Managing Variations in Process Control: An Overview of Sources and Degradation **Methods**

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Abstract Understanding variation is a crucial aspect of managing and improving any manufacturing or product development process. This paper investigates sources of variations in process control. It shows main sources of variability such as actual process variations or measurement variations. Moreover, it attempt to classify causes of variation. Based on state-of-the-art research methods, researchers are able to investigate variability and develop a process to minimize the negative impact of variability on processes. In particular attention is the role of human factors and its diverse impact on process control.

Keywords Process control \cdot Process variation \cdot Lean thinking \cdot Statistical process $control \cdot Measurement$ variation

1 Introduction

In the last few decades, the number of new product introductions has increased dramatically. However, the cruel reality is that the majority of them have never launched to the market and most faced failure. In an increasing competitive environment, for a product to be successful it requires excellence along its entire development process [\[1](#page-8-0), [2](#page-8-0)]. Product development should rely on customer-driven design, which is the thoughtful examination starting from its outmost periphery to the core. However, in practice it is still sometimes a challenge for the producers to provide quality performance, reliability and maintainability which can lead to longer product

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lifespan, shorter lead times, lower development and warranty costs, and lesser scraps and reworks [\[3](#page-8-0), [4](#page-9-0)]. Implementing such framework creates the need for controlling process variations. In most cases they derive from single variables influencing the process such as machine or tool wear, material properties and work environment [[5\]](#page-9-0).

In this paper researchers focus on the role and impacts of human factors on different stages of product life-cycle development and its influence on variations. In order to assess different sources of process variations, methods allowing for their degradation are presented. Particularly, attention is paid to measurement of variations. It is revealed that the emphasis on lean thinking as the behavior and performance of human is not amendable to any mathematical analyses and forecasting. Human capabilities are not uniform and particularly visible in reference to human performance and the interface with technology. On the other hand, the causes and Subcauses of measurement variations can be identified which will allow categorizing variability in five main categories, which are: standard, workplace, instrumentation, operator and environment.

2 Process Control

A process is broadly defined as an adjustment or alteration of raw material into a final product with the application of labor, instruments, and facilities in accordance with customer requirements [[6\]](#page-9-0). Generally, it consists of input and output variables but only some of those variables are chosen to control the process. The inputs, which are under control, are manipulating variables, and uncontrolled variables are disturbances. On the other hand, the outputs are divided into measured and unmeasured variables and their feedback is compared with the desired set of values (see Fig. 1).

In order to control the operation of the process, it is required to measure process outputs or disturbance inputs to adjust inputs in such manner that the proper values are obtained [\[7](#page-9-0)]. If it is possible to achieve such adjustments, then the process can be perceived as consistent and predictable. Regardless of the process, process-control consists of formulating or defining:

- objectives of control,
- control structure.
- control algorithm,
- corrective action to minimize the variances,
- improvements,
- conformance to the desired set values.

Fig. 1 Process representation

The control of an operating unit is generally perceived as the control of each operation separately, even if there are multiple, sometimes conflicting objectives of the unit operation [\[8](#page-9-0)]. Control structure encompasses input and output variables, constraints, operating characteristics, safety, environmental and economic considerations and control structure. It can be a feed forward or feedback. In the first type the disturbance variable is measured and on its basis the manipulated variable is adjusted, whereas in the second one control system measures the output variable, which is compared with the assumed output value to adjust the manipulated variable appropriately [\[9](#page-9-0)]. Moreover, the control algorithm is a mathematical representation of relations between the measured output variable values and the manipulated input variable [\[10](#page-9-0)]. It allows monitoring all operations involved in the process, and undertaking corrective actions and improvements to ensure safe operations, a high-quality product and profit. The output conformance to the desired technical-design specifications is primarily concerned with process variations and ability to control its causes. Incorrectly rejected products or acceptance of faulty products is either costly or negatively effecting company's product reputation [[11\]](#page-9-0).

3 Process Variation

Process variation is inevitable in any manufacturing process. If it is unintended it can negatively influence process performance, customer satisfaction [\[12](#page-9-0)]. Process variation can be resulted from two distinct sources: actual process variation and measurement variation (Fig. 2).

Such a categorization of process variability allows to distinguish major root causes of process variation and develop solution for improvement [\[14](#page-9-0)].

3.1 Actual Process Variation

Actual process variations can be divided into two sources: common and special causes. Common cause variations affect the design of product and production

Fig. 2 Analysis of process variations (adapted from [[13](#page-9-0), [14\]](#page-9-0))

system. They derive from the primary elements of the system in which the process operates. Generally, they can be differentiated into materials, equipment, people, environment and methods, and can be declined due to redesign of the product, appliance of better technology or training. For a process, in which only common variations appear, it is perceived as systematic and in control. Moreover, it is described as:

- repeatable,
- stable.
- consistent.
- predictable.

Such situation characterizes a process performance replicated time after time. On the other hand, special variations are not the component of the designed system and result from unexpected change which appears in one or more parts of the system [\[15](#page-9-0)]. Such process is out of control and it can be described as:

- changing,
- unstable,
- unpredictable.

Previous research shows that common causes account for 80–95 % of all noticed variations in the output of production process. The remaining variations show off as an unexpected change in the process output and their sources can be found in external factors, not inherent in the process [[16\]](#page-9-0).

3.2 Measurement System Variation

Measurement system variation concerns all variations which are identified during a measurement process. Any component of a measurement system can contribute to source of variation (i.e. gages, standards, procedures, software, environmental components). In particularly, it is the sum of variations resulting from repeatability and reproducibility [[17\]](#page-9-0). Repeatability is defined as variation in measurements resulting from the measuring device, or die variation, noticed when the same operator measures the identical characteristic on the same part again and again with the same device. On the other hand, reproducibility encompasses variation due to the measuring system, or the variation which is perceived when various appraisers measure the same characteristic of the component using the same device [\[18](#page-9-0), [19\]](#page-9-0). Therefore, in order to estimate repeatability, each appraiser must conduct the measurement of each part at least twice, whereas, to estimate reproducibility, there is a need to engage at least two operators in the measurement process. Furthermore, the random order of measurement of parts and the possible range of measurements must be ensured. The degree of repeatability and reproducibility show the precision of the measurement instrument [\[20](#page-9-0)].

Category	Cause	1st subcause	2nd subcause
Standard	Traceability Stability Geometric compatibility	Calibration Coefficient of thermal expansion Elastic properties	
Workpiece (part)	Operational definition Adequate datums Cleanliness Interrelated characteristics Elastic deformation Hidden geometry	Mass Elastic properties Supporting features	
Instrument (gage)	Design Build Maintenance	Use assumptions Robustness Bias Amplification Contact geometry Deformation effects Variability Build tolerances Build variation Design validation Calibration	Stability Linearity Sensitivity Consistency Uniformity Repeatability Reproducibility Clamping Locators Measurement points Measurement probes
Person (appraiser)	Skill Understanding Limitations Procedures Attitude	Experience Ability Training Experience Training Educational Psychophysical Social Operational definition Visual standards Background Experience	
Environment	Workstation organization Rhythm and pace Air pollution Lighting Vibration Noise Temperature	Cycles Standard vs ambient Thermal expansion	

Table 1 Measurement system variability—its categories and causes (adopted from [[19](#page-9-0)])

In the ideal measurement system there should be statistically zero mistakes in reference to the measured product [[21](#page-9-0)]. However, in practice it appears that measurement system variability can result from five categories such as standard, workplace, instrument, operator and environment, and their potential causes and subcauses (Table 1).

4 Reduction of Variations

4.1 Lean Thinking

In current manufacturing strategies, lean concepts gained prominence. This term, was coined by IMVP researcher John Krafcik as lean thinking, was meant to reflect: "less of everything" compared with mass production—half the human effort in the factory, half the manufacturing space, half the investment in tools, half the engineering hours to develop a new product in half the time. Also, it requires keeping far less than half the needed inventory on site, results in many fewer defects, and produces a greater and ever growing variety of products [[22\]](#page-9-0). It is the main source of improvement of operations and thereby it influences on quality, increases productivity, reduces lead time to customers and costs [\[23](#page-9-0)–[25](#page-9-0)] (see Fig. 3).

In lean manufacturing systems, the process control focuses on one-piece-flow. Therefore, the part can be inspected at time (i.e. by mistake proofing, visual controls or check sheets) not by random inspection or statistical quality control methods of lot samples. In a case of a defect the production line is stopped due to the application of Autonomation/Jidoka (automation with human touch) until the cause is eliminated [\[27](#page-10-0), [28\]](#page-10-0). In order to prevent/detect the error occurrence false-proofing/ Poka Yoke can be integrated with the production line. It allows achieving the highest levels of quality by elimination/reduction of human errors resulting from the setup, loading, and unloading [\[29](#page-10-0), [30\]](#page-10-0). Furthermore, the tools, which are implemented in lean manufacturing [\[31](#page-10-0)], enable to work through and eliminate overall variation in the process resulting from human activities. In order to achieve it the attention should be directly paid to the matters affecting the workers in the process where the reduction of variation is supposed to be performed, and purposely design in the actions required to achieve and sustain it. It is very crucial to underline the significant of the culture of the company and establish partnerships where particular teams doing the operations trust each other. Furthermore, the independence should be assured in finding new solutions how to achieve the results quicker, better and

Fig. 3 Framework of lean (adapted from [\[26\]](#page-9-0))

less expensive, and then a training, where all employees will be invited to participate, should be organized. It is known that focusing on emergencies does not allow fully committed and competent employees perform at highest performance, and thus, affecting the planned activities necessary to achieve value added. In order to solve the potential of variations, the system of Profound Knowledge can be applied. It consists of four areas:

- appreciation of a system: understanding the overall processes,
- knowledge of variation: range and causes of variation in quality, statistics in measurements,
- theory of knowledge: the concepts explaining knowledge and their limits,
- knowledge of psychology: human nature.

None of these components cannot be separated and must be managed with a delicate balance as they make up the whole system [\[32](#page-10-0)].

4.2 Statistical Process Control

Controlling the process variations on a component is a huge challenge as several factors can affect its functionality. In order to achieve better process control researchers apply statistical process control (SPC). This methodology aims at improving process stability and capability through reducing variability [[33\]](#page-10-0). Its vital part concerns the measurement phase as it provides data indicating variation in the process. When a process is changed a signal should be generated to demonstrate it. The most common statistical process control (SPC) tools employed for monitoring process changes are control charts. However, their practical implications require certain knowledge, and understanding at all steps of SPC implementation, and a human factor is a key element (see Table [2](#page-7-0)).

4.3 Measurements and System Analysis

In order to identify components of variations researchers apply the systematic procedure of Measurement System Analysis (MSA). It is an experimental and statistical method which allows recognizing the differences in the data which result from the actual part measurements and do not refer to variation in measurement methods [[33,](#page-10-0) [34\]](#page-10-0). Its purpose is to:

- Define the degree of the observed variability resulting from a measurement instrument,
- Identify the sources of variability of the measurement system,
- Evaluate the capability of a measurement instrument.

Step	Human factor
Preparation	Understanding statistical principles Understanding of SPC principles and goals Selection of the process, process parameters and quality characteristics Selection of measurement method Verification and ensuring measurement system capability Selection and design of control chart Selection of collection and recording data
Data collection	Accuracy of record of statistics into control chart
Control chart interpretation	Knowledge of the process variability and its causes Identification speed of the process and its variability Ability to interpret correctly control charts
Causes identification	Ability to assign correct cause to signal in control chart
Selection of action for improvement	Knowledge of the process Ability to assign adequate actions to causes
Realization of action for improvement	Speed and accuracy of realization of selected actions

Table 2 Human factor in SPC

MSA enables the evaluation of reliability of important input and major output data in the manufacturing process, comprehend the variations due to people, machines, materials, methods, or environment. If measurement system variation is large in comparison to part-to-part variation, such measurements may not provide useful information which can be used as a reference point for improvements [[21\]](#page-9-0). According to the MSA Reference Manual, MSA defines measurement error components into two groups [[19](#page-9-0)]:

- Accuracy (calibration/bias, linearity, stability),
- Precision (repeatability, reproducibility).

Further, it provides procedures on how to measure each term, however, it should be emphasized that the Gauge Repeatability and Reproducibility Studies (Gage R&R) were introduced to incorporate the procedures recommended for measurement of precision but they do not ensure accuracy related aspects [\[35](#page-10-0)]. The most common methods used for Gage R&R Studies are the ANOVA method and the Average and Range method. The ANOVA method is useful to determine the reproducibility variation due to its operator, operator-by-part and components, whereas the Average and Range method allows distinguishing such categories as part-to-part, repeatability, and reproducibility in the overall variation [[36\]](#page-10-0). The fundamentals of MSA implementation are:

- defined number of operators, parts and repetitions that are subject of the analysis,
- operators who know the measuring instrument and procedures, and normally perform the measurement,
- • a set, documented measurement procedure used by all operators,
- the values of the items selected for testing should represent the entire tolerance range,
- if possible, all the parts should be marked to avoid the impact of within-part variation,
- the resolution/discrimination of the measurement device must be small relative to the smaller of either the specification tolerance or the process variation (at least 1/10th, if this requirement is not fulfilled, process variability will not be recognized by the measurement system—its effectiveness will be blunt),
- the order of the measurement of the parts need to be randomized to avoid memorizing the values, the third party should note down the measurements, the appraiser, the trial number, and the number for each part on a table [[37\]](#page-10-0).

MSA is an essential first step before collecting data from the process to analyze process control or capability, to confirm that the measurement system proceeds consistently, accurately, and adequately to discriminate between parts. It should precede any data-based decision making, including Statistical Process Control, Correlation and Regression Analysis and Design of Experiments [\[38](#page-10-0)].

5 Conclusions

Understanding variation is a crucial aspect of managing and improving any manufacturing or product development process. In particular, it is critical to acknowledge that two types of process variation can be distinguished as actual process variation and measurement variation, both can be contained and measure using the appropriate methods. Their effective application is affected by many technical, methodical, social, environmental and economic factors. Nevertheless, one of the key elements is a human factor contribution to process variability. It is particularly visible in reference to human performance and the application of lean thinking, statistical process control and measurement system analysis.

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