WHO Manual
Organizing a National External Quality Assessment Programme for Health Laboratories and other Testing Sites

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Prequalification of In Vitro Diagnostics (IVDs)

Essential Medicine and Health Products

Geneva

World Health Organization

The WHO manual

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http://apps.who.int/iris/bitstream/10665/250117/1/9789241549677-eng.pdf?ua=1

Data from EQA Participation

- Allow comparison of performance and results among different sites, instruments and reagents
- Provide objective evidence of the testing service's competence to customers, accrediting bodies and regulatory agencies
- Identify areas of improvement for better patient care
- Identify training needs
- Does not adequately assess: Pre-analytic (sample collection and transport) and Post analytic (results evaluation and dissemination)

Introduction and Definitions

- **The manual is based on ISO/IEC 17043:2010.** Conformity assessment – General requirements for proficiency testing. Geneva: International Organization for Standardization; 2010.

- **Proficiency testing**: evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043:2010)
  - NOTE 1 For the purposes of this International Standard, the term proficiency testing is taken in its widest sense
  - NOTE 2 Some providers of proficiency testing in the medical area use the term **"external quality assessment"**.

- **Proficiency test item:** specimen, product, artefact, reference material, piece of equipment, measurement standard or data set provided to one or more participants, or submitted by participants, in a proficiency testing round (ISO/IEC 17043:2010)

- **Inter-laboratory comparison:** organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions (ISO/IEC 17043:2010).

Introduction ctn

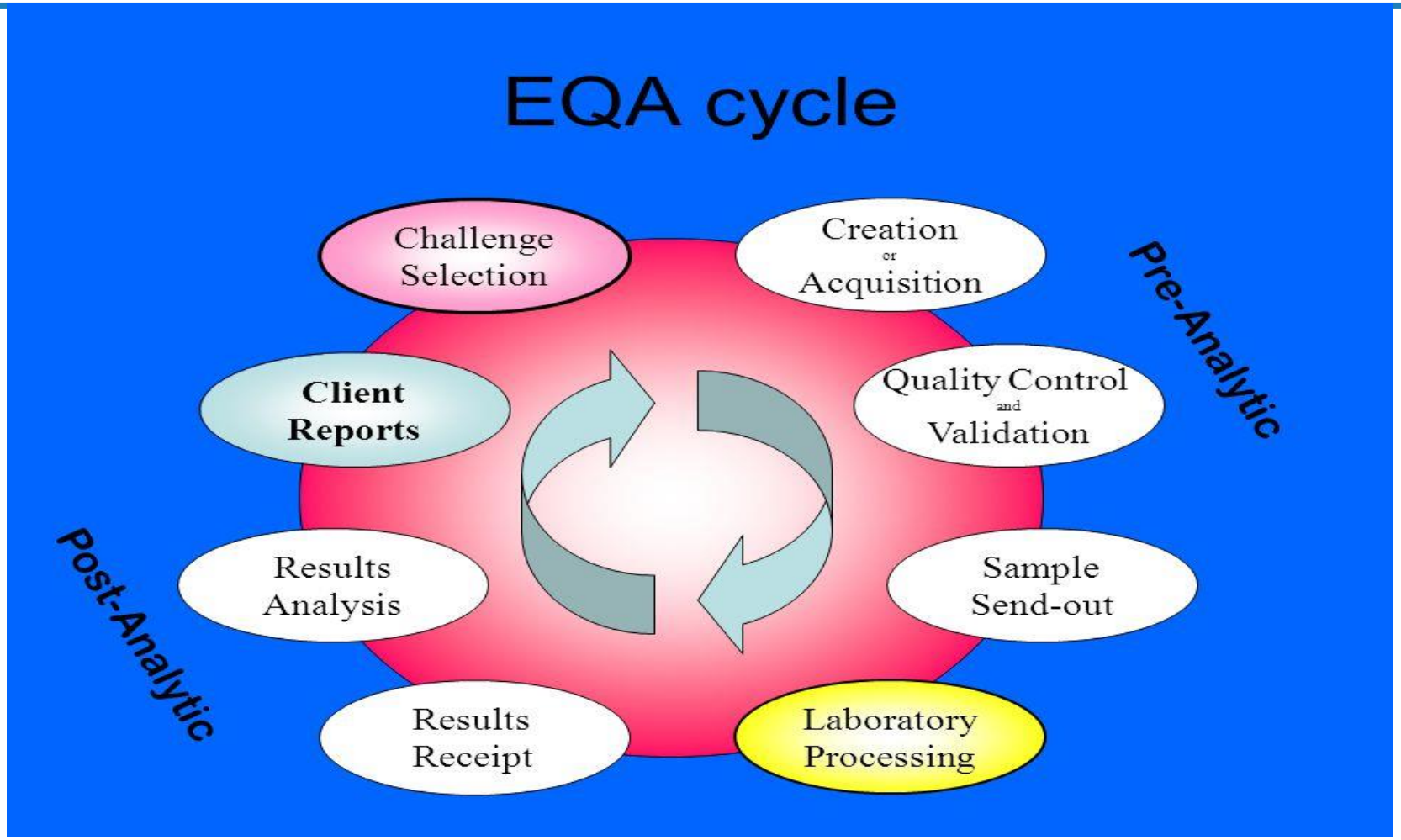
- **Quality management system**: a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization (i.e. areas that can impact the organization's ability to meet customer requirements) (ISO 9001:2015)
- Three main components of quality management system include:
  - internal quality (process) control,
  - proficiency testing (PT),
  - and quality improvement
- An EQA programme may be organized on a sub-national, national, regional or international basis; each has its **advantages and disadvantages**

