# Comparison ISO 15189:2007 and ISO 15189:2012

| ISO 15189:2007 | | ISO 15189: 2012 | | Differences |
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| **1** | **Scope** | **1** | **Scope** | |
| **2** | **Normative references** | **2** | **Normative references** | |
| **3** | **Terms and definitions** | **3** | **Terms and definitions** | |
| **4** | **Management requirements** | **4** | **Management requirements** | |
| **4.1** | **Organization and management** | **4.1** | **Organization and management responsibility** | |
| | | 4.1.1 | Organization | |
| | | 4.1.1.1 | General | |
| | | 4.1.1.2 | Legal entity | |
| | | 4.1.1.3 | Ethical conduct | Laboratory management shall have arrangements in place to ensure the following:<br>a) there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity<br>b) management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work<br>c) where potential conflicts in competing interests may exist, they shall be openly and appropriately declared<br>d)there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements<br>e) confidentiality of information is maintained |
| | | 4.1.1.4 | Laboratory director | Additionally:<br>h) select and monitor laboratory suppliers<br>m) address any complaint, request or suggestion from staff and/or users of laboratory services (see also 4.8, 4.14.3 and 4.14.4)<br>n) design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable |
| | | 4.1.2 | Management responsibility | |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | 4.1.2.1 | Management **commitment** | Laboratory management **shall provide evidence** of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by: |
| | | 4.1.2.2 | Needs of users | |
| | | 4.1.2.3 | Quality policy | Additionally:<br>e) is reviewed for continuing suitability |
| | | 4.1.2.4 | Quality objectives and planning | Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels **within the organization**. The quality objectives **shall be measurable** and consistent with the quality policy.<br>Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements (see 4.2) and the quality objectives.<br>Laboratory management shall ensure that **the integrity** of the quality management system is maintained **when changes** to the quality management system are planned and implemented. |
| | | 4.1.2.5 | Responsibility, authority and interrelationships | |
| | | 4.1.2.6 | Communication | Laboratory management shall have an effective means for communicating with staff (see also 4.14.4). Records **shall be kept** of items discussed in **communications** and meetings.<br>Laboratory management shall ensure that appropriate communication processes are established between the laboratory **and its stakeholders** and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system. |
| | | 4.1.2.7 | Quality manager | Additionally:<br>c) ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization |
| **4.2** | **Quality management system** | **4.2** | **Quality management system** | |
| | | 4.2.1 | General requirements | The laboratory shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | requirements of this International Standard.<br>**The quality management system shall provide for the integration** of all processes required to fulfil its quality policy **and objectives** and meet the needs and requirements of the users.<br>The laboratory **shall**:<br>a) determine **the processes** needed for the quality management system and ensure their application throughout the laboratory<br>b) determine the sequence and interaction of these processes<br>c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective<br>d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes<br>e) monitor and evaluate these processes<br>f) implement actions necessary to achieve planned results and continual improvement of these processes |
| | | 4.2.2 | Documentation requirements | |
| | | 4.2.2.1 | General | |
| | | 4.2.2.2 | Quality manual | |
| **4.3** | **Document control** | **4.3** | **Document control** | |
| | | | | Additionally:<br>b) – page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”)<br>f) changes to documents are identified<br>g) documents remain legible<br>i) obsolete controlled documents are dated and marked as obsolete |
| **4.4** | **Review of contracts** | **4.4** | **Service agreements** | |
| | | 4.4.1 | Establishment of service agreements | Each request accepted by the laboratory for examination(s) **shall** be considered an agreement |
| | | 4.4.2 | Review of service agreements | |
| **4.5** | **Examination of referral laboratories** | **4.5** | **Examination of referral laboratories** | |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | 4.5.1 | Selecting and evaluating referral laboratories and consultants | |
| | | 4.5.2 | Provision of examination results | Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.<br><br>When the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. **The report shall indicate which examinations were performed by a referral laboratory or consultant.**<br><br>The author of any additional remarks shall be clearly identified<br><br>Laboratories shall adopt the most appropriate means of reporting referral laboratories results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, this process shall not be hindered by commercial of financial considerations. |
| 4.6 | External services and supplies | 4.6 | External services and supplies | |
