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

**Part 2:  
Tools and techniques**

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

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*Partie 2: Outils et techniques*  
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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 13053-2 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 7, *Applications 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

Six Sigma<sup>1)</sup> is an approach developed for businesses and organizations seeking to gain a competitive advantage. Six Sigma practices are designed to be instrumental in

- driving process improvement and making statistically based decisions,
- measuring business results with a level of reliance,
- provisioning for uncertainty and error,
- combining high returns and benefits in the short, medium and long run, and
- removing the waste from any process.

The sigma score (written  $Z_{value}$ ) is an indicator of process quality that expresses process performance in terms of an ability to provide a product or a service that meets customer and third party specifications and expectations. It is directly related to either

- a) the proportion of good or positive outputs (yield) provided by a process, or
- b) the proportion of poor or negative outputs [% ppm or defects per million opportunities (DPMO)] from a process.

The following table translates the  $Z_{value}$  as the proportion of defects that might be expected.

**Table 1 — 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 ISO 13053-1:2011, Annex A.

NOTE 2 Calculations are based on a 1,5 sigma shift of the mean.

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

# Quantitative methods in process improvement — Six Sigma —

## Part 2: Tools and techniques

### 1 Scope

This part of ISO 13053 describes the tools and techniques, illustrated by factsheets, to be used at each phase of the DMAIC approach.

The methodology set out in Part 1 of ISO 13053 is generic and remains independent of any individual industrial or economic sector. This makes the tools and techniques described in this part applicable to any sector of activity and any size business seeking to gain a competitive advantage.

### 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 2.1

##### **benchmarking**

method for comparing the performance of the leading organizations in a market segment

#### 2.2

##### **brainstorming**

group creativity technique designed to generate a large number of ideas

#### 2.3

##### **cause and effect diagram**

Ishikawa diagram

fishbone diagram

visual tool often used with brainstorming for the logical organization of potential causes of a problem

#### 2.4

##### **common cause**

source of process variation that is inherent in a process over time

#### 2.5

##### **confidence interval**

interval within which a parameter to be estimated can be expected to lie with a probability of  $\geq 1 - \alpha$ , e.g. generally 95 % or 99 %

#### 2.6

##### **continuous data**

data that have been measured on a scale and that can be subdivided

2.7

**critical-to-quality**

**CTQ**

critical characteristics, the quality performance requirements which must be met to satisfy the customer

2.8

**customer**

organization or person that receives a product

NOTE The customer can be internal or external to the organization.

[ISO 9000:2005, 3.3.5]

2.9

**defect**

non-fulfilment of a requirement related to an intended or specified use

[ISO 9000:2005, 3.6.3]

2.10

**defect opportunity**

any measurable event creating a possible defect

2.11

**defective unit**

unit with one or more defects

[ISO 3534-2:2006, 1.2.16]

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2.12

**design of experiments**

**DOE**

systematic methodology for collecting information to guide improvement of any process

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NOTE 1 Statistical models are developed to represent the process under analysis.

NOTE 2 Simulation tools and optimization can be applied to test and confirm specific improvements.

2.13

**discrete data**

data that can be classified, but not subdivided

NOTE 1 Continuous data, by grouping or otherwise classifying, can be regarded as discrete.

NOTE 2 Data classified according to different attributes are discrete and are called "attribute data".

NOTE 3 Discrete data come from nominal or ordinal scales.

2.14

**environmental aspect**

activity, product or service that could possibly interact with the environment

2.15

**gate review**

project review led by a sponsor each time a DMAIC stage is completed in order to validate the conclusions of that stage

2.16

**input**

resources or data, or both, required to execute a process



**2.17****Kano model**

quality management tool used to prioritize customer requirements

**2.18****measurement system analysis****MSA**

series of studies that explains how a measurement system performs

NOTE Validating measurement systems makes it possible to ensure data consistency and data stability.

**2.19****mistake proofing**

poka yoke

prevention method designed as a simple technique to prevent either

- anyone from making unplanned or unwanted changes to a system, or
- any errors from negatively impacting on a system

**2.20****objective**

target value of a process, determined by the customer

**2.21****operational definition**

clear, concise description of a measurement and the process used to derive it

**2.22****output**

products or services generated through a process

**2.23****Pareto analysis**

methodology used to drill into discrete data to assess the frequency of defects by classification factors

**2.24****process**

set of interrelated or interacting activities that transforms inputs into outputs

**2.25****process map**

graphical display of a process

**2.26****project charter**

document that states the problem to be solved, the improvement goals, the project scope, the project milestones and the project roles and responsibilities

**2.27****quality function deployment****QFD**

method to translate customer requirements into design characteristics and, ultimately, into process control requirements

NOTE The “house of quality” is a tool used by this method.

**2.28****sampling plan**

plan that describes how samples are to be selected

**2.29  
scorecard**

customer-specified evaluation device used to track performance in satisfying customer requirements

**2.30  
special causes**

sources of process variation other than inherent process variation

NOTE Special causes are due to known or exceptional factors, sometimes called assignable causes.

**2.31  
third party**

person or body concerned or impacted by the performance issue in question

**2.32  
top  $Y$**

primary CTQ for both customer and organization

**2.33  
unit**

item produced or handled

**2.34  
voice of the customer  
VOC**

information from the customer that expresses his expectations

NOTE This can require the customer concerned to state targets he needs and will assist the producer to know the customer's position and to understand his or her expectations.

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**3 Symbols and abbreviated terms**

**3.1 Symbols**

- $b_0$  intercept in a regression equation
- $b_1$  coefficient in a regression equation
- $C$  criticality number used in FMEA
- $c$  number of defects (nonconformities)
- $D$  detection ranking used in FMEA
- $d$  accuracy (associated with confidence interval)
- $L$  lower specification limit
- $N$  population size
- $n$  sample size
- $n_{CTQC}$  number of critical to quality characteristics
- $O$  occurrence ranking used in FMEA
- $p$  proportion

$r$	correlation coefficient
$\Sigma$	summation
$\hat{\sigma}$	estimated population standard deviation
$S$	severity ranking used in FMEA
$s$	sample standard deviation
$U$	upper specification limit
$X$	random variable (independent)
$\bar{X}$	mean value of $X$
$Y$	random variable (dependent)
$\bar{Y}$	mean value of $Y$
$\hat{Y}$	predicted value of $Y$
$Y_{\text{DPMO}}$	calculated value of DPMO
$Y_{\text{ppm}}$	calculated value of ppm
$Z_{\text{value}}$	sigma score or value

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### 3.2 Abbreviated terms

ANOVA analysis of variance

COQ cost of quality

COPQ cost of poor quality

CTQ critical to quality

CTQC critical to quality characteristics

DMAIC define, measure, analyse, improve and control

NOTE 1 The DMAIC method for improving an existing process and its output has five phases: define, measure, analyse, improve and control.

DPMO defects per million opportunities

NOTE 2 DPMO can be used to determine the sigma score.

FMEA failure mode and effects analysis

FMECA failure mode, effects and criticality analysis

GRR gauge repeatability and reproducibility study

ppm parts per million

## ISO 13053-2:2011(E)

RACI responsible, accountable, consulted, informed

ROI return on investment

RPN risk priority number

SIPOC flowchart showing (S)upplier, (I)nputs, (P)rocess, (O)utputs, (C)ustomer relationships

### 4 DMAIC process sequence

#### 4.1 Define phase

##### 4.1.1 Objectives

The objectives of this step are to

- a) identify the requirements and expectations of the stakeholders,
- b) identify the voice of the customer and third parties (CTQC, etc.),
- c) select the project team,
- d) develop a process map (SIPOC), visualize the data (Pareto), and
- e) create a project charter.

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##### 4.1.2 Steps

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##### 4.1.2.1 Define: Step 1 <https://standards.iteh.ai/catalog/standards/sist/bd43cdc4-a3a5-44e4-95c4-68bc5afe0dcd/iso-13053-2-2011>

Identify the customers and the third parties, understand their demands and translate them into measurable requirements. Set improvement objectives.

Techniques	Factsheet or International Standard
Customer claims, market feedback, surveys	Factsheet 04, ISO 9001 or other management standards
Third party expectations, ethics surveys	Factsheet 04, ISO 14001 or other management standards
ROI, costs and accountability	Factsheet 01
Six Sigma indicators	Factsheet 20
Affinity diagram	Factsheet 02
Kano model	Factsheet 03
CTQ requirements	Factsheet 04
House of quality	Factsheet 05
Benchmarking	Factsheet 06

**4.1.2.2 Define: Step 2**

Define and set down the team objectives for the project: deadlines, stakes, constraints, risks, return on investment, competencies and scope of the project.

Techniques	Factsheet or International Standard
Project charter	Factsheet 07
Project planning tool: Gantt chart, project schedule	Factsheet 08
RACI competencies matrix	Factsheet 28
ROI, costs and accountability	Factsheet 01
Project risk analysis (in Project charter)	Factsheet 07

**4.1.2.3 Define: Step 3**

Characterize the activity or the process.

Techniques	Factsheet or International Standard
SIPOC	Factsheet 09
Process mapping and process data	Factsheet 10

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**4.2 Measure phase**

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**4.2.1 Objectives**

The objectives are

- a) to visualize the data (by means of a trend chart, histogram, etc.), and
- b) to assess baseline performance for the current process in order to reinforce the project objective.

**4.2.2 Steps****4.2.2.1 Measure: Step 1**

Take the measurable requirements ( $Y$ ) and select one or more critical variables ( $X$ ) to improve.

Techniques	Factsheet or International Standard
Voice of the customer (house of quality, etc.)	Factsheet 05
Voice of third parties (environment, social responsibility, sustainability)	Factsheet 05
CTQ tree diagram	Factsheet 04

4.2.2.2 Measure: Step 2

Define the data to be collected in order to pinpoint the process variation drivers ( $X$ ).

Techniques	Factsheet or International Standard
Prioritization matrices	Factsheet 11
Cause and effect diagram	Factsheet 12
Brainstorming	Factsheet 13
FMEA (Failure Mode & Effect Analysis)	Factsheet 14

4.2.2.3 Measure: Step 3

Double-check the fitness of the metrics selected.

Techniques	Factsheet or International Standard
MSA (Measurement system analysis)	Factsheet 15

4.2.2.4 Measure: Step 4

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Develop a stratified data collection ( $X$  and  $Y$ ) plan.

Techniques	Factsheet or International Standard
Data collection plan	Factsheet 16
Determination of sample size	Factsheet 17

4.2.2.5 Measure: Step 5

Understand and validate the data.

Techniques	Factsheet or International Standard
Normally tests and transformation of non-normal distributions	Factsheet 18
Visual display of data: histogram; box plot (box-and-whisker plot); Pareto chart; run chart	Factsheet 19
Control chart	Factsheet 30

**4.2.2.6 Measure: Step 6**

Measure process performance and/or process capability.

Techniques	Factsheet or International Standard
Indicators: $P_p$ , $P_{pk}$ , $C_p$ , $C_{pk}$ , ppm, DPMO, $Z_{value}$	Factsheet 20

**4.2.2.7 Measure: Step 7**

Confirm or readjust the improvement objectives.

Techniques	Factsheet or International Standard
Compare initial objectives with indicators (Project charter)	Factsheet 07

**4.3 Analyse phase****4.3.1 Objectives**

The objectives are

- a) to identify wastes,
- b) to identify environmental and socially negative impacts,
- c) to select and rank the key process variables ( $X$ ),
- d) to establish relationships between  $X$  and  $Y$ ,
- e) to validate the root cause ( $X$ ) that affects  $Y$ ,
- f) to estimate the weak points of the current design.

**4.3.2 Steps****4.3.2.1 Analyse: Step 1**

Analyse the process to pinpoint non value-adding activities or activities that need improvement.

Techniques	Factsheet or International Standard
Cause and effect analysis	Factsheet 12
Waste analysis	Factsheet 21
Value-stream analysis	Factsheet 22
Services delivery modelling (service process analysis)	Factsheet 23
Process mapping	Factsheet 10