<table>
<thead>
<tr>
<th>Clause</th>
<th>Summary of ISO 15189 additional requirements</th>
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| 4.1.3.d | Ethical conduct  
Procedures to deal with disposal of human samples, remains etc. according to legal requirements |
| 4.1.4  | Laboratory Director  
Change in specific responsibilities of Laboratory Director (or designate) i.e. implementation of the Quality policy; selection of laboratory suppliers and monitoring of same; setting of performance standards including quality improvements, their implementation and monitoring (could be progressed via various parent company committees) |
| 4.1.2.1h | Management commitment  
Management commitment to continuous improvement and effective implementation of the management system needs to be demonstrable through (amongst other things) ensuring that all personnel are competent to perform their assigned duties |
| 4.1.4.4 | Quality objectives and planning  
Management will need to ensure there is appropriate change management to enable the integrity of the system to be maintained during periods of change |
| 4.2.1 | Quality management system: General requirements  
Management system processes will need to be determined and their application demonstrable. The sequence and interface/interaction of the various processes will also need to be determined. Criteria and methods will be required in order to establish that these processes are effectively operated and controlled. The information and resources required in order to support these processes plus the control measures put into place will need to be ensured and available. There will need to be evidence and records available to demonstrate that the monitoring and evaluation of these processes is taking place in order to improve the service and the processes involved |
| 4.3 | Document control  
Reference is made throughout ISO 15189 to required procedures and records. Management will need to ensure that these have been documented as well as other procedures and records required by the laboratory for the on-going implementation of the service. External documents i.e. external to the labs management system such as normative standards, regulations will need to be captured within the Quality management system. |
| 4.6 | External services and supplies  
A procedure to be available for the selection and purchasing of external services such as equipment, reagents, calibration and critical consumables which affect the quality of the results/service. There will need to be criteria established for the selection of services and supplies which should capture the ability to supply the nominated services or supplies in accordance with the laboratory’s requirements. A list of selected and approved suppliers/services shall be maintained. Purchasing information shall describe the requirements for the product or service to be purchased. The performance of suppliers shall be monitored to ensure that the items provided consistently meet the stated criteria |
| 4.9 | Identification and control of non-conformities  
If the potential for reoccurrence of a non-conformity is identified or there is doubt concerning compliance with the management system then the laboratory shall take action to identify the root cause - corrective action shall be determined and documented. |
| 4.11 | Corrective action  
A system by which recorded non-conformities are reviewed needs to be established |
| 4.11 | Preventive Action  
A system for identifying potential non-conformities needs to be defined and implemented with records of the investigation into the root cause. Records will need to be available and the actions taken reviewed for effectiveness |
| 4.13 | Records  
Records for the following will need to be maintained (list not exhaustive)  
a) supplier selection and performance, and changes to approved supplier list;  
b) staff qualifications, training and competency records;  
c) request for examination;  
d) records of receipt of samples in the laboratory;  
e) information on reagents and materials used for examinations (e.g., lot documentation, certificates of supplies, package inserts); |
f) laboratory work books or work sheets;
g) instrument printouts and retained data and information;
h) examination results and reports;
i) instrument maintenance records, including internal and external calibration records;
j) calibration functions and conversion factors;
k) quality control records;
l) incident records and action taken;
m) accident records and action taken;
n) risk management records;
o) nonconformities identified and immediate or corrective action taken;
p) preventive action taken;
q) complaints and action taken;
r) records of internal and external audits;
s) interlaboratory comparisons of examination results;
t) records of quality improvement activities;
u) minutes of meetings that record decisions made about the laboratory's quality management activities; and records of management reviews

4.14.4 Staff suggestions
A system to encourage staff to make suggestions for improvement to the service will need to be available with the retention of appropriate records and evaluation.

4.14.6 Risk management
The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.

4.14.7 Quality Indicators
The mechanism through which these have been established and communicated to users will need to be available.

4.14.8 Reviews by external organisations
Records of external reviews and actions taken e.g. health and safety inspections and any actions required will need to be available to the assessment team.

Management review

Review input
The management review shall take consideration of:

4.15.2
a) the periodic review of requests, and suitability of procedures and sample requirements

b) staff suggestions (see 4.15.4);

c) risk management (see 4.14.6);

d) performance of suppliers (see 4.6); and (o) recommendations for improvement, including technical requirements
The traceability of calibrations performed on critical equipment the function of which impacts on the quality of test result to be traceable to a higher order. Metrological traceability for physical measurements e.g. thermometers can be demonstrated with the use of an ISO 17025 accredited calibration laboratory or by performing the calibration internally in which case the procedure and application will be included in the assessment to ISO 15189 (please refer to UKAS publication TPS 52: http://www.ukas.com/library/Technical-Information/Pubs-Technical-Articles/Pubs-List/TPS%2052.pdf for more information re internal calibration and assessments). For more general information, please refer to:


Where the laboratory examination procedures require the calibration of analysers (or similar), there should be information relating to the traceability of the material used in the calibration. Please see note below for more information.

