
**Quantitative methods in process
improvement — Six Sigma —**

**Part 1:
DMAIC methodology**

*Méthodes quantitatives dans l'amélioration de processus — Six
Sigma —*

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Partie 1: Méthodologie DMAIC
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Contents

Page

Foreword	v
Introduction.....	vi
1 Scope	1
2 Normative references	1
3 Symbols and abbreviated terms	1
3.1 Symbols	1
3.2 Abbreviated terms	2
4 Fundamentals of Six Sigma projects within organizations	3
4.1 General	3
4.2 Voice of the customer	4
4.3 Accountability	4
4.4 Maturity of processes of an organization	4
4.5 Relationship with quality management standard ISO 9001	5
5 Six Sigma measures	6
5.1 Purpose	6
5.2 Defects per million opportunities (DPMO)	6
5.3 Sigma score	7
5.4 Rolled throughput yield (RTY)	7
5.5 Return rate (RR)	8
5.6 Number of problem reports (NPR)	8
5.7 On-time delivery (OTD)	8
5.8 Cost of poor quality (COPQ)	8
6 Six Sigma personnel and their roles	9
6.1 General	9
6.2 Champion	9
6.3 Deployment Manager	9
6.4 Project Sponsor	10
6.5 Master Black Belt	10
6.6 Black Belt	11
6.7 Green Belt	11
6.8 Yellow Belt	11
7 Minimum competencies required	12
8 Minimum Six Sigma training requirements	13
8.1 Recommended training	13
8.2 Training requirements for Champions / Deployment Manager	13
8.3 Training requirements for Sponsors	13
8.4 Training requirements for Master Black Belts	14
8.5 Training requirements for Black Belts	14
8.6 Training requirements for Green Belts	14
8.7 Training requirements for Yellow Belts	14
9 Six Sigma project prioritization and selection	15
9.1 General considerations	15
9.2 Project prioritization	15
9.3 Project selection	16
10 Six Sigma project DMAIC methodology	18
10.1 Introduction	18
10.2 Define phase	19

10.3	Measure phase	19
10.4	Analyse phase.....	20
10.5	Improve phase.....	20
10.6	Control phase.....	21
11	Six Sigma project methodology — Typical tools employed	22
12	Monitoring a Six Sigma project.....	23
12.1	General.....	23
12.2	Gate reviews.....	23
12.3	Project management	24
12.4	Weekly mentoring sessions with a Master Black Belt.....	24
13	Critical to success factors for Six Sigma projects.....	24
14	Six Sigma infrastructures within an organization	25
14.1	General information.....	25
14.2	Large - Over 1 000 employees at a site	25
14.3	Medium – 250 to 1 000 employees at a site.....	26
14.4	Small – Less than 250 employees at a site	26
14.5	Multiple sites	27
Annex A (informative)	Sigma scores.....	28
Annex B (informative)	Training	30
Bibliography.....		32

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13053-1 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 7, *Application of statistical and related techniques for the implementation of Six Sigma*.

ISO 13053 consists of the following parts, under the general title *Quantitative methods in process improvement — Six Sigma*:

— Part 1: *DMAIC methodology*

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— Part 2: *Tools and techniques*

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Introduction

The purpose of Six Sigma¹⁾ is to bring about improved business and quality performance and to deliver improved profit by addressing serious business issues that may have existed for a long time. The driving force behind the approach is for organizations to be competitive and to eliminate errors and waste. A number of Six Sigma projects are about the reduction of losses. Some organizations require their staff to engage with Six Sigma and demand that their suppliers do as well. The approach is project based and focuses on strategic business aims.

There is little that is new within Six Sigma from the point of view of the tools and techniques utilized. The method uses statistical tools, among others, and therefore deals with uncertain events in order to provide decisions that are based on uncertainty. Consequently, it is considered to be good practice that a Six Sigma general program is synchronized with risk management plans and defect prevention activities.

A difference, from what may have gone before with quality initiatives, is every project, before it can begin, must have a sound business case. Six Sigma speaks the language of business (value measurement throughout the project), and its philosophy is to improve customer satisfaction by the elimination and prevention of defects and, as a result, to increase business profitability.

Another difference is the infrastructure. The creation of roles, and the responsibilities that go with them, gives the method an infrastructure that is robust. The demand that all projects require a proper business case, the common manner by which all projects become vetted, the clearly defined methodology (DMAIC) that all projects follow, provides further elements of the infrastructure.

The scope of this part of ISO 13053 limits the document to only cover the improvement of existing processes. It does not go into the realm of Design for Six Sigma (DFSS) or the re-engineering of a process where the DMAIC methodology is not fully suitable, nor does it cover the issue of certification. There will also be situations where any further work on an existing process is not possible, either technically, or in a financially justifiable sense. Other standards dealing with these circumstances are yet to be developed, but when they have been published, ISO 13053 together with those future documents will form a cohesive set of standards ranging from improving existing processes to the development of new ones to deliver Six Sigma levels of performance, and beyond.

1) Six Sigma is a trade mark of Motorola, Inc.

Quantitative methods in process improvement — Six Sigma —

Part 1: DMAIC methodology

1 Scope

This part of ISO 13053 describes a methodology for the business improvement methodology known as Six Sigma. The methodology typically comprises five phases: define, measure, analyse, improve and control (DMAIC).

This part of ISO 13053 recommends the preferred or best practice for each of the phases of the DMAIC methodology used during the execution of a Six Sigma project. It also recommends how Six Sigma projects should be managed and describes the roles, expertise and training of the personnel involved in such projects. It is applicable to organizations using manufacturing processes as well as service and transactional processes.

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2 Normative references (standards.iteh.ai)

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13053-2, *Quantitative methods in process improvement — Six Sigma — Part 2: Tools and techniques*

3 Symbols and abbreviated terms

3.1 Symbols

c	number of defects (nonconformities)
μ	location of the process; population mean value
μ^*	“off-set” location of the process; “off-set” population mean value
n_{CTQC}	number of critical to quality characteristics
n_{units}	number of units surveyed
p	proportion of nonconforming items
R	sample range value
R_{moving}	moving range value usually calculated between successive observations
σ	population standard deviation

ISO 13053-1:2011(E)

u	number of defects (nonconformities) per item
X	value
\bar{X}	sample arithmetic mean value
Y_{DPMO}	calculated number of defects per million opportunities
z	standardized normal distribution deviate
Z_{value}	Sigma score or value

3.2 Abbreviated terms

5S	acronym meaning sort, set, shine, standardize and sustain as used in the “visual factory”/“visual workplace” approach
5-Why	method for finding the potential root cause of a problem
8D	eight disciplines problem-solving method
ANOVA	analysis of variance
C&E	cause and effect
COPQ	cost of poor quality
COQ	cost of quality
CTC	critical to cost
CTQ	critical to quality
CTQC	critical to quality characteristic
DMAIC	define, measure, analyse, improve, control
DOE	design of experiments
DPMO	defects per million opportunities
EVOP	evolutionary operation
FMEA	failure mode and effects analysis
FTA	fault tree analysis
KPI	key performance indicator
KPIV	key process input variable
KPOV	key process output variable
MCA	multiple correspondence analysis
MSA	measurement system analysis
NPR	number of problem reports

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OTD	on-time delivery
ppm	parts per million
QFD	quality function deployment
RACI	responsible, accountable, consulted, informed
RR	return rate
RTY	rolled throughput yield
SIPOC	flowchart showing (S)upplier, (I)nputs, (P)rocess, (O)utputs, (C)ustomer relationships
SOP	standard operating procedure
SPC	statistical process control
TPM	total productive maintenance

4 Fundamentals of Six Sigma projects within organizations

4.1 General

The main purpose of a Six Sigma project is to solve a given problem in order to contribute to an organization's business goals. Six Sigma projects should be undertaken only when the solution to a problem is not known.

The specific activities of a Six Sigma project can be summarized as

- gather data,
- extract information from the data through analysis,
- design a solution, and
- ensure the desired results are obtained.

A practical approach should always be favoured when applying the above activities as shown in Table 1 below.

Table 1 — Fundamentals of Six Sigma

Question	Six Sigma phase	Description
What is the issue?	Define	Define a strategic issue to work on
Where is the process now?	Measure	Measure the current performance of the process to be improved
What is causing this?	Analyse	Analyse the process to establish the main root cause of poor performance
What can be done about it?	Improve	Improve the process through testing and studying potential solutions to establish a robust improved process
How can it be kept there?	Control	Control the improved process by establishing a standardized process capable of being operated and continually improved to maintain performance over time

4.2 Voice of the customer

The “voice of the customer” should provide a permanent feedback loop for the duration of a Six Sigma project. In the context of a Six Sigma project, this might be the Project Sponsor, an internal customer, or an external customer. It is important that every Six Sigma project start with the customers' needs and expectations. Subsequently, the ongoing activities of the project should be checked, at each phase, to confirm that they have not departed from the original customer expectations.

4.3 Accountability

The Six Sigma improvement methodology should be targeted on financial efficiency but should also take into consideration safety and customer satisfaction.

In all cases, an accounting model should be established, as a first step, so that the financial performance of a process is properly evaluated. Subsequently, both the financial department and operations department can look at one set of data and should be able to forecast similar outcomes.

The performance of the project under investigation should be assessed in terms of effectiveness and adaptability for the customer or the efficiency for the business. This should be reviewed regularly with the sponsor of the project.

4.4 Maturity of processes of an organization

Continual improvement comprises a set of actions which improve the performance of an organization. The concept of maturity has been introduced in order to evaluate different levels of performance of an organization and to give a road map for continual improvement projects. Usually, five levels are used:

- Initial (Level 1) – no description of any process in the organization;
- Managed (Level 2) – reactive only on customer demand, the process to respond to the customer has been formalized;
- Defined (Level 3) – the processes of the whole organization are defined;
- Quantitatively Managed (Level 4) – all the processes of Level 3 are quantitatively managed with indicators; and
- Optimized (Level 5) – the processes can be optimized with the use of indicators.

In a Six Sigma organization, the levels of maturity will change gradually. The different stages of progress will provide a general road map of the continual improvement programme and the level of maturity. The levels are shown in Figure 1.

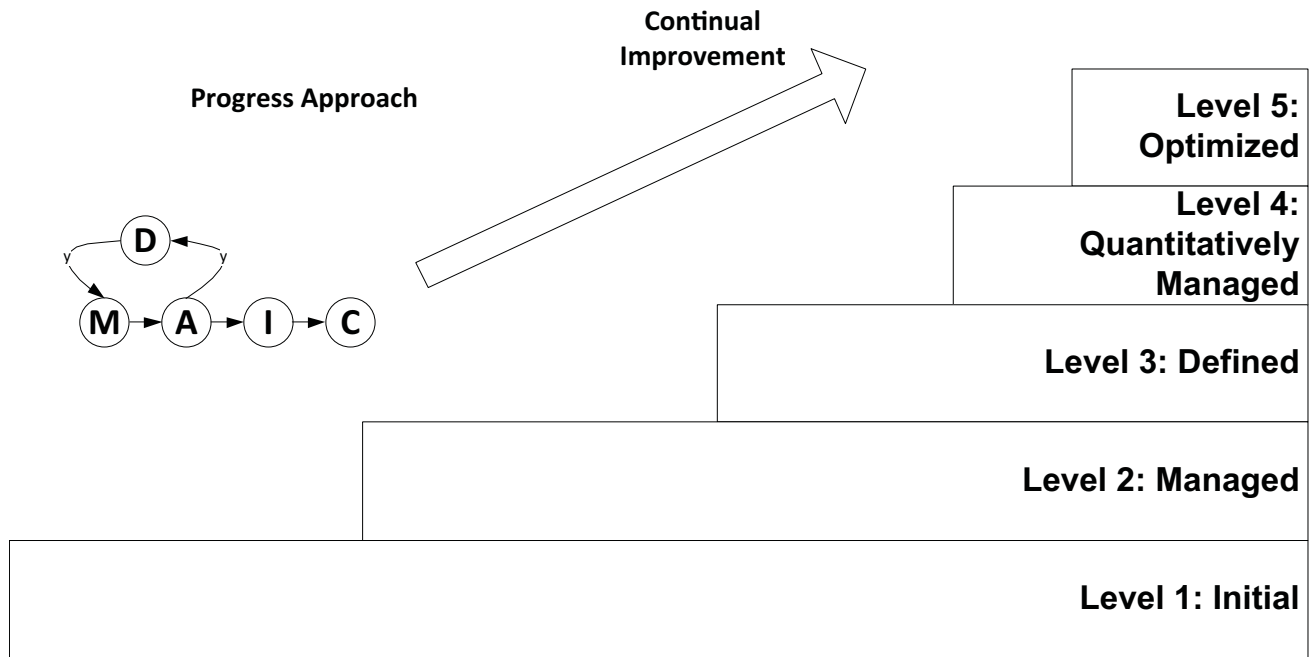


Figure 1 — Continual improvement and maturity level

4.5 Relationship with quality management standard ISO 9001

The quality principles outlined in the quality management system standards ISO 9000 and ISO 9001 call for a factual approach to decision making, a process approach to achieving quality and the practice of continual improvement.

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Six Sigma methods are powerful tools for top performance in each of these areas.

Quality comes out of an enterprise's system. Quality methods such as Six Sigma operate more effectively when they are integrated into an enterprise's operating system and processes, from market research to quality planning to process control and through to life cycle management.

An enterprise introducing Six Sigma should examine its operating systems to understand where existing processes need to be modified. The introduction of a range of methods, based on the use of data and problem-solving methods (such as DMAIC), could help improve the enterprise's operating systems. This can also help the enterprise improve the existing system continually, which is also a requirement of ISO 9001. Companies which follow this route tend to achieve greater productivity, customer satisfaction and a sustainable competitive position in their market place.

Members of an enterprise benefit from the training, learning and application of Six Sigma methods. They become more competent and knowledgeable in statistical thinking, understanding process variability and the resulting application within a quality management system.

Another very important benefit of integration of the Six Sigma methods in the quality management system is the opportunity to collect and store core knowledge on each project and process. This knowledge (on customer satisfaction, design for manufacture, process capability and in-service data on reliability) will be passed on to subsequent project teams, thereby embedding in the enterprise core knowledge which business sustainability needs to survive in the long term and avoiding the loss of knowledge when key people leave or retire.

Customers and stakeholders are the ultimate beneficiaries of Six Sigma integration into a quality management system giving a superior product, lower costs and better consistency from the delivered products.

5 Six Sigma measures

5.1 Purpose

The purpose of measures in a Six Sigma project is to be able to quantify the performance of a process. This enables comparisons, analysis and insights into the causes of performance to be gained. Various business measures can be applied to quantify a problem targeted for resolution by one or several Six Sigma projects. Several measures can be used to quantify the problem during the execution of a Six Sigma project. The following subclauses identify the chief measures that can be used. The choice of measure will depend on the project. Three of these measures often used to stimulate activities for improvement are: “product return rate”, “number of problem reports”, and “on-time delivery”. Continuous measures of these characteristics will tell us more about “by how much” the characteristics need to be improved. A further measure groups most of these as an overall measure – the cost of poor quality.

5.2 Defects per million opportunities (DPMO)

DPMO should be calculated using the following formula:

$$Y_{DPMO} = \frac{c}{n_{units} \times n_{CTQC}} \times 1\,000\,000$$

The potential number of CTQC defects (nonconformities) is counted from the n_{units} surveyed. It measures the achieved quality performance and it is expressed as a rate per million of all such CTQC defects. The value can then be later used to estimate a “sigma score” (or Z_{value}). See Table 2.

Table 2 — Sigma scores

Calculated value of DPMO (Y_{DPMO})	Sigma score (Z_{value})
308 538,0	2
66 807,0	3
6 210,0	4
233,0	5
3,4	6

NOTE 1 A full table of sigma scores can be found in Annex A.
NOTE 2 Calculations are based on a 1,5 sigma shift of the mean.

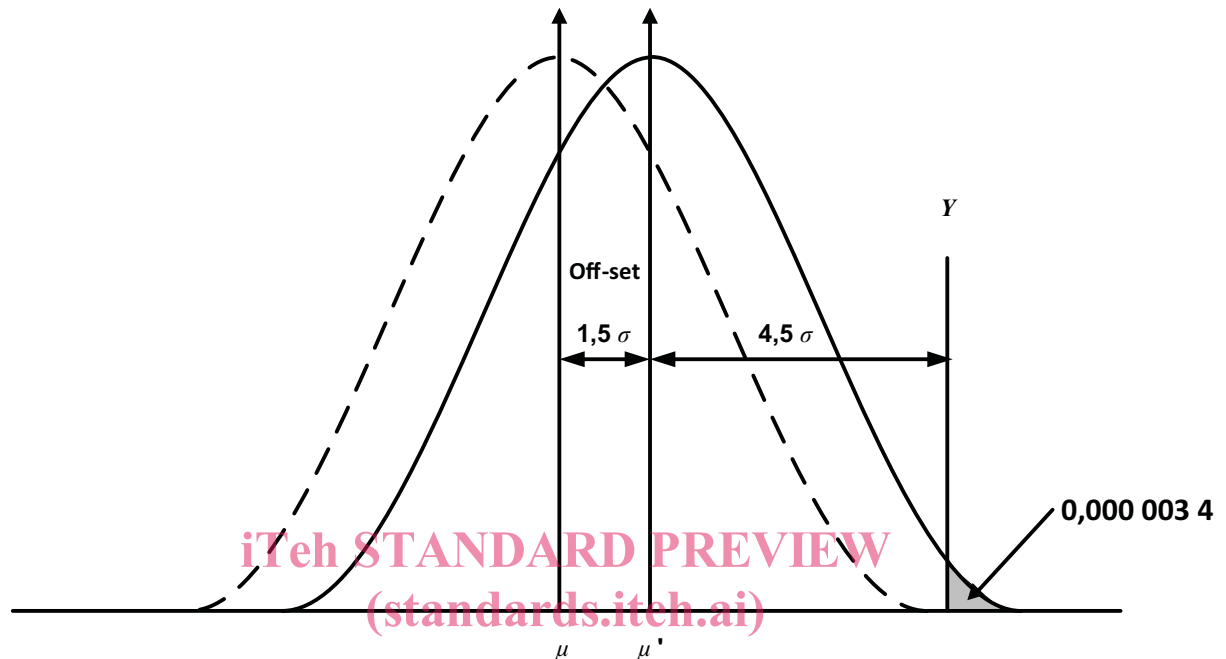
The benchmark used to rank the quality or performance is the sigma score. World class performance has become synonymous with a sigma score of 6, i.e. a performance level of 3,4 DPMO. Thus, a continuous process with a sigma score of 6 has a specification limit that is actually 4,5 standard deviations from the mean value.

As an illustration of how the above calculation can be applied, consider a product that has 1 000 CTQCs associated with it. If all of the characteristics had a performance of 3,4 DPMO, then the probability that the unit will be “defect-free” is $1 - (0,000\,003\,4)^{1\,000}$, or 0,996 606. If a batch of 150 units were produced, the probability that there will be no defects in the batch is $0,996\,606^{150}$, or 0,60. In other words, even though each CTQC has a sigma score of 6, the probability that there is at least one defect amongst a batch of 150 such products will be 0,40. Thus, for such products, the level of DPMO performance for the CTQCs needs to be much higher than a sigma score of 6. A sigma score of 6 is very much the initial threshold level.

5.3 Sigma score

The sigma score is derived from the normal distribution, but with a 1,5 standard deviation “off-set”, chosen historically from custom and practice. See Figure 2. This offset of 1,5 ($= 6 - 4,5$) is called the shift (value).

NOTE The shift of 1,5 sigma captures the estimate of the variation of the process mean between short- and long-term periods.



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Figure 2 — Derivation of the sigma scores

A sigma score of 6 is actually 4,5 standard deviations from the mean value. Therefore, to determine the proportion of the distribution remaining in the tail of the distribution, z is 4,5, using a standardized normal distribution. Table 2 was constructed in this manner. Further values can be read from Table A.1, which has been prepared in the same way.

Naturally, caution is required here since the normal distribution may not always be an appropriate model to use.

5.4 Rolled throughput yield (RTY)

RTY is the probability that a single unit can pass through a series of process steps free of defects.

In the case of multi-stage processes RTY is calculated by multiplying the “first time through yield” for each process step. The “first time through yield” does not include any rework, repair, additional adjustment, delay for down time, etc. It is also called “non-adjusted rate” or “go-through rate”. See the example in Figure 3.