Evaluation of the risk analysis technique in Blood Banks Production Processes

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System Safety Engineering techniques of risk analysis have been developed in order to identify the potential risks, to eliminate or minimize possible occurrences and accidents in the process industries. Risk management is extremely important in terms of damages to man and animals, and to the environment. However, specially in health service areas, there is a lack of structured procedures for risk management in this area that also consider biosafety aspects. The aim of this work is to adapt, combine, implement and evaluate engineering structuralized techniques in a new application aiming at analyzing the risks that are present in whole blood bag processing. The risks evaluated in the production process are directly associated to the quality and safety of the environment, to the people working in the area, as well as to the procedures involved. The analysis techniques used to identify the risks present are CIT (Critical Incident Technique) and PHA (Preliminary Hazard Analysis). The risk matrix is used to quantify the identified risks, though the correlation between categories of severity and frequency. The risk analysis techniques used herewith, are applied in a health service area as a case study, obtaining good general results, identifying the risk activities and risk types. Implementation and application of Safety System Engineering Techniques are highly versatile and capable of identifying the existing risks not only in industrial activities, but also in other segments, as is demonstrated in the present paper for the health service area.

1. Introduction

Risk analysis techniques of system safety engineering came from the necessity of detecting potential risks in order to reduce, or eliminate several accident types. These techniques have presented good application structure in process and industrial activities. The techniques have been very effective for these types of activities, identifying not only the risks, but their causes and consequences, in order to promote accident avoiding actions (Palmer, 2004; Meel *et al.* 2007).

On the other hand, there is still an absence of scientific work available in literature regarding adaptation efforts and the direct application of these existing techniques (Trucco & Cavallin, 2006). In particular, in health service areas, risk management presents deficiency and a lack of structuralized tools to identify the involved risks (Hergon *et al.*, 2005).

Any process related to health services can frequently lead to a labor accident or chronic occupational illness. Many of these accidents can cause death or diseases and could be

avoided. These problems are, in many cases, associated to faults in risk management. There are a number of different types of risks that health service professionals can be subjected to such as: biological; physical; chemical; radioactive; and ergonomic risks. Based on this, it is necessary to know the existing risks of each activity involved in the production section, with the aim of minimizing and preventing exposition (Isbister, 1996).

The objective of this study is to adapt, combine, implement and evaluate an engineering structured risk analysis technique in a new application, aiming at contributing towards the reduction or minimization of possible occurrences and accidents, exclusively involved in the production process of blood bank components, considering biosafety aspects. Using risk identification and qualification, it is possible to adopt measures that are capable of reducing or eradicating hazardous conditions, assuring quality and safety in the productive processes. This work also contributes towards extending the possibilities of usage for system safety engineering techniques, presenting a novel and efficient application in the health area.

In this work, the techniques applied in the production process of blood bank components such as red blood cell concentrate (RBC), fresh frozen plasma (FFP) and platelet concentrate (PC), are obtained from whole blood. It is the most important process in a blood bank, as it allows transfusion medicine practices. The main problem is that in many stages of this process, people are exposed to different risks, specially biological risks, which may cause contamination by virus or bacteria, leading to serious illnesses such as AIDS, Hepatitis B or C, Syphilis, Chaga's disease, among others that are difficult to treat.

2. Applied Methodology

This work is based on the following methodology for the development of a risk analysis technique:

Step 1: *Mapping the Health Facility* - This is the basic step towards knowing the studied area and its routine procedures, obtaining a detailed description of its activities. In this stage, it is important to establish and to develop more personal contact with the people involved in each activity. The information related to the number of procedures, number of involved people, work load, among others, is obtained through direct observation of process, interviews with the people involved, and structured meetings.

Step 2: *Development of the risk analysis technique* - For risk identification, a detailed study of the risk analysis techniques is necessary, in order to find the appropriate techniques to be adapted for the health service area. The Critical Incident Technique (CIT) and the Preliminary Hazard Analysis (PHA) were chosen and adapted for this work. The CIT was chosen because of its ability to identify errors and unsafe conditions, determining possible deviations, and to improve the capacity of evaluation of the system (Carvalho, 2002). The data obtained in the CIT is applied in the PHA. The decision for having chosen the PHA was based on its simple structure, its ease of application in new systems or processes, and its good response level. The PHA technique finds causes, consequences of the generated deviations, and it suggests corrective actions to minimize accidents (Kletz, 1992; Carvalho, 2002). Both must be adapted to the biosafety area, considering biological risks. The risk matrix is used in

order to quantify identified risks. It represents the correlation between two qualitative indexes, the severity category (SC) and the frequency category (FC) (Kletz, 1992). In this work, a modification of the severity category (SC) is necessary to consider biosafety aspects. These categories are used in the PHA application.

Step 3: *Implementing the risk analysis technique* - The third step is the risk analysis technique implementation in the case study area. The CIT and PHA, previously adapted, are applied in the blood-processing sector with the participation of the employees', identifying the risks, in order to quantify the risk level, and evaluating the performance of these techniques in this new area of application.

3. The Case Study Area

The study area is the Blood Bank of Campinas (São Paulo, Brazil), more specifically the blood-processing sector responsible for the preparation, storage and shipment of blood and components. This sector receives and processes nearly 6,500 blood bags monthly. It is subdivided into blood component processing area, responsible for obtaining blood components ready to use, and component distribution area, responsible for preparing the blood components to distribute to the regional hospital blood transfusion services. Throughout the productive process, the blood bags are received and processed, the final products being the blood components. The blood components produced are red blood cell concentrate (RBC), platelet concentrate (PC) and fresh frozen plasma (FFP). This productive process has 26 operational procedures, detailed in 88 activities. There are some important procedures to be carried out in the routine activities in a limited period of time. These activities are performed by nine employees working daily in eight hour shifts. The employees work standing up;, the tension level is high; and the amount of employee's is below the necessary amount for the completion of the tasks.

4. Results

The stage of the mapping health facility generates a structured process, including all the activities involved in the study area. This process is developed through the comparison and confrontation between collaborators' activities and procedures. The structured process of the blood-processing sector is represented by the flowchart as shown in Figure 1. The flowchart is important to obtain a structuralized application of the developed techniques. As shown in the flowchart, all procedures are compiled in ten stages.

During the risk identification stage, the CIT generated quite a lot of information and suggestions, related to unexpected occurrences in the activities during each process stage, called deviations, for instance:

- Blood bag rupture during the labeling stage – it may cause incidents affecting the worker and the environment generating a possible contamination risk;
- Transport of heavy boxes containing blood bags - this procedure can cause light uncomfortable conditions or more serious injuries due to inadequate ergonomic handling;

- Blood bag rupture during the extraction stage - this incident, characterized as a biological risk, can affect people and material via blood contact.

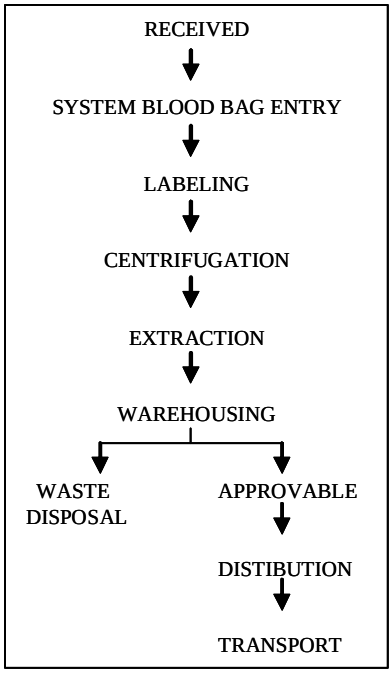

Figure 1. *The flowchart of the blood-processing sector.*

The PHA is applied during the following steps. Based on the identified deviations in the CIT, the PHA is partially applied, in order to find the causes and consequences of each deviation, through structured meetings and interviews with collaborating employees. The next step of the PHA application consists in classifying frequency and severity of the undesirable events. This step can only be performed after the adaptation of the frequency and severity categories, which is a result that is described in the following stage. Then, the event is classified, allowing the final result of the PHA application, i.e., the risk identification to be obtained.

The risk qualification stage, presents the adaptation of the risk category descriptions, considering biosafety, as shown in Tables 1 and 2. Table 1 shows the Frequency Category (FC) that is divided into four levels: extremely remote, improbable, probable and frequent. Table 2 shows the Severity Category that is divided into four levels: abject, borderline, critical and catastrophic. After theses adaptations, each activity of the process is classified in relation to the levels of severity and frequency of undesirable occurrences, according to levels from 1 the 4. The category values are obtained by the average of the answers from the collaborators in the area.

