Journal of Machine Engineering, Vol. 15, No.1, 2015

production, process risk,
criticality assessment,
risk assessment

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ANALYSIS OF MACHINE PRODUCTION PROCESSES BY RISK ASSESSMENT APPROACH

Risk assessment is one of the important ways to analyze and protecting production processes. It facilitates to focus on the risks that really matter to execute a fail-safe manufacturing process or task. Risk management is considered to be a proactive and planned approach in order to encounter problems and reacting to them if they arise. On the other hand it provides assistance to continuous monitoring and evaluating of potential failure that might occurs during a process, moreover, it also explores the ways to avoid probable cost, time delays and quality of a product or service. The output of assessment process such as list of potential failures, their consequences and likelihood, and response system is circulated within the enterprise, so that personnel involved of risks and the criticality of a machine itself that performs the specific production process.

1. INTRODUCTION

This section provides the background of the paper that needs for risk assessment of manufacturing processes. Alongside the background the objective of research also be highlighted and the brief outline of the study will be discussed in this section. Production and manufacturing have similar meanings in this paper, both words are being replaced each other during the whole literature.

1.1. BACKGROUND

Nowadays production companies are striving to get better and better in order to successful and sustain in the competitive world market. Success depends on many factors and one of them is reliability and reliable manufacturing processes particularly. There are external and internal factors that motivate a company to foolproof processes, external factor

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may includes – customers demand for higher quality so as need of reliable products are increased. Internal factors such as identification and measurement of process risk that results in process losses, without it companies can't estimate how much cost incurs and lead time they lose due to unreliable manufacturing processes. Risk assessment is a technique for identifying risks and evaluates them so that opportunity of reduction in cost and lead time can be proclaimed.

Assessment of production processes is a key issue that ensures the stability of manufacturing system operation. It helps to improve product quality and shrinks production losses [1]. Moreover, risk assessment is a proactive approach to recognize probable potential failure of a production operation, consequences of that particular failure and possible causes of failure together with frequency of failure. It leads to determine risk level and setting up risk control strategy.

1.2. PURPOSE

The objective of this paper is to contribute and present a more complete understanding of risk assessment technique in production companies where manufacturing processes are carried out by automated production machines. The paper aims to convey the risk assessment process approach in order to provide a comprehensive view on the tracking of risks and the criticality of a machine that performs the specific production process. Authors have devised the following two general research questions for the study:

(1) What kinds of risks arise from automated production processes?

(2) How does the risk assessment carried out for production processes?

Further research objectives are to classify the consequences and likelihood of the failure that mutually construct the risk level of particular production equipment.

In this study the qualitative case study research methodology is used in order answer the research questions [2]. Information has been collected through on site (production floor) observations and through interviews with machine's operators, technical staff (maintenance specialist) and production managers of two different industrial field production companies, pharmaceutical and automotive industries have been involved in the study.

1.3. OUTLINE OF THE STUDY

The paper comprises of literature review that explore the idea about the risk, risk categories, risk identification, risk assessment and risk response that followed by the techniques used for risk analysis in production companies. Moreover, general risk assessment tool for production processes will be presented with criticality assessment of production machine tools. A case study will also be taken into consideration that will end up with discussion and conclusion of the topic.

2. REVIEW OF LITERATURE

The literature review of the topic will be discussed in this section that consists of defining of risk, how risk can be identified and categorized, and risk assessment in general. Risk handling and control will also be the part of this section.

2.1. RISKS

In order to identify the risk in a process, it is necessary to go through the definitions of risk. In dictionaries risk is defined as a possibility of losses or harmful consequences. From this definition it can perceive that risk has two fundamental components: losses and uncertainty about their occurrence and quantity [3]. Risk can be broadly defined as a chance of danger, damage, loss, injury or any other undesired consequences. It is the product of two factors: Probability of an event which might occur and severity of the event if it occurs (Risk = Probability x Severity) [4].

Sometimes risks are described in a negative context like according to Society for Risk Analysis (SRA) risk is "the potential for realization of unwanted, adverse consequences to human life, health, property, or the environment…" [5]. But risk does not always result in a negative outcome since some risks are taken purely by the hope of a positive outcome. Like the acquisition of a company means major risk taking, but the risk would most likely not been taken if there was no chance of a positive effect [6]. What most authors do agree with is that risk always a state of uncertainty [6],[7],[8].

2.2. CATEGORIES OF RISK

According to Hopkins [6] the risk can be divided into four categories that are discussed below. These risks may result from the failure of any manufacturing process or task that can be observed on production floor:

- *People* – Failure occurring due to lack of the right competence, absence of employees or wrong number of staff, wrong mental attitude of people (for example breaking rules, sabotage and laziness) or personal accidents or injuries. Lack of good leadership and poor company culture falls into this category as well.
- *Premises* – If physical resources are stolen, lost or damaged, it may cause in major disruptions for an organization. Furthermore, insufficient or inadequate access to premises, as well as damage or contamination of premises can also be risks where the company needs to carry out actions in order to avoid or mitigate their negative outcomes.
- *Processes* – In order to avoid process risks, information flow and communication among the process owners have to work properly. Some other process risks are failures in transport, production or software systems.
- *Products* – Disturbances can be caused due to failure of supplier both in terms of late deliveries or poor product.

2.3. IDENTIFICATION OF RISK

Risk identification is a primary step in the risk assessment process as it reveals and determines the possible production process risks as well as conditions that arising risks. By risk identification a company is able to study activities and places where its resources are exposed to risks [9].

Risk identification can be expressed by the following basic elements and the frame of risk identification can be seen in Fig. 1 [10]:

- *Sources of risk* – are elements of the organizational environment that can bring some positive or negative outcome such as the decision to start production of a new item in an organization is strongly influenced by the market conditions. Here the source of risk either availability or not of competitors, needs to customer and quality of raw materials. This risk depends on the way in which the product will meet the market demand, or on the quality of the product, on the time when the product will appear on the market.
- *Hazard* – is a condition or circumstance that increases the chance of losses or gains and their severity. An error of the firm management about the market expansion for a given product is an example for a hazard factor activity that determines the system risk.
- *Peril (vulnerability)* – is something that is close to the risk and it has negative, non-profitable results. Peril can happen at any time and cause unknown, unpredictable loses. Like an industrial accident, car crash, air-craft crash, fire, failure in the machining process, failure of exam. It always causes a loss that is why it does not consider in positive means.
- *Resources exposed to risk* – are objects facing losses or gains. They will be affected if the risk event occurs.

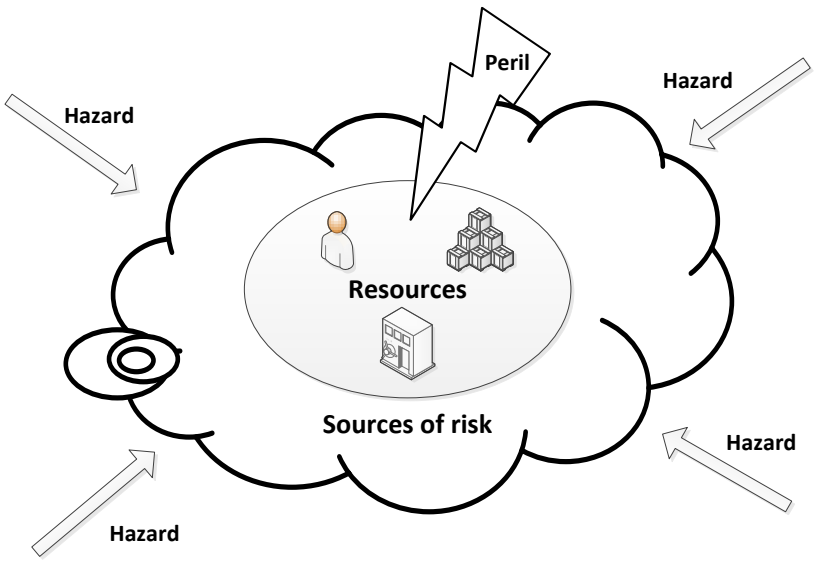

Fig. 1. Risk identification frame: sources of risk - hazard - peril - exposure to risk [10]

2.4. RISK ASSESSMENT

Risk Assessment is a formal and systematic approach to identify manufacturing practice risks related to equipments and supporting systems. It is a very helpful tool that can be applied to plant, equipments and systems which have been in use for many years.

"Risk assessment can be defined as the process of estimating the probability of occurrence of an event and the probable magnitude of adverse effects – safety, health, or financial – over a specified time period" [11]. Furthermore, risk assessment is a process which involves some or all of the following components: potential failure identification, effect assessment, exposure assessment and risk classification [12].

2.5. RISK HANDLING

There are four basic ways to handle a risk that are discussed in many risk management literature and Tonnquist [13] also described as follows. An example of risk handling is shown in Fig. 2:

- *Avoid risks* – The best thing that can be done with a risk is to avoid it–if it can be prevented from happening, it definitely won't hurt the production process.
- *Mitigate risks* – If the risk can't be avoided, it may be mitigated. This means taking some sort of action that will cause it to do as little damage to the process as possible.
- *Transfer risks* – One effective way to deal with a risk is to pay someone else to accept. The most common way to do this is to buy insurance.
- *Accept risks* – When the risk can't be avoided, mitigated, or transferred, it has to be accepted. But even then attention should be paid to other alternatives and it should be known what will happen if it occurs.

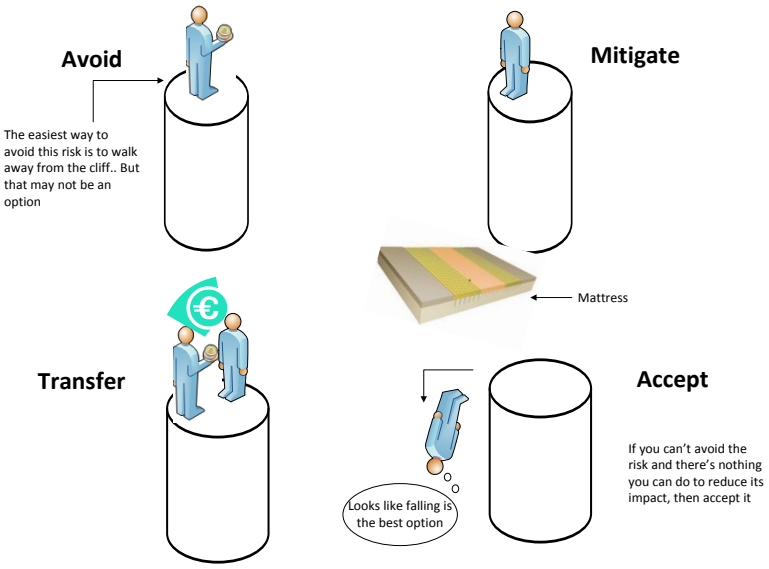

Fig. 2. Risk handling example

2.6. ASSESSING THE RISK

Assessment of risks can be carried out with the help of a tool called process FMEA (Failure Mode and Effect Analysis). Many production companies are using this tool in order to evaluate potential problem and its effects connected to their specific product and process. It has also been widely used in the various manufacturing fields as a tool for accomplish reliable processes [14],[15],[16].

FMEA is a methodology to evaluate a system, design, process, or service for possible ways in which failure can occur [17]. It is a risk analysis tool that can be useful in environments where you have to prevent an event ever happening. Moreover, it analyzes the key outputs and potential failures of each step (task) of a process, and consider the effect of process failure on the product or service concerned [18].

In the following section a risk assessment tool is presented for the evaluation of manufacturing processes and these processes are performed by automated production machine tools.

3. RISK ASSESSMENT TOOL

A tool for helping to identify, evaluate and control risk is illustrated in Fig. 3. The tool facilitates to assess each manufacturing step with respect to critical operations and further it leads to criticality assessment of manufacturing machine center.

