

## Statistisk Kvalitetsstyrning 5.0 poäng (TMS070/MSN320)

Jan Rohlén  
jan.rohlen@varians.se

Erik Ehrling  
ehrling@math.chalmers.se

---

---

---

---

---

---

---

---

## Kvalitet

- **Kvalitet:**
  - en produkts eller tjänsts kvalitet är dess förmåga att tillfredställa kundernas behov och förväntningar.
- **Specifikationskvalitet:**
  - Konstruktionens inneboende förmåga att tillfredsställa kundens förväntningar och behov.
- **Utförandekvalitet:**
  - Graden av överensstämmelse mellan varan och de specifikationer den är tillverkad efter.

---

---

---

---

---

---

---

---

## Kvalitetsbristkostnader

- Sörqvist: "de kostnader som skulle försvinna om ett företags produkter och dess olika verksamheter vore fullkomliga"
- 10-30% av verksamhetens omsättning.

---

---

---

---

---

---

---

---

## Många olika definitioner

### Garvin 8 dimensioner

1. Performance
2. Reliability
3. Durability
4. Serviceability
5. Aesthetics
6. Features
7. Perceived Quality
8. Conformance to Standards

---

---

---

---

---

---

---

---

#### Definition

Quality means fitness for use.

- This is a traditional definition
- Quality of design
- Quality of conformance

---

---

---

---

---

---

---

---

#### Definition

Quality is inversely proportional to variability.

This is a modern definition of quality

#### Definition

Quality improvement is the reduction of variability in processes and products.

---

---

---

---

---

---

---

---

## 1-2. History of Quality Improvement

**Table 1-1** A Timeline of Quality Methods

1700–1900	Quality is largely determined by the efforts of an individual craftsman. Eli Whitney introduces standardized, interchangeable parts to simplify assembly.
1875	Frederick W. Taylor introduces “Scientific Management” principles to divide work into smaller, more easily accomplished units—the first approach to dealing with more complex products and processes. The focus was on productivity. Later contributors were Henry Gilbreth and Frank Gantt.
1900–1930	Henry Ford—the assembly line—further refinement of work methods to improve productivity and quality; Ford developed mistake-proof assembly concepts, self-checking, and in-process inspection.
1901	First standards laboratories established in Great Britain.
1907–1908	AI&T begins systematic inspection and testing of products and materials.
1908	W.S. Gosset (writing as “Student”) introduces the <i>t</i> -distribution—results from his work on quality control at Guinness Brewery.
1915–1919	WWI—British government begins a supplier certification program.
1919	Technical Inspection Association is formed in England; this later becomes the Institute of Quality Assurance.
1920s	AI&T Bell Laboratories forms a quality department—emphasizing quality, inspection and test, and product reliability. B. P. Dudding at General Electric in England uses statistical methods to control the quality of electric lamps.
1922–1923	R.A. Fisher publishes series of fundamental papers on designed experiments and their application to the agricultural sciences.
1924	W.A. Shewhart introduces the control chart concept in a Bell Laboratories technical memorandum.
1928	Acceptance sampling methodology is developed and refined by H. F. Dodge and H. G. Romig at Bell Labs.
1931	W.A. Shewhart publishes <i>Economic Control of Quality of Manufactured Product</i> —outlining statistical methods for use in production and control chart methods.
1932	W.A. Shewhart gives lectures on statistical methods in production and control charts at the University of London.
1932–1933	British textile and woolen industry and German chemical industry begin use of designed experiments for product/process development.
1933	The Royal Statistical Society forms the Industrial and Agricultural Research Section.

1938	W.E. Deming invites Shewhart to present seminars on control charts at the U.S. Department of Agriculture Graduate School.
1940	The U.S. War Department publishes a guide for using control charts to analyze process data.
1940–1943	Bell Labs develop the forerunners of the military standard sampling plans for the U.S. Army.
1942	In Great Britain, the Ministry of Supply Advising Service on Statistical Methods and Quality Control is formed.
1942–1946	Training courses on statistical quality control are given to industry; more than 15 quality societies are formed in North America.
1944	<i>Industrial Quality Control</i> begins publication.
1946	The American Society for Quality Control (ASQC) is formed as the merger of various quality societies. The International standards organization (ISO) is founded. Deming is invited to Japan by the Economic and Scientific Services Section of the U.S. War Department to help occupation forces in rebuilding Japanese industry. The Japanese Union of Scientists and Engineers (JUSE) is formed.
1946–1949	Deming is invited to give statistical quality control seminars to Japanese industry.
1948	G. Taguchi begins study and application of experimental design.
1950	Deming begins education of Japanese industrial managers; statistical quality control methods begin to be widely taught in Japan. K. Ishikawa introduces the cause-and-effect diagram.
1950s	Classic texts on statistical quality control by Eugene Grant and A. J. Duncan appear.

1951	A. V. Feigenbaum publishes the first edition of his book, <i>Total Quality Control</i> . JUSE establishes the “Deming Prize” for significant achievement in quality control and quality methodology.
1951+	G. E. P. Box and K. B. Wilson publish fundamental work on using designed experiments and response surface methodology for process optimization; focus is on chemical industry. Applications of designed experiments in the chemical industry grow steadily after this.
1954	Joseph M. Juran is invited by the Japanese to lecture on quality management and improvement. British statistician E. S. Page introduces the cumulative sum (CUSUM) control chart.
1957	J. M. Juran and F. M. Gryna’s <i>Quality Control Handbook</i> is first published.
1959	<i>Technometrics</i> (a journal of statistics for the physical, chemical, and engineering sciences) is established; J. Stuart Hunter is the founding editor. S. Roberts introduces the exponentially weighted moving average (EWMA) control chart. The U.S. manned spaceflight program makes industry aware of the need for reliable products; the field of reliability engineering grows from this starting point.
1960	G. E. P. Box and J. S. Hunter write fundamental papers on $2^k-p$ factorial designs. The quality control circle concept is introduced in Japan by K. Ishikawa.
1961	National Council for Quality and Productivity is formed in Great Britain as part of the British Productivity Council.
1960s	Courses in statistical quality control become widespread in Industrial Engineering academic programs. Zero defects (ZD) programs are introduced in certain U.S. industries.
1969	<i>Industrial Quality Control</i> ceases publication, replaced by <i>Quality Progress</i> and the <i>Journal of Quality Technology</i> (Lloyd S. Nelson is the founding editor of <i>JQT</i> ).
1970s	In Great Britain the NCQP and the Institute of Quality Assurance merge to form the British Quality Association.
1975–1978	Books on designed experiments oriented toward engineers and scientists begin to appear. Interest in quality circles begins in North America—this grows into the total quality management (TQM) movement.

1980s	Experimental design methods are introduced to and adopted by a wider group of organizations, including electronics, aerospace, semiconductor, and the automotive industries. The works of Taguchi on designed experiments first appear in the United States.
1984	The American Statistical Association (ASA) establishes the Ad Hoc Committee on Quality and Productivity; this later becomes a full Section of the ASA. The journal <i>Quality and Reliability Engineering International</i> appears.
1986	Box and others visit Japan, noting the extensive use of designed experiments and other statistical methods.
1987	ISO publishes the first quality systems standard.
1988	The Malcolm Baldrige National Quality Award is established by the U.S. Congress. The European Foundation for Quality Management is founded; this organization administers the European Quality Award.
1989	The journal <i>Quality Engineering</i> appears. Motorola's six-sigma initiative begins.
1990s	ISO 9000 certification activities increase in U.S. industry; applicants for the Baldrige award grow steadily; many states sponsor quality awards based on the Baldrige criteria.
1995	Many undergraduate engineering programs require formal courses in statistical techniques, focusing on basic methods for process characterization and improvement.
1997	Motorola's six-sigma approach spreads to other industries.
1998	The American Society for Quality Control becomes the American Society for Quality (see <a href="http://www.asq.org">www.asq.org</a> ), attempting to indicate the broader aspects of the quality improvement field.
2000s	ISO 9000:2000 standard is issued. Supply-chain management and supplier quality become even more critical factors in business success. Quality improvement activities expand beyond the traditional industrial setting into many other areas including financial services, health care, insurance, and utilities.

---

---

---

---

---

---

---

---

---

---

---

---

## Statistical Methods

- Statistical process control (SPC)
  - Control charts, plus other problem-solving tools
  - Useful in monitoring processes, reducing variability through elimination of assignable causes
  - On-line technique
- Designed experiments (DOX)
  - Discovering the key factors that influence process performance
  - Process optimization
  - Off-line technique
- Acceptance Sampling

---

---

---

---

---

---

---

---

---

---

---

---

**Walter A. Shewart (1891-1967)**

- Trained in engineering and physics
- Long career at Bell Labs
- Developed the first control chart about 1924

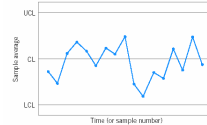




Figure 1-4 A typical control chart.

---

---

---

---

---

---

---

---

---

---

---

---

1-3 STATISTICAL METHODS FOR QUALITY CONTROL AND IMPROVEMENT

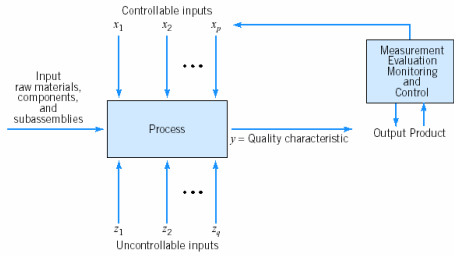


Figure 1-3 Production process inputs and outputs.

---

---

---

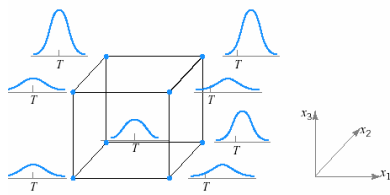
---

---

---

---

---



A factorial experiment with three factors

---

---

---

---

---

---

---

---

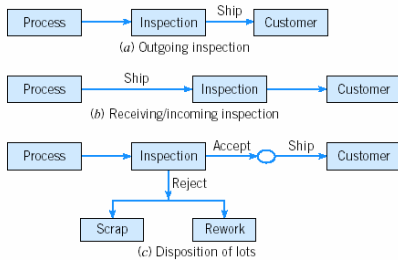


Figure 1-6 Variations of acceptance sampling.

---

---

---

---

---

---

---

---

## 1-4.1 Quality Philosophies and Management Strategies

W. Edwards Deming

- Taught engineering, physics in the 1920s, finished PhD in 1928
- Met Walter Shewhart at Western Electric
- Long career in government statistics, USDA, Bureau of the Census
- During WWII, he worked with US defense contractors, deploying statistical methods
- Sent to Japan after WWII to work on the census



---

---

---

---

---

---

---

---

## Deming

- Deming was asked by JUSE to lecture on statistical quality control to management
- Japanese adopted many aspects of Deming's management philosophy
- Deming stressed "continual never-ending improvement"
- Deming lectured widely in North America during the 1980s; he died 24 December 1993

---

---

---

---

---

---

---

---

## Deming's 14 Points

1. Create constancy of purpose toward improvement
2. Adopt a new philosophy, recognize that we are in a time of change, a new economic age
3. Cease reliance on mass inspection to improve quality
4. End the practice of awarding business on the basis of price alone
5. Improve constantly and forever the system of production and service
6. Institute training
7. Improve leadership, recognize that the aim of supervision is help people and equipment to do a better job
8. Drive out fear
9. Break down barriers between departments

---

---

---

---

---

---

---

---

## 14 Points cont'd

10. Eliminate slogans and targets for the workforce such as zero defects
11. Eliminate work standards
12. Remove barriers that rob workers of the right to pride in the quality of their work
13. Institute a vigorous program of education and self-improvement
14. Put everyone to work to accomplish the transformation

**Note that the 14 points are about change**

---

---

---

---

---

---

---

---

---

---

## Six Sigma

- Use of statistics & other analytical tools has grown steadily for over 80 years
  - Statistical quality control (origins in 1920, explosive growth during WW II, 1950s)
  - Operations research (1940s)
  - FDA, EPA in the 1970's
  - TQM (Total Quality Management) movement in the 1980's
  - Reengineering of business processes (late 1980's)
  - Six-Sigma (origins at Motorola in 1987, expanded impact during 1990s to present)

---

---

---

---

---

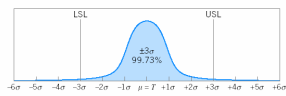
---

---

---

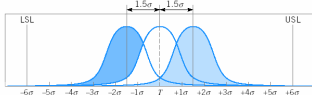
---

---



Spec. Limit	Percent Inside Specs	ppm Defective
±1 Sigma	68.27	317300
±2 Sigma	95.45	45500
±3 Sigma	99.73	2700
±4 Sigma	99.9937	63
±5 Sigma	99.999943	0.57
±6 Sigma	99.9999996	0.002

(a) Normal distribution centered at the target (T)



Spec. Limit	Percent inside specs	ppm Defective
±1 Sigma	30.23	697700
±2 Sigma	69.11	608700
±3 Sigma	93.32	66810
±4 Sigma	99.3790	6210
±5 Sigma	99.97970	23.2
±6 Sigma	99.999660	3.4

(b) Normal distribution with the mean shifted by ±1.5σ from the target

Figure 1-11 The Motorola six-sigma concept.

---

---

---

---

---

---

---

---

---

---

## Six Sigma

- A disciplined and analytical approach to process and product improvement
- Specialized roles for people: Champions, Master Black belts, Black Belts, Green Belts
- Top-down driven (Champions from each business)
- BBs and MBBs have responsibility (project definition, leadership, training/mentoring, team facilitation)
- Involves a five-step process (DMAIC) :
  - Define
  - Measure
  - Analyze
  - Improve
  - Control

---

---

---

---

---

---

---

---

## What Makes it Work?

- Successful implementations characterized by:
  - Committed leadership
  - Use of top talent
  - Supporting infrastructure
    - Formal project selection process
    - Formal project review process
    - Dedicated resources
    - Financial system integration
- Project-by-project improvement strategy (borrowed from Juran)

---

---

---

---

---

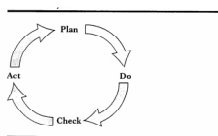
---

---

---

## Six Sigma

- DMAIC is closely related to the Shewhart cycle (variously called the Deming cycle, or the PDCA cycle)



---

---

---

---

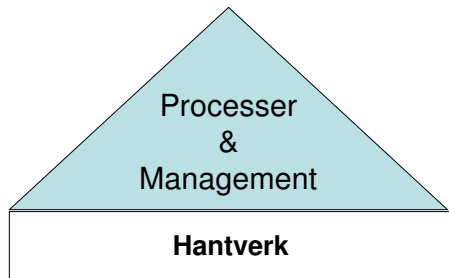
---

---

---

---

## Både process och kompetens



---

---

---

---

---

---

---

---

## Standarder och myndigheter

- ISO 9000
- QS 9000
- ISO TS 16949
- FDA
- ISO 2859
- ISO 3951
- ...

---

---

---

---

---

---

---

---

## Produktansvar

- Skadeståndslagen (vårdslöshet)
- Köplagen
- Konsumentköplagen
- Produktansvarslagen (motiverar SPS)

---

---

---

---

---

---

---

---

## Skada

- Produktskada: En skada på något annat än produkten självt.
- Exempel: TV börja brinna
  - TV'n sönder: **ej produktskada.**
  - Soffan börjar också brinna: **produktskada.**

---

---

---

---

---

---

---

---

## Produktskada lagen

*1§ Skadestånd enligt denna lag betalas för personskada som en produkt har orsakat på grund av en säkerhetsbrist.*

*Skadestånd enligt denna lag betalas också för sakskada som en produkt på grund av en säkerhetsbrist har orsakat på egendom som till sin typ vanligen är avsedd för enskilt ändamål, om den skadelidande vid tiden för skadan använde egendomen huvudsakligen för sådant ändamål. Skador på själva produkten ersätts dock inte.*

---

---

---

---

---

---

---

---

## Vad är en produkt? lagen:

*2§ Med produkter avses i denna lag lösa saker. En produkt som har infogats eller på annat sätt blivit en beståndsdel i någon annan lös egendom eller i fast egendom skall alljämt anses i lagens mening utgöra en produkt för sig.*

*Om en skada har uppstått till följd av en säkerhetsbrist hos en produkt som utgör en beståndsdel i en annan produkt, skall båda produkterna anses ha orsakat skadan.*

---

---

---

---

---

---

---

---

## Produkt

- Fast egendom ej produkt.
- Produkt i fast egendom är en produkt.
- Produkt i en produkt är en produkt.
- Råvara blir en produkt då den blir en handelsvara.
- Tjänst är ej en produkt. (Oklart om datorprogram är en produkt eller tjänst.)

---

---

---

---

---

---

---

---

## Samband produkt ↔ ansvar

- Orsakssamband mellan produkt och ansvar
- Adekvat samband
- Förutsebarhetsläran
- Exempel:
  - Gräsklipparen klipper av stortån: Adekvat
  - Gräsklipparen går sönder. Jag stukar stortån på vägen till verkstaden: ej adekvat samband.

---

---

---

---

---

---

---

---

## Ansvar för skada tre kandidater

- den skadelidande
- den som orsakat skadan
- tredje man såsom staten eller försäkringsbolag

---

---

---

---

---

---

---

---

## Ansvarsgrunder

- Vårdslöshetsansvar: skadeståndslagen:

*1 § Den som uppsåtligt eller av vårdslöshet vållar personskada eller sakskada skall ersätta skadan.*

- Strikt ansvar:

*§§ En produkt har en säkerhetsbrist, om produkten inte är så säker som skäligen kan förväntas. Säkerheten skall bedömas med hänsyn till hur produkten kunnat förutses bli använd och hur den har marknadsförts samt med hänsyn till bruksanvisningar, tidpunkt då produkten satts i omlopp och övriga omständigheter.*

---

---

---

---

---

---

---

---

## Säkerhetsbrist

- Konstruktionsfel
- Tillverkningsfel
- Informationsfel
- Utvecklingsfel
- Systemfel

---

---

---

---

---

---

---

---

## Vem är ansvarig?

- Avtal kan ej inskränka ansvaret!
- Flera kandidater: tillverkaren, importören, underleverantören,...
- Solidariskt ansvar.
- Övertagande företag.
- Enbart juridisk person.
- **Ej** privatperson eller anställd.

---

---

---

---

---

---

---

---

## Exempel på många ansvariga ur GP 27 oktober 2003

### Volvo inför rätta efter tunnelbrand

Efter den stora tunnelbranden i Mont Blanc-tunneln 1999, där en Volvovlastbil var inblandad, ställs nu företaget inför rätta. Tillsammans med 13 andra parter är företaget misstänkt för vållande till annans död.

Det var den 24 mars 1999 som den stora tunnelbranden utbröt i franska Mont Blanc, där 39 personer miste livet. Nu ställs Volvo Lastvagnar inför rätta tillsammans med tretton andra parter som också är inblandade i olyckan. Rättegången skall enligt Reuters hållas i den franska staden Bonneville i närheten av olycksplatsen. Men Volvo Lastvagnar svarar sig fri från alla brottsmisstankar.

## Ansvarsfrihet

8§ Skadeståndsskyldig enligt 6 eller 7 § är inte den som

1. visar att han inte har satt produkten i omlopp i en näringsverksamhet,
2. gör sannolikt att säkerhetsbristen inte funns när han satte produkten i omlopp,
3. visar att säkerhetsbristen beror på att produkten måste stämma överens med tvingande föreskrifter som har meddelats av en myndighet, eller
4. visar att det på grundval av det vetenskapliga och tekniska vetandet vid den tidpunkt då han satte produkten i omlopp inte var möjligt att upptäcka säkerhetsbristen.

## Hur skydda sig?

- Undvik att tillverka och sälja dåliga produkter!
- Systematiskt kvalitets- tillförlitlighets- och systemsäkerhetsarbete.
- Produktansvarsförsäkring
  - Skadestånd
  - Premien
- Avtal med andra företag om regress.

## Systemsäkerhetsarbete

- FMEA
- Felträdsanalyser
- Livslängdsanalyser
- Statistisk processtyrning
- Duglighet
- ...
- Åtgärda upptäckta risker!!!

---

---

---

---

---

---

---

---

## Produktansvarsförsäkring

- Sakskada och personskada
- En juridisk person är försäkrad.
- Täcker anställdas misstag i tjänsten.
- Täcker normal endast rättsligt ansvar, ej mer.
- Täcker ej skador på produkten.
- Kostnader för att avvärja serieskada (recall).

---

---

---

---

---

---

---

---

## Kursen

- Grunder
- Acceptansprovning
- Processtyrning
- Duglighet
- Mätssystem
- Eventuellt lite reglersystem.

---

---

---

---

---

---

---

---