Building the Quality System

Understanding Quality
Understanding Standards

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Understanding ISO-9000

International Standards Organisation (ISO)

http://www.iso.org/

voluntary technical standards
over all sectors of business, industry and technology

1947 : **Product specifications**
Majority of ISO standards
Highly specific documented agreements containing
technical specifications or other precise criteria
used as rules, guidelines, or definitions of characteristics
to ensure materials, products, processes, services are fit for purpose

1987 : Management standard ISO 9000
Brought ISO to the attention of a much wider business community
Differs from the majority of ISO's highly specific standards

ISO 9000 Family

standards and guidelines relating to management systems,
and related supporting standards on terminology and specific tools,
such as auditing (= checking that management system conforms to the standard) *

- **not** a **product standard**
- but a **process standard =**
  - **the way an organization goes about its work**
    (and not directly the result of this work)
  - primarily concerned with **"quality management"**
    Quality refers to **features of a product / service**
    which are **required by the customer**
    Quality management = what organization does to **ensure** :
    - Customer **satisfaction** & **trust**
    - **Compliance** with any applicable regulations
    - Objectives imposed by environment & other **constraints**

    Improve / Optimize performance continually

Summary: - manage processes influencing quality
- use resources effectively and efficiently

* Internal auditing is treated in a separate module 

Generic management system standard

Generic :
the same standards can be applied to any organization:
- large or small
- whatever its product, including services
- in any sector of activity
- business enterprise, public administration, government, health care

ISO Management System Standard :
International **state of the art Quality System**
- **written procedures**, instructions, forms, records
- **effective and efficient use of time, money, resources**
  by systemizing processes :
  - nothing important is left out
  - all waste steps are irradicated
  - business is done in an orderly, structured way
  - everyone is clear about who is **responsible** for doing what, when, how, why and where

Quality System

Core of your Business

Aufbau
Organigram

Ablauf
Processes

Methodically

Quality Management - Process Care — Quality

ensure that **design, developement, implemention** of products/services
are **effective** and **efficient** with respect to the system and its performance

(In-line) Quality Control — Continuity

methodically ensure that processes are under control:
- assign and cure all avoidable fluctuation
- avoid introducing fluctuations by not acting on “chance causes”

Quality Assurance — Trust

planned/systematic actions to provide evidence
needed to establish adequate confidence among all concerned,
that **quality-related activities** are being performed **effectively**,
so that a product or service will **satisfy given requirements for quality**

Understanding
Clinical Laboratory Standards

USA

Clinical Laboratory Improvement Amendements CLIA (1988)

http://www.fda.gov/cdrh/clia/

Detailed :
Very Specific Requirements
Specific about Waivers

Belgium

KB Erkenningsbesluit Klinische Laboratoria (1999)

http://www.ejustice.just.fgov.be/

To be read together with the "Praktijkrichtlijn"

http://www.iph.fgov.be/ClinBiol/bckb33/commission/document_nl/praktijkrichtlijn.pdf

Follows structure of EN-45001
with updates (ISO 17025 / 15189)
Open management norm to be
interpreted and implemented by the laboratories

ISO-15189
Medical Laboratories
Particular Requirements
for quality and competence

ISO-15189 follows structure of ISO-9000

Processes covered
(treated in a **Client-centered** style)

Development of Products/Services
Good Manufacturing Practices
End Control
Distribution (= Lab Reporting)
Client Care

Norm-requirements

4. Management Requirements
5. Technical Requirements

Requirements (ISO-15189 Standard)

4. Management Requirements

1. Aufbau & Ablauf (Organigram & Scope)
2. Quality management system

3. Document control

4-6. External suppliers / Tenders / Contracts

7. Resolution of complaints
8. Identification & Control of Nonconformities

10-11. Corrective & preventive actions
12. Continual improvement

13. Record keeping (Technical & Quality)

14. Internal audit

15. Management review

Requirements (ISO-15189 Standard)

5. Technical Requirements

1. Personnel

2. Accomodation and environmental conditions
3. Laboratory equipment

4. Pre-examination procedures
5. Examination procedures
6. Assuring quality of examination procedures

7. Post-examination procedures
8. Reporting of results

Joint Commission International Accreditation Standards for Hospitals

Joint Commission International

- **AOP.5** Laboratory services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.
- **AOP.5.1** A laboratory safety program is in place, followed, and documented.
- **AOP.5.2** Individuals with adequate training, skills, orientation, and experience administer the tests and interpret the results.
- **AOP.5.3** Laboratory results are available in a timely way as defined by the organization.
- **AOP.5.4** All equipment used for laboratory testing is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities.
- **AOP.5.5** Essential reagents and other supplies are regularly available.
- **AOP.5.6** Procedures for collecting, identifying, handling, safely transporting and disposing of specimens are followed.
- **AOP.5.7** Established norms and ranges are used to interpret and report clinical laboratory results.
- **AOP.5.8** A qualified individual(s) is responsible for managing the clinical laboratory service or pathology service.
- **AOP.5.9** Quality control procedures are in place, followed, and documented.
- **AOP.5.10** The organization regularly reviews quality control results for all outside sources of laboratory Services.
- **AOP.5.11** The organization has access to experts in specialized diagnostic areas when necessary.
- **QPS.3.2** Clinical monitoring includes those aspects of laboratory services selected by the leaders.

Understanding
Audits vis-à-vis Standards

EXTERNAL AUDITS

Certification, registration and accreditation

Certification
the issuing of written assurance (the certificate)
by an independent, external body that has
audited an organization's management system and
verified that it conforms to the requirements specified in the standard.
Registration
the auditing body records the certification in its client register.

Accreditation
refers to the formal recognition by an accreditation body
that a certification body is competent to carry out
ISO 9001 or ISO 14001 certification in specified business sectors.
Accreditation is certification of the certification body.

Accredited certificates issued by accredited certification bodies
may be perceived on the market as having increased credibility.

Certification is not compulsory

An organization **can implement an ISO 9000 or other System** solely for internal benefits :

- increased effectiveness and efficiency of operations
- without incurring the costs of a certification programme

An organization can **decide to have an independent audit**
to confirm that their operations are conform to the standard

Business grounds for such a decision can be:

- contractual, regulatory, or market requirements
  e.g. in Belgian Health Care context: Aids Reference Labs, ...
- customer preferences
  e.g. in health care sector : clinical study sponsors
- part of a risk management programme
  e.g. in health care sector : patient safety concerns
- set clear goals for the development of the management system
- motivate staf developing the system

ISO-15189

A detailed list of contents
is available in the form of an audit checklist from BELAC

- **BELAC 6-102** - Checklist for the evaluation of the conformity towards the requirements of the standard NBN EN ISO 15189

Ongoing Developments

Ongoing Developments : Evolution in laboratory norms

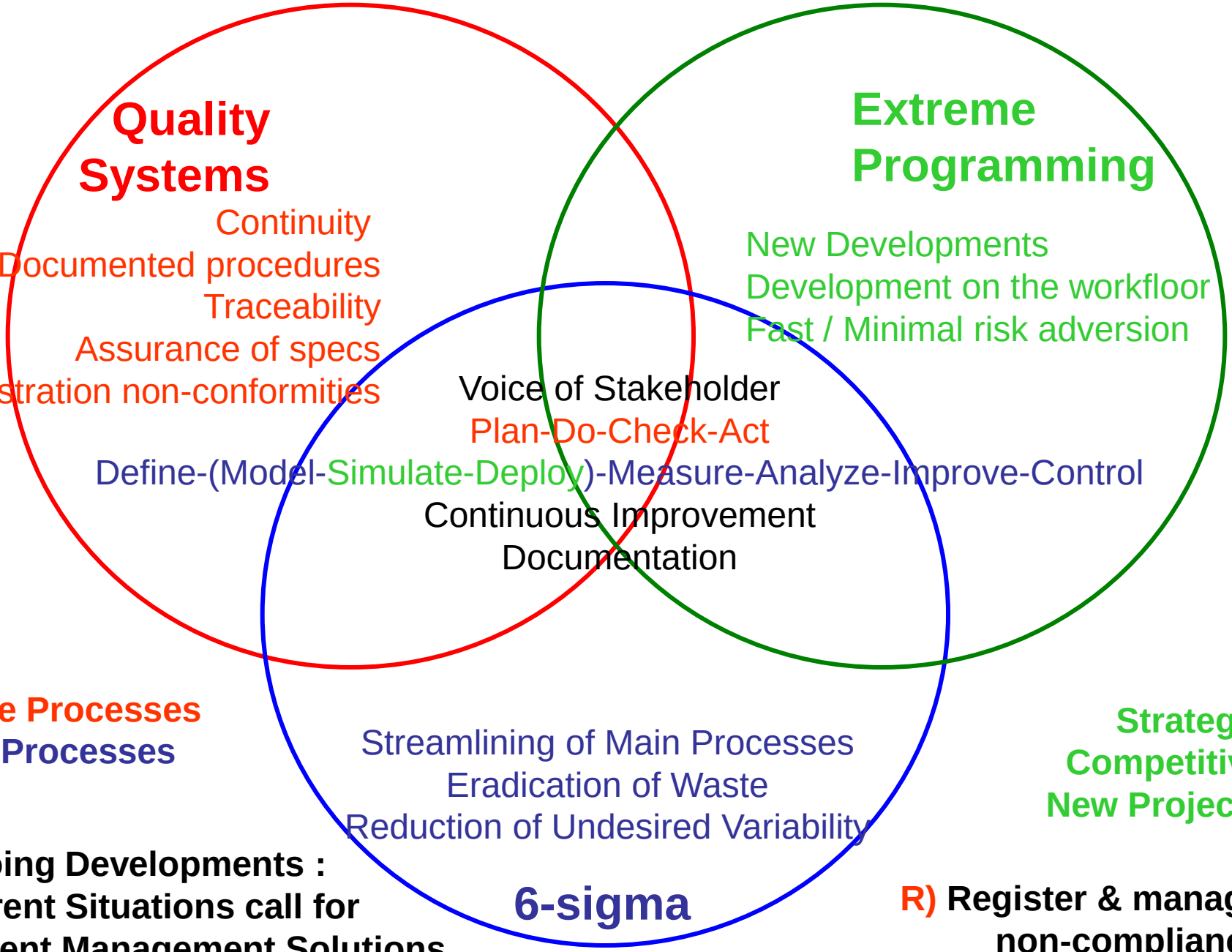
GMP

EN 45001
Structure of "Praktijkrichtlijn"
Specs, Traceability & Audit

ISO 17025
Structure follows ISO-9000
+ Plan-Do-Check-Act Cycle

ISO 15189
Structure follows ISO-17025
+ Waivers (technical requirements) for the medical field
+ Explicit focus on patient-care & -safety

GLP
(One-time) Study contracts
Traceability & *Responsibilities*
Use of Checklists & Inventories



Ongoing Developments : Different Situations call for different Management Solutions

R) Register & manage non-compliance

Ongoing Developments

The ISO 9000 management standard claims to facilitate implementation of Integral Quality Management

Integral Quality Management

1. Focus on clients
2. Leadership
3. Involvement of People
4. Process approach
5. System approach to management
6. Continual Improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

Source:
http://www.iso.org/iso/en/iso9000-14000/understand/qmp.html

Integral Quality Management

1. **Focus on clients**
2. Leadership
3. Involvement of People
4. Process approach
5. System approach to management
6. Continual Improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

Voice of the Customer
Managed Customer Relationships
Balanced approach between satisfying customers and other interested parties

Integral Quality Management

1. Focus on clients
2. **Leadership**
3. Involvement of People
4. Process approach
5. System approach to management
6. Continual Improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

Establish unity of purpose and direction
Setting vision, goals and targets
Communication, values, fairness, …
Integrates knowledge, decides, …
Coaching

Integral Quality Management

1. Focus on clients
2. Leadership
3. **Involvement of People**
4. Process approach
5. System approach to management
6. Continual Improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

→ **Quality is a task of all**
Ownership of Processes
Learning Organisation
Coaching

From : command, control, constraint, contract
To : discipline, trust, stretch, support

Characteristics of expert (= intelligent) behavior

- Expert **attitudes**
  - **Confidence and self-reliance**
  - **Value- / Purpose-oriented**
  - **Empathic, Cooperative, Synergetic**
- Expert **problem solving skills**
  - Can formulate the **right question**
    - sticks to the purpose : Stays on track; Does not lose focus
    - can visualize data sets in order to ask the right question
  - **Recognizes assignable variation** and acts upon this
  - Does not act on random variation
    (recognizes problems without technical solution
    does not introduce variation / deterioration by futile actions)
  - Solves problems using the **simplest, elegant and robust** techniques
  - Organizational talents; multitasking & **time-management**
- **Learns** continuously
  - **Self-observation** : understands why actions / attempts to solve problems / communication of results and solutions fail and learns from this
  - After recognizing failing approaches,
    does **not persist with fruitless attempts**,
    but switches to alternative approaches

Ownership of processes

- In an organization (governing) coalitions form
- **Make actors the authors of change**
- The organization shall **identify & assign owners to main processes**
- **Ownership** does not make one automatically an **expert**
  - ownership allows one to identify with and to act morally
    - owners have to be held **accountable**
  - expert behavior is an attitude = a general competence
    - experts share knowledge
- The "quality control/assurance system"
  - should facilitate problem solving,
  - but it should never assume ownership
- Develop a **culture** op "**knowledge sharing**"
  - hurdles to knowledge sharing:
    - knowledge is power
    - not sharing knowledge makes one irreplaceable
  - make " **expansion of shared knowledge** "
    - a measurable and accountable " **business target** "
  - culture = open (fact-, not opinion-driven) debate ≠ dogmatic

Integral Quality Management

1. Focus on clients
2. Leadership
3. Involvement of People
4. **Process approach**
5. **System approach to management**
6. **Continual Improvement**
7. **Factual approach to decision making**
8. Mutually beneficial supplier relationships

→ **PROCESS EXCELLENCE**
= INTELLIGENT DESIGN

Paradigm 1

Health of an organization depends on growth
(or on sustainable relationships ?)

Growth is controlled
not by the total of resources available,
but by the scarcest resource → Balanced control

Factors key to performance
can be identified & optimized
(and quantitative KPI's can be defined)

Profit is the best way to allocate scarce resources

Profit (= Value) is not a dirty word

Paradigm 2

What is measured can be improved

(and what is not measured cannot be managed)

Quality (= values, perceptions & beliefs)

can be analyzed quantitatively (elicitation)

Paradigm 1 + 2 = 3 : PURPOSIVE SYSTEMS

Example well known in biology / cybernetics :

The foundation of all physiology must be
the physiology of permanence (Darlington)

The **objective** (= operational definition) of **" life "** is
to decrease the local entropy of
that fragment of the universe considered to be " alive "

This is achieved
by shedding disorder, increasing order
through **self-organizational feed-back loops**

Self-correcting Systems

Interchange **intelligence** for **life**

" Intelligent behavior " **evolves** as a consequence of
the ability to **measure and keep account of** effects of a given signal
through feedback loops that return
a message signifying **the magnitude of the result**
= to **place a value on an objective at which to aim**

QUALITY SYSTEM = a PURPOSIVE system EVOLVING by being SELF-CORRECTING


Shewart

Shewart-Deming Cycle
Plan, Do, Check, Act
- feedback loop
- detect and act upon “ assignable variation ”

6-sigma
Define, Measure, Analyze, Improve, Control
- feedback loop
- reduce variation
- detect and act upon “ outliers ”

The ins and outs of the PDCA cycle are discussed in greater detail in the module on Risk Management

QUALITY SYSTEM = INTELLIGENT by TEACHING ITSELF

Substrates of intelligence are in order of increasing complexity

- Data
- Information
- **Representative models**
  - with a requisite variety (Ashby)
- (Esthetic) **designs**

Continual improvement

Intelligence = ability to

- Evaluate
- Select
- **Conceptualize**
- **Proof** → Not everything can / has to be verified experimentally
  Intelligent fail-free (footprint) design

Intelligence evolves into **hierarchical decision systems**

- to **maintain focus**
- to **integrate knowledge**
- to **dissipate / share knowledge**
- to **decide timely** on the basis of the **best available evidence**

Constructive purpose of intelligent management

Evolutionary Development

***Erro ergo sum*: Intelligence is self-correcting**

QUALITY SYSTEM = SCIENTIFIC

Scientific VALUES

Truth
- empirical
- adequate & precise
- generality

Beauty
- simple
- symmetry
- coherence

Morality
- do not harm
- responsive to utilitarian needs

fact-driven

lean

clean

continuous improvement

purposive

Scientific METHOD

Discovery
- choose problem
- formulate hypothesis

Justification
- devise empirical test
- criticize, revise
- non-dogmatic

Application
- technology
- policies

after N. Koertge
Ann. NYAS 775:266 (1996)

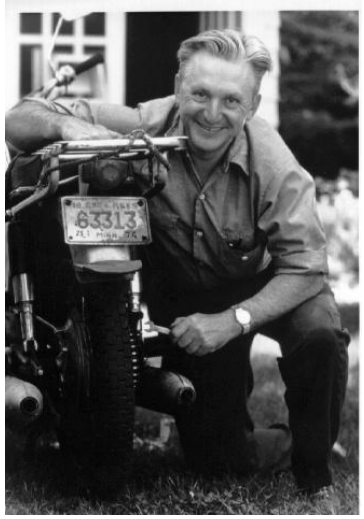
Quality System =
an engineering discipline

QUALITY SYSTEM = ESTHETIC

The **esthetic experience** is the **recognition** of

- **Inner structure (= predictability)**
- **Beauty** and **Elegance (= acceptability)**
- **Increased bandwidth of communication**
  - People can think faster than that they can communicate
  - The esthetic experience increases the bandwidth of communication
  - Increased bandwidth of communication **unifies individuals**

The **esthetic experience** is **valuable** (beyond face-value)



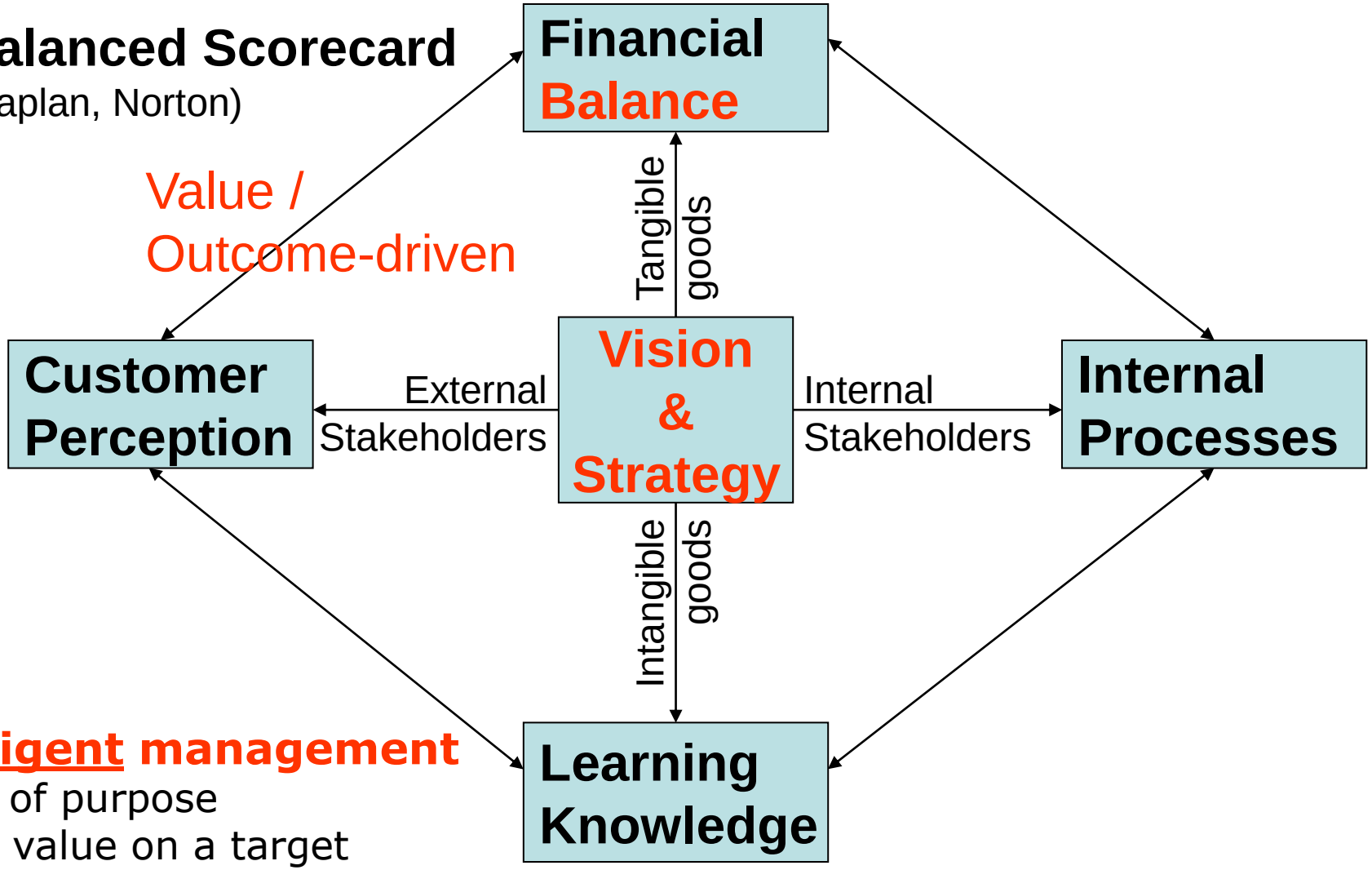
R. M. Pirsig

Ongoing Developments

Different Brands of Management Systems

Balanced Scorecard

(Kaplan, Norton)



Intelligent management

- unity of purpose
- put a value on a target
- identify disequilibria
- optimize processes (excellence)
- measure & keep account (fact-driven)
  of effects of your actions

TOOLS:
Key Performance Indicators

Strategic Planning

Analysis → Objectives → Specs

Strenghts
Weaknesses
Opportunities
Treats

Specific
Measurable
Attainable
Relevant
Timely

Must have
Should have
Could have
Won't have

Stay on Track

Vision
Unity of purpose
Buy-in from stakeholders
Timely

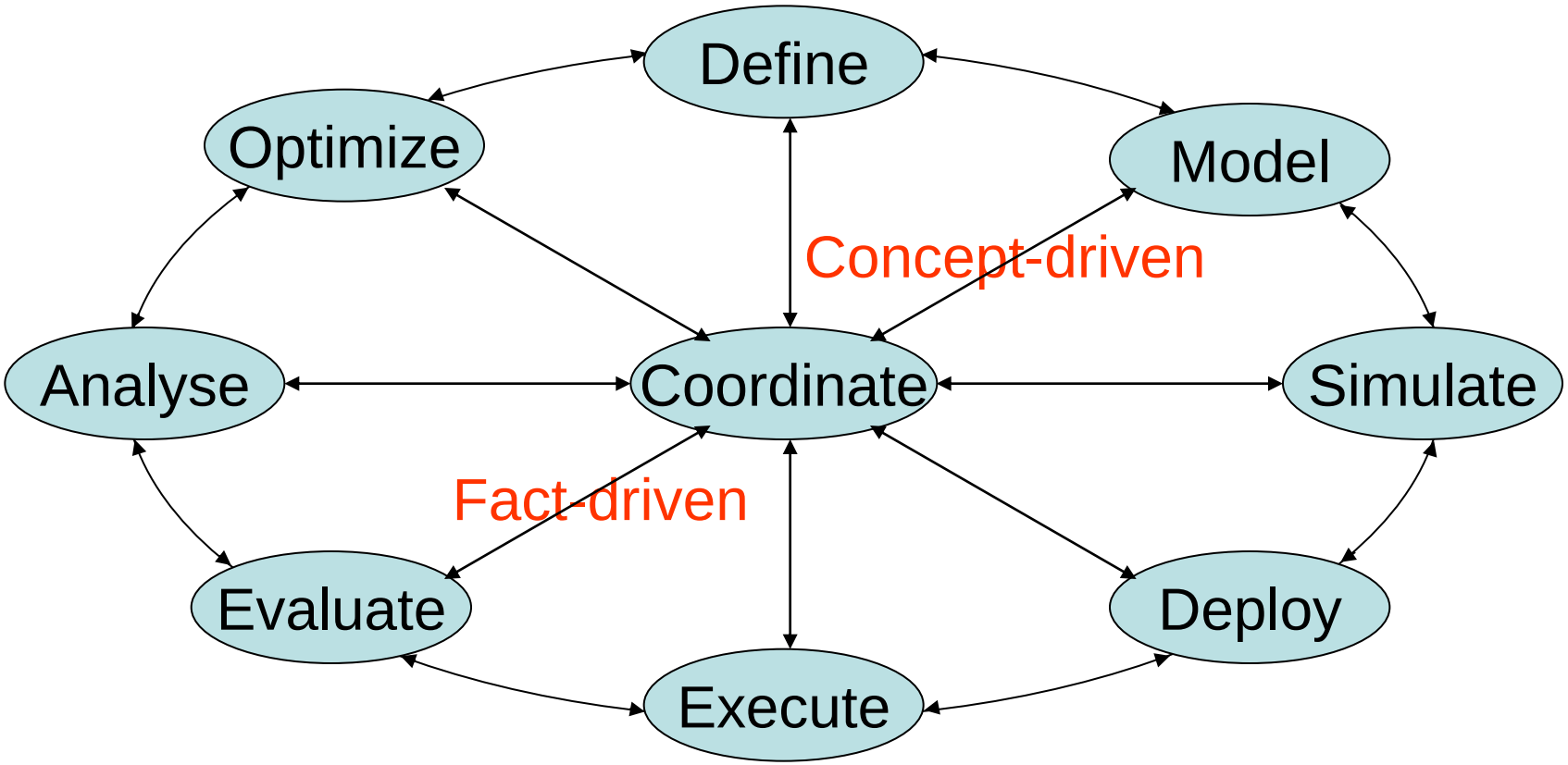
Strategic Management

Purpose = a value to realize

Objectives = a target to aim at

Intelligent design = place a value on an objective
keep account of effectiveness
efficiency
coordinate & get it done in time

