

# June 22, 2011 (Wednesday) 55th EOQ Congress

# CONCURRENT SESSIONS KEMPINSKI HOTEL CORVINUS

Wednesday 8:30 – 12:30 Erzsébet tér 7-8, Budapest V.

## **REGINA BALLROOM I.**

Wednesday 8:30 - 10:30

## **17.1. STANDARDIZATION AND THE NEW ISO 9004**

Session Chair: Kari Jussila, BIT Research Center, Aalto University of Science, Finland

**9.50** Six Sigma Becoming a Standard: The New ISO 9004 Ezgi Avci, Turkish Standards Institution, Personnel and System Certification Department, Turkey

Avci, Ezgi (Turkey)

He has finished High School in Ankara (2001); later he earned BS in Statistics, 2005 and MS degree in Industrial Engineering in 2009 in the Middle East Technical University, (METU). Beginning from 2006 he works at TSE (Turkish Standards Institution) in Ankara as Instructor and Technical Specialist. His professional skills include Statistical Process Control, Problem Solving Techniques, Failure Modes and Effects Analysis, Survey Training, Customer Satisfaction and Six Sigma Training as well as Performance Evaluation Training. He has got a lot of certificates of different training courses, e.g. in the following areas: Human Resources Management, Information Technologies Management, Communication of Good Quality and Life Hapiness, Strategic Management, Quality Management Systems and Quality Management System Internal Audit, Process Management, Statistical Process Control, Failure Modes and Effects Analysis, Problem Solving Techniques, Environmental Management System Documentation and Audit as well as OHSAS (Occupational Health & Safety).

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

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#### Abstract:

The purpose of this paper is to assist an organization for identifying Six-Sigma techniques that can be useful in developing, implementing, maintaining and improving a quality management system in coherence with ISO 9004. This International Standard states that it provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all relevant interested parties and provides guidance for the systematic and continual improvement of the organization's overall performance. Six-Sigma methodology provides tools for organizations to evaluate their processes, to determine their level of maturity, and to facilitate for improvement and innovation. In this paper the correspondance between the Six-Sigma methodology and ISO 9004 standard will be discussed.

Key words: Six sigma, ISO 9004, self-assessment, statistical techniques

#### Introduction:

The sustained success of an organization 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. Sustained success can be achieved by the effective management of the organization, through awareness of the organization's environment, by learning, and by the appropriate application of either improvements, or innovations or both. The ISO 9004 Standard promotes self-assessment as an important tool for the review of the maturity level of the organization, covering its leadership, strategy, management system, resources and processes, to identify areas of strength and weakness and opportunities for either improvements, or innovations, or both (ISO 9004).

The self assessment tool uses five maturity levels, which can be extended to include additional levels or otherwise customized as needed. The organization should review its performance against a specified criteria, identify current maturity levels, and determine its strengths and weaknesses (ISO 9004).

The Six-Sigma methodology can be used coherently with the ISO 9004 to assist the organization in self-assessment and evaluating the maturity level.

#### The Need for Statistical Techniques:

The favorableness of the statistical techniques comes from the variability existing in the input and output of all processes, even under conditions of strict stability. This variability can be seen in the measurable characteristics of processes and products at diverse stages over the total life cycle.Statistical techniques can help to measure, describe, analyze, interpret and model such variability, even with a relatively limited amount of data. Statistical analysis of such data may provide a better understanding of the nature, extent and causes of variability.This could help to solve and even prevent problems that could result from such variability. Statistical techniques can thus allow better use of avaiable data to assist in decision making, and thereby help to continually improve the quality of products and processes to achieve customer satisfaction. These techniques are applicable to a wide range of activities, such as market research, design, development, production, verification, installation and servicing. (ISO/TR 10017).

#### The Six-Sigma Methodology:

The Six-Sigma strategy involves the use of statistical tools within a structured nethodology for gaining the knowledge needed to achieve better, faster and less expensive products and services than the competition. The repeated, disciplined application of the master strategy on project after project, where the projects are selected based on key business issues, is what drives dollars to the bottom line, resulting in increased profit margins and impressive return of investment from the Six-Sigma training (Breyfogle, 2000).

There are many possible implementation strategies of the statistical techniques. The methods are the focus of "what to do" within each phase of the ISO 9004. The big problem of the firms is always that there are lots of statistical techniques but they have no time and knowledge to use them properly in each phase. 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.

We need to select a rational number of these methods and use them logically. The suggested tools and the best practices will help the firms to use the Six-Sigma tools properly while applying the ISO 9004.

