A Holistic Model for the Proactive Reduction of Non-conformities within New Industrial Technologies

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***Abstract*—Non-Conformity Management is a critical activity for each organization striving to achieve the required performance standards and obtain customers' satisfaction, particularly when new technologies are introduced. This activity is usually based on Root Cause Analysis, which is able to solve each relevant nonconformity and is even more important while introducing new technologies and products. A significant limitation in the use of RCA approach relates to the resolution path, usually being very specific for each nonconformity. This paper describes a holistic model capable of managing and proactively reducing non-conformities. This approach allows the identification and resolution of entire sets of nonconformities which, if considered as separate, would appear of little interest; yet, if properly abstracted from the specific problems and regrouped in appropriate holistic clusters, the approach may highlight new critical NCs families to focus on that would not have been detected otherwise, thus allowing further business improvement potential.**

***Index Terms*— product development, new technologies, root cause analysis, TRIZ, non-conformities, HNCR**

I. Introduction

The continuous improvement of business organizations cannot be separated from the development of a robust process of non-compliance management. This is particularly true in the Health Care field, as highlighted in other studies conducted by the authors, such as a case study research about an operating room process optimization inside the VAMC in Detroit [1]. A proactive approach designed to prevent deviations from the conformity standards in the business' processes is the ideal policy of quality standards within the company. However, this approach is limited by the intrinsic complexity of "extended enterprise" (e.g. high number of items, customization, third/fourth-part suppliers, extended supply chain, different legislations, stakeholders) [2]. In this context, it is essential to create a model which allows to manage the non-conformities of all business processes, considering both effectiveness and efficiency. About this subject, the concept of efficiency of the intervention connected to the identification and resolution of non-compliances (NC) has progressively assumed a leading role for corporate management [3].

For a company that runs its business in a tough competitive environment, it is paramount not only to concentrate efforts in the identification of those NCs that have a greater impact on the product/service value, but also to seek the proper balance between resolution capabilities intervention and its related costs [3]. This approach is one of the basic elements of many methods such as Lean Six Sigma [4], Eight Disciplines of Problem Solving (8D) or A3 problem solving [5], [6].

The most common approach to the resolution of NCs is to adopt a strategy called "Root Cause Analysis" (RCA), which consists in trying to skim the end causes of the more critical NCs – chosen through prioritization tools usually based on Pareto principle.

This usually happens after an evaluation of the importance of each specific NC, together with the resources that are available for its resolution. In other words, NCs with a high "weight" in terms of frequencies and impact are solved with a RCA approach, while the less impacting problems are faced only when the event occurs, or even not resolved at all if the resolving cost is much higher than the expected benefit.

This paper deals with the analysis of the strategic limits of the traditional RCA approach, particularly in situations characterized by a wide variety of non-compliances during product development or the introduction of new technologies, which is typical of the present scenario. As an example, the increasing complexity of a typical traditional product should be considered, such as a motorbike and the introduction of new equipment for active or passive safety [7], [8] systems, or new functional materials to obtain better environmental performance [9], [10].

New and emerging technologies have always opened new unexplored paths, which often require at some point the need for effective solutions to identify and solve critical design issues; this is often done by implementing rigorous approaches, principles, and methodologies, as debated in previous studies conducted by the authors, e.g. the implementation of Axiomatic Design applied to Virtual Studio design and television recording [11].

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Specifically, within the scope of this paper, new technologies solicit industries to redefine their knowledge about faults [12] and non-conformities, both in B2C and B2B markets.

The aim of the proposed method is to introduce a strategy to overcome these limitations in the management of NCs. The proposed approach is called Holistic Non-Conformities Reduction approach, (HNCR) and has been already applied in a specific transactional process by the author [13].

II. Limitations of Traditional RCA Approach

The Root Cause Analysis is a structured path whose goal is to identify the actual cause of a problem and the subsequent actions needed to eliminate it [14], [15]. From the above definition, it is evident that the primary focus of the RCA analysis is to address one problem at a time, defining the boundary conditions and actions aimed at seeking its resolution. While choosing the priority of resolution of the various NCs, there are usually two main drivers of selection: the frequency and the severity of impact on the business. These drivers are combined in a priority index typical of Risk Management Approach:

$$Priority = Risk \times Frequency \tag{1}$$

Furthermore, in the traditional RCA approach, there are three other main elements:

- Definition of the real cause of a problem, i.e. the reasons that determine the enchained circumstances for which an event has occurred, thus the actions to be taken to prevent the problem in the future;
- Identification of a reasonable solution: the investigation shall build a picture of the situation into which the event was born, respecting acceptable times and costs ("efficiency of intervention" concept: the cost of the solving intervention must be way less than the NC's);
- Management control: the investigation should highlight the possible actions that the company management can actually perform (proposing solutions which go beyond the management's power of intervention is senseless).

