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Guidance for the

Implementation of a Quality Management System in Drug Testing Laboratories

A commitment to quality and continuous improvement

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Laboratory and Scientific Section
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Contents

1. Foreword: Purpose of the manual

Law enforcement authorities and other clients of drug analysis laboratories, for example, police, customs, prosecutors and defence solicitors, need results that are:

- reliable;
- valid;
- based on standard procedures;
- compatible with results in other laboratories;
- compliant with the evidentiary standards of the respective judicial, administrative and legal systems;
- obtained in an effective and efficient manner in the required timescale;
- value for money.

The quality of the analyses and results of such laboratories have significant implications for the justice system, law enforcement, crime prevention and health policy, as well as for the international harmonization and worldwide exchange and coordination of drug information and data. [1]

The compatibility and acceptance of laboratory results between countries is facilitated by their compliance with EN ISO/IEC 17025:2005 (ISO 17025) [2], the international quality standard for testing and calibration laboratories, and the associated ILAC recommendations G19:2002 for forensic science laboratories [3]. Compliance with ISO 17025 also ensures conformity with the requirements of ISO 9001 that are relevant to drug testing laboratories. However, compliance with ISO 9001 alone is not a substitute for compliance with ISO 17025, as it does not address the technical competence of the testing laboratory.

The guidelines that follow are specifically for drug testing laboratories and are based on the general principles of the ISO 17025 standard. They also take account of the UNODC *Recommended Guidelines for Quality Assurance and Good Laboratory Practice* [4], SWGDRUG Recommendations [5], the requirements of the American Society of Crime Laboratory Directors' Laboratory Accreditation Manual [6], SOFT/AAFS Forensic Toxicology Laboratory Guidelines [7] and *European Laboratory Guidelines for Legally Defensible Workplace Drug Testing.* [8, 9]

Dedication to quality is the fundamental principle of a forensic laboratory. The aim of this document is to provide guidance to deliver high quality in a forensic laboratory, use the appropriate techniques to find the "answers" and to improve it constantly. It is a "how to do document" and includes some areas that are not explicitly covered in depth by ISO 17025.

It is intended to serve as an introduction to laboratory quality management systems and to provide practical guidance to national authorities and analysts for the implementation of such systems based on best practice in the laboratory. "Best practice" may vary between laboratories because the resources at their disposal and the legal requirements are different. For example, on an international scale, the state-of-the-art in instrumentation may stipulate LC-MS-MS as the basis for best practice, but this equipment is unavailable in many laboratories which nevertheless produce good results. Also, in some jurisdictions it may be necessary to quantify drugs or identify specific isomers while it may not be required in other countries. "Best practice" should therefore be interpreted as the best achievable practice within the laboratory and jurisdiction concerned, as long as the work carried out meets the requirements in this document. There are different ways of achieving the end result and these guidelines will assist laboratory managers to ensure that their way is at an internationally acceptable level.

Compliance of all drug testing laboratories with the guidelines that follow is essential to ensure the harmonized performance of drug testing laboratories worldwide. These guidelines can also be used as a basic guide not only for laboratories but also for auditors and inspectors in the evaluation of drug testing laboratories during the accreditation process.

External accreditation to ISO 17025 is the process by which an authorized accreditation body formally recognizes that a laboratory is competent to carry out specific tasks. In the accreditation process, the laboratory demonstrates that its management, operations, personnel, procedures, equipment, accommodation, security, and health and safety procedures meet established quality standards. While it may require a significant investment of resources, it would provide laboratory management, law enforcement authorities and other clients with added confidence in the performance of the laboratory. External accreditation is therefore an appropriate goal in the development of a quality management system and many drug testing laboratories in several countries have now been accredited.

In future, it is possible that only accredited drug testing laboratories will be authorized to function as forensic toxicology laboratories or as police crime laboratories.

UNODC provides support to laboratories in introducing and implementing a quality management system through a number of initiatives, including the provision of reference samples of controlled substances, laboratory manuals on recommended

methods, training opportunities and the International Collaborative Exercises scheme, and by promoting and facilitating the exchange of information, material and data. [10]

Throughout the manual, examples are given to clarify various points made. These are preceded by the phrase "for example". Where this occurs, the examples given are not exhaustive but merely intended to illustrate the respective points.

2. Introduction

Laboratories following the practical guidelines described in this document should meet the requirements of ISO 17025. The guidelines are based on theoretical considerations as well as practical experience gained in the laboratory accreditation process. They are designed to ensure the correct identification of substances, to ensure that the processes undertaken will stand up to legal scrutiny and to provide safeguards to protect the rights of individuals. The aim of the guidelines is to improve the quality of laboratory services and to define common quality assurance criteria.

Attention is drawn to both technical requirements (including the importance of trained staff, appropriate accommodation and environmental conditions, method validation, access to required equipment and reference standards, quality control and the reporting of results) and management requirements (including document control, responsiveness to the needs of the client, preventive and corrective actions, the need for regular audits of compliance with the quality management system and continuous improvement).

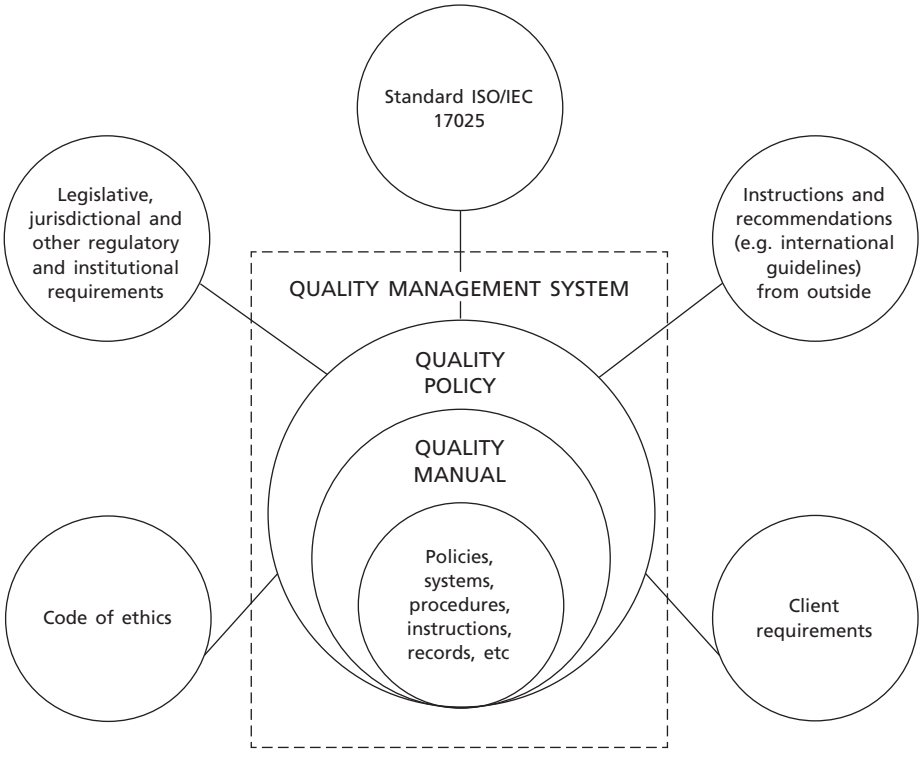
The guidelines consider all key stages of the drug testing process from collection of samples and analysis to the interpretation and reporting of results. Laboratories that carry out all stages of the process should ensure that the guidelines in this document are met in their entirety. In those instances where clients undertake one or more stages of the process within their own organizations, (for example, sample collection or interpretation/review), it is the duty of the laboratory to ensure that the client understands the full implications of this in the drug testing process.

3. Quality Management System

The laboratory must have a Quality Management System (QMS) which covers its activities, including drugs sampling, analysis and reporting, whether these are within the main laboratory facility itself, mobile/temporary facilities, or external locations such as a clandestine laboratory, the roadside or the locus of a large drug seizure. The QMS consists of documentation of the laboratory's policies, systems, procedures and instructions to the extent necessary to assure the quality of its results, to meet relevant jurisdictional, regulatory and safety requirements and to satisfy the needs of the clients.

The hierarchy of the QMS is presented in figure 1.

Figure 1. Hierarchy of the Quality Management System



3.1. Quality policy [11]

The laboratory should have a concise statement from top management declaring its commitment to achieve quality in all aspects of the work of the laboratory. It should also set forth any codes of practice or ethics that apply. This statement constitutes the quality policy of the laboratory. [4]

The whole personnel, from the highest placed director to the assisting staff, are responsible for adherence to this quality policy.

The policy statement should include at least the following points:

- The management's declaration of its commitment to quality and continuous improvement in the performance of the laboratory;
- A management statement that the quality of the work of the laboratory will be fit for purpose, in that it will withstand scientific and legal scrutiny as well as meeting the budgetary and timeliness requirements agreed with the client;
- A management statement that it is committed to providing the resources necessary to manage and operate the quality system;
- A declaration that all staff have a role in ensuring that the laboratory's work is carried out according to the requirements of ISO 17025 and other codes of practice applicable to the type of work, as well as relevant jurisdictional, regulatory and safety requirements as specified in the laboratory's QMS;

Personnel responsible for the QMS should have direct access to the highest level of management concerning laboratory policy.

3.2. Quality manual

The laboratory should have a manual describing the QMS. The quality manual should outline the organization and format of documents used in the QMS as well as the roles and responsibilities of the personnel responsible for management of the QMS and for management of the technical procedures. The quality manual should also document the administrative, organizational and scientific aspects of the work of the laboratory necessary for its proper management.

The documentation should be readily available in the laboratory and accessible to all relevant staff. It should be continuously reappraised and updated to ensure that changing circumstances are taken into account.

The use of documented procedures ensures that the work being performed is under control and achieves its intended purpose, that the requirements of international quality standards are fulfilled and that the results of analyses of seized materials or biological samples can be used with confidence in any subsequent legal proceedings.

4. Management requirements

4.1. Laboratory organization

The quality manual should define the following:

- The organization and management structure of the laboratory and its place in any larger organization, together with the relationships which exist between quality management, technical operations and support services. In addition, if the laboratory is part of a larger organization, the responsibilities of any person in that organization who is involved in, or can influence, the work of the laboratory should be defined;
- Who is legally responsible for the work of the laboratory in the event of legal action being taken (for example, by a client). Legal responsibility might lie with, for example, the director of an organization which incorporates the laboratory, the head of the laboratory or with individual scientists;
- The responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the results;
- Which personnel have managerial and technical authority for quality management, what their specific responsibilities are, nominated deputies and what resources are available to them to carry out their duties. These should include:
  - a quality manager who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the quality system is implemented and followed at all times, has direct access to the highest level of management at which decisions are made on laboratory policy or resources, maintains and updates the quality manual, monitors laboratory practices, ensures the validation of new technical procedures, selects, trains and evaluates internal auditors, recommends training to improve the quality of laboratory staff and proposes improvements in the quality system;
  - a technical manager or the personnel with responsibility for specified technical operations, the provision of the resources needed to ensure the required quality of these operations, the investigation and resolution of technical problems and the evaluation of instrument calibration and maintenance records.

- The arrangements in place for ensuring that the laboratory's management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work, and that they do not become involved in activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity. The reputation of a laboratory is easily lost but is difficult to regain;
- Safeguards for the protection of clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.
- Arrangements for supervision of staff carrying out laboratory work by personnel who themselves have demonstrated competence in the work undertaken.

4.2. Document control

A QMS can only operate effectively if the policies, systems, procedures and methods are documented and kept up to date. Document control is the mechanism by which the QMS documents are created, amended, reviewed, approved, distributed and archived to ensure that all staff use the latest authorized versions.

The quality manager should ensure that all aspects of the laboratory's work are documented in the QMS and that new documents are created by competent personnel and authorized by designated staff before being issued. The quality manager should also ensure that all documents are subject to periodical review and, where necessary, revised to take account of changing circumstances and incorporate best practice. Once approved, the quality manager should arrange for documents to be made available to all relevant staff in their workplace. When changes have been made to existing documents, the quality manager should make sure that the changes are highlighted in the latest versions.

All QMS documents should be uniquely identified and should bear the name/signature of the authorizing person. Each page of a document should be individually numbered as "page x of y pages" and should include the unique QMS document identifier, date of issue and version. This system for page identification minimizes the risk of undetected omission of current pages and undetected retention of obsolete pages.

If documents are held and distributed electronically, they should be read-only versions which may only be edited by authorized staff.

A master list bearing the date of issue and, where appropriate, a complete record of all versions, the dates on which they were made and the name of the authorizing person and distribution list should be maintained. This may be supplemented with a sheet attached to each document identifying the same details.

The laboratory may allow minor changes to printed documents, such as correction of typing errors, to be handwritten on the document in permanent ink, dated and authorized. However, a revised version should be issued as soon as practicable.

Invalid or obsolete documents should be promptly removed from all locations to prevent their accidental use. A copy of each obsolete document should be retained for either legal or knowledge preservation purposes and suitably marked (for example, "not valid").

4.3. Review of client requests

The laboratory should have procedures to ensure that the requirements of its clients are adequately defined, documented and understood and that it has the capability of meeting these requirements before agreeing (making a contract) to do the work. This is termed "contract review" in ISO 17025. The agreement may be written or oral, but if reached orally it should subsequently be documented. If the laboratory does not have the capability, it should attempt to reach agreement with the client on what work it could carry out or would subcontract before any work commences. Any revised agreement should then be documented.

The agreement should be kept under review by the client and the laboratory. If new requirements are requested by the client, or the laboratory is unable to meet the original agreement or the new requirements, this should be communicated between the parties, discussed and a revised agreement reached. Records should also be kept of all communications between the client and the laboratory related to the work being carried out. This will ensure the common understanding of requirements, responsibilities and work to be performed by the laboratory, its clients and all other parties involved.

4.4. Subcontracting of analytical work

If the laboratory uses another party (subcontractor) to undertake work on its behalf, it should have documented policies and processes to ensure that the other party is competent to do the work.

4.5. Purchasing services and supplies

The laboratory should have a policy and procedure(s) for the selection and purchase of services, reagents and laboratory consumable materials which might affect the

quality of its work, for the reception and storage of the reagents and consumables, and for ensuring that the services, reagents and consumables comply with the technical specifications described in the QMS before they are purchased and used.

The laboratory should maintain a record of the actions taken to check compliance and the results of those checks.

4.6. Service to client

The laboratory should ensure that it understands its clients' needs and that they are kept up to date on progress with their work. The laboratory should also request feedback from its clients on its performance. Both negative and positive feedback are important in improving the laboratory's services. Client confidentiality should be respected at all times.

4.7. Complaints

The laboratory should have a system for dealing effectively with client complaints. This should include a requirement to inform customers of any actions taken to resolve the issue and prevent any recurrence. Records should be maintained of all complaints and corrective actions and used as an opportunity to improve quality management in the laboratory. Failure to handle complaints from clients to their satisfaction can adversely affect the laboratory-client relationship.

4.8. Corrective and preventive actions

When the work carried out by the laboratory is inconsistent with its QMS (for example, the work deviates from an operating procedure, or the requirements of its clients), this is termed a "nonconformance" in ISO 17025. The laboratory should have systems in place (for example, for checking work within the laboratory, case file or QMS audit, staff/customer feedback) to recognize when a nonconformance has occurred and how it should be managed. This process should include investigating the cause of the nonconformance and evaluating its significance, informing the client when necessary and authorizing amendment to, release of or recall of the nonconforming work. Every effort should be made to detect nonconformities before the work is released to the client, as release of incorrect results can severely damage laboratory-client relationship and could lead to miscarriage of justice. If the nonconformance could recur without wider action being taken (for example, amending the QMS or staff re-training), then preventive actions should be authorized at an appropriate level to prevent any recurrence.

