INSTITUTO SUPERIOR DE ENGENHARIA DE LISBOA

Departamento de Engenharia Mecâncica

ISEL

A new risk prioritization model for reliability assessment in design phase of new products

BRUNO RICARDO SOUSA DE SÁ

(Licenciado em Engenharia Mecânica)

Trabalho Final de Mestrado para obtenção do grau de Mestre em Engenharia Mecânica

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Setembro de 2017

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Avaliação da fiabilidade de novos produtos na sua fase de conceção

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Abstract (English)

Nowadays, companies take very seriously the subject of product quality, and make great efforts to guarantee that a reliable product is deployed into the market. Early detection of product faults is less costly and easier to correct. Therefore, companies tend to proceed with reliability tasks along all product development stages, such as Failure Modes and Effects Analysis (FMEA) which is a well-known tool used to identify failure modes and thus enhance system reliability through the development of suitable correction actions.

Few companies have the resources to tackle all failure modes so they resort to prioritization methodologies in order to focus on the most critical ones. The most commonly prioritization methodology used worldwide is the Risk Priority Number (RPN). However, it has been raised by scientific community awareness towards RPN shortcomings that may result in misleading prioritization outcomes. Despite all the critics, conventional RPN is still utilized worldwide for prioritization of failure modes, probably due to its simplicity.

In this study, it is proposed an alternative computation model (RPN beta - RPNb) for risk prioritization, which attempts to maintain application simplicity while eliminating some of conventional RPN shortcomings – 1) No consideration of risk drivers' relative importance, 2) repetition of RPN values through different risk drivers' combinations, 3) non-continuity of RPN values scale, and 4) high sensitiveness to variations in risk drivers scoring.

Companies cannot rely on ineffective methodologies to support the decision-making, and implementation of corrective action for reliability improvement is not an exception. It is of utmost importance to replace the utilization of conventional RPN for failure modes prioritization. Based on a comparative analysis of a case study, RPNb presents itself as an apparently robust alternative, capable of delivering sustained results, adjustable to industry/area specific characteristics, through a straightforward computation mode.

Keywords: Reliability, Risk Prioritization Model, Risk Priority Number, Failure Modes and Effects Analysis, RPNb

Abstract (Portuguese)

Atualmente, as empresas tratam a questão da qualidade de produtos com seriedade, e procedem a grandes esforços para colocar no mercado produtos fiáveis. Neste sentido, as empresas promovem tarefas com vista o aumento da fiabilidade durante todo o ciclo de vida do produto. A Análise de Modos de Falha e Efeitos (FMEA) é uma ferramenta usada a nível mundial na identificação de modos de falha e assim promover o aumento da fiabilidade através da implementação de ações corretivas.

São poucas as empresas que possuem os recursos necessários para retificar todos os modos de falha identificados, e como tal recorrem a metodologias de priorização de modo a orientar esforços nos mais críticos. A metodologia de priorização mais comum é o Número Prioritário de Risco (RPN). No entanto, este tem sido alvo de críticas por parte da comunidade científica devido à existência de lacunas que podem levar a resultados enganadores. Apesar das críticas, o RPN convencional é ainda utilizado mundialmente na priorização de modos de falha, provavelmente devido à sua simplicidade.

Neste estudo, é proposto um modelo de computação alternativo (RPNb) para priorização de risco com vista a eliminação de algumas lacunas do RPN convencional – Não consideração da importância relativa dos parâmetros de risco; Repetição dos valores de RPN através de diferentes combinações dos parâmetros de risco; Não-continuidade da escala RPN; Elevada sensibilidade a variações na pontuação dos parâmetros de risco – e a manutenção da simplicidade de aplicação.

Na procura pela melhoria da fiabilidade, as empresas não devem suportar a tomada de decisão em metodologias pouco eficazes. Assim, é importante promover a substituição do RPN convencional na priorização de modos de falha. Neste sentido, e com base no caso de estudo, o RPNb é uma alternativa aparentemente robusta, capaz de fornecer resultados coerentes, ajustadável às características da indústria/área, através de um modelo simples.

Palavras-chave: Fiabilidade, Modelo de Priorização de Risco, Número Prioritário de Risco, Análise de Modos de Falha e Efeitos

INDEX

Figure index

Table index

1. Introduction

1.1. Motivation

This study is a thesis for obtaining a Master Science degree in Mechanical Engineering at Instituto Superior de Engenharia de Lisboa. The course foresees the application of theoretical and experimental knowledge related to design, manufacture, control and management of products, processes and equipment. In this sense, during the course, it was given a significant focus to the concept of reliability and product life cycle.

This study focuses on the reliability topic in the early stages of a product life cycle, since it is during this stage that reliability assessment may bring more added value to the product. Furthermore, it is developed the topic of risk level assessment as a methodology to guide experts/companies on the seeking of reliability improvement.

The subjects here discussed are object of innumerous studies worldwide and deemed as a key topic for companies that aim to compete in a global market. This study comprises an opportunity to apply knowledge obtained throughout Mechanical Engineering course, and to develop competences in a specific subject with relevance to industry worldwide.

1.2. Problem background

The technological progress has been the driving force of economic growth worldwide. Companies have taken advantage of technological progress to expand the market for their products/services, leading ultimately to the existence of a global market that we find ourselves nowadays. Technological progress is still the driving force of economic growth but market competition paradigm has been changing – companies work under a fiercely competitive environment where errors or misjudgments may lead to major consequences.

Currently, it is common to find similar products from different geographies competing in the same market. This competition is further intensified due to facilitated information access about products/services, allowing customers to compare features and cost. The availability of a variety of similar products induces expectations in customers that tend to grow as they become familiar with the existing features or performances of a product.

In order to have a successful product and thus maintaining market share, a company must be able to deliver quality products that attends customer’s expectation, at lower costs and within a short-time frame. Also, the product must be able to compete against alternatives in the market. Figure 1.1 presents the main drivers for product success.

Figure 1.1 – Factors required to product success (Yang G. , 2007)

Reliability takes an important role in the product success. It is intrinsically related to product quality, increasing product competitiveness, and related to customers' expectation. Customers seeks high performance products, such as reliability, and are willing to pay to meet their want. On the other hand, increasing reliability of a product may represent an increase in cost and time to market.

It is common to have quality competing with time to market, and a good balance between them is necessary to avoid errors and/or miss market opportunities with major consequences to the company. There are several examples where the urge to deploy a product into the market led to image and financial consequences due to un-detected faults, such as:

- Batteries exploding in Samsung Galaxy Note 7 led to recall of millions of smartphones with high financial and reputational cost for Samsung (Financial Times, 2016).

Figure 1.2 – Samsung Galaxy Note 7 damaged by battery explosion (Daily Mail Journal, 2016)

- Takata's airbag malfunction is linked to at least 16 deaths worldwide, and led to recall of millions of vehicles from several automakers. Court dispute in the U.S.A led to a penalty of 1 billion dollars (REUTERS, 2017).

Figure 1.3 – Honda advertisement for vehicles recall in sequence of Takata's airbag malfunction (The Honda Way, 2017)

- Leakage of a closure valve in Petrobras platform P-36 led to an explosion that killed 11 workers. The oil rig evaluated in 496 million dollars sank five days after the explosion (NASA, 2015).

Figure 1.4 – Petrobras platform P-36 sinking in March 2001

- Toyota's pedal malfunction is linked to 52 deaths worldwide, and led to recall of approximately 7.5 million vehicles. This event is associated with a 19% fall in the company's cumulative abnormal returns (Gokhale, Brooks, & Tremblay, 2014), and led to a penalty of 1.2 billion dollars (The Washington Post, 2014).

Companies take very seriously product quality, pushed by market conjecture, and make great efforts to guarantee that a reliable product is deployed into the market. It is a challenge for the companies to increase reliability, while shortening design cycle and reducing costs. To meet these challenges, companies seek effective tools, such as risk analysis, to perform reliability tasks and thus assuring product reliability throughout the product life cycle (Yang G. , 2007).

Risk analysis is often associated to Failure Modes and Effects Analysis (FMEA), which is a well-known tool to identify failure modes and to enhance system reliability through the development of suitable correction actions (Zammori & Gabrielli, 2012). Its implementation during early stages of a product life cycle is fomented since early detection of product faults is less costly and easier to correct.

Effectiveness of corrective actions implemented during product development is only as good as the quality of the tools used for reliability enhancement. Therefore, it is crucial companies to be aware of available tools, and their strengths and weaknesses.

1.3. Problem formulation

For the development of a new product, reliability is addressed from planning phase of the life cycle, where product performances are outlined. However, it is during product design and development phase that reliability tasks are strongly implemented to reduce need for repetition, saving time and cost. Verification and validation phase will provide data to ultimate product design before proceeding with production at full capacity (Yang G. , 2007).

When developing a new product, the implementation of reliability tasks up to verification and validation phase of life cycle foresees implementation of corrective action under a pro-active mode, while implementation of corrective actions during production phase and filed deployment phase is usually under a reactive mode. It comes from the fact that data available at early stages is limited and no risk analysis method can guarantee a fault free product before production phase.

FMEA is a powerful tool utilized worldwide for failure modes identification. It is strongly used during early stages of life cycle since it is meant to be a failure modes prospective tool. Its structured framework allows to characterize failure modes drivers (Occurrence (O), Severity (S) and Detection (D)), and then to proceed with risk assessment.

The most common method to assess risk level of a failure mode is through the Risk Priority Number (RPN). In its conventional computation model, RPN is the product of O, S, D drivers, promoting a failure modes prioritization ranking. Companies rely on RPN to identify failure modes that will be addressed first when it comes to corrective actions implementation, and to distinguish failure modes that will be object of corrective action from those that will not.

It is important for a company that RPN is capable of performing a robust risk assessment of failure modes in order to guarantee product reliability, and to avoid implementation of unnecessary corrective actions that comes with a price, both in cost and time. And here lays the issue of using conventional RPN for risk assessment of failure modes.

For several years that it has been raised by scientific community awareness towards some shortcomings of conventional RPN that may diverge risk assessment results from its ultimate purpose. Conventional RPN is deemed as not very robust and sometimes misleading (Bowles & Peláez, 1995). Nevertheless, RPN is still extensively used worldwide, probably due to its simplicity (Lu *et al.,* 2013).

1.4. Research objectives

Assuring reliability of new product entering the market is currently a top priority of companies, as a measure of company value protection – both image and financial. From customer's view, reliability is often perceived as intrinsic feature of a product. It is also often associated to product safety, which is a top concern in several industries. It is then essential for companies to have access to effective tools in order to achieve high reliability.

In that matter, this study will focus on the issue of using conventional RPN as a failure modes prioritization method. It will be performed a literature review of identified shortcomings by scientific community, in order to present sustained and structured information of the risks associated to utilization of conventional RPN. Additionally, it will be performed a brief research on alternatives to conventional RPN as improvement opportunities, in order to understand the reasons behind continuity of utilization of conventional RPN.

As ultimate goal, it will be developed and proposed an alternative computation model for risk prioritization (RPN beta - RPNb), which attempts to maintain application simplicity while eliminating most of conventional RPN shortcomings.

In summary, to fulfill the objectives of this study the steps to be taken are:

1. To perform a literature review on conventional RPN shortcomings, as well as a brief review on improvements opportunities.
2. To develop an alternative computation model that satisfies better the purpose of risk prioritization of failure modes.
3. Correlate the performance of the developed model to conventional RPN model using a case study.

1.5. Research methodology

This study foresees the development of understanding about the role of reliability for conception of new products. The media frequently reports cases where products fail to accomplish its purpose. It is intrinsically linked to the reliability of the product although it may not be the message transmitted in most of the times. Following this lead, it was performed a search for a few cases where malfunction products (low reliability) led to high consequences to companies. This search was based on articles from recognized journals, and economics and finance magazines.

Since this study has reliability in new products as starting point, it was also performed a review on the theoretical basis of reliability, focused in theory of probability and statistics, and on a product life cycle, focused in the reliability tasks. The review was based on reliability and product life cycle dedicated books.

For the first key objective – literature review on conventional RPN shortcomings and improvements opportunities – the literature review was based on articles from relevant scientific journals. A wide search was performed for this topic in the seeking of better understanding of shortcomings root causes. Also, the review on the improvement opportunities had as objective to provide understanding of available alternatives to conventional RPN.

For searching of scientific articles, it was used mostly three platforms – Science Direct (www.sciencedirect.com), Emerald Insight (http://www.emeraldinsight.com/) and Google Scholar (https://scholar.google.pt/). The main keywords were – “risk priority number”, “RPN”, “failure modes and effects analysis”, “FMEA” and “risk analysis”.

For the second key objective – development of an alternative computational model (RPNb) – having as start point the conventional RPN computation model and the root causes of known shortcomings, changes (solutions) were introduced in the computation model and then tested. A solution was accepted when the results obtained were deemed favorable. Each shortcoming was addressed individually, although a single solution could eliminate one or more shortcomings. Besides elimination of the shortcoming, the solution had to be capable of maintaining computation model as much simple as possible. The final computation was built from the integration of accepted solutions.

To verify the validity of RPN beta, it was performed a comparison analysis with a case study chosen from the literature – Failure Mode and Effect Analysis in blood transfusion: a proactive tool to reduce risks (Lu *et al*., 2013). The reason for chosing this specific study is based 1) in the fact it uses conventional RPN for failure modes prioritization, allowing direct comparison of results from both methodologies (conventional RPN vs. RPNb), and 2) the fact that healthcare is an area where un-noticed risks may have highly severe consequences for human life, so failure modes prioritization is of high importance.

An important aspect of the study was to assess the behavior of RPN beta to variations of O, S, D weighting factors. In this sense, it was produced three different scenarios with three different combinations of O, S and D relative importance:

- Scenario S>O>D, where Severity has the higher relative importance, Occurrence has "in between" relative importance, and Detection has the lower relative importance.
- Scenario S>D>O.
- Scenario O>S>D.

The O, S, D scoring for each failure mode in the Lu *et al*. (2013) study was performed by area experts, thus they were assumed in this study as accurate. The comparison analysis between conventional RPN and RPN beta is based on the critical examination of failure modes O, S, D scores.

Judgement on the validity of RPN beta is based on a qualitative and quantitative assessment under the comparison analysis. For the qualitative assessment, it was chosen failure modes with obvious biased RPN values so it would be relatively easy to visualize the error when using the RPN, and the correction when using the RPNb. Supporting it, it was also performed a quantitative assessment, where O, S, D scores differences from two or more failure modes were analyzed. The quantitative assessment brings the advantage of allowing the comparison of similar failure modes, where qualitative assessment would have difficult to provide a conclusion.

1.6. Report walk-through

This report comprises five chapters, each one dedicated to the development of awareness and comprehension of a topic, building a comprehensive overview towards a common objective – the need of improving failure modes prioritization methodology for an enhanced reliability. The report is structured to guide the reader from the conjecture that gave ignition to the idea of performing a master thesis within the subject of reliability and product development, passing through the development of a sounded ground of understanding about the subject, finalizing with a conclusive description of the lessons learned.

In chapter 1, it is performed an introduction to the subject under study, going through the motivation and description of the conjecture that led to the awareness of the necessity to develop a study on the importance of reliability in the development of new products. In this chapter, it is presented also the objectives of this study, as well as the research methodology utilized to sustain the conclusive statements.

The chapter 2 explores the concept of reliability, as well as the concept of product life cycle since the major focus of this study is oriented to the early stages of a product development. Additionally, this chapter comprises a literature review on the active substance of this study – the shortcomings associated to the utilization of conventional Risk Priority Number.

In chapter 3, it is proposed an alternative computation model to conventional Risk Priority Number, as well as the development process that resulted in the final form of the alternative computation model. This chapter finalizes with the description on the differences between both models.

Chapter 4 is complimentary to chapter 3 in the sense that applies the alternative model to a case study in order to assess its validity and effectiveness on failure modes prioritization. A comparative analysis is performed and the results passes through a critical examination.

Chapter 5 and 6 comprise a wrap-up of the study, summarizing the relevant observations found along the study, as well as considerations to have in mind for future studies within this subject area.

2. Literature review

2.1. Reliability

2.1.1. Theory of probability and statistics

Reliability is defined as the probability that a product performs its intended function without failure under specified conditions for a specific period of time (Yang G. , 2007). Being a probability, it is measured using probability theory and statistics.

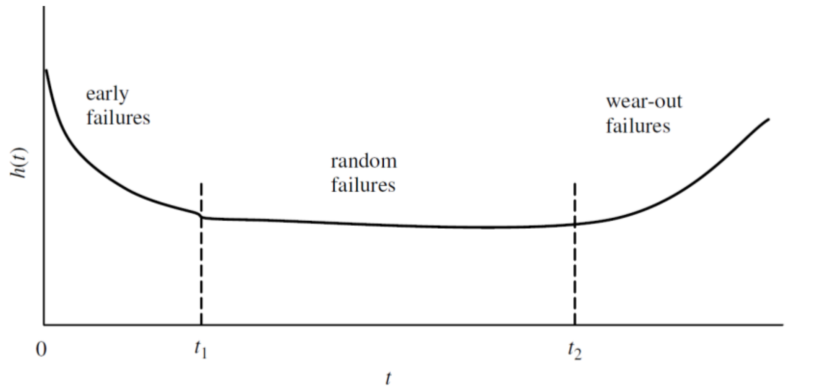

Figure 2.1 – Bathtub curve hazard rate function (Yang G. , 2007)

The Figure 2.1 represents a classical Hazard Rate h(t) of a population of products. The Hazard Rate measures the rate of change in the probability that a surviving product will fail in the next small interval of time.

$$h(t) = \frac{f(t)}{R(t)} \qquad \textit{(Eq. 2.1)}$$

Where, R(t) is the Reliability Function which refers to the probability of success. It can be written as:

$$R(t) = \int_t^{\infty} f(t)\, dt \qquad \textit{(Eq. 2.2)}$$

And, f(t) is the Probability Density Function (pdf) which indicates the failure distribution over the entire time range and represents the absolute failure speed, written as:

$$f(t) = \frac{dF(t)}{dt} \qquad \textit{(Eq. 2.3)}$$

F(t) is the Cumulative Distribution Function (cdf) that refers to the probability that a product will fail by a specified time.

$$F(t) = \int_{-\infty}^{t} f(t)\, dt \qquad \textit{(Eq. 2.4)}$$

The Probability Density Function f(t) and the Cumulative Distribution Function F(t) can be related to each other. Also, the Reliability Function R(t) is the complement of the Cumulative Distribution Function F(t).

From the Figure 2.1 it is possible to identify three distinct periods – early failures, random failures and wear-out failures.

Early failures are usually caused by major latent defects induced by manufacturing process variation, material flaws, design errors and misuse. In this period, the Hazard Rate decreases over time since surviving products tends to not suffer from major latent defects.

In random failures period, the Hazard Rate remains approximately constant. Failures follows a stochastic pattern and therefore it is not predictable. Failures may be caused by minor defects induced by variations in material or manufacturing process, or different operating conditions from specifications. Minor defects tend to take longer time to develop into failures.

In wear-out period, the Hazard Rate increases since the product is reaching its limits (e.g. ageing). In this period failure is eminent and it is attributed to wear-out or degradation, which accumulates and accelerates over time.

Many products do not comprise all three periods of complete bathtub curve but one or two segments. The Cumulative Hazard Function is written as:

$$H(t) = \int_{-\infty}^{t} h(t)\, dt \qquad \textit{(Eq. 2.5)}$$

For reliability purpose, it is usual to characterize a population of a product with:

- Percentile – time by which a specified fraction p of the populations fails.

$$H(t) = F^{-1}(p) \qquad \textit{(Eq. 2.6)}$$

- Mean Time To Failure (MTTF) – it is the expected life of a non-repairable product.

$$MTTF = E(T) = \int_{0}^{\infty} R(t)\, dt \qquad \textit{(Eq. 2.7)}$$

- Variance – it is a measure of the spread of a life distribution.

$$Var(T) = \int_{-\infty}^{\infty} [t - E(T)]^2 . f(t)\, dt \qquad \textit{(Eq. 2.8)}$$

Frequently, standard deviation is used over variation, since it has the same time unit as T.

The most common statistical distribution to measure reliability are:

- Exponential – It is deemed appropriated for modeling random failures but not for failures due to degradation. The argument behind the statement is that random failures are caused by external socks that usually can be modeled using Poisson process. Considering that each shock causes a failure, it is possible to use exponential distribution for modeling product life.

$$f(t) = \lambda . e^{-\lambda . t}, \; t \geq 0 \qquad \textit{(Eq. 2.9)}$$

- Weibull – The Weibull distribution is deemed very flexible and capable of modeling all three periods of the bathtub curve. The generic formulation of Weibull distributions considers three parameters – shape parameter (β), characteristic life ($\alpha = t_{0.632}$) and Location parameter. However, it is possible to apply the distribution based on two parameters only.

$$f(t) = \frac{\beta}{\alpha^{\beta}} . t^{\beta-1} . e^{-\left(\frac{t}{\alpha}\right)^{\beta}}, \; t \geq 0 \qquad \textit{(Eq. 2.10)}$$

- Mixed Weibull – The bimodal mixed Weibull distribution is often used due to its inherent flexibility. In cases where from a product population arises two or more subpopulations, it is desirable and valuable to segregate them and proceed with individual analysis. However, it is often difficult or impossible to make such separation of subpopulations.

$$f(t) = p . f_1(t) + (1-p) . f_2(t), \; t > 0 \qquad \textit{(Eq. 2.11)}$$

- Smallest Extreme Value – it is used for products where failure of the weakest components determines the failure of the product. However, this distribution is not commonly used since it allows the life to be negative, and the probability of failure to be greater than zero for t = 0. Smallest Extreme Value distribution is often associated to Weibull distribution. Considering Weibull y, then t = ln(y) has the smallest extreme value for σ = 1/β and μ = ln(y). This relationship is used to develop accelerated life test plans.

$$f(t) = \frac{1}{\sigma} . e^{\left(\frac{t-\mu}{\sigma}\right)} . e^{-e^{\left(\frac{t-\mu}{\sigma}\right)}}, \; -\infty < t < \infty \qquad \textit{(Eq. 2.12)}$$

- Normal – The Normal distribution is used for a long time due to its inherent simplicity and symmetry, that describes many natural phenomena. It is very useful in statistical analysis. However, it allows the random variables to be negative. It is may be used for products with low coefficient of variation. For analytical studies, it is commonly used jointly with Lognormal distribution.

$$f(t) = \frac{1}{\sqrt{2\pi}.\sigma} . e^{-\left(\frac{(t-\mu)^2}{2\sigma^2}\right)}, \; -\infty < t < \infty \qquad \textit{(Eq. 2.13)}$$

- Lognormal – it is fit for modelling the life of products for which failure cause is fatigue or crack. This distribution is able to model all periods of the bathtub curve since it is able to fit decreasing and increasing Hazard rate depending on subpopulation.

$$f(t) = \frac{1}{\sigma.t}.\emptyset\left(\frac{ln(t)-\mu}{\sigma}\right),\ t > 0 \qquad \textit{(Eq. 2.14)}$$

The technological progress in computation devices has brought capability to handle high complex statistics. It is possible nowadays to utilize Monte Carlo methods for probabilistic design to obtain solutions that otherwise would be extraordinarily difficult to obtain using analytical methods. Several entities, such as NASA and Society of Automotive Engineers, have made significant progress by applying probability analysis to the design function (Abernethy, 2004).

2.2. Life cycle of a product

2.2.1. Stages of life cycle

According to Yang (2007), Product Life Cycle refers to sequential phases from product planning to disposal and it comprises six main stages:

i. Product Planning Phase – At this stage business trends and market completion are analyzed along with customer needs, usually using a multidisciplinary team. If further development of the product is justified, product benefits, features and performances may be put on the table, as well as timelines for market introduction.

ii. Design and Development Phase – This phase is initiated with detailing of product specifications and carry out the concept design that will determine the reliability, robustness and cost. It is also important that the product presents economic feasibility and complies with governmental regulation. Concept design is followed by detailed design where it shall be assured compliance with all system and subsystem requirements. Tolerances and functional parameters are determined as well as materials and components. The implementation of effective reliability programs will reduce repetition.

iii. Verification and Validation Phase – After complete design is achieved, it is initiated the design verification. Several prototypes are built and subjected to a previous defined test plan in order prove the product conformity with all requirements. The test conditions shall be the most similar possible to real world application. In parallel to design verification it should be initiated the production process planning, involving the methods of product manufacturing. The developed process is then tested (process validation) in order to prove the capability to manufacture the product with minimum variation of defined specifications.

iv. Production Phase – Initiated production at full capacity, including all inherent activities such as materials handling, assembly, quality control and management. Final products are subjected to final acceptance tests and then shipped.

v. Field Deployment Phase – This phase involves marketing advertisement, sales services, technical support, field performance monitoring and continuous improvement. Products are sold to customers.

vi. Disposal – "This is the terminal phase of a product in the life cycle. A product is discarded, scraped or recycled when it is unable to continue service or is not cost-effective". The manufacturer shall provide support on disposal in order to minimize associated costs and mitigate environment impact.

There are several other authors proposing different stages divisions – see Figure 2.2. Nevertheless, all proposals follow the same logical sequence which differences do not change the way life cycle is perceived.

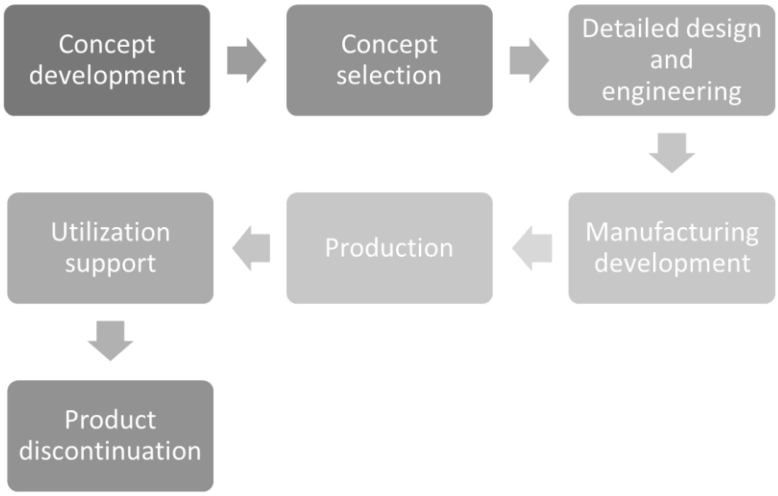

Figure 2.2 – Product life cycle sequence (Bhise, 2014)

2.2.2. Reliability tasks

When applied to engineering, reliability is used to maximize the operability of a product and minimize the effects of failures. Considering reliability in the product life cycle, three main steps must be met:

1. Build maximum reliability into a product during the design and development stage.
2. Minimize production process variation.
3. Appropriate maintenance to alleviate performance and prolong product life.

For the mentioned three steps, there is a large set of reliability methodologies to be employed. However, not all available methodologies shall be applied discretionarily. Instead, an adequate reliability program should be elaborated for each specific product (Yang G. , 2007).

For the manufacturer, it is important to minimize the time and cost associated to product life cycle. Despite it may be a competitive advantage, the manufacturer has also to meet customers' expectations towards the product. It is important that the manufacturer has a balanced integration of reliability programs into the product life cycle since setting reliabilities targets will have effects on cost, time and competitiveness.

Aiming for an overly ambitious reliability target may turn the product cost-ineffective and prolong product development, and thus jeopardize competitiveness. Conversely, low reliability targets may compromise competitiveness by loss of customers' confidence.

An effective reliability program consists of a series of reliability tasks to be implemented throughout the product life cycle. Figure 2.3 presents several reliability tasks that may be implemented in each of the stages.

Use of reliability methodologies is more effective during the development phase where potential failure modes can be ruled out. It will reduce the design-test-fix loop by obtaining correct design at the first time. It may even accelerate design and reduce associated costs. In this sense, Failure Modes and Effects Analysis (FMEA) is a "must have" during the design and development phase of any product.

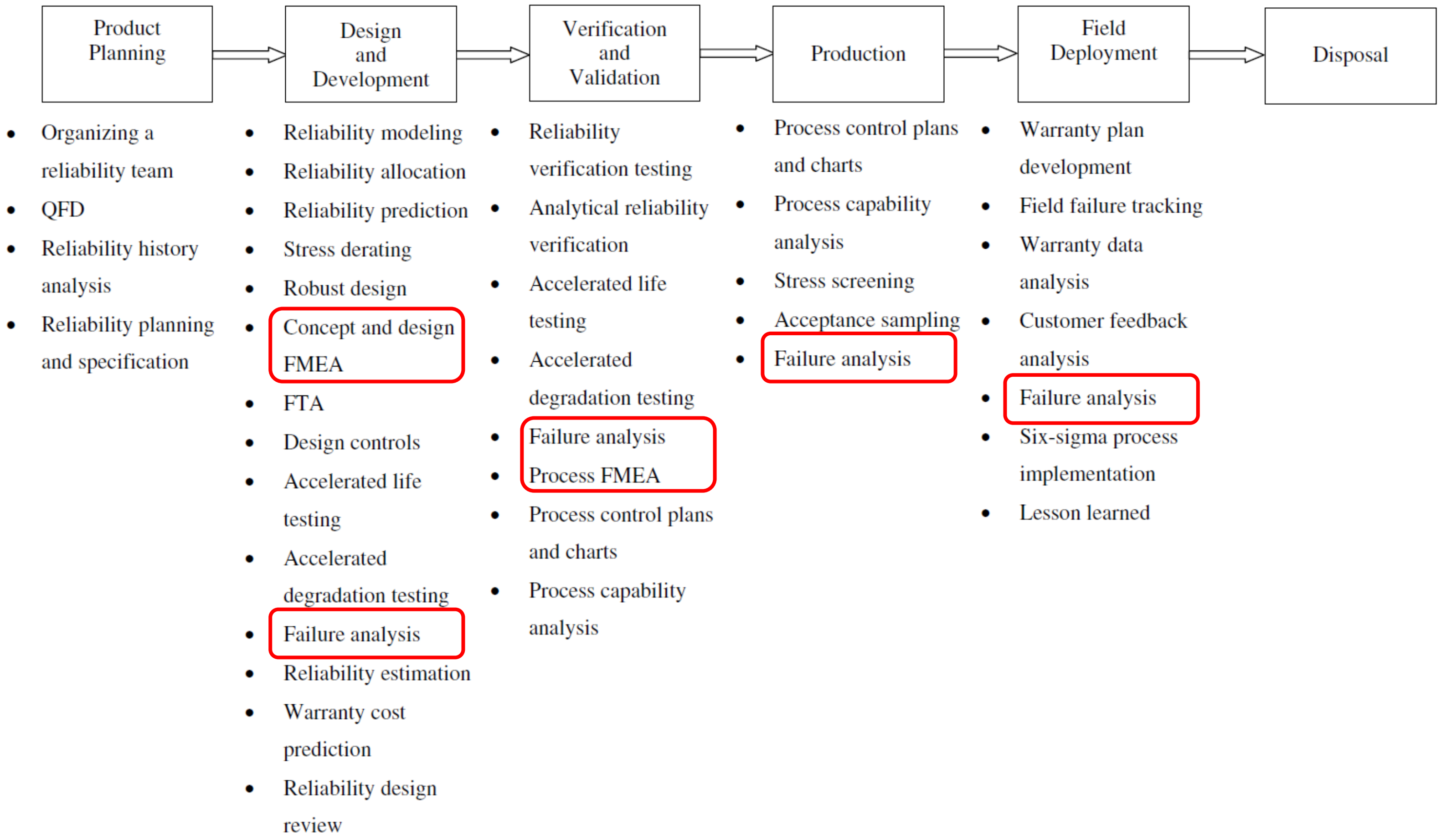

Figure 2.3 – Reliability tasks for a typical product life cycle (Yang G. , 2007)

2.2.3. Failure modes and effects analysis

Failure Modes and Effects Analysis (FMEA) is a well-known tool used to identify the failure modes and to enhance system reliability through the development of suitable correction actions (Zammori & Gabrielli, 2012). It is extensively used worldwide and deemed as very powerful (Zhang & Chu, 2011).

The history of FMEA goes back to mid-1960s when the first formal FMEA was conducted in the aerospace industry, specifically focused on safety issues. FMEA was then adopted by several important industries, such as chemical process and automotive (McDermott, Mikulak, & Beauregard, 2009). For instance, Ford Motor Company has developed industry specific standards for FMEA – Process driven and Design driven (Ford Motor Company, 1988).

Project Management Institute (2013), a worldwide recognized US organization, defines FMEA as "*an analytical procedure in which each potential failure mode in every component of a product is analyzed to determine its effect on the reliability of that component and, by itself or in combination with other possible failure modes, on the reliability of the product or system and on the required function of the component; or the examination of a product (at the system and/or lower levels) for all ways that a failure may occur. For each potential failure, an estimate is made of its effect on the total system and of its impact. In addition, a review is undertaken of the action planned to minimize the probability of failure and to minimize its effects*".

The FMEA framework requires the following of sequential steps that finalizes with a worksheet (Figure 2.4) summarizing the information captured during the process. It is important to document the FMEA process so it is possible to have an easy and controlled follow up throughout the product/process development.

Failure Mode and Effects Analysis Worksheet

Process or Product: ______ FMEA Number: ______
FMEA Team: ______ FMEA Date: (Original) ______
Team Leader: ______ (Revised) ______
Page: 1 of 1

	FMEA Process													Action Results					
Line	Component and Function	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) of Failure	Occurrence	Current Controls, Prevention	Current Controls, Detection	Detection	RPN	Recommended Action	Responsibility and Target Completion Date	Action Taken	Severity	Occurrence	Detection	RPN
1																	
2																	
3																	

Figure 2.4 – Example of a FMEA worksheet

McDermott *et al*, (2009) proposes 10 steps to perform a successful FMEA:

1. Review the process or product – It is important to ensure all team involved in the analysis has the same understanding of the product or process it is being worked on.
2. Brainstorm potential failure modes – At this stage, the team is instigated to present ideas and debate. Several sessions may take place with focus on different elements (ex. People, methods, equipment, materials, etc.). This stage concludes with listing all valid failure modes into the worksheet.
3. List potential effects of each failure mode – For each failure mode, the team identifies potential effects (one or more) in case it occurs. This step must be thorough since this information will feed the assignment of risk factors rankings.
4. Assign a severity ranking for each effect – Usually using a 10-point scale (other scales may be used), where 1 represents the lowest severity and 10 the highest severity, the team attributes a rank for each effect of how serious it would be if a given failure did occur.
5. Assign an occurrence ranking for each failure modes – Usually using a 10-point scale (other scales may be used), where 1 represents the lowest probability and 10 the highest probability, the team attributes a rank to each failure mode of how likely a given failure mode can occur.
6. Assign a detection ranking for each failure mode and/or effect – Usually using a 10-point scale (other scales may be used), where 1 represents the highest detection and 10 the lowest detection, the team attributes a rank to each failure mode and effect of how likely a given failure mode or effect can be detected.
7. Calculate de Risk Priority Number (RPN) for each effect – it is simple calculated through the product of severity, occurrence and detection.
8. Prioritize the failure modes for action – Failure modes are prioritized by ordering them from the highest RPN to the lowest. The team must then decide which failure modes to work on. Some team defines thresholds do distinguish which failure modes are acceptable form those which are not.
9. Take action to eliminate or reduce the high-risk failure modes – sing organized problem-solving processes, the team identifies and implement actions to eliminate or mitigate high-risk failure modes. Ideally, failure modes should be eliminated completely but it seldom is possible. Therefore, the team works on measures to decrease the ranking of severity, occurrence and/or detection.

10. Calculate the resulting RPN as the failure modes are reduced or eliminated – once actions were implemented, new rankings for severity, occurrence and detection should be determined, as well as the calculation of RPN.

The assignment of O, S, D scoring follows usually a standard criteria (Table 2.1, Table 2.2 and Table 2.3) among the scientific community, although several researchers and industries uses their own criteria in order to adapt it to their necessities.

Table 2.1 – Standard criteria for Occurrence scoring (Chang, Wei, & Lee, 1998)

Criteria (chance of occurrence)	Score	Possible failure occurrence rates
Remote chance of failure	1	0
Low failure rate	2	1/20000
	3	1/10000
Moderate failure rate	4	1/2000
	5	1/1000
	6	1/200
High failure rate	7	1/100
	8	1/20
Very high failure rate	9	1/10
	10	1/2

Table 2.2 – Standard criteria for Detection scoring (Chang, Wei, & Lee, 1998)

Criteria (chance of non-detection)	Score	Probability of a defect reaching the customer
Remote	1	0 – 5
Low	2	6 – 15
	3	16 – 25
Moderate	4	26 – 35
	5	36 – 45
	6	46 – 55
High	7	56 – 65
	8	66 – 75
Very high	9	76 – 85
	10	86 - 100

Table 2.3– Standard criteria for Severity scoring (Chang, Wei, & Lee, 1998)

Criteria	Score
Customer will probably not notice	1
Slight annoyance	2, 3
Customer dissatisfaction	4, 5, 6
High degree of dissatisfaction	7, 8
Safety/regulatory consequences	9, 10

Since FMEA is usually (and recommendable) performed by a team, it is common to rise situations where member do not agree on the O, S, D drivers scoring to attributed. In these cases, Stamatis (2003) suggests two path for determining the final score – 1) If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and another says 6, the scoring in this case should be 6 (5 + 6 = 11, 11 / 2 =5.5 ≈ 6). 2) If the disagreement jumps one category, then a consensus must be reached. Even with one person holding out, total consensus must be reach. No average, no majority. Everyone in that team must have ownership of the scoring. They may not agree one hundred percent but they can live with it.

Although FMEA gives experts a structured methodology for failure modes identification, it does not guarantee failure free product. The amount of available data is crucial for the effectiveness of FMEA. Additionally, not all failure modes have to have corrective actions. It is responsibility of the company to define how much relative risk it is willing to take, and then work on corrective actions to bring the risk level of failure modes under that threshold. In this sense, experts turn to Risk Priority Number (RPN) to proceed with failure modes prioritization.

2.3. Risk Priority Number

2.3.1. Introduction to RPN

The Risk Priority Number (RPN) measures the risk level of failure modes, allowing the identification of those to be addressed first when it comes to corrective actions implementation. A high RPN value is representative of a high-level risk failure mode, while a low RPN is representative of a low-level risk failure mode.

The RPN is commonly used in the FMEA and in its conventional computation mode is represented by the product of the failure mode characterization drivers – Occurrence (O), Severity (S) and Detection (D) – as per equation 2.15.

$$RPN = O \times S \times D \qquad \text{(Eq. 2.15)}$$

- Occurrence – The probability or frequency of the failure occurring.
- Severity – The consequence (seriousness) of the failure should it occur.
- Detection – The probability of the failure being detected before the impact of the effect is realized.

The RPN value is intrinsically dependent on the scores of the characterization drivers (O, S, D). Commonly, the scoring scale ranges from 1 to 10 for all the three drivers.

However, different scoring scales are often used by companies, industries or government entities (Bhise, 2014).

It is important to have in mind that prioritization through RPN results are only valid within the same project/product/process analysis. It is not possible to compare RPN results from different analysis since they do not have the same ground basis of O, S, D drivers characterization.

Effectiveness of RPN for failure modes prioritization is of high importance, since it will be the reference for implementation of corrective actions.

2.3.2. RPN shortcomings and existing alternatives

FMEA is a powerful analytical tool used worldwide to examine potential failure modes. It presents a structured framework in a simple and logic format. However, FMEA requires the support of a methodology to differentiate risk level of failure modes – commonly the conventional RPN.

The role of the risk prioritization methodology is of major importance, since it will define which failure modes will be addressed, and which will not. It is then important to have an effective prioritization methodology in order to do not have potential high risk failure modes going un-noticed, as well as not having companies spending un-necessary resources with low risk failure modes.

The conventional RPN provides to examiners a simple and rapid way to prioritize failure modes. However, it has been raised by the scientific community awareness towards shortcomings of the conventional RPN. Several faults are pointed to its computation model that may result in incoherent prioritization outcomes and mislead experts.

Looking through the existing literature, it is possible to find a significant number of published articles pointing out several shortcomings of the conventional RPN, as well as promoting alternative computation schemes.

In a literature review performed by Liu *et al* (2013), it is compiled a set of major shortcoming related to conventional RPN. The three most mentioned shortcomings were – 1) The relative importance among O, S, D is not taken in consideration, 2) Different combinations of O, S, D may produce exactly the same value of RPN, but their hidden risk implication may be totally different, and 3) The three risk drivers are difficult to be precisely evaluated.

The assumption that all three drivers are equally important may not be representative of real world and leads to problems in interpretation of RPN results. For Bowles (1998), although drivers scores are treated as if they represent numeric quantities, it is more of an ordering suggestion as if scores would be a simple labeling.

A score 5 in Severity may not have the same risk level representation as a score 5 in Occurrence. Thus, although two failure modes have the same RPN – for instance, a failure mode characterized as O(5), S(2), D(2) versus a failure mode characterized as O(2), S(5), D(2) – they may represent a significant different risk level in the real world. Different industries have different views on relative importance of each risk driver that conventional RPN lacks the ability to provide.

Provided all three drivers are equally important, if two or more failure modes results in the same RPN value, one may face difficulty in selecting which failure mode demands higher priority for corrective action (Chang & Sun, 2009). This problem comes also from another shortcoming, where different combinations of O, S, D drivers may result in the same RPN value.

The possible O, S, D combinations (1000) for a 10-point scale only present 120 possible RPN outcomes. The RPN values of 60, 72 and 120 can be formed from 24 different combinations each. Only 6 possible RPN outcomes (1, 125, 343, 512, 729 and 1000) are truly unique since they can only be formed through a single combination of O, S, D drivers.

The fact that conventional RPN presents only 120 possible outcomes from 1000 possible O, S, D combinations leads also to a scale continuity issue. It often leads to incorrect assumptions about the behavior in the middle of the range since it presents non-intuitive statistical properties. As it is possible to observe in Table 2.4, the frequency distribution of RPN values is not either normal or uniform (Chang & Sun, 2009).

The steps from one RPN score to the previous and following ones do not present a sound rationale. For instance, the second largest RPN value (900) distances 100 points from the largest (1000), and it is followed by RPN 810, 800, 729 and 720 (Franklin *et al*, 2012). RPN values are not continuous with many holes and heavily distributed at the bottom of the scale 1 to 1000 (Liu *et al,* 2012).

Table 2.4 – Frequency distribution of RPN for a 10-point scale combinations

RPN (Frequency)				
1 (1)	**36 (21)**	**112 (9)**	**243 (3)**	**441 (3)**
2 (3)	**40 (21)**	**120 (24)**	**245 (3)**	**448 (3)**
3 (3)	**42 (12)**	**125 (1)**	**250 (3)**	**450 (6)**
4 (6)	**45 (9)**	**126 (12)**	**252 (9)**	**480 (6)**
5 (3)	**48 (21)**	**128 (6)**	**256 (3)**	**486 (3)**
6 (9)	**49 (3)**	**135 (6)**	**270 (12)**	**490 (3)**
7 (3)	**50 (9)**	**140 (12)**	**280 (12)**	**500 (3)**
8 (10)	**54 (15)**	**144 (18)**	**288 (9)**	**504 (6)**
9 (6)	**56 (12)**	**147 (3)**	**294 (3)**	**512 (1)**
10 (9)	**60 (24)**	**150 (9)**	**300 (9)**	**540 (6)**
12 (15)	**63 (9)**	**160 (15)**	**315 (6)**	**560 (6)**
14 (6)	**64 (10)**	**162 (9)**	**320 (9)**	**567 (3)**
15 (6)	**70 (12)**	**168 (12)**	**324 (6)**	**576 (3)**
16 (12)	**72 (24)**	**175 (3)**	**336 (6)**	**600 (3)**
18 (15)	**75 (3)**	**180 (21)**	**343 (1)**	**630 (6)**
20 (15)	**80 (21)**	**189 (6)**	**350 (6)**	**640 (3)**
21 (6)	**81 (6)**	**192 (9)**	**360 (15)**	**648 (3)**
24 (21)	**84 (12)**	**196 (3)**	**378 (6)**	**700 (3)**
25 (3)	**90 (21)**	**200 (12)**	**384 (3)**	**720 (6)**
27 (7)	**96 (15)**	**210 (12)**	**392 (3)**	**729 (1)**
28 (9)	**98 (3)**	**216 (13)**	**400 (9)**	**800 (3)**
30 (18)	**100 (12)**	**224 (6)**	**405 (3)**	**810 (3)**
32 (12)	**105 (6)**	**225 (3)**	**420 (6)**	**900 (3)**
35 (6)	**108 (15)**	**240 (18)**	**432 (6)**	**1000 (1)**

Considering all possible conventional RPN results, Sankar & Prabhu (2001) present some expected (but incorrect) statistical assumptions versus actual statistical behavior of conventional RPN. The main two pointed out are 1) the fact that the actual average RPN value is 166, although it could be incorrectly assumed an average of all RPN values around 500, and 2) the fact that only 6% of all RPN values are above 500 (the median is 105), although it would have been expected a median near 500.

For purpose of differentiating failure modes with acceptable risk form those with un-acceptable risk, it is common to define a RPN value as threshold. For instance, Dağsuyu *et al* (2016) makes reference to a RPN value of 100 suggested by analysts, while Vázquez-Valencia (2017) opted for a threshold for a RPN value of 300. On the other hand, for Bowles (1998), the set of a threshold is arbitrary and it can lead to unproductive “number games” with possible negative implications for the quality of O, S, D drivers’ scoring.

Considering that the median for conventional RPN scale is 105, choosing a threshold near this value or above may leave potential high risk failure modes un-noticed, although, apparently, it may seem a low threshold for a 1-1000 scale.

Having failure modes with potential high risk going un-noticed, when using conventional RPN, is one of the points highlighted by Sharma & Sharma (2012). Given the example in Table 2.5, one would be focusing in corrective actions for the failure mode with RPN value 180, even though looking to the O, S, D drivers it would possibly make more sense to prioritize the failure mode with RPN value 135.

Table 2.5 – Example of potential higher risk going unnoticed

O	S	D	RPN
3	9	5	**135**
6	5	6	**180**

The computation model adopted for calculation conventional RPN is strongly sensitive (leverage effect) to variations in risk drivers scoring (Yang *et al*, 2008). Under the conventional RPN a two-fold increase in one driver can be offset by a corresponding decrease by half in another driver. As it is possible to observe in Table 2.6, a decrease in Severity from score 2 to score 1 has exactly the same weight as the increase in Occurrence from score 4 to score 8, even though both cases would hardly be deemed as equally important. It leads to a RPN outcome that is a play between relative score of O, S, D drivers rather than its numeric quantities (Bowles, 1998).

Table 2.6 – Geometric cost function behavior of conventional RPN

O	S	D	RPN
4	2	1	**8**
8	1	1	**8**

Braglia & Frosolini (2003) point out that conventional RPN considers only three kind of attributes (O, S, D drivers), mainly oriented in terms of safety, neglecting other important aspects such as economical. However, introducing additional drivers to computation model of conventional RPN would generate an increase of inconsistences in risk level assessment that is provoked by the effect of multiplication.

RPN values based in the multiplication form is also an object of discussion. Actually, there is not a sounded rationale to have risk drivers multiplied instead of another form of drivers correlation (Gilchrist, 1993).

According to Liu *et al* (2013) review, the third most mentioned shortcoming of RPN is related to the difficulty of precisely evaluate O, S, D drivers. Often, the evaluation of these drivers is related to intangible quantities, so it is very difficult to attribute a direct and exact evaluation (Braglia & Frosolini, 2003). This issue is not related to conventional RPN computation model, but in the difficulty of examiners to translate real world uncertainty into FMEA.

To tackle this topic in particular, several authors propose the utilization of Fuzzy logic as a form of improved method to capture real world uncertainty in risk drivers' evaluation. The utilization of Fuzzy logic based methods allows experts to adopt linguist terms in order to convey as much information as possible into risk drivers' evaluation (Kutlu & Ekmekçioglu, 2012).

In the Fuzzy logic based approach presented by Bowles & Peláez (1995) the riskiness and O, S, D drivers are described through linguist terms, and their relationship is characterized using a Fuzzy if-then rule. In the process, O, S, D are fuzzified to match the premise of each possible if-then rule – all rules that comply with premises will contribute to the Fuzzy conclusion set. The conclusion set must then be defuzzified to obtain the raking value of the risk priority.

