	Scheda informativa su nuove norme **La Norma ISO 13053-1 Ed. 1-2012** **Metodi quantitativi per il miglioramento dei processi- Sei Sigma** Quantitative methods in process improvement - Six Sigma - Parte 1:DMAIC methodology

Per conto di AICQ CN[1] - Autore Giovanni Mattana - V. Presidente AICQ CN –Presidente della Commissione UNI 'Gestione per la Qualità e Metodi Statistici'

Peculiarità delle Norma

La ISO 13053, ***Quantitative methods in process improvement- Six* Sigma** consiste delle seguenti parti:

- ***ISO 13053- Part 1: DMAIC methodology***
- ***ISO 13053- Part 2: Tools and techniques***

Questa ISO 13053-1 descrive la metodologia nota come ***Sei Sigma*** che ha come scopo il miglioramento delle organizzazioni .

La metodologia tipicamente comprende cinque fasi: *define, measure, analyse, improve and control* (DMAIC).

Questa parte della ISO 13053 raccomanda *le prassi migliori o quelle preferite* da utilizzare per ciascuna delle fasi della metodologia DMAIC usata durante la attuazione di un progetto sei sigma.

La norma descrive *i ruoli e le competenze e l'addestramento del personale* coinvolto in tali progetti.

È applicabile a organizzazioni che fanno uso di processi manifatturieri come pure a processi relativi ai servizi o ai processi transazionali.

La Bibliografia richiama la iso 9000, la iso 9001, la iso 9004, la iso 21.500 sul project management,

La ISO 13053-1 è stata preparata dal Technical Committee ISO/TC 69, *Applications of statistical methods, Subcommittee SC 7, Application of statistical and related techniques for the implementation of Six Sigma.*

NOTA. La norma sarà pubblicata da UNI in lingua italiana nel prossimo futuro.

L'indice della norma è ben esplicativo dei contenuti.

[1] gennaio 2013 -

Indice

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.

2 Normative references

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.

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

a) gather data,

b) extract information from the data through analysis,

c) design a solution, and

d) 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.

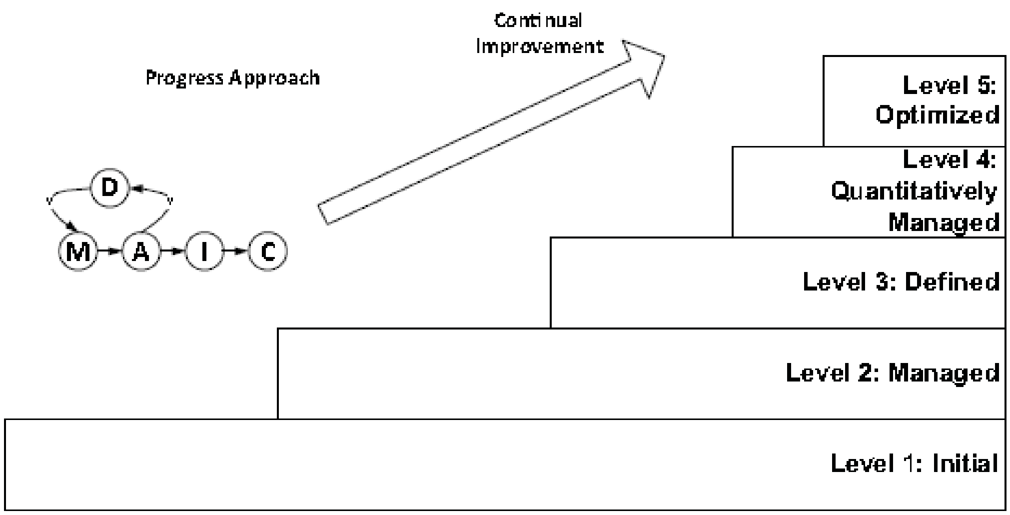

Figure 1 — Continual improvement and maturity level

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 factual approach to decision making, a process approach to achieving quality and the practice of continual improvement.

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 systems 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:

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

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.

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 606150, 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.

