Medical laboratories — Requirements for quality and competence (ISO 15189 : 2012)

5.6 Ensuring quality of examination results

5.6.1 General

The laboratory shall ensure the quality of examinations by performing them under defined conditions. Appropriate pre and post-examination processes shall be implemented (see 4.14.7, 5.4, 5.7 and 5.8). The laboratory shall not fabricate any results.

5.6.2 Quality control

5.6.2.1 General

The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.

NOTE In several countries, quality control, as referred to in this subclause, is also named "internal quality control."

5.6.2.2 Quality control materials

The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples.

Quality control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

NOTE 1 The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made.

NOTE 2 Use of independent third party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

5.6.2.3 Quality control data

The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.

When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. The laboratory shall also evaluate the results from patient samples that were examined after the last successful quality control event.

Quality control data shall be reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions shall be taken and recorded.

NOTE Statistical and non-statistical techniques for process control should be used wherever possible to continuously monitor examination system performance.

5.6.3 Interlaboratory comparisons

5.6.3.1 Participation

The laboratory shall participate in an interlaboratory comparison programme(s) (such as an external quality assessment programme or proficiency testing programme) appropriate to the examination and interpretations of examination results. The laboratory shall monitor the results of the interlaboratory comparison programme(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled.

NOTE The laboratory should participate in interlaboratory comparison programmes that substantially fulfil the relevant requirements of ISO/IEC 17043.

The laboratory shall establish a documented procedure for interlaboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the interlaboratory comparison programme.

Interlaboratory comparison programme(s) chosen by the laboratory shall, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible.

5.6.3.2 Alternative approaches

Whenever an interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.
Whenever possible, this mechanism shall utilize appropriate materials.

NOTE Examples of such materials may include:
— certified reference materials;
— samples previously examined;
— material from cell or tissue repositories;
— exchange of samples with other laboratories;
— control materials that are tested daily in interlaboratory comparison programmes.

5.6.3.3 Analysis of interlaboratory comparison samples

The laboratory shall integrate interlaboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples.

Interlaboratory comparison samples shall be examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples.

The laboratory shall not communicate with other participants in the interlaboratory comparison programme about sample data until after the date for submission of the data.

The laboratory shall not refer interlaboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

5.6.3.4 Evaluation of laboratory performance

The performance in interlaboratory comparisons shall be reviewed and discussed with relevant staff.
When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff shall participate in the implementation and recording of corrective action. The effectiveness of corrective action shall be monitored. The returned results shall be evaluated for trends that indicate potential nonconformities and preventive action shall be taken.

5.6.4 Comparability of examination results

There shall be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals. This is applicable to the same or different procedures, equipment, different sites, or all of these.

NOTE In the particular case of measurement results that are metrologically traceable to the same reference, the results are described as having metrological comparability providing that calibrators are commutable.

The laboratory shall notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed.

The laboratory shall document, record and, as appropriate, expeditiously act upon results from the comparisons performed. Problems or deficiencies identified shall be acted upon and records of actions retained.

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5.8 Reporting of results

5.8.1 General

The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.

The laboratory shall define the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory

The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results.
Reports shall include the information necessary for the interpretation of the examination results.

The laboratory shall have a process for notifying the requester when an examination is delayed that could compromise patient care.

5.8.2 Report attributes

The laboratory shall ensure that the following report attributes effectively communicate laboratory results and meet the users' needs:

a) comments on sample quality that might compromise examination results;

b) comments regarding sample suitability with respect to acceptance/rejection criteria;

c) critical results, where applicable;

d) interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.1) in the final report.

5.8.3 Report content

The report shall include, but not be limited to, the following:

a) a clear, unambiguous identification of the examination including, where appropriate, the xamination procedure;

b) the identification of the laboratory that issued the report;

c) identification of all examinations that have been performed by a referral laboratory;

d) patient identification and patient location on each page;

e) name or other unique identifier of the requester and the requester's contact details;

f) date of primary sample collection (and time, when available and relevant to patient care);

g) type of primary sample;

h) measurement procedure, where appropriate;

i) examination results reported in SI units, units traceable to SI units, or other applicable units;
j) biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable;

NOTE Under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.

k) interpretation of results, where appropriate;

NOTE Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.

l) other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);

m) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;

n) identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed);

o) date of the report, and time of release (if not contained in the report, readily available when needed);

p) page number to total number of pages (e.g. "Page 1 of 5", "Page 2 of 5", etc.).

5.9 Release of results

5.9.1 General

The laboratory shall establish documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall ensure that the following conditions are met.

a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report.

b) When examination results fall within established "alert" or "critical" intervals:
   - a physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see 4.5)];
   - records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.

c) Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information.

d) When results are transmitted as an interim report, the final report is always forwarded to the requester.

e) There are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients. Results provided orally shall be followed by a written report. There shall be a record of all oral results provided.

NOTE 1 For the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.
NOTE 2 Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

See also 4.9.

5.9.2 Automated selection and reporting of results

If the laboratory implements a system for automated selection and reporting of results, it shall establish a documented procedure to ensure that:

a) the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff;

NOTE Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values.

b) the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning;

c) there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination;

d) there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate;

e) results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection;

f) there is a process for rapid suspension of automated selection and reporting.

5.9.3 Revised reports

When an original report is revised there shall be written instructions regarding the revision so that:

a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;

b) the user is made aware of the revision;

c) the revised record shows the time and date of the change and the name of the person responsible for the change;

d) the original report entries remain in the record when revisions are made.

Results that have been made available for clinical decision making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised. When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.