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Lean Normalization and Organizational Stress Test: a New Approach for Quality Management System

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Résumé – Dans cet article, le concept de « Lean Normalization » est présenté. Ce concept propose une nouvelle façon d'aborder la mise en œuvre des normes ISO dans une entreprise, avec 6 étapes inspirées du "Lean Management". Nous développerons chaque étape dans cet article. Nous ouvrons également de nouveaux horizons en proposant une approche différente de l'audit basée sur le stress test organisationnel.

Abstract - In this paper, the concept of "Lean Normalization" is proposed. This concept is a new way of tackling the implementation of the ISO Standard in a company. The "Lean Normalization" is composed of 6 steps inspired by the "Lean Management". We explain every single step in this paper. We also open new horizons for this method with a new approach of the audit called the organizational stress test.

Mots clés - ISO, Lean Management, performance, Norme, audit, stress test.

Keywords - ISO, Lean Management, performance, Standard, audit, stress test.

1 INTRODUCTION

In its literal sense, Lean Management is the management of the "rundown" which allows optimizing the processes of organizations by identifying and removing the superfluous. In the other hand, ISO Certification is delivered by an independent society guaranteeing the efficiency of the organization mainly in Quality and/or Security, and/or Environment Management. Actually those two approaches allow the improvement of the performance in organizations especially in private companies.

Lean Management and ISO Certification aim to improve the company's organization and performance. In order that one or the other is not a constraint during the implementation of Lean or ISO, we develop the concept of "Lean Normalization". This concept puts in synergy Lean and ISO approaches.

2 LEAN MANAGEMENT

Numerous publications deal with Lean Management. A history of the major publications was made by Holweg in 2007 [Holweg, 2007].

In complement to this history, Lyonnet proposes an exhaustive study of the concepts of Lean Management [Lyonnet *et al.*, 2010]. She proposes in her PhD thesis a synthesis which crosses 27 referring authors. She concludes this analysis by stating that 6 concepts are the foundations of a Lean way:

- Elimination of waste: A waste is defined as an action or a not value-creating situation for the customer [Womack and Jones, 2005].
- Just-In-Time: Elimination of the unnecessary outstanding discounted bills of production to ensure a continuous flow of products [Ohno, 1988].
- Continuous Improvement: "Continuous improvement" is also known as Kaizen and is based on "the empowerment of each for the cult of best" [Imai, 1997].
- Perfect Quality: Optimization, perfection and principle of "best quality" [James-Moore and Gibbon, 1997]; [Åhlström, 1998]; [Liker, 2004]; [Womack and Jones, 2005].

- Visual Management: Use of visual indications to guarantee the good progress of the activities [Liker, 2004].
- Human Resources Management: Associated responsibility by participating in the team to be able to make the company win [Ohno, 1988].

We connect these 6 concepts to define Lean Management.

3 ISO AND AUDIT

ISO is a collection of standards which allows organizations to obtain a certification in Quality and/or Environment (standards of the series 9000 and 14000). There is also a series OHSAS 18000 edited by the BSI (British Standard Institute) dealing with the Health/Safety in the work. A workgroup was created in 2013 to update the OHSAS 18000, and to reference it in ISO 45001. This planning will allow guaranteeing a complete compatibility between these 3 future versions.

To obtain a certification it is necessary to be audited by an accredited company. It is extremely rare to detect gaps during these audits, even if they allow maintaining a certain level of requirement, they cannot be considered as tools of performance, that's why we propose a new method which we call the "organizational stress test" which is also synchronized with the steps of "lean normalization".

Obtaining a certification also allows communicating with the customers about it. Afterwards organizations buy a copyright logo from the certifiers, to be able to communicate towards the outside (institutional or particular customer) about their organizational certification.

ISO 9000 standard is set up as a collection of guidelines that help a company to establish, maintain, and improve its own QMS (Quality Management System). Actually, its fundamental purpose was originally to increase customer satisfaction in order to yield business efficiency and financial performance thanks to the process-oriented approach, a holistic view which describes how internal processes interact and can be integrated with one another.

By introducing it, quality of processes, regarded as typical cores of organizations, is supposed to raise performance and effectiveness leading to a decrease of costs due to inefficiency when the system is properly implemented [Rusjan and Alié, 2010; Solomon and Hogan, 2012]. However there is often a huge discrepancy between what an ISO 9001 certificate should bring in theory and what it really implies. As a matter of fact, the primary motivation for many companies is often purely to reach the perceived marketing advantages of the certificate and not really to use the QMS in order to improve their internal organization and performance [Fard and Abbasi, 2010; Bangert, 2012]. The direct consequence of these inadequate motives is that the ISO 9001 QMS implementing process frequently begin by hiring consultants who don't adjust to the particular organization because they are unfamiliar with its business and its culture. Therefore, the resulting Management System doesn't fit the realities of the organizational structure; consultants often attempt to justify their high emoluments by setting up an excessively complex ISO 9001 QMS [Milena, 2013].

These incorrect motives for certification combined with a typical misunderstanding of the ISO 9001 standards intrinsic goal leads inexorably to a basis for boosting one of the trickiest side-effects of the implementation of the QMS: the so-called bureaucracy generally considered by companies as the most important drawback of certification [Martinez-Costa and Martinez-Lorente 2007; Al-Rawahi and Bashir, 2011]. This term refers to the act of producing documents as an end in themselves that offer no added value in performing a business process. It contributes to:

- Adding large amounts of needless paperwork.
- Dealing with procedures at the root of employees unnecessary complications.

These bureaucratic management systems based on a counterproductive excluding principle of organization [Mintzberg, 1981]. are considered to be inherently unable to generate efficiency [Maravelias, 2005.] because they leads to losing valuable time, money, and resources without any tangible benefits in terms of process improvements. This is not a trivial point because the fear of implementing bureaucracy often discourages companies from deciding to implement a QMS and constitutes a huge obstacle to the extensive acceptance of ISO 9001: Benefits seem derisory compared with potential handicaps [Martinez-Costa and Martinez-Lorente, 2007]. Consequently, global surveys have shown unheard decrease in number of ISO 9001 certificates since 2011 (up to 7% in Europe) after a continuous growing for years [The ISO Survey, 2011].

That is the reason why it is a huge necessity to adjust the documentation to the needs of the company to match the fundamental standards' purpose focused on efficiency. Actually when firms search only for certificates, their resulting QMS only formally meets the requirements of the standard from a purely procedural point of view and does not provide much value but on the opposite potential negative effects [Jang, 2008].

The purpose of our research is to contribute to a better understanding of the ISO 9001 requirements which is the key to an effective QMS. Step as recommended by Wilson [Wilson, 1998] who advocates keeping the documentation simple and easy to use.

Our approach, which integrates lean thinking, enables each firm to develop the minimum amount of documentation needed in order to demonstrate the effective planning, setup and control of its processes and their continual improvement (Design of continuous improvement process) to reach the efficiency of its QMS.

4 LEAN MANAGEMENT AND ISO

Micklewright proposes in his book entitled "Lean ISO 9001" published in 2010 [Micklewright, 2010], an explanation of the incompatibility between the lean management and the ISO approaches. Indeed, two departments often coexist in companies: the quality and the lean department, whose objectives are not necessarily the same. According to Micklewright, this lack of organizational synergy would be the source of the break between both approaches so that only the quality control managers and

the lean managers could consult, and have no merging between their departments with separated objectives.

From its point of view, ISO proposes the continuous improvement of the Management system and the Quality, but doesn't suggest which tools or methods to apply.

M. Micklewright identifies documentary entropy in his analysis, which is rarely generative of value.

This entropy is often put forward in publications by being identified as a brake on the implementation of the ISO [Liker, 2010] [Ballé and Beauvallet, 2013].

This method has been well received by the already certified companies, because it proposes a reduction of the existing system, and allows complying the lean management with a certified organization.

We underline however that what is proposed by Micklewright is to apply this method to an existing management system, and not directly to a standard.

Putting in synergy the lean management and the ISO is also approached by [Blecken *et al.*, 2011]. The proposed "toolbox" synchronizes lean tools, ISO chapters and the company processes. Unfortunately, it seems that the synchronization is realized in a very macroscopic way and does not directly impact the documentary structure.

