



Quality management systems – Requirements

Quality standards

Kalevi Aaltonen,
Aalto University

SFS - EN ISO 9001

- 1. Introduction**
- 2. Total Quality Management (TQM) framework**
- 3. ISO 9001 quality standard**
- 4. Certification of quality system**
- 5. Case study: Leadership, quality policy**
- 6. Case study: Purchasing**
- 7. Classification of suppliers**
- 8. Case study: Nokian tyres quality project**
- 9. Case study: ABB Kent Meters Ltd**
- 10. ISO 9004 standard**
- 11. Lessons to learn – if any?**



SFS – EN ISO 9001:2015

Quality management systems - Requirements

Kalevi Aaltonen,
Aalto University



SFS - EN ISO 9001

ISO 9000 –standard family

SFS-EN ISO 9000

**Quality management systems -
Fundamentals and vocabulary**

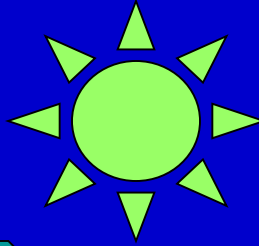
SFS – EN ISO 9001

**Quality management systems -
Requirements**

SFS – EN ISO 9004

**Managing for the sustained success of an
organization - A quality management
approach**

COMPETITORS



ISO 9001

AUTHORITIES

**OPERATION
QUALITY**

**PROCESS
QUALITY**

LIABILITIES

TQM

AWARDS

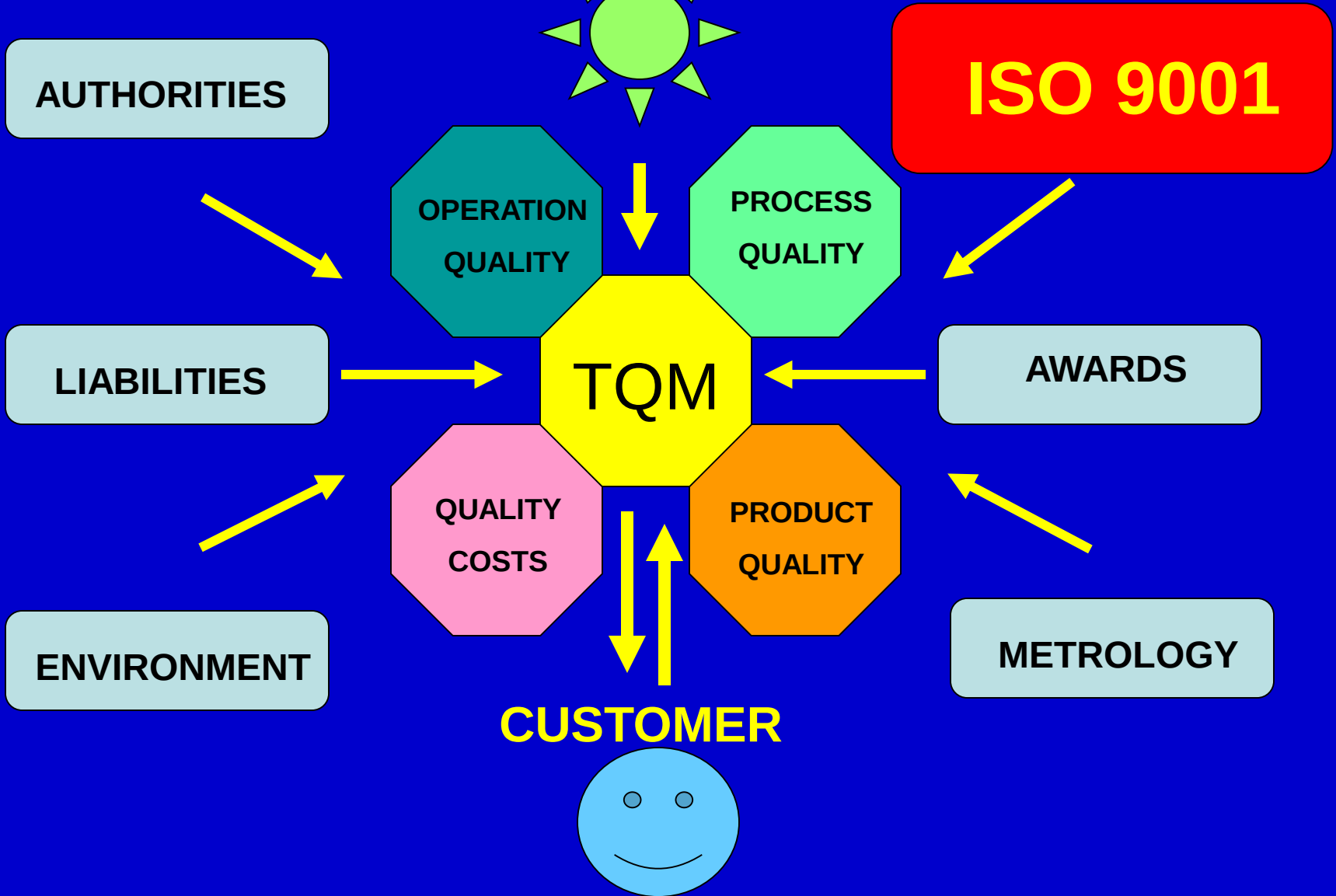
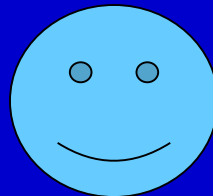
**QUALITY
COSTS**

**PRODUCT
QUALITY**

ENVIRONMENT

METROLOGY

CUSTOMER





ISO 9001



SUOMEN STANDARDISOIMISLIITTO SFS

STANDARDI

SFS-EN ISO 9001

Suomen Standardisoimisliitto SFS ry
Finnish Standards Association SFS

Vahvistettu
2015-10-05

5. painos

1 (1 + 76)

COPYRIGHT © SFS. OSITTAINENKIN JULKAISEMINEN TAI KOPIOINTI SALLITTU VAIN SFS:N LUVALLA. TÄTÄ JULKAISUA MYÖ SUOMEN STANDARDISOIMISLIITTO SFS
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SFS/ICS 03.120.10; 03.100.02; 03.100.03

Korvaa standardit SFS-EN ISO 9001:2008 ja
SFS-EN ISO 9001/AC:2009

Replaces the standards SFS-EN ISO 9001:2008 and
SFS-EN ISO 9001/AC:2009

*Ristiriitatapauksissa pätee englanninkielinen teksti.
Suomenkielisen käännöksen päivämäärä 2015-11-05*

*In case of interpretation disputes the English text applies.
Date of translation into Finnish 2015-11-05*

Laadunhallintajärjestelmät. Vaatimukset

Quality management systems. Requirements (ISO 9001:2015)

Tämä standardi sisältää eurooppalaisen standardin EN ISO 9001:2015 "Quality management systems. Requirements (ISO 9001:2015)" englanninkielisen tekstin.

This standard consists of the English text of the European Standard EN ISO 9001:2015 "Quality management systems. Requirements (ISO 9001:2015)".

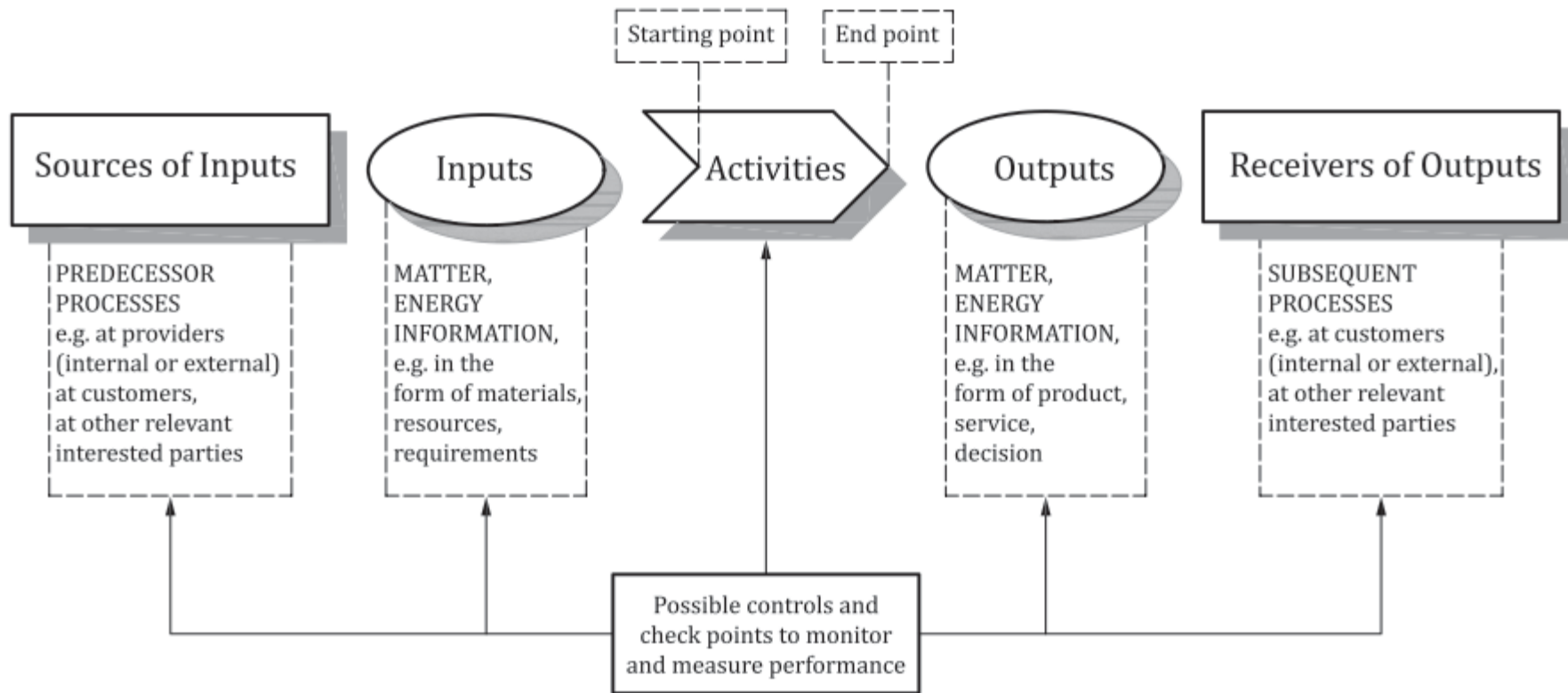
Standardi sisältää myös englanninkielisen tekstin suomenkielisen käännöksen.

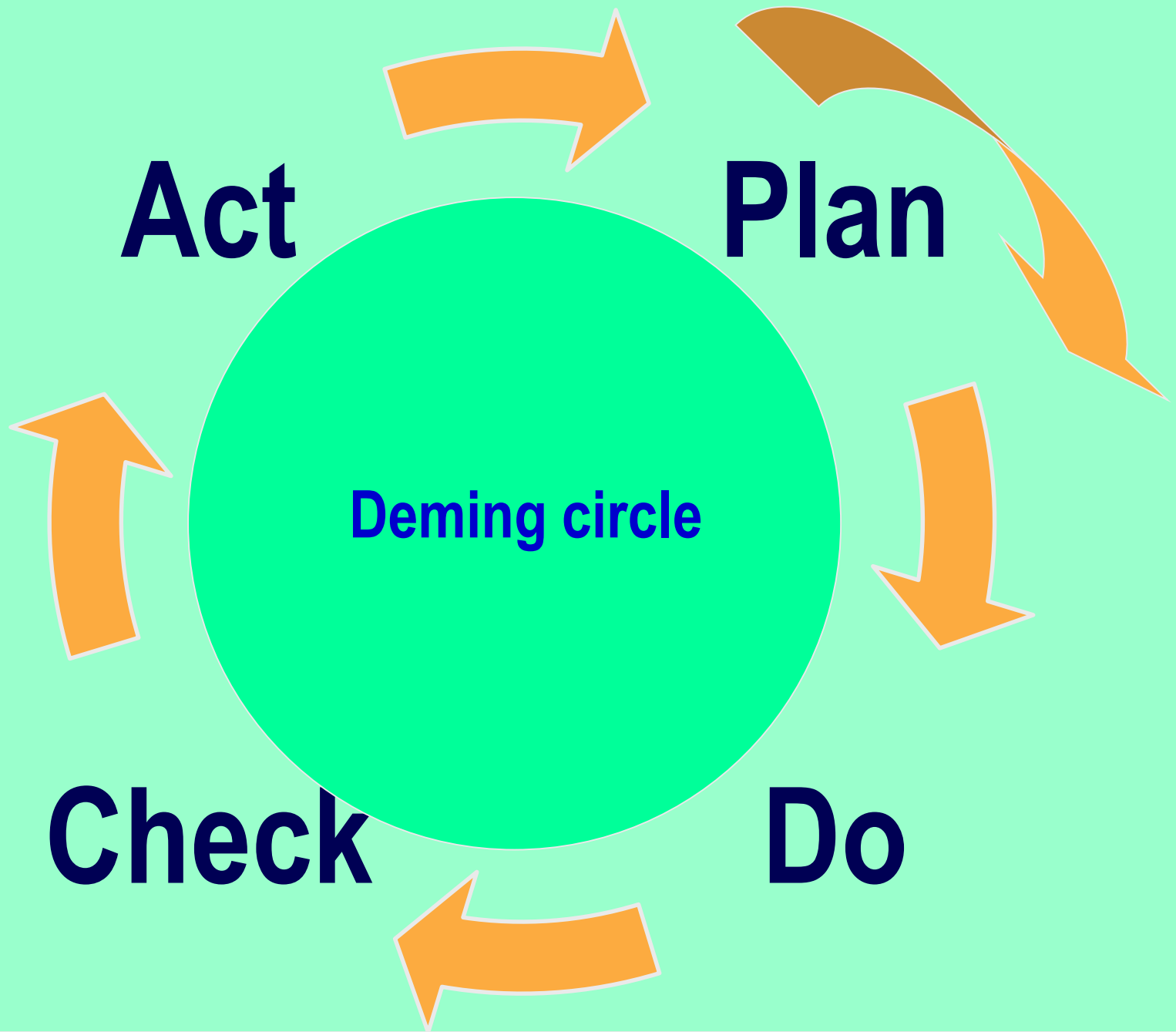
The Standard also contains a Finnish translation of the English text.