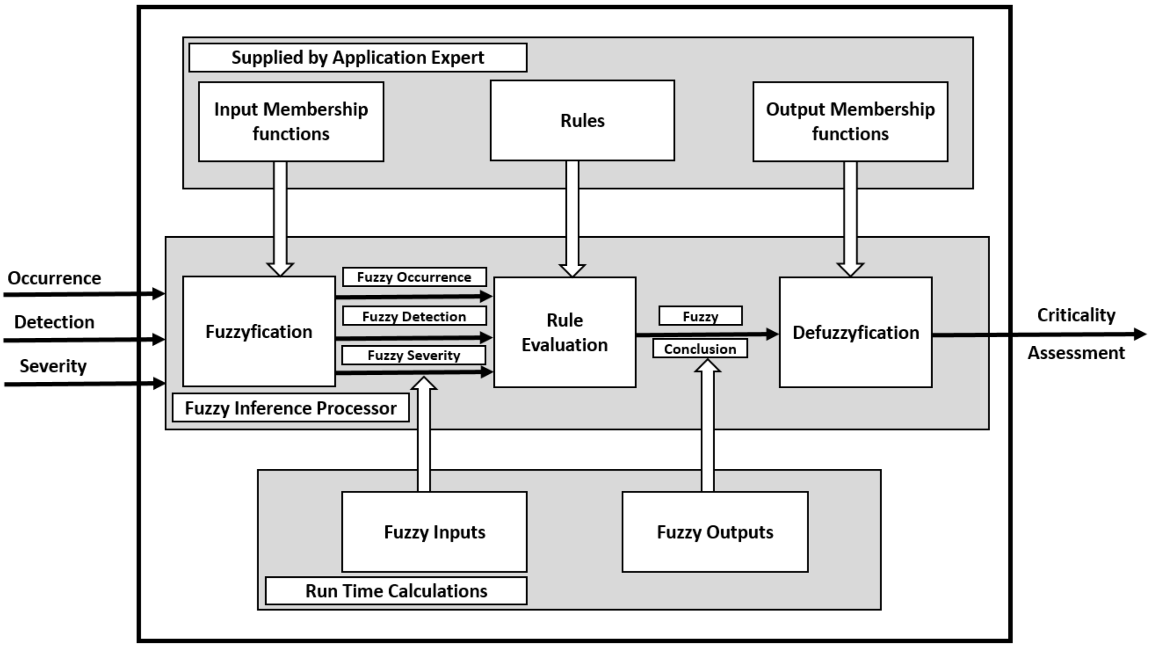

Figure 2.5 – Overall view of the Fuzzy criticality assessment system (Bowles & Peláez, 1995)

The Figure 2.5 pictures the process associated to Fuzzy logic based approach. One of the main disadvantage of this method is related to the need of a large number of rules and a large amount of time, mainly in the process of building the if-then rule base (Yang *et al*, 2008). Additionally, characterization of failure modes using if-then rules with the same consequence but different antecedents will not be able to be prioritized or ranked. (Liu *et al*, 2013).

Great efforts have been oriented to reduce the number of rules required, yet with consequences for the robustness of the system – for instance, any inference from an incomplete rule base will be biased or even wrong because some knowledge cannot be learned from such incomplete rule base (Wang *et al*, 2009).

Fuzzy logic based approaches are the most commonly used as alternative to conventional RPN, but other are also utilized, such as Multi Criteria Decision Making (Franceschini & Galetto, 2001), or even through Monte Carlo simulation (Bevilacqua *et al*, 2000).

3. RPN beta – An alternative to the conventional Risk Priority Number computation model

3.1. Theoretical background

From the literature review on the shortcomings related to utilization conventional RPN, it was made clear that its utilization could result in incoherent prioritization outcomes, thus putting in jeopardy the ultimate objective of the assessment. Liu *et al.* (2013) lists as the most commonly reffered shortcomings the following:

a. The relative importance among O, S, D is not taken into consideration.
b. Different combinations of O, S, D may produce the same RPN value (there are only 120 different results from 1000 O, S, D possible combinations).
c. Frequency distribution of RPN values is not either normal or uniform (RPN values are not continuous with many holes and heavily distributed at the bottom of the scale).
d. O, S, D drivers are difficult to be precisely evaluated (difficulty to translate real world uncertainty into FMEA).
e. RPN computation model is strongly sensitive to variations in O, S, D drivers' evaluations (leverage effect).
f. The RPN considers only three risk factors, mainly in terms of safety.
g. The computation model for calculating RPN is questionable and debatable (there is no rationale as to why O, S, D drivers should be multiplied).
h. Interdependencies among various failure modes and effects are not taken into consideration.

Several alternatives have been proposed in order to surpass the limitations associated to conventional RPN. The approaches taken by the alternatives are diverse and usually oriented to tackle specific shortcomings. Liu *et al.* (2013) lists as the most commonly reffered alternatives the following:

a. Multiple Criteria Decision Making (ex. ME-MCDM, AHP/ANP, Grey theory, etc.).
b. Mathematical programming (ex. Linear programming, DEA/Fuzzy DEA).
c. Artificial intelligence (ex. Rule-base system, Fuzzy ART algorithm, Fuzzy cognitive map).

Some other alternatives can be found in the literature, although most of them result from the integration of the listed above. From the existing alternatives, the ones that uses as base Fuzzy logic are the most exploited. The reason behind utilization of Fuzzy logic based approaches is related to the understanding that it can better capture real world uncertainty into the characterization of O, S, D drivers. Nevertheless, failure modes prioritization through Fuzzy logic based approaches is also object of criticism among scientific community.

Although there is a wide consensus concerning the shortcomings of conventional RPN and although alternative approaches have been suggested for a long time, RPN original computation model is still utilized worldwide for risk prioritization of failure modes. It is possible to find journal articles over 20 years old pointing out conventional RPN shortcomings and proposing alternatives, such as:

- Gandhi & Agrawal (1992) presented a method for FMEA where effects of failure modes were modeled using a digraph and matrices were defined to represent the diagraph. The matrix gives a characteristic function of system to help with identification of structural components of failure mode and effects.
- Gilchrist (1993) presented a model based in the expected cost to the customer that comprises the failure cost along with the probability of failure and probability of the failure not to be detected.
- Ben-Daya & Raouf (1996) presents also an alternative based on a cost model, using Gilchrist (1993) approach as starting point.

In the review performed by Liu *et al*. (2013), it is possible to observe that the amount of articles exploring the topic of failure modes prioritization has been increasing robustly. A quick search for the keywords “RPN” and “FMEA” for the first quarter of 2017 delivered several journal articles where conventional RPN is utilized for prioritization of failure modes, such as:

- Vázquez-Valencia *et al*. (2017) used conventional RPN to prioritize failure modes associated to the technique of secretion suctioning on patient with an endotracheal tube. In this analysis, corrective actions were proposed to failure modes which RPN value surpassed the value 300.
- Delgado-Sanchez *et al*. (2017) conducted an analysis on CIGS thin-film photovoltaic module, resorting to conventional RPN for failure modes prioritization.
- Kang *et al*. (2017) uses a correlation-FMEA based approach for the risk assessment of a floating offshore wind turbine. In this study the prioritization of failure modes is based on the aggregation of conventional RPN values for the different causes of a failure mode and effect.

The literature review performed is clear in showing that shortcomings related to the use of conventional RPN are well acknowledged among scientific community for a quite long time. In some cases, the utilization of conventional RPN may even lead to misdirection from potential high risk failure modes. Having this in mind, it is important questioning why conventional RPN is still broadly utilized. Some question may be raised:

- Is there no consensual alternative to conventional RPN?

Fuzzy logic is often presented as an enhanced methodology to tackle the uncertainty and ambiguity of FMEA analysis, but it presents a drawback regarding application complexity and time consumption. Additionally, some authors point out limitations to this methodology.

- Is there no alternative capable of tackling all shortcomings?

Existing alternatives focus on the elimination of specific shortcomings. Thus, they are not designed to tackle all identified shortcomings.

- Does conventional RPN fit the examiners' study purpose?

Examiners may resort on conventional RPN as a simple guide or verification tool, proceeding then with an extensive analysis of each failure mode using their expertise. Nevertheless, it would be a defective guide.

- Are alternatives too much complex?

Comparing available options for prioritization of failure modes, conventional RPN holds a strong advantage – it has an extremely simple computation model. The simplicity of conventional RPN is very attractive due to its straightforward application and short-time consumption.

- Is it possible to have a prioritization model as simple as conventional RPN without the known shortcomings?

The shortcomings associated to conventional RPN are a widely recognized and scientific community has been providing alternatives. However, conventional RPN tends to be utilized for risk prioritization, probably due to its simple application. Nevertheless, risk prioritization is a key factor in product development, so companies should not rely in methodologies that may jeopardize the purpose of the exercise.

Therefore, in this study, it is proposed a new computation model for risk prioritization (RPN beta – RPNb) which attempts to maintain application simplicity while eliminating most of conventional RPN shortcomings.

3.2. Model proposal

For the development of RPN beta computation model, the strategy adopted was based on the individual targeting of a shortcoming in order to identify and analyze its root cause. Having conventional RPN computation model, changes were introduced to tackle the root cause. A change is considered as accepted solution as it is capable (1) of eliminating the targeted shortcoming and (2) of maintaining the computation model as simple as possible. The final form of RPN beta is obtained through integration of accepted solutions.

The shortcoming selected to be tackled first was – the relative importance among OSD is not taken in consideration. The difficulty to attribute weighting factors to O, S, D drivers comes from the multiplication effect of conventional computational model. It is not possible to attribute an individual weight to one risk driver since it will have effect in the other two risk factors. For instance, if it is attributed the following weights to each O, S, D driver – w_o=0.5, w_s=0.4 and w_d=0.1 – it is the same as applying an overall factor of 0.02 to the RPN value.

$$(0.5\times O)\times(0.4\times S)\times(0.1\times D) = 0.02\times O\times S\times D = 0.02\times RPN \qquad \text{(Eq. 3.1)}$$

To attribute individual weights factors to risk drivers, it is necessary to provide them independency from each other. To achieve the desired independency, it is required to abandon the multiplication form of conventional RPN. Having O, S, D drivers added would allow individual weighting, without any expected loss of information since there was no rationale for having the risk drivers multiplied in the first place. Therefore, the first form of the proposed computation model is given by:

$$RPNa = w_o.O + w_s.S + w_d.D \qquad \text{(Eq. 3.2)}$$

$$w_o + w_s + w_d = 1$$

Since multiplication form is also the root cause for 1) the strong sensibility to variations in O, S, D drivers' scoring (leverage effect), and 2) the non-intuitive statistical distribution (neither normal or uniform), changing to an adding form will also eliminate these two shortcomings. In fact, these two shortcomings are intrinsically related to each other.

The leverage effect of multiplication becomes greater as the O, S, D score increases, generating the heavy distribution of RPN values at the bottom of the scale. The edges of the scale show clearly the leverage effect behavior. The increment from the lowest possible score – O(1), S(1), D(1) – to the next one – for instance O(2), S(1), D(1) – results in a jump of 1 in the RPN (from RPN 1 to RPN 2). On the other hand, the increment from

O(9), S(10), D(10) to the highest possible risk score – O(10), S(10), D(10) – will result in a jump of 100 (from RPN 900 to RPN 1000).

The leverage effect justifies the fact of having larger discontinuities in the top of the scale, and having it eliminated – changing to adding form – will also eliminate the increase in discontinuities.

Having found a solution for three of the shortcomings, the next one targeted was the fact that different combinations of O, S, D may produce the same RPN value.

Although RPNa reduces the frequency of results repetition due to introduction of weighting factors, it still occurs often. For instance, if it is attributed the following weights to each O, S, D driver – w_o=0,4, w_s=0,35 and w_d=0,25 – it would still have only 167 unique possible RPNa results.

Table 3.1 – Example of RPNa values repetition

w_o.O	w_s.S	w_d.D	RPNa
0,4 x 10	0,35 x 3	0,25 x 1	**5,3**
0,4 x 7	0,35 x 5	0,25 x 3	**5,3**
0,4 x 5	0,35 x 8	0,25 x 2	**5,3**

Conversely to conventional RPN, the occurrence of repetition in RPNa is not a result of a "number game" of O, S, D scoring – where a two-fold increase in one driver can be offset by a decrease by half in other driver – but rather by a conflict of O, S, D relative importance. It means that an Occurrence score 5 is equivalent to a Detection score 8 (0,4 x 5 = 0,25 x 8 = 2). Therefore, failure modes with the same RPNa do actually have an equivalent risk level according to relative importance of O, S, D drivers.

RPN values repetition is the result of the same scoring range attributed to O, S, D drivers, which allows to obtain the same value through different combinations. To avoid values repetition, it is required to apply exclusive scoring ranges to each O, S, D driver. There are innumerable ways to perform range distinction but having in mind the drive to maintain the model simple, it was adopted a differentiator factor (1, 11 and 111) for each O, S, D driver as per their relative importance. For instance, assuming a relative importance order of O > S > D, O would be multiplied by 111, S by 11 and D by 1, as per the Table 3.2 below.

Table 3.2 – Exclusive scoring range for O, S, D drivers – for O > S > D

Rank	O	S	D
1	111	11	1
2	222	22	2
3	333	33	3
4	444	44	4
5	555	55	5
6	666	66	6
7	777	77	7
8	888	88	8
9	999	99	9
10	1110	110	10

By attributing different ranges to each O, S, D driver, it is also being attributed a non-intended weighting – O > 10 x S > 100 x D, for O = S = D. This non-intended weighting creates a dominant driver and provokes a biased RPN result.

A possible solution to mitigate the effect of dominancy comprises integration of all three drivers scoring ranges into a wider range (supra-range) where individual influence (from non-intended weighting) becomes negligible. In order to reduce individual influence to approximately 1%, the supra-range must have an order of magnitude of 10^5 ($1110 / 10^5 = 0.01$). It is possible then to obtain the second and final form – RPNb:

$$RPNb = w_o.(10^5 + I_o).O + w_s.(10^5 + I_s).S + w_d.(10^5 + I_d).D \qquad \text{(Eq. 3.3)}$$

$$w_o + w_s + w_d = 1$$

$$I_{o,s,d} = \{1, \quad 11, \quad 111\}, \text{ as per relative importance}$$

In its final form, RPNb presents a scale of magnitude order of 10^6. It is an unusual scale for RPN values and it is not as simple to work with as a 1-1000 scale. It is suggested then to proceed with an interpolation of RPNb values to obtain a 1-1000 scale.

$$RPNbs = \frac{[RPNb(O,S,D) - RPNb(1,1,1)] \times [1000 - 1]}{[RPNb(10,10,10) - RPNb(1,1,1)]} + 1 \qquad \text{(Eq. 3.4)}$$

It is then possible to obtain a unique RPNbs value per O, S, D combination on a 1-1000 scale. It will also allow to facilitate the comparison of results against conventional RPN in the case study.

3.3. Final consideration

Starting with the conventional RPN computation model, two main changes were performed resulting in the elimination of four shortcomings. The first change is related to the calculus form – multiplication form was replaced by adding form – while the second change is related to the risk drivers scoring range – ranges were offset to generate exclusive ranges.

Comparing both computation models, RPNb allows now to attribute weights to O, S, D drivers, thus allows to differentiate the relative importance of each risk driver. The possibility of having relative weight in the assessment of the risk level is helpful for industries to adapt their analysis to market needs. For instance, a smartphone company may attribute higher importance to Occurrence since the frequency of a failure event may have a great impact on customers' choice, and on the other hand, a failure event it is not expected to provoke serious consequence.

In RPNb, the O, S, D drivers have no interdependency, eliminating leverage effect, which means that variations in one driver will have an individual effect on the RPNb value. Not only the effect is individual, it is also the same along all driver scoring range.

As it is possible to see Table 3.3 an increase of Occurrence score by 1 results in the same increment in RPNbs value, independently of Severity and Detection scores. Additionally, an increase of Occurrence by 5 (two-fold) is not offset by a decrease in Detection by 1 (half). Conversely to conventional RPN, RPNb demonstrates an alignment with behavior expectations – i.e. a failure mode characterized as O(10), S(5) and D(1) is expected to have a higher risk level than a failure mode characterized as O(5), S(5) and D(2).

Table 3.3 – O, S, D scoring variations effect in conventional RPN and RPNbs (w_o=0,4; w_s=0,35; w_d=0,25)

O	S	D	RPN	RPNbs
3	3	3	**27**	**223,00**
↓ +1	↓ +0	↓ +0	↓ +9	↓ +27,74
4	3	3	**36**	**250,74**
3	7	7	**147**	**556,05**
↓ +1	↓ +0	↓ +0	↓ +49	↓ +27,74
4	7	7	**196**	**583,79**
5	5	2	**50**	**361,79**
↓ +5	↓ +0	↓ -1	↓ +0	↓ +194,40
10	5	1	**50**	**556,18**

With change of computation model from multiplication form to adding form, it was also changed the distribution frequency along the scale, bringing a more intuitive statistical behavior. As it is possible to observe in Figure 3.1, RPNb presents higher frequency for intermediate values, and frequency decreases towards the edges of the scale. Both RPNbs average and median is 501, which is aligned with expectations. As mentioned before, conventional RPN average is 166, and its median is 105.

