World Health Organization

REGIONAL OFFICE FOR Europe

# WHO EUROPEAN GUIDANCE ON STANDARDS FOR INFECTIOUS DISEASES LABORATORIES

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## ACRONYMS

BSC: Biosafety Cabinet

CPD: Continuous Professional Development

EQAS: External Quality Assessment Schemes

IATA: International Air Transport Association

IEQAS: International External Quality Assessment Schemes

IHR: International Health Regulation 2005

IQC: Internal Quality Control

ISO: International Standard Organization

NEQAS: National External Quality Assessment Schemes

NGO: Non Governmental Organization

PCR: Polymerase Chain Reaction

PPE: Personal Protective Equipment

SI units: International System units

SOP: Standard Operating Procedure

TB: Tuberculosis

UPS: Uninterrupted Power Supply

WHO: World Health Organization

# EXECUTIVE SUMMARY

Good quality laboratory results are required to support diagnosis of disease, to monitor the effectiveness of treatment and to support the safe use of blood. In addition, the results are used for epidemiological purposes and to provide early warning of the outbreak of disease not only at a national level but also in the context of the International Health Regulation 2005 (IHR). All laboratory activities are subject to errors and the purpose of quality monitoring and the introduction of standards is to reduce errors to a minimum and reduce the impact that such errors have on the variability of test results. The effect should be increasing confidence shown by users of the service in the reliability of the results. There are two main classifications of errors:

(a) errors of organization due to, for example, incorrect identification of samples, mistakes in transcription or other clerical errors;

(b) technical errors due to, for example, poor quality of equipment and reagents or performance of the test due to a lack of properly trained staff.

These standards are intended to prompt discussion on how basic standards for *all* laboratories receiving biological samples from patients may be introduced and implemented. It is intended to be an opportunity for the introduction of standards in those countries that have yet to do so. If adopted they could be used to support the introduction of accreditation or licensing systems with which all practising medical laboratories must comply. One of the objectives is that for any individual result it should be possible to establish all activities and products or materials that will have influenced the result (traceability). The standards could also be used to ensure that laboratories seeking reimbursement for work done for patients in an insurance system meet basic quality standards. If successfully implemented by countries, WHO could be assured that data from compliant laboratories meet minimum quality standards and trust the results used in the context of IHR.

Introducing standards will be facilitated if there is an infrastructure on which to base their introduction. A coordinated activity with those in central and reference laboratories taking responsibility for their introduction and implementation at provincial levels and, in turn, for these to give assistance to laboratories at a primary level will assist the rapid introduction of these essential standards to all levels. **At all levels the involvement of laboratory staff is a prerequisite for successful introduction.**

## PURPOSE OF THE DOCUMENT

It is intended to be a minimum set of standards, easily understood by infectious diseases laboratories, and to be used as a stepping-stone towards meeting the requirements of the definitive document, which can be these proposed set of standards reviewed and adapted to the laboratory's context. It is to be expected that central or referral level laboratories will quickly meet these basic requirements and move towards implementing the definitive document. **It is not intended that this document replaces existing national standards which in some countries support a sophisticated accreditation and/or licensing system.**

## TARGET AUDIENCE FOR THIS DOCUMENT

The target audience for this document includes national reference laboratories, head of laboratories, laboratory specialists responsible for laboratory quality and services of the ministry of health in charge of laboratory legislation and supervision. The types of laboratories concerned by these standards are laboratories dealing with infectious diseases specimens for diagnostic or surveillance purposes.

## PROCESS OF DEVELOPMENT OF THESE STANDARDS

These standards were developed by consultants working for the WHO Regional Office for Europe and the WHO Regional Office for the Western Pacific. They were reviewed during 3 workshops with national laboratory specialists and heads of national laboratories from 13 Member States of the WHO European Region. The standards were then corrected according to all the comments made during these workshops and finally presented for general agreement at a subregional workshop (December 2008).

## STANDARDS SECTIONS

These standards are based on the internationally accepted definitive documents ISO 15189 Second edition 2007-04-15 "Medical Laboratories- Particular requirements for quality and competence" and ISO 17025-2005 "General Requirements for the Competence of testing and calibration laboratories".

These standards are structured with 53 numbered standards, allowing countries that wish to develop national standards to go step-by-step in their implementation and progressively make them compulsory in their laboratory legislation.

**N.B.** ***There is emphasis on documentation. Because there are particular biosafety issues with infectious disease, the standards relating to Safety have been emphasized.***

There are 17 sections:

1. Organization and Management

   Standard 1

2. Quality Management system

   Standard 2 to 6

3. Biosafety

   Standard 7 to 15

4. External services and supplies

   Standard 16

5. Advisory services and resolution of complaints

   Standard 17

6. Continuous improvement process

   Standard 18

7. Quality and technical records

   Standard 19

8. Management review

   Standard 20

9. Technical requirements, Personnel

   Standard 21 to 24

10. Accommodation and Environmental conditions

    Standard 25 to 28

11. Laboratory equipment

    Standard 29 to 33

12. Pre-examination process

    Standard 34 to 38

13. Examination procedure

    Standard 39

# 1. ORGANIZATION & MANAGEMENT

## *Standard 1*

The medical laboratory service must be designed to meet the requirements for prevalent disease surveillance and clinical demands, as well as the needs of users of the services. This will include offering interpretation and advice. It will require consultation with clinicians to determine their needs. There should be an organizational chart (organigram) that describes the internal management and supervisory arrangements in the laboratory and its place within the overall institute organization (unless it is an independent laboratory). This chart must be available to and be understood by all laboratory staff. Where possible the quality manager should be a different person from the head of the laboratory.

Heads (Directors) of laboratories have a responsibility to:

- provide staff with the authority and resources to carry out their work;
- with the help of staff develop written procedures and training to ensure confidentiality of patient information;
- provide written documents to describe the responsibilities of all staff;
- ensure that all staff are properly trained for the work they do;
- appoint a member of staff (quality control officer or quality manager) to take responsibility for quality management and to report directly to the laboratory head on a regular basis (at least twice each month and more often if necessary) – see Annex 4; and
- appoint a member of staff to act as safety officer (see Standard 7 and Annex 5).

*In small laboratories individual staff may have more than one responsibility.*

# 2. QUALITY MANAGEMENT SYSTEM

## *Standard 2*

All policies, processes, programmes, procedures and instructions must be documented and developed with the help of all relevant laboratory staff. Heads of laboratories are responsible for ensuring that each document is understood and implemented by all current staff and by all newly appointed ones when they join the laboratory. Once approved all documents must be dated and regularly reviewed.

## *Standard 3*

The laboratory must perform internal quality control (IQC) with every batch of examinations, review the results critically and participate in inter-laboratory comparisons including National or International External Quality Assessment Schemes (NEQAS) or (IEQAS). *Non-compliance with the agreed allowable variation must result in action to restore or improve quality.*

*Where EQAS are not available, laboratories should continuously exchange samples and materials with another laboratory or group of laboratories and compare the results.*

*Guidelines on developing control materials have been prepared by WHO.*

## *Standard 4*

A written document or booklet should be freely available that describes the range and scope of the service available, any restrictions in terms of the opening times of the laboratory, emergency services available and the types of sample and the receptacle to be used for each test requested. It must be distributed to all users of the service, be continuously available in hospital ward offices, casualty and out patient departments and needs updating on a regular basis (at least once a year).

## *Standard 5*

A quality manual (collection of all written documents currently in use) should be kept of all official documents in use within the laboratory. This manual will contain all documents of policies and procedures in current use with an index that will require amendment each time a change is made. The manual requires division into sections that will contain the following major sections:

- main responsibilities of the laboratory;
- staff education, training and employment policies;
- accommodation and environment;
- inventory of instruments and records of their repair and preventive maintenance that complies with the manufacturers instructions as a minimum (in some organizations such information is held by a hospital engineer or biomedical engineer) – laboratory staff will require easy access to such records;
- written procedures that ensure proper calibration and function of all instruments, reagents and analytical systems;

- written safety policies and instructions;
- all written sampling and transport procedures;
- all written examination and reporting procedures – Standard Operating Procedures (SOPs);
- quality assurance systems including IQC and EQAS procedures;
- written policies and procedures on document management; and
- written policies and procedures on customer service and improvement process.

### *Standard 6*

All written procedures issued to laboratory staff must be reviewed and approved by the laboratory head or delegated person prior to issue. Only currently authorised documents should be available for active use at relevant locations, including workbenches and stations. Each must be regularly reviewed, revised if necessary and approved by the delegated senior person or quality manager. Only the head of the laboratory or person with delegated authority can approve any amendments. Obsolete documents must be removed from circulation and archived.

# 3. BIOSAFETY

Medical laboratories are potentially hazardous places in which to work because of the range of inherent dangers present. Those potentially at risk include laboratory staff and visitors. Any one entering the laboratory environment is potentially at risk and it is important for all laboratory staff to recognize the potential dangers and undertake their work in such a way that any risk to themselves and their colleagues is reduced to the minimum. The level of risk depends on the activity of the laboratory and the types and sources of material entering the laboratory. Occupational injuries and illnesses may result from bad practices, ignorance, inexperience and failure to follow established procedures. When producing safety rules laboratory staff should make use of specialist advice contained in:

(1) Laboratory biosafety manual, third edition, World Health Organization, 2004; and

(2) Safety in Health-Care laboratories, World Health Organization, WHO/LAB/97.1

### *Standard 7*

The laboratory head should appoint a member of staff to be responsible for safety management (safety officer). This person works closely with the quality manager but reports directly to the laboratory head for this activity (see Annex 5). In some organizations this person may be part of the multidisciplinary team responsible for safety in the institution (e.g. hospital).

### *Standard 8*

The telephone numbers and addresses of the following should be displayed in the facility:

- The institution or laboratory itself (address and location)
- Director of the institution or laboratory
- Laboratory supervisor
- Biosafety officer
- Fire services
- Hospitals/ambulance services/medical staff (names of individual clinics, departments and/or medical staff, if possible)

### *Standard 9*

Written safety rules must be given to all staff, which are intended to reduce the potential risks to staff and visitors. Staff **must** comply with these rules (see Annex 3) and ensure that visitors are sufficiently briefed to ensure safety.

## *Standard 10*

Written standard operating procedures (SOPs) for safe handling of patient samples at all stages within the laboratory – including phlebotomy, sample transport, sub-sampling, storage, analytical procedures and disposal – must be available at all workstations and given to all appropriate staff (see annex 1 for suggested format). The signed and dated primary copy must be filed in the Director's or delegated manager's office.

A list of diseases of public health emergency of international concern must be available in the laboratory. Written standard operating procedures (SOPs) for safe handling of referral samples must be available and given to appropriate staff.

## *Standard 11*

All staff must wear protective clothing (coats or gowns) and gloves when handling patient samples and other biological materials. These items protect the wearer **only** and must be removed before leaving the laboratory or undertaking clerical or other work to which those not wearing similar protection will be exposed. Hands must be washed immediately after discarding the protection and when leaving the laboratory.

*In high- risk areas or when handling high risk samples additional precautions, including the use of an appropriate category biosafety cabinet, special protective clothing, masks and gloves may be essential. In these circumstances more rigorous disinfection procedures will be required during and after the removal of the protective clothing before leaving the containment area.*

*If working with Risk Group 3 (pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another **or** effective treatment and preventive measures are available) wear full protective clothing (one-piece coveralls, gloves and head covering), have primary devices (BSC level 3) or premises with controlled access and directional airflow.*

*If working with Risk Group 4 (pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly **or** effective treatment and preventive measures are not usually available) wear positive pressure suits in premises having a unit of airlock entry, a shower, double ended autoclave and filtered air.*

## *Standard 12*

Procedures must be written to ensure that all staff knows what to do in the event of a spillage or leakage of biological, chemical or radiochemical material or patient sample, including when containers are broken in a centrifuge.

## *Standard 13*

In the event of any accident, near accident or unusual incident, simple first aid materials must be available and the event, however small, must be recorded in the accident book. The accident book should be reviewed each week by the safety officer and the outcome of follow-up activities recorded. These records must be used to modify the laboratory operating procedures, prevent similar problems in the future and reduce the risks to staff and visitors. (It is important also to record "near misses" or situations where accidents might have occurred.)

## *Standard 14*

The employing authority, through the laboratory director, is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel. The objective of such surveillance is to monitor for occupationally acquired diseases. Appropriate activities to achieve these objectives are:

- Evaluation before starting work of the local availability and utility of possible vaccines and/or therapeutic drugs (e.g. antibiotic treatments) in case of exposure to particular agents (some workers may need to be vaccinated, if the vaccine is available, others may have acquired immunity from prior vaccination or infection; active or passive immunization should be provided when required);

- Exclusion of highly susceptible individuals (e.g. pregnant women or immunocompromised individuals) from highly hazardous laboratory work; and

- Provision of effective personal protective equipment and procedures.

## *Standard 15*

The laboratory must use separate waste disposals for infectious and non-infectious materials. The waste disposals' containers must be safe, adapted and covered. Special containers must be used for sharp disposals, for solvents and radiological wastes.

# 4. EXTERNAL SERVICES AND SUPPLIES

## *Standard 16*

A system must be in place that defines and documents policies and procedures for the selection and use of equipment, reagents and other supplies. Equipment must not be purchased unless minimum criteria are met which will include maintenance support and assurance on the continuity of supply of reagents. Donated equipment must comply with WHO/ARA/97.3 (see reference 15). Systems must be in place to record equipment maintenance, etc., and the dates and batch numbers that individual containers of reagents were brought into use. Reagents should not be used beyond their expiry date.

There must be an up-to-date inventory of all equipment that enables each item to be properly identified (serial no. date, model type, etc.). Disposals must be recorded. Written instructions on sterilization and/or cleaning steps required prior to maintenance or disposal must be adhered to.

An inventory of all consumable supplies is required to avoid stocks of vital supplies running out. Information including quantities, batch numbers, expiry dates and source of supply must be recorded. Lead times between the date of order and receipt should be known to avoid holding excessive quantities of materials that may deteriorate or become out of date during storage.

# 5. ADVISORY SERVICES & RESOLUTION OF COMPLAINTS

## *Standard 17*

The head of the laboratory and other senior staff (when specially authorised) must be prepared to offer advice to clinical staff and other users of the service on the use of the service, the types of sample required and interpretation of the results. In particular in specified circumstances this may include giving interpretive information to patients.

Heads of laboratories must meet regularly with representative users of the service to solve problems and discuss future demands on the service and future developments. Meetings must take place at least once each calendar year or more frequently if required.

All staff must be fully acquainted with the documents required for the receiving, recording and processing of all complaints. Records of complaints, their resolution and minutes of the meetings with the users of the service must be recorded.

# 6. CONTINUOUS IMPROVEMENT PROCESS

### *Standard 18*

All operational procedures must be systematically and continuously reviewed by the head of the laboratory to identify potential sources of non-compliance and to look for opportunities for improvement. A formal review must take place at least once each year.

# 7. QUALITY & TECHNICAL RECORDS

### *Standard 19*

There must be a policy that defines the length of time that various records and all primary samples or sub-samples should be kept or stored. An up-to-date list of all materials held in store and where they may be found must be kept. All disposals, reasons for disposal and methods of disposal must be recorded. These include:

- request forms;
- results and copy reports;
- instrument printouts;
- laboratory workbooks/worksheets;
- calibration records and calculation factors;
- quality control records, results of inter-laboratory exchanges of material and records of participation in EQA;
- incident and accident records;
- corrective actions report;
- stock cards;
- staff training and competency records;
- complaints and their resolution; and
- notes and/or minutes of all formal meetings.

# 8. MANAGEMENT REVIEW

## *Standard 20*

At least once each year the Head of the laboratory, with the quality manager, must review the laboratory's quality management system and all of the services it gives. Changes or improvements should be introduced as a result. The results of the review should be documented, discussed with staff and introduced into a plan that includes goals, objectives and action required for the following year. Laboratory staff must be informed of decisions made and the results of the review.

The review should take account of, but not be limited to:

- reports from supervisors and senior laboratory staff;
- results of EQA or inter-laboratory comparisons;
- changes in the volume and type of work;
- feedback from users of the service;
- monitoring turnaround time (time between receipt of sample and sending out the report); and
- results of continuous improvement process.

# 9. TECHNICAL REQUIREMENTS (PERSONNEL)

*Staff is the most important asset that any laboratory can have. It is important to ensure that the appropriate amount of time is devoted to the effective management of this important resource (in industrialised countries up to 80% of the total laboratory costs is that spent on staff). There should be a continuous programme of staff training and re-training.*

## *Standard 21*

The Head of the laboratory should be a person with the competence to assume the responsibility. Each discipline should be led by a person who has had recent (within the last five years) post-graduate education, training or a programme of continuous professional development (CPD) in the discipline for which he/she has responsibility.

**N.B.** ***Competence is the product of basic academic, postgraduate and continuing education activity, as well as training and experience linked to several years experience in a laboratory.***

## *Standard 22*

There must be sufficient numbers of staff with the appropriate education and training to ensure effective operation of the laboratory and professional supervision by appropriately experienced persons.

## *Standard 23*

All staff must be aware of their duties within the laboratory which should be contained in a written document (job description). All job descriptions must be reviewed annually by the laboratory head, after consultation with the appropriate section head, with the staff member. They must be modified if required after mutual agreement and re-issued.

## *Standard 24*

At least twice each year there should be a meeting between the laboratory head and all staff to disseminate information and discuss problems. The discussion that occurs and results (decisions reached) of the meetings must be recorded.

## 10. ACCOMMODATION & ENVIRONMENTAL CONDITIONS

### *Standard 25*

The laboratory must have adequate space that is properly organized so that the quality of work and the safety of staff, patients and visitors is not compromised. Measures must be taken to ensure good housekeeping (general tidiness, cleanliness and hygiene) and all work areas must be clean and well maintained. Laboratory section leaders should arrange the equipment and workstations to ensure efficient and convenient workflow.

### *Standard 26*

Where primary sample collection is carried out, consideration must be given to all patients and their ability to access the building (including patients with disabilities) and sample collection areas, their comfort, privacy, as well as the need to ensure good quality collection facilities and materials.

### *Standard 27*

Incompatible activities must be separated to prevent cross contamination and to reduce potential safety risks to all staff and visitors.

*Examples of such activities include: TB bacteriology, handling and examination of all high risk samples including all sputa, using radio nucleotides, nucleic acid amplifications, cytology screening (a quiet uninterrupted environment) and controlled environments for large computer systems and some high capacity analysers.*

### *Standard 28 (see also 19)*

Enough storage space with the right conditions must be available to ensure integrity of samples, slides, histology blocks, histology samples, retained microorganisms, documents, manuals, equipment, reagents and other supplies, records and results.

# 11. LABORATORY EQUIPMENT

The standards in this section apply whether the equipment is purchased, leased, on loan, new, reconditioned or has been donated by a nongovernmental organization (NGO).

## *Standard 29*

Before equipment is selected it must meet a set of pre-determined criteria. At the very minimum the following must apply:

- It must be required to fulfil a specified need.
- Assurance must be given from the supplier that appropriate maintenance and emergency servicing can be carried out as required during the expected life of the equipment.
- Assurance must be given from the supplier that there will be a continuity and rapid supply of spare parts and reagents (where appropriate) during the expected life of the equipment.
- Guarantees must be given that sufficient numbers of staff will be trained by the supplier to ensure that the equipment meets its expected potential (this includes internal engineers who may be required to carry out maintenance).
- Account should be taken of the use of energy, any requirement for an uninterrupted power supply (UPS), any requirement for environmental control and future disposal (de-commissioning).

The ability of the suppliers to meet these requirements should be carefully documented and be part of the signed contract/purchase agreement.

## *Standard 30*

On installation (commissioning) the laboratory will check that the equipment achieves the performance agreed and specified, and comply with the manufacturer's specification relevant to the examinations required. A record of the commissioning process must be kept and the subsequent performance must be continuously monitored by the laboratory.

## *Standard 31*

Each item of equipment must be uniquely labelled or identified. Documents and records must be kept for each, which should include the following:

- unique identity and whether new, used or reconditioned when commissioned;
- manufacturer's name, instrument type and serial number;
- manufacturer's or supplier's contact address, telephone number or E-mail address;
- date received and date in service;
- procedure on how to use the equipment and manufacturer's leaflet;
- ongoing record of equipment performance criteria;
- maintenance records;

- spare parts available with respective references for future ordering; and
- damage, malfunction, modification and repair details.

Hospital or institute policy may dictate that such information is held by the hospital or bio-medical engineers department. Laboratory staff will require open access to such records.

### *Standard 32*

Equipment must be maintained in a safe working condition, which includes electrical safety. Manufacturers' instructions must be adhered to.

### *Standard 33*

Where equipment calibration gives rise to correction or calculation factors, procedures must be in place to ensure that any copies are correctly updated. Staff need to routinely and frequently refer to such information and procedures must be in place to ensure that SOPs at the workstations are updated by those authorised to do so.

# 12. PRE-EXAMINATION PROCESS

*Laboratory personnel frequently ignore this part of the quality assurance cycle. It is of such importance that laboratories should consider controlling this part of the quality cycle by collecting all samples and taking responsibility for transport to the laboratory.*

It is a fact that the quality of the final result is profoundly affected by the quality of the sample material. Failure to apply quality principles at this stage will result in a total breakdown in the quality of results from the laboratory despite having good analytical quality.

### *Standard 34*

Proper request forms on which required information is detailed must be used. It must contain enough information to properly identify the patient and the authorised requester. Clinical information including treatment is required to help produce satisfactory interpretation of the results. The form must have space for the following:

- patient identification, gender and date of birth;
- patient location (for return of report);
- identification of the requesting person;
- type of primary sample;
- examinations (tests) required;
- clinical details
- time and date of primary sample;
- space to record time and date of receipt by laboratory.

### *Standard 35*

Proper collection and handling of primary samples must be according to SOPs (see annex 1) prepared by the laboratory. These must also be used by those collecting the primary samples in wards, clinics and elsewhere. These SOPs will cover:

- instructions to patients including their fasting state (when appropriate) and the accurate collection of timed urine samples;
- the type of primary sample container to be used for the various laboratory tests, the volume of material required, any special timing required and any necessary additives including anticoagulants;
- phlebotomy technique including the use of a tourniquet;
- special transport arrangements required between primary sampling and receipt in the laboratory;
- labelling;

- safe disposal of materials used to collect primary samples;
- procedures to follow if the sample quality is sub-optimal or unsatisfactory; and
- recording unusual physical characteristics including lipaemia, haemolysis, icterus, etc.

### *Standard 36*

The laboratory must monitor the transportation of samples to the laboratory so the samples arrive in a suitable time frame, at the correct temperature interval (specified in the sampling SOPs) and in the designated preservatives (specified in the sampling SOPs, if needed), allowing the requested analysis to be performed.

The transport must be safe for the carrier, the general public and the receiving laboratory, according to national regulatory requirements (if in existence). Blood specimen bottles and tubes should be transported upright and secured in a screw cap container or in a rack in a transport box. They should have enough absorbent paper around them to soak up all the liquid in case of spillage.

Transport with the use of triple package will be used when shipping toxic or infectious substances or dangerous goods, according to national regulations for national transport or international regulations for international transport. Follow, therefore, the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations (Infectious Substances Shipping Guidelines 2012) for international transport of dangerous goods. All persons involved in the shipping process will have to be trained to package according to the type of transport used by the laboratory.

Samples air dried on filter paper are exempt from shipping regulations and do not have to be sent to a laboratory via a specialist courier. They can be sent by airmail (note that to avoid damage, they should be sent in hermetically sealed triple packages).

Detailed instructions for packing specimens for shipment in the category A (infectious substances included in an indicative list of specified pathogens that are capable of causing permanent disability, life threatening or fatal disease) and category B (all other infectious substances that are not included in category A) can be found in the WHO document Guidance on regulations for the Transport of Infectious Substances.

### *Standard 37*

There must be a written policy, which is used when incorrectly identified samples are received by the laboratory. Criteria must be developed and adopted for acceptance and rejection.

### *Standard 38*

All primary samples must be given a unique identifying (accession) number and recorded along with the date and time of receipt. Taking aliquots of samples and sub-sampling (removing a portion) should only be undertaken under appropriate levels of laboratory safety (e.g. preferably in a certified Class II biosafety cabinet). When sub-sampling of this same sample or treated part (e.g. centrifuging to use serum, plasma or cells) there must be a written procedure to ensure the accurate transfer of patient identifying information.

Great care must be taken not to contaminate or cross contaminate specimens. This is especially so when they are intended for analysis by PCR because PCR procedures are especially vulnerable to cross contamination after amplification and uncapping of the tube.

Taking aliquots or sub-sampling should be done before the specimen is frozen as repeated freezing and thawing of specimens can reduce the content of virus and alter the consistency of the sample. This should therefore be avoided.

There must be a specified time for the post analysis storage of samples that enables re-examination if necessary. Repeated freezing and thawing of specimens must be avoided to prevent loss of infectivity. Note that certain types of freezer are designated “frost free” and these should not be used for specimen storage, as the temperature cycling involved in keeping them free of ice accumulation can damage specimens.

# 13. EXAMINATION PROCEDURES

## *Standard 39*

Careful selection of the examination procedure is important and will depend on the facilities, equipment and staff available, as well as and the numbers of samples for examination. SOPs must be available for all methods and scientific validation must be available. The methods must be evaluated by the laboratory to ensure they are suitable for the examinations requested. The SOPs must be available in the appropriate language and may be summarized on cards for use at workstations. The SOPs must contain the minimum information as detailed in Annex 1.

# 14. QUALITY ASSURANCE

## *Standard 40*

The laboratory must have an internal quality control system to verify that, for every batch of examinations, the intended quality of results is achieved. *Action must follow where there is non-conformity or non-compliance. This will sometimes mean that the results of a batch of results are initially rejected because the quality control results are outside pre-set tolerance ranges. In these circumstances the patient samples will need to be re-examined after any required corrective action has been taken.*

## *Standard 41*

The laboratory must participate in organized inter-laboratory comparisons, including external quality assessment (EQA), and the results must be critically evaluated. *Corrective action must follow when there is non-conformity or non-compliance.*

## 15. POST-EXAMINATION PROCESS

### *Standard 42*

Authorised staff must review and authorise the release of patient results, within limits of their competence.

### *Standard 43*

Procedures must be in place for the storage of samples post-examination, to enable re-examination if required, for the specified time and for their eventual safe disposal. The storage time for all primary samples and sub-samples, stained microscope slides, histology specimens and blocks must be adhered to.

# 16. REPORTING OF RESULTS

## *Standard 44*

The turnaround times expected for each test should be agreed with users of the service. The laboratory must return the results of the examinations to the requester within the time interval agreed.

If a deadline exists for the tests performance, the users should be informed.

## *Standard 45*

Results must be legible, without transcription mistakes and preferably in SI units. The report should also include:

- identification of the laboratory issuing the report;
- identification and location of patient;
- requester's identification;
- type of sample;
- date and time of primary sample collection, date and time of receipt by the laboratory and date and time of reporting;
- comments on the primary sample that might have a bearing on the result interpretation, e.g. haemolysis, icterus lipaemia, etc.;
- comments on the primary sample quality, which might invalidate the result, e.g. a clotted sample for haematology parameters;
- method of testing used;
- the results and units of measurement where appropriate;
- where possible, the normal reference interval (normal range); and
- identification of person releasing the report.

## *Standard 46*

The laboratory must have procedures for notifying the requester or clinician responsible for the patient's care when results of critical analyses fall outside specified limits. These specified limits should be agreed with clinicians and other users of the service.

## *Standard 47*

There must be a documented procedure for reporting results by telephone. This must include methods of ensuring that the results reach the person authorised to receive and act upon them.

# 17. ALERT AND RESPONSE AND LABORATORY NETWORK

### *Standard 48*

A list of the laboratories which are part of the national system for surveillance and response must be available in the laboratory, designating the laboratories to which can be addressed unknown samples and unexpected events. A clear identification of the referral laboratories is needed for all referral of samples for confirmation of priority diseases. Referral laboratories for analysis not available in the country are identified at international level.

### *Standard 49*

The public health events under surveillance in the national system, such as the public heath emergency of international concern, must be defined according to IHR (2005). A list of priority threats and diseases, with the laboratory's tests required to diagnose them, must be available in the laboratory.

### *Standard 50*

A standardized reporting system must be in place, including a standardized reporting form/software for laboratory data.

In case of an outbreak the laboratory involved will use a data reporting system different from the routine laboratory data system, in a time frame as defined by the national IHR system.

### *Standard 51*

Laboratories must have access to surge-capacity (i.e. additional staff, reagents and equipment available at immediate notice) to face an emergency. Concerning laboratory reagents and/or rapid tests, these must be pre-positioned at national, intermediate and peripheral levels.

### *Standard 52*

Sampling in the field should be undertaken under appropriate levels of safety. The level of personal protective equipment (PPE) to be employed will be determined by the exposure risk. In general PPE to be employed should include:

- A suitable form of respiratory protection
- Non sterile latex gloves (or equivalent if allergic)
- Goggles or face shield
- Gown
- Head covering

It may be necessary to include:

- Impermeable apron
- Suitable rubber boots

## *Standard 53*

On each occasion that sampling in the field is undertaken, for each type of sampling, two specimens should be taken in separate specimen tubes. One can be used for immediate analysis and the other retained for reference purposes, retesting, etc.

Each patient or animal sampled or each environmental sample taken should be given a unique identifier number and accompanied by a field data sheet. The field data sheet must have space for the following:

- specimen identification;
- location of sampling;
- identification of the person having performed the sample;
- identification of the requesting service or person (for return of report);
- type of primary sample;
- examinations (tests) required;
- field details;
- time and date of primary sample; and
- record time and date of receipt by laboratory.

All specimens taken from that source should be marked with that unique identifier, as well as any other numbers needed to identify the particular specimen. This identifier should be used on all documentation concerning the specimen from that source.

Specimen tubes should also be marked with information about the type of specimen in the tube and the date when the specimen was taken.

# ANNEX 1

## STANDARD OPERATING PROCEDURES (SOPS)

THE EXAMPLE GIVEN IS FOR A TEST EXAMINATION BUT THE SAME PRINCIPLES APPLY TO ALL OTHER PROCESSES AND PROCEDURES

Where commercial kits are used package inserts should be included

1. Purpose of examination (or other procedure)
2. Principle of procedure
3. Performance specifications (linearity, precision, accuracy, detection limits, measuring interval, systematic error, analytical sensitivity, analytical specificity)
4. Primary sample type including containers, preservatives and anticoagulants
5. Equipment and reagents to be used
6. Procedural steps (where possible diagrams and flow charts should be used)
7. QC procedures
8. Interferences (lipaemia, haemolysis, icterus etc.) and cross reactions
9. Calculation procedure
10. Reference intervals (normal values)
11. Reporting interval of patient test results
12. Alert/critical values where appropriate
13. Interpretation of results
14. Biosafety precautions
15. Potential sources of variability
16. Documentation

**To avoid excessive documentation at workstations it may be advisable to use a suitable summary on a card that contains the basic instructions that enable the examination to be made. The full and detailed SOP is filed as appropriate.**

# ANNEX 2

## IMPLEMENTING STANDARDS

Laboratories commencing the implementation of standards face a difficult task: WHERE TO START! At the start it will be important to inform and involve the staff in the changes that will take place.

It is simpler than it would appear.

(1) Make some simple and easy- to- implement changes. For example:

- Each laboratory should have a diary, a page a day. **Every** change, however small, should be recorded. Record changes in reagents (new batch, new bottle etc.), changes in photometer light bulbs, new calibration curve and any equipment changes or maintenance etc. Such information is also recorded on quality control charts as an aid to interpretation of any changes in quality.

- Each refrigerator or incubator or any equipment with a temperature control mechanism should have the temperature recorded at the same time each day and remedial action taken if necessary. Keep the current month's record adjacent to or attached to the door or lid of the equipment.

- Record changes in personnel or changes in activity of staff, rotation of staff and those assigned to out of normal hours emergency duty.

(2) Introduce SOPs for a particular procedure or activity one by one. This could be sample collection, including phlebotomy or an SOP for the examination of a particular analyte.

An SOP could, for example, be prepared with the layout suggested in annex 1 (see also WHO/LAB/97.1)

(3) Make arrangements to commence regular meetings with users of the service. This will have the added benefit of keeping users informed of the efforts you are making to improve the quality of the service.

**These are examples only.**

# ANNEX 3

## SUGGESTED MODEL SAFETY RULES FOR MEDICAL LABORATORIES

1. Eating, drinking, smoking and applying cosmetics are prohibited in the laboratory.

2. Mouth pipetting is prohibited.

3. Staff must behave in a safe and responsible manner at all times.

4. Appropriate protective clothing must be worn at all times when in the laboratory and, whenever required, gloves should be worn.

5. The laboratory must be kept clean and tidy and should only contain items necessary for the work carried out.

6. All work surfaces must be appropriately decontaminated at the end of each working day and immediately after any spillages.

7. All staff must wash their hands when leaving the laboratory.

8. Care must be taken to avoid the formation of aerosols or the splashing of materials.

9. All contaminated waste or reusable materials must be appropriately decontaminated before disposal or re-use.

10. Access to the laboratory must be restricted to authorised personnel only.

11. All incidents or accidents must be reported immediately and appropriate action taken to prevent further occurrences.

12. All staff working in laboratories must be adequately trained, both in the duties they perform and in all safety aspects of work.

13. Radioactive waste must be marked before disposal.

**Such safety rules are mandatory for all staff**

# ANNEX 4

## QUALITY MANAGER (QUALITY CONTROL OFFICER)

In large laboratories a member of staff will be appointed in a full time capacity to perform this task. In smaller laboratories it may be one of several responsibilities.

1. The person appointed is responsible to the laboratory Director or Head for the Quality system in the laboratory.

2. The tasks include taking responsibility for:

- monitoring all quality management systems and ensuring that policies are implemented on a continuous basis;
- daily monitoring of all internal quality control;
- ensuring that the laboratory participates in External Quality Assessment schemes and that action is taken on the results;
- investigation of failures to conform to quality standards (non-compliance);
- ensuring that appropriate corrective action is taken;
- training all other staff in the use of the quality systems; and
- writing and implementing quality policies.

The person taking this responsibility should report on a regular basis to the laboratory head (suggest at least twice each month). A major attribute required will be the ability for continuous interaction with all staff and the ability to make use of the results for educational purposes.

# ANNEX 5

## SAFETY OFFICER

The job functions include:

- giving safety advice;
- administering the safety policy;
- assisting in the design and maintenance of the safety programme; and
- training of other staff.

It may also involve membership of a hospital-wide or institution safety committee.

The duties include:

- making regular reports on safety status to the laboratory head;
- maintenance of accident records;
- investigating all laboratory accidents;
- documenting regular safety inspections;
- ensuring that all staff comply with policies, rules and recommendations; and
- ensuring that precautions are taken with the disposal of all waste, including sharps such as lancets and needles.

# ANNEX 6

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# ANNEX 7

## SUGGESTED ADDITIONAL READING


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