TÜV Rheinland in the Health and Life Care Sector.

Quality and safety of medical technology in hospitals in the Netherlands

Rolf Jan den Adel, implementer QMT
Ziekenhuisgroep Twente, the Netherlands

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Main question

Do you wear your seatbelts or do you want to learn to drive a wheelchair?

Do you want to prevent calamities, yes or no?

- If no, wait till one happens, come back later

Hengelo Almelo

If yes, take the necessary steps:

- QMT = **Quality for Medical Technology** is an effective approach (Standard 4.0)
- This lecture is about the experience of applying QMT in the ZGT Hospital, Ziekenhuisgroep Twente, The Netherlands

Message of ZGT-QMT

The main step is awareness that risks really exist

From here:

- Combine quality, safety and risk management
- Take the whole life cycle of technology into account
- Manage structure, technology and people

Stakeholders of the hospital environment

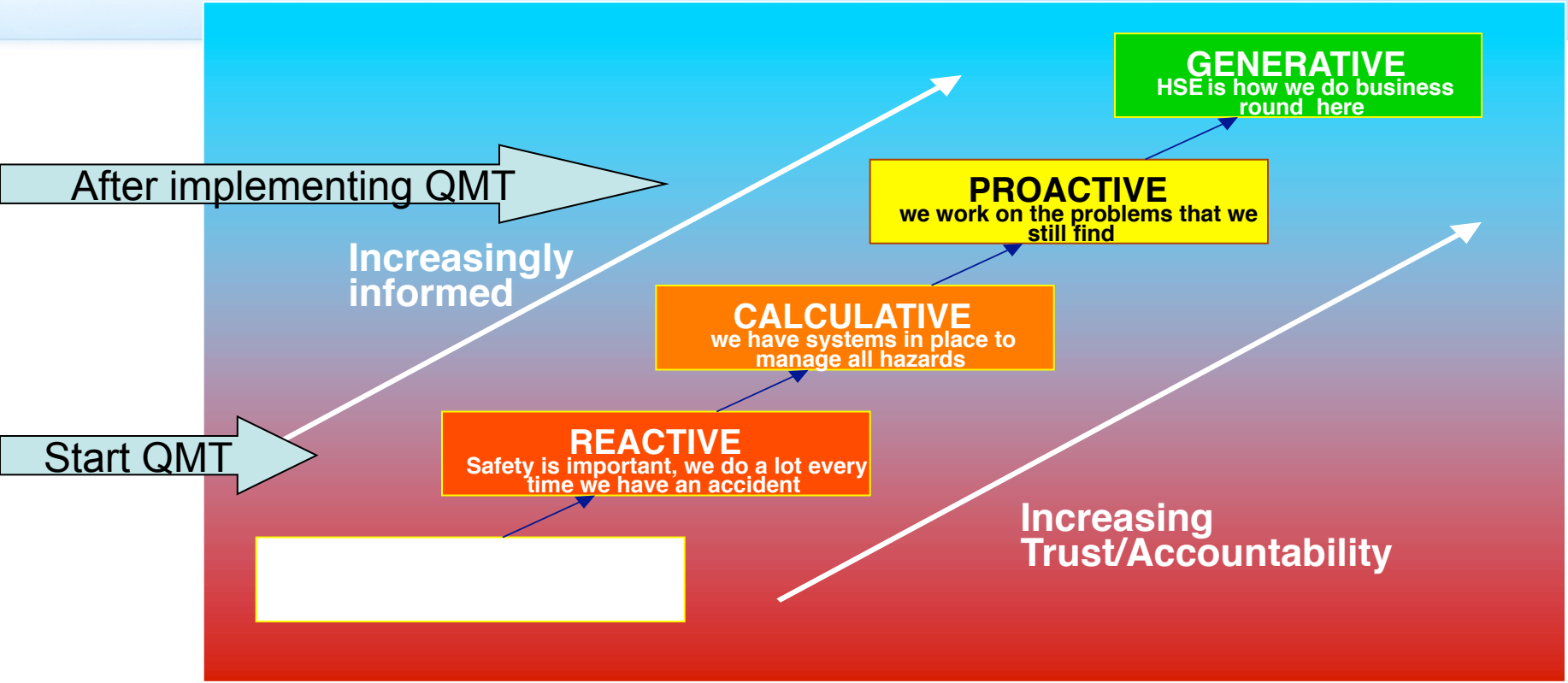
“Stakeholders of the hospitals environment“

Is a different structure needed for doctors, nurses, technicians?

Which process needs to be addressed?

What kind of “Quality (management system)” is needed to support the hospital?

Organisation development



The HSE Culture ladder

(Hudson , 2004)

Critical success factors for implementation

- The **board of directors** must be convinced of the need for the project (ZGT: one dead person makes the difference)
- **People who dare to make the difference** must be involved in the project (innovative minds and ‘steam engines’)
- Both **management of people and management of structure** are necessary
- To realize at all levels that **the process of improving never stops**

Integral quality, safety and risk management as connection between all different requirements

ZGT-QMT 'serves' different (external) parties:

QMT standard

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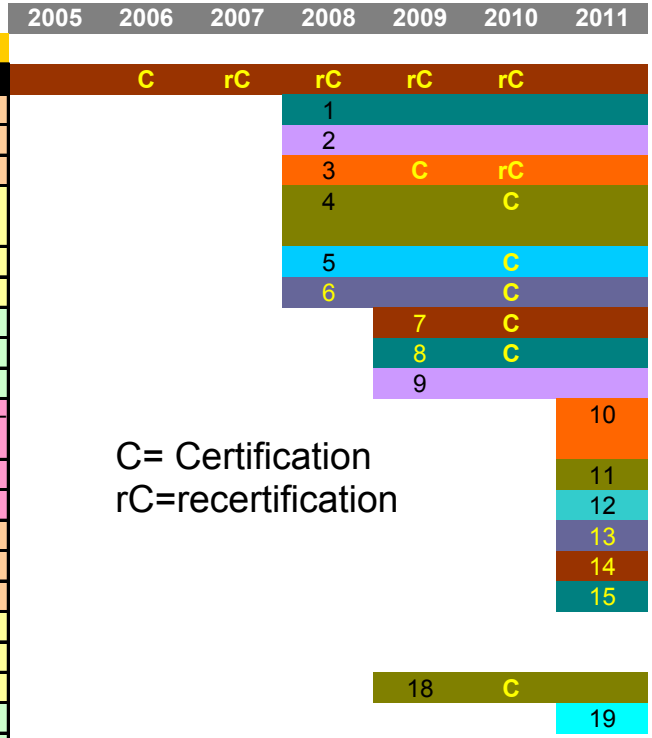
High risk technologies
in order of risk impact in the organization

WG	Technology
0	Patient monitoring
1	Electrical installations
2	Installations Medical gasses
3	Infusionpumps
4	Anesthesia and ventilation technology
5	(Electro)surgery technology
6	Endoscopes + CSA
7	Resuscitation equipment
8	Beds
9	Hospital ventilation systems
10	Radiodiagnostics technology (X-ray, CT)
11	Watersystems (legionella)
12	Cardiovascular equipment
13	Ultrasound
14	Incubators
15	Laser equipment
16	Heating
17	Mobility aids, patient hoists
18	Dialysis equipment
19	Pacemakers
20	Lung function devices
21	Neurofysiological equipment
22	Nuclear medicine equipment (gamma)
23	MRI
24	Other



Order of starting WG

First

Later

Risk/ Impact

High

Low

Technologies defined by TNO

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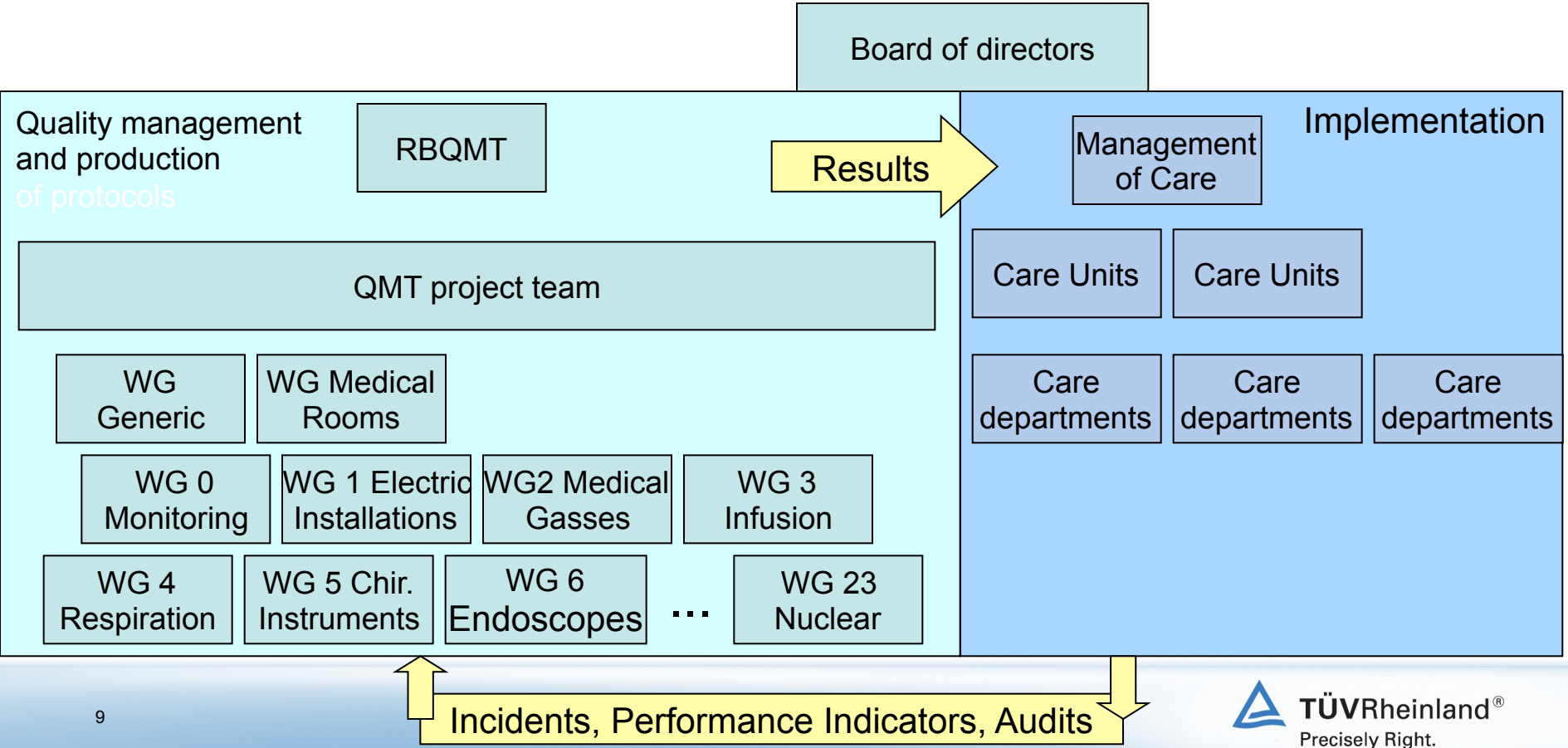
Structure of the QMT project



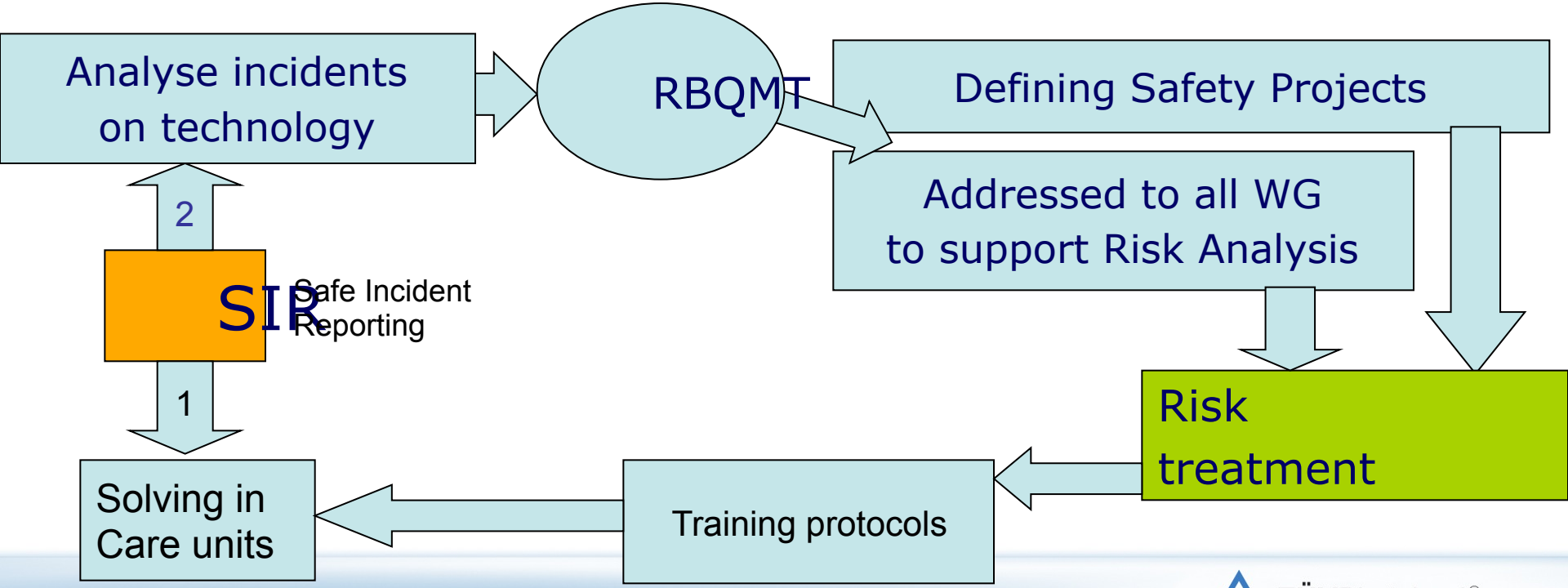
Approach

- Risk management
  - Retrospective risk management
  - Prospective risk management
  - Safety Management System integrated
- Management of structure
  - Review Body for Quality of Medical Technology (RBQMT)
  - Organisation
- People management
  - How to achieve a learning organization

Safety Management System integrated

Retrospective risk analysis

Prospective risk analysis



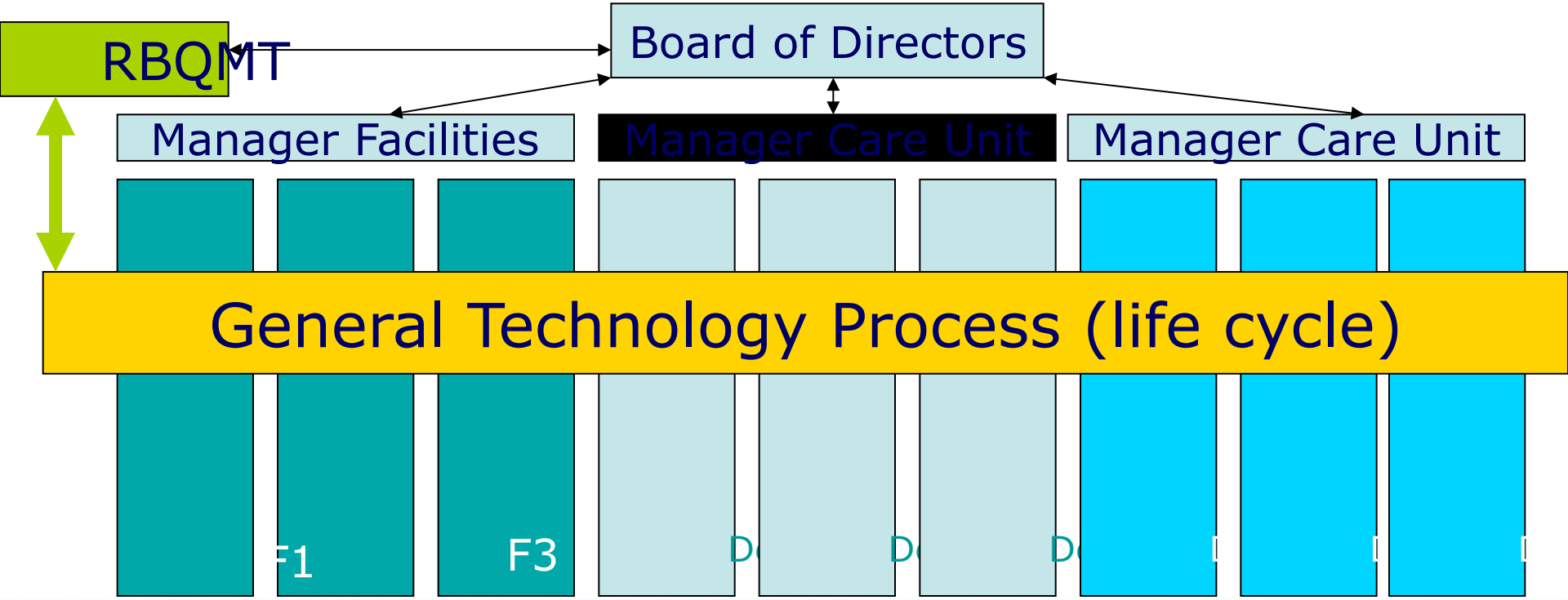
Management of structure

- Quality structure and quality management of the organization and of technology must fit and cooperate vice versa
- Puzzle for technology:
  - All kinds of different departments are involved
  - No one of them is responsible for the whole technology chain
- Therefore a special group is implemented:

- **Review Body for Quality of Medical Technology (RBQMT)**

  responsible for:
  - quality, safety and risk management on medical technology
  - release of new (re)build departments
  - planning of internal audits
  - preparing external audits like TÜV Rheinland executes
  - guiding the QMT project

