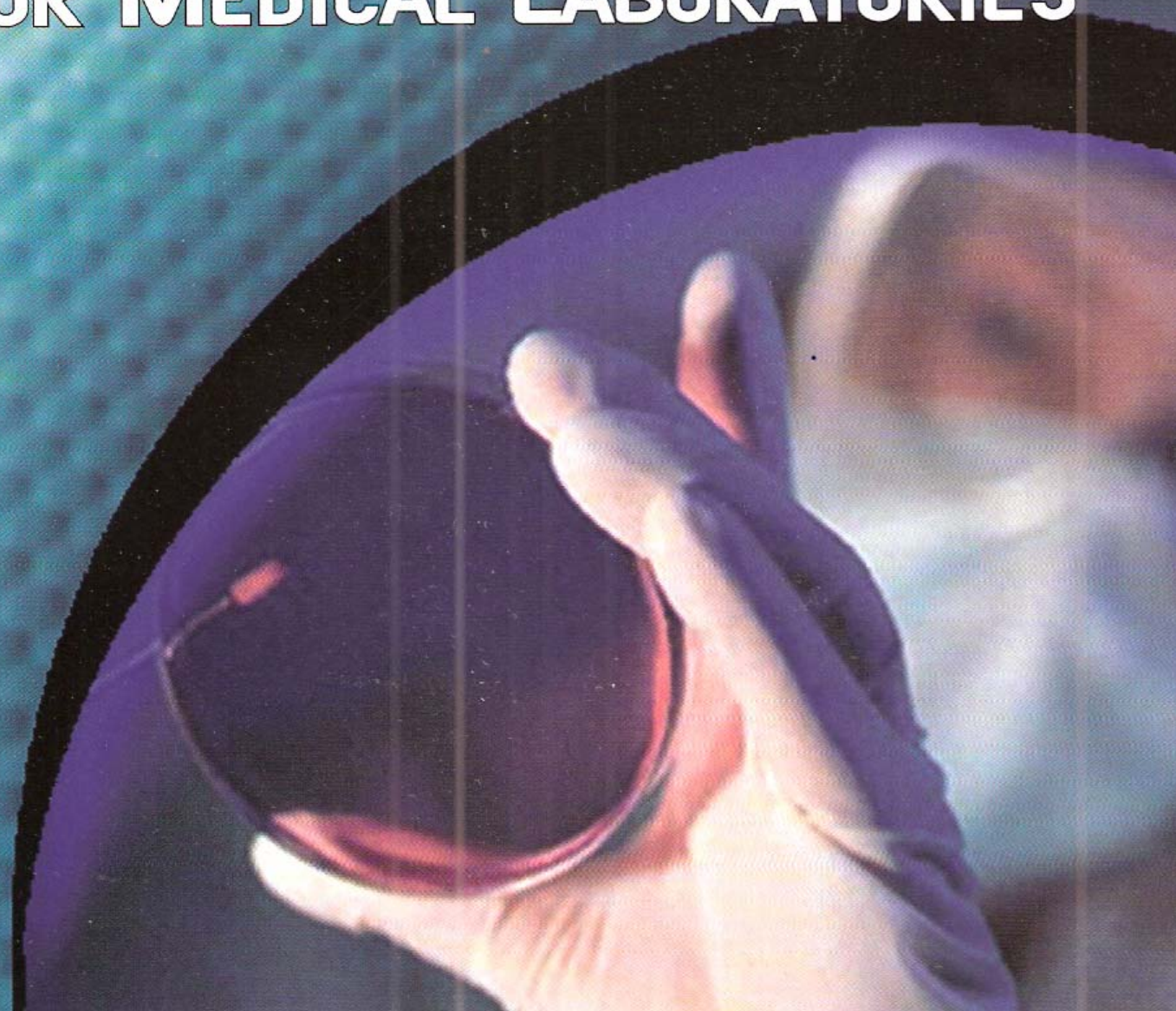




TRINIDAD AND TOBAGO
**laboratory
Accreditation
Service**

SUMMARY OF REQUIREMENTS IN **ISO 15189**

FOR MEDICAL LABORATORIES



ISO 15189 - Medical laboratories – Particular requirements for quality and competence

Management Requirements

4.1 Organization and Management

Laboratory management shall have responsibility for the design, implementation, maintenance and improvement of the quality management system.

4.2 Quality management system (QMS)

The QMS shall have all its procedures documented.

The QMS shall include internal quality control and participation in interlaboratory comparisons. Write a quality policy statement and document a quality manual.

4.3 Document control

Define, document and maintain procedures to control all documents and information. Define retention periods and archive documents for later reference.

4.4 Review of contracts

Ensure that all parties understand and abide by the provisions made in contracts. Keep records of all reviews, including significant changes, and maintain these records.

4.5 Examination by referral laboratories

Have procedures for evaluation and selection of referral laboratories and consultants. Maintain a register of all laboratories used.

4.6 External services and supplies

Ensure external services, equipment and consumable supplies consistently meet the laboratory's standards.

Have an inventory control system and quality records of external commodities purchased.

4.7 Advisory services

Appropriate laboratory staff shall give advice on the choice of examinations and services.

Regular meetings between professional and clinical staff should be arranged.

4.8 Resolution of complaints

Keep records of any complaints or feedback and of investigations or correction action taken by the laboratory.

4.9 Identification and control of non-conformities

When a non conformity is detected:

- Personnel must be designated for problem resolution;
- Corrective action must be defined and taken immediately;
- The deviation must be documented and recorded, and reviewed by staff.

4.10 Corrective Action

Carry out investigations to determine the root causes of problems.

Document and implement any changes made to procedure.
Review all procedures regularly and take action to improve the system.

4.11 Preventive Action

Identify any necessary improvements and areas of nonconformities, either technical or concerning the management system.

Develop action plans and procedures to reduce the likelihood of recurrence of nonconformities.

4.12 Continual Improvement

Review all procedures at regular intervals to identify any potential source of non conformance.

Action plans must be developed, documented and implemented as appropriate.

4.13 Quality and Technical records

Establish procedures for

- Identification
- Collection
- Indexing
- Access
- Maintenance
- Safe disposal of quality and technical records

4.14 Internal Audits

Formally and periodically carry out internal audits to ensure that the QMS is maintained.

4.15 Management review

Laboratory management must periodically review the QMS to maintain and improve the system.

Findings must be recorded and any corrective action needed must be taken immediately.

Technical requirements

5.1 Personnel

Define qualifications and duties for all personnel

Implement the Quality Management System (QMS) and procedures.

5.2 Accommodation and environmental conditions

Ensure the facilities for examination allow for correct performance of tests and reliability of results.

5.3 Laboratory equipment

Provide the laboratory with relevant, functioning and calibrated equipment.

Ensure authorized personnel operate equipment in a safe working environment.

5.4 Pre-examination procedures

Ensure that request forms used contain all necessary information to identify patients, tests and requesters.

Establish a primary sample collection manual.

5.5 Examination procedures

Use only relevant, validated, documented procedures which meet the needs of the users of the laboratory's services.

Record any deviations or changes in procedure.

5.6 Assuring quality of examination procedures

Establish quality control methods to verify attainment of quality results.

Document, record and retain records of results. Take action if results are suspected to be incorrect.

5.7 Post examination procedures

Authorized personnel must review results and determine reliability before releasing results.

Disposal of samples must be in accordance with local standards.

5.8 Reporting results

Results must be reported legibly, unambiguously and in an identifiable manner.

Use an audit log if the present reporting system cannot capture changes or alterations.