| | | | | The laboratory shall select and approve suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements; **however, it may be necessary to collaborate** with other organizational departments or functions to fulfil this requirement. Criteria for selection shall be established.<br><br>Purchasing information shall describe the requirements for **the product or service** to be purchased. |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| **4.7** | **Advisory services** | **4.7** | **Advisory services** | |
| | | | | **The laboratory shall establish arrangements for communicating with users on the following:**<br>a) advising on choice of examinations and use of the services, including required type of sampling (see also 5.4)<br>b) advising on individual clinical cases of examinations (see 5.1.2. and 5.1.6.)<br>d) promoting the effective utilization of laboratory services<br>e) consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria |
| **4.8** | **Resolution of complaints** | **4.8** | **Resolution of complaints** | |
| | | | | |
| **4.9** | **Identification and control of nonconformities** | **4.9** | **Identification and control of nonconformities** | |
| | | | | Additionally:<br>c) the extent of the nonconformity is determined<br>f) the results of any nonconforming **or potentially nonconforming** examinations already released are recalled or appropriately identified, as necessary |
| **4.10** | **Corrective action** | **4.10** | **Corrective action** | |
| | | | | The laboratory shall have a documented procedure for:<br>a) reviewing nonconformities |
| **4.11** | **Preventive action** | **4.11** | **Preventive action** | |
| | | | | The laboratory shall have a documented procedure for:<br>b) determining the root cause(s) of **potential** nonconformities |
| **4.12** | **Continual improvements** | **4.12** | **Continual improvements** | |
| | | | | The laboratory shall continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives. Improvement activities shall be directed at areas of highest priority based on risk assessments. Action |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | plans for improvement shall be developed, documented and implemented, as appropriate. The effectiveness of the actions taken shall be determined through a focused review or audit of the area concerned (see also 4.14.5)<br>Laboratory management shall ensure that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care.<br>When the continual improvement programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur.<br>Laboratory management shall communicate to staff improvement plans and related goals |
| **4.13** | **Quality and technical records** | **4.13** | **Control of records** | |
| | | | | Records shall be created concurrently with performance of each activity that affects the quality of the examination.<br><br>The date and, where relevant, the time of amendments to records shall be captured along with the identity of personnel making the amendments (see 5.8.6).<br><br>Records **shall** include, at least, the following:<br>a) supplier selection and performance, and changes to the approved supplier list<br>b) staff qualifications, training and competency records<br>d) records of receipt of samples in the laboratory<br>g) retained data and information<br>j) calibration functions and conversion factors<br>n) risk management records<br>o) nonconformities identified and immediate or corrective action taken<br>p) preventive action taken<br>u) minutes of meetings that record decisions made about the laboratory's quality management activities<br>v) records of management reviews<br><br>All of these quality and technical records shall be available for laboratory management review (see 4.15). |
| **4.14** | **Internal audits** | **4.14** | **Evaluation and audits** | |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | 4.14.1 | General | The laboratory shall plan and implement **the evaluation** and internal audit **processes** needed to: |
| | | 4.14.2 | Periodic review of requests, and suitability of procedures and sample requirements | Authorized personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.<br>The laboratory shall periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand. |
| | | 4.14.3 | Assessment of user feedback | The laboratory shall seek information relating to user perception as to whether the service has met the needs and requirements of users. The methods for obtaining and using this information **shall include** cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users. Records **shall be kept** of information collected and actions taken. |
| | | 4.14.4 | Staff suggestions | Laboratory management shall encourage staff to make suggestions for the improvement of any aspect of the laboratory service. Suggestions shall be evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management shall be maintained. |
| | | 4.14.5 | Internal audit | **NOTE 1: The cycle for internal auditing should normally be completed in one year**. It is not necessary that internal audits cover each year, in depth, all elements of the quality management system. The laboratory may decide to focus on a particular activity without completely neglecting the others.<br><br>Audits shall be conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system.<br>The audit programme shall take into account the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods |

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| | | | | shall be defined and documented.<br><br>Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. **Auditors shall, wherever resources permit, be independent of the activity to be audited.**<br><br>Personnel responsible for the area being audited shall ensure that appropriate action is **promptly** undertaken when nonconformities are identified.<br>**Corrective action shall be taken without undue delay to eliminate the causes of the detected nonconformities (see 4.10).** |
| | | 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 process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.<br><br>The indicators shall be periodically reviewed, to ensure their continued appropriateness.<br><br>The laboratory, **in consultation with the users,** shall establish turnaround times for each of its examinations that reflect clinical needs. The laboratory **shall** periodically evaluate whether or not it is meeting the established turnaround times. |
| | | 4.14.8 | Reviews by external organizations | Reviews by external organizations,<br>When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory shall take appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of this International Standard. Records shall be kept of the reviews and of the corrective actions and |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | preventive actions taken. |
| **4.15** | **Management review** | **4.15** | **Management review** | |
| | | 4.15.1 | General | |
| | | 4.15.2 | Review input | The input to management review shall include information from the results of evaluations of at least the following:<br>a) the periodic review of requests, and suitability of procedures and sample requirements (see 4.14.2)<br>c) staff suggestions (see 4.14.4)<br>e) risk management (see 4.14.6) |
| | | 4.15.3 | Review activities | The review shall analyse the input information for causes of nonconformities, trends and patterns that indicate process problems.<br>This review shall include assessing these opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives (zie 4.1.2.3e). |
| | | 4.15.4 | Review output | The output from the management review shall be incorporated into a record that documents any decisions made and actions taken during management review related to:<br>a) improvement of the effectiveness of the quality management system and its processes<br>b) improvement of services to users<br>c) resource needs<br><br>Laboratory management shall ensure that actions arising from management review are completed **within a defined timeframe.** |
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| **5** | **Technical requirements** | **5** | **Technical requirements** | |
| **5.1** | **Personnel** | **5.1** | **Personnel** | |
| | | 5.1.1 | General | The laboratory shall have a documented procedure for personnel management and maintain records for all personnel to indicate compliance with requirements. |
| | | 5.1.2 | Personnel qualifications | It includes 5.1.12, additionally:<br>Laboratory management shall document personnel |

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| | | | | qualifications for each position. |
| | | 5.1.3 | Job descriptions | The laboratory shall have job descriptions that describe responsibilities, authorities and tasks for all personnel. |
| | | 5.1.4 | Personnel introduction to the organizational environment | The laboratory shall have a programme to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services. |
| | | 5.1.5 | Training | It incorporates the clauses 5.1.6, 5.1.10, 5.1.13, additionally:<br>c) the applicable laboratory information system<br>d) health and safety<br>e) ethics<br>Personnel that are undergoing training shall be supervised at all times.<br>The effectiveness of the training programme shall be periodically reviewed. |
| | | 5.1.6 | Competence assessment | It includes 5.1.11, additionally:<br>Assigned managerial or technical tasks according to established criteria.<br><br>NOTE 1: Competence of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:<br>a) direct observation of routine work processes and procedures, including all applicable safety practices<br>b) direct observation of equipment maintenance and function checks<br>c) monitoring the recording and reporting of examination results<br>d) review of work records<br>e) assessment of problem solving skills<br>f) examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | NOTE 2: Competency assessment for professional judgment should be designed as specific and fit for purpose. |
| | | 5.1.7 | Reviews of staff performance | In addition to the assessment of technical competence, the laboratory shall ensure that reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships.<br><br>NOTE: Staff performing reviews should receive appropriate training. |
| | | 5.1.8 | Continuing education and professional development | Clause 5.1.9 is extended as:<br>A continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed.<br>Personnel shall take part in regular professional development or other professional liaison activities. |
| | | 5.1.9 | Personnel records | Additionally to 5.1.2:<br>These records **shall** be readily available to relevant personnel and shall include:<br>e) introduction of new staff to the laboratory environment<br>i) reviews of staff performance<br>j) reports of accidents and exposure to occupational hazards<br>g) competency assessments<br>k) immunisation status, when relevant to assigned duties<br><br>NOTE: The records listed above are not required to be stored in the laboratory, but can be maintained in other specified locations, providing they remain accessible as needed. |
| **5.2** | **Accommodation and environmental conditions** | **5.2** | **Accommodation and environmental conditions** | |
| | | 5.2.1 | General | Additionally:<br>Other than the main laboratory premises for example point-of-care testing (POCT) under the management of the |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | laboratory. |
