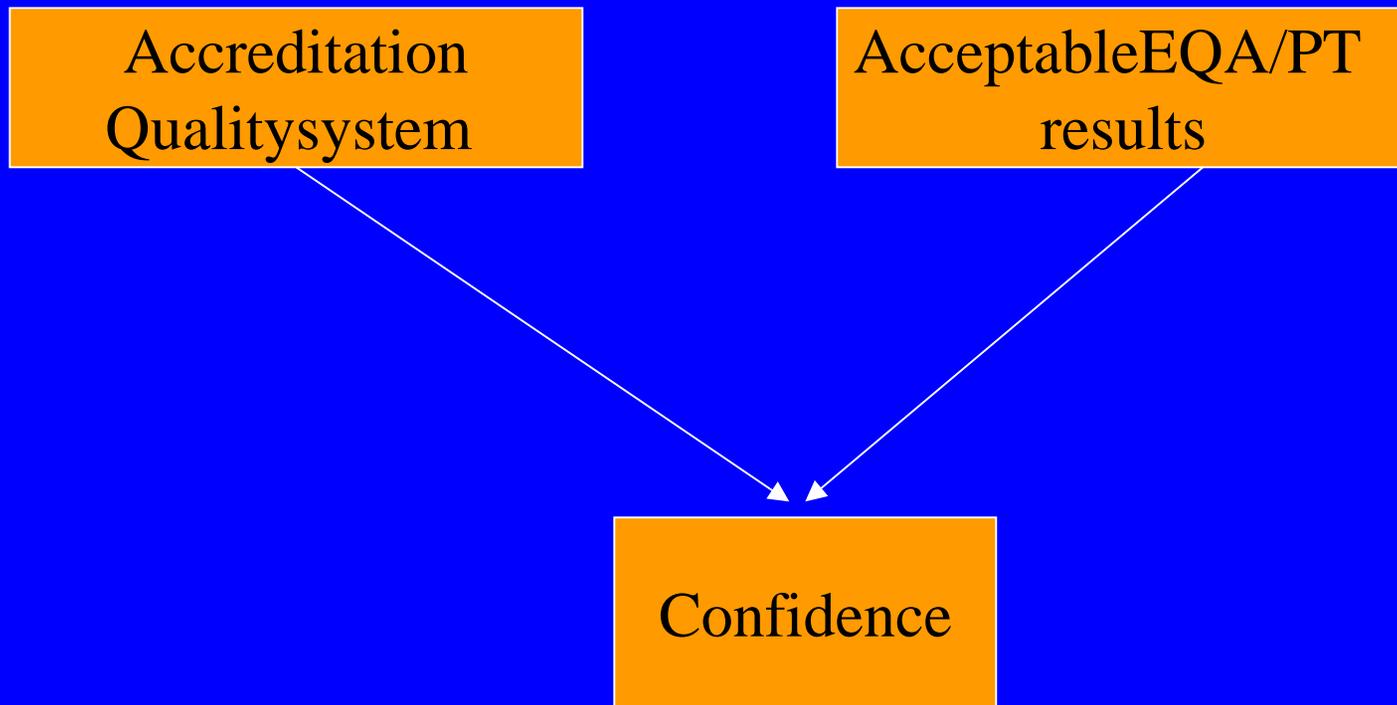


Workgroup 1  
Role of PT/EQA in Laboratory  
Quality Management

WG leader: Jean -Claude Libeer

Quality management standards  
attach great importance to  
PT/EQA

# Confidence in laboratory results



# prEN/ISO DIS 15189: medical laboratories - particular requirements for quality and competence

- 5.6.4 The laboratory shall **participate** in organised interlaboratory comparisons, such as external quality assessment schemes, that encompass the extent and complexity of examination procedures used by the laboratory. The laboratory management shall **monitor** the results of external quality assessment and **participate in the implementation of corrective actions** when control criteria are not fulfilled. Interlaboratory comparison programmes shall be in substantial agreement with ISO Guide 43.
- NOTE External quality assessment programmes should, as far as possible, provide **clinically relevant challenges** that mimic patient samples and that check the **entire examination process** including pre- and post-examination procedures.

# Other guidance documents(1)

- EA-3/04(EALG6)1993:”Guidelines for Proficiency Tests in Accreditation”
- EURACHEM1999:”draft guide on Selection, Use and Interpretation of Proficiency Testing Schemes by Laboratories”.
- ISO/IEC guide 43 -21997:“Selection and Use of Proficiency testing Schemes by Laboratory Accreditation Bodies”.

## Other guidance documents(2)

- EEE-PT:EA,EUROLABand EURACHEM Working Group on Proficiency Testing

“The working group EEE -PT has been established as a joint activity by EA, EuroLab and Eurachem (EEE) to provide support on the use of proficiency testing (PT) to laboratory personnel and accreditation assessors”.

## Other guidance documents(3)

- ILACG13(2000).Guidelinesforthe requirements of the competence for providers of proficiency testing schemes
- ISO/DIS13528:2000. *Statistical methods for use in proficiency testing by interlaboratory comparison*
- IFCC,C -AQ(2002).Guidelinesforthe requirements of the competence for quality assurance programmes organizers in medical laboratories (in preparation)



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## Role of external quality assurance schemes in assessing and improving quality in medical laboratories

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### Abstract

Medical laboratories have a long tradition of external quality assessment.

Starting from pure quality control of laboratory performances, most external quality schemes in Europe evolved into a powerful tool for improving quality of clinical outcome of results.

External quality assurance in medical laboratories not only includes laboratory performance evaluation, but also evaluation of method performance, post-market vigilance, training and help.

In the future, the quality of programmes will further be improved by accreditation of schemes international collaboration and by using IT applications. © 2001 Elsevier Science B.V. All rights reserved.

*Keywords:* Performance evaluation; Education; Vigilance; Quality improvement

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# WG1

- Six subgroups
- Each subgroup has two main questions + a number of more detailed questions
- See the list of your subgroup
- Explain, give examples, make suggestions
- Timeschedule:
  - 8.45-10.15
  - Break
  - 10.45-11.30

# Role of PT/EQA in Laboratory quality management

- For each subgroup:
  - subgroup leader
    - Role:
      - Facilitate subgroup
      - Summarize responses for recorder to record
  - Recorder
    - Role:
      - Record responses
      - Keep track of time

# Subgroup leader/recorder

Provide WG leader with

- Summarized bulleted format of responses by question
- Limit 4 bulleted answers per question to be presented to WG leader

# Role of PT/EQA in Laboratory quality management

- Subgroup 1 -1: Educational values of PT/EQA programs: Ms Nancy Bestic/Nancy Anderson
- Subgroup 1 -2: Mandated versus Voluntary modes of Participation: Dr. Humberto Tiburcio/ Ruth Tembwe
- Subgroup 1 -3: Benefiting from PT/EQA programs: Dr. Sharon Ehrmeyer/John Ridderhof

# Role of PT/EQA in Laboratory quality management

- Subgroup 1 -4: Locating the Root cause of questionable results: **Dr. Beverly Metchock/Rhonda Whalen**
- Subgroup 1 -5: Uncertainty and Measures of Laboratory Quality: **Dr. Richard Jenny/Gene Baillie**
- Subgroup 1 -6: Standardization of Performance and Programs: **Dr. Tadashi Kawai/Judy Delaney**

# Practical arrangements

- Each group discuss the two main questions and subsequent questions
- Formulate your conclusions and findings
- If there is not enough time: pick -up questions from other WG1 subgroups