A standard edited in 2011 also allows making a link between the lean management and the ISO 9001 standard: the FDX 50-819, "Guidelines to put in synergy the lean management and the ISO 9001" [FDX 50-819, 2011]. Its goal is to highlight the most adapted tools of the lean face to face with every chapter of the ISO. However there is no proposal of a documentary model fully appropriate to this standard. It is rather about a synchronization of tools compared with chapters, or requirements. The impacts, whether they are documentary or organizational, will not be estimated during a certification.

A similar approach is recommended by Chiarini [Chiarini, 2011] who resumes the chapters of the ISO, by synchronizing them with the tools of the lean management, and proposes operational tools of application.

Further to this bibliographical analysis, we arrived at the following conclusion: the various studies which synergize lean and ISO or jointly deal with both topics, begin with a comparative perspective of the normative chapters and then an application of lean tools. Therefore the above-mentioned methods propose a simplification of the already existing management system. It is necessary for an organization interesting in obtaining a certification to display, first of all, its management system, before applying specifically the principles of the lean. This sequential approach can be extremely costly in energy for the company, because it requires time and resources. We haven't identified works which would suggest applying directly the lean concepts to an abstracted analysis of a standard. That is the reason why we propose the "Lean Normalization" in this article.

5 THE LEAN NORMALIZATION

In order to improve the implementation of an ISO standard, in synergy with the lean management tools, we propose to apply Lean/Normalization model synthesized in Figure 1. All deployed figures (Figure 1 to Figure 7) are based on the use of the SADT (Structured Analysis and Design Technique) method.

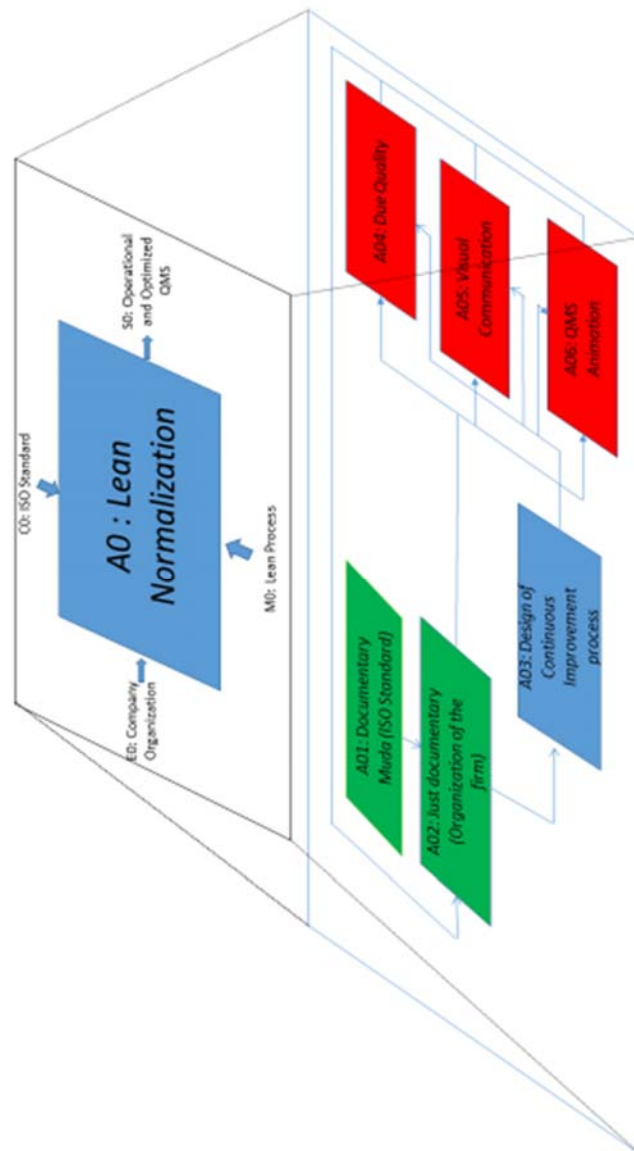


Figure 1. The "Lean Normalization" model

This method called the "Lean Normalization" includes 6 steps adapted from the lean management concepts we selected. The last three steps come true in parallel and in a continuous way. It is about a continuous and parallel process and not a sequential one.

5.1 First step: the documentary muda

Definition: Analysis of the documents needed by a standard (including structuration, typology and number)

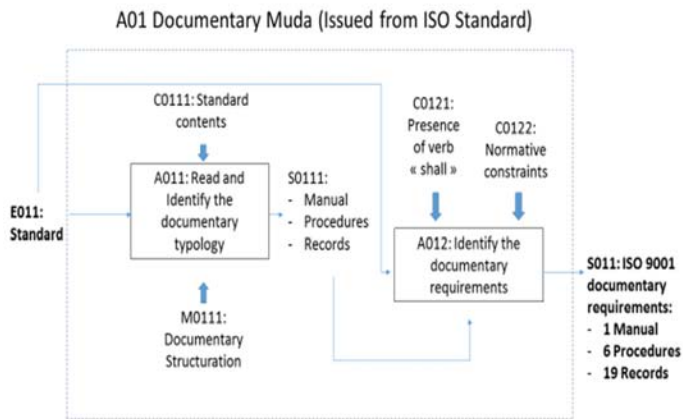


Figure 2. The “Documentary Muda”

Inputs: We only use the standard and nothing else.
Outputs: We identify the exact number and the typology of the due documents.
Target: Documentary "Muda" suggests analyzing the precise documentary requirements necessary in the standard. In our example with ISO 9001, we can find one quality manual, 6 procedures, 19 records.
Tools: We use an Excel file to collect the number and the typology of the due documents and analyze the requirements of the standard.

5.2 Second step: the just documentary

Definition: Coherence of the normative requirements with the existing organization of the company

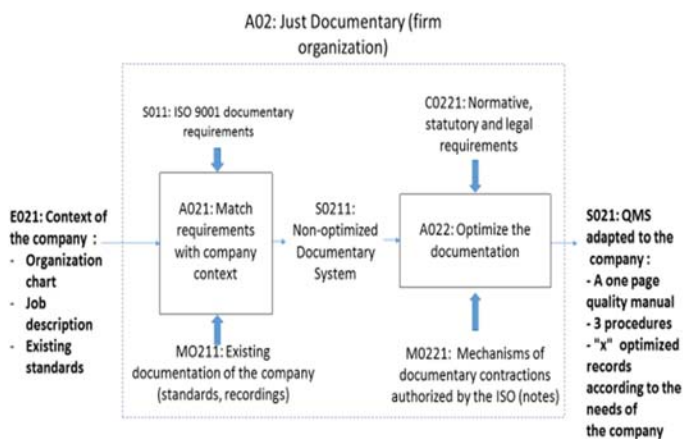


Figure 3. The “Just Documentary”

Inputs: We use all sort of documentary supports inherent to the description of the company (organization chart, job description, existing standards, etc.). In some case, there is no record of the description, and it is necessary to analyze by interviewing the organization of the company

Outputs: The Documentary QMS adapted to the company is in accordance with the standard and also describes the company organization

Target: The just documentary step allows drafting the system documented from the analysis of “mudas” and the company organization with its own documentation and organization. The objective for the organization wishing to be certified is to produce the “just necessary” in terms of documentation.

Tools: We match the documentation of the company and the documentary requirements of the standard.

5.3 Third step: Design of continuous improvement process

Definition: Implementation of optimized processes by applying the Kaizen and Hoshin methods supervised by a Steering Committee.

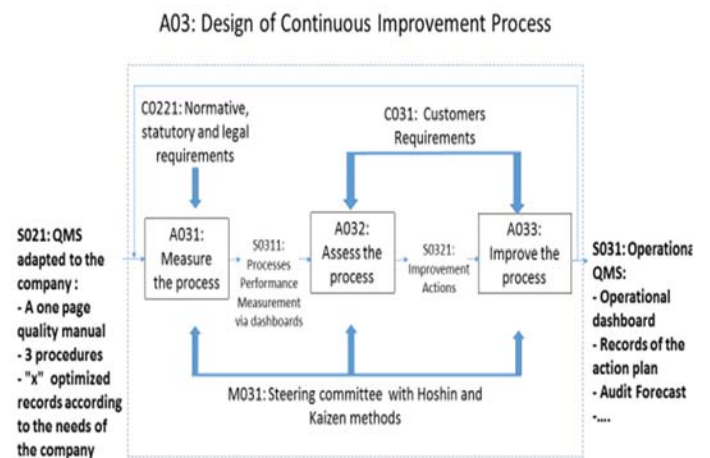


Figure 4. The “Design of continuous improvement process”

Inputs: The optimized documentation of the company
Outputs: An operational QMS with the proof (by record) of the beginning of the Continuous improvement

Target: “The continuous improvement” of the processes needs to go through an analysis of the requirements of ISO 9001 by performing a mapping of all processes. Actually it is not the company which identifies its own processes, but the ISO which is directly brought in the organization.

A steering committee is formed to improve the whole process-based organization by applying the Hoshin and Kaizen methods.
Tools: Supplier Inputs Process Outputs Customer (SIPOC), Steering committee, dashboard

5.4 Fourth step: Due Quality

Definition: Improvement of quality by using the lean management tools.

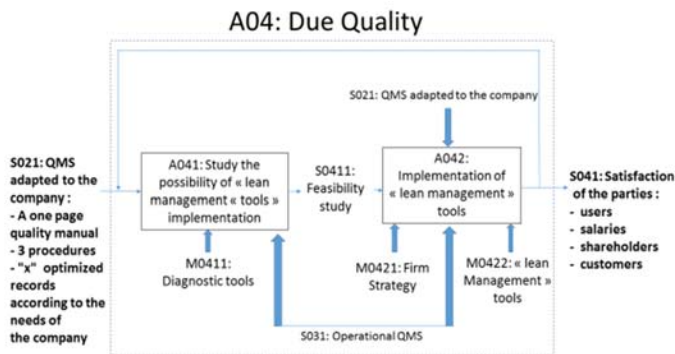


Figure 5. The “Due Quality”

Inputs: We use the adapted and operational QMS
Outputs: All the parties of the company are satisfied by the quality level of the company
Target: The due quality, or "Jidoka of the processes" is implemented through the animation of processes by assigning clearly identified actors. Their function consists in implementing the necessary actions (organizational or operational) to reach targets set by the management of the organization. Their actions can be completely modeled to establish a performance improvement plan. An important point is the fact that, at this step, all the “lean management tools” are compatible with the QMS with a full compatibility of these two approaches.
Tools: We can use audit (or, even better, organizational stress test presented below), and particularly all the “lean management” tools to improve the company's performance (like 5S, 6 Sigma, etc.)

5.5 Fifth step: the Visual Communication

Definition: Communication at all levels of the company by visual points of information

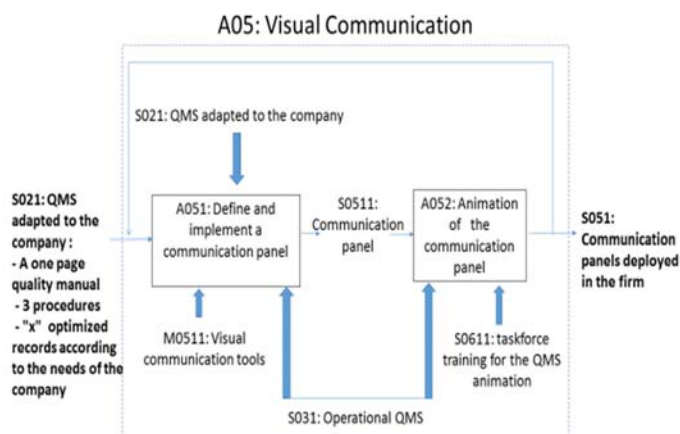


Figure 6. The “Visual Communication”

Inputs: the QMS is adapted and operational
Outputs: The QMS is understood by all the human resources of the company
Target: The “Visual Communication” of the organizational system is interpreted by simplified documentary review in the

firm, where all the contributors find the just necessary to comply with the operational requirements of the standard.
Tools: All the classical tools of the visual communication, like: visual report system, dashboard

5.6 Sixth step: People Management/QMS animation

Definition: Animation of the QMS by a dedicated resource.

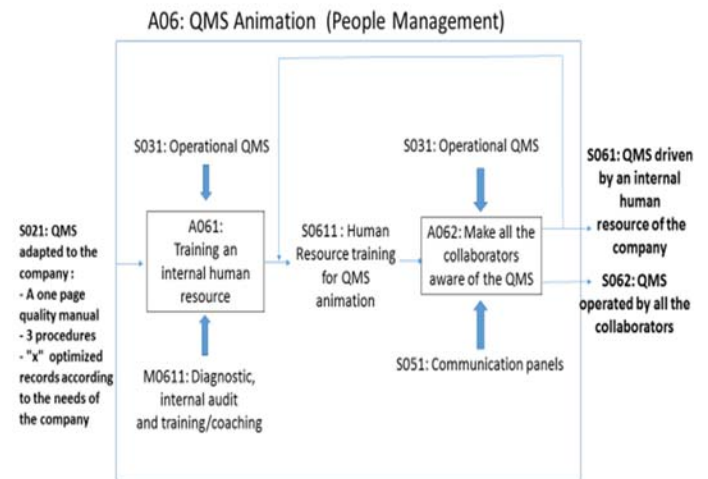


Figure 7. The “QMS Animation”

Inputs: The QMS is adapted and operational
Outputs: A single internal human resource is able to manage the QMS
Target: The "QMS Animation" insures the versatility of the contributors, and the management of the audit maintains the levels of standards requirements (managerial, organizational and documentary). The system can be then "auto-managed". It doesn't require then more than a documentary update of the recordings, and moreover an official appointment of a contributor to hold a quality management position is not strictly needed in practice.
Tools: We can use the audit (or organizational stress test), training, coaching.

6 TOWARDS A NEW PARADIGM: THE ORGANIZATIONAL STRESS TEST

As explained above, major steps of Lean Normalization such as “Due Quality” and “QMS Animation” require being able to evaluate the Quality Management System performance. It is generally acknowledged that audit is the most commonly used process to check the effectiveness of a QMS. We assume that to claim conformity with the essence of the original aim of ISO 9001 an organization has to be able to demonstrate in real time the effectiveness of its processes through its Quality Management System. It is a key point because nowadays it is widely accepted that the audit process requires to provide objective evidence (through observation and measurement) of the effectiveness of its processes and its QMS which is quite different and appears problematic from our point of view. Indeed, as discussed below, audit has obvious drawbacks.

That is the reason why this section is intended to focus on another original and innovative contribution of this paper: what we call the organizational stress test which provides a harmonious complement to Lean Normalization in that it investigates a new way of evaluating companies' performance instead of audit.

6.1. Limits of actual audit process

Once the process-oriented approach is implemented, it is obviously crucial to assess how successfully processes have been implemented and measure the effectiveness of the QMS and of the results that have been achieved. In order to make a judgment about it, a specific key method called audit is performed. It is entirely described in an international standard (ISO 19011) that provides guidelines for management systems auditing considered as a process of systematic examination of a quality system carried out by quality auditors. According to this standard, audit consists in objectively gathering evidence to evaluate how well audit criteria are met which generates a documented report. Actually we can identify three main types of audits:

- Internal audit also known as first party audit: The organization reviews its own systems so that it can get feedback quickly from those who know the company best. However, this audit process cannot always be viewed as impartial.
- Second party audit: It is usually done by customers in order to evaluate the performance of an organization.
- Third party audit: It is an alternative to a Second party audit which leads to deliver a world seal of quality. In fact an independent certification body evaluates the organization in agreement with the ISO 9001 guidelines. If it meets the requirements of the standard, the firm becomes certified.

