PT Data
What to do with the results

Proficiency Testing in GAP Countries
From Concept to Reality

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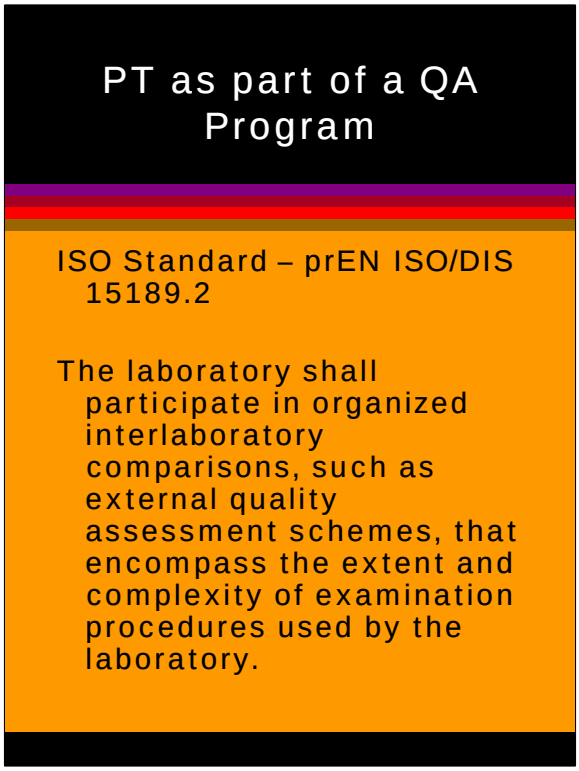


1.This evolving ISO standard is entitled “Medical Laboratories – Requirements for Quality and Competence”. It is now in the final phase of adoption. Among its numerous clauses is this one relating to interlaboratory comparisons. Once adopted at a national level then all medical laboratories in-country 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

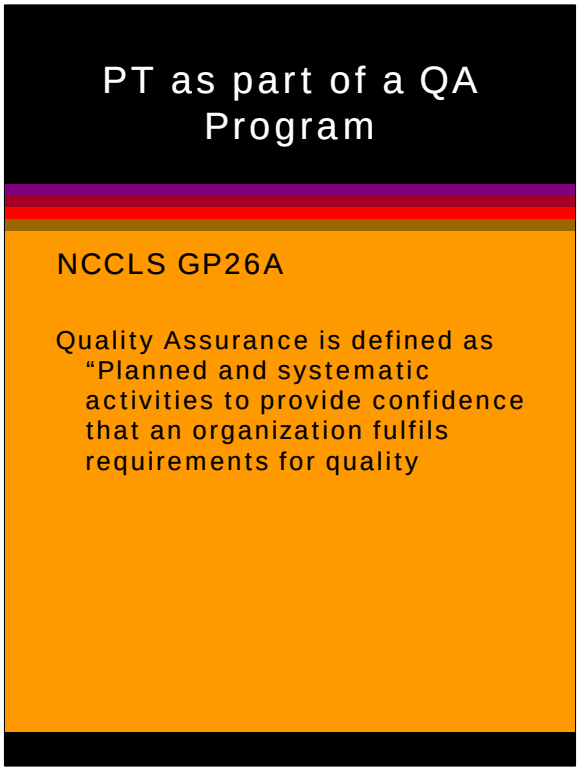
- Addresses the hierarchy of quality stages*
  - quality control
  - quality assurance
  - quality system
  - quality improvement
  - quality management
- Uses a laboratory model to develop a quality system for any component of health care

*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

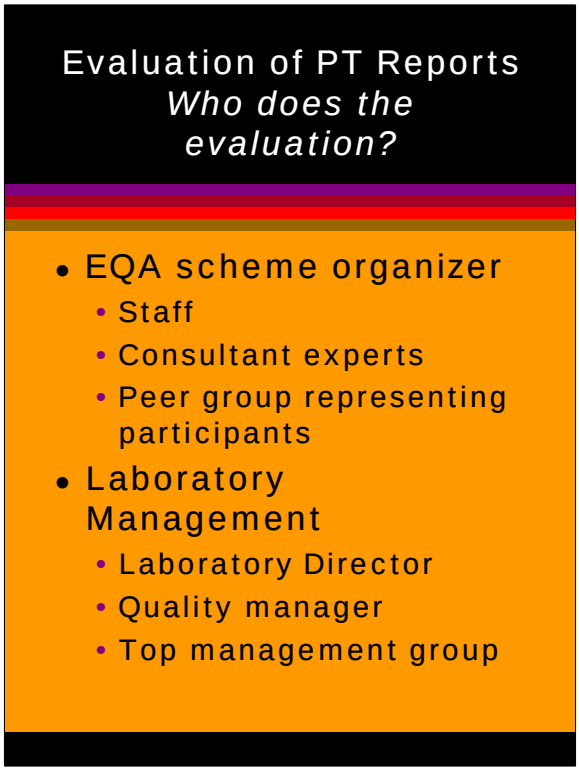
- Quality improvement – emphasis on recognizing opportunities for improvement based on the use of quality indicators
- Quality management – management approach centered on quality, focussed on long-term success through customer satisfaction



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.

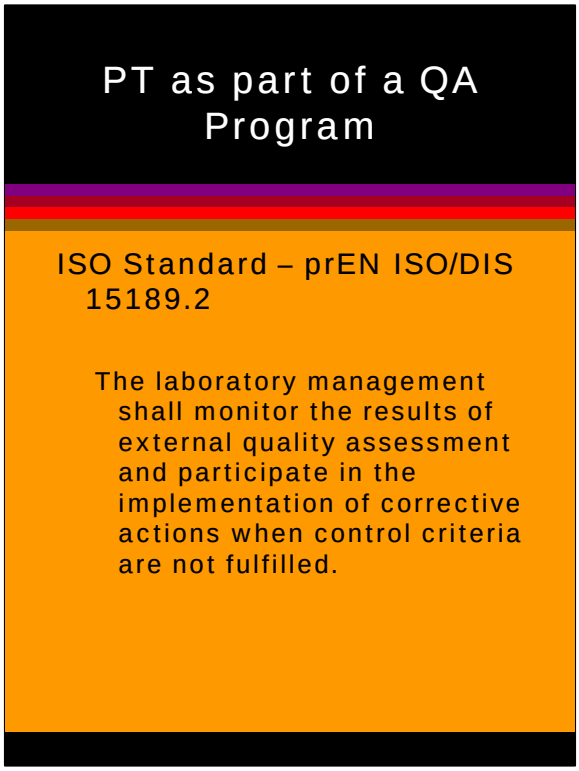
3.Participation in interlaboratory comparisons is one component of an effective QA system



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.

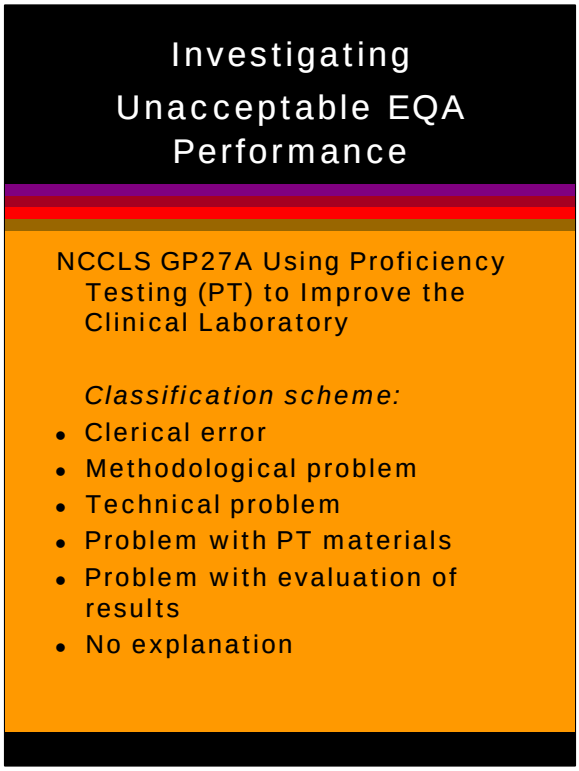
3.The other main group of evaluators lies in each participating laboratory. In many countries a person is named as the Laboratory Director with ultimate accountability for the laboratory performance. In others a group of persons may be appointed with collective responsibility. Regardless, ISO 15189 requires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



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.