Therefore, the goal of RCA is to identify the controllable factors that are the root causes of a certain non-conformity of a product/service, thanks to a deep investigation process which uses a reasonable amount of resources. As mentioned, the concept of "reasonable amount of resources" (time and money) is a direct consequence of what is the impact of the occurrence of the CN in monetary terms. According to this perspective, a non-conformity management approach is naturally inclined to give priority to the NCs of "greater impact" in their singularity, leaving out the "pool" of small NCs, each one being of limited impact on the company's balance sheet (Fig. 1). Thus, the common strategy is focused on the solution of the most important NCs and their prevention, through a definition of correct and reasonable "lessons learned". Instead, other NCs are normally solved one by one through a direct corrective action with a poor structuring of the intervention, as they occur without anything that could prevent them from happening. This choice is also caused by the fact that, intuitively, dealing with a multitude of NCs which seem to be totally unrelated one another is considered a waste of resources.

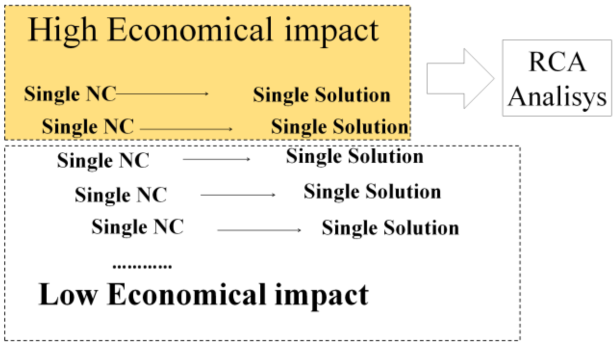

Figure 1. Model of strategic analysis RCA application with the NC of greater impact.

The critical aspect of this approach is that many interesting (often substantial) opportunities of improvement regarding the quality and efficiency of the organization are lost. In fact, individual CNs that often appearing very different from each other might be clustered and solved with the same actions, even if they apparently have no similarity in the causes of occurrence.

The HNCR approach can be used together with traditional RCA to obtain a synergic management of non-conformities (Fig. 2).

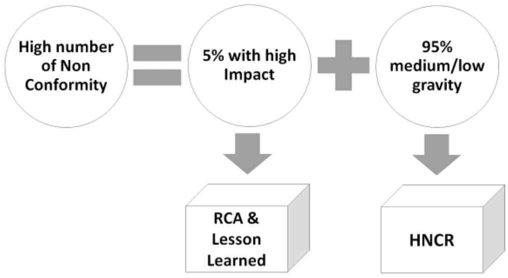

Figure 2. Example of synergic management of RCA approach and HNCR.

III. The HNCR Model

The HNCR approach defines a strategy to leverage historical data and develop a set of solutions which holistically reduce non-conformities. This can be used to build a completely new framework that can be particularly useful overall, especially when considering the relentless shift of the technology as well as the continuous pace of products' release. This approach is of strategic importance for the NC management, because it allows to simultaneously address a cluster of single NC through a general model that could lead to the prevention of non-single NCs.

Tracking the incidents over time can be used to implement a more structured database that may detect more thoroughly those NCs that are available from users' notices. In this case, the assistance service becomes a detector of all the raised issues. Thanks to an activity of analysis and cataloguing, it is possible to re-articulate the same NCs in a multilevel structure, containing unique and structured elementary data. This allows to further deepen the analysis with an impact on more NCs at a time, avoiding the expensive activity required to solve them one by one. This entails valorizing the experience acquired all over the years with "lessons learned" which are useful to solve problems thoroughly, looking for and at the deeper root.

The model suggested so far needs the development of a multilevel network database with an elementary NC data collection. More specifically, this database should:

- Perform multilevel cross correlation analysis among categories;
- Obtain a synthesis of the multilevel network information through graphics, report and data file (these tools should be tailorable to underline trends, detect critical levels or apply Statistical Process Control);
- Detect the holistic critical issues of NCs (i.e. the bigger cluster of NCs);
- Suggest high-level solutions based on TRIZ [16], [17] principles to manage the cluster of NCs.

Such information acts as the starting point to develop improvement projects (through dedicated Working Groups), to increase the robustness of selected processes connected with the critical issues.

IV. The Use of HCNR Model to Reduce Non-Compliance

The basic principle of the HNCR model stems from the desire to "abstract" the individual NC out of the lowest level, extrapolating from each NC a limited number of useful information to revert it to a broader categorization (Fig. 3). This model takes the basic features of the TRIZ [18] method, applied to the specific case of resolution of non-compliance.