All nonconformances, corrective actions and preventive actions should be recorded. Corrective actions should be checked for their effectiveness by authorized staff to show that the work now conforms to the requirements of the QMS/client. Preventive actions should also be monitored to ensure that the nonconformances are not recurring (for example, through audit).

The recognition of nonconformances and the implementation of corrective and preventive actions are essential elements in continuously improving the effectiveness of the laboratory's performance.

4.9. Control of records/Chain of custody

Laboratories should have systems in place for the creation, identification, management, storage, movement/transmission, retrieval and disposal of all records, in both paper and electronic formats.

All laboratory paper records should be easily readable, uniquely identifiable (for example, with the date, author and page number) and made in a permanent medium such as ink. Pencil should not be used. No record should be deleted. Alterations and correction of mistakes which have been made by hand should not obscure the original record and should be signed/initialled and dated. The laboratory should also have measures in place to safeguard original electronic records (for example, by creating backups of computer files), to identify any alterations to them (for example, through the electronic audit trails some manufacturers provide in their software) and to ensure their integrity and confidentiality.

All records should be filed systematically to make retrieval easy. At the same time, they should be treated as confidential, the data protection and legislation requirements for the rights of an individual to privacy, etc., should be observed and access should be restricted to authorized personnel.

Records may be subdivided into quality and technical records.

Quality records include audit reports, proficiency tests, customer feedback, corrective and preventive actions, and management reviews. The records should be uniquely identifiable (for example, with the date, author, etc.) and held in a safe and secure location which is accessible to relevant staff. The laboratory should have a policy for how long these records should be kept, (for example, based on legal requirements). Records for disposal should be treated as confidential waste and incinerated or shredded.

Technical records include all materials relating to cases, including sample submission forms, chain of custody documents, case notes (including drawings and diagrams), photographs, records of telephone conversations, spectra, calibration and

other quality control data, instrumental operating parameters and print-outs, reports, statements, etc., instrument maintenance records, and staff training, competency and authorization records. They should be made at the time the work is done.

Each entry of every record should be traceable to the analyst/examiner and, where appropriate, to a uniquely identified case or exhibit. It should be clear from the case record who has performed all stages of the analysis/examination and when each stage of the analysis/examination was performed, (for example, the relevant dates). All records should contain sufficient information to allow an audit trail to be established showing who did what work and how and when it was done.

Critical findings (for example, odours and visual observations such as colour tests that cannot be independently confirmed from the record at a later time, calculations and data transfers which do not form part of a validated electronic process) should be checked, preferably by a second authorized person.

The laboratory should have documented procedures for the overall review of case records by authorized persons. The case record should include an indication that such checks and reviews have been carried out, when and by whom. This may be indicated in a number of ways (for example, by entries against each finding, entry on a summary of findings or a statement to this effect in the records). If the checker or case reviewer disagrees on any point in the initial record, the reason(s) for the disagreement and any action taken as a result should be recorded.

In general, the records required to support conclusions should be such that, in the absence of the analyst/examiner, another competent analyst/examiner could evaluate what had been performed, interpret the data [12] and, where appropriate, repeat the work. When a test result or observation is rejected, the reason(s) should be recorded. This information is necessary for another analyst to understand how the case was managed.

Technical records should be kept in a safe and secure place, to prevent damage, deterioration, unauthorized access or loss, for a period depending on the needs of the client and any relevant regulations in the laboratory's jurisdiction. The length of retention may also depend on the nature of the crime involved, such that records for serious offences, such as homicide and drug trafficking, are kept longer than those for minor offences, such as simple possession of a controlled drug. This could result in case records being retained indefinitely, being destroyed at the end of the legal process, or some intermediate arrangement. Records for disposal should be treated as confidential waste and incinerated or shredded.

4.10. Internal audit

The laboratory should have a schedule and procedure for periodic audit of all elements of its activities (for example, each test method) to verify that its operations

comply with the requirements of its QMS. The audits should be organized by the quality manager at least once per year and carried out and reported by trained, qualified personnel who are, whenever resources permit, independent of the activity to be audited. When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's work, the findings should be discussed by the auditor, the quality manager and relevant staff, and appropriate corrective actions agreed. The laboratory should promptly notify clients in writing if the audit shows that the laboratory results were incorrect.

The area of activity audited, the audit findings and corrective actions should be recorded. Future audits of the same activity should record how effective the corrective actions have been in order to identify lessons learned and consequently improve the laboratory's performance.

4.11. Management reviews

The quality manager should organize an annual review of the laboratory's QMS and its testing activities to ensure that they remain suitable and effective or to identify any changes and improvements required. The review should be carried out by high level management of the organization of which the laboratory is a part, the quality manager and other relevant staff. The review and any recommended actions should be recorded and the actions carried out within an appropriate timescale, agreed between the reviewers and the quality manager, taking into account availability of resources.

The management review should cover the following areas:

- Changes in the volume and type of work;
- Quality control activities, resources and staff training and other relevant factors;
- The suitability of policies and procedures;
- Reports from managers and supervisors;
- The outcome of recent internal audits;
- Assessments of external bodies;
- Client feedback;
- Complaints;
- The results of inter-laboratory comparisons or proficiency tests;
- Corrective and preventive actions;
- Recommendations for improvement.

5. Technical requirements

5.1. Introduction

Various factors, such as personnel, accommodation and environment, test methods, method validation, equipment, reference standards, sampling and the handling of test items, contribute towards the accuracy and reliability of results and also determine to a large extent the uncertainty of the measurement. These factors should all be taken into account when developing methods and procedures, in the training of personnel, and in the choice and use of equipment.

5.2. Personnel

Staff are the laboratory's most valuable asset. The laboratory should foster an atmosphere wherein employees are encouraged to improve their knowledge and skills, to grow as individuals and to fully develop their potential.

The laboratory should only use personnel with whom it has an employment contract, including temporary staff. The laboratory management should ensure that the staff have the appropriate education, training, experience, knowledge, skills and abilities (i.e. competence) to do the work assigned [13], are appropriately supervised and work in accordance with laboratory's QMS.

The laboratory should have policies and procedures for identifying training needs and providing training for staff to help them achieve and maintain competence (for example, through structured on-the-job training programmes, participation in scientific meetings, conferences and workshops, technical training courses, instrument operation and maintenance courses taught by vendors, in-house technical meetings, courses, seminars, and further education). While staff are being trained they should be more closely supervised and the effectiveness of their training should be monitored and evaluated. Where test- or technique-specific training is given, acceptance criteria should be assigned (for example, observation of the relevant tests or analyses by an experienced officer, or their satisfactory performance in the analysis of quality control/quality assurance samples and correlation of results with those obtained by other trained staff). Where necessary, training programmes should also include training in the presentation of evidence in court.

A record should be maintained for each member of staff of their education, qualifications and training, together with a list of tasks they are competent to perform and authorized to carry out (for example, to perform particular types of test, to issue test reports, to give opinions and interpretations, and to operate particular types of equipment). This information should be readily available to staff and should include the date on which competence and authorization are confirmed, so all staff have a clear understanding of the scope of their assigned tasks and their responsibilities.

Each member of staff should have a current job description which they have agreed with their designated line manager. This should include their responsibilities, duties and required competencies.

(ISO 17025 does not suggest person specifications (educational qualifications, knowledge, skills, competencies, etc.) required for particular jobs. However, recommendations for these can be found in other documents [4, 13]*.)*

5.3. Accommodation and environmental conditions

The types of sample analysed in the laboratory (seized materials or biological specimens, or both) and the number of staff and projected workload will affect the requirements for space, storage and security.

The laboratory premises and environmental conditions should permit the work to be carried out to the required quality standards. Particular care should be taken when work is carried out at external locations rather than in the main laboratory premises. Factors to be considered include space, security, health and safety of staff, temperature and humidity control, lighting, and air flow and ventilation, in addition to the provision of basic laboratory facilities (for example, electricity, gas, water, telephone and computer connections, laboratory benches, safety cabinets, refrigerators and freezers).

Laboratory facilities should enable correct performance of the work and where specific environmental conditions are critical they should be specified, documented and monitored (for example, storage temperatures of samples). Environmentally sensitive equipment should be in low-access areas and microbalances should be protected from vibration and chemical corrosion. Adequate and appropriate space should be allocated for each activity/function and employee. Special accommodation should be provided for the storage of bulk quantities of dangerous materials, such as compressed gases, solvents and hazardous chemicals, to ensure the health and safety of staff. In addition, suitable accommodation is required for the storage of evidential materials to prevent loss, deterioration or contamination and so maintain the integrity and identity of the evidence, both before and after it has been examined.

The laboratory areas should be sufficiently clean and tidy to minimize the risk of contamination and ensure that the quality of the work carried out is not compromised. There should thus be effective spatial separation of incompatible activities (for example, the examination of bulk seized materials and the trace analysis of drugs in biological specimens) which should not be carried out using the same facilities. Measures should also be taken to prevent cross-contamination (for example, between two different bulk seizures or between reference materials and case samples). These measures might include control of staff movement, flow of samples and sharing of equipment (for example, opened biologically hazardous specimens and dirty glassware should not be transported through unprotected areas and glassware for the analysis of seized materials (involving high concentrations of drugs should not be used for the trace analysis of biological specimens).

Drug testing laboratories and evidence storage areas should be kept secure at all times to prevent theft or interference and there should be limited, controlled access. There should be controls at both entry and exit points of buildings and between different secure areas (for example, by use of keys, or magnetic cards distributed to authorized personnel for specific purpose)s. In this way, no unauthorized personnel will be able to handle samples or gain access to restricted areas where drugs, specimens or records are stored.

The laboratory should hold on record a list of all staff who are authorized to enter the secure laboratory areas. This list should be reviewed and updated on a regular basis. Unauthorized persons needing to enter secure areas (for example, other laboratory personnel, clients, service engineers, cleaners, administrative personnel and visitors) should be escorted at all times by authorized personnel and a record of these entries should be maintained.

5.4. Health and safety

The laboratory should have a safety manual containing procedures that address issues affecting the health and safety of the staff and which are designed to safeguard employees from service-related injury and health problems. These should be based on risk assessments of all activities and documented safe systems of work (for example, the need to handle hazardous chemicals, such as those used to spray TLC plates, in exhaust hoods).

Details of the following should be contained in the safety manual:

- Designated staff with responsibility for aspects of safety (for example, safety officer, biological safety officer, fire safety officer, first aid staff). These responsibilities can be held by several people or by a single member of staff;

- Emergency procedures and contact information (for example, what to do in the event of fire, chemical spillages, personal injury);
- Staff training (for example, fire drills and first aid);
- Accommodation (for example, hand wash facilities, emergency showers, first aid cabinets, eye wash bottles, safety cabinets/exhaust hoods, autoclaves, fire extinguishers, solvent and chemical stores, disposal facilities for waste, chemicals, sharps and radioactive material, safety signs/hazard warnings, notices for fire exits and location of safety equipment, and emergency telephone numbers);
- Personal protective equipment (PPE) (for example, laboratory coats, disposable gloves, goggles/safety glasses, face protectors, ear protectors and radiation safety badges);
- General laboratory hygiene/safety (for example, cleaning and disinfection of surfaces, autoclaving of biologically contaminated equipment, the wearing of PPE, prohibition of eating, drinking and smoking in the laboratory, prohibition of laboratory clothing in designated clean areas and prohibition of lone working in laboratories);
- Specific biological hazards (for example, the use of microbiological safety cabinets, immunization of staff, safe disposal of clinical waste, sterilization of equipment and PPE);
- Radioactivity hazards (for example, reference to relevant regulations dealing with the use of radioactive materials).

5.5. Test methods, method validation [14] and procedures

The laboratory should use appropriate methods and procedures for all of its work: sampling, handling, transport and storage of evidence, use of equipment, testing, evaluation and interpretation of results, and reporting. The methods and procedures should be up to date, fully documented and readily available to relevant personnel. The documentation of methods should record:

- The name/reference number of the method;
- The scope of the method (for example, analytes, matrix, concentration range, known interferences);
- The theory and principle of the method;
- A summary of the validation parameters [14] and reference to the location/identity of the file containing the validation data;

- The chemicals, apparatus and equipment required, including technical specifications;
- The reference standards/materials required; the environmental conditions required (for example, room temperature) and any stabilization period needed (for example, equilibration periods for TLC);
- A step by step description of the procedure, including:
  - any special precautions which should be observed (for example, health and safety issues);
  - the requirements for sampling, labelling, packaging, transporting and storing of samples;
  - the preparation of samples, reference materials, controls and calibrators for analysis;
  - the requirements for equipment checks and calibration (for example, running a standard sample, tuning and calibration of a mass spectrometer);
  - the analysis process/test procedure and quality control (for example, use of blanks, controls and calibrators);
  - the recording and processing of results (for example, calculations, preparation of calibration curves and charts), including the criteria and/or requirements for acceptance/rejection (for example, if results are outside the calibration range or quality controls give unacceptable results);
  - the requirements for the reporting of results;
  - the requirements for reporting the uncertainty* of the method.

(Further information concerning uncertainty is given elsewhere [14, 15].)

If a procedure for the identification or quantification of a drug involves the use of more than one method, then the way in which they are linked should be explained (for example, with a flow chart or textual description), as should the combination, evaluation and reporting of results.

Any departure from these methods and procedures should only be allowed if they are justified, authorized, agreed with the client, where appropriate, and documented.

* The word "uncertainty" means "doubt", and so in the broadest sense "uncertainty of measurement" means doubt about the validity of the result of a measurement as well as doubt as to the exactness of the result. Uncertainty of measurement comprises, in general, many components. The laboratory should attempt to identify all the components of uncertainty and make a reasonable estimation and should ensure that the form of reporting of the result does not give a wrong impression of the uncertainty.

Method development and method validation

The methods and procedures used should preferably be based on work published in peer-reviewed scientific journals, (for example, *Forensic Science International, Journal of Analytical Toxicology, Journal of Chromatography* and the UNODC ST/NAR publications which are based on published work) and should take account of the needs of the client. If published methods are not available, in-house methods developed by the laboratory could be authorized, provided they are fit for purpose and meet the needs of the client. In these situations, a record should be kept of what was undertaken, in sufficient detail to make it possible for another suitably qualified individual to understand the method used and the results obtained.

All methods, including non standard/in-house methods, must be "validated" or "verified" to demonstrate that they are fit for purpose and will perform in the laboratory's operational environment. All validations and verifications must be carried out according to the laboratory's approved procedure and be fully documented.

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Validation should be as extensive as is necessary. Guidance on what is appropriate under different circumstances and for different methods can be found in many publications (for example, *UNODC Guidelines on Validation of Analytical Methodology and Calibration of Equipment used for Testing of Illicit Drugs in Seized Materials and Biological Specimens,* and the references therein). Verification is similar to validation but is used when a method has been validated elsewhere and shows that it performs to the required specification in the hands of the laboratory staff. It is discussed fully in the UNODC manual [14].

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory should ensure that computer software developed by the user is documented in sufficient detail and is suitably validated.

The laboratory should record the personnel involved in the validation work, dates, the results obtained, the procedure used, a statement as to whether the method is fit for its intended use and the authorization/approval signature.

When a laboratory introduces a method which has been validated elsewhere, it should first demonstrate the reliability of the procedure in-house against any performance characteristics of the procedure published in the literature. Records of this performance verification should be maintained for future reference.

If a procedure for the identification or quantification of a drug involves the use of more than one method, then each method should be validated/verified.

Composition of a sample run sequence/analytical batch

A run sequence or analytical batch is a group of samples analysed at the same time. It usually contains a mixture of test samples, controls and calibrators. The composition of an analytical batch depends on the methodology to be used and the purpose of the analysis. Three types of methodologies are considered: immunoassays (for biological specimens), qualitative analyses and quantitative analyses. As a general policy, a minimum of 10 per cent of all samples in a batch should correspond to calibrator and control samples. This applies to all types of analysis. [4]

Immunoassays

A batch of samples analysed by immunoassay should contain at least one negative control sample (for example, a drug-free urine sample), one or more calibrator samples—one of which should contain the analyte at the cut-off concentration, and at least one positive control sample. These are usually included in a commercial immunoassay kit.

Qualitative analyses

The qualitative identification of a drug or metabolite should be based on direct comparison of the analytical data for the submitted specimen with the corresponding data obtained for a reference standard analysed at the same time under the same conditions. For this reason, sample batches for qualitative analysis should include reference standards for each of the anticipated drug analytes.

Quantitative analyses

A sequence of samples for quantitative analysis should contain blank samples plus several calibration standards and controls. Six calibration standards are recommended, at concentrations inside the range used in the validation process described below [14]. If the analyte concentration in a sample is outside the range of the calibrators, the specimen should be diluted and re-analysed. As an alternative, additional calibrators can be analysed in order to cover the concentration of the analyte in the specimen, but this approach is less commonly used.

Acceptance of analytical results

Specific criteria for what constitutes a positive test should be established and clearly stated in the method procedure. These should also include requirements for acceptable results for quality control samples. Before a sample can be reported positive for one or more drugs, two separate portions of the sample must be analysed, each portion by at least two different validated test methods. The two methods should

be based on different scientific principles, preferably one of which should provide information on the chemical structure of the analyte (for example, IR, MS; or tandem methods such as GC-MS).

Also, before a sample can be reported positive, the test results should be checked by at least two authorized members of staff (usually the analyst plus one senior scientist) who are familiar with the analytical methods. The checks should include examination of the test results, quality control results, documentation relating to sample handling (for example, the chain of custody record and calculations), and any transcribed data (for example, data copied to a spreadsheet).

Use of control charts in quantitative analysis

An analytical method is in statistical control when results consistently fall within established control limits. Compliance with statistical control can be monitored graphically with control charts (for example, Shewhart and Cusum charts). These are useful for routine analytical methods subject to errors of bias or increased variability. On a control chart, test results for control samples are plotted against time. If the analytical method is in statistical control, all of the results will lie within predetermined control limits, which are also usually marked on the chart:

- The warning limit, which corresponds to ±2 standard deviations of the analytical method from the mean.
- The action limit, which corresponds to ±3 standard deviations of the analytical method from the mean.

A typical example would be a graph of the measured concentrations of control samples against date. In this case, all results should lie on or close to the true value and lie about this value in a normal distribution. However, even if the method is under statistical control, approximately five per cent of results may be expected to fall outside the warning limits. If an observed value falls outside the action limit, immediate measures must be taken to identify the cause and to take remedial action.

As well as highlighting individual results that may deviate from the true value, plots of this type readily show if the mean is different from the true value (bias) or if there is a regular trend causing the results to drift in a given direction.

Competence of the analyst

Laboratories should institute a procedure to identify infrequently performed tests or analyses. For these tests or analyses, there are two methods of demonstrating competence of the analyst, either of which would be equally valid. These are:

- Regular analysis of control samples and use of control charts during periods when casework samples are not being analysed;
- Reverification before the test or analysis in question is performed on a casework sample involving at least the use of an appropriate reference material, followed by replicate testing or analysis of the real sample.

5.6. Equipment

Laboratories should ensure the reliability and performance of the equipment used. Equipment and software required for the work carried out should be fit for its intended purpose and should preferably be available within the laboratory. If equipment outside the laboratory is used, it must comply with the QMS standards. An inventory of equipment should be maintained along with records of their location, date of purchase, service history and maintenance. Major items of equipment (for example, instruments such as spectrometers) should have their own logbook for recording this information kept nearby.

Staff should be trained to use the equipment and only authorized to use it when they have been found to be competent. Training and authorization should be documented in staff records.

When equipment is procured, the manufacturer's specifications should match or exceed the laboratory's requirements. It should be checked on installation to ensure that it meets the manufacturer's specifications (performance verification, usually carried out by the supplier's installation engineer, also known as the "before use check" or "equipment validation"). If an instrument is subsequently moved, the installation check should be repeated and its performance certified if necessary (for example, a balance will usually need to have its calibration checked if it is moved to a new location).

Equipment should also be checked regularly when it is in use, using documented procedures to show that the performance continues to be acceptable (for example, an instrument might be checked before each set of samples is analysed to ensure that it is working properly). This might include checking temperatures, gas pressures, tuning, calibration, etc., depending on the instrument involved. Test samples can also be analysed for checking purposes. Appropriate corrective action is taken when necessary. Up-to-date instructions on the use and maintenance of equipment (for example, abbreviated operating instruction sheets prepared in-house as well as instruction manuals supplied by the manufacturer) should be readily available, preferably adjacent to the instrument, for use by the appropriate laboratory personnel.

Equipment having a significant influence on the accuracy of test results should be calibrated according to a schedule, using documented procedures which are available to authorized users. Equipment should be labelled to indicate the status of calibration (for example, the date when last calibrated and the date or expiration criteria when recalibration is due) to ensure that it is not confused with uncalibrated equipment. Critical equipment (for example, balances, thermometers, pipettes) should be uniquely identified and calibration records, including certificates if available, should be kept.

Staff members responsible for equipment should ensure that regular documented check samples, calibrators and blanks are analysed and that the performance specifications are being maintained. Records should be kept of all calibration, maintenance and servicing, whether by in-house personnel or an outside agency. These should include:

- The unique identifier of the item of equipment and data system, if any;
- The manufacturer, model and serial number;
- The location, if appropriate;
- Performance checks;
- Operating instructions prepared in-house;
- The manual supplied by the manufacturer or reference to its location;
- Dates, results and copies of reports and certificates of all calibrations, acceptance criteria relating to performance, and the due date of the next calibration;
- The maintenance schedule, where appropriate, and maintenance carried out to date;
- Any damage, faults, modification or repair to the equipment.

Identified faults should be brought to the attention of the person responsible for the equipment and for taking corrective actions. If the fault is critical (for example, if the light source of a spectrometer is unstable or a vacuum pump is not holding a sufficient vacuum pressure), the equipment should be withdrawn from service until the problem has been rectified and the manner in which the problem is resolved, and the time and date should be recorded in the logbook for the equipment. Similarly, equipment that has been operated incorrectly, such that it no longer gives reliable results or has been found to be malfunctioning, should be taken out of service. It should be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to be working properly. Analytical results that were obtained during the period of equipment malfunction should be checked and the procedure for control of nonconformities should be initiated (see paragraph 4.8).

5.7. Reference standards, materials and reagents

Reference standards, materials and reagents should be adequate for the procedure used and they should comply with the quality specifications of the method. Lot/batch numbers of standards and critical reagents should be recorded and they should be tested for their reliability.

Standards and reagents should be labeled with:

- Name;
- Concentration, where appropriate;
- Preparation date and/or expiry date;
- Identity of preparer;
- Storage conditions, if relevant;
- Hazard warning, where necessary.

The laboratory should have a reagent solution preparation register that is kept in a suitable location. When a reagent solution is prepared, the person responsible for the preparation should record in that register the date, the ingredient weights and volumes actually used and his or her signature. This information is needed to trace possible sources of error in an analysis. Assigning each batch of reagent with a unique identifying number can be helpful in this respect.

Reference standards, working standards, in-house reference standards, reagents and other materials should be correctly stored to ensure their stability and integrity. An expiry date furnished by a vendor/manufacturer determines the useful lifetime of the standard/reagent/material unless it can be verified beyond that date. Where appropriate, “opened” and “use by” dates should also be recorded.

It is important to note that problems with standards and reagents can arise after they have been received in the laboratory. As soon as a container is opened there is a risk of it becoming contaminated or otherwise changing in composition. Bottles that are not tightly resealed expose their contents to air, with the possible loss or pick-up of moisture and absorption of carbon dioxide or other contaminating vapours. Also, material might be removed or introduced with a contaminated spatula or pipette, and the practices of inserting pipettes into the stock bottle of solvent or other reagent and pouring unused portions of solutions back into reagent bottles should be vigorously discouraged. Solvents used for rinsing equipment (for example, the microlitre syringes used in gas chromatography) should be changed frequently. All personnel involved in this work therefore require appropriate training and need to be fully informed of the quality requirements in order to understand the extreme care needed to preserve the integrity of these materials.

Reference standards should be traceable if possible, which means they can be directly related to national or international standards. Certified Reference Materials (CRMs) can be used if available [4]. A CRM is a reference standard, usually obtained commercially, for which the analyte concentration(s) has been certified by analysis, accompanied by, or traceable to, a certificate or other documentation that is issued by a Certifying Body. However, few CRMs containing controlled substances are available, one exception being alcohol standards.

In the absence of CRMs, commercial reference standards should be used. These commercial reference standards are supplied with a description of their chemical identity, purity and concentration (for example, a "specification and certificate of analysis"). However, it is recommended that the laboratory should independently verify their identity and purity (or concentration) before putting them to use (for example, by inter-laboratory comparisons or within the laboratory using a previously used reference standards).

The reference standards required for each procedure/method used by the laboratory should be documented and should be available in the laboratory. They should be appropriate for the test being performed (for example, the drug purity must be known accurately and for the analysis of drugs in biological specimens they should contain the drug at low concentrations). A record should be maintained describing their source, the date of acquisition and the quantity held in the laboratory, as this information may be required for national drug control authorities. When standards of controlled substances need to be imported or exported, import/export certificates should be obtained from the relevant national competent authority [16].

The procedure for preparing working standards from the original reference standards should be documented and the verification of the final product should be recorded and kept on file.

Reference standards prepared in-house (for example, from seized materials) should be verified as far as is technically and economically practicable by comparison with CRMs, commercially available standards or reference samples [17] supplied by UNODC.

The responsibility for acquiring and maintaining reference standards should be given to a designated person, who should keep a central register of these materials. The register should include all official reference substances and reference preparations and unofficial reference standards procured from various outside sources, as well as all secondary reference standards or working standards prepared at the laboratory.

Calibrators, either prepared from the reference standards or purchased, are used to calibrate the assay. Where possible, calibrators to be used in the analysis of biological specimens should be prepared in a matrix similar to that of the specimens. Initially, a sufficient number of calibrators should be run to determine the characteristics of the calibration curve: a blank and at least five calibration points

are recommended. The stability of the calibration curve should be tested under laboratory conditions by the addition of both positive and negative controls.

Controls are prepared from the reference standards and are used to determine the linearity and stability of a quantitative determination over time. They should be purchased or obtained from a pool of previously analysed samples and weighed or measured separately from the calibrators. Where possible, controls should be matrix-matched to specimens and calibrators.

5.8. Handling of test items

Sampling, labelling and packaging

The laboratory should have procedures for the taking of samples of seized materials and biological specimens, both at the scene and within the laboratory, and these procedures should be available at the locations where the sampling is undertaken. The sampling procedure should ensure that the portion taken for analysis is representative of the whole.

The sampling plan and/or sampling procedure, the identification of the person taking the sample and the environmental conditions, if relevant, should be recorded.

For sampling seized materials, the sampling plans and procedures published by internationally recognized organizations, such as UNODC [4], ENFSI [18] or SWGDRUG [5], are recommended. For sampling biological specimens, the sampling plans and procedures published by UNODC [4] or the European Guidelines for Workplace Drug Testing [8] are recommended.

The general principles are:

- For cases involving a small number of discrete items (typically 10 or less), all of the items should be sampled. If individual items are large they should be either homogenized before samples are taken or multiple samples from the whole item should be taken;
- For cases involving larger numbers of items, it is impractical to sample them all and a sampling strategy should be adopted that will ensure that what is taken is representative of the whole. If the items are not homogeneous, they must first be separated into homogeneous groups and an appropriate sampling plan then devised for each group.

The sampling plan may have a non-statistical basis (for example, a management or judicial directive) or statistical basis (for example, hypergeometric or Bayesian), but should be practical and easy to carry out by non-scientists, avoid unnecessary additional work for the laboratory, be easy to explain and be defensible in court.

The laboratory should provide guidelines to ensure that the materials to be tested are properly sampled, labelled, packaged, preserved and stored before submission to the laboratory. The labelling should be sufficient to allow unique identification of the samples and sub-samples and their relationship with their original source. It is important that the packaging will prevent unauthorized access to and loss or contamination of the samples during transit.

Laboratory receipt, handling and processing

The laboratory should have documented arrangements for the acceptance and return of seized materials and/or biological specimens. Specific requirements should be provided in relation to material or specimens or equipment (for example, needles) that might pose a threat to the health or safety of staff. The documentation accompanying the submitted material should refer to each individual item and provide sufficient information for the laboratory to identify what work is required. There must be an acceptable level of agreement between the details on the sample labels and those on the accompanying documentation or submission form.

Each case should be assigned a unique number and the relevant details entered into the laboratory case record system. Persons delivering material to the laboratory for examination should be given a signed and dated receipt referring to all the material submitted. Subsequent submissions related to the same case should be clearly identified as such using the same unique case number.

At the laboratory, an authorized person should receive and carefully check the samples and documents. One or more identified individuals should also be authorized to reject partially or wholly submissions that do not accord with the laboratory's acceptance policies. They should inform the laboratory manager of any such rejections. Any remedial action taken should always be documented.

When establishing an acceptance procedure, a number of defects such as those listed below should be considered as potential grounds for rejection if they cannot be resolved:

- Error or illegibility in name, identification number or any other information on the label attached to the sample;
- More than one label on the specimen;
- Missing sample or specimen label;
- Sample or specimen number repeated;
- Inconsistency between the samples received and the samples listed on accompanying documentation;

- Inadequate sealing that could prejudice the integrity of the sample or specimen;
- Evidence of tampering;
- No specimen in the specimen container or excessively leaking specimen.

The laboratory should have an effective documented system for the secure storage of samples, both before and after examination; correlating the samples to other information provided with them (for example, the request for analysis), identifying any sub-samples prepared from the samples, and showing the progress of analysis, date of issue of the report of analysis and the date and subsequent means of disposal of any remaining sample after analysis. The system should be designed and operated to ensure that samples cannot be confused physically or when referred to in records or other documents.

The laboratory should also have documented procedures and appropriate facilities to minimize deterioration and avoid loss or damage to the samples during storage, handling and analysis.

If duplicate biological specimens are submitted, one of the two should be used for analysis and the other stored, frozen, for further analysis if necessary.

Where items are retained by the laboratory after analysis, they should be stored for a time specified by the jurisdiction or client.

There should be documented procedures for the disposal of controlled substances and specimens which comply with the applicable laws and procedures of the jurisdiction. Records should be kept of each disposal.

If items are collected from the laboratory for delivery to a subsequent destination (for example, to a court for exhibiting), the details of when the items were handed over, and to whom, should be recorded in a logbook, which should be signed by the recipient.

Specimens such as blood and urine should be considered biologically hazardous and should be disposed of in accordance with any applicable laws and procedures.

5.9. Reporting the results

The results of analyses carried out by the laboratory should be reported accurately, clearly, unambiguously and objectively, and meet the requirements of the client. The report format should be designed to accommodate each type of analysis carried out and to minimize the possibility of misunderstanding or misuse.

If the results of the analysis are likely to be used in courts of law, the following should be considered the absolute minimum for inclusion in the report:

- The title of the report;
- The laboratory's unique identification numbers for the case and each sample or specimen;
- The name of the submitting agency or individual;
- The date the specimen was received by the laboratory
- The date the report was prepared;
- Identifiers for the individual pages of the report;
- A description and unambiguous identification of each item analysed;
- The results of analysis;
- The signature and title, or equivalent identification, printed name and employing laboratory of the person(s) accepting responsibility for the content of the report.

Where required and appropriate, an interpretation of the significance of the analysis results in the context of the case should also be provided.

Terminology

If a particular substance has been identified in accordance with the laboratory protocols it should be reported as "the sample/specimen was found to contain" or "the analysis was positive for" the presence of the specific substance. The terms "negative", "not detected" or "none detected" may be used to indicate the absence of an analyte or analytes. "None detected" is preferable as it indicates that particular substances were absent within the limitations of the test or tests performed, that is below the limit of detection (LOD).

If a substance is detected above the LOD of the assay but below the limit of quantification of the assay (generally considered to be the lowest point on the calibration curve) it may be mentioned in the report as a "trace amount".

If the results of screening/presumptive tests are reported, any result below the designated cut-off value should be reported as "not detected". Results above the cut-off should be confirmed as present using an appropriate technique and then reported as "positive".

All units of measurement used in the report should comply with the requirements of the client.

Opinions and interpretations

When opinions and interpretations are included, the laboratory should document the basis upon which the opinions and interpretations have been made. Opinions and interpretations should be clearly identified as such in the report.

Results obtained from subcontractors

When the report contains results of analysis performed by subcontractors, these results should be clearly identified.

Amendments to reports

Material amendments to a report after issue should be made only in the form of a further report which indicates that it is a supplementary report and quotes the original report reference. When it is necessary to issue a replacement report, this should be uniquely identified and should contain a reference to the original that it replaces.

5.10. Quality control, proficiency testing and inter-laboratory comparisons

There should be an appropriate level of quality control for each analysis. Quality control check samples should be analysed by the defined procedures, at the required frequency. Where control charts are used, a record should be kept of performance outside the acceptable criteria.

Results from the random re-analysis of samples should show an acceptable measure of agreement with the original analyses.

The laboratory should participate in proficiency testing and inter-laboratory comparisons, such as the International Collaborative Exercises (ICE) programme of UNODC which is described in a separate publication [10].

Where deficiencies or opportunities for improvement are identified there should be a process for taking appropriate action. Improvement and corrective actions should be recorded. There should also be an effective system for linking proficiency testing performance with day-to-day quality control.

References

1. United Nations Commission on Narcotic Drugs, Resolution 50/4, *Improving the quality and performance of drug testing laboratories,* 2007.
2. International Organization for Standardization/International Electrotechnical Commission, ISO/IEC 17025:2005 *General Requirements for Competence of Testing and Calibration Laboratories.*
3. International Laboratory Accreditation Cooperation, ILAC-G19:2002 *Guidelines for Forensic Science Laboratories.*
4. United Nations Office on Drugs and Crime, *Recommended Guidelines for Quality Assurance and Good Laboratory Practices,* STR/NAR/25, 1995.
5. Scientific Working Group for the Analysis of Seized Drugs, *Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG) Recommendations,* 2008.
6. American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), *Legacy Accreditation Manual,* 2008.
7. Society of Forensic Toxicologists/American Academy of Forensic Sciences (SOFT/AAS), *Forensic Toxicology Laboratory Guidelines,* 2006.
8. European Workplace Drug Testing Society (EWDTS), *European Laboratory Guidelines for Legally Defensible Workplace Drug Testing,* 2002.
9. London Toxicology Group Workplace Drug Testing Forum, *UK Laboratory Guidelines for Legally Defensible Workplace Drug Testing,* 2001.
10. United Nations Office on Drugs and Crime, Brochure on the *International Quality Assurance Programme* pamphlet, 1998, and *Protocol for the International Collaborative Exercises,* 1998.
11. International Organization for Standardization/International Electrotechnical Commission, ISO/IEC 17025:2005 *General Requirements for Competence of Testing and Calibration Laboratories,* paragraph 4.2.2.
12. International Laboratory Accreditation Cooperation, ILAC-G19:2002 *Guidelines for Forensic Science Laboratories,* paragraph 4.12.2.1.a.
13. United Nations Office on Drugs and Crime, *Staff Skill Requirements and Equipment Recommendations for Forensic Science Laboratories,* 2009.
14. United Nations Office on Drugs and Crime, *Validation of analytical methodology and calibration of equipment used for testing of illicit drugs in seized materials and biological specimen,* 2009.
15. Eurachem, *Quantifying Uncertainty in Analytical Measurement,* 2nd Edition, 2000.
16. The International Narcotics Control Board (INCB), *Guidelines for the import and export of drug and precursor reference standards,* 2007.
17. United Nations Office on Drugs and Crime, *Guidelines for the Request of Standards/Reference Samples of Drugs Under International Control.*

18 European Network of Forensic Science Institutes (ENFSI), *Guidelines on Representative Drug Sampling,* 2007.

Further information about reference documents can be obtained at (2 December 2008):

UNODC	www.unodc.org/
ISO	www.iso.org/iso/home.htm
ILAC	www.ilac.org/
SWGDRUG	www.swgdrug.org/
ASCLD/LAB	www.ascld-lab.org/
SOFT/AAS	www.soft-tox.org/
EWDTS	www.ewdts.org/
LTG	http://ltg.uk.net/
EURACHEM	www.eurachem.org/
ENFSI	www.enfsi.eu/
INCB	www.incb.org/incb/index.html

Annex. Model for a Quality Manual

Introduction

The Quality Manual is the highest level and most generic document stating the general quality policies, procedures and practices of the laboratory. It should outline the structure of the documentation used in the QMS. It should also include or make reference to the supporting procedures, including technical procedures. To a large extent, the contents of the Quality Manual are governed by the requirements of the quality standard to which the laboratory adheres, most commonly ISO/IEC 17025:2005, which is the basis of the ”Guidance for the Implementation of a Quality Management System in Drug Testing Laboratories”.

Purpose of the model

This model is intended to give a framework to be used when preparing a Quality Manual. Where possible, indications of the contents of the sections of the Quality Manual and some suggestions are provided. It is neither possible nor desirable to provide a complete manual since the very process of creating one within a laboratory is a training and educational exercise important to the staff of the laboratory involved. All laboratories vary in their needs and possibilities and these should be reflected in the details of their own, individualized, QMS and the Quality Manual which describes how it works.

How to use the model

Sections of the Model should be filled in using the advice given in this Guidance document. There is no single “correct” way of completing sections of the Quality Manual. The details provided in this document are sufficiently flexible to permit laboratories to impose their own character on the final document, as long as each of the requirements listed in ISO 17025 is addressed.

This model therefore shows the headings for the sections of the Quality Manual as an outline structure. Details of the QMS can be inserted into the relevant places. Some sections may not be relevant and can simply be noted as “not relevant”. Conversely, a laboratory may need to introduce additional sections which do not appear in the general outline provided.

Explanatory notes on information required to be included in the Quality Manual are indicated in italics in this Model.

QUALITY MANUAL FOR DRUG TESTING LABORATORIES

A model

Organization name: _____

Department/Section name, acronym: _____

Address: _____

_____

Version: _____
Number of current version

Valid since: _____
Date of issuance of this version

Replacing version: _____
Number of previous version

Copy: _____
Number of copies of current version

Distribution/Placement: _____
Hard copy/e.g. Laboratory

Electronic version: _____
Laboratory quality folder address

Approved by: _____ Signature: _____
Name, e.g. Laboratory director

Responsible person: _____ Signature: _____
Name, e.g. Laboratory director

Laboratory name:	Revision: Date:	Page: 3/9
Quality Manual		

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Record of updates to quality system

Commitment to the quality system

1. INTRODUCTION: PURPOSE OF THE QUALITY MANUAL
2. INFORMATION ABOUT THE ORGANIZATION
3. QUALITY MANAGEMENT SYSTEM
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   - 4.2. Document control
   - 4.3. Review of client requests
   - 4.4. Subcontracting of analytical work
   - 4.5. Purchasing services and supplies
   - 4.6. Service to client
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   - 4.8. Corrective and preventive actions
   - 4.9. Control of records/chain of custody
   - 4.10. Internal audit
   - 4.11. Management reviews
5. TECHNICAL REQUIREMENTS
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   - 5.2. Personnel
   - 5.3. Accommodation and environmental conditions
   - 5.4. Health and safety
   - 5.5. Test methods, method validation and procedures
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   - 5.10. Quality control, proficiency testing and inter-laboratory comparisons

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Record of updates to the quality management system

The Quality Manual should be formally reviewed at least once a year. Any change to the previous version should be highlighted in the new version.

Version	Date	Approved by	Signature
Insert number of latest version	*Insert date of signature of reviewer*	*Print name of reviewer, usually senior management*	*Insert signature of reviewer*

Continuation sheets are added as required

Laboratory name:	Revision: Date:	Page: 5/9
Quality Manual		

Commitment to the quality management system

I have read the Quality Manual and I am committed to follow the requirements of the Quality Management System.

Date	Name	Signature
Insert date of signature of staff member	*Print name of each staff member*	*Insert signature of each staff member*

Continuation sheets are added as required

Laboratory name:	Revision: Date:	Page: 6/9
Quality Manual		

1. INTRODUCTION: PURPOSE OF THE QUALITY MANUAL

This section should be a brief introduction (one or more paragraphs) to explain what the Quality Manual is and why it is needed.

2. INFORMATION ABOUT THE ORGANIZATION

Provide a description of the structure and purpose of the laboratory or department etc, indicating its organization and structure, legal position, tasks, values, vision, objectives, strategy, finance and budgeting, etc as relevant.

Also provide contact information:

Address:
Phone:
Fax:
Email:
Website:

3. QUALITY MANAGEMENT SYSTEM

3.1. Quality policy statement

Insert a concise statement (usually less than one page) by a top level manager, which should be signed and dated. See Guidance document paragraph 3.1.

3.2 Quality Manual

Insert a statement here about the Quality Manual if not already included at the beginning.

4. MANAGEMENT REQUIREMENTS

4.1. Laboratory organization

This section on organization and management should set down the background and remit of the organization. Diagrams are helpful for showing organizational aspects and the roles of the key staff, including the relationships between the quality manager and other members of the staff. It is recommended that the responsibilities above are shared by different staff members. However, depending on the resources some tasks can be delegated to the same person.

Insert an organization chart showing the management structure of the laboratory, such as:

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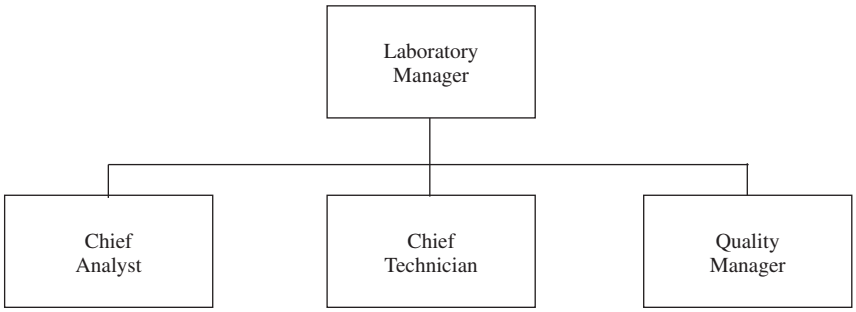

For the following sections, 4.2. to 4.11. outline the policies and practices used in your laboratory and provide reference to the relevant QMS documents.

4.2. Document control

Indicate how your document control is organized (e.g. master list/document register as attachment). See Guidance document paragraph 4.2.

4.3. Review of client requests

See Guidance document paragraph 4.3.

4.4. Subcontracting of analytical work

See Guidance document paragraph 4.4.

4.5. Purchasing services and supplies

See Guidance document paragraph 4.5.

4.6. Service to client

See Guidance document paragraph 4.6.

4.7. Complaints

Describe your procedures to handle queries, complaints and system failures as well as corrective and preventive actions and evaluation of effectiveness. See Guidance document paragraph 4.7.

4.8. Corrective and preventive actions

See Guidance document paragraph 4.8.

4.9. Control of records/Chain of custody

Describe how the control of records and chain of custody are performed in your laboratory. See Guidance document paragraph 4.9.

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4.10. Internal audit

Indicate your system of periodic checks (e.g. annual) or audits to demonstrate that all the technical and administrative processes in place to achieve quality are actually being implemented, followed and recorded. See Guidance document paragraph 4.10.

4.11. Management reviews

The content of the management review should be presented. See Guidance document paragraph 4.11.

5. TECHNICAL REQUIREMENTS

For sections 5.2. to 5.10. outline the policies and practices used in your laboratory and provide reference to the relevant QMS documents.

5.1. Introduction

See Guidance document paragraph 5.1.

5.2. Personnel

Indicate what personnel files are kept and how they are updated. Provide job titles (names of current position holders and responsibilities, qualifications etc., preferably in an annex); security clearance level; competence to approve documents; task authorizations; training records. Describe general requirements for staff training, personal training and development plans, scheduled meetings of staff to discuss the work of the laboratory and other mechanisms by which staff should communicate, etc. See Guidance document paragraph 5.2.

5.3. Accommodation and environmental conditions

Describe here e.g. security control, temperature and humidity control, etc. See Guidance document paragraph 5.3.

5.4. Health and safety

Describe the procedures for maintaining health and safety, the measures to provide a safe working environment for the employees, etc. See Guidance document paragraph 5.4.

5.5. Test methods, method validation and procedures

See Guidance document paragraph 5.5. See Manual of "Validation of Analytical Methodology and Calibration of Equipment used for Testing of Illicit Drugs in Seized Materials and Biological Specimens", 2009, UNODC.

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5.6. Equipment

Describe the practice in your laboratory regarding the identification and record keeping of equipment, etc. See Guidance document paragraph 5.6.

5.7. Reference standards, materials and reagents

Outline policy and practice concerning the preparation, labelling, storage and use of reference standards, working standards and reagents, etc. See Guidance document paragraph 5.7.

5.8. Handling of test items

Describe where information can be found related to procedures in place such as those used for receiving samples, identifying samples against requests for analysis, showing progress of analysis, storage of samples, report issue, disposal of samples, etc. See Guidance document paragraph 5.8.

5.9. Reporting the results

Describe the format and contents of the reports, the procedure for authorizing their release and transmission from the laboratory, etc. See Guidance document paragraph 5.9.

5.10. Quality control, proficiency testing and inter-laboratory comparisons

Describe how the quality of tests is monitored and assessed using reference materials, control charts, quality control check samples, proficiency testing, inter-laboratory comparisons, etc. See Guidance document paragraph 5.10.

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