Organisation with Review Body QMT

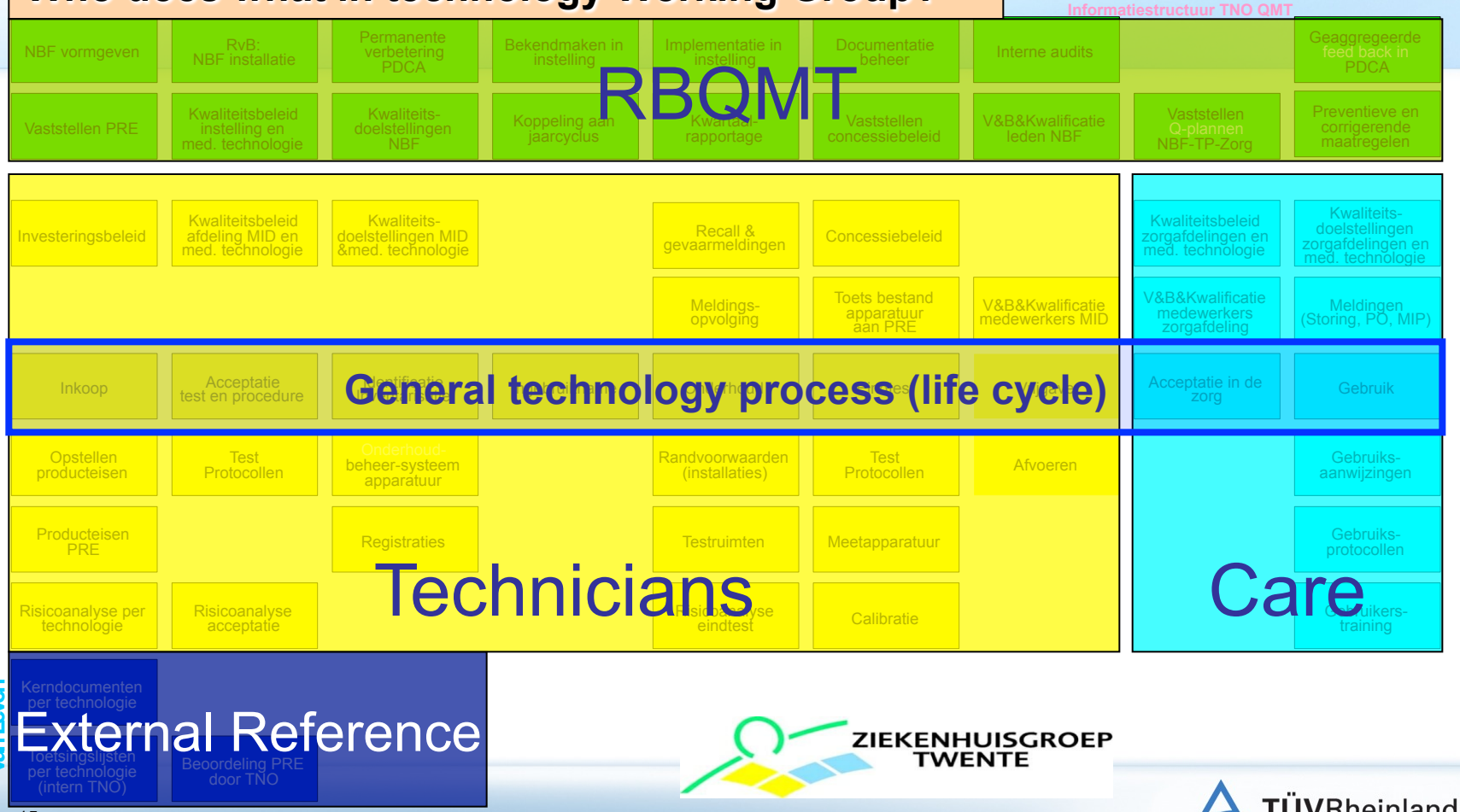


Met dank aan ZaansMC en ZGT

People management

- Multi discipline approach:
  - Physicians
  - Nurses
  - Professionals (Hygiene, Radiation, etc.)
  - Engineers
- Both in technology working groups (WG) as in Review Body QMT
- Task differentiation
- Culture
  - Awareness of risks and safety
  - Safe culture of reporting incidents (SIR)
  - Safe cultural environment (Maslov)

Who does what in technology Working Group?



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Vision on human resources

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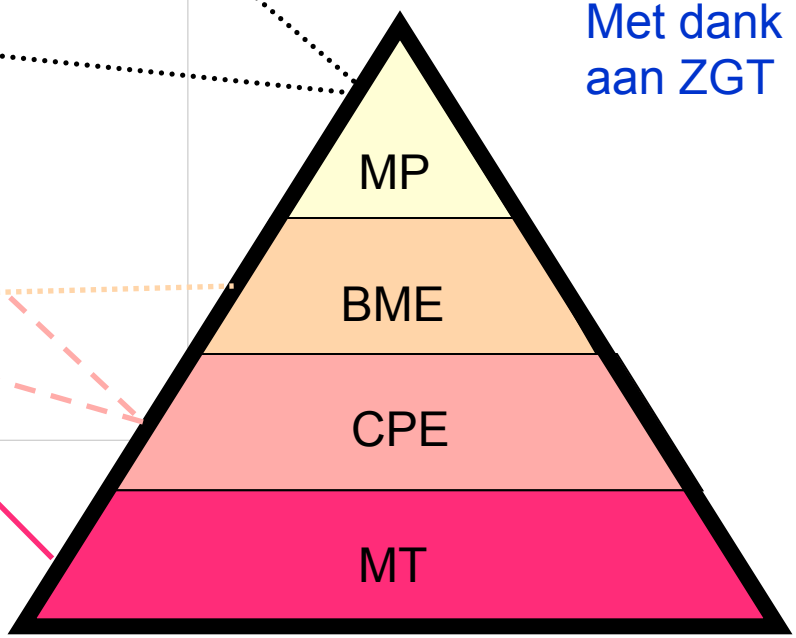
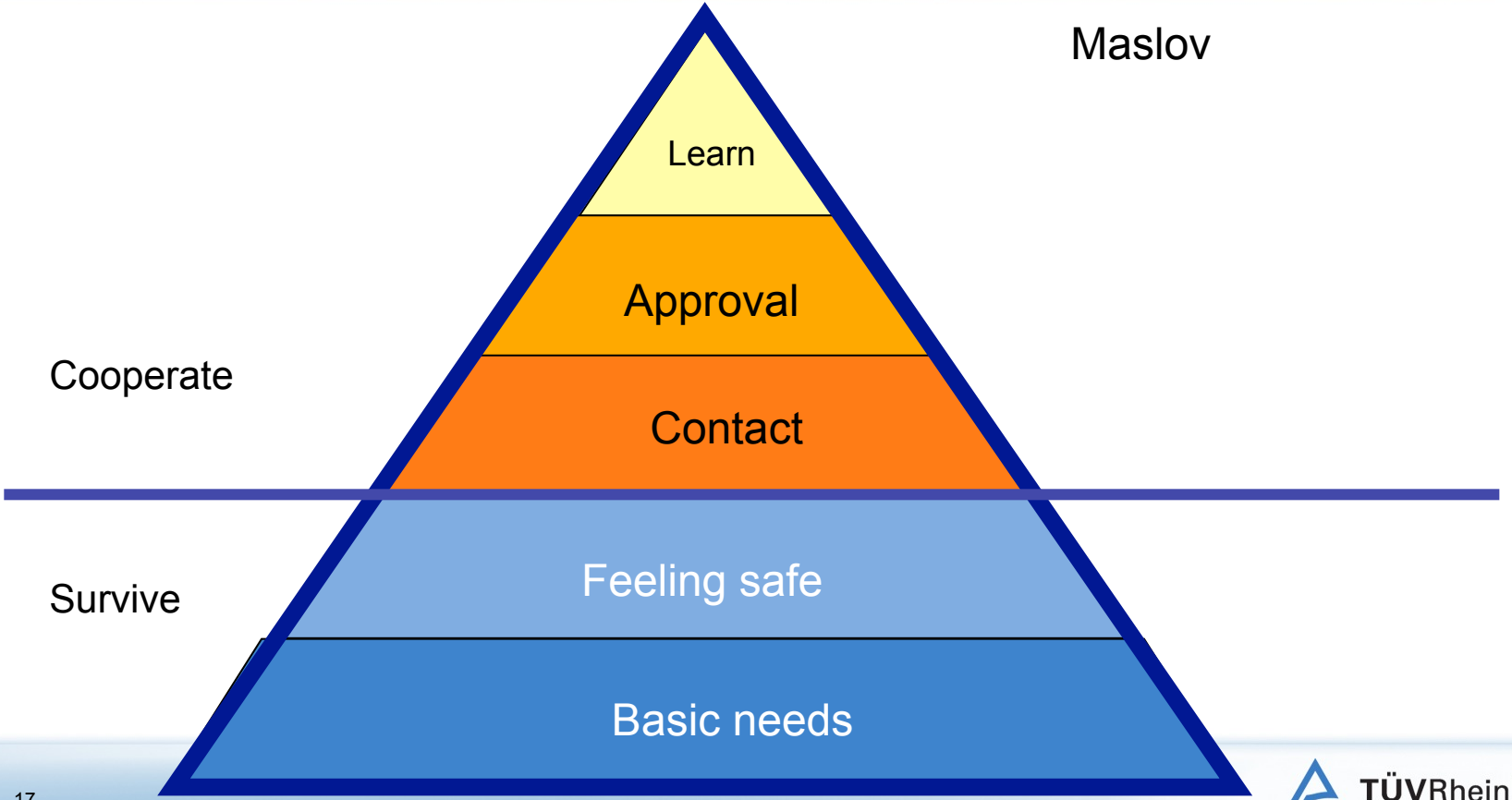


Task differentiation in QMT-technology for

- medical physicist,
- biomedical engineers,
- clinical physicist engineers
- medical technologists

How to achieve a learning organization



Conclusion

- The main gain of implementing QMT in such a broad way is:
  - People management
    - The awareness of risk and safety throughout the hospital as a whole
    - Board of directors, medical doctors, nurses as well as technicians realize their own contribution to a safe use of medical technology
    - The interdisciplinary discussion and cooperation is widely accepted
    - Technicians are better skilled, especially on risk and safety
  - Organization
    - The process of preparation each technology for certification is more effective
    - External certification helped to speed up the implementation of structure
    - Cost reduction due to less failure, task differentiation and less subcontractors
    - Procedures on life cycle of technology are improved
    - Several indicators help to manage the implementation
  - Technology
    - Status of maintenance has improved, as well as the quality of the maintenance itself

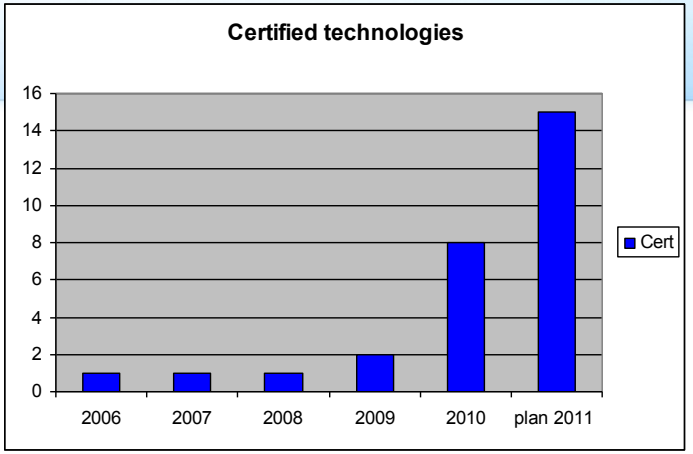
Organization gets in control

Firm internal organization

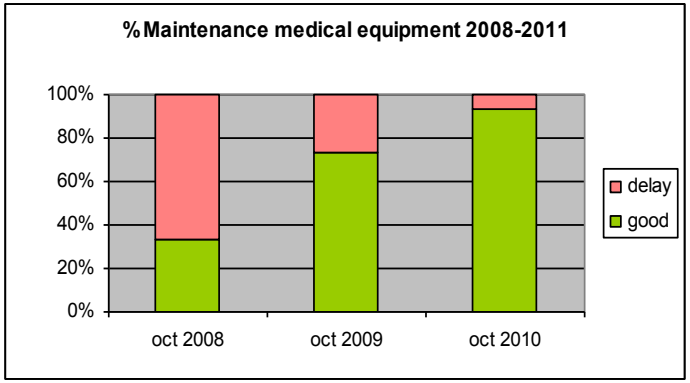
Met dank aan ZGT

Results

Implemented and certified High Risk Technologies



Status of maintenance



Certificaat

Norm: QMT®-norm versie 4.0

Certificaatnummer: QMT-10-26982

TÜV Rheinland Nederland B.V. certificeert:

Certificaathouder: **Stichting Ziekenhuisgroep Twente**
te ALMELO en HENGELO

Scope: **Productbeheersing kwaliteit toegepaste Medische Technologie: Anesthesie en Beademing, Chirurgie, Endoscopie, Reanimatie, Electrisch verstelbare bedden, Dialyse, Patiëntbewaking en Infuustechnologie.**

EA Code: **19**

Tijdens het certificatie-onderzoek is vastgesteld dat aan de eisen van bovengenoemde norm wordt voldaan.
TÜV Rheinland Nederland B.V. zal regelmatig controles uitvoeren.

Geldigheid:
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Directie TÜV Rheinland Nederland B.V.
Postbus 541, 7300 AM Apeldoorn

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Future scenario

- So far the project is focussed at implementation in the hospital itself:
  - The spin off starts to expose itself
  - Triggered by external forces we see a more effective internal organization around all aspects of technology
  - The hospital takes the lead again, gets in control
- Manufacturers are interested in cooperation because of the better insight in actual risks of technology in real use
- Health insurances are interested because of the reduction of incidents leading to a more effective and efficient health care process (cost reduction)

TÜV Rheinland in the Life and Health Care Sector.

Questions