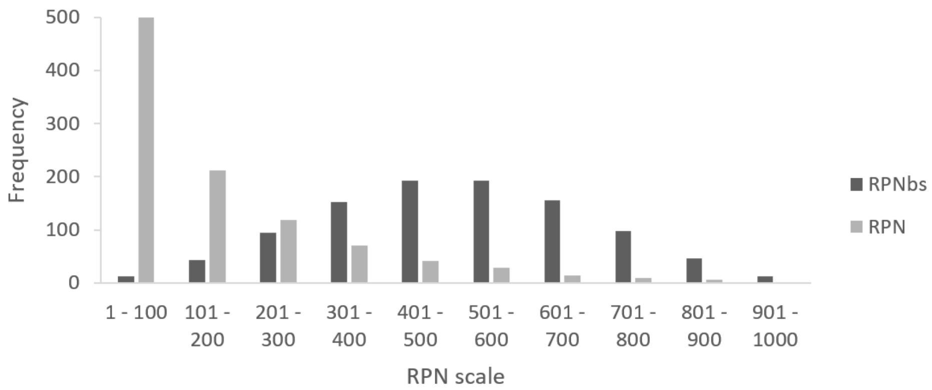

Figure 3.1 – Frequency distribution of RPNbs (w_o=0,4; w_s=0,35; w_d=0,25) and conventional RPN

Note that the frequency distribution presented in Figure 3.1 aggregates RPNbs values into groups, splitting the scale into 10 groups equally ranged. In fact, the overall distribution of RPNbs would be uniform since each value is unique, thus with a frequency of 1 (Figure 3.2). In RPNbs there is no repetition of value – each O, S, D combination produces a unique result (see Appendix A).

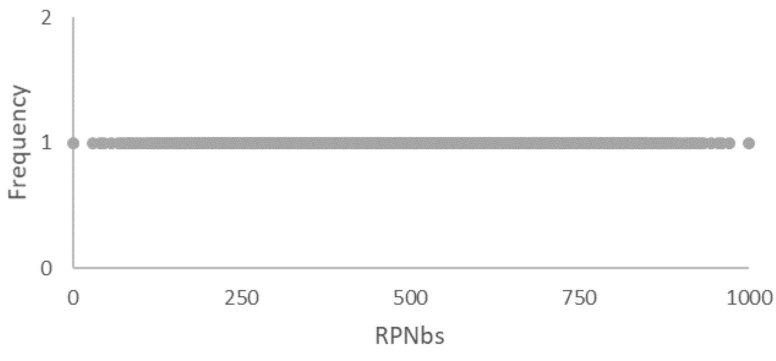

Figure 3.2 – Frequency distribution of RPNbs (wo=0,4; ws=0,35; wd=0,25)

Figure 3.3 presents the plotting of all possible results of conventional RPN (Table 2.4) and RPNb adjusted to the scale 1-1000 (Appendix A). The normal frequency distribution of RPNb is a reflection of the smooth curve promoted by the computation model, that presents an inverted symmetric format around the value 500. When compared to conventional RPN curve, RPNb presents almost no gaps, which means that no risk level is significantly much higher than the immediately previous one.

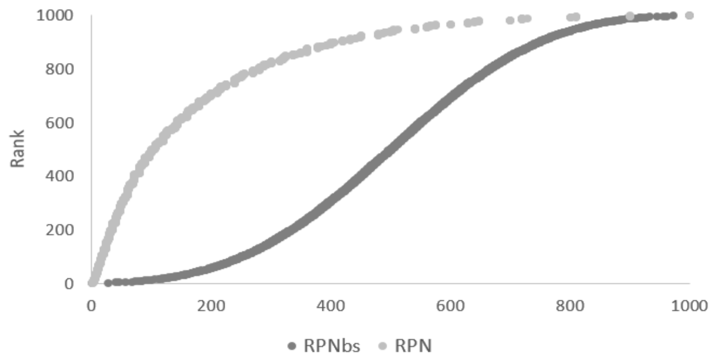

Figure 3.3 – Representation of the curve resulting from the ranking of all possible outcomes of conventional RPN and RPNbs (w_o=0,4; w_s=0,35; w_d=0,25)

RPNb leaves out some other shortcomings, such as the fact that only three drivers are used to assess risk level of a failure mode, or even the domino effect of failure modes – where one failure event provokes another failure event. The rationale to leave these shortcomings out of the development of RPNb is driven by the necessity of maintaining the computation model as simple as possible.

Nevertheless, RPNb is flexible enough to accommodate other drivers than O, S and D, without jeopardize the behavior of failure modes prioritization. However, increasing the number of drivers in risk assessment may increase also the difficulty to interpret the prioritization outcomes.

Comparing both models, RPNb presents characteristics that seem to fit better the purpose of risk assessment, thus it is expected to deliver more coherent results when it comes to prioritization of failure modes.

4. Case study

4.1. Case study description

Having developed RPNb computation model, the following step passes through testing it in order to verify if it responds as expected when utilized for failure modes prioritization in a real-world case. To assess the robustness of RPNb as an alternative computation model to conventional RPN, it was chosen a study performed by Lu *et al.* (2013) – Failure Mode and Effect Analysis in blood transfusion: a proactive tool to reduce risks.

In this study, Lu *et al.* (2013) utilizes conventional RPN to perform the prioritization of identified failure modes for blood transfusion procedures. The fact that it uses conventional RPN allows to perform a direct comparison with RPNb. Additionally, since this study is associated to the healthcare area, where un-noticed risks may lead to highly severe consequences for human life, it may represent an opportunity to understand how RPNb copes when presented to this reality.

According to Lu *et al.* (2013), the blood transfusion process is a complex and high-risk procedure. Therefore, the utilization of proactive safety analysis techniques which help to identify weaknesses in the blood transfusion process is of great value. The option for FMEA is related to its structured analysis, and also to the fact that it is simple to learn and apply. The analysis conducted comprised 6 steps:

1. Establish the context – it was presented the high-risk scenario associated to blood transfusion process, and the objective of the study.
2. Assemble a multidisciplinary team – it was defined a team responsible for conducting the analysis. There was a concern to involve elements that represents the thorough chain of the process.
3. Risk identification – it was design a detailed flowchart of the transfusion process and critical control points in order to enable a complete understanding of the steps involved in the process.
4. Conduct risk analysis – Conducted scoring of O, S, D drivers for the identified failure modes, and determined the RPN values through its conventional computation model.
5. Risk evaluation – Failure modes were ranked to determine the top 5 that would be object of corrective actions to be developed and implemented by the team.
6. Risk treatment – it was utilized the Plan-Do-Check-Act (PDCA) cycle to determine the success of corrective actions.

The team identified the top 5 failure modes as being – 1) insufficient preoperative assessment of the blood product requirement (RPN 245), 2) preparation time before infusion of more than 30 minutes (RPN 240), 3) blood transfusion reaction occurring during the transfusion process (RPN 224), 4) blood plasma abuse (RPN 180), and 5) insufficient and/or incorrect clinical information request form (RPN 126).

Implementation of corrective actions on top 5 failure modes were deemed as very successful and a new scoring of O, S, D drivers showed a significant reduction on their RPN. Lu *et al.* (2013) highlights as an example of success the reduction of discrepancy in preparation time before infusion of more than 30 minutes from 70% to 10%.

Lu *et al.* (2013) stated his belief that application of FMEA contributed greatly to reduce risks associated with the blood transfusion. However, an important subject raised during risk evaluation was the necessity to define a maximum number of failure modes to be targeted for intervention. This necessity came from the limited resources availability which allowed to target a maximum of five failure modes. It expresses the importance of the necessity of having a reliable risk prioritization model in place in order to focus resources towards the most critical failure modes.

4.2. Application of RPN proposed

To fully assess the behavior of RPNb, it was developed three different prioritization scenarios comprising three different combinations of O, S, D relative importance – S > O > D, S > D > O and O > S > D. In all three scenarios, it was attributed the following weight factors:

- Highest relative importance (HRI) – 0.4 → differentiator factor – 111.
- “In between” relative importance (IBRI) – 0.35 → differentiator factor – 11.
- Lowest relative importance (LRI) – 0.25 → differentiator factor – 1.

The weight factors were chosen in order to have two preeminent drivers but not too much so it would not provoke the lowest relative importance driver having a negligible role in the prioritization. The IBRI was assumed as approximately 90% of the HRI. To the LRI it was attributed the difference to 1 – i.e. LRI is such so the sum of all three weight factors is 1 ($W_{HRI} + W_{IBRI} + W_{LRI} = 1$).

In Table 4.1 it is presented the results for all three scenarios using RPNb as the prioritization method, as well as the conventional RPN results, comprising the 19 failure modes identified and characterized by experts in Lu *et al.* (2013).

The comparison analysis to the outcomes of conventional RPN and RPNb computation models was initially based on all 19 failure modes. In a second phase, it was focused only the top 5 failure modes since it was the maximum number of failure modes targeted in Lu *et al.* (2013) due to limited resources availability.

Table 4.1 – Failure modes prioritization: RPNbs vs. conventional RPN

					S = O = D		S > O > D		S > D > O		O > D > S	
FM #	**Failure Mode**	**S**	**O**	**D**	**RPN**	**Rank**	**RPNbs**	**Rank**	**RPNbs**	**Rank**	**RPNbs**	**Rank**
1	Insufficient and/or incorrect clinical information on request form	7	6	3	126	5	517,22	8	483,92	8	467,23	6
2	Blood plasma abuse	6	6	5	180	4	528,26	7	517,16	6	517,16	5
3	Insufficient preoperative assessment of the blood product requirement	7	5	7	245	1	589,33	4	611,53	3	578,14	1
4	Blood group verification incomplete	7	5	3	105	8	478,38	9	456,18	12	422,80	9
5	No etiology detection samples before blood transfusion	8	7	1	56	13	545,01	5	478,42	9	461,72	7
6	Noncancellation of ordering special blood components	7	3	1	21	16	345,24	18	323,04	19	256,28	18
7	Sample for type and cross drawn from the wrong patient or incorrectly labeled	10	1	2	20	17	428,59	13	439,69	13	289,47	14
8	Insufficient/unclear information on the sample label	7	2	2	28	14	334,14	19	334,14	18	250,68	19
9	Delivery of blood sample and/or request form delayed	5	3	6	90	9	395,07	16	428,36	16	394,98	12
10	Inaccurate cross-matching	10	1	6	60	12	539,53	6	595,03	5	444,81	8
11	Incorrect blood components issued	10	1	8	80	10	595,01	2	672,70	1	522,48	4
12	Quality checks not performed on blood products	8	2	5	80	10	461,78	12	495,07	7	394,93	13
13	Blood components for different patients issued at the same time	8	1	3	24	15	367,47	17	389,67	17	272,83	17
14	Blood product delivered to the wrong department	10	1	2	20	17	428,59	13	439,69	13	289,47	14
15	Failure to perform pretransfusion checks	10	1	2	20	17	428,59	13	439,69	13	289,47	14
16	Preparation time before infusion >30 min	8	6	5	240	2	617,12	1	606,02	4	572,64	2
17	Transfusion cannot be completed within the appropriate time	7	4	4	112	6	467,28	10	467,28	10	417,21	10
18	Blood transfusion reaction occurs during the transfusion process	8	4	7	224	3	594,92	3	628,22	2	561,45	3
19	Bags of blood products are improperly disposed of	7	4	4	112	6	467,28	10	467,28	10	417,21	10

4.3. Conventional RPN vs. RPNb

The first impression when looking into the Table 4.1 is that RPNbs values are significant higher than conventional RPN. A simple comparison of the value ranges for each scenario shows:

- Conventional RPN:
  - Lowest value – 20, for FM #7, #14 and #15. All three were characterized as S(10), O(1) and D(2).
  - Highest value – 245, for FM #3. Characterized as S(7), O(5) and D(7).
- RPNbs (S > O > D):
  - Lowest value – 334.14, for FM #8. Characterized as S(7), O(2) and D(2).
  - Highest value – 617.12, for FM #16. Characterized as S(8), O(6) and D(5).
- RPNbs (S > D > O):
  - Lowest value – 323.04, for FM #6. Characterized as S(7), O(3) and D(1).
  - Highest value – 672.70, for FM #11. Characterized as S(10), O(1) and D(8).
- RPNbs (O > D > S):
  - Lowest value – 250.68, for FM #8. Characterized as S(7), O(2) and D(2).
  - Highest value – 578.14, for FM #3. Characterized as S(7), O(5) and D(7).

The outcomes presented by the RPNb places the risk of failure modes around the middle of the scale, while the conventional RPN places the risk in the bottom of the scale, even for the failure mode deemed as the most riskier. It is difficult to accept the interpretation that a FM #7, which has a Severity score 10 presents a RPN value of 20 in a scale of 1-1000. The same happens with FM #3. One would expect a higher result considering its characterization.

In this sense, RPNb is able to produce results more coherent with risk level expectations. One would expect FM #3, #11 and #16 to have values above the average and median of the scale (which is verified), having in mind also that one would expect the value 500 to represent a risk level that is equally distant from the risk level represented by the values 1 and 1000.

The utilization of RPNb led to several changes in the ranking position of failure modes. Table 4.2 presents an overview of all movements provoked by RPNb in comparison to conventional RPN. For all three RPNb scenarios, most of the failure modes moved more at least 3 positions from its ranking position in conventional RPN. Several failure modes have even moved more than 5 positions. For instance, FM #11 raised 9 positions in the ranking, while FM #9 fell 7 positions in the scenario S > D > O. Considering that the bundle is comprised by only 19 failure modes, these movements are quite significant.

Table 4.2 – Rank position movements as result of RPNb in comparison to conventional RPN

FM #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
RPN	5	4	1	8	13	16	17	14	9	12	10	10	15	17	17	2	6	3	6
S>O>D	8 (-3)	7 (-3)	4 (-3)	9 (-1)	5 (+8)	18 (-2)	13 (+4)	19 (-5)	16 (-7)	6 (+6)	2 (+8)	12 (-2)	17 (-2)	13 (+4)	13 (+4)	1 (+1)	10 (-4)	3 (0)	10 (-4)
S>D>O	8 (-3)	6 (-2)	3 (-2)	12 (-4)	9 (+4)	19 (-3)	13 (+4)	18 (-4)	16 (-7)	5 (+7)	1 (+9)	7 (+3)	17 (-2)	13 (+4)	13 (+4)	4 (-2)	10 (-4)	2 (+1)	10 (-4)
O>D>S	6 (-1)	5 (-1)	1 (0)	9 (-1)	7 (+6)	18 (-2)	14 (+3)	19 (-5)	12 (-3)	8 (+4)	4 (+6)	13 (-3)	17 (-2)	14 (+3)	14 (+3)	2 (0)	10 (-4)	3 (0)	10 (-4)

From the correlation analysis to the outcomes from each scenario (Table 4.3), it is possible to observe that conventional RPN has in general a relative low to medium correlation (68% - 88%) to RPNb scenarios, while RPNb scenarios share between themselves a relative medium to high correlation (88% - 94%). These results are aligned with expectations since RPNb introduced changes in the basis of prioritization model, and all three RPNb scenarios were given the same weights even though it was to different O, S, D drivers.

Pearson correlation is a product moment that reflects the extent of a linear relationship between two data sets. It is dimensionless and it ranges from -1.0 to 1.0, representing a total negative linear correlation and a total positive linear correlation, respectively. If zero, there is no linear correlation.

Table 4.3 –Correlation using Pearson of the outcomes from each scenario

PEARSON	RPN	S>O>D	S>D>O	O>D>S
RPN	100%	75%	68%	88%
S>O>D		100%	94%	94%
S>D>O			100%	88%
O>D>S				100%

Further comparison of results from RPNb and conventional RPN will be focused on the top 5 failures modes of each prioritization scenario. A general view shows that the top 3 failure modes from conventional RPN are kept in the top 5 of all three RPNb scenarios, although their position has changed according relative importance of O, S, D drivers. Entrance of new failure modes into top 5 is also different for each RPNb scenario due to differences in relative importance.

Table 4.4 – Failure modes prioritization (top 5): RPNbs vs. conventional RPN

FM #	Failure Mode	S	O	D	S = O = D RPN	S = O = D Rank	S > O > D RPNbs	S > O > D Rank	S > D > O RPNbs	S > D > O Rank	O > D > S RPNbs	O > D > S Rank
1	Insufficient and/or incorrect clinical information on request form	7	6	3	126	5	517,22	8	483,92	8	467,23	6
2	Blood plasma abuse	6	6	5	180	**4**	528,26	7	517,16	6	517,16	**5**
3	Insufficient preoperative assessment of the blood product requirement	7	5	7	245	**1**	589,33	**4**	611,53	**3**	578,14	**1**
5	No etiology detection samples before blood transfusion	8	7	1	56	13	545,01	**5**	478,42	9	461,72	7
10	Inaccurate cross-matching	10	1	6	60	12	539,53	6	595,03	**5**	444,81	8
11	Incorrect blood components issued	10	1	8	80	10	595,01	**2**	672,70	**1**	522,48	**4**
16	Preparation time before infusion >30 min	8	6	5	240	**2**	617,12	**1**	606,02	**4**	572,64	**2**
18	Blood transfusion reaction occurs during the transfusion process	8	4	7	224	**3**	594,92	**3**	628,22	**2**	561,45	**3**

In the scenarios where Severity has the highest relative importance (S > O > D and S > D > O), the new failure modes entering the top 5 present high scores for Severity. Although it is an expected behavior, it is important to note that FM #10 belongs to top 5 for S > O > D but not for S > D > O, even though it presents score 10 in Severity. This is an indicator that RPNb do not focus only in the most relevant O, S, D driver, but rather in the blend of the relative importance of all three drivers.

It is interesting the fact that FM #1 (RPN – rank 5) is excluded from top 5 for all three RPNb prioritization scenarios. When comparing FM #1 to new entrances (FM #5, #10 and #11), one may face difficulty to infer priority through a qualitative assessment. For instance, if weights of O, S, D drivers are not taken in consideration, there is no apparent reason for stating that FM #1 – S(7), O(6), D(3) – has a clear higher risk than FM #5 – S(8), O(7), D(1). However, for conventional RPN they have a distinct ranking position. The same rationale is applicable to FM #10 and FM #11 (Table 4.5). This is clearly an example of a failure mode that gains visibility due to conventional RPN computation model arrangement.

Table 4.5 – Comparing FM #1 (RPN – rank 5) to new entrances

FM #	S	O	D	(Δ)
1	7	6	3	-
5	8 (+1)	7 (+1)	1 (-2)	0
10	10 (+3)	1 (-5)	6 (+3)	+1
11	10 (+3)	1 (-5)	8 (+5)	+3

It must be highlighted the fact that new failure modes entering RPNb top 5 (FM #5, #10 and #11) presented ranks significantly below in conventional RPN (rank 13, 12 and 10, respectively). The most surprising one is FM #11, which went from rank 10 (conventional RPN) to rank 1 (RPNb – S>D>O) and rank 2 (RPNb – S>O>D). FM #11 is also present in the remaining RPNb scenario, although with a lower rank.

One may challenge the ability of FM #11 to be the top 1 risk (RPNb – S>D>O) in comparison to FM #3 (RPN – rank 1). However, looking analytically to both failure modes, FM #11 presents – Severity (+3), Detection (+1) and Occurrence (-4). In general, the score difference is null but taking in consideration that Severity and Detection have higher relative importance than Occurrence, it makes sense that the balance tends to increase FM #11 overall risk.

All three top 5 from RPNb scenarios share the same top 4 failure modes. The difference is encountered on rank 5 failure mode – FM #2, #5 and #10. Comparing O, S, D scores for the three failure modes (Table 4.6), the overall difference is null, or 1 at most.

Table 4.6 – Comparing rank 5 failure mode from RPNb scenarios

	FM #2				FM #5				FM #10			
	S	O	D	(Δ)	S	O	D	(Δ)	S	O	D	(Δ)
FM #2	6	6	5	-	(-2)	(-1)	(+4)	+1	(-4)	(+5)	(-1)	0
FM #5	(+2)	(+1)	(-4)	-1	8	7	1	-	(-2)	(+6)	(-5)	-1
FM #10	(+4)	(-5)	(+1)	0	(+2)	(-6)	(+5)	+1	10	1	6	-
RPNb scenario	O > D > S				S > O > D				S > D > O			

Being similar, the prioritization of failure modes is then defined through the relative importance of O, S, D drivers. For instance, FM #5 has an overall score for Severity and Occurrence of 15 (7 + 8), while FM #2 and FM #10 have an overall score of 12 and 11, respectively. Thus, for a scenario where Severity and Occurrence have higher relative importance, it makes sense that FM #5 have some advantage. The other two failure modes follow the same rationale, providing support to the expected behavior from the introduction of weighting factors.

4.4. Final considerations

From the results presented in the previous chapter, it is obvious that utilization of RPNb has provoked changes in failure modes prioritization. The fact that results correlation range between 68% to 88% is indicative that prioritization paradigm was changed. However, it is important to understand if this change is capable of bringing added value to failure modes prioritization.

Looking into the top 5 failure modes, it is possible to observe that FM #3, #16 and #18 are present in all four prioritization scenarios. These three failure modes present relatively high O, S, D score so it is no surprise they are included in the top 5. Although RPNb performed changes in prioritization paradigm, it is still coherent in maintaining high level risk failure modes in the top.

In the other hand, FM #1 is excluded from top 5 for all three RPNb scenarios. Conversely, FM #11 is included on all RPNb scenarios top 5. As analyzed previously, FM #11 is perceived as having a potential higher risk level than FM #1. In this case, RPNb showed ability to:

1. bring into light a potential high risk failure mode that otherwise could go un-noticed using conventional RPN.
2. move down in the raking, failure modes that due to conventional RPN leverage effect might be object of corrective action leading to un-necessary use of resources.

Having in mind that in the study performed by Lu *et al.* (2013) only the top 5 failure modes were targeted to have correction actions due to limited resources available, utilization of conventional RPN for prioritization may have mean the utilization of valuable resources in a lower risk failure mode (FM# 1) over a higher risk failure mode (FM# 11).

Additionally, utilization of RPNb promotes distinction of failure modes through the weighting factors of O, S, D drivers. When presented with similar failure modes (similar O, S, D scores as it happens with FM #2, #5 and #10), RPNb provides a prioritization based on the relative importance of the O, S, D drivers. This behavior follows the expectations of adapting weighting factors of O, S, D drivers according the specifics of the industry/area under analysis.

In summary, RPNb is able to deliver a more coherent prioritization result than conventional RPN, indicating that modifications performed in computation model were successful towards the elimination of shortcomings.

5. Conclusion and future studies

This study was initiated on the premise that reliability represents a key role in the development of a new product, since it was a feature with great impact on the success of the product when deployed into the market. This premise was reinforced as the review on malfunctioning products showed that it could lead to severe consequences to customers and companies.

It led to the initiative of having a study on reliability and the strategy adopted by companies to comply with the market requirements. The literature review showed that companies, which are committed to improve reliability of their products, tend to implement strong reliability tasks during all product life cycle, with major focus in the early stages. In this sense, FMEA is a "must have" tool and therefore widely utilized.

FMEA is a powerful tool that helps experts to identify failure modes and effects in a structured way. Nevertheless, not all problems are the same and few companies (or even none) have the necessary resources to correct/mitigate all potential failure modes identified under FMEA. Therefore, experts use prioritization methodologies to guide them in the implementation of corrective actions in a logical order.

Risk Priority Number, designated in this study as conventional RPN, was a methodology developed in the 1960's to perform the risk assessment of the failure modes and thus prioritize the implementation of corrective actions. However, conventional RPN is, for some time now, criticized by the scientific community due to its large limitations, which could lead to misleading prioritizations outcomes.

For a company competing in a global market, the prioritization of failure modes holds an important role. It would not only allow savings in time and cost by reducing the test-fix loop, but also will avoid the utilization of unnecessary resources to correct or mitigate low risk failure modes. Therefore, the prioritization methodology must be quite effective, so a company can rely on its outcomes, which conventional RPN is not.

Despite all awareness raised by scientific community for the last two decades towards conventional RPN shortcomings, and efforts to present alternative methodologies, it is still utilized worldwide for prioritization of failure modes. The most plausive hypothesis trying to justify the continuous utilization of conventional RPN is the fact that it has an extremely simple computation model, thus easy to be learned and applied.

The most important reason for conducting a FMEA is the need to improve, and it is only as effective as the effectiveness of the prioritization methodology utilized. Clearly, conventional RPN is not up to the task, and its utilization may even jeopardize the ultimate purpose of FMEA, by leaving un-noticed potential high risk failure modes.

In the addition to the efforts of several researchers, it is proposed in this study an alternative computation model (RPNb) to conventional RPN in order to improve the effectiveness of failure modes prioritization. The difference to other alternatives already presented is that the computation model proposed in this study is driven by the premise that simplicity is the propeller to spread the methodology, and ultimately for the replacement of conventional RPN.

The RPNb was specifically developed to tackle some shortcomings, leaving others out for the sake of simplicity, but still with the objective of obtaining an effective prioritization of failure modes. The RPNb foresees the elimination of the following shortcomings – from the list gathered by Liu *et al.* (2013):

- The relative importance among O, S, D is not taken into consideration.
- Different combinations of O, S, D may produce exactly the same value of RPN, but their hidden risk implications may be totally different.
- RPN values are not continuous with many holes.
- The computation form adopted for calculating the RPN is strongly sensitive to variations in risk driver scoring.

Conventional RPN is also criticized for having a questionable and debatable computation model. Changing it from multiplication form to the adding form in RPNb does not make RPNb free of criticism, but brings it more close to reality perception, as it was concluded form the comparative analysis performed in the case study.

RPNb introduces in the first place the possibility of each industry/area to adjust relative importance of O, S, D drivers according to their perception. It brings more flexibility to the prioritization of failure modes, ending with the "universal truth" assumed in conventional RPN that all industries quantify risk in the same way. RPNb responds accordingly to the relative importance attributed to O, S, D drivers, without provoking a dominance effect of the one with higher relative importance – in the case study, four of the top 5 failure modes were the same for all three RPNb scenarios.

In the comparative analysis under the case study, it was possible to conclude that RPNb was capable of delivering more coherent prioritization scenarios. A critical examination of the O, S, D scores showed that the bundle of top 5 failure modes in RPNb scenarios were perceived as having higher risk level than the bundle in conventional RPN scenario

– the risks entering the top 5 in RPNb scenarios presented higher risk in comparison to the risks leaving out.

An interesting fact is that the movements within the ranking from conventional RPN to RPNb were quite significant (with some failure modes changing 6+ positions in a set of 19), and even quite concerning taking in consideration that studies may be relying in a prioritization method that can deliver a completely wrong outcome.

RPNb presents also advantage in the scale continuity – RPNb values are unique but when gathered in ranges, it gives an impression of having a normal distribution. In fact, it is this characteristic of RPNb that provides robustness to the model – having a risk level that is established by a set of three drivers that ranges equally, it is expected nothing else but a normal distribution of all possible results. Furthermore, it is only possible to have a normal distribution if the model does not present an erratic behavior but a systematic and predictive behavior instead.

In the seeking for continuous improvement, there is no place for ineffective methodologies. It is of utmost importance to replace the utilization of conventional RPN for failure modes prioritization. RPNb presents itself as an apparent robust alternative, capable of delivering sustained results, adjustable to industry/area specific characteristics, through a straightforward computation model. In summary, RPNb is a methodology worth to be considered for failure modes prioritization.

This study focused on the development of an alternative computation model and on its testing through a running of a case study as a first step for validation. However, in order to perform the transition of the RPNb prioritization model from an academic study to a broad implementation by industry, it requires a more comprehensive understanding of model effectiveness on the prioritization of failure modes. Therefore, further studies may be performed promoting the validation of the model and its improvement to overcome additional shortcomings encountered on conventional RPN.

As a first step for the diffusion of RPNb as an alternative to the conventional it was submitted a paper (Sá, Anes, & Marques, 2017) to the Conference IncoME-II 2017 organized by the University of Manchester (UK) – see appendix C.

In the matter of model validation, it would be useful to perform other case studies in different areas of study. Having several studies supporting the results obtained in this study provides to RPNb the necessary empowerment to become an actual alternative to conventional RPN. Industry will be more confident to adopt a new model as its robustness is validated by several sources.

Additionally, it is necessary to perform studies to determine the most fit weighting factors according each industry/area specific characteristics. It is important to identify the order of relative importance of O, S, D drivers and adjust their weighting factors in order to obtain the most added value from RPNb. In this matter, it is also important to understand the range of the weighting factor that does not create a dominance effect of one driver and does not make the driver negligible for the prioritization of failure modes.

Studies oriented to eliminate other shortcomings are also object of relevance. For instance, evaluate RPNb computation model behavior when added a fourth driver. The introduction of an additional driver is not expected to bring instability to the model results. However, a qualitative interpretation of the outcomes may be quite difficult to perform since a fourth driver brings more complexity on the way reality is perceived.

Further studies will be able to help answering the question previously raised – is it possible to have a prioritization model as simple as conventional RPN without the known shortcomings?

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APPENDIX A – RPNbs possible results (w_o=0.4; w_s=0.35; w_d=0.25)

1.00	28.73	39.83	45.42	56.47	67.57	73.16	78.67	84.21	84.26
89.85	95.30	100.90	106.40	111.94	112.00	117.50	117.59	123.04	123.09
128.63	128.69	134.14	134.28	139.68	139.73	145.24	145.32	150.78	150.83
156.34	156.37	156.42	161.88	161.93	162.02	167.42	167.47	167.52	172.97
173.06	173.11	178.51	178.57	178.71	184.07	184.11	184.16	189.61	189.67
189.75	195.15	195.17	195.21	195.26	200.71	200.76	200.80	200.85	206.25
206.30	206.36	206.44	211.81	211.84	211.90	211.95	217.35	217.40	217.49
217.54	222.89	222.91	222.94	223.00	223.13	228.45	228.50	228.53	228.59
233.99	234.01	234.04	234.09	234.18	239.55	239.58	239.60	239.63	239.69
245.09	245.14	245.19	245.23	245.28	250.63	250.65	250.68	250.73	250.78
250.87	256.19	256.24	256.27	256.32	256.38	261.73	261.74	261.78	261.83
261.92	261.97	267.28	267.32	267.34	267.37	267.42	267.56	272.82	272.84
272.88	272.93	272.96	273.02	278.38	278.42	278.44	278.47	278.52	278.61
283.92	283.97	284.01	284.03	284.06	284.11	289.46	289.48	289.51	289.57
289.62	289.65	289.71	295.02	295.05	295.07	295.11	295.16	295.21	295.30
300.56	300.58	300.61	300.67	300.70	300.75	300.80	306.12	306.15	306.17
306.21	306.26	306.34	306.40	311.66	311.68	311.71	311.75	311.76	311.80
311.85	311.99	317.22	317.25	317.27	317.30	317.36	317.39	317.44	322.76
322.81	322.84	322.86	322.90	322.95	323.04	328.30	328.32	328.35	328.40
328.44	328.46	328.49	328.54	333.86	333.89	333.91	333.94	334.00	334.05
334.08	334.13	339.40	339.42	339.45	339.48	339.50	339.53	339.59	339.64
339.73	344.95	344.99	345.01	345.04	345.09	345.13	345.18	345.23	350.49
350.51	350.55	350.58	350.60	350.63	350.69	350.77	350.82	356.05	356.09
356.11	356.14	356.17	356.19	356.23	356.28	356.42	361.59	361.65	361.68
361.70	361.73	361.78	361.82	361.87	367.13	367.15	367.19	367.24	367.27
367.29	367.32	367.38	367.46	372.69	372.73	372.74	372.78	372.83	372.86
372.88	372.92	372.97	378.23	378.25	378.28	378.32	378.34	378.37	378.42
378.48	378.51	378.56	383.79	383.82	383.84	383.88	383.91	383.93	383.96
384.02	384.07	384.15	389.33	389.38	389.42	389.44	389.47	389.52	389.55
389.61	389.66	394.89	394.92	394.94	394.97	395.01	395.03	395.06	395.11
395.20	395.25	400.43	400.48	400.51	400.53	400.57	400.60	400.62	400.65
400.71	400.84	405.97	405.99	406.02	406.07	406.11	406.13	406.16	406.21
406.25	406.30	411.53	411.56	411.58	411.61	411.67	411.70	411.72	411.75
411.80	411.89	417.07	417.12	417.15	417.17	417.21	417.26	417.29	417.31
417.34	417.40	422.63	422.66	422.68	422.71	422.75	422.76	422.80	422.85
422.90	422.94	422.99	428.17	428.22	428.25	428.27	428.30	428.34	428.36
428.39	428.44	428.50	428.58	433.72	433.76	433.81	433.84	433.86	433.90
433.95	433.98	434.04	434.09	439.26	439.32	439.35	439.37	439.40	439.44
439.46	439.49	439.54	439.63	439.68	444.80	444.86	444.91	444.94	444.96
445.00	445.03	445.05	445.08	445.13	450.36	450.40	450.42	450.45	450.50
450.53	450.55	450.59	450.64	450.67	450.73	455.90	455.95	455.99	456.01
456.04	456.09	456.13	456.15	456.18	456.23	456.32	461.46	461.49	461.55
461.58	461.60	461.63	461.69	461.72	461.74	461.77	461.82	467.00	467.05
467.09	467.11	467.14	467.17	467.19	467.23	467.28	467.33	467.36	467.42
472.59	472.65	472.68	472.70	472.73	472.77	472.78	472.82	472.87	472.92
478.10	478.15	478.19	478.24	478.27	478.29	478.32	478.38	478.41	478.46
478.52	483.64	483.69	483.74	483.78	483.80	483.83	483.86	483.88	483.92
483.97	484.06	489.20	489.23	489.28	489.34	489.37	489.39	489.42	489.46