| | | 5.2.2 | Laboratory and office facilities | Parts of Clauses 5.2.4, 5.2.7 and 5.2.8 are incorporated and additionally:<br>The laboratory and associated office facilities shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met<br><br>NOTE: Access control should take into consideration safety, confidentiality, quality and prevailing practices.<br>b) medical information, patient samples and laboratory resources are safeguarded from unauthorised access<br>d) efficient transfer of information<br>e) Safety facilities and devices are provided and their functioning regularly verified<br><br>EXAMPLE: Operation of emergency release, intercom and alarm systems for cold rooms and walk-in freezers; accessibility of emergency showers and eyewash, etc. |
| | | 5.2.3 | Storage facilities | 5.2.9 and additionally:<br>Clinical samples and materials used in examination processes shall be stored in a manner to prevent cross contamination.<br>Storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified by applicable requirements. |
| | | 5.2.4 | Staff facilities | There shall be adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.<br><br>NOTE: When possible, the laboratory should provide space for staff activities such as meetings and quiet study and a rest area. |
| | | 5.2.5 | Patient sample collection facilities | It incorporates 5.2.3 and 5.2.4 and additionally:<br>Patient sample collection facilities shall have separate reception/waiting and collection areas.<br>Facilities at which patient sample collection procedures are performed (e.g. phlebotomy) shall enable the sample collection to be undertaken. |

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| | | | | Sample collection facilities shall have and maintain appropriate first aid materials for both patient and staff needs.<br><br>NOTE: Some facilities may need equipment appropriate for resuscitation; local regulations may apply. |
| | | 5.2.6 | Facility maintenance and environmental conditions | 5.2.10 and additionally:<br>Laboratory premises shall be maintained in a functional and reliable condition.<br><br>5.2.5 and additionally:<br>Results and/or the health of staff. Attention shall be paid to factors such as light, noxious or hazardous fumes and workflow logistics as appropriate to the activities concerned so that these do not invalidate the results or adversely affect the required quality of examination<br>Procedures shall be in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.<br>The laboratory shall provide a quiet and uninterrupted work environment where it is needed.<br><br>NOTE: Examples of a quiet and uninterrupted work area include cytopathology screening, microscopic differentiation of blood cells and microorganisms, data analysis from sequencing reactions and review of molecular mutations results. |
| **5.3** | **Laboratory equipment, reagents, and consumables** | **5.3** | **Equipment** | |
| | | 5.3.1 | Equipment | |
| | | 5.3.1.1 | General | The laboratory shall have a documented procedure for the selection, purchasing and management of equipment.<br><br>The laboratory shall replace equipment as needed to ensure the quality of examination results. |
| | | 5.3.1.2 | Equipment acceptance testing | NOTE: This requirement applies to: equipment used in the laboratory, equipment on loan or equipment used in |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | associated or mobile facilities by others authorized by the laboratory. |
| | | 5.3.1.3 | Equipment instructions for use | Equipment shall be operated at all times **by trained** and authorized personnel.<br>Current instructions on the use, **safety** and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment, shall be readily available. |
| | | 5.3.1.4 | Equipment calibration and metrological traceability | The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:<br>b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment<br><br>Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available. |
| | | 5.3.1.5 | Equipment maintenance and repair | |
| | | 5.3.1.6 | Equipment adverse incident reporting | Adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to the manufacturer and appropriate authorities, as required. |
| | | 5.3.1.7 | Equipment records | These equipment records shall include, **but not be limited** to, the following: |
| | | 5.3.2 | Reagents and consumables | |
| | | 5.3.2.1 | General | |
| | | 5.3.2.2 | Reagents and consumables – Reception and storage | Where the laboratory is not the receiving facility, it shall verify that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevent damage or deterioration. |
| | | 5.3.2.3 | Reagents and consumables – Acceptance testing | |
| | | 5.3.2.4 | Reagents and consumables – Inventory management | |
| | | 5.3.2.5 | Reagents and consumables – Instructions for use | |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | 5.3.2.6 | 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 the manufacturer and appropriate authorities, as required. |
| | | 5.3.2.7 | Reagents and consumables – Records | Where the laboratory uses reagents prepared or completed in-house, the records shall include, in addition to the relevant information above, reference to the persons undertaking their preparation and the date of preparation. |
| **5.4** | **Pre-examination procedures** | **5.4** | **Pre-examination processes** | |
| | | 5.4.1 | General | |
| | | 5.4.2 | Information for patients and users | Additionally:<br>a) the location of the laboratory<br>k) a list of factors known to significantly affect the performance of the examination or the interpretation of the results<br>n) the laboratory's complaint procedure |
