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Integration of the Risk Management Approach in the ISO 9001 V 2015

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Abstract:*Today, control of quality risk is to monitor the various components contributing to high value-added services. That's why companies will increase their approach to change in the quality risk management according to ISO 9001, which appears in its new version in September 2015. In fact, some companies are not yet ready for this change, because the new version of the standard gives no guidance or requirement regarding the methodology for risk analysis. In this paper, we propose a methodology to integrate risk management into the quality process. This approach allows the achievement of the objectives and the improvement and also to serve the competitiveness of enterprises.*

Keywords—**Quality management system, standard ISO 9001, risk management.**

I. Introduction

Since 2000, the consideration of risks in the operation of enterprises is not new, however, their management has made significant progress and become more professional. The maturity level companies face risks depends on several factors, such as business or compliance with regulations that cause them to develop a risk management approach. Indeed, increasingly faced with the issues of risk, companies are today gradually become more sensitive to the need for effective risk management. It becomes an important activity for all companies and proves to be even more important than the consequences caused by mismanagement which are serious (Sghaier et al., 2015). According to ISO 31 000 Standard, risk management is based on identifying, analyzing, assessing and organizing risks into hierarchy, their consequences and the probability of their occurrence and defining the strategy to be consequently adopted.

Nowadays, mastery of the risks becomes a major concern for companies. One of the main objectives is to prevent the impacts of risks upon the quality. In general: « mastery of the risks means both' know 'these risks and the' keep them under control '. To be familiar with them, it is necessary to assess them. To keep them under control, it is necessary to take measures adapted in relation to these risks » (Chevreau,2008). Mastery of the risks according to (Desroches et al.,2015) is directly linked to the actions of reducing risks. In their work (Chevreau,2008) interested only risks that are called 'HSE risk': 'Hygiene' risk has consequences on food safety; 'Security' risk harms the personnel's health and safety at work; 'Environment' risk has negative impact upon environment, without addressing the critical risks in connection with the 'Quality' management system. Where from absence in the company's of a method to anticipate and prioritize their risk quality to ensure customer satisfaction and compliance of their products and their services. Afterwards, we interest at inherent risk in all aspects of a management system of quality. Actually, there are risks in all systems, processes and functions. Our thinking ensures that these risks are identified, monitored and reviewed throughout the design and use of quality management system.

Today, to serve the competitiveness of enterprises, the quality risk management is one of the main objectives of the standard ISO 9001. It contributes demonstrably to the achievement of the objectives and improvement, par example to optimize the performance of production in terms of cost and sustainability of resources, etc... The introduction of the quality risk analysis at several levels can improve the implementation of preventive actions by planning projects that address the risks. These control actions should be implemented with the means necessary and evaluated periodically (Bellon and Boisround, 2013). (Zheng et al., 2015) offers a tool of auto diagnosis which will allow companies to assess their compliance in comparison with the new version of norm.

According to standard ISO 9001 2015, the company must identify the risks that need to be taken into account to ensure that the quality management system can achieve expected results; prevent or reduce adverse effects; Register in a dynamic of continuous improvement; schedule all actions to implement against the risks and opportunities. This determination of risks is linked to the context of the firm (stakes and interested left requirements) and the achievement of the objective qualities of each process by the analysis of their activity. The ISO 9001 V 2015 gives no guidance or requirement regarding the methodology for risk analysis. The use of any method can degenerate a genuine quality approach in some companies. Certainly it can be useful in some cases, but it is necessary to adapt the tool to every situation and need. Therefore, an approach structured to control risk seems to be a relevant approach companies certified ISO 90001 V 2015.

Our objective in this article is to offer a methodology to propose a methodology for integrating risk management into the quality process. In concrete terms, this job will allow to the industrial company to ameliorate their performances whatever their size and is going to develop more and more.

II. Approach to control the quality risk in companies certified ISO 9001 V 2015:

II.1. Pre-requested to the risk analysis process:

II.1.1. Determination of working groups:

II.1.1.1. Committee on risk decision-making management:

This committee of decision-making management of risks is composed of the managers of every entity (pilots of processes as well as managers) and aims to determine the risk management at a global level. Committees are controlled by the QHSE Director and meet monthly. The objects of these meetings are:

The establishment or review

- Company Mission
- Stakeholders (internal / external)
- The context (internal / external)
- Strategy of the company
- Objectives Qualities

The presentation and validation

- The analysis of risk of each of processes
- validation and monitoring of actions contained in the Quality Management Program

II.1.1.2. Committee of risk operational management:

This committee of risk operational management is composed within every process by:

- Pilots of processes and/or managers of entity
- Personnel
- Official representative QHSE

It will aim to define

- Stakeholders (internal / external)
- Context (internal / external)
- Objectives quality
- Risk analysis related to the achievement of objectives
- Proposal of actions to implement
- The execution of actions validated by the committee of risk decision-making management

II.1.1.3. Skills to be acquired by all the participants

All staff personnel will have to follow a training concerning ISO 9001 v 2015 and both committees will have to follow an additional training in risk management as well as on the present proceedings.

II.1.2. Determination of objectives Quality:

Objectives qualities have two aims, meet the requirements of the company and also the requirements of the client. These quality objectives are defined by the management and then determined at the level of all processes. These are achieved through the activities of the process.