We acknowledge that there is no auditor who can ever precisely know what level of assurance is achieved in an audit because the audit process is inherently uncertain and make the level of assurance unobservable:

- The scope and duration introduce high variability in the quality and reliability of audits: The on-site audit activity actually represents a small fraction of manufacturing time for a firm and it often turns into a document check in a meeting room, rather than an inquisitive tour of the factory which reduces the ability of the auditor to see all parts of a complex operation and therefore his capability to find concrete instances of nonconformities even with a proper preparatory phase of the audit.
- The auditor competence and the risks of potential conflict of interest are also problematic. First quality auditors usually have a superficial understanding of the production processes they examine and their individual ability has a significant impact on the outcome of the audit. For example, some auditors can be more documentation driven that is to say they merely focus on searching for noncompliance in the documentary system, which often does not provide any real value to the organizations [Poksinska *et al.*, 2006] because what they fix afterwards is only paperwork but not the real systemic issues. Consequently, the organization obtains a QMS that is only

a documentary system instead of a tool for organizational improvement. In this specific case it often leads to solutions that aim at increasing overall bureaucracy. Moreover even if third-party auditors are better armed to deal with ethical dilemmas, the relationship between money and audit can corrupt its implementation: if a company pays for its own audit, it may be unwilling to hire the auditor in question again when it receives a poor audit.

- Audit is intrinsically an idiosyncratic process because it is a discursive practice influenced by normative, cultural, competitive and regulatory issues [Cooper and Robson, 2006; Khalifa *et al.*, 2007]. The audit does not assume perfect assurance because no two audits are identical meaning that it is essentially a one-off exercise: The attitudes, mood, and attention vary for a given auditor from day-to-day as the characteristics of each client.

All these are factors affect the conclusions of an audit so that even a good audit process can, nevertheless, result in a bad outcome. In other words, audits can eventually reveal strengths and weaknesses in a QMS if they are conducted properly, but cannot guarantee future performance. However, it has been paradoxically established [Al-Rawahi and Bashir, 2011] that organizations spend much more for planning and preparatory stages of an audit than for transactions involved with real quality improvement. That is the reason why we consider that it is necessary to imagine a new tool (which draws its inspiration from Financial Stress Test) to simulate hypothetical scenarios and check how the QMS reacts in real conditions.

6.2 Towards a new concept of quality measurement system based on Stress Testing

Stress testing is a generic term used to describe the process of putting a system through exertion: it is typically used to benchmark systems' performance and limits in order to check its strength and determine the stability of the whole entity in extreme but plausible conditions [Sorge, 2004].

In a fast changing world with high volatility in Economy and complexity of financial products, scenario analysis and stress-testing have become core instruments with complex statistical models [Čihák, 2004] in most monitoring frameworks for financial stability.

Applying macro stress-testing to a Management system seems an interesting area for further work: It is a risk management tool (i.e. fully compatible with the spirit of ISO 9001:2015 that makes risk planning part of the overall quality management process) used to simulate an event and measure how it would impact the firm. We call this method the Organizational Stress Test which restores the key status of risk based thinking in the Process Approach.

In the first instance, there is no need of pure statistical model but the founding principle is to design multiple plausible stress test scenarios applicable to an organization in a reduced time scale which must literally picture possible futures that the Management System might face even extreme shocks (as in a financial stress test).

So here is the operations sequence we propose to apply this method in the specific context of Quality Management:

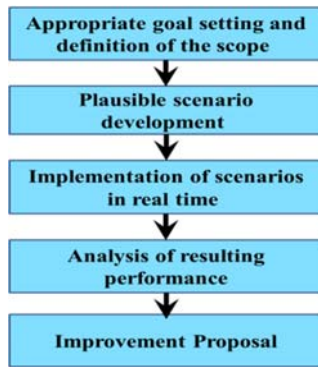


Figure 8. The “Stress test process”

Appropriate goal: Objectives of the stress test and definition of its scope

Plausible scenario development: Choice of stress scenario in different configurations (customer complaints, major non-conformities propagation in manufacturing, crisis situation)

Implementation of scenarios in real time: The QMS manager is a full member of the testing team which analyzes the answer of the organization during the on-site implementation of the organizational stress

Analysis of resulting Performance: The goal is to analyze the robustness of the organization in the face of major shocks engendered by the stress test (processing time, loss of the information, crisis situation)

Improvement Proposal: The primary interest of this approach is obviously to finally propose an action plan of continuous improvement related to the identified harmful situation.

The impact of each scenario is measured by applying it in real time to the QMS: There is no denying that the efficiency of this stress testing program crucially depends on the choice of situations. We can identify two types of scenarios although there is no generally accepted standard [Van Den End, 2006] stating how to choose them:

- Historical scenario based on actual historical events to identify changes in risk factors
- Hypothetical scenario: As an exercise of the imagination, the stress test is limited by the imaginative capacities of those designing the scenarios.

Actually it conducts to a real “What If” Analysis. Below are two examples of alternative scenarios we can foresee:

- A scenario can be complex and involving interactions among many factors over time generated by a set of cascading events. “What if The Quality Manager has been out of the office for a long period and a customer suddenly makes a major claim, how dealing with this issue?”. In this particular case it is quite easy to simulate this event because you only have to isolate the Quality Manager and make sure he won’t help his collaborators. Another interesting point is that Lean Normalization naturally ensures the success of this test (A06 QMS Animation).
- Effects of a scenario can also be generated from a shock to the system resulting from a sudden change in a single variable. For instance if a firm is involved in a Statistical Process Control (SPC) program, “What if the process

triggers some of the control chart detection rules?”. Is the process kept under control? Are Output properly validated? The purpose consists in introducing an artificial failure in the chart and observing how the employees instantly react to process changes and make real-time decisions.

In those cases, interpretation of results is easy. Therefore this Organizational Stress Test is transparent, objective and enables to test the robustness of a company in order to provide confidence in the organization’s ability to consistently provide customers with conforming goods which appears to go further than the conventional audit.

Even if there is still a large amount of challenges ahead (frequency of stress testing, duration of the shocks, nature of documented information...) we assess that is an important area for further research.

7 AN APPLICATION IN A COMPANY

We applied Lean Normalization in the Ervor Company. This firm is a French manufacturer of air compressors.

The QMS is based on one page for Quality Manual, 3 procedures and 20 records.

We worked with a very tight schedule to implement Lean Normalization in this company of 50 workers. We were ready to be audited within 10 days as follows:

- Day 1: Implementation of the draft manual with organizational chart, job description and process mapping (with SIPOC form), identification of measurement tools,
- Day 2: Implementation of procedures for documentary management and audit management,
- Day 3: Implementation of the procedure for corrective and preventive actions and for non-conformities, and customer satisfaction survey,
- Day 4: Establishment of organized Records Management Standards (20) developed jointly with the Senior Management,
- Day 5: Kickoff of implementation of quality assurance by the entire staff, first quality diagnosis,
- Day 6: Implementation of the steering committees of the QMS: Steering committee of the processes and management review, First record of these two authorities,
- Day 7: Implementation of the files for permanent improvement and quality monitoring,
- Day 8: First internal audit,
- Day 9: Second management review, updated by the recordings and the files of the QMS,
- Day 10: End of non-conformity audit.

All the certification audits have been successful without non-conformity or organizational weakness. The Quality of the product is World-famous, and the ISO certification opened up new international markets to this company. We plan to check the efficiency of its QMS with an Organizational Stress Test in the near future.

Ervor has started a new lean management process with a 5S method leading to a full compatibility and synergy with the QMS without identifying breaks or difficulties.

Ervoj wants to implement more lean management tools like the 6 sigma by the end of next year.

8 CONCLUSION

The lean normalization thus allows implementing a standard quickly, in an effective way, and with the just necessary level of documents.

This approach has been already applied in many companies which have benefited from the results of our specific research studies. Any standard can thus benefit from this analysis to reduce drastically the quantity of due documents. The new versions of the ISO standards, planned for September, 2015, should also be compatible with this method, because it is planned to avoid classifying too many documents in processes, procedures, and recordings, but in "documented activity", it gives the way to some freedom for using performance tools to companies eager to be certified.

The Organizational Stress Test is complementary to this approach and is more successful, for the company, than a classical audit because it is a real robustness testing activity for the whole organization.

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