New and Changing U.S. Guidelines and Regulations

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TUFTS UNIVERSITY

Disclosure

- CLIAC Chair PT Workgroup
- CLSI Chairholder POCT Consensus Committee
- CLSI Chairholder EP23 Subcommittee – Laboratory Quality Control Based on Risk Management

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Objectives

- Update on CLIAC Proficiency Testing recommendations
- Discuss changing interpretation of POCT competency requirements
- Describe potential regulatory changes with publication of CLSI EP23 Laboratory Quality Control based on Risk Management

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Audience Response

How do you feel about CLIA Proficiency Testing Requirements?

A) PT is just right, not overburdensome

B) CLIA regulated analyte list is outdated and limits are too broad to be useful

C) PT should be required for all analytes including waived testing

D) PT should be entirely voluntary, as it adds little to the quality of lab

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CLIAC PT Workgroup

- CLIAC Recommendation: Form a workgroup to examine and provide suggestions concerning need for revisions to the CLIA PT requirements.
- CMS and CDC organized workgroup to include stakeholders in the PT process
  - Laboratory experts
  - Accreditation organizations
  - State Surveyors
  - PT program officials
- James H. Nichols, Ph.D. PT workgroup Chair, Gerri Hall, Ph.D. microbiology Co-Chair

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PT Workgroup

- **Objectives: Provide input to CLIAC to make recommendations to HHS regarding changes to subparts H and I of the CLIA regulations:**
  - **Updating the list of CLIA-regulated analytes**
  - **Revising the criteria for acceptable performance (grading criteria), including target values and acceptable limits for current and proposed analytes**
  - **Changes to specialties or subspecialties that do not have regulated analytes, including microbiology**
  - **Clarification of the requirements that address PT referral**
  - **Other changes needed to update and improve required PT**

Issues Raised by Workgroup

- PT is one component of a laboratory's quality system and helps assure quality between inspections
- Concerns regarding PT (cost of materials, staffing turnover) vary with laboratory size
- Physician offices or other small laboratories may not understand PT requirements or the value of PT
- Surveyors and PT programs educate laboratories and provide assistance with PT enrollment
- The list of regulated analytes and grading criteria needs to be updated and should have the capacity to be flexible over time, to the extent permitted by law
- PT should be required for all analytes and instruments, including waived testing and back-up analyzers
- When possible, PT should cover the entire testing process, to include pre-and post-analytical phases

Factors for Adding Regulated Analytes

What factors should be considered for adding regulated analytes to subpart I of the CLIA PT regulations?

- WORKGROUP AGREEMENT:
  - Consider as criteria for analyte inclusion:
    - PT exists and material is available
    - Volume of testing for an analyte
    - Clinical relevance
    - Cost

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Assessing Factors or Criteria

How should the factors or criteria for analyte inclusion be objectively assessed?

- Inclusion criteria need to be weighted or scored
- Clinical relevance is difficult to score
  - Consider: Volume of testing in conjunction with practice guidelines
  - Existence of standardized or reference methods
  - Availability of tests with years of experience in field and with PT and grading

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Number of Analytes to Add

Should there be a reasonable limit on the number of analytes added to each new regulation published for proficiency testing?

- No agreement was expressed on the number of analytes to include
- Consider requiring new analytes in phases.
  - Analytes for which PT is already available and testing is frequently performed should be a priority
  - Three year phase-in after FDA approval was suggested
  - Consider the costs when adding new analytes for PT programs and laboratories
  - Consider the length of time required for making changes to required PT

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Analytes for Consideration

- Individual workgroup members suggested:
  - LDL direct
  - PSA
  - D-dimer
  - INR
  - Myoglobin
  - Vitamin D
  - Vitamin B12
  - Free T3
  - * Hepatitis viral testing other than B
  - * HgbA1c
  - * Markers measured by flow cytometry
  - * Urine drugs
  - * Clinical toxicology
  - * Illicit drugs
  - * Drugs for pain management
  - * FSH
- Strongly consider adding new analytes used to screen blood for emerging infectious diseases
- Consider tests done once in a lifetime or for life threatening conditions: Genetic tests, such as Her-2/neu
- Tests for life threatening conditions, such as troponin, BNP, tumor markers
- Default to all analytes regulated unless there are valid reasons against it

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Deletion of Required PT Analytes

- Suggest criteria be developed for deleting analytes, perhaps the same criteria as for including them
- For some analytes, eliminating required PT may result in increased errors
- Analytes should be removed from the list if laboratories no longer perform testing for those analytes
- Analytes proposed for possible deletion from required PT:
  - Ethosuximide
  - LDH isoenzymes
  - NAPA and procainamide
  - Quinidine
  - T3 uptake

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PT Referral

- Confusion - PT samples must be tested like patients but must not be sent to another laboratory
  - Laboratories in a single organization with multiple CLIA certificates
  - Viewing results from another laboratory is PT referral
  - Some PT referral cases are likely not intentional, but due to lack of understanding
- Allow laboratories to treat PT exactly as patient samples and do reflex or referral testing when it is included in their standard procedure (Quad testing if lab doesn't do all tests)
- Possible criterion = whether the laboratory has the test on its test menu
- Need to have regulatory language to give laboratories the latitude to refer pieces needed to report complete result or report PT only for the parts completed in their laboratory

PT Workgroup

- Recommendations presented at September 2010 CLIAC meeting
- CMS and CDC are reviewing recommendations to determine how to implement and impact
- May result in future changes to interpretation of CLIA PT requirements
- More details available at CLIAC website: http://wwwn.cdc.gov/cliac/default.aspx

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Audience Response

How has your lab adopted to the new staff competency requirements?

A) No problem, the six elements of documenting competency are fair.

B) We've had particular difficulty, especially for the number of POCT staff.

C) We only perform waived testing and the new requirements do not apply.

D) I am not responsible for staff competency.

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Competency Assessment

- CAP Laboratory General Checklist 2010
- GEN.55500 Competency Assessment Phase II
- The competency of each person to perform his/her assigned duties is assessed.
- For nonwaived tests, all six elements must be assessed annually. For waived tests, it is not necessary to assess all elements at each assessment event: the laboratory may select which elements to assess.
- **Evidence of Compliance:** Records of competency assessment for new and existing employees reflecting the specific skills assessed, the method of evaluation

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Operator Competency

- Elements of competency assessment include but are not limited to:
  1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
  2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
  3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
  4. Direct observation of performance of instrument maintenance and function checks
  5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
  6. Evaluation of problem-solving skills

Competency Challenges

- Ongoing supervisory review is acceptable for certain elements (direct observation of test performance, instrument maintenance, problem solving skills)
- Direct observation becomes an issue as number of staff increases
- Assessment of test performance through previously analyzed specimens is also problematic for POCT given stability of some analytes, and quantity of blood available by fingerstick, from neonates, etc.
- Added expense to use proficiency samples or vials of linearity/control solutions for testing as staff numbers increase

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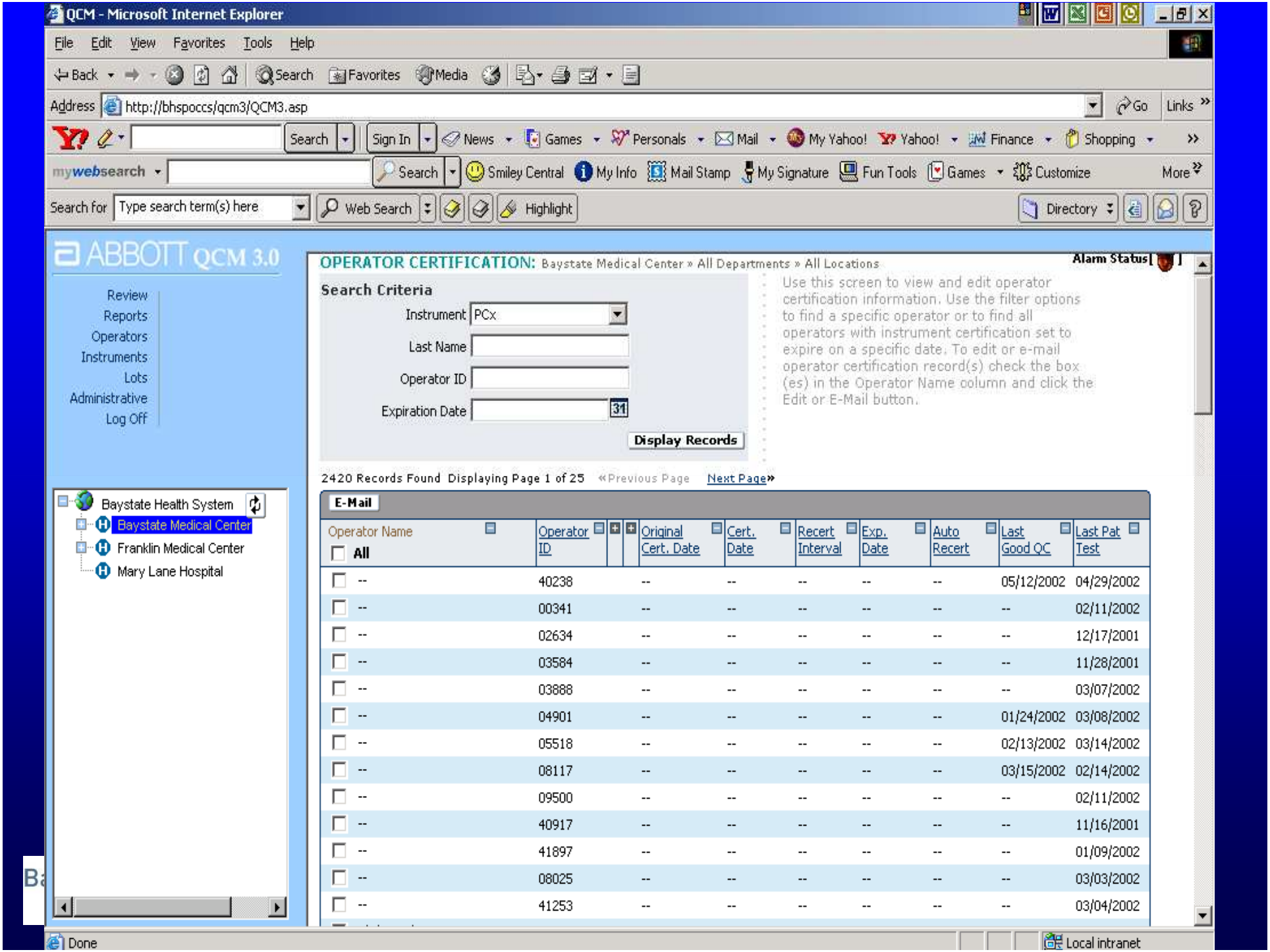
Competency Assessment

- Ways to comply with GEN.55500
  - Utilize QC performance as competency check
  - Annual written exam and observation
  - Nursing Fair (all staff checked on same day)
  - Utilize electronic databases from manufacturer to track and lock out operators after competency expires
  - Commercial vendors available to make customized exams, track scores and maintain records (CAP has a competency assessment program)
  - Linking together problem-solving with knowledge and performance is challenging
  - Optimize processes to minimize decision-making – order entry to test select, data management to interpret result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Display Records
Use this screen to view and edit operator certification information. Use the filter options to find a specific operator or to find all operators with instrument certification set to expire on a specific date. To edit or e-mail operator certification record(s) check the box (es) in the Operator Name column and click the Edit or E-Mail button.
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Baystate Medical Center
Franklin Medical Center
Mary Lane Hospital
E-Mail
Operator Name All
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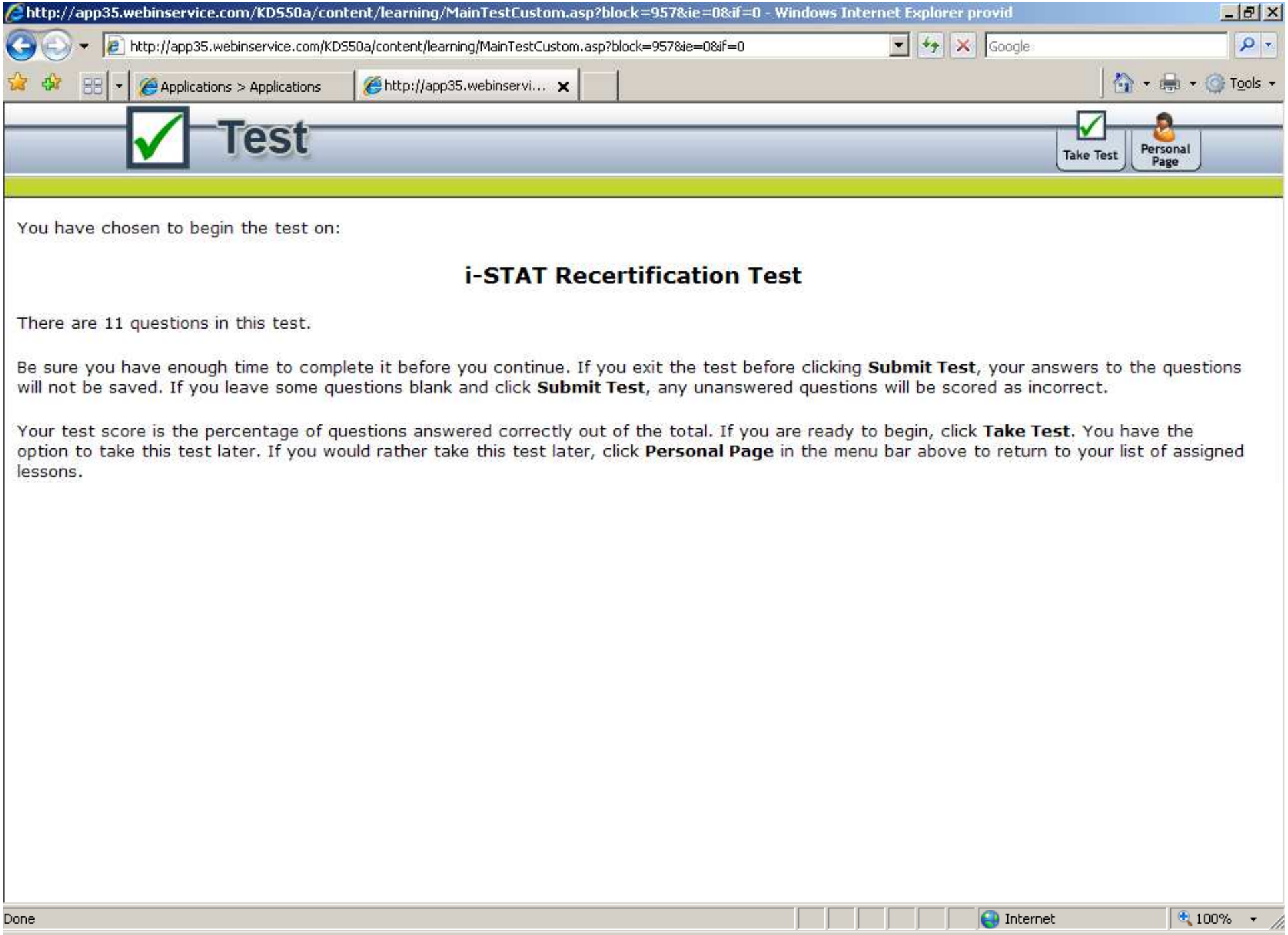
Last Good QC
Last Pat Test
-- 40238 -- -- -- -- -- 05/12/2002 04/29/2002
-- 00341 -- -- -- -- -- -- 02/11/2002
-- 02634 -- -- -- -- -- -- 12/17/2001
-- 03584 -- -- -- -- -- -- 11/28/2001
-- 03888 -- -- -- -- -- -- 03/07/2002
-- 04901 -- -- -- -- -- 01/24/2002 03/08/2002
-- 05518 -- -- -- -- -- 02/13/2002 03/14/2002
-- 08117 -- -- -- -- -- 03/15/2002 02/14/2002
-- 09500 -- -- -- -- -- -- 02/11/2002
-- 40917 -- -- -- -- -- -- 11/16/2001
-- 41897 -- -- -- -- -- -- 01/09/2002
-- 08025 -- -- -- -- -- -- 03/03/2002
-- 41253 -- -- -- -- -- -- 03/04/2002
Done
Local intranet

Web Resources

- A number of companies are now offering web-based training and competency programs
  - **College of American Pathologists**
    - Allows tracking/documentation employee training/competency
    - Develop customized exams and track employee scores
  - **RALS-e-Quiz**
    - POCT data management vendor electronic competency exams and operator scores with web-based access
  - **HealthStream**
    - e-Course library to help sites meet regulatory compliance, not lab specific but good resource for general safety, HIPAA, and nursing specific education programs/interactive assessments
  - **NetLearning**
    - Modules for authoring your own web training, competency, managing staff, and performance reviews
  - **Washington State Medical Training Solutions Program**
    - e-competency exams for a variety of POCT devices with operator administration and web-based access
  - **Abbott/Patient Education Programs LLC**
    - Institution can customize training and competency over web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Take Test
Personal Page
You have chosen to begin the test on:
i-STAT Recertification Test
There are 11 questions in this test.
Be sure you have enough time to complete it before you continue. If you exit the test before clicking Submit Test, your answers to the questions will not be saved. If you leave some questions blank and click Submit Test, any unanswered questions will be scored as incorrect.
Your test score is the percentage of questions answered correctly out of the total. If you are ready to begin, click Take Test. You have the option to take this test later. If you would rather take this test later, click Personal Page in the menu bar above to return to your list of assigned lessons.
Done
Internet
100%

Test

Personal Page

Instructions:

1. Select or enter the **best** answer for each of the 11 questions.
2. Answer all the questions. Remember to scroll down if necessary.
3. Click **Complete the Test** to score your answers and view a report.

Complete the Test

1 . What would cause inaccurate i-STAT results?

Go to question 2.

- A. Bubbles dispensed into the cartridge.
- B. Delayed testing of a sample without anticoagulant.
- C. Inadequate mixing of sample.
- D. All of the above.

---

2 . The room temperature expiration date for CG8, EG7, and G3 i-STAT cartridges is 2 months. The 6+, EC4, Creatinine and Glucose cartridges have a room temperature expiration date of 14 days. The i-STAT cartridge room temperature expiration date:

Go to question 3.

- A. Cannot exceed the manufacturer's expiration date.
- B. Must be clearly marked on the outside of the box when box is removed from refrigerator.
- C. Must be written on each individual cartridge packet when cartridge is removed from the box.
- D. All of the above.

---

3 . Batteries in the i-STAT should be checked daily (use Administration menu, #1). When do the batteries need to be changed?

Go to question 4.

- A. When the low battery icon appears

POCT Jeopardy Categories

PPM	Glucose	Pregnancy	Urine Dipsticks	Influenza	Mystery
100	100	100	100	100	100
200	200	200	200	200	200
300	300	300	300	300	300
400	400	400	400	400	400
500	500	500	500	500	500

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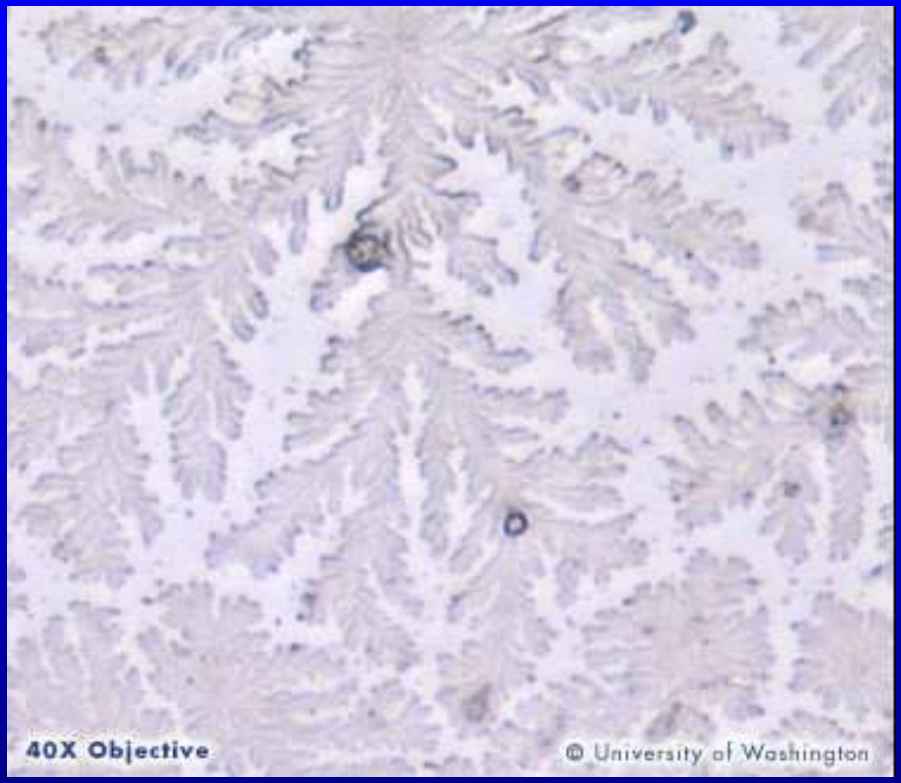
PPM

- 100



A

34 y/o woman presents to ED in possible preterm labor. A swab of vaginal secretions is spread on a glass slide and observed under the microscope after drying show this…

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PPM for 100 Answer

What is Ferning?

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Audience Response
What is your understanding of lab risk?

A) An annual lab requirement for 1 hour of risk management with hospital lawyers.

B) Minimizing potential harm to patients

C) Eliminating laboratory errors

D) All of the above

E) None of the above

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History of QC Regulations

- Two levels of QC each day of testing.
- 1990's –Internal quality control (QC) processes being introduced. What is balance of internal and liquid QC?
- 2004 – Centers for Medicare and Medicaid services (CMS) introduces 3 options for equivalent QC (EQC). Scientific basis for EQC questioned
- EP23 developed as a rational approach to allow the laboratory director to develop a QC plan based on risk for their instrumentation and laboratory.

Clinical Laboratory Improvement Amendments (CLIA)

Equivalent Quality Control Procedures

Brochure #4

What are they, and when can I use them?

Information to assist your laboratory in meeting this CLIA quality control requirement option for nonwaived (moderate and high complexity) test systems!

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published laboratory regulations (CLIA) that became effective April 24, 2003. A summary of equivalent quality control options is included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at http://www.phppo.cdc.gov/CLIA/regs/toc.asp.

Control Procedures - EQC

	Option #1	Option #2	Option #3
Internal QC Extent	ALL	PORTION	NONE
Int/Ext Evaluation	10 days/ 10 days	30 days/ 30 days	NA/ 60 days
EQC/ExtQC Int QC	1/month daily	1/week daily	1/week N/A

Judy Yost QC for the Future Presentation, CLSI, Baltimore, 3/18/2005

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Quality Control Next Steps

- CLSI EP23 document: Laboratory Quality Control Based on Risk Management.
- EP23 would allow laboratory director to determine QC plan specific to device, laboratory setting and how test is utilized provided lab has conducted a risk assessment.

Risk Management

- Clinical laboratories conduct a number of activities that could be considered risk management:
  - evaluating the performance of new devices
  - troubleshooting instrument problems
  - responding to physician complaints
  - estimating harm to a patient from incorrect results
  - taking actions to prevent errors
- So, risk management is not a new concept to the laboratory, just a formal term for what we are already doing every day.

Risk Management Definition

- Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971)

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Risk Definition

- Risk – the chance of suffering or encountering harm or loss (Webster's Dictionary and Thesaurus, 1993 Landoll, Ashland, Ohio)
- Risk can be estimated through a combination of the probability of 1) occurrence of harm and 2) severity of that harm (ISO/IEC Guide 51) and 3) ability to detect an error before it causes harm
  - Risk = (**occurrence**) x (**severity**) x (**detectability**)
- Risk essentially is the potential for an error to occur

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Sources of Laboratory Error

- Environmental:
  - Temperature
  - Humidity
  - Air flow
  - Light intensity
  - Altitude
- Operator:
  - Improper specimen prep, handling
  - Incorrect test interpretation
  - Failure to follow test system instructions
- Analysis:
  - Calibration factor incorrect
  - Mechanical failure

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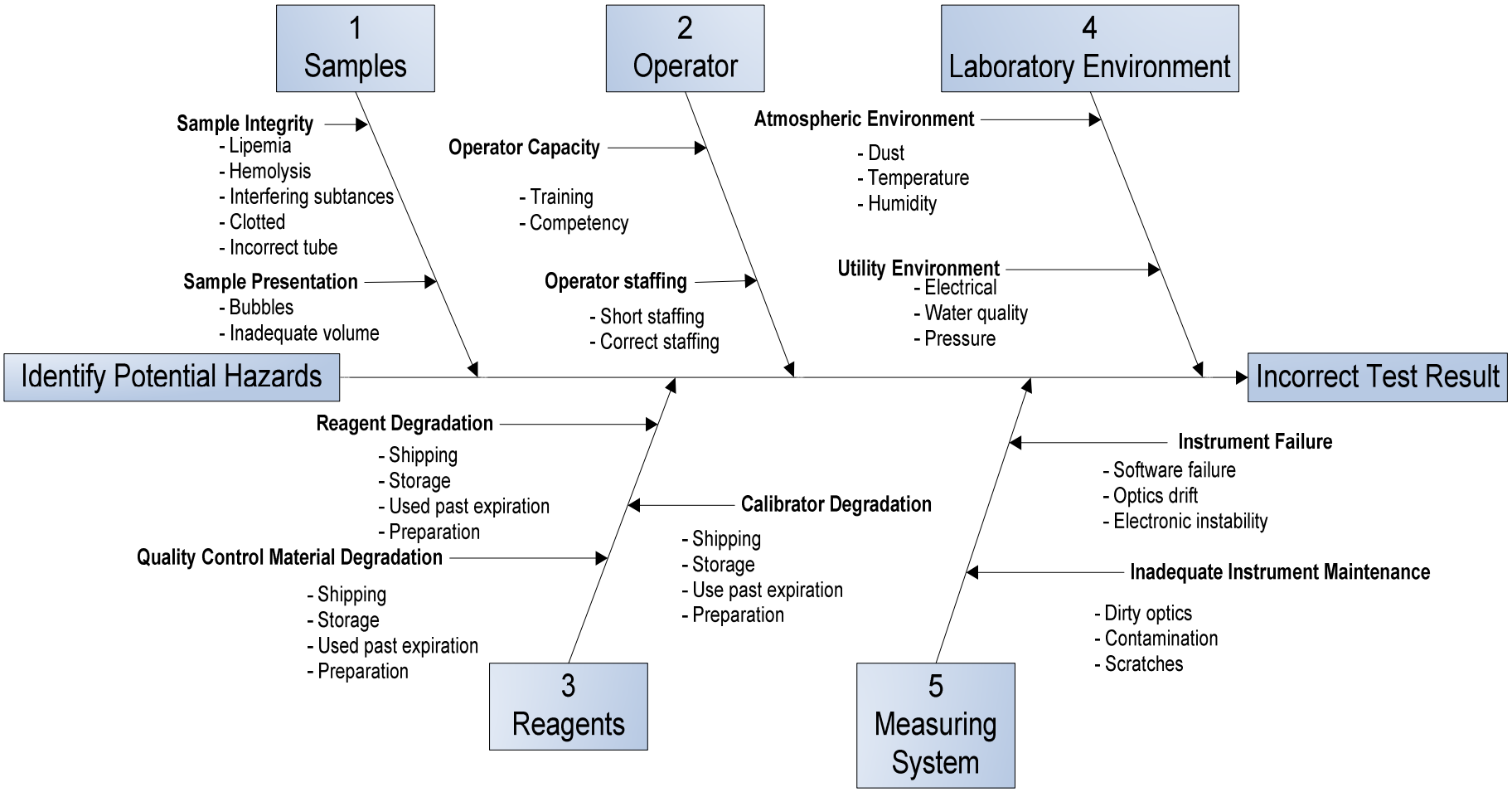

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Quality Control

- A stabilized surrogate sample of known concentration analyzed like a patient sample to determine assay recovery and result stability over time
- Advantages
  - QC has target values, if assay recovers target, then everything is assumed stable (instrument, reagent, operator, sample)
  - QC monitors the end product (result) of the entire test system
- Disadvantages
  - Requires batch analysis or patients can be reported before problem detected
  - When problem detected must go back and reanalyze patients since last "good" QC
- Need to get to fully automated analyzers that eliminate errors upfront, provides assured quality with every sample
  - Until that time, need a robust QC Plan to ensure result quality

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Types of Control Processes

- Internal QC – laboratory analyzed surrogate sample controls.
- External QC – blind proficiency survey, samples sent a few times a year to grade an individual laboratory's performance against other labs

- "On-Board" or Analyzer controls – built in device control processes or system checks
- Other types of controls – Control processes either engineered by manufacturer or enacted by laboratory to ensure result reliability (checking temperature indicator in shipping container on receipt of new reagents, barcoded expiration dates)

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QC Limitations

- No single quality control plan can cover all devices, since devices may differ in design, technology, function, and intended use.
- QC practices developed over the years have provided labs with some degree of assurance that results are valid.
- Newer devices have built-in electronic controls, and "on-board" chemical and biological controls.
- Quality control information from the manufacturer increases the user's understanding of device overall quality assurance requirements so that informed decisions can be made regarding suitable control procedures.

ISO 15198:2004 Clinical laboratory medicine: *In vitro* diagnostic medical devices – Validation of user quality control procedures by the manufacturer.

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Laboratory Manufacturer QC Partnership

- Laboratory directors have ultimate responsibility for determining appropriate quality control procedures for their labs
- Manufacturers if *in vitro* devices have responsibility for providing adequate information about the performance of devices, means to control risks, and verify performance within specification.
- In practice, quality control is a shared responsibility of manufacturers and users of devices

ISO 15198:2004 Clinical laboratory medicine: *In vitro* diagnostic medical devices – Validation of user quality control procedures by the manufacturer.

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CLSI Project: EP23

- Laboratory Quality Control Based on Risk Management.
- James H. Nichols, Ph.D., Chairholder
- EP23 describes good laboratory practice for developing a quality control plan based on manufacturer's risk mitigation information, applicable regulatory and accreditation requirements, and the individual healthcare and laboratory setting

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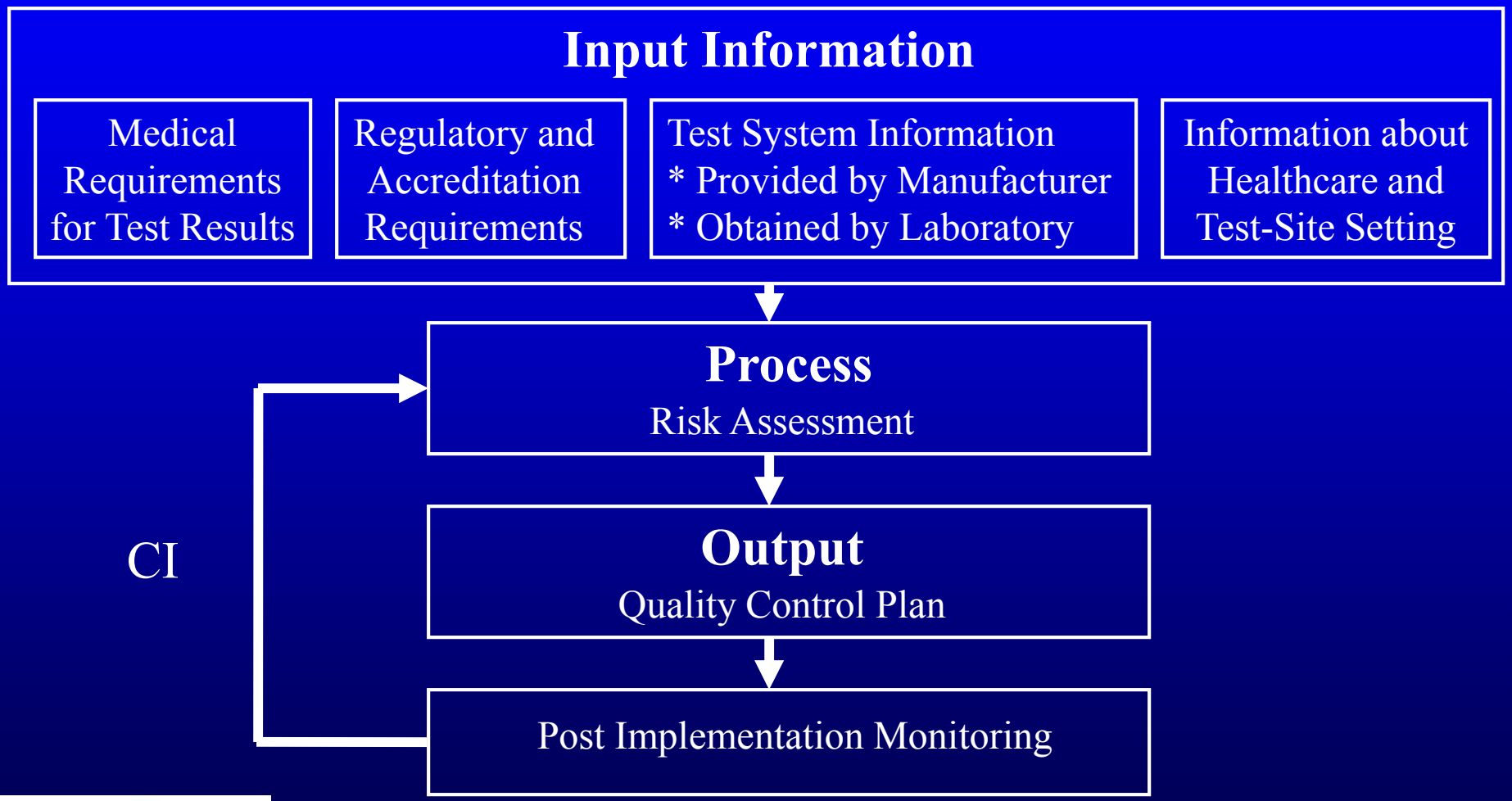
EP23 Laboratory QC Based on Risk Management



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Laboratory Risk Assessment

- If manufacturer and regulated QC processes provide clinically acceptable risk. No further controls may be necessary…
- If risk is unacceptable, then lab needs additional control processes to reduce risk
- Storage conditions – if reagents are refrigerated, quality depends on reliability of staff monitoring refrigerator temperatures or need to use continuous temp monitoring
- Reagent viability – verified by analyzing QC samples
  - increase frequency of analysis to enhance assurance in reagent stability
- Medical Application – QC sample frequency
  - Inpatient – acute care, rapid decisions without time for follow-up requires more frequent QC sample analysis
  - Outpatient – diagnostic, but may be confirmed against symptoms or other testing, may discharge patient before action occurs – time to confirm diagnosis – may require less frequent QC sample analysis
- Optimal mix of control processes dependent on Lab Director, device, medical application of the test, and local regulations.

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Summary

- PT Workgroup has presented recommendations to CMS for updating interpretation of CLIA PT requirements to CLIAC at September 2011 meeting
- New CMS interpretation of operator competency and QC requirements have increased the regulatory burden on laboratories utilizing moderate complexity unit-use devices
- The release of CLSI EP23 may offer an additional alternative for laboratory QC, allowing the laboratory director to determine the appropriate QC plan for a laboratory device.

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POCT regulations in Europe

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Disclosure information of Relevant Financial Relationships

I do not have, and have not had, any relevant financial relationship with any commercial interests within the past 12 months, as pertaining to this presentation.

The content of this CME activity and supplemental materials will promote quality or improvements in healthcare and not a specific proprietary business interest of a commercial interest. Content for this activity, including any presentation of therapeutic options, will be balanced, evidence-based and unbiased.

Topics at a glance

- Overview of the university hospital in Munich
- Quality regulations for POCT applications in the EC
- Special QM requirements for blood gas analyses
- Surveillance of QC measurements by the central lab

Klinkum rechts der Isar der Technischen Universität München

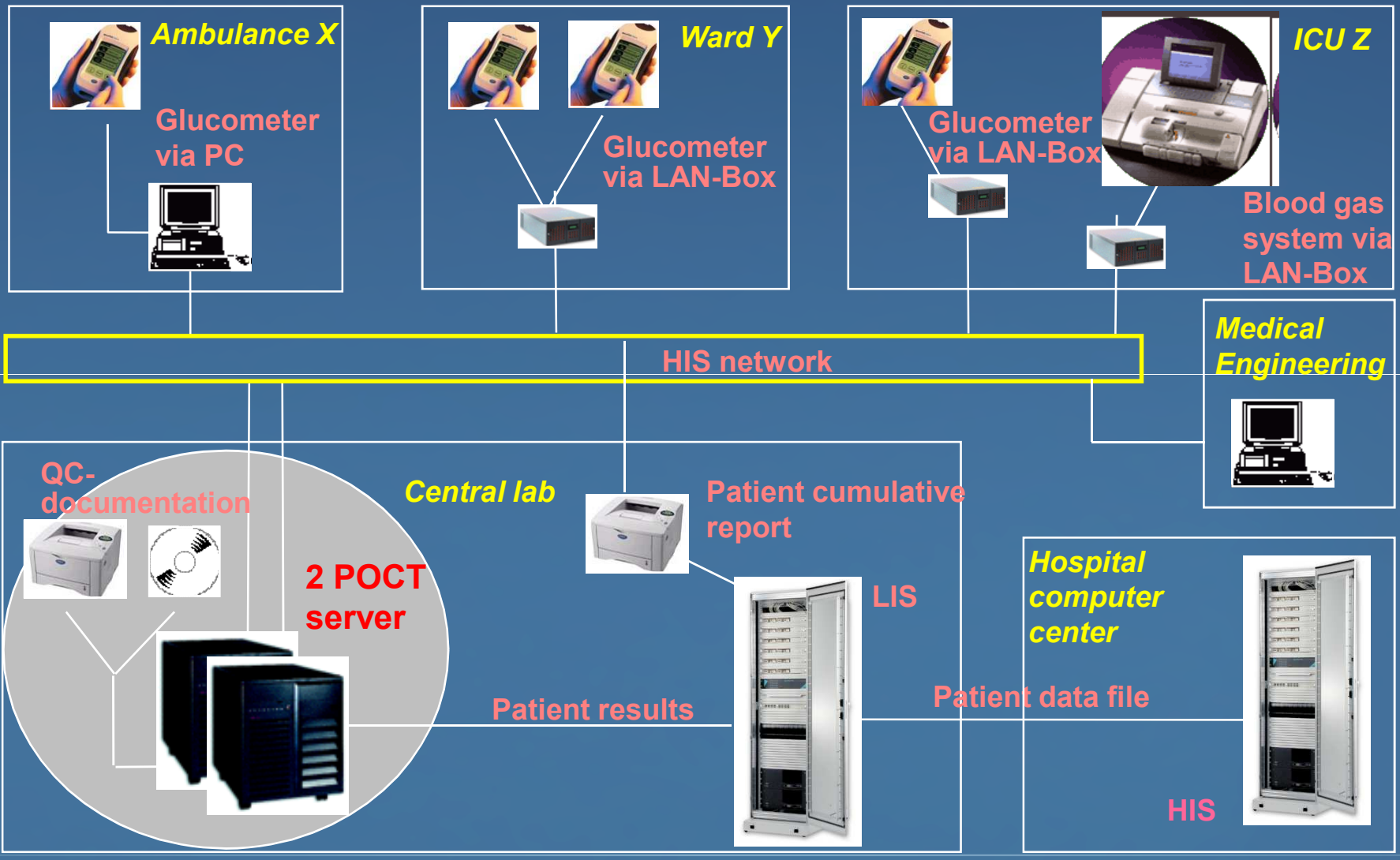
- University hospital, 1100 beds, all relevant disciplines
- App. 60 wards, 38 ambulances, 8 surgery units
- 50,252 in-patients in 2009
- 203,765 out-patients in 2009
- Medical school with 150 students per semester

POC Testing in the hospital

- 130 blood glucose
- 19 blood gas systems
- 1 CoaguChek® (INR measurement) system
- 2 ROTEM / 3 Multiplate viscoelastic systems [in the core lab]
- 5 UriSys (urinary stix) devices

No other POCT allowed due to the fact that the Core Lab is competent for all lab tests. A sophisticated tubing system is available

Online connection of the POCT systems to the HIS and LIS



Important features for new POCT devices (attributes ranked from MOST to LEAST important)

1. Ease of use
2. Cost of analyzer, consumables, service; overall cost of operation
3. Time to first result/turnaround time for all samples onboard
4. Maintenance requirements
5. Reliability and mean time between service calls
6. Size of analyzer / footprint
7. Availability to run samples while the analyzer is performing other functions, i.e., during calibration, maintenance, washing, etc.
8. Menu
9. Company service responsiveness and reputation
10. Ability to run multiple samples at the same time/ability to add STATS at any time
11. Periodical instructions performed by company employees

Quality assessment regulations for POCT applications in the EC

AUDIENCE RESPONSE

Which formal POCT regulation types are found in Europe?

A. Governmental agencies

B. Regional (federal state) agencies

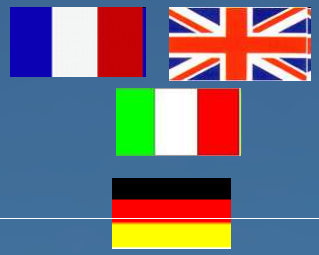
C. Medical self-government

D. All of the above mentioned ones

Survey on EC regulations for the POCT quality assessment

➢ The formal regulations for clinical labs and for POCT within individual countries vary considerably.

Government agencies vs.
Regional agencies vs.
Medical self-government



➢ There are a series of ring trial organizations active in the EU countries, samples for POC whole blood measurements vary considerably.

➢ The constraint for accreditation of clinical labs varies within the EU.

➢ The constraint for QC of POCT is variable within EU countries.

➢ Sanctions for irregularities lack in a series of EU countries.

Ring trial organizations and accreditation agencies:

European co-operation for Accreditation

CSCQ, Switzerland
DEKS, Denmark
INSTAND, Germany
RFB, Germany
DicoCARE VEQ, Italy
ECAT, The Netherlands
EQUALIS, Sweden
Labquality, Finland
UK NEQAS, UK
NKK, Norway
NOKLUS, Norway
SEKK, Czech Republic
SKZL, Holland
Verein f. med. QK, Switzerland
Wales EQAS
OQUASTA, Austria

BAS - Executive Agency “Bulgarian Accreditation Service”
Belgische Kalibratie Organisatie, BKO/OBE; BELTEST
Comité Francais d'Accréditation, COFRAC
Clinical Pathology Accreditation, CPA (UK) Ltd.
Czech Accreditation Institute, o.p.s, CAI
Danish Accreditation, DANAK
Deutscher Akkreditierungsrat, DAR
Entidad Nacional de Acreditación, ENAC
Faggildingarsvið / ISAC - Icelandic Board for Technical Accreditation
Federal Ministry of Economic Affairs and Labour, BMWA
Finnish Accreditation Service, FINAS
Hungarian Accreditation Board, NAT
Instituto Português da Qualidade, IPQ
Latvian National Accreditation Bureau, LATAK
National Accreditation Board, NAB
Norwegian Accreditation, NA
Raad voor Accreditatie, RvA
Servizio di Taratura in Italia, SIT
Sistema Nazionale per l'Accreditamento degli Organismi di Certificazione, SINCERT
Sistema Nazionale per l'Accreditamento di Laboratori, SINAL
Slovenian Accreditation (SA)
Slovak National Accreditation Service, SNAS
Swedish Board for Accreditation and Conformity Assessment, SWEDAC
Swiss Accreditation Service, SAS
United Kingdom Accreditation Service, UKAS

AUDIENCE RESPONSE

Which international norm is important for POCT applications in hospitals?

A. ISO 15189

B. ISO 17025

C. ISO 22870

D. None of the above mentioned ones

POCT: Selected rules and standards for quality assessment in the clinical laboratory

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The RiliBÄK, having legal character, describes quality assurance in medical laboratories AND quality assurance of decentralized POCT. A deployed advisory board holds periodical meetings to discuss new developments.

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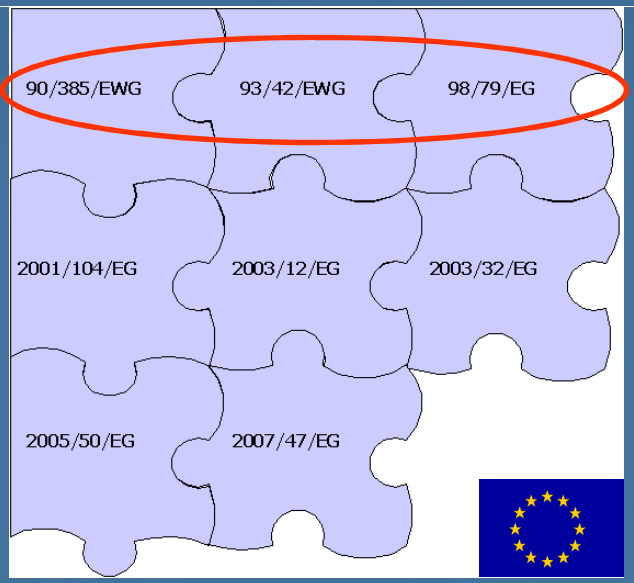
The EU medical device legislation is based on 3 well defined directives



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The guideline is aimed at safe-guarding the quality of analysis carried out in medical laboratories

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The RiliBÄK has a strong relationship to the norms ISO 15189 & 22870. POC tests are classified – similar to CLIA 88 – in „waived“ and non-waived, complex categories.

AUDIENCE RESPONSE

In which part describes the RiliBAEK the quality assessment rules for quantitative POCT determinations?

A. Part A

B. Part B1

C. Part B2

D. None of the above mentioned ones

RiliBÄK 2008 structure

Part A: Description of the quality management in medical laboratories

Part B1: Quanitative determinations of biochemical parameters in various human body fluids

Part B2: Qualitative determinations of biochemical parameters in various human body fluids

Part B3: Microbiological tests

Part B4: Semen analysis

Parts C and D: Advisory board and scientific committees

Part E: Accreditation of reference laboratories and ring trial organizations

RiliBÄK 2008/Part A

- Valid for the central lab AND POCT
- Calls for a quality mangement folder, including chapters concerning quality policy, responsabilities, qualification of POCT users, SOP, pre- and postanalytics, directives for quality controls and instructions for analytical error handling.
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RiliBÄK 2008/Part B1: Internal QC

- 1x per day: Control by an electronic or physical standard
- 2x per day: QC samples in 2 different measuring ranges

- Calculation of the Root Mean Square Deviation (%RSMD), expressed as a percentage relative to a target value.
- Validation of the actual control measurement and of the %RSMD according to table B1, column 3.

- There is no difference between lab and POCT analyses. Only unit-use POCT measurements have a different internal QC frequency: Only once a week!

RiliBÄK 2008/Part B1: External QC

- 4 times a year 2 external QC samples. Validation according to table B1, column 5.

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The RiliBÄK introduced a new quality metric for internal assessments, **Root Mean Square Deviation, abbreviated as %RSMD**, expressed as % relative to a target value. Previous RiliBÄK versions used separate quality goals for bias and imprecision. The %RMSD is now in a move toward a total analytical error type of metric, expressed in a way similar to the ISO concepts of uncertainty. The %RMSD is computed from data acquired during a Control Cycle (CC), a time period that contains at least 15 observations, generally about 1 month, but < 3 months.

$$\%RMSD = \frac{\sqrt{k^2 (SD_{cc}{}^2) + Bias^2}}{TV}$$

SD_{cc} = standard deviation
Bias = difference of observed mean from Target Value (TV)
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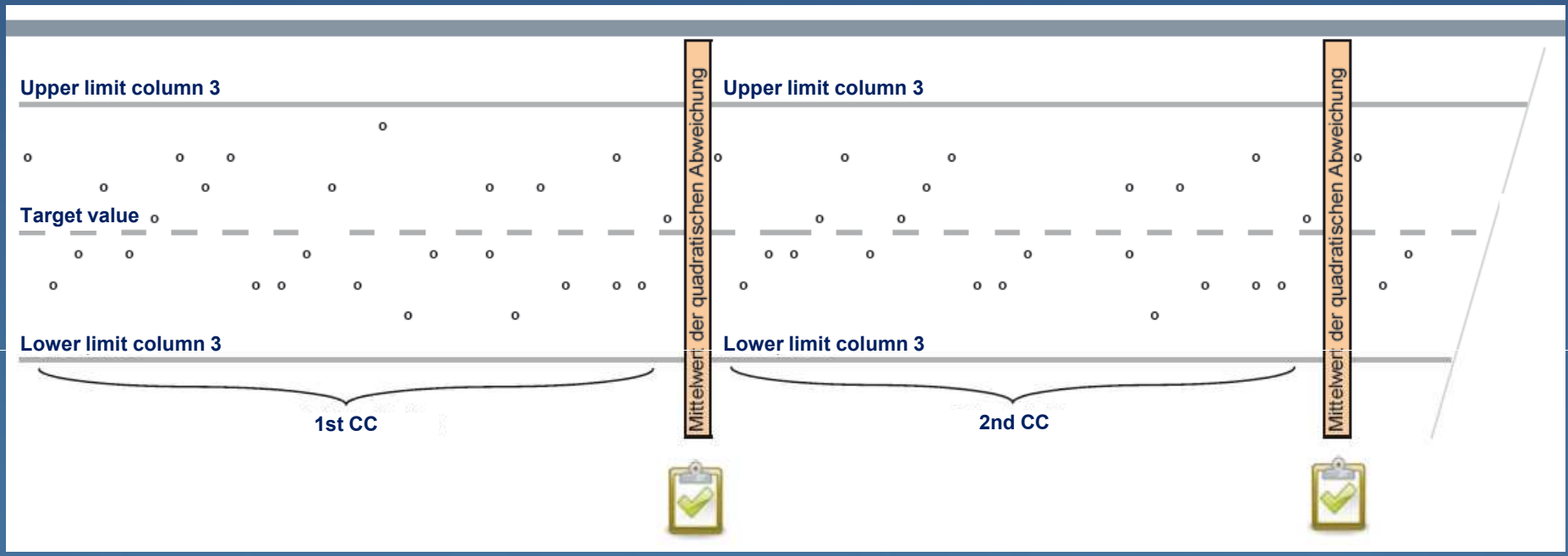
The %RMSD is valid for 67 analytes presented in the Table B1, column 3.
Analytes not listed in this table have to be validated according to **lab-own error deviations Δ_{max}**.

$$\Delta_{\max} = \sqrt{k^2 \times s^2_{ep} + \delta^2_{ep}}$$

$\Delta_{\max}$	**Max. analytical error**
k	**k = 3; empiric coverage factor**
s_{ep}	**empiric standard deviation**
δ_{ep}	**systematic analytical error of the measured control**

RiliBÄK B1 – New Table B 1a, valid for blood gas analyzers



The QC results in the first CC are validated according to Table B1, column 3

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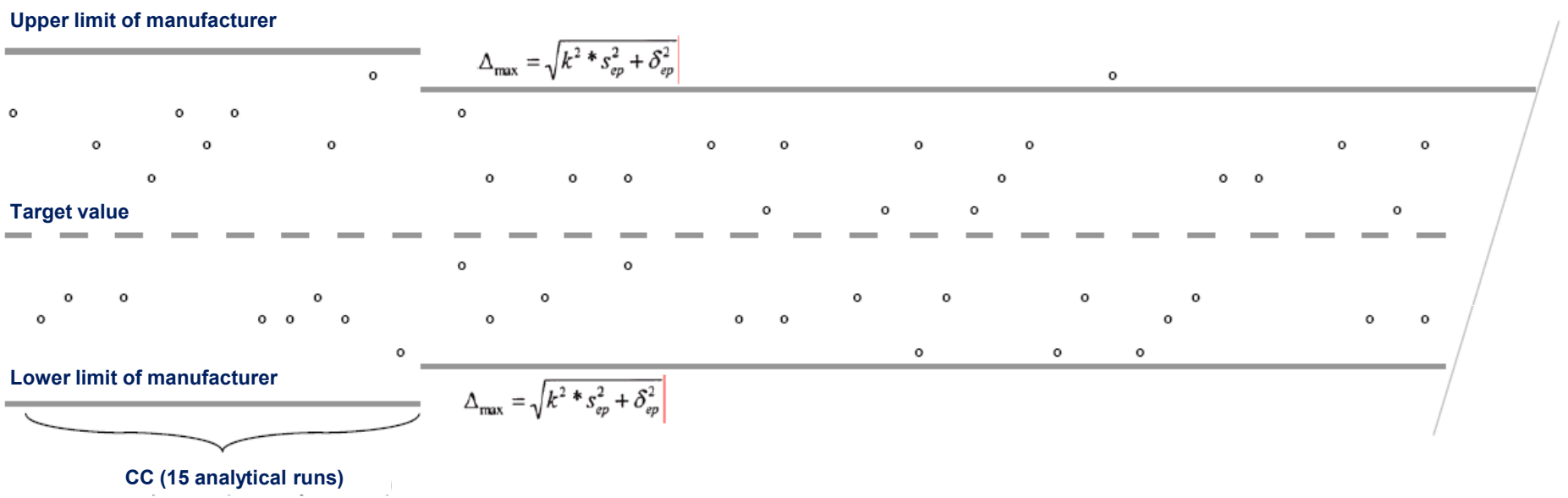
Procedure for parameters not listed in Table B 1a



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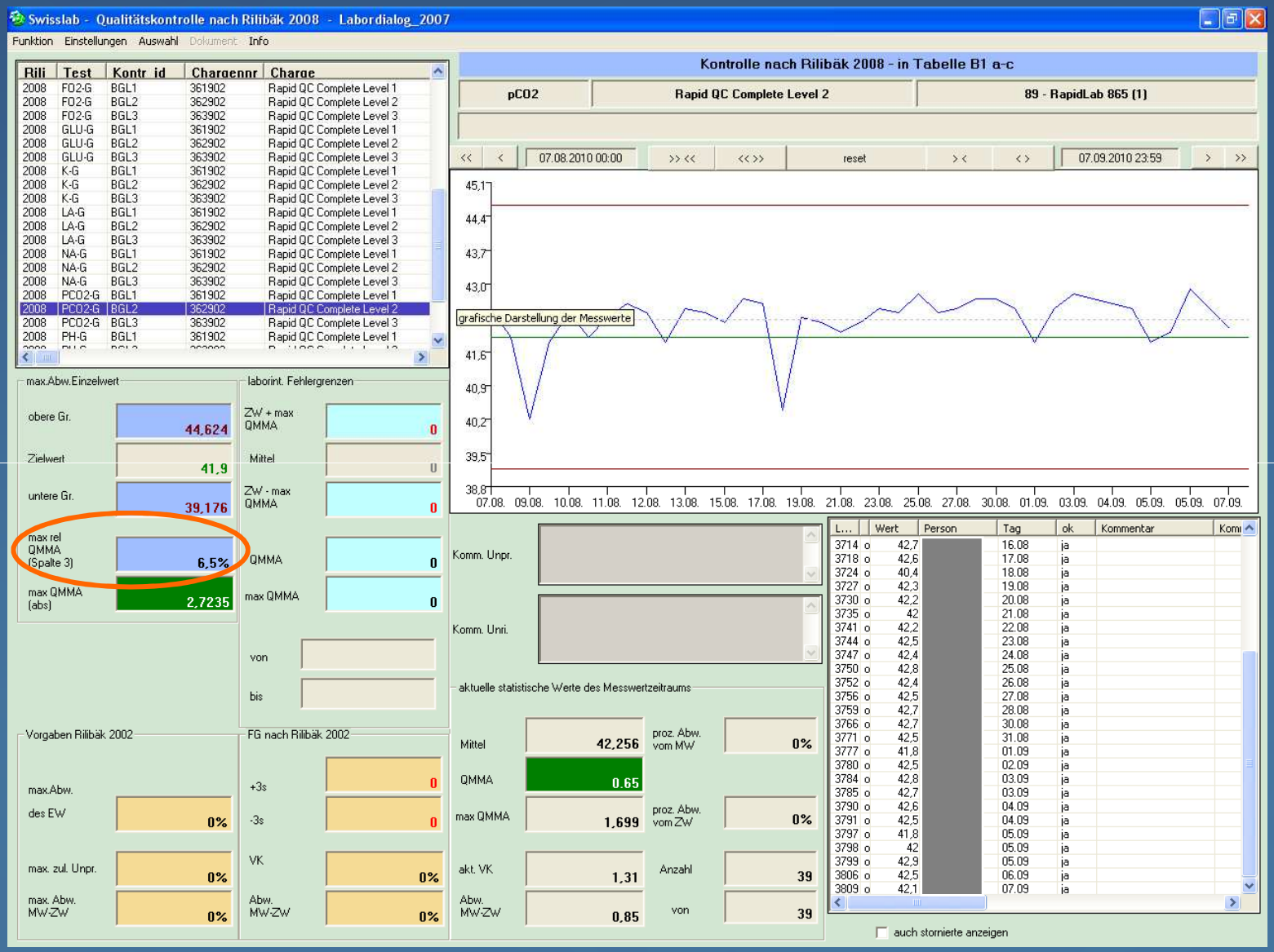
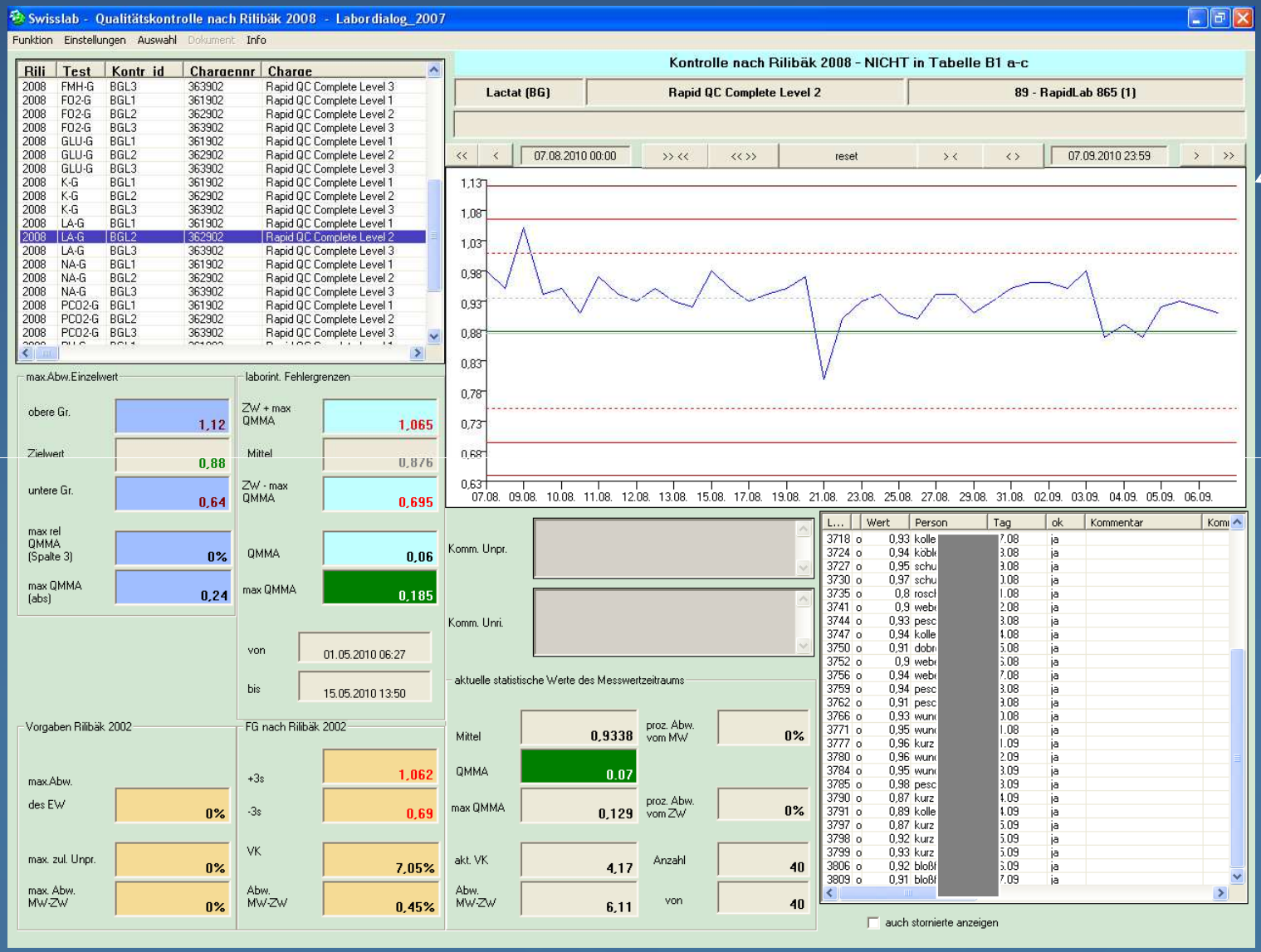
Internal QC

Maximum allowable deviation from target value

	RiliBÄK 2002		RiliBÄK 2008	
	Specification	Measuring range	Specification	Measuring range
pH	0,06%		0,4%	6,75 – 7,80
pCO_2	12,5%		6,5%	15-110 mmHg
pO_2	12,0% 15 mmHg	≥125 mmHg < 125 mmHg	5,5% 7,0%	125-350 mmHg 80-125 mmHg
Na+	6,1%		3%	110-180 mmol/l
K+	9,0%		4,5%	2-8 mmol/l
Lactate	21%		11%	1 – 10 mmol/l



pCO_2 QC according to Table B1



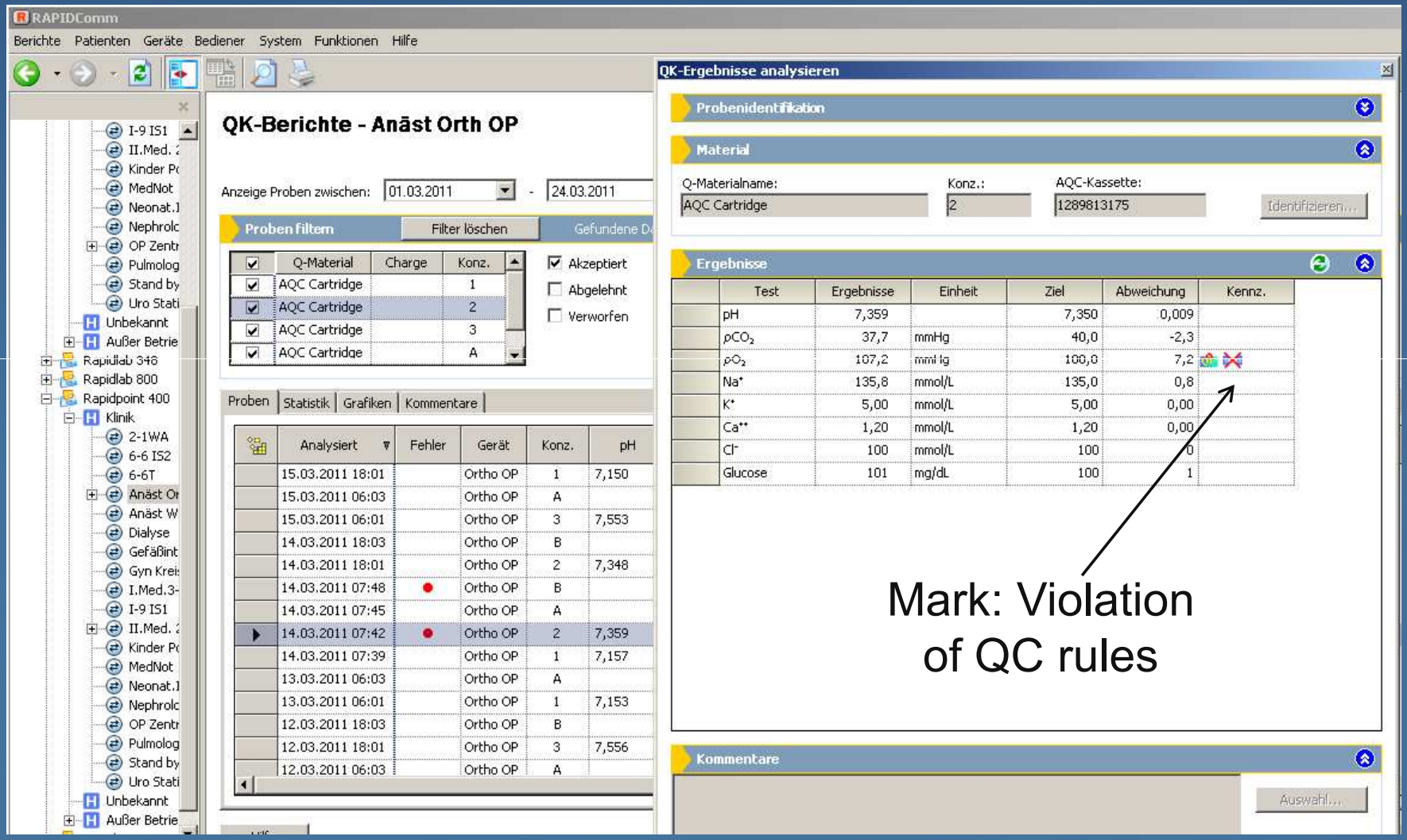
Manufact. error dev.

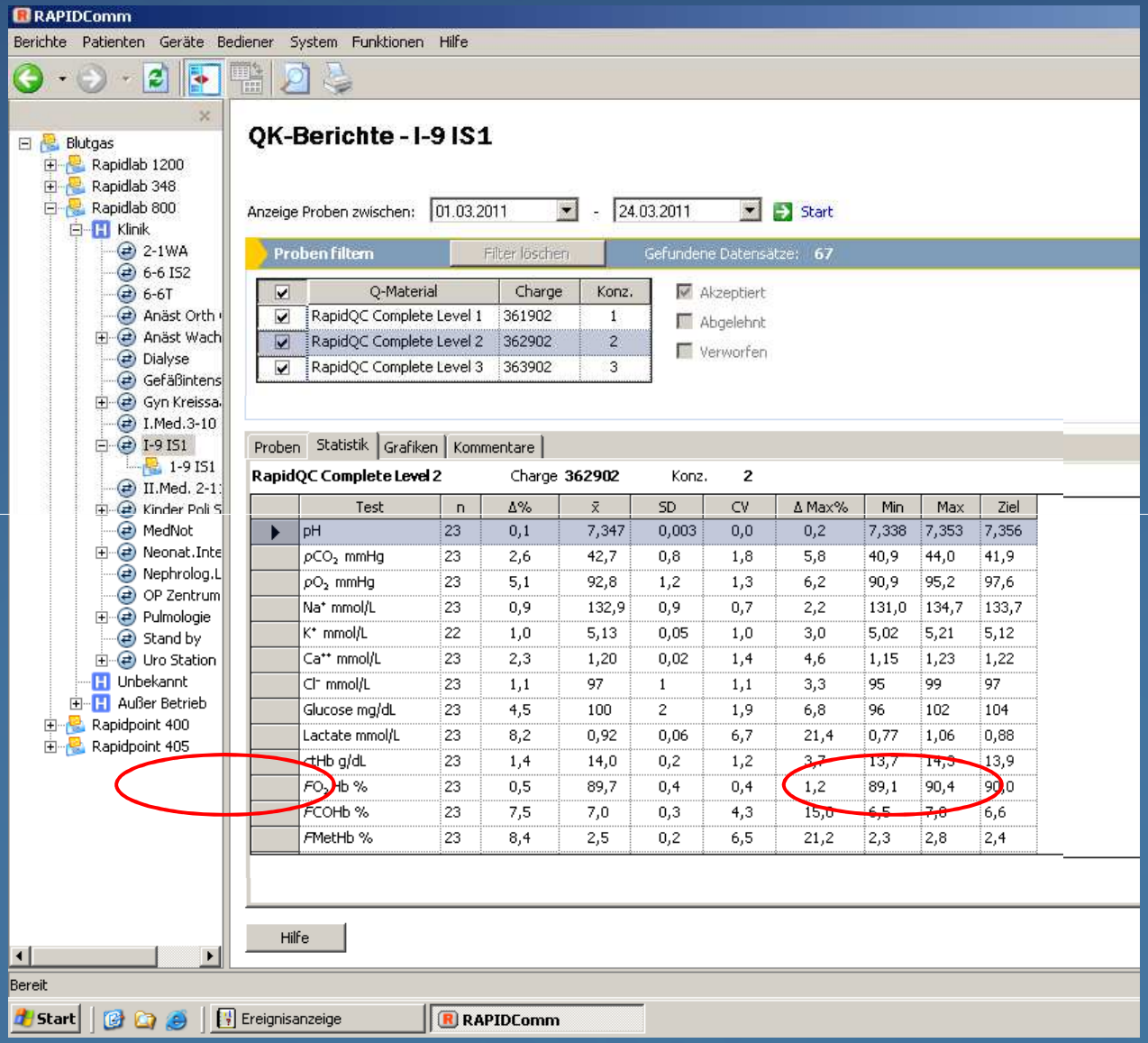
Lab-own. error dev.

Manufact. error dev.

Low con-centrated lactate QC according to the lab-own error deviation

QC report given by RapidComm (included are the RiliBÄK rules)





%Δ=
%RMSD

%Δmax=
Lab-own error deviation

Lactate:
Target 0,88 mM.
Range given by Siemens:
0,64 – 1,12 mM
(+/- 27% max. deviation)

External QC

Maximum allowable deviation from target value

	RiliBÄK 2002		RiliBÄK 2008	
	Specification	Measuring range	Specification	Measuring range
pH	0,06%		0,8%	6,75 – 7,80
pCO_2	12,5%		12,0%	15-110 mmHg
pO_2	12,0% 15 mmHg	≥125 mmHg < 125 mmHg	12% 18%	125-350 mmHg 80-125 mmHg
Na+	6,1%		5%	110-180 mmol/l
K+	9,0%		8%	2-8 mmol/l
Glucose	16%		15%	40-400 mg/dl

RiliBÄK sanctions for irregularities:

- In case of violations of the quality management rules (e.g. QM handbook not available) the surveillance authorities (bureau of standards) punishes by rigorous fines.

- In case of failing the ring trial analyses twice within 6 months, the lab is being excluded from reimbursement for the analytes which were tested in the ring trial.

The RiliBÄK rules are similar to the rules described in the Clinical Governance in the UK

The Clinical Governance is the quality framework for the National Health Service (NHS) in Great Britain

The task of ensuring the Directive is undertaken by the Medicines and Healthcare Products Regulatory Agency (MHRA) and implemented into UK law by the Medical Devices Regulations 2002.

In 2006, a POCT Consultative Group was formed by the Academy of Medical Laboratory Services.

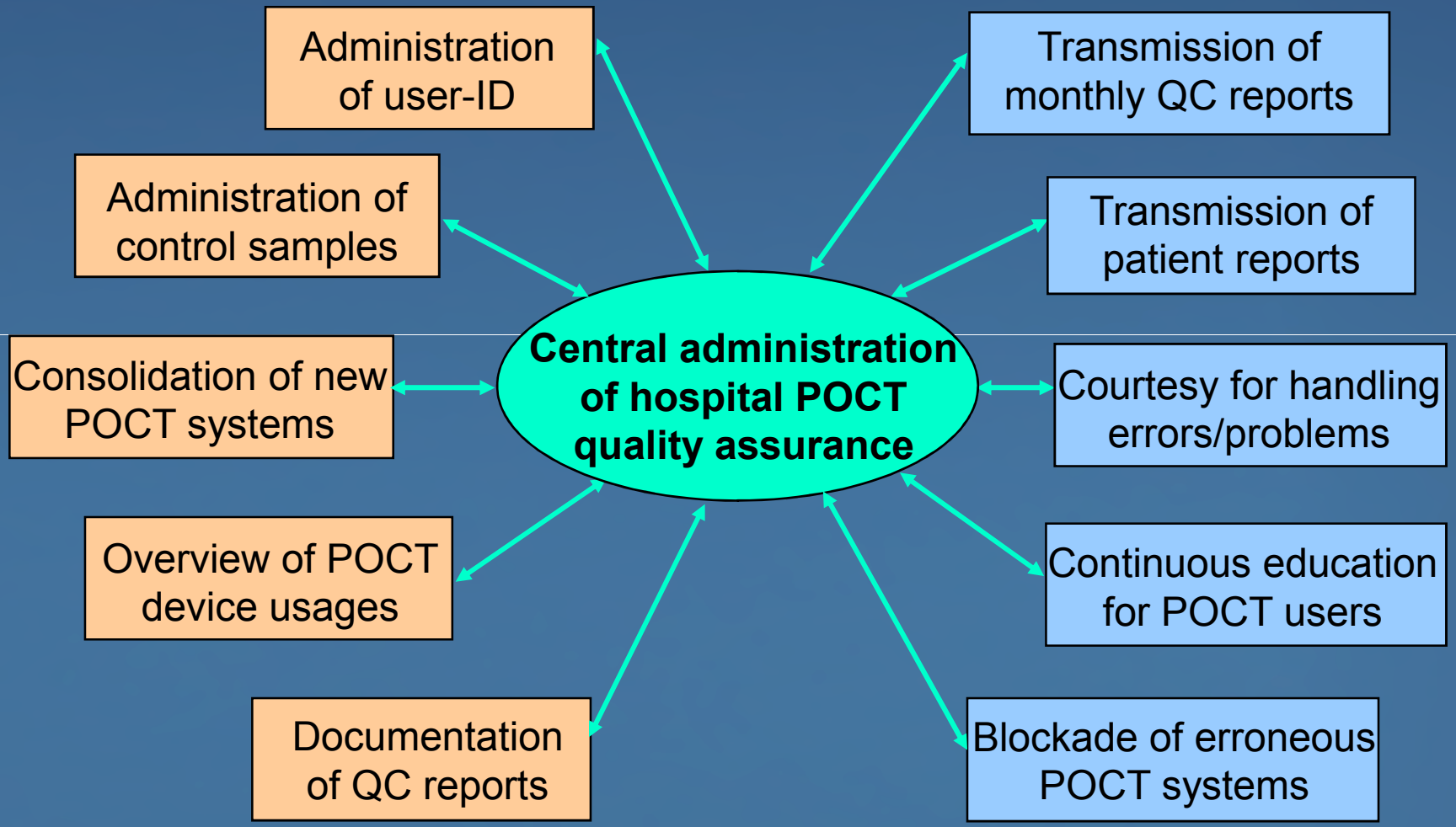
The MHRA released the Device Bulletin DB2010(02) “Management and Use of IVD Point of Care Test Devices“.

Similar guidelines have been produced by the Institute of Biomedical Sciences, the Royal College of Physicians, the British Committee for Standards in Hematology and the Medical Devices Agency.

The guidelines vary only in specifics, examples or scope. The majority of the guidelines agree on the following recommendations:

POCT should be managed under **clinical governance** and there must exist clear lines of accountability. Everyone involved in the management and use of the POCT service, including managerial, technical, scientific, clinical and nursing staff must be aware of their roles and responsibilities. As part of ensuring this, it is recommended that the POCT service be managed through a multidisciplinary POCT Steering Group.

Claims of RiliBÄK (D) and POCT governance (GB): Comprehensive POCT administration



In Germany the institution of a POCT coordination group was demanded for supervising the quality assurance of all decentralized POCT devices.

In Austria as well as in Switzerland, the German RiliBÄK has been adopted in many parts (in particular the POCT rules).

In UK this institution is called POCT steering group.

The POCT coordinator and his team are mostly members of the medical laboratory.

All respective duties for the quality assessment result in a heavy workload. In most cases no new employees can be hired.

On the other hand the POCT coordination discloses new fields of activity for the core lab.

Surveillance of POCT quality control measurements by the central lab

Surveillance of POCT quality control measurements by the central lab

The best way for implementing a comprehensive hospital QA system for POCT is the bidirectional online connection of all devices to the central lab via the HIS/LIS network.

The POCT coordinator should be responsible for the entire quality assurance process.

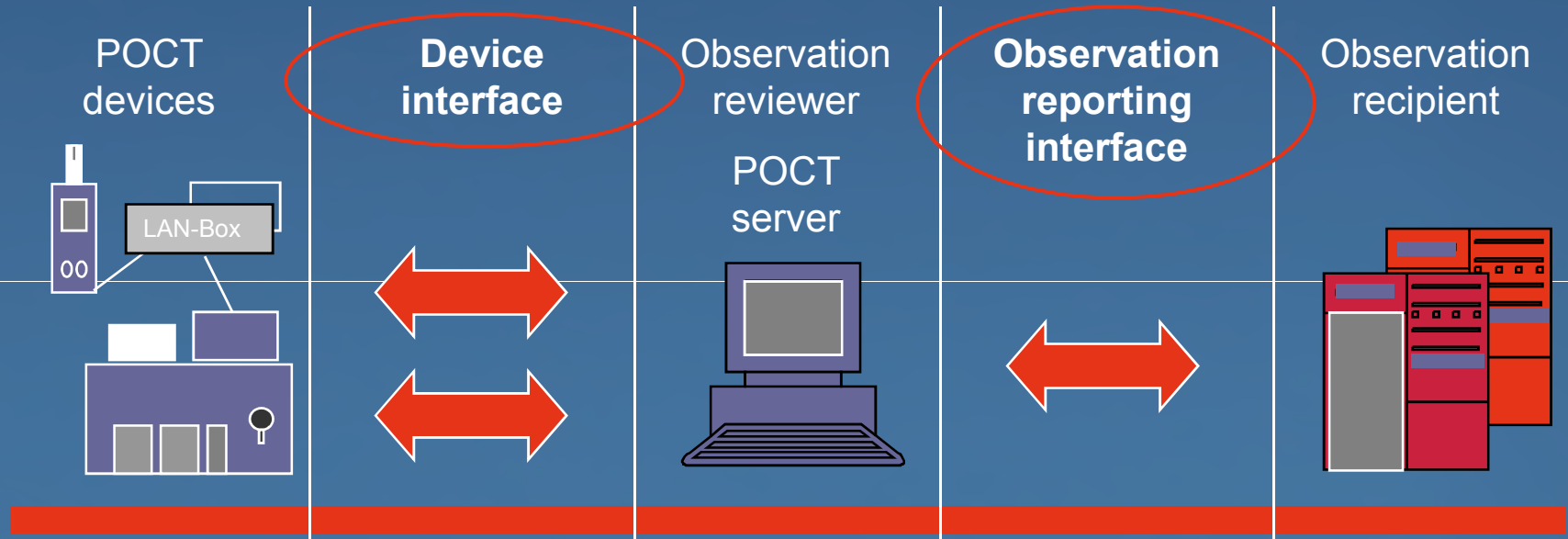
Connectivity solutions for hospital POC devices

The medical communication protocol **POCT1-A** was designed to standardize the communication pathways between POCT devices and the HIS/LIS and to ensure a quality assessment which is in accordance to national and international regulations. Basis were specifications of the CIC (Connectivity Industry Consortium).

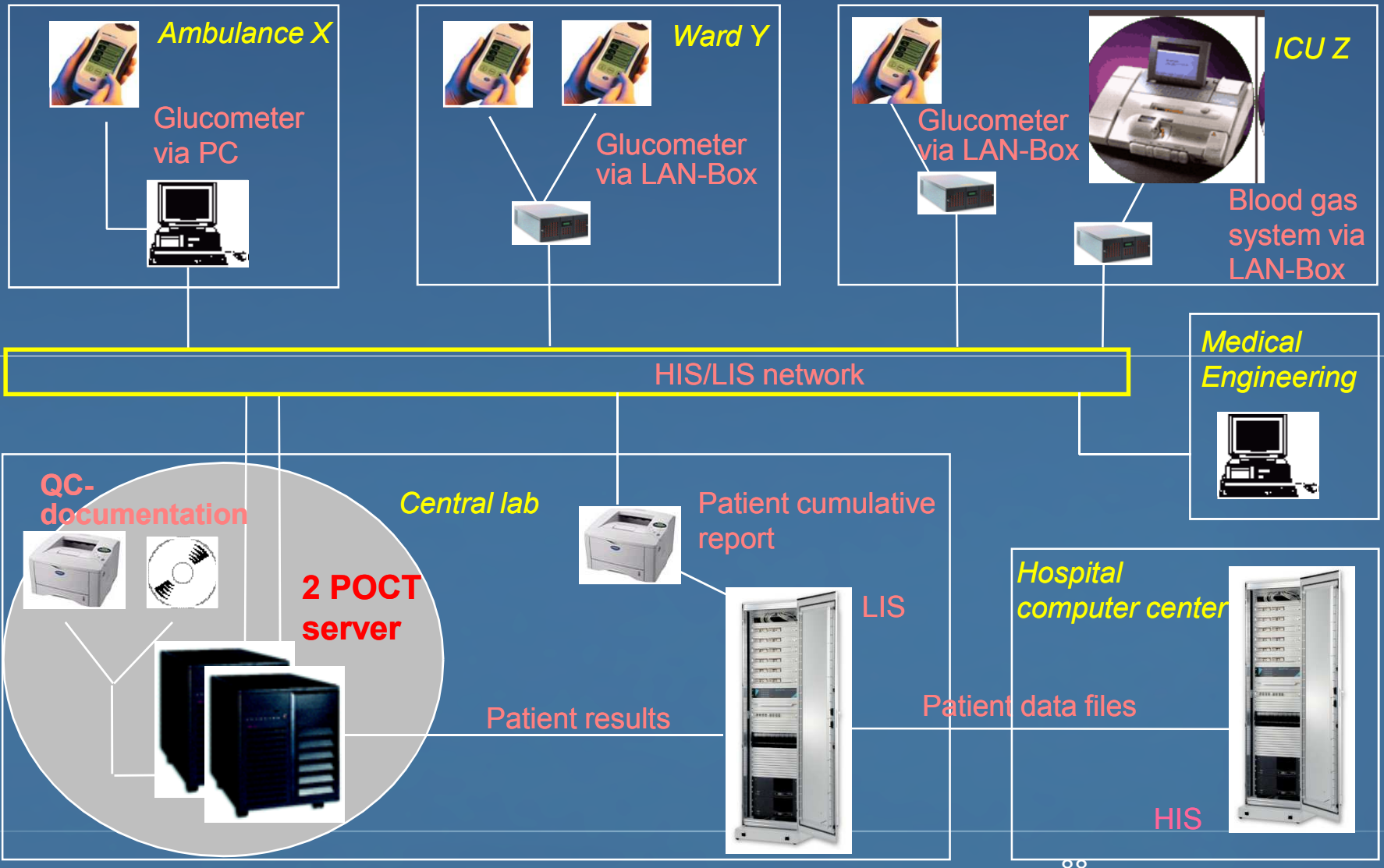
The POCT1-A standard uses the XML format for the communication between POCT device and server.
The POCT1-A gateway is similar structured as the HL7 communication. The standard also defines the procession of measured data within the HIS/LIS systems, as well as the translation of POCT1-A data into a HL7 compliant syntax.

Data management in modern hospital POCT environment

The POCT1-A standard has two communication gateways:
the Device Interface (DI) and the Observation Reporting Interface (ORI).



Connection of POCT systems to the HIS and LIS



AUDIENCE RESPONSE

The European IT-company Conworx is provider of process management solutions for POCT and delivers middleware being the market leader in European hospitals. Name of the software?

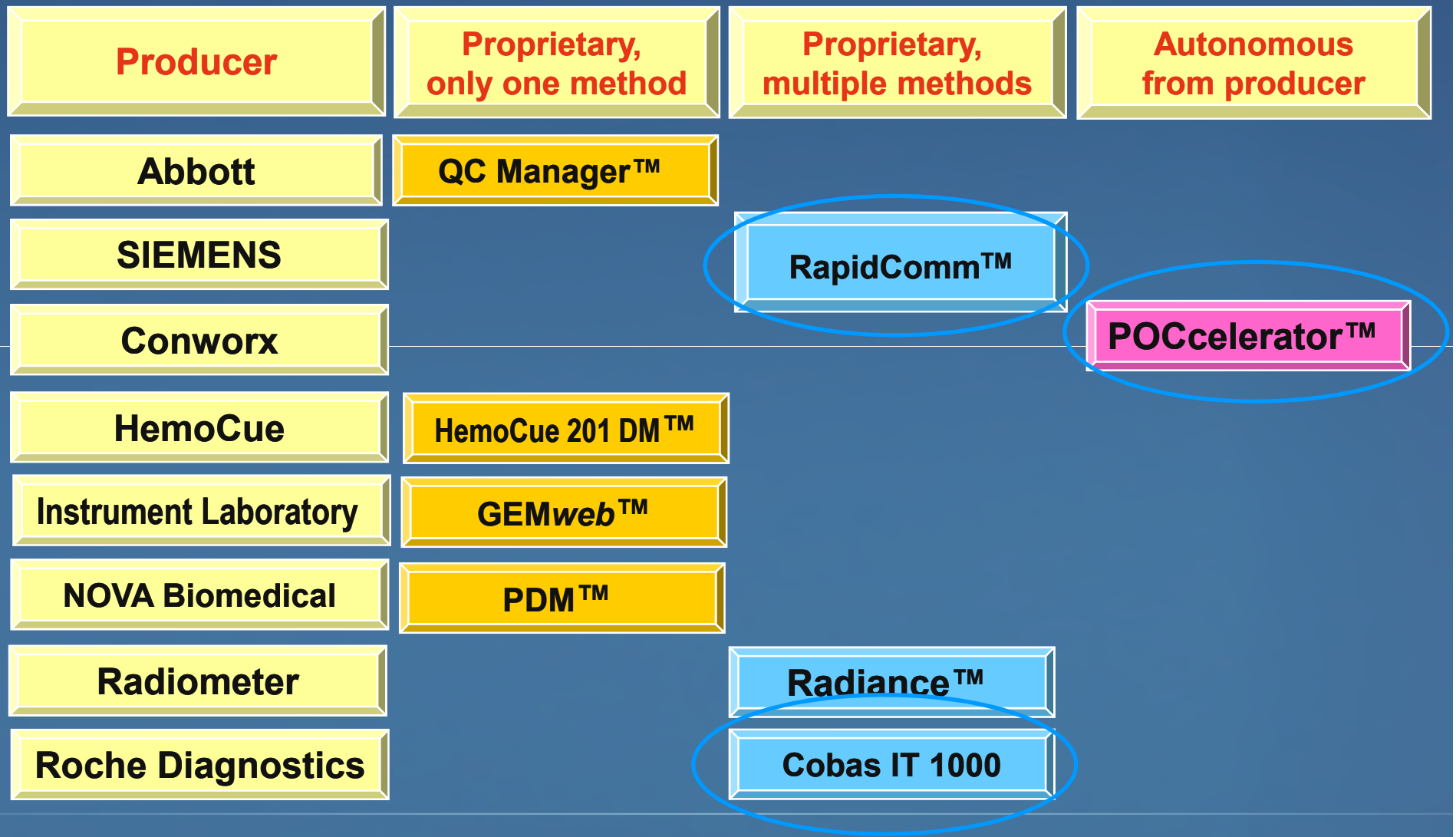
A. Governmental agencies

B. Regional (federal state) agencies

C. Medical self-government

D. All of the above mentioned ones

POCT data management systems in the EU



Marketleader in the EU:

Conworx with POCcelerator

Marketleader in the USA:

Telcor Inc, Lincoln NE, with Quick-Linc/QML and Medical Automation Systems, Charlottesville, VA, with RALS-Plus

Thank you for your attention!

POCT regulations in Europe

Peter B. Luppa, MD
Institut für Klinische Chemie und Pathobiochemie
TU München, Germany

Disclosure information of Relevant Financial Relationships

I do not have, and have not had, any relevant financial relationship with any commercial interests within the past 12 months, as pertaining to this presentation.

The content of this CME activity and supplemental materials will promote quality or improvements in healthcare and not a specific proprietary business interest of a commercial interest. Content for this activity, including any presentation of therapeutic options, will be balanced, evidence-based and unbiased.

Topics at a glance

- Overview of the university hospital in Munich
- Quality regulations for POCT applications in the EC
- Special QM requirements for blood gas analyses
- Surveillance of QC measurements by the central lab

Klinkum rechts der Isar der Technischen Universität München

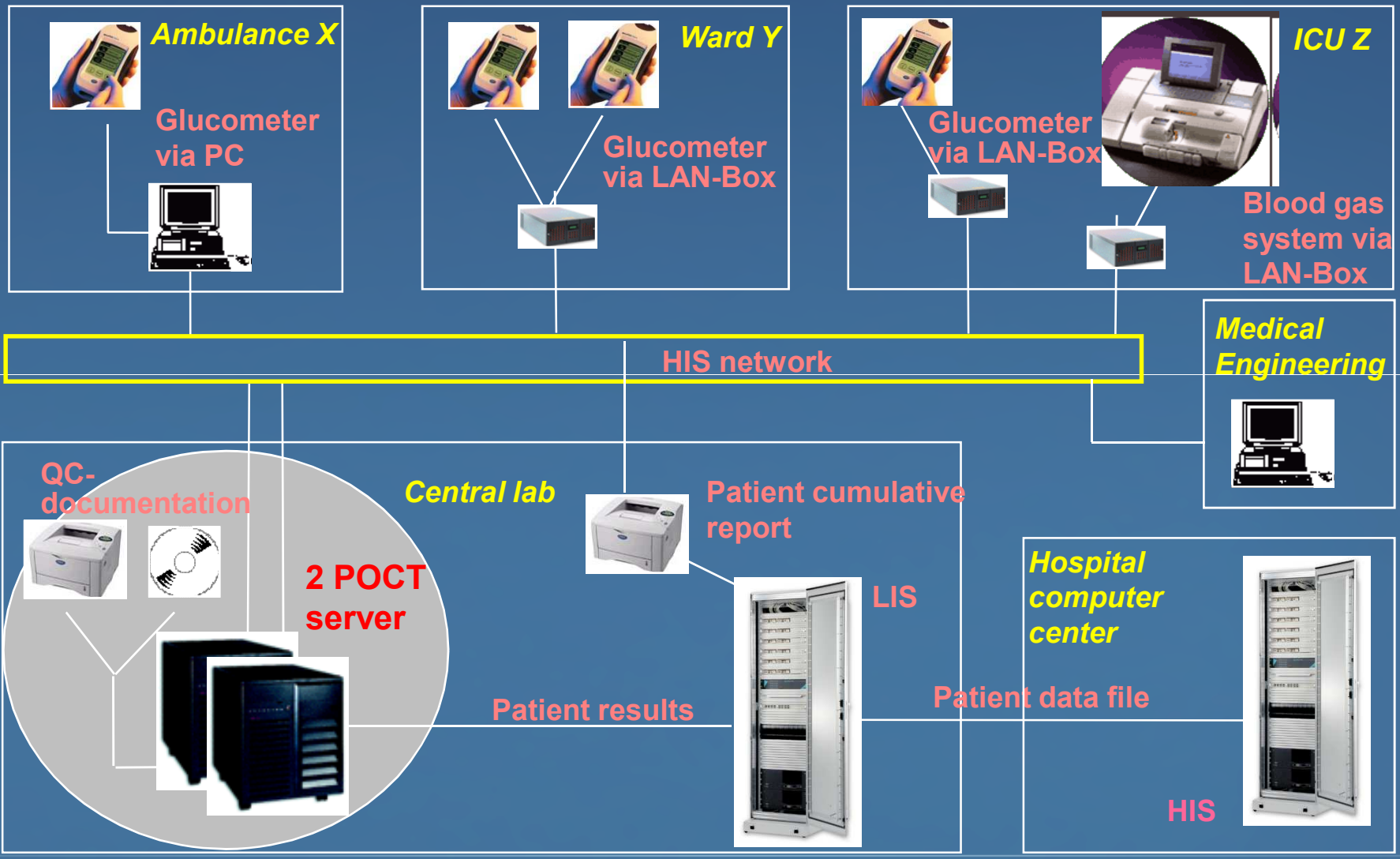
- University hospital, 1100 beds, all relevant disciplines
- App. 60 wards, 38 ambulances, 8 surgery units
- 50,252 in-patients in 2009
- 203,765 out-patients in 2009
- Medical school with 150 students per semester

POC Testing in the hospital

- 130 blood glucose
- 19 blood gas systems
- 1 CoaguChek® (INR measurement) system
- 2 ROTEM / 3 Multiplate viscoelastic systems [in the core lab]
- 5 UriSys (urinary stix) devices

No other POCT allowed due to the fact that the Core Lab is competent for all lab tests. A sophisticated tubing system is available

Online connection of the POCT systems to the HIS and LIS



Important features for new POCT devices (attributes ranked from MOST to LEAST important)

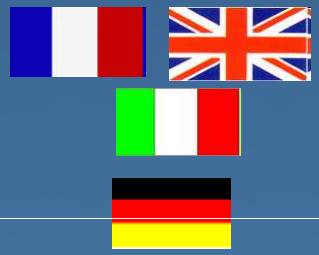
1. Ease of use
2. Cost of analyzer, consumables, service; overall cost of operation
3. Time to first result/turnaround time for all samples onboard
4. Maintenance requirements
5. Reliability and mean time between service calls
6. Size of analyzer / footprint
7. Availability to run samples while the analyzer is performing other functions, i.e., during calibration, maintenance, washing, etc.
8. Menu
9. Company service responsiveness and reputation
10. Ability to run multiple samples at the same time/ability to add STATS at any time
11. Periodical instructions performed by company employees

Quality assessment regulations for POCT applications in the EC

Survey on EC regulations for the POCT quality assessment

➢ The formal regulations for clinical labs and for POCT within individual countries vary considerably.

Government agencies vs.
Regional agencies vs.
Medical self-government



➢ There are a series of ring trial organizations active in the EU countries, samples for POC whole blood measurements vary considerably.

➢ The constraint for accreditation of clinical labs varies within the EU.

➢ The constraint for QC of POCT is variable within EU countries.

➢ Sanctions for irregularities lack in a series of EU countries.

Ring trial organizations and accreditation agencies:

European co-operation for Accreditation

CSCQ, Switzerland
DEKS, Denmark
INSTAND, Germany
RFB, Germany
DicoCARE VEQ, Italy
ECAT, The Netherlands
EQUALIS, Sweden
Labquality, Finland
UK NEQAS, UK
NKK, Norway
NOKLUS, Norway
SEKK, Czech Republic
SKZL, Holland
Verein f. med. QK, Switzerland
Wales EQAS
OQUASTA, Austria

BAS - Executive Agency “Bulgarian Accreditation Service”
Belgische Kalibratie Organisatie, BKO/OBE; BELTEST
Comité Francais d'Accréditation, COFRAC
Clinical Pathology Accreditation, CPA (UK) Ltd.
Czech Accreditation Institute, o.p.s, CAI
Danish Accreditation, DANAK
Deutscher Akkreditierungsrat, DAR
Entidad Nacional de Acreditación, ENAC
Faggildingarsvið / ISAC - Icelandic Board for Technical Accreditation
Federal Ministry of Economic Affairs and Labour, BMWA
Finnish Accreditation Service, FINAS
Hungarian Accreditation Board, NAT
Instituto Português da Qualidade, IPQ
Latvian National Accreditation Bureau, LATAK
National Accreditation Board, NAB
Norwegian Accreditation, NA
Raad voor Accreditatie, RvA
Servizio di Taratura in Italia, SIT
Sistema Nazionale per l'Accreditamento degli Organismi di Certificazione, SINCERT
Sistema Nazionale per l'Accreditamento di Laboratori, SINAL
Slovenian Accreditation (SA)
Slovak National Accreditation Service, SNAS
Swedish Board for Accreditation and Conformity Assessment, SWEDAC
Swiss Accreditation Service, SAS
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CLINICAL AND LABORATORY STANDARDS INSTITUTE® (Formerly NCCLS)

ISO International Organization for Standardization

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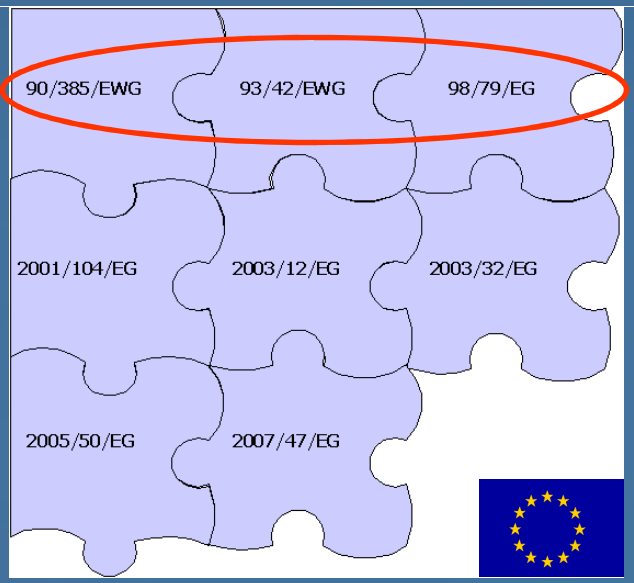

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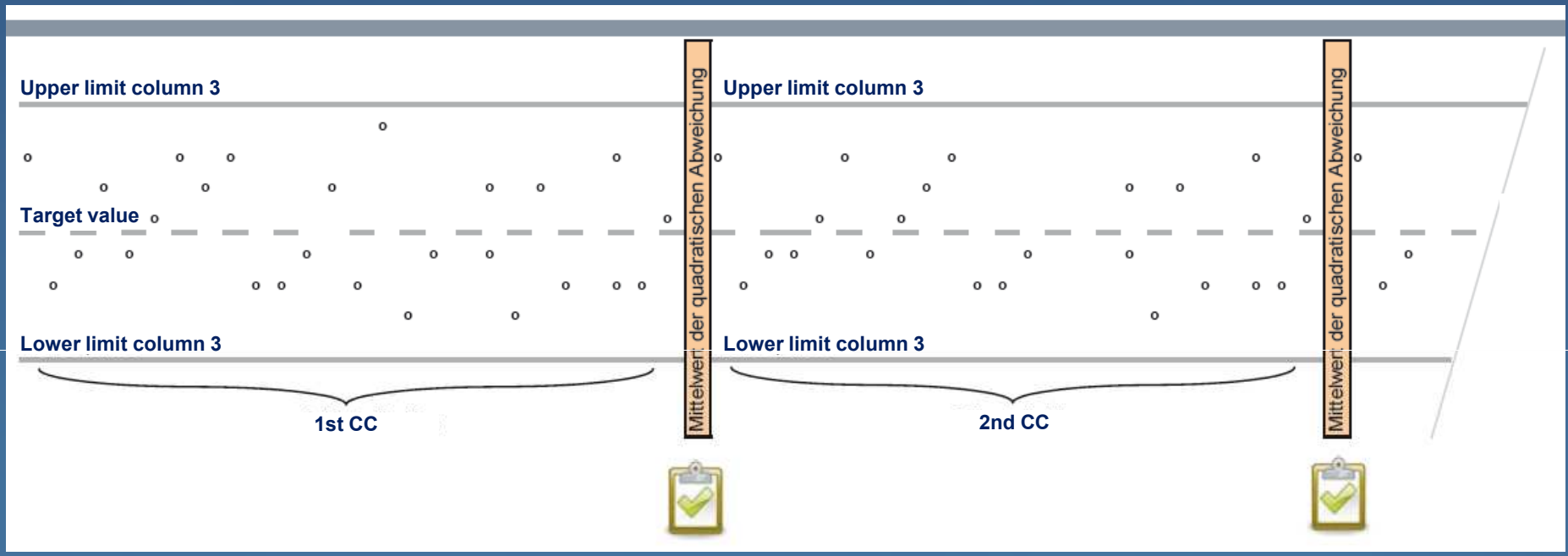

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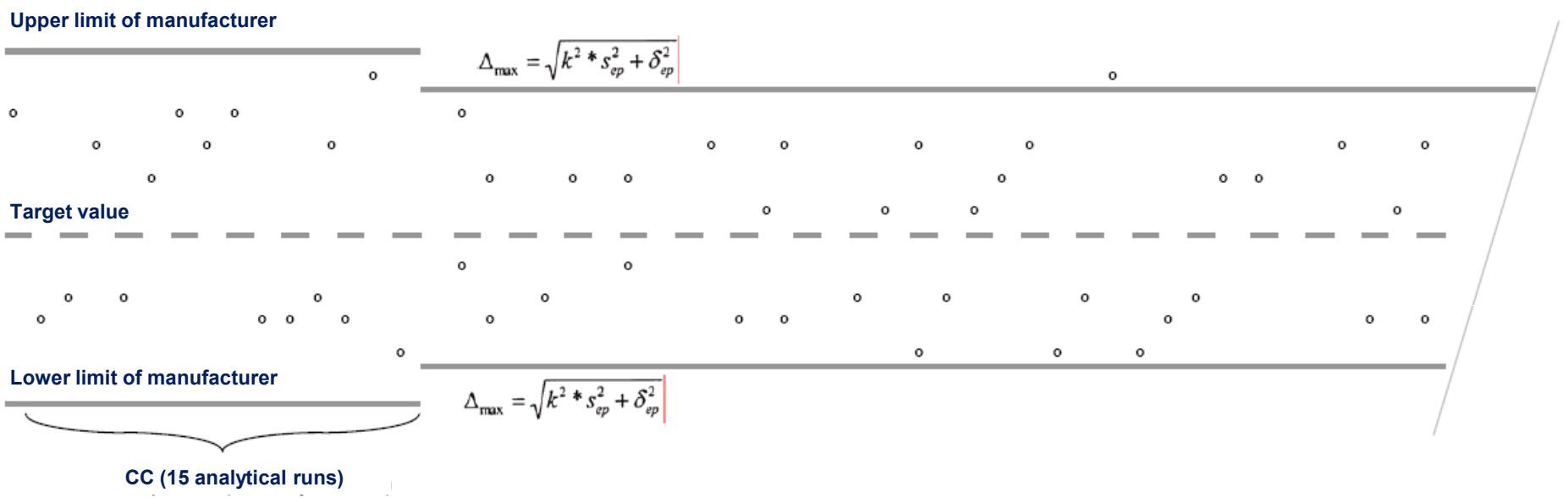

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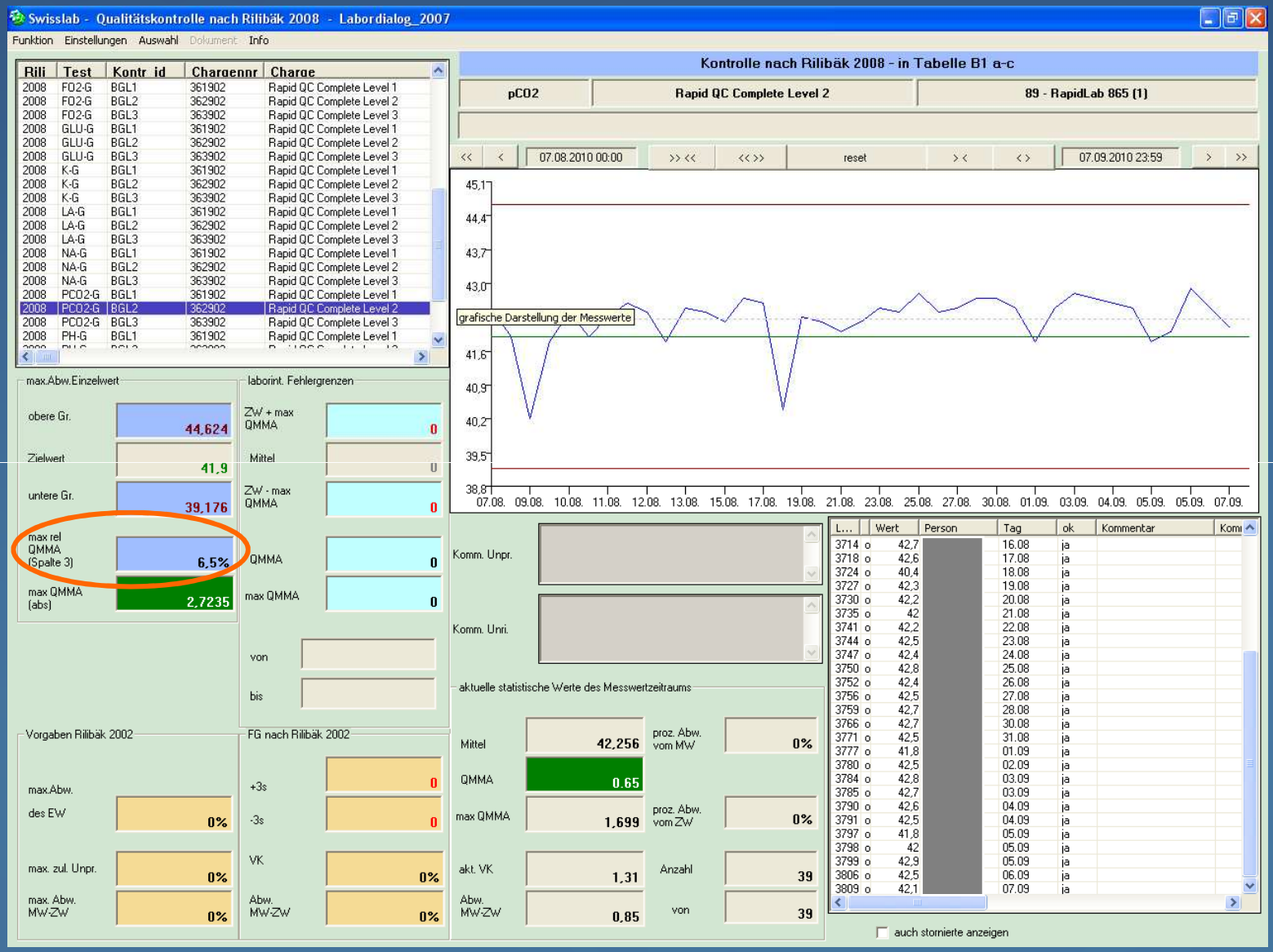
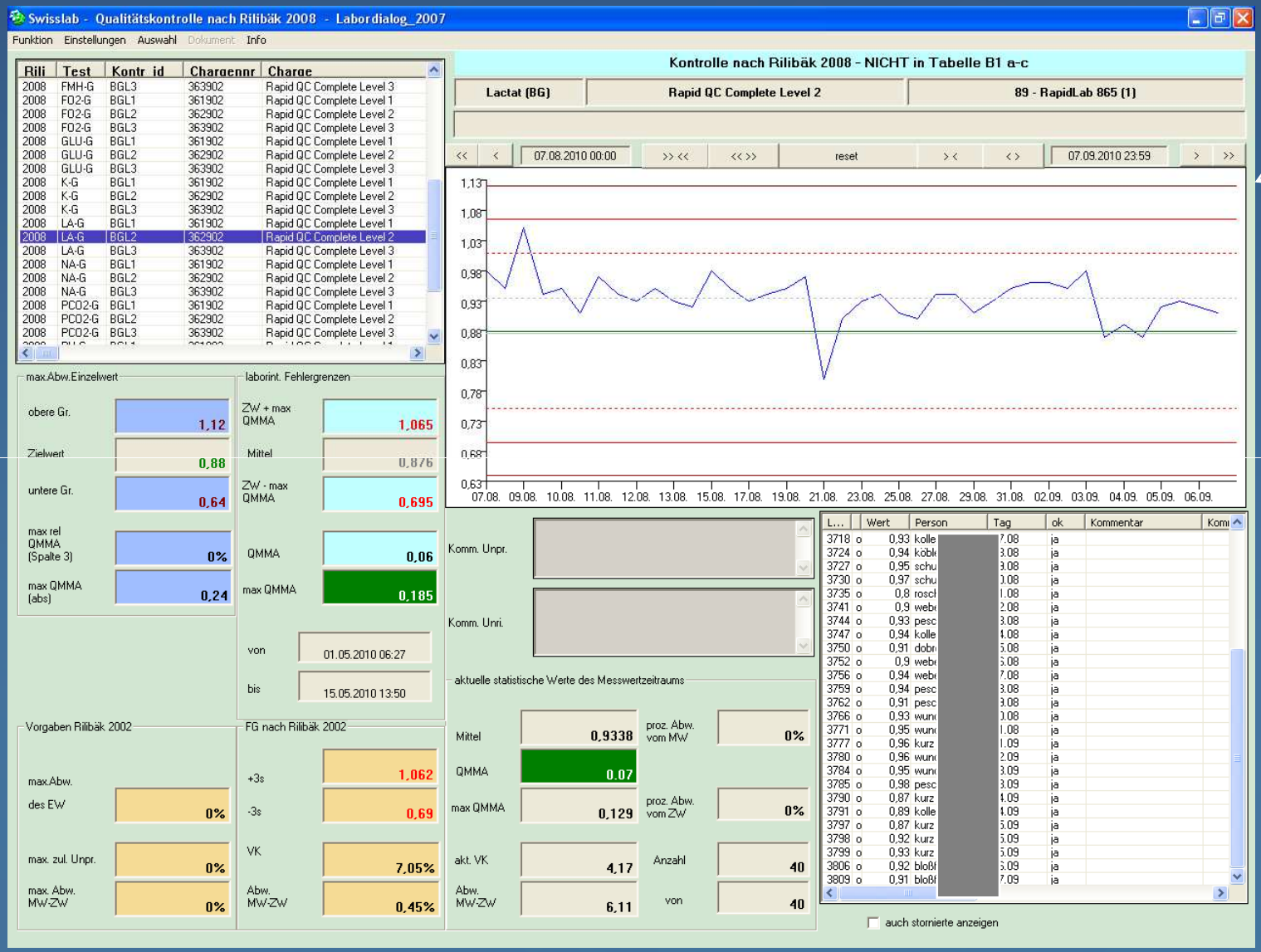
K+	9,0%		4,5%	2-8 mmol/l
Lactate	21%		11%	1 – 10 mmol/l



pCO_2 QC according to Table B1



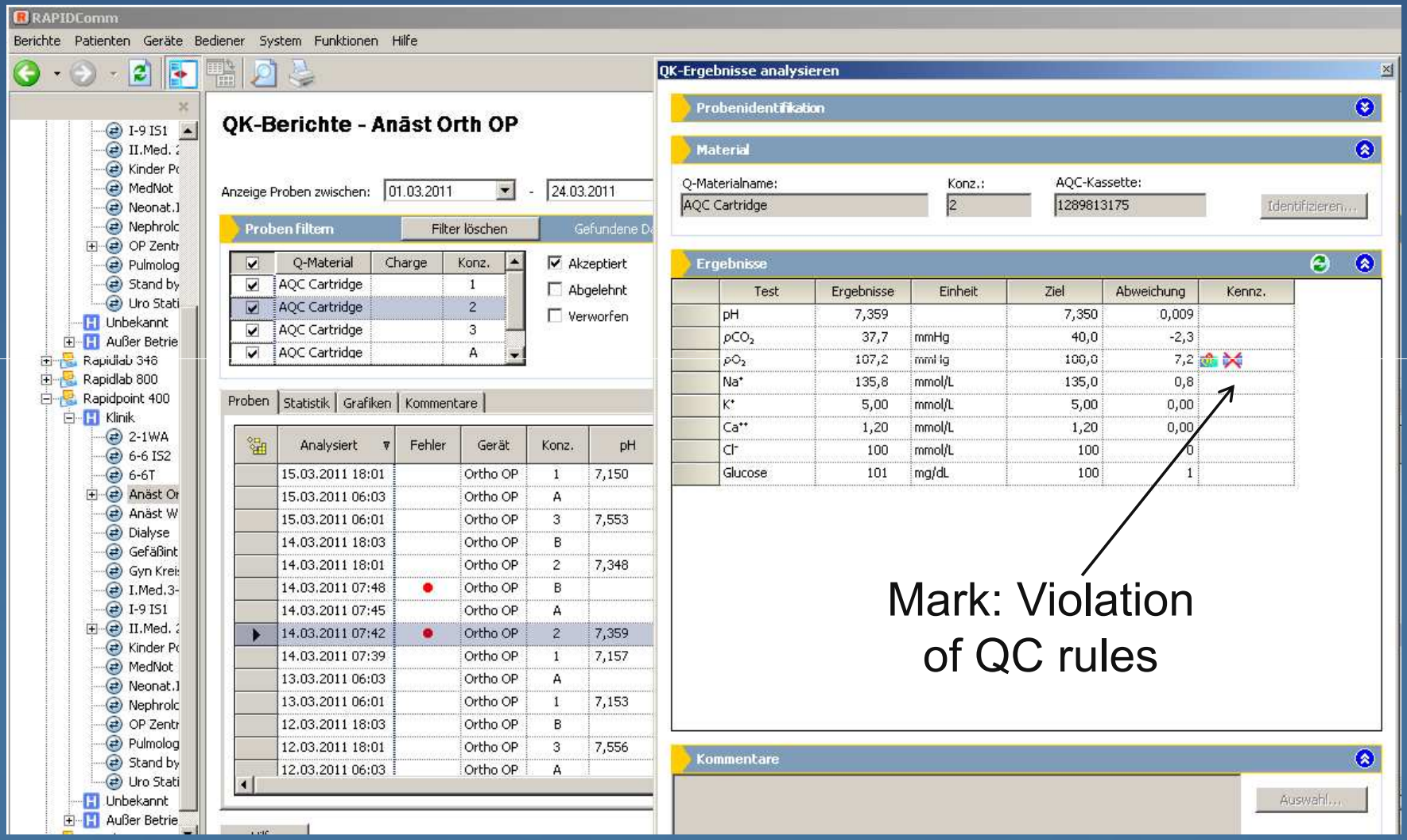
Manufact. error dev.

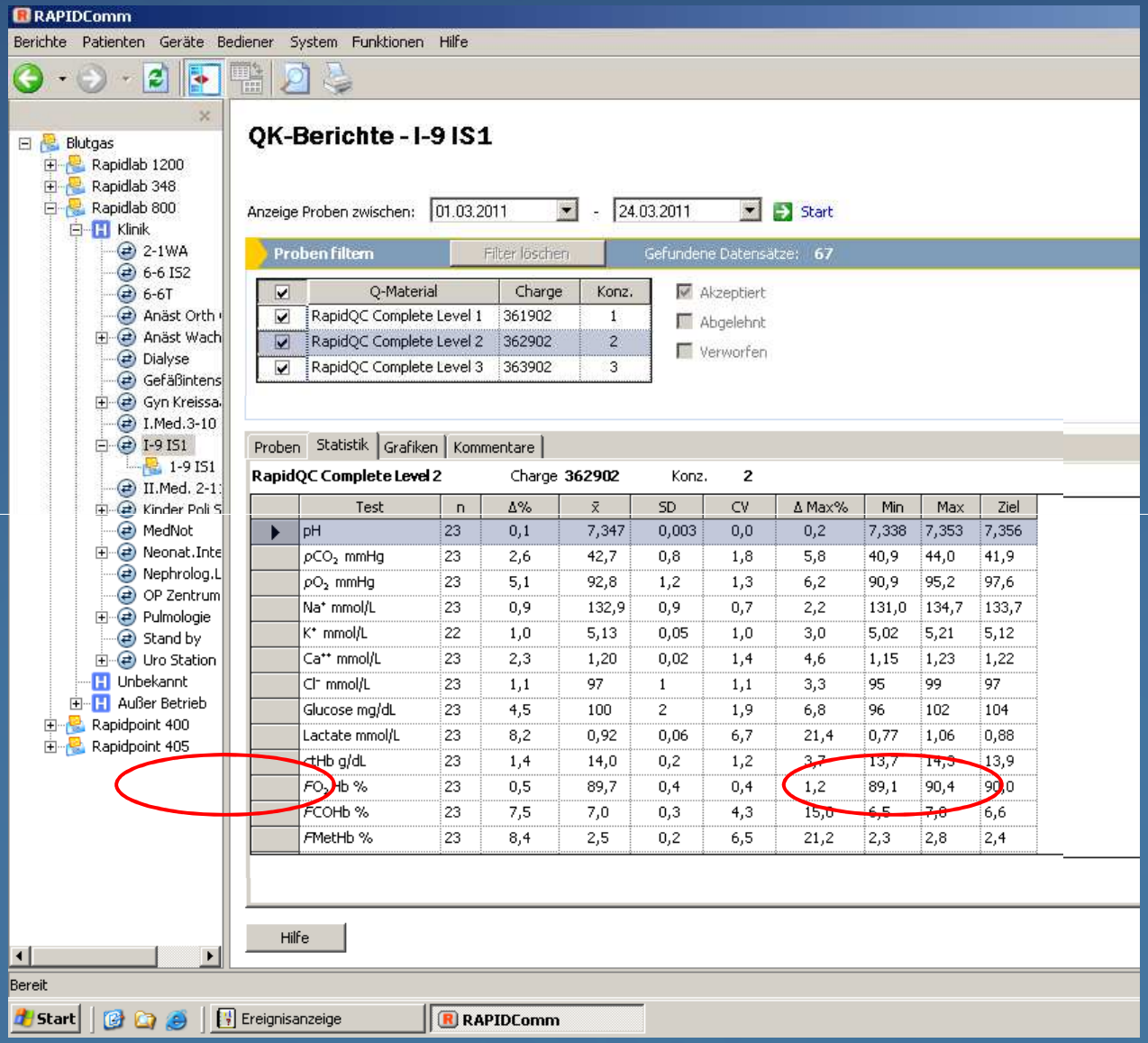
Lab-own. error dev.

Manufact. error dev.

Low concentrated lactate QC according to the lab-own error deviation

QC report given by RapidComm (included are the RiliBÄK rules)





%Δ=
%RMSD

%Δmax=
Lab-own error deviation

Lactate:
Target 0,88 mM.
Range given by Siemens:
0,64 – 1,12 mM
(+/- 27% max. deviation)

External QC

Maximum allowable deviation from target value

	RiliBÄK 2002		RiliBÄK 2008	
	Specification	Measuring range	Specification	Measuring range
pH	0,06%		0,8%	6,75 – 7,80
pCO_2	12,5%		12,0%	15-110 mmHg
pO_2	12,0% 15 mmHg	≥125 mmHg < 125 mmHg	12% 18%	125-350 mmHg 80-125 mmHg
Na+	6,1%		5%	110-180 mmol/l
K+	9,0%		8%	2-8 mmol/l
Glucose	16%		15%	40-400 mg/dl

RiliBÄK sanctions for irregularities:

- In case of violations of the quality management rules (e.g. QM handbook not available) the surveillance authorities (bureau of standards) punishes by rigorous fines.

- In case of failing the ring trial analyses twice within 6 months, the lab is being excluded from reimbursement for the analytes which were tested in the ring trial.

The RiliBÄK rules are similar to the rules described in the Clinical Governance in the UK

The Clinical Governance is the quality framework for the National Health Service (NHS) in Great Britain

The task of ensuring the Directive is undertaken by the Medicines and Healthcare Products Regulatory Agency (MHRA) and implemented into UK law by the Medical Devices Regulations 2002.

In 2006, a POCT Consultative Group was formed by the Academy of Medical Laboratory Services.

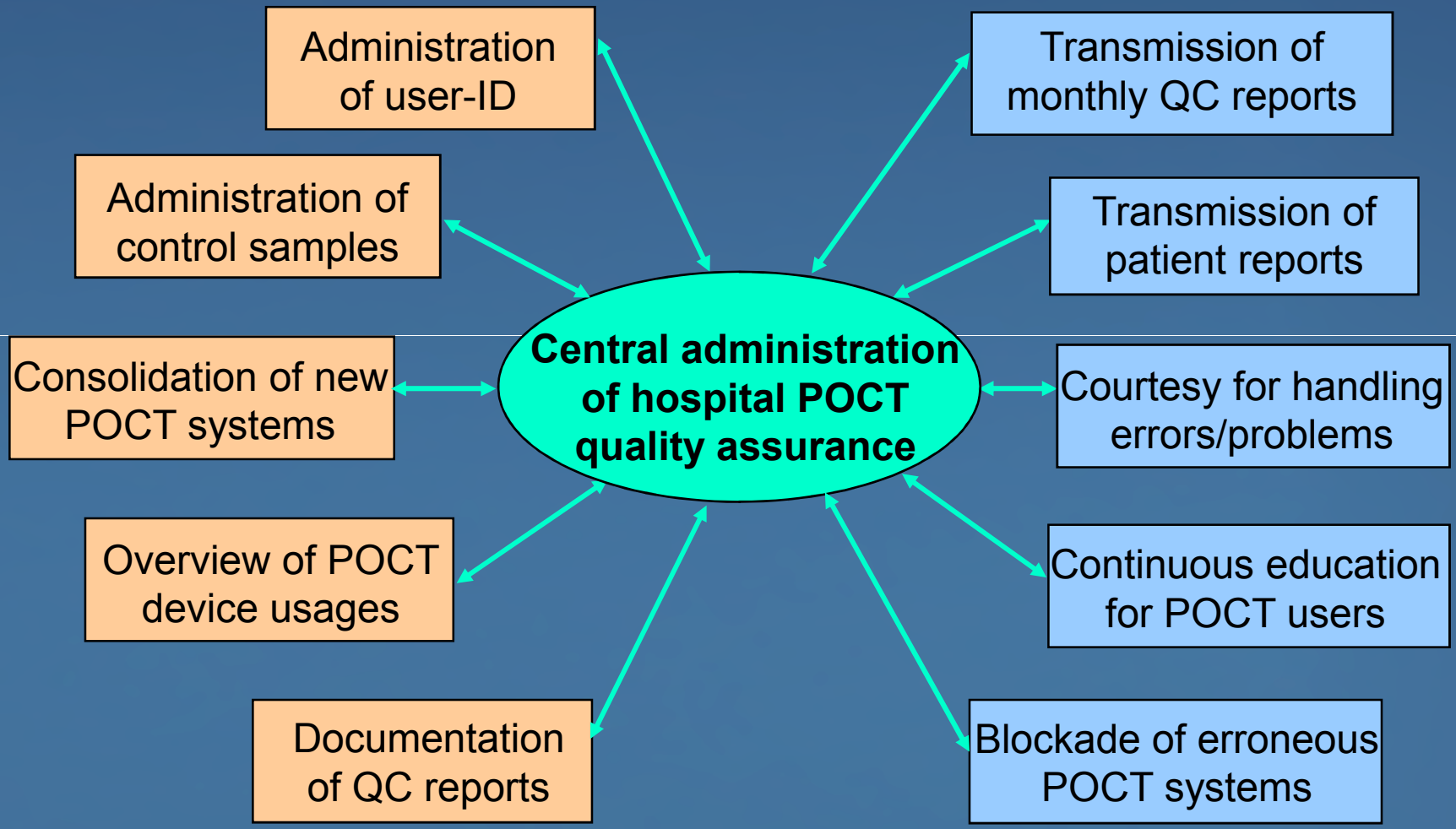
The MHRA released the Device Bulletin DB2010(02) “Management and Use of IVD Point of Care Test Devices“.

Similar guidelines have been produced by the Institute of Biomedical Sciences, the Royal College of Physicians, the British Committee for Standards in Hematology and the Medical Devices Agency.

The guidelines vary only in specifics, examples or scope. The majority of the guidelines agree on the following recommendations:

POCT should be managed under **clinical governance** and there must exist clear lines of accountability. Everyone involved in the management and use of the POCT service, including managerial, technical, scientific, clinical and nursing staff must be aware of their roles and responsibilities. As part of ensuring this, it is recommended that the POCT service be managed through a multidisciplinary POCT Steering Group.

Claims of RiliBÄK (D) and POCT governance (GB): Comprehensive POCT administration



In Germany the institution of a POCT coordination group was demanded for supervising the quality assurance of all decentralized POCT devices.

In Austria as well as in Switzerland, the German RiliBÄK has been adopted in many parts (in particular the POCT rules).

In UK this institution is called POCT steering group.

The POCT coordinator and his team are mostly members of the medical laboratory.

All respective duties for the quality assessment result in a heavy workload. In most cases no new employees can be hired.

On the other hand the POCT coordination discloses new fields of activity for the core lab.

Surveillance of POCT quality control measurements by the central lab

Surveillance of POCT quality control measurements by the central lab

The best way for implementing a comprehensive hospital QA system for POCT is the bidirectional online connection of all devices to the central lab via the HIS/LIS network.

The POCT coordinator should be responsible for the entire quality assurance process.

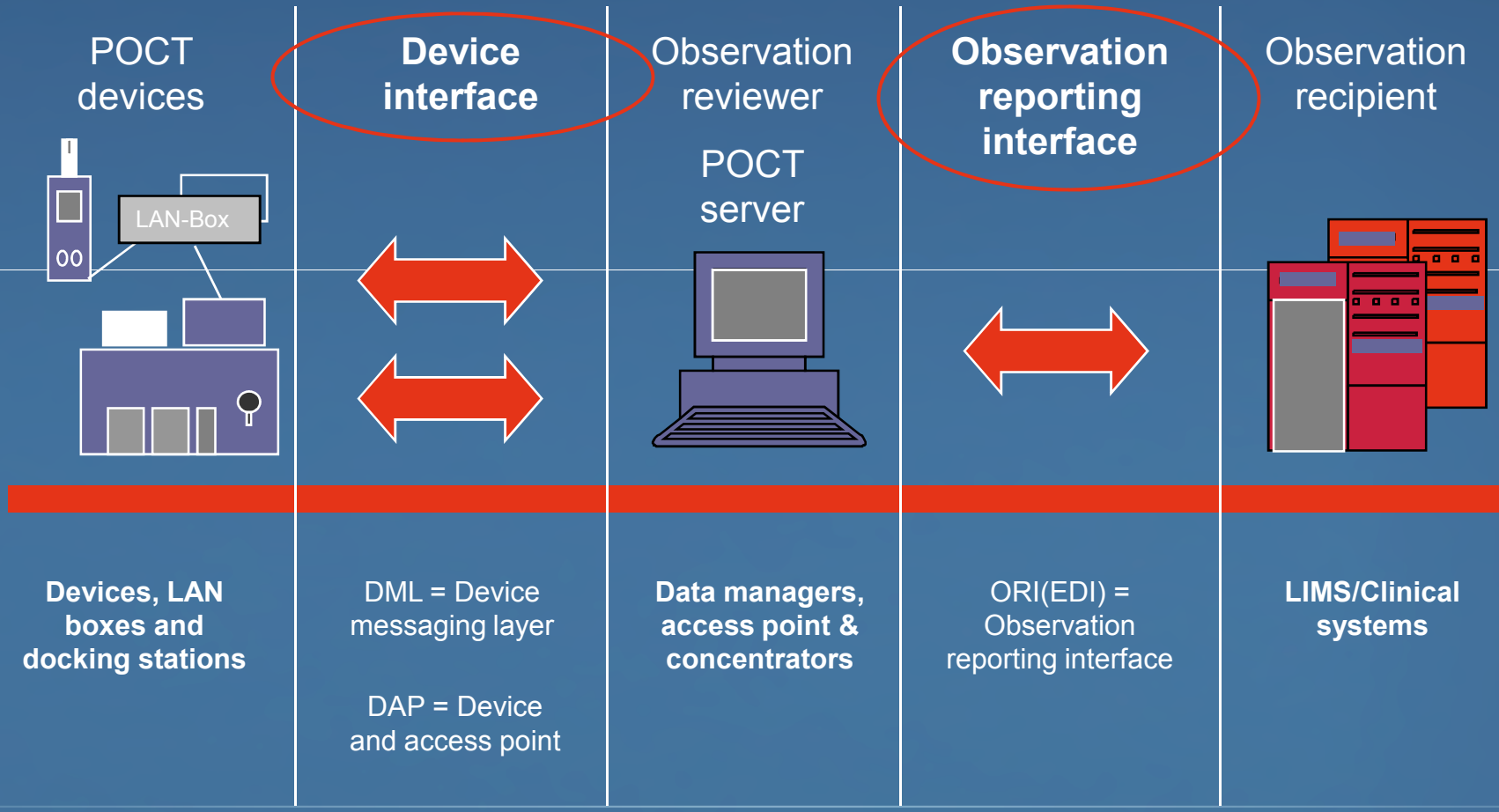
Connectivity solutions for hospital POC devices

The medical communication protocol **POCT1-A** was designed to standardize the communication pathways between POCT devices and the HIS/LIS and to ensure a quality assessment which is in accordance to national and international regulations. Basis were specifications of the CIC (Connectivity Industry Consortium).

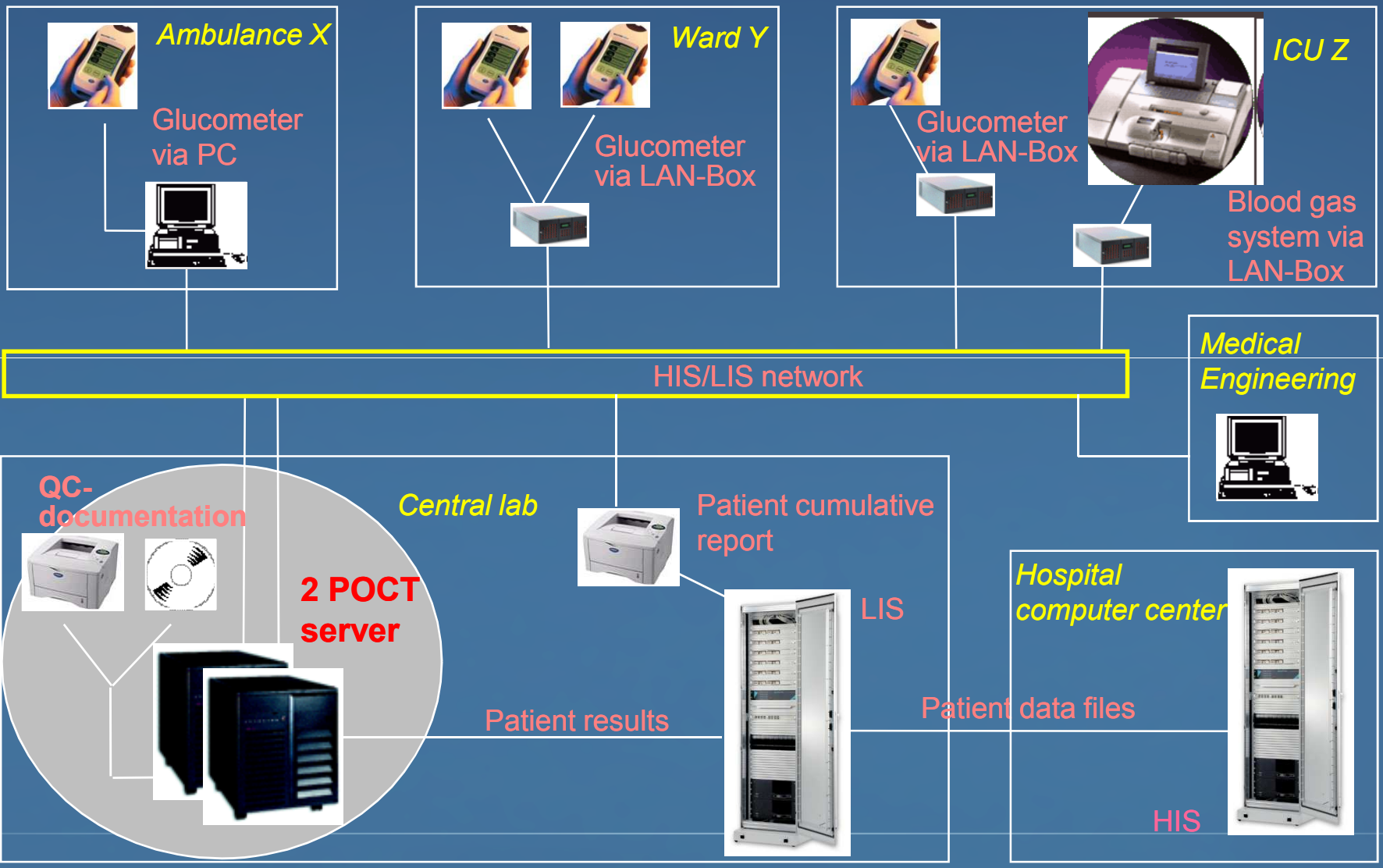
The POCT1-A standard uses the XML format for the communication between POCT device and server.
The POCT1-A gateway is similar structured as the HL7 communication. The standard also defines the procession of measured data within the HIS/LIS systems, as well as the translation of POCT1-A data into a HL7 compliant syntax.

Data management in modern hospital POCT environment

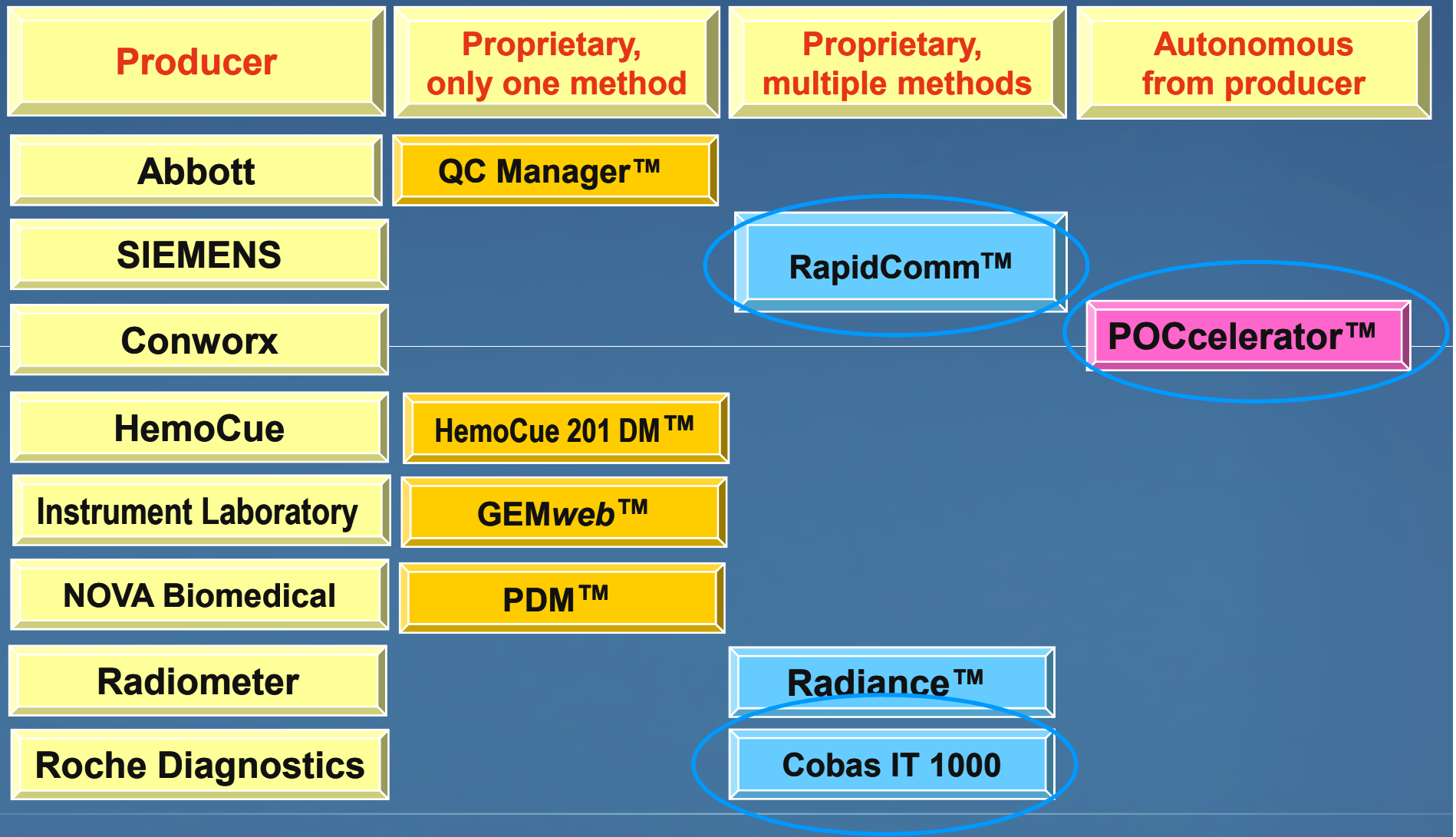
The POCT1-A standard has two communication gateways:
the Device Interface (DI) and the Observation Reporting Interface (ORI).



Connection of POCT systems to the HIS and LIS



POCT data management systems in the EU



Marketleader in the EU:

Conworx with POCcelerator

Marketleader in the USA:

Telcor Inc, Lincoln NE, with Quick-Linc/QML and Medical Automation Systems, Charlottesville, VA, with RALS-Plus

Thank you for your attention!