UNITED NATIONS INTERNATIONAL DRUG CONTROL PROGRAMME
Vienna

RECOMMENDED GUIDELINES FOR QUALITY ASSURANCE AND GOOD LABORATORY PRACTICES

Manual for use by national laboratories

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NOTE

Symbols of United Nations documents are composed of capital letters combined with figures. Mention of such a symbol indicates reference to a United Nations document.

Figures in square brackets [ ] are keyed to the reference list.

ST/NAR/25

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Introduction

Background

Over the last decade there has been an enormous increase not only in the production and supply of illicit drugs, reflected by the huge and mounting quantities of drugs seized by national and international authorities, but also in the rate of drug abuse, i.e. the illicit demand for drugs. The drugs being seized include not only those already under national and international control but also unexpected new illicit drugs or combinations of drugs prepared by chemists working in clandestine laboratories. At the same time there are reports of the growing misuse or abuse of drugs used for medical purposes, such as barbiturates and benzodiazepines.

What was traditionally a problem of developed countries is no longer confined to those countries. Drug abuse is now a global problem affecting developed and developing countries alike: today, no nation is free from this threat.

The extent and diversity of abuse have placed increasing demands on nations to intensify their regulatory efforts; in some cases, they have introduced stringent legislation that may have serious consequences for an individual charged with a drug offence. Ultimately, the outcome of any ensuing legal proceedings would rest on the results of laboratory tests. This has placed greater pressure on national laboratories, which are now required not only to identify seized materials but also to detect drug abuse by analysing biological specimens. In addition, while in the past these laboratories were required to perform only qualitative analyses, they are now required to produce highly reliable quantitative results as well.

In the field of drug abuse, laboratories now have to be able to deal with more substances and to use methods of detection and analysis that are faster yet more accurate and specific. The analysis of biological specimens like urine and blood presents additional challenges because of the need to separate target substances from interferences in blood and urine, which are complex biological matrices.

The international nature of the drug abuse problem requires the speedy exchange of analytical data between laboratories and between law enforcement agencies and laboratories at the national and international levels. The development of internationally acceptable methods of detection and assay is expediting this exchange. The United Nations, through the United Nations International Drug Control Programme (UNDCP) and other bodies of the system, has been instrumental in achieving this aim. Two series of manuals, one dealing with methods for the analysis of seized materials and the other dealing with biological specimens, have been written for use by national laboratories.

Because analytical accuracy is so important, it is increasingly recommended that laboratories should implement effective quality assurance (QA) procedures, stimulate the use of good laboratory practices (GLP) and participate in proficiency testing programmes. These issues were addressed in three UNDCP meetings [1], [2], [3], the first of which made 14 recommendations. Two of the recommendations were that an international drug proficiency testing programme should be set up and that a glossary of quality assurance terms should be prepared.

Purpose of the Guidelines

These Guidelines are the product of the three above-mentioned meetings on quality assurance and good laboratory practices. They are intended to serve as an introduction to these topics and to provide practical guidance to national authorities and analysts in the rapid implementation of internal quality assurance programmes. They are also intended as an introduction to and reference document for the International Proficiency Testing (IPT) programme recommended by the Consultative Meeting at Glasgow [1].

The procedures described in the Guidelines are based on the experience of scientists from laboratories around the world. Many professional organizations have developed guidelines for quality assurance, which were reviewed for the purposes of writing the present Guidelines. While details of quality assurance programmes differ according to their context, a common principle underlies all programmes. In general, these Guidelines attempt to promote and harmonize national efforts by providing internationally acceptable standards. They are being provided to laboratories as an educational document within the training remit of UNDCP, as a means of encouraging them to collaborate and participate with the United Nations in quality assurance matters.

Use of the Guidelines

The components of the quality assurance programme suggested in these Guidelines were chosen on the basis of their proven usefulness. However, while the Guidelines can in part be used directly, it is recommended that the manager of each laboratory should write an in-house quality manual modelled on them, adapting them to the local situation and choosing what details to include.

Attention is drawn to the importance of adequately trained staff, whose cooperation will make a quality assurance programme much more effective.

An important adjunct to the development of an internal quality assurance programme is participation in an external proficiency testing programme. Accordingly, laboratories are encouraged to take part in the IPT programme being set up by UNDCP, which aims to improve the educational level of personnel involved in the analysis of drugs of abuse and to provide laboratories with means of checking their own performance by comparing it with that of other laboratories carrying out similar analyses.

