Implementation of Six Sigma on Corrective Maintenance Case Study at the Directorate of Biomedical Engineering in the Jordanian Ministry of Health

Adnan Al-Bashir
Department of Mechanical and Industrial Engineering
ALHOSN University, UAE
The Hashemite University, Jordan

Akram Al-Tawarah
Department of Biomedical Engineering
Royal Science Society, Jordan

Abstract

Medical equipment needs to be managed effectively and carefully from the first step of buying the equipment till being scraped. This includes purchasing procedure, operational procedures and he maintenance policies used in this regards. Managing the maintenance of medical equipment is vital for the patient and for the hospital itself. One of the main problems in healthcare sector today is the availability of medical equipment, which is largely affected by downtime variation needed to repair the medical equipment. This study presents a process improvement study applied on the Downtime of the medical equipments during the maintenance work in the Jordanian of Health Hospitals, based on customized Six Sigma methodology- DMAIC- (Define, Measure, Analyze, Improve and Control). Data was collected from different locations and different equipments to study the problem and make the necessary actions to resolve or reduce downtime. Obtained results indicate that the downtime reduced by 35% by introducing a new procedure to the clinical engineer to used when dealing with any medical equipment for maintenance work.

Keywords
Six Sigma, DMAIC, Clinical Engineer, Correction Maintenance, Downtime

1. Introduction and Background

MEMP procedures usually need to be improved continuously based on manufacturer's recommendations, organization experience and international standards. This includes corrective and preventive maintenance procedures to improve equipment performance (Young and Frank, 2006).

One of the most important problems facing medical staff in hospital is the, unavailability of medical equipment when needed for use due to repair process, which results from mismanagement in the repair of medical equipment as it may need a long time to fix it more than necessary, leading to a significant in the downtime

In our study we will examine the procedure of corrective maintenance in Directorate of Biomedical Engineering (DBE) in Jordan, taking Prince Hamzah Hospital (PHH) as a case study to implement Six Sigma strategies in reducing downtime of the medical equipments.

A study done by the World Health Organization (WHO) has shown that nearly 50% of medical devices in developed countries are not function and are used incorrectly or are not maintained properly due to the absence of an effective management policy. (Regional Committee for the Eastern Mediterranean, 2006). In order to make a full utilization of medical devices and ensure their availability, a plan and a comprehensive national policy must be exist, (Geeta S,2005). In another study, conducted by Abdelbaset, Evaluate performance, productivity, effectiveness of clinical engineer in Palestine use Canadian Medical and Biological Engineer Society (CMBES) and AAMI as benchmark guidelines , gives MOH in Palestine and medical equipment administration a clear vision about the status of CEs and potential area that need improvement (Abdelbaset, 2004). studies made by Association for the Advancement of Medical Instrument (AAMI) to find suitable metric to measuring CEs performance and using it as benchmarking against other (Binseng, Richard, W, S, 2006). This article provides data and it reports a study of Global Failure Rate (GFR) as a promising benchmark for measuring CE performance. Another article shows the capability and the importance of applying Six Sigma in hospital process and indicates that defect in hospitals process; procedure and outcome were found in many kinds. Traditional quality programs in hospitals that rely on three-sigma thresholds to determine acceptable outcomes, cannot prevent this defect (Carole, Noreen, 2004). DA Cook demonstrated a protocol for measuring downtime and availability for radiotherapy equipment depending on required time for Clinical, Quality control and Maintenance Time (D A Cook, 1997)**.** Another study for maintenance management planning is made by R.Miniati, he made control for the Downtime by failure analysis "R. Miniati, 2008". access to customer satisfaction, reduce defect and work for continuous improvement of basins process in any system, maintenance should be an essential component of this system and given the importance care, follow-up and continuous development to access the World-Class Maintenance Process (WCMP) through the application of the principles Total Productive Maintenance (TPM) and Six Sigma tools that guarantee the effective and productive maintenance that reduce downtime and then access to Six Sigma level (P. Milosavljević, K. Rall ,2005) .

2. Problem Statement

One of the most important problems facing medical staff in hospital is the, unavailability of medical equipment when needed for use due to repair process, which results from mismanagement in the repair of medical equipment as it may need a long time to repair it more than necessary, leading to a significant in the downtime. Downtime is one of the major problems facing the administration of clinical engineering, causing them embarrassment with customers. Existence of this problem besides lacking of importance to seek a proper solution causes many problems in health service.

3. Methodology

Throughout this research, the various DBE procedures related to the Correction Maintenance (CM) of medical equipments were investigated and data were collected from seven public hospitals for 689 different medical equipments, and categorized within 15-fault categories that are associated with 5203 CM work during the period from May 2002 to April 2009. The next step is to verify the kind of problems affecting downtime that influence the quality of service, using DMAIC methodology from Six Sigma and the analysis made using ISHIKAWA diagram, Pareto analysis, Regression analysis, process capability analysis, and accordingly Sigma value was calculated.

Through this study Six Sigma methodology was used and applied in Directorate of Biomedical Equipment (DBE) procedures in studying lost opportunities resulting from Downtime needed for repairing medical equipments, conclusions and many of recommendations are provided to DBE and Prince Hamzah Hospital (PHH) in order to improve their process and quality of service leading eventually to customer satisfaction.

Define Phase

This project aims to study the works of Correction Maintenance in DBE, and then apply Six Sigma methodology to determine the factors affecting availability of medical equipment in the Ministry of Health reduce Downtime and identify repair procedures that take the longest process time. Then propose several mechanisms of action to improve CM procedure.

Many items have been identified by researcher to use them as guidelines and boundaries that must be adhered during the period of time and regarding the cost required.

Measurement Phase; Project Base Line Measurement.

Second phase of the DMAIC methodology is the MEASURE phase, where we here identify the information and data that has been made to complete this phase:

1. Construct DBE repair maintenance process flow chart.
2. Identify all the stakeholders in the MOH, benefiting from the services of DBE and its work. This is influenced by the level of service provided to them. Table 1, illustrates a list of served end-user.

Table 1: Define Customer

Customer name	Quantity
Hospital	30
Health center	685
Dental clinics	332
Pediatric and mother care clinics	348
Blood banks	23

Hence, identifying the complaints source, a brainstorm was conducted from researcher and DBE groups to prepare an ISHIKAWA Diagram (Cause and Effect Diagram) as shown in figure 1.

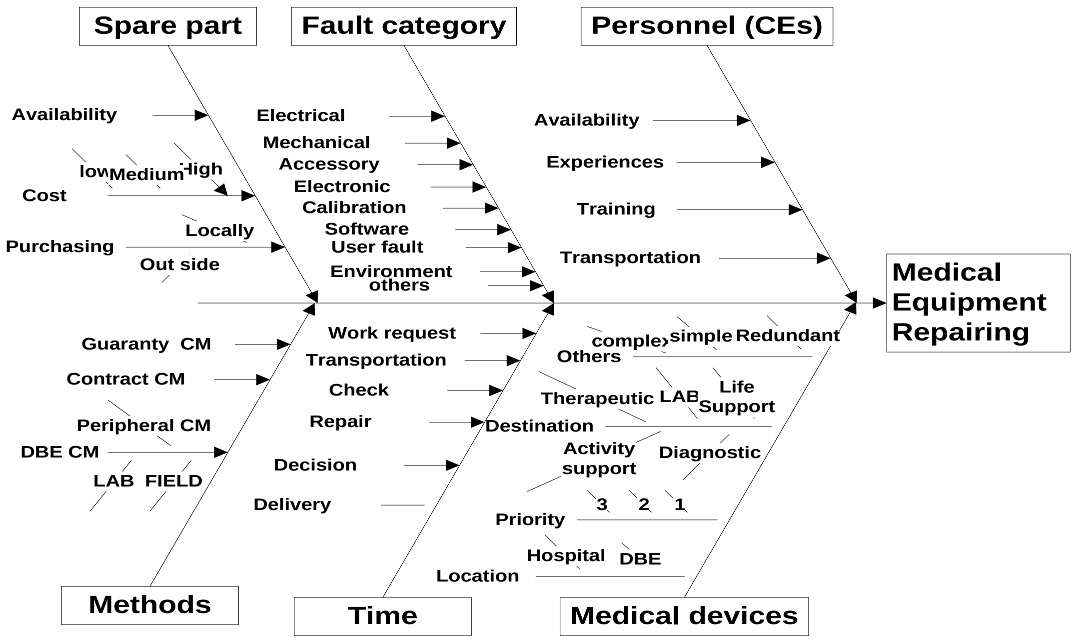

Figure 1: Fish-bone diagram for causes of medical equipment repairs

3. Data were collected from seven public hospitals located at various areas and different distances from the capital city Amman as shown in table 1, to disclose the impact of hospital location in CM procedures. While figure 2, shows percentages of medical devices collected from each hospital.

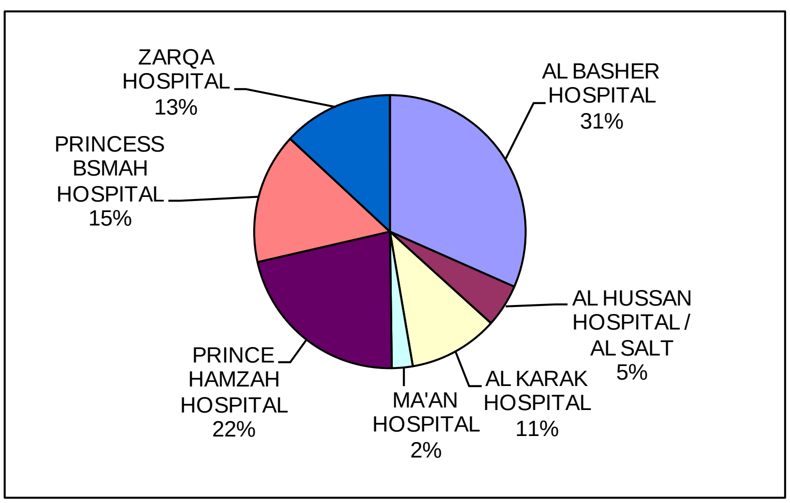

Figure 2: Pie-Diagram Showing Percentage of Medical Equipment Used from Each Hospital.

4. Data collected includes CM information for 689 medical equipments.
5. Data were collected for 5203 CM work and around 15 fault categories from the CMMS, used by DBE from the date of May 5th, 2002 to April 1st, 2009 - activated date of CMMS in DBE and even the date of this research.

Analysis Phase: Root Cause Identification and Verification.

A large number of CM activity for medical devices in the MOH was collected, analyses was made to identify the main sources of the problems causing Downtime for medical equipment.

Analysis According to Destination Used and Priority

The objective of this analysis is to identify the species of medical equipment with large downtime in order to focus research on it, and do the necessary improvements to reduce the period of repair and disseminate the results to all maintenance procedures. This is one reform of philosophies of Six Sigma in identifying problems.

First The graph in figure 3, shows that the percentage of faults is high in the equipment of Diagnostic and Life support, then Laboratory equipments ,Activity support services and, finally, Therapeutic equipments respectively.

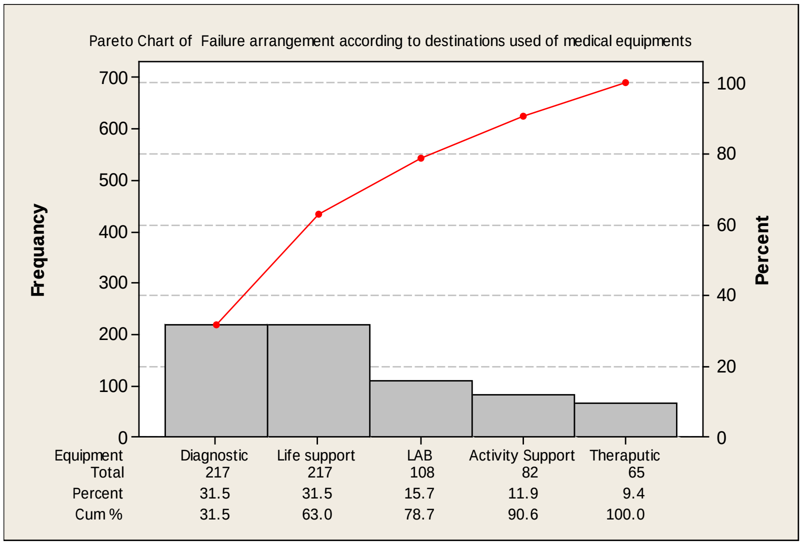

Figure 3: Pareto Chart Represent Destinations of Use Medical Equipments.

Second analysis of the information was based on the division of services depending on the severity, where the adoption of three categories as it is supported in the maintenance system of DBE

- Priority 1, as: ventilators, anesthesia machines, blood gas analyzer, MRI, CT-scan.
- Priority 2, as: blood warmer, hematology analyzer, centrifuge, electrolyte analyzer.
- Priority 3, as: biomexer, ophthalmic meter, densometer, medical balances.

This distribution depends mainly on the importance of this device to the hospital or medical center to provide a service to the patient, and the presence of alternative devices or other types do the same work as well as the location for the hospital and its remote distance from the other hospitals. Figure 4, shows the work made for Corrections Maintenance devices have priority 1.

