

**TRAINING AS PER ISO/IEC
17043:2010 and ISO 13528:2015**



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**BACKGROUND AND
GENERAL ASPECTS OF
PROFICIENCY TESTING**

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**PURPOSE OF
ACCREDITATION OF LABS**

To provide **formal recognition** by an Accreditation Body about the competence and capability of the laboratory to produce **technically valid data and results** which will be accepted by the Trade and Industry all over the world without any hesitation.

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Technically valid data and results?

→ It means that if a product is re-tested in another accredited laboratory by the customer purchasing the product, the results obtained at these two laboratories should match.

→ In case of medical field also this should happen. (e.g) One medical laboratory's result on testing a tumor is benign, while the other has reported the same as malignant. This type of situations should not be encountered.

→ The test results of laboratory should be repeatable and reproducible.

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HOW TO ASCERTAIN COMPETENCE & CAPABILITY OF A LABORATORY?

– On-the-spot assessment of the laboratory by the experts –
ISO/IEC 17025:2017 or ISO 15189:2012

– By evaluating the performance of a laboratory for specific tests or measurements in **Proficiency Testing - ISO/IEC 17043:2010**

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What is Proficiency Testing?

Evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons

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What is the current status of Proficiency Testing?

- ❑ A few **approved PT schemes** are available
- ❑ The **cost of participation in international PT schemes** is high
- ❑ **Demand** for PT schemes is increasing due to accreditation of more laboratories

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DEFICIENCIES IN SELF ORGANIZED INTER LABORATORY COMPARISONS

- **Number of participants** in the ILC is less - 4 or 5 only because of cost considerations.
- **Homogeneity and Stability** of PT items distributed are not ensured.
- **Handling, storage and transport** of PT items is not satisfactory. **Integrity of the sample** is compromised in the process .

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DEFICIENCIES IN SELF ORGANIZED ILC (Continued)

- **Test methods** adopted by individual participants vary.
- **Possibility of collusion and falsification of test results** by the participants.
- Organizer of ILC is also a participant and the **normal tendency** is to **hide the poor performance**.
- ILC scheme is **not organized by a third party, independent agency**. There is always **possibility of bias**

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DEFICIENCIES IN SELF ORGANIZED ILC (Continued)

- Faulty method of performance evaluation of participants- **CLASSICAL Z SCORE**.
- $Z = (\text{Lab value} - \text{Avg. of all labs}) / \text{SD of all labs}$
 $|Z| \leq 2.0 \Rightarrow \text{SATISFACTORY}$
 $2.0 < |Z| < 3.0 \Rightarrow \text{QUESTIONABLE}$
 $|Z| > 3.0 \Rightarrow \text{UNSATISFACTORY}$

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DEFICIENCIES IN Z Score calculation

Lab	Value	Z Score	Lab	Value	Z Score	Lab	Value	Z Score
Lab 1	50	-0.4	Lab 1	50	-0.4	Lab 1	50	-0.3
Lab 2	49	-0.4	Lab 2	49	-0.4	Lab 2	49	-0.3
Lab 3	51	-0.4	Lab 3	51	-0.4	Lab 3	51	-0.3
Lab 4	5000	1.8	Lab 4	5000	2.3	Lab 4	5000	3.02
Lab 5	48	-0.4	Lab 5	48	-0.4	Lab 5	48	-0.3
Mean	1040		Lab 6	51	-0.4	Lab 6	51	-0.3
SD	2214		Lab 7	50	-0.4	Lab 7	50	-0.3
			Mean	757		Lab 8	49	-0.3
			SD	1871		Lab 9	50	-0.3
						Lab 10	51	-0.3
						Lab 11	50	-0.3
						Mean	500	
						SD	1492	

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DEFICIENCIES IN SELF ORGANIZED ILC (Continued)

- Robust statistical methods not followed for performance evaluation.
- Average of all laboratories are considered (**without excluding outliers**) as **ASSIGNED VALUE**. Danger of competent lab becoming outlier and incompetent lab getting a good score
- Test results of different methods (which are not equivalent) are combined to determine A.V & Evaluation criteria

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**DEFICIENCIES IN SELF ORGANIZED ILC
(Continued)**

- **ILC participation is done as a ritual to comply with the requirements of Section 7.7.2 of ISO/IEC 17025:2017**
- **AB assessors do accept such self organized ILC programs due to the absence of credible ILC programs for different products in various fields of testing and calibration.**

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Recent Senrio

- **ISO has promoted Guide 43 as standard ISO/IEC 17043 during 2010 after detailed deliberations with all the stake holders.**
- **Requirements stipulated in ISO/IEC 17043:2010 takes into account all the problems encountered in organization of ILC. It also includes almost all the requirements of ILAC Guide G13.**
- **ISO 13528 is now revised to include latest trends & also statistical methods for Qualitative PT Schemes.**
- **ISO/IEC 17043:2010 is now accepted by the industry, laboratories, accreditation bodies and customers all over the world.**
- **ABs have started accrediting PT providers as per ISO/IEC 17043:2010**

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