Seeking Laboratory Accreditation
Under ISO 15189

An ISO Revision for 2012 and Beyond
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What You Will Learn

- Understand the difference between certification and accreditation
- Understand the difference between a policy, a process and a procedure
- Become familiar with the fundamentals of a quality system under 15189
- Understand the fundamentals necessary to prepare for accreditation under ISO standard 15189:2012
- Develop a general familiarity with ISO 15189

This booklet provides a general overview of ISO 15189 and should not be considered detailed or comprehensive. Those with specific interests should obtain a copy of the actual ISO 15189 standard. The standard can be obtained from national standards bodies, from the ISO organization, or from the Clinical and Laboratory Standards Institute.

For the purposes of readability in this booklet, ISO 15189:2012 has been shortened to ISO 15189.
Accreditation vs. Certification

There is a distinct difference between certification and accreditation. Certification by an agency or organization, as defined by ISO, is a “procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements” [ISO/IEC Guide 2]. Accreditation is a “procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks” [ISO/IEC Guide 2]. ISO 15189 is intended as an accreditation standard and not for certification. For accreditation, the rules require that the accreditation process be carried out by authorized third party organizations: i.e. a person or body that is recognized as being independent of the parties involved; in this case, someone who is independent of the laboratory or the laboratory’s parent organization.

Improving Laboratory Quality with ISO 15189

Medical laboratories assay biological samples for purposes of providing test results used for patient screening, diagnosis, follow-up and treatment, as well as prevention of disease. The laboratory’s aim is not only to provide reliable results to assure the safety of the patient, but to do so within a reasonable turnaround time, with traceability for all laboratory procedures, and with a respect for ethics.

In light of the importance of laboratory output and the potential of harm of incorrect laboratory results, many worldwide opinion leaders in the laboratory profession felt there was a need for an internationally recognized standard of practice for medical labs. This need was driven by the desire to elevate laboratory quality and make efficiency a priority for all laboratories. Another important factor was a need to harmonize laboratory performance. With the increasing mobility of the world’s population, it has become necessary and important to assure that test results reported in one location could be replicated, in terms of medical actions taken, at another location particularly for patients with medical conditions that require on-going monitoring.

While the US has CLIA¹ and some international labs obtain CLIA accreditation, it is a standard that is designed for achievement of minimally acceptable quality only and does nothing for efficiency or harmonization. What the opinion leaders wanted was a “best in class” practice standard that would focus on laboratory competence, process efficiency and effectiveness, provide harmonization of laboratory outputs and demonstrate more than a minimal level of quality.

One candidate standard that could have served a “best in class” standard was ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories. But the opinion leaders rightly held this standard, though excellent for the research or industrial laboratory, did not adequately address the unique structure, operations or needs of medical laboratories. So the International Organization for Standards (ISO) was approached to develop a standard that was unique to medical labs. Consequently, ISO Technical Committee 212, the ISO committee responsible for international “best in class” practice standards that apply to diagnostic manufacturers and medical laboratories, published the first international “best in class” practice standard (ISO 15189 Medical Laboratories – Particular Requirements for Quality and Competence) in 2003 and undertook a major revision in late 2012 that is expected to remain in effect until 2017.

ISO 15189 is a voluntary standard. Governments may adopt the standard as their country standard and many have chosen to do so. In countries like the US that have not adopted ISO 15189, accreditation to the standard is a matter of choice. When not required, ISO 15189 accreditation is driven through a sense of professional ethics by laboratory management who want to ensure their patients and users of the laboratory’s efficiency, competence and quality. Increased satisfaction can, and often does, lead to increased revenues and profit.

¹Clinical Laboratory Improvement Amendments
Preparations and Considerations

Before a laboratory attempts to seek accreditation under ISO 15189, a number of preparations must be made and certain activities accomplished. Laboratory management should first establish a Steering Group (committee). The Steering Group should include representatives from laboratory management and supervision. Efforts should be made to include managers and supervisors that work during times other than normal daytime work hours. These individuals are often excluded from laboratory decision making simply because they work different hours than those who run or manage the laboratory. They are critical to the successful implementation and operation of the quality system. In a 24-hour laboratory setting, these individuals are responsible for the laboratory’s output during nearly 2/3 of the hours of operation.