| | | 5.4.3 | Request form information | Additionally:<br>a) patient identification, including gender, date of birth, and **the location/contact details of the patient**, and a unique identifier<br>e) clinically relevant information about the patient **and the request**, for examination performance and result interpretation purposes |
| | | 5.4.4 | Primary sample collection and handling | |
| | | 5.4.4.1 | General | Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these shall be recorded and included in all documents containing examination results and shall be communicated to the appropriate personnel.<br>Special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, will need a more detailed explanation and, in some cases, written consent. |
| | | 5.4.4.2 | Instructions for pre-collection activities | |
| | | 5.4.4.3 | Instructions for collection activities | The laboratory's instructions for collection activities **shall** include the following:<br>d) in situations where the primary sample is collected as |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions shall be determined and communicated to the appropriate clinical staff |
| | | 5.4.5 | Sample transportation | NOTE: A laboratory which is not involved in primary sample collection and transportation is considered to have satisfied clause 5.4.5.c) above when, upon receipt of a sample whose integrity was compromised or which could have jeopardized the safety of the carrier or the general public, the sender is contacted immediately and informed about measures to be taken to eliminate recurrence. |
| | | 5.4.6 | Sample reception | |
| | | 5.4.7 | Pre-examination handling, preparation and storage | |
| **5.5** | **Examination procedures** | **5.5** | **Examination processes** | |
| | | 5.5.1 | Selection, verification and validation of examination procedures | |
| | | 5.5.1.1 | General | The laboratory shall select examination procedures which have been validated for their intended use. The identity of persons performing activities in examination processes shall be recorded. |
| | | 5.5.1.2 | Verification of examination procedures | Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use.<br>The laboratory shall obtain information from the manufacturer/method developer for confirming the performance characteristics of the procedure.<br>The independent verification by the laboratory shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results.<br>The laboratory shall document the procedure used for the verification and record the results obtained. Staff with the appropriate authority shall review the verification results |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | and record the review. |
| | | 5.5.1.3 | Validation of examination procedures | |
| | | 5.5.1.4 | Measurement uncertainty of measured quantity values | |
| | | 5.5.2 | Biological reference intervals or clinical decision values | The laboratory shall define the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users.<br>When a particular biological reference interval or decision value is no longer relevant for the population served, appropriate changes shall be made and communicated to the users.<br>When the laboratory changes an examination procedure or pre-examination procedure, the laboratory shall review associated reference intervals and clinical decision values, as applicable. |
| | | 5.5.3 | Documentation of examination procedures | In addition to document control identifiers, **documentation shall include**, when applicable to the examination procedure, the following:<br>e) patient preparation<br>h) environmental and safety controls<br>i) calibration procedures **(metrological traceability)**<br>p) instructions for determining quantitative results when a result is not within the measurement interval |
| **5.6** | **Assuring quality of examination procedures** | **5.6** | **Ensuring quality of examination results** | |
| | | 5.6.1 | General | |
| | | 5.6.2 | Quality control | |
| | | 5.6.2.1 | General | 5.6.1 has been redefined as:<br>The laboratory **shall** design quality control procedures that verify the attainment of the intended quality of results.<br><br>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. |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | 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.<br><br>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.<br>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 | **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.<br><br>NOTE: Statistical and non-statistical techniques for process control should be used wherever possible to continuously monitor examination system performance. |
| | | 5.6.3 | Interlaboratory comparison | |
| | | 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. |
| | | 5.6.3.2 | Alternative approaches | |
| | | 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.<br>Interlaboratory comparison samples shall be examined by |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | personnel who routinely examine patient samples using the same procedures as those used for patient samples.<br>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.<br>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.<br>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 | Clause 5.6.6 has been redefined as:<br>'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'.<br><br>Additionally:<br>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.<br><br>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. |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| **5.7** | **Post-examination procedures** | **5.7** | **Post-examination processes** | |
| | | 5.7.1 | Reviews of results | When the procedure for reviewing results **involves automatic selection and reporting**, review criteria shall be established, approved and documented (see 5.9.1). |
| | | 5.7.2 | Storage, retention and disposal of clinical samples | The laboratory **shall have a documented procedure** for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. |
| **5.8** | **Reporting of results** | **5.8** | **Reporting of results** | |
| | | 5.8.1 | General | The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results.<br>Reports shall include the information necessary for the interpretation of the examination results. |
| | | 5.8.2 | Report attributes | Additionally:<br>c) critical results, where applicable<br>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 | Additionally:<br>c) identification of all examinations that have been performed by a referral laboratory<br>d) patient identification and patient location on each page<br>f) date of primary sample collection (and time, when available and relevant to patient care)<br>i) examination results reported in SI units, units traceable to SI units, or other applicable units<br>j) biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable<br>m) identification of examination undertaken as part of a research or development programme and for which no specific claims on measurement performance are available<br>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)<br>o) date of the report, and time of release (if not contained in the report, readily available when needed)<br>p) page number to total number of pages (e.g. “Page 1 of |

# Comparison ISO 15189:2007 and ISO 15189:2012

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| | | | | 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 mayh release results and to whom. The procedures shall ensure that the following conditions are met.<br>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.**<br><br>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.<br><br>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. |
| | | 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:<br>a) the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff<br>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.<br>b) the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning |

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| | | | | 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<br>d) there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate<br>e) results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection<br>f) there is a process for rapid suspension of automated selection and reporting |
| | | 5.9.3 | Revised reports | Additionally:<br>a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report<br>b) the user is made aware of the revision |
| | **(Annex B)** | **5.10** | **Laboratory information management** | |
| | | 5.10.1 | General | The laboratory shall have access to the data and information needed to provide a service which meets the needs and requirements of the user.<br>The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.<br><br>NOTE: In this International Standard, “information systems” includes the management of data and information contained in both computer and non-computerized systems. Some of the requirements may be more applicable to computer systems than to non-computerized systems. Computerized systems can include those integral to the functioning of laboratory equipment and stand alone systems using generic software, such as word processing, spreadsheet and database applications that generate, collate, report and archive patient information and reports. |
| | | 5.10.2 | Authorities and responsibilities | The laboratory shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect |

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| | | | | patient care.<br>The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:<br>a) access patient data and information<br>b) enter patient data and examination results<br>c) change patient data or examination results<br>d) authorize the release of examination results and reports |
| | | 5.10.3 | Information system management | The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:<br>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<br><br>NOTE: Validation and verification include, where applicable, the proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation, hospital patient administration systems and systems in primary care.<br>b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users<br>c) protected from unauthorized access<br>d) safeguarded against tampering or loss<br>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<br>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<br>**g) in compliance with national or international requirements regarding data protection**<br><br>The laboratory shall verify that the results of examinations, associated information and comments are accurately |

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| | | | | 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.<br><br>The laboratory shall have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service.<br><br>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. |
| **Annex A** | **Correlation with ISO 9001:2000 and ISO/IEC 17025:1999** | **Annex A** | **Correlation with ISO 9001:2008 and ISO/IEC 17025:2005** | |
| **Annex B** | **Recommendations for laboratory information systems (LIS)** | **Annex B** | **Correlation with ISO 15189:2007** | **Former Annex B is now section 5.10** |
| **Annex C** | **Ethics in laboratory medicine** | **-** | **-** | **Now in section 4.1.1.3** |