ISO 9001:2015 and Its New Requirement to Address Risk: A Demonstration Case-Study

Filipe Perdigão[1], Celeste Jacinto[1], Sandra Lopes[2] and Ana Sofia Matos[1*]

[1] UNIDEMI – Mechanical and Industrial Engineering, Faculty of Science and Technology, Universidade Nova de Lisboa, Portugal

[2] Lususider-aços Planos SA, Seixal, 2840-075 Aldeia de Paio Pires, Portugal

*Corresponding author, e-mail: asvm@fct.unl.pt

(Received 26 September 2016; final version received 24 February 2017)

Abstract

The recent 2015 edition of ISO 9001 introduces a risk-thinking approach in its new section 6.1. Comparing with previous editions of the standard, the main innovation is the need to address risk and identify improvement opportunities within quality management processes. The aim of this work was to show how the new requirements can be fulfilled. This was achieved through a case-study in an industrial company, by applying a structured analysis to a specific management process. This paper describes a practical example, demonstrating how this type of analysis can be applied to any management process within a companies' quality system. Two methods were used; the first was Failure Mode and Effect Analysis (FMEA/FMECA), and the second was a Hazard and Operability Study (HAZOP). In the latter case, the authors used the designation QF-HAZOP to highlight the fact that this is a HAZOP study applied to the analysis of Quality Functions. The current work is restricted to the study of main process (management function) "Sales", for which the analysis of a particular sub-process, "Sales plan development", is herein presented and discussed step-by-step, to give insight of details. Within "Sales plan development", the results revealed 10 failure modes that, in turn, can originate from 17 potential causes that were organized into 4 "sets of causes" because certain failure modes share the same causes and require similar improvement actions; these are also pinpointed in this paper. With regard to the main process "Sales", this analysis disclosed 38 sets of causes that were categorized by risk level, i.e., by their risk priority number (NPR), using a Pareto Diagram, to establish intervention / improvement priorities. It was also found that, apparently, either FMEA/FMECA or the adapted QF-HAZOP produce similar results. Both constitute useful approaches to fulfil the new requirements of ISO 9001:2015 Quality Standard.

Keywords: Quality, Risk analysis, Risk-based thinking, Quality management, ISO 9001:2015, FMEA / FMECA, HAZOP.

1. Introduction

Until the early 1990s, there were several competitive standards associated with quality systems. The need to standardize procedures emerged at that time, in order to contribute to reducing barriers to international trade and increase efficiency, involving the various stakeholders and especially consumers. This standardization was materialized with the creation of ISO 9000.

Based on a previous British Standard, the BS-5750, created during the 2nd World War for managing the production of ammunition, the ISO 9000 series appeared in 1987, addressing Quality Management and Quality Assurance. Of this series, the most relevant was ISO 9001, which consisted of a quality management model for organizations wishing to certify their management systems. These ISO standards are reviewed every five years by a responsible technical committee in order to remain current and effective. The new ISO 9001:2015 is the last version published and replaces the 2008 version. The changes associated with this new edition require companies to adopt a novel *risk thinking approach* towards quality management (*c.f.* ISO 9001:2015). The evolution of ISO 9001 underlying philosophy is summarized in Table 1.

The requirements comprised in the ISO 9000 series are generic and applicable to any economic sector, regardless of the type of product supplied. However, the diversity of products manufactured, services ren-

Table 1 Evolution of the ISO 9001 standard

Version	Description
ISO 9001:1987	Based on specifications for Quality Management Systems, focusing on specific objectives of each organization, oriented for the Manufacturing Process in order to create a rigorous process and stable production. Focused on the product.
ISO 9001:1994	To modernize the previous version, the emphasis was reinforced on Quality Assurance through prevention and evidence of compliance with documented procedures. Unfortunately, and following the image of the first edition, companies tended to implement its measures through the creation of documentation, which led to excessive bureaucracy.
ISO 9001:2000	The standard sought to make a radical change in thinking by introducing the concept of Process Management as a centerpiece of the standard in the attempt of turning a "document system" into an "documented system". The objective would be to increase the efficiency of the system by implementing performance measures. In this review, the continuous improvement of expectations and customer satisfaction also had great prominence.
ISO 9001:2008	This review contains only minor changes. The aim was to clarify existing requirements and improve the consistency of the approach, in parallel with other management standards (ISO 14001).
	It was launched to reflect the good practices recently associated with quality management. Although there are more strict requirements, the standard in general is much more flexible and has a greater integration with other ISO management criteria, through greater involvement of top management and the introduction of risk analysis.

dered, their specific aspects and the characteristics of the organization, should be properly considered during the design and implementation of a quality management system (Pereira and Requeijo 2012).

The ISO 9001:2015 encourages organizations to follow a sustainable development path, promoting improvements that will reflect on their overall performance. Specifically, this standard is intended to introduce changes in the practice of quality management on technological and increasingly complex dynamic environments. Nevertheless, it is necessary that the standard keeps being generic and helps simplifying the implementation. An important change in this new edition is the requirement to address risk and identify opportunities, compelling managers to identify actions that could potentially affect in a positive or negative way any product or service and/or jeopardize or enhance the whole performance of the organization.

The concept of risk has always been implicit in ISO 9001, but this revision makes it more explicit and builds it into the whole management system. Within this Standard (ISO 9001, 2015), two fundamental objectives are, 1) to give confidence in the organization's ability to consistently provide customers with conforming products and services, and 2) to enhance customer satisfaction. In the context of the Standard, "risk" relates to the uncertainty in achieving these objectives.

To satisfy the new requirement, analytical techniques will then be applied to identify and solve any situations that may be harmful to the company and should also give guidance on future improvement actions. The notion of risk is now an additional concept, not replacing the principles already present in the previous editions. Risk is embedded in the foundations of the standard, since it will be part of the planning phase.

The "process approach" and the PDCA (Plan-Do-Check-Act) philosophy remain two key pillars. Therefore, risk management works towards continuous improvement and preventive action.

From what was mentioned before it becomes clear that the new 2015 edition produced a (new) gap that organizations need to fulfil, namely with regard to risk analysis of management functions.

The objective of this study is to show how the new requirements can be accomplished by applying a preliminary analysis to a specific management process. The case-study presented was carried out in a flat steel manufacturer (coils), in a Portuguese plant of a multinational company.

2. Methods

This section gives a brief explanation on the two methods used and why they were selected for this trial.

2.1 FMEA – Failure Modes and Effects Analysis

Failure Modes and Effects Analysis (FMEA) is a well-established method, which has been in use since the beginning of the 1950s. Ever since, the method has been extensively described in the literature (e.g.:

BS-5760:1991, Stamatis, 2003, ISO/IEC 31010:2009, Awad and Yusof, 2012, Harms-Ringdahl, 2013).

Over the years, this analytical approach has become a very important item among quality tools and has been increasingly adopted worldwide, especially in manufacturing industries (Awad and Yusof, 2012), thus rendering it a popular approach among quality specialists and managers.

This explains why application of FMEA was considered the "natural" choice from the beginning of this work. Additionally, the hosting company was already acquainted with it for use in maintenance and occupational safety management. Any readers not yet familiar with this method can refer to a comprehensive text-book specialized on the subject (Stamatis, 2003).

As its name suggests, the technique focus on identifying component's failure modes, their causes, and their effects on a system (or process). It provides inputs for corrective actions and/or monitoring programmes.

There are variants of the method; consequently, just saying FMEA does not define exactly what an analysis will look like. The most common alternative is FMECA – Failure Modes, Effects, and Criticality Analysis, in which "Criticality" is a function that allows estimating a "risk index" (RPN – Risk Priority Number). This index is established using scales (usually between 1 and 10) for rating severity of failure (S), likelihood of failure occurrence (O) and ability to detect the problem (D). RPN provides an extension to the qualitative analysis; it is a decision factor that delivers a relative risk ranking. The higher the value of RPN, the higher is the potential risk.

There are several application areas of FMEA: **Design** (or product) which is used for components and products, **System** which is used for systems, **Process** which is used for manufacturing and assembly processes. More recently, FMEA/FMECA has also entered the application field of **Service** processes and procedures (Stamatis, 2003). The method also has its limitations, which include: 1) it can only be used to identify single failure modes, not combinations of failures, and 2) the studies can be time consuming and therefore costly. The second constraint also explains why this particular case-study, embracing a single key process, was designed to serve as a "test", or "demonstration case", joining analysts from the company itself and from academia.

A multidisciplinary team applied the method (both methods in fact). There was a "permanent" 5-members team, composed by 3 academics with different backgrounds and 2 senior technicians from the local company, both in managerial positions. However, many other participants, namely certain employees performing the tasks and those responsible for the processes under analysis, were enrolled on several occasions for discussing the details and help deciding the scores.

2.2 HAZOP – Hazard and Operability study

HAZOP is the acronym for Hazard and Operability study, and the method consists of a structured and systematic examination of a planned or existing product, process, procedure or system. It is a technique to identify risks to people, equipment, environment, and/or organizational objectives.

The HAZOP process is a qualitative technique originated in the 1960's (Kletz, 1999). It is based on the use of guide words, which allow the identification of specific "deviations" in the intention of a system's function (ISO/IEC 31010:2009). These guide words are simple words or phrases (e.g.: too little, too much, wrong order, too late, too early, etc.) that are applied to the intention of either a part of an installation or a process step (Harms-Ringdahl 2013). HAZOP is similar to FMEA in the way that it identifies failure modes of a process, system or procedure, as well as their causes and consequences. It differs because it starts with the "deviation" to the intention and works back to possible causes and failure modes, whereas FMEA starts by identifying failure modes (Harms-Ringdahl 2013, ISO/IEC 31010:2009).

The technique was initially developed to analyze chemical processes, but it has been extended to other types of systems and complex operations. Examples of application within other fields are, for instance, the development of SCHAZOP (Safety Culture HAZOP) by Kennedy and Kirwan (1998), to analyze safety management vulnerabilities, and to assist in the improvement of safety management. Such adaptation resembles the current challenge in this work, with the difference that the focus moves from safety management towards quality management.

Another example is the HSE (2005) human-HAZOP technique for the analysis of "human factors", or "human functions" in the management of major accidents hazards.

In alignment with the variants above mentioned, the authors decided to explore the use of HAZOP within quality management functions, the reason it was designated QF-HAZOP, to highlight this new application field.

3. Risk analysis of the quality function "Sales" - Main results

This section is designed to present the main findings of this work. Using the same reasoning as in the previous section (methods), it is structured into two sub-sections, one for each application case.

3.1 Results of FMEA / FMECA analysis

This case-study was carried out as a pilot application case. It covered the "Sales" process, largely due to the fact that this is a key process. Not only it involves several functional areas, but it also requires interaction with a large number of people in leadership positions, rendering this process a quite comprehensive one for a first trial. Roughly, the main process "Sales" is divided into 10 sub-processes, namely:

1. Sales plan development
2. Soliciting orders and negotiation
3. Identification of customer requirements
4. Capacity analysis and acceptance of customer orders and/or contract changes
5. Follow-up and customer information
6. Expedition/ dispatch of orders
7. Preparation and submission of documentation
8. Sales analysis
9. Complaints, treatment, and analysis
10. Evaluation of customer satisfaction

Based on internal documents and several brainstorming sessions, the research team (the permanent team members) produced checklists with anticipated failure modes, which were later validated by the process owners. Not all the failure modes were identified through these checklists; many others were recognized as a result of proactive discussions with those responsible for the process (within further brainstorming sessions). At this early stage, it is sometimes possible to identify opportunities as well, because a failure represents a "deviation" from the normal course of a standard procedure and, in certain (rare) cases, deviations can also have positive impacts, thus revealing an opportunity (see also Deviation analysis by Harms-Ringdahl (2013) for instance).

The next step of FMEA consisted on the identification of the effects. To systematize the process, the expected (negative) effects were previously classified into seven main categories:

1. Non-compliant Product / Service
2. Increase in cost
3. Business loss
4. Extended delivery time
5. Loss of economic and financial flexibility
6. Disruption of production capacity
7. Others – to include special and less frequent cases

For identifying potential causes associated with failure modes, two approaches were used. One of them was the so-called SHELL model (or acronym), which enables the categorization of the components that could potentially generate risk. This model allowed to create 4 categories of causes divided into:

- **Software** – all intangible components, such as norms, rules, regulations, etc., which represent the normal "operational procedures";
- **Hardware** – all technical systems, equipment. or tools (e.g.: displays, controls, etc.);
- **Liveware** – refers to the human element of the system (e.g.: operators, managers), who interact with the other categories;
- **Environment** – includes the external influences and other factors beyond the previous three categories (L-S-H). These influences include organizational factors, such as social or safety climate, economic or commercial pressure, etc., as well as the natural environment in which operations take place.

The second technique used to identify potential causes was the traditional Ishikawa Diagram. In this case the diagram allowed relating causes-to-effects, which facilitates filling in the FMEA table.

The analysis proceeded with the FMEA's evaluation phase. This comprised two different stages: The *Qualitative Analysis*, which described the functional analysis and identified failure modes, effects, and related causes.

The second stage consisted on the *Valuation of Risk*, where the severity indexes (S) are established, as well as the detection (D) and occurrence indexes (O). Table 2 shows the criteria for evaluating severity.

The practical application of FMEA / FMECA is illustrated next, in Tables 3 to 6, using systematically the sub-process "Sales plan development" for demonstration purposes.

Table 3 shows the ten "failure modes" identified in this particular sub-process, together with the corresponding "effects". The list of failure modes (n=10) is

Table 2 Criteria for severity index (S) (FMEA/FMECA)

Level	Severity description	Definition
1	Insignificant	The failure does not cause any noticeable impact on service
2	Very low	Failure can occur unnoticed, although with minor effects on service
3 - 4	Low	Failure is noticeable and slightly affects the service beneficiaries
5 - 6	Medium	Failure has undesirable consequences and let the unhappy the beneficiaries unhappy
7 - 8	High	The mistake affects the service performance significantly
9	Very high	The failure has serious consequences on service performance
10	Catastrophic	Failure is unacceptable and / or irredeemable

the "common denominator" used to link all the tables (i.e., to link the sequence of results, from Table 3 to 6).

The effects of any failure are, commonly, the negative consequences on products and businesses. These effects represent a poorly managed process or organization and can be scored to measure the severity of the failure. An extract of qualitative analysis and valuation of risk (e.g.: severity scoring) is also shown in Table 3.

Once failure modes and effects are identified and scored for severity, the next step consisted in analyzing the "causes" related to each failure mode (Table 4). To carry out this assessment, the potential causes of each failure mode are scored with an occurrence index (O). This index helps identifying the most problematic causes (i.e., those leading to a higher RPN), which require priority improvement from a preventive perspective.

In this study a large number of potential causes were identified, some of which being associated with more than one failure mode. The idea of categorizing "causes" under the acronym SHELL, proved to be useful, because it simplified the assignment of scores to occurrence index (O). Higher scores were assigned to the cause(s) more likely to occur, thus, identifying which might give a higher contribution to its related failure mode(s). Table 4 shows the results of "causes" and "occurrence" for the failure modes under scrutiny in this case-study. To avoid unnecessary repetition of lines, the many causes found were grouped into 4 "sets" enough to accommodate failures with common sets of causes.

Finally, the detection index (D) rates how likely the control measures implemented by the company would preventively detect the failures and causes, as illustrated in Table 5. The scores given assess the quality of the control measures applied, and unveil which sub-processes have better control actions.

Table 3 Application example for "Sales plan development"– *failure modes & potential effects of failure* (FMEA/FMECA)

Failure Modes identified (n=10)	Potential effect of failure	S
- Stagnation in exploring new markets and customers - Lack of monitoring the market price levels	Loss of economic and financial flexibility	4
- Lack of gathering customer information - Sales history not available for a particular client - Not using forecasts for customer needs	Business loss	4
- Lack of information on availability of manufacturing capacity - Insufficient manufacturing capacity for galvanized steel	Disruption of production capacity	8
- Inadequate distribution of sales volumes in the sales plan (by product, market, customer) - Not developing partnerships with suppliers - Inefficiency in completing the company's orders	Increase in cost	4

Table 4 Application example for "Sales plan development" – *potential causes* of failure (FMEA/FMECA)

Failure Modes (n=10)	Potential causes of failure (n=17 causes; 4 sets of causes)	O
- Stagnation in exploring new markets and customers	- Absence of strategy to reach new customers - Outdated network for professional contacts - Insufficient information about competition - Technology and Equipment (Insufficient techno. requirements) - Insufficient data collection and processing of information	1
- Lack of monitoring the market price levels		
- Lack of gathering customer information	- Failure to communicate with the customer - Insufficient data collection and processing of information - Insufficient information about competition - Poor assessment regarding the relevance of business - Technology and Equipment (Insufficient technological requirements)	3
- Sales history not available for a particular client		
- Not using forecasts for customer needs		
- Lack of information on availability of manufacturing capacity	- Inefficient information flow within the company - Unpredictability of orders (quantities / specifications) - Poor production planning	7
- Insufficient manufacturing capacity for galvanized steel		
- Inadequate distribution of sales volumes in the sales plan (by product, market, customer)	- Bad data analysis and results calculation - Breach on procedures - Insufficient data collection and information processing - Unfavorable economic situation	2
- Not developing partnerships with suppliers		
- Inefficiency in completing the company's orders		

Table 5 Application example for "Sales plan development" – *control measures* (FMEA/FMECA)

Failure Modes (n=10)	Control measures *	D
- Stagnation in exploring new markets and customers	Monitoring the DC reporting Monitoring CRU index ORG_17	2
- Lack of monitoring the market price levels		
- Lack of gathering customer information	ERP X3	2
- Sales history not available for a particular client		
- Not using forecasts for customer needs		
- Lack of information on availability of manufacturing capacity	ERP X3 Portfolio balance	6
- Insufficient manufacturing capacity for galvanized steel		
- Inadequate distribution of sales volumes in the sales plan (by product, market, customer)	Sales plan	2
- Not developing partnerships with suppliers - Inefficiency in completing the company's orders	ERP X3	

* The control measures listed in this table use a company coding representation; most are administrative, software and procedures.

Once all three indexes (S, O, D) had been rated for each item in the table, the next step is the calculation of the respective Risk Priority Number (**RPN = S x O x D**), which gives an estimation of the global "risk index": the higher the RPN, the higher is the risk of failure. This is an important attribute of FMECA, since it allows not only prioritizing the risk level(s) within an ordinal scale, but also making post-analysis comparisons between two consecutive evaluations and estimating the level of "risk reduction" after implementing corrective actions.

As already mentioned the several causes were grouped and coded into "sets" of potential causes.

Table 6 illustrates this coding process (VAT 1 to VAT 4) for "sales development plan". It also shows the relevant department associated with each failure mode and the final risk score (RPN). From the table one realizes that, in this sub-process, the set of causes coded VAT3 is critical due to its very high RPN index (336).

Table 6 Application example for "Sales plan development" – *final RPN values* for "sets" of causes (FMEA/FMECA)

Code (sets of causes, see Table 4)	Department	Failure Modes (n=10)	RPN
VAT1	Market	Stagnation in exploring new markets and customers Lack of monitoring the market price levels	8
VAT2	Clients	Lack of gathering customer information Sales history not available for a particular client Not using forecasts for customer needs	24
VAT3	Production	Lack of information on availability of manufacturing capacity Insufficient manufacturing capacity for galvanized steel	336
VAT4	Business	Inadequate distribution of sales volumes in the sales plan (by product, market, customer) Not developing partnerships with suppliers Inefficiency in completing the company's orders	16

In addition, both failure modes originate in the Production Department.

In the main process "Sales" and its 10 sub-processes, a total of 23 specific activities (management functions) were scrutinized. After repeating the analysis to all sub-processes, and considering all things, the "Sales" examination revealed around 54 risk factors (failure modes) that may arise from 38 different sets of causes, considering that certain failures have common causes. The many different causes (38 sets), classified by their respective RPN, were subjected to a traditional Pareto analysis (Figure 1), which helped to pinpoint the most critical ones.

From Figure 1, and according to the well-known 20:80 principle underlying the Pareto law, the authors considered that the five leading "sets of causes" should be examined more carefully. These critical causes are around 13% of the total number of causes, but contribute to ~60% of total "risk level" (total RPN index). After further analysis of these 5 cases, preventive /improvement measures were established, as shown in Table 7. These measures define the future path for improving the Sales process. Noteworthy, the corrective actions identified in Table 7 comprise two key components: "procedures" and "people".

The management of the Production and the Quality systems should be well adjusted to the company's reality.

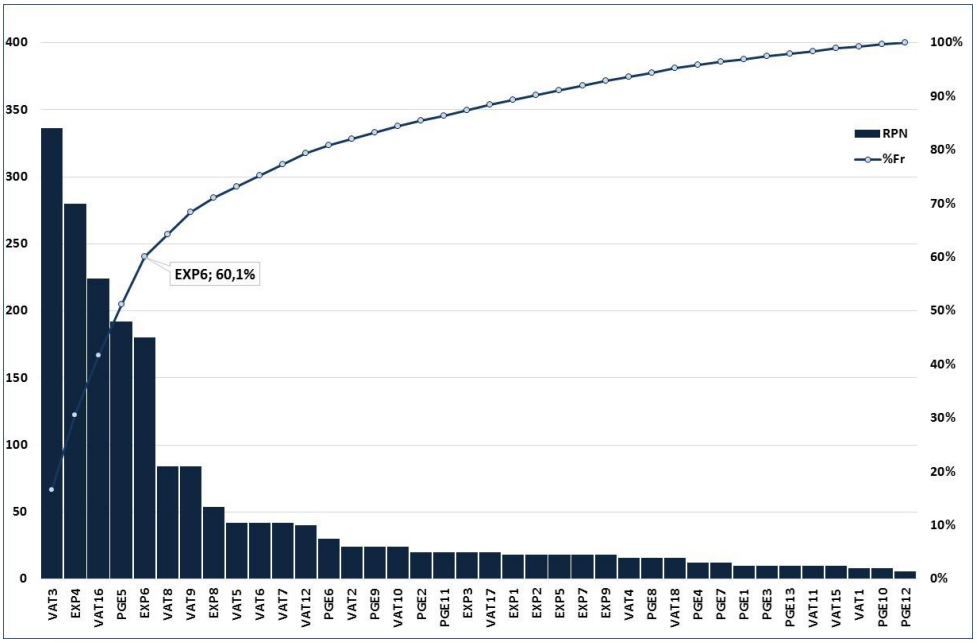

Figure 1 Application example. Pareto Diagram with RPN values for 38 sets of causes – Sales (all sub-processes)

Table 7 Improvement priority actions (all sub-processes of Sales**)**

Item	Improvement actions – Sales
VAT3	Monitoring and updating portfolios on a daily basis
EXT4	Preventive maintenance and purchasing of spare parts for equipment
VAT16	Setting goals and monitoring the process of handling complaints, monthly
PGE5	Strategic Stock (for standard specifications)
EXP6	Increase awareness of those in charge of daily checking the status of repacking activities

Information and equipment should always be available, minimizing bureaucracy and anticipating problems. For instance, through "*preventive maintenance and purchasing of spare parts"* and by "*improving the process of handling customer complaints*", the overall performance is expected to improve.

Moreover, the company's strategy must be tailored to market characteristics, in order to reflect the business risks and, therefore, allow setting an appropriate and well prepared response. To achieve this, measures should be taken such as *"monitoring and updating portfolios on a daily basis"*, as well as defining and keeping a *"strategic stock for standard specifications"*.

In addition, the workers skills should also be taken into account, to ensure that they are specialized and motivated for the work. In this sense, the measures to be taken involve increasing *"awareness of those in charge of the daily checking and repacking activities"*. All these opportunities are related to the continuous improvement ideology.

3.2 Results of QF-HAZOP analysis

With regard to the QF-HAZOP analysis, the risks identified were basically the same of those found with FMEA/FMECA. This is possibly explained by the fact that FMEA/FMECA was used first and the analysis was comprehensive enough. In other words, it is possible that the first method applied, whatever it is, has a leading influence on the results of the second application, since the problems (and potential solutions) are already known.

Nevertheless, the HAZOP application carried the authors to find out the **specific intentions** behind each failure mode, as exemplified in Table 8. This peculiarity, not used by FMEA, pushes the analysts to extend their understanding of the failure modes.

There was no need to modify or change the traditional HAZOP key-words, as they seemed to be sufficient and good enough for detecting "deviations" leading to failure modes. However, this might not be so obvious if the HAZOP analysis had been carried out first. Table 8 also shows an application example of the key-words.

Apparently, there is no evident advantage in using QF-HAZOP over FMEA/FMECA, with the exception of clarifying the functions "intention". By contrast, it was felt that application of FMEA/FMECA was more intuitive and that its ability to estimate a RPN number is useful to establish priorities. Nevertheless, one should be cautious when dealing with RPN indexes, for the ratings are (or can be) rather subjective. In any case,

Table 8 Application example for "Sales plan development" – extract of QF-HAZOP showing specific intention (*in brackets*)

Sub-process	Key-Words	Failure Modes
1 Sales plan development		
1.1Company strategy		
Market	Less	Stagnation in exploring new markets and customers
(Market search)	Less	Lack of monitoring the market price levels
Costumers	No	Lack of gathering customer information
	No	Sales history not available for a particular client
(Organizing customer information)	No	Not using forecasts for customer needs
Operational	Less	Lack of information on availability of manufacturing capacity
(Monitoring manufacturing capacity)	Less	Insufficient manufacturing capacity for galvanized steel
1.2 Budget		
Business	Different	Inadequate distribution of sales volumes in the sales plan (by product, market, customer)
	No	Not developing partnerships with suppliers
(Negotiation and Strategic Planning)	Less	Inefficiency in completing the company's orders

in the authors' opinion, the HAZOP approach is also seemingly accurate for the purpose of this type of analysis.

4. Concluding remarks

This paper described a piloting case-study that shows how to comply with the new edition of Standard ISO 9001:2015, which now requires risk analysis to quality management functions. The illustration case presented here covered the management process (function) "Sales". The analysis allowed the identification of 54 failure modes that were thoroughly examined with two different methodologies.

After applying QF-HAZOP it was felt that FMEA/FMECA has an additional strength related to its ability to rate failure modes and their specific causes. This allows establishing priorities for corrective actions and pinpointing opportunities for intervention. However, care must be taken, since any evaluation step based on ratings, can be quite subjective. The use of FMEA is likely to increase in the future, for there have been recent attempts to convert traditional (i.e., paper-based or spreadsheets) Process FMEA into an open architecture Process FMEA web-based system (Awad and Yusof, 2012). The same authors argue that this more dynamic web-based tool can further assist in analyzing and solving problems quickly and effectively

All in all, both approaches were considered adequate within this new field of application, i.e., to analyze and assess potential risks in quality management functions.

Acknowledgments

The authors are grateful to Lusosider, namely to the personnel of quality, safety, and environmental department and the several heads of other departments, for their helpful collaboration in this study. This research work was partially sponsored by UNIDEMI Research Unit (ref. PEst-OE/EME/UI0667/2014).

References

Awad A. and Yusof S. (2012). A Methodology for Integrating Web Based FMEA and TRIZ. *International Journal of Systematic Innovation* (IjoSI), 2(1), 33-45.

BS 5760 Part 5 (1991). Reliability of systems, equipment, and components. *Guide to Failure Mode, Effects and Criticality Analysis* (FMEA and FMECA).

Harms-Ringdahl, L. (2013). *Guide to safety analysis for accident prevention*. Stockholm, Sweden: IRS Riskhantering AB.

HSE (2005). *Inspectors Toolkit: Human factors in the management of major accident hazards. Health and Safety Executive, Human Factors team*, HSE Books, UK.

Kletz, T. A. (1999). *Hazop and Hazan - Identifying and Assessing process industry hazards.* 3rd edition UK: Institution of Chemical Engineers, Rugby.

Kennedy, R. and Kirwan, B. (1998). Development of a Hazard and Operability-based method for identifying safety management vulnerabilities in high risk systems. *Safety Science*, 30(3), 249-274.

ISO 9001 (2015). Quality management systems: requirements. ISO – International Standard Organization, Geneve.

ISO/IEC 31010 (2009). Risk management – Risk assessment Techniques. ISO-International Organization for Standardization and IEC- International Electrotechnical Commission.

Pereira, Z. & Requeijo, J. (2012). Quality Planning and Statistical Process Control. 2nd Edition. Caparica, Universidade Nova de Lisboa, Portugal (in Portuguese only)

Stamatis, D. H. (2003). Failure Mode and effect Analysis: FMEA from Theory to Execution. 2nd Edition. Wisconsin, US: ASQC Quality Press.

AUTHORS BIOGRAPHIES

Filipe Perdigão holds a MSc degree in Industrial Engineering and Management, from the Faculty of Science and Technology, Universidade NOVA de Lisboa (FCT/UNL).
He is currently an intern Consultant at SAP. At the time of this study, he provided a relevant participation in all the tasks, because this project was also used for developing his MSc thesis.
e-mails: f.perdigao@campus.fct.unl.pt and filipeperdigao3@gmail.com

Celeste Jacinto holds a Chemical Engineering, degree from Univ. of Lourenzo Marques, Mozambique and Universidade de Coimbra, Portgual. She has a PhD in Mechanical & Manufacturing Engineering, University of Birmingham, UK. Since 2003 Celeste Jacinto is an Assistant Professor with Habilitation at the Department of Mechanical & Industrial Engineering, Universidade Nova de Lisboa (FCT/UNL), Portugal. Research work focuses on the area of occupational and industrial safety. Previous employment, accounts for around 20 years in the Manufacturing Industry, as Production Manager, Quality Manager and Project Manager.
URL:http://xenofonte.demi.fct.unl.pt/mcj/, e-mail: mcj@fct.unl.pt

Sandra Lopes is Metallurgical and Material Engineer from Instituto Superior Técnico, Technical University, Lisbon, Portugal.
She works for Lusocider – Aços Planos SA, a steelworks manufacturing in Portugal. At Lusosider she is the local Head of Department for Quality, Safety and the Environment (QSE Manager).
e-mail: Sandra.Lopes@lusosider.pt

Ana Sofia Matos is an Assistant Professor at Faculty of Science and Technology, of Universidade NOVA de Lisboa (FCT/UNL) since 2006. Ana Sofia received her PhD degree in Industrial Engineering from FCT/UNL in 2006 and her master degree in Operational Research and System Engineering from Technical University of Lisbon in 1997. She is the Quality Director of Metrovac (Laboratory for Vacuum Technology and Metrology of the Faculty of Science and Technology) since 2002. Ana Sofia is a permanent member of UNIDEMI – R&D Unit in Mechanical and Industrial Engineering, Faculty of Science and Technology, Universidade NOVA de Lisboa. Her areas of interest include Quality Management, Statistical Process Control, Metrology, Experimental Design and Taguchi Methods.
Corresponding author. e-mail: asvm@fct.unl.pt