Analysts are also expected to consult textbooks on drugs of abuse, analytical techniques and quality assurance, including reference books on statistical procedures used in quality assurance, and they should keep abreast of developments in the field by following current literature on the subject.

The Technical Services Branch of UNDCP would welcome observations on the contents and usefulness of these Guidelines. They may be addressed to:

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I. Quality assurance and good laboratory practices

A. General

The field of quality assurance is beset by an extensive and sometimes confusing terminology that has not been universally agreed on or accepted by laboratories or professional bodies. In recent years several organizations have begun to standardize the use of certain terms [4], [5]. For this reason, UNDCP has prepared a Glossary of some of the most common expressions (ST/NAR/26). Two expressions are of particular importance in establishing the framework for a quality assurance programme and are therefore discussed here: good laboratory practices and quality control.

Good laboratory practices (GLP) refer to the organizational process and conditions under which laboratory studies are planned, performed, monitored, recorded and reported. They involve a system of protocols that should be followed in order to avoid the production of unreliable or erroneous data. The concept of GLP was first introduced by the Food and Drug Administration of the United States of America within regulations concerned with the development of pharmaceutical drugs [6]. Similar regulations were subsequently prepared and adopted by other organizations around the world, including the Organisation for Economic Co-operation and Development (OECD) [7]. Documents have also been issued by the International Organization for Standardization (ISO), for example *ISO Guide 25: General Requirements for the Competence of Calibration and Testing Laboratories*, which in practice are guidelines without the force of legislation [8]. While these regulations are not directly applicable to laboratories involved in the analysis of controlled drugs, the principles contained in them may be adapted for such use.

An integral part of GLP is the care taken to control the quality of the work carried out in the laboratory. Quality control refers to the system of laboratory procedures and processes that control the quality of the laboratory's assay results, making it possible to decide whether the results are reliable enough to be released. Quality control measures are normally part of an overall quality assurance programme or system that inevitably involves personnel outside the laboratory to guarantee that the quality control measures are in fact being carried out. The performance (proficiency) of a laboratory may also be monitored using samples of known composition (usually) supplied for testing by an external organization. Many laboratories participate in a proficiency testing scheme for this purpose. The IPT programme operated by UNDCP is to be published shortly.

All quality systems must be described on paper. Two important parts of this documentation are the quality manual and the standard operating procedures (SOP) manual. The former is a wider-ranging document concerned with all aspects of quality, including the quality policy, the quality system and the quality practices of the laboratory. The SOP manual contains written procedures for certain laboratory

activities, in particular the drug analyses. It is considered in more detail in chapter VII.C. Inevitably, there will be duplication, because some material, for completeness, must be included in more than one context.

B. Quality manuals

All laboratories that analyse seized materials or biological samples should have documentation covering the administrative, organizational and scientific aspects of their work. This documentation, which is often referred to as a quality system or a manual, is widely considered necessary for the proper management of a laboratory's scientific work. To ensure that changing circumstances are taken into account and that the information is updated as needed, the documentation should be continuously reappraised.

The use of documented procedures ensures that the work being performed is under control and achieves its intended purpose, that the required standards are maintained and that the analyses of seized materials or biological samples can be used with confidence in any subsequent legal proceedings. Experience has shown that a quality manual needs to cover the whole range of laboratory activities. These Guidelines address the areas that need to be considered, reviewed and written down to support the objective of achieving quality [9].

1. Format

For ease of amendment, a loose-leaf binder format should be adopted. Copies of a quality manual should be readily available in the laboratory. Each copy should be individually numbered. Each page should be uniquely identified (for example, "page *x* of *y* pages") and should include the date of issue and issue number. The system for page identification should minimize the risk of undetected omission of current pages and undetected retention of obsolete pages.

As sections of the manual will be replaced from time to time, an amendment sheet bearing a complete record of all amendments should be inserted at the beginning. The amendment page should be updated and reissued with each set of revised or new pages.

2. Contents

A quality manual should set out laboratory policy, practice or procedures for the following areas and issues:

- Policy, organization and management
- Handling of specimens
- Reference standards
- Materials and reagents
- Equipment
- Laboratory accommodation and environment
- Methods and procedures
- Reporting
- Complaints and anomalies
- Audit

- Site security
- Proficiency testing and interlaboratory comparisons
- Accreditation and certification

The essential information that should be included under these headings is discussed in chapters II-IX.