Considerations for establishing national EQA Programme

- Advantages
  - Improve PT samples availability, integrity, appropriateness
  - More affordable in the long run
  - Enable provision of better support to failing labs
  - In-country capacity building: sample preparation, data analysis
  - Provide opportunity to increase scope and coverage

- Challenges
  - Initial high cost
  - Challenging PT samples (CD4)
  - Small number of labs

Path of EQA workflow



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Chapter 1&2: Establishing National EQA programme

- The organization of an EQA programme is a **technical process** that includes a number of interacting elements, implementation of all of which will be accomplished only after **the final stage of organization** has been reached

- There are two non-mutually exclusive strategies that can be used to establish a national EQA programme
  - Non-governmental organizations: competitive
  - National agency (a government ministry, professional or academic institution)

- Final goal of an EQA organizing centre: to be accredited to the international standard for providers of EQA programmes (ISO/IEC 17043:2010)

- All public and private laboratories should be encouraged to participate but, wherever possible, participation **should be mandatory**.

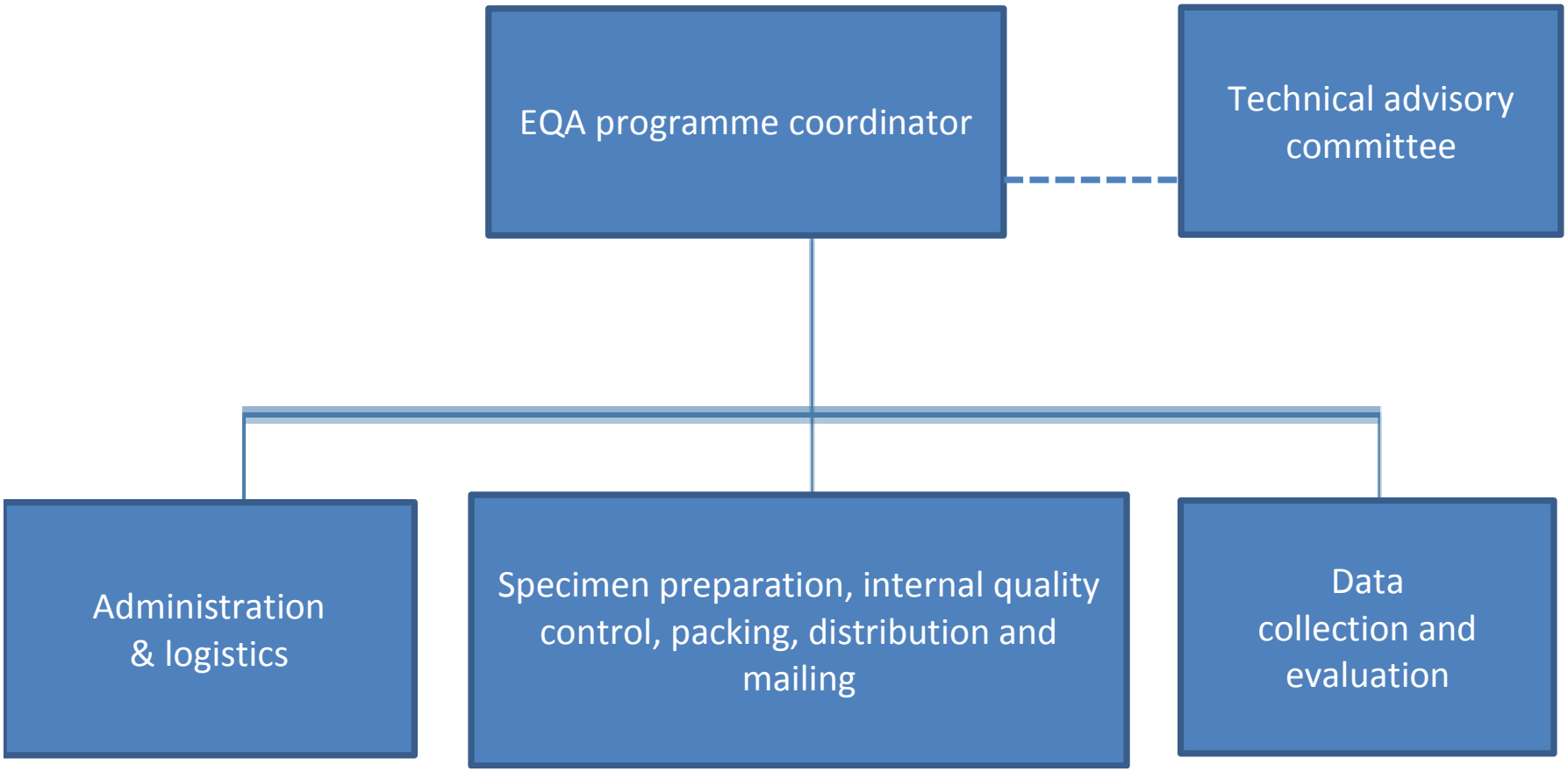
Chapter 2
Situational analysis is critical

- Conduct a risk-based situational analysis of laboratories and other testing services as the basis for planning and implementing an effective strategy for EQA to include
  - **Number, type and location** of laboratories or testing centres
  - Existing **infrastructure** in the laboratories or point-of-care (POC) testing sites
  - type of **laboratory analyses** carried out in the various disciplines
  - existence of **implementation of laboratory quality management** measures
  - availability of support for **supervisory and mentoring** networks;
  - inventory, state of performance and maintenance of **laboratory equipment**;
  - **calibrators, proficiency test items** and their supply;
  - number of **technical and medical professionals**
  - existing **infrastructure for transport** of proficiency test items ;
  - **financia**l aspects for provision of the testing service;
  - ***supply chain management*** system;
  - national **regulatory and licensing** requirements
  - **existing disease-specific EQA programmes etc**

