

## A fuzzy-based multi-stage quality control under the ISO 9001:2015 requirements

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**Abstract:** This work focuses on the problem of non conformity (NC) characterisation in quality management systems (QMS) and introduces a fuzzy inference engine (FE) for NC analysis based on multi-stage quality control. The research has a twofold objective: 1) to characterise NCs based on risk analysis principles, 2) to define NC priorities. The FE is implemented according to the main requirements of the new ISO 9001:2015 Standard regarding risk analysis and NC assessment. The methodology was tested within an assembly line of mechanical components, where a number of NCs were detected and classified with respect to multiple features. Within this classification, risk analysis is explored through the use of failure mode effects and criticality analysis (FMECA). A risk criticality index (RCI) is defined and evaluated, which addresses NC criticality and the relative action priorities. [Received 28 January 2016; Revised 25 March 2016; Accepted 24 June 2016]

**Keywords:** fuzzy inference engine; quality management; non-conformity; NC; risk analysis; failure mode effects and criticality analysis; FMECA; ISO 9001.

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## **1 Introduction**

Quality management (QM) policies in majority of companies evolve continuously over a number of years by focusing on quality issues that may be critical, since quality is broadly acknowledged as one of the key factors to success in global market (Shetwan et al.,2011). QM practices have been extensively researched in almost any industry sector (Wiengarten and Pagell, 2012). Nowadays, Academics and Managers agree that Quality is fundamental to improve competitiveness in industrial firms. This link between Quality and firms' performances is confirmed by Colledani and Tolio (2011), and before by Chi Phan et al. (2011), who explored the relationship between quality management practices and competitive performance in manufacturing companies. Ahire and Dreyfus (2000) state that "Product quality is the result of manufacturing resources – people, processes, materials, and equipment". Results from other empirical studies state that QM practices effectively improve overall performance (Kull and Wachter,2010). In light to these findings, and according to the basic requirements of the new ISO 9001:2015 Standard, it appears fundamental to drive firm efforts and resources towards an embedded risk analysis in QMS prioritisation of interventions to front quality problems. The present research work can be configured within the thread of QM. The methodic approach developed within this study aims to define a new NC classification and ranking encompassing firms' and customers' perspective. The work embeds FMECA analysis and fuzzy inference engine in QMS, to search insights on NC evaluation and the relative corrective actions (CA) prioritisation. Starting from the assumption that NC addressing is the key factor for the continuous improvement (Sousa and Voss, 2002; Rossini et al.,

2014; Sidin and Sham, 2015; Kafetzopoulos et al., 2015), our findings provide the following insights:

- 1 Which can be the most important features that can characterise a quality NC under firm's perspective and customer's perspective
- 2 How a quality NC can be ranked according to its potential risks, to define the correct priority of the relative CA

The remainder of the paper is as follows.

The second section analyses the topic of quality and QM approaches emerging from the most relevant literature findings. The third section describes the industrial context in which the research starts and develops. The fourth section relates about the gist of the research and its methodology, while the fifth section deals with the development of the industrial case and its results. In the sixth section we discuss the advancements of the research. Then, the conclusions draw on the limits, the possible evolutions of this study and the additional insights.

## **2 Literature review**

### *2.1 Quality management and non-conformities in ISO 9001: 2015 perspective*

Quality management acts to manage the conformity of processes according to design and process specifications. QM controls the six factors affecting quality such as man, machines, material, methods, environments and measurements (Chi Phan et al., 2011, Savino et al., 2015). In general, QM encompasses a set of mutually reinforcing principles, and each of them is supported by a set of practices and techniques (Dean and Bowen, 1994; Battini et al., 2012). QM can be defined as a holistic management philosophy that fosters all functions of an organisation through continuing improvement and organisational change (Kaynak and Hartley, 2005).

Sousa and Voss (2002) state that QM has become an all-pervasive management philosophy, finding its way into most sectors of today's business society, while Brun (2010) divides QM into four dimensions;

- 1 quality planning
- 2 quality control
- 3 quality assurance
- 4 quality improvement.

In this context, Six Sigma is considered a new QM method (Zu et al., 2008, Brun, 2010) for strategic process improvement based on statistical methods. Similarly, total quality management (TQM) is a QM philosophy providing a set of practices for continuous improvement, meeting customers' requirements, reducing rework, competitive benchmarking and team-based problem-solving (Agus and Hassan, 2012). Bennouna et al. (2014) analysed the impact of TQM on quality conformance and customer satisfaction identifying four critical aspects for its implementation in companies. The concept of quality conformance is strictly related to NC that can be defined also as an inspection error or as a production mistake found in some phases of a production process

and/or on finished product (Köksal et al., 2013). According to Lari et al. (2002), without an effective corrective and preventive actions program, problems will occur again, continuous improvement will be difficult and any of the other quality system elements might not work properly. QMS are essentially based on the requirements of ISO 9001 standard, where audits evaluate the level of compliance to ISO 9001 requirements. In the context of NC management, Wu et al. (2006) developed an information analysis system to isolate the causes of NCs, thereby reducing the time taken to solve quality-related problems. Under manufacturing perspective, a good internal process quality management means fewer scrap, defects and rework, and leads to a better operational performance (Parveen and Rao, 2009; Mellat-Parast, 2013; Fiegenwald et al., 2014).

Considering the fact that there is no such a company able to operate with infinite resources, we may argue that in QM a key role is played by NC, their CA and by the evaluation of their impact on productivity and production costs. Thus, especially in case of shortage of resources, companies need to have efficient criteria to prioritise NCs and CAs. According to Love et al. (1995), costs of NCs are typically broken down into two areas:

- 1 cost of internal failures (scrap, rework and other excesses before the product is shipped)
- 2 cost of external failures (warranty services, costs of product failures during its use).

The interesting finding of Santa et al. (2014) and Syn et al. (2011) inspired us in modelling our approach. While the first one appraises the impact of technological innovation on performances improvement, the second and the third one revise the use of fuzzy sets in modelling the effects of product defectiveness on costs and customer dissatisfaction.

Some requirements of the recent ISO 9001:2015 standard emphasise risk management and the control of process outputs. Toward this emphasis, we may mention the following;

- 1 implement planned activities at appropriate stages to verify that product requirements have been met
- 2 the application of NC management to products after delivery
- 3 determine methods for monitoring, measurement, analysis and evaluation of risks (ISO, 2015).

This study is focused on the research stream of strategic QM. Through an on-field investigation, it focuses on

- 1 how we can appraise risk regarding product quality at the certain stages of its production process
- 2 which are relevant features of an NC that can allow an efficient NC management and control.

Under academic perspective, the present work gives its contribution in the domain of multi-criteria NC evaluation by means of Artificial Intelligence tools, demonstrating that such tools might allow the appraisal of hidden or unspoken features that, albeit being hardly quantifiable, may still have a big relevance within a firm's quality management system.

From practitioners' point of view the present work is intended to add a practical contribution in terms of how to approach the NC appraisal and management abiding by the new requirements of ISO 9001:2015 standard.

## *2.2 Fuzzy techniques for quality management*

As regards the above objectives, fuzzy sets can be a practical tool to for features evaluations, being widely acknowledged as a suitable mathematical tool to deal with information of different origin and affected by uncertainty and subjectivity (Savino and Mazza, 2014). In recent years fuzzy theory has been considered a key technique for QM within manufacturing system (Yaqiong et al., 2011). In some previous work it has been used to control the key quality parameters, grade product quality to reduce parameters variability and better adjust specification limits (Taylan, 2011).

The core of a fuzzy model is the fuzzy engine (FE), in which an inference process is developed with a set of fuzzy rules and one or more basic conditions (Savino and Mazza, 2014). Fuzzy theory was developed based on the premise that the key elements in human thinking are not numbers, but linguistic terms that can be modelled by fuzzy sets. Under QM perspective, fuzzy approaches have been explored in quality function deployment for modelling customer preferences/attributes and engineering characteristic (Chougule et al., 2013). Earlier, Lao et al. (2012) developed an intelligent food QM system facilitating the selection of the most appropriate quality control operations and suggesting the best storage environment. Syn et al. (2011) developed an expert system using fuzzy logic model to predict the effect of carbon dioxide on laser cutting quality. Fuzzy techniques have been also applied by Kumru and Kumru (2013) to failure mode and effects analysis (FMEA), as one of the well-known techniques of quality management in product or process designs, or to FMECA by Savino et al. (2011). Fuzzy sets applied to QMS can be found also in the work of Savino and Sekhari (2009), and in the one of Lau et al. (2009), who addressed the hidden relationships among process variables with fuzzy association rules.

## **3 Research questions and framework**

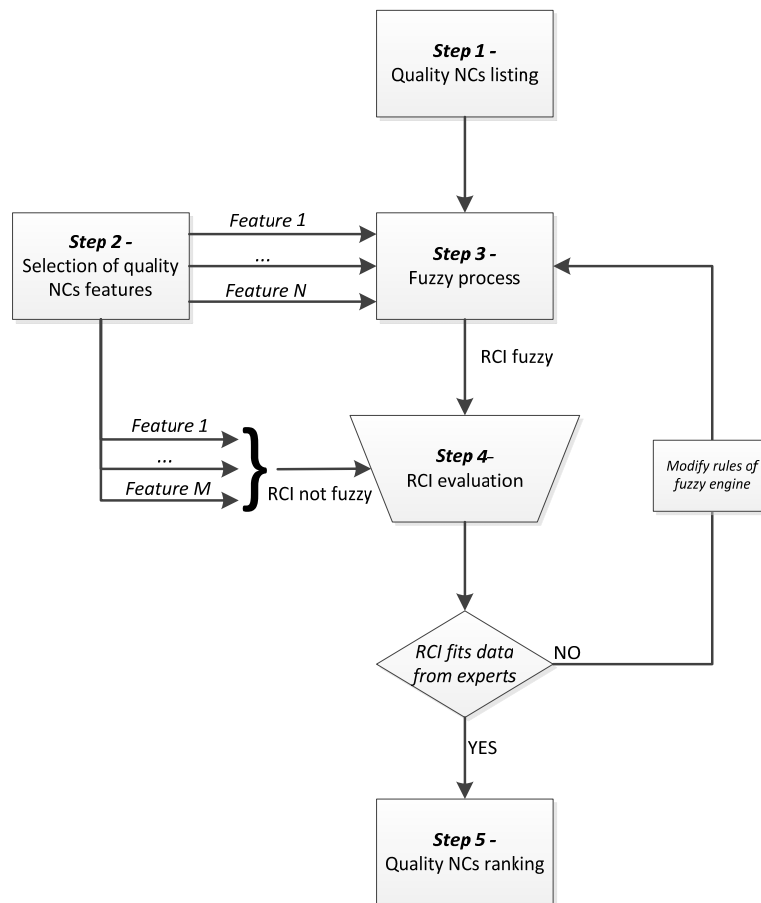
In current literature on QMS, NC classification is based on their frequency and on the impact on final product (Wu et al., 2006; Mazzuto and Paciarotti, 2014). Approaches relative to NC classification and coding are mostly related to product features and defectiveness reduction. Under this perspective, Sun and Liu (2011) focused on reduction of surface quality-related problems of plastic products through raw material selection and debugging of shaping process. Similarly, Savino et al. (2008) defined a set of pointers to front quality NCs and to measure production improvements. Based on these works, we may assert that such QM techniques are post-process based. To comply with the new ISO 9001:2015 requirements, the control of process NC and their monitoring needs also to manage the potential risks relative to NCs. Based on this assumption, different aspects should be selected to completely characterise the risks relative to a NC. Then, these aspects should give the possibility to appraise the CA priority for each NC. According to these considerations, this focused on practice investigation is aimed to answer the following research questions:

RQ1 What are the main factors that may characterise a quality NC?

RQ2 How Fuzzy sets can help in NC ranking as regards to its potential risks?

The empirical study to answer RQ1 is conducted by investigating which can be the most important features of an NC and how they can impact on NC criticality and their prioritisation for CA. We start from audit development and NC detection (Bernardo et al., 2009). With the data of the NC detected on the production line, RQ1 is investigated by addressing each NC for a set of features with respect to the elements of resource related to the traditional and strategic definition of quality (Fiegenwald et al., 2014). This investigation resulted in a set of features based on the above literature review and through the analysis of the claims and the NC detected.

**Figure 1** Research methodology



Answering to RQ2 addresses the requirement of ISO 9001:2015 relative to the control of NC for process outputs. This portion of research required the development of an assessment method for NC criticality within the QMS. This task is pursued by means of the FE. The main objectives are:

- 1 to address the linguistic definitions used by NC auditors for NC classification
- 2 to appraise the NC criticality the QMS as regards where the NC is detected in the production/logistic processes.

This portion of research is developed through a *risk criticality index* – *RCI* computed combining risk priority number (RPN) of failure mode effect analysis (Savino et al., 2011) along with the approach of Liukkonen et al. (2011). The research methodology is structured in Figure 1.

In defining the *RCI*, we are also consistent with the findings of Lari et al. (2002), and Nikolaidis and Nenes (2008) who demonstrated the importance of an effective NC ranking. According to Di Foggia and D’Addona (2013) and Colledani and Tolio (2011) the main factors of risk for an NC are the *cost* (*C*) of the product, the *percentage* (*P*) of the defectiveness and the *NC gravity* (*G*).

The evaluation of *G* risk factor was developed by addressing the *detection point* (*DP*) of the NC. The *DP* is defined as the point in which the NC is detected, linking the *RCI* to the criticality factors by (1).

$$RCI = f(P, C, G, DP) = f\left(P, C, G \sum n_{occ@DP} * DP\right) \quad (1)$$

where  $n_{occ@DP}$  is the number of occurrences of that NC for each *DP*.

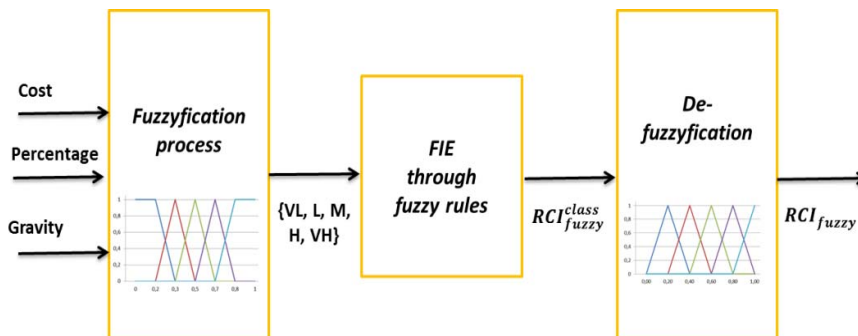
The gravity scale for *DP* is derived by the Likert five point-scale 1:5, usually adopted to assist practitioners for prioritising service attributes to enhance service quality and customer satisfaction (Zhao et al., 2004).

The development of (1) requires a common definition of NC criticality that may encompass *P*, *C* and *G* parameters. For this task the FE has been developed based on two objectives:

- 1 to address the linguistic definitions used by the auditors for NC classification
- 2 to define a fuzzy criticality index ( $RCI_{fuzzy}$ ).for the evaluation of NC criticality.

The suitability of the fuzzy sets to link the linguistic definitions used by NC auditors (Figure 2) was suggested by its previous use in the QMS to process audit data coming from different sources (Chougule, 2013; Yaqiong et al., 2011).

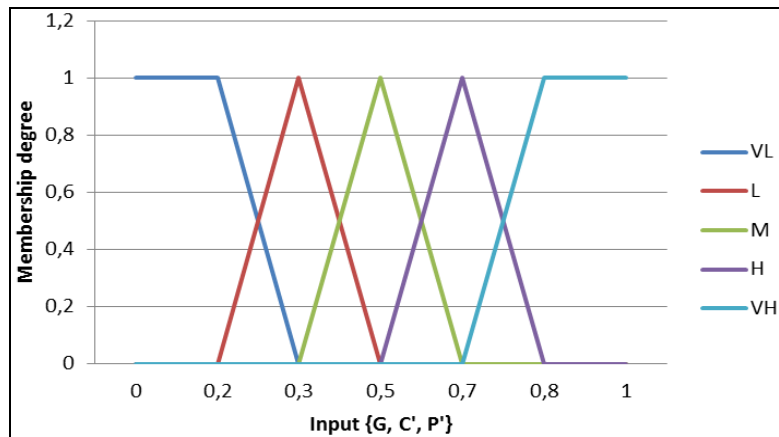
**Figure 2** Fuzzy inference engine (see online version for colours)



The FE is realised with the fuzzy toolbox of Matlab r2010a. It receives in input the classes shown in Figure 4, linked by triangular membership degree (MD) to the crisp

values of  $C$ ,  $P$  and  $G$ . To design the  $FE$ , we followed the research results of Aghaarabi et al. (2008) who used the opinions of quality experts in appraising NC criticality classes to model the inferential rules. Each range of the five fuzzy levels is associated through mixed trapezoidal-triangular functions (Figure 3) already used by Savino and Sekhari (2009) and by Savino and Mazza (2014) to model the linguistic evaluation of NCs.

**Figure 3** MF and classes (see online version for colours)



#### 4 The industrial context

The model is developed within a plant featured by a product mix made of 30 different products. Within this plant, the test bed is a production line of vacuum and water pumps that are around the 20% of the total production.

The line is composed of 15 automatic stations, plus one loading-unloading station and two components-feeding stations. It operates on two working shifts per day with a cycle time of about 20 seconds.

The line is featured by the following main parameters:

- production rate: three pieces/minute
- workforce required to run the line: three operators
- operators saturation rate: 15% (for manual activities such as loading/unloading components)
- incidence of quality controls on product costs: 20%
- NC costs (average): 11€/NC (only scrapped materials costs; does not include the 'hidden factory' costs, e.g., loss of productivity)
- average number of NC (monthly basis): 60 NCS/month.

In this current configuration the quality control is made at the unloading station. This caused often expensive recovery, repairing or replacement activities due mainly to:

- 1 the disposal of the entire product after the NC detection at the end of the line



- 2 the difficulty to prevent the NC due to a not complete addressing of their causes
- 3 the potential detection of an NC also by the end users.

Different CAs were performed for NCs addressing the same cause. Internal audits to determine the effectiveness of each CA were scheduled on an empirical basis, without accomplishing some of the following basic requirements for NC management within ISO 9001:2015:

- 1 planning the activities to verify the product at different stages of the production process
- 2 addressing the potential risk relative to NC and their control by the CAs.

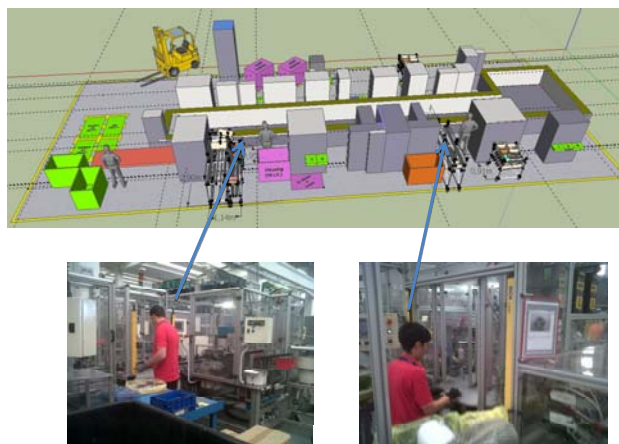
In this context, the research was carried out with a twofold objective. The first one is to control process outputs by determining the NC criticality. The second objective is to investigate how different quality aspects may impact on NC criticality and which of them may have more influence. These objectives are pursued by assessing QA with respect to the involved resources and factors by customer's and firm's side.

## 5 Data development and results

The research methodology was implemented by setting along the production process the following quality control (QC) points

- material acceptance
- station #2
- station #7
- final quality control (end of line)
- customer.

**Figure 4** The in-process QC points set on the production line (see online version for colours)



QC points on the line (Figure 4) have been set at the stations where the feeding of the components is made (#2, #7) and at the end of the line. In the study, around 350 NC occurrences were detected during a production interval (PI) of six months.

Table 1 provides a list of the most frequent NCs detected, that are classified as regards to the description given by the auditor. Then, the NCs are analysed through the risk priority number (RPN), in which the RPN encompasses the three main domains of a failure, namely *severity*, *occurrence* and *detectability* (Savino et al., 2011).

**Table 1** The NCs detected

<i>NC #</i>	<i>Description</i>
1	Packaging cap not present
2	Hydraulic leak
3	Not fastened screw(s)
4	Corteco coupling error
5	Defective valve
6	Gasket fastening
7	Scratches

In this approach we characterise an NC through  $P$ ,  $C$ ,  $G$ ,  $DP$  values of 1. The evaluation of these parameters is set as follows:

$$P = \sum_{i=1}^n NC_i^j / NC_{tot} \quad (2)$$

where

$NC_i^j$  is the number of  $i$  occurrences of the  $j$  NC

$NC_{tot}$  is the total number of NCs occurred on the production lines.

- $C$  is the cost of the product affected by the NC.
- $G$  is related to the perception and consequences of the non-conformity.  $G$  values can range from 0 if the defect is not detectable by the customer to 1 if the NC causes product disposal.
- $DP$  gives a measure of the risk relative to NC detection. The criteria in assigning possible  $DP$  values is consistent with Al-Khalili and Subari (2013) and with Shetwan et al. (2011) the later the NC is detected along quality control stations, the higher is the  $DP$  values. Table 2 reports the possible values proposed for  $DP$  within the NC analysis of the case study.

**Table 2** NC Detection points

<i>DP</i>	<i>Detection point</i>
1	Material acceptance
2	Station #2 of the production line
3	Station #5 of the production line
4	Final quality control
5	Customer

The approach is developed within the described assembly line based on the occurrences of the NCs detected during the PI.

### 5.1 Fuzzy inference engine

The criticality level of each NC is expressed in [1,100] scale. It has been investigated through a survey on the opinions of five different quality managers [#1 to #5] over a set of 14 different NCs. Table 3 shows the results of this survey for the seven most frequent types of NCs.

**Table 3** Criticality survey results

NC	Quality manager				
	#1	#2	#3	#4	#5
Packaging cap not present	20	15	25	20	20
Hydraulic leak	50	60	40	50	40
Not fastened screw(s)	65	60	60	50	65
Corteco coupling error	70	65	75	80	75
Defective valve	65	60	60	55	60
Gasket fastening	75	70	80	90	80
Scratches	15	20	25	25	20

The inferential rules of the FE have been set (Aghaarabi et al., 2013) with the contribution of these results, by linking the fuzzy values of  $P$ ,  $C$ ,  $G$  to the criticality index (CI) with rules reflecting the criticality of each NC type. We adopted as value of CI the mean of the five different values given by the auditor.

Reproducibility is the variation in measurements occurring by resorting to different appraisers. In order to assess the reproducibility we followed the guidelines for measurement system analysis developed by AIAG (AIAG, 2010) as follows. ‘Between appraisers variation’ (AV), is an estimation of the standard deviation of the variation due to reproducibility, and is calculated as follows:

Let:

- $\bar{X}_i$  be the average of all CI by the  $i^{\text{th}}$  assessor;
- $\bar{X}_{diff}$  be the range of all  $\bar{X}_i$ .

Then:

$$AV = \bar{X}_{diff} * K_2 \quad (3)$$

where  $K_2$  is a constant; in case of five appraisers,  $k_2 = 0.403$

Appraisers are not using measuring tool, hence we did not calculate the ‘equipment variation’.

