# Equipment Management And Calibration Based On ISO 15189:2022


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# کارگاه آموزشی سیستم مدیریت کیفیت در آزمایشگاه های تشخیص پزشکی بر مبنای ISO 15189:2022

سنندج

۳۱ مرداد و ۱ شهریور ۱۴۰۳

# challenges

- Sanctions
- High costs of equipment failure
- Short life of equipment
- Refurbished equipment

# CONCEPT

- Any **goods**, **devices**, **necessities**, **biological materials**, **devices**, **software**, **tools, appliances**, **machines, implants**, **materials**, **reagents** are **laboratory calibrators** for medical diagnosis that are for humans alone or in combination with other related items in order to access Each of the treatment goals is used

# 6.4 Equipment

**6.4.1** General

The laboratory shall have processes for the ¶

- Selection, Procurement, Installation,
- Acceptance testing (including acceptability criteria),
- Handling, Transport, Storage, Use,
- Maintenance, Decommissioning of equipment,

in order to ensure proper functioning and to prevent contamination or deterioration.

NOTE Laboratory equipment includes hardware and software of instruments, measuring systems, and laboratory information systems, or any equipment that influences the results of laboratory activities, including sample transportation systems ¶¶.

# 6.4.2 Equipment requirements

a) The laboratory shall have access to equipment required for the correct performance of laboratory activities.

b) Where the equipment is used outside the laboratory's permanent control, or equipment manufacturer's functional specification, laboratory management shall ensure that the requirements of this document are met.

c) Each item of equipment that can influence laboratory activities shall be uniquely labelled, marked or otherwise identified and a register maintained ¶.

d) The laboratory shall maintain and replace equipment as needed to ensure the quality of examination results.¶

# 6.4.3 Equipment acceptance procedure

The laboratory shall verify ¶ that the equipment conforms to specified acceptability criteria before being placed or returned into service.

Equipment used for measurement shall be capable of achieving either the *measurement accuracy or measurement uncertainty*, or both, required to provide a valid result.

- ✓ NOTE 1 This includes equipment used in the laboratory, *equipment on loan*, or *equipment used in point of care settings*, or in associated or *mobile facilities*, authorized by the laboratory.
- ✓ NOTE 2 The verification of equipment acceptance testing can be, where relevant, based on *the calibration certificate of the returned equipment*.

# 6.4.4 Equipment instructions for use

a) The laboratory **shall have appropriate safeguards** to prevent unintended adjustments of equipment that can invalidate examination results.

b) Equipment **shall be operated by trained, authorized, and competent personnel**.

c) Instructions for the use of equipment, including those provided by the manufacturer, **shall be readily available**.

d) The equipment shall be **used as specified by the manufacturer**, unless validated by the laboratory .

# 6.4.5 Equipment maintenance and repair

a) Lab shall *have preventive maintenance programmes*, based on manufacturer's instructions. Deviations from the manufacturer's schedules or instructions shall be recorded ¶¶.

b) Equipment shall be maintained in a *safe working condition* and working order.

This shall include

- Electrical safety
- Any emergency stop devices
- Safe handling
- Disposal of hazardous materials by authorized personnel

c) Equipment that is defective or outside specified requirements, **shall be taken out of service**. It shall be clearly labelled or marked as being out of service, until it has been **verified to perform correctly**.

The laboratory shall examine ***the effect of the defect or deviation ¶ from*** specified requirements and shall initiate actions when non-conforming work occurs.

d) When applicable, the laboratory **shall decontaminate equipment** before service, repair or decommissioning, provide suitable space for repairs and provide appropriate personal protective equipment.

# 6.4.6 Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment shall be *investigated and reported* to either the manufacturer or supplier, or both, and appropriate authorities, as required

The laboratory shall have procedures for responding to any *manufacturer's recall or other notice*, and taking *actions recommended* by the manufacturer. ¶¶¶

# 6.4.7 Equipment records

- Records shall be maintained for each item of equipment that influences the results of laboratory activities. These records shall include the following, where relevant:

a) manufacturer and supplier details, and sufficient information to uniquely identify each item of equipment, including software and firmware ¶¶;

b) dates of receipt, acceptance testing and entering into service;

c) evidence that equipment conforms with specified acceptability criteria;

d) the current location;

e) *condition when received* (e.g. new, used or reconditioned);

f) **manufacturer's instructions**;

g) **the programme for preventive maintenance**;

h) any **maintenance activities** performed by the laboratory or approved external service provider;

i) damage to, **malfunction, modification**, or repair of the equipment;

j) equipment performance records such as reports or **certificates of calibrations** or verifications, or both, including dates, times and results;

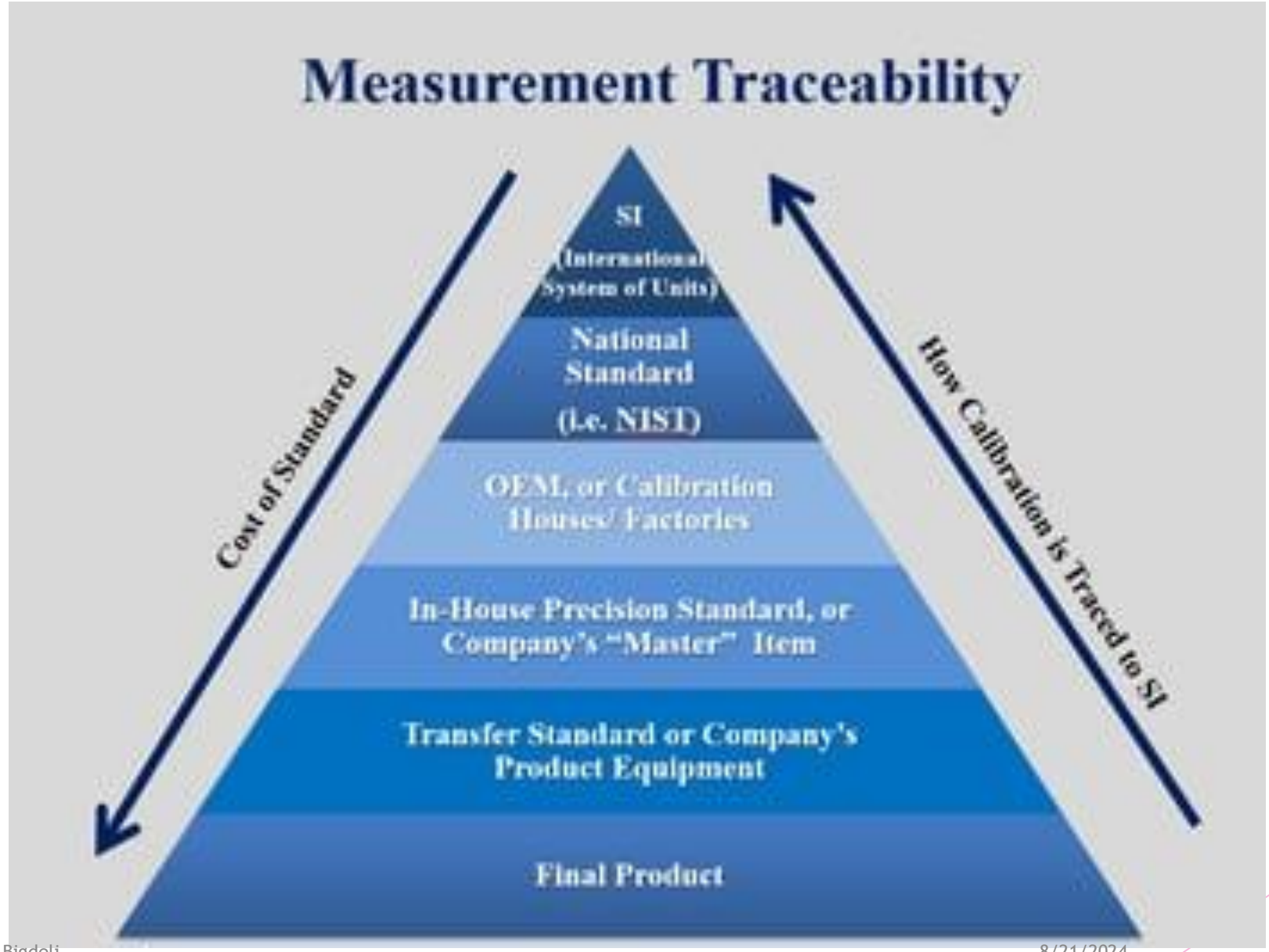
k) **status of the equipment ¶¶**such as active or in-service, out-of-service, quarantined, retired or obsolete.

# 6.5 Equipment calibration and metrological traceability

- **6.5.1 General**

- Lab shall ***specify*** calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results.
- For ***quantitative*** traceability requirements.
- ***methods*** of a measured analyte, specifications shall include calibration and metrological For ***qualitative methods and quantitative methods that measure characteristics rather than discrete analytes*** shall specify the characteristic being assessed and such requirements necessary for ***reproducibility*** over time.

- NOTE Examples of qualitative methods and quantitative methods that may not allow metrological traceability include ***red cell antibody detection***, ***antibiotic sensitivity assessment***, ***genetic testing***, ***erythrocyte sedimentation rate***, ***flow cytometry marker staining***, and tumour HER2 ***immunohistochemical staining***


Measurement Traceability
SI
(International System of Units)
National Standard
(i.e. NIST)
OEM, or Calibration Houses/ Factories
In-House Precision Standard, or Company's "Master" Item
Transfer Standard or Company's Product Equipment
Final Product
Cost of Standard
How Calibration is Traced to SI

# 6.5.2 Equipment calibration

- The laboratory *shall have procedures for the calibration of equipment* that directly or indirectly affects examination results. The procedures shall specify:

  a) Conditions of use *and manufacturer's instructions* for calibration;

  b) *Recording of the metrological traceability*;

  c) *Verification of the required measurement accuracy* and the functioning of the measuring system at specified intervals;

  d) Recording the *calibration status and date of re-calibration;*

  e) Ensuring that, where *correction factors* are used, these are updated and recorded when recalibration occurs .

  f) *Handling of situations when calibration was out of control*, to minimize risk to service operation and to patients .

# 6.5.3 Metrological traceability of measurement results

a) The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented *unbroken chain of calibrations* , each contributing to the measurement uncertainty, linking them to an appropriate reference.

- NOTE

Information of traceability to a higher order reference material or reference procedure can be provided by an examination system manufacturer. Such documentation is acceptable only when the manufacturer's examination system and calibration procedures are used *without modification*.

b) The laboratory shall ensure that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through:

— ***calibration provided by a competent laboratory***; or

- NOTE 1 Calibration laboratories fulfilling the requirements of ISO/IEC 17025 are considered competent for performing calibrations.

— ***certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI***;

- NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.
- NOTE 3 Certified reference material fulfilling the requirements of ISO 15194 are considered suitable.

c) Where it is ***not possible to provide traceability according*** to 6.5.3 a), other means for providing confidence in the results shall be applied, including but not limited to the following:

— ***results of reference measurement procedures***, specified methods or consensus standards, that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison;

— ***measurement of calibrator by another procedure***.

- NOTE ISO 17511 provides further information on how to manage the compromises in the metrological traceability of measurands.

d) For genetic examinations, traceability to ***genetic reference sequences ¶*** shall be established.

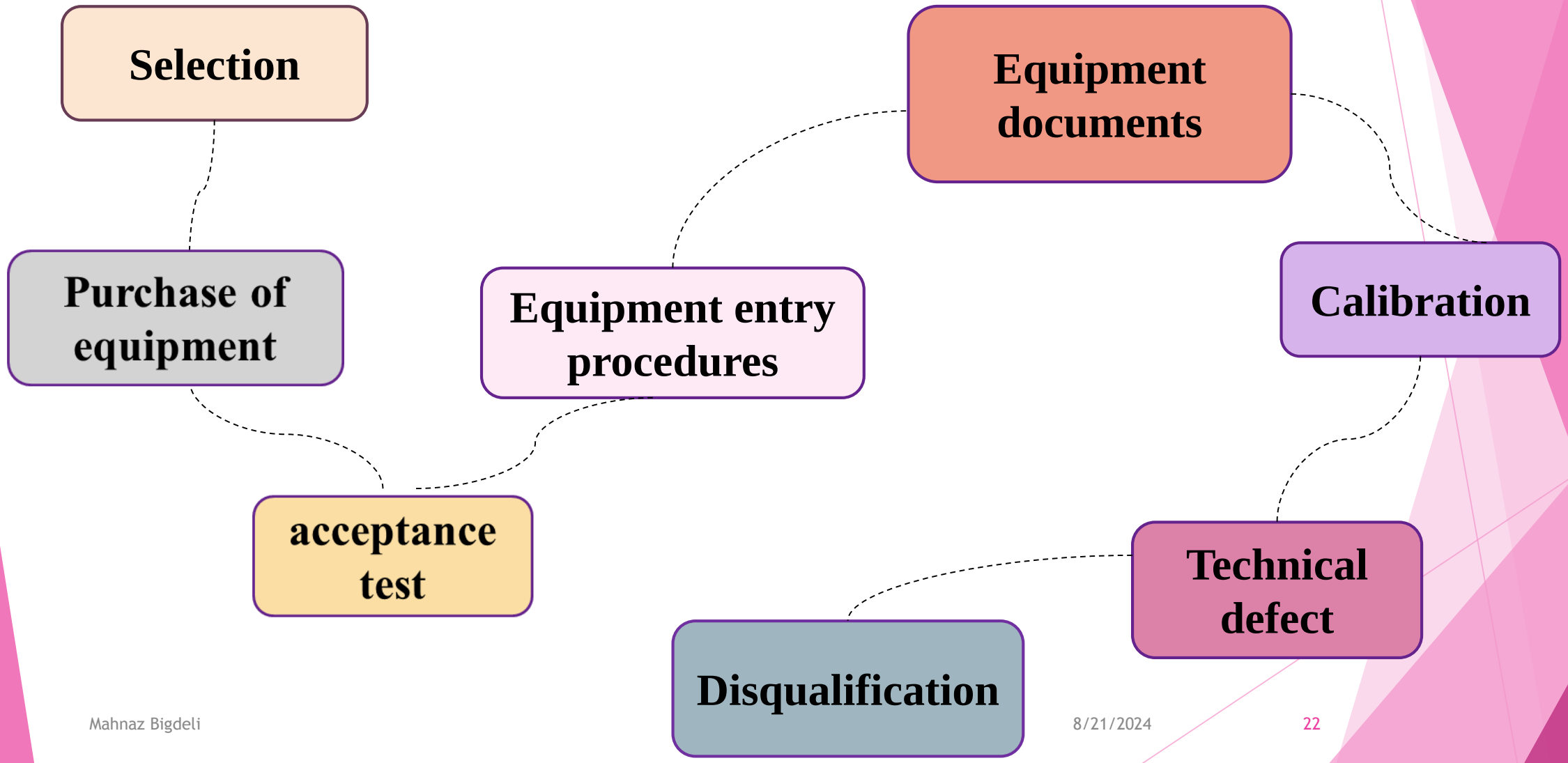
e) For qualitative methods, traceability may be demonstrated by ***testing of known material or previous samples ¶*** sufficient to show consistent identification and, when applicable, intensity of reaction.

# Metrology is the science of measurement. The basics of measurement involve:

- A measurable property, known as a quantity (e.g. concentration)
- Definition of the measurand – the quantity that is intended to be measured.
- The description of the measurand should include the matrix (e.g. plasma); the component (analyte) of interest, and the amount of substance concentration
- The units in which the measurement will be made. Metrological traceability requires the international system of units (SI) or units with well-established conversions
- The uncertainty with which the measurement can be made

- Metrological traceability is the property of a measurement result, which can be related to a reference through a documented unbroken chain of calibrations.
- The components of a reference measurement system comprise reference materials (calibrators) and measurement procedures (methods), both of which exist at different hierarchical levels.

# Road Map Equipment



"The result of long-term relationships is better and better quality, and lower and lower costs."

W. Edwards Deming