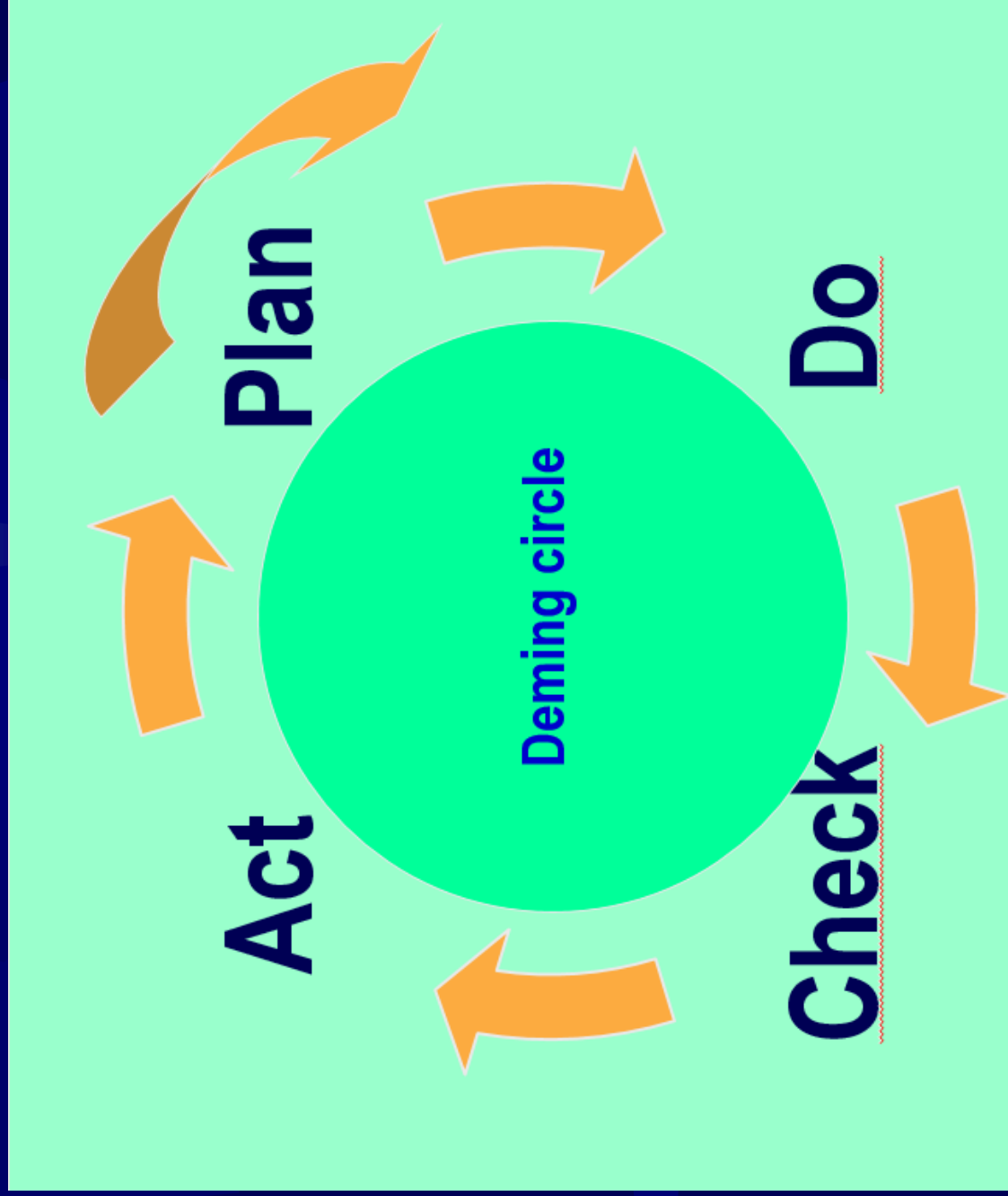
Eurooppalainen standardi EN ISO 9001:2015 on vahvistettu suomalaiseksi kansalliseksi standardiksi.

The European Standard EN ISO 9001:2015 has the status of a Finnish national standard.

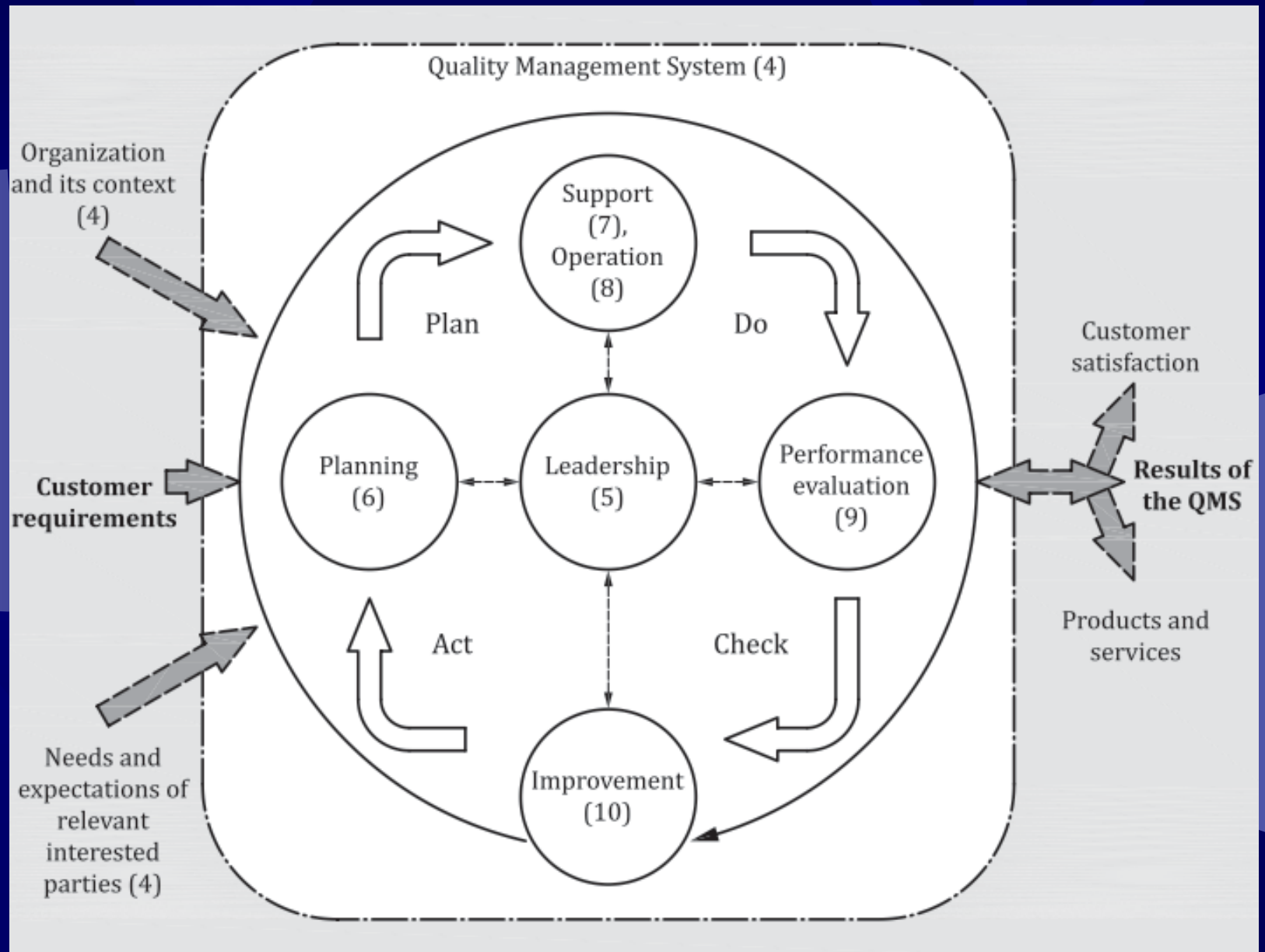
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Representation of the structure of ISO 9001 Standard in the PDCA (Plan, Do, Check, Act) -cycle



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The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

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The potential benefits are:

- a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements
- b) facilitating opportunities to enhance customer satisfaction
- c) addressing risks and opportunities associated with its context and objectives
- d) the ability to demonstrate conformity to specified quality management system requirements.

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The quality management principles are:

- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

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PROCESS APPROACH

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization.

RISK-BASED THINKING

Management of the processes and the system as a whole can be achieved using the PDCA cycle with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results.

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The application of the process approach enables:

- a) understanding and consistency in meeting requirements**
- b) the consideration of processes in terms of added value**
- c) the achievement of effective process performance**
- d) improvement of processes based on evaluation of data and information.**



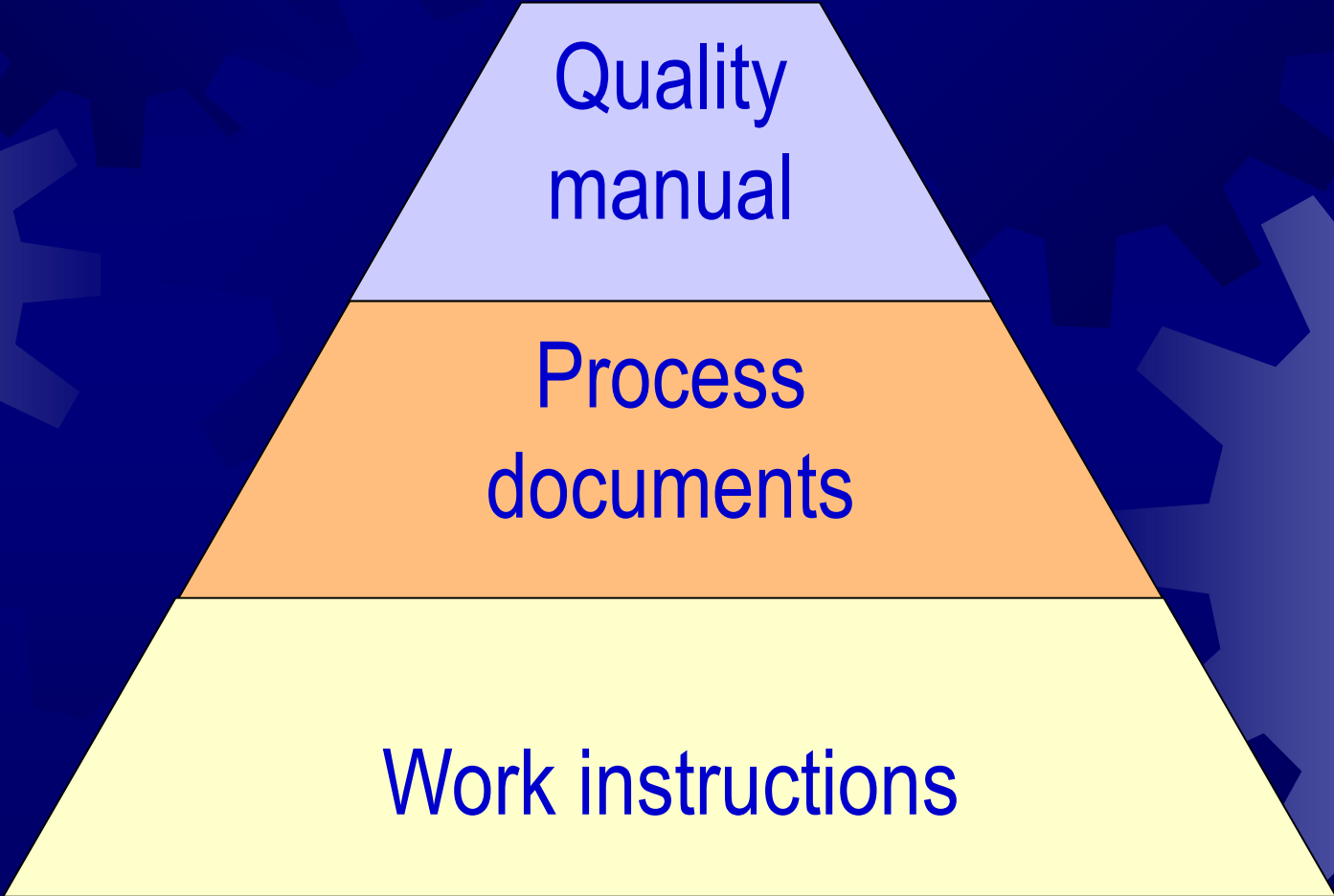
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**Where and when have you bumped
EN ISO 9001 –quality standard or
ISO 9001 –quality label**

Do you trust the label?

