

## **ANNEXURE III**

### **QUALITY ASSURANCE AND ACCREDITATION RULES**

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## **TRANSITIONAL ARRANGEMENTS**

## **PART I. PRELIMINARY**

### **A. SHORT TITLE AND COMMENCEMENT**

A.1 These Rules shall be called the National Health Laboratory Service Quality Assurance Rules and shall come into operation on 1 July 2003.

### **B. INTERPRETATION**

B.1 These Rules must be read in conjunction with the Health Professions Act, 1974 (Act No. 56 of 1974) and the regulations made in terms of that Act.

### **C. REPLACEMENT OF RULES AND TRANSITIONAL ARRANGEMENTS**

C.1 Any Rule made and in force under a directive or provision in the South African Institute for Medical Research (SAIMR) or the Public Service insofar as it affects the quality assurance and accreditation matters of the Service, is hereby replaced insofar as it is inconsistent with any provision of these Rules.

### **D. EXCEPTIONAL CIRCUMSTANCES**

D.1 If circumstances develop which justify deviation from the provisions and measures in a particular rule in these Rules, the Board may, under exceptional circumstances, make determinations, issue directives or approve that alternative provisions and measures be applied; provided that the directives or approved alternative provisions and measures approved by the Minister and comply with the Health Professions Act and regulations made in terms of that Act

## E. COMMUNICATION

E.1 If a manager or employee needs to communicate with the Board on quality assurance or accreditation matters, she or he shall communicate through the executive manager responsible for the Quality Assurance Unit or the Chief Executive Officer.

E.2 Only the Chief Executive Officer and the Board may communicate with the media or other external organisations regarding quality assurance and accreditation matters of the Service.

E.3 The Quality Assurance Unit must communicate all relevant information regarding quality and accreditation to all laboratories and employees of the Service. The communication may be in the form of:

- (a) meetings;
- (b) newsletters;
- (c) websites;
- (d) e-mails;
- (e) workshops; and
- (f) publications on notice boards.

## **PART II. QUALITY ASSURANCE UNIT**

### A. PRINCIPLES

A.1 A set of standardised procedures is required in order to simplify the attainment of minimum acceptable performance by the departments and laboratories of the Service. These need not be prescriptive but should be controlling. Standardised quality assurance procedures will be implemented in order to monitor standards and to inform appropriate allocation of resources. These procedures and programmes may be provided from internal or external sources, depending on availability and

cost. The minimum requirements of these standardized procedures and programmes that will satisfy the need for quality assurance and the manner in which they will be evaluated will be specified in policy documents, standard operating procedures and other procedure manuals that will be updated periodically.

A.2 In instances where no quality assurance is available, inter-lab comparisons (proficiency testing) should be instituted.

## B. ESTABLISHMENT OF THE QUALITY ASSURANCE UNIT

B.1 The Chief Executive Officer must establish a Quality Assurance Unit for the purposes of monitoring the quality of the pathology services and managing a quality assurance and accreditation programme.

B.2 The head of the Unit shall be a full-time employee of the Service.

B.3 In order to ensure that the Unit is able to fulfil its functions for every laboratory in the Service, the Chief Executive Officer will establish positions and specify laboratories that will provide an adequate support infrastructure.

B.4 The unit will comprise a core of sufficient permanent personnel at headquarters to manage the programmes but will work in close liaison with designated quality assurance managers throughout the organisation.

## C. FUNCTIONS OF THE QUALITY ASSURANCE UNIT

C.1 The functions of the Unit are to:

(a) set quality goals for the Service;

(b) develop, a policy, plan and pathology service quality manual, implement its contents and monitor its application;

(c) establish, monitor and evaluate appropriate internal quality control and external quality assurance programmes;

(d) co-ordinate in-house proficiency testing programmes;

(e) co-ordinate standardisation of methods throughout the service;

(f) develop and maintain a bank of organisms for microbiological quality assurance purposes;

(g) formulate policy and implement a programme of accreditation with SANAS or any other national or international accreditation authority;

(h) develop and manage a national laboratory quality audit network for the Service;

(i) develop and support the implementation of teaching and training programmes on quality assurance and control;

(j) assist laboratory managers with the evaluation of instrumentation and reagents;

(k) provide quality guidelines for operational research; and

(l) develop and maintain a library and reference service on quality assurance and control.

C.2 The Unit, in conjunction with specialised laboratories, may develop and manage quality assurance and control programmes for laboratories and pathology services external to the Service and may establish and levy fees for such services.

C.3 Where specific laboratories are accredited as a part of any international reference laboratory network, the Unit will assist those

laboratories in complying with the requirements for the reference laboratory status.

C.4 There shall, wherever possible, be standardisation of equipment and methodologies to ensure harmonization of results within the service, levels of performance consistent with current acceptable practice and appropriate allocation of available resources.

#### D. RECORDS OF THE QUALITY ASSURANCE UNIT

D.1 The Unit must develop and promote the use of standard and consistent terminology for reporting throughout the Service.

D.2 Records must be kept, in an easily retrievable manner, of all documentation relating to the analysis of specimens or performance of other examinations as detailed in the relevant international standards, such as ISO 17025 and/or ISO 15189 or their replacement standards. Records of specimen storage must also be available.

D.3 All records of performance in internal or external programmes are confidential to the participating laboratory, the relevant line manager(s) and the Unit.

D.4 The Unit must develop and monitor procedures for the archiving of documentation including, but not limited to, specimens, patient records, laboratory audits (including safety), periods of archiving, and evaluations of reagents and instrumentation.

D.5 The Unit must develop and manage a policy relating to the revision, authorisation of and storage of all quality policy documentation and standard operating procedures.

D.6 The Unit may obtain outside professional or expert assistance when required.

## E. QUALITY ASSURANCE ADVISORY PANELS

E.1 The Board must establish Quality Assurance Advisory Panels to advise the head of the Unit, the Chief Executive Officer and the Board on quality assurance matters.

E.2 The functions of the Advisory Panels shall be to:

- a. review proposals regarding quality assurance and associated procedures;
- b. review and advise the Unit on plans for (national or international) accreditation of laboratories;
- c. review annually the results of the quality assurance programmes and quality audits and advise the Unit on corrective actions that should be taken;
- d. report to the Chief Executive Officer and, if necessary, the Board regarding the performance of the Unit; and
- e. make recommendations regarding quality matters generally.

E.3 The Advisory Panels will comprise as many professionals as the Board deems appropriate, who need not be employees of the Service, but must include at least one pathologist, one medical scientist, one medical technologist and, the head of the Unit or his or her deputy.

E.4 Meetings of each Advisory Panel will be held on such dates and such times and places as may be determined by resolution of the Advisory Panel not less than twice in each year; provided that further meetings may be called by any member of the Advisory Panel, at the instance of the head of the Unit, the responsible executive manager, the Chief Executive Officer or the Board.

E.5 The members of an Advisory Panel will elect one of the members to be the chairperson on an annual basis.

E.6 When the chairperson is not available to chair an Advisory Panel the members present will select a member to chair the meeting.

E.7 Notice of each meeting of an Advisory Panel must be given to all the members in such manner and form as the Advisory Panel may from time to time determine.

E.8 Minutes of all Advisory Panel meetings must be kept and such minutes must be ratified at the next meeting, and the minutes or summaries thereof, must be made available to the Chief Executive Officer and the Board.

E.9 The Head of the Unit must provide the secretariat of the Advisory Panels.

E.10 The financial costs of the Advisory Panels will be budgeted for and paid by the Service.

### **PART III. DELEGATIONS, AUTHORISATIONS AND RESPONSIBILITIES**

#### **A. PRINCIPLES**

A.1 To enable the head of the Unit to manage the quality programme of the Service effectively and efficiently, the responsible executive manager must empower other employees in the Service by means of appropriate delegations and authorisations, where necessary.

## B. DELEGATIONS AND AUTHORISATIONS

B.1 The responsible executive manager must record a delegation or authorisation in writing.

B.2 The delegation of a power by the responsible executive manager does not prevent her or him from exercising the power personally.

B.3 Any delegation must be signed by the employee to whom the delegation has been given as acknowledgement, one copy of the delegation letter must be kept by the Service and another copy given to the employee.

B.4 Withdrawal of any delegation must be signed by the employee from whom the delegation is being withdrawn, as acknowledgement, one copy of the withdrawal of delegation letter must be kept by the Service and another copy given to the employee. The original signed delegation must be kept on record and all responsibilities must be kept current in the job description of the employee concerned.

## C. GENERAL RESPONSIBILITIES

C.1 It is incumbent upon every employee to ensure that she or he has read and familiarised him or herself with the quality policy documentation as it applies to her or his job. It is also incumbent on the head of the Unit and line managers to ensure that this has indeed taken place and that personnel understand the contents of the documents.

C.2 The responsible executive manager must ensure that prior written approval is obtained from the Chief Executive Officer for any decision that will involve unbudgeted expenditure.

## **PART IV. INTERNAL QUALITY ASSURANCE**

### **A. PURPOSE**

A.1 Internal quality assurance procedures are required to monitor the performance of laboratory analysis or examination with a view to alerting the analyst to any problems that may limit the usefulness of a test result and/or report for its intended purpose. Internal quality assurance must allow for problem identification and corrective action to take place immediately.

A.2 The purpose of planning the quality assurance procedures to be implemented is to ensure that the required quality is obtained at minimum cost. To maximize cost-effectiveness, internal quality assurance procedures must be designed such that due consideration is taken of the quality requirements of each discipline of pathology and where appropriate, of each test or group of tests.

A.3 There must be standardisation of equipment and methodologies to ensure harmonization of results within the service, levels of performance consistent with current acceptable practice and appropriate objective allocation of available resources.

### **B. STRATEGIC PLANNING**

B.1 The head of the Unit must, after consultation with the relevant role-players, draft, implement and monitor a strategic plan for internal quality assurance. In the process of drafting the plan and ensuring that it is constantly relevant, the head of the Unit must;

B.1.1 Define the quality requirements for each test or group of tests based on the performance capabilities of the existing technology such that

the clinical quality needed for proper interpretation of test results and optimal patient management and the clinical requirements are met;

B.1.2 Determine the desired performance characteristics of the analytical or examination procedure so that specified targets can be set; and

B.1.3 Identify the appropriate quality assurance rules for use in each discipline for each test or test group.

B.2 The head of the Unit must develop and maintain a national inter-laboratory quality assurance comparison programme for compulsory participation of all laboratories in the Service under the conditions outlined in Rule IV C.

## C. NATIONAL INTERNAL QUALITY ASSURANCE PROGRAMME

C.1 Participation in a national inter-laboratory quality assurance programme provides an effective alternative mechanism to complement external quality assurance programmes. All laboratories of the Service must participate in the national inter-laboratory quality assurance programme that will be established and managed by the Unit.

C.2 External quality assurance programmes, national or international, may only be used under the conditions prescribed in Rule V.

C.3 The national inter-laboratory quality assurance programme will ensure that the required quality is obtained at minimum cost. To maximize cost-effectiveness, the national inter-laboratory quality assurance programme procedures must be designed such that due consideration is taken of the quality requirements of each discipline of pathology and where appropriate of each test, group or groups of tests. The head of the Unit must, after consultation with the relevant role players;

C.3.1 Define the quality requirements for each test, group or groups of tests based on the performance capabilities of existing technology and current clinical and analytical goals;

C.3.2 Determine the performance characteristics of the analytical or examination procedure so that desirable targets for the national inter-laboratory quality assurance programme performance can be set;

C.3.3 Identify the appropriate acceptance or non-acceptance criteria for the performance of each test;

C.3.4 Determine which analytes, each test, group or groups of tests or examinations cannot be implemented by the national inter-laboratory quality assurance programme; and

C.3.5 Advise on affordable external quality assurance programmes for such tests.

