Gap Analysis – May 2013

Issued: May 2013

Gap Analysis of ISO 15189:2012 and ISO 15189:2007 in the field of Medical Testing

This document had been prepared to highlight the differences between ISO 15189:2007 and ISO 15189:2012. It may be used by facility staff to assist in the preparation for a NATA/RCPA assessment. Refer also to NATA Policy Circular 45 *Implementation of ISO 15189:2012 in the field of Medical Testing.*

Summary of changes

The most notable differences between ISO 15189:2007 and ISO 15189:2012 include:

- Improved layout and listing of subclauses to make it easier to identify specific subclauses within the document;
- A more logical ordering of subclauses under each clause, wherever possible, to reflect the normal flow of activities in a laboratory setting.
- Two new normative sections (5.9 and 5.10);
- Clause 5.8 of ISO 15189:2007 has been split into the requirements for reporting (5.8) and release of results (5.9);
- 5.10 is a new section in relation to Laboratory Information Management which has been taken from Annex B - this was previously informative.

Whilst there has been additional detail included in a number of clauses, in many cases this has not resulted in a change of intent to the requirements.

Gap analysis of general information sections

Title

The name of the standard has been amended to *Medical laboratories - Requirements for quality and competence*

Foreword

- ISO 15189:2012 now includes a foreword describing the ISO process.

Introduction

- When considering an accreditation body, ISO 15189:2012 includes reference to ISO/IEC 17011 rather than 'appropriate International Standards'.
- The management system requirements in Clause 4 meet the principles of ISO 9001:2008 and are aligned with its pertinent requirements.
- Specific reference to clauses 5.2.2, 5.2.6, 5.3, 5.4, 5.5.1.4 and 5.7 to address environmental issues has been made.

1 Scope

- The scope has been expanded to include that, in addition to the Standard being used by accreditation bodies, it may also be used by laboratory customers and regulatory authorities to confirm or recognise the competence of medical laboratories.

2 Normative references

The following changes have been made to the normative references:

- ISO 31, ISO 9000:2005 and ISO 9001:2000, ISO/IEC Guide 43-1 have all been removed; and
- ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99 have been included.

3 Terms and definitions

The terms and definitions now reference ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99.

Definitions appearing in ISO 15189:2007 which have been removed from ISO 15189:2012

- 3.2 *accuracy of measurement*
- 3.5 *laboratory capability*
- 3.8 *measurement*
- 3.13 *quantity*
- 3.17 *traceability*
- 3.18 *trueness of measurement*
- 3.19 *uncertainty of measurement*

Definitions appearing in ISO 15189:2007 which have been renumbered and/or amended in ISO 15189:2012

- 3.3 *biological reference interval* is now 3.4

  This has been amended and further notes have been included.

- 3.4 *examination* is now 3.7

  Additional notes have been included.

- 3.6 *laboratory director* is now 3.9
- 3.7 *laboratory management* is now 3.10

  This has been amended, with 'headed by a laboratory director' removed.

- 3.9 *medical laboratory / clinical laboratory* is now 3.11

  Genetic facilities and the management of patients have been included.

- 3.10 *post-examination processes / postanalytical phase* is now 3.14

This has been amended slightly and includes 'retention and storage of clinical material, sample (and waste) disposal'.

- 3.11 *pre-examination processes / preanalytical phase* is now 3.15
- 3.12 *primary sample / specimen* is now 3.16

This has been amended and includes samples of body fluid, breath, hair or tissue. Additional notes have also been included.

- 3.14 *quality management system* definition is now 3.20
- 3.15 *referral laboratory* definition is now 3.23

  This has been amended slightly and a note has been added.

- 3.16 *sample definition* is now 3.24

  This has been amended slightly.

Definitions appearing in ISO 15189:2012 only

- 3.2 *alert interval/critical interval*
- 3.3 *automated selection and reporting of results*
- 3.5 *competence*
- 3.6 *documented procedure*
- 3.8 *interlaboratory comparison*

  Reference is made to ISO/IEC 17043:2010.

- 3.12 *nonconformity*
- 3.13 *point-of-care testing / POCT / near patient testing*

- 3.17 *process*
- 3.18 *quality*
- 3.19 *quality indicator*
- 3.21 *quality policy*
- 3.22 *quality objective*
- 3.25 *turnaround time*
- 3.26 *validation*
- 3.27 *verification*

Gap analysis of management and technical requirements

ISO 15189:2012 has undergone a major editorial rewrite. Due to the number of editorial changes included in this latest version, only those of significance will be listed in the below table. The onus is on facility staff to become familiar with ISO 15189:2012 in its entirety and ensure compliance with the requirements detailed in the Standard.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
4.1 Organisation and management responsibility			
4.1.1.2	4.1.1	Amended	Previously the laboratory was legally identifiable, now it must be legally responsible.
4.1.1.3	4.1.4, 4.1.5b), 4.1.5c), 4.1.5d)	Editorial	Several subclauses from ISO 15189:2007 have been consolidated under subclause 4.1.1.3.
4.1.1.4 / 4.1.2	4.1.5 and 5.1.4	Amended/New	There are new sections outlining specific responsibilities of the laboratory director (and designated delegates) and management responsibilities. There has been a consolidation of subclauses 4.1.5 and 5.1.4 of ISO 15189:2007.
4.1.2.2		New	The laboratory must ensure that the services provided meet the needs of patients and the laboratory users.
4.1.2.3	4.2.3	Amended	The intent of the laboratory's quality management system is to be defined in a quality policy.
4.1.2.4		New	Laboratory management must establish quality objectives which are measurable and consistent with the quality policy and ensure that planning of the quality management system is carried out to meet the requirements (4.2) and the quality objectives. The integrity of the quality management system must also be maintained.
4.1.2.5		New	Laboratory management must ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the organisation.
4.1.2.6		New	Effective communication must be established both within the laboratory and with laboratory stakeholders.
4.1.2.7	4.1.5i)	Amended	The responsibilities of the quality manager have been expanded to include ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organisation.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
4.2 Quality management system			
4.2	4.2	Significant editorial	This clause has been substantially rearranged and rewritten. The general intent, however, remains.
4.2.2.2	4.2.4	Significant editorial	The quality manual needs to include descriptions of integral elements of the quality management system, laboratory management and a number of documented policies. ISO 15189:2007 included an indication of what may be included in the table of contents of a quality manual. This has been removed from ISO 15189:2012.
4.3 Document control			
4.3	4.3	Amended	This clause has been substantially rearranged and rewritten. All documents must now also include page number to total number of pages (e.g. page 2 of 5) rather than just the number of pages (if applicable).
4.4 Service agreements			
4.4	4.4	Significant editorial	There has been a change to clause name. The clause has been substantially rewritten and rearranged. The general intent, however, remains.
4.5 Examination by referral laboratories			
4.5.1	4.5.1, 4.5.2, 4.5.3	Amended	The requirements have been expanded to ensure that the documented procedures for selecting and evaluating consultants who provide opinions and interpretation for complex testing relates to consultants in any discipline and not just histopathology, cytology and related disciplines. The requirements of 4.5.2a) to d) in ISO 15189:2007 have been removed.
4.5.2	4.5.4	Amended	The report must also indicate which examinations were performed by a referral laboratory or consultant.
4.6 External services and supplies			
4.6	4.6	Significant editorial	Requirements for receipt and storage, acceptance testing, inventory management, instructions for use, adverse incident reporting and records have been included under clauses 4.13 Control of records and 5.3.2: Reagents and consumables.
4.7 Advisory services			
no significant changes			

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
4.8 Resolution of complaints			
no significant changes			
4.9 Identification and control of nonconformities			
4.9	4.9.1, 4.9.2, 4.9.3	Amended	The procedures for identifying and managing nonconformities must ensure that the 'immediate' actions to be taken are defined.
4.10 Corrective action			
4.10	4.10.4	Deletion	The requirement to audit areas where doubt is cast on the compliance with policies and procedures has been removed.
4.11 Preventive action			
4.11	4.11.1, 4.11.2	Amended	Documented procedures for preventive action need to include a number of additional elements.
4.12 Continual improvement			
4.12	4.12.1, 4.12.2, 4.12.3	New	Additional to the requirements is that improvement activities are to be directed at areas of highest priority based on risk assessments.
4.12	4.12.4	Amended	Laboratory management must also communicate to staff improvement plans and goals.
4.13 Control of records			
4.13	4.13.1, 4.13.2, 4.13.3	Editorial	All subclauses from ISO 15189:2007 have been combined under one clause in 15189:2012.
4.13		New	Records must be created concurrently with performance of each activity that affects the quality of the examination.
4.13		New	The date and, where relevant, time of amendments must be captured along with the identity of personnel making the amendments.
4.13	4.13.3	Amended/New	The list of records to be controlled is now a 'must' rather than a 'may'. The list also includes additional quality related records (e.g. supplier selection and performance, minutes of meetings that record decisions, etc.). The length of time that records are retained may vary, however, reported results must be retrievable for as long as medically relevant or as required by regulation. Previously, record retention time was defined by the nature of the examination or specifically for each record.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
4.14 Evaluation and audits			
4.14	4.14	Significant editorial	There has been a change to the clause name. Substantially rewritten and expanded to now include other areas of evaluation not just internal audits.
4.14.2	5.4.9	Amended	The examinations provided by the laboratory are to be reviewed periodically to ensure they are clinically appropriate. The laboratory must also periodically review its collection device and preservative requirements in addition to sample volume to ensure neither insufficient or excessive amounts of sample are collected and the measurand is preserved.
4.14.3		New	The laboratory must seek information relating to user perception as to whether the service has met the needs and requirements of users. Records of information collected and actions taken shall be kept.
4.14.4		New	Laboratory management must encourage staff to make suggestions for the improvement of the laboratory service, with records maintained of those suggestions and actions taken.
4.14.5	4.14.1, 4.14.2, 4.14.3	Amended	There is now a greater focus on the audit programme taking into account the importance of the processes and technical and management areas to be audited, as well as the results of previous audits. Rather than the prescriptive requirement of personnel not auditing their own activities, the laboratory must ensure that the conduct of audits is objective and impartial. Now, wherever resources permit, auditors are to be independent of the activity to be audited. The cycle for internal audits is now contained within a Note.
4.14.5		New	Personnel responsible for the area being audited must ensure appropriate action is promptly undertaken when nonconformities are identified.
4.14.6		New	The laboratory must evaluate the impact of work processes and potential failures on examination results as they affect patient safety and must modify processes to reduce or eliminate the identified risks, with records to be kept of decisions and action taken.
4.14.7		New	The laboratory must establish, monitor and periodically review quality indicators for critical aspects of pre-examination, examination, and post-examination processes.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
4.14.7	5.8.2	Significant editorial	Turnaround times for each examination has been moved from "Reporting" in ISO 15189:2007 to "Evaluation" in ISO 15189:2012. The laboratory must periodically evaluate whether or not it is meeting the established turnaround times.
4.14.8		New	The laboratory must take appropriate immediate actions to nonconformities or potential nonconformities identified by external organisations in the course of a review, with records kept.
4.15 Management review			
4.15	4.15	Significant editorial	The clause has been reworded and split into review input (4.15.2), review activities (4.15.3) and review outputs (4.15.4). Period for conducting management review has been moved to a Note.
4.15.2	4.15.2	Amended	The number of inputs into management review has been expanded to encompass Section 4 activities.
4.15.3	4.15.1, 4.15.3	Amended	Management review must analyse the input information for causes of nonconformities, trends and patterns that indicate process problems. There is also the need to assess opportunities for improvement.
4.15.4	4.15.4	Amended	Records of management review are to include any decisions made and action taken which relate to: the improvement of the effectiveness of the quality management system and its processes; improvement of services to users; and resource needs.
5.1 Personnel			
5.1	5.1	Significant editorial	The clause has been substantially rewritten to divide personnel requirements into different sections (qualifications, job descriptions, introductions, training, competency, staff performance, continuing education and records). The requirement outlining the responsibilities of the laboratory director has been moved to subclause 4.1.1.4.
5.1.2	5.1.1, 5.1.12	New	Laboratory management must document personnel qualifications for each position.
5.1.4		New	A program for staff inductions is required.
5.1.5	5.1.6, 5.1.10	Amended/New	There has been significant expansion of the training requirements, detailing what areas must be covered in a training programme. The effectiveness of the training programme must be periodically reviewed.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
5.1.6	5.1.11	Significant editorial	The Note included under this subclause provides examples of potential competency assessments.
5.1.7		New	In addition to the assessment of technical competence, the laboratory must ensure that reviews of staff performance consider the needs of the laboratory and the individual.
5.1.8	5.1.9, 5.1.12	Amended/New	In ISO 15189:2007, a continuing education program was to be made available to staff at all levels. Now the continuing education program is to be made available to staff who participate in managerial and technical processes and personnel must participate. The effectiveness of the continuing education program is to be periodically reviewed.
5.1.9	5.1.2	Amended	There has been an expansion of the records required to be maintained. This is now a 'shall' as opposed to a 'may' in ISO 15189:2007.
5.2 Accommodation and environmental conditions			
