SPC and Lean Manufacturing
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## Contents

Introduction 1

**Part I. Main Body**

Chapter 1: Introduction to Lean Manufacturing 3
Chapter 2: Just-In-Time Production Concepts 11
Chapter 3: Visual Workplace and Error-Proofing 22
Chapter 4: Total Productive Maintenance 28
Chapter 5: Single Minute Exchange of Die (SMED) 33
Chapter 6: Lean Case Studies 41
Chapter 7: Introduction to Quality 42
Chapter 8: Basic Quality Tools 50
Chapter 9: Introduction Statistical Process Control (SPC) 54
Chapter 10: Is the Process Stable? 63
Chapter 11: Is the Process Capable? 68
Chapter 12: Variable Control Charting 71
Chapter 13: Attribute Control Charting 78
Chapter 14: Case Studies in Quality Management 84

Appendix 85
GE 313 : SPC and Lean Manufacturing

**Course Description:** This course provides the knowledge needed to effectively use Statistical Process Control (SPC). The relationship to quality costs, on-time delivery, concepts of variation, and an analysis of the organization-specific SPC applications will be introduced. Utilizing SPC to improve and maintain consistent production will be covered. The use of Lean manufacturing to shorten the time between the customer order and the product build/shipment by eliminating sources of waste will also be covered through the study of system performance, identification and elimination of waste, elimination of sources of variability, and a good understanding and use of the principles of operations management.

**LEARNING OUTCOMES:** Upon completion of this course, the student should be able to:

- Identify practical occurrences of the seven wastes defined by Ohno, and recommend remedial actions.
- Recognize and apply common engineering tools used in lean manufacturing.
- Discuss management techniques necessary to implement lean manufacturing.
• Plan, implement, and interpret management tools used in Statistical Quality Control.
• Understand the implications of Engineering Tolerances as they relate to Manufacturing use of Statistical Process Control.
Chapter 1: Introduction to Lean Manufacturing

Overview

Lean manufacturing is the production method used to reduce production times as well as response times to customers. Lean manufacturing adopts a method of manufacturing according to demand, but also attempts to reduce waste. Generally, this process will include marketing and customer service personnel who can identify the wants of its customer base and report back to the manufacturer (Kulkarni et al., 2021; Gil-Vilda et al., 2021). The transition from a traditional company to a lean company is complex and needs to be carefully organized in order to maximize income, reduce costs, and to improve productivity (Cimermancic et al., 2022; Pearce & Pons, 2013). Review the slides and video below to learn more about the history of manufacturing and the shift to lean manufacturing. Use the double pointed arrow in the lower right corner to expand slides to full screen.

An interactive H5P element has been excluded from this version of the text. You can view it online here:
https://pressbooks.palni.org/spcleanmanufacturing/?p=5#h5p-1
Lean refers to an item being as slim as possible, like there is no fat, no waste. The fat or waste in a company would be excessive or inefficient operations, but lean manufacturing has no waste (Boardman; Kulkari et al., 2021). There are eight kinds of waste (or muda) in some models. They are: transport, inventory, motion, waiting, over-production, over-processing, defects, and skills. Lean manufacturing focuses on the five following concepts as a way to reduce all of these kinds of waste (Boardman; Brown, 2020; de Bucourt et al., 2011).
Value and Value Stream

This concept is defined by the customer. The organization must have a clear understanding of what value is for the customer. It is wasteful to create a product that customers do not find value in buying (ASCM, 2022). Data provided by continuous customer feedback is how this concept is defined and constantly adapted to meet the needs of the customer base (Boardman). Consider the surveys provided at the end of receipts to elicit feedback on your shopping experience. This type of feedback is important for an organization to adapt with trends and demands.

To track the value of a product, a value stream map can identify the activities that add value or not, including the processes that are essential and cannot be eliminated. Terms to know are value added, non-value added, and essential non-value added (Boardman). Learn more about value stream mapping from these resources:

- This resource What is a Value Stream Map? (2021) shares the reasons you need value stream mapping and common mistakes that are made in the process.

Please also review this series of six videos that provide clear lessons on how to do Value Stream Mapping.
Flow

Flow is defined as characterized by continuously moving through the manufacturing process without time to pause in storage or in transport. Flow eliminates batches and queues from the system so the product continuously moves without delay. Flow should complement the market demand, to keep the process clean and consistent (Boardman; Saylor). Consistent flow reduces waste caused by starting and stopping the production process (ASCM, 2022).

Flow is increased by eliminating bottlenecks. Consider a business a wide mouth jar and a bottle. When the process is consistent and the flow meeting the needs of demand, there is nothing to slow it down as it exits the facility (or jar, for this example). But, if the company is a bottle, when the flow reaches the neck of the bottle, the flow is delayed. This is where the process is running at the least capacity, slowing the flow of the product to the customer. Eliminating these bottlenecks will improve the flow and reduce waste (Boardman; Virasak).
Pull and Pursuit of Perfection

In this lean system, a product is not created until it is asked for by the customer, until it is pulled by the customer rather than pushed by the system. Reduction in lead times to meet the demands of the pull will reduce wasted time spent in storage or transport. These processes are always continuously improving (also known as kaizen), manufacturers encourage internal competition to be more perfect than they were yesterday (Kulkari et al., 2021; ASCM, 2022). Many companies implement continuous improvement practices to promote competition within their field, in addition to the internal structure. (Huang et al 2022).

Customers must pull for products in order for them to be developed in the lean manufacturing model. “Rope Pulling” by r4n is licensed under CC BY-NC 2.0.

An interactive H5P element has been excluded from this version of the text. You can view it online here:

https://pressbooks.palni.org/spcleanmanufacturing/?p=5#h5p-2
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Association for Supply Chain Management (2022). Lean manufacturing. ASCM. https://www.ascm.org/lp/lean-manufacturing/?utm_source=google&utm_medium=cpc&utm_campaign=nb+all+dsa&gclid=Cj0KCQjw_viWBhD8ARlSAHImCd6TDIbJbBsqPJ0coFTpiRTZGokHunL1RRSCWUyNjMrP0ezCT7vWbx4Aq3oEALw_wcB


Chapter 1: Introduction to Lean Manufacturing | 9


Chapter 2: Just-In-Time Production Concepts

Overview

Just-in-time production (JIT) is an inventory management philosophy that reduces inventories to minimum levels. JIT is designed to reduce waste in any form, like that associated with maintaining inventory, but also storage and transport (Saylor, 2019), or wasted time (“Operations Strategy”, 2017). The ideal system would have zero stocked finished goods and WIP, and minimal stocked raw materials. Taiichi Ohno is credited for developing this lean system and for perfecting it within Toyota’s car manufacturing plants in Japan. Related to lean manufacturing, it seeks to reduce or eliminate any part of the manufacturing process that does not add value from the customer’s viewpoint (Saylor, 2019; Rice University). Moreover, it assists organizations to meet their capacity and promotes consistent flow through the manufacturing process (Qureshi et al., 2016).
2013). Here are some examples of waste (Saylor, 2019, Qureshi et al., 2013; Siddiqui, 2022):

- Overproduction
- Long wait time
- Excessive transportation
- Processing wastes
- Storage costs
- Unproductive methods for producing goods
- Defective wastes

Review the series of short videos below to learn what JIT is and it’s connection to Toyota.

Takt Time

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https://pressbooks.palni.org/spcleanmanufacturing/?p=21#h5p-5

https://pressbooks.palni.org/spcleanmanufacturing/?p=21#h5p-20
Takt time is one of the most important calculations involved with lean manufacturing (Soliman, 2020). Takt time is the average time it takes from the start of production of one unit to the start of the next units production, when they are produced sequentially. Takt time is calculated by taking the time to produce the parts and divied it by the number of parts demanded in that interval. It is also based on customer demand, so if a product cannot be produced using takt time, other strategies will have to be used in order to meet the demand (“Takt Time”, 2022). Because the time must represent the actual customer demand rate, do not adjust times for any slow downs, like you would with other calculations (Soliman, 2020). Learn more about takt production and control from this study: Takt Production Monitoring and Control in Apartment Renovation Projects (Keskiniva et al., 2021)

Here’s an example calculation of Takt Time. Please note that customer demand is expressed in the maximum allowable time per unit:

If there are a total of 10 hours (or 600 minutes) in a shift (gross time), less 60 minutes for lunch, 10 minutes for team briefing, and 10 minutes for basic maintenance checks, then the net Available Time to Work = 600 – 60 – 10 – 10 = 520 minutes (31,200 seconds)

If customer demand was 520 units per day and only one shift was available, then the link would be required to output at a minimum rate of one part per 60 seconds in order to keep up with customer demand.

Formula for calculating takt time:
$T = \frac{T_a}{D}$

where $T =$ product assembly time required to meet demand; $T_a =$ net time available to work; $D =$ customer demand

Ways to Meet JIT Goals
Inventory Reduction

An expansive inventory hides a lot of issues, ranging from equipment problems, bad vendors, low quality, and others. Gradually, by lowering the amount of inventory, weaknesses are revealed and can be updated to be more efficient and effective (Rice University). Reducing inventory requires a few, very reliable vendors to deliver both materials and the inventory within very short time frames, generally in small lots. This reduces costs but it can be challenging to find the right vendors (Franco & Rubha, 2017).

Demand-Pull Production System

The demand-pull system functions in such a way that the work flows to the organization that needs work. JIT also addresses concerns and challenges related to production and waste reduction strategies in order to meet its goals, especially without inventory around to cover weaknesses (Rice University). This systems of one of the tools the Toyota Production System uses to achieve success,
the consumer triggers production to meet their requirements at the right time and quantity (Si et al., 2021)

Reduce Lot Sizes

Manufacturing entities that improve their setup can reduce the lot size, increasing competitiveness. (Rice University). Here is an example from the 1980s and 3M, provided by Rice University:

“In the 1980s, the 3M company converted a factory that made a few adhesive products in long production runs into a factory that made over 500 adhesive products in small production runs. To keep unit production costs under control, 3M studied the setups on its coating machines. Since the cost of chemical waste disposal was a major part of the cost of changing over a coating machine to make another product, 3M shortened the length of hoses that needed purging and redesigned the shape of the adhesive solution holding pan on the coating machine to be shallower. 3M also used quick-connect devices, disposable filters, and work teams to speed up setups. The result was that 3M could maintain low unit costs on its coating machines while producing small lots of hundreds of products to meet market demand quickly.”

Plant Loading

This strategy means that companies have the insight to provide
the needed products, at the needed moment and place in time. The concepts are building on each other now, reducing inventory to meet exactly to meet demand, and promoting more effective manufacturing processes to hit goals at the right time (Rice University).

Flexible Resources

The unknown is something that makes JIT enterprises vulnerable and unfortunately, it cannot be eliminated in all cases. The best strategy to overcome uncertainty is a certain level of flexibility built into the organizational structure. Maybe it is drills that can swap bits easily, so one drill can do the work of 10 drills. Or maybe it is the color application method that can switch from one color to another without changing equipment like hoses or nozzles. This bit of flexibility can improve output and make JIT organizations more productive (Rice University); it does require that the equipment is maintained and functioning properly. Additionally, flexible, cross-trained employees and adaptive environments minimize waste by synchronizing the flow throughout the process (Franco & Rubha, 2017).

Flow Layouts

If the layout of the building is a perfect way to improve flow and
productivity. In this situation, manufacturers set up their buildings to have one-way flow of the operation and have respective areas where employees take responsibility and control of their products (Rice University). Generally, this empowers employees to take ownership in their work.

Empowered Employees

Select each of the hot spots below on the graphic to learn more about the effects of empowering employees in the JIT model.

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https://pressbooks.palni.org/spcleanmanufacturing/?p=21#h5p-6
Potential Challenges with JIT

There can be challenges with implementing JIT, beyond the fact that it is a complex system. For example, JIT manufacturing is vulnerable in regards to natural disasters. Because these organizations reduce the amount of on-hand inventory, they do not have stock to spare in the case of tsunami, hurricanes, flood, and other disasters (Qureshi et al., 2013; Siddiqui, 2022). Production is at the mercy of suppliers, so if one thing is off, the rest of the system is delayed (Siddiqui, 2022; Franco & Rubha, 2017). Communication also seems to be a relevant concern in JIT approaches; it is imperative that the communication structure and strategies are conveyed to all of the relevant workers to reliably share information (Qureshi et al., 2013), including maintaining positive relationships with contractors and other entities (Si, 2021).

Learn more about other ideas related to JIT in this study about off-site construction to build productivity and improve performance: A Dynamic Just-In-Time Component Delivery Framework for Off-Site Construction (2021). You can also view this video below as a review of JIT as well as the advantages and disadvantages of this type of manufacturing.
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Learn Transformation (2021, March 5). Just in time in 2021 [Video]. YouTube. [Link]


Matlack, A. (2018, October 2). Beyond engagement: What leaders need to know about empowering others. OpenSource. [Link]

NetSuit (2021, July 9). What is just-in-time inventory management? [Video]. YouTube. [Link]


OpsExcellence (2015, February 10). Takt time, cycle time, lead time [Video]. YouTube. [Link]


Rice University (n.d.). Operations management: Special topic – Just


Overview:

Visual systems are everywhere within the workplace. According to Clarity: Lean and Visual Management (2022), over 80% of people remember what they see and do. By comparison, only 10% of people remember what they hear and 20% of people remember what they read. Visual stimuli are processed 60,000 times faster than text (Clarity, 2022). Visual management involves a three part process, which will be covered below.

What is visual management?

Visual management creates a mental model for users to recall information, using different visual inputs to categorize the information. If the readability of a visual representation is high, it will be processed more thoroughly by the user (Scotland, 2013). A visual management system has a singular goal: out of standard situation is immediately obvious and easily corrected. This includes self-explaining, self-ordering, and self-improving.

Visual management systems have many benefits to organization. First, visual representations make it easy for people to quickly review and comprehend information. Because the flow of information is simple, it keeps the organization flow smooth and orderly, as designed. Visual representations allow mistakes and potential safety hazards to be identified, some even saying makes it impossible to do the wrong thing (Catalysis, 2019). Visual representations, like signs or signals, eliminates or at the very least
reduces miscommunication. Consider the visual cue on some doors to identify if a room is in use or not, clear and consistent communication means the room is used properly without interruptions. Finally, visual management systems allow everyone to see how work is progressing and how their team is improving (Catalysis, 2019).

Three Part System for Visual Management

**Home Border:** Something belongs here. When the item is moved, we have a placeholder to make sure it can come back home. This could be considered an outline of a tool or a parking space for mobile equipment.

**Home Label:** What belongs here? The system helps maintain order. This could be a color-coded or symbol-coded system for organizing tools or other materials.

**ID Label:** Where is my home? The item would be labelled in such a way to direct it back to its home location. An example of this would be labeled file and part drawers for easy location of those items.

Four Levels of Visual Devices

Select each of the five hot spots below to learn more about the four levels of visual devices.

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Error Proofing or Poka-Yoke

Poke-Yoke is a Japanese system which prevents errors. This technique is used to eliminate problems, by eliminating ineffective processes or equipment that are causing the problems. Furthermore, this system does not accept errors to move down the production line. They are fixed as soon as they are identified (Trout, 2022; Pradhan & Gautam, 2020). Another way to control quality and error-proof the manufacturing process is through Statistical Process Control (SPC). This is the standard method for measuring and controlling quality during the process, it is real-time data obtained during the manufacturing process (Singh, 2022). SPC involves a sampling inspection by different entities to detect defects and also self-checks built-into the process. As you watch the video below, consider whether you think SPC or poka-yoke is a better way to error-proof the manufacturing process.

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https://pressbooks.palni.org/spcleanmanufacturing/?p=29#h5p-13
Kanban Inventory Management

As we have covered, lean manufacturing focuses on the reduction and elimination of waste, this can be wasted material, work, or time (Saylor Academy, 2019). The process of eliminating the waste in a company is known as kanban. Kanban is identifies waste, eliminating bottlenecks, through the use of a kanban board. Kanban is a visual inventory management system that uses team velocity, lead and cycle time, and actionable agile metrics to measure capacity and project length (“Kanban”, 2022). This method makes it, through visual demonstrations, what work is happening and identifies the waste. There is a delivery flow system that limits the amount of wasted work in the process. Teams can therefore work more quickly to output a quality item and a developing a more sustainable work environment (Saylor Academy, 2019). Kanban can have many forms, like an order card for a standard number of units, an open space on the floor where a pallet of product should be, or an empty bin with a specific number of parts/spaces to be filled. The goal is to visually manage inventory and reduce verbal communication needs.

Kanban Guidelines:

• Never ship defective items.
• Customer only takes what is needed, therefore, they must have an order placed and only take exactly the number ordered.
• Produce only what is demanded by the customer, limiting excessive inventory.
• Eliminate bottlenecks.

Please watch this short video below about the principles and benefits of kanban.
5 S Method

The 5S Method is a systematic way to clean and organize work centers. The 5S's are:

1. Sort
2. Set in Order
3. Shine
4. Standardize
5. Sustain

The following information is the 5S Method. Review the initial definition of each type of source, flip the card to see examples of that source by selecting “Turn”. After reviewing a card, select the right pointing arrow to move to the next card.
References:


Chapter 4: Total Productive Maintenance

Overview

Total Productive Maintenance is a “holistic approach to equipment maintenance that strives to achieve perfect production” (Lean Production, 2021). TPM does this by preventing breakdown, eliminating elements that slow down the process, and perfects production so defects and accidents do not occur. TPM promotes operational efficiency through proactive and preventative maintenance. The employees are empowered to keep their specific equipment in top shape. TPM's foundation is 5S, so organization is a vital component to its success (Lean Production, 2021). There are six major equipment losses that are monitored through OEE. (Mothilal & Prakash, 2018).

Typical Plant Maintenance Stages

TPM has three maintenance stages: breakdown maintenance, preventative maintenance, and preventative and predictive maintenance.

- **Breakdown maintenance** requires very little team involvement, employees complete the maintenance themselves.
- **Preventative maintenance** has more team members involved as machines are regularly checked and maintained.
- **TPM** (preventative and predictive maintenance) involves the entire team to be proactive and regularly schedule
Overall Equipment Effectiveness (OEE)

Overall Equipment Effectiveness (OEE) is the standard for measuring productivity. Through the use of data, anyone can calculate the amount of manufacturing planned time that is productive. It was developed to support TPM initiatives by accurately tracking progress towards achieving the goal of perfect production. Three items are involved in calculating OEE: **availability**, **performance efficiency**, and **quality rate**. OEE is calculated by multiplying each item (availability x performance efficiency x quality rate) (Mothilal & Prakash, 2018; Candra et al., 2017). Below are each of the formulas that contribute to the calculation of OEE. Beneath each calculation, there is information about the losses each category may sustain in production. There are two losses per category, representing the six major losses effecting manufacturers. It may be beneficial to read more thoroughly about TPM by following this link to [Lean Production](2021).

**Availability** = \( \frac{\text{Run Time}}{\text{Planned Production Time}} \)

- There are two significant losses in this category including unplanned loss and setup/adjustments. These events stop production for a period of time, be it a little or a lot (Lean Production, 2021).

**Performance** = \( \frac{(\text{Ideal Cycle Time} \times \text{Total Count})}{\text{Run Time}} \)

- There are two significant types of performance loss including small stops and slow running. These items cause production to run less than its maximum speed (Lean Production, 2021).

**Quality** = \( \frac{\text{Good Count}}{\text{Total Count}} \)
The two significant types of loss in regards to quality are those items that are produce that do not meet standards (defective) or those that require extra time to be reworked. (Lean Production, 2021).

Sample metrics for different levels of OEE (Lean Production, 2021) If a company scores 100% they are manufacturing as quickly as possible with no errors or stop time.

Test Yourself Example 1:

Using the metrics below, calculate OEE for Little Things Toy Manufacturer and select the correct answer.

Metrics:

- Planned Production Time: 450 minutes
- Changeover: 50 minutes
- Other Downtime: 40 minutes
- Best Cycle Time: 1 part/minute
- Number of parts produced: 342
- Number of non-conforming parts: 17
Test Yourself Example 2:

Using the metrics below, calculate OEE for Tubes Pipe Manufacturer and select the correct answer.

Metrics:

- Planned Production Time: 480 minutes
- Changeover: 60 minutes
- Other Downtime: 30 minutes
- Best Cycle Time: 12 sec (.20 minutes/part)
- Number of parts produced: 1800
- Number of non-conforming parts: 18
Reflection

Review the examples and answer the following questions:

1. Are either of these companies performing at World Class OEE?
2. Where are the biggest losses?

References:


Chapter 5: Single Minute Exchange of Die (SMED)

What is SMED?

Single minute exchange of die (SMED) focuses on reducing changeover and set up times, hopefully changeovers occur in less than one minute. It involves the conversion of internal set-up operations to external ones. It is very helpful to increase productivity (Moreira and Pais, 2011; Trout, 2022).

Importance of SMED to Lean

There are two main categories of improvement when implementing SMED: Human and Technical. The human element in manufacturing is improved through training and organization. The technical side of manufacturing is improved through engineering (Lean Production 2021). A quick change over is so important in lean manufacturing because it impacts the flow of production and takt time. Basically, the more time the process is delayed or stopped there is revenue lost and
waste incurred (Trout, 2022). Consider these calculations to demonstrate the importance of SMED.

Takt time = Time spent producing each unit. With the known sales amount per unit, you can calculate the number of lost sales.

Lost Sales Revenue = Sales per unit x down time (seconds) / takt time in seconds

Example: A toy manufacturer sells action figures for $20 and can produce one unit per 60 seconds. Because their molds are all different, there is roughly 60 seconds of downtime per unit as it shifts from one type to another. So, the lost sales revenue would be calculated as: $20 X 60 seconds / 60 seconds. The toy manufacturer loses $20 (the cost of one unit!) every time they shift to a new mold. How could this process benefit from the use of SMED?

Here is a short, real-life example how SMED processed reduced internal set-up times 46% and increased production quality by 2% per day: The effectiveness of single minute exchange of dies for lean changeover process in printing industry (Indrawati et al., 2018).

How SMED Works

SMED works by shifting internal operations to external operations. Internal operations cause machine downtime, while external operations allow machines to continue to run. For example, at Toyota, a 1000-ton press changeover was improved by SMED, cutting changeover time from four hours to only three minutes.

The process is simple and the benefits are huge (Diaz-Reza et al., 2017; Trout; 2022).

• List all current set up steps and time required (a table is very helpful for this!)
• Categorize the steps as internal or external.
• Convert internal to external
• Reduce internal set-up time
• Reduce external set-up time
• Standardize this work and measure set-up.
• Investigate the elimination of set-up.

Standardized work requires a few things in order to be successful. Takt time is used, to calculate the amount of demand from the customer. The work sequence must be identified and followed, including any changeovers. And finally, WIP and finished good inventories must visually demonstrated with kanban, to make sure no wasteful practices are used in the work.

So consider some of these challenges below and how these could be improved through the use of SMED. Here are specific challenges, typical for metal-stamping press:

• All dies are different sizes and heights.
• Every die needs a different press shut height.
• Dies are held in with long threaded bolts often having stripped threads and badly worn or damaged heads.
• Tools, nuts, and bolts needed for changeover are missing.
• Operator is unable to locate the required tool or die.
• Taking the old die out and/or putting the new die in the machine is at least a two-person job.
• Wasted motion and time.
• Nothing is standardized.
• About 20 to 50% of the time is spent in adjusting and 10% of the time in locating and securing the new tools and dies.
SMED Best Practices

Below are some best practices and recommendations regarding the implementation of SMED (Lean Production, 2021).

**Staged Tooling and Fixtures:**

- If a part or tool must be placed into a fixture prior to an operation, such as machining, add a fixture so that while one part or tool is in the machine, the second can be set up in the fixture.

**Operations Conducted in Parallel:**

- Which is faster? Complete all at once or one at a time?

**Standardized Tools and Hardware:**

- Consider how long it takes for a pit crew to change tires if the replacement tire had a different lug nut configuration.
- Standardized attachment points and methods reduce confusion and the number of fasteners, saving time.
- Standardization also applies to tool storage organization so that tools can be quickly located.

**Quick Attachments:**
• Clamps, cams devices, and u-shaped washers are used for quick attachments
• Pre-tightened bolts during external set-up, only need one final turn to provide clamping force during internal set-up.

No-Adjust Tooling:

• Locating pins, guides, and fixtures to eliminate adjustment

Assisted Tool Movement:

• Large dies or heavy tools can be moved with dedicated die carts, roller tables, or small conveyors than with forklifts or cranes.
• Mechanized tool change equipment allows pre-staging of the replacement tool and may also facilitate changeovers by the base equipment operator without additional indirect labor.

Challenges with SMED

There are a few general obstacles that organizations using SMED may face (Trout, 2022):

• Machine causing a bottleneck
• Costly jobs
• Missed or expedited deliveries
• Job or machine targeted for reduced order sizes

And finally: continuous improvement is important. What can be improved in other set-ups? What other set ups need SMED? Can checklists be created for SMED?
Real-Life Example: The Pit Stop

Pit stops on a race track must take no longer than 10 seconds. As the cars travel at 200 miles per hour, every second in the pit counts. Each second represents over 200 feet on the race track! Therefore, it is imperative that the pit team is as efficient as possible; the margin for victory is literally in inches.

How the pit stop works

Each job is identified and assigned to someone. Everyone knows their job and is focused on the ultimate goal of finishing the stop as quickly as possible. All of the parts and materials are pre-staged before the pit stop even begins (i.e. tires, tools, etc.). Teams have eliminated the use of tools whenever possible like in the use of tear
away windshields, but do use tools where they cannot be eliminated. And finally, pit stop teams continuously train, measure, and perfect their processes. The same sort of diligence, training, and measuring is applied to factories.

References:

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Chapter 7: Introduction to Quality

Overview

The text now will shift from lean manufacturing to SPC and Quality. There are some terms to know as the content shifts. First, is quality. Quality has many definitions, ranging from “degree of excellence” (Merriam Webster), “fitness for use” (NVT QC, 2022), “producing products and services to a predictable degree of uniformity and dependability which meets the customer expectations (Khawaja, 2018), and “conformance to requirements” (British Library). Here, the definition of quality is that it meets the requirements of the customer.

Next is process. What is a process? A process is a transformation of inputs into desired outputs like products, services, and information. Anything can be a process as long as it has an input, change, and an output.

A process is a transformation of inputs into desired outputs
And finally, a control. A control is making a process the way it needs to behave in order to achieve a desired output. In order to have control, an outcome must have the capacity to be recreated. Manufacturers have to study the process to determine if a good part can be produced. Then, data must be collected to analyze how the inputs impact the outputs; this is also known as feedback. And finally, the data is tested to see if the outcome can be recreated. Control must happen at the process input, not afterwards in an inspection process.

**Product Quality**

There are two key aspects to product quality: design and conformance to design.

- **Design** asks whether the product design or specifications meet the intended goal. This includes products designed to customer specifications, like in custom work, but also meets the parameters for intended use.
- **Conformance to Design** asks how well the product achieves the design criteria.

When there are problems, there are some things to consider when determining if the problem is the design or the manufacturing process:

- Weight of the product that routinely exceeds customer criteria.
- Large scrap costs are routinely produced driving up overall cost to the customer.
- Final inspection identifies parts outside of the allowable dimension tolerances.
Cost of Quality

Cost of quality is often referred to as COQ or COPQ (Cost of Poor Quality). Often the costs are hidden costs, which varies by company and industry, but typically exceeds 10% of sales. Learn more about the Global Cost of Quality by watching this video provided by ASQ (2022).

Costs of Poor Quality

**Internal Failure:** Internal failure costs includes many components like the following: process delay, rework, scrap, retest/validation, 8D/RCA/CAPA, downtime, and loss of capacity. These things can be corrected through problem solving and strategic action.

**External Failure:** External failure are things that are beyond the company’s control, but can usually be fixed with problem solving and corrective action. These items include customer returns, warranties, loss of customer sales, sort and repair at customer, lower quality scores.

Figure 1: Total Cost of Quality is equal to the costs of poor quality (internal failure costs and external failure costs) and costs of good quality (appraisal costs and prevention costs).
Costs of Good Quality

**Prevention:** Preventative action is taking a problem, finding the causes, and correcting the issues. Some of the preventative measures are APQP, FMEA, FTA, process capability, variation reduction, lessons learned, education, and training. Preventative action can mitigate the need for corrective action later with external failures.

**Appraisal Costs:** Appraisal costs involve problem and causes detection and is related to the eventual problem solving and corrective action involved in internal failures. Appraisal costs include inspections (incoming, in-process, and final), calibration, auditing, and registration costs.

![Figure 2: A visual representation of each of the categories shared in the text.](image-url)
Framing

SPC stands for Statistical Process Control. This uses data to understand the process, monitor it, and control it to make continuously good products. SPC is a prevention tool and/or cost. SPC aids in the minimization of waste, or bad products, being produced. It requires statistical studies of the process, which change the process settings (inputs) when then data (outputs) support that change.

History of SPC

SPC all began in the United States during the late 1700s when there was no standardized part production. In 1798, Eli Whitney received a contract for 10,000 muskets. He was convinced he could standardize this production process. This was the first production
run and of 700 muskets produced only 14 guns were free from defects. It failed because the process lacked quality and control. There were no engineering tolerances.

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https://pressbooks.palni.org/spcleanmanufacturing/?p=37#h5p-24

In the early 1800s, quality control was introduced. A specification of materials, dimensions, and finish product were created. A quality inspection was conducted by Quality Control. Bad parts were evaluated to determine why they were bad, however, as long as a high percentage of good parts were produced, the process was not considered important. This was a more reactive process, rather than preventative measure to proactively combat problems, they were reacting after the problems occurred.

But then, WWI came and something better needed to be developed so materials could be made in high volumes and shipped immediately, guaranteed to work. This is where statistical quality control or statistical process control began. Dr. Walter Shewhart was a physicist, part of the Western Electric Company’s inspection engineering department that supplied hardware for Bell Telephone Lab. With his probability distributions, he actually contributed to the WWI effort. In 1924, Shewhart created the first SPC control charts. He did this by measuring the heads of over 10,000 troops in order to design a standard headset. He arranged the head widths from small to large and marked the frequency of each size. He was intrigued to find a bell-shaped curve. His charts were eventually called the Shewhart Control Chart or X Bar and R Chart. Learn
more about Dr. Shewhart from this article, remembering his accomplishments. (Smith 2009)

In 1926, H. Dodge and H. Romig developed acceptance sampling which determined how frequently parts should be checked for quality. In 1931, Shewart publishes “Economic Control of Quality of Manufactured Product”, the first publication on control in manufacturing. In 1942, the first training program on SPC was conducted at Stanford and lasted 10 days. This training was delivered by Eugene L. Grant, Holbrook Working, and Dr. W. Edwards Deming.

More history is shown below in the graphic, select each hot spot to learn more about each era.

References:

Hills, R. (2015, June 17). Introduction to statistical process control

Infinity MFG (2017, March 8). Quality (Part 1: Statistical Process Control) [Video]. YouTube. https://www.youtube.com/watch?v=e5g2NmIUdck


Chapter 8: Basic Quality Tools

Overview

This chapter will review the quality tools available that will improve manufacturing processes. It will also cover data collection rules and the importance of stratification.

7 Quality Tools

The following tools were first emphasized by Kaoru Ishikawa, in Tokyo. These tools are meant to improve the process and eventually through practice become an indispensable part of manufacturing (ASQ, 2022). Review the following slides and video to learn more about these quality tools. Each of the quality tool titles are linked to more information, should you like to lean more about any of the tools.

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https://pressbooks.palni.org/spcleanmanufacturing/?p=40#h5p-26
Data Collection Rules

There are few rules to follow in regards to data collection during this process. Follow these rules when collecting data for your work.

- No process without data collection
- No data collection without analysis
- No analysis without decision
- No decision without action.
- Additionally, planning of data collection needs to include a stratification plan

Before collecting data, ask yourself these questions:

- How might the data need to be sorted, separated, or identified?
  - What is the product? (Including: part numbers, serial numbers, order numbers, etc.)
  - Who produced or measured?
  - When was it produced, including the time, shift, and day?
  - Where was it produced, including the plant, production line, machine numbers?
  - Include other important factors from the 4Ms and an E.
- All of these factors should be captured with the data.

Importance of Stratification

Stratification sorts data, people, and objects into categories. This technique is used in conjunction with other data analysis tools. When different types of data have been collected together it can be difficult to sort through to find the meaning. Using stratification can identify patterns (ASQ, 2022).
This tool should be used before collecting data and when there are many sources of potential data. Some sources of data that might need to be stratified could be, but is not limited to: equipment, shifts, departments, materials, suppliers, products (ASQ, 2022).

Once the data is collected and is being plotted with a specific analysis tool, use a system to distinguish data between the sources. This could be coloration or symbols. Then, analyze the data separately, draw quadrants, count points, etc. to connect the similar data (ASQ, 2022). Review the video below to learn more about stratification.

An interactive H5P element has been excluded from this version of the text. You can view it online here:

https://pressbooks.palni.org/spcleanmanufacturing/?p=40#h5p-27

References:

American Society for Quality (2022). The 7 basic quality tools: Quality tools for process improvement. ASQ. https://asq.org/quality-resources/seven-basic-quality-tools


THORS elearning solutions (2022, February 25). What is
stratification? [Video]. YouTube.  https://www.youtube.com/watch?v=SPd7-d8ru8
Chapter 9: Introduction to Statistical Process Control (SPC)

Overview

In this chapter, more information will be provided regarding SPC. Specifically, content will be focused on the Law of Variation and capability studies.

Law of Variation

The Law of Variation is defined as “the difference between an ideal and an actual situation” (ASQ, 2022). Variability can occur in four main areas: special causes, common causes, tampering, structural variation. It is important to note that variation is common in every process (Singh, 2022).

In 1924, Dr. Shewhart developed a new way to deal with variation, identifying two causes of variation: Common Cause and Special Causes. Years later, Deming added tampering to the list of variations (ASQ, 2022).

Common cause is often called noise, which is just variation that is going to happen regardless. It’s inherent to the process (Singh, 2022) and likely cannot be avoided. Special cause is an outcome of unusual circumstances, adding instability to the process (Singh, 2022).
A capability study is the “output of a process” that is expected to meet standards like customer expectations, specifications, or engineering tolerances (“Process Capability”, 2022). Capability studies are important to reduce the cost of production, reduce non-conforming products, and to promote customer satisfaction (Simion, 2017). Read a study about how this process is helpful for quality improvement [here](#).

Capability studies are needed because they offer organizations much-needed insight on how their production can attain their goals while saving costs (Duchek, 2020). A study is appropriate and should be put into place when the process controls are firmly established (“Process Capability”, 2022). A control chart will often determine when the process is “in control” and can be evaluated. Subgroup data are often used because it aids in the evaluation of potential. Subgroups are a group of units produced under similar or identical
conditions. It’s essentially more data that is valuable for capability analysis (Heckman, 2012).

Best Practices

There are some best practices to consider in a capability study, things to remember while collecting the data.

- First, run a long-term capability study. Number all of the parts produced sequentially.
- Collect data in subgroups. An example could be 100 sample parts minimum, subgroups of five, 20-25 subgroups minimum.
- Use the regular production process, people, equipment, measurement tools, etc. The process should be exactly the same so it reflects a true measurement.
- Repeat the steps when the process is adjusted.

Theoretically, it is time to conduct a capability study of the process, create a histogram of the process data, and analyze the histogram. A little bit more information before creating the study about examples of changes and types of studies.

Examples of Changes to a Process Requiring a New Capability Study (Simion, 2017):

- Change in product material

56 | Chapter 9: Introduction Statistical Process Control (SPC)
• Change in process tooling
• Rearrangement of equipment
• Change of component/materials supplier
• Start-up after tooling has been inactive 12 months or more
• Product or process design changes
• Change in inspection methods/tools

**Two Types of Capability Studies in the Manufacturing Process**

Machine capability: this looks at only the variation from a specific machine or operation. This is used to qualify a machine for production. Typically, it is a short-term study with a minimum of 30-50 parts.

