Quality assurance in medical laboratories

WAKA

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Knowledge / Experience / Care

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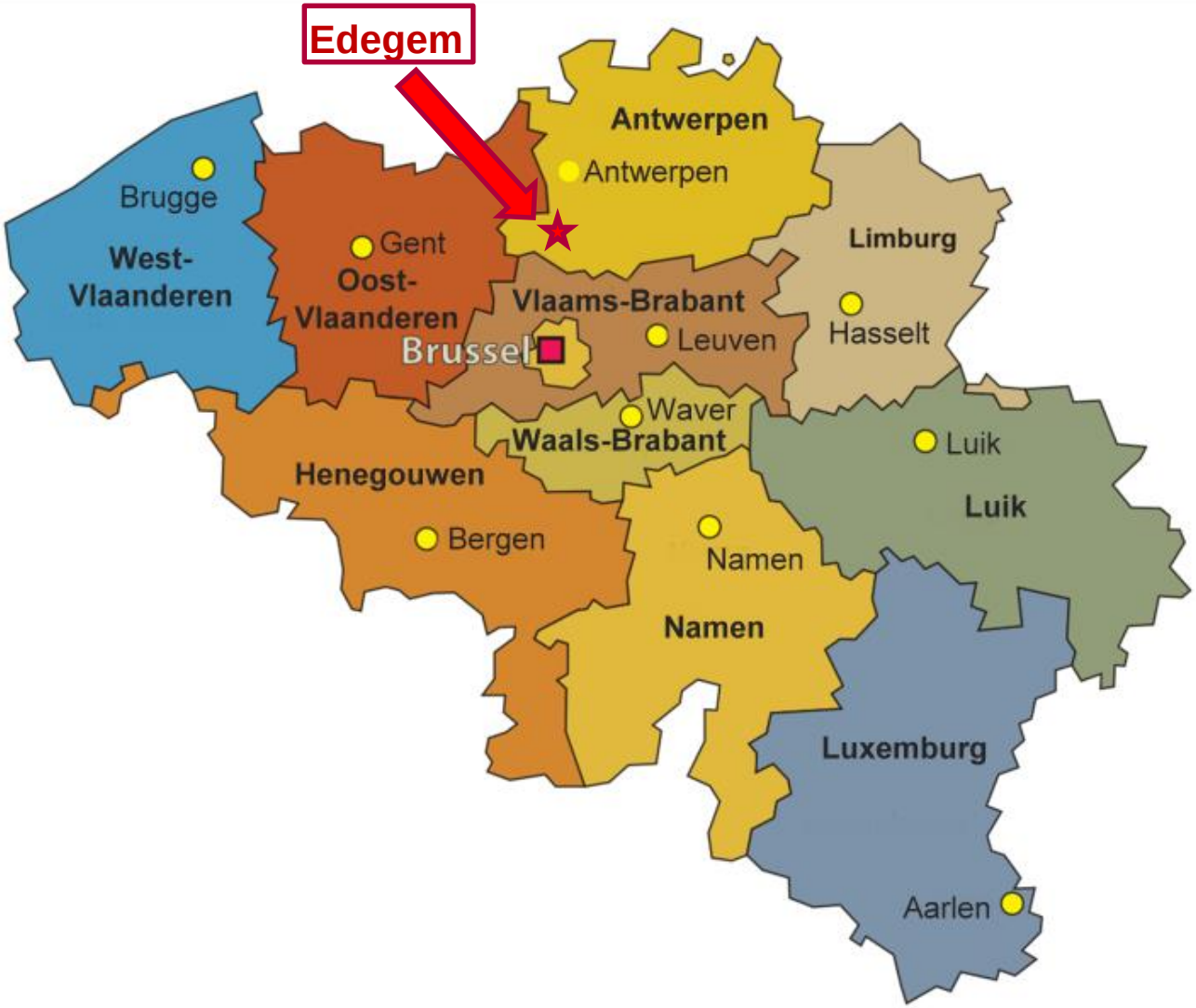
Map of Europe

BELGIUM

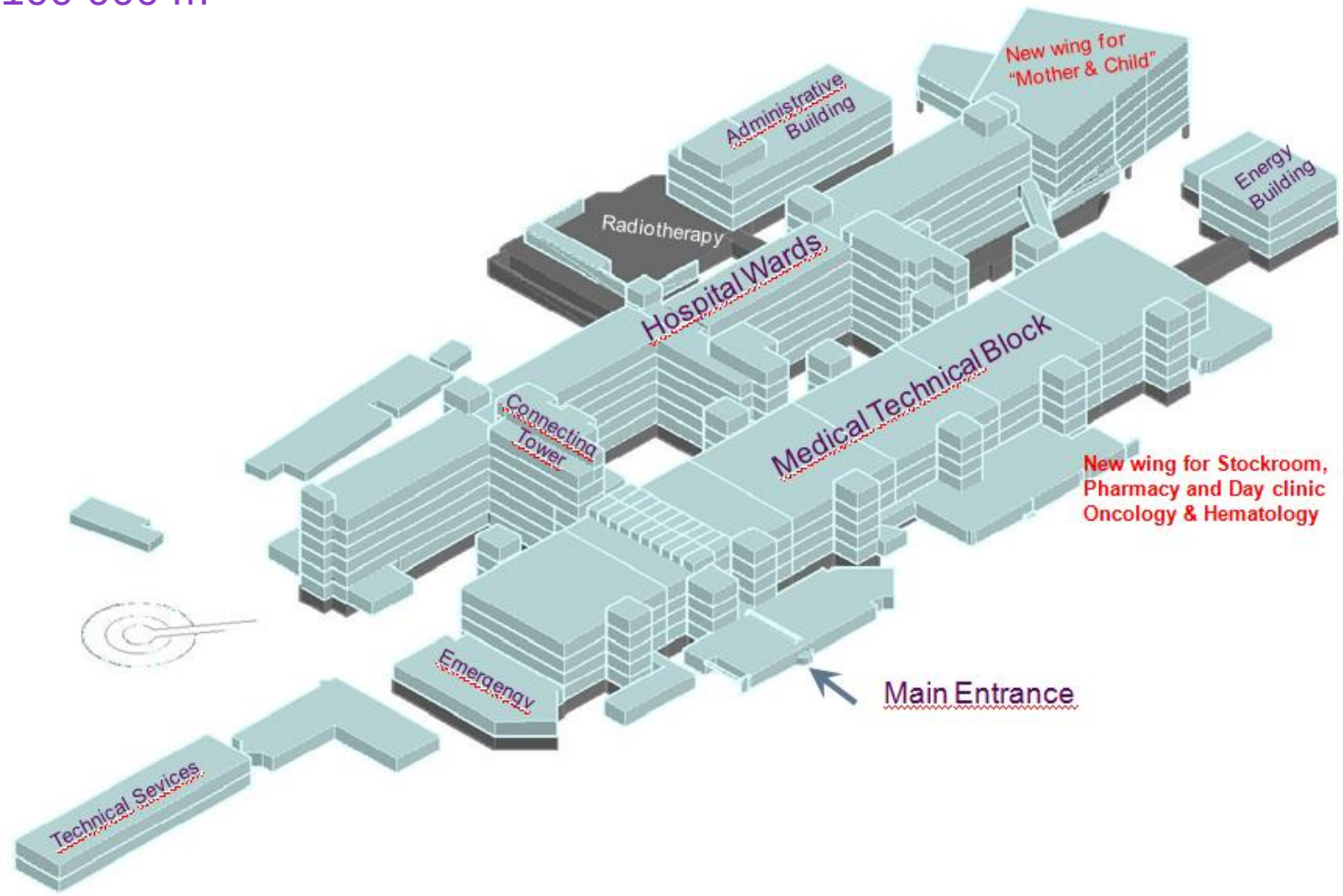
Map of Belgium



Antwerp University Hospital

Three dimensional overview

100 000 m²



About us

573	Recognized beds
> 3000	Employees
> 30.000	Admissions & visits to emergency room
> 600.000	Consultations

- Acute, university hospital
- Hospital accredited by Joint Commission International
- ISO accreditation for laboratories
- GCP certification for several activities

Content

- Quality & quality assurance
- Framework for quality management
- Key elements of a quality management system

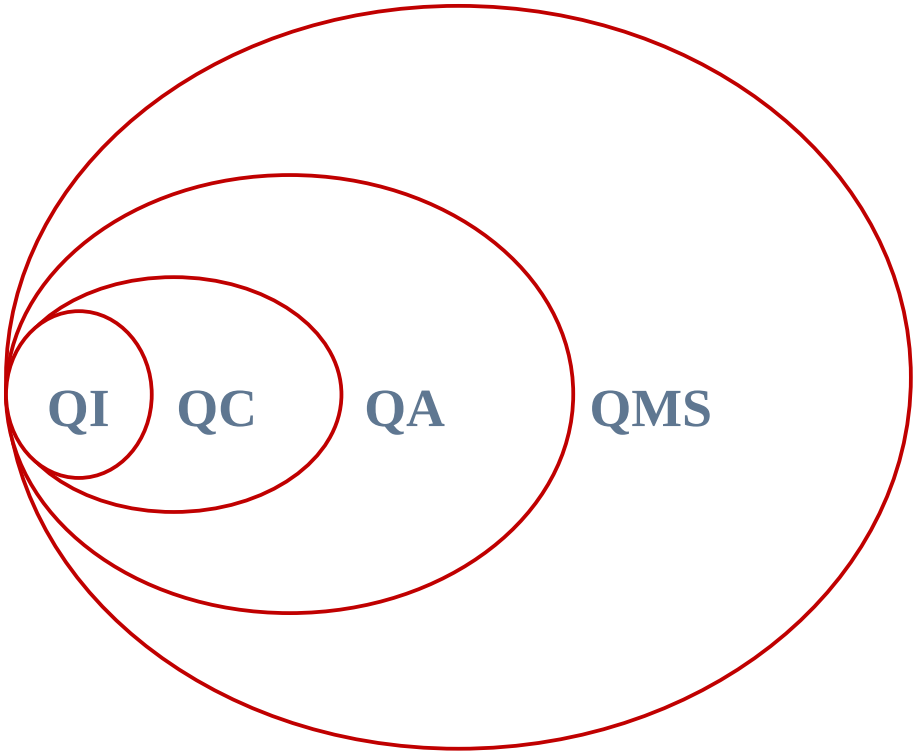
What is quality?

- Within specifications
- Fit for purpose
- Ability to meet client expectations
- The extent to which an organisation, product, service, meets certain requirements, specifications or expectations

What is quality?

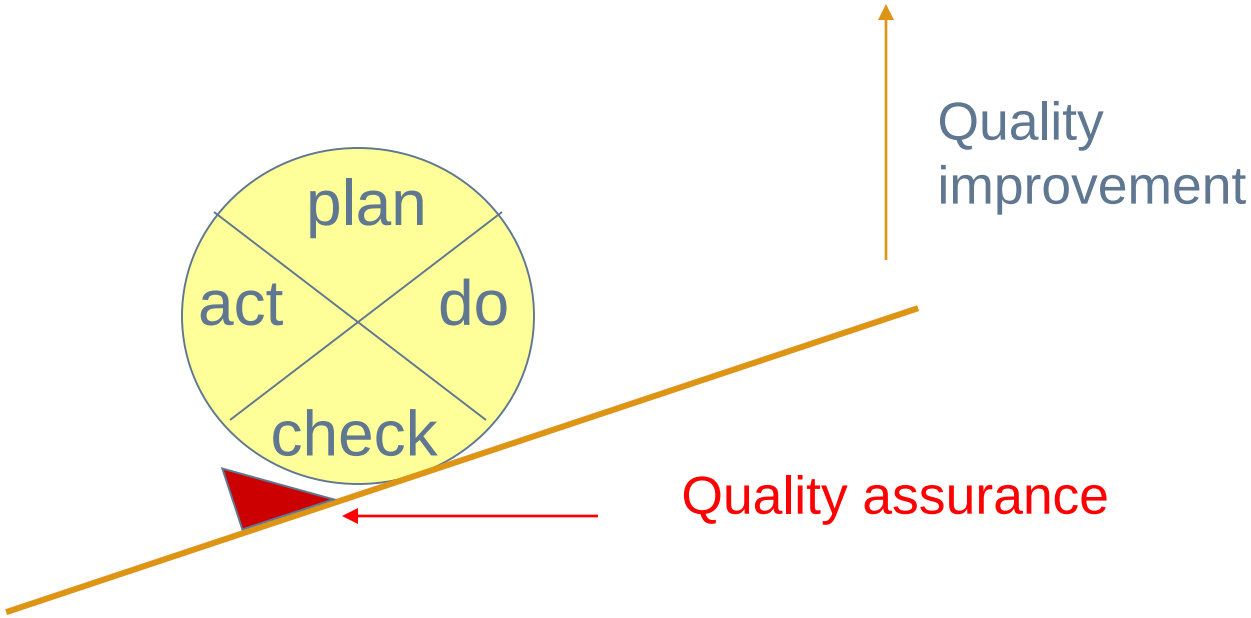
Justified confidence

Quality Management System



Quality Management System (QMS)

Quality improvement



Framework for Quality Management

- **ISO 15189: 2012**

  Medical laboratories – Particular requirements for quality and competence

- **ISO 17025: 2005**

  General requirements for the competence of testing and calibration laboratories

- **ISO 9001: 2008**

  Quality management systems - Requirements

Management requirements

ISO 9001/ ISO 17025/ ISO 15189

- Organization
  - 4.1 Organization and management responsibility
  - 4.2 Quality management system
  - 4.3 Document control
- Process management
  - 4.4 Service agreements
  - 4.5 Examination by referral labs (subcontracting)
  - 4.6 External services and supplies
  - 4.7 Advisory services (competence of clinical biologists)

Management requirements

- Quality assurance and improvement cycle
  - 4.8 Resolution of complaints
  - 4.9 Identification and control of nonconformities
  - 4.10 Corrective action
  - 4.11 Preventive action
  - 4.12 Continual improvement
  - 4.13 Control of records
- Compliance with QMS and the standard
  - 4.14 Evaluation and audits
- Review of the QMS
  - 4.15 Management review

Technical requirements

Quality Assurance of the primary process (4M,1E)

- **M**en (competence)
  - 5.1: Personnel
  - 5.2: Accomodation and **E**nvironmental conditions
- **M**aterials, **M**ethods, **M**achines
  - 5.3: Laboratory equipement, reagents and consumables
  - 5.4: Pre-examination procedures (primary sample collection manual)
  - 5.5: Examination procedures
  - 5.6: Assuring quality of examination procedures
  - 5.7: Post-examination processes
- Product quality
  - 5.8: Reporting of results
  - 5.9 Release of results
  - 5.10 Laboratory information management

Key elements QMS

1. Organization – personnel
2. Documentation
3. Accomodation & environmental conditions
4. Pre-examination process
5. Equipment
6. Validation
7. Quality control
8. Release of results

Organization & personnel

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Organization & personnel

- Qualification of personnel reflects
  - Education
  - Training – Tuning
  - Experience
  - Skills
  - → In relation to the complexity
  - → Appropriate to the tasks performed
- Jobdescription
- Personnel records
  - Educational and professional qualification
  - Training and experience
  - Competence assessment

Organization & personnel

- Assess competence/ skills by established criteria
  - Observation
  - Review / supervision of work records
  - Problem solving skills
  - Previously analysed samples
  - Proficiency testing

