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| 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.

1. Name of Auditor carried out Internal Audit:
2. Internal auditor or
3. External auditor
4. 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 |  |  |
| 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 |  |  |
| 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 |  |  |
| 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 |  |  |
| 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 |  |  |
| 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: