Health Professions Council of South Africa

ANNEXURE 1

INFORMATION ON TRAINING UNITS APPLYING TO BE PART OF A CLUSTER LABORATORIES

Abbreviations:

GLP - "Good Laboratory Practice" and all the rules and regulations which apply.
HOD - Head of department
SOP - Standard operating procedures or Work instructions
QC - Quality Control

1. PERSONNEL AND ORGANISATION OF CLUSTER LABORATORY
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. ***NB*Please Complete for Each Unit in the Application – Print and Submit as Many as Needed****

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 Is the person-in-charge involved in:	YES	NO
1.1.5.1 Development of training programmes?		
1.1.5.2 Approval of changes in methodology and procedures?		
1.1.5.3 Review of laboratory reports?		
1.1.5.4 Review of quality control programmes?		
1.1.6 Is the person-in-charge readily available for consultation with:		
1.1.6.1 Referring medical practitioners?		
1.1.6.2 Medical administrators?		
1.1.6.3 Laboratory personnel?		
1.1.6.4 Computer personnel?		
1.1.7 If the person-in-charge is absent are there suitable relief arrangements?		

1.2 Laboratory Staff

	YES	NO
1.2.1 Are there appropriate and competent qualified staff to perform procedures of the laboratory to acceptable standards? **NB:** Medical Laboratory Scientist, Medical Technologists and Medical technicians must perform any test within their scope of practice provided that there is proof that they have been trained to do so.		

1.2.2 Have these persons received formal training in performing these tasks?		
1.2.3 Please attach total staff complement with appropriate qualifications and HPCSA registration numbers.	**Appendix A**	
1.2.4 Do staff working in high-risk areas have regular medicals?		
1.2.5 Are there vaccination records available for students and staff members?		
1.2.6 Are confidentiality agreements available for all staff?		

1.3 **Staffing Policies**

	YES	**NO**
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, employment contract, copy of ID, work permit if an employee is not a South African Citizen?		
1.3.2.3 A job description specifying duties/ responsibilities?		
1.3.2.4 Incident reports where applicable?		
1.3.3 Are records kept on staff participation in Continuing Professional Development programmes?		
1.3.4 Have all staff been instructed in the safe handling of infected material?		

1.4 **Education and Training**

	YES	**NO**
1.4.1 Does the laboratory have a structured, documented training programme in place?		
1.4.2 Does the training programme involve:		
1.4.2.1 Orientation of new personnel?		
1.4.2.2 Special attention to laboratory ethics and safety?		
1.4.2.3 Bench training coordinated by qualified personnel?		
1.4.2.4 In-service seminars or lectures?		
1.4.2.5 Use of teaching aids (audio-visual, manuals etc.)?		
1.4.2.6 Rotational training schedule?		

1.4.3 If the laboratory was approved by HPCSA to offer training, at what level does training take place:		
Student Laboratory assistant		
Student Medical Technician		
Intern Medical Technologist		
Student Medical Laboratory Scientist		
1.4.4 Is there a documented procedure that outlines the review of the training program? The review should include: Setting targets against objectives, review of quality indicators, documented follow-up actions when set targets are not met, documented changes to operations, communication of review process. If yes, please provide.		

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. e.g., POCT sites.

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.

	YES	NO
2.1 Is there adequate uncluttered space provided for:		
2.1.1 Workbench?		
2.1.2 Storage (including refrigeration)?		
2.1.3 Administration (including reporting areas)?		
2.2 Are work areas provided with adequate electrical, water and gas utilities (double adapters long lengths of gas tubing, should be avoided)?		
2.3 Is there an adequate specimen collection area suitably separated from laboratory work areas?		
2.4 Is there a staff library?		
2.4.1 If no, does the staff have adequate access to current textbooks/journals or the Internet?		
2.5 Is there a Tea room/ Recreation room?		
2.6 Does the laboratory environment provide:		
2.6.1 Adequate lighting?		
2.6.2 Adequate ventilation?		
2.6.3 Adequate air conditioning (particularly where sensitive instruments are in use)?		

2.7 Is the laboratory cleaned regularly and maintained in good order?		
2.8 Are there adequate facilities for waste disposal consistent with good laboratory practice and local government requirements?		
2.9 Does the laboratory have an emergency power supply to maintain essential services?		
2.9.1 If not has alternative arrangements been made?		
2.10 Does the laboratory have a direct outside telephone line for emergency use?		
2.11 Are glassware in good condition and properly stored?		
2.12 Are benches decontaminated daily?		
2.13 Are records kept of decontamination procedures?		

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

	YES	NO
3.1.1 Does the laboratory have a designated safety officer?		
3.1.1.1 Name the designated person		
3.1.2 Does the laboratory have a safety committee? If yes		
3.1.2.1 How often do they meet?		
3.1.2.2 Are minutes kept of the meetings?		
3.1.3 Does the laboratory have written safety manual?		
3.1.3.1 If yes: Is this available in each laboratory?		
3.1.4 Has all staff been trained in the correct safety procedures?		
3.1.5 Are records of this training kept?		
3.1.6 Have policies regarding "Injury on duty" and "Diseases contracted through exposure at work" been developed?		

3.2 Fire

	YES	NO
3.2.1 Is an operational Fire Alarm system installed in the building housing the laboratory?		
3.2.2 Is there a backup system?		
3.2.3 Is the fire alarm audible in all sections of the laboratory?		
3.2.4 Are fire drills held periodically?		
3.2.4.1 If yes: State the periods fire drills are held		

3.2.5 Is smoking prohibited in all areas except in designated smoke area?		
3.2.6 Are there sufficient and appropriate fire extinguishers (not the powder type) in the laboratory?		
3.2.6.1 If yes: Are these serviced and inspected on a regular basis?		
3.2.6.2 If yes: Are records kept?		
3.2.7 Are there fire blankets available in the laboratory?		
3.2.8 Are there sufficient fire hoses in the passages?		
3.2.8.1 If yes: Are these checked regularly to ensure that they are in good working order and, that hoses reach all areas?		
3.2.8.2 If yes: Are records kept?		
3.2.9 Are all staff familiar with the correct use of appropriate extinguishers?		
3.2.10 Are there clear evacuation routes?		
3.2.11 Are evacuation routes diagrammed and posted?		
3.2.12 Are volatile chemicals and flammable solutions appropriately stored?		
3.2.13 Does the laboratory comply with the local fire regulations?		

3.3 Accidents and First Aid

	YES	NO
3.3.1 Are detailed records of laboratory accidents kept?		
3.3.2 Are policies altered to prevent recurrences?		
3.3.3 Are first-aid facilities available? If yes:		
3.3.3.1 Are first-aid boxes available in the laboratory?		
3.3.3.2 Are the first-aid boxes regularly checked against an inventory kept inside?		
3.3.3.3 Do these boxes comply with the OHS Act?		
3.3.3.4 Is the person in charge of the First Aid boxes qualified in First Aid?		
3.3.3.5 Is the First Aid's training of the person in charge still valid?		
3.3.4 Is there an eyewash facility available in each laboratory?		
3.3.5 Is there an emergency shower available?		
3.3.6 Is there a protocol for the management of accidental injury following exposure to blood or body fluids?		
3.3.7 Is there a policy on needle stick injury?		

3.4 Equipment Safety

	YES	NO
3.4.1 Are written safety procedures available for all equipment?		
3.4.2 Does apparatus conform to acceptable safety standards?		