Documentation

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Documentation

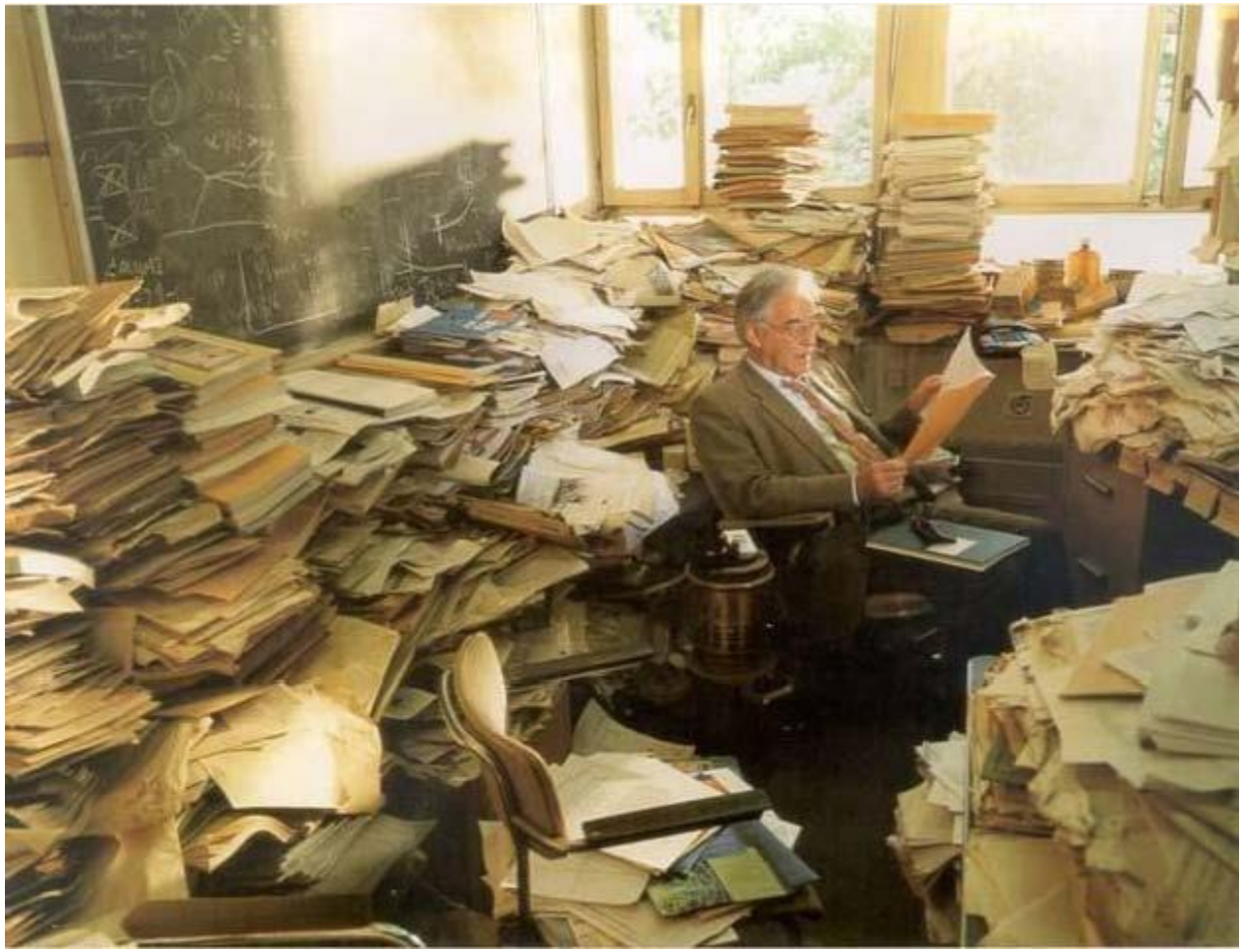
- Scope: documents that may vary based on changes in version or time.
  - Instructions, procedures,manuals, ….
  - Product inserts,
  - Software, databases, ….

- Aim: standardization → reduce variation

Documentation

- Instructions for use, safety and maintenance
  - Manuals, language of the user
  - Available for te user (electronic manuals, websites, ….)
  - Actual version
- Software
  - History of SW versions
  - Software upgrades:
    - Release notes: impact of changes
    - Validation/ verification (! loss of data, incompatibilities opening old files)
- Product inserts
  - Version control (! available on website, notices)
  - Documented review of impact of changes

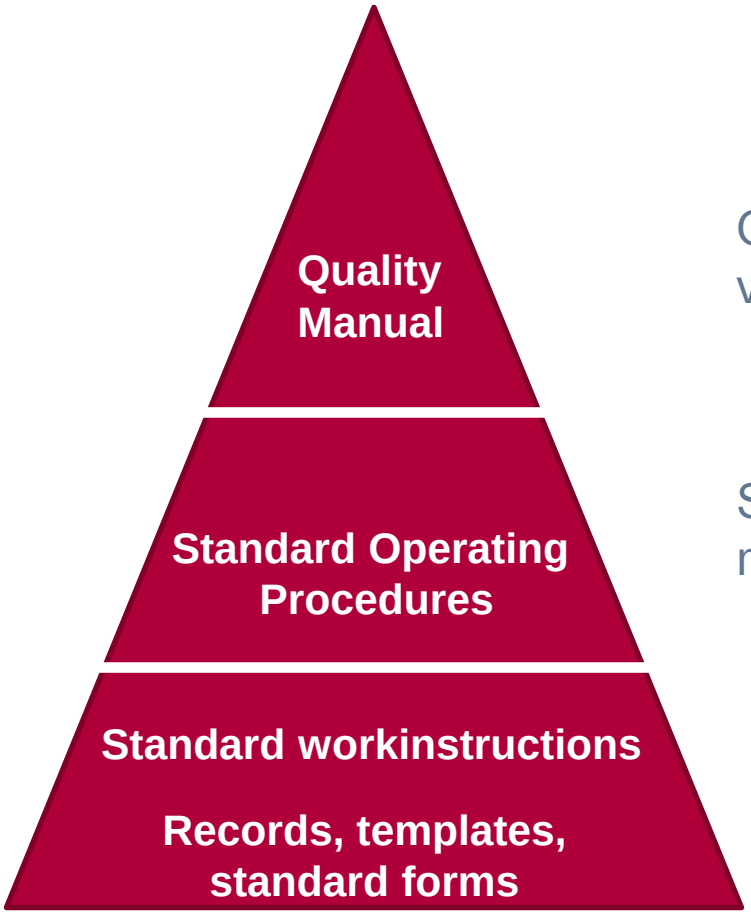
Documentcontrol



Documentation - Requirements

- Current
- Available - obsolete versions
- Approved - authorized
- Clear language
- No room for interpretation
- Periodicaly reviewed
- Changes identified by author and date
- Standardized format
- Organized – easy to locate

Documentation



QM: "**where**" are we heading
vision & values

SOP: "**what**" do we do
mandatory principles

Standard workinstructions: "**how"** do we do it
guidance & tools

Learning & support

How do we **learn** what to do and how to do it

Writing Instructions

WHAT? Reference (standard)

+

HOW? Agreements (fill in by the lab)

Check

Practice, reality

Documentation

"I have six honest serving men,

They help in all I do,

Their names are **W**here and **W**hat and **W**hen and **H**ow and **W**hy and **W**ho".

Rudyard Kipling

Accomodation & environmental conditions

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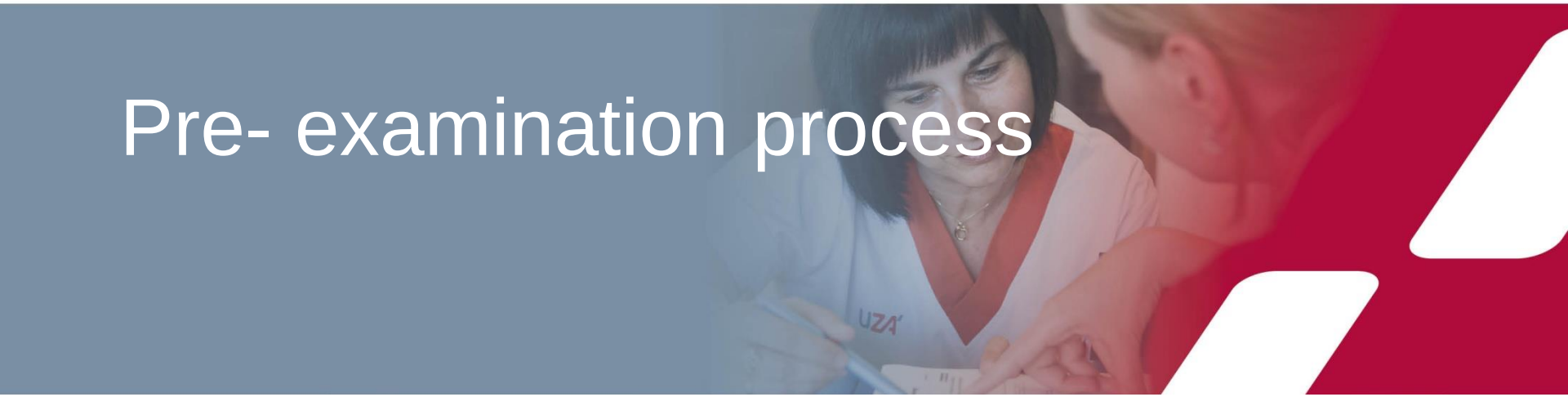
Accomodation & environmental conditions

- Lab design
  - Follows sample flow
  - Incompatible activities
- Lab conditions
  - Influence on quality of samples and results
  - Prevent cross contamination
  - Monitoring true blancs , negative control samples
- Storage conditions
  - Samples
  - Reagents
  - consumables

Pre- examination process



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Pre-examination process

- Instructions for sample collection
- Recipients, additives
- Clinical information
- Correct labelling
- Transportation and handling
- Criteria for acceptance and rejection
- Condition at reception
- Traceability of portions to primary sample
  → chain of custody!
- Storrage conditions, stability , time interval to re-analysis
- Factors affecting the results (interferences)

Equipment

Instrument lifecycle

IN

- Selection and purchasing
- Identification
- Acceptance testing
- Training
- Calibration
- Validation
- Maintenance
- Repair
- Out of service

OUT

Chaired responsibility
vendor – lab

Selection and purchasing

- Scope
  - equipment that affects the quality of the tests
  - incl. on loan and back-up instruments
- Selection of approved suppliers based on criteria
- Monitor performance of suppliers
- Service contract
  - Not only financial
  - Content of preventive maintenance
  - Instrument calibration, metrological traceability
  - Intervention times/ back up

Acceptance testing

- Upon installation and before use
- Certificate of conformity (production)
- Installation report (in the lab by the vendor)
  - Prove that specifications are met
  - Capable of achieving the necessary performance
  - Performance specifications related to intended use

Calibration

- According to manufacturers instructions
- Acceptance criteria
  → impact on QC (shift)
  → use real samples as QC material (critical decision levels)

- Metrological traceability
  - Measurement result can be related to a higher standard through a documented unbroken chain of calibrations (established calibration hierarchy)

Maintenance & Repair

- Logbook
- Preventive maintenance
- Following (at a minimum) manufacturer’s shedules & instructions
- Run QC-samples before and after intervention
- Defective equipement clearly labelled out of service
- Verify performance using specified acceptance criteria
- Before routine use
- Examine the effect on previous results

Equipment records (1/3)

- Identification: manufacturer’s name, type and serial number or unique identification (labnumber)
- Contact information
- Date of receiving
- Date of entering into service
- Location
- Condition when received: new, used, reconditioned
- Manufacturer’s instructions
- Records of acceptance testing
- Records of maintenance carried out
- Schedule of preventive maintenance

Validation

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Validation

When?

- Before introduction to routine use
- Whenever changes are made to a validated procedure

Who?

- Validation by the manufacturer
- Verification by the lab (implementation validation)
  if used without modifications

Validation

What?

- Methods
  - Non-standard, modified standard methods
  - In house methods (! open channel without application note)
  - Standard methods used outside their intended scope (matrix)

- IT systems
  - Datatransfer and integrity
  - Excelfiles
    - Validated formulas, macro’s
    - Secured against unintended changes

Validation

How?

- Validation procedure
  - Plan (incl. criteria), results, conclusion, attachments
  - Raw data, identity of the persons performing activities

- Performance characteristics verification
  - Repeatability
  - Reproducibility
  - Accuracy
  - Metrologic traceability
  - Check reference values

Quality control

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Internal Quality Control

Goal: ensure quality of examination process

- Draw complete proces
- Determine critical steps based on risk analysis
- Design quality control procedures
- Quality control materials
  - React as patient samples
  - Concentrations near critical decision values
  - Covering full analytical range
  - Use independent third party control materials
- Frequency based on stability and risk of harm due to errorneous results
- Quality control rules focused on error detection
- Review data, compare to initial performance

Interlaboratory comparisons

Goal: comparability of lab results

- Appropriate to the examination & interpretation of results
- Samples should mimic patient material
- Relevant to the entire examination proces
- Provide clinical relevant challenges
- Handle as routine patient samples

Release of results

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Release of results

- Violation of IQC rules
  - Reject results
  - Take correctieve action
  - Re-analyse QC samples
  - QC-samples within specifications
  - Re-examine relevant patient samples
    - After the error condition
    - After the last successful
  - Decide wich result should be released

- Performance criteria not fulfilled
  - Review IQC data
  - Review patient results

Effective actions

What is Quality?

"Quality is never an accident;
It is always the result of high intension,
sincere effort, intelligent direction
and skillful execution;
it represents the wise choice
of many alternatives"

William A. Foster

Quality is a Journey, not a Destination


time for discussion