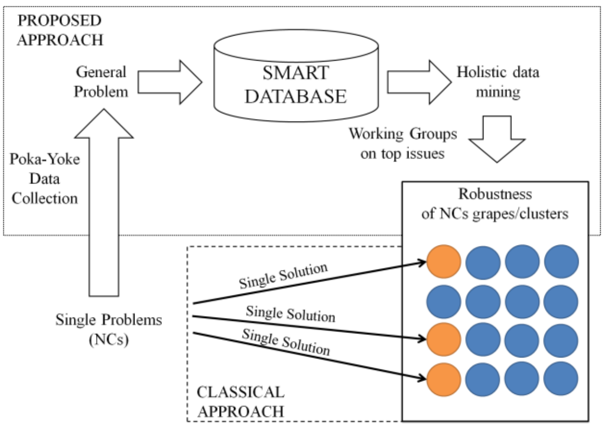

Figure 3. Implementation of the model HNCR

According to the approach of standard RCA applied to the resolution of the NC, it could be tried to give each specific NC an equally specific answer. However, when applied to individual NC lower level, this approach is extremely inefficient (high use of scarce resources for a low economic return).

The HNCR model tries to overcome this strategic gap, developing an approach that allows to attack an entire cluster (category) of low level NCs, thus making the process more robust and preventing the NC cluster from happening again. This aim fits clearly in a strategy of "lessons learned" aimed at implementing a true proactive strategy to foil the recursive occurrence of entire groups of already occurred low-level NC.

The HNCR model is divided along the following steps:

- Registration of codified, individual NCs using a minimal syntax;
- Defining categories of NCs;
- Abstraction of individual NC;
- Breakdown of individual NC into defined categories;
- Definition of solution approaches for each cluster of NCs;
- Contextualization of the model for each category of NC, in the light of each NC.

Therefore, it is crucial to design and create intelligent databases to enable the identification of such cluster.

What follows is a simple example to help understanding the potential of the HNCR model, when practically applied.

Within a generic company named "XYZ", there are recurrently two non-compliances:

- The technical department asks the purchasing department to ensure the supply of raw materials needed for the final product: the non-compliance lies in the fact that very often the purchasing department orders material with not-suitable quality (to save money);
- Within the product, numerous interfaces between the different components are present: among these, one is often responsible for poor quality of the final product, yet the cause of this problem has not been identified so far.

Apparently these two NCs look like entirely uncorrelated one another, if they are examined individually. However, this is not true: the two NCs can, in fact, be traced to one of the categories in the HNCR model, which will be called INTERACTION. In fact, both NCs face a problem of interaction between two subjects (or two objects) within which the causes of the NCs gravitate, and consequently the insufficient quality of the business process as well.

In the HNCR model, the non-conformity management detects this affinity and brings together the two NCs INTERACTIONS, accurately defined in the corresponding category. Then, the software implementation of the HNCR model allows to shift from the first module, related to the treatment of information about NC (data collection and elaboration), to a subsequent module resolution of the NC cluster.

In the specific example outlined in this paper, some of the simplest strategies of resolution of the cluster are identified as:

- Add a third entity (object) to resolve the incorrect interaction that determines the NC (the incorrect interaction is not the ultimate cause of the specific

NC, but is a higher-level cause of it), e.g. introducing technical training for the purchasing department staff, to make clear – for those responsible of the orders – the real needs, in terms of quality of the materials, of the technical department.
- Redefine the power of the subjects (objects): a "top-down" decision would clearly state the power between the parties, defining which of the two should dominate and how, in order not to discover internal conflicts of competence (first NC).

The previous example shows, intuitively, how a proper clustering of individual NCs, picked from an ad-hoc structured database, allows the tackling and resolution of many NCs by means of a single action, thereby maximizing the efficiency of improvement-based activities. These issues are of great interest within the current industrial landscape, which is increasingly pushed towards quality maximization and business efficiency, in times of a continuous technology shift. To reach these targets, it is essential to resolve – as definitively as possible – the highest number of non-conformities that may arise in the product-process made available to the market. This paper presents the HNCR model as a suitable candidate to address these kind of problems, introducing a proactive approach to systematically study individual non-compliances (with a lower impact on company revenues) whose resolution further improve business performance with maximum internal efficiency.

V. Conclusions

The HNCR model presented in this paper is a systematic method that allows the study of individual low-impacting non-compliances, whose resolution would permit an additional improvement of the business' performance. This approach is based on two successive steps: abstraction of the specific problems to identify critical holistic clusters, and resolution of high level criticality through the definition of more robust processes starting from TRIZ principles. This approach leads to the reduction of costs related to individual solutions made in an offhand way through:

- Solving entire clusters of NCs with the same holistic causes;
- Facilitating the identification and sharing of more robust solutions;
- Allowing the dynamic cataloguing and archiving of corrective actions refreshed compared with the complexity and mutability of the specific product or installation;
- Improving the performances of the procedures transferring themselves into the provision of benefits to citizens;
- Improving knowledge management of work processes, encoding problems, solutions and best practices and facilitating the transfer of knowledge business.

The software implementation of the model, together with the application, both in the context of new product development and in the introduction of new technologies, will be the subject of future developments of this study.

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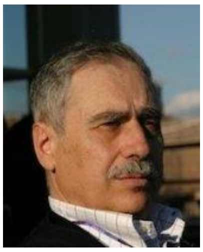

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