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

The integration of the Six Sigma tools into managing for the sustained success of an organization will be discussed in Table 1.1. The first two colums of the table is taken from ISO 9004 Annex C to demonstrate the correspondance between ISO 9004:2009 and ISO 9001:2008.

The last column in Table 1.1 indicates the Six-Sigma methods that can be appropriately used in each subclause of ISO 9004.

Subclause in ISO 9001:2008	Subclause in ISO 9004:2009	6-Sigma Technique(s)
5.3 Customer Focus	4.4 Interested parties, needs	Cause-and-effect matrix,
	and expectations	Quality function deployment,
		Data relationship matrix,
		Balanced scorecard,
		Descriptive statistics,
6.2.2 Competence, training	6.3.2 Competence of People	Descriptive statistics,
and Awareness		Sampling
7.4.1 Purchasing Process	6.4. Suppliers and Partners	Descriptive statistics,
	6.4.1 General	Hypothesis testing, Gauge
		R&R, Processs capability
		analysis, Regression analysis,
		Reliability analysis, Sampling,
		Design of Experiments
6.4 Work Enviroment	6.6 Work Enviroment	Histogram, Check Sheets,
		Pareto Chart, Brain Storming,
		Nominal Group Technique,
		Cause and Effect Diagram,
		SPC charts
7.1 Planning of Product	7.2. Process Planning and	Descriptive statistics,
Realization	Control	Measurement analysis, Process
7.5 Production and Service		capability analysis, Sampling,
Provision		Regression analysis,
		Reliability analysis, SPC
		charts, Time series analysis
8.1 General	8.1 (Monitoring	Flowchart/Process Man
off General	our (monitoring,	1 10 wentur / 1 100055 1014p,
7.6 Control of Monitoring	measurement, analysis and	Fishbone Diagram, Cause-and-
7.6 Control of Monitoring and Measuring Equipment	measurement, analysis and review) General	Fishbone Diagram, Cause-and- Effect Measurement analysis,
7.6 Control of Monitoring and Measuring Equipment	measurement, analysis and review) General	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis,
7.6 Control of Monitoring and Measuring Equipment	measurement, analysis and review) General	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling,
<ul><li>7.6 Control of Monitoring and Measuring Equipment</li><li>8.2.3 Monitoring and</li></ul>	measurement, analysis and review) General 8.2 Monitoring	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	measurement, analysis and review) General 8.2 Monitoring	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and</li> </ul>	8.2 Monitoring	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis,
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> </ul>	measurement, analysis and review) General 8.2 Monitoring	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis,
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> </ul>	measurement, analysis and review) General 8.2 Monitoring	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> </ul>	8.2 Monitoring	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> </ul>	measurement, analysis and review) General 8.2 Monitoring	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and</li> </ul>	8.3.1 (Measurement) General	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis Descriptive statistics,
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> </ul>	8.2 Monitoring 8.3.1 (Measurement) General	<ul> <li>Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis,</li> <li>Sampling,</li> <li>Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis,</li> <li>Process capability analysis,</li> <li>Sampling, SPC charts, Time series analysis, Reliability analysis</li> <li>Descriptive statistics,</li> <li>Sampling</li> </ul>
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> </ul>	8.3.1 (Measurement) General	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis Descriptive statistics, Sampling
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and</li> </ul>	8.3.2 Key Performance	<ul> <li>Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis,</li> <li>Sampling,</li> <li>Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis,</li> <li>Process capability analysis,</li> <li>Sampling, SPC charts, Time series analysis, Reliability analysis</li> <li>Descriptive statistics,</li> <li>Sampling</li> <li>Descriptive statistics, Gauge</li> </ul>
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	8.3.1 (Measurement) General 8.3.2 Key Performance Indicators	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis Descriptive statistics, Sampling Descriptive statistics, Gauge R&R, Analysing Distributions
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	<ul> <li>8.2 Monitoring</li> <li>8.3.1 (Measurement) General</li> <li>8.3.2 Key Performance Indicators</li> </ul>	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis Descriptive statistics, Sampling Descriptive statistics, Gauge R&R, Analysing Distributions Probability and Hazard
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	<ul> <li>8.2 Monitoring</li> <li>8.3.1 (Measurement) General</li> <li>8.3.2 Key Performance Indicators</li> </ul>	<ul> <li>Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling,</li> <li>Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis</li> <li>Descriptive statistics, Sampling</li> <li>Descriptive statistics, Gauge R&amp;R, Analysing Distributions Probability and Hazard Planning, Basic Control</li> </ul>
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	<ul> <li>8.2 Monitoring</li> <li>8.3.1 (Measurement) General</li> <li>8.3.2 Key Performance Indicators</li> </ul>	Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling, Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis Descriptive statistics, Sampling Descriptive statistics, Gauge R&R, Analysing Distributions Probability and Hazard Planning, Basic Control Charts,Process capability
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	<ul> <li>8.2 Monitoring</li> <li>8.3.1 (Measurement) General</li> <li>8.3.2 Key Performance Indicators</li> </ul>	<ul> <li>Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling,</li> <li>Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis</li> <li>Descriptive statistics, Sampling</li> <li>Descriptive statistics, Gauge R&amp;R, Analysing Distributions Probability and Hazard Planning, Basic Control Charts,Process capability analysis, Sampling, Time</li> </ul>
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	<ul> <li>8.2 Monitoring</li> <li>8.3.1 (Measurement) General</li> <li>8.3.2 Key Performance Indicators</li> </ul>	<ul> <li>Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling,</li> <li>Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis</li> <li>Descriptive statistics, Sampling</li> <li>Descriptive statistics, Gauge R&amp;R, Analysing Distributions Probability and Hazard Planning, Basic Control Charts,Process capability analysis, Sampling, Time series analysis, Reliability</li> </ul>
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> </ul>	<ul> <li>8.2 Monitoring</li> <li>8.3.1 (Measurement) General</li> <li>8.3.2 Key Performance Indicators</li> </ul>	<ul> <li>Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling,</li> <li>Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis</li> <li>Descriptive statistics, Sampling</li> <li>Descriptive statistics, Gauge R&amp;R, Analysing Distributions Probability and Hazard Planning, Basic Control Charts,Process capability analysis, Sampling, Time series analysis, Reliability analysis, Sampling, Time series analysis, Reliability analysis</li> </ul>
<ul> <li>7.6 Control of Monitoring and Measuring Equipment</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.4 Monitoring and Measurement of Product</li> <li>8.2 Monitoring and Measurement</li> <li>8.2.1 Customer Satisfaction</li> <li>8.2.3 Monitoring and Measurement of Processes</li> <li>8.2.3 Internal Audit</li> </ul>	<ul> <li>8.2 Monitoring</li> <li>8.3.1 (Measurement) General</li> <li>8.3.2 Key Performance Indicators</li> <li>8.3.3 Internal Audit</li> </ul>	<ul> <li>Fishbone Diagram, Cause-and- Effect Measurement analysis, Process capability analysis, Sampling,</li> <li>Descriptive statistics, Design of Experiments Hypothesis testing, Measurement analysis, Process capability analysis, Sampling, SPC charts, Time series analysis, Reliability analysis</li> <li>Descriptive statistics, Sampling</li> <li>Descriptive statistics, Gauge R&amp;R, Analysing Distributions Probability and Hazard Planning, Basic Control Charts,Process capability analysis, Sampling, Time series analysis, Reliability analysis, Sampling, Time series analysis, Reliability analysis</li> <li>Descriptive statistics,</li> </ul>