These objectives can be determined by taking two components, namely

- The strategic directions and issues of the company
- The company (Parties stakeholders and environment) requirements

The objective qualities stem from a major question which is what our process brings to meet these various requirements.

II.1.3. Determination of the process:

We will then have to verify that the identified processes allow to respond to the strategic directions and also the QHSE charter. So first check the consistency of the process mapping with the new requirements specified in the QHSE charter.

Following the revision of process mapping, we will have to review the various processes in their detail, to know:

- The objectives of the processes and their consistency with the company's strategy.
- The means of monitoring and measurement of processes and their consistency with the objectives of the process. Questions such as these will be to settle
- Identity card of the applicant process:
  - ✓ The mission of the process.
  - ✓ The objectives and indicators of the process.
  - ✓ The input and output data.
  - ✓ The necessary information documented.
  - ✓ The necessary skills.
  - ✓ The means put in place.
- The different activities managed by the process allowing the achieving of objectives.

II.2. Risk Analysis Method:

Once the prerequisites in place, participants of processes can identify the risks of internal and external context in the process:

- Internal identification with the activities of analysed process and internal company context.
- External Compared with contexts (internal and external) of the process

The analysis of risk should only focus on achieving a quality objective and not on the activities of the process or respect for requirements of the interested parties.

II.2.1. Determination of event, uncertainties:

Events can come:

- The activities of the studied process
- The activities of internal interested parties (process)
- External interested parties
- External context

These events are related to one or several uncertainties that must be formulated neutrally. Uncertainty must also be formulated so as to always be reported to the analysis objective.

II.2.2. First assessment:

The identified events are evaluated using the likelihood that is the occurrence of appearance of it.

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Note	Explanation of the scoring of the likelihood
1	Unpredictable event (never happened)
2	Predictable event (already happened at least once where comes once a year)
3	Possibility of significant occurrence (several times per year)
4	Possibility of occurrence quasi systematic (several times not month)

Uncertainties linked to events are assessed with the aid of the consequence which is the impact of the appearance of this one in comparison with analyzed objective.

Note	Explanation of the grading of the consequence
1	Beneficial effect on the attack of objective
2	No visible effect on the achievement of the objective / reversible effect on the achievement of the objective
3	Irreversible effect on the achievement of the objective or reversible effect on the achievement of the objective with impact on other objectives of the company
4	Irreversible effect on the achievement of the objective and impact on other objectives of the company

The event-uncertainty torque is then evaluated using a matrix in order to prioritize couples on which it is necessary to work first and foremost.

Prioritization matrix		Vraisemblance			
		1	2	3	4
consequence	1				
	2				
	3				
	4				

Color	Explanation of the color code
	Couple already mastered by the process, no need to analyze the means of prevention\/protection
	The impact caused by the torque is not very important, it is not necessary to analyse the means of prevention\/protection
	The impact generated by the couple is significant enough, it is necessary to analyze the means of prevention\/protection
	The impact generated by the couple is very important, it is necessary to analyze the means of prevention / protection

II.2.3. Definition of residual risk according to the means of prevention, protection:

For couples events-uncertainty of color red and black, it is necessary that the process identifies the means of prevention and protection put in place.

Color	Explanation of the color code
	Couple mastered by the process, no need to put in place actions
	Controlling of couple prevention / protection is adequate, it is not necessary to put in place actions in the immediate
	Controlling of couple prevention / protection is insufficient, it is necessary to implement the actions
	Controlling of couple prevention / protection is very poor, it is necessary to implement the actions in emergency

Note	Explanation of the notation of the means of preventions and/or protection
1	The means of prevention\/protection are not controlled nor identified
2	The means of prevention\/protection are identified, but not controlled
3	The means of prevention / protection are identified and controlled
4	The means of prevention\/protection are effective and revalued periodically

II.2.4. Implementation of actions:

According to the color code of the second matrix, the necessary actions will be set up :

- Yellow:The pilot of concerned process will be able to decide or not implement an action a short, medium or long term
- Red :The driver of the process concerned must put up an action a short, medium or long term
- Black :The driver of the process concerned must imperatively to set up an action a short or medium term action

These actions should be defined at this level of detail:

- Description of the action
- Responsible for implementing
- Date of realization
- Discounted Results of actions

Actions can be taken to another level as the analysis process. For example, a process may propose an action that will be carried out by another process to be able to control the prevention and protection at its level.

II.2.5. Program of management Quality:

Once all the supplemented analyses and actions at the level of every process decided. All of those is to consolidate in a summary picture of actions by process to be validated by the General management. This summary table should include:

- Processes concerned by the implementation of the action uncertainty about the action to put in place
- Color code the couple event / uncertainty
- Color of the couple protection\/prevention
- Process implementation of the action
- Description of the action
- responsible for the realization
- planned completion Date
- discounted Results

A monitoring accomplished by Direction QHSE with the pilots of concerned processes will be accomplished to avoid any delay

Prioritization matrix		Protection			
		4	3	2	1
Prevention	4				
	3				
	2				
	1				

of implementation.

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I. CONCLUSIONS:

The standard NF EN ISO 9001 'Quality Management Systems' is what is the standard of management of the most common quality in the world. Risk management (products, customers, operational ...) is a new requirement of this standard. To respect this new requirement, it is needed for the companies the means or proper tools. This is why the objective of this article is to provide a structured approach to integrate risk analysis in this release. This will help companies to improve their performance regardless of their size and will develop more and more and therefore achieved their objectives.

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