Business Project Management



Intelligent project management

- learn from the facts
- conceptualize
- integrate and coordinate (unity of purpose = stay on track)
- timely (right place, right time)

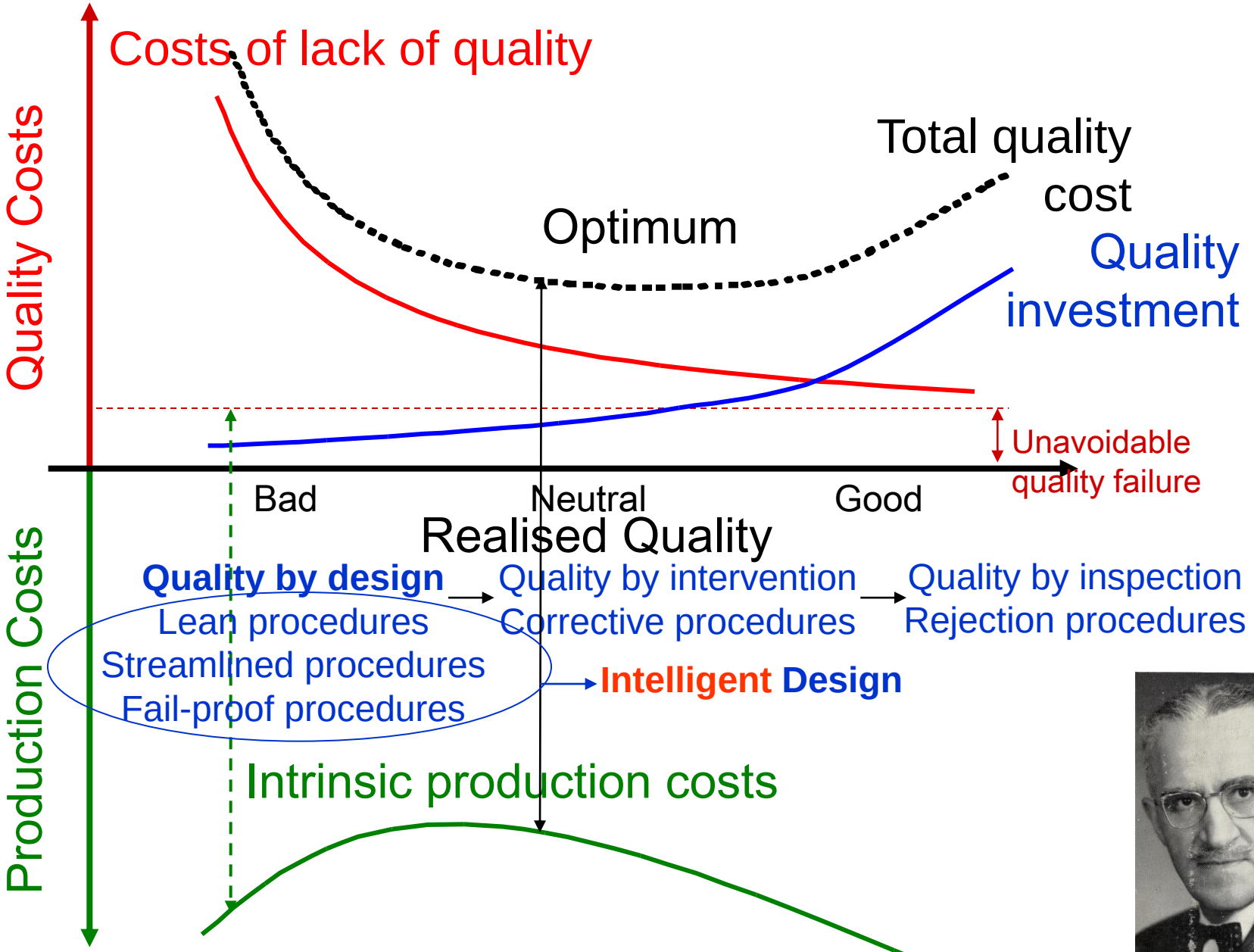
Ongoing Developments

Redefining Quality

From
features of a product or service
required by the customer
To
… … …

Quality can be negatively defined by accounting for
the costs of a lack of quality

viewpoint : profitability


Costs of lack of quality
Quality Costs
Total quality cost
Optimum
Quality investment
Unavoidable quality failure
Bad
Neutral
Good
Realised Quality
Quality by design
Quality by intervention
Quality by inspection
Lean procedures
Corrective procedures
Rejection procedures
Streamlined procedures
Fail-proof procedures
Intelligent Design
Intrinsic production costs
Production Costs

J. M. Juran

Economy of the Quality System

Risk Management

↓

Reduce complexity

↓

Inventory of what is necessary
Remove what is not needed
Optimize flow and organization
Managed maintenance

↓

A lean clean machine

↓ ↓

Reduced Error Rate
Increased Availability, …

Reduced Production Costs

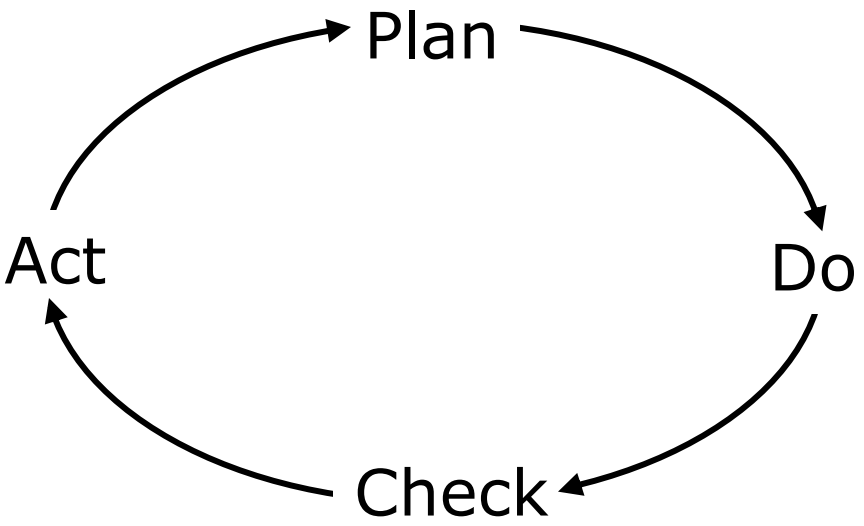
↓ ↓

Increased Quality/Costs

Economy of the Quality System

"Do it Right the First Time"
(P. B. Crosby)

Conformance to Requirements



Primary Prevention

Primary Prevention

Standard = Zero Defects
Measurement = Price of nonconformance

The ins and outs of the PDCA cycle are discussed in greater detail in the module on Risk Management

MIND MAPPING

HOW TO MAKE PROFIT ?

ADD VALUE

Valuable

Adequate
Capable

Available
Accessible
Flexible

Exceed Expectations !

Who's or Which PURPOSE does it suit ?

Fit for purpose ?

Optimized for purpose ?

Which legitimate stakeholder will object when we cut out a step ?

CUT LOSSES

Overcapacity
Overproduction

Waste:
Moving
Handovers
Stocks
Scrap & Rework
End of line control

METHODIC APPROACH

Emotional Intelligence

- Communicate the business plan
- Make the actors the authors of change
- Avoid & manage emotions / Manage knowledge
- Use anxiety and fears as motor of change

Operational Intelligence

- Focus on the business plan / purpose / timeline
- Make scarcity of resources motor of change
- Focus on primary process
- Optimize by minimizing losses
- Design for quality in stead of end of line control

viewpoint : profitability

Quality System optimizes processes
and in that process
pays back for the quality investment
= cost-effectiveness

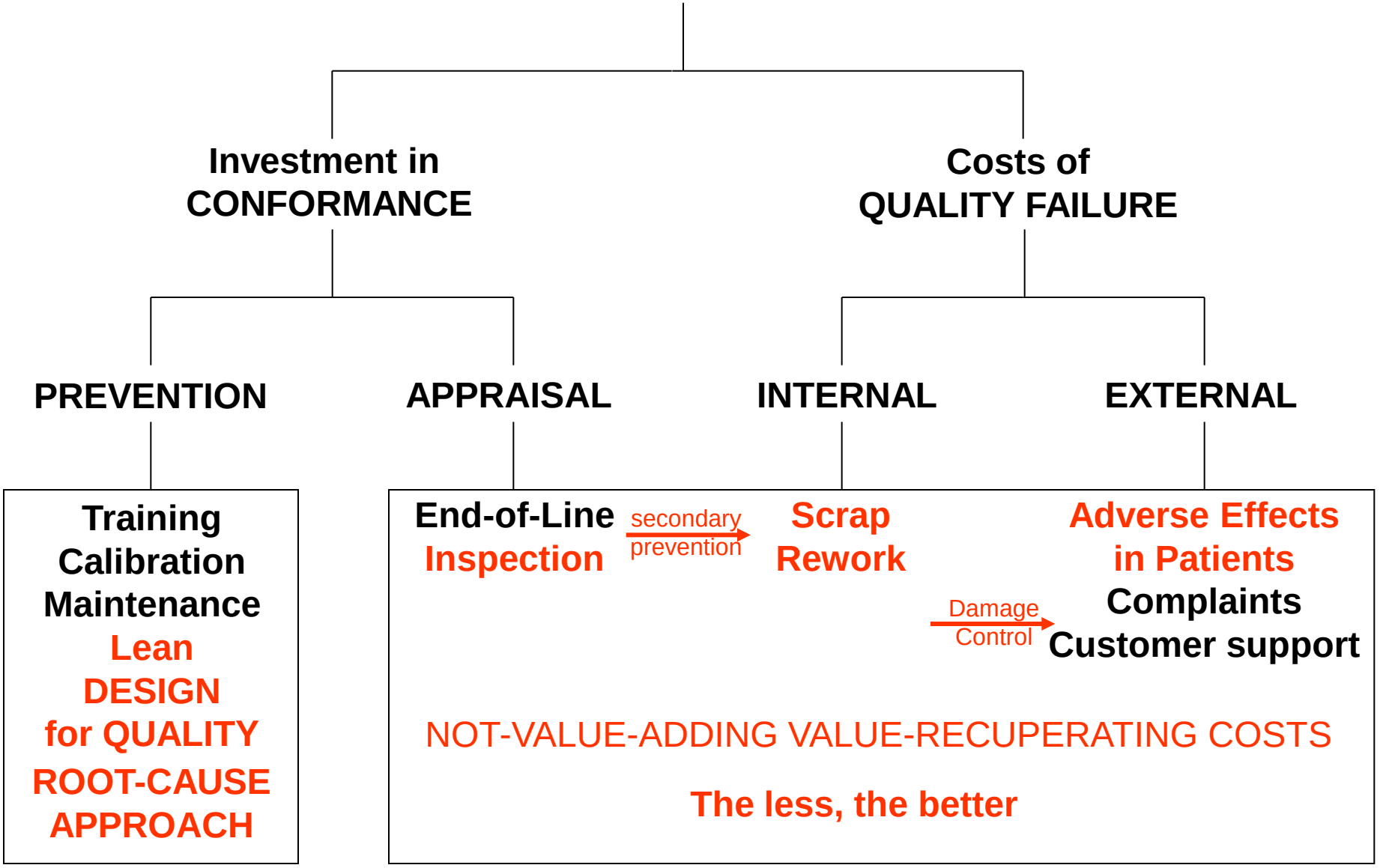
viewpoint : profitability

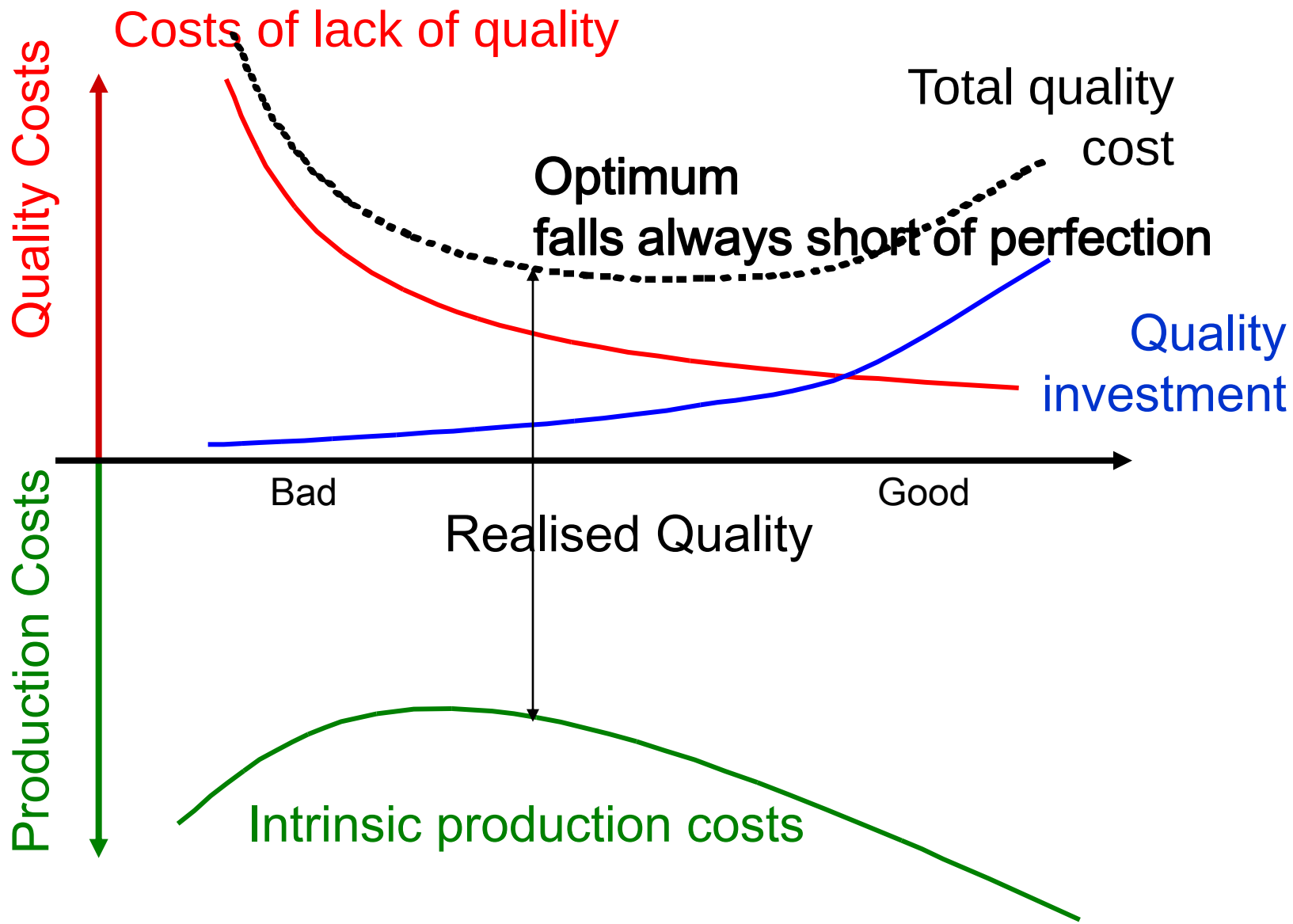
How to convince your organisation to make an investment with a positive return ?

COMPONENTS OF QUALITY INVESTMENT

A.V. Feigenbaum

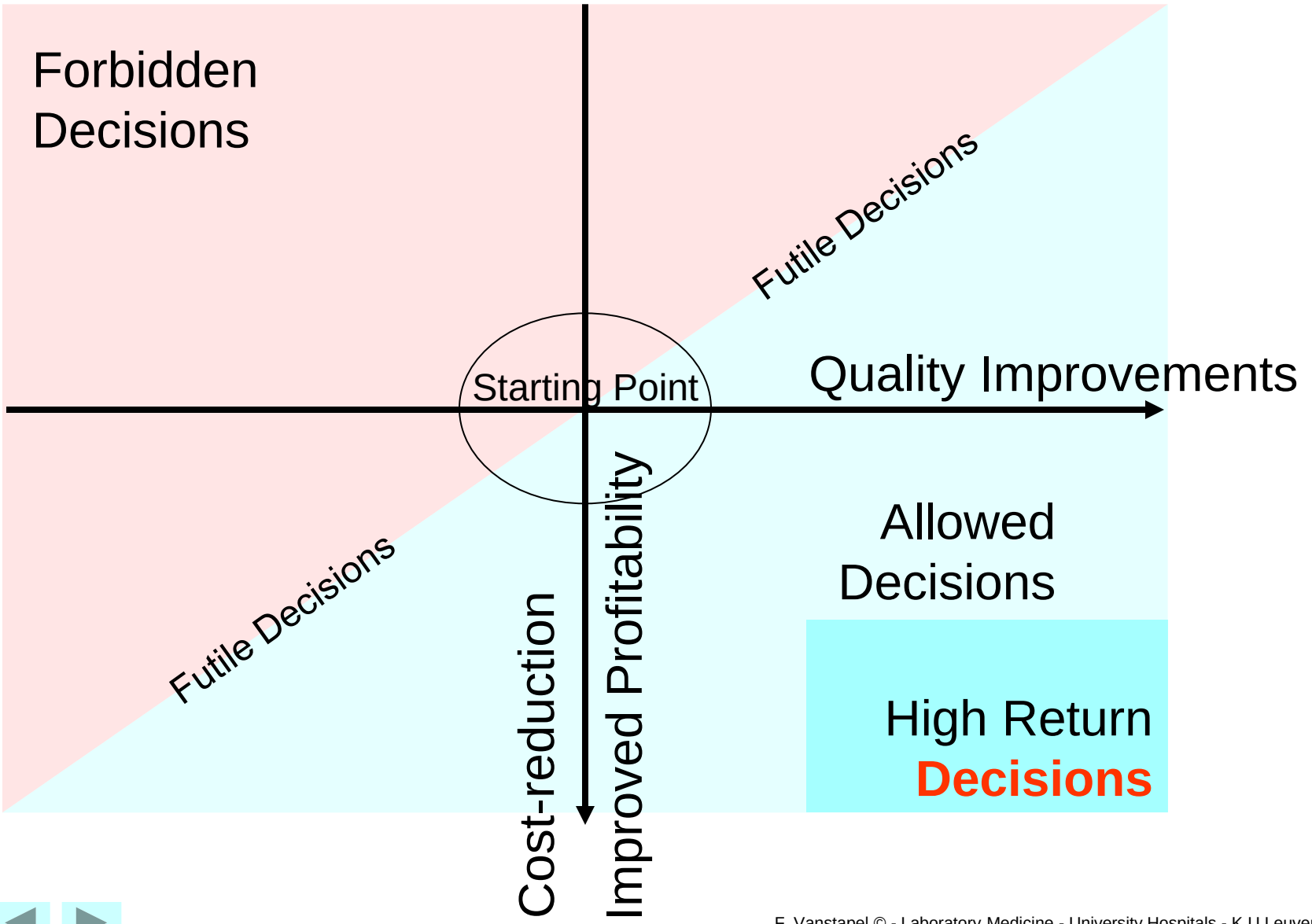
ADD VALUE — **CUT LOSSES**





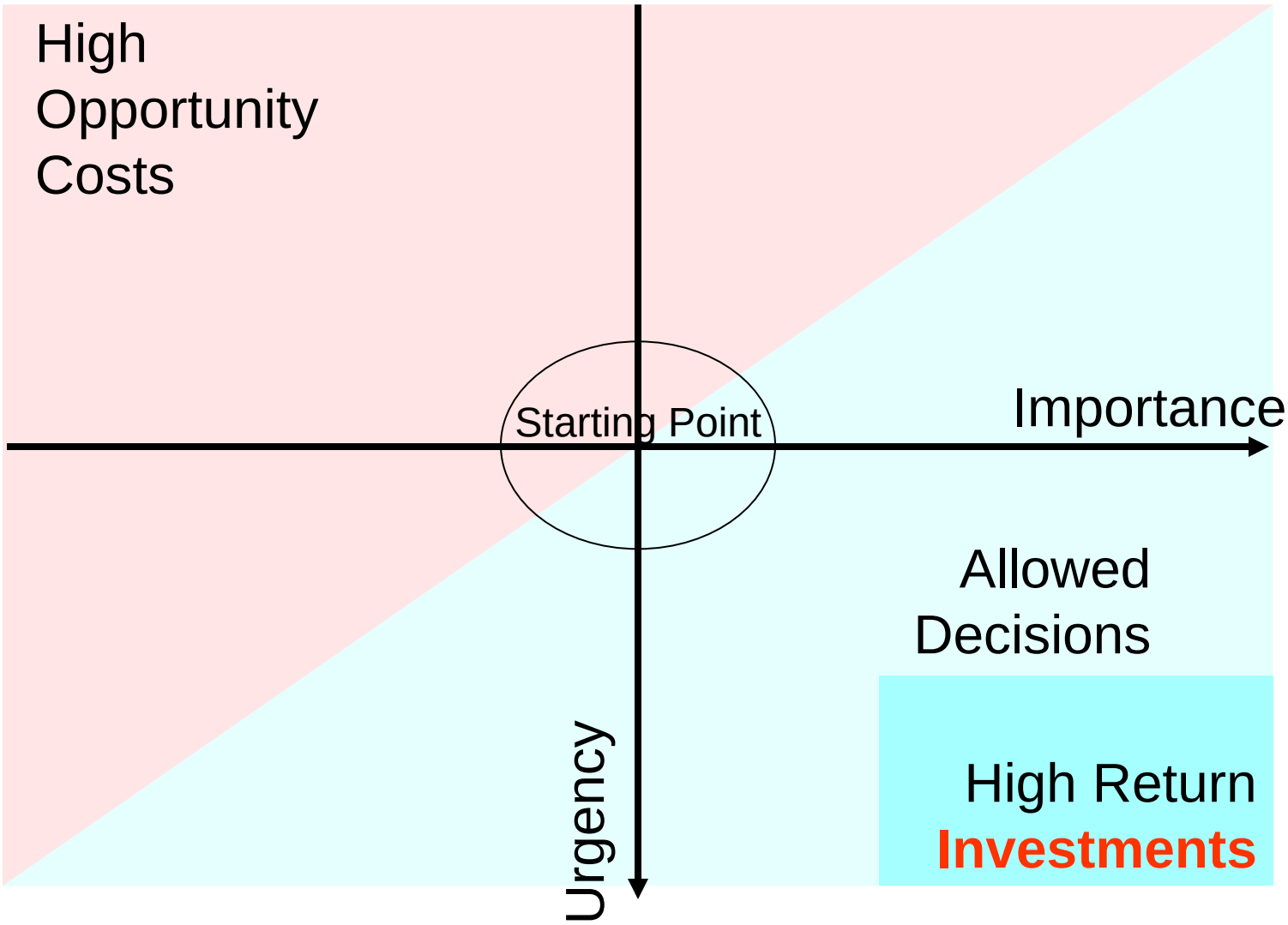
After J. M. Juran

Strategic Decisions
Viewpoint : Profitability



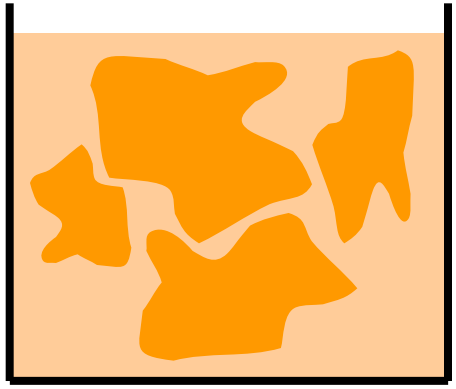
Strategic management of scarce resources

Viewpoint : Time Management

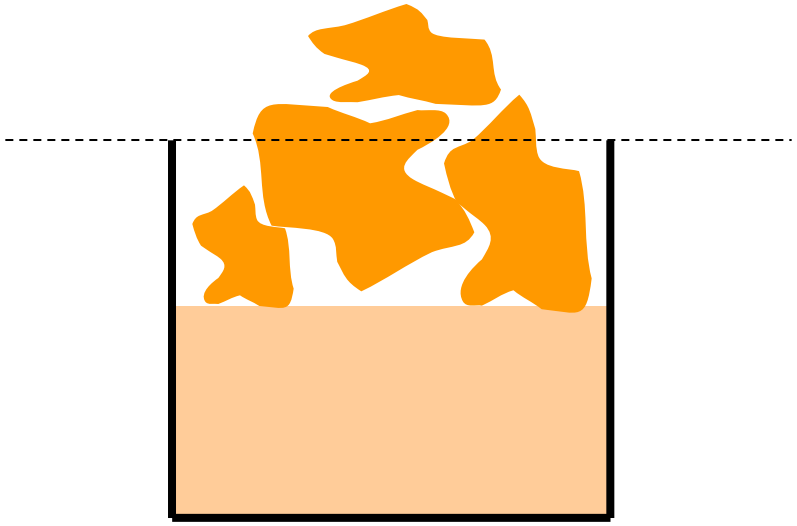


Strategic management of scarce resources

Viewpoint Time Management



Get it all done



Don’t finish your important projects

viewpoint : profitability

Quality System
optimizes cost-effectiveness
and in that process
preserves scarce resources

viewpoint : profitability

Quality System requires
continued investment
to fight spontaneous deterioration
to adjust to changing circumstances

When to measure ?

- Analysis: identify rate-limiting steps & targets
- Quantitative signals for process-steering
  - are specific as opposed to in-tangible purposes
  - have to be relevant & valid
- Before- and after-measurements
  - *i.a.* for internal marketing purposes

When to distrust measurements ?

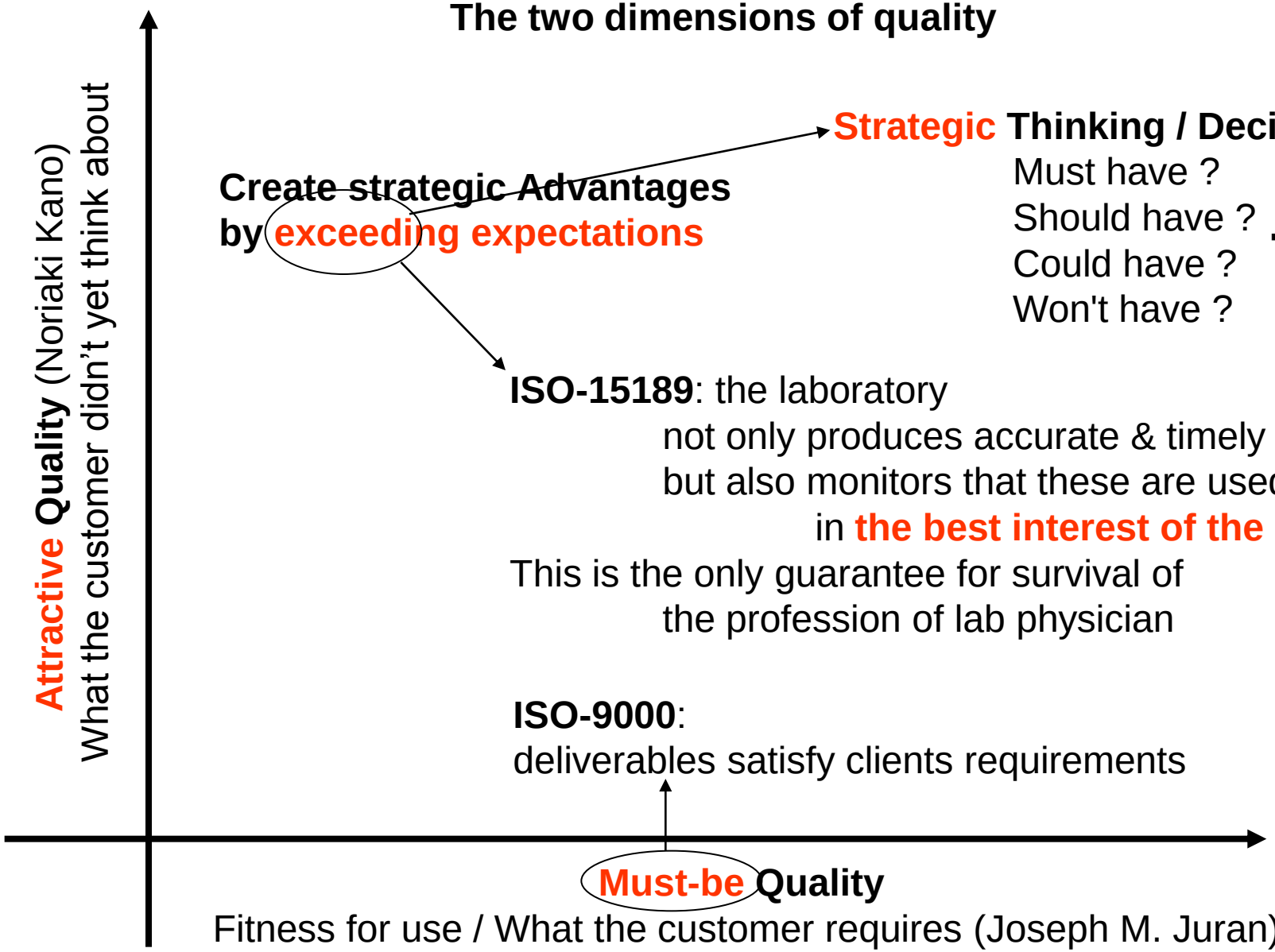
- Is their a hidden agenda ?
  - decisions better be based on data,
    but the majority of data should serve process steering
- Is the measurement relevant & validated ?

When not to measure ?

- Design from first principles
- Fail-safe POKA-design
  - except for the purpose of validation of POKA implementation

viewpoint : innovative creation of quality
creates
competitive market advantages

The two dimensions of quality



Strategic Thinking / Decisions

Create strategic Advantages
by exceeding expectations

Must have ?
Should have ?
Could have ?
Won't have ?

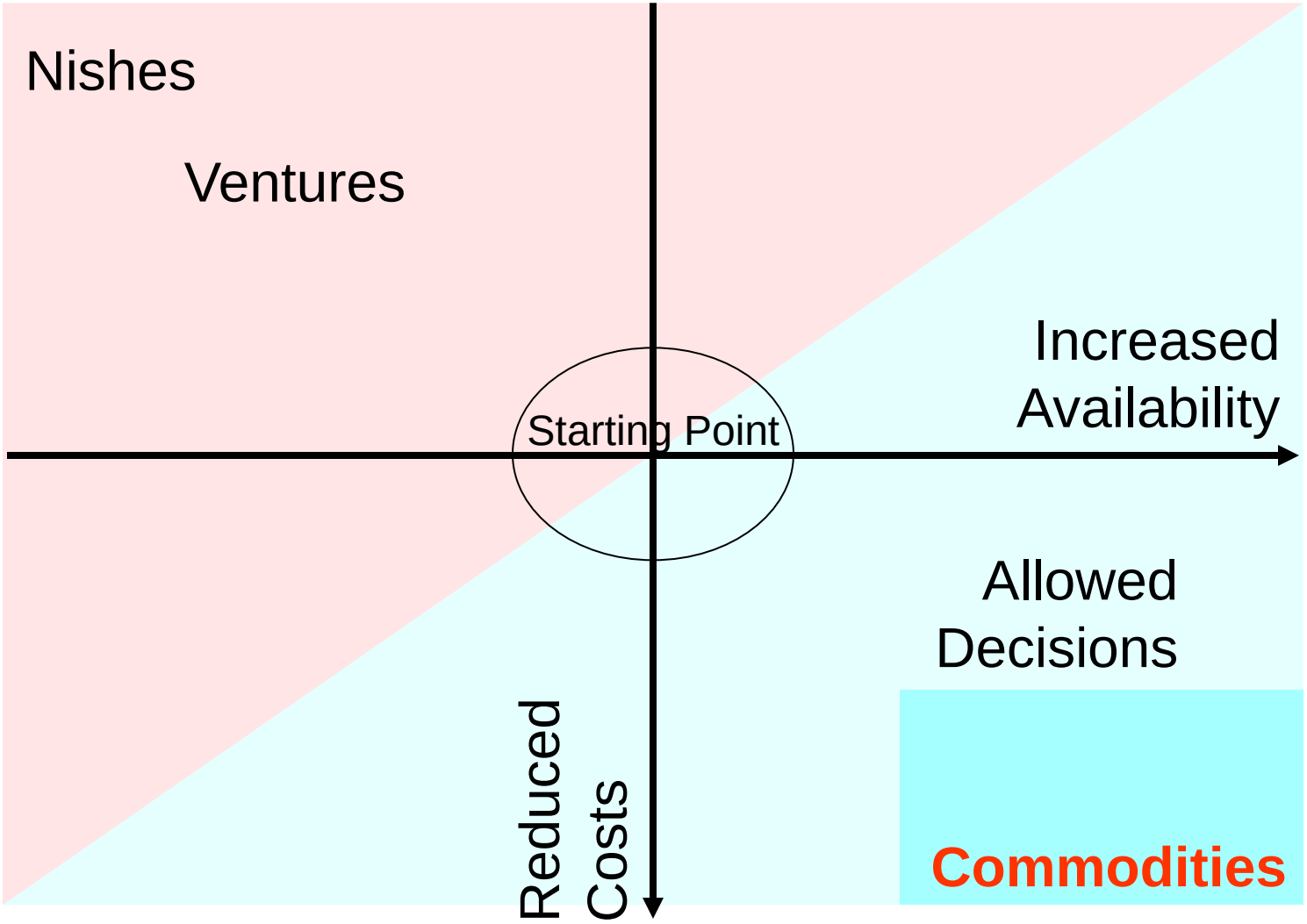
Keep it **simple !**

ISO-15189: the laboratory
not only produces accurate & timely results
but also monitors that these are used
in **the best interest of the patient**
This is the only guarantee for survival of
the profession of lab physician

ISO-9000:
deliverables satisfy clients requirements

Strategic management of scarce resources

Viewpoint : Market Share



MOTORS for driving INNOVATION

Sustainability	***versus***	**Growth**
Collaborative entrepreneurship	***versus***	**Competition**
Creativity	***versus***	**Inertia**

Recipe

- **Maximize synergies**
- **Learning organisation: Knowledge sharing**
- **Make these accountable business targets**

long-term viewpoint : sustainable quality

from a selfish to a mutually beneficial cooperative attitude

" The tragedy of the commons " (Garrett Hardin)
We try to maximize our individual profit,
but we compete in an environment where the resources are limited,
and hence growth cannot be sustained indefinitely.

" The broken window fallacy " (Frédéric Bastiat)
Every investment makes the money roll,
but also implies lost opportunities for alternative investments.

Maximize what can be achieved within given constraints

R)
social responsibility
cooperative strategies :
mutually beneficial relationships
non-resource-consuming / non-technical solutions :
innovation

cfr. approach : maximize profitability = cost-effectiveness

From **linear value chains** (Michael Porter)

Supply – Product chain =
succession of **value adding steps**

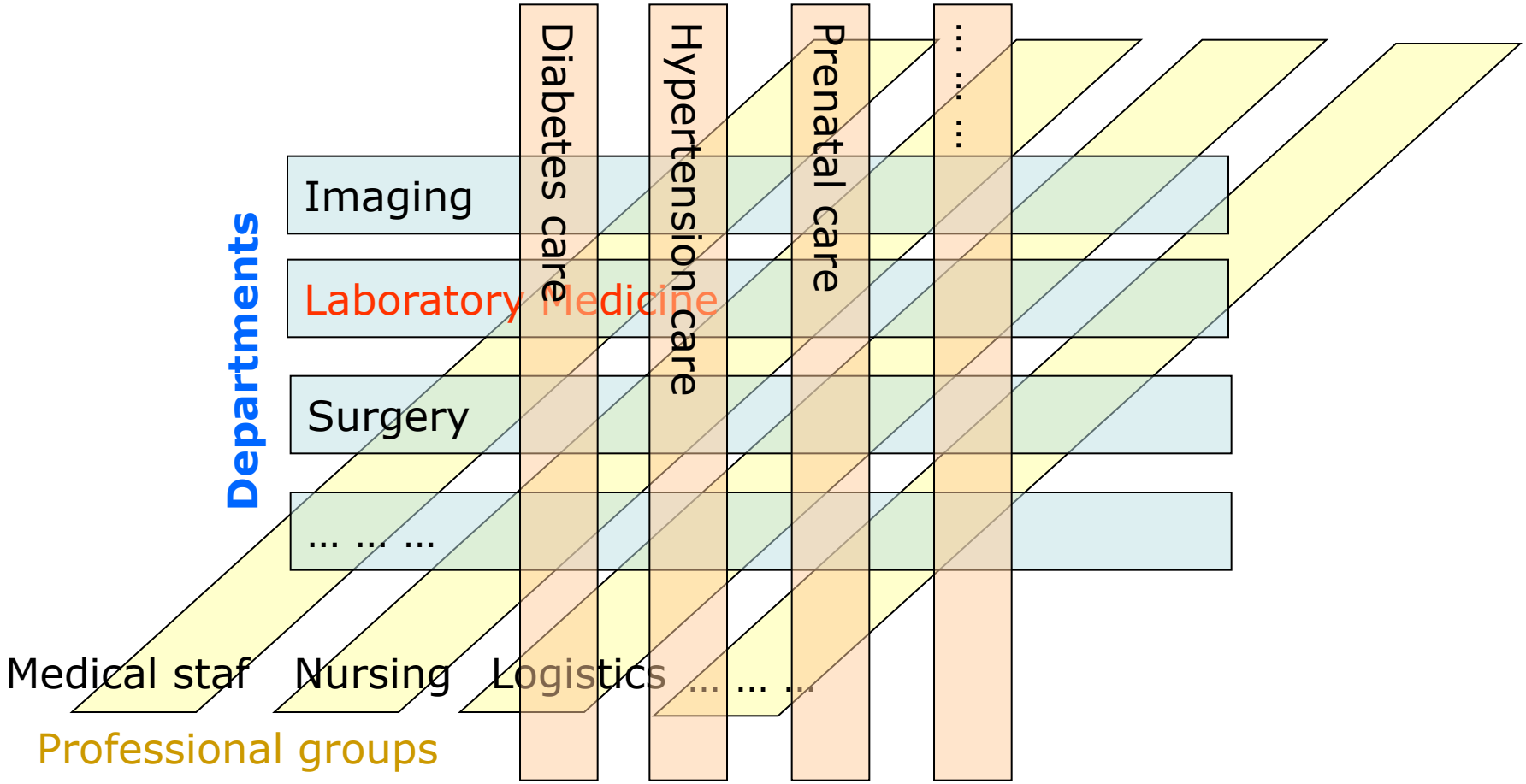
to **interactive value networks** (grids)

Value comprises
- **health**, social good, well-being, wealth
- tangible components:
  - **flow** of goods and revenue &
  - services: **equitable healthcare**,
    - research, development, design,
    - production, marketing, sales, and distribution
- less tangible components:
  - knowledge, intelligence, benefits, social good

Value is created
- in internal and external networks
- through **exchange** between partners (stakeholders)
  - and the **relationships** between roles

From **profit** *to* **flow & exchange of value**
From **optimized chains** *to* **optimized grids**

Ultimate value is realized in the Patient Care Programs



The hospital as a tridimensional grid

Care extends beyond the walls of the lab and the own hospital

Patient care programs / Clinical paths

To **optimize value** these have to be **managed intelligently**

- define the care program
  (often extending over primary caretakers and other hospitals)
- define desirable outcomes
- define measurable outcome targets
- identify waste and useless complexity
- identify imbalances in resource utilization / capacity
- optimize procedures / document & implement protocols
- evaluate attainment of targets / variance & compliance with procedures
- have hierarchical integration / decision systems to overview the path
- design corrective actions
- audit the path

In short :
in the absence of a Shewart-Deming Plan-Do-Check-Act cycle
there is no clinical path

Patient care programs / Clinical paths

The laboratory can play key roles in clinical path development

- participate in designing diagnostic & care algorithms
- share knowledge
    - knowledge about quality / management systems
    - knowledge about operational / logistic management
    - data-mining for outcome & compliance measurements
- participate in optimizing resource utilization
    - optimize sequence of laboratory and other diagnostic procedures
    - optimize availability (TAT) of results for critical decision steps
- extend quality-specs beyond the walls of the lab
    - management of pre- and post-analytical steps
    - test specs (availability, analytical specs) fit for purpose
    - automation of diagnostic algorithms / test requisition
    - automation of reporting / interpretation support
- extend quality-specs beyond the walls of the hospital
    - commutability / exchange of lab results in regional networks
- … … …

Integral Quality Management

1. Focus on clients
2. Leadership
3. Involvement of People
4. Process approach
5. System approach to management
6. Continual Improvement
7. Factual approach to decision making
8. **Mutually beneficial supplier relationships** → **WIN / WIN**

Literature – Internet Resources

The 8 principles of Quality Mangement

- http://www.iso.org/iso/en/iso9000-14000/understand/qmp.html

Praktijkrichtlijn

- http://www.iph.fgov.be/ClinBiol/bckb33/commission/document_nl/praktijkrichtlijn.pdf