies the User that the company has been updated. r) Step 7 is executed.
Step 5: Delete model	f) This sub flow starts when the User requests to Delete a company; g) The system requests a confirmation of exclusion. h) The User confirms the request. *i)* The system deletes the company and all projects and evaluations performed on this company and notifies the User that the company has been deleted. j) Step 7 is executed.
Step 6: View model	g) This sub flow starts when the User requests to view a company; *h)* The system shows the company information. i) Step 7 is executed.
Pre-Conditions	
Title	
The User must be signed in before the User can select any of the options.	
Post-Conditions	
Title	**Description**
Success	The Company entered data is stored.
The company was not added or updated	The User entered invalid data or chose to cancel the model management request. In either case, there is no change in the information stored.
Extension Points	
None	

Name	[UC07] Manage Assessment instrument
Brief Description	The Manage Assessment instrument use case allows the User to add, edit, view and delete assessment instruments.
Actor(s)	Administrator
Flow of Events	
Basic Flow	

This use case starts when the User accesses the option *Models* that enables him/her to manage information regarding all assessment models.

1. The use case starts when the User needs to maintain (add, update, view or delete) assessment instruments.
2. According to the operation desired by the User, one of the sub flows is executed:
3. If the customer wants to add an assessment instrument, the Add assessment instrument sub flow is executed.
4. If the customer wants to edit an assessment instrument, the Edit assessment instrument sub flow runs.
5. If the customer wants to delete an assessment instrument, the Delete assessment instrument sub flow is executed.
6. If the customer wants to view all assessment instrument stored, the View assessment instruments sub flow is executed.
7. The use case ends.

Alternate Flows

Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the request. At which point, the processing is discontinued, the user account remains unchanged.
Step 3: Add assessment instrument	a) This sub flow starts when the User requests to Add an assessment instrument; b) The system prompts the Assessment instrument information. c) The User enters the information requested. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the assessment instrument has been created. f) Step 7 is executed.
Step 4: Edit assessment instrument	a) This sub flow starts when the User requests to Edit an assessment instrument; b) The system displays the assessment instrument information. c) The User updates the assessment instrument information. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the assessment instrument has been updated. f) Step 7 is executed.
Step 5: Delete assessment instrument	a) This sub flow starts when the User requests to Delete an assessment instrument; b) The system requests a confirmation of exclusion. c) The User confirms the request. *d)* The system deletes the assessment instrument and all projects and evaluations performed and notifies the User that the company has been deleted. e) Step 7 is executed.
Step 6: View assessment instrument	a) This sub flow starts when the User requests to View an assessment instrument; *b)* The system shows the assessment instrument information.

	c) Step 7 is executed.
Pre-Conditions	
Title	
The User must be signed in before the User can select any of the options.	
Post-Conditions	
Title	**Description**
Success	The assessment instrument entered data is stored.
The assessment instrument was not added or updated	The User entered invalid data or chose to cancel the assessment instrument management request. In either case, there is no change in the information stored.
Extension Points	
None	

Name	[UC08] Manage Users
Brief Description	The Manage Users use case allows the User to edit, view and delete users.
Actor(s)	Administrator
Flow of Events	
Basic Flow	
This use case starts when the Administrator accesses the option *Users* that enables him/her to manage information of all users. 1. The use case starts when the User needs to maintain (edit, view or delete) users. 2. According to the operation desired by the User, one of the sub flows is executed: 3. If the customer wants to edit a user, the Edit user sub flow runs. *4.* If the customer wants to delete a user, the Delete user sub flow is executed. *5.* If the customer wants to view all users stored, the View Users sub flow is executed. *6.* The use case ends.	
Alternate Flows	
Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the request. At which point, the processing is discontinued, the user account remains unchanged.
Step 3: Edit user	a) This sub flow starts when the User requests to Edit a company; b) The system displays the user information. c) The User updates the user information. d) The system validates the entered information. *e)* The information is stored in the selected user account. The system notifies the User that the selected user has been updated. f) Step 6 is executed.
Step 4: Delete user	a) This sub flow starts when the User requests to Delete a company; b) The system requests a confirmation of exclusion.

	c) The User confirms the request. *d)* The system deletes the user and all companies, projects and evaluations performed and notifies the User that the user has been deleted. e) Step 6 is executed.
Step 5: View user	a) This sub flow starts when the User requests to view a user; *b)* The system shows the user information. c) Step 6 is executed.
Pre-Conditions	
Title	
The User must be signed in before the User can select any of the options.	
Post-Conditions	
Title	**Description**
Success	The User entered data is stored.
The user was not added or updated	The User entered invalid data or chose to cancel the user management request. In either case, there is no change to the user account.
Extension Points	
None	

Name	[UC09] Manage Safety/RE Evaluations
Brief Description	The Manage Safety/RE Evaluations use case allows the User to add, edit, view and delete Safety/RE Evaluations.
Actor(s)	Internal Evaluator, External Evaluator, Administrator
Flow of Events	
Basic Flow	
This use case starts when the User accesses the option *Safety/RE Evaluations* that enables him/her to manage information regarding the Safety/RE Evaluations he/she is allowed to manage. 1. The use case starts when the User needs to maintain (add, update, view or delete) Safety/RE Evaluations. 2. According to the operation desired by the User, one of the sub flows is executed: 3. If the customer wants to add a safety/RE evaluation, the Add Safety/RE Evaluations sub flow is executed. 4. If the customer wants to edit a safety/RE evaluation, the Edit Safety/RE Evaluations sub flow runs. *5.* If the customer wants to delete a safety/RE evaluation, the Delete Safety/RE Evaluations sub flow is executed. *6.* If the customer wants to view all safety/RE evaluations he/she has previously stored, the View Safety/RE Evaluations sub flow is executed. *7.* The use case ends.	
Alternate Flows	
Title	**Description**
User Cancels Request	At any time, the User may choose to cancel the request. At which point, the processing is discontinued, the user account remains unchanged.

Step 3: Add Safety/RE Evaluations	a) This sub flow starts when the User requests to Add a company; b) The system prompts the Company information. c) The User enters the information requested. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the company has been created. f) Step 7 is executed.
Step 4: Edit Safety/RE Evaluations	a) This sub flow starts when the User requests to Edit a company; b) The system displays the company information. c) The User updates the company information. d) The system validates the entered information. *e)* The information is stored in the User's account. The system notifies the User that the company has been updated. f) Step 7 is executed.
Step 5: Delete Safety/RE Evaluations	a) This sub flow starts when the User requests to Delete a company; b) The system requests a confirmation of exclusion. c) The User confirms the request. *d)* The system deletes the company and all projects and evaluations performed on this company and notifies the User that the company has been deleted. e) Step 7 is executed.
Step 6: View Safety/RE Evaluations	a) This sub flow starts when the User requests to view a company; *b)* The system shows the company information. c) Step 7 is executed.
Pre-Conditions	
Title	
The User must be signed in before the User can select any of the options.	
Post-Conditions	
Title	**Description**
Success	The Company entered data is stored.
The company was not added or updated	The User entered invalid data or chose to cancel the company management request. In either case, there is no change in the information stored.
Extension Points	
Use Case: See diagrams with results	

Name	[UC10] See diagrams with results
Brief Description	The See diagrams with results use case allows the User to view the results of safety/RE evaluations in a graphical way.
Actor(s)	Registered User
Flow of Events	

Basic Flow	
1. This use case starts when the User accesses the option See results from View Safety/Re evaluations. 2. The system displays the information requested.	
Alternate Flows	
Title	
None	
Pre-Conditions	
Title	
The User must be signed in before selecting the option.	
Post-Conditions	
Title	**Description**
Success	Diagrams would be displayed on the current page.
Extension Points	
None	

APPENDIX D – TOOL USER MANUAL

This chapter presents the user manual of Uni-REPM Tool.

Uni-REPM Tool
User Manual

1 CONTACT

In case of doubts, suggestions or issues, please contact us:

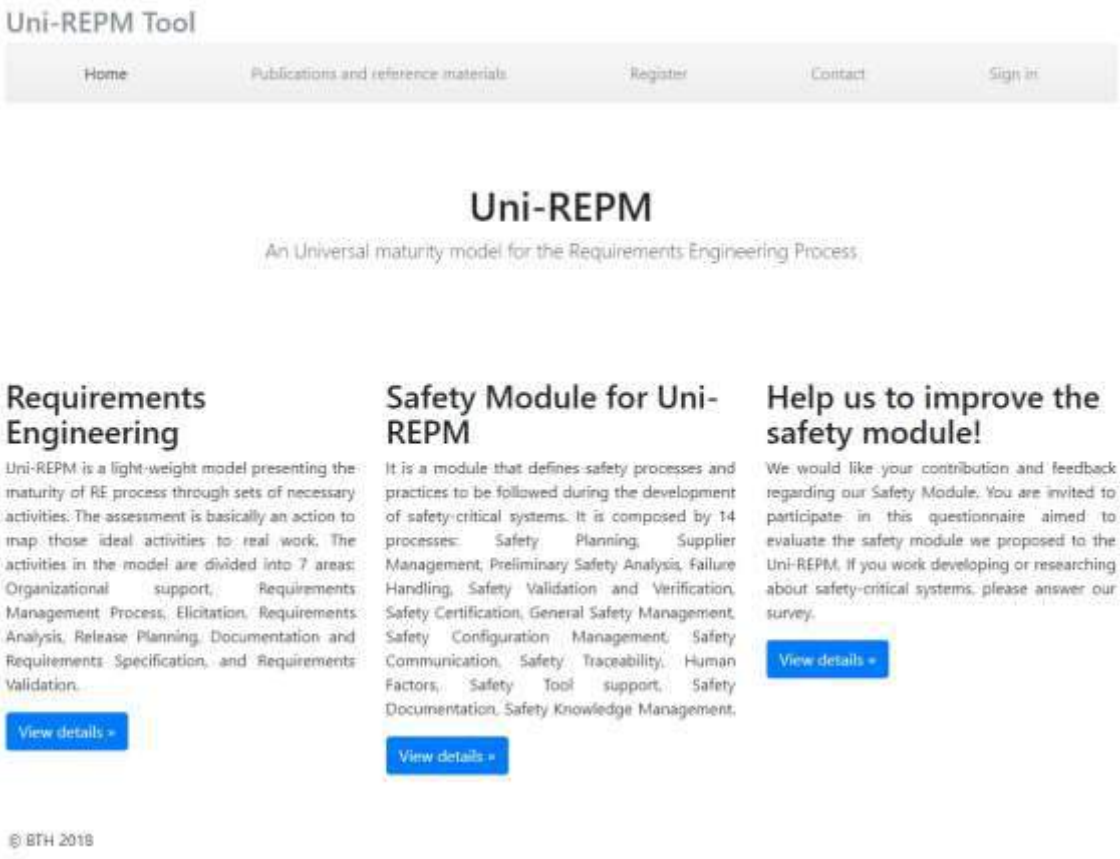
- Using the contact form available at: http://www.unirepm.com/contact/contact.php
- Sending an email to: unirepm@gmail.com
- A link (for tool demo) can be found at https://youtu.be/nvZCdUmA61U.

2 ACESSING UNI-REPM TOOL

The address for accessing the Uni-REPM tool is:

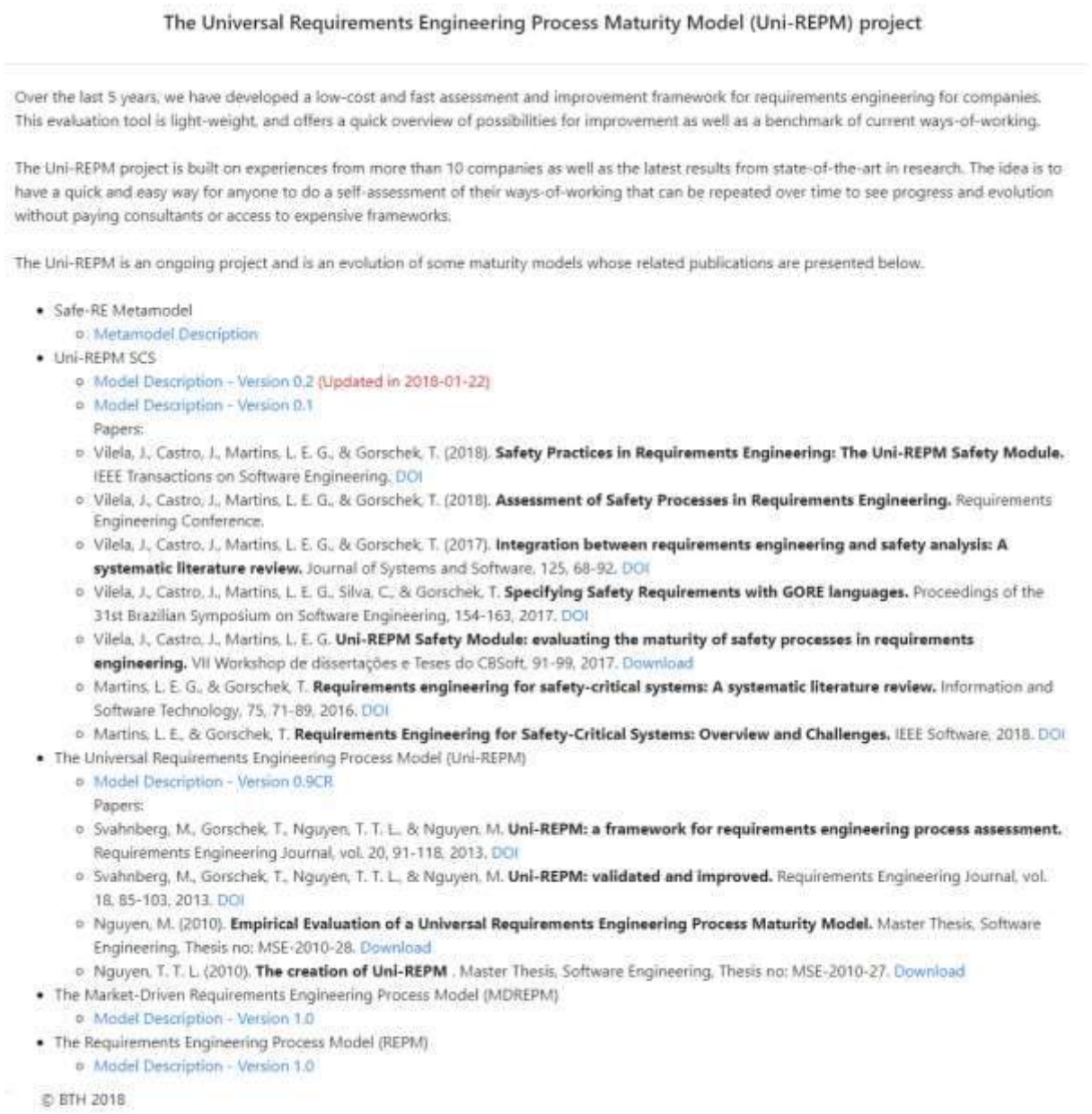
http://www.unirepm.com

The index page has a menu in which you can find the Publications and reference materials about Uni-REPM project, you can Register to perform evaluation, Contact us or Sign in.



When you click at Publications and reference material, the following page is displayed[1].

[1] This page is frequently updated.



The Universal Requirements Engineering Process Maturity Model (Uni-REPM) project

Over the last 5 years, we have developed a low-cost and fast assessment and improvement framework for requirements engineering for companies. This evaluation tool is light-weight, and offers a quick overview of possibilities for improvement as well as a benchmark of current ways-of-working.

The Uni-REPM project is built on experiences from more than 10 companies as well as the latest results from state-of-the-art in research. The idea is to have a quick and easy way for anyone to do a self-assessment of their ways-of-working that can be repeated over time to see progress and evolution without paying consultants or access to expensive frameworks.

The Uni-REPM is an ongoing project and is an evolution of some maturity models whose related publications are presented below.

- Safe-RE Metamodel
  - Metamodel Description
- Uni-REPM SCS
  - Model Description - Version 0.2 (Updated in 2018-01-22)
  - Model Description - Version 0.1

  Papers:
  - Vilela, J., Castro, J., Martins, L. E. G., & Gorschek, T. (2018). **Safety Practices in Requirements Engineering: The Uni-REPM Safety Module.** IEEE Transactions on Software Engineering. DOI
  - Vilela, J., Castro, J., Martins, L. E. G., & Gorschek, T. (2018). **Assessment of Safety Processes in Requirements Engineering.** Requirements Engineering Conference.
  - Vilela, J., Castro, J., Martins, L. E. G., & Gorschek, T. (2017). **Integration between requirements engineering and safety analysis: A systematic literature review.** Journal of Systems and Software, 125, 68-92. DOI
  - Vilela, J., Castro, J., Martins, L. E. G., Silva, C., & Gorschek, T. **Specifying Safety Requirements with GORE languages.** Proceedings of the 31st Brazilian Symposium on Software Engineering, 154-163, 2017. DOI
  - Vilela, J., Castro, J., Martins, L. E. G. **Uni-REPM Safety Module: evaluating the maturity of safety processes in requirements engineering.** VII Workshop de dissertações e Teses do CBSoft, 91-99, 2017. Download
  - Martins, L. E. G., & Gorschek, T. **Requirements engineering for safety-critical systems: A systematic literature review.** Information and Software Technology, 75, 71-89, 2016. DOI
  - Martins, L. E., & Gorschek, T. **Requirements Engineering for Safety-Critical Systems: Overview and Challenges.** IEEE Software, 2018. DOI
- The Universal Requirements Engineering Process Model (Uni-REPM)
  - Model Description - Version 0.9CR

  Papers:
  - Svahnberg, M., Gorschek, T., Nguyen, T. T. L., & Nguyen, M. **Uni-REPM: a framework for requirements engineering process assessment.** Requirements Engineering Journal, vol. 20, 91-118, 2013. DOI
  - Svahnberg, M., Gorschek, T., Nguyen, T. T. L., & Nguyen, M. **Uni-REPM: validated and improved.** Requirements Engineering Journal, vol. 18, 85-103, 2013. DOI
  - Nguyen, M. (2010). **Empirical Evaluation of a Universal Requirements Engineering Process Maturity Model.** Master Thesis, Software Engineering, Thesis no: MSE-2010-28. Download
  - Nguyen, T. T. L. (2010). **The creation of Uni-REPM** . Master Thesis, Software Engineering, Thesis no: MSE-2010-27. Download
- The Market-Driven Requirements Engineering Process Model (MDREPM)
  - Model Description - Version 1.0
- The Requirements Engineering Process Model (REPM)
  - Model Description - Version 1.0

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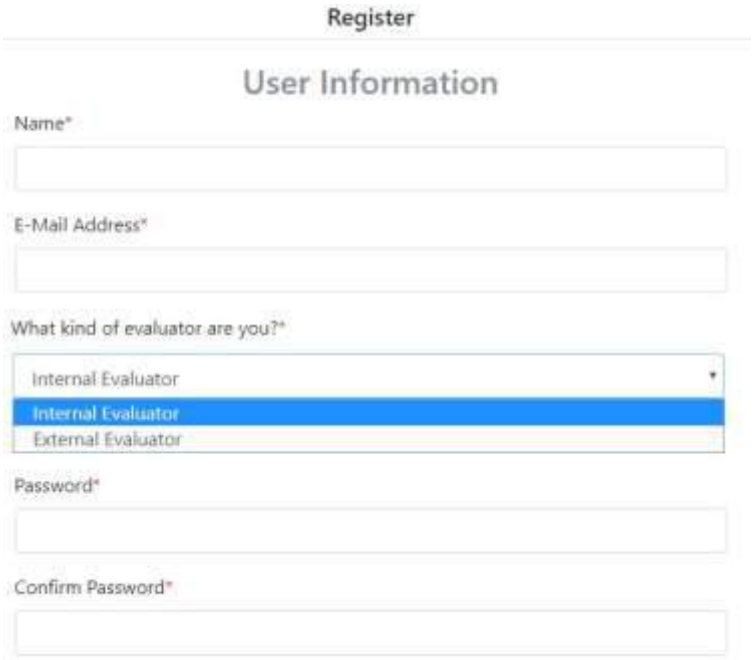
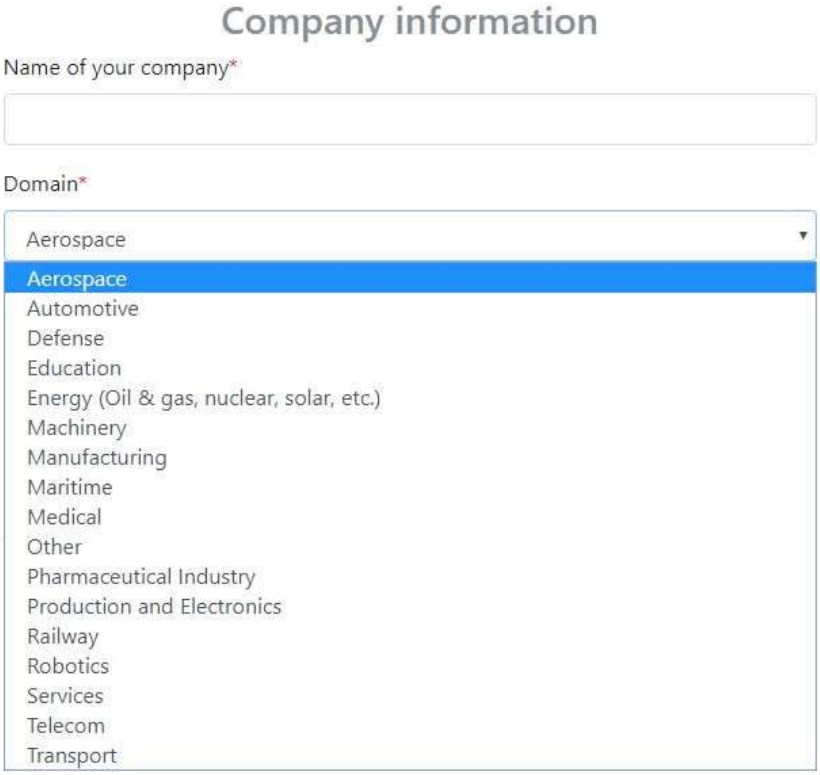
3 REGISTERING

The evaluation instrument both for RE and Safety is only available to registered users. In case you are not registered, please fill in the information required in the form displayed in the following figures.

The form asks information about the user and the type of evaluator: internal evaluates projects of his/her own company; external evaluator can register companies and projects.



It also requests information[2] about the company being evaluated and the domain.



[2] Fields with (*) are required.

Company information

Name of your company*

Domain*

Aerospace

Phone

Country*

Address

Street*

Number*

Neighborhood*

Complement

ZIP Code*

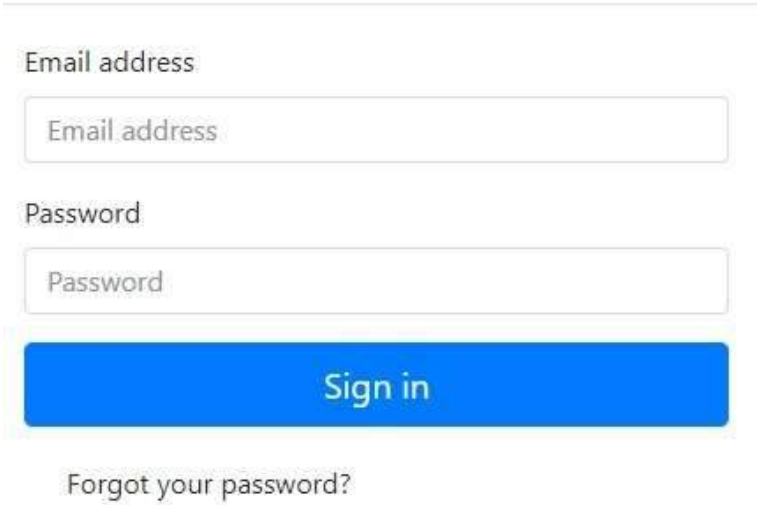
City*

State*

Good to go!

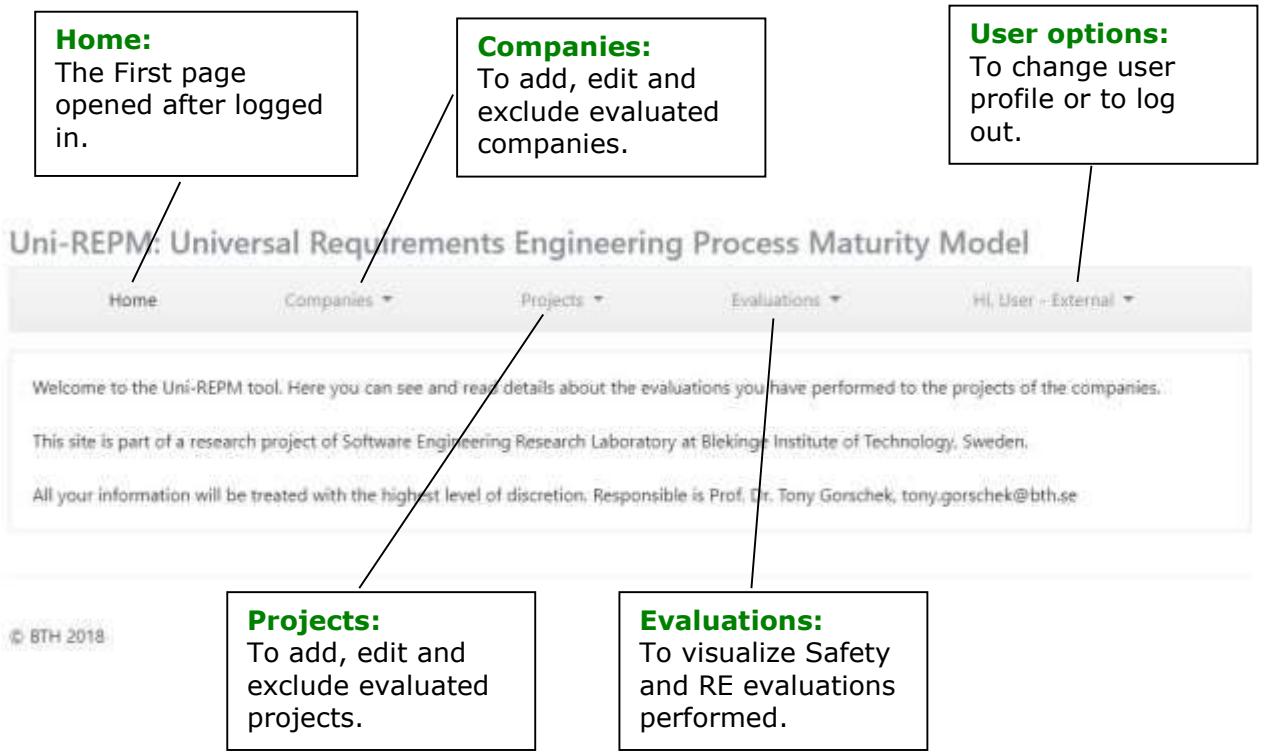
4 SIGN IN

After registering, to access the evaluation instrument, provide email and *password.*



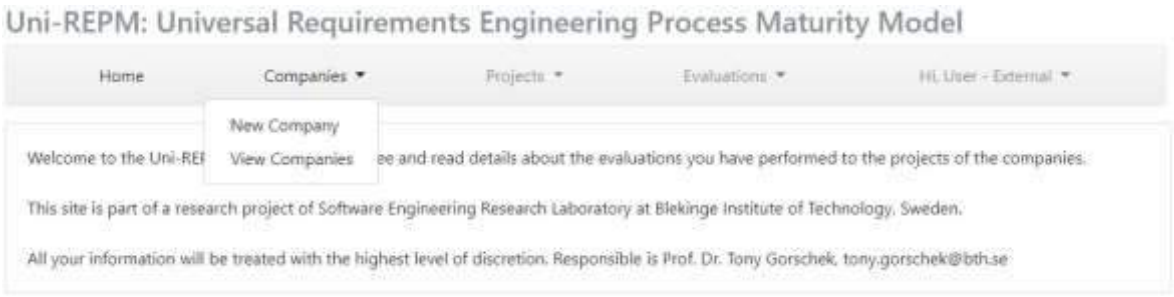
5 OVERVIEW OF INTERFACE

After log in, click on the tab corresponding to the menu that you want to access.



Note: The tab companies is available since the user is of external type.

6 MANAGING COMPANIES

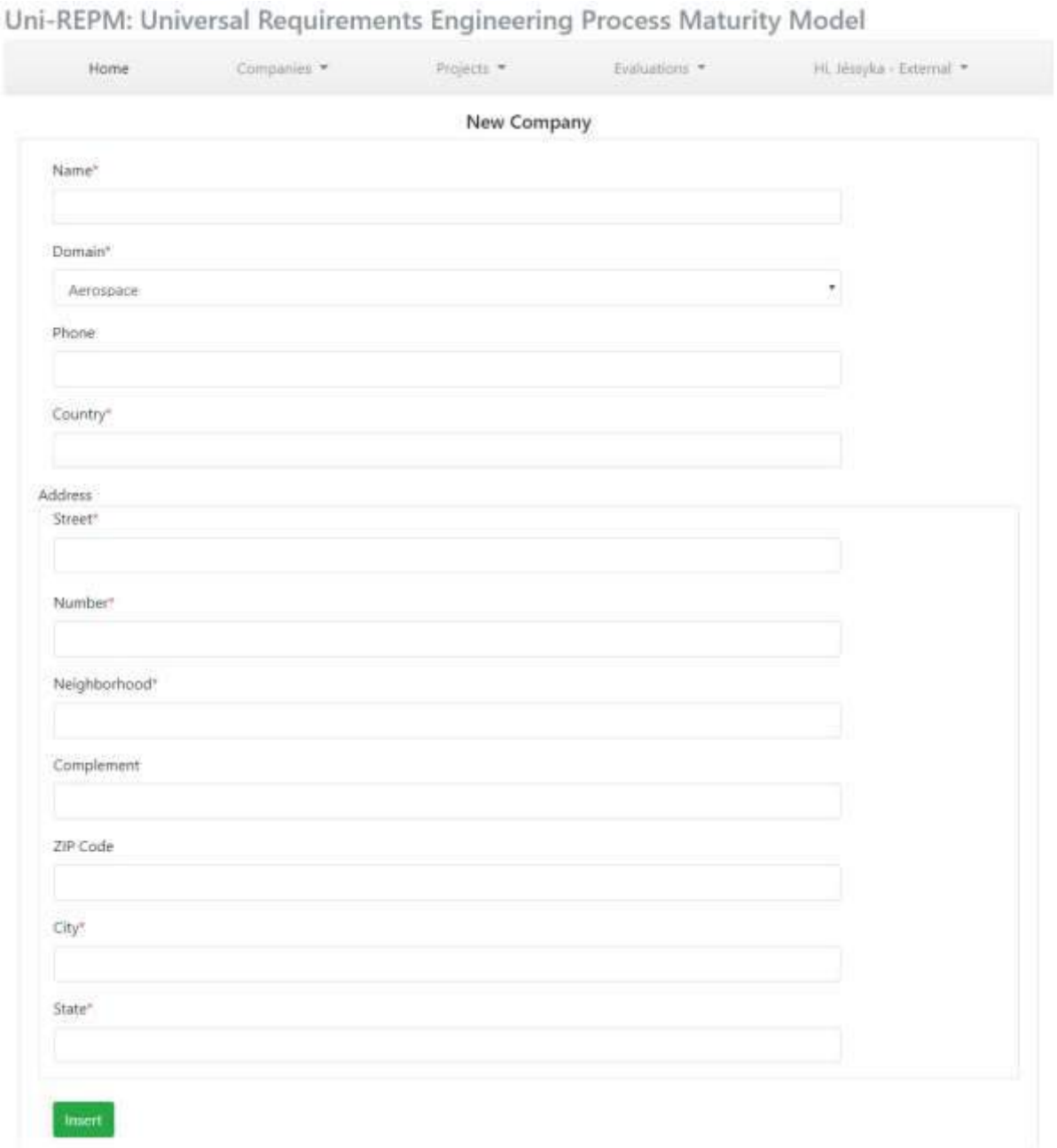


6.1 View Companies

To see the companies already saved, the user must be logged in, and click on Companies/View Companies. A form similar to figure below is displayed. The Edit option is available to update the information about the selected company.

6.2 Add a new company

To add a new company, the user must be logged in, and click on Companies/New Company. The form below is displayed.



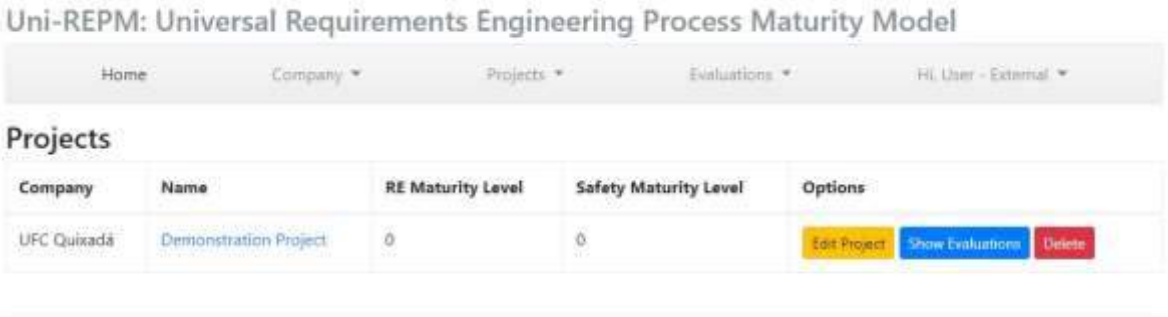
7 MANAGING PROJECTS

7.1 Add a new Project

To add a new Project, the user must be logged in, and click on Projects/New project. The form below is displayed.

7.2 View Projects

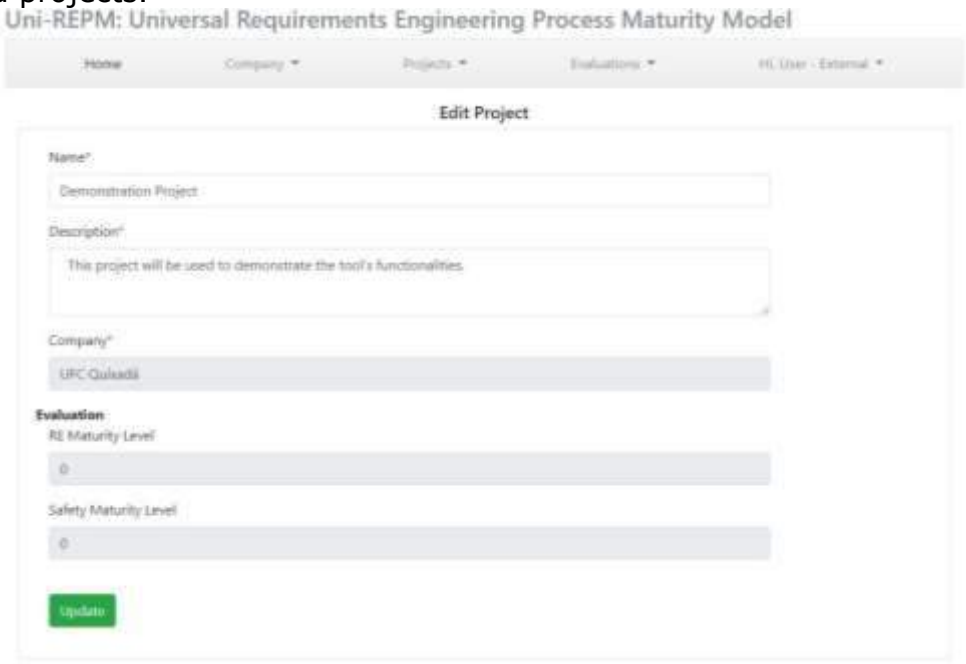
To see the projects already saved, the user must be logged in, and click on Projects/View Projects. A form similar to figure below is displayed.



The name of the project corresponds to a link. When we click on it, the projects details are shown.

7.2.1 Editing Project details

The Edit option is available to update the information about the selected projects.

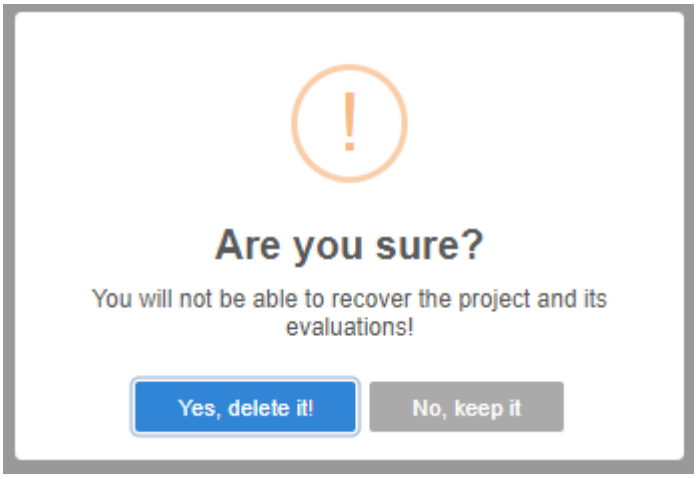


7.2.2 Visualizing evaluations

When we click on Show Evaluations, all evaluations performed in the selected project are presented.

7.2.1 Removing Projects

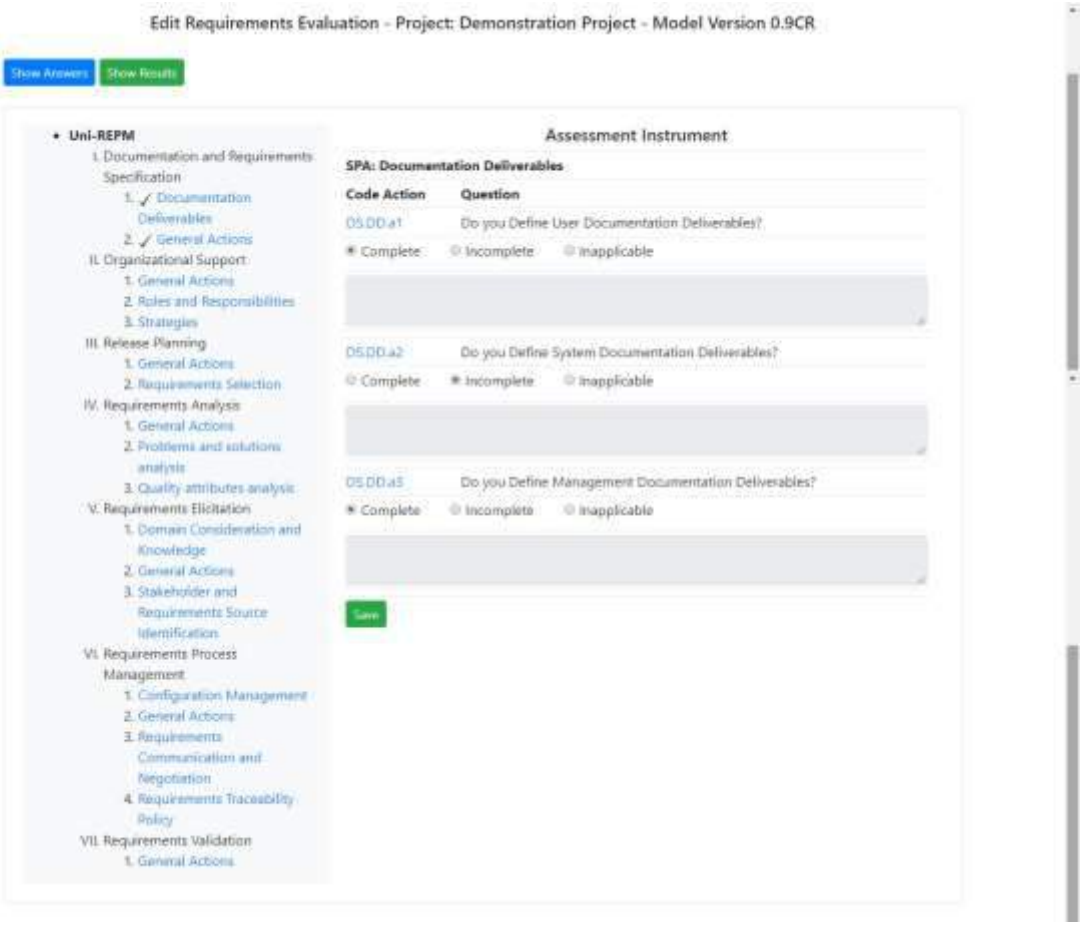
To delete a Project, you should click on Delete. Then, a confirmation message will be shown. If you really wants to delete the project, select the option *Yes, delete it!.*



8 PERFORMING EVALUATIONS

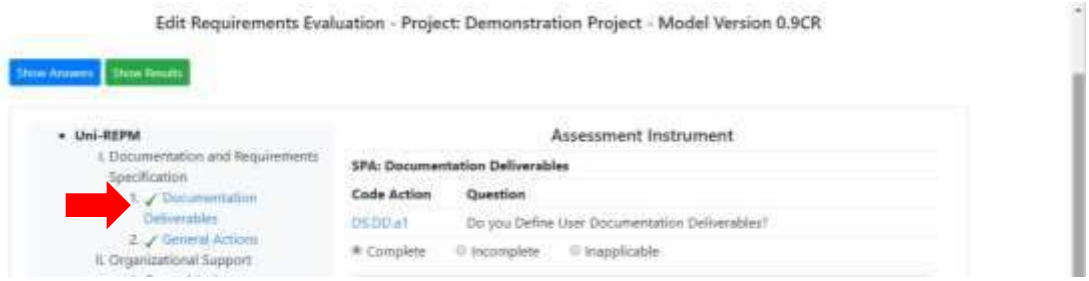
The evaluation questionnaire can be accessed by selecting View Projects/Show Evaluations/Edit Answers.

After the selection, the questionnaire is presented.



To answer the questionnaire, click in a subprocess area, the corresponding actions are displayed, select the answers (the comment area will be enable) of all questions and click on Save.

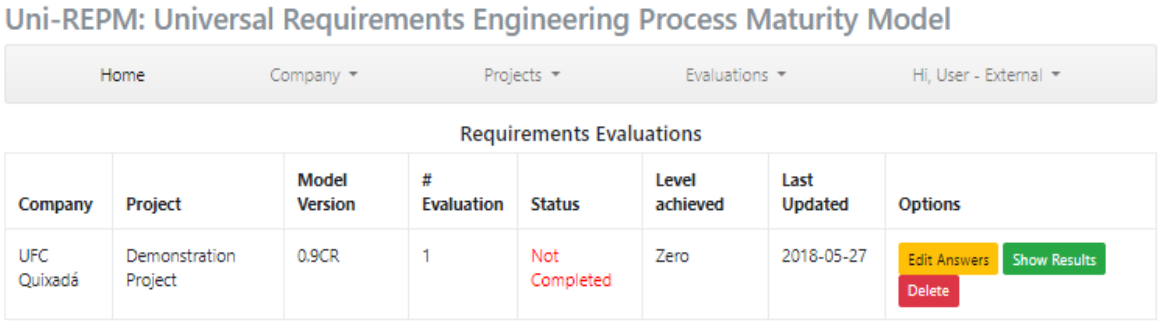
After answering all questions of a subprocess area, the symbol ✓ is displayed in the form.



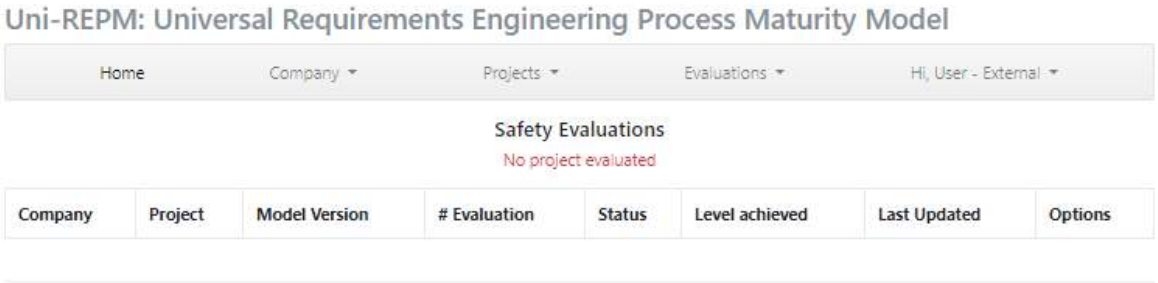
9 VISUALIZING EVALUATIONS

The Evaluations tab allows visualizing RE Evaluations and Safety Evaluations.

If you click in one of these options, the evaluations of the selected type that were already performed by the logged user are shown.



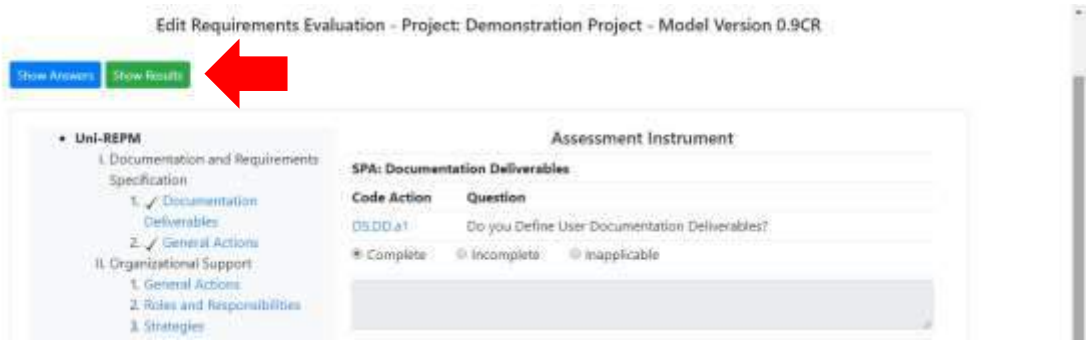
In case of none evaluation has been performed, a message is presented in the tool.



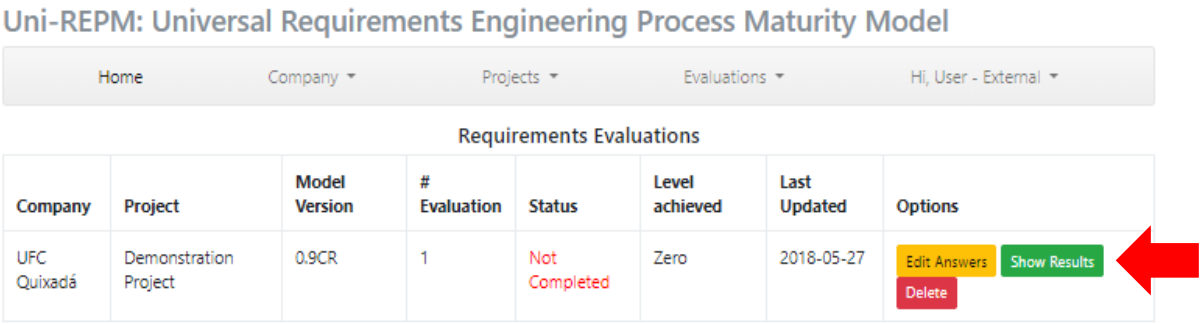
10 VISUALIZING THE EVALUATION RESULTS

The results of the evaluations can be acessed in two ways:

- From the evaluation questionnaire:



- From the evaluations Menu:



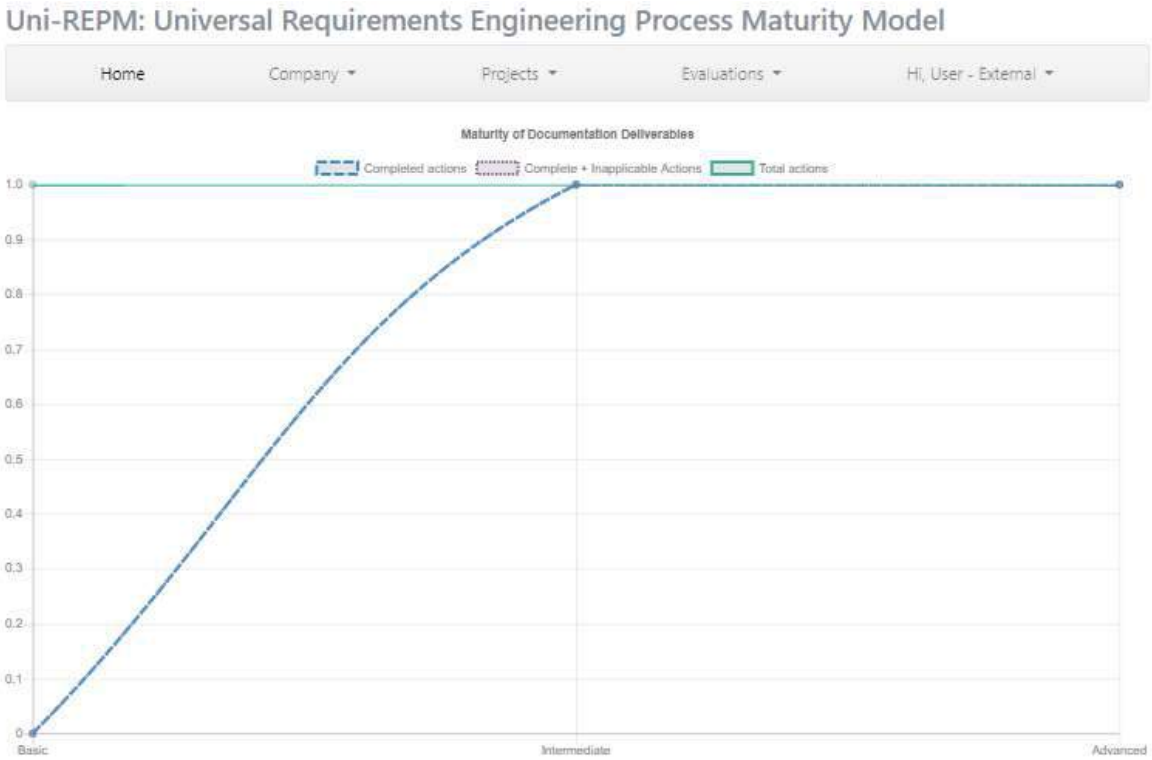
The results are displayed in two formats: tabular and charts (bar and lines) as illustrated in the next sections.

10.1 Tabular

The number of complete, incomplete and innaplicable actions is presented in tables for all main process areas grouped by the subprocess areas. The maturity level level achieved is also presented.

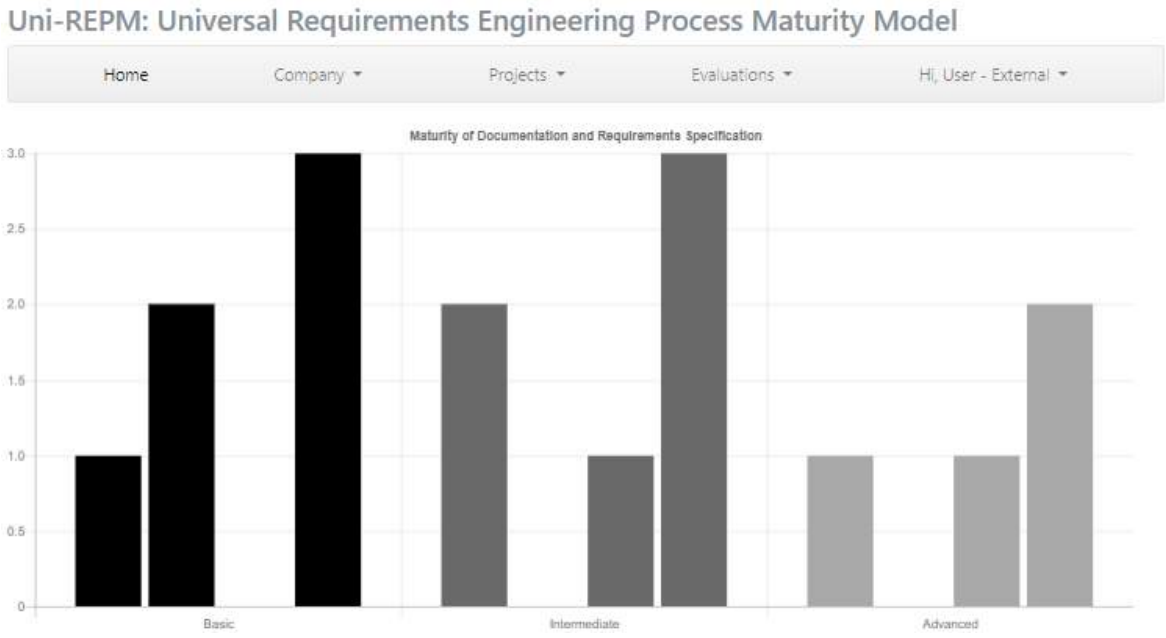
10.2 Line Chart

The complete, incomplete and inapplicable actions of the main process areas and subprocess areas are displayed in a line chart depending on the user selection.



10.3 Bar chart

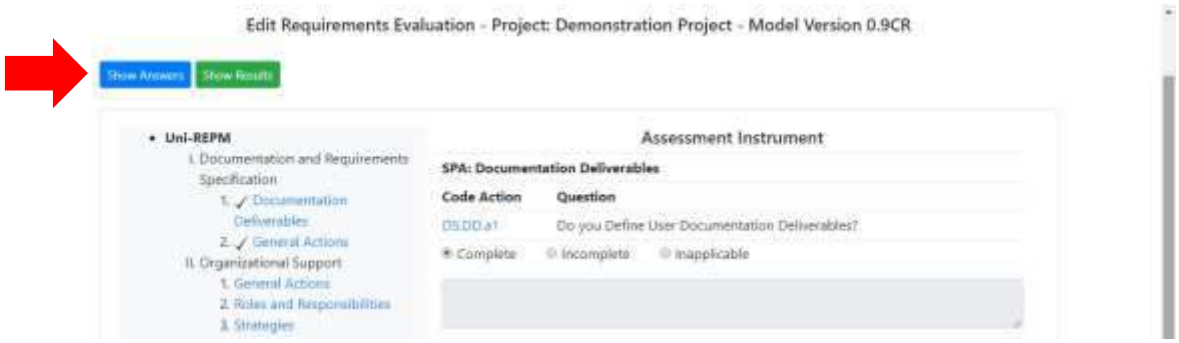
The complete, incomplete and inapplicable actions of the main process areas and subprocess areas are displayed in a bar chart depending on the user selection.



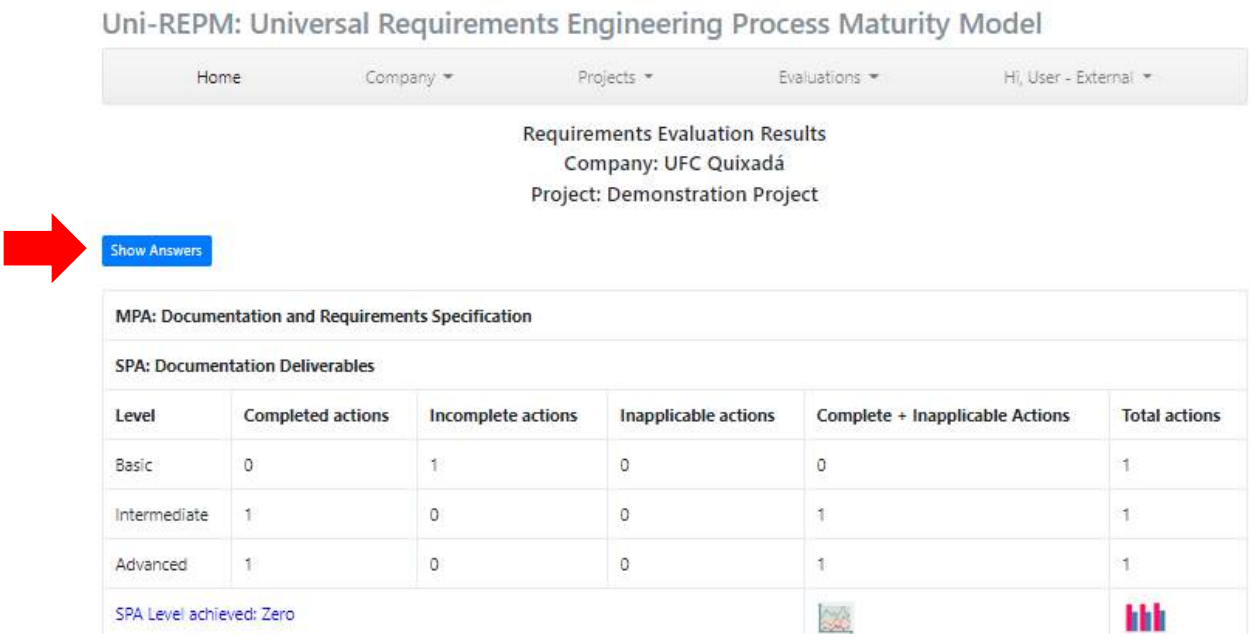
11 VISUALIZING THE SELECTED ANSWERS AND COMMENTS

The answers and comments of each question of the evaluation questionnaire can be acessed in two ways:

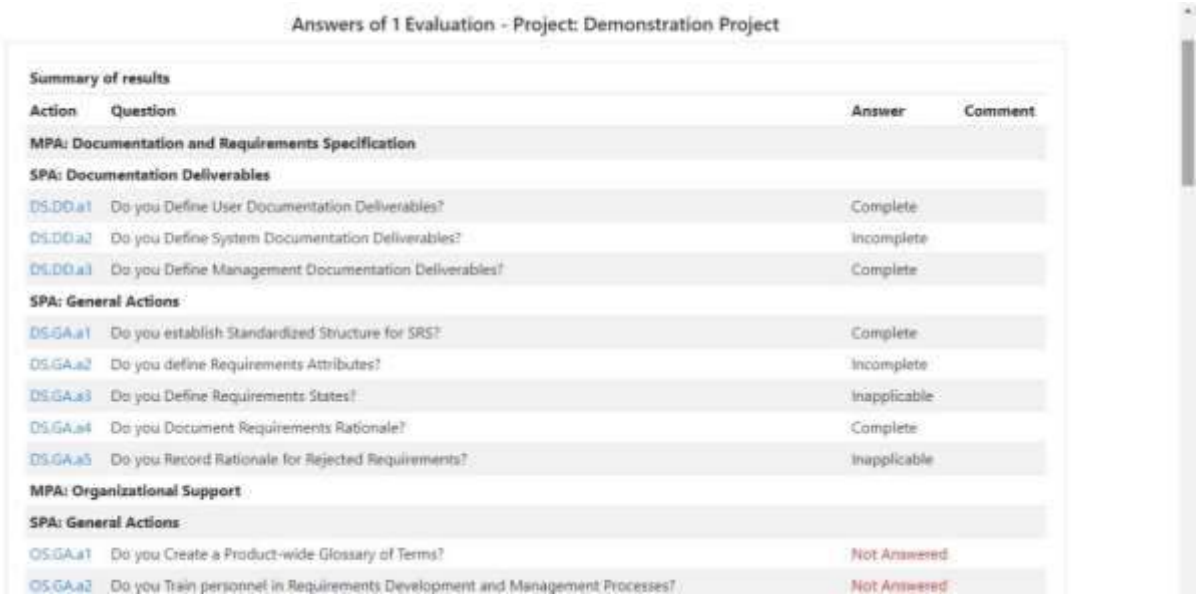
- From the evaluation questionnaire:



- From the evaluations Results visualization:

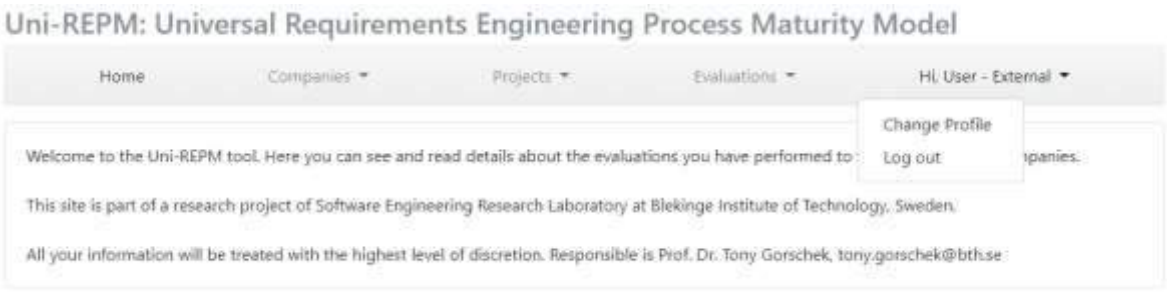


Independently of the way used, all answers and comments are displayed as shown below.