‘Part variation’, PV, measures the variability between the averages CI of the various NCs, and is an estimation of the standard deviation of the so-called part-to-part variation. As we are considering more than 10 parts, it is advisable to calculate the part variation directly as a sample standard deviation, rather than estimating it through the average

range, since the range statistics efficiency plummets for  $n > 10$ . The total variation (TV) is expressed by equation (4)

$$TV = (PV^2 + AV)^{0.5} \quad (4)$$

By applying the (3) and (4) we obtained:

$$AV = 1.439$$

$$PV = 26.355$$

$$TV = 26.395$$

According to the standards in use in the automotive industry, a measurement system is considered acceptable when the ratio  $\%AV = AV/TV$  is less than 10%. In our case,  $\%AV = 5.5\%$ , so we concluded that the judgement of appraisers does not significantly affect the assessment of CI values.

Then, the final CI calculations for the most frequent types of NCs are summarised in Table 4.

**Table 4** Output of the data processing

#	NC	Gravity [0,1]	Cost [€]	Occurrences – detection point					Criticality index [1–100]
				DP1	DP2	DP3	DP4	DP5	
1	Packaging cap not present	0.4	3.00	32					20
2	Hydraulic leak	0.5	7.00		17	13			48
3	Not fastened screw(s)	0.3	7.00				27		60
4	Corteco coupling error	0.2	3.00		47				73
5	Defective valve	0.9	9.95				20		60
6	Gasket fastening	0.5	13.00					4	79
7	Scratches	0.3	6.00	10					21

The input values of fuzzy functions for  $P$  and  $C$ , namely  $P'$  and  $C'$ , are as the following:

- $P' = \frac{P}{P_{\max}}$  where  $P_{\max}$  is the incidence of the most common NC in the PI
- $C' = \frac{C}{C_{\max}}$  where  $C_{\max}$  is the higher production cost of all the products in the PI.

The fuzzy process works as follows:

Values  $P$  and  $C$  are divided by the corresponding maximum ranges. With respect to the case study,  $P_{\max} = 4.2\%$  and  $C_{\max} = 13$ . Then, according to  $G$ ,  $P'$  and  $C'$  it is possible to evaluate the MD and the corresponding membership class. As an example, for the NC#1:

- $G = 0,4 \rightarrow$  NC belongs in *L* class ( $NC1G'_{class} = L$ ) with  $MD = 0.5$  ( $NC1G'_{md} = 0.5$ ) and to *M* class ( $NC1G''_{class} = M$ ) with  $MD = 0.5$  ( $NC1G''_{md} = 0.5$ )
- $P' = 0,50 \rightarrow$  NC belongs to *M* class ( $NC1P_{class} = M$ ) with  $MD = 1$  ( $NC1P_{md} = 1$ )
- $C' = 0,23 \rightarrow$  NC belongs to *VL* class ( $NC1C'_{class} = L$ ) with  $MD = 0.78$  ( $NC1C'_{md} = 0.78$ ) and to *L* class ( $NC1C''_{class} = L$ ) with  $MD = 0.22$  ( $NC1C''_{md} = 0.22$ ).

Table 5 reports the values of four NCs detected during the PI and their costs. The results of the FE, with MD and classes, are shown in Table 6.

**Table 5** NC values

#	Non conformity description	Gravity – $G$	Percentage – $P$ [%]	Cost – $C$ [€]	$P'$	$C'$
1	Packaging cap not present	0.4	2,1	3	0.50	0.23
2	Hydraulic leak	0.5	2,0	7	0.48	0.54
3	Not fastened screw(s)	0.3	1,8	7	0.43	0.54
4	Corteco coupling error	0.2	3,1	3	0.75	0.23

**Table 6** MD values

NC#	Gravity – $G$	MD and class – $G$	$P'$	MD and class – $P'$	$C'$	MD and class – $C'$
1	0.4	$NC1G'_{md} = 0.5$ $NC1G'_{class} = L$ $NC1G''_{md} = 0.5$ $NC1G''_{class} = M$	0.50	$NC1P_{class} = M$ $NC1P_{md} = 1$	0.23	$NC1C'_{md} = 0.78$ $NC1C'_{class} = VL$ $NC1C''_{md} = 0.22$ $NC1C''_{class} = L$
2	0.5	$NC2G_{class} = M$ $NC2G_{md} = 1$	0.48	$NC2P'_{class} = L$ $NC2P'_{md} = 0.05$ $NC2P''_{class} = M$ $NC2P''_{md} = 0.95$	0.54	$NC2C'_{md} = 0.77$ $NC2C'_{class} = M$ $NC2C''_{md} = 0.23$ $NC2C''_{class} = H$
3	0.3	$NC3G_{class} = L$ $NC3G_{md} = 1$	0.43	$NC3P'_{class} = L$ $NC3P'_{md} = 0.4$ $NC3P''_{class} = M$ $NC3P''_{md} = 0.6$	0.54	$NC3C'_{md} = 0.77$ $NC3C'_{class} = M$ $NC3C''_{md} = 0.23$ $NC3C''_{class} = H$
4	0.2	$NC4G_{class} = VL$ $NC4G_{md} = 1$	0.75	$NC4P'_{class} = H$ $NC4P'_{md} = 0.5$ $NC4P''_{class} = VH$ $NC4P''_{md} = 0.5$	0.23	$NC4C'_{md} = 0.78$ $NC4C'_{class} = VL$ $NC4C''_{md} = 0.22$ $NC4C''_{class} = L$

Once variables  $P'$ ,  $C'$  and  $G$  have been made as fuzzy values, one of the five fuzzy classes is associated to  $RCI_{fuzzy}$ , according to a set of fuzzy rules obtaining  $RCI_{fuzzy}^{class}$ .

By fixing a class for  $G$ , fuzzy rules matrixes allow to get the class assignment for  $RCI_{fuzzy}^{class}$  according to membership classes of  $C'$  and  $P'$ .