3.4.3	Is the laboratory on an earth leakage system?		
3.4.4	Are measures taken to minimise formation and dissemination of aerosols when centrifuging blood or bacterial specimens?		
3.4.5	Are biohazard cabinets used in the laboratory when hazardous bacteria, fungi, or viruses are handled?		
3.4.6	Are adequate fume cupboards provided where necessary?		
3.4.7	Are adequate laminar flow provided where necessary?		
3.4.8	Are the surrounding areas of instruments disinfected at least once a day?		
3.4.9	Is effluent disinfected before being discarded directly into the municipal waste?		
3.4.10	Are safety pipettes available for handling of:		
	3.4.10.1 Acids and corrosive chemicals?		
	3.4.10.2 Infected material?		
3.4.11	Are facilities adequate for disinfection of contaminated pipettes?		
3.4.12	Are containers for sharp instruments available in all laboratories?		
3.4.13	Are SOPs written regarding the prevention of injury of personnel by cutting instruments?		
3.4.14	Is the condition of each piece of equipment satisfactory?		
3.4.15	Are defective apparatus documented?		
3.4.16	Are defective equipment clearly marked		
3.4.17	Is equipment serviced regularly? If yes:		
	3.4.17.1 By whom?		
3.4.18	Are records available of instrument services and operation checks?		
3.4.19	Are operating manuals including calibration instructions available for all the types of equipment?		

3.5 **Prevention of laboratory-acquired infection**

		YES	**NO**
3.5.1	Are the appropriate signs available and in use?		
3.5.2	Is eating, drinking, smoking and application of cosmetics prohibited in all laboratories/areas where specimens are handled?		
3.5.3	Is storage of food in laboratory refrigerators or cupboards prohibited?		
3.5.4	Is mouth pipetting prohibited?		
3.5.5	Are suitable laboratory coats worn in all laboratories?		
3.5.6	Are laboratory coats supplied to all staff members and laundered by the laboratory?		
3.5.7	Are laboratory staff prohibited to leave the laboratory wearing their laboratory coats?		
3.5.8	Are suitable gloves provided in the laboratory for use where necessary?		
3.5.9	Are hand wash facilities with elbow taps provided in every laboratory?		
3.5.10	Is there an SOP for decontamination of all spillage?		
	3.5.10.1 If yes: Are staff well informed about these procedures?		
3.5.11	Are detailed SOPs available for the proper transportation of specimens to avoid breakage and spills?		

3.5.12	Are there detailed SOPs available on the receipt of broken specimens?		
3.5.13	Are SOPs written to prevent exposure of personnel to unfixed/partially fixed, biohazardous material?		
3.5.14	Are SOPs written to prevent exposure to noxious fumes and reagents in the laboratory?		
3.5.15	Are SOPs available for the proper handling of specimens?		
3.5.15.1	Do these include criteria for rejection of specimens?		
3.5.16	Are the arrangements for preservation of specimen quality satisfactory?		

4. PROCEDURES

The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples. 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

		YES	NO
4.1.1	Has a fully comprehensive specimen collection and handling manual been created?		
4.1.2	Are there SOPs covering:		
4.1.2.1	Method of collection?		
4.1.2.2	Positive identification of the patient?		
4.1.2.3	Preparation of the patient?		
4.1.2.4	Nature of the sample to be collected?		
4.1.2.5	Need for special timing for collection?		
4.1.2.6	Appropriate preservation or anticoagulant blood is adequately mixed before sampling (e.g. sequential testing of the same specimen)?		
4.1.2.7	Safety precautions in the handling of specimens?		
4.1.2.8	Appropriate preservative or anti-coagulant?		
4.1.2.9	Need for special handling between time of collection and time received (e.g. refrigeration)?		
4.1.2.10	Instructions for labelling?		
4.1.2.11	A system in use by which damaged or unsuitable specimens can be rejected or partially tested?		
4.1.2.12	Action steps to follow when specimens are lost?		
4.1.3	What provision is made for storage of specimens prior to testing or referral?		
4.1.4	For how long and what storage conditions are specimens retained after testing?		

4.2 Reception

	YES	NO

4.2.1	Are the procedures in this area documented?		
4.2.2	Are the SOP's for this area related to e.g., use of gloves, procedures for handling leaking specimens and contaminated forms written?		
4.2.3	Is there an SOP for specimens received after hours?		

4.3 **Specification Identification**

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

4.4 **Rejection of Unsuitable Specimens**

		YES	NO
4.4.1	Is there an SOP on the handling of unsuitable/inadequately labelled specimens?		

