CHAPTER II



THEORETICAL CONCEPTS

2.1 Introduction

Now, the successful companies have to have a competitive advantage. Quality of the product for end users is one of many issues that customers can perceive the quality of company and product itself. And product quality for end user become a competitive advantage in many companies. Molex Thailand is one of those companies.

Continuous product quality improvement is the concept to make a competitive advantage in many companies. With this concept, Molex Thailand will gain a lot of benefits and will be able to complete and penetrate to the international markets. With continuous product quality improvement, we can satisfy, delight and over expectation of customers. Now Molex Thailand use "Fitness to standard" as a quality concept. Molex Thailand produce harness wire to conform the customer specification and standard. In practical, it is not enough to satisfy customer requirement. Every harness makers can do it. Hence, Molex Thailand have to be able to exceed customer expectation, satisfy and delight customers requirements.

2.2 Main principles for continuous product quality improvement

Basically, this thesis focus on quality of product for the end users. So there are three main issues that needed to be considered and needed to pay highly attention especially the continuous improvement program.

- 2.2.1 Customers focus or Quality focus
- 2.2.2 Process improvement
- 2.2.3 Total Involvement

2.3 Support needed

Continuous improvement program needed to have supportation from management level which are listed as following

2.3.1 Leadership

- 2.3.2 Training
- 2.3.3 Organisation structure
- 2.3.4 Communication
- 2.3.5 Rewarding
- 2.3.6 Evaluation

2.4 Steps for quality improvement

Moen and Nolan stated that there are three steps for quality improvement

- 2.4.1 Charter of the team
- 1 Define responsible staffs and objectives
- 2 Find the problems, boundaries and expected results
- 2.4.2 Current knowledge
- 1 Analyse current situation
- 2 Propose the problem process
- 3 Identify the related staffs
- 4 Define the quality characteristics
- 5 Draw out the work flow
- 6 Apply Pareto Diagram to find the critical effect
- 7 Apply cause-effect diagram to find the root cause
- 8 Define implementation plan
- 2.4.3 Improvement cycle (Deming Cycle)
- 1 Plan: To achieve those objectives fully
- 2 Do: Implement the plan
- 3 Check: that the objectives are being achieved
- 4 Action: Take corrective action if they are not

2.5 W.E. Deming stated 14 points:

They are many important things that Molex Thailand should consider and apply these points. Some of them, Molex Thailand did it well but some are need to be improved

2.5.1 Pay attention to improve quality of products and services

Now, Mr. Roy Wong, G.M, has an attention for quality improvement and he also supports to all staffs about product quality improvement for end users.

2.5.2 Accept all new quality management concepts

We try to dominate on self management rather than on ordering management. In other word, we try not to order the subordinators but we try to let them manage their work by themselves. We show how value they have in Molex Thailand. Then good quality from their work will be the end result of this concept.

- 2.5.3 Stop inspection at the end of process but controlling during the process instead. Inspection at the end of process is not a preventive approach and it does not solve the root causes as well
 - 2.5.4 Stop completing with price

Actually, what Molex Thailand sell to customers are product, price, services, quality and delivery. Price is not the only things that customers concern.

- 2.5.5 Improve productivity and services system
 PDCA or Deming Cycle = Plan --> Do --> Check --> Act
- 2.5.6 Continuous quality training support

To remind about quality to staffs, then they do the quality job from their heart.

2.5.7 Leadership culture

To promote "Do It Right First Time Concept" to staffs. With ownself leader, they will response their performance. As a result, they try to do their job right at the first time.

2.5.8 Dare to ask question.

Supervisor encourage subordinators to ask questions which they don't understand. Then they know how and what they should do for improvement

2.5.9 Overcome any obstructions for co-ordination

To reorganise the organisation which can lead to a good co-ordination between departments and sections.

- 2.5.10 Target will be meaningless if we do not have a clear implementation plan
- 2.5.11 To avoid a quota which identify in term of figure

We should not measure only the quantity of production but we should consider other things such as quality as well.

2.5.12 To avoid the quota for production.

In other word, we should not consider only the volume. Otherwise, it will destroy the self esteem of staffs.

2.5.13 To arrange the training

This training will improve and enhance the quality of product and the way to communicate between department. This kind of training should be arranged quite more often so that it will make the continuous improvement come true.

2.5.14 Acting is rather than talking

Source: Vitoon Simachokdee, 1997: 8-22

2.6 Cost of quality

Taguchi stated that quality is money. Any quality activities are needed to spend money and cost of quality can be classify into 4 criteria which are listed out and described as following.

2.6.1 Prevention Cost

There will be an expenditure for preventing reject parts. This is also a cost of good sold

2.6.2 Appraisal Costs

There will be an expenditure for quality evaluating and quality inspection.

2.6.3 Internal Failure Costs

There will be an expenditure for reworking reject parts

2 6.4 External Failure Costs

There will be an expenditure for reworking and sorting after shipping to customers.

2.7 Quality Management :QM

There are four issues that should be considered for quality management and they are described as following.

- 2.7.1 Every employees responsible for quality of their own job and have ownership. For example, operators have self inspection.
- 2.7.2 Every employees do their job right at the first time
- 2.7.3 Every employees understand "Internal customer" and "External customer"
- 2.7.4 Customer is the one who define the definition of their requirement

2.8 Failure Mode and Effect Analysis (FMEA)

FMEA is a technique that identify and help to eliminate known and potential failures. FMEA input must come from all team member effort. One of the most important factors for the successful implementation of an FMEA program is timeliness. In other word, doing "before the event", not do "after the event".

2.8.1 There are three possible events that FMEA technique can be applied.

- 2.8.1.1 When it has a new design, product, process or service.
- 2.8.1.2 When it has a changing in design, product, process or service.
- 2.8.1.3 When improvement of the design, product, process or service are considered.
- 2.8.1.4 When new application in the existing system is considered, and even change the vendor.

Chapter III point out some parts that incurred in quality problem, to know whether that typical problem will be reoccurred in the same part or not, and also to know whether there are other problems that might be happened in that part or not. These are difficult and the risk is there. Consequently, FMEA technique can help to eliminate the potential failure of that part and it is an interactive process which is never ending. This FMEA technique is a dynamic tool of improvement. In order to facilitate documentation of the analysis of potential failures and their consequences, a process FMEA form have to be developed.

2.8.2 Compound of FMEA form

In FMEA form, it should be composed of some identification on the form. The Potential Failure Mode and Effects Analysis Form is shown in Figure 2.1

1 FMEA Number

Enter the FMEA document number, which may be used for tracking

2 Item

Enter the name of process and part that is going to be analysed

3 Process Responsibility

Enter department, OEM, and person also include supplier name if known

4 Prepared By

Enter the name of engineer who prepare FMEA

5 Model of product

Enter the name of model

6 Key Date

Enter the initial FMEA due date

7 FMEA Date

Enter the date original FMEA was complied and the latest revision date

Enter the date original FMEA was complied and the latest revision date

8 Core Team

List the name of the responsible person and departments which have the authority to perform task

9 Process Function

Enter the description of process being analysed

10 Potential Failure Mode

Enter the manner of potential failure in that process function. In other word, the nonconformance at typical operation. The assumption of FMEA should be made that the incoming parts are correct.

List the potential failure mode for typical operation in term of process, component characteristic. The failure could occur, but may not necessarily occur. The following question should have answer.

- 10.1 How can the part or process miss the specification?
- 10.2 Regardless of specifications, what would customer consider?
- 10.3 Example of the failure modes
- 10.3.1 Bent
- 10.3.2 Cracked
- 10.3.3 Grounded
- 10.3.4 **Binding**
- 10.3.5 Deformed
- 10.3.6 Open Circuit
- 10.3.7 Burred
- 10.3.8 Dirty
- 10.3.9 Short Circuit
- 10.3.10 Improper set-up
- 10.3.11 Tool damage

Rem Model Year(spirehicle) Core Tears	·		FAILL	POTENTIA IRE MODE AND EFF (PROCESS FI	ECT8	ANALYSIS		Pol	EA Hunder of _ pursed By EA Date (Crip.)			
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11 Potential Effects of Failure

Potential Effects of Failure are the effects of the failure that will affect to both internal and external customer. We should describe in term of what customer might notice or experience. For the end customer, we should state in term of product performance.

11.1 Example of the effect to the internal customer

Does not connect

Does not match

Damage machine/tooling

Can not crimp

Can not fasten

Endanger operator

11.2 Example of the effect to the end customer

Unstable

Erratic Operation

Inoperative

Poor appearance

Intermittent Operation

12 Severity (S)

Severity can be described in term of seriousness of the potential effect. Severity should be estimated on a "1" to "10" scale. This is subjective and need brainstorming and argument in FMEA ream then come out with consensus

Effect	Severity of Effect	Ranking
Hazardous- without warning	The failure may be endanger operator or machine. The failure failure affect to operation and/or not conform with government regulation. The failure will occur without warning	10
Hazardous- with warning	The failure may be endanger operator or machine. The failure failure affect to operation and/or not conform with government regulation. The failure will occur with warning	9
Very High	Major disruption to the production line. 100% of product may be scrapped. The product can not be used, loss of primary function. Customer is very dissatisfied	8
High	Minor disruption to the production line. Product might be sorted and a portion (less than 100%) will be scrapped. The product can be used, but it has a reduced level of performance. Customer is dissatisfied	7
Moderate	Minor disruption to production line. A portion (100%) of product might be scrapped, no sorting. The product is usable but some accessory inoperable. Customer experiences discomfort.	6
Low	Minor disruption to production line. 100% of product might be reworked. The product is operable but some accessory work with a lower level of performance. Customer experiences have some dissatisfaction	5

Very Low

Minor disruption to production line. The product might be sorted

and a portion (100%) is reworked. Defect is noticed by most

customers

Minor

Minor disruption to production line. A portion (less than 100%) 3

of the product might be reworked on-line but out-of-station.

Defect is noticed by average customers

Very Minor

Minor disruption to production. A portion (less than 100%) of the 2

product might be reworked on-line but in-station. Defect is noticed

by discriminating customers

None

No effect

1

13 Classification

This column is used to identify the special process characteristics for component that may require additional process control.

14 Potential Causes of Failure

Potential Cause of Failure is defined as how the failure could occur and be described in term of something which be able to be controlled. FMEA team should list the causes of each effect as much as the team can. For this heading, design of experiment, DOE might be applied to identify the major cause that is the most contribute to the effect and might be applied to identify the cause that can be the most easily controlled.

- 14.1 The example of the potential causes of failure which be able to be measured and controlled
 - 14.1.1 Improper length-over, under
 - 14.1.2 Improper heat treat-time, temperature
 - 14.1.3 Improper torque-over, under

Only specific errors should be listed; (e.g., operator fails to install seal) We should not list the ambiguous phrases (e.g., operator error, machine malfunction). The ambiguous phrases should not be used.

15 Occurrence (O)

Occurrence is how often the specific failure cause is occurred. The occurrence ranking number has a meaning rather than a value. We can estimate the occurrence scale from "1" to "10"

Probability of Failure	Possible Failu	re Rates	Cpk	Ranking	
Very High: Failure is almost inevitable	More than or	equal to 1 in 2	Less than 0.33	10	
	1 in 3		More than or		
			equal to 0.33	9	
High:	1 in 8		More than or		
General associated with processes similar to previous processes that			equal to 0.51	8	
have often failed	1 in 20		More than or		
			equal to 0.67	7	
Moderate:	1 in 80		More than or		
Generally associate with processes similar to previous processes which			equal to 0.83	6	
have experience occasional failures, but not in major proportions	1 in 400	More than o	or equal to 1,00	5	
Low:	1 in 2,000	More than o	r equal to 1.17	4	
Isolated failures associate with similar processes	1 in 15,000	More than o	r equal to 1.33	3	
Very Low:	1 in 15,000	More then	or equal to 1.50) 2	
Only isolated failures associated with almost identical processes	1 m 13,000	More than	or equal to 1.50		
	T 41			_	
Remote:	Less than or	More than	or equal to 1,67	l .	
Failure is unlikely. No failure ever associated with almost identical	equal to 1 in 1,500,000	7111		He He	
processes	1,500,000				

16 Current Process Control (Detection Method)

Current Process Controls are description of the controls that either prevent the extent possible failure or detect the existing failure. These controls can be process control such as SPC Statistical Process Control.

- 16.1 There are three types of Process Control which to be considered.
- 16.1.1 Prevent the causes or reduce the rate of occurrence
- 16.1.2 Detect the causes and lead to corrective actions
- 16.1.3 Detect the failure mode

17 Detection (D)

Detection is an assessment of the probability that proposed current process control will detect a potential cause and the probability that will detect the subsequent failure mode. We estimate the detection in term of scale "1" to "10".

Do not automatically presume that the detection ranking is low due to the occurrence is low. Random quality check are unlikely to detect the existence of an isolated defect and should not influence the detection ranking. Sampling on a statistical basis is a valid detection control. The Evaluation Criteria: The team should agree on an evaluation criteria and ranking each process control or detection method.

Detection	Criteria: Likelihood the existence of detect will be detected by process control before subsequent process	Ranking
Almost impossible	Do not know the control variable to detect failure mode	10
Very Remote	Very remote likelihood current control will detect failure	9
Remote	Remote likelihood current control will detect failure	8
Very Low	Very low likelihood current control will detect failure	7
Low	Low likelihood current control will detect failure	6
Moderate	Moderate likelihood current control will detect failure	5
Moderately High	Moderately high likelihood current control will detect failure	e 4
High	High likelihood current control will detect failure	3
Very High	Very high likelihood current control will detect failure	2
Almost Certain	Current control almost certain to detect the failure. reliable detection control are known with similar processes	1

18 Risk Priority Number (RPN)

The risk priority number is the product of multiplication of Severity (S), Occurrence (O) and Detection (D) ranking. We can not solve all quality issue so RPN will be applied in order to prioritise the important of quality issue. $RPN = (S) \times (O) \times (D)$

This value of RPN can help to rank the most critical concerns in the process. RPN will be in the range of "1" and 1,000". For the highest value of RPN, the team should take the corrective action first.

19 Recommended Action

If the causes are not fully understand, a recommended action might be determined by (DOE) design of experiment. The purpose of any recommended action is to reduce severity, occurrence and detection ranking. If there is no action for specific cause, it should be entered "NONE" in the column. The most important thing for effective FMEA program is to have the effective corrective action and the effective follow-up program. The following actions have to be considered.

- 19.1 To reduce the probability of occurrence, process revisions are required.

 An action-oriented of statistical methods could be implemented with on-going feedback for continuous improvement and defect preventation
 - 19.2 Process revision can bring a reduction of severity ranking
- 19.3 To increase the probability of detection, process revisions are required.

 Increase frequency of quality control is not a positive corrective action. It should only be a utilised temporary measure. Permanent corrective action is required. Even though we change the current control so as to increase probability, we should focus on defect preventation rather than defect detection.

20 Responsibility

Enter the person who responsible for the recommended action and enter the target completion date.

21 Action taken

Enter a description of the action and the target completion date after implementation.

22 Resulting RPN

After corrective action have been identified, estimated and recorded the resulting occurrence, severity and detection rankings, recalculate the RPN should be done again. All result RPN should be reviewed and if further action is considered, we should repeat step 19 through 22

Source: Source: Chrysler Corporation, Ford Motor company, General Motor Corporation, 1995: 5-45

2.9 Process improvement

ECRS principle can be applied to process improvement. ECRS stand for eliminate, combine, rearrange and simplify. This should be done in process improvement.

- 2.9.1 Eliminate: Eliminate the non value steps out of the current processes
- 2.9.2 Combine: Combine the similar processes into one process.
- 2,9.3 Rearrange: Relocate the sequence of steps so as to have more efficient output
- 2.9.4 Simplify: Turn many complicated steps into a simple step

2.10 Ishikawa stated that quality via statistic (7 QC Tools)

2.10.1 Check sheets

Check sheet is the sheet which be organised and designed for the collecting data purposes. It has the blanks for recording easier and guide the collector to be able to fill data in the right position. Then after filling data in the form, the reader can read easily and understand easily as well. Then the reader can bring that information to process to the next step. Therefore, whenever creating the check sheet, they should have two objectives.

The first objective is to help collector to be able to fill the data easily and the second objective is to help reader to be able to use that data easily. Table 2.1 show the example of check sheet. This table 2.1 classify type of defects and the summation of each reject type. Then with this check sheet, the most frequent defect type can be identified.

Table 2.1- Example of check sheet

CHECK SHEET

Product: Process name: Type of reject: Total inspection: Note:	ม วา เกมกิจกยา เริ่	Date: Section: Inspector name: Lot no:
Type of reject		Summation of each reject type
A	MH MH MH II	17
В	MY MY 1	11
С	THE THE THE THE !	26
0 D	///	3
Others	/ ////	5
	Total	62
The number of	THE THE THE THE THE	

In table 2.1, there are 4 quality problems which are A, B, C, D, and others. If the identification is only the number of reject parts, it can not identify the cause of reject part and can not identify the frequency of causes. In table 2.1, the summation of each quality issue is 62 from the total production 1525. Actually, there are 42 reject parts from 1525, so there are some parts which have more than one quality issue.

Table 2.2- Check sheet which can show the cause of reject

Machine	Name of employee		Mon	Tı	Jes	W	/ed	Th	urs	F	ri		Sat
!		00	jo	000	0	000	0000	0000	0	0000	00	0	1
ļ	A	X	X		XX	XXX	XXX	X	XX				XX
1		•						**					•
A -	В	0	000	0000	000	0000	0000	0000	000	00	0000	00	0000
!		XX	XXX	XX	XX	XX	X	XX	X	XX		×	XX
		•	*			*	•		**	*			*
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	C	X	×	Ī		T	X]			
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Remark: O is the reject type I

X is the reject type II

* is the reject type III

In table 2.2, this table shows a bit in detail. There are two machines and four operators. They collect the data twice a day from Monday to Saturday. They collect data in the morning and in the afternoon. Each machine is controlled by two persons and each person responsible his machine week by week. There are five quality issues. From table 2.2, Mr.B is the one who has the most quality problem especially on Wednesday. Then, Wednesday is needed to be investigated and Mr.B also needed to be reviewed.

2.10.2 Histograms

Histogram can show the frequency of the events by using the rectangular graph which has the same width. The histogram can be useful for showing the range of values measured and incidence frequency. The height of rectangular represent frequency.

Firstly, creating the frequency table and secondly, drawing the histogram graph. Histogram can help to be able to see the distribution of data and the frequency of each issues. In figure 2.2 show how the histogram look like. In this figure, the x axis is the strip length (mm) and y axis is the frequency of each strip range.

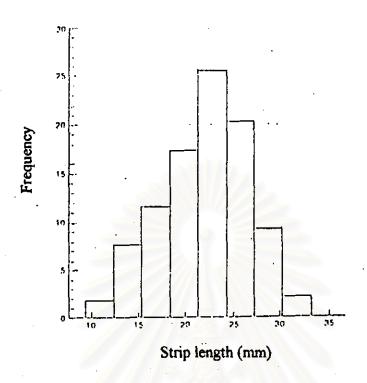
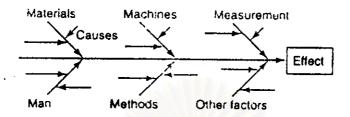


Figure 2.2- Histogram

2.10.3 Cause and effect Diagram (Fish Bone Diagrams)

It is a diagram which use the arrow to show the causes that impact the effect. Not only that, this diagram is able to see the relationship between the quality problem and the factors. Generally, this tool concerns on material, method, machine, and man. It is called 4M. In figure 2.3 shows cause and effect diagram. The following steps are the simply steps for making this diagram.

- 1 Select the problem and draw the core line
- 2 Consider 4M and draw the branch line
- ? Add the causes according to each M and draw the line straight out from the first branch line



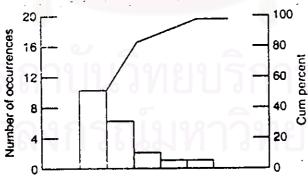
- All contributing factors and their relationship are displayed
- Identifies problem areas where data can be collected and analyzed

Figure 2.3- Cause and Effect Diagram

Source: Montgomery, D. C, 1996

2.10.4 Pareto Analysis

This diagram is used for ranking the problems and showing the critical quality problems from many ones. The most frequent problem should be solved first rather than tackling all the problems at the same time. Before making this diagram, classification the type of causes and effects is needed to be considered. Then collect the data and summarise the data of each causes. After that drawing Pareto diagram which start from the most frequent problem to the least frequent problem



- Identifies most significant problems to be worked first
- Historically 80% of the problems are due to 20% of the factors
- . Shows the vital few

Figure 2.4- Pareto Diagram

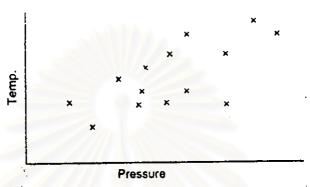
Source: Montgomery, D. C, 1996

2.10.5 Graphs

Graph can help to interpret the data more easily and graph also help to present and show the detail of data.

2.10.6 Scatter Diagrams

This diagram help to determine the correlation between two variables. This scatter diagram is shown in figure 2.5



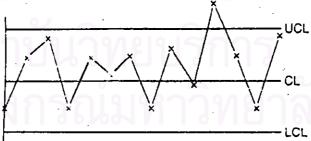
- Identifies the relationship between two variables
- A positive, negative, or no relationship can be easily detected

Figure 2.5- Scatter Diagram

Source: Montgomery, D. C, 1996

2.10.7 Process Control Charts

These charts are used to prevent and monitor defects during the manufacturing processes. The manufacturing processes are monitored and adjusted if a there is a statistically significant change in the processes are detected. The example of process control charts is shown in figure 2.6



- Helps reduce variability
- Monitors performance over time
- Allows process corrections to prevent rejections
- Trends and out-of-control conditions are immediately detected

Figure 2.6- Process Control Chart

Source: Montgomery, D. C, 1996

2.11 Acceptance sampling plan

There are a number of ways to classify acceptance sampling plans. The popular one is by attributes and variables. Attributes are expressed on a "fail and pass" basis. Variables are quality characteristic that are measured on a numerical scale. Basically, there are 3 types of sampling plan.

2.11.1 Single sampling plan

n units sample are selected at random from the lot (N units) and the quality of that lot based on the information contained in that samples.

2.11.2 Double sampling plan

This is more complicated. After take an initial sample, a decision based on either accept that lot, reject that lot or take a second sample. Then, the initial information and the second information are combined and lead to the final decision. A double sampling plan is defined by four parameters. Figure 2.7 show the double sampling plan.

- n1 = sample size on the first sample
- c1 = acceptance number of the first sample
- n2 = sample size on the second sample
- c2 = acceptance number for both samples

In figure 2.7, there are four parameter such as n1 = 50, c1 = 0, n2 = 100 and c2 = 2. Therefore, the number of defectives in the first sample size n1 is observed as d1. If d1 is less than or equal to c1 = 0, that lot is accepted on the first sample. But if d1 is greater than c2, that lot is rejected.

But if d1 is greater than c1 but less than or equal to c2, a second random sample size n2 = 100 is drawn from the lot and the number of defectives d2 are observed. The summation of d1 and d2 is considered. If d1+d2 is less than or equal to c2, that lot is accepted. But if d1+d2 is greater than c2, that lot is rejected.

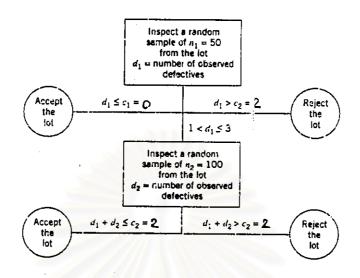


Figure 2.7- Double Sampling Plan

Source: Montgomery, D. C, 1996: 632 with adaptation

2.11.3 Multiple sampling plan

This concept required more than two samples to lead the final decision. Sample sizes in multiple sampling are usually smaller than they are in single and double sampling plan. A multiple sampling plan is an extension of double sampling. Table 2.3 show the multiple sampling plan.

Table 2.3- Multiple Sampling Plan

Cumulative Sample size	Acceptance Number	Rejection Number
25	0	3
50	· 1	4
75	19 17 31 919 17	005 5
100		7
125	7	9

2.12 Lot Formation

The characteristic of lot is also influence the effectiveness of the acceptance sampling plan. Basically, there are three major forming lots for inspection

- 2.12.1 Lots should be homogeneous: Goods in the lot should be produced by the same machines, the same operators and come from the common raw materials at the approximately time. When lots are not homogeneous, it is more difficult to take corrective action to delete the cause of defectives.
 - 2.12.2 Larger lots are more economical than small lots
- 2.12.3 Lots should be related to the materials handling systems of both vendors and customers. Moreover, it should minimise shipping risks and minimise repackaging processes.

2.13 Military Standard 105E (ANSI/ASQC Z1.4, ISO 2859)

Standard sampling plan for inspection by attributes were developed during World War II MIL STD 105E is the most popular one. The standard provides for three types of sampling plan: single sampling, double sampling and multiple sampling. Each type of sampling plan can be applied this standard. There are three general levels of inspection such as normal inspection, tightened inspection and reduced inspection. In other word, we classify the level of defects and tackle them with different level of inspection.

First level of Inspection: Reduced inspection is used when it required less inspection. It required about one-half the amount of inspection as level 2 which can save inspection cost.

Second level of inspection: Normal inspection is used at the beginning of inspection activity. It is used when the situation is normal and there is no signal for quality problem. But it should not be used in the situation of either high inspection cost or limited model.

Third level of inspection: Tighen inspection, it is used when it required strengthen inspection which is about twice as much normal inspection. This type of inspection require more samples and lead to a higher cost of inspection. When confident level of quality problem is high in that lot, this type of inspection should be applied.

Not only that but there are also four special inspection levels, S-1, S-2, S-3, and S-4. They use very small samples and only used when large sampling risk can be tolerated. The switching rules for normal, tightened and reduced inspection, MIL STD 105E is shown in figure 2.8

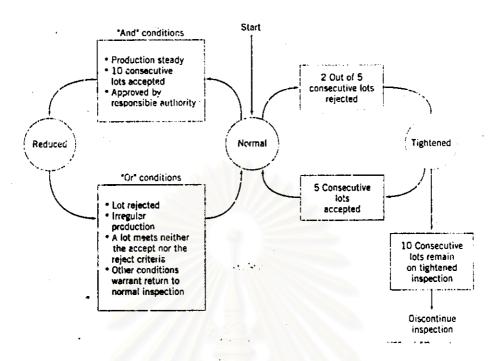


Figure 2.8- Switching rules for normal, tightened, and reduced inspection MIL STD 105E

Source: Montagomery, D. C, 1996: 638

In figure 2.8, there are five activities which is described below.

2.13.1 Normal to tightened

Tightened inspection is used instead of normal inspection when two out of five consecutive batches have been rejected on original submission.

2.13.2 Tighten to normal

Normal inspection is used instead of tighten inspection when five consecutive batches are accepted on original submission.

2.13.3 Normal to reduced

Reduced inspection is used instead of normal inspection when all bellowing four conditions are satisfied.

- 1 The proceeding 10 lots have been on normal level and none of all ten batch are rejected
- 2 The total number of defectives in all preceding 10 batches' samples is less than or equal to the applicable limit number specified in the standard

- 3 Production is steady. And recently, there is no other problems have occurred
- 4 Reduced inspection is considered by the authority responsible person

2.13.4 Reduced to normal

Normal inspection is used instead of reduced inspection when any of bellowing four conditions are satisfied.

- 1 Any batches is rejected
- 2 Production is irregular
- 3 Other conditions warrant that normal inspection be instituted
- 4 The batch is accepted when the sampling procedure terminates, but normal inspection is reinstituted starting with the next lot

2.13.5 Discontinuance of inspection

If 10 lots remain on tightened inspection, we should stop inspection and start seeking other causes that might come from the other areas. For example, if we apply this concept in the outgoing, we should investigate in the each manufacturing activities.