Islamic Government of Afghanistan
Ministry of Public Health

Guide to the Proper Practice of Medical Analyses

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SUMMARY

1 INTRODUCTION

1.1 Purpose

Medical analysis is a component of preventive, diagnostic, prognostic and therapeutic processes. Placed under the responsibility of the biologist, this analysis includes sample collection, the execution of the analysis, the confrontation between clinical and biological parameters, the validation and the interpretation of results. These results contribute to the diagnosis and the prescription of the care.

This is why quality assurance must be the essential and constant preoccupation of any biologist. Quality assurance is achieved through the proper execution of medical analyses.

This *Guide to the Proper Practice of Medical Analyses* is intended for all medical laboratory workers, whatever their qualification, to assist them to improve the quality of laboratory services.

The rules and recommendations contained in the guide do not aim to impose the particular method to be employed in any given analysis, as that is a matter of professional judgement for the biologist, except in cases where the method is prescribed by regulations.. The choice of optimal method falls to the biologist; based on widely accepted practice and recommended by national or international panels of experts in clinical biology.

These rules and recommendations provide a reference guide of what is necessary to procure, organize, check, comply with, study, and retain in order to obtain accurate and precise results.

The standard operating procedures in this guide relate to all stages of the analysis, from the biological sampling until the handing-over of results. These procedures associated with quality control are an element of the quality assurance system of medical laboratories. Their implementation and their practice can be checked by the MoPH, supported by the Central Laboratory of Kabul.

The measures contained in the guide apply to all laboratories carrying out medical analyses, public or private. This application of this guide is compulsory in all health facilities.

It is the responsibility of biologists to coordinate and manage the implementation of quality assurance activities, including transport of samples and establishing the procedures for biological waste disposal (chapter 2.5 of this guide).

This guide does not apply to cytopathology and anatomy activities**.**

1.2 Definition of Terms

1.2.1 Medical Analyses

"Medical analyses are the biological examinations that contribute to the diagnosis, the treatment or the prevention of human diseases or any other modification of the physiological state, other than the acts of cytopathology and anatomy carried out by the specialists in this discipline".

1.2.2 Quality Assurance

- *Management of Quality:* the group of pre-established and systematic actions necessary for a product or a service to satisfy the quality requirement.
  In the field of medical analysis, quality assurance facilitates the organisation of tasks and applies to the pre-analytical, analytical and post-analytical stages.

- *Quality:* quality is the capacity of a product, process or service, to satisfy the expressed or implicit needs for the user.
  In the field of medical analysis, it is the appropriateness of the means implemented to the information requested by the doctor, as well as meeting the expectations of the patient.

- *External Evaluation of Quality (E.E.Q.):* also known as *external quality control*. It refers to control, by an external organisation, of the quality of the results provided by a laboratory. This retrospective control allows an inter-laboratory comparison and assessment in order to improve the quality of the work of the participating laboratories. The external organisation sends the same samples to the various laboratories, gathers the results obtained, studies and transmits them with comments to the participating laboratories.

- *Internal Quality Control (C.Q.I.):* Its refers to the procedures implemented in a laboratory in order to allow the control of the quality of the results of the analyses during the analysis process.

1.2.3 Analysis Reports

Documents written, validated and signed by the biologist comprising results of qualitative and/or quantitative analyses accompanied by comments issued as often as necessary or is governed by the regulation. These results must be presented in accordance with the template in annexe B of this guide.

1.2.4 Confidentiality

All information relating to patients is confidential and must be protected by professional secrecy. Results of medical analyses can be communicated only to the patients themselves, to a third person duly authorised by the patient, to the doctor who requested the analyses and any other doctor appointed by the patient.

1.2.5 Samples

- *Biological Sample:* specimen obtained by collection or by taking sample and on which one or more medical analyses will be carried out.

- *Sample of Calibration:* sample of qualitatively and quantitatively defined composition, adapted to the method used, for one or more components, often compared to reference standards and intended for the calibration of the techniques used in some biological disciplines.

- *Control Sample:* sample adapted to the method used and intended to evaluate the accuracy and the fidelity of the results.

