



# Preparations & Considerations When Seeking Laboratory Accreditation Under ISO 15189

Particular Requirements for Quality & Competence





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## Particular Requirements for Quality & Competence

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### Published by

Bio-Rad Laboratories, Inc.  
Quality Systems Division

### Acknowledgement

The author would like to acknowledge the valuable contribution Dr. Claude Giroud Ph.D. of Bio-Rad Laboratories (Marnes-La-Coquette, France) has made to the relevance of this booklet's content. As chair of the European Diagnostic Manufacturer Association's (EDMA) Accreditation Working Group, he has provided both insight and guidance in the writing of this material and kept the author focused on the spirit and intent of this international standard for medical laboratories.

# Forward

The duties of medical laboratories consist essentially of analyzing biological samples for purposes of screening, diagnosis, follow-up, and the treatment and prevention of disease. The laboratory's aim is not only to provide accurate results but also to do so within a reasonable turn around time, with traceability of all laboratory procedures, a respect for ethics and to assure the safety of patients and staff alike. A quality management system for laboratories sets standards for the requisition of the analysis, patient identification and preparation, collection, transportation, storage, processing and examination of patient samples, in addition to setting standards for validation and interpretation of patient test results. In order to obtain recognition for service and output quality, medical laboratories seek to demonstrate compliance with international standards. The reasons for doing this vary from mandatory requirements for accreditation by governmental agencies to pressures brought by peers or patients.

To answer this need for a recognized laboratory practice standard, ISO Technical Committee TC 212 developed ISO 15189 *Particular requirements for quality and competence* as an international consensus document. This work was undertaken to provide laboratories around the world a harmonized laboratory practice standard specific for clinical/medical laboratories. Many world opinion leaders felt the existing standard ISO 17025 *General requirements for the competence of testing and calibration laboratories*, while an excellent standard for the research or industrial laboratory, did not adequately address the unique structure, operation and needs of medical laboratories. ISO 15189 is intended as an accreditation standard, as opposed to a certification such as to ISO 9000.

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 some national standards bodies, from the ISO organization, or from the Clinical and Laboratory Standards Institute (formerly NCCLS).

After reading this material, you should:

- Understand the difference between certification and accreditation
- Understand the fundamentals necessary to prepare for accreditation under an ISO standard (i.e. ISO 15189)
- Understand the difference between a policy, a process and a procedure
- Become familiar with the fundamentals of a quality system under ISO
- Gain general familiarity with the content of ISO 15189

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] . ISO 15189 is intended as an accreditation standard and not for certification

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]. For accreditation, the rules require that the accreditation process be carried out by ‘third party’ organizations: that means not by peers, not by ‘first parties’ (suppliers) and not by ‘second parties’ (customers). ‘Third party’ is defined as a person or body that is recognized as being independent of the parties involved, in this case independent of the laboratory or the laboratory’s parent organization.



A third party organization that is granted authority to accredit laboratories may accredit those laboratories that successfully demonstrate competence and compliance with the requirements specified by a particular laboratory practice standard. For example, in the United States, the accrediting organization must demonstrate its practice standards comply with or exceed the minimum requirements established under the US CLIA<sup>1</sup> regulation. Outside the United States, laboratories may be accredited by an organization that bases its performance requirements on ISO 17025 or ISO 15189.

Many countries around the world have one or more organizations responsible for the accreditation of their laboratories. Adoption of ISO 15189 will help countries employ a uniform approach to determine medical laboratory competence. It will also encourage laboratories to adopt internationally accepted practices, where possible.

Laboratories without viable accreditation schemes in their countries can seek accreditation by established schemes offered elsewhere.

Any accreditation that is based on ISO 15189 shall include all the requirements specified by the standard. However, third party accrediting organizations or bodies may require a higher standard of performance. For example, ISO 15189 requires the laboratory to have an internal quality control program. A laboratory may create an internal program that specifies control materials to be tested only once per week for each test performed. Technically, the laboratory meets the requirement for ISO 15189. However, the accrediting organization, at its discretion, may interpret the requirement from a higher performance perspective and require the laboratory to test control materials each day the test is performed in order to receive their accreditation. This is one way accrediting organizations can differentiate themselves and encourage laboratories to strive to meet higher standards of performance and quality.