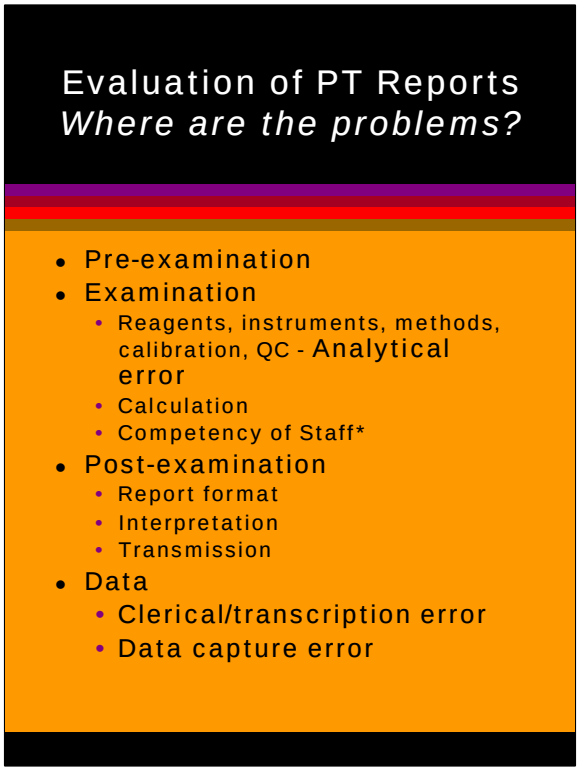
3.The laboratory must identify the problem in the documented performance and carry out a root cause analysis before designing and implementing corrective actions.



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.

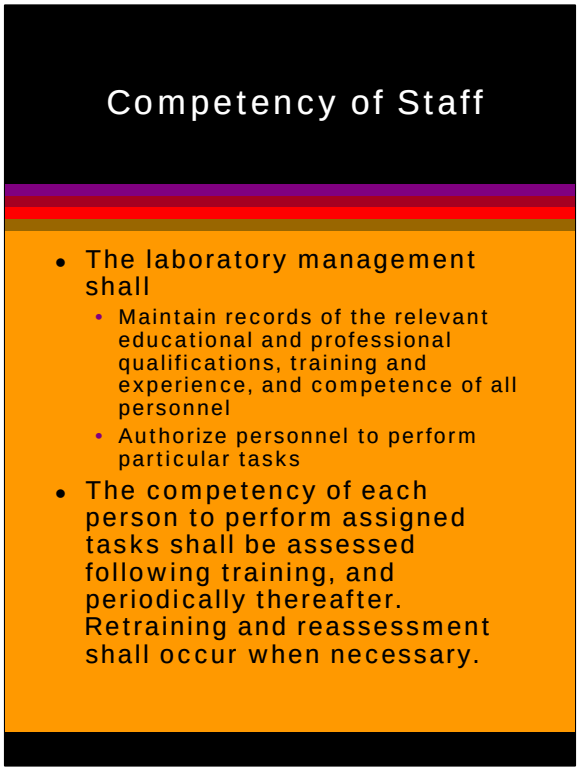


1.The problems may lie anywhere along the path of workflow.

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.



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

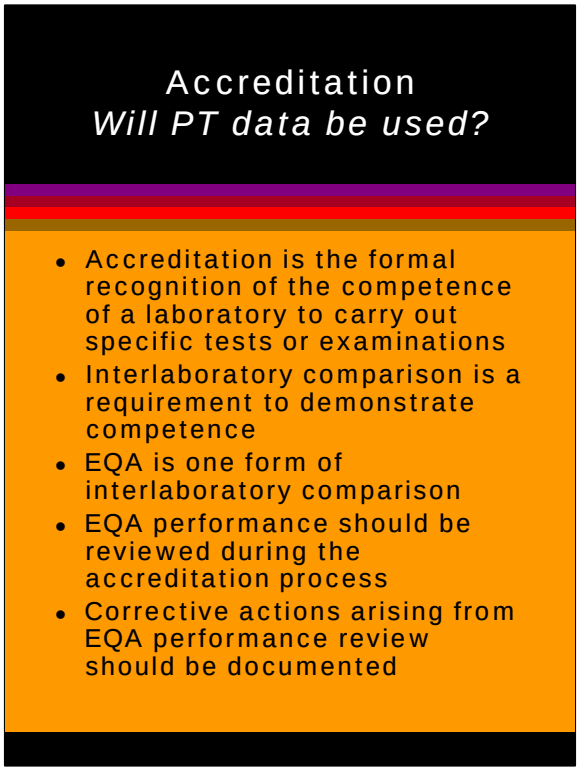
-assess competency

-provide re-training and assessment

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 verity information, assist the participant in investigating the problem, share experiences and make new observations such 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



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

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