Process capability: this version includes all machines. The aim is to understand the combined variation from all sources. Typically, this is a long-term study, at least 30 days, and parts are randomly sampled from the finished inventory.

**Practice**

Now, plan the study of the process. How many parts are needed? At minimum, there should be 25 subgroups and 100 parts total. Automotive preference is 300 consecutive parts and 100 subgroups; a minimum of 30 subgroups (or parts) are usually ran for initial runs. Increasing the quantity of data will more accurately reflect the process; again why subgroups are helpful additions to a capability study. The normal production process, people, equipment, and everything should be used in order to receive the right data on the process. Repeat the process when changes occur.

The next phases of the process will be to number and label all of the parts, measure and record all parts, collect and record stratification data, and keep all parts until data collection and analysis are complete. Often these parts are separated and treated
as scrap until the process is approved. Customers may need samples for approval, as well.

Now create a histogram. Remember that histograms vary by the location of the curve, the height of the peak and span of the curve, and the shape of the curve (symmetrical or skewed).

Now to analyze the histogram. Consider these things. A stable or in-control process has a consistent histogram that is predictable. The shape of the curve is consistent over time (and typically normal), the histogram is typically normal, but can be skewed. Only common cause variation is impacting the process, like normal wear in tooling. An unstable histogram or out-of-control process means that the histogram varies over time, the process is not predictable. Assignable cause variation at play, like broken equipment. Answer the following questions regarding predictable variability.
Review the charts below. Can you decide which chart is all data and which chart is broken into subgroups? Consider how this would be helpful in real-life scenarios. Move the bar to the right to see the first chart, Move the bar to the left to see the second chart.

Now some more information about the charts, to demonstrate why subgroups are helpful in data collection. These charts represent data collected on the type of learning materials used in three different groups (main campus, TrineOnline undergraduate, and TrineOnline graduate). This data does not tell the audience what kind of learning materials used, just counts how many courses are logged in the respective categories. The second chart has all of the subgroups. These subgroups provide more meaning to the data, showing which courses require a book, which are OER, zero cost, and so on. This provides significantly more meaning than the first chart. While the first chart does provide some information, it’s not necessarily the information needed. Subgroups offer that insight to
what is really going on in an organization and can be applied to many environments.

Analyze the Data

There are certain measures of centrality used when analyzing data. These are mean, median, and mode. From an manufacturing process perspective, how would this data be helpful in knowing whether you can and are making good parts?

There are also measures of spread: range and sigma. Range provides the variation between maximum and minimum values. Sigma is the standard deviation from the mean. Calculating sigma can be complicated as multiple equations can be used. Sigma is always an estimate and is always less than the true process standard deviation. Sigma is important because it tells us how much normal variation exists.

This is a normal distribution curve. (Toggerson & Philbin)

Interact with this simulator to engage with normal distribution (University of Colorado).
References:

American Society for Quality (2022). What is the law of variation? ASQ. https://asq.org/quality-resources/variation


Chapter 10: Is the Process Stable?

A Stable Process

A stable process is predictable, where a capable process can reliably produce parts within specification limits (more on this later). A process is stable if it has a constant mean and a constant variance over time. Processes must prove to be stable before they can be used (IST, 2012), because it makes the production process more efficient (ISIXSIGMA, 2022). The tool used to determine stability is a histogram. More than 100 samples are logged over a long period of time and are plotted. It can be beneficial to calculate control limits and add those to the plotted data as well (IST, 2012).

Stability is required before evaluating for capability, because the process must be well understood. It must be a good process before determining if it is capable. All of the special causes of variation in the system are evaluated for stability before determining if they are capable. For example: a manufacture is handling a claim process where the amount of time required to process claims would be stable and consistent, all known variations identified. If this process is not stable, it may not be capable to meet customer demands in a timely fashion (benchmark 6ix sigma, 2017).

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Value of a Histogram

A histogram is a visual representation of data, which the viewer can generally understand easily and interpret the data. Histograms are used when evaluating data that is continuous and counted as separate distinct values (or discrete data). Histograms are valuable to convey information effectively and to show changes implemented within a process (Presentationeze, 2013). Histograms can also identify outliers in a process (Frost, 2019). Learn more about using histograms to understand data with this article.

An interactive H5P element has been excluded from this version of the text. You can view it online here:

https://pressbooks.palni.org/spcleanmanufacturing/?p=46#h5p-34
Determining Stability

If the process is not stable, the data would not be reliable enough to estimate anything, whether its future performance of capability of a lot of things (Haynes, 2022). In these situations, you will examine the data for non-normal conditions and/or outliers and typically, run the assessment again (van de Merbel et al., 2014).

AIAG Method for Stability

This content is from the Automotive Industry Action Group which provides education and information to a wide range of people. Their process of using SPC and maintaining control is outline below, but originated from this source: (SPC) Statistical Process Control (AIAG, 2022). Learn more by selecting the link.

There are two phases in SPC control studies:

- Identify and eliminate the special causes of variation in the process. This will stabilize the process and provide control.
- Next, predict future data based on the control data. Once stabilized, the process can be used to determine capability.
Test Yourself

Review the each of the hot spots below on the histogram. Then, answer the review questions to test your knowledge.

References


SPC for Excel (2019, May 1). What do these histograms tell you? The answers [Video]. YouTube. https://www.youtube.com/watch?v=XUeU4tvkXAO

Chapter 11: Is the Process Capable?

A Capable Process

A capable process should meet the customer’s expectations, reliably producing parts within the specification limits. In order to calculate capability, complete the following steps. First, estimate sigma or standard deviation. Calculate the process control limits. Finally, compare control limits to the specification limits, calculating \( \text{Cp} \) and \( \text{Cpk} \).

Control limits use sigma and the process average (average of the averages). After calculating the process average, identify the upper control limit and the lower control limit. \( \text{Cp} \) compares the control limits to the span specific limits. \( \text{Cpk} \) is two separate calculations comparing the LCL to the LSL and the UCL to the USL.

There is a buffer zone between the control limits and the specification limits. This determines how capable the process is in producing in-specification parts. The buffer zone impacts scrap, rework, and sorting for bad material costs (COPQ). The buffer zone

68 | Chapter 11: Is the Process Capable?
also determines equipment and tooling needs, in addition to long-term sampling rates.

Watch the video below to learn more about Cp, Cpk, Pp, Ppk and how to interpret those results. Then, it may be beneficial to read this study: Process Capability Improvement of an Engine Connecting Rod Machining Process (2013).

Something to think about: Why are minimum Cp/Cpk values required before using SPC charting?

Determining Capability

When a process is in control but not capable, first, “center the output of the process on the target value and re-evaluate to see if the output became capable” (Key Performance, 2014). If the process is still not capable, there is a bigger problem. The process needs to be modified in order to reduce variations and increase capability.

Learn more about analyzing normal and non-normal data with the following video:
References:


Chapter 12: Variable Control Charting

Overview

This chapter is an introduction to SPC Control Charts. A control chart is a graph used to see how a process changes over time. Data are plotted in chronological order with a central link through the middle to show the average. Control charts are usually used in pairs, where the top chart monitors the average and the bottom chart tracks the range of distribution (ASQ, 2022).

A control chart is used in one of the following scenarios (ASQ, 2022):

- Controlling ongoing processes and adapting as needed
- Predicting the range of outcomes
- Decide if a process is stable
- Analyze patterns of variation
- Determine the direction of improvement projects

General Charting Information

There are two kinds of data, variable and attribute data. Attribute data are measurements like static numbers or can be described as either yes or no. Where variable data are measures that can be manipulated in a meaningful way, like temperatures, length, width, etc (Khillar, 2021)
Slide the center bar to learn more about the difference between these types of data (Khillar, 2021).

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https://pressbooks.palni.org/spcleanmanufacturing/?p=52#h5p-40

Before conducting a sample, there are some factors that may influence the decision. These are: size of the population, cost involved, and convenience (Sharma, 2019). A sample size should have a minimum of two subgroups, but the preferred number is five subgroups. But, the manufacturing process may dictate the sample size. Sample frequency is usually determined by the average number of parts or time between tool changes divided by five.

An interactive H5P element has been excluded from this version of the text. You can view it online here:
https://pressbooks.palni.org/spcleanmanufacturing/?p=52#h5p-41
Average and Range Charts

Average charts are control charts where the subgroup average (x-bar) is used to evaluate the stability of the process (ASQ, 2022). A range chart (r-chart) “evaluates the stability of the variability within a process” (ASQ, 2022).

Three-sigma limits are calculations of data that are within three standard deviations from an average. This generally refers to process that are efficient with quality outputs. Three-sigma limits set the upper and lower control limits in control charts which thereby establish limits for a controlled process (Kenton, 2022). Generally, you can expect 99.7% of the outcomes to occur within the 3-sigma limits. However, even with a perfectly centered process, there is still a .3% change that a product will be produced beyond the +/- 3 sigma control limits. Two-sigma zones may also be used, which means that 95.5% of outcomes will occur in this area.


Rules for adjusting

There are a few possible rules for adjusting, in order to maintain control. This is not an exhaustive list. Only use the criteria that make sense for your process. Furthermore, over-adjustment is not beneficial for the sampling.

- One of the sampled points is in Zone 3
- Seven points are on one side of the center line.
- Six points are trending up or down.
- 14 points in a row alternating above and below the center line
- Two of the three points are in Zone 2.

An interactive H5P element has been excluded from this version of the text. You can view it online here:
https://pressbooks.palni.org/spcleanmanufacturing/?p=52#h5p-42

Individuals and Moving Range Charts

Individual charts are very simple. They show change in process centering. These charts are not as effective at detecting small changes like a Mean chart. But they can show changes in variability with careful attention to the data. To set up this type of chart, the center link is at the middle of the specification limits or is the mean of the previous study (or a different, suitable value). Moving range (MR) is x or the previous x-value. Individual control limits are three sigma from the center line and warning lines are placed at two sigma from the center line.
Average and Sigma Charts are charts that compare the range and the standard deviation of a process. This is used for large subgroups, like nine or more.

Two Types of Manufacturing Process Capability Studies

Machine capability

- A specific machine or operation is examined, used to qualify a machine for production. Usually, this is a short-term study, with a minimum of 30–50 parts.
- Individual machines are sampled sequentially.

Process capability

- This includes all machines to better understand the combined variation from all sources. This is typically a long-term study (more than 30 days). The parts in this study are randomly sampled from the finished inventory.

An interactive H5P element has been excluded from this version of the text. You can view it online here: https://pressbooks.palni.org/spcleanmanufacturing/?p=52#h5p-43
References


Argolytics (2021, December 22). What is a moving range control chart? [Video]. YouTube. https://www.youtube.com/watch?v=lZ4hD0sPlcE


Chapter 13: Attributes Control Charting

Overview

Typically attribute are counted, not measured and the charting is usually different as well. There are four common charts: np, p, c, and u. First, np, which means the number defective. p means the percentage that are defective. c represents the number of non-conforming products. And u means the number of non-conforming per unit.

np – Number Defective charts

np charts are the easiest to use. These detail the number of defective parts. What is beneficial about these charts is that they are consistent to the sample size and consistent to the control limit. Here is an example of an np chart:
p – % Defective charts

p charts show a proportion of defective parts of the entire group. It is inconsistent with the sample size and the control limits vary with sample size. Here is an example of a p chart:
c – Number Non-conformities charts

c charts provide the number of non-conformities. It may not be possible to know the total number. It is consistent with the sample size (area, unit, etc.). It is also consistent with control limits. Here is an example of a c-chart:
u – Number Non-conformities per Unit charts

u charts show the proportion of non-conforming items per unit produced. This is usually inconsistent with the sample size. Control limits will vary with the sample size. Here is a u chart:

References:

CQE Academy (2021, July 14). Attribute data control chart examples!! How to select/create the p, np, c, and u charts [Video]. YouTube. https://www.youtube.com/watch?v=p-gvwkHePaU

Montgomery, Douglas (2005). Introduction to Statistical Quality Control


This is where you can add appendices or other back matter.