4.5 **Methods**

		YES	NO
4.5.1	Are there SOP's covering detailed instructions for each test procedure?		
4.5.2	Are the SOP's in 4.5.1 validated?		
4.5.3	Are current package inserts available for all reagents and kits used in the laboratory?		

4.6 **Quality Assurance Programme**

		YES	NO
4.6.1	Does the laboratory have a documented quality management program (quality manual) that covers all the areas of the laboratory as well as the beneficiaries of the service?		
4.6.2	Are there written in-house safety guidelines?		

4.7 **Reports**

4.7.1	Does the report form contain the following:	YES	NO
	4.7.1.1 Name of laboratory which performed the tests?		
	4.7.1.2 The names and identification numbers of the patient?		
	4.7.1.3 Name of clinician (with the HPCSA /or SANC number requesting the work?		
	4.7.1.4 Laboratory accession number?		
	4.7.1.5 References values for each test?		
	4.7.1.6 Date/time of specimen collection?		
	4.7.1.7 Comment on inadequate/unsuitable specimen?		

	4.7.1.8 Date/time of issue of report?		
4.7.2	Do records of the original results identify:		
	4.7.2.1 Who did the work?		
	4.7.2.2 Who reviewed and validated the results?		
	4.7.2.3 Who made any amendments		
4.7.3	Is there a SOP written to minimise transcription errors?		
4.7.4	Are records retained on the computer or other storage system?		
4.7.5	Are there SOPs in use for the handling of clerical errors and unusual laboratory results?		
4.7.6	Are SOPs written for the timeous correction of mistakes?		

4.8 **Records**

		YES	NO
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?		
4.8.2	Is there an SOP for accelerated communication of seriously abnormal results?		
4.8.3	Are all reports given in writing (or where given verbally for specific reasons, later confirmed in writing)?		
4.8.4	Is there an SOP regarding conveying results, telephonic reports and records kept?		
4.8.5	Are suitable records kept of the dispatch of and return of referred test results		

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			
		YES	NO
4.9.1	Is there an up-to-date maintenance record for all items of equipment?		
4.9.2	Are there operating manuals available for:		
	4.9.2.1 Water baths?		
	4.9.2.2 Incubators		
	4.9.2.3 Hot air ovens		
	4.9.2.4 Autoclaves?		
	4.9.2.5 Biological safety cabinets?		
	4.9.2.6 Anaerobic workstations?		
	4.9.2.7 Centrifuges?		
	4.9.2.8 Microscopes?		
	4.9.2.9 Test Instrumentation?		
	4.9.2.10 Storage equipment?		
	4.9.2.11 Other small equipment?		
4.9.3	Is there a schedule or system for the regular checking of the critical operating characteristics for all instruments?		
4.9.4	Are the equipment manufacturer's operator manuals readily available to testing staff, and where possible, available in the language understood by staff?		

4.9.5	Are function checks documented in a convenient manner to detect trends or malfunctions?		
4.9.6	Are tolerance limits for acceptable function written for specific instruments wherever appropriate?		
4.9.7	Are instruments provided with methods for minor troubleshooting and repairs?		
4.9.8	Are records maintained for each instrument to document all repairs and service procedures?		
4.9.9	Are adjustable automatic pipettes/dispensers checked for accuracy and reproducibility at regular intervals and the results recorded?		

4.10 **Reagents**

		YES	NO
4.10.1	Are all reagents and standards properly labelled as to content and concentration?		
4.10.2	Are reagents dated on receipt, preparation and/or when placed in service?		
4.10.3	Are expiry dates indicated on the reagent containers?		
4.10.4	Are reagents stored properly i.e. refrigerated when necessary?		
4.10.5	Are new reagents checked against old reagents or other reference material prior to being placed in service?		

5 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**

5.1.1	Name the designated staff member responsible for monitoring QC		
5.1.2	To whom does the person report?		
		YES	NO
5.1.3	Is there an Internal Quality Control (IQC) programme to cover all tests performed?		
	5.1.3.1 If yes, please state which IQC system is used for each test procedure.		
5.1.4	Is there an External Quality Control (EQA) programme?		
	5.1.4.1 If yes, please state which EQA system is used for each test procedure.		