It may be helpful to remember that people tend to resist change and one key to successfully implementing change is to provide the opportunity to participate when planning the changes. Participation can be aided by video-recorded meetings for later viewing, email notifications, conference calling, Skype®, or various other online / social media mechanisms. Where these are not possible or practical, Steering Group meeting times should be set so that those individuals working non-traditional hours (or days) can attend.

Once formed, the Steering Group should prepare a gap analysis, write a quality policy for the laboratory, select a Quality Manager, and oversee development of a Quality Manual.

Gap Analysis
Under the direction of the Steering Group, the laboratory should describe or itemize all of its existing policies, processes and procedures. Next, a comparison to ISO 15189 requirements (or accreditation requirements as appropriate) should be made. A gap exists where the laboratory does not fully meet the stated requirements. The remainder of this booklet assumes a major gap exists, because the laboratory has no quality management system in place and must start from the beginning.

Quality Policy
The quality policy is a statement of purpose for the laboratory. It should describe, as briefly as possible, what the laboratory is about, why it exists, and what the laboratory’s overall goals or objectives are. The wording should be general in scope. One approach to writing a quality policy is to describe commitments the laboratory is willing to make and then how (in general terms) the laboratory will meet those commitments.

Ideally, the quality policy will be no more than one paragraph in length.

An Example Quality Policy
This Laboratory is committed to producing reliable patient test results in a manner necessary to insure appropriate and timely patient care. The laboratory will strive to produce reliable patient test results by combining processes that promote efficiency with technology appropriate to the laboratory mission and operated by staff that is both trained and competent to perform the work.
Quality Manager

The Quality Manager is responsible for the continued integrity of the quality system. In this capacity the Quality Manager must:

• Ensure the components of the quality management system (QMS) are current and relevant
• Ensure the QMS is audited at regular intervals
• Keep laboratory management informed of all activities and findings of the QMS
• Ensure all staff are committed to, and actively involved in, the QMS
• Facilitate introduction of new quality system procedures or modifications to existing procedures
• Act as liaison between the laboratory and other interfacing departments of the parent organization, as well as internally – between various departments within the laboratory itself

Selecting a Quality Manager begins with the Steering Group deciding whether the Quality Manager should be a full-time position. A full-time Quality Manager would be focused solely on maintaining and evolving the quality management system. Alternatively, the Quality Manager may have responsibilities in addition to those of managing the quality system, which may be an ideal situation since it keeps the Quality Manager engaged in operational activities.

If the laboratory is a large operation or has a complex organizational structure, consideration should be given to making the Quality Manager position full-time. This also reflects management’s commitment to the quality system, which is key to obtaining accreditation under ISO requirements. If the laboratory is a small operation, or perhaps focused on specialized testing, a part-time Quality Manager would be both practical and feasible.

The Quality Manager should have good written and oral communication skills and be an able negotiator. Often the Quality Manager must negotiate, particularly with departments outside the laboratory, like Nursing or Purchasing, to reach consensus on a policy, process or procedure.

Quality Manual

The Steering Group also oversees the development of a Quality Manual by creating working groups (committees) that are responsible for writing policies, processes and procedures for each element (Quality System Essential or QSE) of the quality management system. The Steering Group must make every effort to involve all laboratory staff in working groups, regardless of job classification or hours of employment. The Steering Group should offer guidance and direction to the working groups, but otherwise let the working groups develop the quality system necessary to meet the stated goals of the quality policy and the requirement of the ISO 15189 standard.

Keep in mind that the ISO approach is a horizontal system and not vertical or “top down” approach. It is participative and collaborative, not dictatorial or authoritarian. Everyone in the organization, from the Laboratory Director to the person who files patient reports, should actively participate in developing the quality management system. Each laboratory employee should also have an opportunity to initiate change, when necessary, once the quality management system is in place.

