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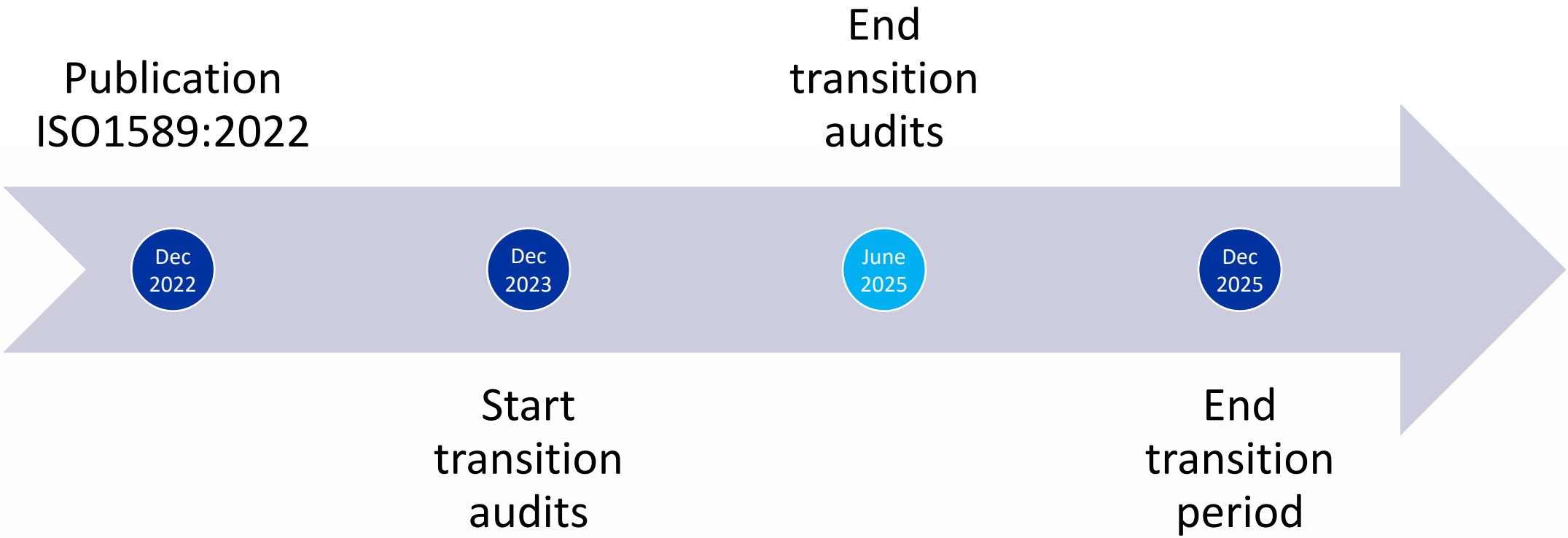
Brussel
WORKSHOP
Johan Guns
Transition to ISO 15189:2022
Medical Laboratories Requirements for quality and competence

TIMELINE


Publication ISO1589:2022
End transition audits
Dec 2022
Dec 2023
June 2025
Dec 2025
Start transition audits
End transition period

GENERAL CONSIDERATIONS

ISO 15189:2022

Management system – 15 pages

Technical requirements – 23 pages

ISO 15189:2022

General requirements – 4 pages

Technical requirements – 23 pages

Management system – 6 pages

In line with ISO 17025:2017

ISO 22870 POCT is incorporated

Focus on: patient, processes and risks

CASE 1

The auditor has noted that GP request forms frequently lack essential information, such as collection hours. This issue is not reported in the error code to avoid causing offence to the GP.

Which type of deviation will you report?

- A
- B
- No deviation

4.1 IMPARTIALITY

Impartiality

- Commitment to impartiality
- Safeguard impartiality

Pressure

- Monitor the activities of the laboratory
- Monitor the relationships of the organization and personnel

Threats

- Identify threats
- Elimination or mitigation of threats

CASE 2

The auditor noted that the laboratory often sends legally required non-coded patient results and personal data to Sciensano. The patient has not given consent for this.

Which type of deviation will you report?

- A
- B
- No deviation

CONFIDENTIALITY

Personal data patients:

- Data on a public domain
  - Inform the patient in advance
- Data used in the management of non-conformities or complaints
  - Agreement with the patient
- Sharing data, for example with the government
  - Inform the patient in advance

CASE 3

The auditor finds that the patient cannot inform the lab regarding potentially helpfull information to interpret lab results.

Which type of deviation will you report?

- A
- B
- No deviation

REQUIREMENTS REGARDING PATIENTS

Following processes should be implemented:

- Provide opportunity for patients to provide useful information;
- Provide information regarding costs, if applicable;
- Periodic review of tests offered by the laboratory to ensure they are clinically appropriate and necessary;
- Ensuring availability and integrity of patient samples upon closure (discontinuation procedure);
- Making relevant information available upon patient request;
- Enforce patient rights (exclude discrimination).

CASE 4

The auditor notes that the laboratory does not have an instruction for use for the new automate. The lab defends that the daily operations are described in the analytical SOP and that the manufacturer's operating manual is included in their quality system.

Which type of deviation will you report?

- A
- B
- No deviation

EQUIPMENT

- Consideration may be given to not having a device procedure for every device;
- The laboratory should investigate what resulted from a failure and take actions if necessary if non-compliant activities took place;
- Calibration and metrological traceability:
  - Both equipment impacting directly and indirectly on a measurement result;
  - Records of measurement uncertainty calibrations.

REAGENTS

Any change to research kit or any new lot or supply should undergo an entry control before putting into use or reporting research results;

The laboratory must establish a stock management system with a distinction between quarantined and released reagents and consumables;

Inserts (instruction for use) must be readily available;

Adverse incidents due to reagents and consumables should be investigated and reported to the manufacturer or supplier and, if applicable, to the competent authority (MDR/IVDR);

When reagents are prepared, resuspended or mixed (in-house), the preparation date, an expiry date and the name of the technician must be recorded

CASE 5

The auditor notes that the laboratory has a procedure for performing POCT but no SLA with the hospital departments involved.

Which type of deviation will you report?

- A
- B
- No deviation

POCT

Agreements with POCT users:

- SLAs should be concluded with other services (sites) within the organisation that use POCT;
- POCT users should be identified;
- Annex A - specific requirements POCT.

CASE 6

The auditor notes that the laboratory lacks a number of job descriptions.

Which type of deviation will you report?

- A
- B
- No deviation

PERSONNEL

The need for job description as such is no longer required in the standard but it does say that you shall specify competence requirements for each function influencing the results of the laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience.

CASE 7

The laboratory determines the TAT from sample receipt to result reporting. The pre-analytical impact is not measured because the collection time is often not known.

Which type of deviation will you report?

- A
- B
- No deviation

PRE-ANALYTICAL REQUIREMENTS

- Informed consent for each patient. This does not usually have to be in writing. For more risky collections, a written IC should be present;
- Records of the collection date and time and the person performing the collection;
- The laboratory should periodically evaluate the suitability of sample transport;
- If sample stability is important, the time between collection and analysis should be specified and monitored.

CASE 8

The auditor notes that no measurement uncertainty was determined for half of the accredited quantitative and semi-quantitative tests.

Which type of deviation will you report?

- A
- B
- No deviation

MEASUREMENT UNCERTAINTY

a) The MU of measured quantity values shall be evaluated and maintained for its intended use, where relevant. The MU shall be compared against performance specifications and documented. NOTE ISO/TS 20914 provides details on these activities together with examples.
b) MU evaluations shall be regularly reviewed.
c) For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU estimation shall be documented.
d) MU information shall be made available to laboratory users on request.
e) When users have inquiries on MU, the laboratory's response shall take into account other sources of uncertainty, such as, but not limited to biological variation.
f) If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative, based on a threshold, MU in the output quantity shall be estimated using representative positive and negative samples.
g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process.
h) MU should be taken into consideration when performing verification or validation of a method, when relevant.

CASE 9

The auditor noted that the laboratory uses three Cobas 8000 devices to run different parameters on more than 1 device. The second and third devices were partially validated. Once in use, Internal Quality Control (IQC) was performed on each device. External Quality Control (EQC) was always performed on the first device.

Which type of deviation will you report?

- A
- B
- No deviation

ANALYTICAL PHASE

- The laboratory selects and uses research methods that have been validated for their intended use to ensure clinical accuracy;
- If validated methods are modified, the clinical impact should be evaluated;
- If qualitative results (pos./neg.) are based on quantitative output data, measurement uncertainty must be determined and followed up;
- IQC concentration levels should be near clinical decision limits and cover the measurement range of the study method where possible;
- If EQA results fall outside the acceptance criteria, it should be investigated whether or not this is clinically significant for patient samples;
- Comparability of test results should be ensured between different test methods, equipment and sites. Comparability should be evaluated periodically. Users should be informed of clinically significant differences.

IQC

The laboratory shall have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making.

1) The intended clinical application of the examination should be considered, as the performance specifications for the same measurand can differ in different clinical settings.

2) The procedure should also allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure should avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both.

3) The use of third-party IQC material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer

IQC

The laboratory shall select IQC material that is fit for its intended purpose. When selecting IQC material, factors to be considered shall include:

1) stability with regard to the properties of interest;

2) the matrix is as close as possible to that of patient samples;

3) the IQC material reacts to the examination method in a manner as close as possible to patient samples;

4) the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.

CASE 10

The auditor observes that the laboratory relays critical results but does not document this process.

Which type of deviation will you report?

- A
- B
- No deviation

POST – ANALYTICAL PHASE

When examination results fall within established critical decision limits:

a) the user or other authorized person is notified as soon as relevant, based on clinical information available;

b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification;

c) the laboratory shall have an escalation procedure for laboratory personnel when a responsible person cannot be contacted.

CASE 11

The laboratory has developed an emergency plan based on a risk analysis. The emergency plan is not included in the training plan. The emergency plan was also not tested.

Which type of deviation will you report?

- A
- B
- No deviation

CONTINUITY PLAN

The laboratory shall ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption.

Plans shall be periodically tested and the planned response capability exercised, where practicable.

The laboratory shall: a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel; b) provide information and training as appropriate to relevant laboratory personnel; c) respond to actual emergency situations; d) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact

CASE 12

The laboratory conducted 6 risk analyses using FMEA in the past year. The auditor considers this insufficient.

Which type of deviation will you report?

- A
- B
- No deviation

RISK MANAGEMENT

The laboratory shall identify risks and opportunities for improvement associated with the laboratory activities to:

a) prevent or reduce undesired impacts and potential failures in the laboratory activities;

b) achieve improvement, by acting on opportunities;

c) assure that the management system achieves its intended results;

d) mitigate risks to patient care;

e) help achieve the purpose and objectives of the laboratory

CASE 13

The auditor notes that the lab conducted 11 internal audits last year. These were audits on new or modified tests.

Which type of deviation will you report?

- A
- B
- No deviation

RISK BASED AUDITING

The laboratory shall plan, establish, implement and maintain an internal audit programme that includes:

a) priority given to risk to patients from laboratory activities;

b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities;

c) specified audit objectives, criteria and scope for each audit;

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VRIJE UNIVERSITEIT BRUSSEL

Universitair Ziekenhuis Brussel