

Assuring quality and competence

A guide for medical laboratories seeking
accreditation to ISO 15189

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Tests performed by clinical laboratories have markedly improved in accuracy, reproducibility, and speed. There is more agreement between laboratories, and the tests offer better specificity with disease conditions and diagnostic capability. This change has occurred due to technological advances and the introduction of quality management systems (QMSs) in the laboratories. Dependence on laboratory tests has increased; simultaneously the clinicians and patients have higher expectations.

To meet these challenges a laboratory must establish a QMS and acquire competence to perform the task. A third-party audit by an independent body not only ensures that both these have been attained, but also instils confidence in laboratory personnel and clients. There are several reputed accreditations which specify the requirements of the QMS and competence of personnel, and, following a rigorous audit, certify the laboratory that meets these requirements. Conformity with the requirements of ISO 15189 is gradually becoming more popular the world over, and many countries have established accreditation bodies for this standard.

Most of the contributors to this book have been assessing clinical laboratories for accreditation. They have observed that many well qualified and experienced Laboratory Directors find it difficult to comprehend the requirements. Sometimes even the assessors do not fully understand the intent of the clauses.

The book is designed to help everyone understand the clauses of the ISO 15189:2012 Standard. Based on their experience, the authors have provided several examples of nonconformities that make it easier to understand the intent of the clause. It is our objective that this book help laboratories find a smoother path to accreditation. It is also our hope that laboratories already accredited will use it to understand the clauses better, and in their pursuit of continual improvement.

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4.7 Advisory Services

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I Explanation Of The Clause

The laboratory is required to establish a system for providing advisory services to users. According to the Standard, it must cover the following: list of tests and procedures offered, choosing the right tests, effective use of the services, type of sample, and the indications, limitations, and recommended frequency of testing.

- a Laboratories are required to inform users about the tests and procedures they offer.** The laboratory should advise users regarding the clinical indications for tests as well as their limitations. For example, if a laboratory offers a d-dimer test it should inform users of the fact that an elevated d-dimer is not specific for thrombosis. In addition, users should be informed of pre-analytical requirements of sample collection. This includes patient preparation, type and quantity of specimen required, time of collection, and storage and transport conditions. The schedule (day of the week or specific dates) for tests that are not performed daily should also be provided. The request form should be designed so that the referring clinician can provide relevant demographic details and clinical information. Pre-analytical requirements in the hospital setting are generally provided on the Hospital Information System (HIS) or the Laboratory Information System (LIS). The information can also be provided in manuals and circulars. Large multi-centric clinical laboratories have catalogues containing details (including scheduling) of the tests they perform, sampling requirements, collection timings, and TAT. The laboratory should also advise clients on the optimal usage of tests. For example, it may advise HbA_{1c} testing every six months for stable diabetics, or quarterly in those who have not met glycemic goals [American Diabetes Association, 2003].
- b Laboratories must provide advice on individual cases, and offer professional judgments.** Most stand-alone laboratories design their reports to give the test result and reference intervals followed by an interpretation. Laboratories also advise further tests that are likely to help establish the diagnosis or to be useful in monitoring the patient's condition. The laboratory often needs to advise users regarding the clinical indications of tests. Patients and clinicians will often ask for, or should be advised of, the implications of a test result. In addition, the laboratory also needs to provide advice on a case-by-case basis. For example, a known diabetic with a fasting blood glucose of 150 mg/dL should be advised HbA_{1c} determination to assess control of diabetes mellitus. Or, a patient with microcytic hypochromic anemia may also need to be advised tests to exclude iron-deficiency anemia or a thalassemia trait (Box 4.7-1). It is equally important that users are adequately apprised of the limitations of the investigations. For example, a report of an ELISA test must contain the sensitivity and specificity of the test. A positive direct anti-globulin test (Coombs' test) should be followed by statements indicating that the test may be positive in 1/11000 to 1/114000 apparently healthy blood donors. Depending upon the technique and the clinical profile frequency, the false positivity is reported to be 1% to 15% [Karp and King, 2015].

Box 4.7-1 Advice regarding choice of investigations

A 40-year-old female came to the OPD for with headaches. Her laboratory findings were: RBC $4 \times 10^9 / \mu\text{L}$; Hb: 10.2 g/dL; Hct: 31.7 %; MCV: 79.1 fL; MCH: 25.5 pg; MCHC: 32.1 g/dL; RDW: 16.2 CV%; Platelets: 1,086,000/ μL . The patient was admitted to neurology due to headache and very high platelet count. The internal medicine consultant made a diagnosis of essential thrombocythemia, and prescribed hydroxyurea. The neurologist requested the laboratory's hematologist to exclude the possibility of a laboratory error. The hematologist noted the marked thrombocytosis, and observed that the red cell indices were suggestive of iron deficiency anemia – a common cause of high (and occasionally very high) platelet counts. The hematologist suggested further tests to determine iron status and start iron therapy pending report.

Further investigations confirmed iron deficiency. Iron therapy resulted in normalization of the platelet count.

- c Laboratories must offer judgments on the interpretation of the results of examinations.** Practically all clinical laboratories incorporate an interpretation of the test result in their report. The result should be correlated with clinical findings whenever they are provided or can be obtained. It is a healthy practice to communicate with the treating physician in order to arrive at a definite diagnosis. Whenever there is a doubt, discuss the result with the requesting physician and if necessary repeat the test.
- d Laboratories must promote effective utilization of laboratory services.** Laboratories should ensure that its services are optimally utilized. This refers mainly to the choice and frequency of examinations. Inappropriate utilization may include under-utilization (not ordering a test that should have been ordered), over-utilization (requesting too many or too often), or ordering wrong tests [Uras, 2015; Krasowski et al, 2015]. Much work has gone into this area, and several recommendations have been offered. One obvious method of improving utilization is by providing comprehensive information to users. Other methods include clearly stating the cost when the clinician orders a test, and placing automated limits on repetitive tests [Krasowski et al, 2015]. The laboratory can develop a process of periodic dialogue with users about their expectations from the laboratory including their targets for TAT.
- e Laboratories must offer advice on scientific and logistic matters.** Analytical instruments have markedly improved during the last 3 decades in their ruggedness, precision, speed, storage capacity, communication, and interfacing. The LIS can store data and perform delta checks. It can flag abnormalities in the report, failures in IQC, and delays in reporting. It can electronically deliver reports and handle many other requirements. In spite of these advances, errors do occur – though less often than before. About 60-90% of errors occur due to a failure of the QMS in the pre-examination phase of testing. It is, therefore, important to explain to users (clinicians) that errors in test results are mostly due to faults in sampling [Hawkins, 2012]. The laboratory may need to explain how a sample should be collected, and why a sample was rejected.

Communication with users

The Standard has not prescribed any definite method of communication and allows laboratories to evolve their own systems. There could be several methods of establishing efficient communications with users.

Large multi-centric laboratories communicate with clients by one or more of these procedures:

- Maintaining a directory of services containing a list of tests performed, frequency of testing, pre-analytical requirements, TATs, and the charges for each test. The directories are distributed to prominent physicians, large hospitals and corporate clients.
- Providing all this information on their websites.
- Supporting CME programs, which, besides educating, gives laboratories the opportunity to advertise the services they provide.
- Offering discounted packages.

Medium and small-sized laboratories have fewer resources, and usually restrict themselves to advertising through pamphlets.

Communication in hospital-based laboratories is mainly with treating physicians, who are generally on the premises. There are greater opportunities for frequent interaction, which is far more intense and scholarly.

Communication is strengthened when laboratory physicians advise clinicians on the management of patients with infectious diseases and the selection of suitable antibiotics. They should also serve on infection control committees and tumor boards, and participate in clinical rounds.

II Quality Manual

A Policies

The management of KBG Hospital and its Laboratory firmly believe that effective communication with users is extremely important for the Laboratory's success. A strong advisory service reduces the risk of errors originating in the pre-analytical phase. Patient care is improved, and wasteful testing reduced, by interaction with clinicians – providing a choice of tests, interpretation of results, and advice regarding further investigations.

B Processes and procedures

The KBG Hospital Laboratory has developed a procedure for Advisory Services.

KBG Hospital Laboratory, Indira Estate Jamnagar, Gujarat	
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UID: KBG-DP-Clause 4.7-Advisory Services-2014-07-04. The present document has been reviewed and replaces UID KBG-DP-Clause 4.7-Advisory Services-2013-07-03	
Title: Procedure for Clause 4.7 Advisory Services	
Author: QM	Approved and authorized by: LD
Accessibility:	
For alteration: LD and QM with approval of the LD	
For application: Residents and Consultants	
Amendment: No amendment was required.	
Scope: This document describes the procedure for Clause 4.7 Advisory Services as applicable to KBG Hospital Laboratory	
Responsibility: The LD has delegated responsibility to the QM for this document's development, review, and submission for authorization.	

The Laboratory communicates with clinicians, patients, and other users regarding

- a** its services, information on the type and collection of samples, indications and limitations of tests, and appropriate frequency of requests for a specific test.
- b** individual cases, to offer advice.
- c** interpretation of examination results.
- d** information on scientific, administrative, and logistic matters.

The Laboratory provides advisory services to clinicians as follows:

- a** Verbal consultations, including telephonic conversations: no records are maintained.

- b** Written opinions on inpatients when requested by the treating consultant. The request and the opinion (duly signed and stamped) are recorded in the patient's file. No other record is maintained.
- c** Written consultations requested by clinicians from outside the Hospital. An electronic record of the opinion along with a scan of the original request are chronologically filed. The opinion is printed on the Laboratory's stationery and signed above his name and designation by the person providing it. The records are retained for 5 years.
- d** In addition, the Laboratory has the following procedures regarding advisory services:
- e** Where relevant the validated report includes an interpretation (including limitations) of the result and advice on further tests.
- f** The departments of Histopathology and Cytopathology hold ten clinicopathological meetings a year where clinicians and Laboratory physicians participate, and cases of interest are presented. The sWchedule is prepared in December of the previous year. Electronic records of the meetings are maintained and retained for 5 years.
- g** Certain clinical consultants often come to the Laboratory to review microscopic slides. This is done most frequently by consultants from Clinical Hematology, Dermatology, and Nephrology.
- h** The HOD of Microbiology is the Chairman of the Infection Control Committee and the committee which monitors the appropriate use of antibiotics.
- i** Clinicians frequently seek advice from microbiology consultants on choosing the right antibiotic.
- j** The Histopathology consultants are members of the Hospital's Tumor Board.
- k** The Hematopathology consultants are members of the Lymphoma Leukemia Board.
- l** The list of examinations (tests) offered by the Laboratory is accessible to Hospital staff. It has the following five columns: Name of the test; Sample requirements (collection, containers/vials); Frequency; TAT; Referral laboratories. The list is available on the Laboratory's webpage, as well in its Directory of Services.
- m** The Laboratory promotes the utilization of services through the clinicopathological meetings, by participating in ward rounds with clinicians, inviting them on Management Review Meetings, and by organizing continuing medical education (CME) programs. The records of Management Review Meetings are retained (see Clause 4.15).

About this book

This book **explains in lucid detail the intent of the ISO 15189 Standard**. This will make it easier for a laboratory to understand and implement its clauses.

Accreditation implies quality. This book **explains the science behind the clauses**, to help labs achieve quality and continual improvement.

It also illustrates, using a fictional lab as an example, **how a lab needs to maintain its quality manual**.

If you are planning accreditation for your lab, this book will save you money and time.

You will learn, from people who are or have been assessors themselves, what assessors look for.

Guidance from the experts

The chief editor of this book is Dr Swaroop Krishan Sood, a long-time leader in laboratory medicine. He was Chairman of the Technical Committee for the preparation of NABL Document 112. He was also Chairman of the Accreditation Committee of the NABL.

Most of the other authors have years of experience as assessors (many as lead assessors) for the NABL.

The book will be published online in March 2017.

A print version of the book will also be available soon.

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