Process Compliance Re-Certification Efficiency Enabled by EPF-C ∘ BVR-T: a Case Study*

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Abstract. With today's ever increasing demands on process (re)certification, enabling (re)certification efficiency is paramount. Within the EU AMASS project, we delivered a tool-chain, called, in this paper, EPF-C ∘ BVR-T, obtained by the integration of EPF Composer (EPF-C) and BVR Tool (BVR-T). This tool-chain supports process engineers in the engineering and compliance demonstration activities as well as variability and change management. The compliance recertification efficiency enabled by the tool-chain has not been evaluated for changes triggered by different jurisdictions, which impose the release of new standards. Thus, to fill this gap, in this case study paper, we focus on the medical domain, precisely on the evolution of the ISO 14971 process for risk analysis and evaluation for medical devices. Based on a set of efficiency-related criteria, we evaluate the recertification efficiency enabled by the change management strategy implemented in the tool-chain.

Keywords: (Re)certification · Process compliance · ISO 14971.

1 Introduction

With today's ever increasing demands on process (re)certification, enabling (re)-certification efficiency is paramount. The AMASS project [18] has delivered the first de-facto platform for (re)certification [17]. This platform includes a tool-chain, called EPF-C ∘ BVR-T in this paper, obtained by integrating EPF Composer (EPF-C) and BVR Tool (BVR-T). EPF-C ∘ BVR-T supports process engineers in the engineering and compliance demonstration activities as well as variability and change management. The compliance recertification efficiency of the tool-chain has been illustrated and partially demonstrated in the space domain taking into consideration recertification needs in case of different types of changes, e.g. criticality level [4], concern (safety/security [6]). However, the tool-chain has not been evaluated in the medical domain and never for handling the recertification effort needed in case of products crossing jurisdictions and thus

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having to comply with different versions of the same standard. As known, medical devices are governed by a broad range of national and international regulations and medical equipment certification standards. These regulatory requirements are complex and vary between regions, which can make it challenging to gain medical approval for products within a specific targeted market. An evident example is represented by the requirements, included within ISO 14971:2007 and its evolution (EN ISO 14971:2012, ISO 14971:2019), regarding the process for risk analysis and evaluation. When published, ISO 14971:2007 was internationally endorsed. Then, EN ISO 14971:2012 was released for the European market only as a version harmonised with a set of EU directives (90/385/EEC [3], 93/42/EEC [2], and 98/79/EC [16]). As a consequence of the new release, recertification was mandatory. Manufacturers of medical devices targeting an international market had to struggle to reconfigure their processes (i.e., provide new evidence) to get approval from the different regulatory bodies within the different jurisdictions within and outside EU. ISO 14971:2019 brought changes, making it internationally endorsed again. Given the challenging regulatory context in the medical domain and given the concrete need for a solution, in this paper, we present a reduced but meaningful portion of a case study focused on the ISO 14971-compliant process for risk analysis and evaluation. The interested reader may refer to [13] for the complete case study. During the execution of the case study, we use EPF-C ∘ BVR-T to engineer compliant processes as well as manage the variability and change in relation to the different versions of ISO 14971. Then, based on a set of efficiency-related criteria, we measure the re-certification efficiency, enabled by EPF-C ∘ BVR-T and we analyse the results.

The rest of the paper is organised as follows. In Section 2, we give an overview of EPF-C ∘ BVR-T for efficient process compliance management. In Section 3, we recall the fundamental information regarding the ISO 14971 and its evolution. In Section 4, we present the case study design and its execution. In Section 5, we present the analysis of the case study. In Section 6, we discuss related work. Finally, in Section 7, we draw our conclusion and sketch future work.

2 EPF-C ∘ BVR-T

EPF-C ∘ BVR-T [10] is a tool-chain, obtained by integrating EPF Composer (EPF-C), which was recently brought back to the future [11], and BVR Tool (BVR-T). EPF-C ∘ BVR-T supports efficient compliance management via reuse enabled by managing commonalities and variabilities, i.e., by implementing Safety-oriented Process Line Engineering (SoPLE) [5]. On the one hand, EPF-C (Eclipse Process Framework Composer)[1], which implements a metamodel that covers the major parts of SPEM 2.0 (Software & Systems Process Engineering Metamodel) [12], is used to model the base process and its related library. Essential elements are described in Table 1. A *role* represents who does a unit of work, defined in a *task definition*. *Artifacts* and *deliverables* identify types of work

[1] See https://www.eclipse.org/epf/

products resulting from a task. *Guidelines*, *checklist*, and *practices* represent supplementary free-form documentation.

Table 1: Subset of Icons Used in SPEM 2.0/EPF Composer [12].

Role	Task Definition	Deliverable	Artifact	Practice	Checklist	Guidance
						

On the other hand, BVR-T (Base Variability Resolution Tool)[2], which implements the BVR metamodel [7], is used to orthogonally model (VSpec model via VSpec editor), resolve (Resolution model via the Resolution editor) the variability at abstract level. Once a new configuration is solved, the binding between the abstract representation and the concrete representation (compliant to the EPF Composer's implemented metamodel) can be realised (Realization model via the Realization editor). More precisely, VSpec permits users to model the variability in a feature diagram-like fashion, embracing best practices of product line modelling and thus inheriting the efficiency of product line engineering best practices.

Element	Symbol
Choice	
Constraint	
Group	

Table 2: VSpec

As Table 2 recalls, a choice represents a yes/no decision, a constraint, given in BCL (Basic Constraint Language), specifies restrictions on permissible resolution models, and a group dictates the number of choice resolutions, e.g., 1..1, which refers to *xor* in which one of the child features must be selected. For sake of clarity, we point out that Table 2 only recalls the BVR modelling elements used in this paper. Resolution permits users to make choices at variation points, where desired variants can be selected. Resolution also includes the possibility to validate the choices. Erroneous choices violating the cross-variation points constraints can be detected. Realization permits users to bind abstract resolutions with the concrete elements in the base model.

3 ISO 14971 and Its Evolution

ISO 14971 is the standard that was developed specifically for medical devices. It deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment. This standard specifies a process through which the manufacturer of a medical device can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of the controls throughout the life cycle of the medical device. The content of ISO 14971 has been evolving over the years and different versions were published, incorporating consensus-based modifications and refinements. In this paper, we limit our attention to ISO 14971:2007[8], EN ISO 14971:2012[1], and ISO 14971:2019 [9], and, more specifically, to the portion of the process that deals with risk analysis and evaluation.

[2] See https://github.com/SINTEF-9012/bvr

Fig. 1 depicts the portion of the process considered in this paper. On the right side of Fig. 1 two main differences are highlighted: 1) Risk Acceptability Principle, known as RAP, which stands for the principle that is followed for reducing risks related to medical devices, 2) Treatment of negligible risks. These differences emerge by conducting a comparative study of the different versions. Such differences are shown in detail in Table 3, where ALARP stands for *As Low As Reasonably Practicable*, while AFAP stands for *As Far As Possible*, which implies that all risks have to be reduced without there being room for economic considerations.

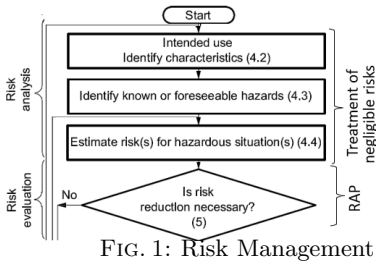


FIG. 1: Risk Management

TABLE 3: Risk Identification and Evaluation Differences among ISO 14971 Versions

Standard	**Treatment of negligible risks**	**Risk Acceptability Principle (RAP)**
ISO 14971:2007	Discard negligible risks	ALARP (Demands risk reduction)
EN ISO 14971:2012	Take all risks (including negligible)	AFAP (Requires risk reduction)
ISO 14971:2019	Take all risks (including negligible)	ALARP/AFAP (Without affecting benefit-risk ratio)

The reader may refer to [13] for a complete analysis of ISO 14971 evolution focused on risk analysis and evaluation.

4 Case Study Design and Execution

In this section, we present the design and the execution of a reduced but meaningful portion of a case study, designed according to the guidelines given in [15].