489.48	489.51	489.56	494.74	494.79	494.82	494.84	494.88	494.93	494.96
494.98	495.02	495.07	495.10	495.15	500.33	500.38	500.42	500.44	500.47
500.52	500.55	500.57	500.61	500.66	505.84	505.89	505.92	505.97	506.01
506.03	506.06	506.11	506.15	506.17	506.20	506.25	511.43	511.48	511.51
511.53	511.57	511.60	511.62	511.65	511.71	511.76	511.79	516.93	517.02
517.07	517.11	517.13	517.16	517.19	517.21	517.25	517.30	517.35	522.47
522.53	522.58	522.61	522.67	522.70	522.72	522.75	522.80	522.84	522.89
528.07	528.12	528.17	528.21	528.22	528.26	528.29	528.31	528.34	528.40
533.57	533.63	533.66	533.71	533.76	533.80	533.82	533.85	533.88	533.90
533.94	533.99	539.17	539.22	539.25	539.27	539.30	539.36	539.39	539.41
539.44	539.50	539.53	544.67	544.76	544.81	544.84	544.86	544.90	544.95
544.98	545.00	545.04	545.09	550.26	550.32	550.35	550.40	550.44	550.46
550.49	550.54	550.57	550.59	550.63	555.86	555.91	555.94	555.96	556.00
556.03	556.05	556.08	556.13	556.19	561.31	561.36	561.45	561.50	561.53
561.55	561.59	561.62	561.64	561.67	561.73	566.90	566.95	567.01	567.04
567.09	567.13	567.15	567.18	567.23	567.27	572.41	572.49	572.55	572.60
572.63	572.65	572.69	572.72	572.74	572.77	572.82	578.00	578.05	578.09
578.14	578.19	578.23	578.24	578.28	578.31	578.33	578.36	583.59	583.65
583.68	583.70	583.73	583.78	583.82	583.84	583.87	583.92	589.10	589.19
589.24	589.27	589.29	589.32	589.38	589.41	589.43	589.46	594.69	594.74
594.78	594.83	594.86	594.88	594.92	594.97	595.00	595.02	600.15	600.28
600.34	600.37	600.39	600.42	600.46	600.48	600.51	600.56	605.74	605.79
605.88	605.93	605.96	605.98	606.02	606.05	606.07	606.10	611.33	611.38
611.44	611.47	611.52	611.55	611.57	611.61	611.66	616.84	616.92	616.97
617.03	617.06	617.08	617.11	617.15	617.17	617.20	622.43	622.48	622.51
622.57	622.62	622.65	622.67	622.71	622.74	622.76	628.02	628.07	628.11
628.13	628.16	628.21	628.25	628.26	628.30	633.53	633.61	633.67	633.70
633.72	633.75	633.80	633.84	633.86	639.12	639.17	639.21	639.26	639.29
639.31	639.34	639.40	644.57	644.71	644.76	644.80	644.82	644.85	644.88
644.90	644.94	650.17	650.22	650.30	650.36	650.39	650.41	650.44	650.48
650.50	655.76	655.81	655.86	655.90	655.95	655.98	656.00	656.04	661.26
661.35	661.40	661.46	661.49	661.51	661.54	661.57	661.59	666.86	666.91
666.94	667.00	667.05	667.08	667.10	667.13	672.45	672.50	672.53	672.55
672.59	672.64	672.67	672.69	677.95	678.04	678.09	678.13	678.15	678.18
678.23	683.55	683.60	683.63	683.69	683.72	683.74	683.77	689.00	689.14
689.19	689.23	689.24	689.28	689.31	689.33	694.59	694.65	694.73	694.78
694.82	694.84	694.87	700.19	700.24	700.29	700.32	700.38	700.41	700.43
705.69	705.78	705.83	705.88	705.92	705.94	705.97	711.28	711.34	711.37
711.42	711.48	711.51	711.53	716.88	716.93	716.96	716.98	717.02	717.07
722.38	722.47	722.52	722.55	722.57	722.61	727.97	728.03	728.06	728.11
728.15	728.17	733.43	733.57	733.62	733.65	733.67	733.71	739.02	739.07
739.16	739.21	739.25	739.26	744.61	744.67	744.72	744.75	744.80	750.12
750.21	750.26	750.31	750.34	750.36	755.71	755.76	755.80	755.85	755.90
761.30	761.36	761.39	761.41	761.44	766.81	766.90	766.95	766.98	767.00
772.40	772.46	772.49	772.54	777.86	778.00	778.05	778.08	778.10	783.45
783.50	783.59	783.64	789.04	789.09	789.15	789.18	794.55	794.63	794.69
794.74	800.14	800.19	800.23	800.28	805.73	805.78	805.82	805.84	811.24
811.32	811.38	816.83	816.88	816.92	822.28	822.42	822.48	827.88	827.93
828.02	833.47	833.52	833.57	838.97	839.06	839.11	844.57	844.62	844.65
850.16	850.21	855.67	855.75	861.26	861.31	866.71	866.85	872.30	872.36
877.90	877.95	883.40	883.49	889.00	889.05	894.59	900.09	905.69	911.14
916.73	916.78	922.32	927.83	933.42	944.52	955.57	961.16	972.26	1000.00

APPENDIX B – Extended abstract (Portuguese)

Este estudo teve como princípio a importância do papel da fiabilidade durante o desenvolvimento de um novo produto para que este tenha sucesso no mercado global. A ideia de que a fiabilidade é de elevada relevância é suportada pela existência de casos de produtos com falhas que resultaram em consequências severas para os utilizadores e empresas.

Neste sentido, procedeu-se ao estudo da fiabilidade e da estratégia adotada pelas empresas para enfrentar as exigências do mercado. A revisão bibliográfica mostrou que as empresas, que estão comprometidas em melhorar a fiabilidade dos seus produtos, tendem a implementar diversas tarefas durante o ciclo de vida do produto com vista o aumento da fiabilidade, com maior foco nas fases iniciais. Neste sentido, a Análise de Modos de Falha e Efeitos (FMEA) é uma ferramenta indispensável e como tal utilizada a nível mundial.

FMEA é uma ferramenta robusta na identificação de modos de falha e efeitos de modo estruturado. No entanto, nem todos os problemas são semelhantes e poucas empresas (ou mesmo nenhuma) têm os recursos necessários para corrigir ou mitigar todos os potenciais modos de falha identificados através do FMEA. Neste sentido, os profissionais utilizam metodologias de priorização como suporte na decisão de implementação de ações corretivas de uma forma lógica.

O Número Prioritário de Risco (RPN), designado neste estudo como RPN convencional, é uma metodologia desenvolvida nos anos 60 com vista a avaliação de risco dos modos de falha e assim permitir a priorização de implementação de ações corretivas. No entanto, o RPN convencional é, já há algum tempo, criticado pela comunidade científica devido às suas lacunas que podem levar a uma interpretação enganadora dos resultados obtidos na priorização.

Para uma empresa a competir num mercado global, a priorização de modos de falha representa um ponto de significativa importância. A priorização permite otimizar recursos financeiros e tempo de desenvolvimento através da redução do ciclo teste-correção, assim como permite evitar a utilização desnecessária de recursos a corrigir ou mitigar modos de falha de risco baixo. Desta forma, a metodologia de priorização deverá ser suficientemente eficaz de modo a que a empresa possa suportar as decisões nos resultados obtidos. Neste sentido, o RPN convencional não se apresenta como eficaz.

Apesar de haver uma consciencialização por parte da comunidade científica durante as duas últimas décadas relativamente às lacunas apresentadas pelo RPN convencional, e ainda de existirem esforços com vista a apresentação de alternativas, o RPN convencional é ainda utilizado mundialmente na priorização de modos de falha. A hipótese que se apresenta como mais representativa na justificação da contínua utilização do RPN convencional centra-se no facto de o modelo de computação ser extremamente simples, e como tal é facilmente aprendido e aplicado.

A principal razão para se realizar a FMEA é a necessidade de melhoria da fiabilidade, e esta melhoria é apenas tão eficaz quanto a eficácia da metodologia de priorização utilizada. Claramente, o RPN convencional não está apto para desempenhar a tarefa de priorização, sendo que a sua utilização pode mesmo colocar em causa o objetivo da realização da FMEA uma vez que poderá negligenciar a avaliação de modos de falha com um nível de risco elevado.

Adicionalmente aos esforços de vários investigadores, este estudo propõe um modelo de computação alternativo (RPNb) ao RPN convencional, de modo a melhorar a eficácia da priorização de modos de falha. O RPNb diferencia-se das alternativas existentes no sentido que se foca no desenvolvimento de um modelo simples. Este foco baseia-se na premissa de que a simplicidade é a razão para se conseguir uma ampla dispersão da metodologia, que resulte na substituição do RPN convencional.

O RPNb foi desenvolvido com o propósito específico de eliminar algumas das lacunas do RPN convencional, deixando de parte outras lacunas conhecidas, por uma questão de manter a simplicidade do modelo, mas tendo como principal objetivo a melhoria da eficácia na priorização dos modos de falha. O modelo RPNb visa a eliminação das seguintes lacunas:

a. A importância relativa entre os parâmetros O, S, D não é tida em consideração.
b. Combinações diferentes dos parâmetros O, S, D podem resultar num mesmo valor RPN (existem apenas 120 valores RPN diferentes em 1000 combinações O, S, D possíveis quando se utiliza uma escala de pontuação 10).
c. A frequência de distribuição dos valores RPN não apresenta uma distribuição normal ou uniforme (os valores RPN não são contínuos, a escala apresenta imensas quebras, e a distribuição é centrada na parte inferior da escala).
d. O modelo de computação do RPN convencional é fortemente sensível a variações nas pontuações dos parâmetros O, S, D (efeito de alavanca).

A reformulação do modelo de computação com vista a eliminação das lacunas acima descritas, passou por 1) modificação do formato de cálculo da multiplicação para a adição, 2) inserção de fatores de ponderação, e 3) criação de uma supra-escala. A forma final do RPNb é dada pela seguinte equação:

$$RPNb = w_o.(10^5 + I_o).O + w_s.(10^5 + I_s).S + w_d.(10^5 + I_d).D \qquad \text{(Eq. 3.3)}$$

$$w_o + w_s + w_d = 1$$

$I_{o,s,d} = \{1, \quad 11, \quad 111\}$, de acordo com a importância relativa

Onde,

$W_{o,s,d}$ – é a importância relativa dos parâmetros O, S, D.

$I_{o,s,d}$ – é o fator diferenciador.

O RPN convencional é criticado por possuir um modelo de computação questionável, ou seja, não existe racional para que os parâmetros O, S, D sejam multiplicados. A modificação do formato multiplicação para o formato adição não torna o RPNb livre de críticas, mas permite a obtenção de resultados mais representativos da realidade. Esta aproximação à realidade é suportada pelo estudo comparativo entre as duas metodologias, com base no caso de estudo desenvolvido por Lu et al,. (2013) – ”Failure Mode and Effect Analysis in blood transfusion: a proactive tool to reduce risks”.

O RPNb promove a possibilidade de cada indústria/área ajustar a importância relativa dos parâmetros O, S, D de acordo com a sua visão. Este modelo aumenta a flexibilidade na priorização de modos de falha, terminando com a necessidade de as indústrias/áreas quantificarem o risco da mesma forma existente no RPN convencional. Os resultados apresentados pelo RPNb ajustam-se de acordo com a importância relativa atribuída aos parâmetros O, S, D, sem provocar um efeito de dominância do parâmetro com maior importância relativa sobre os restantes. No caso de estudo, verificou-se que 4 dos modos de falha presentes no top 5 marcam presença nos 3 cenários RPNb.

Na análise comparativa com vista o teste do modelo de computação alternativo, foi possível concluir que o RPNb é capaz de fornecer cenários de priorização mais coerentes. Uma análise crítica às pontuações dos parâmetros O, S, D mostrou que o conjunto de modos de falha presentes no top 5 nos cenários RPNb são considerados como tendo maior risco agregado do que o conjunto no cenário resultante do RPN convencional. A suportar esta conclusão, verifica-se que os riscos que entram no top 5 de modos de falha nos cenários RPNb, em substituição dos modos de falha que estavam anteriormente no top 5 no cenário do RPN convencional, apresentam maior potencial de risco.

É um aspeto importante o facto das movimentações nos cenários de priorização promovidos pelo RPNb serem bastante significativas (alguns dos modos de falha sofreram movimentações superiores a 6 posições num total de 19). Este aspeto é preocupante tendo em consideração que muitos estudos se têm suportado nos resultados de um método de priorização que pode fornecer cenários bastante enganadores.

O PRNb apresenta ainda melhorias na continuidade da escala, sendo que apresenta valores RPNb únicos mas que quando divididos por gamas apresentam um perfil com distribuição normal. Efetivamente, é neste perfil que se sustenta a robustez do modelo RPNb – tendo em conta que avaliação do nível de risco é feita através de um conjunto de 3 parâmetros que possuem uma mesma escala, é expectável que a combinação de todos os resultados possíveis forme um perfil com distribuição normal. É apenas possível obter uma distribuição normal se o modelo apresentar um comportamento sistemático e previsível, em vez de um comportamento errático.

Na procura pela melhoria da fiabilidade, as empresas não devem suportar a tomada de decisão em metodologias pouco eficazes. Assim, é importante promover a substituição do RPN convencional na priorização de modos de falha. Neste sentido, e com base no caso de estudo, o RPNb é uma alternativa aparentemente robusta, capaz de fornecer resultados coerentes, ajustáveis às características da indústria/área, através de um modelo simples.

Palavras-chave: Fiabilidade, Modelo de Priorização de Risco, Número Prioritário de Risco, Análise de Modos de Falha e Efeitos

APPENDIX C – RPN beta – An alternative to the conventional Risk Priority Number computation model

The following paper was developed based on this research and it was submitted to the Conference IncoME-II 2017 (2nd International Conference on Maintenance Engineering – University of Manchester, UK). The paper was accepted for the Conference Proceedings and for publication in Journal of Maintenance Engineering.

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RPN beta – An alternative to the conventional Risk Priority Number computation model

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Abstract: Companies competing in a global market seek continuous increase of product/service reliability while reducing costs and time to market. FMEA is a powerful tool to identify potential failure modes, with RPN taking an important role in the prioritization of corrective actions implementation. However, scientific community has for a long time pointed out shortcomings to conventional RPN that may jeopardize prioritization results. In this paper, it is presented the RPN beta (RPNb) as a simple and robust alternative to conventional RPN.

Key words: Reliability, FMEA, Risk Priority Number, computation model, RPNb

1.0 Introduction

Under the current global and highly competitive market environment, the success of a new product is dependent on the cost, competitiveness, quality, its ability to meet consumers' expectations, and time to market [1]. It is usual to have quality competing with time to market, and a good balance between them is necessary to avoid errors and/or miss market opportunities with major consequences to the company. There are several examples where the urge to product deployment led to image and financial consequences due to un-detected faults. Toyota recall due to accelerator pedal fault is a well-known case [2].

Nowadays, companies take very seriously product quality and make great efforts to guarantee that a reliable product is deployed into the market. Early detection of product faults is less costly and easier to correct. Therefore, companies tend to proceed with risk analysis along all product development stages, commonly within a Failure Modes and Effects Analysis (FMEA) framework [1]. FMEA is a well-known tool used to identify the failure modes and to enhance system reliability, through the development of suitable corrective actions [3]. Several methodologies can be used to assess risk within FMEA framework, being the Risk Priority Number (RPN) the most commonly used worldwide.

In FMEA, each failure mode is characterized by three drivers – Occurrence (O), Severity (S) and Detection (D) – and the most critical failure modes are addressed first when it comes to corrective actions implementation. To define prioritization of failure modes based on risk level, it is then used the RPN. In its conventional computation model, RPN is the product of the O, S, D drivers:

$$RPN = O \times S \times D \tag{1}$$

Although conventional RPN is widely used, it has been raised by scientific community awareness towards some shortcomings that may diverge the conventional RPN estimates from its ultimate purpose. Despite all the critics, conventional RPN is still utilized worldwide for prioritization of failure modes, probably due to its simplicity.

In this study, it is proposed a new computation model for risk prioritization (RPN beta) which attempts to maintain application simplicity while eliminating most of conventional RPN shortcomings.

2.0 RPN – shortcomings

Liu *et al* (2013) [4] has performed a wide review about the RPN shortcomings and potential impacts in the RPN outcomes interpretation. In summary, for the conventional RPN the most relevant shortcomings identified were:

a. The relative importance among O, S, D is not taken into consideration [5].
b. Different combinations of O, S, D may produce the same RPN value (there are only 120 different outcomes from 1000 possible combinations) [6].
c. The frequency distribution of the RPN values is not either normal or uniform (RPN values are not continuous with many holes and heavily distributed at the bottom of the scale) [5].
d. The O, S, D drivers are difficult to be precisely evaluated (difficulty to translate FMEA uncertainty) [6].
e. RPN computational model is strongly sensitive to variations in the O, S, D drivers' evaluations (leverage effect) [6].
f. The RPN considers only three risk factors mainly in terms of safety [7].
g. The computational model for calculating RPN is questionable and debatable (there is no rationale as to why O, S, D should be multiplied) [7].

h. Interdependencies among various failure modes and effects are not taken into consideration (domino effect is neglected) [5].

Researchers have been presenting several approaches to eliminate or mitigate the above shortcomings for the conventional RPN. The most common approaches found in literature are:

a. Multiple Criteria Decision Making (ex. ME-MCDM, AHP/ANP, Grey theory, etc.) [8].
b. Mathematical programming (ex. Linear programming, DEA/Fuzzy DEA) [5].
c. Artificial intelligence (ex. Rule-base system, Fuzzy ART algorithm, Fuzzy cognitive map) [9].
d. Other (ex. Cost base model, Monte Carlo simulation, probability theory) [6].

Although there is a wide consensus concerning the shortcomings of conventional RPN, and alternative approaches have been suggested for a long time, the conventional RPN computation model is still utilized worldwide. It is possible to find journal articles over 20 years old pointing out conventional RPN shortcomings and proposing alternatives – [9], [10]. Since then, the amount of journal articles exploring this topic has been increasing robustly [4]. In the first quarter of 2017, it was possible to identify several journal articles where conventional RPN is utilized to prioritize failure modes – [11], [12].

Being that conventional RPN shortcomings are well acknowledge among scientific community for a quite long time, it is important questioning why conventional RPN is still broadly utilized. Some questions may be raised:

- Is there no consensual alternative to conventional RPN?
- Is there no alternative capable of tackling all shortcomings?
- Are alternatives too much complex?
- Does conventional RPN fit the study's purpose?

Comparing available options for prioritization of failure modes, conventional RPN holds a strong advantage – it has an extremely simple computation model. The simplicity of conventional RPN is very attractive due to its straightforward application and short-time consumption.

3.0 RPNb – alternative computation model

For the development of RPN beta, it was focused individually the shortcomings identified in conventional RPN and analyzed their root causes. Then a potential solution was tested and accepted, as favorable results were obtained. The final computation model for RPNb was built from the integration of accepted solutions.

In addition, the RPNb was accepted taking in consideration the drive of keeping the computational model simple. The first shortcoming to be tackled was:

i. The relative importance among O, S, D is not taken in consideration:

The difficulty to attribute weighting factors to O, S, D drivers comes from the multiplication effect of conventional computation model. It is not possible to attribute an individual weight to one risk driver since it will have effect in the other two risk drivers. For instance, if it is attributed the following weights to each O, S, D drivers – w_o=0.5, w_s=0.4 and w_d=0.1 – it is the same as applying an overall factor of 0.02 to the RPN value.

$$(0.5 \times O) \times (0.4 \times S) \times (0.1 \times D) = 0.02 \times O \times S \times D = 0.02 \times RPN \quad (2)$$

Multiplication of O, S, D drivers is also the root cause for 1) the strong sensibility to small variations in the O, S, D drivers scores (leverage effect), and 2) non-intuitive statistical distribution (neither normal nor uniform).

To affect each O, S, D driver individually, it is required to abandon the multiplication approach to provide independency between each O, S, D driver. It does not result in information loss of any kind, as there is no rational to have O, S, D drivers multiplied in the first place. The sum of the O, S, D drivers was the solution adopted since it allows the individual weighting of the O, S, D drivers and eliminates the other two shortcomings referred above. Therefore, the first form of the alternative computation model is given by:

$$RPNa = w_o.O + w_s.S + w_d.D \quad (3)$$

$$w_o + w_s + w_d = 1 \quad (3.1)$$

ii. Different combinations of O, S, D may produce the same RPN value:

Although RPNa reduces the frequency of results repetition due to the introduction of weighting factors, it still occurs often. For instance, if it is attributed the following weights to each O, S, D driver – w_o=0.4, w_s=0.35 and w_d=0.25 – it would still have only 167 unique possible RPNa results.

Conversely to conventional RPN, the occurrence of repetition in RPNa is not a result of a “number game” of the O, S, D scores but a conflict of the O, S, D relative importance. It means that an Occurrence rank 5 is equivalent to a Detection rank 8 (0.4 x 5 = 0.25 x 8 = 2). Therefore, failure modes with the same RPNa do have an equivalent risk level according to relative importance of O, S, D drivers.

The RPN values repetition is result of the same scale attributed to O, S, D drivers, which allows to obtain the same value through different combinations of O, S, D drivers. To avoid values repetition, it is required to apply exclusive ranges to each O, S, D driver. There are innumerable ways to perform range distinction but having in mind the drive to maintain the model simple, it was adopted a multiplication factor (1, 11 and 111) for each O, S, D driver as per relative importance. Assuming a relative importance order of O>S>D, O would be multiplied by 111, S by 11 and D by 1, as per the *Table 1* below.

Table 1 – O, S, D drivers range according relative importance (ex: O>S>D)

Rank	O	S	D
1	111	11	1
2	222	22	2
3	333	33	3
4	444	44	4
5	555	55	5
6	666	66	6
7	777	77	7
8	888	88	8
9	999	99	9
10	1110	110	10

By attributing different ranges to each O, S, D driver, it is also being attributed a non-intended weighting – O > 10 x S > 100 x D, for O = S = D. This non-intended weighting creates a dominant driver and provokes a biased RPN result.

A possible solution to mitigate the effect of dominancy comprises integration of all three drivers range into a wider range (supra-range) where individual influence (from non-intended weighting) becomes negligible. In order to reduce individual influence to approximately 1%, the supra-range must have an order of magnitude of 10^5 ($1110 / 10^5 = 0.01$). It is possible then to obtain the second and final form of RPNb:

$$RPNb = w_o.(10^5 + I_o).O + w_s.(10^5 + I_s).S + w_d.(10^5 + I_d).D \qquad (4)$$

$$w_o + w_s + w_d = 1 \qquad (4.1)$$

$$I_{osd} = \{1, \quad 11, \quad 111\}, \text{as per relative importance} \qquad (4.2)$$

In its final form, RPNb presents a scale with an order of magnitude of 10^6. It is an unusual scale for RPN values and it is not as simple to work with as a 1-1000 scale. It is suggested then to proceed with an interpolation of RPNb values to obtain a 1-1000 scale.

$$RPNbs = \frac{[RPNb(O,S,D) - RPNb(1,1,1)] \times [1000-1]}{[RPNb(10,10,10) - RPNb(1,1,1)]} + 1 \qquad (5)$$

It is then possible to obtain a unique RPNbs value per O, S, D combination with a 1-1000 scale. It will also allow comparing easily results with conventional RPN in the case study.

Having in mind the objective of the proposed computation model, an overview of the RPNb shows a model that:

a. Maintains application simplicity – it has a straightforward application formula (eq. 4) to calculate RPNb value.
b. Attributes weights to O, S, D drivers – RPNb allows to differentiate relative importance among O, S, D drivers.
c. Eliminates values repetition – each O, S, D combination produces a unique RPNb value.
d. Eliminates leverage effect – There is no interdependency among O, S, D drivers, which means that variations of one driver will affect RPNb value individually. As it is possible to observe in *Table 2*, the increase score in Occurrence means a proportional increase in RPNb, independently of S and D scores. Conversely to conventional RPN, variations verified in RPNb are aligned with behavior expectations – a failure mode characterized as O(10), S(5) and D(1) is expected to have a higher risk level than a failure mode characterized as O(5), S(5) and D(2).

Table 2 – O, S, D drivers variations effect in conventional RPN vs. RPNbs (w_o=0,4; w_s=0,35; w_d=0,25)

O	S	D	RPN	RPNbs
3	3	3	**27**	**223,00**
+1	+0	+0	+9	+27,74
4	3	3	**36**	**250,74**
3	7	7	**147**	**556,05**
+1	+0	+0	+49	+27,74
4	7	7	**196**	**583,79**
5	5	2	**50**	**361,79**
+5	+0	-1	+0	+194,40
10	5	1	**50**	**556,18**

4.0 Case study using RPNb

To assess the robustness of RPNb as an alternative computation model to conventional RPN, it was chosen a study performed by Lu et al. (2013) [13] – Failure Mode and Effect Analysis in blood transfusion: a proactive tool to reduce risks.

The basis behind this option are 1) the fact that it uses the conventional RPN to perform failure modes prioritization and 2) the fact that healthcare is an area where un-noticed risks may have highly severe consequences for human life – failure modes prioritization is of high importance.

For the assessment of RPNb behavior to variations of O, S, D weighting factors, it was performed the analysis to three different combinations of relative importance – S>O>D, S>D>O and O>S>D. For all three combinations, the weights were – highest relative importance (0.4), in between relative importance (0.35) and lowest relative importance (0.25). This study does not intend to dictate the relative importance of O, S, D drivers for healthcare area but to assess results fitness to attributed weights.

The O, S, D scoring of each failure mode in the Lu *et al*. (2013) [13] study was performed by experts thus they were assumed in this study as accurate. Therefore, the results correlation between RPNb and the conventional RPN will be based on the critical examination of these failure modes O, S, D scores.

Applying conventional RPN and RPNb to the case study, it is obtained the following failures mode prioritization (limited to top 5 of each analysis):

Table 3 – Failure modes prioritization (top 5): RPNbs vs. conventional RPN

					S = O = D		S > O > D		S > D > O		O > D > S	
FM#	Failure Mode	S	O	D	RPN	Rank	RPNbs	Rank	RPNbs	Rank	RPNbs	Rank
1	Insufficient and/or incorrect clinical information on request form	7	6	3	126	5	517,22	8	483,92	8	467,23	6
2	Blood plasma abuse	6	6	5	180	**4**	528,26	7	517,16	6	517,16	**5**
3	Insufficient preoperative assessment of the blood product requirement	7	5	7	245	**1**	589,33	**4**	611,53	**3**	578,14	**1**
5	No etiology detection samples before blood transfusion	8	7	1	56	13	545,01	**5**	478,42	9	461,72	7
10	Inaccurate cross-matching	10	1	6	60	12	539,53	6	595,03	**5**	444,81	8
11	Incorrect blood components issued	10	1	8	80	10	595,01	**2**	672,70	**1**	522,48	**4**
16	Preparation time before infusion >30 min	8	6	5	240	**2**	617,12	**1**	606,02	**4**	572,64	**2**
18	Blood transfusion reaction occurs during the transfusion process	8	4	7	224	**3**	594,92	**3**	628,22	**2**	561,45	**3**

4.1 Paradigm S>D>O

Looking specifically to scenario S>D>O, it is possible to observe (*Table 3*) that that top 3 failure modes from conventional RPN are kept in top 5 of RPNb prioritization, although their position in the raking has changed. Additionally, it must be highlighted the fact that FM #11 went from rank 10 (conventional RPN) to rank 1 (RPNb).

Looking in a qualitative way to the O, S, D scores, one may have difficulty to identify FM #11 (RPNb – rank 1) as having a higher overall risk than FM #3 (RPN – rank 1) but clearly FM #11 presents a higher overall risk than FM #1 (RPN – rank 5). In this sense, RPNb is able to bring to light a potential high risk that otherwise may go un-noticed using conventional RPN.

One may challenge the ability of FM #11 to be the top 1 risk (RPNb) and FM #3 the rank 3 (RPNb). However, looking analytically to both failure modes, FM #11 presents – Severity (+3), Detection (+1) and Occurrence (-4). In general, the score difference is null but taking in consideration that S and D have higher relative importance than O, it makes sense that the balance tends to increase FM #11 overall risk.

4.2 RPNb vs. RPN overall results

A general view of all three RPNb scenarios shows that the top 3 failure modes from conventional RPN are kept in the top 5, although their position has changed according relative importance of O, S, D drivers. Entrance of new failure modes into top 5 are also different for each scenario due to different relative importance.

In the scenarios where Severity has higher relative importance, the new failure modes entering the top 5 present also high scores for Severity. It is important to note that FM #10 belongs to top 5 for S>O>D but not for S>D>O although it presents score 10 in Severity, which is an indicator that the RPNb do not focus in the most relevant O, S, D driver but rather in the combination of the relative importance of each one.

It is important to note that new failure modes entering RPNb top 5 (FM #5, #10 and #11) presented ranks significantly below in conventional RPN (rank 13, 12 and 10, respectively). The most surprising one is the FM #11 as mentioned before.

It is also worth mentioning the fact that FM #1 (RPN - rank 5) is excluded from top 5 for all three RPNb prioritization. In this case, a simple qualitative analysis would led to the perception that FM #1 – S(7), O(6) and D(3) – have apparently a lower overall risk than FM #5 – S(8), O(7) and D(1) – or than FM #11 – S(10), O(1) and D(8). This is clearly an example of a failure mode that gains visibility due to conventional RPN computation model arrangement.

5.0 Conclusion

Considering the information presented in this paper, it is possible to conclude about RPNb that:

- It presents a more robust computation model – RPNb eliminates several shortcomings associated to conventional RPN.
- It delivers more coherent prioritization results – RPNb results are analytically sounded and less likely to leave relevant failure modes un-noticed.
- It adapts prioritization to relative importance – O, S, D weighting factors are relevant for failure modules prioritization. It means that each industry/area can adopt their own weighting factors to better adjust prioritization results according the industry/area characteristics.
- It presents a simple computation model – RPNb results from the direct implementation of O, S, D drivers and respective weighting factors.

It is recognized worldwide that conventional RPN presents several shortcomings that may jeopardize risk prioritization results leading to potential erroneous focus when it comes to implement corrective actions. Although several alternatives have been proposed, conventional RPN is still widely utilized.

For a company competing in a global market, failure modes prioritization holds an important role since it means savings in time and cost. However, it is extremely important to have a reliable prioritization methodology so it does not leave un-noticed potential high level risks.

Comparing to conventional RPN, the RPNb presents characteristics that fits better the purpose of a FMEA analysis. RPNb has a more robust computation model thus it is expected to deliver a more coherent result when it comes to prioritization of failure modes

RPNb presents itself as a robust alternative for failure modes prioritization, capable of delivering sustained results adjusted to industry/area specific characteristics, through a straightforward computation model. In conclusion, RPNb is a methodology worth to be considered for failure modes prioritization.

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