<sup>1</sup> Clinical Laboratory Improvement Amendments

# Preparations and Considerations When Seeking Laboratory Accreditation Under ISO 15189

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 must include representatives from laboratory management and supervision. Efforts must be made to include managers and supervisors that work during times different from normal daytime work hours. These individuals are often left out of laboratory decision making simply because they work different hours than those who own, run or manage the laboratory. These individuals are critical to the successful implementation and operation of the quality system because, in a 24-hour laboratory setting, they are responsible for the laboratory's output during nearly 2/3 of the laboratory's hours of operation. Remember that people tend to resist change and one key to successfully implementing change is to provide the opportunity to participate when planning the change. Participation can be aided by videotaping meetings for later viewing, email, or conference calling. 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 global 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. Then a comparison to ISO 15189 requirements (or accreditation requirements as appropriate) should be made. A gap exists where existing policies, processes or procedures do not fully meet the stated requirements. The remainder of this booklet assumes a major gap exists, because the laboratory has no quality system in place and must start from the beginning.

## Global Quality Policy

The global 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, what the laboratory's overall goals or objectives are. The wording should be general. One approach to writing a quality policy is to describe what commitments the laboratory is willing to make and then how (in general) the laboratory will meet those commitments.

### For example:

**“XYZ Hospital 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 that is 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 Manager must:

- Insure the components of the quality system are current and relevant
- Insure the quality system is audited at regular intervals
- Keep laboratory management informed of all activities and findings of the quality system
- Insure that all staff are committed to and actively involved in the quality system, adhere to its policies, and document system failures or non-conformances (deviations from the accepted norm)
- Facilitate introduction of new quality system procedures or modifications to existing procedures
- Act as liaison between the laboratory and other interfacing departments of the hospital and internally between various departments within the laboratory itself



Selecting a Quality Manager can be a difficult task. First the Steering Group and laboratory management must decide whether the Quality Manager should be a full time person focused solely on maintaining and evolving the quality system or should the Quality Manager share responsibility for the integrity of the quality system with other laboratory responsibilities. If the laboratory operation is large or has a complex organization, consideration should be given to a full time Quality Manager. 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 could 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 resort to negotiation, particularly with departments outside the laboratory such as 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 (or committees) that are responsible for writing policies, processes and procedures for each of element (quality system essential or QSE) of the quality system. The Steering Group must make every effort to involve all laboratory staff in working groups, regardless of job classification or hours of work. 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 appropriate for the quality system essential (QSE) on which the committee is working. Keep in mind that this ISO approach is a horizontal system and not vertical or "top down". It is participative and collaborative, not dictatorial or authoritarian. Everyone in the organization, from the Laboratory Director to the person who files patient reports, must actively participate in developing the quality system. Each laboratory employee should also have an opportunity to initiate change, when necessary, once the quality system is in place. The Quality Manual identifies laboratory management by name and position held in the organization, defines the reporting structure of the laboratory (organizational chart), provides a general description of the laboratory operation, and states the global quality policy for the laboratory. The global quality policy and organization chart is then followed by a compendium of high-level quality policies for each quality system essential of the quality system. The global quality policy, organization chart, and high level quality policies for each element of the quality system comprise the Quality Manual.

## To Summarize

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 to develop a global quality policy for the laboratory, to prepare a gap analysis, appoint a Quality Manger, and oversee development of the Quality Manual. The Quality Manual consists of a description of the laboratory, an organizational chart, the global quality policy and a compendium of high level policies for each quality system essential (QSE) of the quality system.

# ISO Documentation

## Constructing the Framework of a Quality System with Policies, Processes, and Procedures

A policy specifies intent and direction. Policies may be developed by the Steering Group, such as the global quality policy for the laboratory. However most policies originate from the formed 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, are general and 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 work 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.

There is limited published material on how to write a policy or process or how to create a quality system specifically for a clinical/medical laboratory. There are two guidelines, however, that are very helpful. They are available from the Clinical and Laboratory Standards Institute (formerly NCCLS), a global standards organization specializing in laboratory and clinical standards, and titled GP26-A2: *Application of a Quality System Model for Laboratory Services* and HS1-A2: *A Quality System Model for Health Care*. GP26-A2 and HS1-A2 provide good insight and direction on how to analyze laboratory operations and use that analysis to create policies, processes and procedures.