8.4. Analysis of Data	8.4. Analysis	Multivariate Charts, Boxplots,
		Hypothesis Testing,
		Comparison Tests,
		Bootstraping, ANOVA, Linear
		Regression
8.5. Improvement	9.1 (Improvement,	Design of Experiments,
	Innovation and Learning)	Response Surface
	General	Methodology, Taguchi Design
8.5 Improvement	9.2. Improvement	Design of Experiments,
		Response Surface
		Methodology, Taguchi Design
7.3. Design and	9.3. Innovation	Design of experiments, TRIZ,
Development		

Table 1.1 The Corresponce between ISO 9004 and the Six-sigma Methods

## **Conclusion:**

The Six-Sigma techniques mentioned in Table 1.1 are neither complete nor exhaustive , and do not prevent the use of any other tehnique which can be useful to the organization. For further study; the advantages, disadvantages, application examples of each method can be studied. Moreover; a check-list for evaluation of the maturity level can be prepared by using the Six-Sigma tools.

### References:

- 1. ISO 9001, Quality Management Systems Requirements
- 2. ISO 9004, Quality Management Systems Guidelines for Performance Improvement
- 3. ISO/TR 10017, Guidance on Statistical techniques for ISO 9001:2000
- 4. Breyfogle, Forest (2000), Implementing Six Sigma: Smarter Solutions Using Statistical Methods, John Wiley & Sons, New Jersey