Tables from 7a to 7e report the five matrixes for gravity values from  $VL$  to  $VH$ , respectively

**Table 7a** Fuzzy rules –  $G=VL$

$C' \backslash P'$	$VL$	$L$	$M$	$H$	$VH$
$VL$	$VL$	$VL$	$L$	$M$	$H$
$L$	$VL$	$L$	$M$	$M$	$H$
$M$	$L$	$L$	$M$	$M$	$H$
$H$	$M$	$M$	$M$	$H$	$H$
$VH$	$M$	$M$	$H$	$H$	$H$

**Table 7b** Fuzzy rules –  $G=L$

$C' \backslash P'$	$VL$	$L$	$M$	$H$	$VH$
$VL$	$L$	$L$	$L$	$M$	$H$
$L$	$L$	$L$	$L$	$M$	$H$
$M$	$L$	$L$	$L$	$M$	$H$
$H$	$M$	$M$	$M$	$H$	$H$
$VH$	$M$	$M$	$M$	$H$	$H$

**Table 7c** Fuzzy rules –  $G=M$

$C' \backslash P'$	$VL$	$L$	$M$	$H$	$VH$
$VL$	$L$	$M$	$M$	$H$	$H$
$L$	$L$	$M$	$M$	$H$	$H$
$M$	$M$	$M$	$M$	$H$	$H$
$H$	$M$	$M$	$M$	$H$	$H$
$VH$	$H$	$H$	$H$	$H$	$H$

**Table 7d** Fuzzy rules –  $G=H$

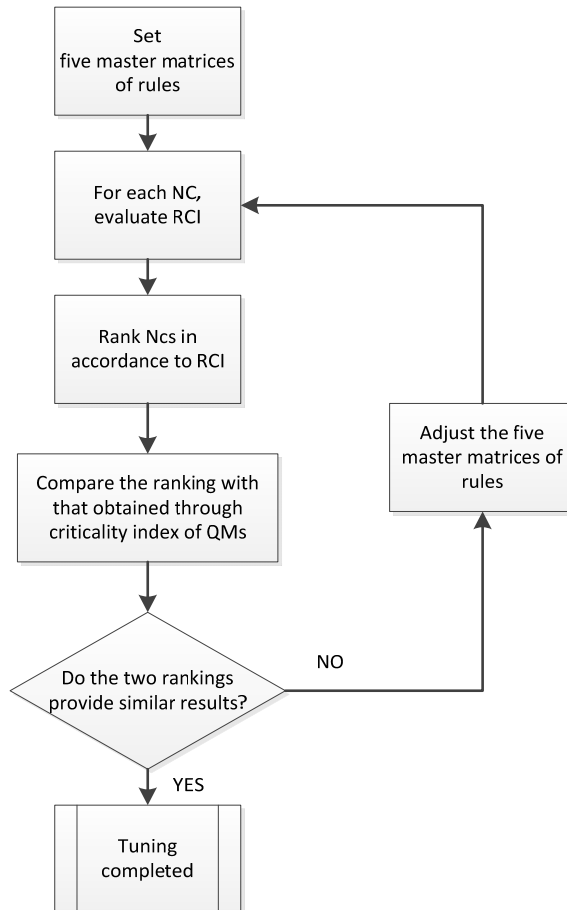
$C' \backslash P'$	$VL$	$L$	$M$	$H$	$VH$
$VL$	$M$	$M$	$H$	$H$	$H$
$L$	$M$	$M$	$H$	$H$	$H$
$M$	$M$	$M$	$H$	$H$	$VH$
$H$	$M$	$H$	$H$	$H$	$VH$
$VH$	$M$	$H$	$H$	$VH$	$VH$

**Table 7e** Fuzzy rules –  $G=VH$

$C'$ \ $P'$	$VL$	$L$	$M$	$H$	$VH$
$VL$	H	H	VH	VH	VH
$L$	H	H	VH	VH	VH
$M$	H	H	VH	VH	VH
$H$	H	VH	VH	VH	VH
$VH$	H	VH	VH	VH	VH

The rules of the FE were established with the principle of giving higher priority to those NCs that may generate risks toward customers' side and that are frequent. From an operative point of view, we started from the above set of five master matrices of rules. Then, according to the results of the auditors, rules have been modified to guarantee a good correspondence between the NCs ranking obtained from the criticality index of Table 4 and through the RCI. In Figure 5 the flowchart of the tuning procedure is reported.

**Figure 5** FE rules tuning



As an example, the output of such tuning provided the following implications:

- $\{G' = VH; P' = VL; C' = VL\} \rightarrow RCI_{fuzzy}^{class} = H$
- $\{G' = VL; P' = VH; C' = VL\} \rightarrow RCI_{fuzzy}^{class} = H$
- $\{G' = VL; P' = VL; C' = VH\} \rightarrow RCI_{fuzzy}^{class} = M.$

With reference to the NC#1

- $\{NC1G'_{class} = L, NC1P_{class} = M, NC1C'_{class} = VL\} \rightarrow RCI1'_{fuzzy}^{class} = L;$   
 $MD1' = 0.5 \times 1 \times 0.78 = 0.39$
- $\{NC1G'_{class} = L, NC1P_{class} = M, NC1C''_{class} = L\} \rightarrow \text{implies } RCI1''_{fuzzy}^{class} = L;$   
 $MD1'' = 0.5 \times 1 \times 0.22 = 0.11$
- $\{NC1G''_{class} = M, NC1P_{class} = M, NC1C'_{class} = VL\} \rightarrow \text{implies } RCI1''_{fuzzy}^{class} = M;$   
 $MD1'' = 0.5 \times 1 \times 0.78 = 0.39$
- $\{NC1G''_{class} = M, NC1P_{class} = M, NC1C''_{class} = L\} \rightarrow \text{implies } RCI1'''_{fuzzy}^{class} = M$  with a membership degree  $MD1''' = 0.5 \times 1 \times 0.22 = 0.11.$

Table 8 reports MD values and classes for  $RCI_{fuzzy}$  for the NCs.

**Table 8** MD and classes for  $RCI_{fuzzy}$

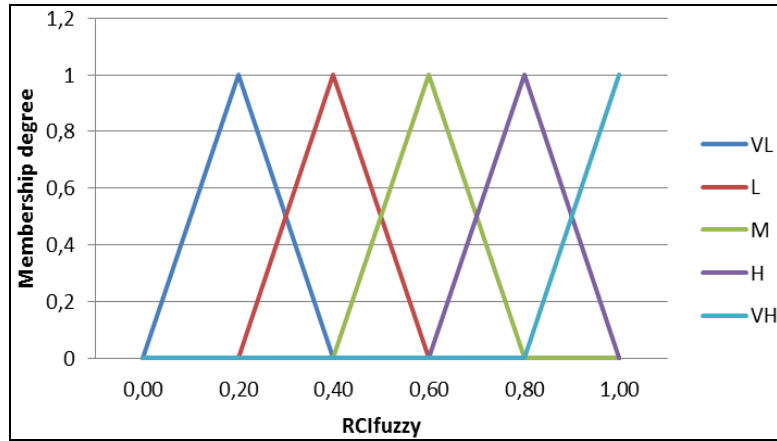
NC#	MD and class – G	MD and class – P'	MD and class – C'	MD and class – $RCI_{fuzzy}$
1	$NC1G'_{md} = 0.05$ $NC1G'_{class} = L$	$NC1P_{class} = M$ $NC1P_{md} = 1$	$NC1C'_{md} = 0.78$ $NC1C'_{class} = VL$	$RCI1_{fuzzy}^{class} = L, MD1' = 0.5$
	$NC1G''_{md} = 0.05$ $NC1G''_{class} = M$		$NC1C''_{md} = 0.22$ $NC1C''_{class} = L$	$RCI1_{fuzzy}^{class} = M, MD1'' = 0.5$
2	$NC2G_{class} = M$ $NC2G_{md} = 1$	$NC2P'_{class} = L$ $NC2P'_{md} = 0.05$	$NC2C'_{md} = 0.77$ $NC2C'_{class} = M$	$RCI2_{fuzzy}^{class} = M, MD2 = 0.26$
		$NC2P''_{class} = M$ $NC2P''_{md} = 0.95$	$NC2C''_{md} = 0.23$ $NC2C''_{class} = H$	
3	$NC3G_{class} = L$ $NC3G_{md} = 1$	$NC3P'_{class} = L$ $NC3P'_{md} = 0.4$	$NC3C'_{md} = 0.77$ $NC3C'_{class} = M$	$RCI3_{fuzzy}^{class} = L, MD3' = 0.31$
		$NC3P''_{class} = M$ $NC3P''_{md} = 0.6$	$NC3C''_{md} = 0.23$ $NC3C''_{class} = H$	$RCI3_{fuzzy}^{class} = M, MD3'' = 0.14$
4	$NC4G_{class} = VL$ $NC4G_{md} = 1$	$NC4P'_{class} = H$ $NC4P'_{md} = 0.5$	$NC4C'_{md} = 0.78$ $NC4C'_{class} = VL$	$RCI4_{fuzzy}^{class} = M, MD4' = 0.39$
		$NC4P''_{class} = VH$ $NC4P''_{md} = 0.5$	$NC4C''_{md} = 0.22$ $NC4C''_{class} = L$	$RCI4_{fuzzy}^{class} = H, MD4'' = 0.11$



## 5.2 RCI evaluation

According to the requirements of ISO 9001:2015 as regards risks analysis, the potential prioritisation of NCs is investigated starting with the  $RCI$  values and its classes. Based on previous findings, this study uses the  $VL$ ,  $L$ ,  $M$ ,  $H$ , and  $VH$  classes defined by triangular MFs (Figure 6).

**Figure 6** MF for  $RCI_{fuzzy}$  value (see online version for colours)



Referring to the example of NC#1, the de-fuzzy process to obtain the crisp values works as follows

- $RCI_{fuzzy}^{class} = L$  with the membership degree of 0.5 contributes to the CI, labelled as  $CI' = 0.3$
- $RCI_{fuzzy}^{class} = M$  with the membership degree of 0.5 contributes to the CI, labelled as  $CI'' = 0.5$
- The overall priority number is obtained as the weighted average of these two contributions with the respective membership degree:

$$NC\#1 \rightarrow RCI_{fuzzy} = \frac{0.5 \times 0.3 + 0.5 \times 0.5}{0.5 + 0.5} = 0.40$$

Table 9 shows the  $RCI_{fuzzy}$  values for the four NCs of the assembly line described in Table 5.

The assignment of the RCI is now made according to equation (5):

$$RCI = f(RCI_{fuzzy}, RCI_{notfuzzy}) = RCI_{fuzzy} \sum n_{occ@DP} * DP \quad (5)$$

NC#1 has been detected 32 times in material acceptance ( $DP = 1$ ), generating  $RCI = 12.8$ . Table 10 gives the DP values and RCI for the four NCs. From that, we can see how NC#1 has the lowest criticality value with respect to the NC#3, even if it presents a higher  $RCI_{fuzzy}$ . This is due to the detection points of NC#3, that increases the  $RCI$  value.

**Table 9**  $RCI_{fuzzy}$  values

$NC\#$	$MD$ and $class - QPN_{fuzzy}$	$RCI_{fuzzy}$ value
1	$QPN1^{class}_{fuzzy} = L; MD1' = 0.5$ $QPN1^{class}_{fuzzy} = M; MD1'' = 0.5$	0.4
2	$RCI2^{class}_{fuzzy} = M; MD2 = 0.26$	0.43
3	$RCI3^{class}_{fuzzy} = L; MD3' = 0.30$ $RCI3^{class}_{fuzzy} = M; MD3'' = 0.14$	0.30
4	$RCI4^{class}_{fuzzy} = M; MD3' = 0.39$ $RCI4^{class}_{fuzzy} = h; MD4'' = 0.11$	0.51

**Table 10**  $RCI$  values

$NC$	$RCI_{fuzzy}$ value	$Detection\ points$					$RCI$	$Criticality\ index\ [1-100]$
		1	2	3	4	5		
1	0.4	32					$0.4 \times 32 = 12.8$	20
2	0.43		17	13			$0.43 \times (17 \times 2 + 13 \times 3) = 31.39$	50
3	0.30				27		$0.30 \times 27 \times 4 = 32.4$	60
4	0.51					47	$0.51 \times 47 \times 2 = 47.94$	75

From Table 10 we may see how DP values strongly impact on the overall criticality, modifying the final ranking of the NCs. Compared to the ranking imposed by the CI of the case study, we may see how this approach is able to reflect the same criticality order through  $RCI$ . It is worth mentioning that, differently from the [1–100] scale of the criticality index,  $RCI$  has not upper bound, depending on the number of occurrences of the NC at the different detection points.

## 6 Discussion

Table 4 and Table 5 empirically support the following answer to RQ1: The NC are now analysed with respect to their main elements of risk and through the use of specific detection points. This potentially extends the finding of Colledani and Tolio (2011) and of Shetwan et al (2011) toward the two statements that

- 1 the occurrence of NC and its detection stage is more important than the impact of the same NC on product costs
- 2 the propagation of the NC within the production stages impacts on NC criticality more than the percentage of the same NC.

In answering to RQ1, we may argue that the DP should to be included in QA, since a different criticality can be assigned to a certain NC as regards to its DP, starting from material acceptance up to customer delivering. Table 9 and Table 10 may give an answer to RQ2. Through the FE, the analysis of the four NCs allowed to combine the elements of

risk characterising a NC, obtaining a RCI that reflects its ranking. The RCI defines the rank for CA priorities, answering to RQ2 and being consistent with the importance of an effective appraisal of NC criticality. This answer potentially extends the ambiguous results of others (Colledani and Tolio, 2011; Sun and Liu, 2011) as regards the determination of priorities for NCs resolutions. The assessment method developed in this study can be considered as the first step towards the compliance of new ISO 9001:2015 Standard as regards the addressing of risks related to product nonconformities. The output of the FE and the RCI values of Table 10 potentially extend the finding of Wu et al. (2006) and Chougule et al. (2013) toward the statement that a QMS should always have a concurrent appraisal of NC with

- 1 artificial intelligence tools
- 2 data mining techniques.

An interesting aspect of the approach lies in its dynamicity and flexibility. By appropriate changes on the FE, it has the possibility to update and modify NCs ranking in different industrial environments. Such changes can have different impacts on production costs. By updating variables boundaries it is possible to adapt the system to the new production context. For example,  $C_{max}$  depends on firm production mix and market conditions, which can modify production costs, while  $P_{max}$  depends on the ability of the firm to properly front NC, thus measuring quality performances.

By stressing on the importance to anticipate the detection of NCs, this focused-on-practice study may suggest the first way to be compliant with the requirements of the new ISO 9001:2015 as regards to NC management and with reactive QC approaches (Lou and Huang, 2003).

In this sense, equation (3) shows that the contribution to RCI is provided by the DP values. As per Table 10, an NC with high cost, high percentage and high gravity but detected at  $DP = 2$  will have a lower rank than a NC with a lower cost, percentage and gravity, but detected by the customer ( $DP = 5$ ).

Table 11 reports the incidence of NC costs on production costs ( $NC_c/P_c$ ) computed during the pilot study.

From this table, we may note that NC #4 has quite a high incidence on production costs if compared with the other NCs. Without the developed system the quality manager would have prioritised the NC with higher severity, even if it has the lowest incidence on production costs. This analysis confirms that the approach developed within this study is able to give the correct priorities to those NC that may have a real impact on the overall firm's performances.

**Table 11** Incidence of NC costs on production costs

<i>NC#</i>	<i>Gravity – G</i>	<i>P'</i>	<i>C'</i>	<i>NC<sub>c</sub>/P<sub>c</sub></i>
1	0.4	0.50	0.23	10%
2	0.5	0.48	0.54	11.5%
3	0.3	0.43	0.54	11%
4	0.2	0.75	0.23	15%

Based on the above findings, our work empirically supports the following industrial implications:

- 1 the compliance of ISO 9001:2015 requires the evaluation of the risk of the NC along production and logistic chain, and this requirement is more relevant than the traditional element of resources of NC
- 2 some new requirements of the new ISO 9001:2015 may be supported by artificial intelligence tools for NC control and to evaluate NC priorities.

Based on the results of Tables 9 and 10, the following points can be made:

- 1 with the ISO 9001:2015 Standard, NC may be perceived as a QMS resource, providing information on which can be the elements addressing the risks relative to product quality
- 2 the FE that drives NC evaluation suggests that IT and artificial intelligence tools may exist among the new core resources of QMS developed according to the new ISO 9001:2015 standards.

## **7 Conclusions**

Most of the current research on QMS neither devoted a great deal of attention for NC addressing, nor investigated methods for driving integrations toward an efficient measurement of NC criticality.

The present study intended to fill this gap by investigating which may be the main elements of risk for NC and how these elements may contribute to evaluate NC criticality. The work has been developed within an industrial case regarding the definition of an objective and flexible tool related to NCs characterisation and prioritisation, to align the QC of a production line with the requirements of the new ISO standards.

Through the use of a FE, we contributed to bring clarity on NC management, control and prioritisation with a manifold approach for NC assessment towards the requirements of ISO 9001:2015. The main results overcome the potential subjectivities that can affect NCs evaluations, thus supporting the quality managers to propose the correct NC criticality for CA prioritisation.

All research works, no matter how well conducted, may have limitations. In this study, two main limitations occurred. First, the methodology was tested within one firm and with a limited audit dataset. This methodology should be tested across a wider range of data within a variety of firms. Secondly, the QC results may be obtained from

- 1 more auditors
- 2 in different production and services contexts.

Though these limitations, the approach can support quality managers to prioritize interventions, where CAs are now aimed mainly to anticipate detections through appropriate quality gates. In addition, response accuracy may be improved if measures are obtained from different sources. In light of these practical considerations, this study may suggest that the following future practical investigations are needed:

- 1 an assessment of the core resources for a QMS under the perspective of risk management
- 2 a way to measure the capability of firms to manage NCs
- 3 how to measure the attitudes of firms for risk management.

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