## For example

### ISO 15189 QSE 5.6:

#### Assuring quality of examination procedures

**Policy:** The laboratory shall implement and use an internal quality control program designed to detect those analytical errors, which can invalidate the reliability of patient test results.

Notice here the wording is general and specifies the intent of the laboratory. The wording assigns through implication the responsibility for the quality of testing to laboratory management/supervision by using the words “the laboratory shall. . .”

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

Notice here the wording is a bit more specific and describes in general the process to be used to transform the intent of the policy into action.

**Procedure:** Procedure(s) supporting this process would give specific directions for monitoring analytical quality including but not limited to:

- 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

There may be more than one policy per QSE and, there are often multiple processes for each policy.

## For example, another process and procedure for the previous policy:

**Process:** Laboratory staff shall test quality control materials at an interval and in combinations suitable to detect analytical error.

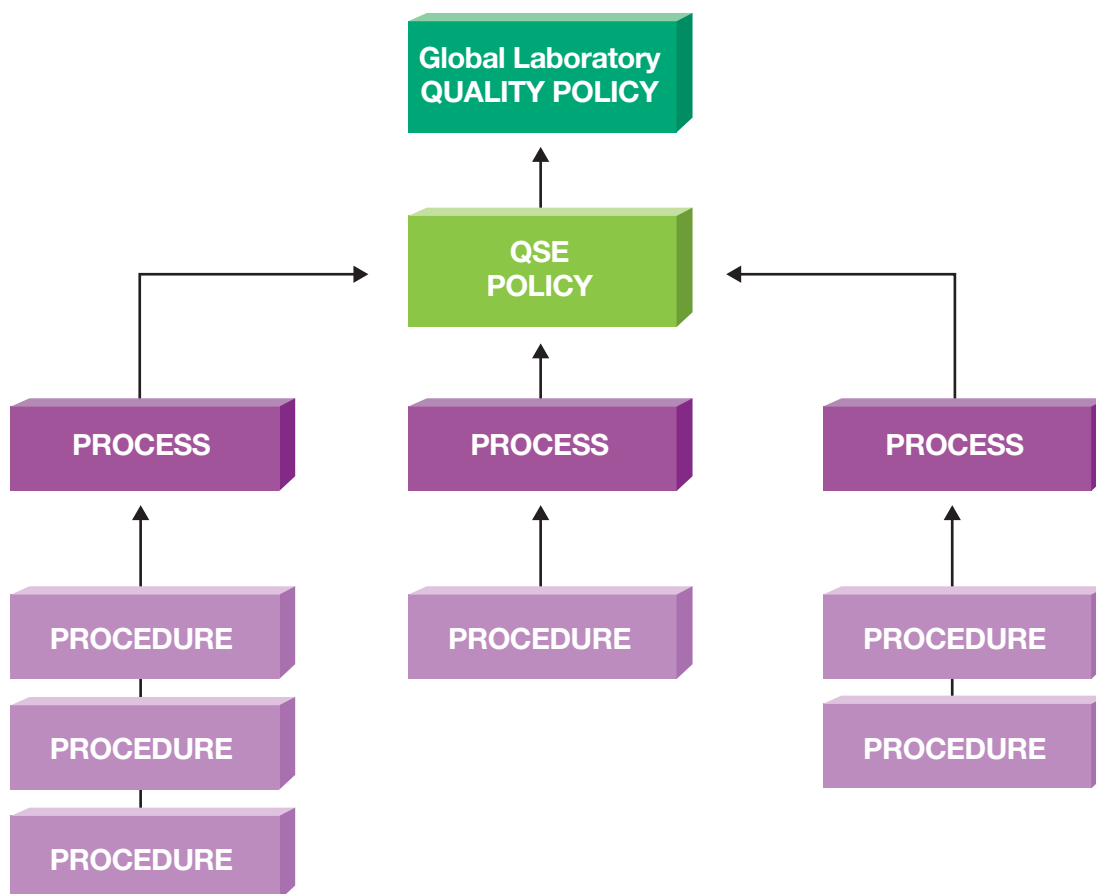
Again this process supports the original quality policy to insure reliable patient test results. It assigns responsibility to laboratory staff.

**Procedure:** The procedure would give specific directions about:

- When to test quality control materials
- Which concentrations of the control material to test (normal, abnormal low and/or abnormal high)

The graphic below illustrates how each procedure is traceable to a process that in turn is traceable to the QSE's 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.

In the preceding example, there was one policy developed for the ISO 15189 quality system essential (QSE) "Assuring quality of examination procedures". In turn, this policy was supported by two processes and several procedures. Usually, there are many policies and procedures for every elemental quality policy. Overall, all policies, processes and procedures should trace to the Global Laboratory Quality Policy stated in the Quality Manual.



## **ISO 15189 has 23 QSEs. The following material provides an overview of each QSE according to its section number in the standard. Some examples are given and insights shared where appropriate.**

### **QSE 4.1 Organization and Management**

The laboratory must be legally identifiable and free of any financial or political conflicts of interest. Laboratory management is responsible for the design, implementation and maintenance of the quality system. This is to be accomplished through policies and procedures and by granting authority and responsibility to individuals to develop and maintain the 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. This is often accomplished through the Steering Group.

### **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 9000-2000 defines a document as “information (meaningful data) and its supporting medium”. In HS1-A2, the Clinical and Laboratory Standards Institute (formerly NCCLS) defines document as “. . . an item of a factual or informative nature”. As a general rule, a master document can be either a hard 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 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 based on an ISO standard.

### **QSE 4.4 Review of Contracts**

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

Contracts need not always be formal documents between the laboratory and some outside resource. Contracts can be verbal and informal in the form of agreements, which may then be codified as policy. An example of this would 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. Consequently, clients or customers may take different forms depending on the laboratory operation. Table 1 identifies some of these customers.

**Table 1: List of potential laboratory customers**

Type of Laboratory	Potential Customers/Clients
<p><b>Hospital-based</b></p> 	<ul style="list-style-type: none"> <li>• Emergency</li> <li>• Infection control</li> <li>• Intensive care units</li> <li>• Medical school (if part of institution)</li> <li>• Medical staff</li> <li>• Nursing administration</li> <li>• Outpatients</li> <li>• Pharmacy</li> <li>• Radiology</li> <li>• Referring clinicians</li> <li>• Research laboratories (if part of institution)</li> <li>• Suppliers/vendors</li> <li>• Utilization review</li> </ul>
<p><b>Remote or Clinic-based</b></p>	<ul style="list-style-type: none"> <li>• Community</li> <li>• Main or parent laboratory</li> <li>• Medical staff</li> <li>• Referring clinicians</li> <li>• Suppliers/vendors (not always-depends on autonomy)</li> </ul>
<p><b>Reference Laboratories</b></p>	<ul style="list-style-type: none"> <li>• Clinicians</li> <li>• Governments (including military)</li> <li>• Pharmaceutical companies</li> <li>• Referring laboratories</li> <li>• Suppliers/vendors</li> <li>• University-based research entities</li> </ul>

**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. Beyond this, 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 results 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, and verify 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 major pieces of laboratory equipment, reagents and consumables already have numerous certifications from various organizations or government agencies, including the US FDA<sup>2</sup> Quality System Regulations (QSRs) and ISO (ISO 9000-2000, 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/accuracy and little stability.

## **QSE 4.7 Advisory Services**

The laboratory should meet regularly with clinical staff regarding services and clinical interpretations.

## **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 system and 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 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, meaning that whatever occurred did not conform to the quality system. Nonconformances must be recorded, root cause investigated and documented, and corrective action taken and documented. Testing may be stopped and results held until the nonconformance is resolved, depending on the nature and criticality of the nonconformance. Results reported during the nonconformance should be recalled when the nonconformance is of a critical nature. Nonconformances would include testing a plasma sample when a serum sample is required for the test, using expired reagents, modifying the test procedure without approval such as 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 once root cause is 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. Preventive action plans might include regular review of data generated from routine testing of quality control materials –looking for trends or bias perhaps. Plans may also include active participation in an external quality assessment (EQA) scheme (proficiency testing in the United States).

<sup>2</sup>Food and Drug Administration



#### **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 nonconformances or client complaints and therefore need closer scrutiny or tighter control.

#### **QSE 4.13 Quality and Technical Records**

ISO 9000-2000 defines a record as a "document (information and supporting medium) stating results achieved or providing evidence of activities performed."

A definition is also provided in the the Clinical and Laboratory Standards Institute (formerly NCCLS)

HS1-A2 standard. Here a record is defined as "a document that furnishes objective evidence of information obtained, activities performed or results achieved."

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, and patient test requisitions, records of specimen referrals, nonconformity records, complaint records, and 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 Internal Audits**

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

ISO 15189 specifically requires annual internal audits. Staff usually performs internal audits. It is important to recruit and train internal auditors from all sections of the laboratory operation. It is possible to find 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. Again, documenting actions taken creates a quality record.

#### **QSE 4.15 Management Review**

Management must review the quality system at regular intervals, usually annually but shorter intervals are encouraged when a quality system is new. The purpose of the review is for management to assess its level of commitment to the quality system during the past 12 months, evaluate the effectiveness of the system and recommend changes as necessary. The review shall include an overview of all nonconformances during the year, the actions taken, preventive measures put in place, feedback from clients, results of the internal quality control program, 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, and use certificated or licensed personnel when required. The Laboratory Director must possess knowledge and experience to direct the laboratory and support the professional and consultative services required. Management must provide adequate training, continuing education or access to training for technical staff, and assess staff competency at regular intervals. Management must also have policies and procedures in place to protect the privacy of patients and integrity of patient records whether printed or electronic. ISO 15189 provides a comprehensive list of responsibilities for the Laboratory Director, or designee, from community relations to staff morale.

## **QSE 5.2 Accommodation and Environmental Conditions**

The laboratory shall have adequate space and a safe environment 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, and 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 is defined as instruments, reference materials, consumables, reagents and analytical 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 co-factors to modify raw data or transform a patient test result, the laboratory must have procedures in place to ensure that old co-factors are removed, deleted or otherwise made unavailable and replaced with the new factors. 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.

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.



#### **QSE 5.4 Pre-examination Procedures (Pre-analytical)**

##### **Requests for testing must provide:**

- Some form of patient identification
- The name of the ordering physician or other person authorized to order testing
- The clinician's address
- Type of primary sample collected
- The anatomic site where appropriate
- The 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

The laboratory shall also have procedures on how to accept verbal requests.

##### **In addition, the laboratory shall have approved procedures for proper specimen collection that address specific collection requirements such as:**

- Preferred sample type (venous, arterial, capillary, urine, spinal fluid)
- Type of anticoagulant
- Sample volume considered acceptable
- Patient identification

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.

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 and the temperature during transport, since some samples must be kept at room temperature, others at 2-4°C or frozen.

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) and at a temperature that ensures stability of the sample in the event the sample is needed for retesting.

#### **QSE 5.5 Examination Procedures (Analytical)**

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, procedure or 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.

## **QSE 5.6**

### **Assuring Quality of Examination Procedures**

The laboratory shall have an internal quality control (QC) program to verify the quality of patient test results produced. While the character of the internal quality control program is not specified in the ISO standard in an effort to allow for flexibility, such a program should include regular testing of quality control materials at a frequency sufficient to detect error in the analytical process when error occurs. The frequency of QC should depend on test stability, test frequency (e.g., daily versus weekly), the average number of samples processed (e.g., 5 versus 500) and the method used (e.g., colorimetric versus immunoassay). A rule of thumb could be to test control materials each day a test is performed and at concentrations that challenge the reportable range.

The laboratory shall determine the uncertainty of measurement for each test where relevant and possible. There is still some discussion in the laboratory community about how uncertainty should be calculated. Some support the procedure described in the Guide to Uncertainty of Measurement (GUM). This procedure is burdensome, complicated and not relevant to clinical laboratory testing. It is appropriate for a metrology laboratory, not a clinical laboratory. A simplified procedure that produces results very similar, if not identical to the GUM procedure, has been recommended by EDMA (European Diagnostic Manufacturers Association). This procedure allows laboratories to use data that are commonly provided by interlaboratory comparison programs and published biological variation data.

A program for calibration shall be designed and 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 trueness. An illustration of the calibration traceability chain is provided in the diagram on the facing page.

Laboratories are encouraged to participate in interlaboratory comparison programs to assess relative accuracy when they are unable to measure trueness. Use of trueness controls or reference materials is very expensive. Interlaboratory comparison programs offer a cost-effective and reliable alternative.

Participation in an external quality assessment program (EQA) is required. A wide variety of programs exist, from small private programs of limited scope to large commercial programs such as those offered by Bio-Rad Laboratories or Randox. Commercial programs are often cost effective and are international in scope. The College of American Pathologists (CAP) in the United States, Labquality in Finland and CEQAL in Canada are examples of three non-commercial providers of EQA programs.

## **QSE 5.7**

### **Post Examination Procedures (Post-analytical)**

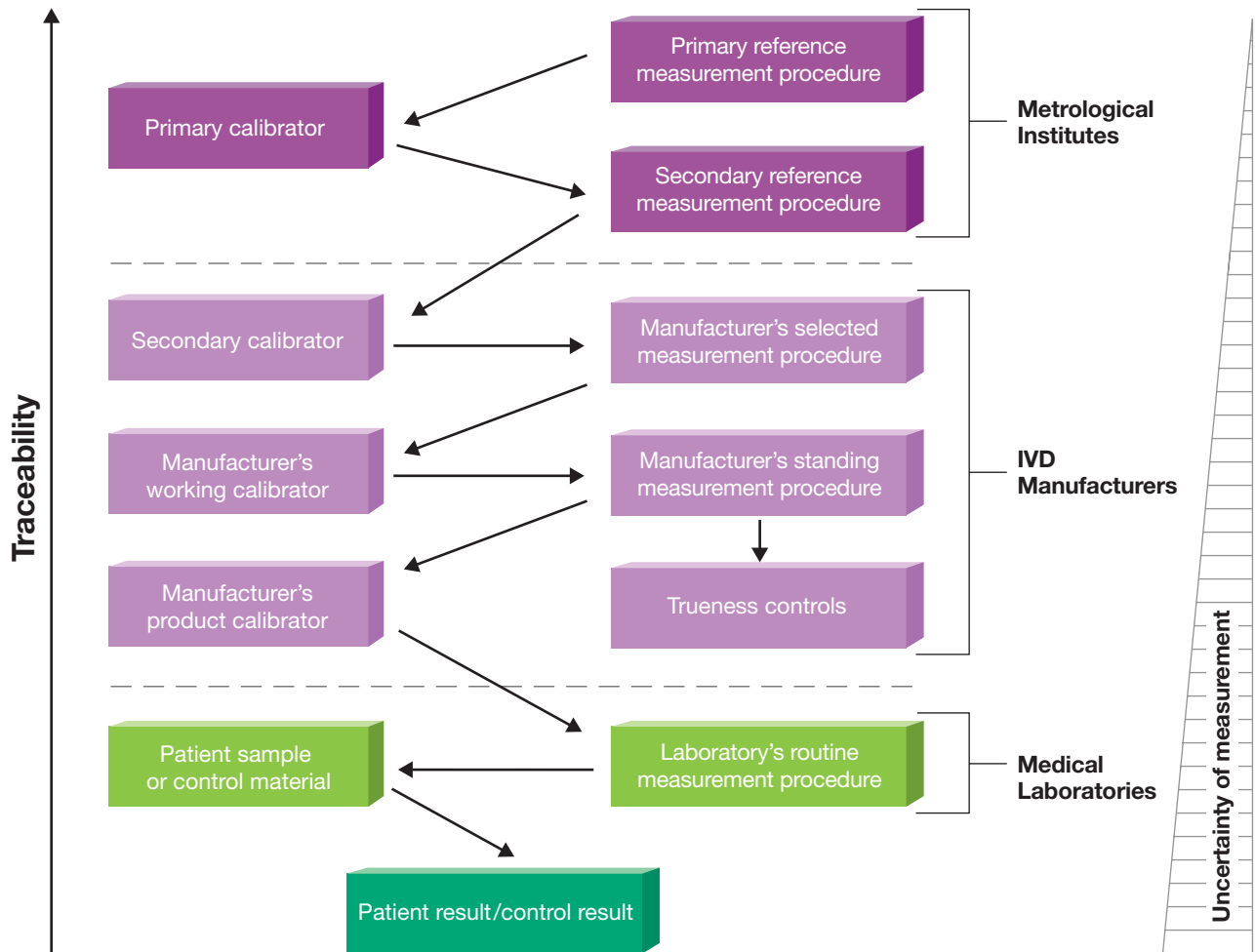
Authorized personnel shall routinely examine results before reporting. Used samples shall be disposed in a safe and environmentally sensitive manner.

## **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 the patient, date and time of specimen collection, the test performed, the reference or normal range, the laboratory interpretation where appropriate, the name or initial of the person who performed the test, and the authorized signature of the person reviewing the report and releasing the 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 if 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 some government requirement.

**Table 2: Traceability**



Modified from ISO 17511:2003 (E) *In vitro diagnostic medical devices-Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials*

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.

These laboratories measure the chemical concentration of substances in various media, such as water, solutions, etc. The accuracy expected of these laboratories can sometimes exceed 4 to 5 decimal places. Such accuracy is not required for clinical decision making or measuring the biological effectiveness of care given. When the two standards are compared, they have very similar QSEs except for the analytical portions of the standards.

**Laboratories who wish to obtain a copy of ISO 15189 may contact one of the following organizations or a local national standards body.**

**International Organization for Standardization**

Web: [www.iso.org](http://www.iso.org)  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
E-mail: [sales@iso.org](mailto:sales@iso.org)  
Post: ISO, 1, rue de Varembe  
CH-1211 Geneva 20, Switzerland

**Clinical and Laboratory Standards Institute (formerly NCCLS)**

Web: [www.clsi.org](http://www.clsi.org)  
Phone: +1 610 688 0100  
Fax: +1 610 688 0700  
Post: 940 West Valley Road, Suite 1400  
Wayne, PA 19087, USA

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**Laboratories interested in the GP 26 or HS1 standards should contact the Clinical Laboratory Standards Institute.**

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**Laboratories wishing to obtain more information about certification or accreditation may contact any of the following organizations:**

**Asia Pacific Laboratory Accreditation Cooperation (APLAC)**

Web: [www.ianz.govt.nz/aplac](http://www.ianz.govt.nz/aplac)  
(provides listing of member accrediting organizations by country)

**OneWorld-Lab, LLC**

Web: [www.oneworldlab.com](http://www.oneworldlab.com)  
Phone: +1 410 340 1786  
Fax: +1 866 280 0199  
Post: 1700 Union Avenue, Suite B  
Baltimore, MD 21211 USA

**College of American Pathologists (CAP)**

Web: [www.cap.org](http://www.cap.org)  
Phone: +1 847 832 7000  
Fax: +1 847 832 8000  
Post: 325 Waukegan Road  
Northfield, IL 60093-2750 USA

**International Laboratory Accreditation Organization (ILAC)**

Web: [www.ilac.org](http://www.ilac.org)  
(provides listing of member accrediting organizations by country)



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*Clinical  
Diagnostics Group*

**Website** [www.bio-rad.com/diagnostics](http://www.bio-rad.com/diagnostics) **U.S.** 1-800-2BIO-RAD **Australia** 61-2-9914-2800 **Austria** 43-1-877-8901 **Belgium** 32-9-385-5511 **Brazil** 5521-3237-9400  
**Canada** 1-514-334-4372 **China** 86-21-64260808 **Czech Republic** 420-241-430-532 **Denmark** +45-4452-1000 **Finland** 358-9-804-22-00 **France** 33-1-47-95-60-00  
**Germany** +49-(0)89-318-840 **Greece** 30-210-7774396 **Hong Kong** 852-2789-3300 **Hungary** +36-1-459-6100 **India** 91-124-4029300 **Israel** 972-3-9636050 **Italy**  
+39-02-216091 **Japan** 81-3-6361-7070 **Korea** 82-2-3473-4460 **Mexico** +52(55)5488-7670 **The Netherlands** +31-318-540666 **New Zealand** 64-9-415-2280 **Norway**  
47-23-38-41-30 **Poland** 48-22-3319999 **Portugal** 351-21-472-7700 **Russia** 7-495-721-14-04 **Singapore** 65-6415-3188 **South Africa** 27-11-442-65-08 **Spain** 34-91-  
590-5200 **Sweden** 46-8-555-127-00 **Switzerland** 41-61-717-95-55 **Thailand** 662-651-8311 **United Kingdom** +44-(0)20-8328-2000