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Methodological design for the prevention of risk in production processes

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Received: April 2nd, 2014. Received in revised form: February 23th, 2015. Accepted: July 11th, 2015.

Abstract
This paper proposes a methodological design based on the development, creation, adaptation and implementation of some analysis tools and the deployment of the risk management process content in standard ISO 31000. This allows for the design of a monitoring and quality control system of critical variables associated with equipment and operating conditions for the purpose of identifying and mitigating sources diversions product specifications. It also seeks to harmonize work philosophies with international management standards. The validation was performed by an industrial company from the city of Barranquilla. The content of this paper provides professionals and industry with a way to address and improve the capacity of any type of manufacturing process in any organization through standardized steps.

Keywords: Statistical process control; risk management process; risk assessment; critical variables; analysis tools.

Diseño metodológico para la prevención de riesgos en procesos de producción

Resumen
La presente investigación propone un diseño metodológico fundamentado en el desarrollo, creación, adaptación e implementación de algunas herramientas de análisis y en el despliegue del proceso de gestión de riesgo contenido en la norma ISO 31000, permitiendo diseñar un sistema de monitoreo y control de calidad de variables críticas asociadas con condiciones de operación de equipos, para identificar y mitigar en línea potenciales fuentes de desviación de especificaciones de producto, armonizando filosofías de trabajo con normas internacionales de gestión y cuya validación se realizó en una empresa del sector industrial de la ciudad de Barranquilla. El contenido de este artículo ofrece a los profesionales e industriales una forma de abordar y mejorar cualquier tipo de proceso de fabricación en cualquier tipo de organización por medio de pasos estandarizados.

Palabras clave: Control estadístico de procesos; Proceso de gestión de riesgos; Evaluación del riesgo; variables críticas; herramientas de análisis.

1. Introduction

Organizations' concern to offer the best product or service requires the use of a large number of statistical tools and standards to achieve optimum quality, to meet needs and largely fulfill the expectations of its customers or users [1].

The statistical and quality tools have been widely used to assist the operation of production systems and compliance with products and services' specification requirements [2-9]. They are implemented by organizations to demonstrate their commitment and orientation to continuous improvement [10]. Moreover, risk management has been vital in the financial [11,12], the Project Management [13-16], the Health and Safety [17] and the information technology sectors [18].

Problems arise when it is necessary to combine statistical techniques with management rules for compliance with national and international standards.

Given that, until now, there is little evidence of the implementation of a risk-based approach in production systems. In this paper we present a methodological design that enables the integration of some statistical and quality

tools with the deployment of the risk management process contained in ISO 31000. It has been designed to become a useful tool for the detection and mitigation of defects in lines of production and the identification of potential sources of non-conformities, as well as harmonizing working philosophies with national and international standards of management. The methodological design has been implemented for industrial production, more precisely, in a company in the industrial sector in Barranquilla-Colombia that is dedicated to transformation of glass and aluminum.

This article is organized as follows. Section 2 describes our methodology and its constituent parts. The computational results are presented in Section 3 and show the effectiveness of our method and final remarks are made in Section 4.

2. Methodological design

The proposed methodological design has been established as a simple process that summarizes the steps to be followed in order for it to be implemented it in any production process. The steps begin with the identification and description of products and processes to be monitored and then the proposed actions to mitigate undesired deviations, risks and non-conformities identified in the manufacturing process are reviewed and monitored (Fig. 1).

Also, seeking to provide guidance and clarity the following section describes each of the steps:

- Identification and description: In this first step, processes and products which will be monitored are identified, a detailed description of the production stages, activities, working methods and resources used is presented. This seeks to find possible failings or deviations, risks and causes of nonconformity.
- Implementation and Classification: In this step, the implementing of the statistical and quality tools is classified using the cause-effect diagram, as well as the causes of nonconformities, deviations or risks identified in each process identified for monitoring. Additionally, instruments for monitoring and statistical process control are implemented by means of control charts, and finally, using the Pareto chart, occurrences of deviations or non-conformances are identified. The tools implemented at this stage will depend on the type of process that is being analyzed.
- Analysis: At this stage a statistical analysis of processes and data analysis of the occurrence of nonconformities based on the results obtained in the implementation stage and classification is performed.
- Mitigation: In order to reduce risks, deviations and non-conformities detected in the production process and the deployment of the risk management process is proposed according to ISO 31000. Also, containment actions, reaction actions and prevention actions will be implemented to mitigate the occurrence of nonconformities are identified.
- Monitoring and review: Being a process of continuous improvement, monitoring and reviewing of the effectiveness of the proposed actions is performed. At this stage, new actions are recommended in case the actions first suggested have not been effective, or if updating the system in the step of identifying of new risks is desired.

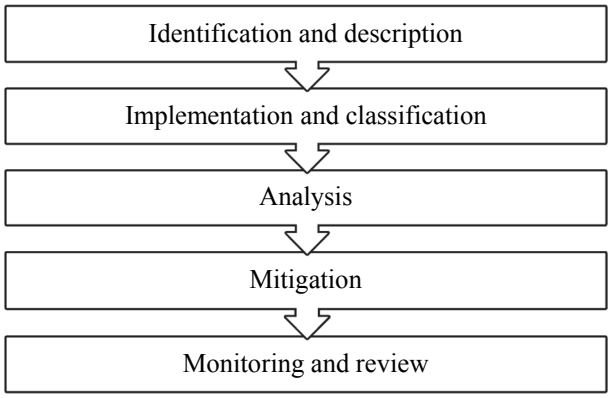

Figure 1. Steps to implement the methodological design.
Source: The authors.

3. Results and analysis

To validate the proposed methodological design that was described in the previous section, a company founded in Barranquilla, Colombia was identified that is dedicated to the manufacture and processing of glass and aluminum. We focus on the study and analysis of the glass production line, which consists of eight threads of transformation: cutting, polishing rectilinear, Polishing Curved, Pierced, washing and drying, design, Sandblasting and Tempered. The Flowchart Glass Production is shown in Fig. 2. For the purpose of showing the development of the methodological design its application in the Cutting process will be presented. There are similar results in the remaining processes.

3.1. Identification and description

Operations and tools used in the cutting process, particular aspects that may be relevant in the operation, the sequential steps in the processing activity of the glass and the identification and analysis of causes of nonconformities, deviations or related risks were identified.

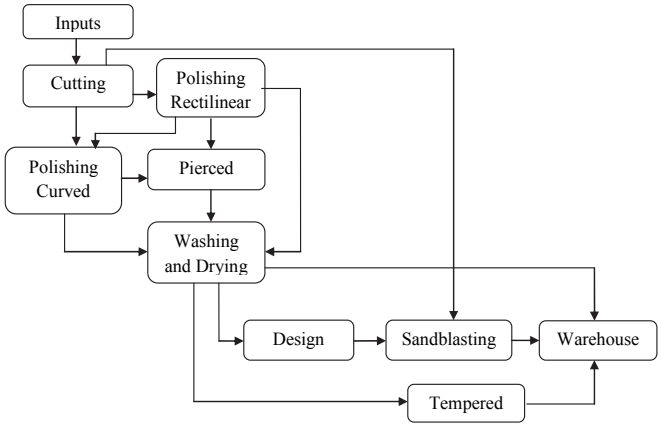

Figure 2. The Flowchart Glass Production. Source: own authorship
Source: The authors.

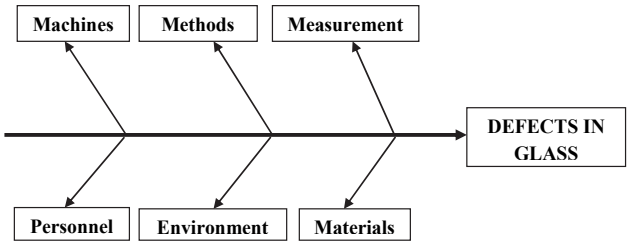

Figure 3. Cause-effect Diagram to Glass.
Source: Adapted from [19]

3.2. Implementation and classification

Table 1.
Causes of defects in glass

Sources	Causes
Personnel	- During the transfer to the buffer, the glass may break partially or completely if there is a lack of coordination among operators. - When removing the raw glass of the crate that protects it, may suffer bumps that can partially or completely break the module. - Failures may occur in the dimensions of the glass cut by poor fit of the measurement rule.
Methods	- On making the cut without lubricant, flaws can occur in the dimensions of the foil because when picking excess generated by the court, workers cannot follow the cut line and the separation extends in another direction causing damage to the glass. - The glass may suffer scratches due to the presence of glass shavings adhered to the cutting table by precuts. - For circular surfaces, not properly remove the excess glass, the court may deviate from the default line. - Scratches can occur due to inappropriate handling of the glass. - If the operator does not adequately remove small excesses of the cut edge, it can cause a defect of hoarfrost.
Machines	- The poor condition of the cutting tools can cause a bad cut which in turn is causing errors in dimensions.
Materials	- The glass that arrive from the warehouse of supplies would be spotting inside.
Measurement	- A wrong measurement on the sheet of glass to be cut can cause failures in the final dimensions of the sheet.
Environment	- Weather conditions and the characteristics of the warehouse caused the ingress of moisture which in turn causes spots on glasses temporarily stored.

Source: Adapted from [19]

In this second stage, by using the cause-effect diagram the classifying of origin of some of the deviations is achieved, and the risks and non-conformities are identified at the stage of identification and description. Some are shown in Fig. 3 and Table 1.

To determine the frequency of occurrence of defects in glass in the cutting process, (scratches, breaks, inadequate cuts and others) (See Figs. 4-6), the Pareto diagram is implemented, which looks to prioritize and recognize if the process is critical in the production line. The Pareto diagram is shown in Fig.5.

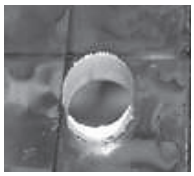

Figure 4. Hoarfrost

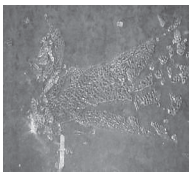

Figure 5. Break

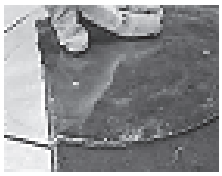

Figure 6. Cuts inadequate

Source: The authors

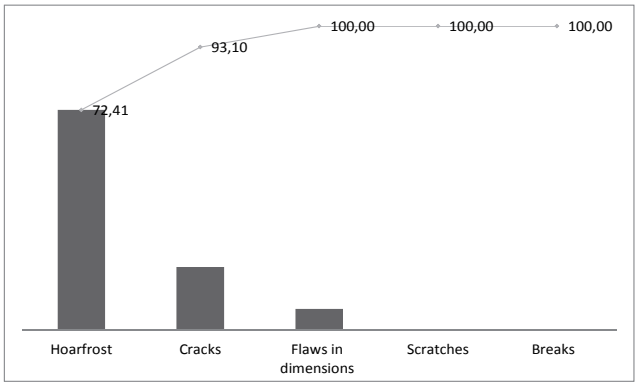

Figure 5. Pareto diagram for the cutting process
Source: The authors

Table 2.
Cutting process samples

Samples	Defects	Samples	Defects
1	3	21	4
2	1	22	6
3	1	23	5
4	5	24	3
5	3	25	0
6	0	26	1
7	5	27	3
8	0	28	2
9	5	29	0
10	3	30	5
11	1	31	4
12	2	32	4
13	0	33	0
14	3	34	3
15	0	35	3
16	1	36	2
17	1	37	0
18	0	38	4
19	1	39	2
20	0	40	2

Source: The authors

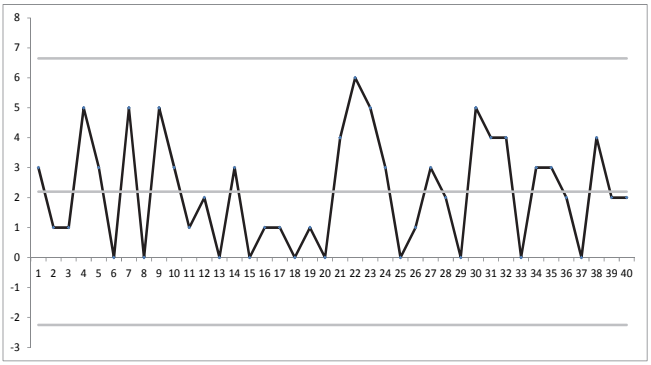

Figure 6. Control Chart "C" Cutting process
Source: The authors

Also, as a tool for monitoring and following up all processes in the manufacture of glass, chart "c" is used. This is because the behavior is analyzed for the occurrence of defects in a product unit, which is represented by a sheet of glass. To calculate the control limits, forty product samples were taken in each process and the defects found in each sample, caused by identified sources, were quantified. To determine the sample size Montgomery's [19] theory was used, which suggests that the sample size should provide a 50% probability of detecting a shift in the process. Evidence for this application is shown in Fig.6. Defects for 40 samples taken randomly from the cutting process are presented in Table 2.

After the processing of the data, the value of the lower, central and upper limits of the process were:

$$LCL = \bar{c} - 3\sqrt{\bar{c}} = -2.24 \quad (1)$$

$$CL = \bar{c} = 2.17 \quad (2)$$

$$LCL = \bar{c} + 3\sqrt{\bar{c}} = 6.59 \quad (3)$$

3.3. Analysis

The analysis was performed taking into account the classification of nonconformities by the cause-effect diagram. The analysis of the incidence of defects was prioritized through the Pareto and statistical control charts.

It is noted that in the process of cutting that about 93% of nonconformities correspond to Hoarfrost and Cracks, often caused by personnel and the methods used in the process. Furthermore, it is evident that the maximum number of defects per unit of product is 6.59 with a mean of 2.17. For this case, the lower control limit is negative so it is replaced with zero, since there can be no adverse effects in the glass.

3.4. Mitigation

This phase is performed under the general approach of the risk management process included in ISO 31000:2009, and it also takes into consideration the treatment and management of risk on causes of deviations or non-conformances identified in phase of identification and description.

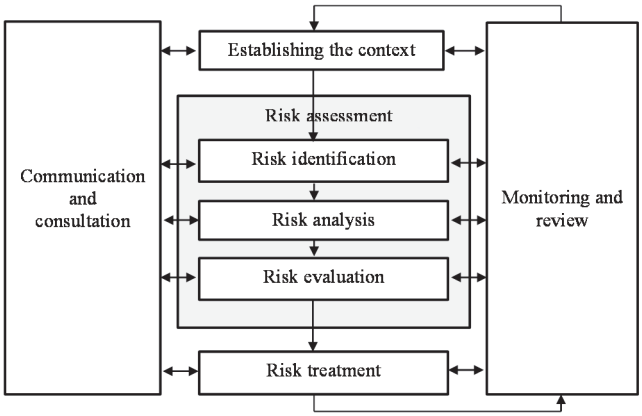

Figure 7. Risk management process - ISO 31000.
Source: [21, 22]

Table 3.
Matrix of Criteria and Consequences

			RISK CRITERIA		
			QUALITY	COST	TIME
CONSEQUENCES	5	CATASTROPHIC	Critical defects, unusable products	Loss of 100% of the product cost	5 or more weeks of delays in production or delivery times
	4	HIGHER	Major defects. Unacceptable to the customer	Increase of unit cost to 20-40% by reprocessing	Delays of 2 to 5 weeks are presented in the production or delivery times
	3	MEAN	Major defects. It requires reprocessing	Increase of unit cost to 10-15% by reprocessing	Delays of 1 to 2 weeks are presented in the production or delivery times
	2	LESSER	Minor defects	Increase of unit cost to 5% by reprocessing	Insignificant delays in production or delivery times
	1	UNIMPORTANT	Product quality is not effected	The unit cost is not increased	There are no delays in production or delivery times

Source: Adapted from [20]

Risk management involves the company establishing elements that are suitable in terms of infrastructure and culture. By applying a systematic and logical method for establishing the context, identifying, evaluating, treating, monitoring and

communicating risks associated with any activity, function or process in a way that will enable organizations to minimize losses and maximize profits [20-22]. The different stages of risk management are presented in Fig. 7.

- ✓ Establishing the context: The establishing of criteria for risks, the impact of which will affect product quality, costs and production times, is determined by the identified processes, stages and activities. Table 3 shows the criteria used in this research.
- ✓ Risk identification: The identification of risks in terms of what can happen and how it can occur, are contained in the information collected at the identification stage and the description of the proposed methodological design.
- ✓ Risk analysis: The possibility risk occurrence and consequences based on the Qualification matrix and Risk Analysis (Table 4) was measured. The risk evaluation is assigned when the possibility and the consequences of each risk are multiplied. We can see in Table 4 that for each level of consequence and possibility - into a range from one to five- the risk can take values from 1 to 25. The information on the possibility and consequences of risk were provided and coordinated by the company's experienced staff who were directly involved with the process.
- ✓ Risk evaluation: To determine how priority is a risk, we refer to results obtained in the qualification matrix and risk analysis. By observing the various qualifications of risk and its class, considering its value within a range from 1 to 25, the risks can be classified as very low, low, moderate, high or very high.
- ✓ Risk treatment: At this stage, the "Matrix of actions" (Table 5) is created with the aim of proposing and implementing the necessary actions to mitigate the risks of higher priority.

The actions matrix, seeks to minimize risk impacts, deviations or causes that give rise to non-compliance of the product in the different production stages. Through various actions taken at each stage of production, there are aims to reduce the possibility of occurrence and any negative consequences that may result from the presence of risk or causes of undesired deviations. The effectiveness of the actions will be reflected in the reduction in the occurrence of risks and nonconformity of the product.

The matrix of actions is built on MS Excel worksheets and its structure sequentially shows the causes or risks identified in the different processes that affect the product. In the worksheets the risks are described -what they are and how these risks are presented. Subsequently, the risk assessment is presented in terms of possibility and consequence. This is in order to focus attention on the risk values that are higher, because they represent a greater impact on the deterioration of quality, resource consumption and delays in production and delivery times.

Additionally, containment actions, reaction and prevention are proposed in case of occurrence of the risk. This will allow the operation of any process to make decisions in real time to prevent or contain more serious results.

3.5. Monitoring and review

Samples are collected to update the analysis tools in the glass production line are taken at least every two days. This is to maintain the proper functioning of the methodological design. This will help identify any unnatural cause that affects the process or will otherwise recognize if the proposed actions to mitigate the risks are efficient and definitely include them in the process.

Also, the updating of the risks in each of the processes should be performed in a period not exceeding 90 working days, after implementing the action or actions needed to reduce or eliminate these risks in order to identify new causes of deviations. If the actions are effective and permanently eliminate or reduce some of the identified risks, management must keep records of the results contributing to the theme of lessons learned within the organization.

Table 4.
Matrix Qualification and Risk Analysis

		POSSIBILITY				
		1	**2**	**3**	**4**	**5**
		EXCEPTIONALLY	OCCASIONALLY	REGULARLY	GENERALLY	ALWAYS
CONSEQUE-NCES	**5**	5-Low	10-Moderate	15-High	20-High	25- Very High
	4	4-Low	8-Moderate	12-High	16-High	20-High
	3	3-Very Low	6-Low	9-Moderate	12-High	15-High
	2	2-Very Low	4-Low	6-Low	8-Moderate	10-Moderate
	1	1-Very Low	2-Very Low	3-Very Low	4-Low	5-Low

Source: Adapted from [20]

Table 5.
Matrix of actions for the process of cutting

RISK	DESCRIPTION	POSSIBILITY	CONSEQUENCES	VALUE OF RISK	EVALUATION	CONTAINMENT ACTION	CORRECTIVE ACTION	PREVENTIVE ACTION	RESPONSIBLE
No lubrication of the cutting tool	Fault may occur in the dimensions of the sheet, since, at the time of removing the surplus generated by cutting, these do not follow the cut line and extending in the separation direction causing other damage	1	2	2	Very Low	The operator must isolate the nonconforming product of the workspace determining the possibility of later use or final disposal	- If there are excess in the dimensions must be removed in order to accommodate the dimensions - If there are shortfalls from the dimensions should replace the glass - Where will you find the Frosty borders should adjust the respective setting in the process of polishing straight or Curved	- Verify that this lubricated cutting tool. - In cases where the cutting tool does not have lubrication system, check that the cutting area is lubricated.	Operator of the cutting process
Cutting table with glass remains	The glass may suffer scratches due to the presence of remains of previous cuts adhered to the surface of the cutting table.	3	3	9	Moderate	The operator must isolate the nonconforming product of the workspace determining the possibility of later use or final disposal	Perform respective treatment in the area of Polish in order to clean up scratches	Clean the worktable before and after the following operation	Operator of the cutting process
No use of equipment for transporting glasses	Sometimes the operator does not use transport equipment and producing partial or total breaks the glass by uncoordinated transport	3	5	15	High	The operator must isolate the nonconforming product of the workspace determining the possibility of later use or final disposal	Replace the glass or remove the area affected to meet specifications	- Tools for easy removal of the glass sheet to the storage - Use permanent equipment for the transfer of glasses	Management Operator of the cutting process

Source: The authors

4. Conclusions

We have presented a methodological design for the identification, treatment, mitigation and monitoring of deviations from product specifications in production processes. In developing the paper we were able to combine statistical and quality tools with international management standards. In addition, we have proposed solutions to mitigate the causes or risks that generate deviations or non-conformances to the monitored product. During the validation of methodological design, some improvements were implemented to minimize the occurrence of risks and to take the best course of action based on the operating characteristics of the company.

The statistical and quality tools helped process the data collected, contributed to the analysis, and helped with understanding and monitoring of processes. Also, graphics monitoring identified any positive or negative change due to the treatment of risks.

Also, the design and implementation of the "Matrix of Actions", based on the ISO 31000:2009 for risk management, allowed us to make a diagnosis for each of the processes and propose actions to prevent significant risks for the organization.

Finally, The Risk Management process establishes a course of action and proposed activities that guide the operator of the production process to make decisions in real time and to prevent or contain undesirable results. It is suggested that these are applied in an environment of services or production processes that require the use of different types of control charts or instrument for monitoring processes.

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