C.4 For the national inter-laboratory quality assurance programme to accomplish the intended purpose the head of the Unit must, after consultation with the relevant Advisory Panel:

- a. define the control material or materials to be used;
- b. obtain such material or materials, store them appropriately and distribute the materials to all participating laboratories;
- c. advise the laboratories on the frequency at which the internal quality control materials should be used;
- d. establish guidelines for the return of results within prescribed time scales and prescribed formats;
- e. analyse the returned data and prepare and return individual reports to the laboratories;

- f. use the information obtained from the database to establish intra-laboratory and inter-laboratory imprecision and laboratory bias;
- g. ensure that data, reports and feedback relating to a laboratory are treated confidentially and not divulged to any other person or persons other than the laboratory manager and the relevant manager;
- h. establish guidelines for responding to situations that are out of control, including, but not limited to, means of identification of the problem, procedures for taking appropriate corrective action, and for documenting all actions that are taken;
- i. establish a system for the appropriate maintenance and storage of all documentation relating to national internal quality assurance procedures, with due regard to Rule II D;
- j. review the national internal quality assurance data with the relevant managers on a regular basis;
- k. provide appropriate guidance and assistance to managers and their laboratories as deemed necessary; and
- l. provide educational materials and training courses that will enable local managers to train all of their personnel involved in the testing or examination process in internal quality assurance.

## D. REVIEW AND OVERSIGHT

### D.1 The responsible executive manager must:

- a. evaluate the performance of laboratories and their methods based on information provided by the internal quality assurance programme;
- b. ensure that appropriate corrective action is taken based on the programme data and reports; and

- c. ensure that training, education and review or replacement of methods and or analysers occurs taking account of the programme reports.

D.2 The head of the Unit will be responsible for implementing the national inter-laboratory quality assurance programme and for bringing persistent poor performance to the notice of the responsible executive manager.

D.3 Laboratory managers will be accountable to their line managers for the analysis or examination of the appropriate sample, return of results within the desired timeframe, review of the national inter-laboratory quality assurance programme reports, for taking the relevant corrective action within a reasonable time and for storing the results in the prescribed manner.

D.4 The line managers will be responsible for ensuring that all laboratories under their management take appropriate corrective action based on the results of the national inter-laboratory quality assurance programme.

D.5 The responsible executive manager is responsible for regularly briefing the Chief Executive Officer on the performance of all laboratories and specific quality problems associated with particular instrumentation or reagents.

## **PART V. EXTERNAL QUALITY ASSESSMENT**

### **A. PURPOSE**

The purpose of an external quality assessment strategy is to ensure that independent (international or private national) quality assurance

programmes, where necessary as provided for in Rule V B.2, are obtained at minimum cost.

## B. PLANNING

B.1 The head of the Unit will be responsible for planning the overall external quality assessment strategy and training appropriate personnel in matters relating to quality assurance.

B.2 External quality assessment programmes may only be used under the conditions prescribed in these Rules:

- a. in addition to participation in the national quality control programme, all reference laboratories or departments must, wherever possible, participate in relevant external quality assessment programmes provided by independent accredited providers; and
- b. other laboratories who have been authorised to provide tests for which the Unit does not provide a national quality control programme should also participate in an international programme.

B.3 External quality assessment programmes that compete with existing Unit programmes may only be used under exceptional circumstances and after consideration by the relevant Advisory Panel and approval by the responsible executive manager.

B.4 Decisions on such exceptional participation will take into account the size and type of the laboratory, the scope of investigations undertaken, cost effectiveness, programme availability, material stability and any other relevant external quality factors, including accreditation requirements.

B.4.1 The head of the Unit will, after consultation with the relevant role-players make recommendations to the responsible executive manager which external quality assessment programme or programmes the Service will participate in and the level of participation of individual laboratories and/or departments.

B.5 Where laboratories are participating in an approved external quality assessment programme for prescribed analytes, the manager of the laboratory in which the tests are carried out will be the designated responsible person. Implementation and management of the external quality assessment programme will be done in conjunction with the head of the Unit and the responsible executive manager.