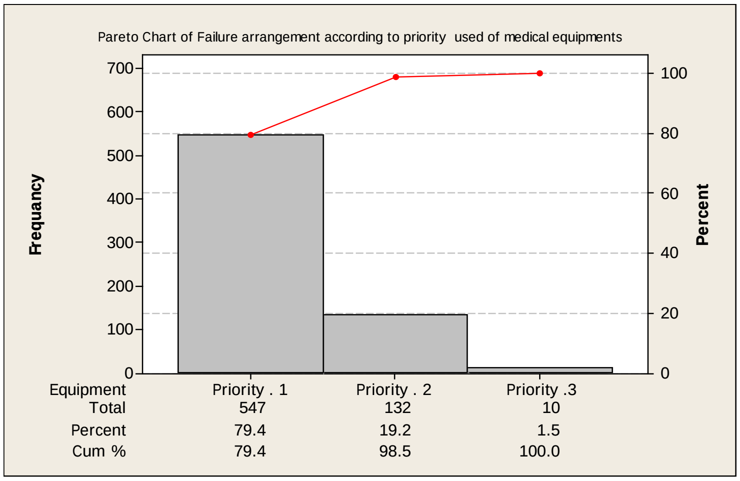

Figure 4: Pareto Chart Represent Failure Arrangement According To Priority of Medical Equipments.

Analysis According to Fault Category

An analysis of the data collected, depending on the quality of the fault category that were detected in the reports of corrective maintenance performed. Where sixteen-categories have been identified depending on corrective action found in CMMS which are: “Electrical”, “Mechanical”, “Electronic”, “Software” ,“Calibration”,” Installation”, “Transportation”, ”Accessories”, “Clean”, “Environment”, “User Fault”, “Misuse”, “False Alarm”, “scrap”, “ Training” and “ Other (Unclassifiable)”. Figure 5 shows the percentage of the faults causes, where it appears that the bulk of the causes of faults are electrical, mechanical, accessory or electronic.

Sigma Value Calculated

Calculated sigma value and assess the performance efficiency of Correction Maintenance work at the DBE depending on DT. Through this knowledge, the performance of CEs in the DBE can be detected and provides a tool to depict the performance of correction maintenance within DBE. It also helps to work the necessary improvement of the performance required in order meet the desire for customer satisfaction. Table 2, shows the main elements used to calculate sigma value for DT.

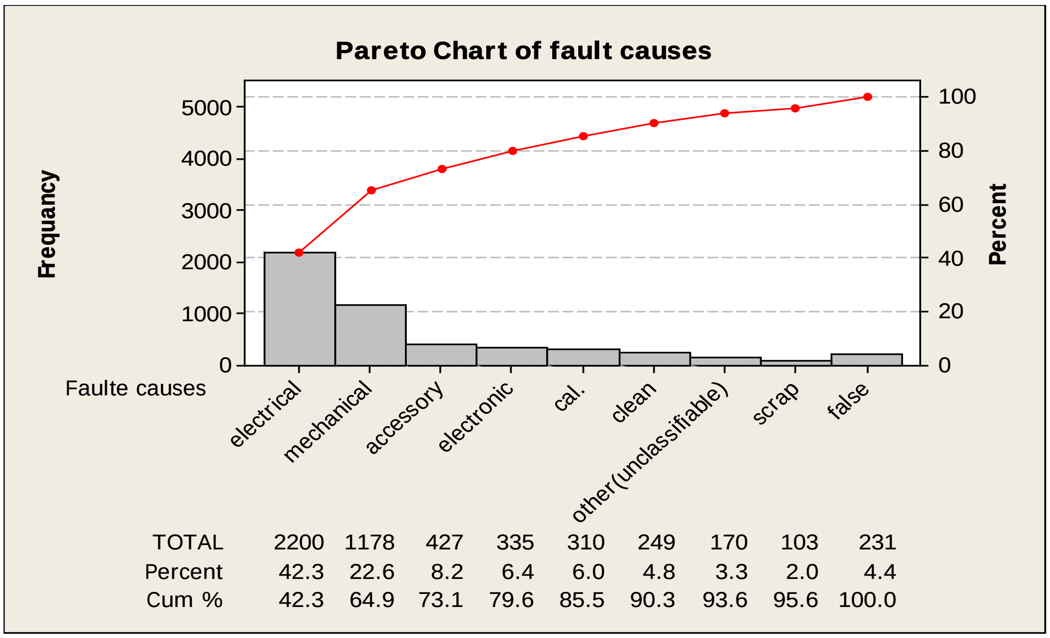

Figure 5: Pareto chart for Failure arrangement according to fault category

Table 2: Identify sigma level for DT

Maintenance Action/ Repair	Average Downtime / Days	Assumption Average Downtime / Days	Number Of Case	Number Of Defects
Electrical	4.3379	3	2227	746
Mechanical	4.552	4	1201	417
Electronic	29.733	25	341	114
Accessory	5.0931	4	430	129
Total cases	4199			
Opportunities	4			
Total defects	1406			
Shift	1.5			
Calculated				
Defect Per Unit	0.335			
DPMO	83710.407			
% Defect	8.371			
% Yield	91.629			
Process Sigma	**2.881**			

Risk Priority Number (RPN) Analysis

Table 3, illustrates the risk associated with potential problems of downtime for these medical devices.

Table 3: RPN for high risk medical equipment

Equipment Name	A) Severity Rate 1-10 10=Most Severe	B) Occurrence probability Rate 1-10 10=Highest Probability	C) Detection Probability Rate 1-10 10= Lowest Probability	Risk Priority Number "RPN" A*B*C
Anesthesia unit	10	5	9	450
Bio-Chemistry Analyzer	9	9	10	810
Blood gas analyzer	9	9	10	810
Defibrillator with ECG Monitor	8	5	6	240
Hematology Analyzer	8	8	10	640
Ventilator/ adult	10	6	8	480
Ventilator/baby	10	6	8	480
X-ray radiographic bucky unit	9	7	10	630

Phase Four: Improvement; possible solution

This study aims to make the necessary improvement on the mechanism of the CM procedure for medical devices at the Jordanian MOH. Where, we do the following:

1. Prince Hamzah Hospital in Amman was selected to improve mechanism CM, through applying Six Sigma methodologies.
2. As problem-solving Team is needed, it was identified to make improvement on CM, all concerned people where part of the team.
3. Team was informed of Six Sigma benefit, tools, it's important as a quality method used to reduce defect and inform them about its advantages to reduce DT as a defect in CM to ensure optimum utilization of medical equipment.
4. The next figure 6 shows a new proposed CM action to Follow-up through CEs in PHH workshop for medical devices CM process.

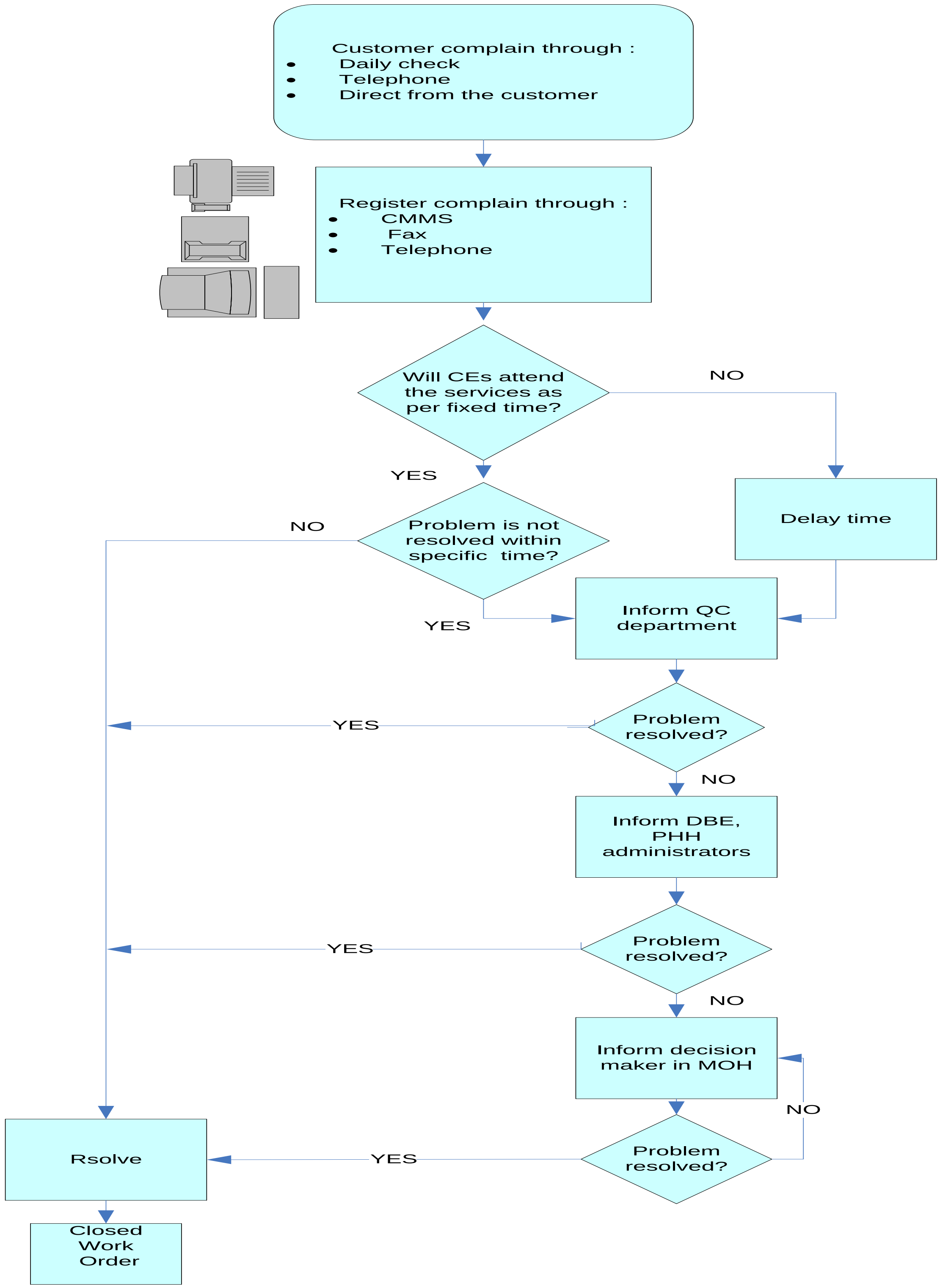

Figure 6: New Proposed CM Action Plane

Control; Sustain the Gain

Control phase is an essential and necessary for any performed work need continuous monitoring and improvement. It is imperative to control CMs activity and take measurement for maintenance procedures ,equipment performance and any faced problems continually over the time ,in order to find best practice, worst practice, trend and appropriate solutions that able to make implementation of CMs is safely, fast, high-quality, inexpensive and meets the desire of customers satisfaction , which requires the participation of everyone, whether are CEs or operators.

As we see in improvement phase, sigma value increase from 2.881σ to 3.708 σ and in long run we expect the ability to increase its value. To maintain the improvement achieved, following activity must be included:

- Plans, strategies, maintenance procedures and logistic work must be essentially control continuously through Quality Control department.
- Making control chart to asses CEs performance and downtime for medical devices.
- Checking stability and capability of the CM process.
- Improved CM procedure must be standardization and documented.
- Purchasing order, decision needed, and delivery time must be monitor continually using control chart.
- Activate penalty system for the suppliers. regarding delivery time for spare parts needed
- Activate penalties system for the delay in the processing of orders request, execute orders, delivery time and reception process.
- Peripheral workshop employees must be given more attention, qualified technically and managerially and strict control program must be implemented including all their activities.
- Control CEs productivity by using new managerial methods and daily work sheet.
- Implement PPM frequently and on the time.
- Analyze CEs productivity continuously to discover problem then solve it.

Other wise occurring of problems, variability, breakdown, costly and unsafe CM is essential due to human factor. But executing Six Sigma methodology is the best practice to insure nearly no defects and reaches customer satisfaction.

Conclusion and findings

It was shown from the model that the main factors affecting the down time were check time, decision time and the delivery time, not the actual maintenance time. Therefore, a lot of work should be made to minimize their effect on the downtime. The model indicates that the staff availability was not the main factor affecting the downtime. There are many other factors that have negative effect on the downtime such as: delay by the maintenance staff in the detection devices failure, delay in the registration requests for the service, CM not performs as it should be, delay in the closing of work orders.

A small modification on the CM process has a great affect on increasing the sigma level from 2.881 to 3.708 without any extra cost. According to RPN analysis, attention is needed for high risk medical equipment, especially Bio-chemistry analyzer, Blood gas analyzer, Hematology analyzer, X-ray machine, and ventilator devices

Applying Six Sigma methodologies and its philosophy is the best choice for Maintenance Management System, and it is the best practice that we need in order to achieve improvements in CM for minimizing Downtime, reducing cost, customer satisfaction, and reach World Class Maintenance.

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