1. An approved laboratory must be able to provide the apparatus and working environment considered necessary for Good Laboratory practice, to the standard determined by the Professional Board.

2. An approved laboratory must provide practical training in basic routine tests under conditions whereby each employee is given adequate instruction in, and every opportunity to carry out, all the tests and procedures considered by the Professional Board to be consistent with adequate training in the category in which the employee is being trained.

3. An approved laboratory must have in its employ a qualified medical technologist or pathologist who must be registered in the category in which technologists/technicians/ are to be trained. If a laboratory functioned without such a registered person for longer than 6 months, it will be asked for an explanation and the Professional Board will then reconsider the continued recognition of such a laboratory for training of Medical Technologists.

4. In the event of the resignation of the registered medical technologist in charge of training, and no immediate replacement can be obtained, the students already in training will be permitted to continue under a pathologist registered in that specific category, however no new students may be accepted until a suitable replacement for the medical technologist has been obtained.

5. An approved training laboratory must have the ratio between registered medical technologists and technicians as the Professional Board may determined from time to time.

6. An approved training laboratory may not have in its employ more than five pupil technologists and/or technicians in respect of every medical technologist registered in the specific category.

7. The Professional Board has the right to inspect the laboratory at any time.

8. In the event of a laboratory being unable to cover all facets of training in a particular category, such a laboratory may apply for restricted recognition for training purposes. In such cases proof must be provided that the required training not performed by that laboratory is obtained at another recognized training laboratory.

9. Any laboratory applying for restricted registration must in the opinion of the evaluators be able to provide a substantial portion of the training required for that particular category.
10. In terms of rule 4 of the ethical rules a practitioner must confine himself / herself in the use of a **practice name** to his / her name or where practitioners practise in partnership or as a juristic person, the names of such practitioners.

11. Accredited laboratories must inform the Professional Board in writing of name changes to the names of such practices. These practices may be re-evaluated for possible continued accreditation.

**PREAMBLE**

The questionnaire asks for general information of the practice in your laboratory. It is also intended to stimulate a self-evaluation of the procedures applied. While you consider the answer to the various questions you may realise that there are certain shortcomings in the organisation of your laboratory or the procedures that are used. As such shortcomings come to light, you will probably wish to take remedial steps. Such changes would be voluntary, of your own design and within the means at your disposal. Any changes instituted should result in improvement in the standard set in your laboratory and cause little or no anxiety to you or your staff. You are also invited to make comments on the contents of the questionnaire itself.
PROFESSIONAL BOARD FOR MEDICAL TECHNOLOGY

APPLICATION FOR APPROVAL OF TRAINING LABORATORIES

CHECKLIST FOR EVALUATION OF LABORATORIES

LABORATORY DETAILS

Name of laboratory: .................................................................................................................................

(See 10 above)

(Inappropriate practice names contrary to the stipulations in the Ethical Rules may not be used)

Branch (if applicable): .............................................................................................................................

Any other branch to be evaluated as part of this application: .................................................................

Date of Previous Application and or Accreditation and Categories accredited (If applicable)
................................................................................................................................................................
................................................................................................................................................................

Categories applied for: ............................................................................................................................

Owner(s) of laboratory: ............................................................................................................................

Practice number: .......................................................................................................................................}

Head of laboratory: .................................................................................................................................

Contact person: ........................................................................................................................................

Postal Address: ........................................................................................................................................

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Physical Address: .....................................................................................................................................

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Phone Number: ........................................................................................................................................

Fax Number: .............................................................................................................................................

E-mail address: .........................................................................................................................................

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### List of staff members

<table>
<thead>
<tr>
<th>Surname, Initials and Title</th>
<th>HPCSA Registration Number and registered categories</th>
<th>Qualifications</th>
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<td>Name of proposed supervising MT</td>
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<td>Histology Techniques</td>
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<td>Virology</td>
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<td>Other</td>
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The applicant and manager of the owning institution/laboratory must sign this form as an indication of their commitment to training of Medical Technology students.

