Chapter 2

Chapter two

2.1.1 Notable approaches to Quality Control:

There is a tendency for individual consultants and organizations to name their own unique approaches to quality control; a few of these have ended up in widespread use:

Table: 2.1 Notable approaches to Quality Control

Terminology	**Approximate year of first use**	**Description**
Statistical quality control (SQC)	1930s	The application of statistical methods (specifically control charts and acceptance sampling) to quality control
Total quality control (TQC)	1956	Popularized by Armand V. Feigenbaum in a Harvard Business Review article and book of the same name. Stresses involvement of departments in addition to production (e.g., accounting, design, finance, human resources,

		marketing, purchasing, sales).

Statistical process control (SPC)	1960s	The use of control charts to monitor an individual industrial process and feedback performance to the operators responsible for that process. Inspired by control systems.
Company -wide quality control (CWQC)	1968	Japanese - style total quality control.
Total Quality Managemen t (TQM)	1985	Quality movement originating in the United States Department of Defense that uses (in part) the techniques of statistical quality control to drive continuous organizational improvement.

Six Sigma (6σ)	1986	Statistical quality control applied to business strategy. Originated by Motorola.

2.1.2 Total Quality Management:

Total Quality Management “TQM” is an approach to management of an organization that integrates the needs of customers with a deep understanding of the technical details, Costs and Human resource relationship. It has four main components: quality planning, quality control (QC), quality assurance and quality improvement. Quality management is focused not only on product and service quality, but also on the means to achieve it. Quality management, therefore, uses quality assurance and control of processes as well as products to achieve more consistent quality.

Quality Improvement can be distinguished from Quality Control in that Quality Improvement is the purposeful change of a process to improve the reliability of achieving outcome. Quality Assurance is the planned or systematic actions necessary to provide enough confidence that a product or service will satisfy the given requirements.

Quality Control is the ongoing effort to maintain the integrity of a process to accomplish the reliability of achieving an outcome.

2.2 waste reduction:

Waste is an activity or process that’s adds costs but adds no value for the customer.

It is a source to minimize the quantity of the waste required to be treated and achieved usually through better design and /or process management.

2.2.1 Type of waste in manufacturing:

1. Scrap.
2. Inventory.
3. over production.
4. Waiting time.
5. Unnecessary motion.
6. Unnecessary transportation.
7. Over processing.

2.3 Methodologies used in six sigma project define, measure, analysis, improve, and control (DMAIC):

The DMAIC project methodology has five phases:

• Define the system, the voice of the customer, and the project goals, specifically.

• Measure key aspects of the current process and collect relevant data.

• Analyze the data to investigate and verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered. Seek out root cause of the defect under investigation.

• Improve or optimize the current process based upon data analysis using techniques such as design of experiments, mistake proofing, and standard work to create a new, future state process.

• Control the future state process to ensure that any deviations from target are corrected before they result in defects. Implement control systems such as statistical process control, production boards, visual workplaces, and continuously monitor the process.

2.3.1 Define phase of the Project:

Define the problem and scope the work effort of the project team. The description of the problem should include the voice of the customer and/or business as well as how long the issue has existed. Hence, identify the customer(s), the project goals, and timeframe for completion. The appropriate types of problems have unlimited scope and scale, from employee problems to issues with the production process or advertising. Regardless of the type of problem, it should be systemic part of an existing, steady state process wherein the problem is not a one-time event, but has caused issuing for a couple of cycles. Define phase start with:

1. Identify product and/or process to be improved.

2. Identify the customers, their needs and requirements.

3. Quantify the gap(s) between process outputs and customer requirements.

4. Define the performance standards or measures.

5. Establish project objectives.

6. Ensure resources are in place for the improvement project.

2.3.2 Define Phase Deliverables of the project:

1. Product or process balanced against strategic business requirements.

2. Customer, critical-to-satisfaction requirements

3. Linkage of customer requirements to process outputs

4. Team formed with charter describing purpose, goals and benefits of the project.

5. Financial benefits approved by Finance Department

6. A high-level process map of major processing events occurring in the process.

7. Project plan with milestones and deliverables.

2.3.3 Define Phase Topics of the project:

1. Defining Values and Customer Relationships
2. Metrics
3. Project Selection and Definition
4. Team Building
5. Project Management
6. Finance
7. Deliverables

2.3.4 Measure phase of the project:

Measure the current process or performance. Identify what data is available and from what source. Develop a plan to gather it. Gather the data and summarize it, this usually involves utilization of graphical tools. Measure phase usually start with:

1. Map out the Current Process.

2. Determine how the process currently performs.

3. Look for what might be causing problem.

4. Create a plan to collect the data.

5. Ensure your data is reliable.

2.3.4.1 Key Tools have the project applied:

1. Process Map

2. C&E Matrix

3. Measurement System Analysis

4. Data Collection Plan

5. Baseline Control Charts

6. Process Capability Analysis

7. Graphic Techniques

2.3.4.2 Measure phase deliverables:

1. Validated project definition

2. Detailed process map with outputs and labeled inputs

3. Clearly defined process output measures (Y’s)

4. Measurement System Analyses on the Y’s

5. Control charts on baseline, process performance

6. Process capability and entitlement

7. Assessment of current control plan

8. C&E Matrix to determine focus within process

9. FMEA to assess and prioritize process risk

10. Low hanging fruit actions assigned to team

11. Valid data in accordance with the data collection plan

12. Graphical interpretation of data

2.3.5 Analysis phase of the project:

Analyze the current performance to isolate the problem Through analysis (both statistical and qualitatively), begin to formulate and test hypotheses about the root cause of the problem. Analyze phase start with:

1. Identify the Cause of the Problem.

2. Closely examine the process.

3. Visually inspect the data.

4. Brainstorm potential cause(s) of the problem.

5. Verify the cause(s) of the problem.

2.3.5.1 Key Tools have the project applied:

1. Cause analysis (fish bone).

2. Potential of Vital Causes.

3. Five whys analysis.

2.3.5.2 Analysis phase deliverables of the project:

1. A prioritized list of potential sources of variation.

2. Variation Component Studies.

3. Measurement Analysis on the X's.

4. Data collected to validate sources.

5. Graphical and statistical analysis of data P-value establishing level of significance and probability.

6. Correlation and regression analysis to determine variable relationships.

7. Reduced list of potential key input variables that affect the output(s).

8. Updated control charts, process map & FMEA.

9. Results to data (compared to baseline).

10. Translate customer requirements into functional process requirements.

2.3.6 Improve phase of the project :

Improve the problem by selecting a solution. Based on the identified root cause(s) in the prior step, directly address the cause with an improvement. Brainstorm potential solutions, prioritize them based on customer requirements, make a selection, and test to see if the solution resolves the problem. Improve phase start with:

1. Implement and Verify the Solution(s).
2. Brainstorm solutions that might fix the problem.
3. Select the practical solutions.

4. Develop maps of processes based on different solutions.

5. Select the best solution(s).

6. Implement the solution(s).

7. Measure improvement.

2.3.6.1 Key Tools have the project applied:

Action plan.

2.3.6.2 Improve phase deliverables of the project:

1. Systematically experiment with KPIVs

2. Determine optimum conditions of KPIVs to result in optimum KPOV to meet CTQ

3. Proposed optimum operating conditions and solution

4. Proposed operating tolerances

5. Continue to lean process

6. A new (improved) process performance baseline and capability

7. Validated ‘significance’ of improvements

8. Confirmation plan or results.

2.3.7 Control phase of the project:

Control the improved process or product performance to ensure the target(s) are met. Once the solution has resolved the problem, the improvements must be standardized and sustained over time. The standard-operating-procedures may require revision, and a control plan should be put in place to monitor ongoing performance. The project team transitions the standardized improvements and sustaining control plan to the process players and closes out the project. Control phase start with:

1. Maintain the Solution(s).
2. Continuously improve the process.
3. Ensure the process is being managed and monitored properly.
4. Expand the improved process throughout organization.
5. Share and celebrate your success.

2.3.7.1 Key Tools have the project applied:

1. Control Plan
2. SPC
3. Mistake Proofing
4. Quick Setup
5. TPM
6. Standard Operations

2.3.7.2 Control phase deliverables of the project:

1. Approved Control Plan encompassing documentation required to maintain improvements
2. Lock in optimum KPIVs

3. Monitor and control KPIVs to generate optimum KPOV

4. Continue to lean process

5. Meet CTQ consistently; sustainable results

6. Documented project and process improvements

7. Statistically validated process performance monitoring

Vehicle.

2.4 Seven Quality Tools:

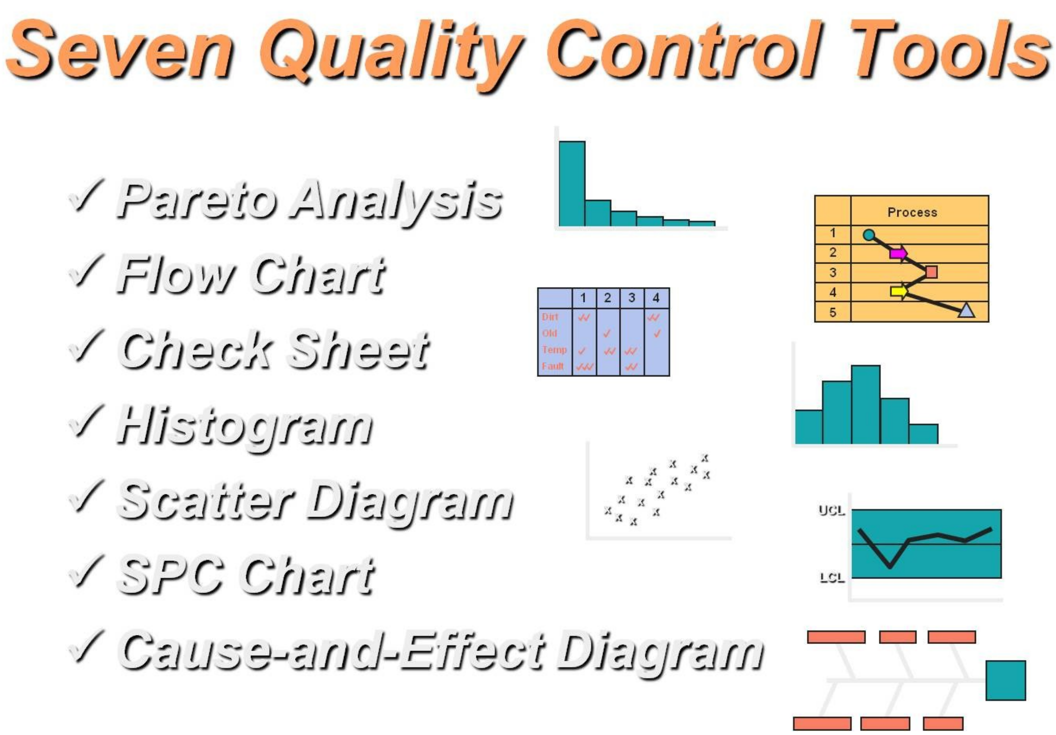

Fig 2.1 Seven Quality Control tools

2.4.1 PARETO CHART:

A Pareto chart is a bar and line chart that displays data in a hierarchical order identifying where any given problem occurs most frequently.

The objective of a Pareto chart is to identify the 20% of the places that account for 80% of the problem. Pareto identified that problems are not evenly distributed, and there is commonly an 80:20 rule (the data won't be exactly 80:20).

A Pareto chart will enable resources to be targeted at the 20% of the wards with 80% of the problem resulting in the greatest gains for quality improvement.

The bars display the number of events per area of interest. The line displays the cumulative % of events, i.e. the percentage of each bar added onto the

next together. So the bigger numbers will have a greater percentage impact.

2.4.2 Cause and effect matrix (C&E) :

It helps to discover which factors affect the outcomes of your six sigma initiative. Is the tool which is used to prioritize potential causes identified C&E diagram or a CTQ tree?

2.4.3 Fishbone Diagram:

The fishbone diagram is a cause-and-effect diagram that can be used to identify the potential or actual cause (s) for a performance problem. Fishbone diagrams provide a structure for a group's discussion around the potential causes of the problem.

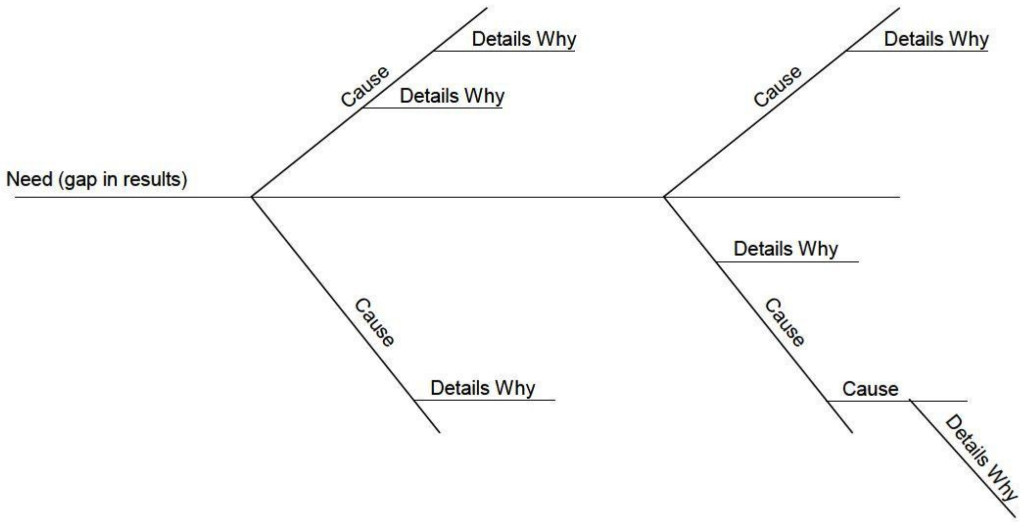

Fig 2.2 Fishbone Diagram

2.5 Case study (Rubber gloves manufacturing processes) :

Rubber gloves manufacturing processes, and particularly the process studied and investigated in this paper, are generally comprised of seven steps, namely: (1) raw material testing, (2) compounding, (3) dipping, (4) leaching and vulcanizing, (5) stripping and tumbling, (6) quality control and (7) packing. These process steps are illustrated in Figure

Fig 2.3 Case study (Rubber gloves manufacturing processes)

2.5.1 Define phase of the project:

The first stage of the Six Sigma and DMAIC's methodology is "define". This stage aims at defining the project's scope and boundary, identifying the voice of the customer (customer requirements) and goals of the project. However, before defining these elements within the project, the Six Sigma team has to be set up. In the case of this improvement project, the team was comprised of three people, which included a production manager, an experienced operator from the shop-floor and the improvement project leader. Nonthaleerak and Hendry suggest that a Six Sigma project should be selected based on company issues related to not achieving customers' expectations. The chosen projects should be focused on having a significant and positive impact on customers as well as obtaining monetary savings. Regarding to these suggestions, the problem selected to be tackled through this project was to reduce/eliminate quality defects on gloves. In order to ensure that the research is in-control and focuses on the project problem explicitly, the boundary of the project had to also be defined and clearly indicated. This research was set to experiment solely with the gloves of "Medium" (M) size. The improvement team and organization decided to initially focus on this particular product not only due to this size had historically had the highest number of rejected products but also the largest orders from customer. Finally, a project charter, which is a tool used to document the targets. The project charter is presented in the table below:

Table: 2.2 Defects reduction in rubber gloves

Project Title: Defects reduction in rubber gloves
Background and reasons for selecting the project: A large amount of rubber gloves has been rejected by customers due to they were defective. This problem causes several types of losses to the company, for example: time, materials, capital as well as it creates customers' dissatisfaction, which negatively affects the organization's image.

Project Goal: To reduce the defects by 50% after applying Six Sigma into the gloves manufacturing process	
Voice of the Customer (VOC):	Product’s quality
Project Boundary:	Focusing the gloves solely on “Medium” (M) size
Team members:	Production manager, an experience shop-floor operator and the improvement project leader
Expected Financial Benefits:	A considerable cost saving due to the defects reduction
Expected Customer Benefits:	Receiving the product with the expected quality

2.5.2 Measure phase of the project:

The “measure” phase of the DMAIC problem solving methodology consists of establishing reliable metrics to help monitoring progress towards the goals, which in this research consisted of reducing the number of quality defects in the rubber gloves manufacturing process. Particularly, in this project the “measure” phase meant the definition and selection of effective metrics in order to clarify the major defects which needed to be reduced. Also, a collection plan was adopted for the data to be gathered efficiently. One of the metrics defined was simply *number of defects per type*. In addition, two other metrics were used to compare the “before and after” states of the gloves manufacturing process when conducting the Six Sigma’s project. These factors were *quality level*, which was measured through *DPMO*, and the *Sigma level* of the process. After defining the total number of defects, the DPMO and Sigma level of the gloves manufacturing process were calculated. According to the company’s records, there were two major types of defects which had contributed to the gloves to be rejected by the customers. These two major defects were leaking and dirty gloves. The results are summarized in Table below:

Table: 2.3 result of case study

Type of defects	**Number of defects**	**Percentage of defects**
Leaking	**4495**	**19.51**
Miscellaneous	**1686**	**7.32**
Dirty	**788**	**3.42**
Total	**6969**	**30.25**

As a next step, a Pareto analysis was carried out to identify the utmost occurring defects and prioritize the most critical problem which was required to be tackled. The collected data was generated in the form of a Pareto chart, indicated that the highest rate of defects was caused by leaking gloves. In particular, this type of defect contributed to over 60 percent of the overall amount of defects. Therefore, the improvement team and organization decided to initially focus on the reduction of the leaking gloves defect. The leaking gloves defect rate was then translated into the quality and Sigma levels as "Quality level – 195,095 DPMO" and "Sigma level – 2.4 Sigma".

Figure Gloves defects Pareto chart

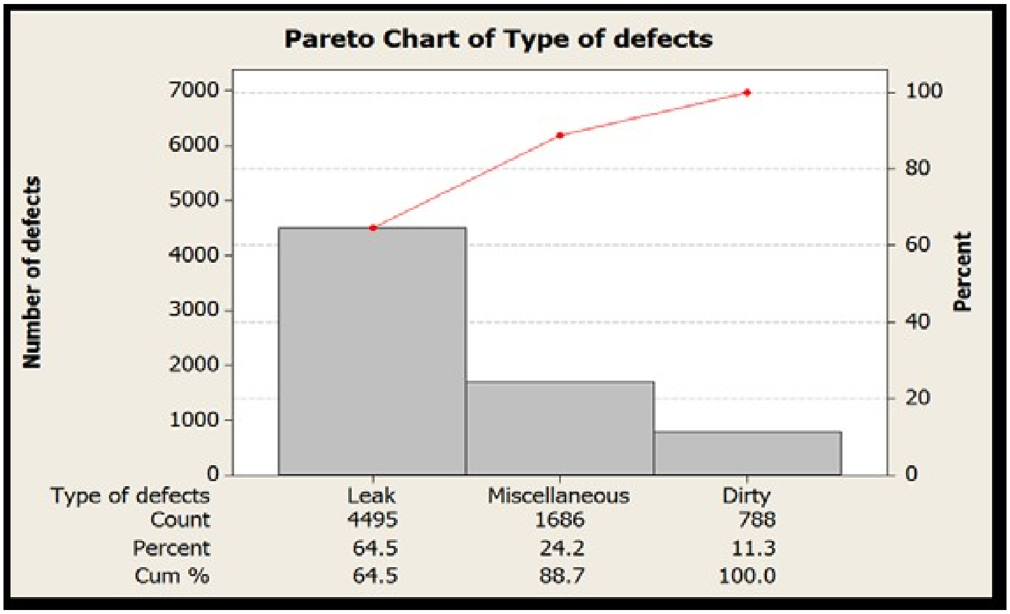

Fig 2.4 Case study Gloves defects Pareto chart

2.5.3 Analyze phase of the project:

This phase in the DMAIC improvement methodology involves the analysis of the system, in this case the manufacturing process that produces the rubber gloves, in order to identify ways to reduce the gap between the current performance and the desired goal(s). To do this, an analysis of the data is performed in this phase, followed by an investigation to determine and understand the root cause of the problem (defects). In order to gain an enhanced comprehension and understanding of the glove production process, the analysis phase of this project started from illustrating the manufacturing process using a flow chart represents a detail picture of the different stages of the gloves manufacturing process. Analysis was carried out to identify the root cause(s) of the leaking gloves quality defect. Several brainstorming sessions were conducted to identify based on the improvement team members' experience, possible causes as to why the leaking problem in gloves occurred. Cause-and-effect diagram was constructed. The cause-and-effect diagram, also known as Ishikawa or fishbone diagram is known as a systematic questioning technique for seeking root causes of problems by providing a relationship between an effect and all possible causes of such effect. Once completed, the diagram helps to uncover the root causes and provide ideas for further improvement.

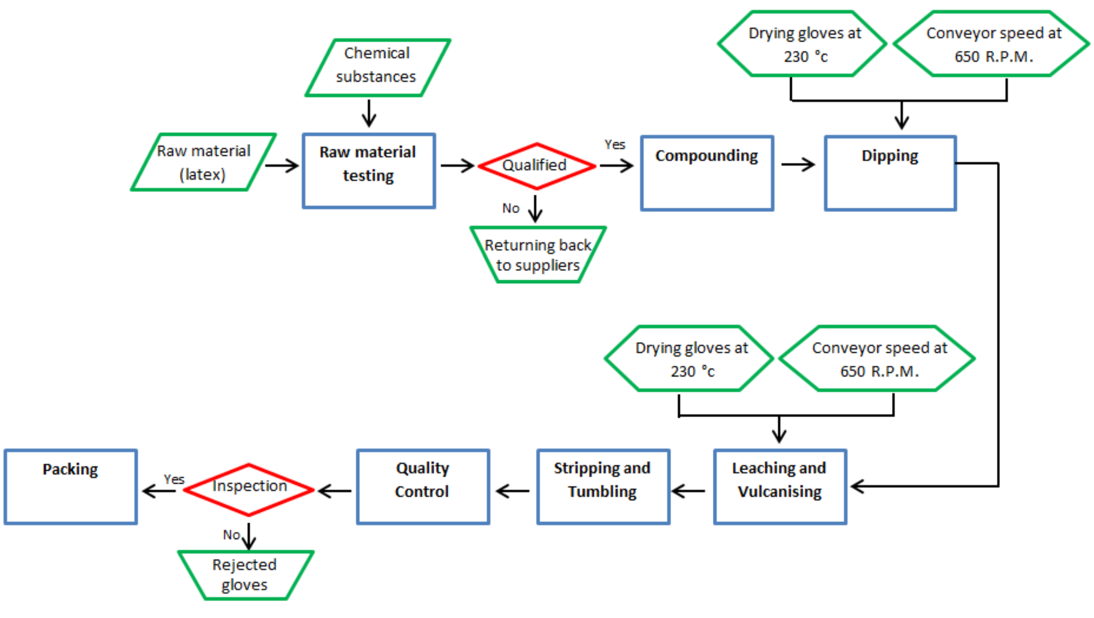

Figure 2.5: Gloves manufacturing process flowchart

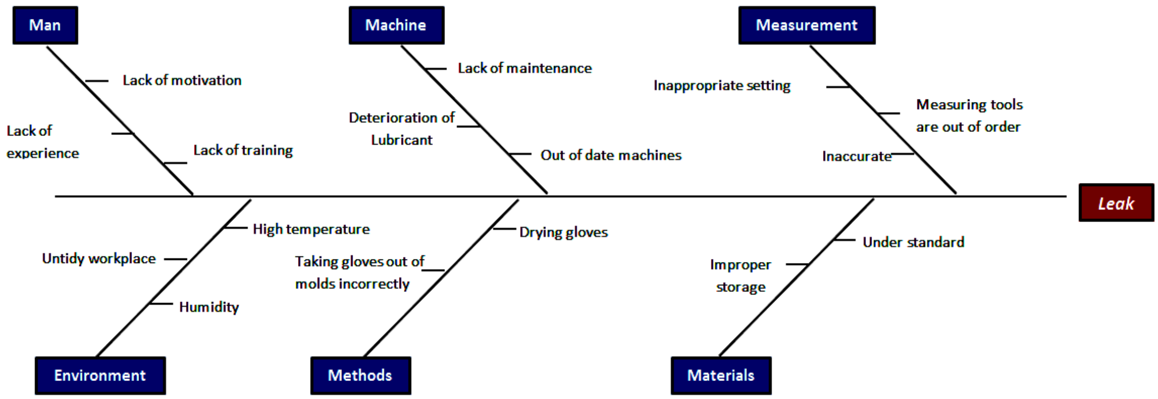

Figure 2.6: Cause-and-effect diagram related to the leaking gloves quality problem

2.5.4 Improve phase of the project:

After the root cause(s) has/have been determined, the DMAIC's "improve" phase aims at identifying solutions to reduce them. suggests the use of design of experiments (DOE), which is defined as a statistical technique to investigate effects of multiple factors. in the "improve" phase. According to Montgomery, benefits of DOE can be decreasing variability and lowering the overall expenses. Therefore, although experience and common sense dictated the existence of a correlation between oven's temperature and conveyor's speed with the number of leaking gloves.

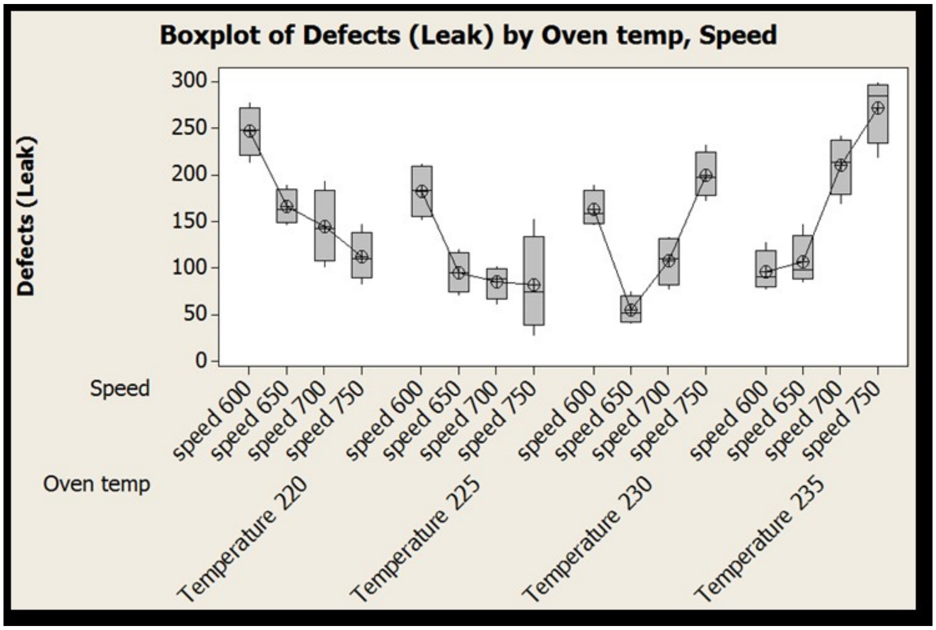

Figure 2.7 :defects by oven temperature and conveyors speed

presents the results of the trial and a comparison between the "before and after" setting the new parameters. The results indicate that the optimum parameters indentified in the experiment improved the gloves manufacturing process by reducing the amount of leaking gloves by about 50%. This resulted in a reduction of DPMO from 195,095 to 83,750 and a Sigma level improvement from 2.4 to 2.9. Consequently, the initial targets set for DPMO and Sigma level. see Table below, were exceeded.

Table: 2.4 result of case study

Type of defects	% of defects Before the improveme nt	% of defects After the improvement

Leak	**19.51**	**8.38**
Miscellaneous	7.32	3.88
Dirty	3.42	2.44
Total	30.25	14.70

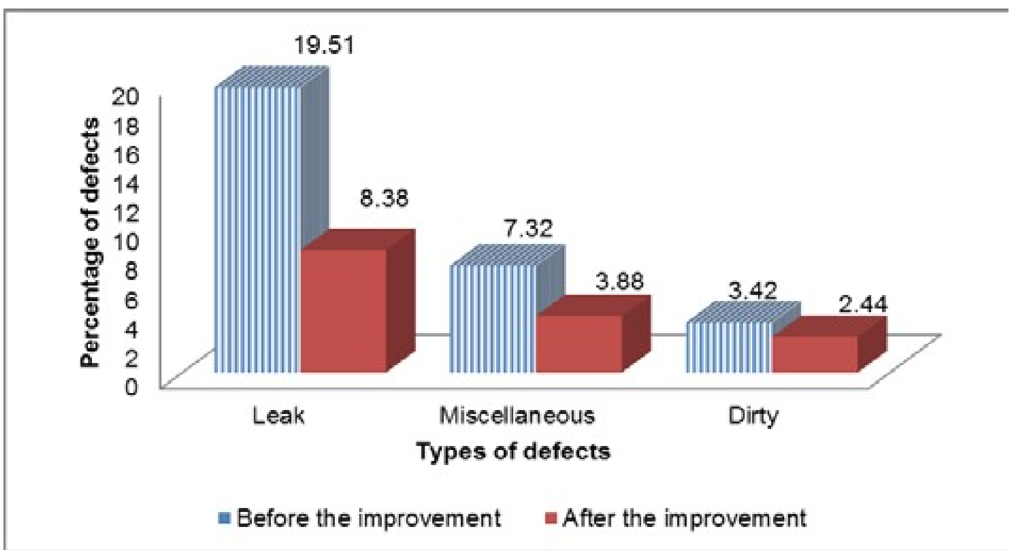

Figure 2.8: "Before and after" states of conducting the Six Sigma project in the gloves manufacturing process

2.5.5 Control phase of the project:

The aim of the "control" phase is to sustain the gains from processes which have been improved by institutionalizing process or product improvements and controlling ongoing operations. However, due to time limitation, this stage is still under implementation at the Thai rubber gloves manufacturing organization studied in this paper.

2.5.6 Results, Discussion and Conclusions of the project:

This paper presented a successful case study of defects reduction in a rubber gloves manufacturing process by applying Six Sigma principles and the DMAIC problem solving methodology. Therefore, the paper can be used as a reference for Manufacturing Industrialists to guide specific process improvement projects.