

## 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, transperancy

✓ Suppliers; mutual benefits, continiuty,

Employees; good work environment, job security etc.

# ISO 9004 & ISO 9001

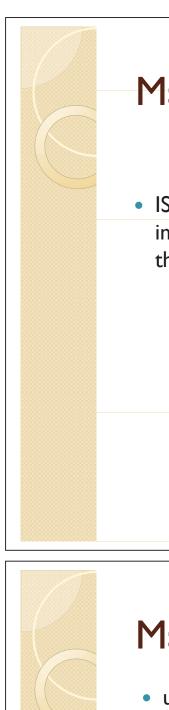
ISO 9004:

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



## Sustained Success

- 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 begining from basic level to best practice.

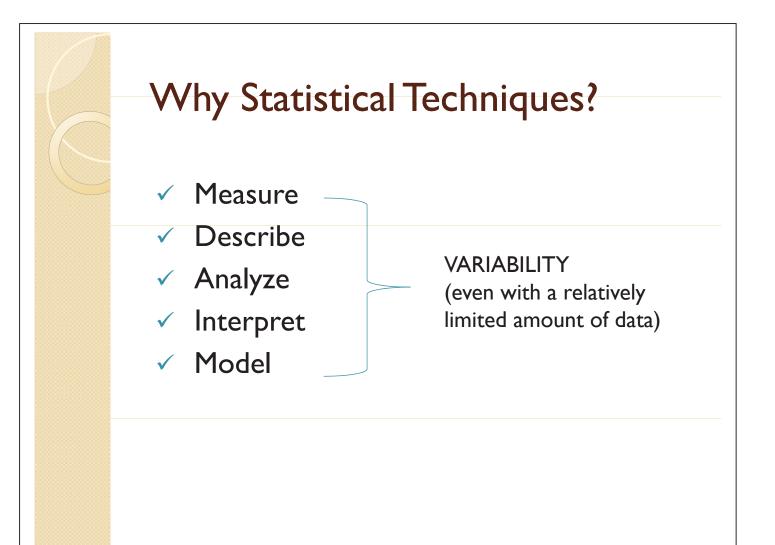
#### Self-assessment

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?

#### **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 tha 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 emprically

#### 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 tok 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 Six-Sigma Subclause in ISO 9001:2008		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 matr 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	Descriptive statistics,
	6.4.1 General	Hypothesis testing, Gauge
	Supplier evaluation, initial	R&R, Processs capability
	control results, selection of	analysis, Regression analysis,
	supplier, cost of incoming	Reliability analysis, Sampling,
	materials, cost of transportation,	Design of Experiments
	performance of the partners,	
	improving capabilities of the	
	suppliers, risks associated in the	
	relations with the suppliers and	
	the partners	

#### 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,
<ul><li>7.1 Planning of Product</li><li>Realization</li><li>7.5 Production and Service</li><li>Provision</li></ul>	<ul> <li>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</li> <li>processes, activities and methods, measurement, monitoring and analysis,</li> </ul>	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)

1 General 6 Control of Monitoring and leasuring Equipment
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#### The correspondance between ISO 9004 and The Six-Sigma Techniques (cont'd)

8.2.3 Monitoring and	8.3.2 Key Performance Indicators,	Descriptive statistics, Gauge R&R,
Measurement of Processes	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	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,



- 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

