Procedure for Internal Audit and Format

Aims and objectives:

To ensure that the laboratory conducts internal audit to provide information on whether the management system is functioning appropriately for continuous improvement of the quality and operating systems established by the laboratory are effective covering the followings.

Procedure:

a) The periodicity of internal audit shall be at least once in a year ensuring that all the departments of the laboratory are covered under the internal audit appropriately.

b) To conform that the laboratory's own requirements for its management system, including the laboratory activities are functioning as per ISO-17025 requirements;

c) The laboratory quality and management system is effectively implemented and maintained;

c) The internal audit can be undertaken within the laboratory inter-departmental process or by engaging an independent third party/outsourced competent to carry out this activity, as the case may be.

d) Each department/discipline of the laboratory will cover under internal audit process so as to complete all the laboratory activities within the periodicity;

e) The QM of the laboratory shall ensure that the results of the internal audit findings are reported to the Management;

f) The Management shall be responsible for implementation of appropriate correction and corrective actions without undue delay;

g) The QM shall retain records as evidence of the implementation of the internal and the audit results.

h) The format for conducting internal audit will cover the following major areas which will be kept updated based on need of the laboratory from time to time.

   (i) Name of Auditor carried out Internal Audit:

   (ii) Internal auditor or

(iii) External auditor

(iv) Date(s) of Internal Audit:

i) Format of the internal audit of the laboratory is as follows:

Areas of Audit	Areas Audited	Findings	Is corrective action Required
Organizational Structure	Is the structure well defined		
	Is the role and responsibility of the organization clearly defined		
	Is the actual activities conforms to the defined roles		
	Do the various committees meet as per assigned frequencies		
	Are the minutes of the meetings properly filed and updated		
QM/OM checklist/ formats	Do the manuals cover all the aspects as per ISO 17025		
	Do the manual reflect the actual procedures		
	Is a person assigned to manage the manuals		
	Is the person appropriately trained for maintaining the manuals		
	Are the contents of the manual known to the concerned personnel of the laboratory		

Areas of Audit	Areas Audited	Findings	Is corrective action Required
	Is the manual updated		
	Is the master document properly signed and controlled		
	Is the updated part distributed to relevant persons		
Deployment of laboratory personnel	Are number of personnel proportional for the quantum of work undertaken		
	Are the minimum requirement of staff defined in terms of qualification, training, experience, etc.		
	Do the personnel meet the defined minimum requirement		
	Is the performance appraisal of the personnel done regularly as per policy		
	Are the records of the personnel maintained as per ISO 17025 requirements		
	Is the record up to date		
	Do all the relevant personnel have signed the confidentiality agreement		
	Is the conflict of interest declaration of relevant personnel updated		

Areas of Audit	Areas Audited	Findings	Is corrective action Required
	Is the conflict of interest criteria resolved before assigning work		
	Are the personnel aware of their roles and responsibilities		
	Are the personnel trained as per the policy		
	Is the training record up to date		
	Are the personnel provided with enough resources for the proper fulfillment of assigned activities		
	Are new personnel given adequate orientation/training before assigning activities		
Analysis of samples	Is the analysis of samples undertaken within reasonable time		
	Is the report complete		
	Is the report having relevant annexures		
	Do the analysis reports reach the client within reasonable time		

Areas of Audit	Areas Audited	Findings	Is corrective action Required
	Do the analysis report formats cover all aspects		
	Do the analysis clearly understand and follow the procedures of analysis		
	Has feedback been taken from interested party		
Quality Management System	Are there clear procedures and policies for internal audit		
	Are internal audits conducted annually		
	Are internal audits documented		
	Is the internal audit result presented to the top management		
	Do the management review take palace as per scheduled frequency		
	Have corrective actions been implemented in given time frame		
	Have the staff with conflict of interest excluded from respective inspection and certification decisions		
Documentation	Are there clear policies and procedures for document management		

Areas of Audit	Areas Audited	Findings	Is corrective action Required
	Are the documents numbered, approved and stored as per procedures		
	Is it easy to retrieve the current version of the documents		
	Are the old version archived properly		
	Are all the documents up to date		
	Are updated versions distributed to relevant persons		
	Are there enough documents for efficient functioning of the accreditation process		
	Are the forms and formats easy to use by the respective users		
Records	Are all the records as per the approved list kept		
	The records of each operator are kept properly		
	Is the system of record keeping ensure confidentiality		

Areas of Audit	Areas Audited	Findings	Is corrective action Required
	Is it easy to retrieve the records?		
	Are old records kept properly for the specified period		
Procedure for Complaints, Appeals and Redressal	Are all complaints/referral requests to the laboratory recorded, investigated and reports sent within stipulated period		
	Is procedure for public complaint exists		
	Are all the complaints and appeals received properly filed		
	Have action been initiated on the complaints/appeals		
	Are the complaints/appeals sufficiently followed up		
	Is the resolution of the complaints/ appeals made known to the complainant?		
	Are the complaints/appeals resolved within specified time		

Signature of Auditor:

Name:

Date: