

*PT Data*  
*What to do with the*  
*results*

Proficiency Testing in GAP Countries  
From Concept to Reality

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## PT as part of a QA Program

ISO Standard – prEN ISO/DIS 15189.2

The laboratory shall participate in organized interlaboratory comparisons, such as external quality assessment schemes, that encompass the extent and complexity of examination procedures used by the laboratory.

1. This evolving ISO standard is entitled “Medical Laboratories – Requirements for Quality and Competence”. It is now in the final phase of adoption. Among its numerous clauses is this one relating to interlaboratory comparisons. Once adopted at a national level then all medical laboratories in-country will have to meet this standard. Where a recognized EQA scheme is not available then other mechanisms of interlaboratory comparison will have to be invoked.

# Quality System Model for Health Care — NCCLS GP26-A

- Addresses the hierarchy of quality stages\*
  - quality control
  - quality assurance
  - quality system
  - quality improvement
  - quality management
- Uses a laboratory model to develop a quality system for any component of health care

# \*Quality Hierarchy

- Quality control – operational techniques and activities that are used to fulfil requirements for quality and regulatory compliance
- Quality assurance – planned and systematic activities to provide confidence that an organisation fulfils requirements for quality
- Quality system – comprehensive and coordinated efforts to meet quality objectives

## \*Quality Hierarchy II

- Quality improvement – emphasis on recognizing opportunities for improvement based on the use of quality indicators
- Quality management – management approach centered on quality, focussed on long-term success through customer satisfaction

# PT as part of a QA Program

## NCCLS GP26A

Quality Assurance is defined as  
"Planned and systematic  
activities to provide confidence  
that an organization fulfils  
requirements for quality"

1. NCCLS GP26A describes a quality management system for health care. When applied in the laboratory it defines 12 Quality System Essentials to be applied to the pre-analytical, analytical and post-analytical path of workflow.
2. It defines quality assurance as shown on this slide.
3. Participation in interlaboratory comparisons is one component of an effective QA system

## Evaluation of PT Reports *Who does the evaluation?*

- EQA scheme organizer
  - Staff
  - Consultant experts
  - Peer group representing participants
- Laboratory Management
  - Laboratory Director
  - Quality manager
  - Top management group

1. As the EQA scheme organizer you design, implement and carry out the interlaboratory comparison including setting the standard for acceptable performance.

2. It is unlikely that you will have the staff or the in-house expertise to provide expert commentary on performance. ISO Guide 43 part 1:1997 Development and Operation of Proficiency Testing Schemes suggests enlisting technical advisers with respect to a) overall performance b) variation within and between laboratories c) variation between methods d) sources of error and e) recommendations or general comments. We use a mix of expert consultants and scientific committee members.

3. The other main group of evaluators lies in each participating laboratory. In many countries a person is named as the Laboratory Director with ultimate accountability for the laboratory performance. In others a group of persons may be appointed with collective responsibility. Regardless, ISO 15189 requires the appointment of a quality manager who has delegated authority and responsibility for the quality management system.

# PT as part of a QA Program

ISO Standard – prEN ISO/DIS 15189.2

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.

1. The ISO standard covers the same ground as GP26A. It specifies the actions to be taken by the management of the laboratory concerning the results of interlaboratory comparisons.
2. The requirements are twofold: monitor the results and implement corrective actions when performance does not meet expectations.
3. The laboratory must identify the problem in the documented performance and carry out a root cause analysis before designing and implementing corrective actions.

## Investigating Unacceptable EQA Performance

NCCLS GP27A Using Proficiency  
Testing (PT) to Improve the  
Clinical Laboratory

*Classification scheme:*

- Clerical error
- Methodological problem
- Technical problem
- Problem with PT materials
- Problem with evaluation of results
- No explanation

1. In 1999, NCCLS issued three approved guidelines dealing specifically with quality issues. I have spoken about GP26A. GP22A deals with continuous quality improvement and the third, GP27A addresses the effective use of external quality assessment to improve quality in the clinical laboratory.

2. There is a very helpful section (section 7) on investigating unacceptable EQA performance.

3. It speaks to classifying the problem. Note – problem not error. The scheme shown here can be very helpful in carrying out a root cause analysis. Further categorization is provided under each of these headings but I don't have time today to discuss them.

## Evaluation of PT Reports *Where are the problems?*

- Pre-examination
- Examination
  - Reagents, instruments, methods, calibration, QC - Analytical error
  - Calculation
  - Competency of Staff\*
- Post-examination
  - Report format
  - Interpretation
  - Transmission
- Data
  - Clerical/transcription error
  - Data capture error

1. The problems may lie anywhere along the path of workflow.

2. The integrity of the challenge may have been compromised during preparation, shipping or after receipt by improper storage or handling.

3. On the examination front great care should be taken to ensure that the EQA challenge materials do not exhibit a matrix effect in the examination system used by the participating laboratory. Analytical problems should be investigated to determine whether any error is random or systemic

4. My next slide speaks to competency of staff but before going there let me emphasise that post-examination problems occur frequently and that incorrect data capture by the EQA scheme organizer is certainly not unknown.

## Competency of Staff

- The laboratory management shall
  - Maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel
  - Authorize personnel to perform particular tasks
- The competency of each person to perform assigned tasks shall be assessed following training, and periodically thereafter. Retraining and reassessment shall occur when necessary.

1. Over time we all tend to become complacent and make assumptions that are unwarranted. This certainly applies to professional competence as is recognized in much of the world by the increasing requirements for health professionals to demonstrate continuing competence through professional development.

2. ISO 15189.2 has four specific requirements of laboratory management relating to staff competence:

- maintain records
- authorize performance of tasks
- assess competency
- provide re-training and assessment

## Action Plan for Remediation

- The aim is quality improvement
- Confirm your observations through
  - Correspondence
  - Review of documents
  - Review of peer group performance
  - Ruling out matrix effect
- ? On-site visit with recommendations
- Share observations
- Communicate suggestions

1. In some jurisdictions, performance in approved EQA schemes is a condition of payment for patient sample testing. The greater aim is use of interlaboratory comparisons as a quality improvement tool.

2. There are many times when performance does not match that intended by the EQA scheme organizer. Don't always assume that you are right and the lab is wrong. Dialogue with the participant about unacceptable results allows the organizer to verify information, assist the participant in investigating the problem, share experiences and make new observations such as unknown bias of an instrument reagent system.

3. Ensure that your process is fair and equitable. You may have to provide information to an accreditation agency and that takes me to my next slide

## Accreditation

*Will PT data be used?*

- Accreditation is the formal recognition of the competence of a laboratory to carry out specific tests or examinations
- Interlaboratory comparison is a requirement to demonstrate competence
- EQA is one form of interlaboratory comparison
- EQA performance should be reviewed during the accreditation process
- Corrective actions arising from EQA performance review should be documented

1. The first bullet speaks to accreditation. ISO Guide 58 (soon to be ISO17011) as well as the ILAC (International Laboratory Accreditation Cooperation) requirements specify the standard that a laboratory accreditation body must meet.

2. Any laboratory seeking accreditation can expect that the accreditation body will review their PT/EQA performance. In some jurisdictions the EQA scheme organizer will have provided the performance data directly to the accreditation body

3. The accreditation body will be most interested in the process for the investigation of problems, as well as the documentation and implementation of corrective actions

## Requesting Resources *Using PT data to promote improvement*

- Be professional but know what you are up against
- Develop advocacy and negotiating skills
- Develop the business case
  - Identify your needed resources and associated budget
  - Show that you have taken all possible remediable actions within your existing resources
  - Present your impact analysis
  - Use a risk management strategy
- Set your priorities and trade-off as needs be

1. Whether you are an EQA scheme organizer or a clinical laboratory person you are faced with limited resources. In recent years increasing demands for limited health care dollars has created a highly competitive market place.

2. As a manager of these limited resources you face knowledge and skill set requirements that were unnecessary even a generation ago. You have to be able to demonstrate that what you do adds quality and value to health outcomes and is an effective use of health dollars.

3. Acceptable performance in an EQA scheme can ensure continued funding. Performance problems can be used to advocate and negotiate for additional resources but you will need the skills. Is it going to be you, radiology, or pharmacy that gets the money this year?

4. Develop your business case, think like an administrator. The slide shows some of the approaches you might take

5. Have a fall back position