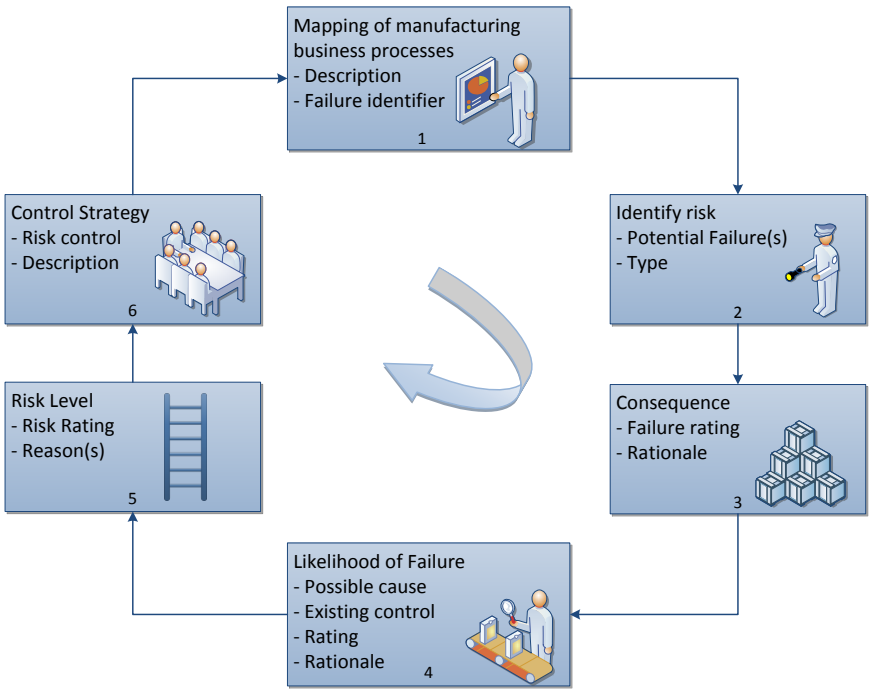

Fig. 3. Risk Assessment Tool

The risk assessment process consists of six steps, starts with mapping of manufacturing business process that shows the main functions and/or process being carried out at equipment (machine). It can be a process flow of particular machine center. It also includes the unique identifier that assigned to failures associated with risk type (risk types are discussed later in this section).

Second step of this approach is described possible failures that may impact *operator safety*, *product quality*, or *process integrity (cost and time delay)*. Failures may occur if the proposed production task would fail, if the users were to make an error, or if there was a failure in the manufacturing business process itself.

Next step is the consequences of failure, they are the after–effects of potential failures or the extents to which a potential failure might impact products' quality and/or process integrity or harm operator' safety. Rating (High/Medium/Low) is given to each potential failure to describe its severity. Impact assessment scale for consequences is provided in table 1, while rationale justifies the rating given to the consequence of potential failure according to its severity.

Table 1. Impact assessment scale of consequences

Impact Rating	Description
High (H)	- Product is unusable or ineffective (unacceptable to customer) - Severe potential harm to operator that leads to long term effects
Medium (M)	- Risk has potential for non-serious impact on operator safety and/or product quality - Customer may notice some difference that is annoying or causes inconvenience - Process integrity (e.g. time delay) suffer significantly
Low (L)	- Risk has little or no potential impact on operator safety and/or product quality - Damage would not result from failure or wrong operation without failure of other processes

Table 2. Probability Assessment Scale of Occurrence

Likelihood Rating	Description
High (H)	- The failure is almost certain to occur - Control measures are not defined or are not adequate - A Failure would be difficult to detect
Medium (M)	- The failure could occur - Control measures may be breached - A Failure could be detected but not reacted to in a timely fashion
Low (L)	- The failure is almost certain not to occur - Control measures are failsafe - A Failure would be detected and reacted to in a timely fashion

Table 1 and 2 are also presented the classification of ratings for consequence and likelihood respectively, they are developed with respect to the study of case companies. These classifications might have different descriptions according to companies' needs, goals and priorities.

Forth stage of risk assessment tool defines the frequency of potential failure, also it causes and existing controls for mitigating it. Possible cause description is the part of this stage, while it also states all the possible causes for the potential failures along with description that the assessor can think about. Furthermore, existing control indicates the present controls/checks used to mitigate or avoid the potential failure. It describes if the presence of existing controls either make the potential failure less likely to occur or increases the detect-ability of the potential failure. If it is highly detectable, then the likelihood of occurrence may be reduced. High, medium or low rating is given to each potential failure to describe its frequency of occurrence and probability assessment scale for occurrence can be seen in table 2. Here rationale justifies the rating given to the likelihood of potential failure according to its frequency of occurrence.

In the fifth step risk level tells the overall risk associated with the potential failure. It is based on the likelihood and consequence ratings. The ratings of risk level are given according to the Fig. 4. The processes for which the risk level rating lies in the *high* (red) region must immediately be stopped until proper controls are defined and used. If risk level lies in *medium* (yellow) region then the processes must be considered as inadequately controlled and so require further control measures. The processes for which the risk level rating appears in the *low* (green) can usually be considered as trivial risk and so the risk associated can be considered as adequately controlled.

Last step of risk assessment process defines the methods for mitigating the risks associated with each failure. It includes Risk Controls and Additional Description/Comments if necessary. Likely control could be supplier assessment/audit, technical control, standard operating procedure (SOP) control, Operation support, etc.

Risk Rating		**Likelihood**		
		Low	Medium	High
Consequence	High	M	H	H
	Medium	L	M	H
	Low	L	L	M

Fig. 4. Risk Level Matrix

3.1. KINDS OF RISK

Risks initiate from uncertainty and the main source of uncertainties faced during the automated production processes are due to the software collapse in production machines, machine operator carelessness and machine component failure. The study found useful and illustrative to analyze the risks as grouped in three types, the risks coming from:

- *Software* – Failures may occur due to the software associated with the PLC based equipments. The software may not be obtained from a well-established supplier, or the system may not be owned by reliable and pre-validated supplier that having good same software history.
- *Operator (User)* – The user error indicates human errors during operation, such as negligence.
- *System/Component* – The risk type deals with the hardware used in particular equipment. Any component that malfunctions during the operation will be included in this type. For example, worn out bearings and deformed gear teeth profile.

3.2. CRITICALITY ASSESSMENT

Criticality assessment of production machines is performed to find the vital functions that are carried out by specific production machine. Here the purpose is to identify the most risky operations of a machine and the most critical machine in production area. Automated machine tools are assessed for the impact or criticalities they possess based on the manufacturing business process are being performed by them. In this study criticality assessment is organized as: enlist all processes of equipment (machine) and evaluates their impact on product quality, operator safety and process integrity followed by risk description of that specific process.

4. RELEVANCE OF RISK ASSESSMENT TOOL

4.1. APPLICATION OF TOOL

A pharmaceutical company was selected for the case study and to implement suggested risk assessment tool for evaluating production equipment that producing medication products. Pharmaceutical industry aims to produce safe and effective medicines with efficiency and profitability. In order to achieve these objectives, qualified personnel from many scientific and commercial disciplines are needed. The industry needs specialists with qualification in biological, chemical and pharmaceutical sciences, but there is also a requirement of assessing the risks associated with various processes and the risks connected with equipments in the manufacturing facility, so that risks to the manufacturing processes can be deemed to be low or none.

Risk to humans not only results from chemical exposures or accidents but also due to improper medicine quality that may impact severely on patient's safety. One of the reasons of bad quality medicines is the way they are being produced in the pharmaceutical industries. Risk to human health as a consequence of improper medicines quality found in modern societies is a matter of grave concern to the world community. Risk Assessment promises a systematic way for developing appropriate strategies to aid public health risk policy decisions in the arena of human exposures to hazards.

Ref.	Function description	Impact on patient safety and/or product quality YES or NO	Risk description
1	Conveying the actuator box by conveyor	No	---
2	Sensing the actuator box by sensor	No	---
3	Insertion of the can into the actuator box by the can pusher	No	---
4	Sensing the can in the actuator box by sensors	Yes	In case of no can in the actuator may lead to market compliant.
5	Feeding the carton by vacuum system	No	---
6	Printing the manufacturing and expiry date, batch and price of the product on carton	Yes	No or incomplete information printed on the product is a concern about patient's safety & product quality, hence product will be rejected

Manufacturing Business Process	MBP.failureID	Potential Failure(s)	Consequence		Likelihood of failure				Risk Level		Risk Control Strategy	
			Rating	Rationale	Cause Type	Possible Cause Description	Existing Controls	Rating	Rationale	Rating	Rationale	Risk Controls	Additional Description/ Comments
Sensing the can and the actuator by sensors	MBP 4.1	Sensor does not sense the actuator or can or always senses	M	Sensing of no actuator or no can will immediately stop the machine and hence resulting in production loss or empty damaged cartons will be delieverd because sensor always senses the actuator	Software	Malfunctioning of software or software error	Visual	L	Experience has shown similar failures to be very rare	L	NA	NA	NA
	MBP 4.2		-		User	-	-		-	-	-	-	-
	MBP 4.3		M		System/ Component	Worn out cam profile generates improper to and fro motion of sensor bars or the mechanism may be jammed due to inadequate lubrication or the motor belts do not have proper tension or have broken or the mechanical components like bearings have worn out or exhibit play	Visual	M	The failure could be detected but not reacted to in a timely fashion	M	NA	NA	NA
Printing the manufacturing and expiry date, batch and price of the product on carton	MBP 6.1	Wrong, misprinting or no printing of information on the carton	-	No or incomplete information printed on the product impacts product and integrity of information such that intolerable harm would occur with loss of records leading towards the harm to patients (end user)	Software	-	-		-	-	-	-	-
	MBP 6.2		H		User	The operator has not timely checked the proper quantity of ink in the roller or has not set the information correctly	Visual inspection	L	The failure could be detected and reacted to in a timely fashion	M	NA	NA	NA
	MBP 6.3		H		System/ Component	Loose digits in the printing roller due to loose fasteners, empty ink roller, mechanical problems in the rotating motor such as belt slip and improper tension in the belt or worn out bearings due to improper lubrication	Visual	L	Proper preventive maintenance is carried out regularly and Experience has shown similar failures to be very rare	M	NA	NA	NA

Fig. 5. Criticality and Risk Assessment Formats with Example of a Machine's Risk Assessment

The formats of risk assessment and criticality assessment for this case study can be seen in Fig. 5. These formats were designed with the help of risk assessment tool. There were twenty machines (equipment) assessed at the company's production area and example of one of the machine's risk assessment is also presented in Fig. 5. The equipment is 'Cam Cartoner' used for packaging of a product by cam mechanism.

These formats are used to identify critical processes of all the equipments based on the risk levels associated with each process. The risk level shows a cumulative effect of likelihood of failure and severity of the failure. Once the likelihood and severity ratings for a process are known, the risk level can be found using the risk level matrix in Fig. 4.

The process for which the risk level rating lies in the red (high) region of risk level matrix have been classified as the 'Most Critical Process'. It is therefore required to stop the machine and halt the production until the risk level is reduced to yellow (medium) or green (low) region. The machine would not be stopped if the rating lies in yellow region and in this case the process is classified as 'Moderately Critical' but further control measures are necessarily required to reduce the rating to green region. The processes for which the risk level rating appears in the green can usually be considered as 'Least Critical' and so the risk associated can be considered as adequately controlled. The identification of critical processes for all the equipments is an important part of the study, as it can be used to evaluate the overall performance of the equipments. If for example, a particular equipment whose many processes are classified as 'Most Critical Process', definitely requires immediate attention for improvements and which means more controls are needed to mitigate the associated risks with equipment. After carrying out the risk assessment for equipments it can be decided that whether the equipments were in satisfactory operating conditions or not.

4.2. RESULTS

The study could have been revealed that some of the equipments must be stopped and more control measures need to be defined. Some equipment may be allowed to operate but the associated risk level may still increase that means it is necessary to define proper controls to decrease risk level.

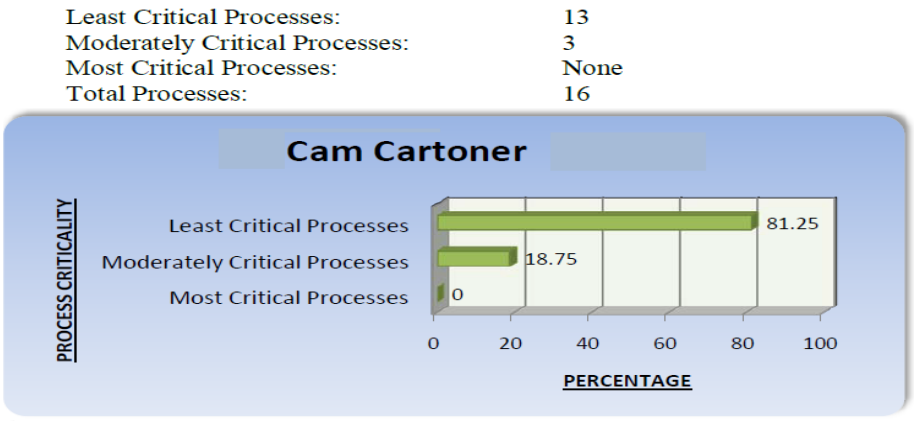

Fig. 6. Percentage Criticality Chart for Cam Cartoner Machine

The results are obtained on the basis of Risk Assessment. Based on the risk level associated with each process performed on a particular machine, the process can be classified into one of the three categories: ‘Least Critical Process’, ‘Moderately Critical Process’ and ‘Most Critical Process’. After that a ‘Percentage Criticality Chart’ is constructed for each machine which is in fact a measure of performance of the processes performed on that machine.

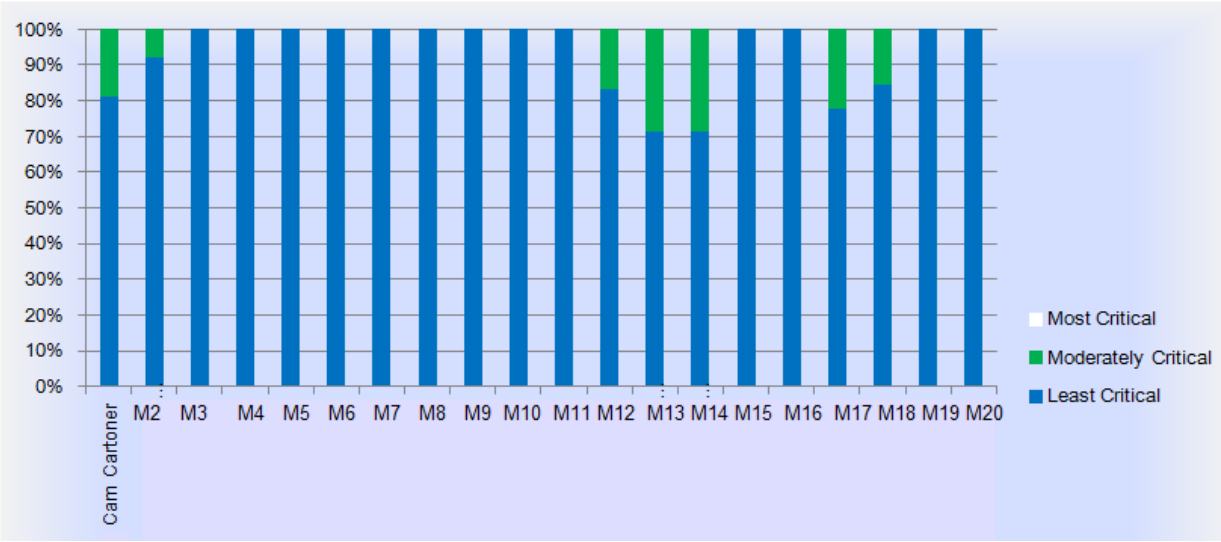

Fig. 7. Critical Processes Related to Each Machine Showing in Percentages

The ‘Percentage Criticality Chart’ facilitates the comparison of different processes classified into the three different criticality categories, just described. The percentage criticality chart of ‘cam cartnor’ machine is shown in Fig. 6 and the results for all the other equipment are summarized in Fig. 7.

5. CONCLUSION

Among the twenty equipments under study, no machine was found to be in a condition executing any of the ‘Most Critical Processes’, which if present, would definitely require immediate stoppage of the production. Seven machines require more control measures and appropriate risk control strategies to reduce the risk level (currently lying in the Yellow region of the risk level matrix). The remaining thirteen machines can safely be operated according to defined standard operating procedures.

The Risk Assessment should be reviewed and updated continuously to keep it alive document. In particular, it should be updated following any significant changes in the premises, significant changes in staffing levels, or work processes on the site. Even with no changes, it is good practice to review the risk assessment at intervals not exceeding twelve months.

The potential failures and associate risks of production processes are identified. Risk classification and mitigation plan are formalized for analyzing and protecting manufacturing processes of case company. Basically, every department in a company analyzes their production-related risk that would be end up in the form of a complete risk evaluating process for the whole company. Proper risk assessment leads to have useful information and helps in effective decision making prior to any process failure's occurring. We should keep in mind every production company has specific process and procedure, and it depends on company's business process nature that how they would conduct risk assessment and classified respective risk types, and risk ratings. Better communication among all process owners is required to assess the acceptability of the level of risk on the production process.

One of the future researches could be the development cost based approach for risk assessment and other could be identification of possible risks in collaborative partner network of small-medium enterprise SMEs.

ACKNOWLEDGEMENT

This research was supported by European Social Fund's Doctoral Studies and Internationalization Programme Dora.

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