Where internal and external calibrations are performed, the following will need to be considered:

The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results and that includes:

a) taking into account conditions of use and the manufacturer's instructions;
b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;
c) verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;
d) recording the calibration status and date of recalibration;
e) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated; and
f) safeguards to prevent adjustments or tampering that might invalidate examination results.

Metrological traceability shall be to the higher metrological order available.

NOTE Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer’s examination system and calibration procedures are used without modification. Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

a) use of certified reference materials;
b) examination or calibration by another procedure; and
c) mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

5.3.1.4

Equipment acceptance testing

The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned (see also 5.5.1)

NOTE This requirement applies to: equipment used in the laboratory, equipment on loan, or equipment used in associated or mobile facilities by others authorised by the laboratory.

Each item of equipment shall be uniquely labelled, marked or otherwise identified.

5.3.1.2

Equipment records

5.3.1.7

Records shall be maintained for each item of equipment that contributes to the performance of examinations. These equipment records shall include, but not be limited to, the following:

c) contact information for the supplier or the manufacturer;
d) date of receiving and date of entering into service;
f) condition when received (e.g. new, used, or reconditioned);
g) manufacturer's instructions;
h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;
j) equipment performance records that confirm the equipment's on-going acceptability for use.

The performance records referred to in j) shall include copies of reports/certificates of all calibrations and/or verifications including dates, times and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, to fulfil part or all of this requirement.

These records shall be maintained and shall be readily available for the lifespan of the equipment or longer, as specified in the laboratory’s Control of Records procedure (see 4.13).
Reagents and consumables - Acceptance testing

New lots/batches of reagents shall be verified as performing satisfactorily before being used in conjunction with patient samples. If the formulation changes then the performance should again be verified.

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 the manufacturer and appropriate authorities, as required.

Reagents and consumables - records

Records shall be maintained for each reagent and consumable that contributes to the performance of examinations. These records shall include but not be limited to the following:

a) identity of the reagent or consumable;
b) manufacturer's name and batch code or lot number;
c) contact information for the supplier or the manufacturer;
d) date of receiving, the expiry date, date of entering into service, and where applicable, the date the material was taken out of service;
e) condition when received (e.g., acceptable or damaged);
f) manufacturer's instructions;
g) records that confirmed the reagent's or consumable's initial acceptance for use; and
h) performance records that confirm the reagent's or consumables' on-going acceptance for use.

Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the person or persons undertaking their preparation and the date of preparation.

Pre-examination processes

General

The laboratory shall have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.

Information for patients and users

The laboratory shall have information available for patients and users of the laboratory services. The information shall include as appropriate:

- (g) instructions for patient collected samples

Pre-examination handling, preparation and storage

The laboratory shall have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities, and during handling, preparation and storage.

Measurement uncertainty of measured quantity values

The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.
Examination procedures
Shall be documented in a language understood by staff in the laboratory and be available in appropriate locations. Condensed information e.g., laminates, cards, etc., shall correspond to the documented procedure.

5.5.3 In addition to document control identifiers, documentation shall include, when applicable to the examination procedure, the following:
   e) patient preparation;
   f) laboratory clinical interpretation;
   g) references.

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.

5.6.3.3

Post examination procedures:
5.7.1 When the procedure for reviewing results involves automatic selection and reporting, review criteria shall be established, approved, and documented (see 5.8.4).

Report content
5.8.3 The report shall include, but not be limited to, the following:
   a) a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;
   i) other comments such as cautionary or explanatory notes (e.g., quality or adequacy of 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;
   p) page number to total number of pages (e.g., "Page 1 of 5," "Page 2 of 5," etc.).

Automated selection and reporting of results
A documented procedure will need to be available to ensure that the criteria for automated selection and reporting are defined, understood, and implemented. The documented criteria will need to be verified as functioning effectively both before use and also after any changes to the system that could affect their functionality. Any sample interferences that could impact on the result, e.g., haemolysis, will need to be indicated; where necessary and relevant, a process to be established for ensuring that analytical warning messages generated from the instruments are incorporated into the reporting criteria.

Results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection. There is a process for rapid suspension of automated selection and reporting.

5.9.2

Revised reports
5.9.3 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;
   c) the revised record shows the time and date of the change and the name of the person responsible for the change; and
   d) the revised report includes any changes or alterations that have been made.

5.9.3 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.

5.9.3 When the reporting system cannot capture amendments, changes, or alterations, a record of such shall be kept.

Laboratory Information Management:
Information system management
5.10.3 The system(s) used for the collection, processing, recording, reporting, storage, or retrieval of examination data and information shall be:
   a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented, and verified before implementation;
   b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;
   c) protected from unauthorized access;
d) safeguarded against tampering or loss;
e) operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;
g) in compliance with national or international requirements regarding data protection.

The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g., computer systems, fax machines, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory shall verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

The laboratory shall have documented contingency plans to maintain services in event of failures or downtime in information systems that affects the laboratory's ability to provide service. When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, laboratory management shall be responsible for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard.