ISLAMABAD HEALTHCARE REGULATORY AUTHORITY

Minimum Service Delivery Standards For Clinical Labs

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1 SCOPE

This IHRA Standards prescribe the management and service provision standards for clinical laboratories. For laboratories existing within hospitals and healthcare facilities will be covered through the laboratory component of that healthcare establishment's standards.

2 NORMATIVE REFERENCES

IHRA 1003:2020 IHRA Standards for Clinical Laboratories

3 TERMS AND DEFINITIONS, AND ABBREVIATIONS

For terms and definitions, please see IHRA 1010:2020 (IHRA Standards – Terms and Definitions on Healthcare).

4. STANDARDS AND INDICATORS

Each standard is described through indicator(s), which are color coded as red (highly critical) and yellow (critical).

4.1 Responsibilities of Management

Standard 1: The laboratory is easily identifiable.

Indicator 1: The laboratory is identifiable with name on a sign board.

Indicator 2: The laboratory sign board conforms to the prescribed local legal standards.

Indicator 3: The laboratory is registered with Islamabad Healthcare Regulatory Authority.

Indicator 4: The laboratory is licensed with Islamabad Healthcare Regulatory Authority.

Indicator 5: Associated collection centers are reflected in the Registration Certificate/ License issued by the Islamabad Healthcare Regulatory Authority.
Indicator 6: Signed valid MOU, showing linkage with any other Laboratory or organization for referral of specialized tests, exists.

Standard 2: A technically qualified and experienced individual heads the laboratory.

Indicator 7: The individual heading the laboratory is a qualified pathologist having valid professional registration and requisite experience.

Standard 3: Responsibilities of Management are defined.

Indicator 8: Those responsible for lab management lay down the laboratory's mission statement.
Indicator 9: Those responsible for management lay down a detailed laboratory policy and standard operating procedures (SOPs).
Indicator 10: Those responsible for management develop an emergency policy and standard operating procedures.
Indicator 11: Those responsible for management approve sufficient budget and allocate the resources required to accomplish the mission.
Indicator 12: Those responsible for management establish the laboratory's organogram.
Indicator 13: Those responsible for management, appoint the section heads in the laboratory.
Indicator 14: Those responsible for management, support research activities.

4.2 Facility Management and Safety

Standard 4: The management is aware of and complies with the laws, bylaws, rules and regulation, and facility inspection requirements under the relevant building and associated codes applicable to laboratory.

Indicator 15: The management is conversant with the relevant laws and regulations and knows their applicability to the laboratory.

Indicator 16: The management regularly updates any amendments in the prevailing relevant laws and rules.
Indicator 17: The management ensures implementation of these requirements.

Standard 5: Facility work flow design conforms to scope of services.

Indicator 18: Space allocation and effective separation exists between administration and technical laboratory areas.
Indicator 19: Measures are taken to restrict movement of the technical staff working in different sections of the laboratory.

Standard 6: The laboratory has plans for fire and non-fire emergencies within the sections.

Indicator 20: Plans and provisions for early detection of fire and non-fire emergencies exit.
Indicator 21: Provisions for abatement of fire and non-fire emergencies exist.
Indicator 22: Provisions for containment of fire emergencies exist.
Indicator 23: Displayed safe exit points in case of fire and non-fire emergencies exist.
Indicator 24: Mock drills are held at least twice in a year.
Indicator 25: Staff members are trained for their role in case of such emergencies.

4.3 Human Resource Management

Standard 7: Staff deployment is in accordance with the scope of laboratory work.

Indicator 26: Job description for every post is identified and documented.
Indicator 27: Eligibility criteria, regarding qualification and experience for every job is available.
Indicator 28: Recruitments are according to laid down eligibility criteria.

Standard 8: The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs.

Indicator 29: An appropriate orientation plan exists for newly inducted employees.
Indicator 30: Each staff member is made aware of laboratory wide policies and procedure as well as section/unit/services/program specific policies and procedures.
Indicator 31: Each staff member is made aware of their rights and responsibilities.

Indicator 32: All employees are oriented on dealing with patients and responsibilities.

Standard 9: An annual appraisal system for evaluating the performance of employees exists as an integral part of the human resource management process.

Indicator 33: Well documented performance appraisal tools exist in the laboratory.

Indicator 34: All the employees/consultant/ students/ voluntary workers are made aware the performance appraisal tools at the time of induction.

Indicator 35: The appraisal is used as a tool for further development

Indicator 36: Performance appraisal is carried out at pre- defined intervals and is documented.

Standard 10: Documented personal record for each staff member exists.

Indicator 37: Personal files are maintained in respect of all full time/part time employees, which include records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel.

Standard11: In- service staff capacity building record is documented.

Indicator 38: In-service training plan for staff members is available.

Indicator 39: All records of in-service training and education are contained in the personal files.

Standard 12: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of laboratory professionals, including doctors, technologists and others.

Indicator 40: A system for the verification of documents of and certificates of employees exists in the laboratory

Indicator 41: Verification of credentials/documents is done in the laboratory for any newly added qualification/training certificate.

4.4 Management of Equipment and Reagents

Standard 13: Ensure quality of equipment and reagents through standardized procurement procedures.

Indicator 42: The procurement procedure of the laboratory is laid down.
Indicator 43: Specification for all the equipment and reagents/kits/consumables to be purchased is documented.
Indicator 44: Procurement orders are clear, dated and signed.
Indicator 45: Procured items are regularly entered into stock registers.

Standard 14: Safe handling and storage of laboratory reagents.

Indicator 46: Documented policies and procedures guide the safe storage and use of reagents to ensure the continuing quality, integrity and confidentiality of sample materials, documents, equipment, reagents, consumables, records, results, and any other items that could affect quality of examination results.
Indicator 47: An accurate and up-to-date inventory of reagents, biological agents and toxins is maintained.
Indicator 48: The policies of reagent management include a procedure of alert for near expiry reagents.
Indicator 49: Labeling of reagents is as per SOPs.

Standard 15: Comprehensive procedure for equipment management and maintenance exist in the laboratory.

Indicator 50: Logbooks of all equipment are available.
Indicator 51: Regular periodic maintenance and calibration record of all the equipment is available in the logbooks.
Indicator 52: Document and relevant log sheet is displayed on each equipment.
Indicator 53: Emergency contact number/s is/are displayed on all equipment.
Indicator 54: Equipment inventory is maintained having following information:
a) Identity of the equipment
b) Manufacturer's name, type identification, and serial number or other unique identification
c) Contact information for the supplier or the manufacturer and on-call service

d) Date of receiving and date of entering into service

e) Location

f) Condition when received (E.g., new, used or reconditioned)

g) Manufacturer's instructions

h) Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory

i) Up to date, current instructions on use, safety and maintenance of equipment, including relevant manuals and directions for use provided by the manufacturer

Indicator 55: Equipment are registered with Drugs Regulatory Authority of Pakistan (DRAP).

4.5 Recording and Reporting System

Standard 16: The Laboratory has a complete accurate laboratory record for every patient.

Indicator 56: Electronic record of every patient is maintained.

Indicator 57: Every laboratory record has a unique identifier.

Indicator 58: The record provides an up-to-date and chronological account of each patient's record of tests.

Indicator 59: Only authorized person to make entries in the laboratory record and results shall be reviewed by authorized person before they are released.

Indicator 60: Every laboratory record entry is dated, timed and the person making entries can be identified.

Standard 17: A comprehensive reporting system exists in the laboratory.

Indicator 61: A computerized reporting system is available.

Indicator 62: Critical results and notifiable diseases are reported.

Standard 18: The laboratory record supports continuity of patient care.

Indicator 63: Minimum reporting time for every test is documented.

Indicator 64: Reports are accessible to individual patients through a specific code.

4.6 Quality Assurance

Standard 19: The laboratory has a comprehensive and documented quality assurance (QA) program.

Indicator 65: Laboratory has quality assurance (QA) SOPs.
Indicator 66: There is a designated focal person responsible for quality assurance (QA) activities in the laboratory.
Indicator 67: Quality assurance (QA) SOPs are communicated and coordinated among the staff.

Standard 20: External quality assurance (EQA) compliance procedure and tools are available in the laboratory.

Indicator 68: External quality assurance (EQA) of the laboratory is ensured through external assessment by national/internally recognized bodies.
Indicator 69: Records of external quality assurance (EQA) reports are maintained.

Standard 21: Internal quality assurance (IQA) is ensured through standardized laboratory practices.

Indicator 70: Policies and procedures guide the safe collection of specimens.
Indicator 71: Policies and procedures guide the identification and proper labeling of specimens.
Indicator 72: Policies and procedures guide the safe handling of specimens.
Indicator 73: Policies and procedures guide the safe transportation of specimens.
Indicator 74: Policies and procedures guide the safe processing of specimens.
Indicator 75: Policies and procedures guide the safe disposal of specimens.
Indicator 76: Availability of controls for internal quality assurance (IQA) is ensured.
Indicator 77: Process cycle records are maintained.

Standard 22: Continuous laboratory improvement is documented.

