Implementation Of Quality Control Analysis Techniques On A Blood Product As A Case-Study

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Abstract

Abstract Save and high blood quality is an indispensable need for every patient. Providing adequate blood products for the patients is the aim of the hospital KH(deliberately didn't mention the name of hospital) that's why they introduced the quality management department to be sure of serving the hospital needs by operating under the 10 quality system essentials to be in control of all of its processes in a cost-effective way. KH is an accredited member with the American Association of Blood Banks (AABB) since 1989, and participating of the Collage of American Pathologists (CAP) since 1994 in order to make sure of being developed in their services. In this work the a comprehensive field study was implemented to analyze the quality of the system in order to know its weaknesses and try to improve it, and to assure that safety is applied according to specific standards to provide safety environment to the employees, customers and visitors in all areas of the blood bank. The main causes or errors that lead to discarding blood units are studied. As a result of this work suggested solutions were obtained to reduce studied. As a result of this work suggested solutions were obtained to reduce causes or errors. Safety aspects were analyzed and improved; issues related to quality management such as filing system of documents tracking information flow between blood bank departments were improved.

Keywords: Quality Control, Blood bank, Blood Bags quality, System Outline, Errors Reports

Back Ground

Quality control is a serious part in KH organizational structure that's way they have the quality management department which was established in 1997 to insure high quality procedures in all of the blood bank departments by functioning under the 10 Quality System Essentials (QSE) that will be mentioned later.

The objectives of studying quality and safety in KH are to minimize the number of discarded blood bags due to different kinds of errors by

identifying the reasons of discards and how to reduce them. Also the aim is to observe their safety system and try to improve it to insure safe environment for the workers, visitors and donors.

System Outlines

The system outlines which contain the following elements as shown in Figure-1:-

(a) Decisions:

The main objectives of the decisions are:-

- Improve the quality of the blood bags by reducing the errors.
- Improve the efficiency of the employees.

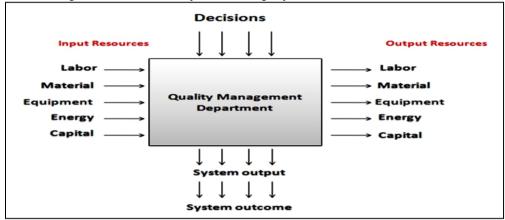


Figure-1 System outlines.

(b) Inputs Resources:

The main inputs resources are:-

- 1. Labors:
- Supervisor
- Coordinators
- Secretary
- 2. Materials:
- Papers
- Records
- 3. Equipments
- Tables
- Chairs
- Computers
- Machines
- 4. Energy
- Electrical
- 5. Capital:

• Building

(c) Outputs Resources:

Contain all un-used input resources.

(d) System output:

It is responsible on:

- Training employees
- Error and accidents documentation
- The system outcome will be:
- Higher quality system.
- Controlling errors and accidents

The Quality Management Department (the case-study):

Quality management has several sub departments, but in this work the first two departments will be discussed in details (as a case-study), which includes:

- 1. Safety Unit.
- 2. Quality Control Unit.
- 3. Quality Assurance Unit.
- 4. Training and Continuing Unit.

Quality plan:

To maintain processes in a validated state, the standard operation procedures (SOP's) will be implemented on KH utilizes process control measures. SOP's documents contain the followings:

- Purposes
- Responsibilities
- Restrictions or Requirements
- Definitions
- Principles
- Procedures

Process control begins when a new procedure or policy is implemented or when the existing one is changed. Process controls measures utilize include:

- Written Standard Operation Plan (SOP's).
- Forms and records linked to (SOP's).
- Personnel training and competency assessments.
- Quality control of equipment and reagents.
- Preventive maintenance of equipment.
- Facility safety training.
- Performance of external proficiency testing and inspections.
- Internal self-assessment.
- Written changed control procedure.

Quality System Analysis

To know the current status of KH in quality department, the observed and the historical data of the department was reviewed for 2014. Quality department in KH has several types of documents including (errors reports and accident /incidents reports). Also they have an archive that goes back to 1995 they keep in case they need to review old reports and all of the archive is kept manually.

Errors reports

In case of any error happens in any of the blood bank departments an error report is filled and sent to the quality management department to investigate the error and gives a review about it. Figures -2 and 3 show samples of the error reports. As can see in figure- 2 the date of report, occurrence and the date of discovering the error is needed to be filled.

Date of Report:	Date of Occurrence:	Date of Discovery:
This form should be initiated	within TWO WEEKS of the date of discovery.	
Instructions: The individual id	entifying the error should complete this section.	
Summary of event- Describ		
What immediate Corrective	ACTION taken?	
THE INTEGRED CORRECTIVE		
ndividual completing repor		

Figur-2a: Report of error form

Management S	aff member of th	e QA Unit to complete:	
Do you concur v f not, please de	ith the staff asses scribe your assess	sment of the event? ment of the event, and process	Yes I No I NA revision or other follow-up, if applicable:
Was PREVENTIVE	Action taken to p	revent recurrence?	Yes No NA Describe action taken:
s retraining a pa Retraining is sci date- within 30 (rt of the preventive neduled	e action?	□Yes □No □NA
	Number of Statement of Corrective		Root Causes and System Improvement to Prevent Recurrence
Error Type	Recurrence	Action	Inspirorement to rearent recountering
Service Se	Recurrence	Action	
Service Se	Recurrence	Action	

Figur-2b: Report of error form

Types of Errors

After reviewing all reports of errors for 2014 the types of errors were summarized as follows:

• Open system: The blood bag opens due to any reason like leakage, bad handling and sealing.

- Data entry: Wrong, missing, no and delays
- Switching and missing label.
- Wrong procedure.
- Manufacturer error.
- System/equipment failures.
- Broken samples and units.

Analysis

The highest percentage of errors occurred in 2014 was due to open system errors (32%) followed by the others as showed in figure-3, the bars in red color are all due to errors in data entry.

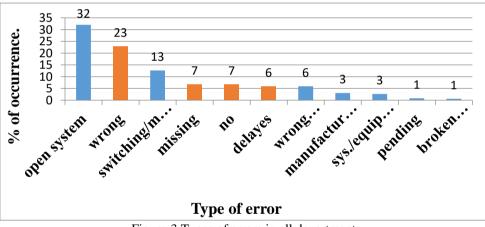


Figure-3 Types of errors in all departments.

Open system:-

The open system errors were analyzed since it has the highest number of occurrence during 2014 and they are:

- Manufacture error.
- Improper sealing.
- Improper welding.
- Miss-handling.
- Personal error.
- Leakage during labeling.
- Faulty storage.
- Improper use of machine.

- Fell down.
- Leakage during CAD.

The Analysis

The collected data show that manufacture error has the highest occurrence (45%) among all other reasons. This indicates that the supplier has a poor quality management and KCBB should change their blood bags supplier to a better one because loosing blood bags could mean losing lives.

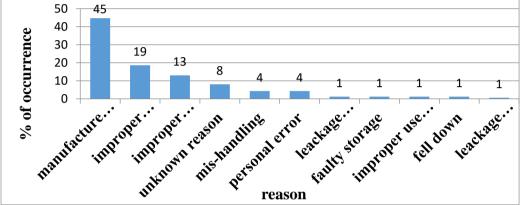


Figure-4: Reasons of Open System Errors.

Tuble 1 Open i	System Litois	
open system :		
manufacture error	44.7204969	44.7205
improper sealing	18.6335404	18.63354
improper welding	13.0434783	13.04348
unknown reason	8.07453416	8.074534
mis-handling	4.34782609	4.347826
personal error	4.34782609	4.347826
leakage during labeling	1.24223602	1.242236
faulty storage	1.24223602	1.242236
improper use of machine	1.24223602	1.242236
fell down	1.24223602	1.242236
leakage during CAD	0.62111801	0.621118
improper stocking	0.62111801	0.621118
while centrifuge	0.62111801	0.621118

Table-1 Open System Errors

Cause and Effect Diagram

Figures-5 (a & b) show the cause and effect diagrams for discarding blood bags and for open system errors which was developed after brainstorming and some literature reviewing

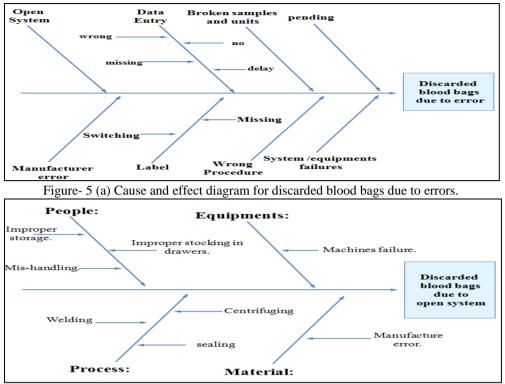


Figure-5(b) Cause and effect diagram for open system.

Discarded blood bags

After collecting the errors reports data, the errors that led to discarding the blood bag were analyzed in order to know the percentage of blood bags discarded due to error in 2014. The pie chart shown in figure - 6(a) represents the percentage of discarded blood bags due to all reasons during 2014 from the whole number of blood bags enters the blood bank. Figure-6 (b) shows that 12% of blood units discarded in 2014 was due to errors and the rest 88% was due to expiration of the blood bags.

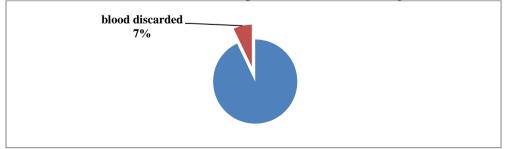


Figure- 6(a) Percentage of blood bags discarded.

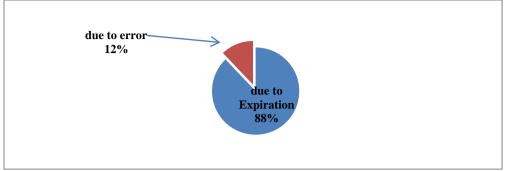


Figure-6 (b) Percentage of blood bags discarded.

Quality control charts

To determine the current approach of Quality Department in KH Central Blood Bank, a historical data for 2014 has been reviewed. KH Quality Department main responsibilities are in detecting errors, accidents and incidents through whole KH departments and labs. Also, it is concerned in investigations and the corrective actions to maintain the high quality level.

Blood Bag Quality features

There are certain features of the blood bags which could lead to discard them if they are not meeting these feature's specifications, which are:

- Lipoid
- Interix
- Hemolytic
- Bloody
- Volume
- Open System
- Prolonged donation:
- Block / clot
- Block / sickle cell
- Manufacture error
- ABO-discrepancy
- Switching labeling
- IAT-positive
- Reject donation
- Not valid component
- Expired

These features vary in their severity; the most Sevier feature is determined to be studied. Which is the volume? The blood bag volume has to be between 300-576 mL³. If the blood bag is low or high it has a proportion with anti-clotting could cause clogged arteries for the patient.

Volume Quality Chart

In order to do further investigations and determine the root causes for each of the previous blood bags features were shown in volume quality chart figure-7. Data collection for the blood bag's features for:

- 2014 (Jan Dec):
- Control Chart: X bar R
- Number of Samples: 30
- Size of Each Sample : 10
- The samples are randomly chosen from whole 2014 data.
- Control Chart: P chart
- 100% sample inspection.

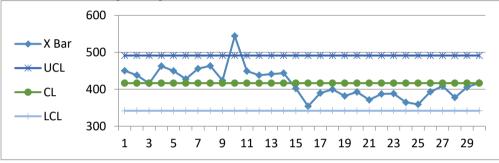


Figure - 3: Volume Quality Chart.

Investigation

The blood bag volume is affected by donation process. The time of donation process must not exceed 20 minutes. A correlation between the donation process time and blood bag volume was found. If the process exceeded 20 minutes it will be high volume and if doesn't exceed 20 minutes it will be low volume, So as a solution the donation duration must accurately be measured to avoid this kind of error.

KH Safety Department

Safety Department in KH has an important role in whole blood bank building, departments and labs. It deals with:

• How to manage risk: for example donation risk, security and training courses

• How to have a safe Blood Bank: for example employees' safety, donor's safety and testing blood for safety.

• How to have safe processes: for example blood donation process, blood testing processes and SOP following.

KH Central Blood Banks Safety Committee was formed in March 2010, which consists of 17 members. It identified the tasks entrusted to this committee, which is limited to:

• Prepare an annual plan for keeping security and safety of staff and donors from electrical hazards, fire, chemicals and infections.

Development of annual laws and regulations relating to the security and safety of the staff and donors.

• Promoting security awareness among staff and to observe any errors or incidents that may affect their work.

• Develop a contingency plan in the event of any threat to health or environmental cooperation with the Commission on the contingency plan.

Organizing a yearly placebo evacuation.

• Renewal of safety signs in all divisions and evacuation maps with the developments in management including the warning sirens, exits signs and fire tools.

Schedule an annual report for safety and security needs. Elaborate brochures talk about security and safety of staff.

Organize regular lectures especially for new staff security and safety procedures.

Upgrade the safety SOP of Laboratories. Initiate periodic exams of safety for all staff in both languages Arabic and English.

Organize special interior and exterior annual training courses to security and safety.

In addition on 22/04/2010 this committee has worked to activate the evacuation plan and application of placebo in the building of the KH Central Blood Bank. So, they updated the map of the building and exit signs depending on the emergency exits. This evacuation done within the help of General Administration of Civil Defense, Fire Service Directorate, the Department of Medical Emergencies and Directorates Governorate Security

and the Information Security Department. The evacuation has been successive comparing with the previous years because it was completed in a period of time does not exceed 25 minutes which indicates the efficiency of the staff, donors and the high level of security and cultural awareness they have. Thus, the goal was vocalist of the process of evaluation placebo in the event of a fire or other emergency.

Transfusion safety

Transmitted infections can be eliminated or reduced through:

- Strategy for blood safety. Laboratory safety. Fire safety. 1.
- 2.
- 3.
- Electrical safety. 4.
- Mechanical safety. 5.

Strategy for blood safety: is to collect blood only from voluntary donors at low risk with testing all donated blood for infections such as: (HIV, Hepatitis, Syphilis). Also blood donors should be healthy and at lowest risk of transfusion transmitted diseases.

Laboratory safety has several aspects like:

• Personal safety: safety of employees and labs technicians, all employees should follow the (SOP) of safety in order to insure their personal safety all the time.

• Biological safety: to maintain clean work environment for the blood bank workers.

• Chemical safety: all chemicals should be kept in a proper place and all flammable liquids must be kept in fire proof boxes.

• Dangerous waste disposal: all dangerous wastes should be disposed properly by following the (SOP).

properly by following the (SOP). Fire safety: fire extinguishers should be provided properly in several areas around the building and smoking is prohibited. Workers should be trained on the procedures to follow when hearing a fire alert. In KH central blood bank they perform a fire drill every two years to make sure that workers and visitors of the blood bank are aware of the procedures followed in case of fire. Electrical safety: all electrical devices and electricity outputs should be inspected periodically to insure that they are safe and nonhazardous and all electrical switches should be switched off at the end of the day.

Mechanical safety: All equipments should be inspected and maintained at regular intervals of time.

Accidents / incidents reports

Each member of the safety committee is responsible of reporting any accident or incident that occurred in the lab under his or her responsibility, as shown in figures-8 (a - d).

ACCIDENT/ INCIDENT REPORT					
LAB/UNIT NAME:					
DATE OF INCIDENT	TIME OF INCIDENT	NAME / Occupation OF INJURED PERSON /INVOLVED IN THE INCIDENT		EMPLOYEE GENDER	
1 1	: am/pm	1999 - A. A. A. Mary	1		female
	chemical exposure □ as chemical spill □ ra Impulse noise □ bu suffocation □ pu ssion □ pinch	ibestos exposure diological spill Jrn uncture/needle stick other:	apply)	ger 1 nd 1 n 1 o	d: (Check all that forso vhole body ther

Figure- 8(a): Accidents / incidents report form.

What material directly harmed the employee?	
What material directly harmed the employee?	
What material directly harmed the employee?	
what material directly harmout the only i	
Reviewed on: 15 April 2011	QM003/SAF/3FA
	QM003/SAF/3FA ts / incidents report form.
Figure-8(b) Accident	ts / incidents report form.
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Figure-8(b) Accident	ts / incidents report form.
Figure-8(b) Accident	ts / incidents report form.

Date injured person sample withdrawn	VDM results for sample involved	VDM result for injured person sample	Recommendation from health care
	on of viral disease marker		
	nittee comments and sign		

Figure-8(c): Accidents / incidents report form.

Figure-8(d) accidents / incidents report form.

Types of accidents/incidents

After collecting and analyzing data of accidents/incidents reports were drawn in figure-9, which shows the percentage of accidents/incidents occurrence in all of KH departments in 2014.

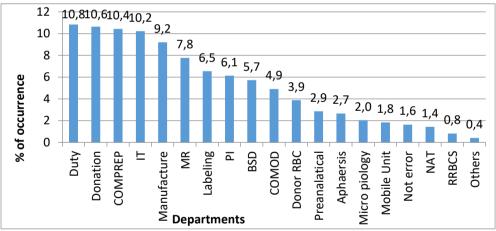


Figure-9: Percentage of accidents/incidents occurrence in all departments.

Analysis

As the previous figure shows the highest accidents/incidents occurrence was during duty (10.8) and that could be because of workers fatigue due to high load of work for each worker since the number of workers during duty is low. Figure -9 shows the different reasons of accidents/incidents that happen during duty. This figure illustrates clearly that the wrong procedure has the highest occurrence (35%) during duty. This

proofs that personal errors are the main reason of accidents/incidents during duty.

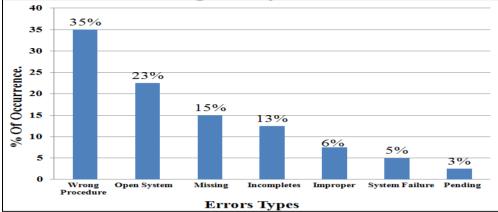


Figure- 10: Percentage of accidents/incidents occurrence in duty.

Rapid Upper Limb Assessment (RULA)

RULA is a postural targeting method for estimating the risks of work-related upper limb disorders. RULA assessment gives a quick a systematic assessment of the postural risks to a worker. The analysis can be conducted before and after an intervention to demonstrate that the intervention has worked to lower the risk of injury. The expected results of RULA are:

- Fewer errors from duty.
- Improve employee's performance.
- Proper work place for employees.

RULA scoring classification:

The main classifications are:

- **CLASS I (1 or 2):** Posture is acceptable if it is not maintained or repeated for long periods.
- **CLASS II (3 or 4):** Further investigation is needed.
- **CLASS III (5 or 6):** Further investigation and changes are required soon.
- CLASS IV (6+): Investigate and change now.

Technician's positions in labs:

Figure (11) was taken while the technician was loading the centrifuge with the blood bags. The final score according to RULA was 5 which mean Investigation and changes are required soon.



Figure- 11: Technician working on centrifuge.

Figure (12) was taken while the technician was testing the blood bags. The final score according to RULA was 6 which mean Investigation and changes are required soon.



Figure- 12: Technician testing blood samples.

Figure (13) was taken while the technician was printing the blood bag label and sticks it to the bag. The final score according to RULA was 4 which mean further investigation is needed and changes may be required.



Figure.13 Technician is labeling the blood bags.

Figure (14) was taken while the technical was documenting the result of the test. The final score according to RULA was 4 which mean further investigation is needed and changes may be required.



Figure- 14: Technician is documenting the test result..

RULA Findings:

- Most employees are suffering from varicose veins and backache.
- A small number of workers so the working load is much higher and the chance of making an error are high. There are two solutions:

(a) Suggested Solutions:

• The centrifuging worker: The work should be spliced into two parts and each part is performed by a different worker.

• The labeling worker: the table level should be low and the worker should be provided with a chair.

• The documenting worker: The computer is better to be on a disk with a chair.

(b) General solution:

A solution for quality and safety problems that were listed above should be automated for the whole processes system in order to minimize the errors that lead to discarding the blood bags and to lower the load on the labs technicians as will.

Table-2 summarizes the comparison between the two processing systems. It is clear that there is a big difference between the manual processing and the automated processing.

1 able 2. Comparison between the manua	i processing and the automated processing.
Manual processing	Automated processing
23 steps.	10 steps.
33 minutes for one whole	averaged 14 minutes
Blood unit.	Per whole blood unit processed.
one operator can process on average76	one employee, working a 6-hour shift
Blood bags during a 6-hour shift.	Can process 95 blood bags on average.
3 months training.	2 weeks training.

Table-2: Comparison between the manual processing and the automated processing.

The Results

Due the application of the above solutions the following results were obtained:

- 70% decrease on errors.
- Employees Fatigue will decrease.
- 40% decrease in operational tasks.
- 32% less time required to process one whole blood unit.

So the (12%) discarded blood units that was calculated earlier will be reduced to 3.6% only if we automated the whole processing system.

Building safety

In order to assure a safe working environment for the blood bank employees and for the donors and visitors of KH, some errors in the building were analyzed and some changes were recommended in order to overcome those errors to provide a better place for people around the KH building. These changes are:



Figure- 15(b): The Recomanded Fire cabinet.

Figure 15(a) shows a misplaced fire cabinet in the middle of the passage way because it will disturb the moving people that uses this passage way, while figure -15(b) shows the recommended way to place a fire cabinet which is inside the wall instead of in the passage way.

(b) Using Broken air conditioner:

Figure -16(a & b) shows a broken A/C (Air conditioner) that will lead to a serious problem in the ventilation system and could expose the building to different kinds of viruses and bacteria. In figure-16 (a) is the recommendation of how the A/C for the KH should look like.



Figure- 16(a): Broken air conditioner.



Figure-16(b): Proper air conditioner.

(c) Replacing the output electrical sources:

Figure-17(a) shows a broken electrical output source that will lead to an electrical shock for any one that handle it improperly or even it could lead to an electrical fire .In figure-17 (b) is the recommendation of how the electrical output source should be.



Figure- 17(a): Improper electrical output source.



Figure- 17(b): Recommended electrical output source.

Figure-17 (c) shows how electrical boxes in KH looks likes which is very hazardous for any one came near to it. Figure-17 (d) shows the right way to keep electrical boxes safe.



Figure- 17(c): Exposed electrical box in KCBB.



Figure.17 (d): Safe electrical box.

(d) The proper storage:

Figure-18 (a) shows the storage unit in KH which shows randomness and chaos in keeping any inventory because the stuff are not organized and also they could easily full down on any person and hurt him/her. Figure-18(b) shows the recommended proper way to organize the storage unit.



Figure- 18(a): Storage in KCBB.



Figure-18 (b): Proper way of keeping storage.

Risk analysis

According to accidents/incidents reports the following risk types and blood bank areas were found:

Risk Types:

- Biological Exposure
- Biological Spell
- Electrical Shock
- Heat Illness
- Crush
- Fall
- Explosion
- Chemical Exposure
- Chemical Spill
- Impulse Noise
- Suffocation
- Burn

Puncture

Areas:

- Medical facility •
- Lab •
- Cold Room
- Work shop
- Office space
- Construction site

Risk matrix

Tables 2 and 3 show the construction steps in applying risk matrix. The risk matrix table-4 is used to quantify the identified risks, though the correlation between categories of severity and frequency. Table-2: The Frequency:

Categories	Classification	Description	
А	Extremely Remote	Scenario that depends on multiple faults in the system or subsystems. This fault is possible, but improbable during installation or activity.	
В	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).	
с	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-3: The Severity	
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.	
п	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.	
ш	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	cure with reduced treatment time. 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.	

Accident type / Area	Medical Facility	Lab	Cold Room	Work Shop	Office Space	Construction Site
Biological Exposure	D3	D3	B2	C1	A1	A1
Biological Spell	D4	D4	B3	D3	A3	A1
Electrical Shock	C4	C4	C4	C2	B2	B1
Heat Illness	B2	B2	B2	A2	A1	C1
Crush	B2	B2	A1	A1	A1	Al
Fall	D3	D3	C2	C2	A1	A1
Explosion	B3	C3	C3	B2	A2	B2
Chemical Exposure	D4	D4	B2	B1	A1	A1
Chemical Spill	D4	D4	B3	D1	A1	A1
Impulse Noise	C3	C3	C3	C2	D2	D2
Suffocation	C4	D4	A3	C1	C1	C1
Burn	C4	C4	A2	B1	B1	B1
Puncture	A3	A3	A1	A2	A2	A2

Table-4: The Risk Matrix:

Risk Matrix analysis

The analysis of the risk matrix show that the high risk incidents are in (Medical Facility & Labs), which are:

- Biological Exposure.
- Biological Spell.
- Fall.
- Chemical Exposure.

т

• Chemical Spill.

Establishing the solution approaches leads to systematic understanding and improving the safety. Table-5 shows a summary of suggested solution as a result of the risk analysis.

able.5: Accidents/incidents solutions.	able.5:	Accidents/incidents solutions.
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Incidents	Goal	Improvement ways
Biological Exposure	More attention	PPE, regular Sterilizing, labs layout improving
Biological spell		
Fall	Better handling	Trolleys with hoods, reduce slippery floors, increase the working tables height
Chemical Exposure	More attention	PPE, regular Sterilizing , labs layout improving
Chemical Spill		

Conclusions

From the analysis of the present work case-study data the following conclusion can be drawn; KH central blood bank has a lot of discarded blood bags due to errors and quality features. All the contingency reasons were studied and analyzed. Brainstorming some recommendations and solutions

based on engineering management were suggested. KH is not 100% safe working environment. In order to be a safer place, the suggested recommendations and solutions were implemented. The consequence results have shown great improvements in the safety system of the KH and applying and using the Engineering tools, equipments and instruments. Furthermore, to improve the archiving system to be more efficient and effective a computerized system was suggested to be implemented.

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