



## Six Sigma Becoming a Standard: The New ISO 9004

### ISO 9004 & ISO 9001

ISO 9004:

- ✓ provides a **wider focus** on quality management than ISO 9001
- ✓ addresses the needs and expectations of **all** relevant interested parties such as customers, owners, suppliers, employees etc.

## ISO 9004 & ISO 9001

### ISO 9004:

needs and expectations of relevant interested parties are different;

- ✓ Customers; quality, price etc.
- ✓ owners; sustained profitability, transparency
- ✓ Suppliers; mutual benefits, continuity,
- ✓ Employees; good work environment, job security etc.

## ISO 9004 & ISO 9001

### ISO 9004:

- ✓ provides **guidance** for the systematic and continual improvement of the organization's overall performance

## Sustained Success

of an organisation is achieved by:

- ✓ its ability to meet the needs and expectations of its customers and other interested parties, over the long term and in a balanced way so top management should
  - have a long-term planning perspective,
  - constantly monitor and regularly analyse the organization's environment,
  - identify all its relevant interested parties, assess their individual potential impacts on the organization's

## Sustained Success

- establish mutually beneficial relationships with suppliers, partners and other interested parties,
- competing needs and expectations of interested parties,
- identify associated short and long-term risks and deploy an overall strategy for the organization
- anticipate future resource needs (including the competences required of its people), and plans,



# Maturity Model

- ISO 9004 Standard promotes self-assessment as an important tool for the review of the maturity level of the organisation.



# Maturity Model

- understanding and satisfying the needs and expectations of interested parties,
- monitoring changes in the organization's environment,
- identifying possible areas for improvement and innovation,
- defining and deploying strategies and policies,
- setting and deploying relevant objectives,



# Maturity Model

- managing its processes and resources,
- demonstrating confidence in its people, leading to increased motivation, commitment and involvement,
- establishing mutually beneficial supplier and other partner relationships..



# Maturity Model

- There are 5 maturity model beginning from basic level to best practice.



## Self-assessment

The completion of a self-assessment should result in an action plan for improvement and/or innovation that should be used as an input to top management for planning and review.



## The Need for Statistical Techniques

Variability:

- can be seen in the **measurable characteristics** of processes and products at diverse stages over the total life cycle.
- The favorableness of the statistical techniques comes from the variability existing in the **input and output** of all processes

# Why Statistical Techniques?

- ✓ Measure
- ✓ Describe
- ✓ Analyze
- ✓ Interpret
- ✓ Model

VARIABILITY  
(even with a relatively  
limited amount of data)

# Why Statistical Techniques?

## RESULT:

- ✓ provide a **better understanding** of the nature, extent and causes of variability
- ✓ solve and **even prevent** problems that could result from such variability.
- ✓ assist in **decision making**
- ✓ to continually **improve the quality** of products and processes to achieve customer satisfaction



# The Six-Sigma Methodology

- Use of statistical tools within a **structured methodology**
- Gain the knowledge needed to achieve better, faster and **less expensive** products and services than the competition
- Increased profit margins and impressive return of investment



## Some of the Methods





# Sampling

- Systematic statistical methodology for obtaining information about some characteristic of a population by studying a representative fraction (i.e. sample) of the population.



# Hypothesis Testing

- Statistical Procedure to determine, with a prescribed level of risk, if a set of data (typically from a sample) is compatible with a given hypothesis..



## Gauge Repeatability and Reproducibility

- Measurement systems analysis involves the understanding and quantification of measurement variance to process variability and variance spread.
- Assesses the statistical properties of repeatability, reproducibility, bias, stability and linearity. Collectively, these techniques are sometimes referred to as “gauge R&R”.



## Process Capability Analysis

- Tools that are used to assess a process relative to specification criteria.
- The examination of the inherent variability and distribution of a process, in order to estimate its ability to produce output that conforms to the range of variation permitted by specifications.



## Design of Experiments(DOE)

- Offer a structured approach to change many factor settings within a process at once and observe the data collectively for improvements/ degradations.
- Not only yield a significance test of the factor levels but also gives a prediction model for the response.



## Reliability Analysis

- Are often performed to “ensure” that the frequency of failures of a component or assembly is below a criterion. Often this test is performed during initial model builds or initial production.



## Regression Analysis

- Relates the behaviour of a characteristic of interest(usually called the response variable) with potentially causal factors.
- Such a relationship is specified by a model that can come from science, economics, engineering,etc, or it can be derived empirically



## Statistical Process Control Charts

- Is a graph of data derived from samples that are periodically drawn from a process and plotted in sequence.
- The “control limits” on the SPC charts describe the inherent variability of the process when it is stable.



## Time Series Analysis

- Is a family of methods for studying a collection of observations made sequentially over time.



## Cause and Effect Matrix

- A tool that can aid with the prioritization of importance of key process input variables.
- The prioritization by a team can help with the selection of what will be monitored to determine if there is a cause and effect relationship and whether key process input variables are necessary.



## Process Flowcharting

- Provides a complete pictorial sequence of what happens from start to finish of a procedure.
- Applications include procedures documentation, manufacturing processes, work instructions and product development steps.
- Can minimize the volume of documentation, including ISO 9000 documentation.



## Quality Function Deployment

- A tool that can be used to give direction on what should be done to meet the needs of the customer.
- Uses a team concept where many organizations can break down barriers so that product definition and efforts have direct focus towards the needs of the customer.
- Used to organize and provide for the transfer of knowledge.

## Pareto Chart

- A tool that is helpful to identify the source of common causes in a specified process.
- The Pareto Principle simply states that a “vital few” of the manufacturing process characteristics cause most of the quality problems on the line, while a “trivial many” of the manufacturing process characteristics cause only a small portion of the quality problems.

## Why is it difficult to use statistical Techniques in ISO 9004?

- ✓ There are lots of statistical techniques  
BUT  
they have  
**NO knowledge**  
to use them properly in the phases.
- ✓ Each of these methods gives different results.
- ✓ If the firms need these results for improving customer satisfaction and fulfilling critical requirements, they must be careful about which methods they will use.

## The correspondance between ISO 9004 and The Six-Sigma Techniques:

Subclause in ISO 9001:2008	Subclause in ISO 9004:2009	6-Sigma Technique(s)
5.3 Customer Focus	4.4 Interested parties, needs and expectations, price, quality, satisfacion , customer trends, diffrent market trends	Cause-and-effect matrix, Quality function deployment, Data relationship matrix, Balanced scorecard, Descriptive statistics,
6.2.2 Competence, training and Awareness	6.3.2 Competence of People, efficiency of the training programs, training hours, awareness, need of a training , the gaps between what is available and what is currently needed competence	Descriptive statistics, Sampling

## The correspondance between ISO 9004 and The Six-Sigma Techniques:

Subclause in ISO 9001:2008	Subclause in ISO 9004:2009	6-Sigma Technique(s)
7.4.1 Purchasing Process	6.4. Suppliers and Partners 6.4.1 General Supplier evaluation, initial control results, selection of supplier, cost of incoming materials, cost of transportation, performance of the partners, improving capabilities of the suppliers, risks associated in the relations with the suppliers and the partners	Descriptive statistics, Hypothesis testing, Gauge R&R, Processs capability analysis, Regression analysis, Reliability analysis, Sampling, Design of Experiments



## The correspondance between ISO 9004 and The Six-Sigma Techniques:

Subclause in ISO 9001:2008	Subclause in ISO 9004:2009	6-Sigma Technique(s)
6.4 Work Enviroment	6.6 Work Enviroment; work place recognition, safety rules, work load and stress , ergonomy,	Histogram, Check Sheets, Pareto Chart, Brain Storming, Nominal Group Technique, Cause and Effect Diagram,
7.1 Planning of Product Realization 7.5 Production and Service Provision	7.2. Process Planning and Control, analyses of the organization's environment, short- and long-term forecasts of market developments, objectives to be achieved, potential financial and other risks, process inputs and outputs, interactions with other processes, activities and methods, measurement, monitoring and analysis,	Descriptive statistics, Measurement analysis, Process capability analysis, Sampling, Regression analysis, Reliability analysis, time series analysis

## The correspondance between ISO 9004 and The Six-Sigma Techniques (cont'd)

8.1 General 7.6 Control of Monitoring and Measuring Equipment	8.1 (Monitoring, measurement, analysis and review) General, assessing strengths, weaknesses, opportunities and threats, determining alternative, competitive or new product offerings, anticipating current and expected changes in statutory and regulatory requirements, understanding the labour market and its effect on the loyalty of people in the organization, understanding the social, economic, ecological trends and local cultural aspects relevant to the organization's activities,	Flowchart/Process Map, Fishbone Diagram, Cause-and-Effect Measurement analysis, Process capability analysis, Sampling,
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## The correspondance between ISO 9004 and The Six-Sigma Techniques (cont'd)

8.2.3 Monitoring and Measurement of Processes	8.3.2 Key Performance Indicators, the importance of individual products to the organization, both at the present time and in the future, the effectiveness and efficiency of processes, the effective and efficient use of resources, profitability and financial performance	Descriptive statistics, Gauge R&R, Analysing Distributions Probability and Hazard Planning, Basic Control Charts, Process capability analysis, Sampling, Time series analysis, Reliability analysis
8.2.2 Internal Audit	8.3.3 Internal Audit, audit results	Descriptive statistics, Sampling

## The correspondance between ISO 9004 and The Six-Sigma Techniques (cont'd)

8.2.2 Internal Audit	8.3.3 Internal Audit, audit results	Descriptive statistics, Sampling
8.4. Analysis of Data	8.4. Analysis, those existing products and activities that currently provide the most value for its interested parties, new products and processes needed to meet the changing needs and expectations of its interested parties, the evolving demands for the organizations' products in the long term, the influence of emerging technologies on the organization, new competences that could be needed,	Multivariate Charts, Boxplots, Hypothesis Testing, Comparison Tests, Linear Regression

## The correspondance between ISO 9004 and The Six-Sigma Techniques (cont'd)

8.5. Improvement	9.1 (Improvement, Innovation and Learning), General, products, processes and their interfaces,	Design of Experiments, Response Surface Methodology,
8.5 Improvement	9.2. Improvement, Effectiveness and efficiency of the improvement process itself	Design of Experiments, Response Surface Methodology, Taguchi Design
7.3. Design and Development	9.3. Innovation the need for innovation, establish and maintain an effective and efficient innovation process,	Design of experiments,

## REFERENCES

- *ISO 9001, Quality Management Systems – Requirements*
- *ISO 9004, Quality Management Systems – Guidelines for complaints handling in organizations*
- *ISO/TR 10017, Guidance on Statistical techniques for ISO 9001:2000*
- *Breyfogle, Forest (2000), Implementing Six Sigma: Smarter Solutions Using Statistical Methods, John Wiley & Sons, New Jersey*



THANK YOU