4.1 Case Study Design: Objective and Selection

The objective of the case study is the evaluation of the cross-jurisdiction/cross version re-certification efficiency enabled by the change management strategy implemented in EPF-C ∘ BVR-T. With this goal in mind, we expect to answer the following question: is the cross-jurisdiction/cross-version recertification, enabled by EPF-C ∘ BVR-T, efficient? To evaluate the re-certification efficiency (i.e., the relationship between results achieved (recertification artefacts provision) and resources used (effort in terms of modelling time), as done in our previous work [4], we adopt and re-interpret in the context of process engineering a set of metrics, see Table 4. As Table 4 shows, Cp_i defines the set of process components for each process. The intersection of the common Cp_i(s) is equal to Size of Commonality (SoC). SoC is the input for the $PrRi$, which measures the extent of reusability of the common components for a specific process.

As case study, we select the evolution of the ISO 14971 process for risk analysis and risk evaluation (recalled in Section 3).

TABLE 4: Reuse Metrics.

Size of Commonality (SoC)	Product-related Reusability (PrRi)
$SoC = \mid \bigcap_{i=i}^{n} Cp_i \mid$	$PrR_i = \frac{SoC}{\mid Cp_i \mid}$

4.2 Case Study Execution and Results

We model the process in EPF-C, and the VSpec and the Resolution in BVR-T. Fig. 2 shows the modelling of process elements in EPF-C related to the three versions of the standard ISO 14971 (recalled in Section 3). For space reasons, in this paper, we only focus on the guidance part of each EPF-C plugin (highlighted in green). With a red square, we highlight the applicable RAP and treatment of negligible risk for each standard (recalled in Table 3).

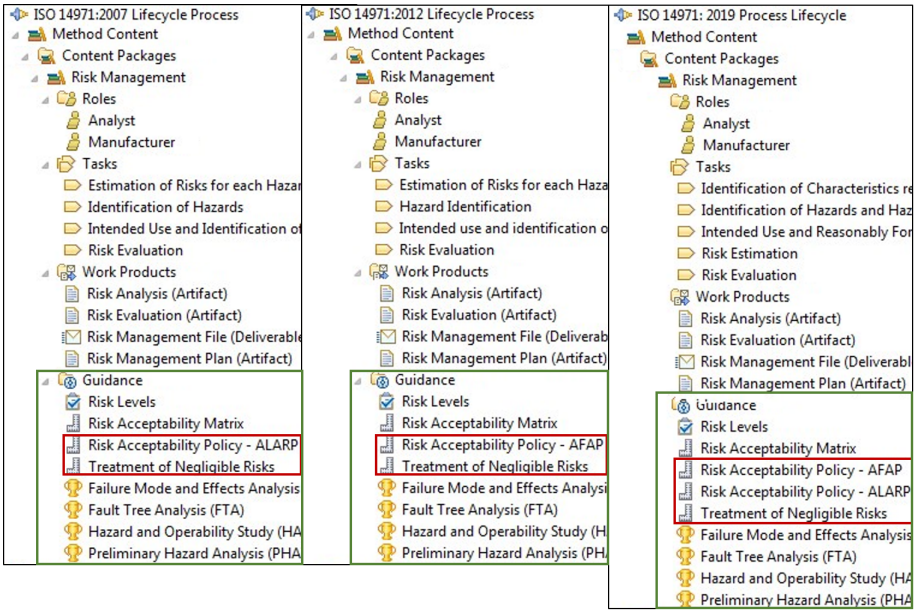


FIG. 2: EPF-C Plugins Targeting ISO14971:2007, ISO14971:2012 and ISO14971:2019

We model the variability for negligible risk in BVR VSpec (see Fig. 3). In particular, *Discard_negligible_risks* and *Take_negligible_risks_into_account* are defined in the VSpec as optional-multiplicity 1..1, implying that only one of them shall be applied, according to the constraints of the applicable standard. In a similar way, we model the variability associated with RAP (see Fig. 4). For the complete VSpec, embracing all the process elements considered in Fig. 2, the interested reader may refer to [13]. Once the variability is modelled, the resolution is performed. For example, if the process model must comply with EN ISO

14971:2012, we set true for the option *Take_negligible_risks_into_account* for the risk analysis (see Fig. 5a), while we set true for the option *AFAP* for the risk evaluation (see Fig. 5b).

