Revision ISO 15189

Chapter 6

Chapter 6 – Resource requirements

6.2 Personnel

6.3 Facilities and environmental conditions

6.4 Equipment

6.6 Reagents / consumables

6.7 Service agreements

6.8 Externally provided products /services

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Chapter 6 – what is new?

6.2 Personnel: no new requirements. Requirements are less prescriptive and less detailed.

6.3 Facilities and environmental conditions: no changes

6.4 Equipment: minor changes e.g. reaction on manufacturer's recall or other notice

6.5 Equipment calibration and metrological traceability: more detailed but no new requirements

6.6 Reagents and consumables: minor changes e.g. reaction on manufacturer's recall or other notice

6.7 Service agreements: Agreements with POCT operators included

6.8 Externally provided products and services: Some general requirements

6.4 Equipment

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 (see 7.3.3 and 7.3.4 for details).

6.4 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.

d) The equipment shall be used as specified by the manufacturer, unless validated by the laboratory (see 7.3.3).

6.4 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.

6.5 Equipment calibration and metrological traceability

Metrological traceability

Details:

Clear distinction between **equipment calibration** and **traceability of results**

Differentiation of requirements for

- Quantitative methods
- Qualitative methods
- Genetic examinations

6.5 Equipment calibration and metrological traceability

6.5.1 General

- The laboratory shall specify calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results.
- For **quantitative methods** of a measured analyte, specifications shall include calibration and metrological traceability requirements.
- **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.

6.5 Equipment calibration and metrological traceability

6.5.1 General

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.

6.5 Equipment calibration and metrological traceability

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:

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

6.5 Equipment calibration and metrological traceability

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.

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

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

6.5 Equipment calibration and metrological traceability

6.5.3 Metrological traceability of measurement results

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.

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.

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6.6 Reagents and consumables

6.6.1 General

The laboratory shall have processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables.

6.6 Reagents and consumables

6.6.5 Reagents and consumables — Instructions for use

Instructions for the use of reagents and consumables, including those provided by manufacturers, shall be readily available. Reagents and consumables shall be used according to the manufacturer's specifications. If they are intended to be used for **other purposes see 7.3.3.**

6.6 Reagents and consumables

6.6.6 Reagents and consumables — Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables 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.

6.7 Service agreements

6.7.2 Agreements with POCT operators

Service agreements between the laboratory and other parts of the organization using laboratory supported POCT, shall ensure that respective responsibilities and authorities are specified and communicated.

NOTE Established multidisciplinary POCT committees can be used to manage such service agreements as described in Annex A.

Annex A (normative)
Additional requirements for Point-of-Care Testing (POCT)

- Some requirements from former ISO 22870 are implemented in this annex.
- But no new requirements compared with ISO 22870
- Laboratories acting as POCT-Provider have to fulfill all relevant requirements of ISO 15189 incl. requirements specified for POCT e.g. 6.7.2; 7.3.1; 7.3.7.3; 7.4.1.7; 8.9.2; annex A

6.8 Externally provided products and services

6.8.1 General

The laboratory shall ensure that externally provided products and services that affect laboratory activities are suitable when such products and services are:

a) intended for incorporation into the laboratory's own activities;

b) provided, in part or in full, directly to the user by the laboratory, as received from the external provider;

c) used to support the operation of the laboratory.

It can be necessary to collaborate with other organizational departments or functions to fulfil this requirement.

NOTE Services include, e.g. sample collection services, pipette and other calibration services, facility and equipment maintenance services, EQA programmes, referral laboratories and consultants.

6.8 Externally provided products and services

6.8.3 Review and approval of externally provided products and services

The laboratory shall have procedures and retain records for:

a) defining, reviewing, and approving the laboratory's requirements for all externally provided products and services;

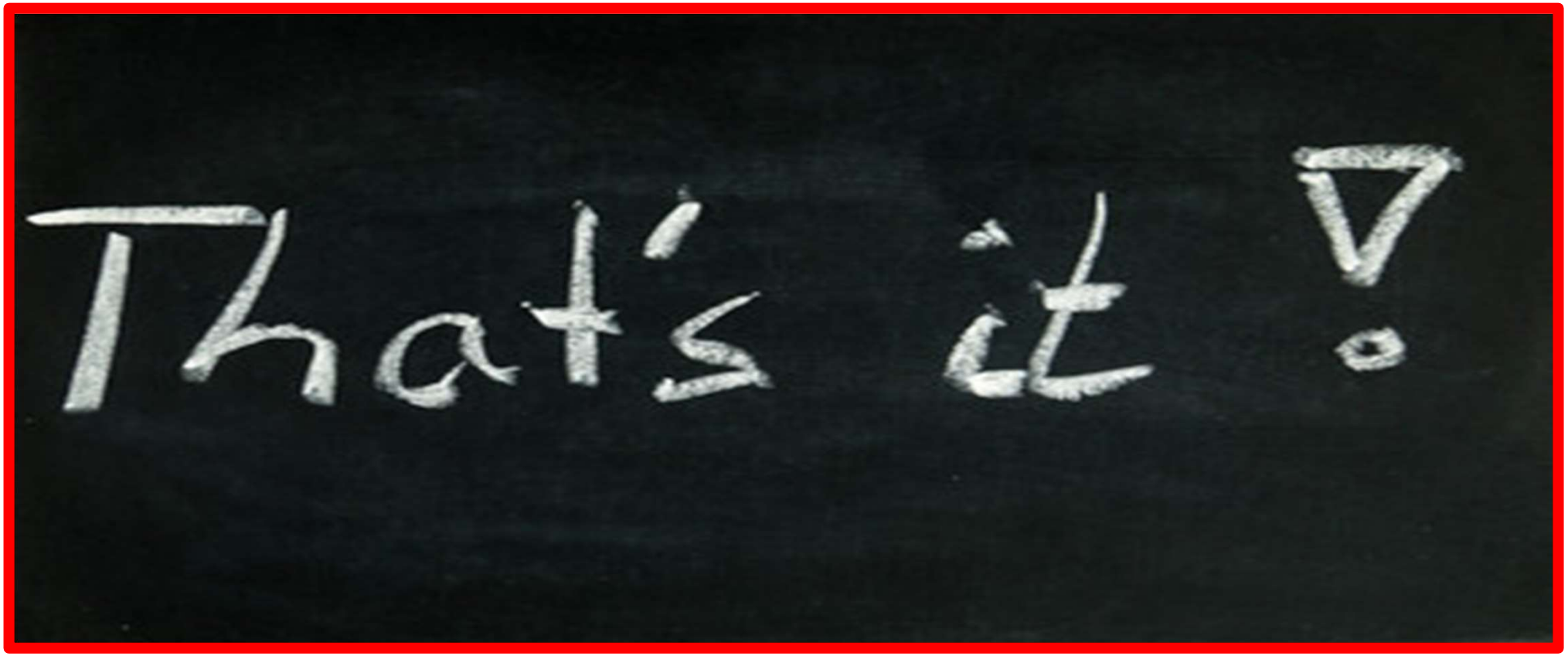
b) defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers;

c) referral of samples;

d) ensuring that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of this document, before they are used or directly provided to the user;

e) taking any actions arising from evaluations of the performance of external providers.

Thank you for your attention



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