## C. INTERNATIONAL PROGRAMMES

C.1 In recommending participation in any international external quality assessment programme the head of the Unit must consider whether the provider will be able to:

(a) provide value for money;

(b) take responsibility for the delivery of control samples or specimens to the individual laboratories well in advance of the due date for return of results;

(c) provide samples that will cover the pathological range expected to be found in patients in Southern Africa;

(d) provide clear guidelines, prescribed time scale and a prescribed format, and training where appropriate, for the return of results;

(e) analyse the returned data critically, prepare and return individual reports to the laboratories in a format or formats that are acceptable

to the Unit taking account of the particular requirements of each discipline or speciality;

(f) deliver the reports to the individual laboratories within an acceptable, specified time scale using a communication method that is suited to the individual participating laboratories, whether postal, facsimile or electronic mail;

(g) clearly identify poor performance of individual laboratories and bring such poor performance to the attention of the responsible executive manager;

(h) maintain strict anonymity of participant laboratories; and

(i) be prepared to liaise, as appropriate, with the Unit, on training and educational activities relating to quality assurance in the Service.

## D. REVIEW AND OVERSIGHT

D.1 The head of the Unit must;

(a) evaluate the performance of laboratories and their methods based on information provided by the external quality assessment reports;

(b) ensure that appropriate corrective action is taken based on the report findings; and

(c) ensure that training, education and review or replacement of methods and or analysers occurs taking account of the reports.

D.2 The laboratory manager will take full responsibility for the analysis or examination of the appropriate sample, return of results within the desired timeframe, review of the external quality assessment report, taking the relevant corrective action within a reasonable time and for storing the results in the prescribed manner.

D.3 In instances where appropriate action has not been taken by the relevant line manager the head of the Unit will inform the responsible executive manager.

D.4 The responsible executive manager must inform the Chief Executive Officer of the performance of participating laboratories in external quality assessment programmes on a regular basis.

## **PART VI. ACCREDITATION**

### **A. PURPOSE**

A.1 The purpose of accreditation is to provide the clients, and thus their patients, with the confidence that the Service's pathology service and its laboratories are managed in a competent, safe, ethical and reliable manner and that the results are consistent and accurate. For this reason the accrediting body must be independent and impartial so that the standards can be seen to be the same for all participants and the accreditation rating has specific meaning.

A.2 The major laboratories and the laboratories directly associated with academic institutions will receive preference for national accreditation so that they can serve as "hubs" for preparing the more peripheral laboratories for accreditation.

A.3 Line managers should work towards the international standards for operation of medical laboratories as laid down in ISO 17025 or ISO 15189, or their successor standards, regardless of whether the laboratory is to be formally accredited.

## B. PLANNING

B.1 The Board must, after consultation with the Chief Executive Officer and the responsible executive manager, adopt an accreditation policy.

B.2 The responsible executive manager will be responsible for developing plans and implementing the accreditation policy and process.

B.3 The head of the Unit must develop a plan for phasing in the accreditation of Service laboratories. In doing so the head of the Unit must consult widely.

B.3.1 The head of the Unit may:

- (a) constitute accreditation working groups comprising appropriate managers, pathologists, medical scientists and medical technologists for any pathology discipline or activity;
- (b) nominate personnel from each discipline to convene the local discipline or departmental working group;
- (c) allocate resources to any working group for the detailed planning of the accreditation process; and
- (d) disseminate relevant information on accreditation to the managers and working groups to enable them to plan the process.

B.4 The accreditation plan should include procedures for:

- a. document control (standard operating procedures, laboratory quality manuals, safety manuals, laboratory technical records, personnel records);
- b. writing, reviewing and distribution of standard operating procedures
- c. ensuring that time frames are adhered to;
- d. ensuring that all personnel of the Service are made aware of the accreditation process and of their responsibilities in this process;
- e. conducting internal quality audits in Service laboratories to identify all non-conformances and to stipulate time frames for the implementation of appropriate corrective actions;
- f. identifying laboratories that are considered ready for accreditation;
- g. identifying laboratories that are in need of special help in preparing for accreditation;
- h. identifying personnel from accredited laboratories that can assist with the process;
- i. submission of an application for accreditation assessment; and
- j. should specify a hierarchy of documents relating to quality assurance, quality control and accreditation and their formats (policies, procedures, standard operating procedures, forms and records).

## C. INTERNATIONAL ACCREDITATION

C.1 The Service will encourage reference laboratories to seek international approval or recognition, in addition to national accreditation, from international agencies such as the World Health Organisation in situations where there is significant advantage to be gained for the Service in obtaining international work or where the status has a positive influence on the teaching and research objectives of the Service and its associated tertiary education institutions.

C.2 The process of pursuing and achieving international accreditation must comply with the provisions of Rule VI.B.

## **PART VII. TRAINING**

### **A. PRINCIPLES**

A.1 Quality assurance training should support the main objectives of the Unit. Courses should be developed and presented to all parties, internal or external to the Service, that are interested in quality management and accreditation.

A.2 Quality assurance courses should meet the requirements of all professional personnel. The responsible executive manager shall ensure that the course structure and content are in keeping with international standards and developments.

A.3 Any course presented by the Service must meet the requirements of the respective professional bodies for continuous professional development programmes.

A.4 The aims of the quality assurance courses should be to enable all persons attending to understand the importance of their work and thus be able to bring about continuous improvement in the quality of pathology services provided.

### **B. COURSES**

#### **B.1 Personnel Quality Assurance Training**

B.1.1 The Chief Executive Officer must ensure that all personnel of the Service receive the appropriate level of training in quality assurance so

that each member of the personnel has the necessary skills to perform his or her functions to the highest possible standards.

B.1.2 The Service shall strive to include the inputs of nationally and internationally recognised experts in presentation of quality assurance training courses.

B.1.3 Each member of the personnel of the Service is responsible for maintaining and regularly updating his or her quality assurance training and for ensuring that recent quality assurance training is updated in his or her personal records. The management of the Service must assist all personnel in updating their quality assurance training and records.

B.1.4 All laboratory and departmental managers must ensure that adequate provision is made for the continuous quality assurance training of their personnel.

B.1.5 Personnel of the Service who attend national or international quality assurance courses or meetings must provide constructive feedback at an appropriate forum and endeavour to introduce relevant new practices in the laboratories of the Service through the appropriate channels.

B.1.6 Training logs must be kept for all personnel with dates and signatures of the training officers.

## B.2 External Quality Assurance Training

B.2.1 The Service shall support the participation of personnel in private sector and/or international quality assurance courses and meetings within the provisions of the budget.

B.2.2 The Service shall offer quality assurance training to private sector laboratory professionals, interested students and to foreign students to the

extent that the capacity exists and will levy appropriate fees for the training courses.

## **PART VIII. INTERNAL LABORATORY QUALITY AUDIT**

### **A. PRINCIPLES**

A.1 For the effective maintenance of a quality system all relevant activities must be audited on a regular basis. The purpose of these audits is to establish whether the objectives that are defined in the relevant Quality Manual and/or the relevant quality standard are being achieved.

### **B. RESPONSIBILITIES**

B.1 The head of the Unit must ensure that there is a Standard operating procedure for internal quality audits.

B.2 The head of the Unit must compile an internal quality audit plan annually and ensure that the quality audits are carried out according to the official procedures.

B.3 All line managers must ensure that corrective actions following internal quality audit are monitored and reported to the responsible executive manager.

## **TRANSITIONAL ARRANGEMENTS**

1. The existing quality assurance arrangements and structures that are in place at the time of the commencement of these Rules are hereby replaced.

2. Any delegations that have been given to any employee prior to the commencement of these Rules will be deemed to be delegations in terms of these Rules insofar as they do not conflict with the provisions of these Rules and shall continue in effect until such time as they are amended, withdrawn or replaced.
3. All existing delegations must be formalised in writing and signed by the employee to whom the delegation has been given as acknowledgement; one copy of the delegation filed by the Service and a copy given to the employee. The recorded job description must be updated to include the responsibilities that are delegated.
4. Any existing external quality assessment programme that was in place at any laboratory prior to the commencement of these Rules shall continue in place as if established in terms of these Rules insofar as it does not conflict with the provisions of these Rules and shall continue in effect until such time as it is amended, cancelled or replaced.
5. Contracts in respect of any existing external quality assessment programme must be formalised in writing and a copy of the contract forwarded to the Chief Executive Officer.

