

# ISO 13528 – Criteria for Evaluation of PT Performance

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# **Evaluation of PT Participants**

> Third-party assessment of laboratory performance

∞ PT schemes have different objectives.

∞ Evaluation of PT Participants:

Provide an assessment of laboratory results against **pre-established criteria** that align with the objectives of the scheme.

### **Pre-Established Criteria for Evaluation**

Section 8 of ISO 13528 gives guidance on methods to determine a criteria for evaluation of performance.

The basic approach for all purposes is to compare laboratory results with an assigned value....and to give some allowable deviation from that value.

The allowable deviation is commonly defined as:

 $3 \times \sigma_{pt}$ 

where  $\sigma_{pt}$  = the standard deviation for proficiency assessment.

Repeatability and reproducibility known about the only allowed measurement method.

∞ Use of information from previous rounds of the PT scheme.

Regulatory or expert statement of acceptability

∞ Repeatability based on a general model.

∞ Data from the same round of the PT scheme.

# **Choosing a Method...**

...depends on the objectives of the scheme and what information is available.



**Externally Derived Criteria** 



Historical Data – Other Participants

Historical Data – Method Measurement Uncertainty



Emerging Contaminant – new PT scheme





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#### **Repeatability and Reproducibility of a Measurement Method**

#### What you have

- Historical data Method Measurement Uncertainty
- A standardized measurement method

#### What you get

- Performance scores that are not subject to variation from reported results
- Consistent interpretation of performance scores
- "Garbage in garbage out"

#### **Repeatability and Reproducibility of a Measurement Method**

When the measurement method used for PT is standardized and information on  $\sigma_R$  and  $\sigma_r$  is available,  $\sigma_{pt}$  may be calculated by:

$$\sigma_{pt} = \sqrt{\sigma_R^2 - \sigma_r^2 (1 - 1/m)}$$

- $\sigma_R$  = information on reproducibility
- $\sigma_r$  = information on repeatability
- *m* = # of replicate measures per round per participant

#### **Repeatability and Reproducibility of a Measurement Method**



Old Family Recipe – comes out consistently delicious every time





- Criteria will not vary round to round
- Empirically based results

### Data from Previous PT Rounds



- From previous rounds of PT with the <u>same measurand</u> and <u>comparable property values</u>,  $\sigma_{pt}$  can be determined.
- This is a useful approach when there is no agreement among experts about fitness for purpose.
- A lab with improved performance may fail.

#### **Data from Previous PT Rounds**



Traditional Recipe – good, but may not keep up with current tastes

# **Regulatory Defined Limit**

#### What you have

• Externally Derived Criteria

What you get

- Performance scores that are not subject to variation from reported results
- Consistent interpretation of performance scores
- Fitness for purpose defined externally

# **Regulatory Defined Limit**

A regulatory requirement may be set for the maximum allowable measurement error.

In this case, a percentage or raw number may be given as the Regulatory Defined Limit, and  $\sigma_{pt}$  can be determined from it (e.g., divide by 3).



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### **Regulatory Defined Limit**



Mother-in-Law's Recipe – don't dare to change anything



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### **Expert Perception**

 $\sigma_{pt}$  may be set by internal technical expert, a panel of external experts, a regulatory authority, or accreditation body.

This method is especially useful for emerging contaminants.

The evaluation criteria may change with each round as additional knowledge is gained.



#### **Expert Perception**



I hope the experts know what they're saying – it may be delicious, it may be awful

# General Model – e.g., Horwitz / Thompson

#### What you have

- Single allowed test method
- Known method reproducibility

#### What you get

- Performance scores that are not subject to variation from reported results
- Consistent interpretation of performance scores
- Empirically based evaluation
- Reproducibility may lead to wide acceptance criteria

# **General Model**

- Horwitz estimates reproducibility based on the concentration of the PT item.
- E.g., using Horwitz, lead in drinking water at 10 μg/L would have acceptance limits of +/- 2.2 μg/L.
- $\sigma_{pt}$  derived from acceptance limits, perhaps 2.2/2 = 1.1 µg/L.

- General models are based on observations from collaborative trials of many parameters over an extended time period.
- The model should be fit for purpose.



### **General Model**



# Cake that may, or may not, fit the occasion



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### **Data from Same PT Round**



# **Data from Same PT Round**

 $\sigma_{pt}$  is calculated from the results of participants in the same round of the proficiency testing scheme.





#### **Data from Same PT Round**



Variety – impacted by the results from each round



 $\swarrow$  There is a cake  $\sigma_{pt}$  for every occasion.

 $\gg$  Fitness for purpose is the guiding principle.