Chapter 3-6
Steps in establishing national EQA

- Obtain Government commitment:
  - appropriate legislation or regulation(s),
  - encourages provision of appropriate EQA services taking into account the national priorities
- Identify organizing centre(s) which should have the required competencies to run an EQA programme, supported by relevant experts depending on the type of analytes included in the programme, as described in ISO/IEC 17043:2010
  - Personnel including technical advisory committee
  - room facilities, equipment, etc
- Prepare a Plan and organize of PT rounds with approximate timelines for all stages (planning, implementation (range -18 months to +2 months)
- Ensure adequate and appropriate packaging and shipment arrangements (international std)
- Prepare essential EQA documents
- Ensure capacity to do data entry and evaluation (Statisticians, software etc)

Structure of an EQA programme organizing centre



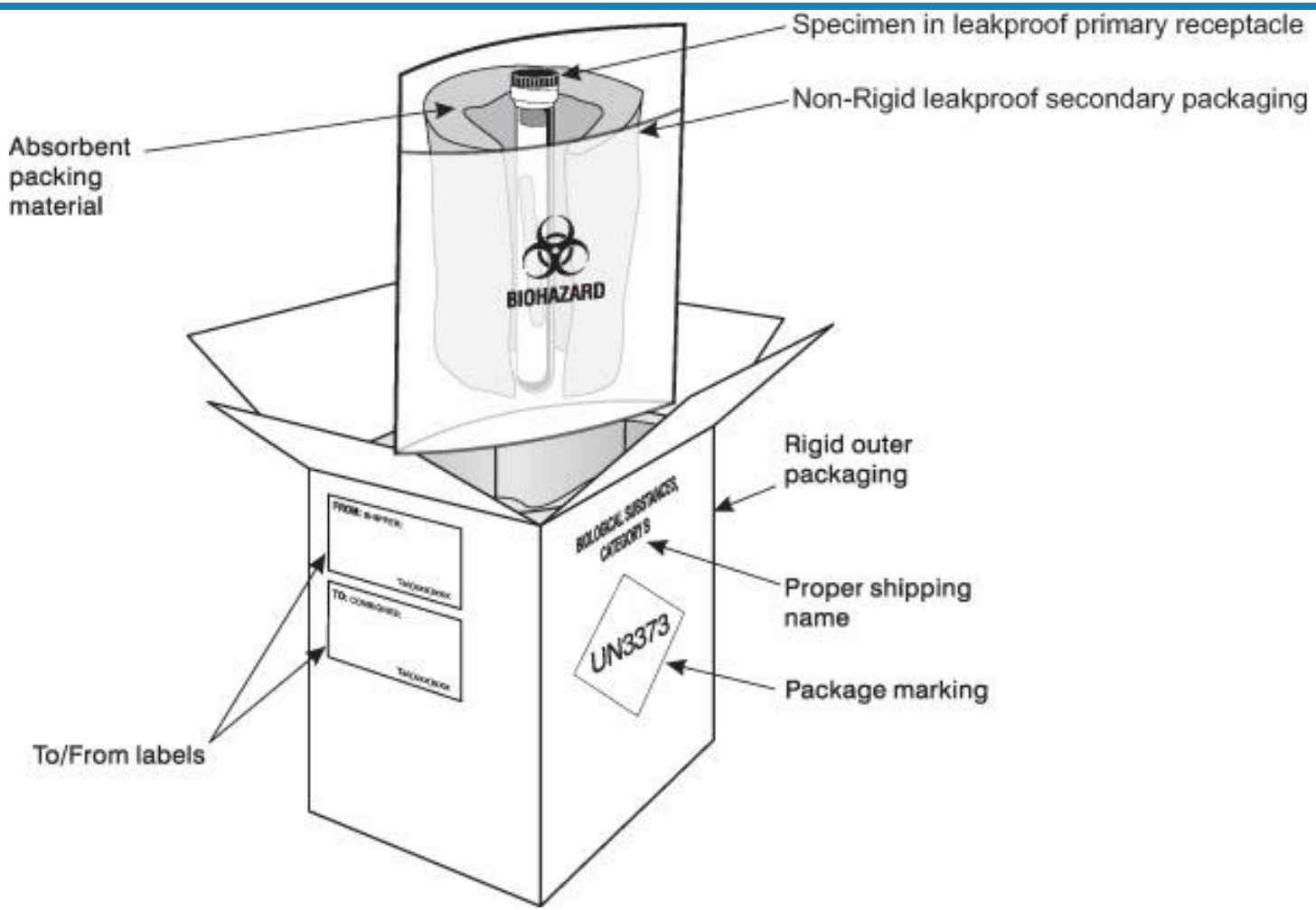
Timelines for planning and implementation of a PT round

Stage	Check date*	Action
Planning	–18 months	Identification of laboratory disciplines and sub-disciplines
	–16 months	Decision on frequency of PT rounds in a particular discipline
	–14 months	Determination of dates of mailing of proficiency test items
	–12 months	Preparation or ordering of proficiency test items (for non-perishable stable items)
	–12 months	Ordering of packing materials
	–3 months	Confirmation of delivery of proficiency test items and packing materials
Implementation	–1 month	Control of the availability of proficiency test items Safety checks, adjustment of analytes
	–1 month	General review of preparatory work for the PT round Informing of participants about despatch and closing dates by post or email
	–3 weeks	Validation of target values and viability of microbiological specimens; preparation of questionnaire and marking key
	–2 weeks	Printing of addresses, forms, etc. In-house processing; aliquot dispensing and aliquot testing
	–1 week	Packaging of proficiency test items
	–1 day	Dispensing and packing of perishable EQA materials e.g. fixed blood specimens In-house validation of panels before despatch
	Day 0	Delivery for mailing
	+1 week	In-house validation of despatched proficiency test items
	+2 weeks	Closing date – this will vary according to the type of test (some are performed daily, some weekly, etc.), and to specimen transit and data return times
		Data entry completion (for manual data entry, two entries are advised) Data analysis and validation
	+3 weeks	Printing of PT round reports and generation of corrective action templates
	>3 weeks	Assessment of remarks, questions and comments Update of the programme's historical records
		Storage of leftover proficiency test items, where stability of analyte permits

Requirements for Packaging and Transportation of EQA material

- Regulated under the United Nations regulations for the transport of dangerous goods
  - Infectious substances are Class/Division 6.2
- Packaging type will depend on its classification under the regulations, on whether the specimen is classified as
  - Category A (Infectious substances are substances which are known to contain, or are reasonably expected to contain, pathogens),
  - Category B Diagnostic specimens, assigned to UN 3373, are human or animal materials that are being transported only for the purpose of diagnosis or investigation or Exempt.
- Determine the appropriate type of packing and transport.
  - Category A infectious substances UN 2814 or UN 2900 packaging should follow packing instructions P620. Biological substances,
  - Category B, UN 3373, packaging should follow packing instructions P650.
- Both Category A and Category B items require a **triple package** but each has different safety testing requirements.
- Exempt specimen packaging also requires triple packaging but with less stringent safety testing. An example of the triple package

Triple package for transporting biological substances, category B



Chapter 3-6 cont
Steps in establishing national EQA ctn

- Ensure Capacity to prepare **proficiency testing round reports**
- Establish a **well-organized record system** including for PT round records, data analysis and participants performance
- **Make cost estimation**:
  - EQA programme requires specific investments and financial obligations to ensure a sustainable service
    - an allocated budget from government authorities
    - twinning with other EQA organizers
    - fees from participants
    - commercial suppliers
    - academic centres
    - long-term benefactors including trusts
    - support from development partners as a short-term measure
  - Cover the whole process (personnel, reagents, equipment, packaging, transport, analysis, training etc)

Calculation of expenses should include, but not be limited to:

- Rent of premises.
- General costs (water, communication, electricity, insurance).
- Salaries for personnel or man-hours required.
- Information technology infrastructure and maintenance.
- Costs for maintenance and repair of laboratory equipment.
- Proficiency test items, which can be purchased or produced locally
  - costs of the proficiency test items (serum, plasma, urine, whole blood, etc.).
  - investments for local production
  - evaluation of proficiency test items (i.e. test kits, reagents, calibrators, consumables, etc.)
  - assessment of stability and homogeneity of the proficiency test items.
- Packaging
  - packaging of proficiency test items
  - envelopes and labels for mailing.
- Administration of PT rounds
  - registration of participants
  - invoicing of participants (if applicable).
- Printing of forms, reports and catalogue.
- Mailing and/or courier costs
  - of proficiency test items
  - of reports.
- Evaluation of PT rounds
  - reimbursement of costs for experts (as appropriate)
  - costs for use of informatics (as appropriate)
  - costs for organizing meetings of experts and workshops for participants (once or twice a year).
- Training/corrective actions for participants.
- Miscellaneous costs
  - programme development costs
  - programme financial management
  - programme quality management system
  - staff training and development.

Chapter 7&8
Proficiency test items

- An ideal EQA (PT) item should be
  - as similar as possible to patient specimens;
  - homogenous, as indicated by **homogeneity testing**;
  - **stable** at least for the PT round turnaround time;
  - **safe**;
  - **negative for infectious agents** unless specifically required for the PT round;
  - where applicable, **ready for use** with a pierceable septum;
  - **sterile**, except for specific instances such as microbiological PT rounds; acceptable matrix, homogeneity and stability properties
- Establish to mechanism to collect and characterize the PT item(human, animal, artificial, Microbial)
- Ensure there is knowledge on the preparation of specific proficiency test items (Heamatology, bacteriology, parasitology, , Serology, Clinical chemistry, Nucleic acid testing, CD4, Histology)

Chapter 9
Evaluation of EQA results

- **Before evaluating the participants results Ensure:**
  - the PT **challenge** participants have received is **consistent** with the planned value (**controlled sample**);
  - Participants have received the **same** challenge material (**homogeneity**);
  - if there is a predetermined correct target value, laboratory results have provided **evidence that the challenge is fair and reasonable** to the extent that all laboratories can be expected to achieve a valid result (**equity**);
  - where collective laboratory results form the basis of a consensus value, laboratory **results will be compared and analyzed in a fair and equitable manner** (**comparability**);
  - the probability or **risk of specimen degradation** has been studied and, to the extent possible, contained (**stability**).
  - For review of proficiency testing of quantitative values, **measurements in a laboratory should not be considered as perfect**; some variation may be introduced into the testing process (**measurement uncertainty**)

Chapter 10
Proficiency testing round report

- PT round report should be sent to all participants to them to compare their laboratory's performance with that of peer laboratories conducting similar analysis
- The laboratory or testing site manager shall share the EQA report with everyone in the laboratory or testing site and develop appropriate corrective action
- EQA programme should include a procedure for monitoring performance over time

Chapter 11-12
Monitoring and evaluation

- EQA should be an educational tool
- EQA programme maintains a process of quality improvement
- Monitors its performance against performance indicators.
- Evaluation should be undertaken at least once a year and an annual report produced

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More WHO PQDx Workshops

- **Sunday 04/12 - Seminar #14: WHO workshop on Prequalification of In Vitro Diagnostics (IVDs) for national regulatory authorities.**
  - Time: 13:00 – 17:00
  - CTICC room location: 2.44-2.46
- **Tuesday 06/12 - Seminar #30D: WHO workshop on post-market surveillance of IVDs (for end-users) and external quality assessment schemes.**
  - Time: 19:00-20:30
  - CTICC room location: 1.6
- **Wednesday 07/12 - Seminar #42: Assuring the quality of in vitro diagnostics (IVDs): WHO Prequalification of IVDs (PQDx) and Emergency Use Assessment and Listing (EUAL).**
  - Time: 19:00-20:30
  - CTICC room location: 1.6

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