SIGNATURE: ..................................................  SIGNATURE: ..................................................
(Manager)  (Applicant)

NAME: ..................................................  NAME: ..................................................
(Please print)  (Please print)

Date: ..................................................  Date: ..................................................
1. **PERSONNEL AND ORGANISATION**

Relevant Standards: The management of the laboratory must formulate the quality goals with respect to the education and skills of the laboratory. The laboratory must have a policy and procedures for identifying training needs and providing training of personnel. The training program must be oriented on present and future tasks of the laboratory. Personnel performing specific tasks must be qualified on the basis of appropriate education, training, experience and/or skills, as required.

1.1 **Person-in-Charge**

1.1.1 Name  
1.1.2 Qualifications  
1.1.3 Years of relevant Experience  
1.1.4 Hours per week spent in this laboratory

1.1.5 Does the person-in-charge direct other laboratories?  
(If so, how many other laboratories)  

1.1.6 Is the person-in-charge involved in:  
1.1.6.1 Development of training programmes?  
1.1.6.2 Approval of changes in methodology and procedures?  
1.1.6.3 Review of laboratory reports?  
1.1.6.4 Review of quality control programmes?  

1.1.7 Is the person-in-charge readily available for consultation with:  
1.1.7.1 Referring medical practitioners?  
1.1.7.2 Medical administrators?  
1.1.7.3 Laboratory personnel?  
1.1.7.4 Computer personnel?  

1.1.8 If the person-in-charge is absent are there suitable relief arrangements?  

1.2 **Laboratory Staff**

1.2.1 Is there adequate and competent qualified staff to perform procedures of the laboratory to acceptable standards?  
Both technologists and technicians may perform any test provided that there is proof that they have been trained to do so.  

1.2.2 Are any procedures/tests being performed by persons not qualified to carry out those procedures/tests?  
1.2.2.1 If yes: Do inexperienced staff have access to technical advice from senior staff at all times?  

1.2.3 Have these persons received formal training in performing these tasks?  

1.2.4 Please attach total staff complement with appropriate qualification, registration number and training records.  

1.3 **Staffing Policies**

1.3.1 Are records maintained on all current employees?  
1.3.2 Do these records include:  
1.3.2.1 Formal qualifications (or required licenses)?
1.3.2.2 Dates of employment, etc.? YES NO  
1.3.2.3 A job description specifying duties/ responsibilities? YES NO  
1.3.2.4 Incident reports where applicable YES NO  
1.3.3 Are records kept on staff participation in Continuing Professional Development programmes YES NO  
1.4 Education and Training
1.4.1 Does the laboratory operate in-service training programmes (if no, go to 1.4.4.) YES NO  
1.4.2 Does the training programme involve:
   1.4.2.1 Orientation of new personnel? YES NO  
   1.4.2.2 Special attention to such matters as laboratory ethics and safety? YES NO  
   1.4.2.3 Bench training coordinated by laboratory supervisors? YES NO  
   1.4.2.4 In-service seminars? YES NO  
   1.4.2.5 Use of teaching aids (audio-visual, manuals etc.)? YES NO  
1.4.3 If the laboratory is an accredited (registered) training laboratory, at what level does training take place:
   1.4.3.1 Elementary training (technical assistant)? YES NO  
   1.4.3.2 Technician? YES NO  
   1.4.3.3 Student Medical Technologist? YES NO  
   1.4.3.4 Post diploma Medical Technologist? YES NO  
   1.4.3.5 Are records kept of the above? YES NO  
1.4.4 How are evaluations of training programmes made:
   1.4.4.1 Against objectives? YES NO  
   1.4.4.2 By person-in-charge? YES NO  
   1.4.4.3 By trainee? YES NO  

2. ACCOMMODATION AND ENVIRONMENTAL CONDITIONS
Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to ensure proper performance of calibrations or tests. The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises. The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned. There shall be effective separation between neighbouring areas when the activities therein are incompatible.

Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

2.1 Is adequate uncluttered space provided for:
   2.1.1 Workbench? YES NO  
   2.1.2 Storage (including refrigeration)? YES NO  
   2.1.3 Administration (including reporting areas)? YES NO
### 2. Work Areas

2.2 Are work areas provided with adequate electrical, water and gas utilities (double adapters long lengths of gas tubing, should be avoided)?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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2.3 Is there an adequate specimen collection area suitably separated from laboratory work areas?

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<th>YES</th>
<th>NO</th>
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2.4 Is there a staff library?

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<th>YES</th>
<th>NO</th>
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2.4.1 If no, does the staff have adequate access to current text books/journals or the Internet?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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2.5 Is there a Tea room/ Recreation room?

