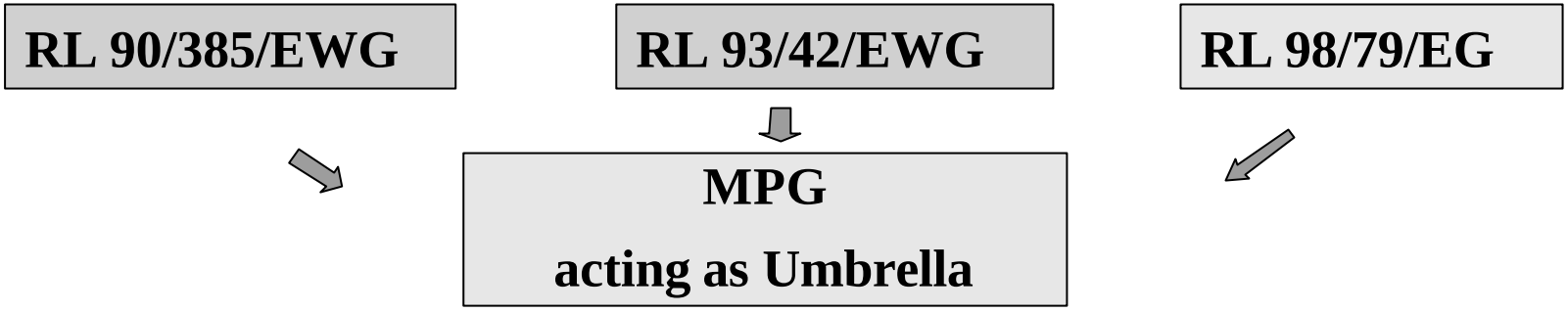
Qualitymanagement at the Point of Care – an Industry View

Düsseldorf, 15. November 2006

The Medical Device Law



Detailed regulations of MPG (Authorisation acc. § 37 MPG):

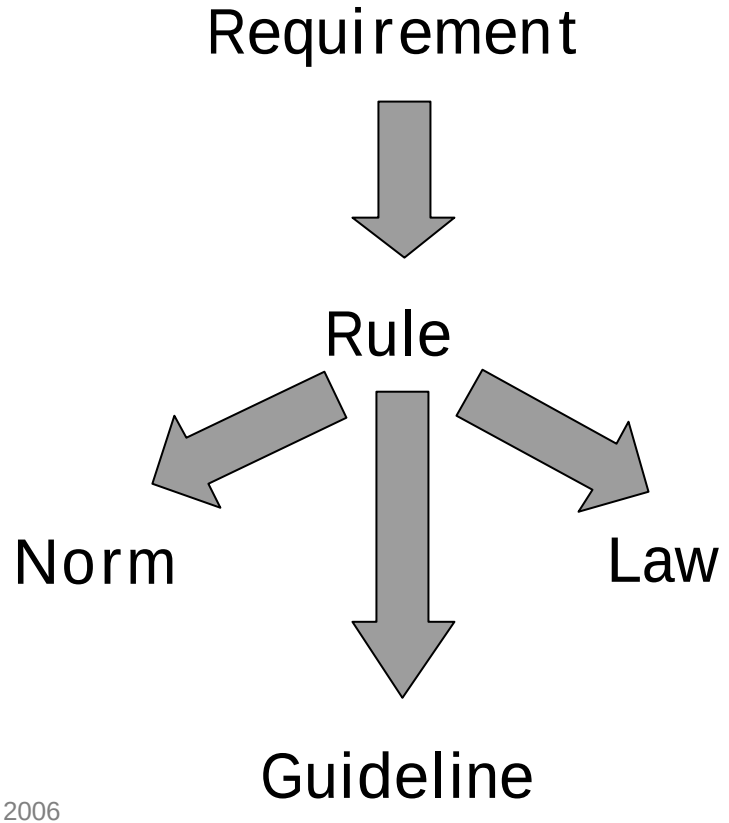
- **MPV (Action of Conformity)**
- **MPSicherheitsplanV (Events)**
- **MPBetreibV (users regulation)**
- **MPVerschrV (duty of prescription)**
- **MPVertrV (Distribution)**
- **V DIMDI (Vigilance and Databases)**
- **BundesKostenV (fees and expenses)**

- Governmental need for regulation (MPG) Implementing actual needs

operational Target

Guarantee of minimum Quality

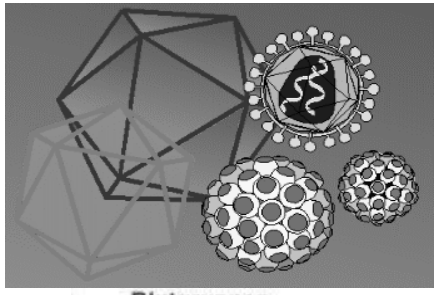
Patient- and User protection

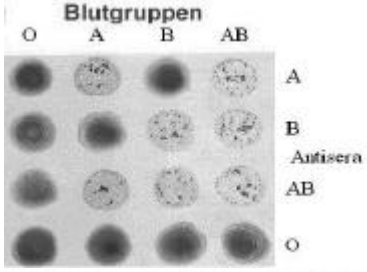


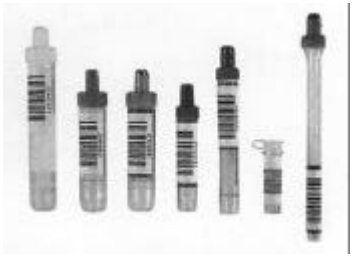
Mod acc. Prof. Vogt, 4. wissenschaftliches Abbott Symposium 10/11. May 2006

Klassifizierung von In-vitro-Diagnostika

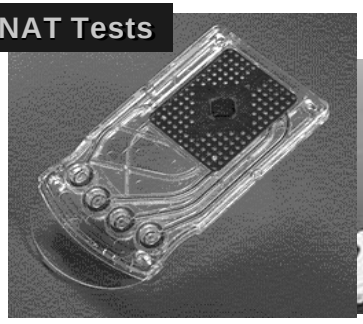
- **Produkte in Anhang II (Liste A)**
- **Produkte in Anhang II (Liste B)**
- **Produkte zur Eigenanwendung**
  ("Home-Tests", außer Anhang II)
- **Alle übrigen In-vitro Diagnostika**
  (z.B. für Leistungsbewertungszwecke)







NAT Tests



Legal Standards for Quality Assurance

IVDD

Obligates the manufacturer to provide relevant information for usage and to perform Quality Control

MPG

MPBetreibV

Obligates the user to perform Quality Control, to employ the guidelines of the German Physicians Board (Rili-BÄK) and to train staff as well as to follow the manufacturers instructions for use, maintenance, etc., §§2 et sqq

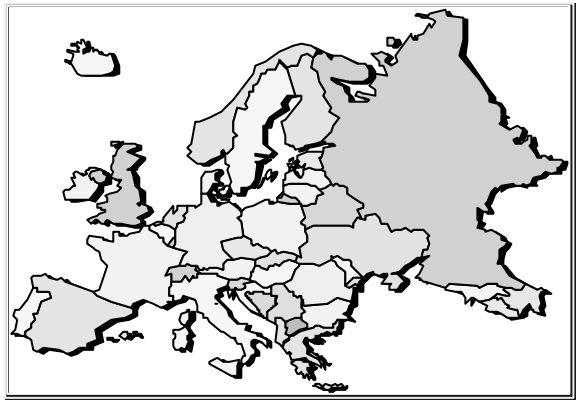
Rili-Bäk

Requirements for manufacturers

- to fulfill the essential requirements as outlined in Annex I of the IVDD
- to implement the principle of integrated safety
- to hold technical documentation, and to conduct risk analysis and performance evaluation
- to implement an efficient Quality System
- to establish a systematic product surveillance system

CE- Marking

The CE-Mark symbolyses the safety and functionality of a medical device according to its intended use (= Quality as set by the manufacturers specifications). In applying a CE-Mark the manufacturer documents that he has fulfilled all legislative requirements (§ 6 Sentence 3 MPG).



Informationen given by the manufacturer: Instructions for use

Essentials of Instructions for use, among which should be:

- list of active ingredients
- Where neccessary: Sample pretreatment procedure
- Reference ranges, measurement procedure and calculation of results
- Performance data
- Statements about internal QC and validation
- Traceability of calibration
- Safe combination with other products or equipment
- Verification of proper installation or maintenance,
- Precautionary measure concerning waste disposal (for exsample chemicals, infectious materials, accumulators)
- release date of the instructions for use (Commodity No.).

In Germany at a minimum all safety related informations need to be provided in German language or in the language of the user (§ 11 MPG).

Legal Obligation for Quality Assurance (SGB V § 135a)

(1) Die Leistungserbringer sind zur Sicherung und Weiterentwicklung der Qualität der von ihnen erbrachten Leistungen verpflichtet. Die Leistungen müssen dem jeweiligen **Stand der wissenschaftlichen Erkenntnis** entsprechen und in der **fachlich gebotenen Qualität** erbracht werden.

(2) Vertragsärzte, zugelassene Krankenhäuser.... sind nach Maßgabe der §§ 136a, 137 und 137 d verpflichtet, sich an **einrichtungsübergreifenden Maßnahmen der Qualitätssicherung** zu beteiligen, die insbesondere zum Ziel haben, die Ergebnisqualität zu verbessern. Zugelassene Krankenhäuser....sind nach Maßgabe der §§ 137 und 137 d verpflichtet, **einrichtungsintern ein Qualitätsmanagement einzuführen und weiterzuentwickeln.**

Requirements for Users (physicians) of IvD (MPBetreibV)

- Examination of suitability of the IvD for the planned purpose
- Examination of safety of the IvD
- Usage according the manufacturers specifications
- Compliance with the manufacturers guidelines for Quality assurance
- Consideration of guidelines for the appraisal of results

In compliance with guidelines means:

4. The diagnosis of a Diabetes is allowed only with results from glucose measurements done with an established quality controlled laboratory method. Systems for Lay-usage are not suitable for this purpose at all.

Evidenzbasierte Leitlinien der DDG, Aktualisierung 10/2004, Seite 6

Qualitymanagement at the Point of Care – An Industry View

POCT is limited to only a small group of analytes like Bloodgases, Glucose (other Clin.Chem assays), Cardiology markers and Coagulation testing

Usage sites are (outside of a central laboratory) Wards, Physicians offices, Mobile Intensive Care Units, Ambulances or Intensive Care Units

These constellations are asking for specific rules which secure the quality of the measurements.

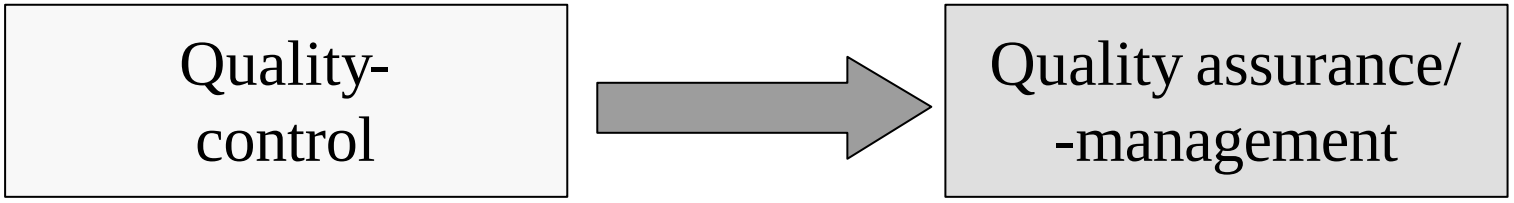
Objectives for Quality Assurance at the POCT:

- Adequate Quality Control for systems with single sample measurement and Unit-use-Reagents and for complex analytical systems (elektrode based BG-Systems, CC-Systems)
- Minimisation of risk for patients and users of POCT-Systems
- Taking into account the manufacturers standards for Quality control as a minimum requirement

Draft of the new Guideline of the German Physicians Board (Rili-BÄK) 2006:

Guideline of the Germans Physicians Board for quality Assurance of Quantitative Laboratory Medical Examinations

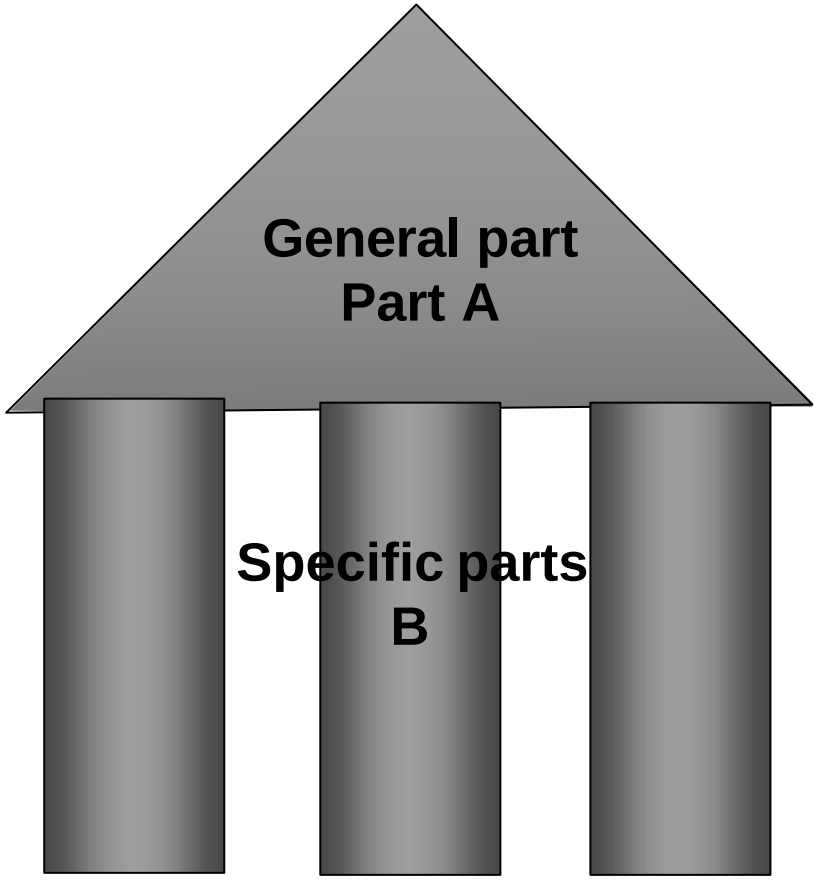
Guideline of the German Physicians Board for Quality Assurance of Laboratory Medical Examinations



since 1972

2007

Draft of the new Guideline (Rili-BÄK) 2006:



Prof. Vogt, 4. wissenschaftliches Abbott Symposium 10/11. Mai 2006

Draft of the new Guideline (Rili-BÄK) 2006:

general part (A):
Includes for the laboratory relevant elements of the Quality Management (Structure- and Process Quality)

- Structure
- Ressources
- Laboratory testing requisits (Pre-analytics, analytics, Post-analytics)
- Quality management system
- Internal and external QC

Draft of the new Guideline (Rili-BÄK) 2006:

Specific Part B1 POCT:

Only systems which perform single sample measurement with unit-use-reagents are considered to be POCT systems

Conventional, elektrodebased BG Systems are underlying full QC requirements and are considered not to be POCT systems

Users of Glucose Striptest systems have to perform daily QC, each day patients are measured.

Draft of the new Guideline (Rili-BÄK) 2006:

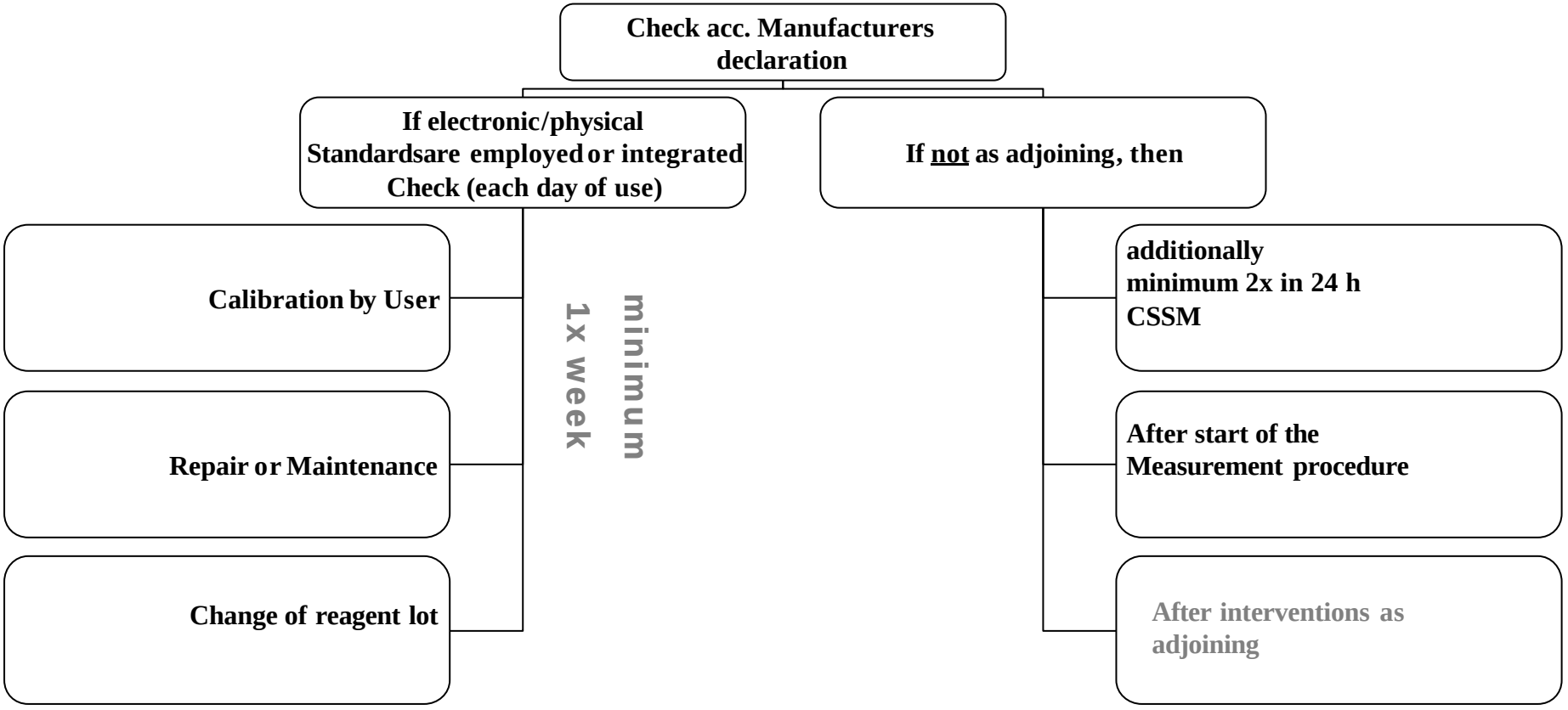
Specific Part B1 POCT:

But systems employing Unit-use-Reagents and having an integrated QC system, which prevents the release of erroneous results have to be checked only once a week with a liquid control material

For parameters not listed in table 1 the manufacturers instructions for internal QC have to be performed and assessed according pregiven target values and ranges

Draft of the new guideline (Rili-BÄK) 2006:

Specific Part B1: POCT – QC requirements:



Draft of the new Guideline (Rili-BÄK) 2006:

Specific Part B1 POCT:

a control sample single measurement is required:

- before a patient sample is measured the first time a day
- after calibration performed by the user
- after repair or maintenance
- after employing a new lot of reagents (strips) or unit use reagents

Draft of the new Guideline (Rili-BÄK) 2006:

Specific Part B1 POCT:

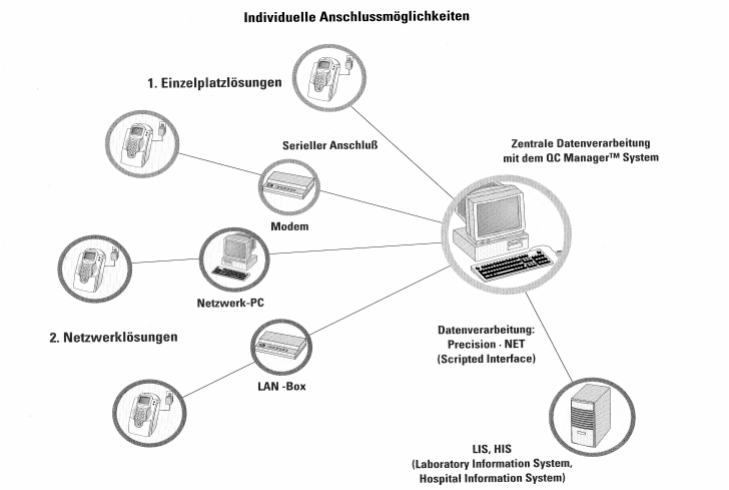
the relief from participation on ring trials (EQAS schemes) is valid when:

- POCT testíng in hospitals is performed under supervision of the central laboratory and the measurand is analysed from the identical sample material also in the central laboratory

- physicians in phycicians offices are performing and documenting internal QC according the requirements of the new guidelines (Rili-BÄK)

POCT in Hospitals

- Integration into the QM-System of the hospital
- defined responsibilites (POCT-Manager) and processes according Part A of the new guideline (Rili-BÄK)
- EDP-Network and monitoring of QC under supervision of the central laboratory



POCT outside the hospital:

- defined responsibilities and processes according Part A of the new guideline (Rili-BÄK)
- Verification of the suitability of the IvD device for the planned purpose of usage in the POCT
- Fixed processes for performing QC having regard to the manufacturers specifications for internal QC and the requirements of the new guidelines (Rili-BÄK) Part B1

Conclusion I:

The interlogging of Industry presettings for the marketing and distribution of IvD under the CE-Mark with the requirements for user‘s quality management systems is usefull for reducing substantially the risk for patients

The medical device law users guidelines (MPBetreibV) advices the user to comply with the duties lined out in the regulation leading to further risk reduction when employing IvD

Essential is the evaluation of the suitability of the IvD for the planned purpose by the responsible physician to ensure a safe and meaningful diagnosis

Conclusion II:

The new Guideline (Rili-BÄK) reflects the technical configuration of the systems used in POCT settings in its requirements for internal QC

The involvement of the central laboratory is reasonable and desirable to support a correct and quality assured usage of POCT systems

The consideration of manufacturers advice for QC as a minimum and the capability to adjust the requirements of the QC within the quality management system according the medical needs is essential

It might be helpful to refer to the international standards ISO 15189 specific for the medical laboratory and the recently published ISO 22870 specific for POCT

Thank you for your attention!

Qualitymanagement at the Point of Care – An Industry View