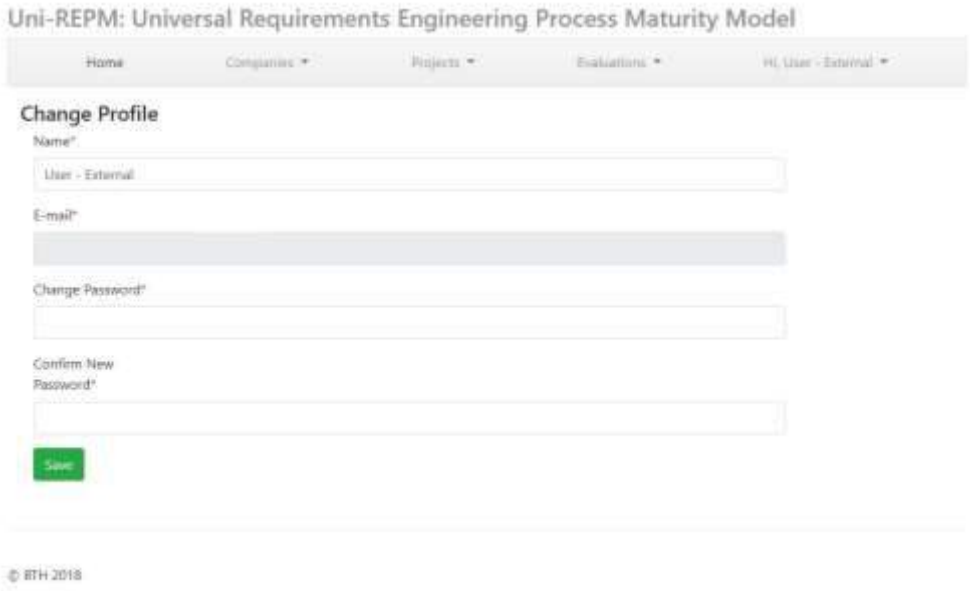


12 MANAGING USER PROFILE

If you want to change your name or password, click in the tab that displays your name and select the option *Change profile*.



Then, the following form will be presented.



APPENDIX E – ARTIFACTS USED IN STATIC VALIDATION

This appendix contains the artifacts (profile questionnaire, and module evaluation questionnaire) we used to conduct the static validation.

Profile questionnaire used in static validation

1. Subject profile

1) Please provide your email.

2) What is your highest education level?
( ) Bachelor's degree ( ) Master's degree ( ) Ph.D. ( ) Other: _____

3) For which type of organizations have you worked, and the number of years in each of those organizations? Select more than one options, if necessary. Enter numbers of years of experience in the right text field.
( ) Academia _____
( ) Industry _____
( ) Research Institute _____
( ) Other? Which? _____

4) For which domain have you worked for? Select more than one options, if necessary.
( ) Energy (Oil & gas, nuclear, solar, etc.)
( ) Transport
( ) Manufacturing
( ) Medical
( ) Aerospace
( ) Pharmaceutical Industry
( ) Production and Electronics
( ) Automotive
( ) Defense
( ) Machinery
( ) Maritime
( ) Railway
( ) Robotics
( ) Telecom

5) In which roles do you have experience? Select more than one option, if necessary.
( ) Requirements engineer
( ) Designer (architecture and detailed design)
( ) Developer/programmer
( ) Tester
( ) Safety analyst/expert (internal to the company)
( ) Security analyst/expert (internal to the company)
( ) Independent assessor (consultant or external to the company)
( ) Project leader or manager
( ) Researcher
( ) Teacher (Professor, lecturer etc.)
( ) System engineer
( ) Product engineer
( ) Other, Please describe_____

6) How many years of experience do you have in developing safety-critical systems?
_____

7) Have you worked with any safety standard? Select more than one option, if necessary.
( ) DO-178
( ) ISO 26262
( ) EN 50126
( ) ECSS
( ) IEC 61508
( ) IEC 60601
( ) ISO 12100
( ) ISO 13849
( ) MIL-STD-882
( ) Other, Please describe_____

8) Have you followed a maturity model?
( ) CMMI
( ) MPS.BR
( ) ISO 15504
( ) Other, Please describe_____

9) If you have followed, do you prefer a generic maturity model or a specific maturity model? Please explain you answer.
_____
_____
_____

1) How important is the adoption of maturity models in projects in your opinion?

( ) Very important

( ) Somewhat important

( ) Neither important nor unimportant

( ) Somewhat unimportant

( ) Very unimportant

2. Company Practices

(please fill in this section case you are currently working developing SCS)

10) How long established is your company?
( ) Less than 5 years
( )6 – 10 years
( )11 – 20 years

( ) 21 – 50 years
( ) Other: _____

11) How many employees work in your company?
_____

12) How many employees work with requirements definition?
_____

13) How many employees work with safety analysis and safety requirements specification?
_____

14) Do you know what is the project success ratio in your company? If yes, please write an average percentage. _____

15) What is your current role and responsibilities?
_____
_____
_____

16) How many years of experience do you have in your current role?
_____

17) How many requirements are there in a typical project you work?
_____

18) How many safety requirements are there in a typical project you work?
_____

19) Have your company had problems in the system developments due to errors in the safety requirements specification? If yes, please provide some examples.
_____
_____
_____

20) Does your organization currently use some Maturity Model? Which one? If yes, in which level is it classified?

_____

21) Does the company face problems with the adoption of maturity models? If yes, please describe
_____
_____

22) What is the main reason for adopting maturity models?

_____

_____

23) How important is the adoption of maturity models in projects in your opinion?

( ) Very important

( ) Somewhat important

( ) Neither important nor unimportant

( ) Somewhat unimportant

( ) Very unimportant

24) Are safety-related processes (i.e. process or activities specific to safety) addressed in the Requirements Engineering phase in the typical projects you are involved in?
( ) Yes
( ) No
( ) Other_____

25) If yes, How are they addressed?

_____
_____
_____

26) If No, what is the rationale behind not considering safety-related processes in the Requirements Engineering Process?

_____
_____
_____

27) Is there guidance such as a procedure or policy or process in your project or organization described that helps the stakeholders on how to address safety activities in the requirements engineering process?
For example a document describing what artefacts should be produced, which information should be specified, which activities should be conducted, how to perform safety analysis?
( ) Yes
( ) No

28) Do you agree that the requirements engineers need better guidance to handle safety-related activities?
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

29) Does your company follow the processes below? Select more than one option, if necessary.

( ) Safety Knowledge Management (to provides transparency in the development process by making sure that projects and the company have the required knowledge and skills to accomplish project and organizational objectives.)
( ) Safety Tool support (to facilitating the appropriate execution of the corresponding tasks and manage all safety-related information that should be created, recorded and properly visualized)
( ) General Safety Management (to cover project safety management activities related to planning, monitoring, and controlling the project)
( ) Safety Planning (to provide safety practices and establish a safety culture in the company)
( ) Safety Configuration Management (to address the control of content, versions, changes, distribution of safety data, proper management of system artifacts and information important to the organization at several levels of granularity)
( ) Safety Communication (to improve the safety communication by establishing actions related to many safety terms, methods, process to support the safety analysis and assurance processes)
( ) Safety Traceability (to handle the traceability among artifacts helping to determine that the requirements affected by the changes have been completely addressed)
( ) Supplier Management (to manage the acquisition of products and services from suppliers external to the project for which shall exist a formal agreement)
( ) Preliminary Safety Analysis (to address the realization of a preliminary safety analysis to avoid wasting effort in next phases of system development)
( ) Failure Handling (to handle failures in system components that can lead to hazardous situations, addition of redundancy as well as protection mechanisms)
( ) Safety Certification (to describe actions related to system certification)
( ) Human Factors (to handle issues regarding system's users and operators that can lead to hazards and shall be considered during the RE stage of safety-critical system development)
( ) Safety Documentation (to record all information related to system's safety produced in RE phase)
( ) Safety Validation and Verification (to define actions to requirements validation and the definition of strategies to the verification of requirements aiming to obtain requirements clearly understood and agreed by the relevant stakeholders)

Module evaluation questionnaire used in static validation

1. Uni-REPM Safety Module

1) Which the following processes (or focus areas) presented in the module do you consider important and should it be considered in the requirements engineer process?

Process	Don't know	Not Needed	Desirable	Essential
Safety Knowledge Management				
Safety Tool support				
General Safety Management				
Safety Planning				
Safety Configuration Management				
Safety Communication				
Safety Traceability				
Supplier Management				
Preliminary Safety Analysis				
Failure Handling				
Safety Certification				
Human Factors				
Safety Documentation				
Safety Validation and Verification				

2) Do you think that other safety-related process is also important for the development of a safety-critical systems? If so, list the processes and briefly explain why you consider them to be important.

_____
_____
_____

3) The safety processes in the module are easy to understand.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

4) To all safety actions below, mark with an X the alternative that seems most appropriate.

Legend:

DN = Don't Know, ND=Not Needed, D= Desirable, E = Essential

1- Basic Level, 2- Intermediate Level, 3- Advanced Level

Practice	Level	Opinion			level a-dequate	change to 1,2 or 3
		ND	D	E	Y	
Requirements Elicitation						
Supplier Management						
Establish and maintain formal agreements among organization and suppliers	2					

Identify and document the products to be acquired	2					
Select suppliers and record rationale	2					
Specify all external systems and safety-related software	1					
Establish and maintain detailed system integration procedures for the external systems and safety-related software	1					
Define the safety standards that suppliers must follow	1					
Documentation and Requirements Specification						
Human Factors						
Construct operator task models	2					
Document human factors design and analysis	1					
Evaluate prototypes, requirements and technical UI restrictions	1					
Model and evaluate operator tasks and component black-box behavior	2					
Define interfaces considering ergonomic principles	2					
Specify Human Machine Interface requirements	2					
Safety Documentation						
Record safety decisions and rationale	3					
Ensure that safety requirements are incorporated into system and subsystem specifications, including human-machine interface requirements	1					
Document all lifecycle and modification activities	1					
Develop and document training, operational and software user manuals	2					
Document System Limitations	1					
Provide a safety manual	2					
Document lessons learned	2					
Ensure that safety-related information is incorporated into user and maintenance documents	2					
Maintain hazard and risk analysis results for the system throughout the overall safety lifecycle	3					
Include a summary of safety requirements	1					
Requirements Analysis						
Preliminary Safety Analysis						
Identify and document safety-critical computer software components and units	1					
Simulate the process	3					
Identify and document system hazards	1					
Identify and document hazards, hazardous situations and harmful events due to interaction with other equipment or systems (installed or to be installed)	1					
Specify the type of initiating events that need to be considered	1					
Obtain and document information about the determined hazards (causes, probability, severity, duration, intensity, toxicity, exposure limit, mechanical force, explosive conditions, reactivity, flammability etc.)	1					
Identify and document hazardous materials	1					
Identify and document consequences of hazards, severity categories and affected assets	1					
Conduct risk estimation	1					
Conduct risk evaluation for each identified hazard	1					
Identify and document risk mitigation procedures for each identified hazard	1					
Collect safety requirements from multiple viewpoints	3					
Identify and document pure safety requirements	1					
Identify and document safety-significant requirements and safety integrity levels	1					
Identify and document safety constraints and how they could be violated	1					
Identify and document possible control flaws and inadequate control actions	1					
Identify and document safety functional requirements	1					

Identify and document operational requirements	1					
Perform and document the feasibility evaluation of safety functional requirements	2					
Prioritize hazards and safety requirements	2					
Identify and document analysis and verification requirements, possible safety-interface problems, including the human-machine interface, and operating support requirements	1					
Perform interface analysis, including interfaces within subsystems (such as between safety-critical and non-safety-critical software components)	2					
Consolidate preliminary system safety technical specification	1					
Failure Handling						
Define requirements for the avoidance of systematic faults	1					
Specify Fault-detection procedures	1					
Specify Restart-up procedures	1					
Document the system behavioral model	2					
Identify and document Common-cause failures (CCF) and how to prevent them	2					
Perform reliability and system performance analysis	1					
Release Planning						
Safety Certification						
Conduct safety audits	2					
Demonstrate the preliminary level of safety achieved by the system	1					
Evaluate the threat to society from the hazards that cannot be eliminated or avoided	1					
Construct preliminary safety and hazard reports	1					
Construct preliminary safety cases	1					
Demonstrate preliminary compliance with safety standards	2					
Ensure that the hazard report is updated with embedded links to the resolution of each hazard, such as safety functional requirements, safety constraints, operational requirements, and system limitations	3					
Document the division of responsibility for system certification and compliance with safety standards during safety planning	2					
Specify a maintenance plan	1					
Requirements Validation						
Safety Validation and Verification						
Define the safety validation plan for software aspects of system safety	1					
Define the safety verification plan	1					
Define the technical strategy for the validation of external systems and safety-related software	2					
Define pass/fail criteria for accomplishing software validation and verification	2					
Develop safety test plans, test descriptions, test procedures, and validation and verification safety requirements	2					
Define and maintain a software integration test plan	1					
Validate safety-related software aspects	2					
Ensure that there is no potentially hazardous control actions	2					
Perform safety evaluation and verification at the system and subsystem levels	1					
Conduct joint reviews (company and customer)	2					
Ensure that the stakeholders understand software-related system safety requirements and constraints.	2					
Document discrepancies between expected and actual results	2					
Verify the behavioral model	2					
Ensure that software requirements and interface specification are consistent	2					
Perform safety inspections	2					
Identify and fix inconsistencies safety requirements specification	2					

Organizational Support						
Safety Planning						
Develop an integrated system safety program plan	1					
Define and document requirements for periodic functional safety audits	2					
Define and document the interface between system safety and all other applicable safety disciplines	1					
Delineate the scope of safety analysis	1					
Establish the hazards auditing and log file	1					
Establish working groups and structures	1					
Define and document the regulations and safety standards to be followed	1					
Identify any certification requirements for software, safety or warning devices or other special safety feature	1					
Define and document requirements completeness criteria and safety criteria	3					
Review safety experience on similar systems	2					
Specify the general safety control structure	3					
Specify operating conditions of the machine and installation conditions of the electronic parts	1					
Determine the required performance level	1					
Identify and document the hazard analysis to be performed; the analytical techniques (qualitative or quantitative) to be used; and depth within the system that each analytical technique will be used (e.g., system level, subsystem level, component level)	1					
General Safety Management						
Identify and document the system development methodology	1					
Identify and document safety lifecycle for the system development	1					
Identify and document competence requirements for the safety activities	1					
Set safety policy and define safety goals	1					
Identify and document responsibility, accountability and authority	1					
Define system safety program milestones and relate these to major program milestones, program element responsibility, and required inputs and outputs	1					
Use of indicators on engineering documentation to assess the product properties and the development progress	3					
Prepare progress reports in a period of time defined by the project	2					
Monitor project and take corrective actions	2					
Safety Tool support						
Use of verification and validation tools	2					
Specify justifications for the selection of the off-line support tools	3					
Assess offline support tools which can directly or indirectly contribute to the executable code of the safety related system	3					
Record information of the tools in the baseline	2					
Use of tools with support to cross reference and maintain the traceability among safety information in the software specification	3					
Use of computer-aided specification tools	2					
Define and use tools to support the safety process and workflow management	3					
Safety Knowledge Management						
Establish and maintain an infrastructure to share knowledge	3					
Develop a safety information system to share knowledge in the organization	3					
Define control access mechanisms to the safety information system	3					
Maintain employees competence information	3					
Document a strategy to manage the knowledge	2					

Define a lifecycle for projects artifacts	2					
Define and maintain a strategy for reuse	3					
Reuse the stored knowledge	3					
Document the use of stored knowledge	3					
Notify users about problems, new versions and exclusions of artifacts in use	3					
Manage assets	3					
Requirements Process Management						
Safety Configuration Management						
Maintain accurately and with unique identification all safety configuration items and safety information (hazards, safety requirements, risks, etc.)	3					
Use a tracking system within configuration control (both system and subsystem, including software) for tracing hazards and their resolution	1					
Define and document change-control procedures	3					
Define and document safety configuration items to be included in the baseline	1					
Document configuration status, release status, the justification (taking account of the impact analysis) for and approval of all modifications, and the details of the modification	3					
Document the release of safety-related software	1					
Perform safety impact analysis on changes	2					
Specify and follow the template for software modification request	1					
Document the procedures for initiating modifications to the safety-related systems, and to obtain approval and authority for modifications	2					
Maintain and make available the software configuration management log	2					
Appoint all deliverable documents according to the rules defined in the Configuration Management Plan	2					
Upload all documents on the safety information system	3					
Safety Communication						
Establish formal communication channels among stakeholders	1					
Establish formal communication channels among different organizational levels	2					
Define a method of exchanging safety information with the suppliers	1					
Establish a common nomenclature	1					
Train people continuously in system engineering and safety techniques (education)	1					
Use of a common safety information system for system specification and safety analysis	3					
Keep stakeholders updated regarding the progress of all safety-related activities	3					
Construct a repository of common hazards	3					
Define and follow templates for system artifacts	1					
Document how conflicts will be resolved	1					
Identify, record and resolve conflicts	1					
Produce all the deliverables documents based on the official document templates	2					
Make available safety-related software specification to every person involved in the lifecycle	1					
Safety Traceability						
Define and maintain traceability policies	3					
Define and maintain bi-directional traceability between the system safety requirements and the software safety requirements	3					
Define and maintain bi-directional traceability between the safety requirements and the perceived safety needs	3					

Link and maintain bi-directional traceability between environmental assumptions and the parts of the hazard analysis based on the assumption	3					
Define and maintain bi-directional traceability between system and subsystem verification results and system specification	3					
Define and maintain bi-directional traceability between validation results and system specification	3					
Define and maintain bi-directional traceability among system hazards into components.	3					
Justify reasons for not traced software requirements	3					

5) Do you think that other actions are also important for the requirements engineering process of safety-critical systems that are not presented in the module? If so, list other actions and briefly explain why you consider them to be important.

_____
_____
_____

6) The safety actions in the module are easy to understand.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

7) To what extent do you believe the safety module will help requirements engineers to perform safety-related activities or tasks in the project?

( ) To a large extent

( ) To a moderate extent

( ) To some extent

( ) To a little extent

( ) Not at all

8) I would adopt the safety module in my company.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

9) If you have further comments about the module, please state below.

_____
_____
_____

10) Do you want to participate in future studies? If yes, please provide your email address.

_____

APPENDIX F – QUESTIONNAIRE USED IN DYNAMIC VALIDATION

This appendix contains the questionnaire of the Case Study: Evaluation of the "Uni-REPM - Safety Module" and Tool from the point of view of the practitioners.

Case Study: Evaluation of the "Uni-REPM - Safety Module" and Tool from the point of view of the practitioners

1. Subject's Profile

1) What is your position/job scope?
   _____

2) How long have you experienced in safety-critical systems? _____

3) Which specific area(s) in safety-critical systems does your job focus on?
   _____

2. Company Practices

4) What industry domain does your company belong to? _____
5) How long established is your company?
   ( ) Less than 5 years
   ( ) 6 – 10 years
   ( ) 11 – 20 years
   ( ) 21 – 40 years
   ( ) More than 40 years
   ( ) Other: _____

6) How many employees work with safety requirements definition/specification? _____

7) Does your organization currently use some Maturity Model? Which one? If yes, in which level is it classified? _____
   a. Does the company face problems with the adoption of maturity models? If yes, please describe.
      _____
      _____
      _____
      _____
      _____

3. Project Details

Considering a typical project that you have developed/managed, please answer the questions below:

8) What is the project about? What is the product?
   _____
   _____
   _____

9) How many man-hours for the project? (how many people involved in the project? How long does it last?)_____

10) How many safety requirements are there in the project? _____

11) Which system development methodology is used in this project? (agil, traditional, etc.) _____

12) Additional info you would like to share about the project?
_____
_____
_____

4. Subject's feedback – about the module

13) Are you familiar with the terminology used in the Uni-REPM safety module?
    a. Which term(s) do you find hard to understand?

_____
_____
_____
_____

14) The safety processes in the module are easy to understand.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

15) The safety actions in the module are easy to understand.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

16) Do you perform any additional action(s) that is (are) not covered in the model?
    a. Please describe the actions.

_____
_____
_____
_____
_____
_____

17) Are there actions you would have missed if you do not know about the safety module?
_____
_____
_____

18) Are there any conflicts between the module and the standards/existing company practices?

_____
_____
_____

19) To what extent do you believe the safety module will help your company to improve the safety-related activities or tasks in the projects?

( ) To a large extent ( ) To a moderate extent ( ) To some extent ( ) To a little extent ( ) Not at all

20) I would adopt the safety module in my company.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

21) If you have further comments about the module, please state below.

_____
_____
_____
_____
_____

5. Subject's feedback – about the tool

22) I could effectively complete a safety evaluation using this software tool.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

23) This software tool has all the functions and capabilities I expect it to have.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

24) Overall, I am satisfied with how easy it is to use this software tool.
( ) Strongly agree ( ) Agree ( ) Neither agree nor disagree ( ) Disagree ( ) Strongly disagree

25) If you have further comments about the software tool, please state below.

_____
_____
_____
_____
_____

Thank you for your participation!