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<tr>
<th>YES</th>
<th>NO</th>
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2.6 Does the laboratory environment provide:

<table>
<thead>
<tr>
<th>2.6.1 Adequate lighting?</th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>2.6.2 Adequate ventilation?</td>
<td>YES</td>
<td>NO</td>
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<tr>
<td>2.6.3 Adequate air conditioning (particularly where sensitive instruments are in use)?</td>
<td>YES</td>
<td>NO</td>
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2.7 Is the laboratory cleaned regularly and maintained in good order?

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<tr>
<th>YES</th>
<th>NO</th>
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2.8 Are there adequate facilities for waste disposal consistent with good laboratory practice and local government requirements?

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<thead>
<tr>
<th>YES</th>
<th>NO</th>
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2.9 Does the laboratory have an emergency power supply to maintain essential services? If not has alternative arrangements been made?

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
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2.10 Does the laboratory have a direct outside telephone line for emergency use?

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<th>YES</th>
<th>NO</th>
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2.11 Are glassware in good condition and properly stored?

<table>
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<th>YES</th>
<th>NO</th>
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2.12 Are there written SOPs for handling and cleaning glassware?

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<th>YES</th>
<th>NO</th>
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2.13 Is there a sufficient supply of laboratory grade water for rinsing glassware?

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<th>YES</th>
<th>NO</th>
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2.14 Are benches decontaminated daily?

<table>
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<th>YES</th>
<th>NO</th>
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2.15 Are records kept of decontamination procedures?

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<th>YES</th>
<th>NO</th>
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### 3. HEALTH AND SAFETY

Occupational Health and Safety Act covers all statutory aspects of Safety to which all laboratories must conform.

#### 3.1 Safety Personnel

3.1.1 Does the laboratory have a designated safety officer?

| YES | NO |

3.1.2 Name the designated person

3.1.3 Does the laboratory have a safety committee?

| YES | NO |

If yes:

3.1.3.1 How often do they meet?

3.1.3.2 Are minutes kept of the meetings?

| YES | NO |

3.1.4 Has the laboratory a written safety manual?

| YES | NO |

If yes:

3.1.4.1 Is this available in each laboratory?

| YES | NO |

3.1.5 Has all staff been trained in the correct safety procedures?

| YES | NO |

3.1.6 Are records of this training kept?

| YES | NO |

3.1.7 Have policies regarding "Injury on duty" and "Diseases contracted through exposure at work" been developed?

| YES | NO |
3.2 Fire

3.2.1 Is an operational Fire Alarm system installed in the building housing the laboratory?  
YES  
NO
3.2.2 Is there a backup system?  
YES  
NO
3.2.3 Is the fire alarm audible in all sections of the laboratory?  
YES  
NO
3.2.4 Are fire drills held periodically?  
YES  
NO
3.2.5 Is smoking prohibited in all areas except in designated smoke rooms?  
YES  
NO
3.2.6 Are there sufficient and appropriate fire extinguishers (not the powder type) in the laboratory?  
YES  
NO
   If yes:

   3.2.6.1 Are these serviced and inspected on a regular basis?  
YES  
NO
   3.2.6.2 Are records kept?  
YES  
NO
3.2.7 Are there fire blankets available in the laboratory?  
YES  
NO
3.2.8 Are there sufficient fire hoses in the passages?  
YES  
NO
   If yes:

   3.2.8.1 Are these checked regularly to ensure that they are in good working order and, that hoses reach all areas?  
YES  
NO
   3.2.8.2 Are records kept?  
YES  
NO
3.2.9 Are all staff familiar with the correct use of appropriate extinguishers?  
YES  
NO
3.2.10 Are there clearly marked exits?  
YES  
NO
3.2.11 Are evacuation routes diagrammed and posted?  
YES  
NO
3.2.12 Are volatile chemicals and flammable solutions stored in a flammable store and appropriate containers?  
YES  
NO
3.2.13 Does the laboratory comply with the local fire regulations?  
YES  
NO
3.2.14 Has the laboratory been inspected by the local Fire Department?  
YES  
NO

3.3 Accidents and First Aid

3.3.1 Are detailed records of laboratory accidents kept?  
YES  
NO
3.3.2 Are policies altered to prevent recurrences?  
YES  
NO
3.3.3 Are first-aid facilities available?  
YES  
NO
   If yes:

   3.3.3.1 Are first-aid boxes available in the laboratory?  
YES  
NO
   3.3.3.2 Are the first-aid boxes regularly checked against an inventory kept inside?  
YES  
NO
   3.3.3.3 Do these boxes comply to the OHS Act?  
YES  
NO
   3.3.3.4 Is the person in charge of the First Aid boxes qualified in First Aid?  
YES  
NO
3.3.4 Is there an eyewash facility available in each laboratory?  
YES  
NO
3.3.5 Is there an emergency shower available?  
YES  
NO
3.3.6 Is there a protocol for the management of accidental injury following exposure to blood or body fluids?  
YES  
NO
3.3.7 Is there a policy on needle stick injury?  
YES  
NO

3.4 Equipment

3.4.1 Are written safety procedures available for dangerous equipment?  
YES  
NO
3.4.2 Does apparatus conform to acceptable safety standards? YES NO
3.4.3 Is the laboratory on an earth leakage system? YES NO
3.4.4 Are measures taken to minimise formation and dissemination of aerosols when centrifuging blood or bacterial specimens? YES NO
3.4.5 Are biohazard cabinets used in the laboratory when hazardous bacteria, fungi, or viruses are handled? YES NO
3.4.6 Are adequate fume cupboards provided where necessary? YES NO
3.4.7 Are adequate laminar flow provided where necessary? YES NO
3.4.8 Are the surrounding areas of instruments disinfected at least once a day? YES NO
3.4.9 Is effluent disinfected before being discarded directly into the municipal waste? YES NO
3.4.10 Are safety pipettes available for handling of:
   3.4.10.1 Acids and corrosive chemicals? YES NO
   3.4.10.2 Infected material? YES NO
3.4.11 Are facilities adequate for disinfection of contaminated pipettes? YES NO
3.4.12 Are clay slabs used for sealing micro haematocrit tubes discarded and not reused? YES NO
3.4.13 Are containers for sharp instruments available in all laboratories? YES NO
3.4.14 Are SOPs written regarding the prevention of injury of personnel by cutting instruments? YES NO
3.4.15 Is the condition of each piece of equipment satisfactory? YES NO
3.4.16 List any defective apparatus.
   3.4.16.1 By whom (list). LIST Appendix C
3.4.17 Are defective equipment clearly marked YES NO
3.4.18 Is equipment serviced regularly?
   3.4.18.1 By whom (list). LIST Appendix D
3.4.19 Are records available of instrument services and operation checks? YES NO
3.4.20 Are operating manuals including calibration instructions available for all the types of equipment? YES NO

3.5 Prevention of laboratory-acquired infection

3.5.1 Have all staff been instructed in the safe handling of infected material? YES NO
3.5.2 Do staff working in high risk areas have regular medicals? YES NO
3.5.3 Are the appropriate signs available and in use? YES NO
3.5.4 Is eating, drinking, smoking and application of cosmetics prohibited in all laboratories/areas where specimens are handled? YES NO
3.5.5 Is storage of food in laboratory refrigerators or cupboards prohibited? YES NO
3.5.6 Is mouth pipetting prohibited? YES NO
3.5.7 Are suitable laboratory coats worn in all laboratories? YES NO
3.5.8 Are laboratory coats supplied to all staff members and laundered by the laboratory? YES NO
3.5.9 Are laboratory staff prohibited to leave the laboratory wearing their laboratory coats? YES NO
3.5.10 Are suitable gloves provided in the laboratory for use where necessary? YES NO
3.5.11 Is suitable facial protection provided where there is a risk of generating infectious aerosols or droplets which may be inhaled, swallowed or settle on the eyes? YES NO

3.5.12 Are hand wash facilities with elbow taps provided in every laboratory? YES NO

3.5.13 Are benches and equipment decontaminated daily? YES NO

3.5.14 Is there an SOP for decontamination of all spillage? If yes:

3.5.14.1 Are staff well informed about these procedures? YES NO

3.5.15 Are detailed SOPs available for the proper transportation of specimens to avoid breakage and spills? YES NO

3.5.16 Are there detailed SOPs available on the receipt of broken specimens? YES NO

3.5.17 Are SOPs written to prevent exposure of personnel to unfixed/partially fixed, biohazardous material? (List) YES NO

3.5.18 Are SOPs written to prevent exposure to noxious fumes and reagents in the laboratory? YES NO

3.5.19 Are SOPs available for the proper handling of specimens? YES NO

3.5.19.1 Do these include criteria for rejection of specimens? YES NO

3.5.20 Are the arrangements for preservation of specimen quality satisfactory? YES NO

4. PROCEDURES

The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the lack of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

4.1 Specimens

4.1.1 Has a fully comprehensive specimen collection and handling manual been created? YES NO

4.1.2 Are there SOPs covering:

4.1.2.1 Method of collection? YES NO

4.1.2.2 Positive identification of the patient? YES NO

4.1.2.3 Preparation of the patient? YES NO

4.1.2.4 Nature of the sample to be collected? YES NO

4.1.2.5 Need for special timing for collection? YES NO

4.1.2.6 Appropriate preservation or anticoagulant blood is adequately mixed before sampling (e.g. sequential testing of the same specimen)? YES NO

4.1.2.7 Safety precautions in the handling of specimens? YES NO

4.1.2.8 Appropriate preservative or anti-coagulant? YES NO

4.1.2.9 Need for special handling between time of collection and time received (e.g. refrigeration)? YES NO

4.1.2.10 Instructions for labelling? YES NO

4.1.2.11 A system in use by which damaged or unsuitable specimens can be rejected or partially tested? YES NO

4.1.2.12 Action steps to follow when specimens are lost? YES NO

4.1.3 What provision is made for storage of specimens prior to testing or referral? YES NO
4.1.4 For how long and what storage conditions are specimens retained after testing?

4.2 Reception
4.2.1 Are the procedures in this area documented? YES NO
4.2.2 Is an SOP for this area e.g. use of gloves, procedures for handling leaking specimens and contaminated forms written? YES NO
4.2.3 Is there an SOP for specimens received after hours? YES NO

4.3 Specification Identification
4.3.1 Is the specimen given a unique identification on receipt (Laboratory Requisition Number)? YES NO
4.3.2 Is this identification used through all steps of the test procedure? YES NO
4.3.3 Is this identification quoted on all documentation pertaining to that specimen? YES NO

4.4 Rejection of Unsuitable Specimens
4.4.1 Is there an SOP on the handling of unsuitable/inadequately labelled specimens? YES NO
4.4.2 Are suitable records kept of the dispatch of and return of referred test results? YES NO

4.5 Methods
4.5.1 Are there SOPs covering detailed instructions for each test procedure where no kit is used? YES SOP NO
4.5.2 Are the SOPs in 4.5.1 validated? YES NO

4.6 Quality Assurance Programme
4.6.1 Is there a written Quality Assurance Document which covers ALL aspects of patient care by the laboratory? YES NO
4.6.2 Are there written in-house safety guidelines? YES NO

4.7 Reports
4.7.1 Does the report form contain the following:
   4.7.1.1 Name of laboratory which performed the tests? YES NO
   4.7.1.2 The name of the patient? YES NO
   4.7.1.3 Name of clinician requesting the work? YES NO
   4.7.1.4 Laboratory accession number? YES NO
   4.7.1.5 References values for each test? YES NO
   4.7.1.6 Date/time of specimen collection? YES NO
   4.7.1.7 Comment on inadequate/unsuitable specimen? YES NO
   4.7.1.8 Date/time of issue of report? YES NO

4.7.2 Do records of the original results identify:
   4.7.2.1 Who did the work? YES NO
   4.7.2.2 Who reviewed and validated the results? YES NO
   4.7.2.3 Who made any alterations? YES NO

4.7.3 Are SOPs written to minimise transcription errors? YES NO
4.7.4 Are records retained on the computer or other storage system? YES NO
4.7.5 Are there SOPs in use for the handling of clerical errors and unusual laboratory results? YES NO
4.7.6 Are SOPs written for the timeous correction of mistakes? YES NO
4.8 Records

4.8.1 Is an SOP written to ensure that laboratory reports are treated as confidential, and are they only reported to the referring practitioner or to such person(s) as he/she nominated?  
YES NO

4.8.2 Is there an SOP for accelerated communication of seriously abnormal results?  
YES NO

4.8.3 Are all reports given in writing (or where given verbally for specific reasons, later confirmed in writing)?  
YES NO

4.8.4 Is there an SOP regarding conveying results, telephonic reports and records kept?  
YES NO

4.9 Equipment

It is not the purpose of this evaluation to specify the type of equipment that must be used by a laboratory. However, it is essential that all equipment in use is suitable for the tests being performed.

4.9.1 Is there an up-to-date maintenance record for all items of equipment?  
YES NO

4.9.2 Are there operating manuals available for:

  4.9.2.1 Water baths?  
  YES NO

  4.9.2.2 Incubators?  
  YES NO

  4.9.2.3 Hot air ovens  
  YES NO

  4.9.2.4 Autoclaves?  
  YES NO

  4.9.2.5 Biological safety cabinets?  
  YES NO

  4.9.2.6 Anaerobic workstations?  
  YES NO

4.9.3 Is there a schedule or system for the regular checking of the critical operating characteristics for all instruments?  
YES NO

4.9.4 Are instructions for instrument checking systems written (i.e. manufactures manual or SOPs prepared by the laboratory)?  
YES NO

4.9.5 Are function checks documented in a convenient manner to detect trends or malfunctions?  
YES NO

4.9.6 Are tolerance limits for acceptable function written for specific instruments wherever appropriate?  
YES NO

4.9.7 Are instruments provided with methods for minor troubleshooting and repairs?  
YES NO

4.9.8 Are records maintained for each instrument to document all repairs and service procedures?  
YES NO

4.9.9 Are adjustable automatic pipettes/dispensers checked for accuracy and reproducibility at regular intervals and the results recorded?  
YES NO

4.10 Reagents

4.10.1 Are all reagents and standards properly labelled as to content and concentration?  
YES NO

4.10.2 Are reagents dated on receipt, preparation and/or when placed in service?  
YES NO

4.10.3 Are expiry dates indicated on the reagent containers?  
YES NO

4.10.4 Are reagents stored properly (i.e. refrigerated when necessary)?  
YES NO

4.10.5 Are fresh reagents checked against old reagents or other reference material prior to being placed in service?  
YES NO
## QUALITY ASSURANCE

### Relevant Standard:

The laboratory must establish, implement and maintain a quality management system appropriate to the scope of its activities including the type, range and volume of testing and/or calibration activities it undertakes. The laboratory must document all of its policies, systems, programmes, procedures, instructions and findings, to the extent necessary to enable the laboratory to assure the quality of the test and/or calibration results it generates. Documentation used in this quality management system must be communicated to, understood by, available to and implemented by the appropriate personnel.

### 5.1 General

<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1.1</td>
<td>Is there a designated staff member responsible for monitoring QC?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.2</td>
<td>To whom does the person report?</td>
<td></td>
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<tr>
<td>5.1.3</td>
<td>Is there an internal Quality Control Programme to cover all tests performed?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.4</td>
<td>Is there an external Quality Control (EQA) programme?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.4.1</td>
<td>If yes, please state which EQA system is used for each department.</td>
<td>LIST</td>
<td></td>
</tr>
<tr>
<td>5.1.5</td>
<td>Is there intra-laboratory control specimens system for results checking within the laboratory group?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.6</td>
<td>Are Quality Control records kept?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.7</td>
<td>If yes:</td>
<td></td>
<td></td>
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<tr>
<td>5.1.7.1</td>
<td>For how long?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.7.2</td>
<td>Are these records readily available?</td>
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<tr>
<td>5.1.8</td>
<td>Is the archive system in operation?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.9</td>
<td>Are results used for:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.9.1</td>
<td>Evaluating performance?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.9.2</td>
<td>Identifying problems?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.9.3</td>
<td>Method development?</td>
<td></td>
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<tr>
<td>5.1.10</td>
<td>Are the results from internal and external QC programmes available to all laboratory staff?</td>
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<tr>
<td>5.1.11</td>
<td>Is an SOP written for preparing and handling control materials for each procedure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.11.1</td>
<td>State the frequency of which QC are run.</td>
<td></td>
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<tr>
<td>5.1.11.2</td>
<td>Is there an SOP to follow when the QC results fall outside the acceptable limits?</td>
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<tr>
<td>5.1.11.3</td>
<td>Is there a record of what corrective action was taken (and by whom)?</td>
<td></td>
<td></td>
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<tr>
<td>5.1.12</td>
<td>Are there SOPs for validation and verification of new methods, procedures and equipment?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5.2 Controls and Standards

<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.2.1</td>
<td>Are all controls labelled properly i.e. contents, concentration etc.?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2.2</td>
<td>Do all standards have labels showing dates of receipt, opening for use and expiry?</td>
<td></td>
<td></td>
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<tr>
<td>5.2.3</td>
<td>Are controls used at different levels (i.e. intermediate and low)?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.2.4  Are quality control data:
  5.2.4.1  Evaluated daily?  YES  NO
  5.2.4.2  Is data charted?  YES  NO
  5.2.4.3  Is this displayed prominently?  YES  NO

5.2.5  Are ongoing and updated records kept?  YES  NO

5.2.6  Is frequency of calibration in accordance with instruments
  and/or reagent manufactures recommendations?  YES  NO

5.2.7  Is calibration traceable to the EQC results?  YES  NO

5.2.8  Are QC results used to determine process failure?  YES  NO

6.  LABORATORY COMPUTER SYSTEM (If Applicable)

6.1  Do computer manuals exist which includes the following aspects of
  the computer operation and maintenance?  YES  NO
  6.1.1  Is the computer system protected against unauthorised
  access?  YES  NO
  6.1.2  Preservation of data in case of fire, flooding etc.  YES  NO
  6.1.3  Fire fighting equipment in the computer room?  YES  NO
  6.1.4  Are there defined levels of programme access for various
  staff members?  YES  NO
  6.1.5  Is there a documented stated policy for correction of test
  request errors?  YES  NO
  6.1.6  Is there a procedure for the changes of any results entries
  and errors?  YES  NO
  6.1.7  Is there a documented policy for the verification of results
  coming online from instruments before final entry into the
  patient files?  YES  NO
  6.1.8  Is there a documented policy for final verification for results
  before they are reported and are accessed or accessible by
  the wards and clinicals/or sent out to private practitioners?  YES  NO
  6.1.9  Is there a special library or other system to allow comment on
  unsuitable specimens (haemolysis, delayed specimen)?  YES  NO
  6.1.10  Is the staff member who entered the results identifiable and
  traceable?  YES  NO
  6.1.11  Is a system in existence for the timeous retrieval of results?
  YES  NO
  6.1.12  Is there a procedure for the daily back-up data?  YES  NO
  6.1.13  Do instructions exist and where relevant a schedule for the
  maintenance of hardware?  YES  NO
  6.1.14  Are there records of all hardware and software changes and
  repairs?  YES  NO
  6.1.15  Are all changes to hardware and software validated prior to
  acceptance?  YES  NO
  6.1.16  Are changes to hardware and software done by qualified
  persons?  YES  NO
  6.1.17  Is there a procedure for the shutdown of the computer, for
  software and/or hardware failure?  YES  NO
  6.1.18  Is there an audit trail within the system permitting the
  identification of data input and/or editing for all stages of the
  analytical process?  YES  NO
  6.1.19  Is there an emergency after hour’s service for software and
  hardware problems and telephone numbers displayed in an
  area where they are freely accessible to the staff?  YES  NO
  6.1.20  Is there a hardcopy file of all patient data (results of tests and
  test process hard copy) maintained?  YES  NO
6.1.21 At the end of each working day is a housekeeping exercise constituted, recorded and performed to make sure that all requested test results are in fact sent out or where there are test batches done on certain days, these test batches are checked to make sure that the results have gone out or will be going out?

YES  NO

6.1.22 When computers are used to capture data directly or to control test runs, is the laboratory able to demonstrate the adequacy of the total system?

YES  NO

NOTE: The individual current syllabi of the different disciplines are used in conjunction with this checklist to see if the laboratory has the necessary resources to train students in the specific discipline.

7. DEFINITIONS

7.1 GLP - “Good Laboratory Practice” and all the rules and regulations which apply.

7.2 HOD - Head of department

7.3 SOP - Standard operating procedures or Work instructions

8. REFERENCES

8.1 Interim South African Medical and Dental Council Pilot Study on Accreditation of Pathology Laboratories, 1995.

8.2 Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health (UK), 1989.

8.3 ISO/IEC 17025 Standard

Update: 2001-09-03