5.1.5	Is there intra-laboratory control procedure for results checking within the laboratory group?		
	If so, please specify.		
5.1.6	Are Quality Control records kept? If yes:		
	5.1.6.1 For how long?		
	5.1.6.2 Are these records readily available?		
5.1.7	Is the archive system in operation?		
5.1.8	Are results used for:		
	5.1.8.1 Evaluating performance?		
	5.1.8.2 Identifying problems?		
	5.1.8.3 Method development?		
5.1.9	Are the results from internal and external QC programmes available to all laboratory staff?		
5.1.10	Is an SOP written for preparing and handling control materials for each procedure?		
	5.1.10.1 State the frequency of which QCs are run.		
	5.1.10.2 Is there an SOP to follow when the QC results fall outside the acceptable limits?		
	5.1.10.3 Is there a record of what corrective action was taken and by whom?		
5.1.11	Are there SOPs for validation and verification of new methods, procedures and equipment?		

5.2 **Controls and Standards**

		YES	NO
5.2.1	Are all controls labelled properly i.e., contents, concentration etc.?		
5.2.2	Do all calibrators have labels showing dates of receipt, opening for use and expiry?		
5.2.3	Are controls used at different levels (i.e. intermediate and low)?		
5.2.4	Are quality control data:		
	5.2.4.1 Evaluated daily?		
	5.2.4.2 Is data charted?		
	5.2.4.3 Is this displayed prominently?		
5.2.5	Are ongoing and updated records kept?		
5.2.6	Is frequency of calibration in accordance with instruments and/or reagent manufactures recommendations?		
5.2.7	Is calibration traceable to QC results?		
5.2.8	Are QC results used to determine process failure?		

6. LABORATORY COMPUTER SYSTEM (If Applicable)		
	YES	**NO**
6.1 Do computer manuals exist which includes the following aspects of the computer operation and maintenance?		

6.1.1	Is the computer system protected against unauthorised access?		
6.1.2	Preservation of data in case of fire, flooding etc.		
6.1.3	Firefighting equipment in the computer room?		
6.1.4	Are there defined levels of programme access for various staff members?		
6.1.5	Is there a documented stated policy for correction of test request errors?		
6.1.6	Is there a procedure for the changes of any results entries and errors?		
6.1.7	Is there a documented policy for the verification of results coming online from instruments before final entry into the patient files?		
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 clinics or sent out to private practitioners?		
6.1.9	Is there a special library or other system to allow comment on unsuitable specimens (haemolysis, delayed specimen)?		
6.1.10	Is the staff member who entered the results identifiable and traceable?		
6.1.11	Is a system in existence for the timeous retrieval of results?		
6.1.12	Is there a procedure for the daily back-up data?		
6.1.13	Do instructions exist and where relevant a schedule for the maintenance of hardware?		
6.1.14	Are there records of all hardware and software changes and repairs?		
6.1.15	Are all changes to hardware and software validated prior to acceptance?		
6.1.16	Are changes to hardware and software done by qualified persons?		
6.1.17	Is there a procedure for the shutdown of the computer, for software and/or hardware failure?		
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?		
6.1.19	Is there an emergency after-hours service for software and hardware problems and telephone numbers displayed in an area where they are freely accessible to the staff?		
6.1.20	Is there a hardcopy file of all patient data (results of tests and test process hard copy) maintained?		
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?		
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.		

7. APPENDICES

Appendix A: Staff Complement Record
Appendix B: Student Interview Guide
Appendix C: Annual Report for PBMT approved units for training in Medical Technology Profession

8. REFERENCES

Guidelines for the approval of cluster training laboratories (Form 108A)
Guidelines for the approval of training laboratories: (Form 108B)
HPCSA Quality Management System (QMS)
Policy relating to registration and training of student and intern Medical Laboratory Professionals: (Form 160MT)
HPCSA Ethical guidelines for the Health Professions
ISO/IEC 17025 Standard
ISO/IEC 15189 Standard