6 Six Sigma personnel and their roles

6.1 General

An organization seeking to implement Six Sigma should consider the following roles and whether they are applicable to its implementation. Some roles may need to be assigned full time occupation depending upon the size of the organization and the complexity of the projects (see Clause 14, Tables 8, 9 and 10). A schematic representation of what the interrelationships can be is shown in Figure 4.

6.2 Champion

This individual is likely to be a senior member of the organization, e.g. director or a vice president of uality, and one who carries a large degree of influence within the organization. The person will a) determine the strategy for the deployment of Six Sigma throughout the organization, and b) be responsible for setting and promoting business objectives with regards to the Six Sigma Initiative.

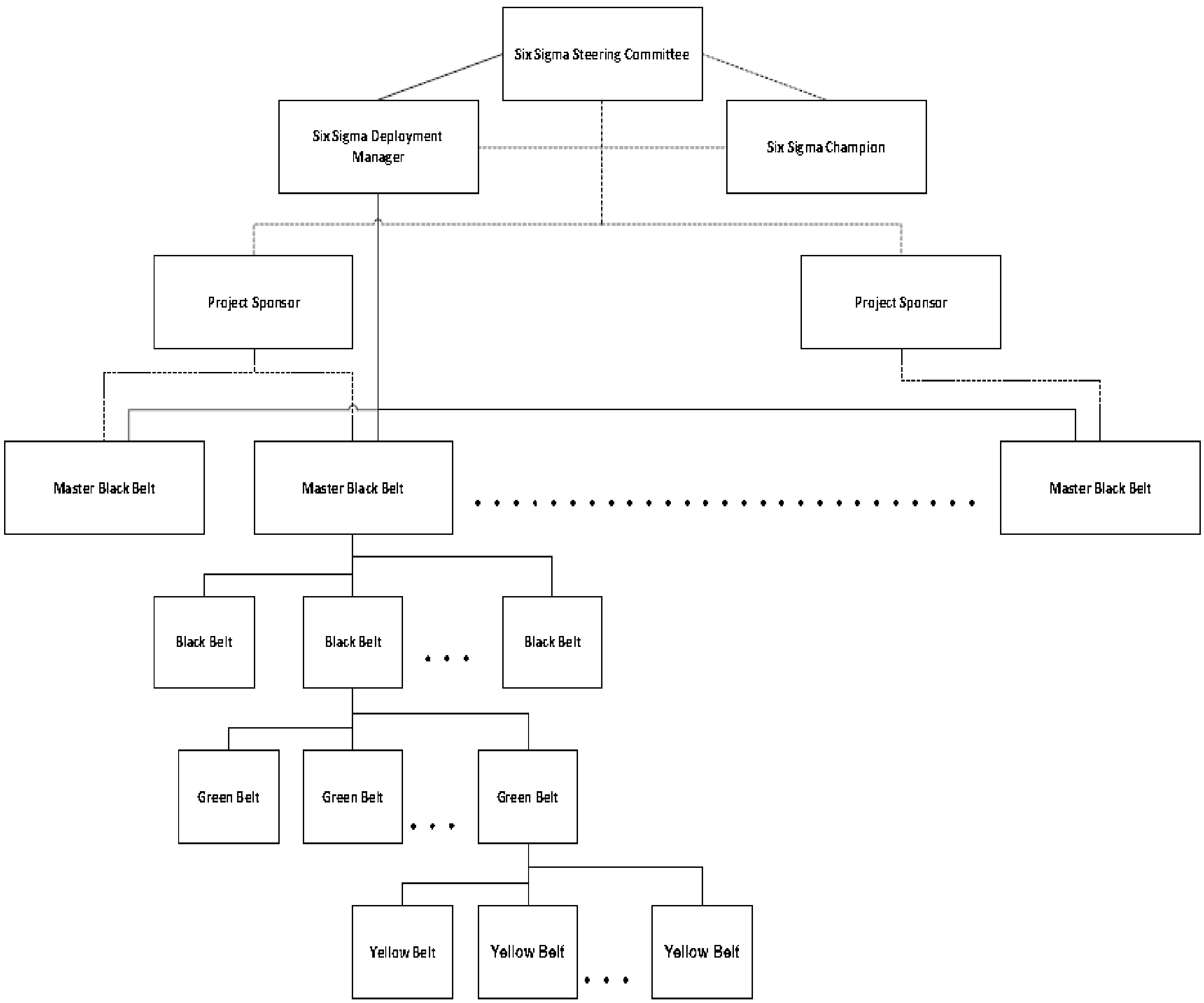

Figure 4 — Example of Six Sigma roles and their interrelationships

Nei paragrafi 6.3, 6.4, 6.5 , 6.6, 6.7, 6.8 la norma descrive I compiti delle varie figure citate:

- **Deployment Manager**
- **Project Sponsor**
- **Master Black Belt**
- **Black Belt**
- **Green Belt**
- **Yellow Belt**

7 Minimum competencies required

The recommended minimum competencies required of the Six Sigma personnel identified in Clause 6 are shown in Table 3. The table indicates the minimum level of competency for each skill/role combination. A numerical value has been assigned to each skill ranging from 0, where no competency is considered necessary for a particular role, to 3, where the particular skill is considered highly necessary for a particular role.

Table 3 — Minimum competency requirements to fulfil a given role

Skill	Master Black Belt	Black Belt	Green Belt	Yellow Belt
Business perception	3	2	1	1
Computer literacy	3	3	1	1
Customer focus	3	3	3	3
Interpersonal skills	3	3	2	1
Motivational skills	3	3	2	1
Numeracy	3	2	1	1
Practical problem solving skills	3	2	3	1
Presentation skills	3	3	2	0
Process improvement experience	3	2	1	0
Process management skills	3	3	2	0
Project management skills	3	3	2	0
Results driven	3	3	2	2
Six Sigma tools knowledge	3	2	1	1
Statistical skills	3	2	1	0
Statistical software use	3	3	1	0
Training skills	3	3	1	0
Coaching skills	3	2	2	0

Level 0 - Not needed; Level 1 - Basic competence; Level 2 - Proficient user; Level 3 - Highest level of ability.

NOTE A value of 0 in the table indicates that, to fulfil the given role, a certain skill may not be needed. It does not mean that the individual in the role has no knowledge of that particular skill.

8- Minimum Six Sigma training requirements

Table 4 — Recommended minimum course durations

Category	Champion[a] / Deployment Manager	Sponsor	Master Black Belt[b]	Black Belt	Green Belt	Yellow Belt
Instruction[c] (days)	3	1	10	20	5	1
Tutorials (days)	-	-	2	5	1	0
Number of qualifying Six Sigma projects	-	-	2	2	1	0

[a] To become a Champion, it is not enough to just complete the Champion Training.

[b] A Master Black Belt will have previously completed Black Belt training and performed this role for at least two years and will consequently have completed a number of Six Sigma projects.

[c] The instruction given is assumed to be delivered in a classroom. Some companies substitute some of this time with distance "e-learning".

The Master Black Belt training is usually split into two weeks separated by a short interval of time, e.g. two weeks.

The Black Belt training is usually divided into five four-day durations, or some other suitable division e.g. four five-day durations, each separated by about three to four weeks.

Nei paragrafi 8.2 , 8.3, 8.4 , 8.5, 8.6, 8.7 la norma descrive I requisiti di addestramento per le varie figure citate:

- **Champion/Deployment Manager**
- **Sponsor**
- **Master Black Belts**
- **Black Belts**
- **Green Belts**
- **Yellow Belts**

9 Six Sigma project prioritization and selection

9.1 General considerations

Projects should be selected to meet clear organizational objectives. Only projects where the solution is not known in advance may be considered for Six Sigma projects.

The outcome of each project should contribute to the overall improvement of the profitability of an organization. Organizations should keep lists of potential Six Sigma projects, ranked according to some measure of potential profit, in order to assist in such a selection process. Some projects might appear easier to do than others and this should be taken into account when the choices are made.

9.2 Project prioritization

There are several different ways of assessing the relative merits of competing potential Six Sigma projects.The graph, shown in Figure 5, is an example of one approach. Competing Six Sigma projects are rated for their degree of difficulty in their execution and for their potential profit. These values represent co-ordinates that are then plotted onto the graph.

Projects that lie in the box labelled “Priority 1” are those that should be done before others since they represent projects that have a large profit potential and carry a low level of difficulty in their execution. It can be a matter of debate whether some projects laying in Priority 3 should be done before some of those lying in Priority 2. Those lying in Priority 4 might never be selected unless an important customer of the organization requires a Priority 4 project to be executed.

9.3 Project selection

9.3.1 General checklist

The Six Sigma DMAIC method is best suited for resolving chronic problems. Acute problems are better dealt with by other purpose problem-solving methods such as 8D or methods described in ISO 9004:2009, Annex B will also be useful depending on the problem.

The following list, although not exhaustive, indicates the criteria that should be used to measure potential Six Sigma projects against.

a) Does the potential project have recurring events?

b) Do measures exist? If “no”, can measures be established in an appropriate amount of time?

c) Do you have the ability to control, i.e. manipulate, the process?

d) Will the potential project improve customer satisfaction?

e) Is the potential project aligned to at least one of the business measures (indicators)?

f) Will the potential project deliver savings?

g) Will the potential project have a high probability of being completed through the application of DMAIC within 6 months from its start?

h) Is it possible to set “success” criteria for the project?

If the answers to the above questions are “yes”, the potential project should be regarded as appropriate to execute.

At the gate review, the Project Sponsor can decide whether the project is appropriate. This involves a decision about whether or not the proposed project is meaningful (to the business strategy), measurable (measures can be developed for the process) and manageable (the proposed project scope is appropriate).

10 Six Sigma project DMAIC methodology

10.1 Introduction

A Six Sigma project is usually executed by the DMAIC process illustrated in Figure 8.

Each phase of the methodology should be followed in the sequence *define, measure, analyse, improve and control*. However, once data have been gathered and analysed the project should be reviewed and, if necessary, re-defined, re-measured and re-analysed. The first three phases should be repeated until the project definition agrees with the information derived from the data. The methodology should only proceed to the final two phases once the project definition is stable.

Regular reports (see Clause 12) should be submitted to the Project Sponsor at all phases. Regular gate reviews should be held with the Project Sponsor at each phase of the DMAIC process.

Refer to ISO 13053-2 for further information on the tools and techniques identified in the following subclauses.

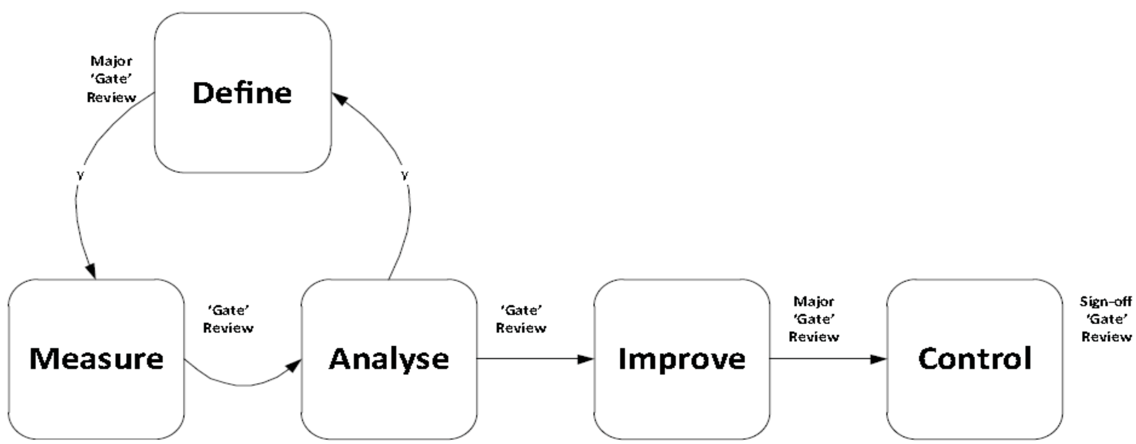

Figure 8 — Example of Six Sigma DMAIC sequence

Nei paragrafi 10.2, 10.3, 10.4 , 10.5, 10.6, la norma elenca le tecniche maggiormente usate in ciascuna fase:

- **Define**
- **Measure**
- **Analyse**
- **Improve**
- **Control**

11 Six Sigma project methodology — Typical tools employed

The following table summarizes many of the tools that are typically used within a Six Sigma project. Further information on some of the tools listed can be found in ISO 13053-2.

Table 6 — Typical Six Sigma tools and techniques

Tool (technique)	Factsheet number[a]	Define	Measure	Analyse	Improve	Control
Capability / performance	20	R	R	R	R	R
CTQC	04	M	M		M	M
Customer focus group	05	S				
Descriptive statistics	19	S	S	S	S	S
Financial justification	01	M				R
Gantt chart	08	R				
Kano model	03	S				
Non-conformance opportunities identification	04	R				
Pareto diagram	19	S	S	S	S	
Prioritization matrix	11	R			R	
Process flow chart	10	R		S	R	
Project charter	07	M				
Project review	31	M	M	M	M	M
Project risk analysis	07	M				
QFD	05	R		R	R	
RACI matrix	28	R			R	
Service delivery modelling	23	S	S		S	S
SIPOC	09	R			S	
Six Sigma indicators	20	M			M	
Value stream analysis	22	R				
Waste analysis	21	R	R	R		
Benchmarking	06		R		R	
Data collection plan	16		M			
MSA	15		M	M		M
Probability distribution (e.g. normality) tests	18		M (for continuous data) R (for others)	M (for continuous data) R (for others)		
Sample size determination	17		M	M	M	
SPC	30		R	R		R
Trend chart	19		S			S

Table 6 (*continued*)

Tool (technique)	Fact sheet number[a]	Define	Measure	Analyse	Improve	Control
Affinity diagram	02			S		
ANOVA	24, 26			R	R	
C&E diagram	12			R		
DOE	26			R	R	
Hypothesis tests	24			R	R	
Process FMEA	14			R	M	
Regression and correlation	25			R	R	
Reliability	27			R	R	
5-why analysis	—			S		
Brainstorming	13				S	
MCA	—				S	
Mistake proofing (poka yoke)	29				R	R
Solution selection	11				R	
TPM	27				S	S
5S	29				S	S
Control plan	29					M

[a] Factsheets are given in ISO 13053-2.

NOTE M – Mandatory; R – Recommended; S – Suggested.

12 Monitoring a Six Sigma project

12.1 General

The Six Sigma project should be regularly monitored in order to know if it is running to schedule and whether other measures of viability of project are satisfactory.

Regular reports should be submitted to the Project Sponsor.

La norma tratta i seguenti altri aspetti del capitolo:

12.2 Gate reviews

12.3 Project management

12.4 Weekly mentoring sessions with a Master Black Belt

13 Critical to success factors for Six Sigma projects

Two items critical to a successful outcome of a Six Sigma project are the existence of well-defined and maintained stakeholder management plans and that the project should be data driven.

The project should be reviewed to confirm that a stakeholder management plan exists and is up-to-date.

14 Six Sigma infrastructures within an organization

14.1 General information

The type of infrastructure chosen by any organization will depend on several factors and there are neither “right” nor “wrong” arrangements. What works for one organization may not work for another. The ratios of the roles are to provide a critical mass, which can be adjusted for any industry or service, for the successful deployment and ongoing function of the Six Sigma initiative.

The factors tend to be the following:

a) the overarching structure imposed by a central facility;
b) the number of employees at the site; and
c) the nature of the business.

14.2 Large - Over 1 000 employees at a site

14.3 Medium – 250 to 1 000 employees at a site

14.4 Small – Less than 250 employees at a site.

Annex B

L’annesso B della Norma riguarda l’addestramento e considera:

B.1 Typical Black Belt training agenda

B.2 Typical Green Belt training agenda