WHO Regional Publications, Eastern Mediterranean Series 14

Quality Systems for Medical Laboratories

Guidelines for Implementation and Monitoring

World Health Organization
Regional Office for the Eastern Mediterranean

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Foreword

Throughout the world, from the largest hospital to the smallest office laboratory, quality systems are continuously being defined. Such quality systems are needed to focus laboratory personnel on the issues of quality management.

Quality management principles associated with organizational structures, responsibilities, procedures, processes, and resources have evolved exponentially throughout the 1980s and 1990s. Such evolving principles are consistent with laboratory medicine's position as one of the largest service industries in the world - a position that few laboratory workers worldwide realize.

The Commission on World Standards of the World Association of Societies of Pathology and, I am sure, other organizations active in laboratory standard development will support with enthusiasm these guidelines for the implementation and monitoring of quality systems in medical laboratories.

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World Association of Societies of Pathology
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Preface

Various methods are already available to provide safe, accurate and reproducible measurements and observations in laboratory medicine. However, it is necessary to adhere to formalized procedures to maintain and improve services. The objectives of the present document are to assist laboratories to:

- Introduce, maintain and improve appropriately specified levels of service quality.
- Provide the basis for assuring (guaranteeing) an adequate quality of services to the customer.
- Provide a basis for possible future accreditation of laboratories by describing a quality system and its specifications.

This publication aims to cover the needs and demands of laboratories at intermediate or higher levels. Smaller laboratories will benefit from maximum adherence to the principles and strategies which are presented. Their mode of operation may not, however, permit immediate and meticulous fulfilment of all requirements.

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Abbreviations

CEN	Comité Européen de Normalisation (European Committee for Standardization)
EN	European norm
ISO	International Organization for Standardization
SI	Système International (international system of units of measurement)
TQM	Total quality management
VIM	Vocabulaire international des termes fondamentaux et généraux de métrologie (international vocabulary of basic and general terms in metrology)

Part I

Implementation and Monitoring of Quality Systems

Introduction

There are reports, although infrequent, of patients who have been incorrectly diagnosed, inappropriately treated, but who have been successfully cured. However, most cases of erroneous diagnosis of a disorder result in faulty or delayed treatment and may have a fatal outcome. Logically, successful treatment requires correct diagnosis based on the accuracy, reproducibility, and interpretability of investigations and examinations.

Correct clinical diagnosis is a combination of scientific knowledge, clinical experience, observations, and measurements, as well as consideration of the individual medical history. It is a paradox that we have a tendency to question objective measurements more than subjective observations; in reality, we rarely evaluate our own judgements or attitudes towards making observations. Observations originating in physical examinations often include considerable subjective elements. Most objective information is derived from the evaluation of properties, such as electrocardiography patterns, haemoglobin concentrations, or antibiotic susceptibility patterns of micro-organisms.

The quality of laboratory services is directly related to the excellence and uniformity of the information provided for medical care. For measurements, accuracy, i.e. trueness and precision, is a frequently used concept to describe the analytical goals and laboratory performance. The quality of the laboratory investigations may be monitored by comparing results of known and unknown samples with those obtained by other laboratories. While this might be necessary in establishing measurement procedures, it does not necessarily provide an incentive for improving laboratory performance or sufficient information to introduce corrective action. In setting up a measurement procedure, an extensive validation process is carried out to establish a stable analytical system. It is essential to design a control system by which the analytical system can be monitored and evaluated before releasing the results.

It is an increasingly accepted fact that a higher quality of service can be provided when the entire operation, including organization, management, processing, and reporting, is addressed in the quality system. Such a systemic approach aims at continuously identifying and preventing possible sources of error that influence the outcome of the process. This systemic (holistic) approach to quality - total quality management (TQM) - has been successfully applied in many institutions and industries around the world. The basic document outlining the systemic approach to quality is the

ISO 9000 series of standards. The ISO/IEC Guide 25 particularly addresses laboratory services. The CEN (Comité Européen de Normalisation) has further developed aspects on TQM in the EN 45000 series. Other local, national, and regional standards also exist, as well as interpretations and guides to the international standards.

The present document will provide laboratories with practical advice on how to implement the ISO standards in their services. To achieve formal fulfilment, it is good advice also to acquire a copy of the standard and to observe its rules and regulations. Meanwhile, we hope that the present document will raise awareness of, if not to say enthusiasm for, quality. Experience indicates that quality cannot be stimulated by purely administrative and regulatory means. On the contrary, such measures may be of no benefit but rather may result in the opposite effect if they are not understood by those who perform the actual work. The most efficient quality system is a unique, personalized system, created by the staff concerned, in which all individuals are conscious of their responsibilities and driven by team spirit towards good working practice. Without such a spirit the guidelines are no more than printed matter.

This publication outlines principles for laboratories practising laboratory medicine. It contains guidelines and a set of checklists designed to assist the laboratory by self-assessment of its own performance (Part II). In principle, the guidelines apply to all kinds of laboratories, independent of their size or function.

General aspects

Definitions of terms used in this document are found in Annex 1.

Certain principles should be followed in all work of quality control. They can be summarized as follows:

Documentation

This should include a description of the organization and specifications of all aspects of laboratory work. Activities should be described without ambiguity and in sufficient detail, and no activity should be regarded as completed unless it has been documented.

Organization

The responsibilities and duties of all staff should be defined. The need for continuing education and training of staff should be recognized and described.

Preventive and corrective actions

It is generally recognized that errors can be traced primarily to defects in the system rather than to individuals. Therefore, it becomes important to improve education and training, equipment, organization and work flow, rather than merely blaming people. TQM requires that mechanisms be established to prevent and avoid inadequate actions and erroneous results. All staff should, therefore, be encouraged to observe and document incidents which indicate where failures and malfunctions exist or may develop (near misses).

Internal and external audit

A regular internal auditing process, by which all critical moments of the operation, organizational as well as technical, are scrutinized, has been found to be most useful. The outcome of the audit should be discussed with the staff concerned. Of equal importance are regular reviews of the total operational process by external peers.

Feedback

It is imperative that each operator receive feedback on the results of work. Feedback can be in many forms, such as results of quality improvement work, financial outcome and participating in planning and other strategic activities. Feedback circuits encourage responsible actions aimed at improving the working process.

Quality manual

The detailed description of the quality system should be documented in a manual. Laboratory staff should be familiar with the contents of the manual. The manual should be kept up-to-date.

Validation of measurements and observations

Well-established and scientifically recognized (e.g. published in a peer reviewed journal) methods should be used throughout the laboratory. The laboratory is nevertheless obliged to validate its ability to carry out the measurement according to the specifications.

Validation may be of varying complexity, depending on previous experience and the procedure studied. Items such as analytical specificity and sensitivity, limits of detection, measuring range, linearity, and interferences should be considered. Accuracy (trueness and precision) should be demonstrated. Suitable calibration and quality control and assessment schemes should be established. The validation should be properly documented and the protocol saved and available. Medical validity of tests may be included in the validation protocol.

Calibration

Measurements involve the transformation of instrument signals into quantities which are of interest to the user. This transformation includes a calibrator and a calibration procedure. Calibrators should be traceable, i.e. their concentration should be traceable to national or international reference material or basic quantities of the measuring system (e.g. SI) by an unbroken chain of comparisons. If a reference method or reference material is not available, other measures must be taken to ascertain an agreement of the results within a laboratory (e.g. through quality control schemes) and between laboratories (e.g. through external quality assessment schemes or interlaboratory comparisons of patient samples).

Transferability

The ultimate goal of TQM in the laboratory is to establish and maintain methods which give results which are reproducible, i.e. results which would also have been obtained in other laboratories, using other instruments, methods, etc. for measurement of the same analyte in the same sample. This is recognized as transferability of results. Transferability is a prerequisite for using global, regional, or national reference intervals and for benefiting from research and the experience of others. In some texts, "commutability" is the term used for transferability.

Quality assurance

Quality assurance involves all measures that can be taken to improve the efficiency and effectiveness of the laboratory and thus enhance the trust in the laboratory results. The expectations of the laboratory performance are laid down during the validation process and address the accuracy (trueness and precision) of measurements and observations (the measuring system), as well as availability and turnover. Quality control is designed to monitor the stability of the measuring system. This is achieved by internal quality control procedures which use a suitable set of control materials and control rules. Interlaboratory comparisons are an additional tool to assure the stability of measuring systems and to describe the state of the art. In addition, external quality assessment schemes have an educational value.

Quality manual

This chapter outlines the content of a quality manual. Certain aspects are detailed in subsequent chapters. The reader may also refer to the original literature cited in the list of references.

A proper document management system should be established and applied to all documents related to the quality manual. This system should detail the history of the documents and make all traceable additions, revisions and amendments. The document management system also addresses the distribution of documents within and outside the laboratory.

The quality manual should contain the following statements:

General

- A quality statement:
  - a commitment to quality.
- A statement that all personnel are informed of the quality statement and its implications:
  - all staff have access to the quality manual and its annexes
  - the laboratory focuses on customer needs.
- The legal status of the laboratory.
- Liability insurance of the laboratory and its staff.
- Health and safety measures.

Staff and education

- Job descriptions and specifications - recurrent approval of operational skills (see pages 17–22).
- Job rosters and hours of work.
- Employment procedures.
- Introduction and orientation of the new employee.
- Continuing education and training:
  - internal programmes
  - external programmes.
- Staff appraisal.

Management

- Organization:
  - organogram describing the laboratory as part of the health organization (national, regional, or hospital, as appropriate)
  - description of the internal laboratory organization indicating the individuals responsible.
- Procedures for dealing with complaints and corrective actions.
- Financial management:
  - budget preparation and monitoring
  - purchasing policy
  - purchasing monitoring
  - billing procedures.
- Workload: statistics for monitoring the workload should allow for:
  - assessment of workload
  - comparison between laboratories
  - any required link with financial requirements
  - any government requirements.
- Communications and information dissemination:
  - minutes of staff meetings, administrative and educational circulars
  - memoranda and their circulation
  - measures to ensure that decisions have been communicated and understood
  - feedback to operators on the quality of the work.
- Management of stores:
  - procedures of acquisition (tendering)
  - procedures of internal requests
  - stocktaking
  - a regular inventory.

Handling of samples

- Sampling handbook (see pages 23–24).
- Laboratory guidelines for:
  - identification of patient and sample
  - transportation of sample
  - deviation from standard appearance (e.g. haemolysis, lipaemia)
  - storage of sample
  - disposal of sample.

Requests, reports, and records

- Requests:
  - unambiguous information on the patient (including age and sex), requester, property (analyte) ordered, and time of sampling
  - unambiguous link to the specimen
  - relevant information for medical consultations, when applicable.
- Reports:
  - unique identification of name and address of the laboratory, the requester
  - date of the sampling and the identification of the patient
  - the name of the property (analyte), result, unit of measurement, and reference interval
  - any observed characteristics that might influence the results (e.g. haemolysis, lipaemia etc.)
  - any appropriate comments or interpretations
  - the signature of the staff responsible (may be retained in the computer system)
  - describe available report routes and means (e.g. telephone, telefax, or mail)
  - all results should also be transmitted in written form.
- Records:
  - requests and individual results related to patient specimens
  - internal control and external quality assessment (proficiency) records (examples of internal quality control charts are given in Annex 3)
  - equipment maintenance
    complaints and action taken
  - the time period in which each request, result, report, or record should be archived.

Quality monitoring

- The operational and functional activities pertaining to quality:
  - use of reference materials and methods
  - internal quality control
  - external quality assessment and interlaboratory comparisons.
- Arrangements for feedback and corrective actions whenever failures are detected:
  - document failures and "near misses"
  - a logbook for all instruments.
- Internal auditing to be carried out regularly and address at least the following:
  - assessment of internal control and external assessment schemes
  - methodological issues

- logistic issues (stores, instruments, reagents)
- maintenance, service, and calibration of instruments
- turnaround time
- clerical issues (transcription of codes, specimen identification, reports, etc.)
- medical and patient related issues (e.g. reference intervals)
- educational issues (e.g. new methodology, improving performance levels)
- complaints and appraisal
- audits should be minuted and communicated to the staff; any required action should be followed up.

- External auditing should be carried out by peers and/or a specially appointed agency.

Measurements

- Validation of measurement procedures:
  - measurement characteristics (linearity, specificity, interferences, etc.)
  - selection of calibrators.
- Guidelines for writing descriptions of measurement procedures (see pages 25–28).

Technical

- Instruments (see pages 29–31):
  - calibration of essential properties of the instrument
  - calibration of volumetric and gravimetric devices (e.g. pipettes)
  - maintenance schemes.
- Computer hardware and software:
  - description and specifications of hardware, including network and interfaces
  - description of software
  - validation procedures for new or amended software
  - document management system for additions and amendments
  - description of rules for access to programmes and databases.

Venue and facilities

- Description of laboratory layout and facilities (e.g. water, air quality condition, sewage).
- Handling of hazardous waste (chemical and biological).
- Cleaning, care, and maintenance of the laboratory.

Subcontracting and collaboration

- Collaborating laboratories (i.e. laboratories to which samples may be referred).
- Service contracts (i.e. agreements with manufacturers or supplies).

Medical

- Selection of quantities (analytes):
  - to meet the medical needs to diagnose, monitor, and prevent disease.
- Analytical goals (total allowable uncertainty of measurement or observation):
  - to be defined in relation to the medical needs.
- Consultations:
  - to suggest diagnostic strategies and interpret results.

Safety manual

The following items should be considered for inclusion in the safety manual. Some items are covered by national or local regulations and should be amended accordingly. There may be additional items which should also be considered.

General guidelines

- Accidents should be avoided by preventive actions:
  - choose methods without hazards
  - avoid flammable materials in method selection
  - avoid carcinogenic and other toxic substances
  - indicate clearly all hazards in method documentation.
- All staff are to be issued with and made aware of these laboratory safety regulations upon appointment.
- All specimens must be regarded as potentially hazardous or contagious.
- Admittance to the laboratory should be restricted.

Laboratory staff

- Potential hazards should be avoided.
- Regulations which apply to the materials being used should be known and followed.
- Gowns or protective coats:
  - must be worn when working in the laboratory
  - must not be worn outside the laboratory; if necessary use a separate coat.
- Protective gloves should be removed before handling telephones, keyboards, etc.
- Pipetting by mouth is not allowed.
- Automatic samplers and diluters should be used whenever possible.
- A rubber bulb system or equivalent must be used if a glass volumetric pipette is required.
- Eating, drinking, or smoking is not permitted in the laboratory.
- Drinks and foodstuffs must be kept only in a refrigerator set aside uniquely for this purpose.
- Lipstick or cosmetics should not be applied in the laboratory.

- Labels must not be licked. Pencils and pens must not be placed in the mouth.
- Instruments or machines connected to power and water supplies should not be touched or turned off except by those authorized to do so.
- Specific instructions for packaging and transportation of biological material should be observed.

High-risk infectious diseases

Although all specimens are potentially hazardous, high-risk samples should be identified:

- diseases of particular risk should be listed, (lymphadenopathy syndrome and AIDS, hepatitis B and C, tuberculosis, anthrax, shigella, salmonella [including typhoid], plague, psittacosis, Creutzfeld-Jacob disease, slow virus disease, brucella, etc.)
- instructions for handling high-risk specimens should be communicated to all relevant staff.

Fire

- Instructions for evacuation in case of fire should be known by all staff.
- Suitable fire extinguishers should be available and fire drills should be conducted regularly.
- Emergency exits should be clearly marked.
- Smoke detectors and sprinklers should be installed, if possible.
- Equipment and reagents which are prone to initiate or propagate fire should be identified and removed whenever possible.

Laboratory safety

- Special care should be taken to ensure protection of staff and patients by:
  - appointing a safety manager and educating staff
  - identifying hazardous materials and work areas
  - proper handling of hazardous materials and reagents (chemical and biological hazards)
  - using sterile instruments and equipment for sampling
  - using protective measures (gloves, coats and glasses) whenever handling unknown samples, patients, or hazardous materials and reagents.

- There should be rules and instructions for handling radioactive materials.
- Instructions for prevention of use of aerosols should be available.
- Hoods and forced ventilation should be in place, with instructions for their use.
- Toxic substances and chemicals:
  - all chemicals are to be assumed toxic
  - international hazard symbols on labels should be recognized and separate storage areas provided for materials which are explosive, flammable, toxic, corrosive or radioactive
  - storage should be indicated with the hazard symbol
  - chemicals that must not be stored together should be indicated.
- Compressed gases and cryogenic substances (e.g. liquid nitrogen, solid carbon dioxide):
  - handling and storage instructions
  - location
  - cylinder maintenance and security
  - empty cylinder storage.
- Histopathology hazards:
  - list disease specimens which are not accepted for frozen section
  - list specimens to be handled in a biosafety cabinet (e.g. lymph nodes, if handled fresh).

Spillage and contamination

- If spillage occurs:
  - use disinfectants for cleaning blood, urine, or other biological substances
  - chemical spills should not be cleaned up until appropriate scientific advice has been sought
  - all spills and accidents must be reported as soon as practically possible to the section head.
- An emergency eye wash facility should be available and used immediately for all specimen or chemical contamination of the eyes.
- Contaminated glassware (and other consumables) and sharp waste must be placed in special bags (clearly indicated) and sterilized (or incinerated) before disposal.
- Work areas where spillage risk is great may be protected by plastic-backed absorbent covers which should be changed regularly.
- Corrosive spills are to be contained and absorbed with special acid spill granulate.
- Centrifuges, water-baths, and specimen mixers are to be cleaned regularly.

Waste disposal

- Detailed orders for handling waste should be developed and should include:
  - disposal of tissue and blood
  - disposal of "sharps" and "non-sharps"
  - microbiological waste
  - chemical waste
  - radioactive waste.

Guidelines for staff

These guidelines can be used in the preparation of a manual for staff. They should be regarded as an "aide memoire" to the preparation of a laboratory instruction manual. The guidelines list topics to be considered.

A manual of personnel and administrative procedures

- All staff should be provided with a copy of the administrative instructions; the important items should be brought to the new staff members' attention when they are introduced to the laboratory.

General and employment information

- Brief outline of the department, its branches and divisions.
- Description of staff establishment and lines of technical and administrative responsibility. List of key personnel in the department and a general description of their functions and responsibilities.
- Safety instructions and regulations with specific reference to the safety manual.

Rules and procedures for staff

- This should include:
  - duties, obligations, and privileges of staff
  - classification of staff
  - conditions of employment
  - attendance and leave
  - staff relations
  - disciplinary measures.

Administrative procedures

- This should include:
  - annual leave, sick leave, study and other leaves
  - accrued days off
  - rosters.

Communication, acquisition, and dissemination of information

- This should include:
  - timing of and attendance at staff meetings
  - method of submission of items by staff
  - notification to staff of matters resolved.

Cleanliness and general appearance

- This should include:
  - laboratory coat, protective clothing, and laundering provisions
  - laboratory policy regarding use of gowns and protective clothing outside the laboratory
  - advice on suitable footwear.

Courtesy statement

The reputation of the laboratory depends on the manner in which patients and visitors are treated by all staff. Therefore, any discourtesy, whether in writing, by telephone, or directly, reflects most unfavourably on the profession as a whole and on particular departments.

Confidentiality and statements to the public

- In many countries the confidentiality maintained by all staff in the health care system is regulated by laws to protect the integrity of patients. It is internationally agreed that it is mandatory for all staff to observe the utmost discretion with regard to their duties. **On no account** are patients' affairs of any kind to be discussed, or any laboratory reports or records to be disclosed to any unauthorized person, whether within or outside the department.
- Normally, only the director of the laboratory may make statements to the public.

New staff

- All staff should attend an orientation programme addressing organizational and practical issues.
- A staff member should be specifically appointed to carry out the orientation and introductory programme.

- The new staff member should be provided with:
  - appropriate protective clothing and advice on the method of its replacement
  - an introduction to the features of laboratory safety
  - an explanation of the fire drill
  - an introduction to the director, appropriate executive persons in charge, personnel responsible for finance
  - all necessary personnel cards, bank forms, tax forms, etc. for completion.

Off-duty hours

- The required availability of staff in case of emergencies and after-office hours should be clarified (e.g. medical, technical, scientific, computer, and other relevant staff members).

Accidents and sickness when on duty

- Emergency alert routines (number to dial/page, switch notification, location of first aid).
- Procedures for reporting all accidents.

Staff health

Modification of this section may be extensive, depending on national regulations, the laboratory, and on consent of the staff member.

- The following headings should be considered, as appropriate:
  - medical examination upon appointment
  - history, physical examination, and examinations such as:
    - blood test, chest X-ray
    - hepatitis B, HIV, syphilis, rubella and tuberculosis serology
    - tests for other occupational diseases, as appropriate
    - test for colour blindness
  - hepatitis A, B, and C and rubella immunization should be offered if required.
- Staff who are dealing with radioactive substances should take special note of radiation hazards and should be able to prove their familiarity with codes and regulations applicable to radioactivity.

Security

- Admittance to the laboratory and procedures for locking the laboratory should be described (if applicable, refer to the safety manual).

Suggested headings for job descriptions

Responsibilities: By definition responsibilities cannot be delegated.

Professional

General statements.

Administrative

General statements.

Duties: Duties may be delegated.

Professional

Supervision (position in the hierarchy of the organization).
Education and training.
Methods and equipment selection and documentation.
Methods and equipment maintenance and development.
Specimen processing (measurements and observations).
Quality management.
Consultations.

Administrative

Planning and budgeting.
Laboratory space allocation.
Document and form design.
Purchasing of equipment and consumables.
Staffing schemes.
Maintenance schemes.
Interdepartmental liaison/coordination.
Representation of the department on committees.
Safety.
Disaster plan for the laboratory.
Documentation standards.

Staff qualifications should be defined to meet the demands of the laboratory. Likewise, work assignments should be consistent with the education, training, and experience of the individual. Skills should be documented and subject to continued improvement. This is a responsibility for the employer as well as for the employee.

The development of laboratory science and technology requires that a considerable amount of training and continuing education is carried out in the laboratory.

In most laboratories, different tasks can be identified, e.g. operational, technical, scientific, and consultational. The education programme should provide appropriate information to the employees who are responsible for the different tasks.

Operational tasks

- Sample collection (if applicable).
- Specimen receipt, identification, and registration.
- Evaluation of specimen suitability.
- Specimen processing (measurements and observations).
- Evaluation of control results.
- Validation of results.
- Reporting.

Technical tasks

- Installation, maintenance, and service of equipment.

Research, development, and educational tasks

- Research projects.
- Development, application, and assessment of new concepts and techniques.
- Supervision of quality systems.

Consultational tasks

- Medical staff to advise on evaluation and interpretation of laboratory reports, including:
  - significance of results from a technical perspective
  - scientific and biological basis and the clinical significance of the laboratory report
  - suitability of the analytical procedure and any further procedures to assist in solving a clinical problem
  - selection and evaluation of new diagnostic methods

- designing diagnostic strategies
- monitoring of patients and therapeutic intervention
- monitoring and evaluation of infection control reports
- continuous information on achievements of interest and importance for clinicians.

Laboratory handbook for users

There must be meticulous control of the collection and identification of specimens, including the method of collection, selection of containers and preservatives, labelling, storage and transport. Therefore, the laboratory should prepare a handbook containing relevant information for the user of laboratory services. The date of each revision should be given. In addition to laboratory-specific information, the handbook should contain information on patient preparation, sampling techniques, and reference intervals. The laboratory handbook can be produced as a collaborative effort by several laboratories for the benefit of all. Most laboratories, in addition to general information about their operation, offer a summary of the characteristics of their examinations, presented as a table as shown under the physician's book (Annex 2). The following points should be considered:

General requirements

The handbook should list all available analytes and include agreed terms (nomenclature including abbreviations) for each analyte, type of specimen (system), reference intervals and units, and peculiarities related to sampling, e.g. patient preparation, sample transportation, and storage conditions.

Uncertainty of measurement and scale

Allowable standard deviation (coefficient of variation, total variance) of the measurement should be defined. When answers are given on an ordinal scale, the possible answers should be given (e.g. U-glucose, amount-of-substance concentration [test strip, ordinal scale: 0, 1, 2, 3], arbitrary units).

A listing of handling of rare measurements or measurements performed by subcontracted laboratories should be available in the laboratory.

Individual laboratory requirements

- Location and postal address.
- Appropriate telephone directory.
- Office, laboratory, and collection hours.
- How to request a test (routine and emergency).

- Special instructions may be necessary for:
  - microbiology, e.g. handling of transport media
  - parasitology, e.g. protocol for drug resistance testing
  - clinical chemistry, e.g. drug monitoring protocols
  - haematology, e.g. bone marrow aspiration protocol.
- List:
  - specimen identification (labelling)
  - specimen containers and their provision
  - specimen transport to laboratory
  - procedures or examinations which require an appointment
    time and mode of reporting results
  - regular meetings with clinicians - times and location
  - complaints procedure
  - accounting policies and charging rates, when applicable.

Collection handbook

A separate collection procedures manual may be compiled. This manual should contain all relevant information so as to ensure proper handling of the sample. The manual may be a suitable excerpt from the laboratory handbook. Instructions on collection procedures should be available in all collection areas.

Description of measurement procedures

A manual listing and describing all methods and procedures that were authorized by the person in charge and are used in the laboratory must be available in the work areas. A master copy should be held by the person in charge. Copies of source literature for the methods in use should be available in the laboratory. The following points should be included, when and where appropriate:

Title

The title should specify the system, component, kind of quantity (property), and unit of measurement, when applicable.

Example:

- Serum sodium ion, amount of substance concentration (flame photometry), mmol/L
- (Cervix) epithelium surface cell, morphology (Pap, microscopy).

References

References to literature should have a standardized format.

Example:

- Baer DM, Belsey RE. Limitations of quality control in physicians' offices and other decentralized testing situations. *Clin Chem,* 1993, 39(1):9-12.
- Young DS. *Clinical chemistry*. New York, Mosby,1990.

Principles of measurement/observation

A short, informative statement which describes the principle of the measurement.

Example:

- Sodium ion concentration is measured in serum or urine using flame photometry.
- Sputum is subjected to culture using Loewenstein-Jensen medium.

Clinical significance

Give reasons why the test is usually requested and indicate the significance of results in relation to reference intervals. Suitable information can be found in textbooks.

Example:

S-TSH

The thyroid gland is stimulated by hormones from the pituitary gland (thyroid stimulating hormone, TSH). A feedback loop exists by which the thyroid hormones regulate the production of TSH. An increased concentration of TSH in serum may be an indication of low thyroid function (hypofunction). A decreased concentration of TSH may indicate a (autonomous) hyperfunction of the thyroid gland. Both findings may require additional investigation before a definitive diagnosis can be made. Production of TSH is also regulated by the thyroid releasing factor (TRF) or may be autonomous.

Sampling conditions and requirements

- State the conditions for patient preparation, e.g. fasting, special diets.
- Specify the type of specimen, i.e. the system in which the component should be measured or observed, e.g. plasma, serum, urine, sputum, etc.
- State the minimum volume (amount) of specimen to be provided for analysis.
- List specific containers, i.e. tubes with anticoagulants, coatings, sterile, as necessary.
- State the stability of the specimen under given conditions.
- State any other preanalytical requirements peculiar to the measurement.
- State the criteria for unacceptable specimens and any physical or other criteria which may compromise the results of the measurements.
- State handling and transport conditions.

Reagents

- List the reagents used in the procedure and their acceptable grade.
- Indicate any hazardous reagents or procedures used and which safety precautions must be taken.
- List the amount or concentration of reagents that are used and how they should be prepared.

Example:

Sodium citrate, 0,05 mol/L
Sodium citrate, dihydrate 14,7 g
Water, distilled, to 1000 mL.

Working guanine solution, 50 mg/L
Stock guanine solution, 1 g/L.
Borate buffer, 0,1 mmol/L
Dilute 1 part stock solution + 19 parts borate buffer
Prepare fresh

Instrumentation

- List all necessary instruments, including measuring and delivering devices such as pipettes, and any settings or programming of the instruments. Describe the scheme for preventive maintenance as appropriate.
- Refer to separate manuals for instrument maintenance and service.

Measurement procedure

- Write detailed instructions step by step; use the present imperative form.

Example:

Take 0,5 mL of sample
Add 1,5 mL of reagent X
Incubate for 15 minutes and read in spectrometer ABC at
540 nm, using a microcuvette.

Calibration and calculation

- List the calibrators.
- State:
  - traceability of calibrators to recognized reference material
  - commercial sources
  - directives for preparation
  - storage requirements and shelf-life.
- Describe:
  - calibration procedure
  - calibration intervals
  - number of calibrators.

- Describe:
  - transformation of signal value to physical value (calibration function)
  - use of the calibration function, step by step, if applicable.

Measuring range

- State:
  - detection limit
  - measuring range above which the sample should be diluted
  - dilution procedure and diluent to be used.

Interferences

- State known interfering substances.

Measurement performance and control procedures

- State the analytical goals in terms of total coefficient of variation (within and between variation).
- State:
  - number of controls, their source and level of concentration
  - directives for preparation
  - shelf-life of reagents
  - applicable decision rules and corrective actions.
- State participation in any external quality assessment schemes or organized, split patient sample comparisons.

Signature

- The date of acceptance of the procedure should be indicated together with the signature of the director of the laboratory or a delegate.
- The procedure manual should be reviewed regularly and a special record should be kept describing all revisions and amendments.

Instruments and measuring system

The equipment provided must be appropriate for its intended function and in good working order. The preparation of three kinds of documents is recommended:

- operating and maintenance manuals
- a logbook for each instrument
- an inventory.

Operating and maintenance manuals

- Operating manuals written in the local language should be readily available for equipment. Staff using such equipment or external service personnel should be able to check the critical operating characteristics by independent methods (e.g. temperature, volume, speed of centrifugation, absorbance, wavelength, calibration function). This may require additional training of staff.
- A preventive maintenance programme should be implemented as described in the maintenance manual. This is normally provided by the manufacturer and should be translated if necessary. The following areas should be covered in the programme:
  - service requirements
  - service intervals and reminder system
  - special safety considerations.
- Checks should be carried out at intervals appropriate to the equipment and its workload.

Logbook

- Records of calibration, repair, and maintenance of each instrument should be continuously updated and kept for the life cycle of that item.
- Temperatures of refrigerators and freezers should be monitored and documented, continuously if necessary (blood bank).
- Regular cleaning and decontamination of instruments, water-baths and other equipment should be documented as recommended by the manufacturer.
- When voltage stabilizers are used, their function should be regularly checked and documented.

Inventory

A list of all major equipment should be made and kept up to date. It might be practical to state a certain value below which the equipment is not listed. The list should indicate for each listed item, as appropriate:

- the inventory number (instrument identification, also to be found on the instrument)
- type and model, and year and cost of acquisition
- servicing agency (commercial, intramural, laboratory staff)
- the location of the instrument and the individual responsible.

Causes of unacceptable results of measurements

Whenever the control system indicates a reject, the measuring system should be checked in a logical and systematic manner depending on the nature of the error signal. Some complex instruments may have built-in routines or signals to amend faulty signals. The following points should be considered:

Equipment and method problems

- Instrument or equipment faulty, repaired, replaced, or not validated.
- Faulty calibrator.
- Faulty or inappropriate reagents.
- Incorrect setting of the instrument or calibration procedure.
- Faulty calibration of pipettes or other measuring devices.
- Inappropriate measurement conditions.
- Inappropriate quality control material (outdated, erroneously reconstituted).
- Inappropriate control rules.

Technical problems

- Misinterpretation or misidentification of specimen features (lipidaemia, haemolysis, etc.).
- Incorrect reconstitution of control material.
- Time delay between reconstitution and analysis of control material.
- Incorrect pipetting.
- Incorrect calculations or run accepted in nonlinear range.
- Sample transposition during processing.
- Poor humidity and/or temperature control in the room.
- Incorrect incubation/reaction temperature.
- Bacterial or other contamination of specimen or glassware.
- Carry-over from other samples.

Clerical errors

- Transcriptional error.
- Results reported in wrong units.
- Decimal point error.

Part II

Laboratory Self-assessment Checklist

Introduction

A quality manual must contain certain information to fulfil its purposes and in some cases also the norms and regulations (e.g. ISO/IEC Guide 25 or EN 45001). In previous sections most of these issues have been addressed. In the following sections a number of questions have been formulated to allow the laboratory to review and check if appropriate action has been taken. The relevance of the questions to a specific laboratory will depend on its responsibilities and tasks. Therefore, all questions need not result in a positive answer for every laboratory. Questions are listed in different sections focusing on specific areas of laboratory services and management. More than one section of the checklist will be relevant for the reviewing process. For example, the section on equipment applies to all kinds of laboratories, independent of their area of responsibility. Likewise, similar questions may occur in different sections of the checklist.

Terms such as "adequate" are used in the checklist; details of what is regarded as adequate will vary but, in general, facilities and procedures will be regarded as adequate when they do not constitute a limiting factor in the performance of tests or procedures, and are compatible with applicable safety and staff amenity standards.

It would be beyond the limits of this document to provide an exhaustive checklist. Questions and answers related to a specific technology and spectrum of analytes may therefore be included by the reviewer or the supervising authority.

General checklist

Is there a quality manual?

Does the quality manual address:

- the internal organization of the laboratory?
- daily surveillance of results (routine and urgent)?
- limits of acceptability of results (analytical goals)?
- recording, documentation. and archiving of all quality control results?
- the use of calibrators and controls?
- internal audit procedures?
- safety regulations?

Is there an organization chart?

Have the operational responsibilities of each member of the laboratory been documented? Is there a designated quality officer(s) responsible for monitoring quality?

Have documentation procedures been defined and are they distributed throughout the laboratory?

Is there documented evidence of quality for any laboratory to which work is referred (subcontracted)?

Has the person in charge approved the use of the outside referral laboratories?

Are there procedure manuals available for:

- all measurements and observations?
- maintenance of instruments?

Are there comprehensive instructions for writing procedure manuals?

Are copies of the procedure manuals available in the work areas?

Are all procedure manuals continuously revised to reflect changes in methods of operation?

Internal quality control and external quality assessment

Are analytical goals specified for all quantities?

Is there a documented internal quality control programme?

Are quality control results checked for each batch of results before they are reported?

Are there written criteria as to whether batches of results are to be accepted or rejected (control rules)?

Are quality control charts kept up to date at all times and regularly reviewed? (Examples of internal quality control charts are given in Annex 3).

Is evidence available to show that corrective measures are being taken when necessary?

If some measurements are done by more than one procedure, are checks made to ensure that the results are comparable?

Does the laboratory take part in external quality assurance (proficiency) programmes?

Are records kept of all external quality assessment results?

Are results from external quality assessment programmes available to laboratory staff?

Is evidence available to show that corrective measures arising from the internal audit are being taken?

Does the laboratory have established collaboration with a mentor laboratory?

Health and safety

Does the laboratory have a designated and properly trained person in charge of safety?

Is the person in charge of safety known to all laboratory staff?

Is there a safety education programme comprising:

- chemical hazards?
- microbiological hazards?
- physical hazards?
- use of safety glasses and other measures for personal protection?
  personal hygiene?
- use and removal of protective clothing (including gloves)?
- emergency equipment and procedures?
- first aid?

Does the laboratory comply with:

- fire regulations?
- electricity regulations?
- water and sewage regulations?
- hazardous materials regulations?
- noise and ventilation regulations?
- radioactive substances regulations?
- postal and other distributor's shipping rules?

Are personnel immunizations current?

Do staff have regular occupational health check-ups?

Is a safety manual (or list of special precautions) available?

Do staff exposed to radioactivity wear monitoring devices?

When work is done with radioactive reagents and chemicals, is the laboratory checked for background radiation?

Are monitoring devices regularly checked, the results monitored and archived?

Is there a recognized mechanism for reporting all laboratory accidents and the corresponding action(s) documented?

Are personnel required to wear a gown and gloves for specimen preparation and handling?

Are staff instructed to remove gloves before handling **any** non-contaminated surface, stationery, or equipment?

Are there written instructions for the safe handling and disposal of specimens, used glassware, biological media, and animal remains?

Are there written instructions for handling spills of contaminated materials?

Are these instructions known to the laboratory staff?

Are decontaminating solutions appropriately used for their specific purpose?

Is the laboratory equipped with fire extinguishers?

Are all personnel familiar with the operation of the fire extinguishers?

Are there regular fire drills?

Is the functioning of the fire extinguishers regularly inspected?

Is the laboratory equipped with first-aid equipment?

Are personnel instructed in the use of safety and first-aid equipment that might be available (e.g. emergency showers, gas masks)?

Are there regular checks of the measures to be taken in case of emergency?

Are volatile and/or flammable chemicals stored in areas or containers specially designed for the purpose?

Are areas where volatile fluids are used suitably ventilated?

Are vessels containing flammable liquids kept covered when not in use?

Are staff instructed in the safe handling of acids, alkaline solutions, and corrosive or hazardous chemicals?

Are fume cupboards provided when needed and:
- do they function properly?
- are they checked regularly?

Are all specimens treated as potentially infectious?

Is mouth pipetting prohibited?

Are suitable devices available to avoid mouth pipetting?

Are measures taken to minimize the formation of aerosols?

Are there documented procedures for disinfection of instruments and work space?

Does a protocol exist whereby service personnel can be informed that an item of equipment requiring maintenance or repair may be contaminated internally by infectious material?

Are there designated and adequate sharps containers?

Are gas cylinders handled according to regulations?

Are staff informed about the hazardous nature of ultraviolet light and radioactive materials?

Is smoking, eating, and drinking allowed in laboratory work areas?

Is all waste disposed of daily in a way that poses no direct or residual hazard to the community?

Is all contaminated and potentially infectious material adequately sterilized before disposal or cleaning?

Are any laboratory design features creating a hazard listed?

If diluents containing sodium azide are used:

- have procedures been evaluated to see if solutions containing azide are being emptied into lead or copper disposal systems?
- are warning notices posted about the potential hazard?

Facilities

Is adequate space provided for:
- specimen collection?
- analytical work?
- workbenches?
- instruments?
- storage of chemicals?
- storage of consumables?
- refrigerated storage?
- specimens?
- administration?
- records?

Are work areas provided with adequate:
- lighting?
- power points?
- stable electrical power?
- ventilation?
- temperature and humidity control?
- water supplies (tap and deionized/distilled)?
- drainage/sewerage?
- biological waste disposal?
- chemical waste disposal?

Is there a staff library?

Is there a meeting room?

Is there a sufficient number of adequate staff and rest rooms?

Is the laboratory appropriately and regularly cleaned and maintained in good order?

Is there an emergency power supply to maintain essential services?

Is there a direct outside telephone for emergency use?

Staff

Person in charge/laboratory manager

Is the person in charge involved in:
- staff training programmes?
- staff appraisal?
- assessment of procedures of measurement and approval of their changes?
- review of quality assessment programmes?

Is the person in charge readily available for consultation with:
- laboratory staff?
- medical doctors?
- administrators?

Is there a suitable relief arrangement in case of absence of the person in charge?

Other staff

Staffing policies:
- is there a defined staff structure?
- is there a staff manual, including all staff rules, procedures, and privileges?
- are all the staff aware of their duties, privileges and responsibilities?

Do current records include:
- résumé of training and experience?
- formal qualifications or necessary registration?
- dates of employment, etc?
- job description?
- work injury records?
- tasks performed in the laboratory?
- continued education?

Are the staff properly educated?

Do staff perform tests without proper training or experience?

Is there a formal certification of staff qualified to make specified measurements?

Is there a supervisor assigned to new or non-qualified staff?

Do less experienced staff have access to technical advice from senior staff at all times?

Is the after-hours service provided by qualified and experienced staff?

Is the quality of work carried out after hours checked at the earliest opportunity?

Are staff not directly involved in routine work but using the same equipment (e.g. research staff) certified?

Training programmes

Are the objectives of the training clear and understood by both trainee and supervisor?

Does the training programme involve:
- orientation of new personnel?
- scientific and procedural matters?
- occupational health and safety?
- bench training?
- access and use of teaching aids?
- seminars, external courses, projects etc?

Is the training evaluated against objectives?

Are technicians appropriately trained on specific instruments?

Equipment, Instrumentation, reagents, methods, and reports

Are operating and maintenance manuals available for all types of equipment?

Are all staff who use the equipment familiar with the detailed methods of operation?

Is the equipment adequate for the choice and number of tests being performed?

Is there an equipment inventory?

Is electrical equipment properly connected, earthed, and checked regularly?

Are equipment and measuring devices (pipettes, diluters, photometers etc.) calibrated and tested regularly?

Are fundamental quantities (e.g. temperature, wavelength, stray light, absorbance) of complex instruments regularly checked?

Are performance and tolerance limits defined for each analytical instrument, component, or procedure of a system?

Is there a reference thermometer available to check the bias of all working thermometers in use?

Are regular temperature checks made of water baths, incubators, refrigerators, freezers, heat blocks, etc?

Is the equipment well maintained?

Is equipment that is out of order clearly identified?

Are calibration, maintenance, and service records kept on file and steps taken to rectify faults?

Autoclaves

Is the autoclave of adequate size for the workload?

Are autoclaves checked regularly for efficient functioning by means of spore strips?

Are autoclaves checked by thermograph and temperature tape on each run?

Are heat-proof gloves available for loading and unloading the autoclave?

Are face shields and protective aprons available while working at an autoclave?

Is regular maintenance of the autoclave undertaken and logged?

Incubators

Is there a sufficient number of incubators in relation to the daily workload?

Are there incubators working at 25 °C, 30 °C, 35-37 °C, 42 °C, with controlled CO_2 atmosphere?

Are all incubators clean and well maintained?

Microscopes

Are staff properly instructed how to use a microscope?

Are microscopes properly cleaned after use and well maintained?

Are work stations for microscopy ergonomically designed?

Are there sufficient binocular microscopes available with oil immersion objectives?

Are there low power stereo microscopes available?

Are there magnifying glasses (x6 to x12) available?

Is an ocular with a calibrated micrometer for the microscope available?

Is the illumination adequate on all microscopes?

Is a dark ground microscope available?

Is a phase contrast microscope available?

Is a fluorescence microscope available?

Are the hours of use of high energy light sources recorded?

Are ultraviolet globes changed in accordance with the maker's instructions?

Is the ultraviolet light source in the fluorescence microscope adequately shielded to protect personnel?

Are microscopes stored under appropriate conditions?

Are microscopes serviced at regular intervals?

Are the correct spare fuses and bulbs kept for each model of microscope used in the laboratory?

pH meters

Are pH meters and their electrodes properly maintained?

Are pH meters regularly checked with buffers before use?

Are calibration buffers of adequate quality?

Balances

Are staff properly instructed how to use a balance?

Are the balance pans and the environs of the balances clean?

Are balances mounted on a vibration-free stand?

Are balances located in an area free of draughts and without marked temperature fluctuations?

Are certified weights available for daily checks?

Are balances regularly checked, serviced, and calibrated?

Centrifuges

Are there appropriate centrifuges for the specific needs available in the laboratory?

Are centrifuge bowls decontaminated daily?

Are centrifuges provided with safety locks?

Are necessary precautions taken to avoid use of aerosols?

Pipettes and volumetric glassware

Is all volumetric glassware of the required degree of accuracy and, where necessary, verified?

Are pipettes and diluters calibrated periodically?

Are safety devices available to avoid mouth pipetting?

Are damaged pipettes discarded?

Refrigerators/freezers

Is there sufficient refrigerator and freezer storage for specimens and reagents needing cold storage?

Is cold storage available at the following temperatures: 0 °C to –4 °C, –20 °C, –40 °C, –70 °C or below?

Are refrigerators used for storage of biological materials and reagents equipped with an alarm system?

Safety cabinets

Is there a safety cabinet for handling of contagious specimens or organisms?

Does the biological safety cabinet meet minimum requirements for protection of workers from infectious agents and protection of cultures from contamination?

Is the functioning of the cabinet tested each day of use?

Are filters maintained according to a regular schedule?

Are ultraviolet lamps replaced in accordance with the manufacturer's instructions?

Is the cabinet checked annually by an inspecting authority?

Photometers

Are routine function checks performed on each day of use?

Are cuvettes and other optical surfaces cleaned regularly?

Are cuvettes regularly checked for background absorbance?

When using flow-through cuvettes, is the carry-over regularly checked?

Are lamps checked regularly for darkening or film?

Are filters clean from scratches and in a good usable condition?

Is the wavelength and absorbance calibration of the photometers checked regularly with solutions or filters?

Is the stability of a signal checked regularly?

Are there regular checks run for stray light?

Are calibration curves verified after servicing or recalibration of the instrument?

Nephelometers

Is the light source checked regularly?

Are the multiplier tubes checked regularly?

Are disposable cuvettes stored to prevent contamination by dust, etc?

Specimens

Does the laboratory provide written instructions for the collection and transport of specimens which:

- are available to all users?
- outline patient preparation and collection techniques?
- give details of specimen storage and preservation?
- give transport requirements?

Are instructions provided to patients relating to:

- proper collection of specimens (and preservation where necessary)?
- fasting or other special requirements ?

Are appropriate containers, swabs, etc. provided by the laboratory or other approved source?

Does the laboratory request form include space for remarks on clinical history (including vaccination when relevant) and source of specimen?

Are validated measures taken to ensure that the appropriate preservative has been taken for the collection and transport of specimens for a specific laboratory investigation (e.g. anticoagulants, enzyme inhibitors, antimicrobials)?

Are specimens numbered and recorded as soon as they enter the laboratory?

Does the laboratory assess the acceptability of specimens received?

Does the laboratory check that all specimens received are properly labelled and authorized?

Do written instructions exist to deal with poorly labelled specimens?

When specimens are received, is registration made of:

- the name or other sufficient identification of the patient?
- the specimen identification?
- the name of the person referring?
- the date (and time when relevant) of specimen collection?
- the date and time the specimen was received in the laboratory?

Is adequate identification of specimens provided through all phases of laboratory analysis?

Are specimens adequately stored within the laboratory from the time of receipt until they are finally discarded?

Is refrigeration used to preserve specimens:
- at the collection site?
- in the laboratory?
- during transportation?

Are incubators/refrigerators/freezers available for off-hours storage of specimens when appropriate?

Are there suitable facilities for storage of specimens in the laboratory?

Reagents, media, and reference materials

Are all reagents, stains, or media properly labelled and dated with the time of receipt or preparation?

Are old and outdated reagents discarded in a safe manner and observing environmental regulations? There may be regulations for handling the reagents used. The laboratory may be obliged to find environmentally safe disposal routines.

Are reagents correctly stored?

Is distilled or deionized water available and used as appropriate?

Is the quality of purified water specified and monitored?

Are reagents or media of appropriate quality used?

Are the manufacturer's recommendations for reconstitution, storage, and expiry followed for all reagents?

Are the reagents tested with normal and abnormal controls before use?

Are biological reagents used of a reputable purity and potency?

Are new biological reagents checked against the old before being taken into use?

Are reagents, stains, and/or media subject to quality control procedures?

Are sufficient quantities of reagents and/or media kept in stock?

Are the conditions for storage specific, safe, and appropriate for the reagents and media?

Is the quality of stored, diluted reagents (e.g. pH, colour, ion concentration, absence of water) routinely checked before use?

Are calibrators used and do they comply with the method of investigation?

Do the calibrators used have values within the reference interval?

Are calibrators traceable to reference materials?

Are reference materials and/or strains used and do they comply with the method of investigation?

Are reference materials used for control of each series of measurement or investigation?

Methods

Does the nomenclature of quantities and units follow that nationally agreed?

Is there an operational procedures manual which includes a description of all procedures in the laboratory?

Are copies located in the work areas?

Does the procedures manual follow a standard protocol of preparation?

Are the manuals reviewed and updated regularly?

Who reviews procedures manuals?

Do procedures manuals include:

- when the procedure was introduced to the routine and the latest data reviewed or updated?
- instructions for the collection, preservation and transport of specimens?
- sufficient information on reagent and kit preparation?
- a step-by-step outline of the procedure?
- traceability of calibrators?
- internal quality control and external quality assessment schemes?
- any hazards of the procedure?
- notes on interfering substances?
- instructions for reporting results?
- reference intervals?
- alternative procedures as "backup" for automated tests, or instructions for referral of specimens?

Are all written instructions rigorously followed?

Are relevant current textbooks and periodicals available?

Are copies of relevant original literature related to the methods available?

Reporting and recording

Is there a formal mechanism for reporting?

Is there a documented procedure for accelerated handling of:

- seriously abnormal results?
- urgently requested specimens?

Is there a recognized system of nomenclature used for reporting results?

Are there procedures to check for transcription, calculation, or data entry errors?

Are results legible?

Are final reports despatched without undue delay?

Does the report include:

- the patient's name, age, and sex?
- the patient's record number (for hospitals)?
- the requesting doctor's name and address?
  the ward or clinic (for hospitals)?
- the name of the laboratory?
- a telephone number for enquiries?
- the date and time of collection of the specimen?
- a laboratory access number for each specimen?
- the type of material (system) tested (e.g. urine, plasma)?
- a reference interval for each quantitative test?

Are the reference intervals adjusted when appropriate (e.g. for age and sex)?

Are the reports scrutinized and signed before release? Is this for:

- all reports?
- a random sample of reports?
- reports selected as meeting some predetermined criteria?

Can multiple copies of a report be generated and sent to more than one user, if requested?

Can a replacement report be generated if the original is lost?

When results are amended after reporting, does the replacement report indicate this?

If measurements are performed outside the laboratory, are the results later reported and archived?

Are reports routinely distributed by:

- physical distribution of paper?
- electronic transmission (e.g. telefax, e-mail, remote printing)?
- direct transfer to user's computer?

Do reports generated within the laboratory show that:

- dangerously abnormal results should be phoned?
- biologically unlikely results should be checked?
- changes from previous results which are significant require checking?
- clinically significant trends or unusual results require consultation with clinical staff?

Are medical comments given on the significance of the results?

Are steps taken to ensure that laboratory reports are treated as confidential?

Are laboratory results only reported to the referring/requesting ward or physician?

Can laboratory results be traced back to the analyst?

Is there a documented procedure for urgent results?

Are there documented procedures for handling of clinically critical results?

Are acceptance limits determined by:

- mean value of internal controls ±2SD?
- other (specify)?

Are all final reports provided as written reports?

Are reference intervals reported for all tests?

Is the reference interval for adults based on:

- a local, defined (reference) population?
- values quoted by the maker of the kits used?
- published data?

Is the reference interval for children based on:

- a local, defined (reference) population?
  values quoted by the maker of the kits used?
- published data?

What is the estimated reporting time for each report issued by the laboratory?

Does the report state the inadequacy in quality or quantity of a specimen obtained, if necessary?

Are preliminary reports (e.g. in case of urgency or after microscopic examination of specimens) validated before release?

Are results and/or reports filed in a separate register in the laboratory?

Does the filing system allow retrieval of all results obtained for a particular patient?

Are photographs, slides, and other information kept on record?

Are results obtained on internal quality control specimens stored for all methods?

Is there provision for separate quality control summaries and comparisons, when the same test is done by more than one method?

Are archival summaries of quality control statistics made so that long-term changes can be reviewed, as necessary?

Are archived results retrievable by:

- patient name?
- medical record number?
- laboratory number ?

Is archival storage on:

- paper?
- microfiche or microfilm?
- floppy disk?
- tape?
- other machine-readable media (e.g. CD-ROM)?

Does the laboratory report notifiable diseases to the appropriate authority?

Does the laboratory keep records on diagnosis of notifiable diseases?

Are reports containing evidence of malignancy or possible malignancy kept according to national regulations?

Are reports kept on file for a minimum period?

Is a record kept of the date and staff who have carried out the laboratory investigations?

Accounting reports

Is there provision to check that a test has been performed before an account is issued?

Is there provision for suppressing charging for a specimen or for a test?

Is there an audit trail to check what has occurred if an account is questioned?

Can the system accommodate changes in test classification or grouping, as required from time to time?

Clinical chemistry

Are preanalytical conditions stated when necessary?

Are the functions of analytical and preparatory instruments checked and calibrated before being used for measurement?

Is the quality of water used appropriate for the intended laboratory investigations?

Is the quality of reagents specified and checked?

Is the shelf-life of reagents observed?

Are dilutions of specimens, calibrators, and control materials made using appropriate equipment and according to the state of the art?

Proteins

Are proteins measured by precipitation, agglutination, or flocculation methods?

Are proteins measured by complexiметric methods?

Are proteins separated by electrophoretic techniques measured by densitometry?

Are electrophoretically separated proteins eluted from the carrier before measurement?

Are protein reference materials and calibrators available?

Is electrophoresis done at a constant temperature or at the temperature of the ambient environment?

Is the current or voltage checked during electrophoresis?

Is the quality of buffer solutions checked before use for electrophoresis?

Is the purity of solvents to be used for high performance liquid chromatography (HPLC) checked before use?

Is the specificity, cross-reactivity, and reactivity of antibodies checked before use?

Electrolytes

Are gases used in flame photometry of sufficient purity?

Are selective electrodes routinely checked before each run?

If both flame photometry and ion selective electrode measurement are used, is information provided about the difference of results?

If complexiметry is used for the determination of electrolytes (e.g. Ca^{++}, Cu^{++}, Mg^{++}, Fe^{++}), is care taken that samples have not been stabilized with complexing agents (e.g. EDTA)?

Enzymes

Are storage conditions for samples and reagents specified and adhered to?

Are standard/recommended/reference methods used for the measurement of enzymes?

Is care taken for strict adherence to temperature control during measurement?

Is care taken that the appropriate wavelength is being used for each measurement?

Metabolites

Are reference materials and methods available?

Hormones

Are traceable calibrators available?

Is the analytical specificity, sensitivity, and limit of determination checked for each method for hormone measurement?

Is the laboratory authorized to continue measuring supporting quantities in the same sample?

Haematology and haemostaseology

Haematology

Is the procedure for haemoglobin measurement standardized?

Has the constant packing time for haematocrit been determined and recorded for each centrifuge?

Are blood cell counting chambers regularly examined to ensure that the lines are bright and free from scratches?

Are correct standard thick glass cover slips used?

Is the diluent regularly checked for background count? Is the lysing fluid used in cell counters also checked?

Is the appropriate minimum number of cells counted during microscopical examination (100 for white blood cells, 100 for platelets)?

In semi-automatic cell counters, is the minimum/maximum time for lysing determined at regular intervals?

Are manual and automated cell counting procedures checked daily with reference materials of known values?

Are the instruments checked for background count?

Is the lysing reagent checked for background count?

Is the quality of blood films satisfactory in respect of:

- staining?
- debris?
- morphology and distribution of cells?

Are slides uniquely identified?

Does the report include an evaluation of cell morphology?

Is blood for reticulocyte counting stained and examined within 24 hours of collection?

Haemostaseology

Are instructions provided on the appropriate sampling procedures for coagulation testing?

Are timers used in coagulation studies checked periodically?

Are prothrombin time results for patients on oral anticoagulants reported as INR (International Normalized Ratio)?

Are all measurements of functional quantities (e.g. prothrombin time) made under strict temperature control?

Are different reference intervals reported for automated and manual methods (as appropriate)?

Cytogenetics and cytology

Cytogenetics

Does the cytogenetics laboratory have its own wash up sterilization facility?

Does the laboratory have its own darkroom?

Are tissue culture facilities in a separate room?

Is the number of cells routinely counted and karyotyped for:

- peripheral lymphocyte analysis?
- bone marrow cultures?
- amniotic fluid?
- chorion villus specimens?
- other tissues?

What banding techniques are used:

- Giemsa?
- other (specify)?

Are accessory banding techniques employed where necessary (e.g. C, R)?

Are other techniques used such as,

- sister chromatid exchange?
- late replication?
- prometaphase examination?
- other (specify)?

Is there a genetic counselling service available to work with the laboratory?

Are all tissue culture procedures conducted under appropriate sterile conditions?

Cytology

Are fine needle aspirations attended by a pathologist?

Are gross macroscopic descriptions recorded and included in a report if appropriate?

Are reports of malignancy or suspected malignancy immediately issued and later confirmed?

Are all abnormal results authenticated by a pathologist?

Do abnormal reports include recommendations for further clinical or cytological investigations?

Does the laboratory match histological sections received with abnormal smears previously reported to determine their predictive accuracy?

Does the laboratory have a procedure to be followed if the coloscopic findings and biopsy results should differ significantly?

Does the record system allow easy identification of all Pap smears processed by the laboratory in a given time frame?

Is every abnormal Pap smear compared with records from previous investigations?

Microbiology

Bacteriology

Are organisms isolated and identified to a limited extent and referred to another laboratory for definitive identification?

Are organisms isolated and definitively investigated?

Are reference cultures of bacteria maintained to check:

- culture media?
- strains?
- sensitivity discs?
- reagents (where applicable)?

Are adequate procedures and appropriate media used for the isolation and identification of bacterial pathogens in:

- throat swabs and nasopharyngeal swabs?
- wound swabs?
- urethral-cervical swabs?
- sputum?
- urine?
- faeces?
- blood?
- spinal fluid?
- gastric aspirates?

Are the procedures suitable for the isolation of:

- streptococci?
- staphylococci?
- meningococci?
- Haemophilus sp?
- Neisseria sp?
- corynebacteria?
- Gram-negative bacilli?
- anaerobes?
- Candida sp?
- Campylobacter sp?
- vibrio?

- Aeromonas sp?
- mycobacteria?

Are microscopical investigations of stained specimens routinely performed?

Is the quality of staining routinely checked?

Are precautions taken in the collection of true sputum?

Are urine specimens received with added preservative?

Are quantitative colony counts in urine cultures done?

Are urethral-cervical cultures inoculated directly or received in transport medium?

Are there instructions for the selective addition of antimicrobials in the diagnosis of certain bacteria?

Are rapid isolation and identification techniques used for enteric pathogens in patients with diarrhoea?

Are cerebrospinal fluid (CSF) specimens processed immediately after receipt?

Is the macroscopic appearance of CSF recorded?

Is a differential cell count in CSF done?

Are blood cultures incubated to recover:

- aerobic organisms?
- CO_2 dependent organisms?
- anaerobic organisms?
- fastidious organisms?

Are all blood cultures examined early each day and isolates identified by visual inspection and by microscopy, if necessary?

Are apparently negative blood cultures subcultured within 24 hours and at 48 hours?

Are special procedures established to minimize the loss of anaerobes from wound aspirates?

Are both aerobic and anaerobic media routinely inoculated with wound aspirates?

Are selective methods used to detect/recover strict anaerobes?

Is the production of ß-lactamase identified in relevant organisms?

Are methods and devices correctly used to generate an anaerobic incubation environment?

Is anaerobiosis assessed by use of:

- a dye indicator?
- control cultures of strict aerobes and strict anaerobes?

Is antibiotic susceptibility tested by means of:

- agar dilution?
- disc diffusion?
- broth-disc method?
- broth dilution?

Is antibiotic susceptibility testing standardized by means of reference strains?

Is the quality of antibiotic discs routinely checked by means of incubation with reference strains?

Are antibiotic discs stored in a desiccated state and used within their specified shelf-life?

Is the inoculum size standardized?

If dilution tests are used, is there adequate control of the strength and identity of diluted drugs?

Parasitology

Are parasites identified to the extent required for diagnosis and assistance in the selection of therapy?

Are specimens investigated for parasites to be referred to other laboratories for identification?

Are specimens prepared for fresh examination?

Are specimens preserved for later examination?

Are appropriate staining techniques used?

Are bench aids provided with criteria for the identification of eggs and parasites?

Does the examination of stools include:

- unstained and iodine-stained wet mounts?
- a concentration procedure?
- a permanent stained preparation?
- use of modified Ziehl-Neelsen?
- safranine/methylene blue staining to detect cryptosporidia?

If ether is used for concentration, is the work done under well ventilated conditions in the absence of any source of ignition?

If zinc sulfate is used for concentration, is the solution checked for density and stored in a tightly stoppered bottle?

If haematoxylin stain is used. is the working solution prepared fresh on each day of use?

Are stains routinely checked with control specimens?

Are both thick and thin films made?

For thick films, are at least 100 fields examined under oil immersion before a report of "no parasites seen" is given?

Are films made from capillary rather than venous blood?

If anticoagulated blood is used, are films made immediately?

Are slides adequately identified?

Virology

Is virus diagnosis provided by:

- viral serology?
- DNA technology?
- cell + culture and viral isolation service?

Are virus isolation systems specified for types of viruses suspected and/or source of specimens?

Are continuous cell lines checked for mycoplasms?

Are animal sera used for growth media checked for absence of toxicity to cells?

Are records kept for all types, passage number, source, and media used for their growth and maintenance?

Are two or more host systems used for diagnostic isolation?

Are inoculated cultures checked at least every other day for cytopathic effect?

Are negative cultures passed at least once in cell culture?

Mycology

Are organisms identified to a limited extent and referred to a reference laboratory for definitive identification?

Are preliminary screening procedures, such as direct preparations and stains, performed?

Is a biological safety cabinet routinely used for handling cultures of fungal pathogens?

Are suitable selective media used for the growth and isolation of dermatophytes?

Are incubation temperatures defined and followed under culture conditions?

Are organisms definitely identified with or without susceptibility testing?

Are procedures for differentiation and identification of fungi adequate in respect of the type of work undertaken?

Do differential procedures include:

- chlamydospore formation?
- biochemical tests?
- slide cultures?
- animal pathogenicity?

Serology

Do the serological procedures that are used have an acceptable sensitivity and specificity for antigen or antibody detection?

Are positive and negative controls routinely run in serological reactions?

Are complement, heterophile, rheumatoid factor, and antibody controls run with each test run, where appropriate?

Is complement titrated in the presence of each test antigen?

Are rapid serological tests done for the detection of pathogens in:

- blood?
- central spinal fluid?
- urine?
- throat swabs?

Immunology and immunochemistry

Are the methods validated by:

- comparison with a reference method (Western blot, PCR, etc.)?
- comparison with a reference or mentor laboratory?
- reference to instructions by supplier?
- other procedures?

Does the validation include:

- checking the analytical sensitivity and specificity of the method?
- interferences?
  cross-reactivity?
- detection limit?

Are measurements calibrated using material traceable to national or international reference materials (if available)?

Does the laboratory participate in national or international exchanges of serum (patient samples)?

Has a mentor laboratory been identified?

Are difficult or ambiguous results referred to a mentor laboratory?

Is internal quality control monitoring the precision and trueness?

Is control material include in all runs?

Are reactive and non-reactive controls used for measurements which do not require a concentration (titre)?

Is the concentration (titre) of the reactive control at the level of significance for the assay?

Are dose-response curves and anti-time courses performed with each run (when appropriate)?

Are the reconstitution, use, and storage of lyophilized and reconstituted materials described?

Do procedures require complement inactivation of the specimen?

Are specimens tested immediately upon receipt? If not, are specimens stored at: –20 °C, –70 °C?

If measurements are performed by radioimmunodiffusion. are the temperature conditions routinely kept constant?

If measurements are performed by nephelometry:

- are all diluents filtered to remove particulate matter?
- are blank readings made for all test and reference sera?

If haemaglutination tests are used:

- are precautions taken to avoid interference from heterophile antibodies?
  are red cell suspensions standardized?

If fluorescence microscopy is performed:

- what magnification of the fluorescence microscope is used?
- is the adequacy of the fluorescent illumination checked?
- are dead cells identified?
- are more than 300 living cells counted?
- are monocytes discriminated from lymphocytes?
- are slides examined for fluorescence within four hours of preparation?
- are reactive and non-reactive control sera used for each antibody?
- is each slide routinely screened by more than one person?
- are difficult or ambiguous samples referred to a reference or mentor laboratory?
- is the working dilution of the fluorescein isothiocyanate (FITC) reagent determined by chequer-board titration?
- what is the heavy chain specificity of the FITC reagent?

If analysis by flow cytometry is performed:

- are cells prepared:
  by the haemolysis of whole blood?
  using the Ficoll-Paque method?
  by another procedure?
- are cells tested for viability?
- are cells brought to room temperature prior to measurement?
- are lot-specific factors in different batches of monoclonal reagents controlled?
- is the flow cytometer monitored by optimum performance?
- are haemopoietic and non-haemopoietic cells, within the gate population, distinguished?

If lymphocyte proliferative studies are performed:

- is blood collected into a preservative-free anticoagulant?
- are lymphocytes separated from blood using the Ficoll-Paque method?

- are more than two normal donor controls used in each assay?
- if lymphocyte proliferative stimulants are used:
  - are they of immunological grade?
  - are they stored below 4 °C?
  - are dose-response curves and anti-time courses performed with each run?
- if a mixed leucocyte culture is used, is the stimulator population treated to prevent its proliferation in the lymphocyte culture?
- are cultures checked for bacterial contamination?
- is the serum used in the proliferation medium assessed for optimum performance?
- is the quality of the serum monitored from batch to batch?

If a radioallergosorbent test (RAST) is performed:

- is a reference standard used for each specific RAST allergen?
- is a reference standard used for calculating the RAST score in each run of assays?

If immunoblotting is performed:

- are the molecular mass and purity of the antigens checked?

Blood transfusion

Introduction

The checklist on blood transfusion services draws special attention to the analysis and handling of blood that will be used as a therapeutic agent. This implies also legal aspects that are related to a laboratory service. However, the checklist has been limited to items that are part of a laboratory's responsibility, while aspects related to the responsibility of the therapy are not addressed. The items addressed in the following list of questions will not release the appropriate supervisors from assuming responsibility for the operation and respecting all relevant national regulations.

Blood collection and storage

Are there written instructions for the collection procedure, including donor preparation and handling of collected units, etc?

Are the persons responsible for venesection trained and qualified for the task?

Are the necessary medical supplies and equipment for blood donation readily available?

Are there clear criteria about the acceptability of a donor?

Is a medical practitioner immediately available if needed in case of accident during blood donation?

Is the donor unambiguously identified?

Does the blood bank issue special identity papers which identify the donor and significant blood group details?

Does the donor's examination include details of physical examination, laboratory results (including HIV, HBsAg, etc.), past and present illnesses, and history of previous transfusion or pregnancy?

Is the donor haemoglobin, erythrocyte sedimentation rate (ESR) and S-alanine aminotransferase checked routinely before venesection?

Is a sample of blood from each donation tested for HBsAg, HIV-1, HIV-2, anti-HCV, syphilis, and other transfusion-transmissible infections as required?

Do instructions for the collection and handling of specimens include, where appropriate:

- type and amount of unit of donated blood?

- specified anticoagulant?
- time of collection?

Is the following information recorded on the blood pack label:

- date of collection?
- expiry date?
- required storage temperature?
- amount of blood, haemoglobin concentration, and type of anticoagulant and its concentration?
- ABO and Rh(D) group?
- name, address, and telephone number of the blood bank?
- traceability of donor

Is blood cooled to 4 °C immediately (after 0,5 but within 1 hours) after collection?

Is blood stored in separate refrigerators so that there can be no confusion regarding:

- blood group?
- unprocessed blood?
- blood suitable for cross-matching?
- cross-matched blood?
- quarantined or rejected blood?
- autologous blood?
- outdated blood?

Does only laboratory staff have access to blood stores?

Are stock control procedures carried out daily to ensure efficient use of the blood held?

Are refrigerators free of materials other than blood products?

Is there a visual blood bank alarm system in case of power failure of the refrigerators?

Is there an audible alarm system for temperature deviations or power failure in refrigerators?

Is staff trained how to react properly in cases of alarm ?

Is reserve power available?

Laboratory testing

Are request forms and recipient blood samples checked to enable positive identification before laboratory processing commences?

Is an antibody screen or cross-match performed within 72 hours of collection?

Does the routine procedure include testing for:

- anti-A, anti-B, anti-A,B?
- anti-D, anti-Cc, anti-eE?
- A1, A2, B, red cells?
- unexpected antibodies?

Is the strength of reaction recorded for each stage of the grouping procedure according to a defined agglutination scoring system?

Is blood typed as Rh negative retested using a method designed to detect weak forms of D?

Is a method in place to detect clinically significant antibodies?

In cases where antibodies are present or where there is a history of antibody reaction, is antigen negative blood selected and cross-matched using the laboratory's usual serological technique?

Does the transfusion service confirm the ABO group on all red cell components and the Rh type on all Rh negative units before issue?

Where "computer cross-match" is used instead of serological techniques, does the management system conform to national standards?

Is there a separate protocol for neonates and other special circumstances (e.g. emergency)?

Is an autocontrol used:

- with the antibody screen?
- with the cross-match?

If a recipient is receiving repeated transfusions:

- is a fresh specimen taken for cross-matching immediately before blood is required, if the previous specimen was taken more than 72 hours earlier?
- is the specimen regrouped?
- is the new specimen screened for unexpected antibodies?

Is a check on recipient identity, the unit, and compatibility label made and recorded at time of issue of blood from the laboratory?

If antenatal specimens are routinely tested, does the procedure include:

- ABO/Rh(D) grouping?
- antibody screen?
- antibody identification?
- antibody titre, if required?
- phenotype of maternal and paternal specimen, where necessary?
- investigation of cord blood for ABO and Rh(D) type and indirect antiglobulin test?

Is there postnatal follow-up of Rh(D) negative women?

Is a document procedure in place for follow-up of recipients with antibodies and for consultation with the referring medical person in charge?

Is a postpartum maternal blood sample from at-risk negative women tested to detect a fetal-maternal haemorrhage sufficient to require more than a single dose of Rh immune globulin?

Are all recipient specimens stored at 4 °C and kept for up to 10 days?

Transfusion

Is a pretransfusion record completed for each recipient before blood is issued?

Does the record contain the following information:

- recipient's surname and given names in full?
- hospital record number and date of birth?
- ABO/Rh(D) blood group?
- antibody screen result?
- test results?
- donation number, ABO/Rh(D) blood group
- signature of person performing compatibility test?

Is a compatibility label carrying the appropriate details securely attached to each unit, once pretransfusion testing has been completed?

Does the label contain the following information:

- recipient's family name and given names in full?
- hospital record number or date of birth, when no number is given?
- ABO/Rh(D) group?
- donation number and ABO/Rh(D) group?
- statement of compatibility?
- date of compatibility testing?

Is each unit checked daily for colour, appearance, and expiry date and cross-matched immediately prior to release for transfusion?

Are transfusion reactions or incidents reported immediately to the laboratory?

Is there a standard operating procedure defined for the investigation of transfusion reactions?

Are remnants of all packs given immediately before or during the reaction kept for eventual re-examination?

Does the re-examination procedure include:

- checking that all packs have been given to the recipients for whom they were intended?
- examination of all packs given to the recipient?
- re-group and antibody screen on recipient's pre- and post-transfusion specimens?
- direct antiglobulin test on recipient's pre- and post- transfusion specimens?
- re-cross-match on blood in all available donor packs given before or during reaction with recipient's pre- and post- transfusion specimens?
- re-group on residual blood in all available donor packs given before and during reaction?
- screen for unexpected antibodies on residual blood in all available donor packs given before and during reaction?
- culture and smear of residual blood in all available donor packs?

Is there a protocol detailing laboratory tests to be carried out on the recipient to determine the nature and extent of the recipient's transfusion reaction (e.g. serum or urine for free haemoglobin, haemoglobin derivatives, serum haptoglobin, blood culture, etc.)?

Computer services

Introduction

The use of this checklist will vary greatly between laboratories because of the wide range of complexity of computer systems. Where only small or partial computer-based systems are in use, it is still appropriate to ensure that the principles behind the detailed questions are appreciated and considered.

Documentation

Have the objectives of the system been defined and documented?

Have the data, information, and processing requirements been defined and documented?

Have the equipment performance requirements been defined and documented?

Have management requirements in terms of data integrity, confidentiality, privacy, security, and accountability been defined, documented, and implemented?

Have management requirements on backup, long-term storage, and archiving been defined, documented, and implemented?

Have the hardware and software compatibility requirements been defined and documented for data storage, the CPU, local area networks, terminal emulation, backups, audit trails, and security?

Have external data exchange systems and their compatibility been defined and documented?

Hardware

Is there a brief description of all laboratory computer systems, including:

- date of manufacture and purchase?
- serial number?
- the servicing agent and arrangements?
- memory capacity?
- secondary storage (floppy disk, optical disk, tape) capacity and access principle? number of terminals?
- number of on-line connections?

- location of terminals or other parts of the network (if applicable)?
- manufacturer, type, and model?
- operating manuals and troubleshooting procedures?

Can the computer system handle a rate of data input equal to the maximum rate of data output of the transducer and A/D converter?

Have the ergonomic requirements of keyboard, visual display, software, furniture, and accessories been implemented?

Is the main computer area air-conditioned with a dedicated system, if required?

Is the main computer area secured against fire, theft, and water damage?

Is the main computer area or important work station protected against power surge, spikes, and low or high voltage?

Software

Is there a brief description of all laboratory computer systems software, including:

- name and version number?
- supplier's name?
- a succinct description of the function of the software?
- a description of any modifications made to it, where applicable, with dates?

Is there a complete record of all software installation, testing and/or modification, including:

- dates of tests?
- purpose of tests?
- names of personnel performing the tests and/or making modifications?
- list of input test data used?
- output of tests?
- conclusions drawn from tests?

Is there a dedicated data set and area allocated for tests of amended or new software?

Are dates recorded when software was taken into routine use?

Does the laboratory have sufficient in-house competence for testing and installation of acquired software?

Is there an updated backup version of all programmes and system instructions?

Is there a list of all software titles residing on the system, with dates and version numbers?

Does each software application which exists on the system have a user manual?

Are software manuals amended when the software operations are changed?

Operations

Have operating procedures been documented for the care of magnetic media (hard disks, floppy disks, tapes) when labelling, handling, or storing the media?

Have operating procedures been defined for the management of data libraries, including floppy disk libraries, tape libraries, backup procedures, off-site backups, authorization?

System management

Has a system manager been assigned to each system throughout the laboratory?

Does the system manager play an active role in the administration and surveillance of the day-to-day use and requirements of the system?

Has the system manager defined staff training procedures for each software package?

Is there a defined procedure for disseminating information on system changes?

Are complete operations and servicing records kept?

Have operating procedures been documented for the care and servicing of computer hardware, peripherals, read/write heads, and servicing requirements?

Do documented backup procedures exist for each separate computer configuration?

If there is more than one backup in existence at any one time, is there a system of multiple or progressive backups, with adequate documentation?

Is a logbook used for each system, which records the time, date, operator, and particulars of each backup?

Are the backups stored in a secure place which minimizes the effect of fire, water damage, laboratory fumes, strong electromagnetic fields, and dust?

Recovery

Are the recovery procedures documented in a systems recovery manual?

Are one or more persons trained in the correct recovery procedures as documented?

Have these people practised the recovery procedures?

When a recovery is performed, are the time, date, and other particulars entered into an appropriate logbook, e.g. backup logbook or recovery logbook?

Risk management

Has a risk management plan been implemented and is it reviewed periodically?

Have threats been documented

- in terms of actual and perceived threats?
- in terms of environmental factors, authorized users, and unauthorized users?

Has the vulnerability of the system been assessed in terms of natural disasters, environmental factors, the housing facility, access, and personnel (both trusted and unknown).

Are there sufficient security measures to prevent any involuntary or unauthorized access to, or manipulation of, the system?

Have contingency plans been documented for action, in the event of loss of power, or loss of processing site extended systems down-time, including air-conditioning, data storage devices, printers, personal computer, mini-or mainframe?

Has management reviewed the above assessments and then selected appropriate countermeasures, e.g. locked doors, audit trails, software access systems, passwords?

Do users keep their passwords secure?

Does documentation exist for action to be taken in case of system failure, physical damage to the system (fire, flood, lightning strike, etc.), and death or absence of key personnel?

Are waste paper, disks, and tapes disposed of properly, considering their degree of confidentiality?

Can the organization function without the main computer facility?

Are all wires, cables, etc. adequately located and protected from traffic, spills, and gases?

Are software and data files stored so as to be protected against theft or intentional misuse?

Data management

If requests for one patient have been entered into the computer erroneously, can these requests be corrected leaving an audit trail?

If requests have been linked to the wrong patient, can this be corrected leaving an audit trail?

Are data entered into the computer:

- via automatic hardware input?
- by hand?

If by hand, is the input checked via a documented standard operating procedure?

Can the system generate a paper copy of data entered?

Testing process

Does the computer provide lists of work for particular work areas?

Do the worklists provide loading information for analytical instruments?

Does the computer system allow quality control results to be entered along with patient results?

Does the computer use the results of quality control samples to assess if a batch of results is out of range, using a formal acceptance algorithm (control rule)?

Instrument interfaces

Is interface software properly documented?

Is interface hardware exchangeable and spares available?

Are instructions for interface handling and maintenance easily accessible?

Who is responsible for updating of interfaces?

Calculations

Is every algorithm for calculation of results from raw data (e.g. RIA calibration curves) soundly based and appropriate to the assay?

Are calibration curves viewed and validated by laboratory staff before acceptance of the calculated results?

Can the computer automatically calculate results for tests which are derived from other tests, e.g. creatinine clearance?

Results

Are the results entered on-line and/or off-line into the computer system?

Are all results protected from being reported until validated?

Are there automated methods of entering results other than on-line ones (e.g. document reader)?

Does the computer highlight dangerous (life-threatening) numeric results ?

If abbreviated comments are being entered, does the computer display the full comment for verification during result entry or subsequently?

Modification of reports and results

Is the modification of the data limited to those who need this facility?

Do these people only have the ability to modify those data files which are relevant to them?

Does the system provide an audit trail to keep historical records of modified files?

Are there documented procedures to follow if data are altered after reports have been issued?

If data are altered after reports have been issued, does the system have the ability to send amended reports?

Does the audit trail allow recovery of the originally reported result?

Are all reports and amended results signed?

Patients' reports

Does the system generate printed reports?

Are reports available through terminals in wards or other non-laboratory areas as:

- hard copy?
- visible on screen only?

How would reports be produced if the system were down for 24 hours:

- urgent results only, reported manually?
- full reversion to manual system?

Does the system make provision for storage and reporting of comments on:

- the unsuitability of a specimen for one or more of the requested analyses?
- the relationship of a result to a reference interval?
- the relationship of a result with reference to the preceding result (D-check)?

Does the system make provision for storage and reporting of free-text comments on the results, or descriptions of qualitative results, as:

- predetermined comments?
- any text required?

Are any results or combinations of results commented on by the system without human intervention:

- by comparison with simple criteria?
- by an expert system?

If an expert system is used, has its accuracy been verified?

Transferring/copying data

When transferring or copying data, is there an error-checking process?

When transferring or communicating files across dedicated or normal telephone lines, is the confidentiality of the data ensured?

What process ensures that the confidentiality is maintained?

Quality control reports

Does the system produce graphical or numerical summaries of quality control results or patient means and calculate appropriate statistics?

Accounting reports

Does the system transfer information from the request entry process to a billing system?

Management reports

Does the system provide reports on:

- all specimens received (a log)?
- tests not performed within a predetermined time?
- monthly workload by number of specimens?
- monthly workload by total number of measurements?
- monthly workload by number of each measurement?
- monthly workload by source?

Annex 1
Definitions

Accreditation specification (requirement): the analytical and operational goals described by the uncertainty of measurement, timeliness, diagnostic performance etc.

Accuracy: closeness of the agreement between the result of a measurement and a true value of the measurand.

Note: 1. Accuracy is a qualitative concept.

2. The term precision should not be used for "accuracy".

Analyte: component indicated in the name of a measurable quantity (of measurand).

Bias: systematic error of the indication of a measuring instrument.

Note: The bias of a measuring instrument is normally estimated by averaging the error of indication over an appropriate number of repeated measurements.

Calibration: the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

Note: 1. The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system or material measure, or the assignment of values to marks on arbitrary scales.

2. A calibration may also determine other metrological properties. The result of a calibration may be recorded in a document, sometimes called a calibration certificate or calibration report.

3. The result of a calibration is sometimes expressed as a calibration factor, or as a series of calibration factors in the form of a calibration curve. [VIM* 6.13]

Calibration function: signal of the measuring system as a function of the stated value of the measurand.

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* International Vocabulary of Basic and General Terms in Metrology, ISO, Geneva, 1993.

Note: 1. The calibration function may be presented as an equation, simplest with a calibration factor, or as an analytical calibration curve (sometimes ambiguously called "analytical curve" or "standard curve").

2. The stated value may be the assigned value of a reference material.

Certified reference material (CRM): reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence. [ISO Guide 30:1992, VIM 6.14]

External quality assessment: checking of results of measurements or observations, produced at a certain site, by comparison with the results obtained by other sites on the same material distributed by an external agency that also analyses the data statistically.

Note: 1. Another term is "interlaboratory test comparison". [ISO/IEC Guide 2:1986, 12.5]

2. External quality assessment is the preferred term in laboratory medicine.

Internal quality control: operational techniques and activities within a production site that are used to ensure that requirements for quality of services are fulfilled.

Measurand: measurable quantity subject to measurement.

Measurement: set of operations having the object of determining a value of a measurable quantity. [VIM 2.1]

Measurement procedure: set of operations, described in detailed terms, used in the performance of particular measurements according to a given method. [VIM 2.5]

Measurement signal: quantity that represents the measurand and which is functionally related to it. [VIM 2.8]

Measuring system: complete set of measuring instruments and other equipment assembled to carry out specified measurements. The measuring system may also include materials such as chemical or biological substances or both. [VIM 4.5]

Mentor laboratory: laboratory assuming a responsibility for one or several laboratories with a view to establishing traceability of results to reference materials, as well as supporting the collaborating laboratory(ies) in education and development.

Observation: set of operations having the object of classifying a property according to a nominal or ordinal scale.

Organizational structure: the responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions. [ISO 8402]

Precision: closeness of the agreement between independent results of measurements obtained under prescribed conditions.

Note:
1. Precision of measurements can be measured on an ordinal scale such as (low, medium, high).
2. Precision is usually expressed numerically by statistical measures of the inverse concept "imprecision of measurements".
3. Precision depends only on the distribution of "random errors of measurement".

Principle of measurement: scientific basis of a method of measurement. [VIM 2.3]

Property (in a general sense): Attribute of a phenomenon, body, or substance that may be distinguished qualitatively.

Note: All properties may be related to nominal and ordinal scales, but "measurable properties" are generally related to difference or ratio scales.

Quality: the totality of features and characteristics of a product or service that influence its ability to satisfy stated or implied needs. [ISO 8402]

Quality assurance: all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality. [ISO 8402]

Quality manager: a person or persons having responsibility for quality assurance within the laboratory. This person shall be designated by the laboratory management and have direct access to top management. It is advisable that the quality manager be part of the laboratory team and with direct responsibilities in the working process rather than having administrative functions only.

Quality management: the part of the overall management function that determines and implements the quality policy. [ISO 8402]

Quality manual: a document stating the quality policy, quality system, and quality practices of an organization.

Note: The quality manual may call up other documentation relating to the laboratory's quality arrangements. [ISO/IEC Guide 25]

Quality plan: a document setting out the specific practices (what and how), resources (who and with what), and sequence (when and in which order) of activities relevant to the laboratory (a particular project). [ISO 8402]

Quality policy: the overall quality intentions and direction of an organization as formally expressed by top management. [ISO 8402]

Quality system: the organizational structures, responsibilities, procedures, processes, and resources needed to implement quality management. [ISO 8402]

Quantity (measurable or physical): attribute of a phenomenon, body, or substance that may be distinguished qualitatively and determined quantitatively.

Reference material: material or substance, one or more of whose property values are sufficiently homogenous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. [ISO Guide 30:1992, VIM 6.13]

Split patient sample comparison: comparison of results of measurements or observations at different sites on aliquots of patient (actual) samples. This may reveal matrix effects which might severely interfere with certain procedures, and establish corrective functions if any bias is revealed.

Test: a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process, or service according to a specified procedure.

Note: The result of a test is normally recorded in a document sometimes called a test report or a test certificate. [ISO/IEC Guide 2 :12.1. amended]

Traceability: property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. [VIM 6.10]

Trueness: closeness of the agreement between the average value obtained from a large run of results of measurements and a true value.

Note:
1. Trueness of measurement can be measured on an ordinal scale such as (low, medium, high).
2. Trueness is usually expressed numerically by the statistical measure "bias" that is inversely related to trueness.

Verification: confirmation by examination and provision of evidence that specified requirements have been met.

Note: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation, or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision to restore to service, to perform adjustments, to repair, to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the measuring instrument's individual record.

Annex 2

Physician's handbook

A laboratory needs a means to inform its users in hospitals and primary health care systems of its services and requirements. Many items will be of a local character but there is also basic information which is common to most laboratories.

The contents of the handbook should focus on the requirements of preanalytical preparation of the patient and samples, the routines for requests in everyday work, as well as emergencies, routines for reporting relevant telephone numbers, postal and street addresses, etc.

All aspects of the interaction between the clinician or patient and the laboratory should be included in the handbook.

Most laboratories, in addition to general information about their operation, offer a summary of the characteristics of their examinations. The summary is often presented as a table and the following layout may serve as an example of such a table. The contents of the table could, with advantage, be shared by several laboratories with minor adjustments to fit local conditions. This would greatly simplify its production and updating.

Headings

System - the material used for the examination.

Component - the entity of the properties which are to be examined.

Reference interval - including the units used. If available and relevant, ethnic, sex and age-related reference intervals should be included.

Container - tube, addition, bottle, etc.

Minimum account of testing material

Examination frequency - emergency (stat) - daily - weekly, etc.

Cost - it might be useful to mention relative costs, etc.

Comments - special preanalytical requirements, eg:

- sampling conditions (e.g. fasting, supine, sterile)
- shipping (e.g. by mail, at –20 °C)

Example

System	Component	Reference interval	Container	Minimum amount of testing material	Examination frequency	Cost	Comments
S	Sodium	M&F 132-145 mmol/L	Tube without addition	2 mL	Stat	2	
B	Glucose	3,5-5,5 mmol/L	Tube with addition heparin-fluoride	100 mL	Stat	7	Plasma should be separated before shipment

Annex 3

Quality control charts

INTERNAL QUALITY CONTROL CHART

This document mustbe kept at the working station. For any details, seethe Operating Manual Procedure.

Laboratory :	**Laboratory Section :**	**Year / Month :**	**Operating Manual Procedure N° : .....**
Instrument :	**Reagents :**	**ID :**	**Page : 1 / 2**

LEVEL 1

QC Material :	**Expiry date :**	**Lot N° :**	

Analytes											
Target values										**Accepted /**	
Day / batch	**QC Results**									**Rejected**	Signature

LEVEL 2

QC Material :	**Expiry date :**	**Lot N° :**	

Analytes											
Target values										**Accepted /**	
Day / batch	**QC Results**									**Rejected**	Signature

Report for rejected results from internal quality control materials

Laboratory :	Laboratory Section :	Year / Month :	Operating Manual Procedure N° :
Instrument :	Reagents :	ID :	Page : 2 / 2

When rejected, the laboratory technician takes note of any corrective action (batch change, instrument check, etc.).
At the end of each month, the laboratory supervisor reviews these registration sheets and makes the comments for any decisions or action to be taken in view of the results.

LEVEL 1

Day	Report	Signature

LEVEL 2

Day	Report	Signature

Monthly results review : comments, actions, resolutions	Date : ...../...../....	Signature:
.....		
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.....		

INTERNAL QUALITY CONTROL CHART

EXAMPLE FOR URINE STICKS

This document must be kept at the working station. For any details, see the Operating Manual Procedure.

Laboratory :	**Laboratory Section : Urine sticks**	**Year / Month :**	**Operating Manual Procedure N°**
Instrument :	**Reagents :**	**ID :**	**Page : 1 / 2**

LEVEL 1

QC Material :	**Expiry date :**	**Lot N° :**	

Analytes	pH	Proteins	Glucose	Ketones	Bilirubin	Blood	Nitrites	Urobilinogen	Leukocytes	Density	Accepted / Rejected	Signature
Target values	>=8,5	0,3 or 1,0 g / L	14 or 28 mmol /L	Positive	Small-large	Small-large	Positive	0,1 - 2 µmol/L	Negative	1,000 - 1,010		
Day / batch	QC Results											

LEVEL 2

QC Material:	**Expiry date:**	**Lot N° :**	

Analytes	pH	Proteins	Glucose	Ketones	Bilirubin	Blood	Nitrites	Urobilinogen	Leukocytes	Density	Accepted / Rejected	Signature
Target values												
Day / batch	QC Results											

Report for rejected results from internal quality control materials

Laboratory :	**Laboratory Section : Urine sticks**	**Year / Month :**	**Operating Manual Procedure N°**
Instrument :	**Reagents :**	**ID :**	**Page : 2 / 2**

When rejected, the laboratory technician takes note of any corrective action (batch change, instrument check, etc.).
At the end of each month, the laboratory supervisor reviews these registration sheets and makes the comments for any decisions or action to be taken in view of the results.

LEVEL 1

Day	Report	Signature

LEVEL 2

Day	Report	Signature

Monthly results review : comments, actions, resolutions	**Date : ...../...../...**	**Signature:**
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INTERNAL QUALITY CONTROL CHART

EXAMPLE FOR ESSENTIAL CLINICAL CHEMISTRY TESTS

This document must be kept at the working station. For any details, see the Operating Manual Procedure.

Laboratory :	**Laboratory Section : Blood chemistry**	**Year / Month :**	**Operating Manual Procedure N° :**
Instrument :	**Reagents :**	**ID :**	**Page : 1 / 2**

LEVEL 1

QC Material :	**Expiry date :**	**Lot N° :**	

Analytes	Alkaline phosphatase	Amylase	AST	Bilirubin (total)	Calcium	CO_2	Creatinine	Glucose	Potassium	Protein	Sodium	Accepted / Rejected	Signature
Target values													
Day / batch	QC Results												

LEVEL 2

QC Material :	**Expiry date :**	**Lot N° :**	

Analytes	Alkaline phosphatase	Amylase	AST	Bilirubin (total)	Calcium	CO_2	Creatinine	Glucose	Potassium	Protein	Sodium	Accepted / Rejected	Signature
Target values													
Day / batch	QC Results												

Report for rejected results from internal quality control materials

Laboratory :	Laboratory Section : Blood chemistry	Year / Month :	Operating Manual Procedure N°
Instrument :	Reagents :	ID :	Page : 1 / 2

When rejected, the laboratory technician takes note of any corrective action (batch change, instrument check, etc.).
At the end of each month, the laboratory supervisor reviews these registration sheets and makes the comments for any decisions or action to be taken in view of the results.

LEVEL 1

Day	Report	Signature

LEVEL 2

Day	Report	Signature

Monthly results review : comments, actions, resolutions	Date : ...../.....	Signature:
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INTERNAL QUALITY CONTROL CHART

EXAMPLE FOR ESSENTIAL HAEMATOLOGY TESTS

This document must be kept at the working station. For any details, see the Operating Manual Procedure.

Laboratory :	**Laboratory Section : Haematology**	**Year / Month :**	**Operating Manual Procedure N°**
Instrument :	**Reagents :**	**ID :**	**Page : 1 / 2**

LEVEL 1

QC Material :	**Expiry date :**	**Lot N° :**

Analytes	Haematocrit	Haemoglobin	Leukocytes	Platelets	Prothrombin	PTT	Reticulocytes	ESR	Sickle cell			Accepted / Rejected	Signature
Target values													
Day / batch	QC Results												

LEVEL 2

QC Material :	**Expiry date :**	**Lot N° :**

Analytes	Haematocrit	Haemoglobin	Leukocytes	Platelets	Prothrombin	PTT	Reticulocytes	ESR	Sickle cell			Accepted / Rejected	Signature
Target values													
Day / batch	QC Results												

Report for rejected results from internal quality control materials

Laboratory :	**Laboratory Section : Haematology**	**Year / Month :**	**Operating Manual Procedure N°**
Instrument :	**Reagents :**	**ID :**	**Page : 2 / 2**

When rejected, the laboratory technician takes note of any corrective action (batch change, instrument check, etc.).
At the end of each month, the laboratory supervisor reviews these registration sheets and makes the comments for any decisions or action to be taken in view of the results.

LEVEL 1

Day	Report	Signature

LEVEL 2

Day	Report	Signature

Monthly results review : comments, actions, resolutions	Date : ...../...../....	Signature:
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INTERNAL QUALITY CONTROL CHART

EXAMPLE FOR ESSENTIAL URINE CHEMISTRY TESTS

This document must be kept at the working station. For any details, see the Operating Manual Procedure.

Laboratory :	Laboratory Section : Urine Chemistry	Year / Month :	Operating Manual Procedure N°
Instrument :	Reagents :	IC :	Page : 1 / 2

LEVEL 1

QC Material :	Expiry date :	Lot N° :	

Analytes	Bilirubin	Glucose	HCG	Ketone bodies	Protein	Density	pH				Accepted / Rejected	Signature
Target values												
Day / batch	QC Results											

LEVEL 2

QC Material :	Expiry date :	Lot N° :	

Analytes	Bilirubin	Glucose	HCG	Ketone bodies	Protein	Density	pH				Accepted / Rejected	Signature
Target values												
Day / batch	QC Results											

Report for rejected results from internal quality control materials

Laboratory :	Laboratory Section : Urine chemistry	Year / Month :	Operating Manual Procedure N°
Instrument :	Reagents :	ID :	Page : 2 / 2

When rejected, the laboratory technician takes note of any corrective action (batch change, instrument check, etc.).
At the end of each month, the laboratory supervisor reviews these registration sheets and makes the comments for any decisions or action to be taken in view of the results.

LEVEL 1

Day	Report	Signature

LEVEL 2

Day	Report	Signature

Monthly results review : comments, actions, resolutions	Date : ...../...../....	Signature:
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INTERNAL QUALITY CONTROL CHART

EXAMPLE FOR ESSENTIAL SPINAL FLUID TESTS

This document must be kept at the working station. For any details, see the Operating Manual Procedure.

Laboratory :	Section : Spinal fluid	Year / Month :	Operating Manual Procedure N°
Instrument :	Reagents :	ID :	Page : 1 / 2

LEVEL 1

QC Material :	Expiry date :	Lot N° :	

Analytes	Glucose	Leukocytes	Particle type	Protein									
Target values												Accepted /	
Day / batch	QC Results											Rejected	Signature

LEVEL 2

QC Material :	Expiry date :	Lot N° :	

Analytes	Glucose	Leukocytes	Particle type	Protein									
Target values												Accepted /	
Day / batch	QC Results											Rejected	Signature

Report for rejected results from internal quality control materials

Laboratory :	Section : Spinal Fluid	Year / Month :	Operating Manual Procedure N°
Instrument :	Reagents :	ID :	Page : 2 / 2

When rejected, the laboratory technician takes note of any corrective action (batch change, instrument check, etc.).
At the end of each month, the laboratory supervisor reviews these registration sheets and makes the comments for any decisions or action to be taken in view of the results.

LEVEL 1

Day	Report	Signature

LEVEL 2

Day	Report	Signature

Monthly results review : comments, actions, resolutions	Date : ...../...../....	Signature:
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INTERNAL QUALITY CONTROL CHART

This document must be kept at the working station. For any details, see the Operating Manual Procedure.

Laboratory :	Section	Year / Month :	Operating Manual Procedure N°
Instrument :	Reagents :	ID :	Page : 1 / 2
QC Material :	Expiry date :	Lot N° :	

Analytes												
Target values											Accepted /	
Day / batch	QC Results										Rejected	Signature
Mean												
SDI												
CV %												

Report for rejected results from internal quality control materials

Laboratory :	Section :	Year / Month :	Operating Manual Procedure N°
Instrument :	Reagents :	ID :	Page : 2 / 2

When rejected, the laboratory technician takes note of any corrective action (batch change, instrument check, etc.).
At the end of each month, the laboratory supervisor reviews these registration sheets and makes the comments for any decisions or action to be taken in view of the results.

Day	Report	Signature

Monthly results review : Comments, actions, resolutions	Date : ...../...../....	Signature:
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