5.2	5.2	Significant editorial	This clause has been restructured into designated accommodation areas, including laboratory and office facilities (5.2.2), storage facilities (5.2.3), staff facilities (5.2.4) and patient sample collection facilities (5.2.5). Facility maintenance and environmental conditions (5.2.6) are also clearly defined.
5.2.3	5.2.9, 5.2.6, 5.2.10	Amended	Included is the requirement for clinical samples and materials used in examination processes to be stored in a manner which prevents cross contamination.
5.2.4		New	There must be adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing.
5.2.5	5.2.2, 5.2.3, 5.2.4	New	There is now a requirement for separate reception/waiting and collection areas. Also, sample collection facilities must have and maintain appropriate first aid material for patient and staff needs.
5.2.6	5.2.1, 5.2.10, 5.2.5, 5.2.6	Amended	The monitoring of environmental conditions has been extended to also include where they may influence the health of staff.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
5.3 Laboratory equipment, reagents, and consumables			
5.3	4.6, 5.3	Significant editorial	Laboratory equipment (5.3 in ISO 15189:2007) and reagents and consumables (4.6 in ISO 15189:2007) have been brought together under clause 5.3 in ISO 15189:2012. Requirements for laboratory equipment have been divided into general (5.3.1.1), acceptance testing (5.3.1.2), instructions for use (5.3.1.3), calibration and metrological traceability (5.3.1.4), equipment maintenance and repair (5.3.1.5), adverse incident reporting (5.3.6) and records (5.3.1.7). Requirements for reagents and consumables have been divided into general (5.3.2.1), reception and storage (5.3.2.3), acceptance testing (5.3.2.3), inventory management (5.3.2.4), instructions for use (5.3.2.5), adverse incident reporting (5.3.2.6) and records (5.3.2.7).
5.3.1.4	5.3.2, 5.3.9, 5.3.13	New	The laboratory must have a documented procedure for the calibration of equipment that directly or indirectly affects examination results.
5.3.1.4		New	Metrological traceability must be to a reference material or reference procedure of the higher metrological order available. Where this is not possible, or relevant, other means for providing confidence in the results must be applied.
5.3.1.7	5.3.3, 5.3.4	Amended	The performance records that confirm the equipment's ongoing acceptability for use must include copies of reports/certificates of all calibrations and/or verifications. Previously this was not a requirement of ISO 15189:2007 but a 'should'.
5.3.2.2		New	Where the laboratory is not the receiving facility, the receiving location must have adequate storage and handling capabilities to prevent damage or deterioration and this must be verified.
5.3.2.4	4.6.3	New	The system for inventory control shall segregate uninspected and unacceptable reagents and consumables from those accepted for use.
5.3.2.5		New	Instructions for the use of reagents and consumables, including manufacturer's instructions, are to be readily available.
5.3.2.6		New	Adverse incidents and accidents that can be attributed directly to specific reagents and consumables must be investigated and reported to the manufacturer and authorities, as required.
5.3.2.7	4.6.3	Amended	There has been an expansion of the records required to be maintained.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
5.3.2.7		New	Where reagents have been prepared or completed in-house, records must also include the person(s) undertaking their preparation and the date of preparation.
5.4 Pre-examination processes			
5.4	5.4	Significant editorial	This clause has been substantially rewritten and restructured. Pre-analytical processes is now divided into: general requirements (5.4.1); information for patients and users (5.4.2); request form information (5.4.3); primary sample collection and handling (5.4.4); sample transportation (5.4.5); sample reception (5.4.6); and pre-examination handling, preparation and storage (5.4.7).
5.4.2	5.4.3	Amended	The amount of information which is required to be available to patients and users of the laboratory services has been increased.
5.4.3	5.4.1	Amended	A number of additional details are to be included on the request form (or electronic equivalent) in relation to patient identification.
5.4.4	5.4.2, 5.4.3	Significant editorial	The requirements for primary collection and handling have been split into general (5.4.4.1), pre-collection activities (5.4.4.2) and collection activities (5.4.4.3).
5.4.4.1		New	Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these must be recorded and included in all documents containing examination results and be communicated to the appropriate personnel.
5.4.4.3d)		New	Where primary sample collection is performed by clinical staff as part of a clinical practice, information and instructions regarding primary sample containers, necessary additives, necessary processing and sample transport conditions must be communicated to those staff.
5.5 Examination processes			
5.5	5.5	Significant editorial	This clause has been rewritten and restructured. Examination processes is now clearly divided into: selection, verification and validation procedures (5.5.1); biological reference intervals and clinical decision values (5.5.2); and documentation of examination procedures (5.5.3).
5.5.1.1	5.5.2	Amended	The identity of persons performing activities in examination processes must be recorded.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
5.5.1.2	5.5.2	Amended/New	Validated examination procedures used without modification must be subject to independent verification by the laboratory prior to routine use. Information is to be obtained from the manufacturer regarding the performance characteristics of the procedure. The verification must confirm that the performance claims for the procedure have been met. The procedure used for verification must also be documented, with the obtained results recorded. Verification results are to be reviewed by the appropriate staff. Previously the laboratory was required to 'evaluate' methods and procedures selected for use, ensuring that they give satisfactory results before being used for medical examinations.
5.5.1.3	5.5.2	Amended	Greater detail regarding the situations when validation of examination procedures is required has been included in this clause. Validation must be performed for non-standard methods, laboratory developed methods, standard methods used outside their intended scope and validated methods subsequently modified.
5.5.1.4	5.6.2	Amended/New	Previously the laboratory was required to determine the uncertainty of results, where relevant and possible. Now the laboratory must determine uncertainty of measurement (MU) for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The performance requirements for the measurement uncertainty of each procedure must be defined and the MU estimates regularly reviewed. When interpreting measured quantity values, MU must be considered and the laboratory must make MU estimates available to laboratory users, upon request. Where examinations include a measurement step but do not report a numerical result, the laboratory should estimate the MU for the measurement step where it can assess the reliability of the examination procedure or has influence on the report result.
5.5.2	5.5.5	Amended	The basis for reference intervals or decision values must be documented and this information communicated to users

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
5.5.3	5.5.3	Amended/New	The information to be included in the documentation of examination procedures is now a requirement. ISO 15189:2007 listed these as 'should'. Additional items for procedures include: patient preparation; instructions for determining quantitative results where the result is not within the measurement interval; and references. Also, the laboratory must now, if it intends to change an existing examination procedure such that results or their interpretations could be significantly different, explain to users of the laboratory service of the implications after validating the procedure.
5.6 Ensuring quality of examination results			
5.6	5.6	Significant editorial	There has been major rewording of the clause, with subclauses created to separate quality control (5.6.2) and interlaboratory comparisons (5.6.3).
5.6.1		New	There are overarching general requirements for ensuring the quality of examination results. These require the laboratory to ensure: • the quality of examinations by performing them under defined conditions; • appropriate pre and post-examination processes are implemented; • results are not fabricated.
5.6.2.2	5.6.1	New	QC material shall: • react in a manner as close as possible to patient samples; • be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from erroneous result.
5.6.2.3		New	The laboratory must have a procedure to prevent patient results being released in the event of a QC failure. When QC rules are violated and there is likely to be clinically significant errors, the results are to be rejected and patient samples re-examined after the errors have been corrected. The laboratory must also evaluate patient results that were examined after the last successful QC event. QC data must be regularly reviewed to detect trends, with preventative action taken and recorded.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
5.6.3.1	5.6.4	New	A procedure for interlaboratory comparison participation must be documented and include responsibilities and instructions for participation. Additionally, the documented procedure must include any performance criteria that differ from the criteria used in the interlaboratory comparison programme.
5.6.3.3		New	Interlaboratory comparison samples must be integrated into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. They must also be examined by personnel who routinely examine patient samples. The laboratory must not communicate with other participants until after submission dates. Additionally, referral for confirmatory examinations cannot occur prior to the submission of data, even when this would routinely be done for patient samples.
5.6.3.4		New	Performance in interlaboratory comparisons shall be reviewed and discussed with relevant staff.
5.7 Post-examination processes			
5.7.1	5.7.1	Amended/New	The procedures for the review of examination results prior to release must also include evaluation of the results against internal quality control. Automatic selection and reporting of results requires review criteria to be documented (see 5.9.1).
5.7.2		New	The laboratory must define the length of time clinical samples are to be retained.
5.8 Reporting of results			
5.8.2	5.8.3k), 5.8.5	Significant editorial	There is increased emphasis on ensuring “report attributes” effectively communicate laboratory results and meet the users’ needs. Previously, this was included under 5.8.3k) and 5.8.5 of ISO 15189:2007.
5.8.3	5.8.3	Amended/New	Reports must include: identification of all examinations performed by a referral laboratory; patient identification and patient location on each page; examinations undertaken as part of research and development and page number to total number of pages (e.g. page 1 of 5).
	5.8.4	Deletion	The recommendation to follow the vocabulary and syntax of listed organisations has been removed.

ISO 15189:2012 Clause No.	Corresponding ISO 15189:2007 Clause No.	Change	Comments or summary of change
5.9 Release of results			
5.9.2		New	New clause covering requirements and criteria for automated selection and reporting of results.
5.10 Laboratory information management			
		New	Previously included as Annex B in ISO 15189:2007 which was informative.

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section	Amendment
5.4.13	The previous version of this gap analysis indicated that the requirement that a written policy on verbal requests is no longer required. This was an error and has been deleted.