1.2.6 Evaluation

Study of the quality of a process, a technique or an instrument allowing the specification of its characteristics and the adaptation to the required goal.

1.2.7 Staff

All staff perform a function in the laboratory. The staff must have qualifications in conformity with the law. This staff have the duty to update their knowledge of developments in medical analyses while taking part as regularly as possible in training, conferences, congresses, seminars and workshops organized by universities, learned societies and professional associations. Directors and staff in charge of laboratories have a duty to ensure the continuing education of their staff in the field of medical analyses.

1.2.7.1 Biologist

Any person holding the diploma or title required by the legislation in force (doctor or pharmacist-biologist), to practice the speciality or to manage a medical laboratory.

1.2.7.2 Technician

Any person holding a diploma or a qualification complying with regulations, who ensures, under the supervision of the biologist, the execution of the medical analyses.

1.2.7.3 Laboratory assistant

Any person who ensures, under the control of laboratory technicians, the preparation and the maintenance of materials requiring detailed attention in their handling and the maintenance of the facilities.

1.2.7.4 Secretary

Any person contributing to the reception of the patients and working on documents used or establish by the laboratory.

All the staff working in public or private medical laboratories are subject to rules of professional secrecy and must respect provisions of this guide.

1.2.8 Taking Samples

Act allowing the obtaining a biological sample.

1.2.9 Procedures

Operations to be carried out, precautions to be taken and measurements to be applied detailed in specific procedure documents for each laboratory.
These procedures can include detailed instructions.

1.2.10 Qualification

Operation intended to show that an analytical system or an instrument works correctly and gives the expected results.
For the staff, qualification refers to the vocational training acquired and required by the relevant regulations in force. It is maintained by the continuous internal or external training in which the staff of the laboratory must take part.

1.2.11 Analytical System

All analytical means made up of a method, an apparatus, software, of one or more reagent(s), of one or more calibration sample(s), of one or more control sample(s), which allow the determination of a component according to a defined operating procedure.

1.2.12 Transferability

Quality of an analytical process allowing it to be used in a great number of laboratories.
Quality of an analytical result allowing comparison with those obtained in other laboratories.

1.2.13 Reference Values

Results obtained for a given component in a population of reference in which individuals are free of pathology or treatment that could modify their value.
References values can vary in particular according to the geographical origin, the sex and the age of individuals. They are generally expressed by taking account of lower and higher limits determined by statistical study. They can be established by the biologist, according to the analytical techniques used, or possibly checked when using data from scientific publications.

1.2.14 Validation

An operation to ensure that a result has been obtained under satisfactory technical conditions and that it is compatible with the medical background of the patient. This validation is at the same time analytical and biological.
The analytical validation comprises the checking of the conformity of conditions of execution to procedures and takes results obtained with control samples into account.
The biological validation is the coherence and the credibility checking of the whole results of analyses coming from a same file, and their comparison with former results. It can require the knowledge of the clinical state of the patient and treatments implemented. A biologist is responsible for this task.

2 RULES OF OPERATION

2.1 Organisation

Any medical laboratory must have a system of quality assurance based on procedures and written instructions concerning various stages of analysis and the conditions of their execution.
Quality does not only depend on the analysis itself, but on the general organisation of the laboratory, the qualifications and the motivation of the staff as well as the application of operational procedures during the various stages of the analyses: pre-analytical, analytical and post-analytical.
A system of quality assurance must be permanent and must envisage a trace of controls carried out and effectiveness of the corrective actions. Without this trace, it is difficult, and sometimes impossible, to find an error and/or to analyze its causes in order to avoid its repetition.
The quality assurance of the various services or units of a health facility must have the same objective.

2.1.1 Obligations of persons in charge of medical laboratories in the organisation and the carrying out of analyses

The whole of the staff of the laboratory is concerned with the system of quality assurance which is placed under the authority and the responsibility of the director of the laboratory or of the head of service or department.
The organisation of the system of quality assurance of the laboratory can be delegated by the director of laboratory or the head of service or department to a biologist or to a person in charge of the management of the system of quality, who must have the vocational training, competence and the experience necessary to achieve this task.

The organisation of a such quality systems is based on some precise rules:

- **Concerning the staff:**

- to establish a flowchart of the laboratory;
- to ensure that the staff are suited to the tasks that are entrusted to them and have had the necessary training;
- to ensure that each operation carried out at the laboratory is entrusted to a person with suitable qualifications, training and experience;
- to place at the disposal of the staff procedures, operating procedures and this guide;
- to inform the personnel of the implementation of all new procedures or operating procedure modifications.

- **Concerning procedures:**

- to ensure that procedures in force, written, checked, approved and dated, are implemented by the personnel;
- to ensure that any justified modification of procedure is written, approved, recorded, dated, communicated and that the personnel are trained in the application of this modification;
- to preserve a chronological file of all the procedures;
- to take care of the execution, by a qualified and competent staff member, of the quality assurance programme defined by this guide;
- to proceed, in the event of dysfunction revealed by the quality control, with all operations likely to correct anomalies and ensure the recording of corrective measures undertaken and to evaluate their results;
- to ensure of the lawful management of the files (chapter 5 of this guide).

- **Concerning installations, equipment, instrumentation, consumables and reagents:**

- to ensure that installations and equipment of the laboratory are functional;
- to ensure that consumables are suitable;
- to ensure that reagents are available, not out-of-date, preserved under conditions defined by the manufacturer and in conformity with the regulations in force;
- to ensure that equipment, consumables and reagents used are adapted to the evolution of scientific knowledge.

- **Concerning staff safety:**

- to ensure that measures concerning the health and the staff safety and the environmental protection, in particular prohibition to smoke and prohibition to introduce, to preserve and to consume foodstuffs in rooms of sample taking, reception and analyses, are applied;
- to establish and implement applicable procedures relating to hygiene and staff safety, for example: use of gloves and protective glasses, wearing of laboratory coats, prohibition to put pipettes in one's mouth, to not put the cap back on needles after taking samples, use of hoods during handling of dangerous products and/or contaminants, cleaning of worktops and equipment with respect of the length of action of disinfecting and decontaminating;
- to ensure of the waste disposal: to handle, preserve and eliminate waste by taking all the precautions necessary to avoid contaminations (chapter 2.5 of this guide).

2.1.2 Obligations of the biologist

The biologist must, in accordance with regulations:

- validate the results of the medical analyses after having ensured him(her)self that it has been carried out in accordance with recommendations of this guide;
- sign the report of analyses;
- ensure that their transmission is done within an appropriate time for its correct clinical use and under conditions of confidentiality preserving the professional secrecy (chapter 3.5 of the guide).

2.1.3 Obligations of the staff

Staff must conform with all procedures and instructions in force in the laboratory. Staff are obligated to apply the regulations of this guide and must take into account its recommendations.

2.2 Installation

2.2.1 Organisation and maintenance

The organisation of the laboratory must be designed to isolate activities involving the potential for contamination of the operator and/or analysis and to avoid pollution inside as well as outside.
It must include storage areas at various temperatures for consumables**,** raw materials and reagents. There must be different from zones of conservation of biological samples. The storage sections of the raw materials and/or toxic or potentially dangerous or contaminant reagents must be separate.
The term “zone” does not presume particular dimensions. It can be a simple distinct compartment in an enclosure or in a room.
The cleaning of the material and the sorting of waste must be done under conditions of safety for the staff and so as to ensure the quality of analyses.
A procedure specifies the methods of maintenance of the buildings (frequency, cleaning products to be used and instructions).

2.2.2 Safety

All necessary provisions must be taken to respect lawful obligations against explosion and fire hazards.
Installations for the distribution of combustible gas and flammable substances must be in conformity with the regulations and be regularly checked by a person or an organisation qualified for this purpose.
Flammable, dangerous and radioactive substances must be preserved under the lawful conditions and within the authorized storage limits.
Toxic products must be maintained in their original packing before their use and be stored in a zone reserved for this purpose. When they enter into the composition of reagents, the packing of those must clearly carry, according to each case, the label "corrosive", "irritant" or "poison".

2.3 Instrumentation

A medical laboratory must have adequate equipment and must be equipped with all the necessary equipment according to the analyses that it carries out.
These devices can be included in automated analysis equipment envisaged for this purpose.
The list of essential equipment is available in *The Strategic Plan for Medical Laboratories* according to their level in the Health System.
The biologist must keep up to date a list of analyses carried out with the equipment present and keep it at the disposal of authorities.
In certain cases, qualitative research or an orientation of the diagnosis can require only elementary equipment; in other cases, a particular dosage can require a very powerful equipment.
The analytical system used for obtaining the results must be selected according to desired performances and results of expert analysis carried out independently of the manufacturer or the salesman. If the selected analytical system is not the subject of independent expert analysis of the manufacturer, the biologist must ensure that provided results are in conformity with requirements expected and thus transferable.
The biologist must assure him(her)self that the installation, operation and maintenance methods recommended by the manufacturer of the equipment are employed.
Apparatus must periodically and effectively be inspected, cleaned, maintained and checked according to the procedures in force. The whole of these operations as well as visits of maintenance and repair of the manufacturer or the maintenance organisation must be written in an register of maintenance for each instrument.

User manuals and maintenance of apparatus must be placed permanently at the disposal of the staff and be respected. The operation of apparatus must be checked as frequently as recommended by the manufacturer.

2.4 Materials and reagents

The small equipment essential to the operation of apparatus must be in conformity with standards specified by manufacturers and must be used only according to the use and methods envisaged by the instruction manual.
The biologist must check that the reagents are employed according to the procedures recommended by the manufacturer in their instructions for use.
The reagents prepared and/or reconstituted at the laboratory must carry the date of their preparation and/or reconstitution and the use-by date. Operational procedures concerning the preparation and the control of the reagents thus obtained must be present and followed.
The stability of the reagents prepared and reconstituted at the laboratory must be indicated and checked.
Any out-of-date reagent must be disposed of appropriately.
Precise instructions on their storage conditions must be respected.
Reagents presenting a toxic character and/or potential contaminants must be stored under particular conditions. The personnel must be informed of the particular storage requirements, of measures to be taken to avoid any risk and of the procedures to be followed in the event of an incident.

2.5 Waste Disposal

Elimination of waste disposal must be undertaken without compromising the health of staff and without polluting the environment.

For their elimination, used materials for the sample collection can be classified in two categories:
- sharp objects or cutting material which must obligatorily be collected in specific containers;
- other waste materials which constitute a risk.

The waste, produced by sample collection activity and carrying out of analyses, must be separated into:
- hazardous waste,
- other waste comparable to household rubbish.

2.5.1 Hazardous Waste

It is separated in two groups :
- potentially contaminated waste: waste with infectious risks (including the remainders of analyzed biological samples) to which it is appropriate to add certain waste which, even in the absence of infectious risks, must be eliminated in accordance with the above-mentioned provisions: cutting or sharp object waste, blood products and anatomical waste.
- toxic or chemical products.

For each group, an elimination approach must be implemented with specific methods of conditioning, storage, transport, treatment and pre-treatment.

2.5.2 Waste comparable to household rubbish

It must be stored in containers for elimination by the same means as for household rubbish after agreement with the local community.

3 EXECUTION OF ANALYSES

3.1 Procedures and written instructions

3.1.1 General information

Any medical laboratory must have procedures and written instructions, dated and technically validated in order to ensure the quality of results and conformity to this guide.
In each zone of specific activity of the laboratory, operational procedures and instructions relating to the operations that are carried out there must be immediately available. Books, articles, manuals and handbooks can be used to complement the procedures.
These procedures and instructions should not be fixed in time, but must be adapted to the evolution of knowledge and to the technical data. Any modifications to a procedure must be in writing. It must be approved by the biologist, director of the laboratory or department, if necessary, by the biologist responsible for the activity concerned, and possibly after the opinion of the person in charge of quality assurance. It must be the subject of informational notifications and staff training.

The mixing of several samples resulting from different individuals is forbidden for individual medical analyses: each biological sample must be treated separately.

3.1.2 Applications

Available procedures and instructions are concerned with, in particular, the following points:

- instructions relating to the preparation of the patient and methods of the sample taking;
- the choice of the container into which the sample will be placed;
- mode of sample taking;
- identification of the patient and of the sample: family name, first name, sex, date of birth;
- mode of registration of the patient and results;
- the possible transport of the samples;
- preliminary treatment of the sample (centrifugation, distribution into aliquot, etc.);
- interferences of drugs and/or food likely to modify results of the analysis;
- conservation before and after analysis;
- equipment (use, maintenance, calibration, checking);
- conditions of use of reagents;
- the carrying out of the analysis with a description of the method used. It is important that this method is adapted to up to date theoretical knowledge and technical data. As far as possible, it will follow the recommendations of national or international biology learned societies;
- rules of analytical and biological validation;
- transmission of the analyses;
- hygiene and safety of the laboratory;
- quality assurance;
- management of the computer systems, if applicable.

3.2 Taking, identification and conservation of biological samples

3.2.1 Collection of biological samples

The biologist gives all information useful to Doctors for carrying out of medical analyses. Samples must, as far as possible, being associated with a "medical monitoring sheet" which comprises all the information necessary to the proper practice of analyses and to the interpretation of results. A minimal "standard model" of this sheet appears at annexe B. This sheet can be electronic.
The director of the laboratory must request this medical monitoring sheet must from the doctor who requests analyses, each time that it is useful to provide the details of the request or for the proper carrying out of analysis or for the interpretation of the results.

The sample taking can be carried out by the doctor who requests the analysis, the biologist or qualified and authorized staff in accordance with the regulations in force. These people must be informed of the procedures of sample taking of the laboratory, of the risks of errors in results of poorly conducted sample taking and of the need to specify to the biologist any incident that has occurred during the sample taking.

The biologist checks the conformity of biological samples accepted in the laboratory. He/she must be able to refuse any sample taken or transmitted under conditions not conforming with the technical and lawful procedures. The reason for this refusal will be made available to the doctor who requests the analysis. When it concerns a difficult or unique sampling, the criteria for acceptance must be assessed with prudence; the result must mention these possible qualifications if necessary. Whenever possible, it is desirable that the sampling is carried out at the laboratory.

The sample taking must always be carried out with sterile equipment that is single use. The container intended to receive the biological sample must be adapted to the nature of the sample and of the analyses. In particular, the nature of the container, its closing system, the nature and the quantity or concentration of the auxiliary substances that it can contain must be known and specified according to the sample for which they are intended. The container must be designed to avoid any risk of contamination and pollution.

3.2.2 Identification of the sample

3.2.2.1 General cases

- Primary tubes or containers

The labelling of containers containing biological samples must be done at the time the sample is taken and by the person taking the sample. Labelling must be designed to avoid any errors in the identity of the patient. It must mention, in addition to identity and date of birth, provided by the patient himself as far as possible, the sex, the nature of the sample, the name of the person who took the sample, the date and, each time that a procedure envisages it, the hour and the localization of the sample taking.
If the size of the tube does not allow the affixing of a label comprising the whole of the above mentioned information, this labelled tube is placed in an individual container where all the indications above are mentioned in order to avoid errors.
The biologist must set up a procedure allowing identification of the biological sample to the patient, even if the identity of the patient is incomplete or approximate, or when anonymity is wished. This procedure will also include instructions if the biological sample provided does not have any identification.
If a bar code is used, it should not mask the information stated in the first subparagraph of this article.

- Secondary tubes or containers

During the preparation of aliquot fractions, the labelling of secondary tubes or containers must be done according to rigorous procedures allowing the identification of the sample without ambiguity.

3.2.2.2 Specific case: blood grouping

To validate a blood group card, it is necessary to do two determinations of the blood group ABO-Rh(D) on two different samples carried out at different times.

3.2.2.3 Transport and transmission of the samples

The transport of samples must comply with rules that ensure the integrity of the sample and staff safety. Procedures written by the laboratory that carries out the analysis must fix the particular conditions of time of transport, of temperature of conservation and integrity of the packing of the biological samples.
The transport of biological samples must be carried out as soon as possible at the laboratory, taking all precautions necessary to avoid risks of contamination and degradation of the components. The airtight containers containing biological samples must be inserted in a box, wrapped in an absorbent material and the unit placed in sturdy external packaging, carrying names and addresses of the laboratory recipient and the shipper.
These rules apply whatever the quality of the person taking the sample, the origin of the sample and the means of transport used.
If the sample must be transmitted to another laboratory, the "monitoring medical sheet " (paragraph 3.2.1) (or a copy made by the biologist) must be attached.
Dates and hours of receipt of the biological samples at the laboratory must be recorded.

3.2.3 Conservation of the samples

Conditions of conservation must conform with hygiene and safety requirements in force to avoid any contamination of personnel or any pollution.
Samples of calibration and control must be preserved carefully under conditions specified by the manufacturer. The period of validity must be respected, in particular for samples reconstituted from freeze-dried substances, which must carry the date of reconstitution. All the precautions must be taken to avoid the phenomena of evaporation and contamination.
If execution of the analyses has to be difered, the aliquot samples and their fractions must be preserved under conditions which preserve their quality.
After execution of the analyses, the samples can be preserved to allow a later comparison or checking.
Conditions of identification, closing of the containers and temperature of conservation must be rigorously observed to avoid any risk of error, qualitative and/or quantitative modification and contamination. The shelf life for each particular case must, if it is not specified, be fixed by the biologist and registered in the operational procedures.

3.3 Validation of results

The validation of results is twofold: it comprises an analytical validation, which can be carried out by the executive staff under the responsibility of the biologist, and a biological validation, which is exclusively within the competence of the biologist.
The analytical validation of the examinations must be subjected to written precise procedures. It should be carried out only after having checked the indicators of correct operation of instruments and taking into account the results of the internal quality control.
The biological validation must ensure the compatibility of results of analyses carried out for the same patient at different times, taking into account, if necessary, variations of its clinical state, the treatments undergone and former results.
A system incorporating assistance for the validation process does not discharge the biologist from his/her responsibility for biological validation.

3.4 Expression of Results and Reports of Analyses

3.4.1 Expression of results

The expression of results must be precise and unambiguous. Reference values must be indicated. The method of analysis and/or the reagents used must be specified each time that they can influence the expression of the result, as well as when regulations require it.
For quantitative results, if necessary, the analytical performances of the method can be indicated. Units of the International System (I.S.) must be used when they exist.

3.4.2 Reports and signature

Reports of analyses must be reproduced on the letterhead of the laboratory comprising the information required by regulations and must be signed by the biologist.
Reports can be communicated only after the operations of validation. However, for in-patients and in the case of analyses requested as a matter of urgency, partial results can be transmitted under conditions defined by the biologist and under his/her responsibility, before the biological validation of the whole of the results requested. They must be confirmed as soon as this is carried out, by a biologist and the attending clinician must be informed of this situation.

3.5 Transmission of Results

3.5.1 Conformation to the legislation and respect of professional secrecy

Results of analyses are given directly to the patient by hand or are sent to him/her in a sealed envelope, with the patient's name and his address. Results of analyses can also be transmitted to the doctor who requested the analyses, if the patient is not opposed. When the patient is hospitalized, results are addressed to the doctor who requested the analyses and are given to the patient.
The biologist of a health care establishment must be able to make sure that the device set up for the routing of the reports towards the units of care meets the criteria of confidentiality and conformity established in coordination with the clinicians and the management team.
When the result of a medical analysis brings into play a critical prognosis, the biologist must make every effort to meet with the doctor or medical team providing treatment, and inform them as soon as possible.

3.5.2 Result predicting a serious or fatal forecast

If results cannot be communicated to the doctor who requested analyses (for example, due to a change of doctor, analyses carried out on the initiative of the biologist, or added at the request of the patient), the biologist must ask the patient to appoint a doctor to him/her with whom they can discuss the results.
If no doctor is appointed, it is up to the biologist himself/herself to inform the patient with all the prudence and sensitivity required, depending on how alarming the results are.
Any alarming result that the biologist has to give can be communicated to the patient only directly and during a meeting for that purpose. The biologist must then encourage the patient to consult a doctor as soon as possible.

3.5.3 Reports of analyses carried out on legal requisition

They can be addressed only to the applicant authority requesting the analysis, under conditions guaranteeing the confidentiality.

4 QUALITY ASSURANCE

4.1 Obligations of the person in charge of quality assurance

The organisation of the system of quality assurance of the laboratory can be delegated by the director of the laboratory or the head of service or of the department to a biologist or to a person in charge of the management of the system of quality assurance. This person must have the training, competence and the experience necessary to achieve the task entrusted to him/her.
It must ensure in particular:

4.1.1 Concerning the staff

- that operational procedures concerning hygiene and staff safety are implemented;
- that each operation carried out at the laboratory is entrusted to a subordinate with suitable qualifications, training and experience;
- that the staff are instilled with the concept of quality assurance and trained in the implementation of "quality" practices.

4.1.2 Concerning procedures and written instructions

- that they are validated;
- that they are implemented;
- that the staff are informed of any modifications to procedures, that these modifications are approved by the director of the laboratory or the head of service or department and are written, dated and communicated to the staff. The staff are trained in their application;
- that they are maintained in a chronological file.

4.1.3 Concerning quality control

- management of the laboratory's programme of external and internal quality control;
- correct use of the data provided by quality controls and the correction of anomalies;
- information to the director or the head of service or department of observations relating to the system of quality assurance;
- maintenance and correct operation of the equipment;
- good management of the documents that contribute to traceability, in particular those concerning the reagents and the period of use of each batch;
- implementation of internal evaluations;

4.1.4 Concerning the computer processing system (if existing)

- implementation of operational procedures concerning data security;
- confidentiality and respect of access procedures;
- conservation of folders and files of the computer processing system.

4.2 The External Evaluation of Quality (E.E.Q.)

EEQ is about the self-checking which must proceed in a climate of reciprocal confidence. The individual results produced at the time of this control are confidential.
The participation in the national programme of external evaluation of quality is obligatory.
Rigorous participation, reflecting the practices of the laboratory, is essential for the usefulness of this evaluation. The results will be very significant for the total analysis that will be carried out at the national level.
The individual and total results of the external evaluation of quality are analyzed collectively by all the teams of the laboratory in order to remedy the errors that could be raised. The critical study of the anomalies detected by the quality control can induce the questioning of the methods used at the laboratory. It can also be useful to engage in a dialogue with the persons in charge of the quality control to clarify the reasons for an unexplained unmatched result. A trace of decisions induced by the results of the external evaluation of quality must be preserved at the same time as the individual reports of the laboratory are filed and archived for five years.
The rigour of this step is justified because it provides good information to the biologists on the quality of their services. This information makes it possible for the biologists to correct the anomalies highlighted.
The Central Laboratory of Kabul will be in charge of organising this national quality control programme.

4.3 Internal Quality Control

Internal quality control is essential to make it possible to detect anomalies and errors of measurements in order to remedy them immediately. It is organized by the biologist.
It comprises all measures intended to check the various phases of the activity allowing the obtaining of results, and in particular the analysis of control samples carried out under the same conditions as those applied to the biological samples.
Procedures must specify the frequency of checking of control samples and values acceptable for each component. They must also comprise instructions concerning measures to be taken in the event of anomalies being noted.
Note that control samples cannot replace samples of calibration and, conversely samples of calibration cannot be used as control samples.
In the disciplines implementing a macroscopic and/or microscopic examination, it is useful to preserve the pathological parts having been used for the diagnosis and which can constitute an element of reference.

5 STORAGE AND CONSERVATION OF FILES

5.1 Documents to preserve

The files of the laboratory must comprise a minimum set of documents, specified below:

- the chronological statement of the analyses carried out by the laboratory or transmitted by this laboratory to another laboratory. This statement must be preserved for a five years period;

- personal results of analyses carried out by the laboratory. These results must be preserved for a period of at least five years.

- results of the analyses which it carried out for the needs of the external quality control must be preserved for five years;

- the report of measurements taken to correct anomalies observed following the results of the external quality control, to be retained for five years;

- results of internal quality controls, at least three years;

- a specimen of procedures and their modifications comprising the date of their implementation, throughout their use and retained for at least one year after the end of their use;

- documents relating to instruments and their maintenance, during the utilisation period of this material and retained for one year following;

- documents relating to the reagents and the consumable materials, during the utilisation period.

5.2 Conditions of conservation

The files must be stored in an area or a room adapted to this use, allowing the conservation of documents without deterioration (temperature, hygrometrical state in particular).
All measures necessary to ensure the confidentiality of personal results must be taken.
If documents are preserved in data-processing form, the storage procedure must be established to avoid any accidental loss of information. These must be presented on a medium guaranteeing their preservation for an indefinite period and their integrity.
The filed information must be accessible for consulting throughout the period of archival.
The organisation and the classification must allow the documents to be consulted rapidly and easily.

APPENDIX A: RULES OF ORGANISATION AND OPERATION

This appendix summarizes and comments on the lawful texts. It relates to the private medical laboratories.

Reports and signatures.

For private medical laboratories, the report of analyses must mention in an apparent way the name and the address of the laboratory which carried out the analyses as well as the name of the director or the deputy manager under the control of which analyses were carried out. The signatory of the report guarantees the accuracy of these details.

Buildings

Any laboratory must at least include: a reception room, an office of the secretariat and files, a room for sample collection allowing the isolation of the patients, one room assigned to the technical activities of the laboratory.

Signage

Any medical laboratory is announced to the public by a professional plate affixed to the door of the building in which this laboratory is installed. This plate cannot comprise other indications than:

- Name of the director and/or biologist
- Discipline(s) of medical analyses carried out (Hematology, Parasitology, Immuno-serology, Biochemistry, Bacteriology, Virology, Mycology, Toxicology)

Equipment

Any laboratory must be equipped with the minimum equipment necessary for the good conduct of the various categories of analyses practised by the aforementioned laboratory, envisaged by the regulations, in particular by the *Guide to the Proper Practice of Medical Analyses*.

Staff

a) Directors and director-assistants:

The directors and assistant directors of the laboratory must hold one of diplomas of State of a doctor of medicine or pharmacy, and have received specialized training: certificates of special studies, exemptions or equivalences or diplomas of specialized studies of medical analyses.
They must be registered with the relevant professional organisation.
Lastly, people not having the necessary diplomas and certificates can be authorized, in exceptional circumstances, by the Minister of Public Health, after consultation with the Central Laboratory of Kabul to exert functions of directors and director-assistants of laboratories.

b) Technicians:

Technicians must hold a title or diploma recognized by the Ministry of Public Health and be included on a list stablished by the Ministry of Public Health.
The minimum manpower of the technicians exerting their functions in the laboratory is determined according to the annual activity of the laboratory and this activity depends on the total number of analyses carried out in the course of the preceding calendar year.
This minimum manpower is in the following way given for the technicians exerting their full-time function:
a) Annual activity of the laboratory less than 2000 analyses: at least one technician;
b) Activity ranging between 2000 and 6000 analyses: at least two technicians;
c) Activity ranging between 6 000 and 10 000 analyses: at least three technicians;
d) Activity higher than 10 000 analyses: at least an additional technician by section of 3 000 analyses.

Appendix B
- CONFIDENTIAL DOCUMENT -
Medical monitoring sheet

Identification of the patient *
Name: First name: Sex:
Maiden name:
Date of birth:
Address or service of hospitalization:
Regulation
Requesting Doctor: Date from the request:
Emergency degree: Normal Urgent Priority
Requested analyses:

Date of the sample collection Hour: Place:
by (name and quality):
Number of samples transmitted to the laboratory:
Nature: blood urine others

Clinical information **

- Physiological/pathological statute (gravidity…)

- Hour of the last meal:

- Treatment in progress:

- Hour of the last take of medication:

Reserved at the laboratory. Time of receipt of the samples:
If transmitted samples to Date:

at the laboratory:

Requested analyses:

Pretreatment before transmission:

Note:

***** When the identity is missing, is incomplete or dubious, a procedure of special identification must be set up, conceived to avoid any error of attribution.
****** Certain clinical information concerning the pathological state can appear only with the express agreement of the patient.