Indicator 78: Gaps are identified through QA reports and used as tools for improvement.
Indicator 79: Corrective actions are implemented upon identification of gaps.
Indicator 80: Measures are taken to minimize recurrence of errors.

4.7 Biosafety and Biosecurity

Standard 23: The laboratory has a comprehensive and coordinated biosafety program.

Indicator 81: Availability of laboratory biosafety SOPs.
Indicator 82: Biosafety SOPs are communicated to the laboratory staff.
Indicator 83: The laboratory has a designated qualified technical for ensuring biosafety activities.
Indicator 84: Regular biosafety monitoring reports are generated in the laboratory.

Standard 24: Continuous staff biosafety measures are ensured and documented.

Indicator 85: The laboratory has appropriate consumable, equipment and facilities to ensure bio-safety.
Indicator 86: All staff involved in the handling and disposal of laboratory waste shall receive regular vaccination.
Indicator 87: Annual medical check-up of all staff is documented.

Standard 25: Patient and visitor biosafety is ensured and documented.

Indicator 88: Proper ventilated waiting areas for patients and visitors are available.
Indicator 89: Patients and visitors are not allowed inside the laboratory working area.

Standard 26: There is a documented procedure of bio-risk management.

Indicator 90: All incident reports are documented.
Indicator 91: Required disinfectants/spill kits are available in the laboratory.

Standard 27: Measures to ensure biosecurity in the laboratory are practiced.

Indicator 92: Only authorized persons are permitted to enter the sample storage area.
Indicator 93: Any transportation of samples is properly recorded.

Standard 28: The laboratory has a well-designed, comprehensive and coordinated waste management plan.

Indicator 94: Written laboratory waste management SOPs are available.

Indicator 95: Waste management SOPs are communicated to the laboratory employees.
Indicator 96: The laboratory has appropriate consumable, collection and handling systems and equipment for waste management.
Indicator 97: Contracts with waste disposal service organizations are available.
Indicator 98: Waste transported from collection centers for final disposal is recorded.

4.8 Access, Assessment and Continuity of Care

Standard 29: Laboratory services are easily accessible.

Indicator 99: The laboratory's location for collection of samples is easily accessible.
Indicator 100: Basic facilities are accessible in the laboratory.
Indicator 101: There are clean toilets/washrooms with bolts, preferably separate for males and females.
Indicator 102: Facilitated toilets for disabled patients with wheel chair access are available in the laboratory.
Indicator 103: Disabled patients are facilitated for phlebotomy.
Indicator 104: Directional arrows pointing towards various important areas for patients are displayed in the laboratory.

Standard 30: Laboratory services are provided as portrayed/claimed.

Indicator 105: Laboratory services being provided are displayed.

Standard 31: A comprehensive audit system for laboratory performance assessment exists in the laboratory.

Indicator 106: There is a system to monitor and measure the performance of the laboratory biannually against the stated mission.
Indicator 107: Procured kits and their consumption are compared with test performed during laboratory performance audit.

4.9 Care of Patients

Standard 32: Emergency handling of patients is guided by protocols.

Indicator 108: Protocols for providing first aid/emergency care to the patients are documented.
Indicator 109: Relevant contact numbers for emergency evacuation/referral are available in the laboratory.

Standard 33: Sentinel events are intensively analysed.

Indicator 110: The laboratory has defined sentinel events.
Indicator 111: Sentinel events are intensively analyzed when they occur.

Standard 34: The laboratory policies and procedures support domiciliary services to the patients (where applicable/claimed).

Indicator 112: The laboratory is equipped with means of communication and transport services for home-based patient sample collection.
Indicator 113: The laboratory has appropriate means of collection and transportation of home-based samples.

4.10 Patient Rights and Education

Standard 35: A system exists for obtaining consent when it is required.

Indicator 114: The laboratory has listed those situations where specific informed consent is required.
Indicator 115: The policy describes who can give consent when a patient is incapable of independent decision-making.

Standard 36: Patient and families have a right to information on expected costs.

Indicator 116: The tariff list is available to patients.
Indicator 117: Patient/families are informed about the additional reports which are generated or included in the report with the same sample and cost.

Standard 37: Patient rights for appeal, complaints and confidentiality are protected.

Indicator 118: Patient's complaints are accepted by the laboratory and properly registered.

Indicator 119: Proper actions and remedial measures are taken in response to patients' complaints.

Indicator 120: Confidentiality of patient record is maintained.

Bibliography

1. Minimum Service Delivery Standards for Clinical Laboratories, Punjab Healthcare Commission.
2. National Laboratory Quality Standards of the Islamic Republic of Pakistan (2018).