**How do the customer react to ISO 9001
–quality certificate?**

ISO 9001 –documented information



A pyramid diagram illustrating the hierarchy of documented information in ISO 9001. The pyramid is divided into three horizontal layers. The top layer is light blue and contains the text 'Quality manual'. The middle layer is orange and contains the text 'Process documents'. The bottom layer is yellow and contains the text 'Work instructions'. The background of the slide is dark blue with faint, large gear shapes. On the left side, there is a vertical strip with a colorful, abstract, and textured pattern.

Quality
manual

Process
documents

Work instructions



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1 Scope

2 Normative references

3 Terms and definitions

4 Context of the organization

5 Leadership

6 Planning

7 Support

8 Operation

9 Performance evaluation

10 Improvement



SFS - EN ISO 9001

1 Scope

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4 Context of the organization



4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the quality management system

4.4 Quality management system and its processes

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5 Leadership

5.1 Leadership and commitment

5.2 Policy

5.3 Organizational roles,
responsibilities and authorities



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6 Planning

6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

6.3 Planning of changes



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7 Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information



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8 Operation



8.1 Operational planning and control

8.2 Requirements for products and services

8.3 Design and development of products and services

8.4 Control of externally provided processes, products and services

8.5 Production and service provision

8.6 Release of products and services

8.7 Control of nonconforming outputs

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9 Performance evaluation

9.1 Monitoring, measurement,
analysis and evaluation

9.2 Internal audit

9.3 Management review



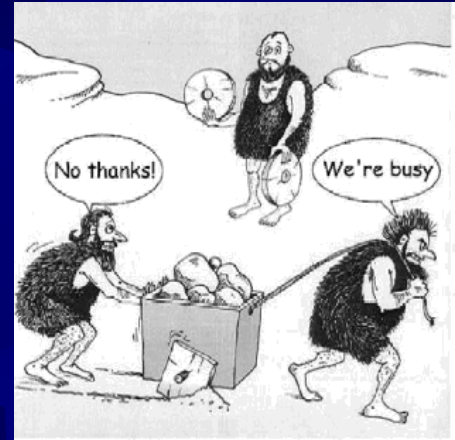
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10 Improvement

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement



SFS - CERTIFICATES



ISO 9001

[Laatujärjestelmien sertifiointi](#)



ISO 14001

[Ympäristöjärjestelmien
sertifiointi](#)



BS 7799

[Tietoturvallisuusjärjestelmien
sertifiointi](#)



OHSAS 18001

[Työterveys- ja
työturvallisuusjärjestelmien
sertifiointi](#)



[Metsien sertifiointi](#)



HACCP/DS 3027, BRC, PDV

[Elintarviketurvallisuuden sertifiointi](#)



[QWeb-verkkosivujen
sertifiointi](#)



[Puun alkuperäketjun hallinnan sertifiointi](#)

SFS - CERTIFICATES



ISO 9001:2008

**BUREAU VERITAS
Certification**



ISO 9001



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Certification costs

Preinformation	10 hours
Quality manual check	20 hours
Planning meeting	10 hours
System audit	80 hours
TOTAL	120 hours

$120 \text{ hours} * 100 \text{ euro/hour} ==> 12\,000 \text{ euro}$

Follow-up 1...2 times / year ==> 3000 euro

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Summary

ISO 9001 Standard helps to develop a practical quality system

Standard emphasizes processes, customer satisfaction and risk-based thinking and decision making

Quality certificate does not justify lazing around but gives a boost to reach the world class quality system

Certified quality system is just another investment project

Customers expect to see a certified quality system

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Case studies

1. Learn the structure of **ISO 9001** standard
2. Learn the structure of **ISO 9004** standard
3. Find out the detailed information on: **Quality policy** and compare the text in standard to company quality manuals
4. Find out the standard requirements for **Purchasing** and compare the information in company quality manuals
5. What are the requirements of the ISO 9001 for **statistical process control methods** and what is the SPC message in company quality manuals



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1 Scope

2 Normative references

3 Terms and definitions

4 Context of the organization

5 Leadership

6 Planning

7 Support

8 Operation

9 Performance evaluation

10 Improvement

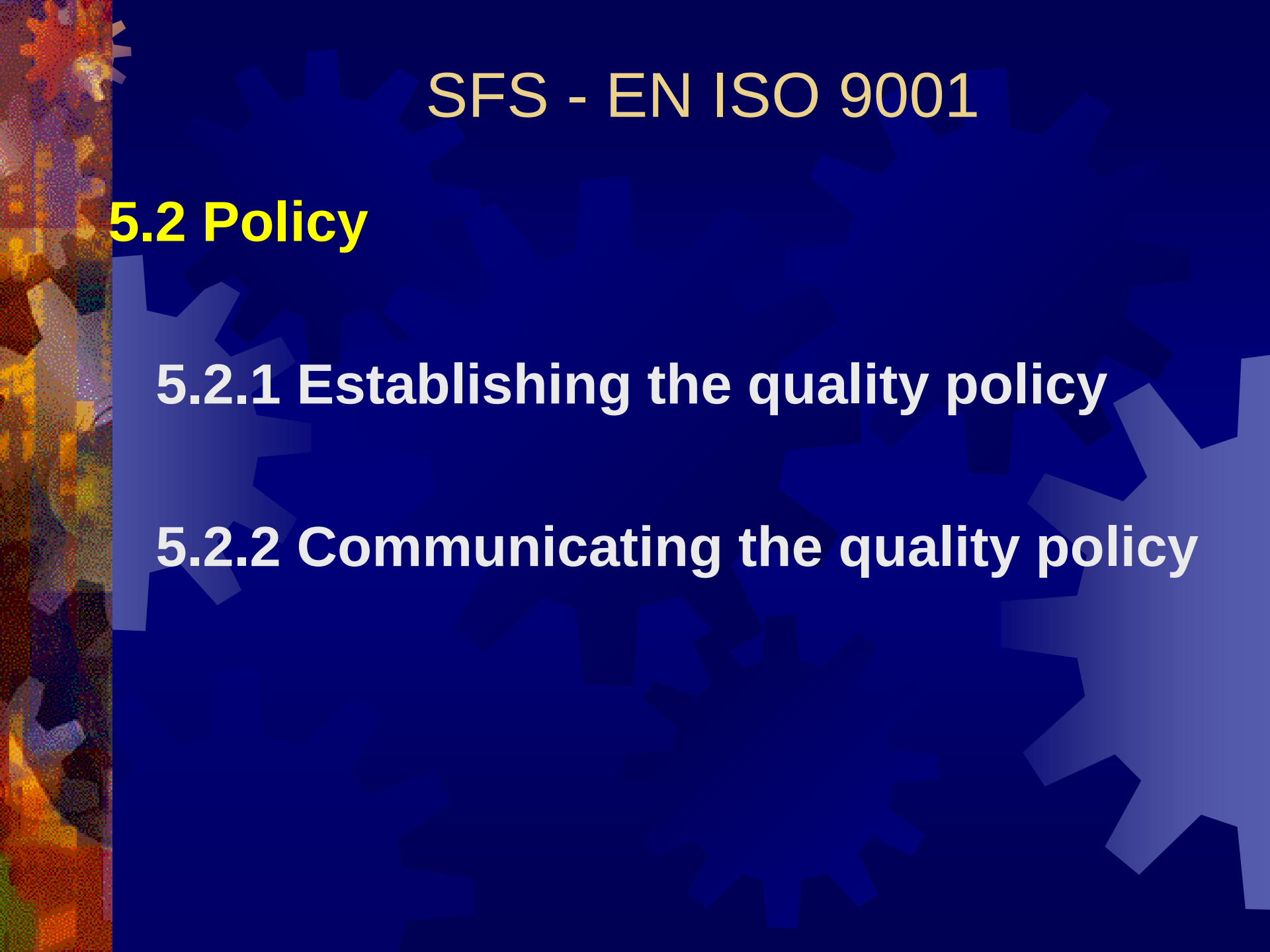
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5 Leadership

5.1 Leadership and commitment

5.2 Policy

5.3 Organizational roles,
responsibilities and authorities



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5.2 Policy

5.2.1 Establishing the quality policy

5.2.2 Communicating the quality policy

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5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

- a) is appropriate to the purpose and context of the organization and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

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5.2.2 Communicating the quality policy

The quality policy shall:

- a) be available and be maintained as documented information;
- b) be communicated, understood and applied within the organization;
- c) be available to relevant interested parties, as appropriate.

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Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system
- c) provides a framework for establishing and reviewing quality objectives
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

Grundfos, pump and the final customer





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Grundfos quality policy

The management of the company commits to follow Grundfos Group quality policy. The policy is inspected regularly to ensure the suitability. Quality policy is communicated within all organizational levels.

Konecranes



Konecranes



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Konecranes quality policy

- Our goal in making products is perform zero-defect work conformant with customer requirements
- We commit to supply products and services precisely as specified and on time
- We commit to clearly define each task, make sure information is communicated and understood accurately and perform each job properly the first time – every time
- In all our products and operations the key principle is: Reliability first!

Outotec Turulan konepaja



Outotec Turulan konepaja



Outotec Turulan konepaja





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Outokumpu Turula quality policy

Outokumpu Turula manufactures technically demanding machines and production equipment for the industry.

Our objective is to be a competitive supplier in the product groups defined in our strategy plans.

In all our activities we take into consideration customer satisfaction. We take into consideration the expectations and requirements of our customer, our personnel, authorities and other interest groups.

We continuously improve our business activities, production technology and know-how and proficiency of our personnel.



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Outokumpu Turula quality policy

Environmental, health and security issues form an integral part of our operational responsibility. We implement the guidelines defined by the Outokumpu Group.

We utilise the quality award criteria as tools to indentify the development needs in our operation and to monitor the results of the taken measures.

The management team of Outokumpu Turula Oy is committed to this quality policy and requires that all our personnel implement it.

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Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

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Purchasing information

Purchasing information shall describe the product to be purchased, including, where appropriate,

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.



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Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

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Konecranes purchasing





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Konecranes purchasing

Subcontractor policy

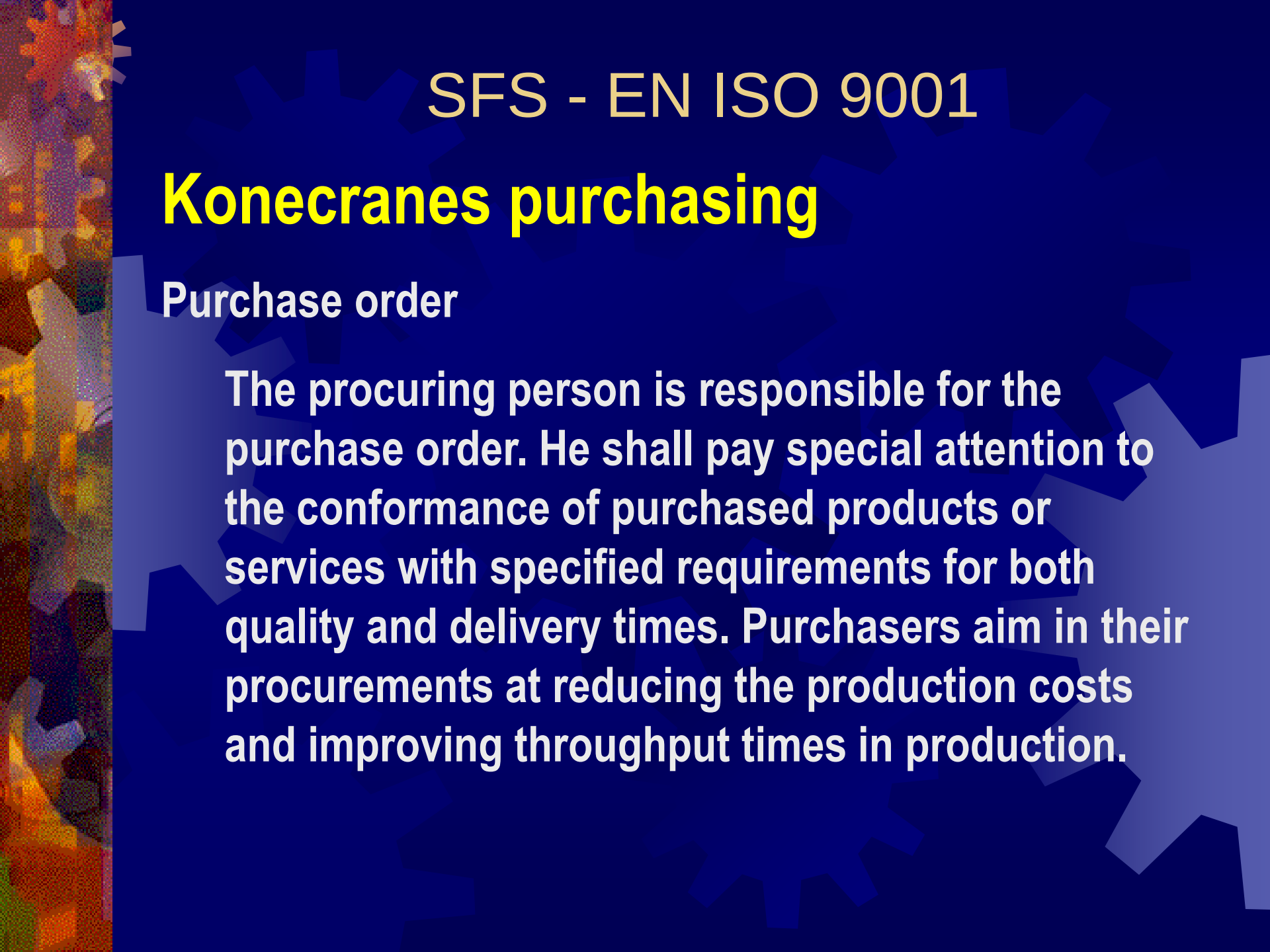
Konecranes specializes in manufacturing assemblies and components and performing work phases of proprietary know-how or sufficient volume to justify investments in maximally efficient production. All other assemblies or components are preferably subcontracted, either within Konecranes or to an outside manufacturer.

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Konecranes purchasing

Relationship with an outside manufacturer engaged via a strategic subcontracting decision, will be built for long-term cooperation whose duration is affected by:

- quality and its reliability
- delivery time and its reliability
- cooperative capability
- improvement rate in quality and volume
- price

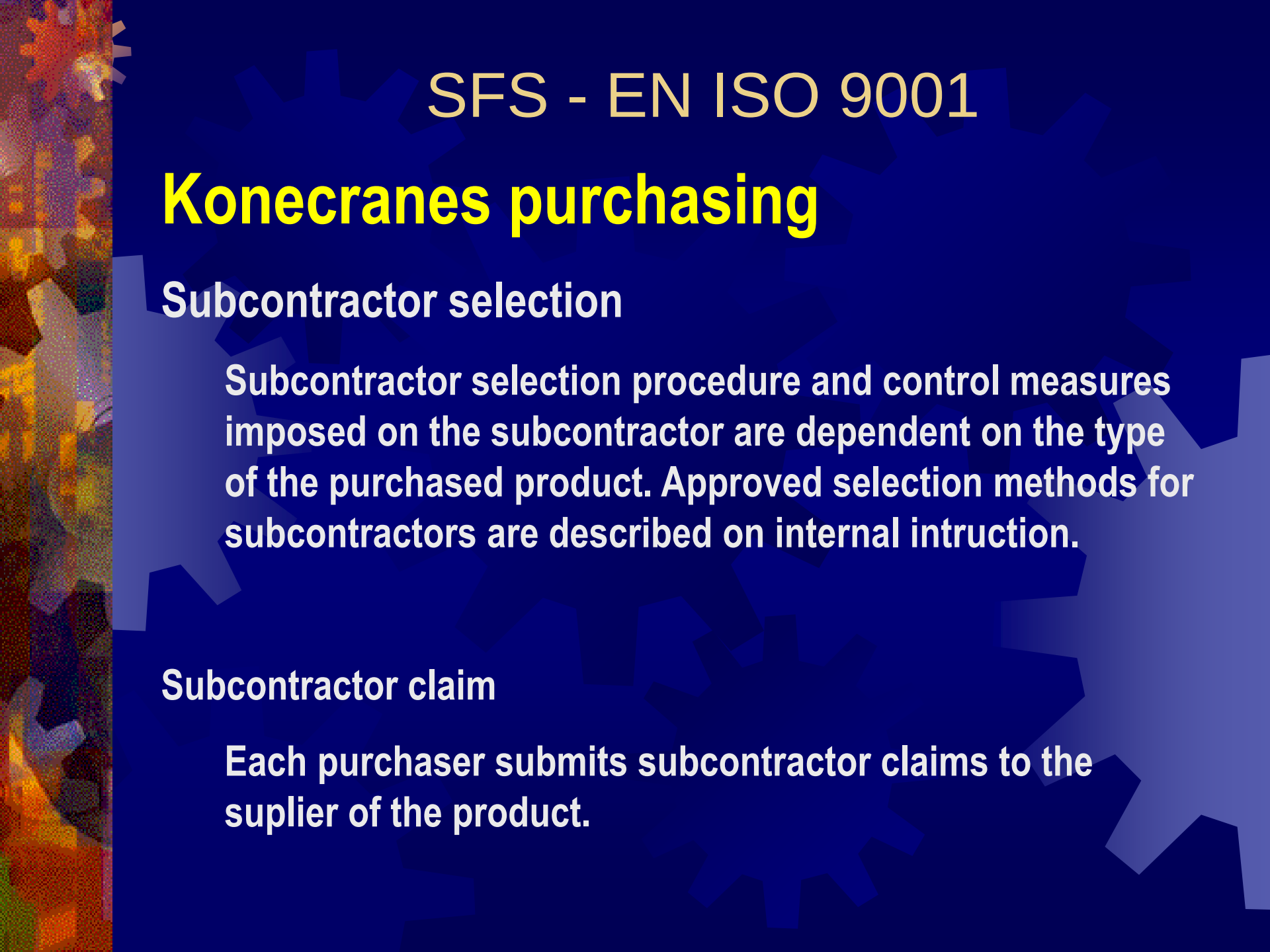


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Konecranes purchasing

Purchase order

The procuring person is responsible for the purchase order. He shall pay special attention to the conformance of purchased products or services with specified requirements for both quality and delivery times. Purchasers aim in their procurements at reducing the production costs and improving throughput times in production.



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Konecranes purchasing

Subcontractor selection

Subcontractor selection procedure and control measures imposed on the subcontractor are dependent on the type of the purchased product. Approved selection methods for subcontractors are described on internal instruction.

Subcontractor claim

Each purchaser submits subcontractor claims to the supplier of the product.

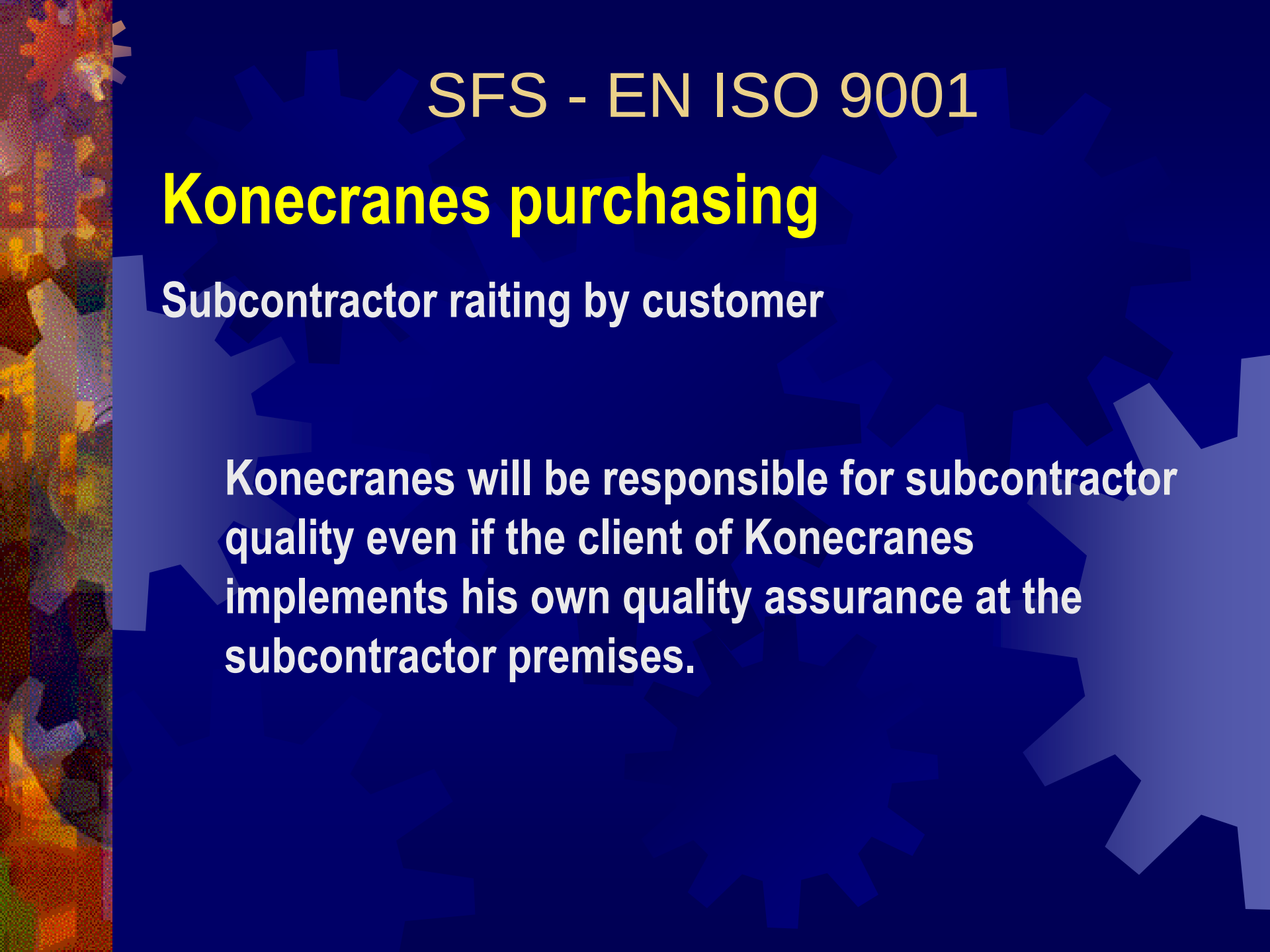
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Konecranes purchasing

Purchasing information

Purchasing initiatives are triggered by information from the materials flow control system, production planning or design. Such information contains data which unambiguously define the product or service to be procured.

The purchaser is responsible for the conformance of the purchased product or service with specifications in the order confirmation and purchase contract.



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Konecranes purchasing

Subcontractor rating by customer

Konecranes will be responsible for subcontractor quality even if the client of Konecranes implements his own quality assurance at the subcontractor premises.



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Konecranes purchasing

Billing and import forwarding

Invoice controller is responsible for verifying the correct billing of the product or service and oversees payment to subcontractor in agreed time.

Import forwarding is responsible for duty declaration of imported material and transport of material to incoming material reception.



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Purchasing

1. Selection and evaluation of suppliers
2. Purchasing information
3. Product identification and acceptance
4. Supplier feedback and claims

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1. Selection and evaluation of suppliers

- Right products, on time, competitive prices
- Audit and evaluation on suppliers quality system
- Evaluation of production processes and resources
- Evaluation of sample products
- References
- Purveyor list



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2. Purchasing information

- Technical specification
- Quality standards and authority claims
- Testing and inspection instructions
- Reclamation procedures
- Labels of products and package
- Inspection protocols
- Product liability

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3. Product identification and acceptance

- Inspection categories (knowledge about products and suppliers; quality systems)
- Written instructions
- Information and filing
- Traceability

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4. Supplier feedback and claims

- Claims on quality and delivery times
- All defective products must be returned
- Indicators: reclamation %, delivery reliability, ranking -lists
- Do not forget acknowledgements (supplier of the year award)

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Classification of suppliers



Main supplier and subcontractor award winners K.Hartwall Oy Ab managing director Vesa Tempakka and Head of Delivery Operations Christer Bauer and Comptel Oyj personnel manager Niina Pesonen.

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Classification of suppliers

1. Class

Supplier is capable to deliver products according to written quality requirements

2. Class

Supplier needs assistance and instructions in quality assurance and testing

3. Class

No demanding orders, 100 % acceptance testing



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New supplier; establishing deliveries

- Cooperation (management and specialists)
- Education and training
- Common rules and framework
- Quality consulting
- Lending measurement equipment and tools
- Cooperation in calibration activities

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Classification of suppliers



Main supplier and subcontractor award winners Rolls-Royce Oy Ab, Sourcing manager Harri Järvenpää, manager Kari Välimaa, Oy Toppi Ab, managing director Tero Toppi, salespersons Eeva-Liisa Tanskala ja Antti Kivilahti

Purchasing strategy; product classification

A. Class

Strategical components; always in house

B. Class

Flexible parts; capacity balancing, numerous alternative suppliers, price competition

C. Class

Always subcontracting = partner alliance



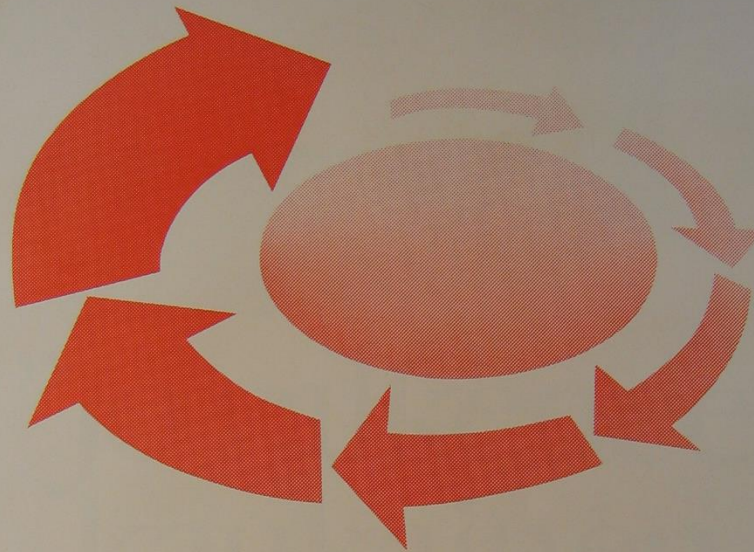
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Statistical quality control methods

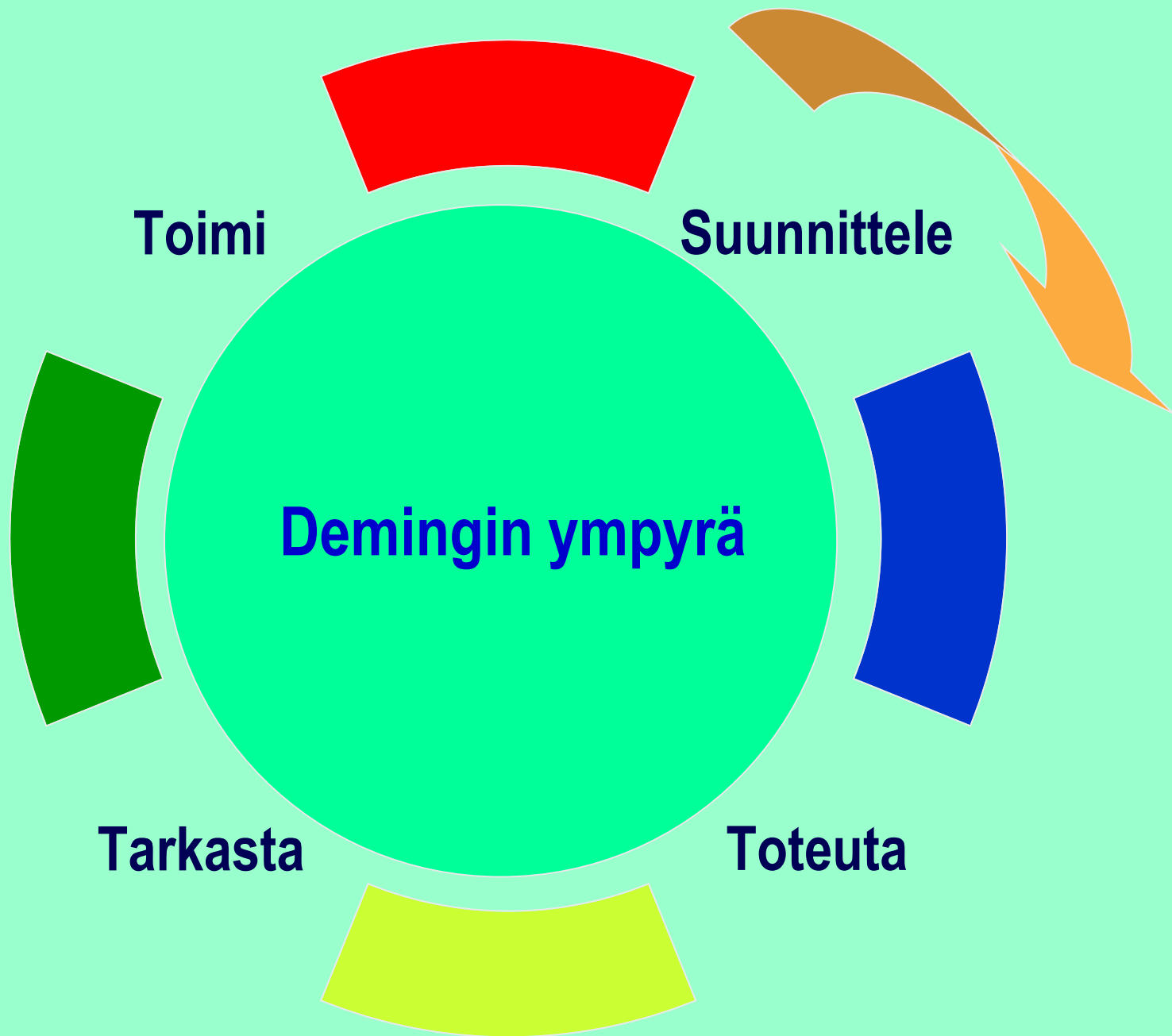


Nokian tyres – quality project





Quality circle – quality tyre
Big thing
(ISO 9001)





Quality circle (tyre) turns step by step

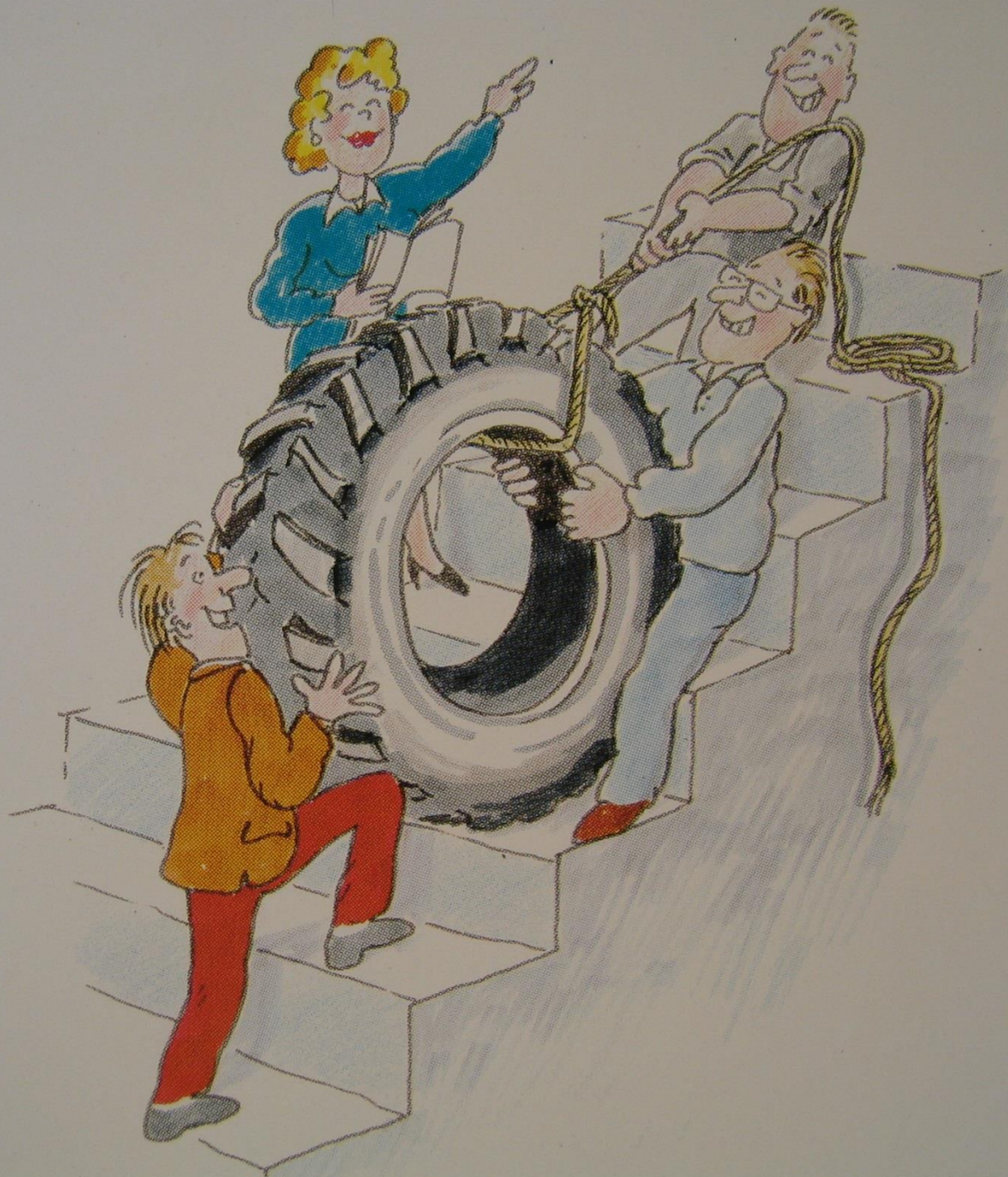
Laadun parantaminen etenee projekteittain yhteisin ponnistuksin



kerrallaan

Improving quality proceeds project by
project with common efforts





Galileo Galilei "Eppur si muove"
"And yet it moves"
"Se pyörii sittenkin"



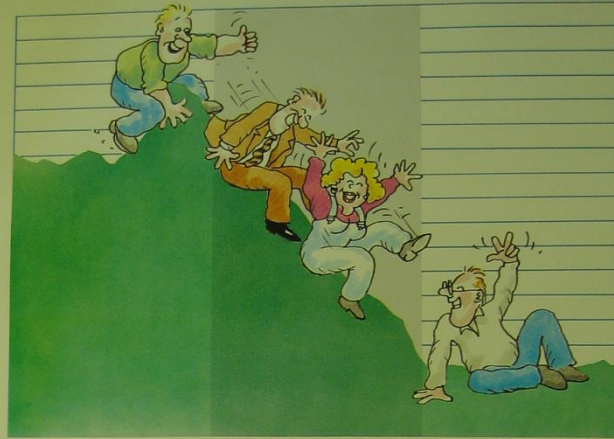
"And yet it
moves"

We need will, effort and team work
to turn the quality circle with good results



Laaturengas.
Iso asia





Costs
down by skill
not by luck

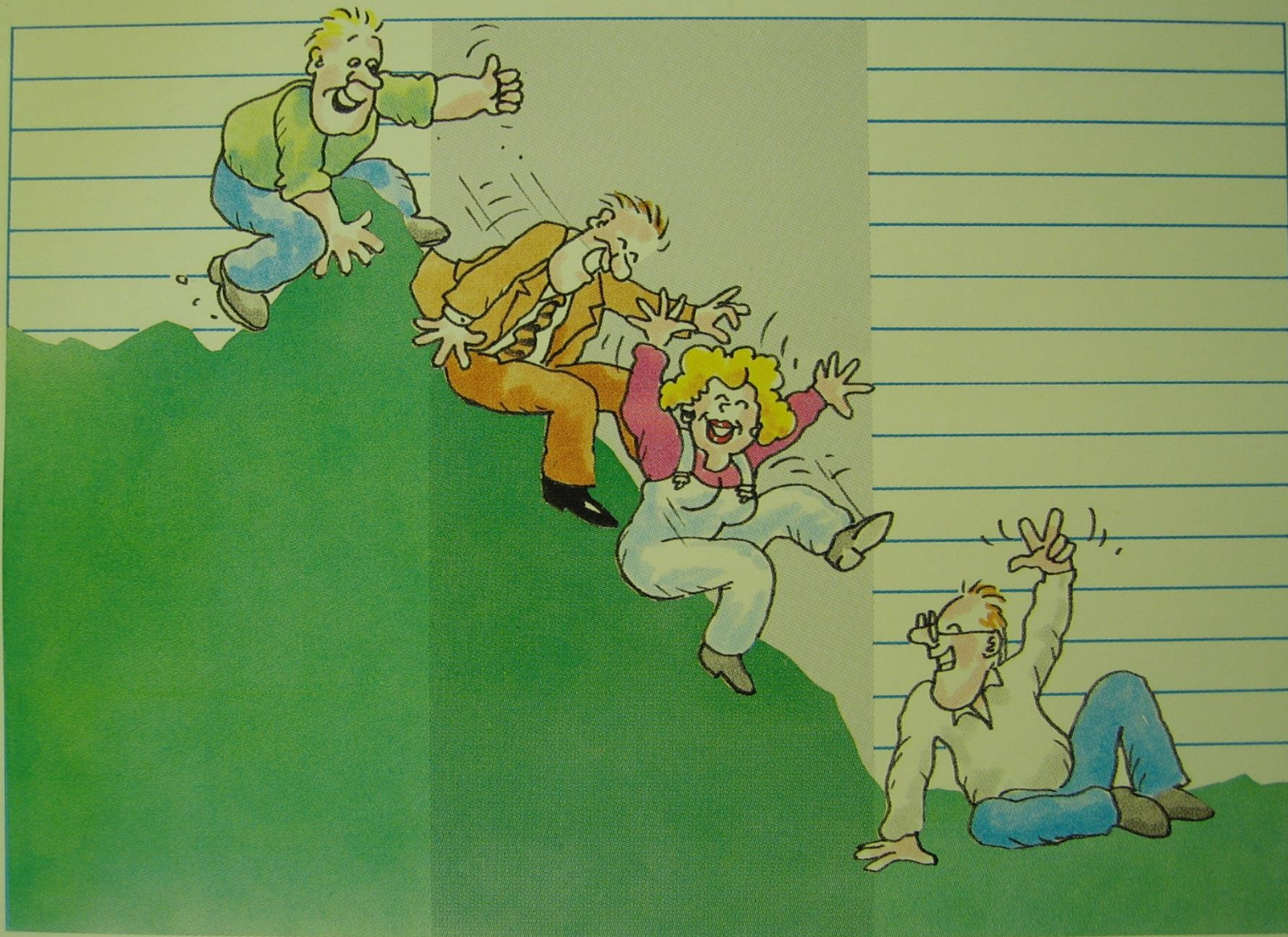
Laadulla tulosta



Quality generates profit



Laaturengas.
Iso asia





Poem by Eino Leino:
Jo valkenee kaukainen ranta ...
It dawns after all...

”The happy
ones...”

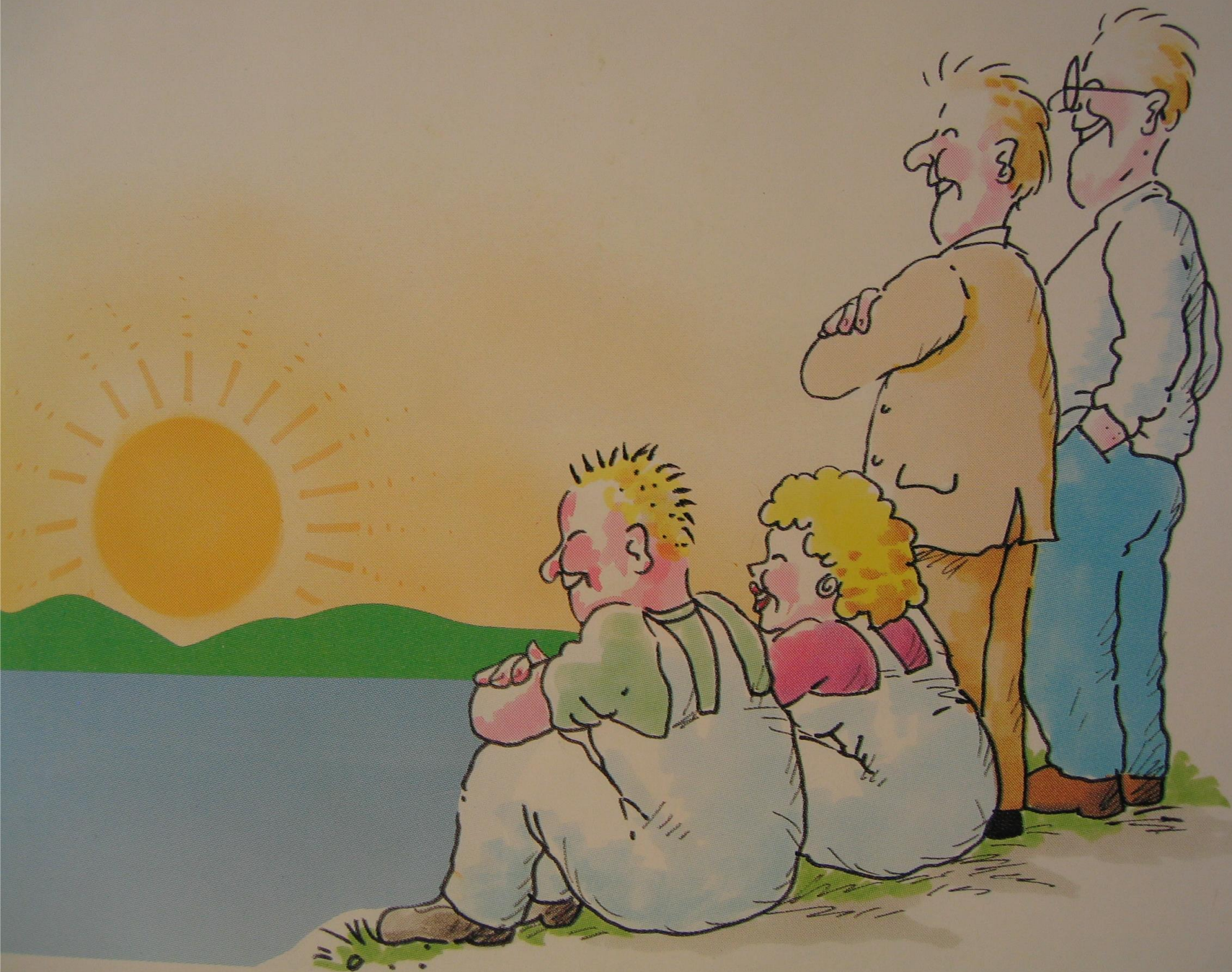
Laatutyö jatkuu.



Quality work continues



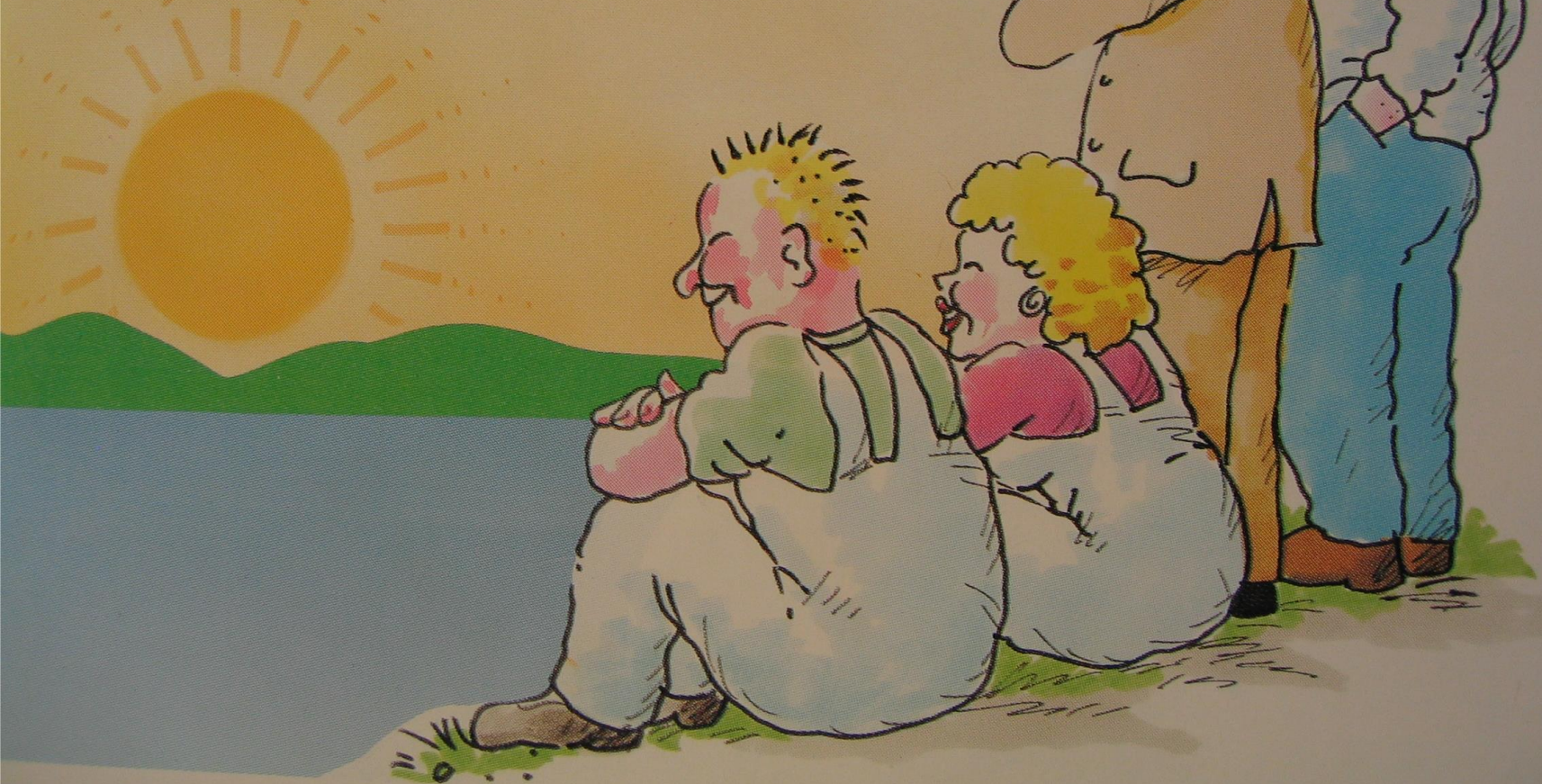
Laaturengas.
Iso asia





Lasse
Kurkilahti

Ari
Arvio





QUALITY CAMPAIGN

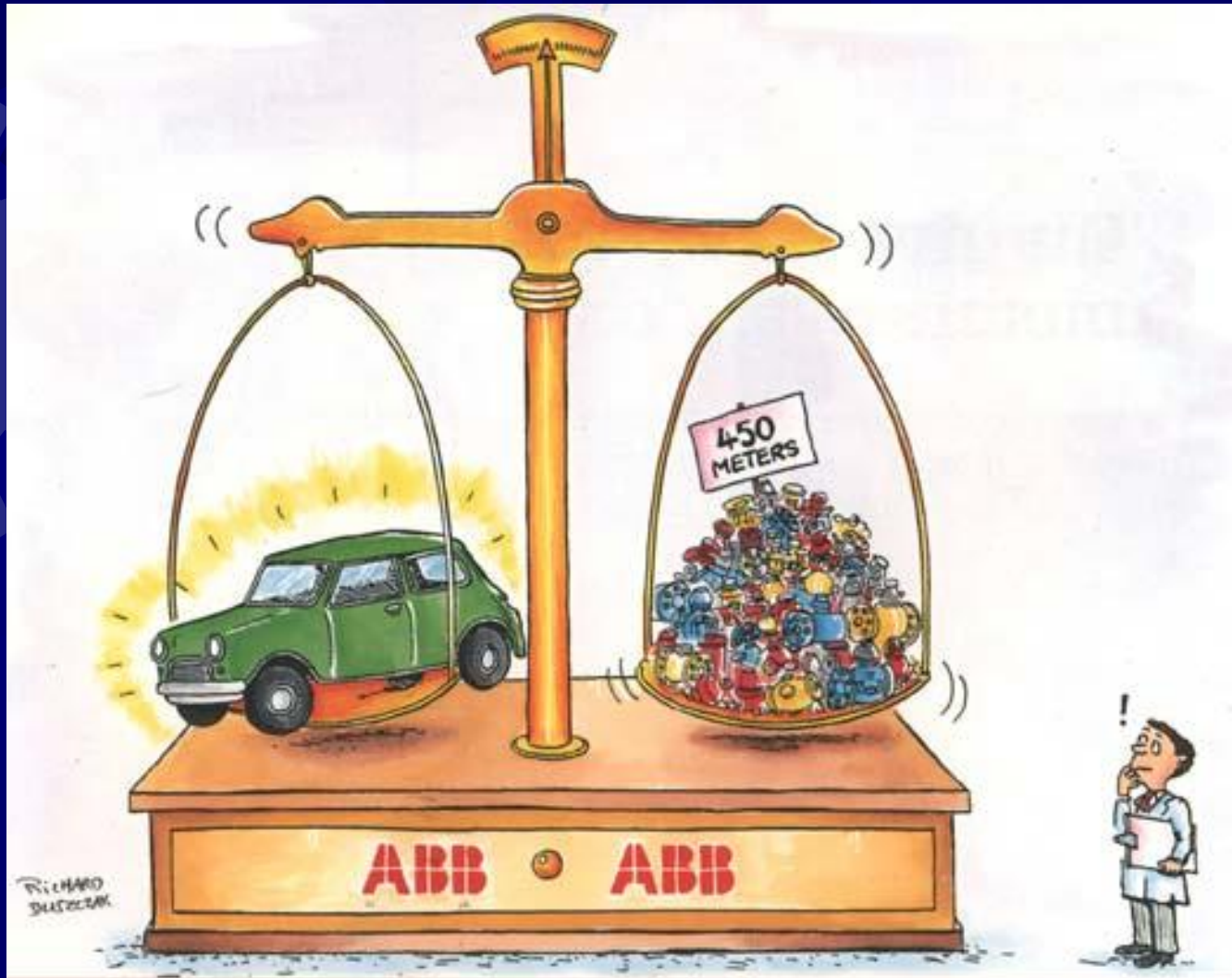
**TOTAL CUSTOMER
SATISFACTION...**

ABB Kent Meters Ltd

DRAWINGS

© Richard Duszczak

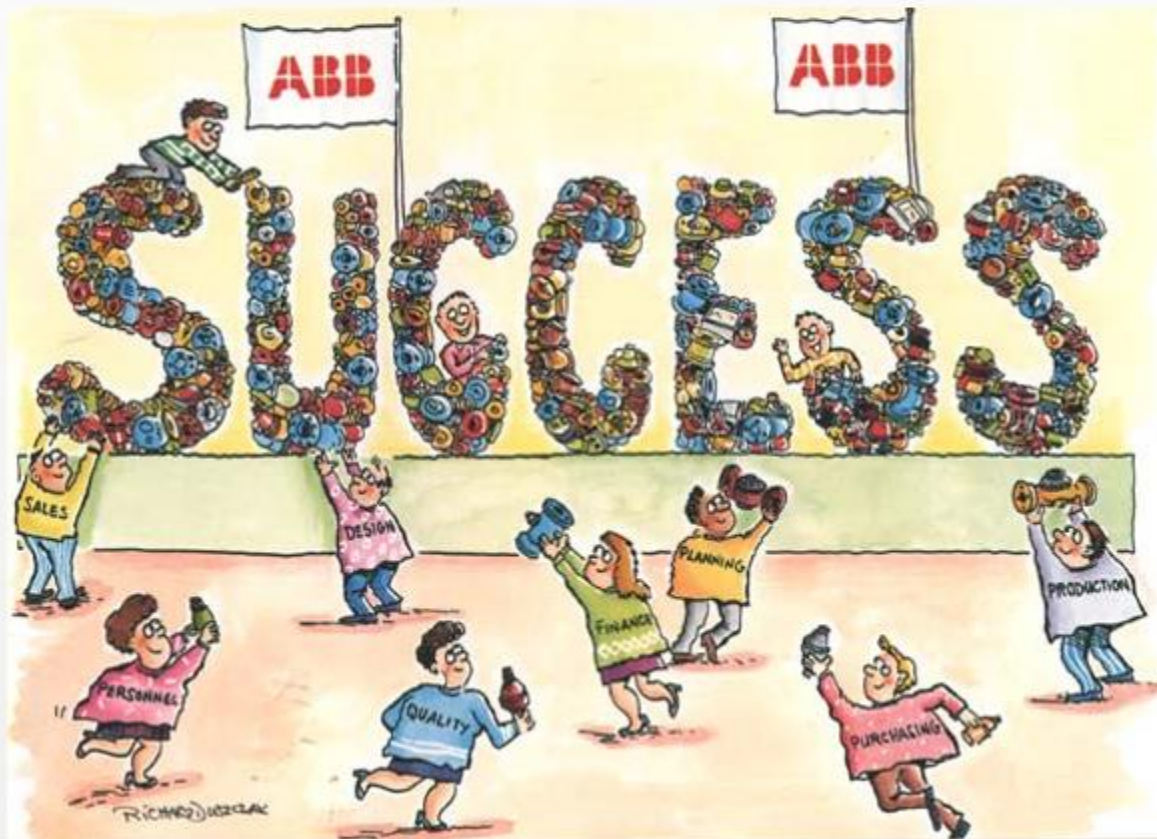
Quality costs
450 flowmeter per day = small car



"Quality is everyone's business"

We all contribute to the success of our business.

We all can contribute to making it better



"Quality improvement is a continuous process"

The journey on the road to total quality is one of continuous improvement.

As we get better, so does our competition



"We find new ways of doing things."

Groups of people are trained and are continuously working to find 'better ways of doing things'.

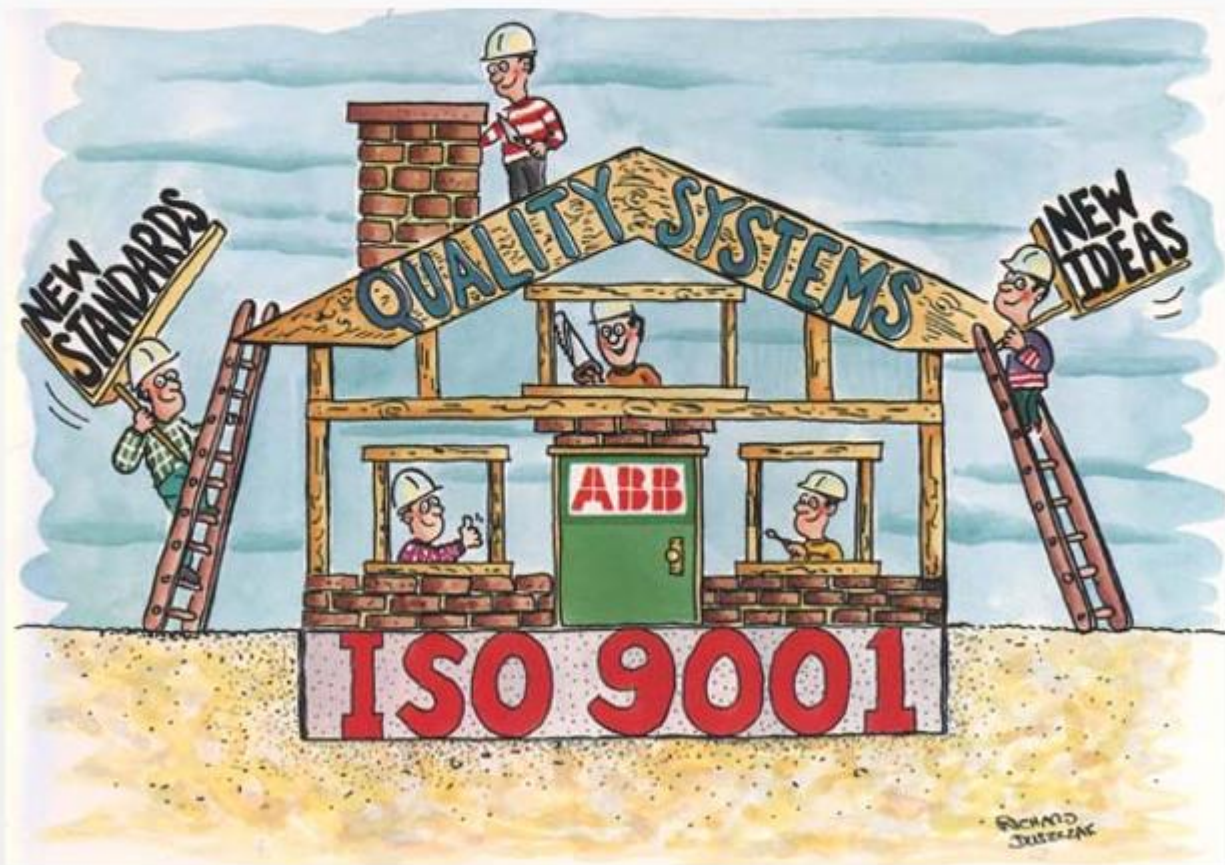
These are known as Quality Improvement Teams.



"New standards become new ideas"

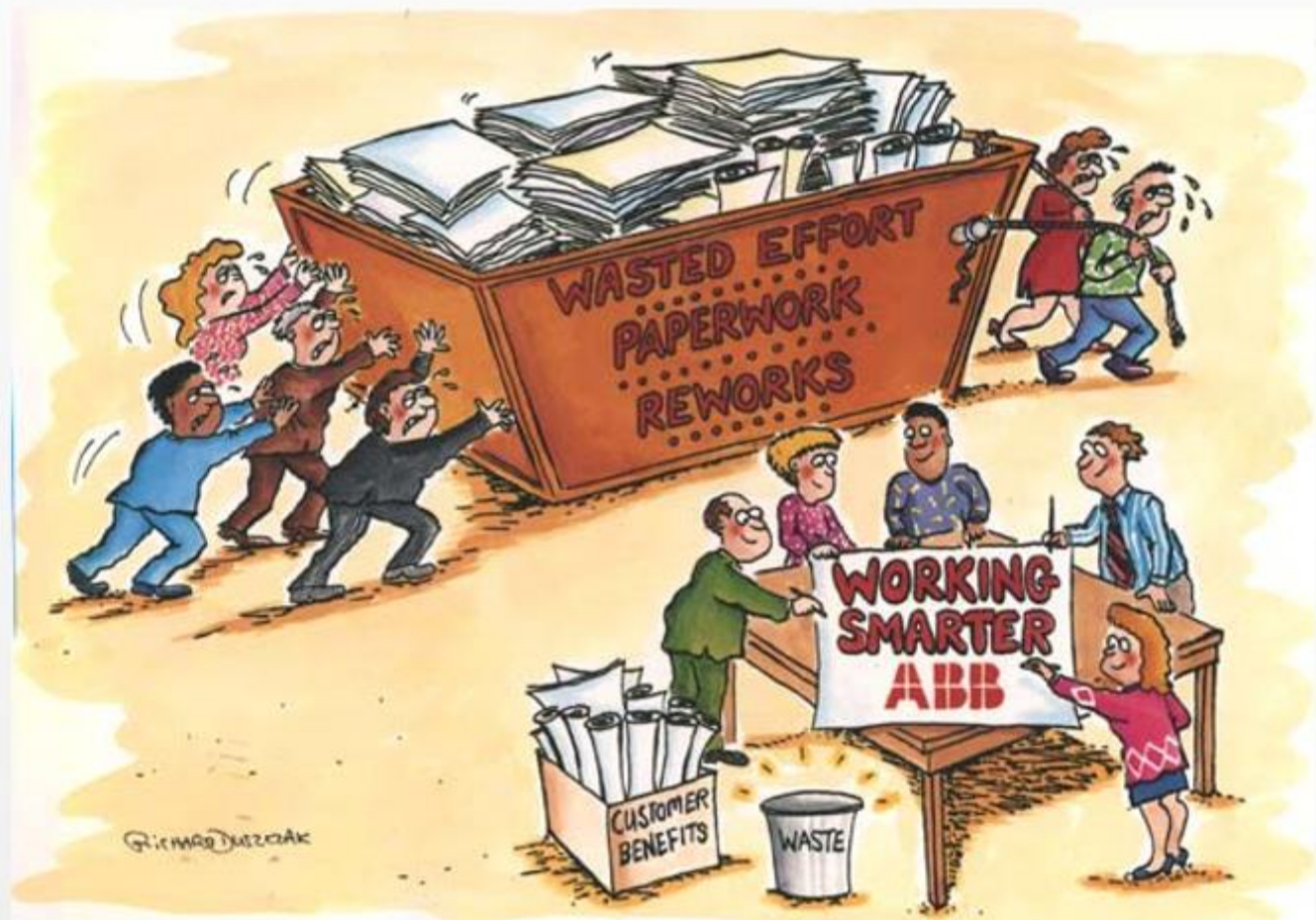
Once we have found new ways of doing things, we incorporate them in our Quality Systems.

ISO 9001 was the foundation, now we start to build the house.



"Good communications are essential"

We are working together to give total customer satisfaction, so we need to tell each other exactly what we are doing, where we are going and how we plan to get there.



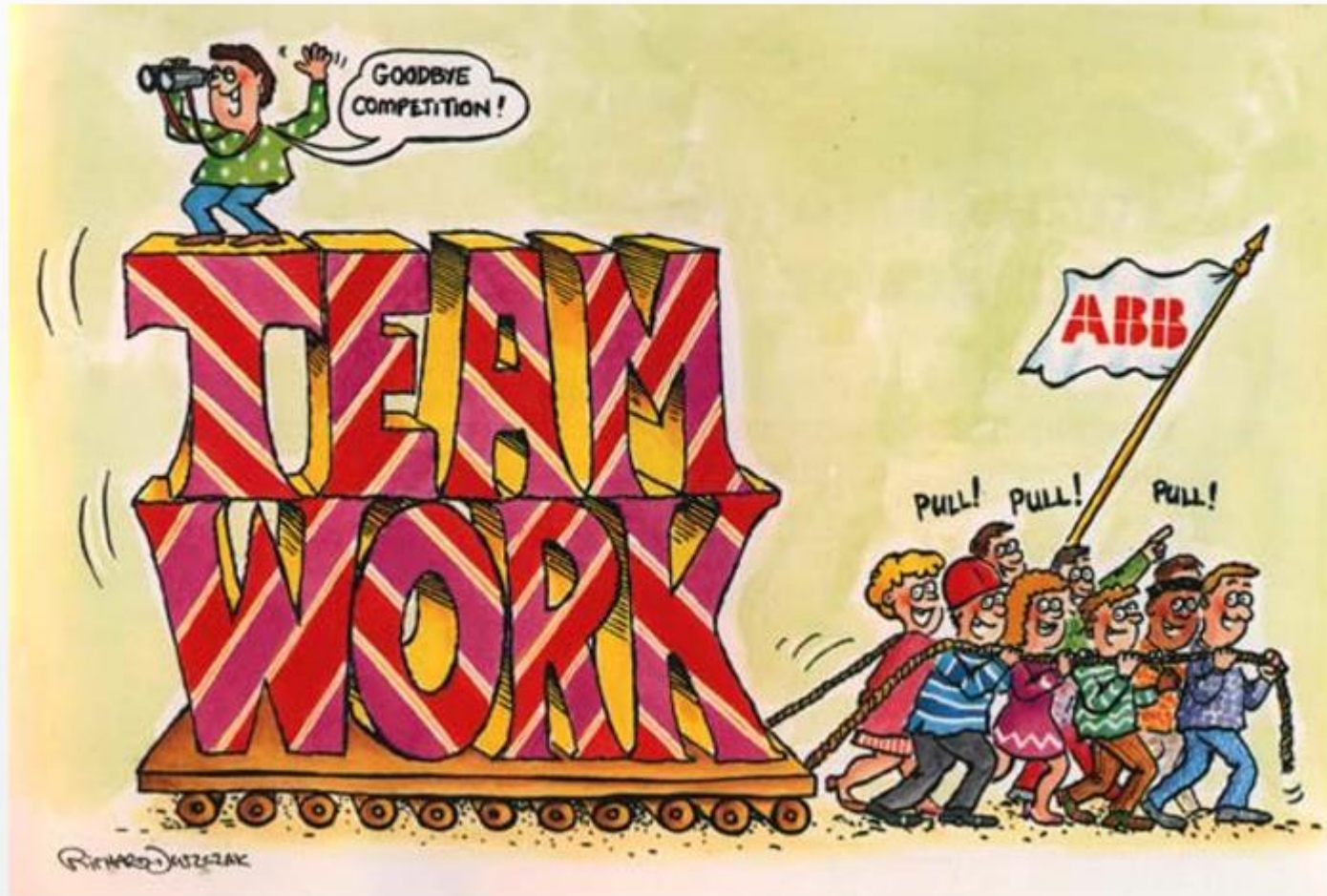
"Training for quality"

Training courses are being carried out that will provide us all with the necessary skills to identify and eliminate waste.



"Progress requires teamwork"

Total Quality Management is all about pulling together, combining skill and knowledge.



"Total customer satisfaction"

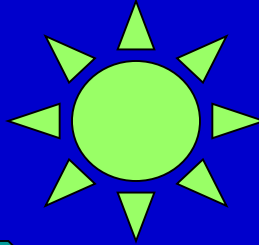
Being the best in the business will bring satisfaction, rewards and greater security to all of us.



EVERYONE'S HAPPY! (Brochure complete!)



COMPETITORS



ISO 9004



**OPERATION
QUALITY**

**PROCESS
QUALITY**

TQM

AWARDS

**QUALITY
COSTS**

**PRODUCT
QUALITY**

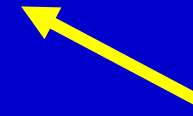
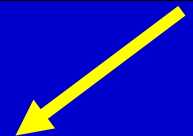
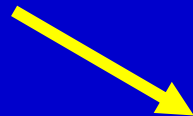
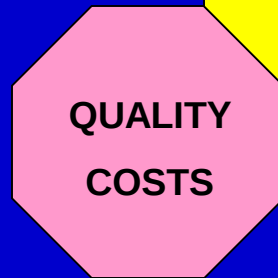
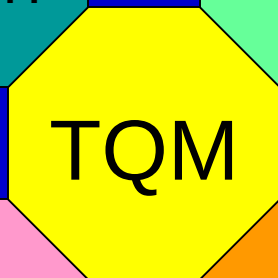
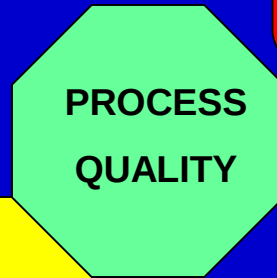
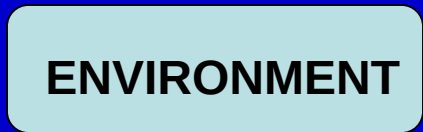
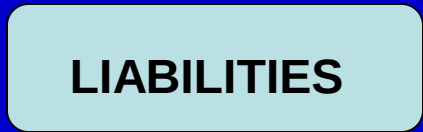
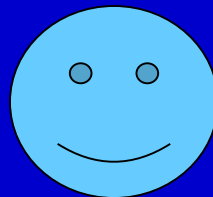
METROLOGY

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ISO 9004



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STANDARDI

SFS-EN ISO 9004

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Vahvistettu
2009-12-14

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ICS 03.120.10

Korvaa: SFS-EN ISO 9004:2001

Replaces: SFS-EN ISO 9004:2001

Tämä standardi on vahvistettu englanninkielisenä

This standard is approved in English

MANAGING FOR THE SUSTAINED SUCCESS OF AN ORGANIZATION. A QUALITY MANAGEMENT APPROACH (ISO 9004:2009)

Tämä standardi sisältää eurooppalaisen standardin EN ISO 9004:2009 "Managing for the sustained success of an organization. A quality management approach (ISO 9004:2009)" englanninkielisen tekstin.

Eurooppalainen standardi EN ISO 9004:2009 on vahvistettu suomalaiseksi kansalliseksi standardiksi.

This standard consists of the English text of the European Standard EN ISO 9004:2009 "Managing for the sustained success of an organization. A quality management approach (ISO 9004:2009)".

The European Standard EN ISO 9004:2009 has the status of a Finnish national standard.



SFS - EN ISO 9004

**MANAGING FOR THE SUSTAINED
SUCCESS OF AN ORGANIZATION.
A QUALITY MANAGEMENT APPROACH**

SFS - EN ISO 9004

Introduction

1. Scope
2. Normative references
3. Terms and definitions
4. Managing for the sustained success of an organization
5. Strategy and policy
6. Resource management
7. Process management
8. Monitoring, measurement, analysis and review
9. Improvement, innovation and learning

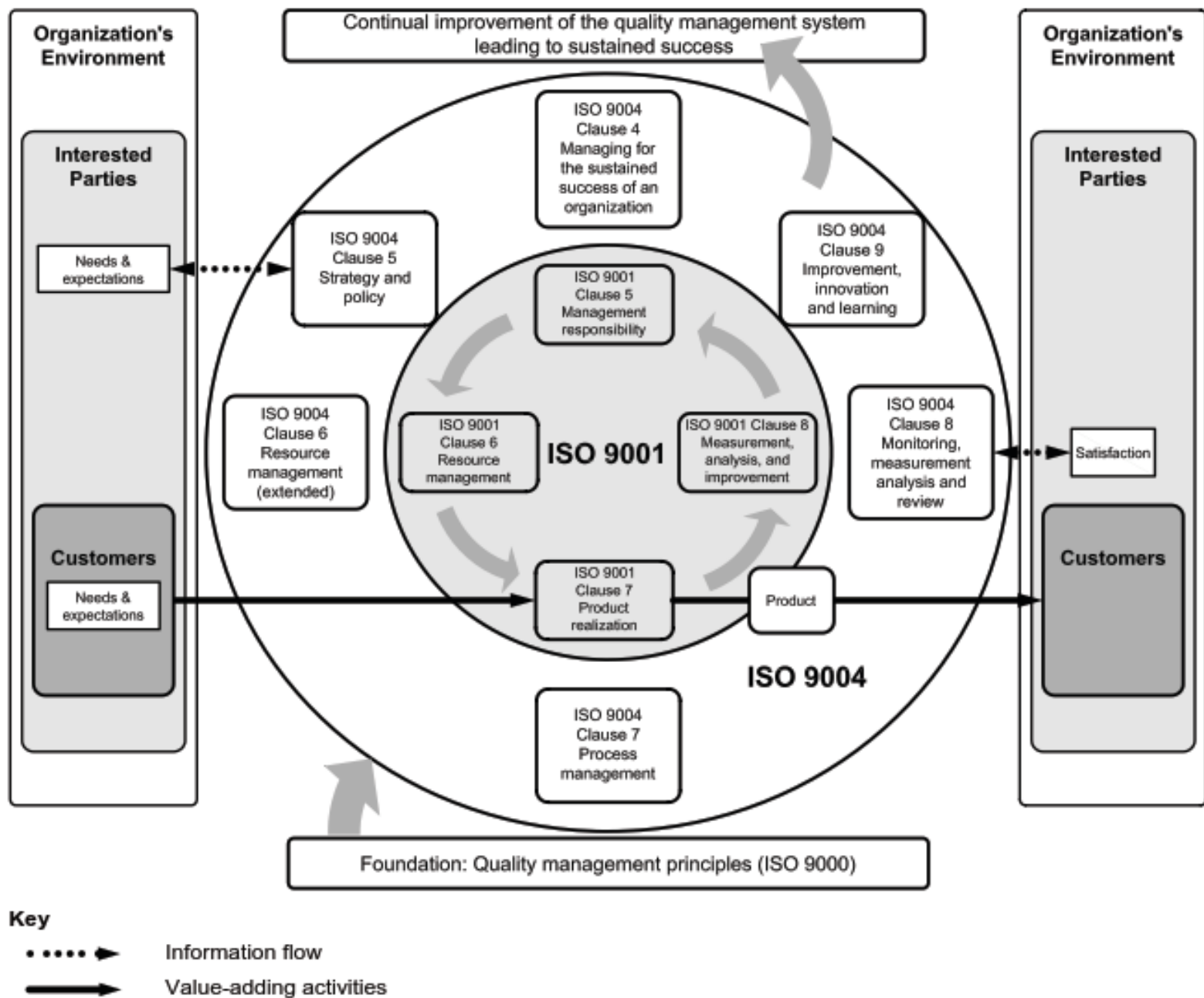


Figure 1 — Extended model of a process-based quality management system

Self-assessment

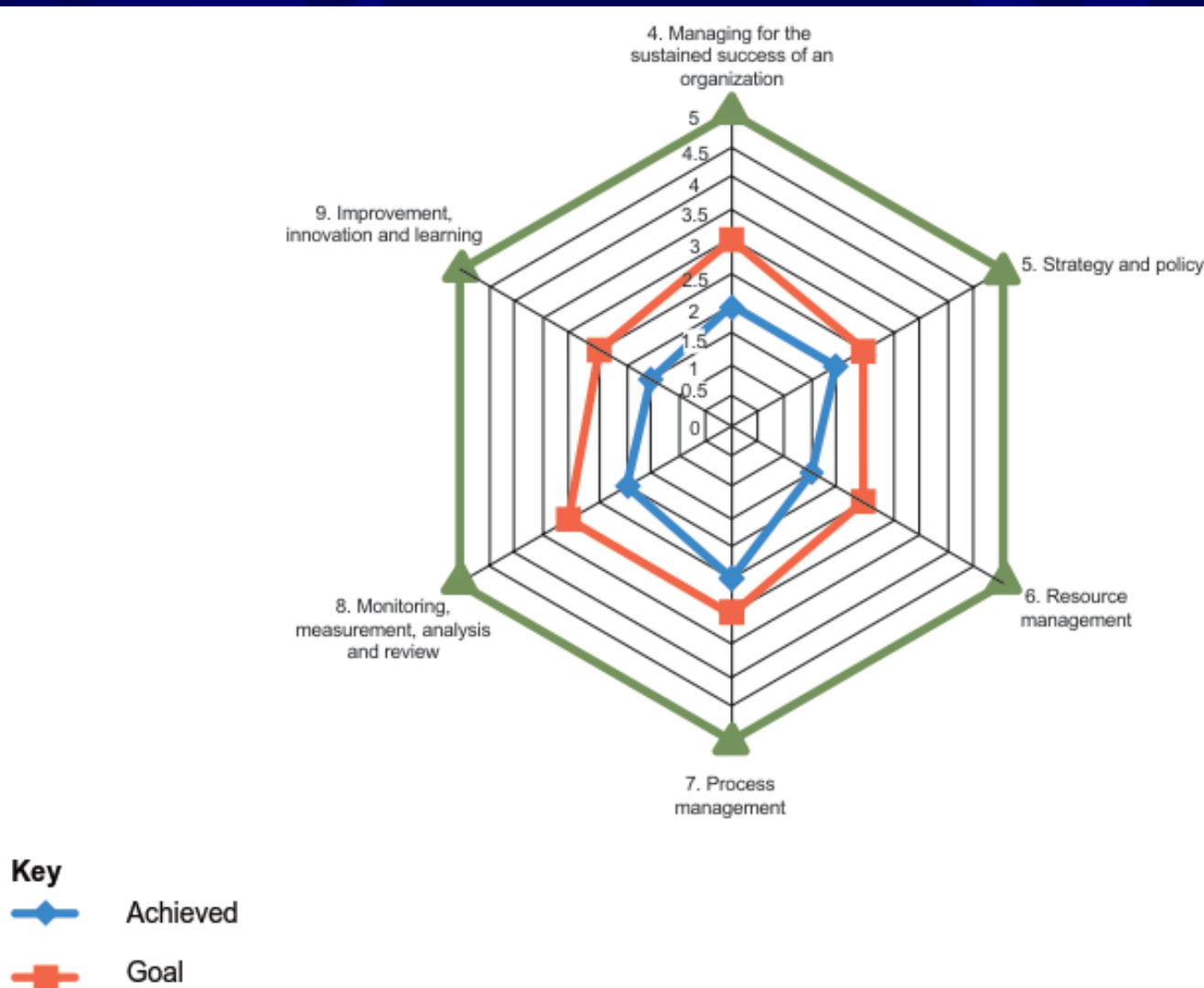


Figure A.2 — Example illustration of the results of a self-assessment

LESSONS TO LEARN:

- **TQM –framework ... quality is a must ... quality is not a separate issue in business operations!**
- **ISO 9001 quality standard is the solid foundation to business development actions**
- **Leadership and quality policy pave the way to the new business behaviour and financial success**
- **Quality standards ephasize streamline processes, customer satisfaction and risk-based thinking and decision making**

Vita, si scias uti, longa est , Seneca
(Life, if well lived, is long enough)

The background is a dark blue field filled with various-sized, semi-transparent blue gears. On the far left, there is a vertical strip of colorful, abstract, and pixelated patterns in shades of orange, red, and yellow. The word "QUESTIONS" is written in a large, bold, yellow, sans-serif font, centered horizontally. Below it, a large yellow question mark is also centered.

QUESTIONS

?

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your future professional career.**





Acta est fabula. Plaudite!

(Play is over. Applaud!)

(emperor Augustus)

