



World Organisation
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PROFICIENCY TESTING – ENHANCING QUALITY ASSURANCE OF RABIES DIAGNOSTIC LABORATORIES

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KVAFSU - CVA RABIES DIAGNOSTIC LABORATORY



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ಕೆವಿವಿಫೈನಿಸ್ಕಿಯು - ಸಿವಿವಿ ರೇಜನ್ ರೋಗನಿರ್ಣಯ ಪ್ರಯೋಗಾಲಯ

ವಿಶ್ವ ಪ್ರಾಣಿ ಆರೋಗ್ಯ ಸಂಸ್ಥೆ ಅನುಮೋದಿತ

ಸೂಕ್ಷ್ಮಜೀವಾಣು ಶಾಸ್ತ್ರ ವಿಭಾಗ,

ಪಶುವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯ, ಕವಪಮೀವಿವಿ, ಹೆಬ್ಬಾಳ, ಬೆಂಗಳೂರು-560024

Mandates of WOAHA Reference Laboratory in India

- **Provide consultancy services**
 - **Test and disease consultancy**
 - **Disease surveillance on rabies & non-rabies lyssa viruses**
 - **Control strategies**
 - **Diagnostics**
- **Improving surveillance of rabies in animals**
 - **To ensure systematic surveillance - accurate reporting of rabies cases**
 - **Dog vaccination**

- **Building laboratory capabilities in the countries**

- **Training in all Quality assurance systems**

- Health & safety procedures

- Biosafety and biosecurity awareness & practices

- **Knowledge transfer and training**

- Sample collection, Submission & Processing

- Antigen detection methods

- Molecular diagnostic methods

- Antibody detection methods

- Proficiency testing**

- Inter laboratory comparisons

- Developing quality standards

Why Proficiency Testing (PT) ?

- Same sample tested in 2 labs – Lab A & Lab B
- The **results** of Lab A & Lab B **may or may not be consistent** with each other even if
 - tested by the same person in both the labs
 - tested by the different persons in both the labs

Therefore,

- To ensure that a **single analyst within a lab** is able to **consistently reproduce the same result** on the **same sample**
- The result produced by the analyst should **reflect the result** that would have come **from any other analyst in the lab**
- Any result from the lab as a whole should **reflect the results** that are agreed upon **by many other labs**

Quality & Uniformity in Diagnosis and diagnostics

Ensuring validity of results

- Inhouse quality control checks
- Intra laboratory comparisons
- Inter laboratory comparisons (ILC)
- Proficiency testing (PT)

ILC / PT

- One of the techniques by which **data/results** produced by a lab/method /procedure **is validated**
- A **means of quality control** for objectively assessing the quality control procedures of a lab
- A method to **check lab's testing performance**
 - Performance **within it's** own lab (Intra lab comparisons)
 - with other labs** (Inter lab comparisons)
- Provides **additional confidence** to the customers
- It is a **pre-accreditation** activity

Objectives of ILC/PT

- **Method validation** & determine the uncertainty of results – via determination of the standard deviations of repeatability (results when same condns are used) & reproducibility (results when diff condns are used)
- **Reference material characterization** - gains value to CRMs – to use for a specific test/method
- Assess the **reliability of the test results** of the laboratory
- Meet the **requirements of ISO/IEC 17025**

Accreditation - ISO/IEC 17025

Clause 5.4.5.2

Lab should validate

- Non standard methods
- Lab designed / developed methods
- Amplification and modification of standard methods
- Procedures for sampling, handling and transportation

By use of

- Calibration using **Reference standards** or Reference materials
- **Comparison** of results achieved **with other methods**
- **Inter laboratory Comparison or Proficiency testing**
- Systematic assessment of **factors influencing results**
- Assessment of the **uncertainty of results** based on scientific understanding of the theoretical principles and practical experience

Clause 5.9

Assuring the quality of test and calibration results

This monitoring shall be planned & may include but not limited to

(b) participation in inter laboratory comparison and proficiency testing programmes

Maintenance of accreditation status

To maintain the accreditation status, a lab has to have a minimum of

- **One participation** prior to gaining accreditation
- One participation relating to **each major scope (test)** of accreditation

How is ILC done ?

Testing the same /similar samples by diff laboratories in accordance with predetermined conditions and comparing the results

- Samples tested in a laboratory are given codes (include as many no. of samples as feasible)
- The reagents necessary for the test and SOP of the test is shared with the lab performing ILC
- The performing laboratory will test your samples as per the SOP shared and the results communicated back to the laboratory

How is PT different from ILC ?

- The purpose of PT is similar to ILC
- But does not involve
 - ✗ evaluation of performance of methods
 - ✗ assigning values to CRMs or assessing their suitability for use in a test
- **PT includes** the participation of a **reference laboratory** and uses their results to determine participant performance.
- ILC does not require use of a reference laboratory/coordinating body.

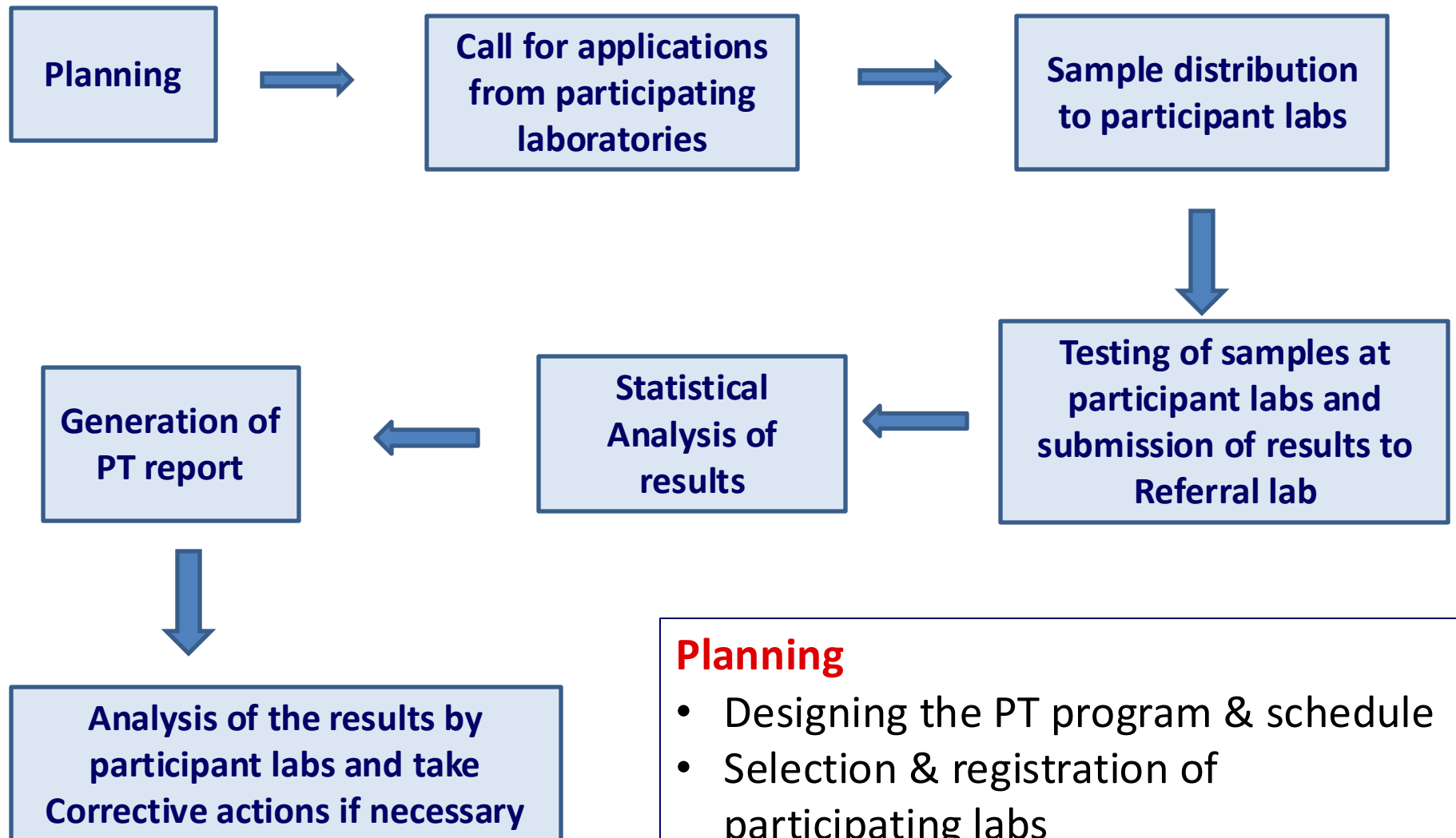
ISO/IEC 17043

- International standard to determine the competence of organizations that provide proficiency testing – **PT providers**
- Consists the technical & management requirements for PT Providers

PT Process

- Sending to a number of laboratories a series of samples as similar as possible
- Running a series of tests by all participating laboratories
- Determining a reference value to be found for the test results
- Evaluating the difference b/w the results of each laboratory and the reference value

Evaluation of participant performance against pre-established criteria



Planning

- Designing the PT program & schedule
- Selection & registration of participating labs
- Preparation of PT sample panel (homogenous & stable)

Advantages of participating in PT schemes

- Allow laboratories to **assess their conduct of specific tests** compared to similar laboratories.
- This opportunity to compare data can **minimize risk of errors, biases /differences** which may occur when operating in isolation.
- Independent appraisal of laboratory's data **compared to reference values** (or other performance criteria) or **to the performance of similar laboratories**.
- Results from such participation provide lab managers with either a **confirmation that laboratory's performance** is satisfactory **or** an **alert that investigation of potential problems** within the laboratory is required.

- Identification of problems in labs & initiation of actions for improvement
 - ✓ inadequate test/ procedure
 - ✓ effectiveness of staff training
 - ✓ calibration of equipment
- **Validation of uncertainty** claims

Thank You