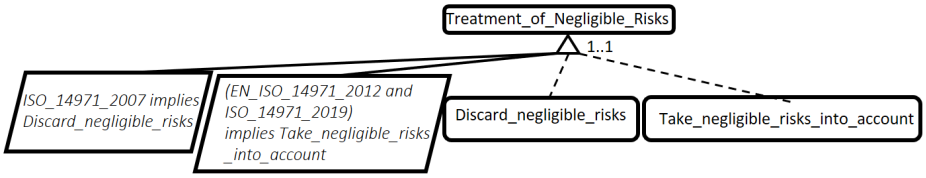


Fig. 3: BVR VSpec for the Treatments of Negligible Risk

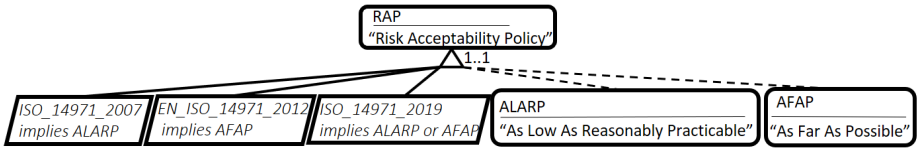
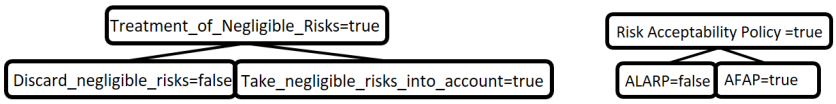


Fig. 4: BVR VSpec for RAP



(A) (B)

Fig. 5: Resolution Models.

In the guidance part of the three standards (see Fig. 2), we find 6 elements that are common. Thus, Size of Commonality (SoC) for this portion is 6. In total, 8 guidance elements are required in ISO 14971:2007 and EN ISO 14971:2012, and 9 in ISO 14971:2019. Thus, the Product-related Reusability (PrRi) is $6/8 = 0.75$ for ISO 14971:2007 and EN ISO 14971:2012, and $6/9 = 0{,}67$ for ISO 14971:2019 in this portion of the standard. The interested reader may refer to [13] to find the complete measurement, which does not only focus on the guidance part.

5 Case Study Analysis

In this section, we analyse the results and answer the question presented in Section 4.1. The computation of SoC and PrRi shows a positive gain in terms of reusability. Thus, we can answer that the change management strategy, implemented in EPF-C ∘ BVR-T, is efficient when applied for handling changes related to cross-jurisdiction/cross version in the context of ISO 14971. As a consequence, this suggests that the provision of the new evidence, needed for recertification, can be obtained by reusing a significant amount of pre-existing evidence in terms of modelling artefacts. Thus, also the recertification is efficient.

6 Related Work

In the literature, other solutions have been proposed to increase efficiency via reuse, while engineering/assuring safety-critical systems and their processes, and case studies have been conducted to show their benefits. In the context of the OPENCOSS[3] project, for instance, a systematic approach for reusing safety certification artefacts was applied to a cross-domain (railway and avionics) case study [14] resulting into 50% of reuse. In contrast, our case study focuses on the medical domain and in the context of different jurisdictions. To the best of our knowledge, in the medical domain, our work represents a novelty and perhaps the seminal evidence to trigger the attention to the potential efficiency increase that could be gained by systematising and managing the variability that exists within the broad range of national and international regulations and medical equipment certification standards.

7 Conclusion and Future Work

In this paper, we conducted a case study-based evaluation of the process compliance recertification efficiency enabled by EPF-C ∘ BVR-T. Precisely, the ISO 14971 process for risk identification and evaluation for medical devices was in focus. EPF-C ∘ BVR-T was used to model the process evidence needed for certification, systematise reuse, and manage change (i.e., reconfigure to successfully re-certify). Based on a set of criteria, we evaluated the efficiency of the change management strategy, implemented in EPF-C ∘ BVR-T, and the results enabled us to draw conclusion on the recertification efficiency. Specifically, the case study showed that, via EPF-C ∘ BVR-T, efficient reconfiguration (i.e., efficient provision of artefacts needed for the recertification process) is possible. Thus, for instance, manufacturers targeting an international market can efficiently reconfigure and validate their processes to satisfy the requirements within/outside EU. This evaluation could represent the starting point for the adoption of the tool chain EPF-C ∘ BVR-T in the medical domain. In the future, we aim at conducting a larger evaluation by considering the entire ISO 14971, as well as related standards (e.g., software process improvement, and security). In addition, in cooperation with industrial partners, we aim at evaluating EPF-C ∘ BVR-T in realistic industrial settings, where processes are typically not derived by following the standard requirements by the book.

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