Table 1. *The Frequency Category (FC).*

Categories	Classification	Description
A	**Extremely Remote**	Scenario that depends on multiple faults in the system or subsystems. This fault is possible, but improbable during installation or activity.
B	**Improbable**	The fault is less likely to happen during the facility or activity's useful life. Occurrence depends on more than one fault (human or environmental).
C	**Probable**	A predictable occurrence during the facility, activity or system's useful life. It depends on one unique fault (human or environmental).
D	**Frequent**	Several occurrences that are predictable during the facility, activity or system's useful life. Occurrences are related to the imminent dangers present.

Table 2. *The Severity Category (SC).*

Categories	Classification	Description
I	**Abject**	The fault will not cause a greater deterioration in the system, neither will produce functional harms or injuries, nor contribute with a risk to the system. No population impact or measurable harm will occur. No harm will reach the external and internal population.
II	**Borderline**	The fault will deteriorate a part of the system, but will not result in greater harm or injuries and can be compensated or controlled easily. The harm will be considered irrelevant to the external and internal population.
III	**Critical**	The fault will deteriorate the system causing injuries and substantial harm. It can also result in an unacceptable risk requiring immediately corrective actions. The occurrence can cause harm to the system due to leaking and contamination caused by infectious materials or agents reaching people and areas (environment and equipments). The fault will cause injuries (illnesses) of moderate severity with possibility of treatment and/or cure with reduced treatment time.
IV	**Catastrophic**	The fault will cause high severity deterioration in the system, resulting in its total loss as well as a possible human death. The harm will be irreversible to the system due to leaking of infectious materials or agents reaching people and areas (environment and equipments). The fault will also cause high severity harm (illness), with little or no treatment possibility whatsoever and/or cure with long recovery/treatment time.

Table 3 presents the Risk Matrix, which correlates the FC and SC obtained values, and it defines four risk levels: critical, serious, tolerable and abject.

Table 3. *The Risk Matrix.*

SEVERITY	PROBABILITY A	B	C	D
IV	2	3	4	4
III	1	2	3	4
II	1	1	2	3
I	1	1	1	2

The maximum risk level of each process stages, that is a PHA result, is shown in Figure 2. Each process stage is made up of several activities, and each activity has a risk level obtained through the risk matrix. The value of the maximum risk level of each stage is the activity value of greatest risk level. The labeling, centrifugation, extraction, warehousing, approvable, waste disposal, distribution and transport stages present the greatest risk level (Critical Risk), which correspond to nearly 80% of the stages process. Figure 2 indicates process stages which have more probability of accident occurrence. It can be observed that from 10 process stages of the sector, 8 are in unsafe conditions. This indicates that they must be investigated with more detail to prevent accidents. In order to do so, the critical risk stages are detailed separately by risk types such as biological, ergonomic, dropping accidents and other accidents.

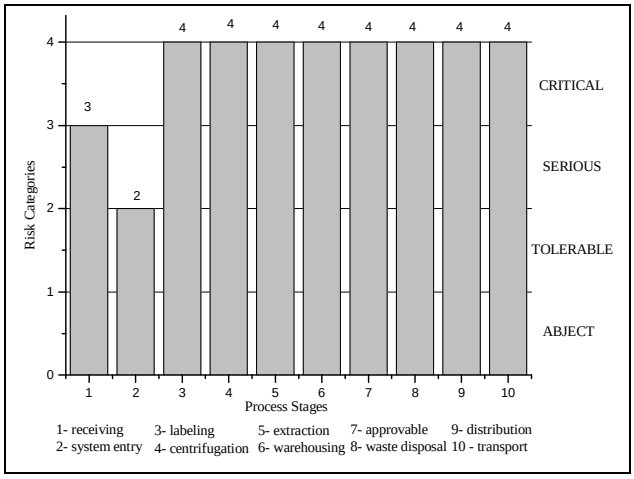

Figure 2. *The maximum risk level of the process stages.*

The relationship between the risk types (biological, ergonomic, dropping accidents and other accidents) and the critical risk in the process stages is shown in Figure 3. The labeling, centrifugation, extraction, and waste disposal stages indicate more critical relevance in the biological risks activities. The biological risks are strongly related to blood component leakage during the processing and distribution sector. Throughout the entire activity of blood bag processing, there is no serological control or analysis of the blood bags. Therefore people handling the blood bags have no knowledge whether the fluid contained viral or bacterial contamination such as: AIDS, Hepatitis B or C, Syphilis, Chaga's disease and others. The extraction, warehousing FFP, approvable FFP, approvable RBC, distribution FFP and transport of blood components stages show the critical risks related with ergonomic issues. The ergonomic risks are related to transport of heavy boxes, refrigerated environments at a low temperature and the height of some machinery. This type of risk can cause injuries from simple discomfort to serious occupational diseases of repetitive efforts. These identified issues can be used in preventive and corrective action plans to minimize and eliminate occurrences and occupational accidents which can even cause diseases.

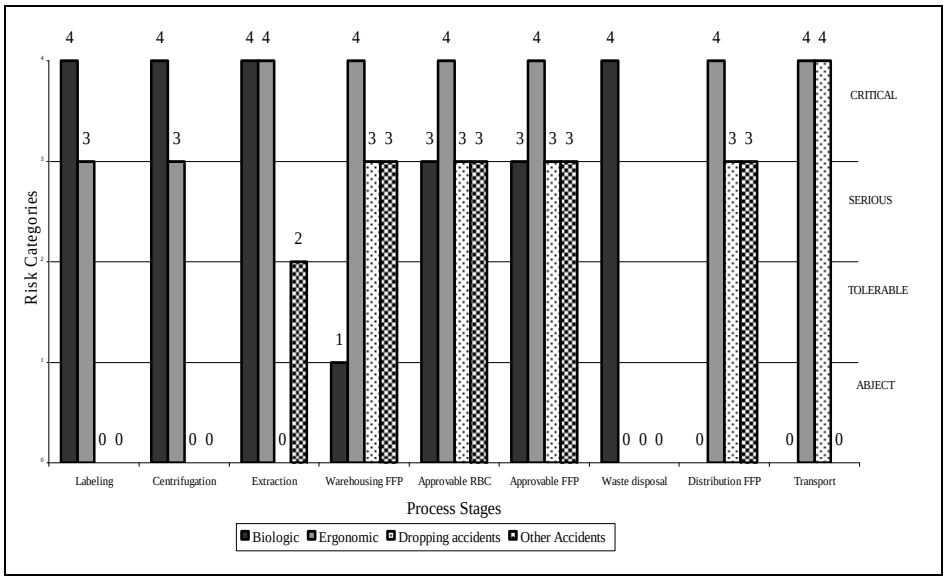

Figure 3.*The relationship between the types of risks and the critical risk.*

5. Conclusions

The System Safety Engineering risk analysis techniques are known by their robust structures to identify the risks, their causes and consequences in industrial processes and

activities. In health service areas, there is a lack of structuralized tools for risk identification, affecting risk management and exposing employees' health.

The application of the studied techniques showed efficiency in the health service area, particularly in blood bank productive processes, identifying risks and the most problematic areas. The CIT presented ability to identify deviations as well as the PHA, making the application faster, as the collaborators became aware of the possible faults that could occur. The CIT was the basis for the PHA application. Furthermore, the CIT associated with PHA presented a greater applicability, resulting in an easier and faster risk analysis method. In addition, the categories adapted for productive processes in the health areas covers occupational events, accidents involving biological contamination and infectious diseases.

The technique applications presented the biological contamination and ergonomic risks as being the most critical issues. The biological risks were identified as a result of blood bag leakage due to dropping, manufacturing defects and inappropriate storage conditions or blood bag handling. The ergonomic risks, on the other hand, may cause problems from discomfort to diseases, the result of repetitive efforts and exposure of the worker's biotype to inappropriate circumstances. The faults found may cause immediate consequences and exposure of individuals to critical risk conditions. Therefore, it is necessary to make a preventive and corrective action plan to minimize and eliminate theses deviations.

Finally, the results obtained in this study showed the flexibility and feasibility of the application and implementation of System Safety Engineering techniques in identifying the risks present in activities. These techniques are applicable not only in industries, but also in other production and service sectors, such as the studied health. These risk analysis tools are one of the pillars for building a safety culture in the health service areas.

6. References

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