

TÜV Rheinland in the Health and
Life Care Sector.

**Quality and safety of medical technology
in hospitals in the Netherlands**

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Ziekenhuisgroep Twente, the Netherlands**

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



Kwaliteitsdocument

QMT norm

versie 4.0

TNO Kwaliteit van Leven



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



TÜVRheinland
Precisely Right.

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“

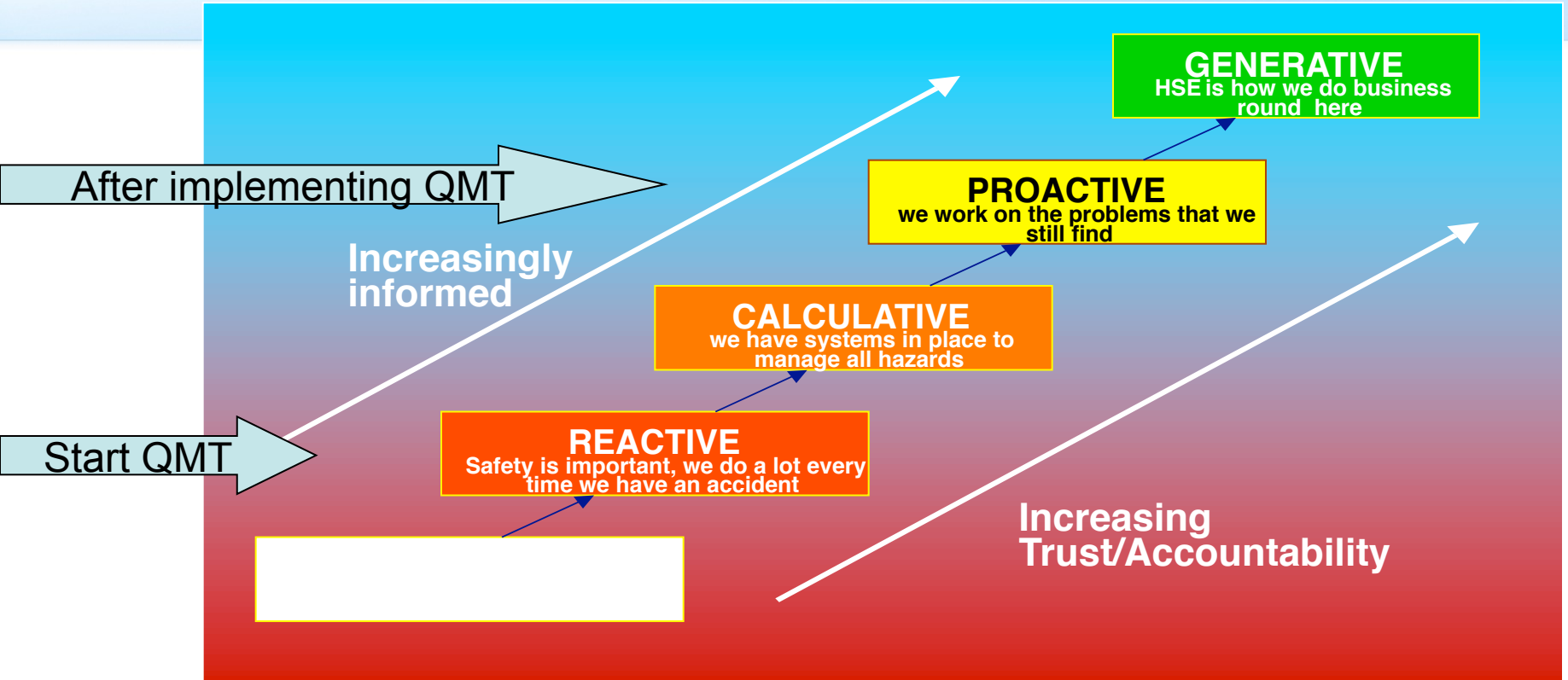
Is a different structure needed for doctors, nurses, technicians?

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



Met dank aan ZGT

High risk technologies in order of risk impact in the organization

WG Technology	2005	2006	2007	2008	2009	2010	2011
0 Patient monitoring	C	rC	rC	rC	rC		
1 Electrical installations				1			
2 Installations Medical gasses				2			
3 Infusionpumps				3	C	rC	
4 Anesthesia and ventilation technology				4		C	
5 (Electro)surgery technology				5		C	
6 Endoscopes + CSA				6		C	
7 Resuscitation equipment					7	C	
8 Beds					8	C	
9 Hospital ventilation systems					9		
10 Radiodiagnostics technology (X-ray, CT)							10
11 Watersystems (legionella)							11
12 Cardiovascular equipment							12
13 Ultrasound							13
14 Incubators							14
15 Laser equipment							15
16 Heating							
17 Mobility aids, patient hoists							
18 Dialysis equipment				18	C		
19 Pacemakers							19
20 Lung function devices							
21 Neurophysiological equipment							
22 Nuclear medicine equipment (gamma)							
23 MRI							
24 Other							

C= Certification
rC=recertification

Technologies
defined by TNO

Order of
starting WG

Risk/
Impact

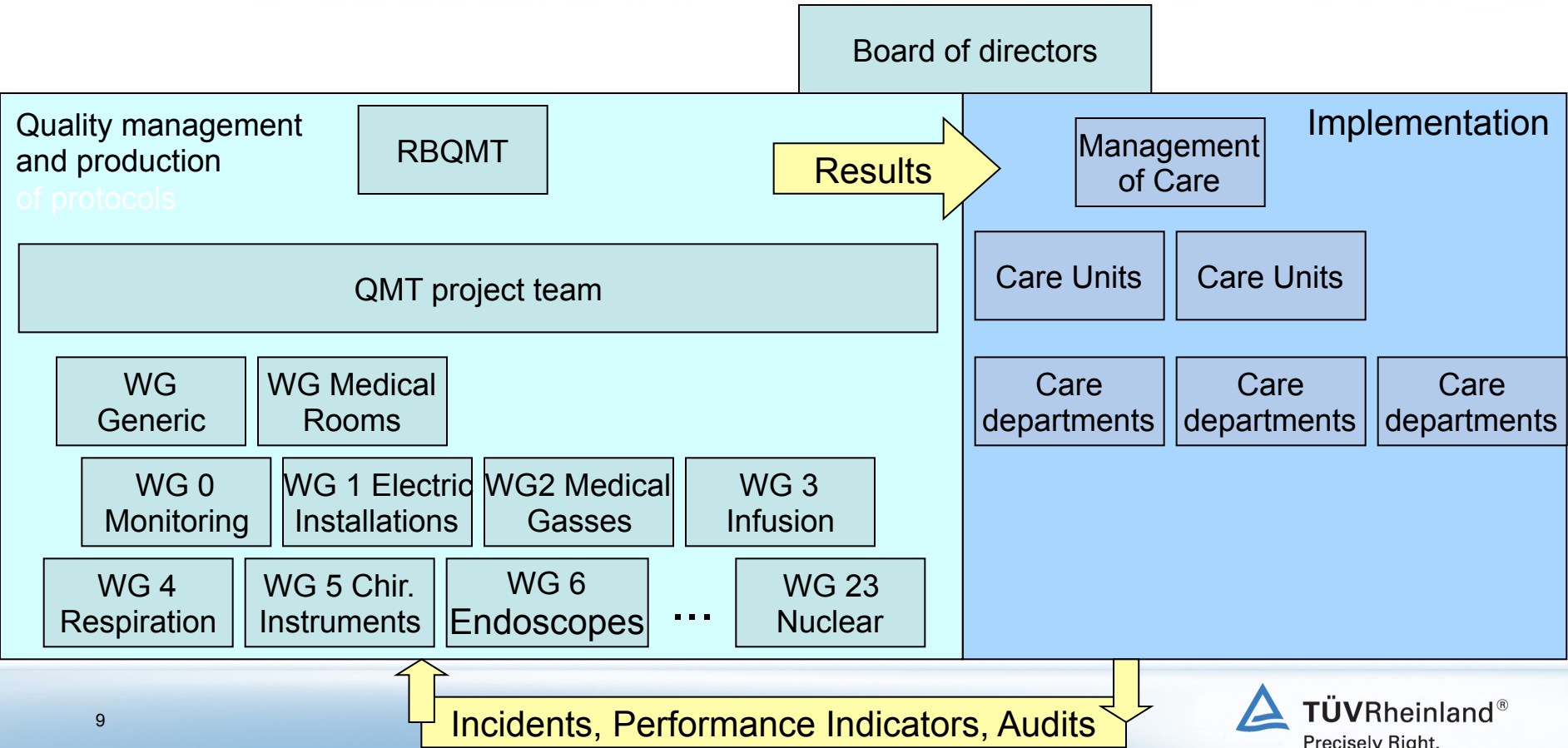
First

High

Later

Low

Structure of the QMT project



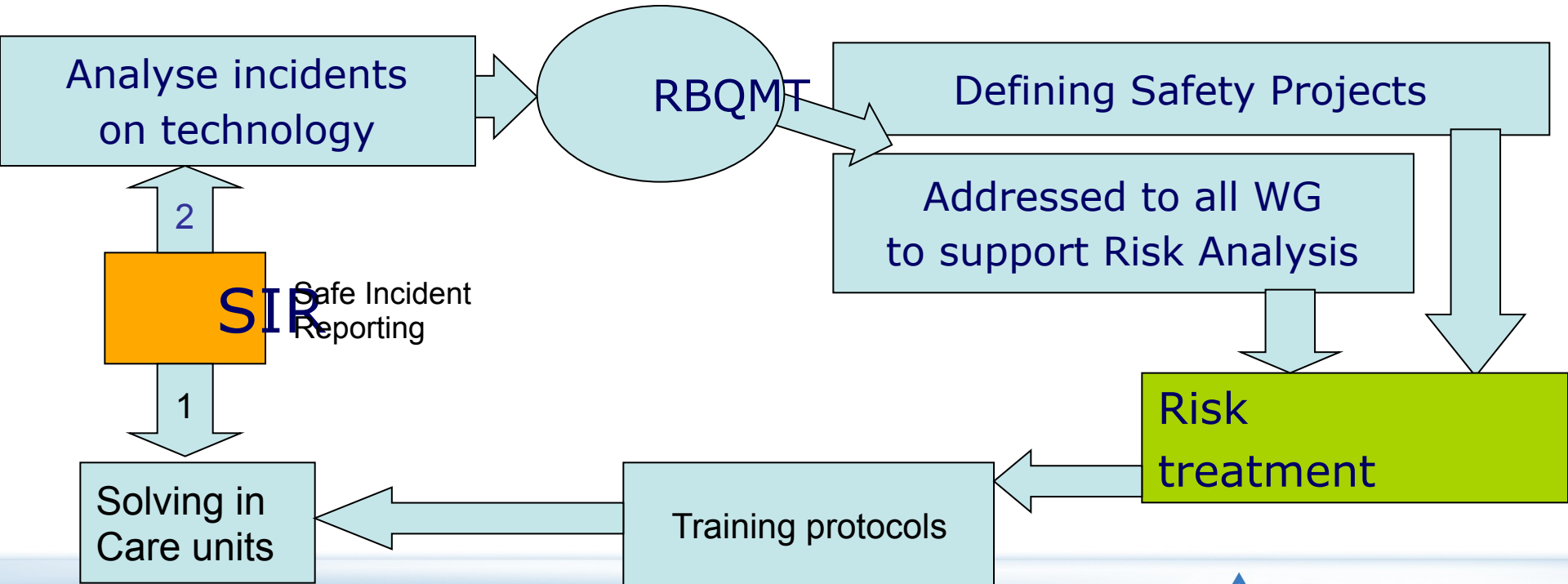
Approach

- 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

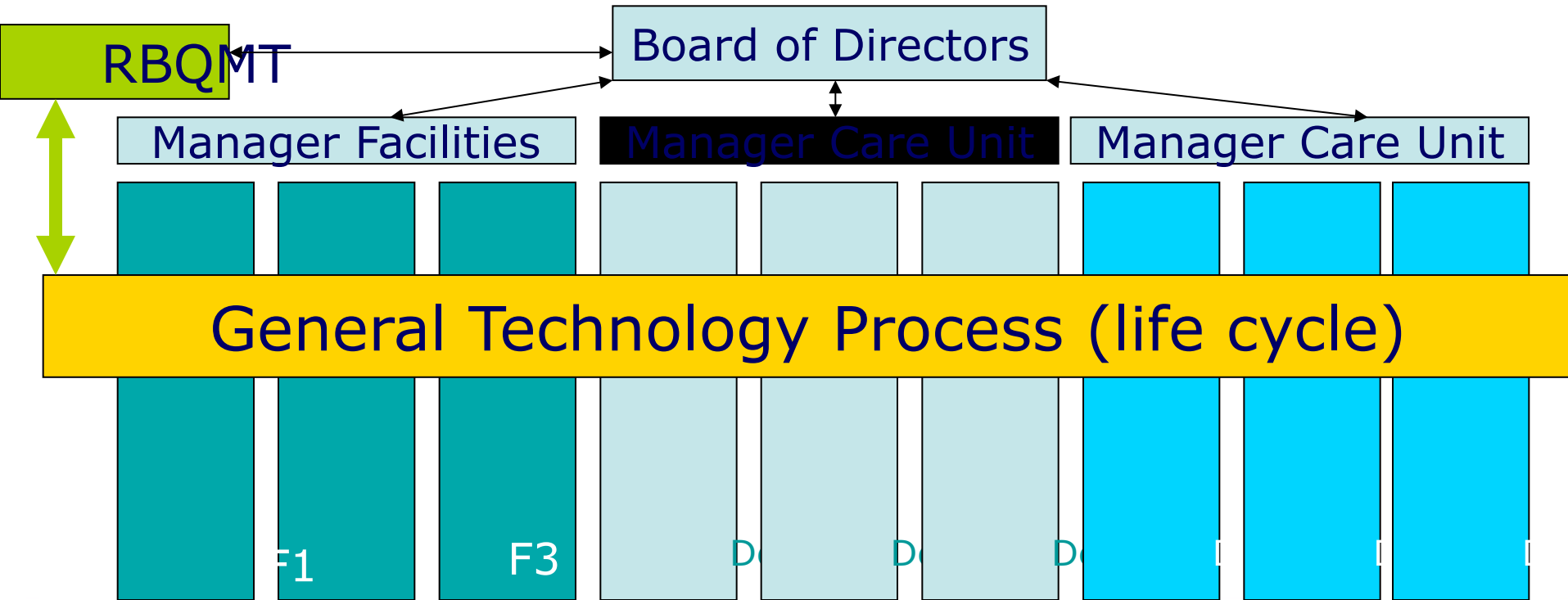
Prospective risk analysis



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



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?

RBQMT

Q-plan NBF

NBF vormgeven	RvB: NBF installatie	Permanente verbetering PDCA	Bekendmaken in instelling	Implementatie in instelling	Documentatie beheer	Interne audits	Geaggregeerde feed back in PDCA
Vaststellen PRE	Kwaliteitsbeleid instelling en med. technologie	Kwaliteitsdoelstellingen NBF	Koppeling aan jaarcyclus	Kwantitatieve rapportage	Vaststellen concessiebeleid	V&B&Kwalificatie leden NBF	Preventieve en corrigerende maatregelen

Handboek MID Q-plan TP

Investeringsbeleid	Kwaliteitsbeleid afdeling MID en med. technologie	Kwaliteitsdoelstellingen MID & med. technologie	Recall & gevaarmeldingen	Concessiebeleid	Meldingsopvolging	Toets bestand apparatuur aan PRE	V&B&Kwalificatie medewerkers MID	Kwaliteitsbeleid zorgafdelingen en med. technologie	Kwaliteitsdoelstellingen zorgafdelingen en med. technologie
Inkoop	Acceptatie test en procedure	General technology process (life cycle)					Acceptatie in de zorg	Gebruik	
Opstellen producteisen	Test Protocollen	Onderhoud beheer-systeem apparatuur	Randvoorwaarden (installaties)	Test Protocollen	Afvoeren	Gebruiks-aanwijzingen			
Producteisen PRE	Risicoanalyse per technologie	Risicoanalyse acceptatie	Registraties	Testruimten	Meetapparatuur	Gebruiks-protocollen			
Risicoanalyse per technologie	Risicoanalyse acceptatie	Risicoanalyse eindtest	Calibratie	Gebruikers-training					

Handboek Zorgen met de technologie
Q-plan Inbedding Zorg

Technicians

Care

TN Kwaliteit van Leven

Kerndocumenten per technologie	Beoordeling PRE door TNO
Toesingslijsten per technologie (intern TNO)	

External Reference

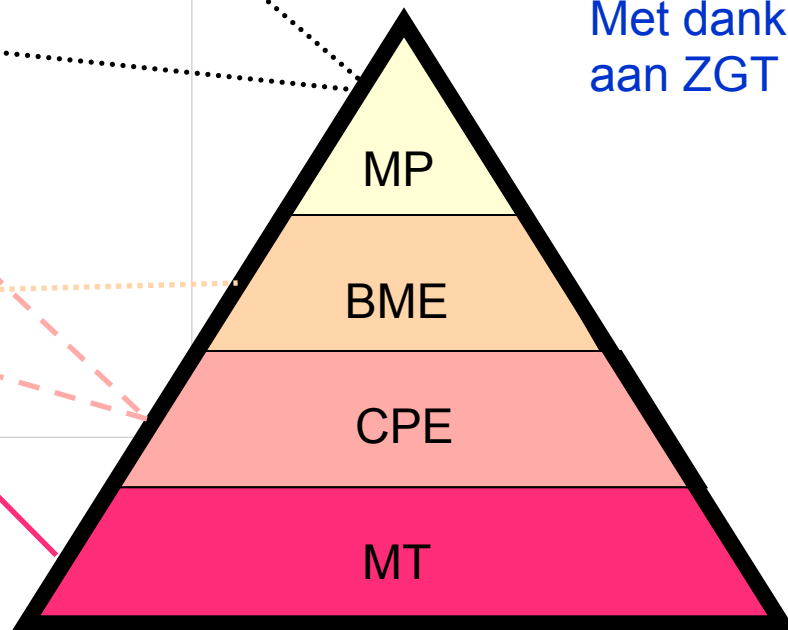




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Vision on human resources

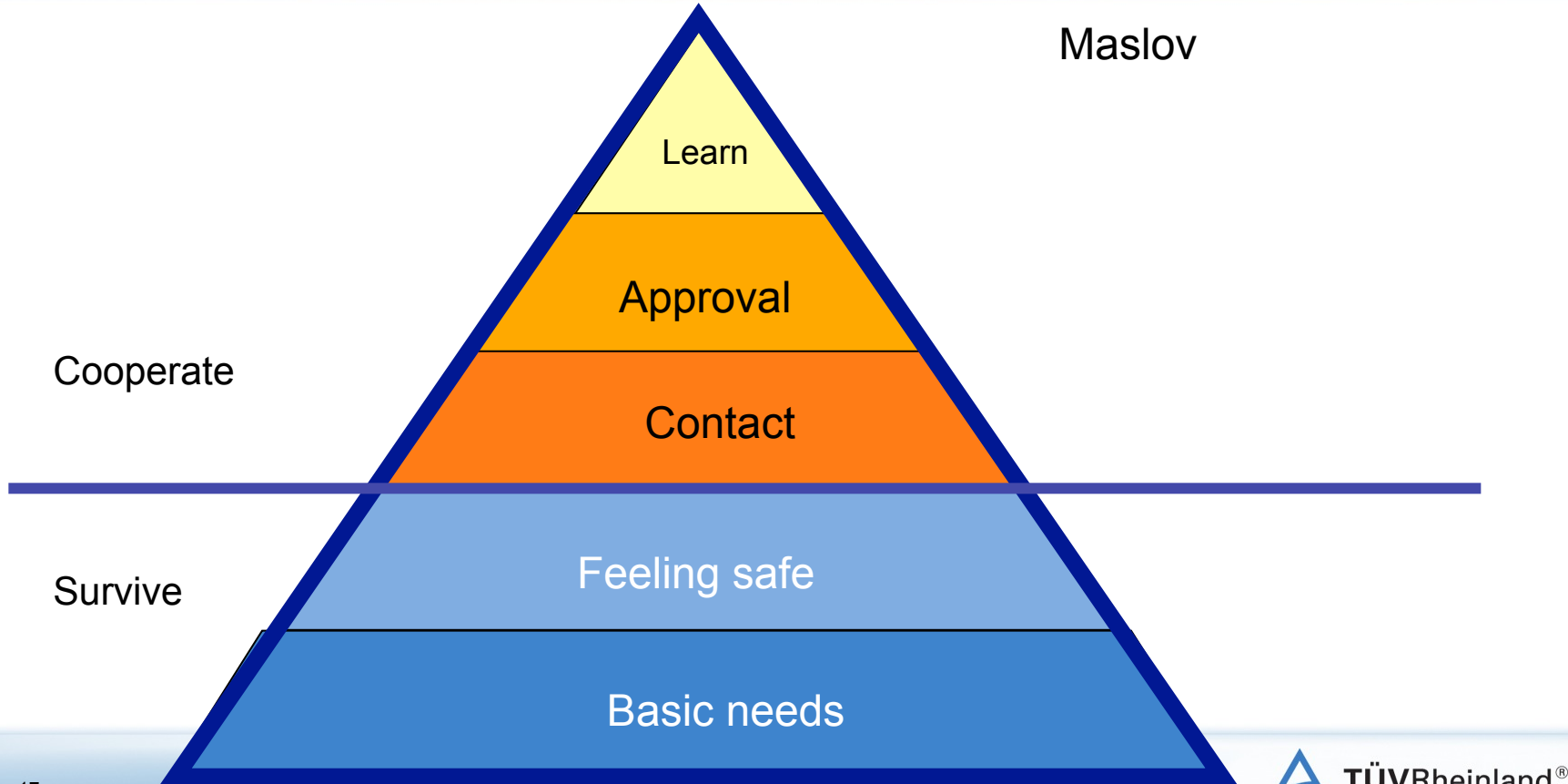
Met dank aan ZGT



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

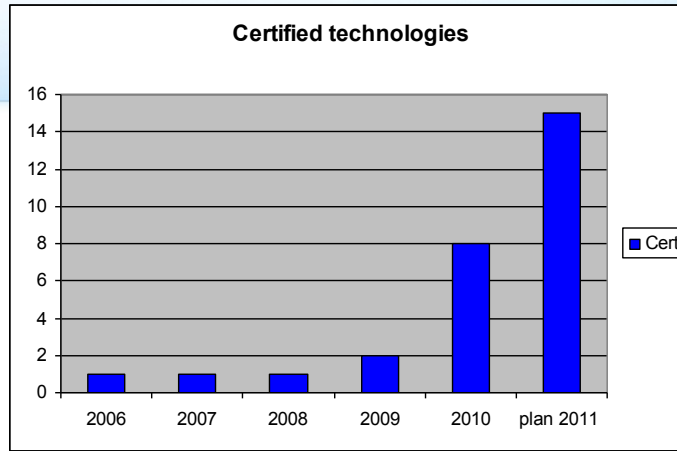
Firm internal organization



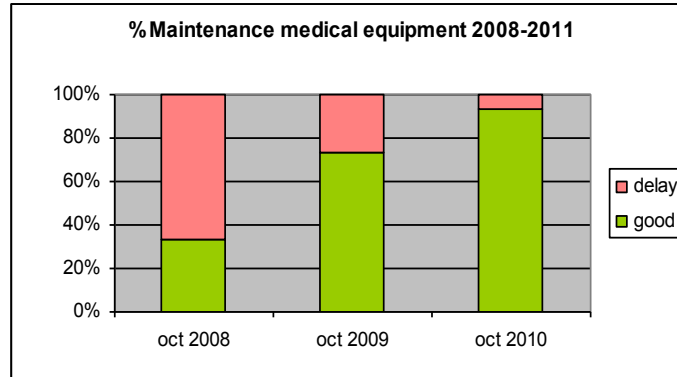
Met dank aan ZGT

Results

Implemented and certified High Risk Technologies



Status of maintenance



versie: 2010/11/11

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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, Elektrisch verstelbare bedden, Dialyse, Patiëntbewaking en Infautechnologie.**

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.

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 Vervaldatum: **13 juli 2015**
 Uitgifte eerste certificaat: **17 juni 2006**


 Directie TÜV Rheinland Nederland B.V.
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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