EFQM

Process Survey Tool for Manufacturing Process Management

Process survey tools from Philips are advanced maturity grids for processes or functions. Philips has deployed these tools throughout its entire company and wishes to share its experiences with the business community. The intellectual property within the Process survey tools as owned by Philips is freely offered to EFQM for production and distribution to its partners and network. Copyright protected sources are mentioned in the text.

Process Survey Tool For

Manufacturing Process Management

EFQM and Philips

Philips is one of the founding members of EFQM and has been a member ever since. A long-standing relation with the EFQM evolved which resulted in many forms of co-operation. Philips is strongly involved in the model development as well as the design of the award process. One the members of the Group Management Committee of Philips is Governor of the EFQM and year on year several Philips employees take part in EQA assessments and other activities like study groups. Philips uses the EFQM Excellence Model as their prime assessment and improvement methodology in all parts of the organisation worldwide.

The company wide improvement program in Philips is called "BEST" (Business Excellence through Speed and Teamwork). This program consists of several approaches and tools and is strongly embedded in the business processes. One of the most important tools used in the BEST program are the Process Survey Tools (PST) that are meant to assess the maturity of a process. As part of its strategic commitment to helping organisations generally improve their performance, Philips has decided to make some of the PSTs available widely through EFQM and its partners network.

About EFQM

EFQM® is a membership based not for profit organisation, created in 1988 by fourteen leading European businesses, with a Mission to be the driving force for sustainable excellence in Europe and a Vision of a world in which European organisations excel.

EFQM has promoted the concept of partnership with similar National organisations in Europe and its members to help promote sustainable excellence in European organisations. All of these National organisations have worked with EFQM to develop the Fundamental Concepts of Excellence and to promote the EFQM Excellence Model. Contact details for our partners can be found at http://www.efqm.org

By January 2004, EFQM membership had grown to around 700 organisations from most European countries and most sectors of activity. Together with the National organisations the membership network runs to thousands of organisations with several million individuals employed in those organisations.

In addition to being the owner of the EFQM Excellence Model and managing The European Quality Award, EFQM also provides a portfolio of services for its members.

About Koninklijke Philips Electronics

Koninklijke Philips Electronics of the Netherlands (NYSE: PHG, AEX: PHI) is one of the world's biggest electronics companies and Europe's largest, with sales of EUR 29 billion in 2003. With activities in the three interlocking domains of healthcare, lifestyle and technology and 165,600 employees in more than 60 countries, it has market leadership positions in medical diagnostic imaging and patient monitoring, color television sets, electric shavers, lighting and silicon system solutions. News from Philips is located at www.philips.com/newscenter.

Introducing Process Survey Tools

Process Survey Tools (PSTs) are maturity grids designed for specific processes or functions. PSTs help to assess the maturity of a process or function and give clear indications on how to improve to reach next levels of maturity. Each process is broken down into a number of " elements" or sub-processes that make up the entire process. Typically there are 10 to 15 elements in each of the PST processes.

For each of the elements, a maturity scale has been created – ten levels of maturity starting from basics in step 1 and culminating in worldclass performance in step 10.
By assessing their position against the maturity scales for each of the elements, organisations can establish a "maturity profile" for a particular process and gain an insight into the steps they need to take to move in the direction of world class. The procedure clearly provides a basis for benchmarking progress with others within or outside the organisation.

The level descriptions in the elements are based on various sources and own Philips' experience. They all reflect expert knowledge on the road to worldclass for the described processes.

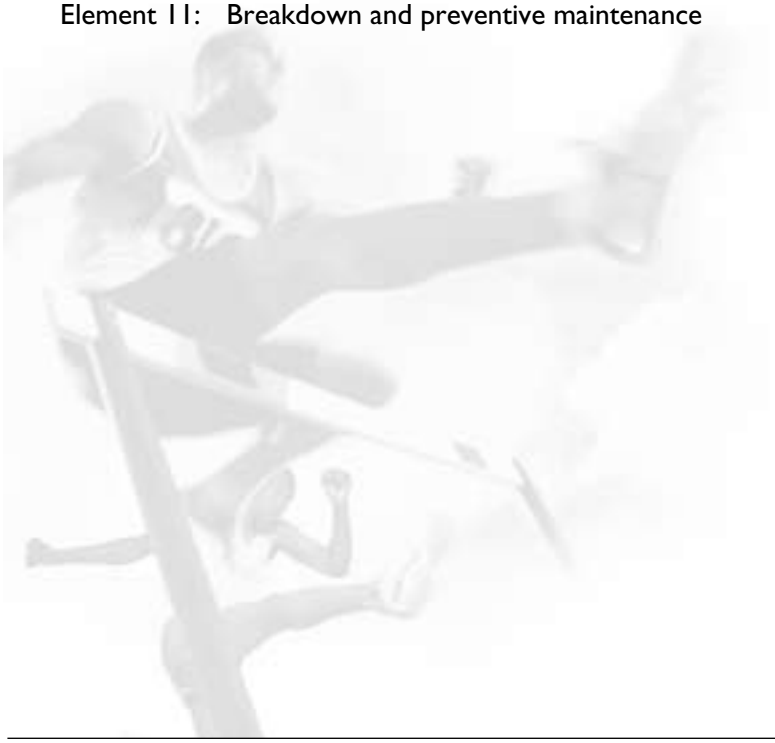
Software will be made available to facilitate the assessment process as well as for presenting results as bar charts, spider diagrams and for analysing performance over time. This software will be known as the **PST supporting e-Tool**
For more information on how to apply the PSTs, please use the separate **PST Guide** that accompanies each PST.

Positioning against the EFQM Excellence Model

For any organisation, improving performance from self-assessment or other approaches usually means working for improvement in the whole network of processes through which the organisation's goods and services are produced and delivered. Processes lie at the heart of the EFQM Excellence Model.

There are clear links between the criteria of the EFQM Excellence Model and processes for which there are PSTs - for example:
"Marketing and Sales" links into criterion part 5c
"Manufacturing" links into criterion parts 4e and 5d.
"HRM" links into criterion 3.
Thus the PSTs will be of assistance and provide guidance to organisations, using self-assessment against the EFQM Excellence Model, wishing to improve their processes.
Clearly the maturity steps for each of the elements are specific to the process under consideration and therefore are defined differently for different elements. However the logic of the PDCA cycle is built into the levels of the maturity scales for each of the elements of all of the processes and, to a substantial degree, these levels reflect the RADAR tool of the EFQM Excellence Model.

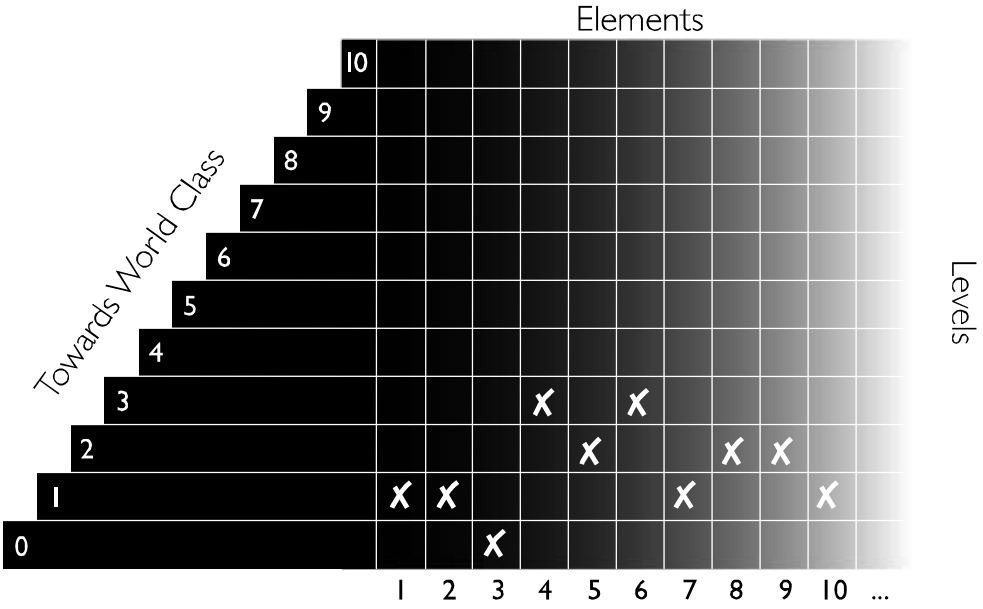
Content overview



1 Assessment criteria

The assessment criteria are developed from many sources around the globe, and adapted by Philips incorporating their learning, and also to make it applicable for their processes and specific improvement needs. This has been used as the basis for developing a more widely applicable survey tool - retaining the same elements and assessment criteria but broadening the scope of the descriptions and scoring guidelines to make it easier to apply across a wider range of industry.

The resulting eleven elements covered in the survey are scored on a ten-point scale. Scoring guidelines are given for each element.



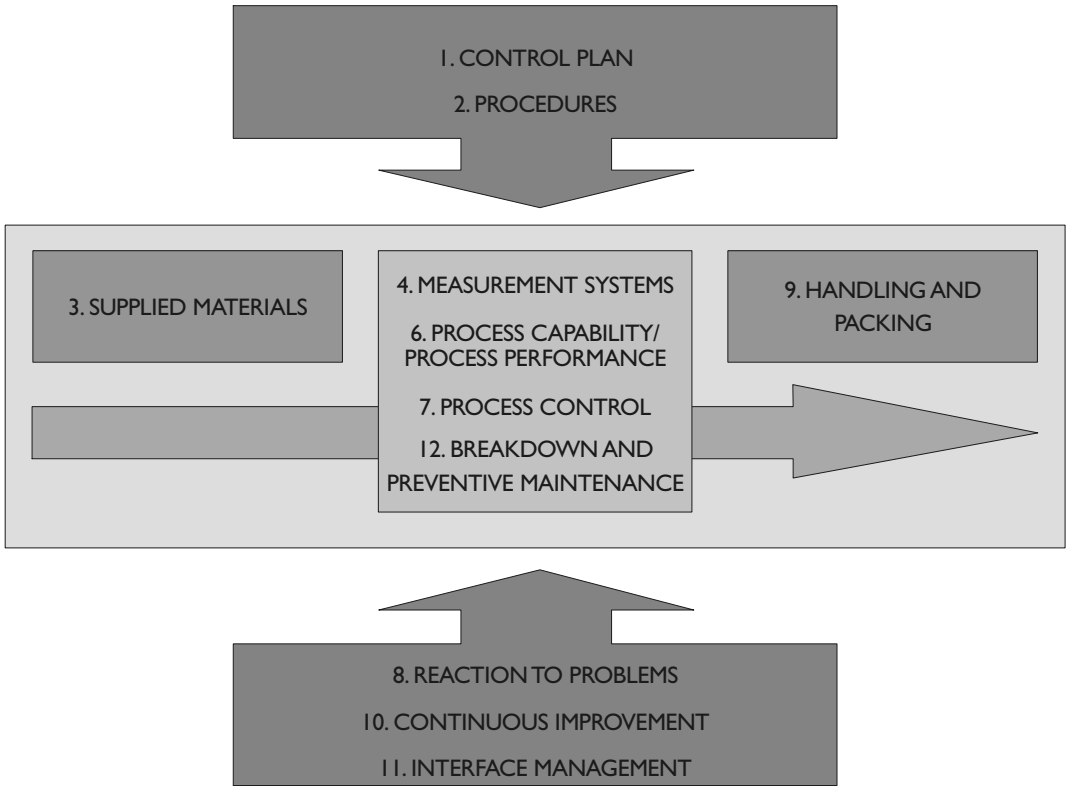
Scoring is on a strict "step" principle, i.e. the conditions for step 1 must be completely satisfied before moving on to step 2, etc.

As far as possible the scoring guidelines were not changed. For the elements measurement systems, process capability/process performance and process control more attention is paid to training aspects. The reason is that training is important for these statistical tools and there exists a lot of confusion about the right application of them.

These scoring guidelines can be used in two ways: self-assessments and comparisons (benchmarking). Comparisons can be made between departments, factories, etc. The best in class can be the benchmark for the others. For both cases it is useful to calibrate the scores against a standard. A so-called calibration process can do this. More assessors do an assessment and they make a comparison between their scores. Differences need to be discussed and adapted. These “lead assessors” can calibrate other assessors, etc. By organizing such a process it is possible to assure a common level of all assessors. It is then possible to compare the results of the factories and find the best in class.

2 Elements

The preparation and execution of a sound control plan provides the foundation for the quality system defining the manufacturing process control. The elements of the survey tool are:



The "manufacturing process" and also the boundaries must be defined. Reference can be made to EFQM Excellence model: Criterium 5 - Process.
A process can be considered as a network of interdependent components that work together to achieve benefits for stakeholders. Components include people, procedures and equipment.
Stakeholders include customers, shareholders, employees and suppliers.

It is important to assess the process of *planning* as well as *execution* for each element.

- The planning should show a systematic approach and be purposeful towards the customer needs.
- The execution should be disciplined, demonstrate the effective use of tools and leading to achievement of the desired results.

Before applying the self-assessment it is helpful to consider the type of industry you are in and the relative importance to be placed on the different aspects of process control. The questions can generally be applied to most types of manufacturing operation, only the emphasis and scope might vary in different cases.

3 Scope and application

The survey tool is primarily for self-assessment, and is not intended as a quality audit; it is to support learning and improvement by reflecting against "world class" standards and by making comparison with other activities.

This survey tool can be used to:

- Assess the current performance of a manufacturing process
- Plan, implement and review improvement in process management
- Stimulate the sharing of best practice
- Sharpen the focus on customer requirements and the ability to meet these requirements

The survey tool can be used to assess any manufacturing process. These may range from continuous flow through small batch production, and from component part production to pure assembly processes. The manufacturing process being assessed may indeed embrace various combinations of these as sub processes.

However this survey tool may not be appropriate for products in development, products where numbers are too small to assess variability or where time intervals between production runs are so long that customer expectations may change.

4 Clarification of specific terms used

Most terms and definitions will be familiar, but for clarity, the following terms are amplified:

- **Customer:** Both internal (within own organisation) and external (outside) customers are considered. Formally identified representatives for external customers may be used where contact is impossible or impractical.
- **Significant product characteristics:** Refers to those product characteristics which are significant to customers or to the business as a whole
- **Some:** more than one, or less than 30 %
- **Several:** more than 30 %
- **Many:** more than 50 %
- **Numerous:** more than 60 %
- **Most:** more than 75 %
- **Virtually all:** more than 90 %
- **All:** 100 %
- **World Class:** Excellence recognised by the customer as better in that aspect than all competitors.

Element 1: Control plans

A (process) control plan is a list of product characteristics, process parameters and/or quality characteristics of supplied materials that need to be measured and monitored.
A (maintenance) control plan is a list of equipment performance characteristics that need to be measured and monitored.

Product characteristics, process parameters and supplied material characteristics can be measured on sample basis or continuously (100%). Results can be given as measurement data like weight, length, time and temperature or as reject-% in case of attributive (=good/reject) measurements like visual inspections, etc.

Equipment performance characteristics can be presented by the overall equipment efficiency (OEE) or subdivided into breakdown, set-up and adjust, speed loss and idling (6 big losses). Also MTBF (Mean Time Between Failure) and MTTR (Mean Time To Repair) are examples of performance characteristics. Start-up losses and rejects must be covered by the (process) control plan.

Control plans will depend on the nature of the business. A single control plan may be adequate for a mass-produced single product, whilst a number of separate control plans may be required in a multi product environment. A control plan should exist for each product or group of products exhibiting common characteristics e.g. common customer requirements and common critical influence for cost.

Measurements can be done for two reasons:

- to assess whether the value of the characteristic or parameter is significantly different from the usual distribution in order to readjust the process (same/significantly changed);
- to assess whether the value of the characteristic or parameter meets the specification (good/reject).

There must be a clear instruction of how to respond when the measurement is not between the control limits (out of control action plan or OCAP) or outside the specification limits (repair procedure).

An ideal control plan is one that assures stable processes that deliver products with a predictable quality and quantity on equipment with a stable and predictable performance. Further the ideal control plan gives a good overview and understanding to what extend the specifications are met, as well the product characteristics and process parameters as the equipment performance. This understanding is used to define and monitor improvement actions (lowest cost of non-quality). It should show the links from customer requirements, through specification of product characteristics, to the process (including incoming materials), demonstrating by evidence that a good process has been used to prepare the plan. Documents such as engineering drawings should be included or referenced in the control plan.

The specifications of the product characteristics, process parameters and supplied material characteristics must cover the customer requirements. The results (presented as reject-% and/or process capabilities) of the measurements items that are listed in the control plan, must give a good impression of the produced quality.
The specification of the equipment performance characteristics must cover the equipment requirements. The observed losses due to the items listed in the control plan must cover the overall equipment performance.

The cost of non-quality is the total costs of external rejects (e.g. replacements, guarantee, etc.), internal rejects (waste, repair) and equipment losses (breakdown, set-up and adjust, speed loss and idling). Similar definitions can be used.

The characteristics and parameters of the control plan need to be significant and representative for the process performance.

- An essential element is the determination of significant product characteristics, their related process parameters and characteristics of supplied materials on one-hand and equipment performance characteristics on the other.
- The control plan should translate customer requirements into product specifications and these have to be translated into process and supplied materials requirements using Quality Function Deployment (QFD), houses of quality and/or critical parameter sheets. Requirements of equipment performance should be derived from business demands.
- The plan should also be adequate in its scope and content; covering the total manufacturing process (from supplier to customer) and supported by flowcharts, router sheets or process plans that summarise the key process steps and reference the measurements, control points and methods. These should also include time and cost if appropriate.

The control plan needs to be derived from appropriate sources by relevant people.

- For changes to existing products/processes, the manufacturing groups are usually responsible for taking the lead in modifying the control plan, drawing on the experience and involvement from other groups with information about the manufacturing process, equipment, materials and supplier problems, customer complaints, line rejects, quality costs etc.
- For new products or processes, the development group usually has the responsibility to set up the control plan, also involving the other groups to draw on knowledge and feedback e.g. from similar processes, potential risk analyses, other prevention methodologies and pre-production activities.

The process of setting-up and reviewing control plans needs to assure that characteristics and parameters of the control plan are significant and representative.

- The process to identify these parameters and characteristics, their targets and limits should be based on a joint effort between development, manufacturing and maintenance – using process and equipment FMEAs (Failure Mode and Effects Analysis), or any similar methods to assess the plan as it is being developed.
- Cross-functional teams should be used, with customer (or representative) involvement as appropriate, to determine the significant characteristics.
- The process for determining significant characteristics should be documented.
- The process to review control plans of existing processes should be based on QFD and FMEAs, as well as actual customer complaints and/or equipment performance.
- Where the product designs are specified / owned by the customer, use should be made of customer design reviews, FMEAs and similar. (These should be included in the contract review activities). Production can be seen as customer for equipment performance.
- The customer or a reference group needs to be brought into the quality planning process. Customers can be internal as well as external.

The plants quality planning and review effort need to be acceptable and documented.

- Available documentation (e.g. procedures, feasibility evaluations, control plans, flow charts, risk / problem analyses, meeting minutes) needs to indicate how well the plants quality planning and review effort operate.
- The quality planning and review effort are living and get the appropriate level of management attention.

- Results in terms of progress towards the expected level of internal and delivered quality performance are visible.

Scope of prevention analysis methods and control plans.

Preventive analysis methods (such as FMEA) and control plans should not only relate to "technical/manufacturing" processes but, where appropriate, should also cover other areas of the organisation such as:

- Logistic processes (e.g. product handling, storage, packaging and traceability).
- Quality control (e.g. incoming/outgoing).
- Quality assurance (e.g. reliability/liability).
- Maintenance (e.g. preventive and scheduled).

N.b.
FMEAs are the preferred method, but K-T (Kepner & Trego) "Potential Problem Analysis" (PPA) is also acceptable. The important aspect is the systematic use of such tools to identify and reduce quality risks in the realisation phase and in the operation of the total supply chain. The analysis needs to reflect customer impact and also internal quality performance.

CONTROL PLAN												
Name product: Standard Bulb				Flowchart: A3				Date first release: 1999-04-15				
Codenummer: 245 67834 5691				Dept/unit: Bulb coating				Date last update: 2004-06-20				
Endproduct: Incandescent lamp				Plant: Lamp factory								
Process Flow		Machine,		Characteristics		Method		Control	OCAP	FMEA	R&R	C_p
No.	Name subproces	device,tools	Process	Product	Product/Process	Measuring	Sample size	Method				C_{pk}
			Parameter	Parameter	Specification	Method	Frequency					C_{pm}
A3.1	Bulb coating	Coating eq.		Contamination LV235-160-011 LV235-160-012	Not present	Visual	25/hour	p-chart LV235-160-033	LV984-300-010	FMEA		
A3.2	Filling bulb	Filling eq.	Filling pattern		Smooth LV235-160-011 LV235-160-012	Visual	10/hour		LV984-300-010			
A3.3	Drying bulb	Oven	Weight powder		LV235-262-051	Balance	3/hour	x-R chart LV235-160-033	LV984-300-010		8%; 6%	
				Dryness bulb	Be dry LV235-262-052	Visual	10/hour	LV235-160-033	LV984-300-010			
				Temperature	LV235-260-061	Thermocouple	1/day	I-R chart LV235-160-033	LV984-300-010			
A3	General	Reject level					1/hour	Registration LV235-160-033				

Example control plan

Element 1: Control plans

1	Control plans are available on request, but there is little evidence that they are used in practice.
2	Control plans exist, but there are major deficiencies and/or they do not reflect actual practice.
3	Control plans are available as formal (quality system) documents (e.g. ISO 9000), which include flowcharts. They are in use, with only minor deviations observed.
4	Significant product characteristics have been translated into related control points in the process, and these are incorporated in the control plans. The control points must cover the processes as well as the machines and machine groups that are critical. These control plans reflect actual practice and are well understood by production and maintenance personnel. Control loops and measurement systems are shown on the flow charts. Cost of non-quality is measured for waste in the manufacturing process and can be derived from the performance of the parameters.
5	Process FMEAs have been conducted to determine risks to the product, process and machines and the design of the control plans have taken these into account. The selection of significant characteristics is verified by customer input and by potential and realized failure costs. Cost of non-quality figures are used to identify critical processes.
6	The plant has satisfactorily completed control plans, which are derived from an understanding of customer requirements, machine requirements and FMEAs. They cover all necessary aspects - including supplied materials, spare parts, logistics and packing/storage, so cost of non-quality can be made visible. There is evidence of a careful and thorough customer-driven determination of significant characteristics. The control methods are incorporated in the control plans and flowcharts. There are clear, written instructions what to do in case of out of control (OCAP) or out of specification (repair procedure). It is shown that (all) relevant people were involved.
7	Records indicate that product, process, machine or logistic capability problems have been identified and corrective action plans are established. A regular, formal review process for the control plan, FMEAs, choice of significant characteristics and control methods has been defined and evidence exists to demonstrate the involvement of the plant or operations manager in the review process.
8	The plant has satisfactory control plans and process FMEAs. Audits verify that the plans are effective, and there are only minor concerns. The plans have been agreed with, or accepted by the customer(s) whenever partnerships exist. At least one formal review (defined as per 7) has taken place, with a plan to conduct regular reviews (e.g. every six months).
9	The plant has been extremely thorough with the preparation of fully adequate control plans and process FMEAs, with a good working relationship with customers on quality planning. FMEAs are living documents. Several review rounds have been completed, and the learning from these is evident.
10	The plant has documented evidence of a close and very effective working relationship with customers on quality planning. Learning from control plan reviews with regard to product, process and machine and logistics capabilities has been incorporated in designs. The site is recognised as a 'best practice' site for control plans, both in terms of their preparation and in the quality performance standards achieved, so that others can conduct internal benchmarking.

Element 2: Procedures

Procedures describe how the main activities of a process should be carried out.

With many manufacturing processes, much of the variability in the product results from the inconsistency in the way we do things. Good procedures can help to reduce this process variation. Procedures are an often neglected, but extremely important, foundation for a good control of processes and a useful instrument in the war against variation.

It is a requirement that all manufacturing units are certified to ISO9000 or equivalent.
The plant should have available and use appropriate written procedures including a satisfactory change control procedure within its quality system.

Procedures/documents should be available for the relevant quality related functions/processes; for example:

- Control plan
- Contract review
- Planning for quality (Quality Manual)
- Machine and process capability studies
- Process control (SPC)
- First piece and in-process inspection
- Final inspection and outgoing quality assessments
- Internal quality audits
- Batch identification and traceability
- Measurement systems and analysis
- Gauge calibration
- Supplier evaluation and rating
- Quality of supplied materials
- Sampling plans to use for incoming materials and outgoing products
- Batch release
- Batch rework instructions
- Documentation change control
- Problem solving
- Complaint reporting and response
- Initial sample evaluation for new or changed products, machines or processes
- Change control
- Cost of non-quality studies
- Procurement of spare parts
- Preventive maintenance
- Breakdown maintenance

Procedures need to be adequate.

They should be written in a way that makes it easier to run the process.

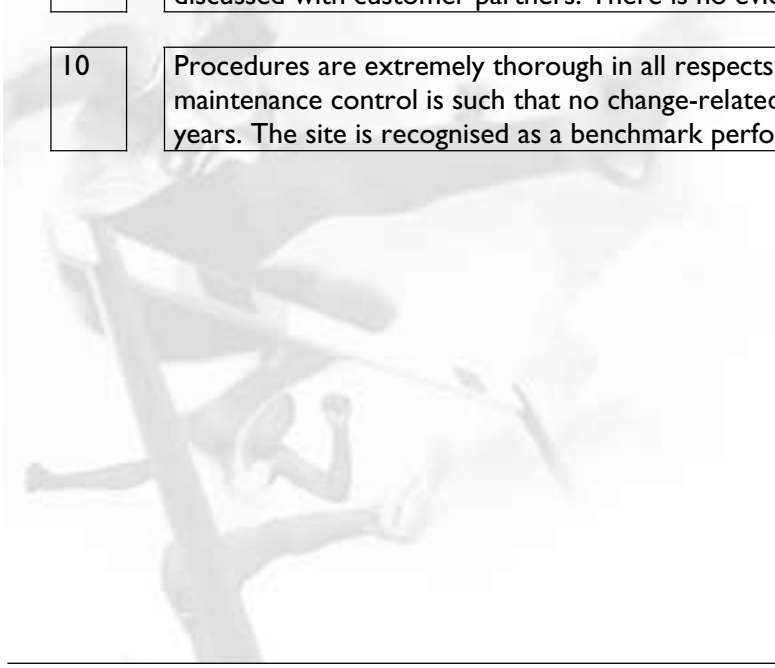
Procedures should be implemented as written.

A formal review system is needed to verify implementation.

The change control system must operate effectively.

Element 2: Procedures

1	Only verbal quality and maintenance related procedures are used.
2	Some written quality and maintenance related procedures exist but with major deficiencies.
3	Some written quality and maintenance related procedures exist, and are used, but the system of change control is inadequate.
4	Adequate written procedures are available for most quality and maintenance related functions, with an adequate change control system. However, the procedures give cause for concern - e.g. there is an inadequate procedure for controlling changes to the manufacturing process or spare parts, with inherent risks to quality.
5	Satisfactory written procedures exist for virtually all quality and maintenance related functions and processes (including change control). Implementation and application are generally observed to be satisfactory. A process change control procedure exists and has been effectively used, but there may be a minor concern in this area (e.g. no checklists with reference to proposed changes).
6	The plant has an effective change control procedure covering local adaptations to the product, process, machine, spare parts and externally originated changes. There is good discipline in how the procedures are applied.
7	The plant has verified by regular conformance audits that there are no concerns relating to changes to procedures, products, processes, machines and spare parts.
8	Updated FMEAs and control plans are reviewed prior to document or process changes being implemented. Process FMEAs are living documents. Procedures are in place for approving 'emergency' changes, which are valid only for a limited period of time.
9	The plant's and maintenance representatives visit their internal and external customers to prevent change-related concerns. Past changes are reviewed, and proposed future changes are discussed with customer partners. There is no evidence of non-conformances.
10	Procedures are extremely thorough in all respects. The effectiveness of the plant's and maintenance control is such that no change-related concerns have occurred in the past five years. The site is recognised as a benchmark performer in this field.



Element 3: Quality of supplied materials

This element provides a focus on the quality of supplied materials and spare parts. If supplier delivery performance is identified in the control plan as a critical process, then this should be subject to assessment in element 6 (process capability / process performance) and element 7 (process control).

The plant should have an adequate and effective system for assuring the quality of incoming products, spare parts and services.

- There are two methods for controlling incoming quality: supplier implementation of SPC (Statistical Process Control) and incoming inspection. These may be used singly, together, or combined with an audit programme to develop an effective quality system for incoming products. Sampling plans used for incoming inspection must have acceptance numbers of zero, and the plant should be moving systematically to a system based on a supplier implementation of SPC.

- Suppliers and sub-suppliers should be encouraged to meet the requirements of this system. Their quality systems should reflect this.

Quality agreements should be in place with key suppliers.

Suppliers should be encouraged to use SPC.

Evidence of statistical control and capability should be required from suppliers.

Suppliers should use the cost of non-quality approach.

- Evidence of SPC in the form of control charts should be obtained from (sub)-suppliers.

- Adequate reaction rules (PDCA) have to be determined to deal with supplier deliveries in the event that stability and/or capability is not achieved.

- Purchasing staff needs to be adequately trained to give suppliers SPC support when required.

The quality system concerning incoming material must be adequate.

A vendor rating system must be implemented and appropriately used.

Element 3: Quality of supplied materials

1	The plant conducts and documents initial sample evaluations.
2	The plant performs incoming inspection, but the sample sizes are substantially below requirements and lots can be accepted when the sample contains defects.
3	The plant performs incoming inspection with adequate sample sizes. However, the sampling plan allows acceptance of lots from which the samples contained major defects. First attempts to define and agree with suppliers about their control plans on significant SPC parameters and control points are started.
4	Where the plant performs incoming inspection, a zero acceptance-sampling plan is used. Initial ship-to-stock programmes are started, eliminating incoming inspection, but still deficiencies are noted. AQL agreements are only in place as a protection for any breakdown of SPC based arrangements. Several supplier audits have taken place. A basic supplier rating system is in use, which includes measures of product and spare part quality.
5	Statistical evidence is available from one or more key suppliers. This evidence may indicate instability or non-capability. Appropriate interim containment actions have been implemented. In the event that incoming inspection is eliminated, an adequate feedback-loop is used to react to production problems. Purchasing personnel are adequately trained to support the supplier's SPC drive. Suppliers' control plans have been formally agreed.
6	The evidence from one or more key suppliers indicates that stability and capability have been demonstrated. Documented evidence is available that the supplier delivers SPC data according to the quality agreements. There is evidence of regular reviews of line rejects by suppliers, followed by analysis and corrective actions. Many suppliers have involved the plant in their FMEA analysis. Quality measurement is an integral part of a well defined, objective and formal supplier rating system. Formal audits have taken place on most suppliers.
7	Statistical evidence of stability and capability is available from all key suppliers. An adequate incoming inspection system (per 4, above) is used on an exception basis. Documented and effective containment actions are used when required. Demonstrated use of a supplier rating system is available.
8	Statistical evidence is available from most related suppliers (direct manufacturing, product and spare part support). There are improving trends on the supplier rating system. Regular formal audits take place for virtually all suppliers.
9	The plant has documented evidence of significant supplier quality improvement. Virtually all suppliers have control plans that have included measures resulting from FMEAs conducted by teams that have involved plant personnel.
10	Evidence shows that for virtually all supplier-related problems, the containment and/or corrective actions taken have resulted in no recurrence within one year.

Element 4: Measurement systems

Adequate measurement systems must be available to provide process engineers, operators and supervisors with variable data and the results of good/not good assessments. This information is needed for (in line) quality control and maintenance.

- Examples of good/not good assessments: visual inspection of products and running/not running of equipment, etc. For all measurements listed in the control plans a measurement system evaluation has to be done. When the result is not good, improvement actions are needed.

The characteristics and parameters being measured need to be relevant and impact customer or internal requirements.

- It is important to measure what need to be measured independent whether it is easy or not. A good control plan gives a list of these measurements. See also element 1: Control plans.
- The measurement systems of suppliers need to be audited to ensure adequate capability and calibration.

The selection of critical characteristics and parameters should be effectively incorporated in gauge planning and design.

- All critical features need to be checkable.
- All measurements of variables and good/not good inspections that are part of the control plan need to be subject to measurement system evaluations.
- For measurements of variables the R&R- or Isoplot-method can be used; for good/not good inspections the "Ford attribute gauge study" or the Kappa-method can be used.

All operators, engineers and managers must have understanding of the relevance and content of MSE (Measure Systems Evaluations).

- A training plan is needed for all relevant people.
- It can be shown that relevant people have been trained.
- Execution and results of MSEs are reviewed by colleagues on a regular basis for better understanding.

Gauges, test equipment and personnel need to be appropriately located throughout the plant's operations.

Areas for gauging, measuring, and testing the product need to be adequate and well lighted.

The plant must have an effective gauge and test equipment maintenance program.

Gauges and test equipment are periodically inspected and calibrated. Records can prove that.

- When there are multiple units of the same measuring and test equipment, correlation between them must be measured, analysed, and, when necessary, corrected for.
- This information has to be used, where appropriate to determine calibration and maintenance intervals.

Element 4: Measurement systems

1	Either limited general purpose measuring/test equipment is available, or there is some evidence of gauge planning. The maintenance program for measurement systems is based on verbal procedures with no records maintained.
2	Only general purpose measuring equipment (e.g. micrometers) is available when specialised equipment is needed. There are some elements of a gauge maintenance program, but it is neither well thought-out nor well implemented (e.g. poor procedure, no records).
3	Elementary special purpose measuring/test equipment only is available. The plant has a gauge maintenance program, but the evidence shows it is very poorly implemented. Measurement system evaluations (R&R for variable data and Kappa techniques for attributive measurements) have been started. Appropriate training has been started.
4	Adequate special purpose measuring/test equipment is available with some evidence of gauge planning. The plant has a fairly well planned gauge maintenance program, but evidence shows that it is not well implemented (e.g. some records, no written instructions, frequencies not maintained). Some measurement system evaluations (R&R for variable data and Kappa techniques for attributive measurements) have been conducted, but the outcome shows many deficiencies. A training plan for all relevant people exists.
5	Complete special purpose measuring/test equipment is available with evidence of effective gauge planning. The plant has implemented a gauge maintenance program, but a significant number of deficiencies were found. Many measurement system evaluations (R&R for variable data and Kappa techniques for attributive measurements) have been conducted, but only some of them are < 30% (for R&R) or > 0.7 (for Kappa). All relevant people have been trained.
6	Measuring equipment is available for virtually all significant characteristics. Most of the measurement system evaluations have been conducted using the R&R method or Kappa techniques and improvements are visible. The evidence shows that the plant has effectively implemented a gauge maintenance program, but it is not yet fully documented. Colleagues on a regular basis review execution and results of MSEs.
7	Virtually all measurement system evaluations are available. Improvements show that many of them are < 30% (R&R) or > 0.7 (Kappa). There is a well-planned and effectively implemented gauge maintenance program.
8	Improvements in gauge variation are driven by a PDCA approach. Progress is regularly reviewed by management. There is a well-planned and effectively implemented gauge maintenance program, and absolute values are recorded as opposed to pass/fail results. The percentage of "out of calibration" is tracked, and there is a good reducing trend. All of the measurement system evaluations have been conducted and improvements show that many of them are < 30% (R&R) or > 0.7 (Kappa).

9	There is an extremely well planned, innovative, and effectively implemented gauge maintenance program (e.g. comprehensive procedure, variable data records, full written instructions, no deficiencies found, and calibration due-date identification). Statistical methods are used to determine calibration and maintenance intervals. There is an effective computerised recall system for maintenance. Most of the measurement system evaluations are < 10% (R&R) or > 0.9 (Kappa).
10	The plant has innovated in the measuring and measurement process in some manner meaningful to the customer. The site is recognised as a benchmark performer in this field. All of the measurement system evaluations are < 10% (R&R) or > 0.9 (Kappa).

Element 5: Process capability / process performance

Process capability (or process performance) studies need to be conducted on significant product characteristics and process parameters as covered by the control plans (see element 1).

- Product characteristics, process parameters and supplied material characteristics can be measured on sample basis or continuously (100%). Results can be given as measurement data like weight, length, time and temperature or as reject-% in case of attributive (=good/reject) measurements like visual inspections, etc.

- Equipment performance characteristics can be presented by the overall equipment efficiency or subdivided into breakdown, set-up and adjust, speed loss and idling (6 big losses). Also MTBF (Mean Time Between Failure) and MTTR (Mean Time To Repair) can be taken as performance characteristics. Start-up losses and rejects must be covered by the (process) control plan.

- Process capability studies are carried out to assess the combined performance of all the components of a process, including materials, equipment, people and procedures. Performances are often given as percentages: overall equipment efficiency, breakdown, set-up and adjust, speed loss and idling, start-up losses and rejects. The disadvantage of this way of working is that it is not suitable anymore when the fraction (ppm-level) is small in comparison with the volume.

- A statistically more accurate way of working is to predict a reject level using the measurement data. Using these data, the average and standard deviation can be calculated. When the average and standard deviation are known, the reject fraction can be predicted more accurately based on the distribution characteristics.

Process capability indices can be taken as performance indicators and be converted to a reject fraction and vice versa.

- Process capability studies and process performance studies are seen as equivalent in this survey tool.

Capabilities for a shift of the average of 0 to 1.5 sigma from target				
Specification width	C_{pk}	C_p	ppm	Qualification
+/- 3 sigma	1 - 0.5	1	1350 - 66811	Unacceptable
+/- 4 sigma	1.33 - 0.83	1.33	63.4 - 6210	Sufficient
+/- 5 sigma	1.67 - 1.17	1.67	0,29 - 233	Good
+/- 5.5 sigma	1.83 - 1.33	1.83	0.019 - 31.7	Very good
+/- 6 sigma	2 - 1.5	2	0.002 - 3.4	World Class

- The formulas for the process capability indices are:

$$C_p = \frac{USL - LSL}{6\sigma}$$

$$C_{pk} = \frac{Min\{(USL - \mu);(\mu - LSL)\}}{3\sigma}$$

- Very important is the way of collecting the data. The samples taken must be representative for the "normal, long-term" production; this includes:
  - equipment or process adjustments,
  - production start-up and interruptions,
  - parallel equipment and tool exchange,
  - raw material from several batches.

- The calculated standard deviation relates to the "long-term" standard deviation. Therefore the C_p and the C_{pk} are also called the "long-term capabilities".

- On the other hand it is possible to take samples that are representative for the "optimal, short-term" production; requirements are:
  - the equipment is running stable on normal speed (has past start-up phase);
  - no equipment or process settings are changed;
  - without any equipment interruption (short duration of the experiment);
  - raw material is taken from one batch (possibly with known, small spread);
  - production is on the very same equipment by one operator.

- The calculated standard deviation relates to the "short-term" standard deviation. In that case the C_p is abbreviated as C_m and the C_{pk} as C_{mk}. The C_m and C_{mk} are called machine capabilities or "short-term capabilities". It is also possible to calculate the "short-term" standard deviation using the moving range of the individual measurements.

- Cost of non-quality has a clear relation with reject-levels (product, process and supplied materials) and equipment performance (breakdown, set-up and adjust, speed loss and idling). Because process capabilities are used to predict reject-levels, process capabilities can be used for monitoring and decreasing the cost of non-quality.

Customer requirements need to be clearly understood. See element 1.

- The customer considers the measured product characteristics important and all significant customer requirements are covered by measurements.
- The specification limits of these product characteristics should truly reflect the customers' needs.
- The process capabilities and reject-% together must reflect the overall equipment efficiency.

All operators, engineers and managers must have understanding of the relevance and content of process capabilities.

- A training plan is needed for all relevant people.
- It can be shown that relevant people have been trained.
- Calculation and results of process capability studies are reviewed by colleagues on a regular basis for better understanding. Important issues are:
  - The data need to be gathered over a sufficiently long period, different equipment, crews etc.
  - The samples need to be representative for the total production including rejects.
  - The standard deviation must be calculated in the right way. When sample standard deviations are used, this is only justified when the process is stable. Else, the standard deviation should be calculated based on the data as one group.
  - The amount of data must be enough to calculate the process capability with sufficient accuracy.
  - If a computer program is used to carry out the data analysis its methods of calculating the standard deviations should be understood.

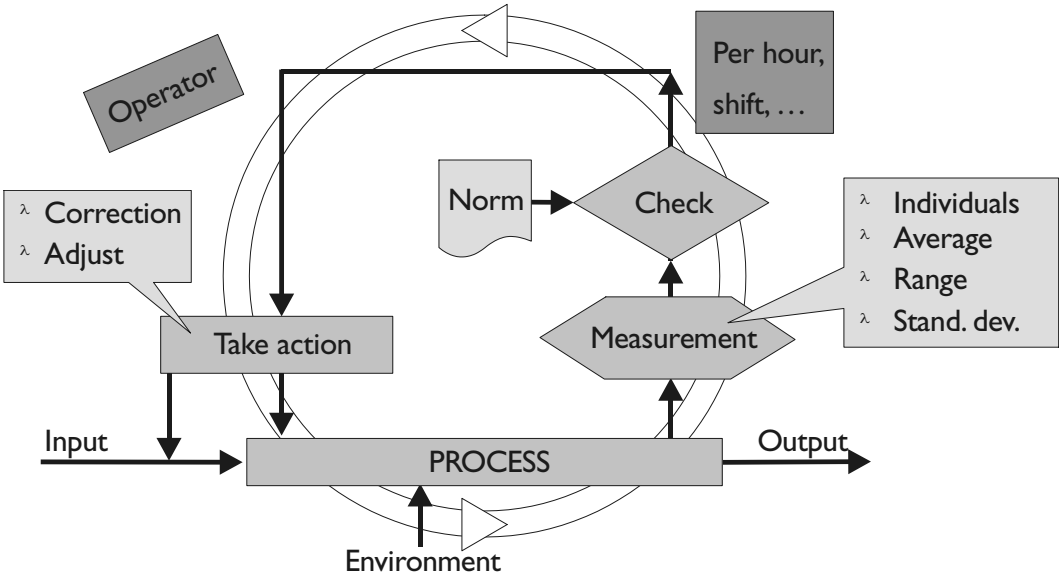
Process capabilities need to be used for improvement.

- The presented process capabilities and reject-% are reviewed regularly in order to define improvement actions.
- High priority should be given to those characteristics that have a major contribution to the cost of non-quality or involve liability risk.

Element 5: Process capability / process performance

1	Only pilot applications of process capability studies have been conducted and these were not properly documented.
2	Pilot applications have been conducted and documented, but they did not include appropriate analysis methods, such as control charts, histograms and C_{pk} data.
3	Appropriate statistical analysis methods have been used for some applications, but the reaction to the results is inadequate. Appropriate training has been started.
4	Appropriate analysis methods have been used, and process capability studies have been conducted on many of the significant product characteristics and process parameters, as determined in the control plans. A training plan for all relevant people exists.
5	Process capability studies have been conducted on virtually all of the significant product characteristics and process parameters, as determined in the control plan. Several of the C_{pk} indices are greater than 1. Some deficiencies exist (e.g. only limited containment actions are taken) in either the analysis methods or the reaction to results. A start has been made to use cost of non-quality to identify important parameters and measure results. Process performances are also calculated as C_{pk}. All relevant people have been trained.
6	Studies include adequate analysis and reaction to the specified capability requirements and to the results (e.g. appropriate containment actions taken). Many of the C_{pk} indices are greater than 1.0 and results show an improvement in yield / cost of non-quality. 50% of the sub-processes have a C_{pk} above 1.3. Colleagues on a regular basis review execution and results of process capability studies.
7	Process capability studies have been conducted on all (100%) of the significant product characteristics and process parameters, as determined in the control plan. The studies use the appropriate analysis techniques and correct data collection and are well documented. Process improvements and containment actions have been implemented when required. Many of the C_{pk} indices are greater than 1.3. Cost of non-quality (process waste) is continuously decreasing. 80% of the sub-processes have a C_{pk} above 1.3.
8	Studies have been conducted beyond control plan requirements. Where pre-control is applied, the stability of the process must be understood and capability studies repeated at the appropriate frequency that has been determined (otherwise minimum twice per year is recommended). Most of the C_{pk} indices are greater than 1.3 and several are greater than 1.6.
9	There is evidence that significant and documented improvements in process capability have been achieved. Virtually all of C_{pk} indices are greater than 1.3, with numerous being at least 1.6. Cost of non-quality figures are at a constant low level.
10	There is evidence that most of the C_{pk} indices are greater than 1.6. The site is recognised as a benchmark performer in this field. All of the sub-processes have a C_{pk} above 1.3.

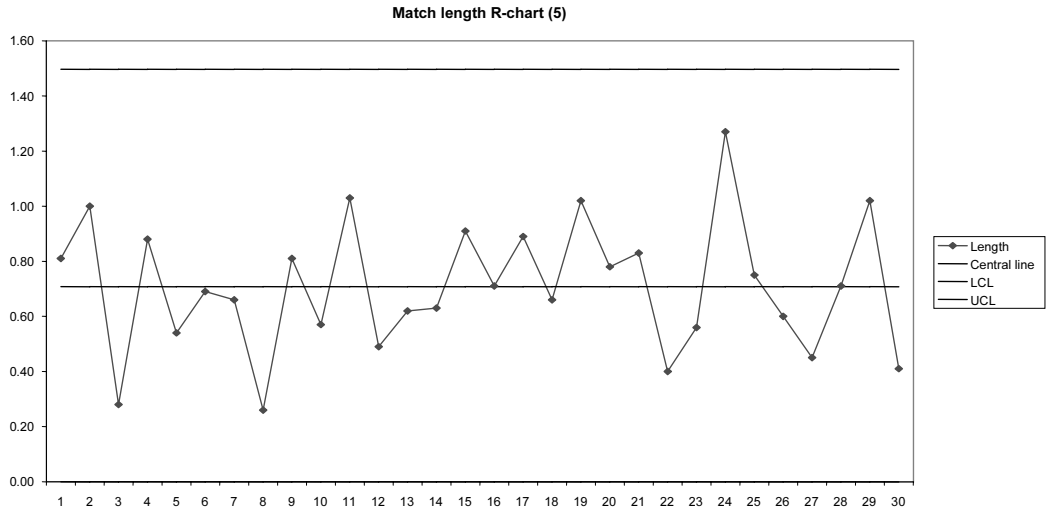
Element 6: Process control



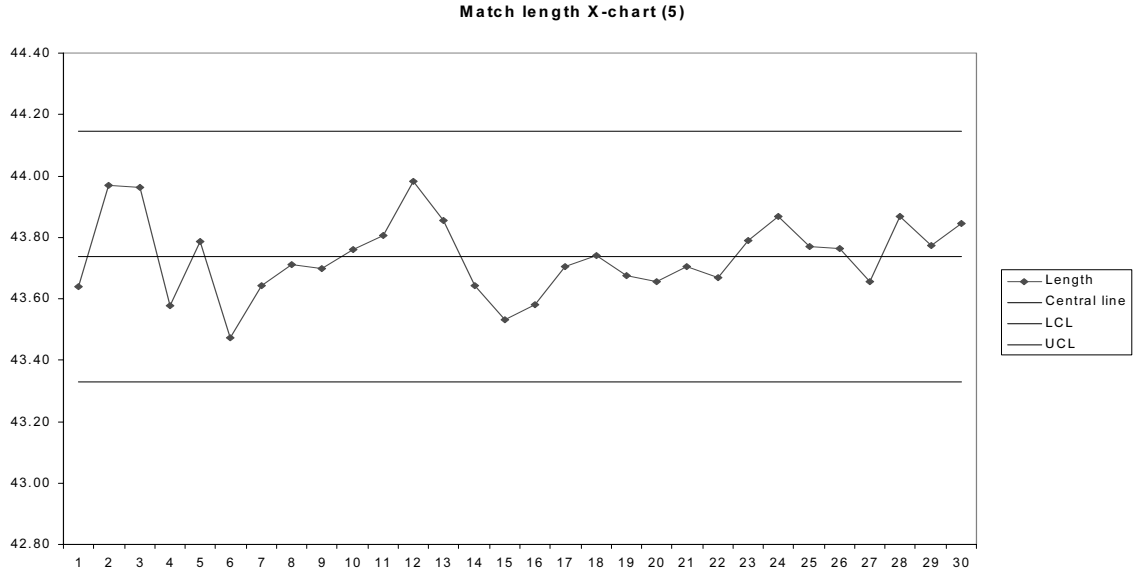
First control loop

Statistical process control (SPC) should be utilised for significant product characteristics, process parameters and characteristics of supplied materials.
SPC should also be used for performance characteristics as reject-%, breakdown, set-up and adjust.

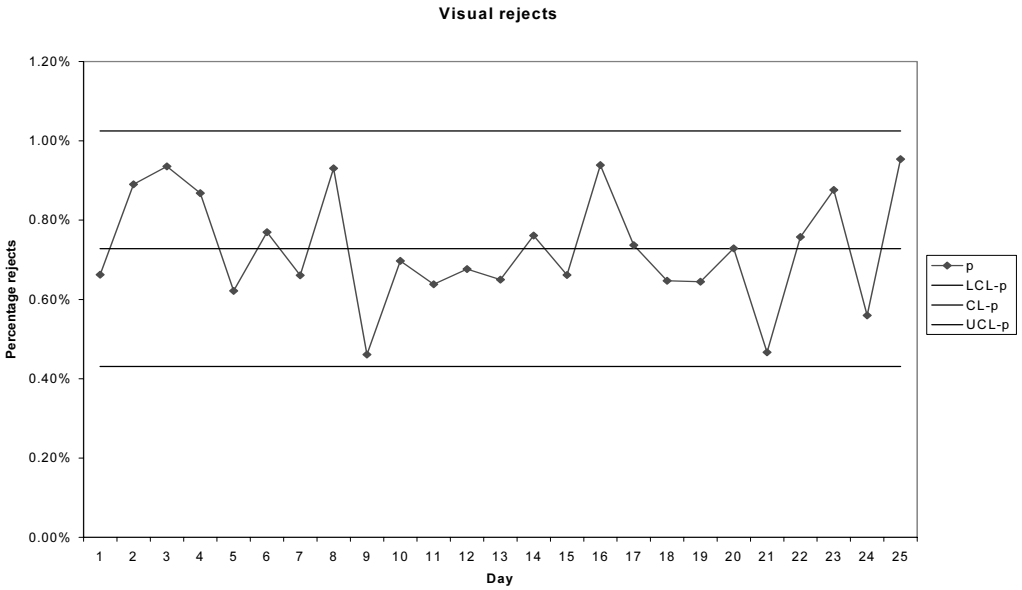
- The control plan describes which characteristics are taken into account, the measurement frequency, sample size and who is responsible for the measurements.
- SPC is executed by using control charts. Examples are: $\overline{x}$ -R, $\overline{x}$ -s, individual and moving range, p-, np-, c- and u-chart.



Example R-chart

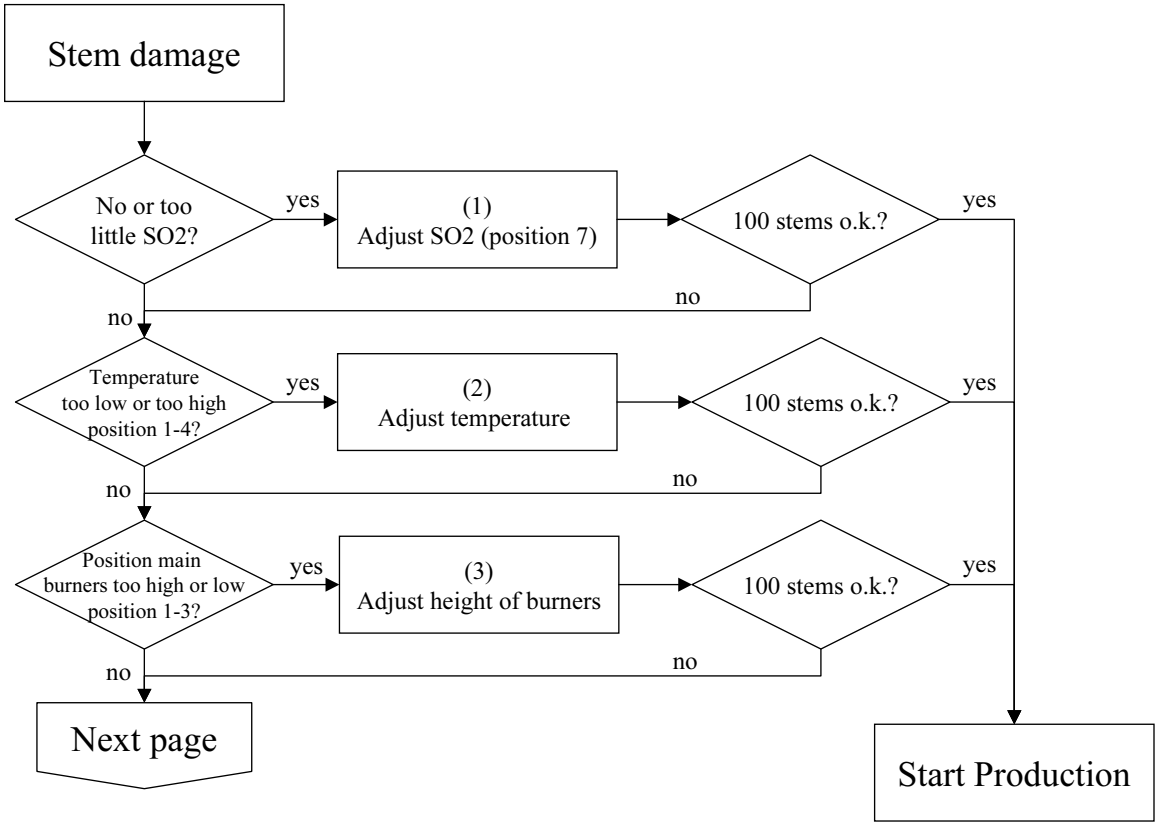


Example $\bar{x}$ -chart



Example p-chart

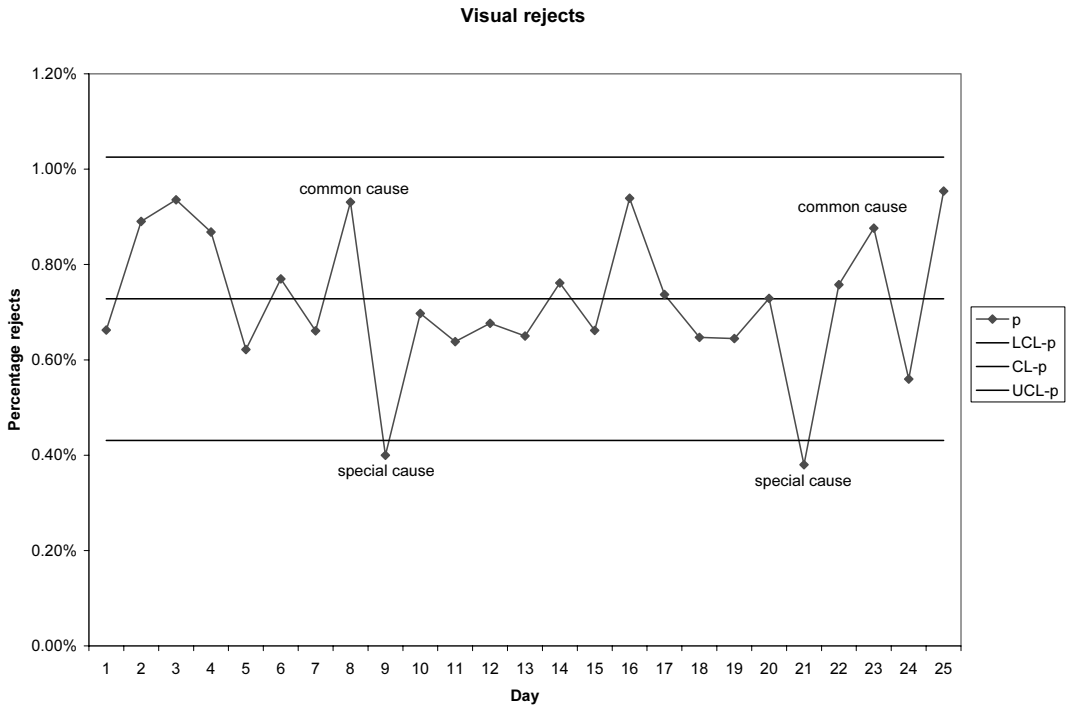
For each chart an OCAP need to exist. This is a procedure that has to be followed in case of an *out of control* situation.



Example of an OCAP

All operators, engineers and managers must have understanding of SPC (Statistical Process Control) and the relevance of process stability.

- A training plan is needed for all relevant people.
- It can be shown that relevant people have been trained.
- Choice and calculation of control charts by colleagues gives better understanding. Important issues are:
  - The frequency of taking samples should be high enough to detect occurring special causes timely.
  - The sample size should be large enough to detect occurring special causes.
  - The most suitable type of control chart should be chosen for each specific situation.
  - Control limits should be calculated in the right way.
  - If a computer program is used to carry out the data analysis, its methods of calculation should be understood.
- All employees should understand the distinction between common and special causes.
- Managers should realise that operators cannot be expected to reduce common cause variation.
- Operators have to realise that they have to take action in case of an *out of control* situation.
- Operators have to realise that actions taken while in control will harm the capability of the process.
- The potential for over-control should be recognised.



Example common and special causes

Data should be collected, monitored, documented and used for taking actions (first control loop).

- The collected data (control plan) should be monitored using control charts.
- There need to be documented procedures for reacting to *out-of-control* situations.
- There needs to be a registration of the use of the OCAPs.
- The characteristics to be measured and related OCAPs should be reviewed on a regular basis. (See element 1: Control plans)

Data should be accessible and used for analysis and improvement (second control loop).

- Registration of *out of control* situations is necessary and also the actions that have been taken.
- Registration of *out of control* situations is used for the selections of improvement possibilities.
- Existing data should be analysed and used for finding root causes.
- Multi-vari charts should be used to identify families of variation and support improvement.
- Previous charts should be available and used for trend analysis, performance review and process improvement.
- Problems should be permanently solved and not recur.

Element 6: Process control

1	The plant has no SPC in use, but applies a structured combination of 'in-process' control and final sample inspection that assures an adequate level of product quality to satisfy customers' current requirements.
2	A thorough analysis has been made on effectiveness of current approaches. Managers and engineers have had adequate training to allow identification of improvement opportunities from using SPC.
3	Improvement opportunities for applying SPC have been identified. Appropriate training for operators and support staff has started and at least one pilot application of SPC is in progress. A first start has been made with implementation of control loops for significant characteristics according the control plan. Measurement data are shown on control charts and OCAPs are used for actions to be taken.
4	There is a training plan for all relevant personnel. The plant has a number of pilot applications in progress, with participation of operators concerned. Many of the significant characteristics according the control plan are shown on control charts and related OCAPs are in use. Documented registration of and reaction to out-of-control conditions has many deficiencies.
5	The plant has been using appropriate SPC methods for most of the significant characteristics as determined by the control plan for at least three months. Documented registration of and reaction to *out-of-control* situations show some shortcomings. A start has been made with reduction of these situations. Analysis of OCAP registration, process data and breakdown maintenance could be used for this. Cost of non-quality need to be made visible. All relevant people have been trained.
6	The plant has been using appropriate SPC methods on virtually all of the significant characteristics as determined by the control plan for at least the last six months. The first control loop is closed for virtually all significant characteristics. Reactions to *out-of-control* situations are well documented with only minor shortcomings. OCAPs are in use. There is clear evidence of management involvement in reviewing the effectiveness of SPC activities. The second control loop is closed for many significant characteristics. Colleagues on a regular basis review choice of the kind of control charts and calculation of control limits.
7	The plant has been effectively using appropriate SPC methods on all significant characteristics as determined by the control plan for at least the last year or since identification of characteristics as significant. Appropriate reaction is documented for virtually all *out-of-control* situations. Teams including line operators meet to reduce both special and common cause variation. All first and second control loops are completely closed.
8	Special causes of variation are virtually eliminated. Control charts and other SPC techniques are regularly discussed in review meetings to identify opportunities for improvement.
9	Many control charts show evidence of process improvement through reduction of common cause variation. A formal structure of teams - which include operators, SPC specialists and process/product experts exists. These teams meet regularly to seek ways of reducing variation.
10	Most control charts show evidence of process improvement through reduction of common cause variation. Process improvement is a part of everyone's job and senior managers coach others in the application of SPC and conduct regular reviews of effectiveness.

Element 7: Reaction to problems

The factory must react appropriately to problems.

- Quality and maintenance problems may be either quality issues causing problems with the customer or issues causing rejects or equipment problems in the production with consequential cost of non-quality (loss of yield, material losses or downtime etc.).

These problems need to be effectively communicated to all members of the organisation.

- There needs to be an effective procedure for registration of quality and maintenance problems, which considers all relevant details. Important maintenance aspects are: reaction time, time to repair, nature of breakdown, parts used and suspected causes.
- Overviews of these data and conclusions need to be communicated with members of the organization.
- At best this will be through a routine meeting involving production, technical and maintenance personnel. Other typical methods are non-conforming product displays and Pareto charts located on spot where they will be seen by the employees.
- People need to be aware of their specific responsibilities to either respond to, or inform others of particular quality issues or breakdown situations.

Root causes of failures need to be determined and verified. After that corrective actions need to be taken.

- A formal and disciplined stepwise method of problem solving should be utilized.
- The PDCA improvement cycle includes the following steps:
  - setting priority (what to work on) (plan),
  - collect information and relevant data (plan),
  - root cause analysis and verification (do),
  - describe and test corrective action/solution (do),
  - realize the improvement (check),
  - standardize (design rules, working procedures, process and operator certification) (act).

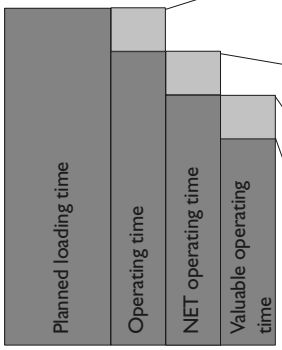
- A well-documented traceability procedure should be in place.
- Deviations in cost of non-quality should be investigated and explained.

Quality and maintenance problems should be well communicated with management.

- Any system used must be visible for top management.
- Top management should have understanding of the composition of the cost of non-quality. Therefore it is necessary that the cost of non-quality is used for priority setting in solving problems (lowest level). On the next level it will be used for analysis and for doing that it must be visible (intermediate level) and at the end the reduction of the cost of non-quality is taken as a measure for progress (highest level).
- This information should be used for defining and starting-up improvement projects.
- The results of these projects should be communicated to the management.
- As a minimum, some written alert of all quality and maintenance problems must be generated.
- A quality complaints procedure should be operational.
- Customer response time should be measured and followed.

- Non-conforming (spare) parts and materials should be analyzed. These include both non-conforming parts detected in the process and those returned by customers.

- Categories of cost of non-quality



Issue: 6 big losses	Example causes for non performance	Example remedies
breakdown	equipment capability SFM	maintenance strategy ownership
set up and adjust	non-SMED	involvement equipment design
speed loss	equipment sensitivity operation standards	robust design standards preventive maintenance
small stops and idling	auxiliary equipment performance	order & cleanlines
start-up loss	process capability process control	process expertise SPC
rejects	non spec. materials operating conditions	equipment design periodic maintenance

Element 7: Reaction to problems

1	Communication of manufacturing process (quality and maintenance) problems, returned product analysis, equipment performance and problem solving takes place, but is handled entirely on a verbal basis.
2	There are some elements of a quality problem and equipment performance communication system present, but the system is not used. Analyses of returned or rejected products, equipment performance and subsequent problem solving is carried out but is poorly documented.
3	A potentially adequate means of communicating quality problems and equipment performance exists but is not used effectively. Problem solving takes place but has not isolated the root causes of problems.
4	A quality problem and equipment performance communication system exists, but there are significant shortcomings in communication with the workforce or communication with the management. Problems are dealt with, however, major concerns exist around returned and rejected product analyses, equipment performance and/or problem solving methods.
5	A satisfactory quality problem and equipment performance communication system exists (including the use of cost of non-quality figures) between all personnel involved in the process. A disciplined step-wise problem solving approach is generally used, and appropriate people have been trained in its use. Returned and rejected products analyses are performed.
6	There are effective systems to communicate quality problems and equipment performance to the workforce and to management. Returned and rejected products and equipment performance are completely analysed and a regularly planned reviews of the issues take place involving all relevant personnel. Cost of non-quality figures are analysed and deviations explained. There is a formal sign-off by authorized people before customer complaints are closed.
7	The plant seeks customer agreement before signing-off problems as solved. Customer visits are established where appropriate for both management and production personnel.
8	Evidence shows that all complaints are satisfactorily completed, with adequate corrective action, within the specified completion time. Innovative methods (TV monitors, unique displays) are used to communicate quality problems, equipment performance and progress in their solution.
9	The cycle time to respond to external complaints is formally monitored and targets are established in agreement with customer representatives.
10	Evidence shows that containment and/or corrective actions taken have resulted in no recurrence of either the complaint or internal problems within one year.

Element 8: Handling and packing

The handling, storage and packaging of materials and products must be adequate to achieve and preserve product quality.

- The means of receiving and delivering materials and components to the production process should be designed and executed in such a way to prevent damage or potential quality problems, either in the handling or at the point of use.

- The design of handling and manufacturing methods in the production process should include assessment of risks of introducing errors (use of wrong material, incorrect assembly etc) and of potential damage to parts. Particular attention should be paid to materials that can have a significant impact on customer requirements.

- Storage areas for incoming, in-process and finished products should be reviewed regularly to establish if any conditions exist which could affect product quality. During the assessment, attention should also be paid to handling, including stock rotation.

- The product unit should have evidence that indicates that the customer has been notified of essential packing data and that questions on packaging are discussed with the customer.

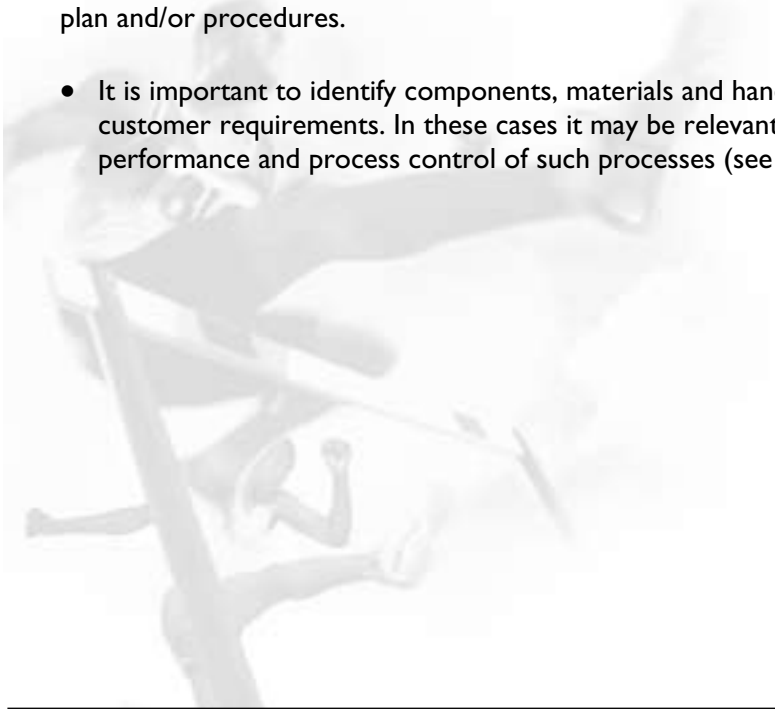
- Packaging should be formally reviewed for adequacy. This element addresses packaging in the total chain, and therefore refers to possible damage or deterioration of the packaging itself as well as preventing damage or contamination of the contents.

- Packaging or handling specifications are being adequately satisfied.

- Specific controls should be in place to prevent mixing of similar products or parts during handling, storage and delivery. Where applicable, particular attention must be paid to avoiding mixing of similar products in outgoing packaging.

The handling, storage and packaging of materials and products must be adequately covered in the control plan and/or procedures.

- It is important to identify components, materials and handling that can have a significant impact on the customer requirements. In these cases it may be relevant to consider the process capability / process performance and process control of such processes (see elements 6 and 7).



Element 8: Handling and packing

1	Some deficiencies (i.e. evidence of adverse effects on product quality) exist in handling, storage and packing. The situation has been reviewed, and there is concern that the current handling/storage methods are insufficient to prevent product damage and/or deterioration.
2	Deficiencies exist, but a credible plan has been developed to address the identified problems. However, the packing, storage, handling and transportation are still insufficient to prevent damage and deterioration of materials or products in the total supply chain.
3	Deficiencies exist but an internal improvement plan has been implemented. There is routine auditing of handling and packing methods, stock and storage areas to detect any deterioration.
4	Although quality problems attributable to handling, packaging or shipping are infrequent, there are still some incidents. A review of the risks in handling, packing and transport has taken place and corrective actions implemented.
5	There are known aspects of handling, packing or shipping which require attention even though no quality deterioration has occurred. Controls are in place to ensure the necessary degree of product traceability and to avoid mixing of similar materials or products.
6	The level of internal scrap and/or rework caused by handling throughout the supply chain is known and improvement actions have shown results. A process of formal assessments and reviews of the risks in handling, packing and transportation has been implemented. Documentation is available showing customers are informed of packaging data.
7	Handling, packaging and storage methods are satisfactory for preventing quality problems and preserving product quality. Error proofing methods have been introduced in production to prevent quality problems from handling and packing. The methods used for product handling and storage (including traceability and segregation aspects) have been agreed with the customer.
8	Documentation is available showing customer acceptance, through audits of both packaging and product handling/storage. Documented testing of the packing is routinely performed and results of internal and external audits are used to improve the packaging, handling and storage.
9	There have been no customer complaints relating to handling and packing for the past 12 months. Costs of non-quality due to packing and handling are minimal for the type of business with no significant disruption from introduction of new suppliers, materials or products.
10	The production unit has innovated in the areas of handling, packing or shipping resulting in significant benefits to the customer, and the site is recognised as being a benchmark performer in this field.

Element 9: Continuous improvement

The plant must have a definite program to bring about continuous improvement in the organization.

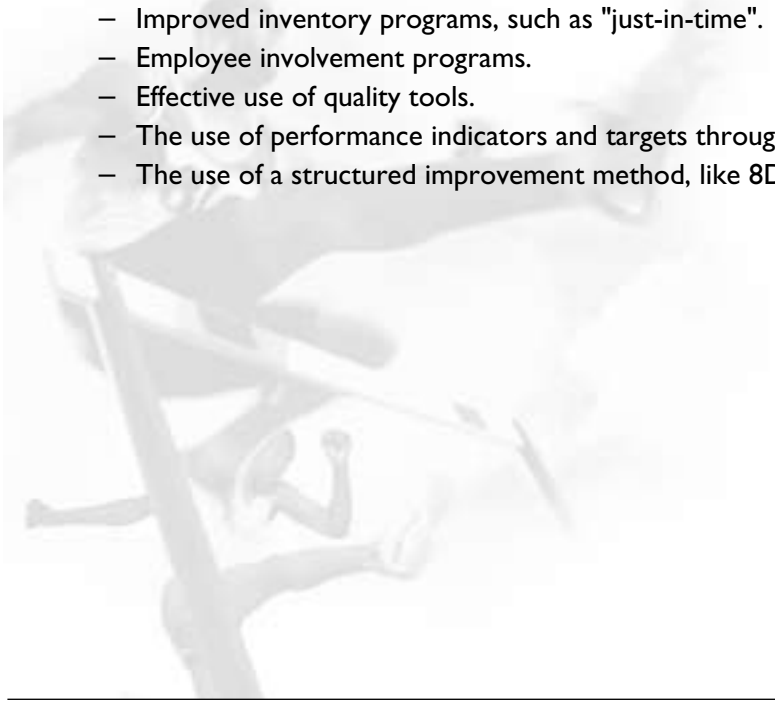
- Improvement plans should be detailed, specific and be developed according a written procedure. The procedure should be based on policy deployment (e.g. Hoshin planning).
- Priorities should be set by higher management and based on the defined policy.
- The plans must be focused on specific problem areas: e.g. technology management, technology knowledge and transfer, improvement methods and tools, way of working, etc.

The plant demonstrates a movement towards *manufacturing excellence*.

- Managers should attend relevant training programs.
- Managers should communicate their policy and from that policy derived sub-goals with their employees.
- Managers should stimulate an inter-departmental approach/way of working.
- New developments, improvements projects and actual production and maintenance results should be evaluated on a regular basis and adequate actions taken.
- Managers should be active in coaching and deploying training within the organisation.
- There should be follow-up activities in place (benchmark visits, renewal processes in place etc.).

Improvement priorities should be identified and project teams established.

- Continuous improvement of the organisation and the way of working should be treated as a key business objective.
- Identify any indication of such significance, such as:
  - Training and educational program, particularly in statistical methods.
  - Definition of breakthrough projects, led by people that are highly experienced in leading improvement projects, methodology and tools.
  - Training and coaching of engineers and operators.
  - Investments for process improvements.
  - Improved inventory programs, such as "just-in-time".
  - Employee involvement programs.
  - Effective use of quality tools.
  - The use of performance indicators and targets through-out the organisation.
  - The use of a structured improvement method, like 8D.



Element 9: Continuous improvement

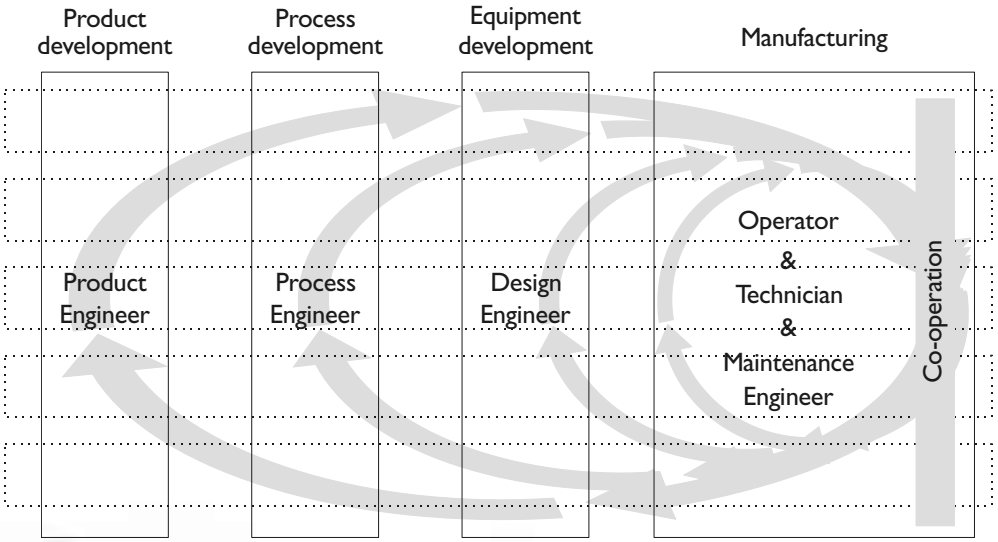
1	The plant has a policy related to continuous improvement, but there is no evidence that the policy is implemented.
2	The plant has a policy on continuous improvement, but thus far only planning discussions have occurred. Training is sparse.
3	A credible plan for continuous improvement has been developed. Implementation has just begun but no documented results are available. Some managers have had training in *manufacturing excellence* (or equivalent programmes).
4	Pilot improvement projects have begun, and show some encouraging results. Coaches/facilitators have been identified to support the improvement teams.
5	Several pilot projects are finished and show positive results. Training needs have been identified and training modules used selectively to provide many individuals and teams with the necessary skills. Improvement leaders have been identified, trained and allocated to specific projects. Improvement teams use a common improvement approach.
6	A formal structure (e.g. Hoshin) of assignments - which identify targets and ownership - and teams, is in place. A training plan, covering needs for individuals has been used to form the basis of a training program. Most team members have been trained in appropriate improvement skills. Managers review progress and take action when necessary.
7	Improvement project teams, that are departmental and cross-functional, meet regularly, report to management, and have achieved improvement on at least one major process. Several improvement projects have resulted in quality and yield gains with reduced cost of non-quality or logistic improvements. All team members have been trained in appropriate improvement skills.
8	Many improvement projects show quality and yield gains with lower cost of non-quality or logistic improvements. Appropriate tools for continuous improvement are used (e.g. 7 tools), and performance indicator displays show overall progress and relationships - e.g. using flag diagrams. Internal training programs are being repeated, recognising that there is a need for annual renewal.
9	Numerous improvement projects have resulted in a structural reduction in the cost of non-quality, by addressing root causes. Training programs are improved by reviewing progress during the past years. There is strong drive (culture) throughout the organization to improve.
10	A comprehensive and detailed improvement program is in effect and major improvements have been realised on virtually all processes. Improvement teams from the site have been recognised by others external the site or organization. The site is recognised as a benchmark performer in this field.

Element 10: Interface management

The plant must have a definite program to bring about interface management in product design (ppm), process design (yield) and equipment design.

- Improvement plans should be detailed, specific and be developed according a written procedure. The procedure should be based on policy deployment (Hoshin planning).
- Priorities should be set by higher management and based on the defined policy.
- Improvement plans may address the full range of manufacturing activity: products, processes, equipment, logistics, packing, delivery etc.
- The plans must be focused on specific problem areas: e.g. scrap, re-work, time, costs, customer quality concerns etc.

Interfaces between product, process and equipment development on the one hand and manufacturing and maintenance on the other must be organized and maintained.



- Technology management and knowledge are key elements for improvement. The degree of improvement depends on the way the sharing of knowledge and information is organized.
- There needs to be a well-organized and formal exchange of know-how between the product development, process development and equipment development department on the one hand and manufacturing and maintenance on the other.
- It should be likely that during the different phases of development the synergy will be maximal.
- During design review measurement and inspection results should provide good feedback from manufacturing/maintenance to product, process and equipment design with the objective to improve the customer satisfaction, reduce the reject level, reduce maintenance and consequently reduce downtime.

Element 10: Interface management

1	The plant has a policy related to interface management, but there is no evidence that the policy is implemented. There is some feedback of production (process and maintenance) experience to development (product, process and equipment), but this is through informal contacts.
2	The plant has a policy on interface management, but thus far only planning discussions have occurred. There is some formal sharing of experience and data between developers (products, process, equipment) and users (production and maintenance). There is evidence of structural information feedback starting between competence centres and development.
3	A credible plan for interface management has been developed. There is an awareness of sharing production (process and maintenance) problems and experiences with development (product, process and equipment).
4	Within the production and maintenance departments there is awareness of the problems and experiences in the manufacturing process identified through FMEA or PPA analysis and in-process measurements and problem analyses. There is a formal feedback through structured meetings to the equipment, product and process development departments.
5	Production and maintenance personnel are informally involved in some phases of new product, process and/or equipment creation or modifications and there is some sharing of information with development departments.
6	A formal structure (e.g. Hoshin) of assignments - which identify targets and ownership - and teams, is in place. There is a mandatory formal integral involvement of production and maintenance personnel during the acceptance and release of products, processes and equipment. There is evidence of this through the minutes of structured and formal meetings. It is visible that their experiences are used in new developments.
7	Cross-functional teams of production and development meet regularly, report to management, and have achieved progress in their way of working. Production and maintenance personnel are involved in pilot runs to ensure adequate training, preparation and understanding of future requirements.
8	Production and maintenance are formally involved in the design phase of new products, processes and equipment. There is evidence of this through structured and documented meetings to ensure that all identified improvements have been incorporated and the cost of non-quality is reduced.
9	There is an ongoing process (involving production and maintenance personnel on the one hand and developers (product, process and equipment) on the other to ensure that products, processes and equipment realize their requirements and performance and are optimized where possible.
10	There is full awareness of the production and maintenance issues derived from business objectives with the equipment, process and product development process and there is no repetition of known problems.

Element 11: Breakdown and preventive maintenance

The goal of a maintenance program is to determine and describe the optimal maintenance method for an installation, assembly or component in accordance with requirements as described in the control plan and safety and environmental regulations.

Maintenance methods are:

- Failure based or Breakdown Maintenance (FBM)
- Preventive maintenance
  - Condition (or inspection) Based Maintenance (CBM)
  - Use based (or periodic) Based Maintenance (UBM)

A breakdown situation is a condition where the machine fails to realise its agreed and specified performance – an unplanned stoppage.

Preventive maintenance is generally a planned activity based on CBM or UBM and described in a maintenance instruction.

The following aspects must be covered by the breakdown maintenance process:

Organisation

- The maintenance organisation should be the result of a joint analysis between key business managers, of the business demands.
- The balance between centralised and decentralised resources needs to be formally considered and optimised.
- It needs to be understood that a *world class* breakdown maintenance activity can be achieved through a combination of both centralised and decentralised resources.
- Locations, both central and decentral, should be fully equipped to satisfy the business needs.
- The maintenance team and production management should have a clear understanding of static (fix and leave) and dynamic (leading to improvement) repair processes and the consequences of both to the productivity of the processes.
- There should be a clear differentiation between breakdown and preventive maintenance.

Procedures and instructions

- Procedures are implemented for repair activities in breakdown situations, to describe the management process involved, e.g. communication, logging of data and allocation of tasks.
- Repair instructions are the instructions for carrying out the actual repair. They will clearly depend on the complexity of the situation. A minimum requirement is a simple checklist of key attention points before and after repair. More complex situations may require flowcharts, drawings or photographs.

Communication system

- There should be an effective procedure for registration of breakdowns and data collection, which considers all relevant details. A formal maintenance management system may be used. Relevant data are:
  - reaction to repair,
  - time to repair,
  - nature of breakdown,
  - parts used and
  - suspected causes.
- All people need to be aware of their specific responsibilities to either respond or inform others of particular breakdown situations.

Analysis process/problem solving

- Each activity contributing to maintenance throughput time needs to be analysed. Initially this can be a global analysis. If relevant, a detailed analysis can follow.
- Elements of the analysis should be:
  - the breakdown and consequences,
  - the communications concerning this breakdown,
  - the responses to it,
  - the repair that has been done,
  - the return to normal production and
  - the filed record of the activity.
- The purpose of this analysis should be to reduce cycle time and in particular to ensure that simple short repair processes are not preceded by complex and lengthy procedures.

Skills

- There is a need for an adequate analysis by management of the skills necessary to deal with the full range of potential breakdowns. This should be a dynamic process.
- These skills should be acquired or developed in a systematic manner.
- The tasks and responsibilities for each group of personnel concerned with the equipment in the production process should be defined.
- There should be an ongoing review process for management involving all levels of personnel to ensure the best development and deployment of people performing maintenance tasks.
- Awareness training is needed for everybody, including managers, about the effective deployment of maintenance in the organisation.
- A detailed training plan for all levels of personnel is needed.
- First line breakdowns are defined as those where in particular situations and with appropriate training the line operator can perform the repair.

The following aspects must be covered by the preventive maintenance program:

Lubrication

- Lubrication should be recognised as a major issue and subject to dynamic review.
- Analysis of lubricants with respect to performance, environment, stocks and supplies should be part of management reviews.
- Reducing the diversity of lubricants should be systematically worked on.
- Lubrication instructions and schedules should be written and subject to review.
- Specific responsibilities for operators and staff need to be included.
- Diagrams of equipment and lubrication points should be included in the work instructions and located near the equipment.

Cleaning

- Machines should be kept clean and in excellent condition.
- A good distinction should be made and understood between functional and cosmetic cleaning and the cleaning activities should be managed by the right people.

Modular replacements

- Preventive schedules should be developed dynamically by analysis of the effect of maintenance on the throughput time of the total process.

- This should result in the transition from single part to sectional or modular replacement when necessary.
- There should be evidence of the use of SMED (Single Minute Exchange of Die) in this process.

Skills

- Procedures and training programs should be in place to ensure that each person involved with the manufacturing process is able to use his skills at an optimal level.
- Clear systems should be in place to optimise the total available skills through teamwork.
- All aspects as inspection, monitoring, lubrication and replacement of parts or modules, should be included in training programs.

Element 11: Breakdown and preventive maintenance

1	Breakdown conditions are understood and there are reasonable responses to them. Some systematic replacement of spare parts takes place and routine cleaning and lubrication is carried out. There is no condition monitoring and no registration of breakdowns. Procedures and work instructions are not written and based on experience. Resources are not always available and tasks not allocated.
2	Some procedures and work instructions are written, but not effectively used. There is some random monitoring of equipment and registration of breakdowns. Not all spare parts are available and early warning systems are limited to observations of such events as oil levels, noise and vibration. Cleaning schedules are in place and effectively implemented. There is no plan for upgrading skills for maintenance personnel.
3	Most procedures and work instructions are written and effectively used. Strategic spare parts are available, but there is no planned availability for the other spare parts. Maintenance personnel are available to deal with the most frequently occurring breakdowns. Some elementary preventive maintenance actions (UBM/CBM) take place and this is documented. Some training has been organized for managers, maintenance personnel and operators.
4	All procedures and work instructions are written and effectively used, but a formal review process is not always applicable. Most spare parts are available, but there is no system in place to monitor the use and stock level of these. There is a simple registration system for breakdowns, but this is limited to log books with little analysis. Effective training is in place at all levels.
5	Breakdown conditions and the requirements for the performance of equipment are well understood by all parts of the organization. Data collection is in place to collect and analyze the results of preventive maintenance, but it has some weaknesses. Management review sessions take place regularly (at least annual), to review preventive and breakdown maintenance. Review of skill requirements and training plans for updating these, are in place.
6	There is a clear monitoring and recording system for spare parts, but this is not totally effective. Many of the key equipment parts have been identified for the preventive maintenance schedule. Throughput time analysis using e.g. SMED reviews and the benefits of modular replacements are being analyzed. Many preventive and breakdown (registration) tasks are now deployed to production operators. They receive appropriate training.
7	The maintenance management process is in place, but is primarily used by the maintenance organization. The management of spare parts is an integral part of the maintenance process. Lubrication is recognized as a key issue and significant strides have been made in the use of a reduced number of modern lubricants. Detailed analysis of the main elements of maintenance throughput time is now in place including the nature and frequency of breakdowns, specification conditions and preventive maintenance. The location of maintenance personnel and deployment of tasks is the outcome of detailed studies to optimize the total system.

8	The maintenance management process embraces all functions and is accepted by manufacturing management as an integral part of the total business. It involves other functions including purchasing, logistics and F&A. The focus on improvement work includes reducing the cycle time of breakdowns and cost reduction. Throughput time analysis for replacing parts is in place for these schedules and some modular replacement units have been produced and are available. There is evidence of throughput time reduction in some cases and SMED reviews and improvements are part of regular reviews. Teams are involved in this process.
9	Improvement projects are part of an overall business improvement plan. There is complete acceptance of the need for teamwork and deployment of tasks. All critical equipment parts are subject to preventive maintenance. There is evidence that modular replacement is in place where appropriate and this is the outcome of the routine dynamic review process. SMED techniques have resulted in many throughput time reductions with some significant gains. There is a detailed training matrix covering all levels of maintenance and production to update skills, both technical and social to facilitate improvements, including team working.
10	Detailed preventive and breakdown tasks are in place. Tasks are allocated to various levels in the organization according to skill levels, which are reviewed regularly. Many teams involving operators and technical staff are involved in improvement work, which is yielding clear benefits. There is a process to feed back data on machine conditions to equipment engineers. The preventive and breakdown activity is recognized as a model for best practice in the industry.

List of acronyms

AQL	Acceptable Quality Level
CBM	Condition (or inspection) Based Maintenance
CL-p	Control Limit
EFQM	European Foundation for Quality Management
F&A	Finance & Accounting
FBM	Failure based or Breakdown Maintenance
FMEA	Failure Mode and Effects Analysis
LCL-p	Lower Control Limit
LSL	Lower Specification Limit
MSE	Measure Systems Evaluation
MTBF	Mean Time Between Failure
MTTR	Mean Time To Repair
OCAP	Out of Control Action Plan
PDCA	Plan Do Check Act
PPA	Potential Problem Analysis
PPM	Parts per Million
OEE	Overall Equipment Efficiency
QFD	Quality Function Deployment
QIC	Quality Improvement Competition
QSS	Quality Systems Services
R&R	Repeatability & Reproducibility
SMED	Single Minute Exchange of Die
SPC	Statistical Process Control
UBM	Use based (or periodic) Based Maintenance
UCL-p	Upper Control Limit
USL	Upper Specification level

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