The Quality Manual includes an organizational chart that identifies laboratory management by name and position held in the organization and defines the reporting structure of the laboratory. It also includes a general description of laboratory operations, states the quality policy for the laboratory, and has the compendium of quality policy for each QSE.

Steering Group

Before beginning the development of a quality system, laboratory management should appoint a Steering Group comprised of laboratory management and supervision. This Group is responsible for developing a quality policy for the laboratory, preparing a gap analysis, appointing a Quality Manager, and overseeing development of the Quality Manual. The Quality Manual consists of a description of the laboratory, an organizational chart, the quality policy and a compendium of high level policies for each Quality System Essential (QSE) of the quality system.
A policy specifies intent and direction. Policies may be developed by the Steering Group, such as the quality policy for the laboratory; however, most policies originate from the working groups. There can be more than one policy for each QSE.

A process describes activities that transform the intent of a policy into action. Processes, developed by the working groups, provide general instructions, assign responsibility for activities required to meet the intent of the policy, and are general in scope, not prescriptive. There may be multiple processes for each QSE.

Procedures are step-by-step instructions that define how to perform a single, specific task. They are usually developed by staff familiar with the actual task, and can be product inserts or instrument manuals that describe how to perform a specific test or perform a specific activity or function. There may be multiple procedures for each process.

Clinical and Laboratory Standards Institute (CLSI) has developed a helpful guidance series on how to develop, implement, and maintain a quality management system. Those guidelines are labeled with a QMS prefix followed by a number, such as QMSXX for Quality System Guidelines. More information and the guidelines may be found at www.clsi.org.
1. Policy
“The laboratory shall implement and use an internal quality control program designed to detect those analytical errors that can invalidate the reliability of patient test results.”

Wording in a policy is general in terms and specifies the intent of the laboratory. The wording assigns the responsibility for the quality of testing to laboratory management/supervision by using the words “The laboratory shall . . .”

2. Process
“Laboratory testing personnel shall use Westgard rules and biological variation limits for all quantitative tests to monitor the analytical quality of the test procedure (examination).”

Here the wording is more specific and describes in general the process to be used that will transform the intent of the policy into action.

3. Procedure
Procedure(s) supporting this process would give specific directions for monitoring analytical quality.

Some Examples of Procedures
- How to determine which Westgard rules are appropriate for a specific test
- How to interpret rule violations
- How to react when a Westgard rule indicates error is present
- How to set biological variation limits for each test
- How to react when biological variation limits are exceeded

In the example above, there was one policy developed for the ISO 15189 Quality System Essential (QSE) “Ensuring quality of examination results”. Often, there are many policies and procedures for every elemental quality policy. Overall, all policies, processes and procedures should trace to the Laboratory Quality Policy stated in the Quality Manual.

The illustration below demonstrates how each procedure is traceable to a process that in turn is traceable to the QSE policy(s) contained in the Quality Manual. Remember a policy statement sets direction and intent for a QSE. There can be one or more policies per QSE at the laboratory’s discretion.

Example Policy
ISO 15189 QSE 5.6: Ensuring quality of examination results:

Section 5.6.2.1 Requirement: The laboratory shall design quality control procedures that verify the attainment of the intended quality of results.
Understanding Each Quality System Essential

ISO 15189 has 25 Quality System Essentials. The following is an overview of each QSE according to its section number within the standard. Some examples are given and insights shared where appropriate.

**QSE 4.1: Organization & Management**

The laboratory must be legally identifiable and free of any financial or commercial conflicts of interest. Laboratory management is responsible for the design, implementation and maintenance of the quality management system. This is to be accomplished through policies and procedures, and by granting authority and responsibility to individuals to develop and maintain the management system. Laboratory management must provide adequate financial, educational and human resources, so that the laboratory can meet its stated objectives and mission. Management must also appoint a Quality Manager and deputies as required.

**QSE 4.2: Quality Management System**

Policies, processes and procedures shall be documented and communicated to all personnel. The laboratory shall have a quality policy statement documented in the Quality Manual. The laboratory shall have a Quality Manual.

**QSE 4.3: Document Control**

ISO 9000:2005 defines a document as “information (meaningful data) and its supporting medium.” In HS01-A2, CLSI defines document as “… an item of a factual or informative nature.” As a general rule, a document can be either a paper copy or electronic. It is something that is not written on, except perhaps for an approval signature and date of approval, or stamped with a seal to show that it is the master document. Procedures, product inserts, material safety data sheets, research papers or journal articles that might support a testing protocol are all examples of documents.

ISO 15189 requires that all documents be controlled. They must be approved for use by appropriate laboratory authority, usually the Laboratory Director. They must be reviewed at regular intervals to ensure continued relevance. This can be easily accomplished by having a master list, or inventory of documents, that shows which documents are currently in use, their revision number and the date of revision. The master list also identifies obsolete documents, which must be removed from all points of use.

Obsolete documents can be archived, but precautions must be taken to avoid inadvertent use. The laboratory must also have a procedure for making amendments and corrections to documents. All amended documents must be reviewed and approved for use by the appropriate laboratory authority. Maintenance of documents is a core requirement for achieving accreditation.

**QSE 4.4: Service Agreements**

At regular intervals, the laboratory must review any agreement for services it provides to its clients (including but not limited to clinicians, health care bodies, health insurance companies, pharmaceutical companies, and other departments such as pharmacy or nursing within the hospital structure) to ensure that the laboratory can meet the requirements such as methodologies, turn-around times, availability of expert opinion, etc. Records of these reviews shall be kept and maintained by the laboratory, and should include deviations.

Service Agreements do not always need to be formal documents between the laboratory and some outside resource. They can be verbal and informal, which may then be codified as policy. An example of this could be an agreement with medical staff by a laboratory in a hospital environment to meet a certain turn-around time for tests coming from the emergency department or the intensive care unit which later becomes a documented laboratory policy.

The illustration on page 9 identifies some of these laboratory customers.
**QSE 4.5: Examination by Referral Laboratories**

Laboratories frequently select referral laboratories (laboratories that provide analytical support to the primary laboratory) based solely on cost. ISO 15189 specifically requires laboratories to have a procedure for evaluating and selecting referral laboratories, as well as consultants who provide opinions for histopathology and/or cytology. Laboratories are also required to monitor the quality of referral laboratories. Selecting only laboratories that operate under an accredited quality system can be an initial means to accomplish this objective.

Alternately, the laboratory may submit previously determined specimens as unknown samples to the referral laboratory for analysis or interpretation, or require referral laboratories to share their performance scores from relevant EQA (proficiency testing) schemes. The laboratory must maintain a register of all referral laboratories it uses, and a register of all tests referred and results reported.

**QSE 4.6: External Services and Supplies**

The laboratory is required to have policy and procedures in place that describe what must be done before selecting an outside vendor. There should be verification that purchased services meet laboratory requirements/needs and purchased supplies meet manufacturer specifications, particularly for equipment, supplies, and consumables used to produce a laboratory test result. The laboratory can also begin by purchasing supplies, especially those critical to producing a test result, from vendors that operate under a certified or accredited quality system.

Most manufacturers of laboratory equipment, reagents and consumables already have numerous certifications from various organizations and government agencies, including the US FDA (Food and Drug Administration) Quality System Regulations (QSRs) and ISO (ISO 9000, or ISO 13485), or must comply with the European IVD Directive (CE Mark). The recommendation is to avoid purchasing from vendors who operate outside of a quality system, since they might produce products that may be low in cost but have poor reliability as a result of poor quality.
QSE 4.7: Advisory Services

The laboratory should meet regularly with clinical staff regarding services and clinical interpretation of results.

QSE 4.8: Resolution of Complaints

Complaints by laboratory clients about laboratory staff or services represent a primary opportunity to identify weaknesses in the quality management system and present an opportunity for improvement. The laboratory must keep a record of the complaint. The record should include the nature of the complaint, the date of occurrence, individuals involved, any investigations undertaken by the laboratory and the resolution.

QSE 4.9: Identification and Control of Nonconformities

When an occurrence conflicts with a stated policy, process or procedure, the occurrence is classified as a nonconformance (event), meaning that whatever occurred did not conform to the quality management system. Nonconformance events must be recorded, root cause investigated and documented, corrective action taken and then documented. Testing may be stopped and results withheld until the nonconformance is resolved, depending on the nature and criticality of the nonconformance. Results reported during a situation or period of nonconformance should be recalled when the nonconformance is of a critical nature. Nonconformance occurrences would include testing a plasma sample when a serum sample is required for the test; using expired reagents; modifying the test procedure without approval, as in increasing incubation temperature to shorten incubation time; using tap water to reconstitute reagents when the procedure requires use of distilled water; and improperly preserving a sample for later testing.

QSE 4.10: Corrective Action

The laboratory must have a procedure that describes and documents the reaction by the laboratory to a nonconformance occurrence once a root cause has been identified. The laboratory shall also monitor and document the effectiveness of the corrective action over time.

QSE 4.11: Preventive Action

The laboratory shall have appropriate and effective action plans to reduce the likelihood of nonconformance situations. Preventive action plans might include regular review of data generated from routine testing of quality control materials – looking for trends or bias. Plans may also include active participation in an external quality assessment (EQA) scheme (proficiency testing in the United States).

QSE 4.12: Continual Improvement

Laboratory management must review all operational procedures at regular intervals. The frequency should be no less than annually. Management shall implement quality indicators to monitor the laboratory’s overall contribution to patient care. The quality system should be reviewed for redundancies, such as policies or procedures that do little to enhance quality; and for inherent weaknesses, such as areas that have frequent nonconformance events or client complaints and therefore need closer scrutiny or tighter control.
QSE 4.13: Control of Records

ISO 9000:2005 defines a record as a “document (information and its supporting medium) stating results achieved or providing evidence of activities performed.” A definition is also provided in the Clinical and Laboratory Standards Institute QMS01-A4 standard. Here a record is defined as “evidence of results achieved or activities performed.” As a general rule, a record is something that is written upon. It can be electronic or on paper. Records include quality control records, instrument printouts, patient test reports, patient test requisitions, records of specimen referrals, nonconformity records, and complaint records. Records also include any log or list that is constantly modified by the laboratory, such as specimen acquisition records, calibration and maintenance logs, out-patient registers, and contact logs with outside clients. Records must be kept and maintained by the laboratory for specified periods of time as defined by the laboratory, government agencies, or accrediting bodies.

QSE 4.14: Evaluation and Audits

The quality system must undergo internal and external audits. The purpose of both internal and external audits is to verify the laboratory is in compliance with the quality management system. An external audit is usually performed by some agency or organization approved for such purposes. Passing the audit usually leads to accreditation of the laboratory. External audits typically occur every two years.

ISO 15189 recommends annual internal audits. Internal audits are usually performed by trained and qualified staff. It is important to recruit and train internal auditors from all sections of the laboratory operation. It is possible that a clerk, particularly one who is inquisitive, may make a very insightful and thorough auditor. Internal audit findings are documented and the laboratory must develop a plan to correct and/or respond to the findings. A reminder: documenting actions taken creates a quality record.

QSE 4.15: Management Review

Management must review the quality system at regular intervals. Normally this would be done annually, but shorter intervals are encouraged with a new quality system. The purpose of the review is for management to assess its level of commitment to the quality management system during the past 12 months, to evaluate the effectiveness of the system and to recommend changes as necessary. The review shall include an overview of all nonconformance events during the year, the actions taken, preventive measures put in place, feedback from clients, results of the internal quality control program, and performance in EQA or proficiency testing. Findings and actions taken by laboratory management as a result of the annual review are documented and become a quality record.

QSE 5.1: Personnel

Laboratory management must have and maintain job descriptions, including qualifications to perform specific jobs functions. Certified or licensed personnel should be utilized when required. Personnel making judgments regarding test results must possess appropriate knowledge and experience.

Management must provide adequate training, continuing education or access to training for technical staff, and assess staff competency at regular intervals.
QSE 5.2: Accommodation and Environmental Conditions

The laboratory shall have adequate space and a safe environment in which to perform testing. It must provide adequate lighting, ventilation, water, waste and refuse disposal. Attention should be given to dust, electromagnetic interference, ambient temperature and humidity levels, electrical supply, as well as sound and vibration levels. Records of environmental conditions, particularly temperature and humidity, should be kept and maintained where relevant or required. Work areas shall be clean and well maintained. Precautions must be taken to prevent cross contamination, particularly in laboratories performing mycobacteriology or nucleotide amplification techniques. The laboratory must also be designed to accommodate patient disabilities and privacy.

QSE 5.3: Laboratory Equipment

Laboratory equipment as defined in ISO 15189 are instruments, reference materials, consumables, reagents, analytical systems, and laboratory information systems. The laboratory shall have adequate equipment to perform testing to meet its stated laboratory mission. It must verify the equipment meets performance requirements specified by the laboratory or claimed by the manufacturer. The laboratory shall have policies and procedures that specify regular monitoring of instrument calibration and preventive maintenance.

Calibration and maintenance records must be maintained, including reports/certificates of all calibrations and/or verifications which should include dates, times, acceptance criteria, results, adjustments, and due date of the next calibration and/or verification. When equipment requires use of cofactors to modify raw data or transform a patient test result, the laboratory must have procedures in place to ensure that old cofactors are updated. Other requirements for information to be maintained by the laboratory such as equipment location, manufacturer, and condition when received are specified.

To comply with the requirements of the standard, the laboratory should verify the accuracy and imprecision claimed by the manufacturer for each test on a new instrument or kit before reporting any patient test results. Another means to check quality requirements for new reagent lots is to test control samples or reference materials before and after a reagent lot change to ensure that the test continues to operate within specification. The same holds true after recalibration, major maintenance or replacement of any major parts.

A program for calibration shall be executed to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference. Where none of these are possible or relevant, other means shall be applied, including participation in a suitable interlaboratory comparison program. Assurance of calibration traceability should be obtained from the manufacturer of the calibration material. It follows then that any sample tested by a method calibrated by a material traceable to a reference system, is itself traceable to this reference system. This applies to patient samples and control materials.

However, control materials are not required to be traceable unless they are intended to measure trueness. Most controls in use in laboratories today monitor day-to-day variation, not trueness, and are therefore exempt from the requirement for traceability.
Requests for testing must provide:

- Some form of patient identification
- Name of the ordering physician or other person authorized to order testing
- Clinician’s address
- Type of primary sample collected
- Anatomic site where appropriate
- Test requested
- Patient gender
- Date of birth
- Pertinent clinical information as appropriate for purposes of test interpretation
- Date and time of sample collection and receipt in the laboratory
- Preferred sample type (venous, arterial, capillary, urine, spinal fluid)
- Type of anticoagulant
- Sample volume considered acceptable

The laboratory shall maintain a record of all samples received. When a sample is transported to or from the laboratory, efforts must be made to monitor the time lapse between sample collection and receipt by the laboratory. In addition, the temperature during transport should be mentioned, since some samples must be kept at room temperature, others at 2-8°C or frozen.

The laboratory shall also have procedures on how to accept verbal requests, as well as approved procedures for proper specimen collection that address specific collection requirements. Procedures shall also describe requirements for patient preparation and storage of specimens once collected. The laboratory shall reject primary specimens not meeting identification or specimen requirements.
QSE 5.5: Examination Processes

The process of analysis shall be specified by validated written or electronic procedures maintained in and by the laboratory. Procedures may be authored by the laboratory or may be previously published materials including, but not limited to, product inserts, instrument manuals, textbooks, journals, or international guidelines. Test procedures developed by the laboratory (in-house procedures) must be validated and fully documented before being put into use. All procedures must be in a language commonly understood by laboratory staff. Reference intervals used by the laboratory must be reviewed at regular intervals the Laboratory shall determine the uncertainty of measurement for each quantitative test. CLSI guidance document C51, Expression of Measurement of Uncertainty in Laboratory Medicine describes one method to calculate this statistic.

QSE 5.6: Ensuring Quality of Examination Results

The laboratory shall have an internal quality control (QC) program to verify the quality of produced patient test results. While the character of the internal QC program is not specified in the ISO standard, in an effort to allow for flexibility, such a program should include regular testing of QC materials at a frequency sufficient to detect errors in the analytical process when error occurs. Laboratories should also consider the use of independent control materials; either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturers. ISO 15189 further requires that QC frequency be determined by taking into account both the performance of the test and potential risk of harm to a patient from an incorrect result.

Participation in an external quality assessment program (EQA) is required. A wide variety of programs exist, ranging from small private programs of limited scope to large commercial programs such as those offered by Bio-Rad Laboratories, Inc.

Commercial programs are often cost effective and international in scope. The College of American Pathologists (CAP) in the United States, Labquality in Finland and UK NEQAS in the United Kingdom are examples of three non-commercial providers of EQA programs.

QSE 5.7: Post Examination Processes

Authorized personnel shall routinely examine results before reporting. Once a sample is used, it must be maintained in the laboratory for a specified period of time (or as required by regulation or for accreditation) at a temperature that ensures stability of the sample, in the event that the sample is needed for retesting. Used samples shall be disposed of in a safe and environmentally sensitive manner.

QSE 5.8: Reporting of Results

Test results must be reported on forms approved by laboratory management under the quality system and must clearly identify:

- Patient
- Date and time of specimen collection
- Test performed
- Reference or normal range
- The laboratory interpretation where appropriate
- Name or initial of person performing the test
- Authorized signature of person reviewing the report and releasing the results

QSE 5.9 Release of Results

The results must be legible, without transcription mistakes and reported only to persons authorized to receive them, such as the ordering physician or nursing staff in a hospital environment. The report must also indicate whether the sample received was unacceptable for testing. Reports of test results are quality records and must be kept for a period of time specified by the laboratory or a government requirement. The laboratory must have procedures for handling critical values, automated reporting of results and revised reports.
QSE 5.10 Laboratory Information Management

The laboratory must have a documented procedure to protect the confidentiality of patient information. Authority and responsibility of the information system must be clearly identified in addition to responsible use of the system by laboratory staff. Since Laboratory Information Systems are intended to process/handle laboratory and patient data, including transfer of data, the lab must verify the data is accurately reproduced.

Computer software must be validated as appropriate before being put into use. Precautions must be taken to protect the integrity and privacy of the patient data archived in electronic formats. Access to the programs must be restricted to prevent alteration or destruction of data by unauthorized persons.

Conclusion

ISO 15189 is a standard for laboratory practice that was born from international cooperation and consensus. It was developed because many in the laboratory industry who favored having a clinical/medical laboratory standard felt that the existing ISO 17025 standard was not appropriate. ISO 17025 is intended for metrology laboratories.

Those laboratories measure the chemical concentration of substances in various media, such as water, solutions, etc. The accuracy expected of those laboratories can sometimes exceed 4 to 5 decimal places. Such accuracy is not required for clinical decision making. When ISO 15189 and ISO 17025 are compared, they have very similar QSEs except for the analytical portions of the standards.
Contact Information

Obtain a Copy of ISO 15189:2012

International Organization for Standardization
Web: www.iso.org
Phone: 41-22-749-01-11
Address: ISO
1, ch. de la Voie-Creuse
Case postale 56
CH-1211 Geneva 20
Switzerland

Clinical and Laboratory Standards Institute
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940 West Valley Road
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USA

Information on ISO 15189 Accreditation

To obtain a list of authorized accreditation bodies for your country, contact:

ASIA PACIFIC REGION
Asia Pacific Laboratory Accreditation Cooperation (APLAC)
Web: www.aplac.org

UNITED STATES
The American Association for Laboratory Accreditation (A2LA)
Web: www.a2la.org

OTHER REGIONS
International Laboratory Accreditation Organization (ILAC)
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