C. Costs of quality assurance

Quality assurance in a laboratory is not obtained free of charge: practically all of the laboratory resources used in setting up and maintaining a quality system have inherent costs. Most organizations that have set up a system agree that the initial period involves the highest costs in terms of staff time but that later on, when personnel are used to incorporating quality assurance measures in their work and can see the benefits of them, the running costs are less. The cost of a quality assurance system is estimated to amount to 10-20 per cent of the laboratory's operational costs [10].

A cost-benefit analysis would be useful, and possibly essential, before initiating a quality system. The benefits, which are usually less tangible and more difficult to quantify than the costs, include the following:

- Compliance with existing or forthcoming regulations
- Preparation for accreditation
- Improved laboratory credibility and public image
- Improved staff morale
- Reduced incidence of sample re-analysis, data correction and unreliable data
- Improved service to clients and provision of procedures for complaints

The costs should be evaluated under the following headings:

Prevention costs, which are the costs of carrying out laboratory operations according to good laboratory practices and within proper quality assurance guidelines, so as to prevent unacceptable data from being generated in the first place;

Appraisal costs, which are the costs of monitoring the functioning of the laboratory and quality system. They include, for example, evaluation of the performance of analytical equipment and procedures, quality audits, proficiency testing programmes and quality assurance assessment;

Correction costs, which are the costs of taking remedial measures if the quality system discovers any deficits in the laboratory operations.

II. Policy, organization and management

A. Quality policy

The section of the manual that deals with quality policy should clearly and concisely state the intent of top management to achieve quality in all aspects of the work of the laboratory and should set forth any codes of practice or ethics that apply. The policy statement should include at least the following points:

- That all laboratory work should be carried out according to the requirements of GLP or other codes of practice applicable to the type of work;
- That the objectives are, for example, to upgrade the overall performance of the laboratory with respect to quality, to provide continuing assessment of the quality of analytical data, to identify good analytical methods, to record instrument performance as a basis for validating data and projecting future repair or replacement needs, to ensure chain-of-custody requirements and to highlight training needs;
- That management is committed to providing the resources necessary to operate the quality system;
- That it is the responsibility of staff to familiarize themselves with the quality manual and to comply with its requirements at all times;
- A general statement on how the quality system will be managed.

B. Quality system

The quality system section should set out the overall aims and form of the quality system, individual responsibilities and how the system is managed. It is important to describe any tiers of documentation, the records kept, the auditing and review procedures in place to assure quality is being achieved and maintained and the mechanism whereby documentation is controlled.

C. Organization and management

1. General

This section on organization and management should set down the background and remit of the organization and how it interacts with those who will be supplying it with materials to analyse. Diagrams would be particularly 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. There should be job descriptions and clearly defined roles and responsibilities for the various technical and administrative posts within the organization, together with detailed statements of the qualifications, training received (both prior to starting work and on the job)

and the experience needed by the holders of these posts. The laboratory should also have policies for the recruitment of new staff and the training and experience they need before they work on seized material or biological specimens. Staff should not undertake or be asked to undertake duties for which they are unqualified or for which they have not been trained.

2. *Laboratory manager*

The laboratory should have at least one individual qualified to assume professional, organizational, educational and administrative responsibility (the laboratory manager). The minimum qualification should be a university degree in one of the natural sciences, with appropriate experience in the scientific disciplines relevant to the operation of the laboratory. This experience should include a good background in forensic chemistry for a laboratory engaged in the analysis of seized materials. If the laboratory is also engaged in the analysis of drugs in body fluids, additional experience and training in analytical forensic toxicology is essential.

The laboratory manager should be engaged in and responsible for the day-to-day management of the drug testing laboratory, even in a multispeciality establishment where another individual has overall responsibility. The laboratory manager should be responsible for ensuring that there are enough adequately trained and experienced personnel to supervise and conduct the work of the laboratory. He or she should ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their performance and verifying their skills.

The laboratory manager should ensure that the laboratory has an SOP manual (see chapter VII) that is complete and up-to-date and that it is available to the personnel performing tests and used by them. The SOP manual should be reviewed, signed and dated by the laboratory manager whenever procedures are first placed into use or changed, or when a new individual assumes management responsibility. Copies of all procedures and the dates on which they come into effect should be maintained.

The laboratory manager should be responsible for maintaining a quality assurance programme to ensure the proper performance of all tests and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for ensuring and documenting the validity, reliability, accuracy, precision and performance characteristics of each test and test system. (A large, multispeciality organization that includes a drugs-testing laboratory normally appoints a quality manager, who is likely to be divorced from the day-to-day running of the laboratory and occupied solely with quality matters generally, ensuring that the drugs testing laboratory and other sections of the organization comply with the organization's quality policy.)

If the quality control system fails to meet performance specifications or if there are errors in reporting results or in the analysis of proficiency testing specimens, the laboratory manager should be responsible for taking the remedial actions necessary to restore satisfactory operation. He or she should ensure that test results are not reported until the corrective actions have been taken and that they are accurate and reliable.

3. *Supervisor for test validation and analytical work*

The laboratory should have at least one qualified individual who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports (see also chapters VII.E and VIII). This individual may be

any employee who is qualified to be responsible for day-to-day operation of the drug testing laboratory and should also be responsible for supervision of the analysts. He or she should have training and experience in four areas:

- The theory and practice of the procedures used in the laboratory, so as to have a thorough understanding of quality control practices and procedures;
- The review, interpretation and reporting of test results;
- Maintenance of the chain of custody;
- Proper remedial actions to be taken when test systems are out of control limits or when aberrant test or quality control results are detected.

4. Other personnel

Both technical and non-technical staff should have the training and skills needed for the tasks assigned, and the laboratory should offer continuing education for its personnel.

5. Personnel files

The personnel file of a staff member should include a resume of training and experience; a copy of the certification or licence, if any; references obtained on appointment to the position; a job description; records of performance, evaluation and advancement; incident reports; results of tests that establish employee competency for the position held, such as a test for colour blindness, if appropriate.

III. Handling of specimens

The quality manual should contain details of the arrangements for receiving, uniquely identifying, recording and handling materials on which staff will work, together with details of the arrangements for their eventual return or disposal when the work is completed. In some instances, laboratories involved in the analysis of biological specimens are also responsible for collecting the samples and transporting them to the laboratory, so these tasks must be included in the quality manual. Guidelines for sample collection and transportation to the laboratory are given in two UNDCP manuals [11], [12].

A. Seized materials

1. Acceptance

The quality manual should clearly state the arrangements for the acceptance of seized materials at the laboratory. One or more identified individuals should be authorized to reject partially or wholly cases that do not accord with the laboratory's acceptance policies and should inform the laboratory manager. Any remedial action taken should always be documented.

To be accepted by the laboratory, the submitted material should be correctly packaged and not subject to contamination during transit. Ideally, the submitting authorities should have access to standard packaging material to ensure high standards. They should take proper precautions with material 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. Each item should bear a label with adequate description and sufficient information to identify it uniquely. There must be an acceptable level of agreement between the details on the labels and those on the accompanying documentation or submission form.

On acceptance by the laboratory, each case should be assigned a unique number and the relevant details entered into the laboratory case record system to establish continuity. Material should be kept in a secure location until it is needed for examination by the scientist. Persons delivering material to the laboratory for examination should be given a signed and dated receipt referring to all the items submitted.

2. Description

The quality manual should specify the way in which seized materials are to be described in the laboratory record of the work. It is convenient to keep all the submission paperwork, messages, discussions, examination records and instrument printouts related to a specific case in a logically structured file that also includes a

comprehensive log of the movements and location of the submitted material. To this end, standard preprinted examination sheets or forms should be used. These have space for the scientist to describe the appearance, weight and other characteristics of the material, to record the packaging and details on the labels, to sign his or her initials or name and to write the date the examination took place. Second opinions, when sought, should also be recorded on these sheets.

3. Sampling

The sampling procedures used by the laboratory should be described in the quality manual and in the individual analytical protocols. Those published by UNDCP are recommended.

The principal reason for a sampling procedure is to produce a correct and meaningful chemical analysis. Because most qualitative and quantitative methods used in forensic science laboratories to examine drugs require very small amounts of material, it is vital that these small amounts should be entirely representative of the bulk from which they have been drawn. Sampling should be undertaken so as to conform to the principles of analytical chemistry as laid down, for example, in national pharmacopoeias or in publications such as that of the Association of Official Analytical Chemists (AOAC) [13].

There may be situations where, for legal reasons, the normal rules of sampling and homogenization cannot be followed. Sometimes, for example, the analyst may wish to preserve some part of an exhibit as visual evidence. At other times, it may be necessary to perform separate assays on two powder items rather than combining the powders and performing a single assay on the mixture. This may happen because each has been separately exhibited by the seizing officer and the legal system within which the analyst works requires an individual result for every exhibit that is to be taken before the court.

To preserve valuable resources and time and reduce the number of quantitative determinations needed, a forensic analyst should, where possible, use an approved sampling system. He or she may need to discuss individual situations with both seizing officers and legal colleagues.

The simplest situation is where the submitted item consists of a single package of material. The material should be removed from its container or wrappings, placed in a clean, clear plastic bag and the net weight recorded. If appropriate, the material should be thoroughly homogenized before the chemical tests are run, although presumptive testing may be applied at this stage if it is thought that the sampling or homogenization process will be lengthy or if there is still some doubt as to the identity of the material. The simplest way of homogenizing a powder is to shake it thoroughly within the clear plastic bag to which it has been transferred. If the powder contains aggregates, they may be broken down by passing them through successively finer sieves, by pounding them with a mortar and pestle or by using a specially adapted commercial food mixer or food processor. Alternatively the technique of coning and quartering can be applied [14].

If the submitted material consists of more than one package, the analyst should examine the contents of all the packages by eye and possibly by some simple colour test or thin-layer chromatography. This is done to determine if all the packages contain the same material or if one or more contain material different from that in the majority of packages. If one or more packages obviously differ in content, they should be segregated and subjected to separate analysis. Material that comes in more than one package may be sampled as follows:

- If there are fewer than 10 packages, sample all of them;

- If there are 10-100 packages, randomly select 10 packages;
- If there are more than 100 packages, randomly select a number of packages equal to the square root of the total number of packages rounded to the next higher integer.

If the powders are found to be the same, the contents of a number of packages may be combined; the combined bulk may then be homogenized in, for example, an adapted food processor. Alternatively, the bulk may be subjected to coning and quartering.

When different types of material have been identified in the various packages, each subgroup should be composited as described above.

4. Disposal

The arrangements for the disposal of seized controlled substances at the conclusion of any court proceedings, if that responsibility rests with the laboratory, should be described in the quality manual and should comply with any applicable laws and procedures of the jurisdiction. Seized drugs may not be used for medicinal purposes without breaching the terms of the 1961 Single Convention.

B. Biological specimens

1. General

The purpose of these Guidelines is to describe procedures that will guarantee optimum validity of results. Urine is the sample of choice for the detection of drug abuse. Apart from being readily accessible by non-invasive procedures, practically all drug metabolites are excreted in urine and the metabolites can be detected for a longer period than in blood. The use of blood and other biological materials like hair and saliva for establishing the illicit consumption of drugs has not yet been generally accepted.

To maintain the validity of analytical results in the forensic context, particular care should be given to the supervision of sample collection, transportation and storage [11]. This supervision must be carried out by trained personnel who have a clear understanding of the legal implications of the procedure and should be done by direct visual observation. Proper surveillance must be maintained at all times, but every effort must be made to maintain the privacy and dignity of the individual. The supervisor should also ensure that no attempt is made to add contaminating or reactive substances to the urine.

When it is necessary to transport samples to an analytical laboratory, security and a clearly established chain of custody must be maintained.

These Guidelines are applicable to situations where urine samples are collected away from the analytical laboratories. They should be adapted or modified to suit the local situation. For example, if samples are stored and no freezer facilities are available, the analyst should incorporate stability checks into the quality control programme.

2. At the collection site

The following tasks should be undertaken at the collection site:

- Personnel at the collection site are responsible for the collection, labelling, packaging and transportation of samples, ensuring that the collection and storage procedures have the proper documentation and necessary security methods;
- All staff must be given enough training to understand the collection process and the significance of the laboratory results;
- The collection of specimens must be supervised and witnessed by trained and authorized personnel;
- Suitable toilet facilities must be available before the collection of urine is considered;
- The collection room must be surveyed for any substance which could be used to invalidate the sample and should be set up without soap dispensers or cleaning agents;
- The urine samples should be collected in duplicate in two 50-millilitre bottles. Each bottle should be filled at least two-thirds full. Plastic containers and rubber stoppers should be avoided whenever possible as non-polar drugs and their metabolites such as the cannabinoids are very prone to adsorb on some plastic and most rubber surfaces. If, for practical reasons, disposable plastic containers are used, individual laboratories should conduct tests to ensure that they do not alter the composition or concentration of the drug(s) or metabolite(s) in the urine;
- Immediately after collection, the temperature and the pH of the fresh sample should be measured and recorded. If adulteration is suspected, the laboratory should be notified;
- The bottles should be securely stoppered, sealed and labelled. Steps should be taken to ensure that the integrity of the sample is maintained, by use, for example, of a security seal consisting of sealing wax imprinted with a departmental seal or some other measure that will show if the sample has been tampered with. It is important that the donor should witness the sealing of the bottles and sign or initial the seal or label;

Ways in which samples can be invalidated

Various chemical substances can be introduced into the sample. Table salt, detergents or some common household items such as hypochlorite (bleach) can destroy the drugs or affect the assay to generate false negative results.

Illicit substances can be added to the urine to produce positive results.

A pinhole can be made in the bottom of the container, causing it to leak.

By squeezing a fluid-filled bulb placed under the arm, with a tube leading to the genital area, the subject can release water or other substances that dilute or contaminate the urine.

Urine from friends not using drugs can be substituted.

Water can be scooped from the lavatory into the collection container to dilute the urine.

- Specimen labels should be affixed to the urine containers and not to the lids. This will prevent accidental or intentional switching of specimens and/or identifying labels. A label should contain at least the information shown in the model label below;
- Personal information on the specimen donor is to be supplied on a drug analysis request form. This form accompanies the specimen to the laboratory;
- The specimen donor should not be involved in the post-collection handling of the sample (labelling, packing or transportation to the laboratory);
- Strict security should also be observed in the storage and dispensing of empty cups, request forms, labels and packing materials.

Model label

Name of donor _____

ID number _____

Date and time of collection _____

Place of collection _____

Name of person supervising the collection _____

Drug(s) to be tested for _____

Sample number _____

3. Transport and storage

After the request form has been completed, it is given together with the sample to the dispatch person for transmission to the laboratory. Samples should be protected from direct light and heat during transportation and storage, preferably in an insulated box containing ice or some other cooled packing.

It is important that samples are kept cool and in the dark for the entire period between collection and analysis.

The designated dispatch person is responsible for transporting the samples to the laboratory and for maintaining appropriate chain-of-custody records to ensure that the samples are not tampered with during transit.

4. At the laboratory

To maintain a chain of custody that will be legally supportable in court proceedings, it is important to have procedures for acceptance or rejection of specimens arriving at the analytical laboratory. Such procedures assess the adequacy of the chain-of-custody documentation accompanying the specimens, the clarity of the labelling on the specimens and possible tampering with the samples prior to their receipt in the laboratory.

At the laboratory an authorized person should receive and carefully check the samples and documents. When establishing a sample acceptance procedure, a number of defects should be considered as grounds for specimen rejection:

- Error in name, identification number or any other information on the label attached to the sample
- Missing sample in a batch submitted
- Missing or torn specimen container seal
- Missing summary sheet for submitted batch
- Missing specimen label
- Specimen not listed in batch summary sheet
- Insufficient urine in container
- Smudged or torn label
- Excessively leaking bottle
- Evidence of label tampering
- Specimen number repeated
- Duplicate sample in the same security box
- Samples brought in unlocked security box
- Illegible writing on the label
- No urine in the specimen container
- More than one label on the specimen
- Information on the label not written in indelible ink

One of the two duplicate urine samples should be used for analysis and the other stored, frozen, for further analysis if necessary. After ensuring that the samples and request forms are in order, a written acknowledgement of receipt should be made, signed and given to the dispatch person. The laboratory should maintain good records and strict security to ensure the integrity of the samples and confidentiality of the results. If the analysis is delayed beyond one or two days, urine specimens should be stored (frozen, if possible) in a locked refrigerator. When frozen, specimens will generally be stable for several months.

5. Specimen retention and disposal

Specimens should be stored until no longer needed. Factors influencing the retention period include the following:

- The possibility that a second analysis or defence analysis may be needed;
- The possibility that the list of analytes may later be extended to include additional substances;
- The time required for the medico-legal process, if any, to be completed: in some jurisdictions, the specimen must be produced in court and may only be disposed of when permission is given by the appropriate authority.

Specimens such as urine should be considered biologically hazardous and should be disposed of in accordance with locally prescribed laws and procedures for the disposal of clinical waste material. The procedures to be used must be specified in detail. They might include the following:

- Disposal of liquid specimens via a suitable sluice after sterilization with bleach or another agent;

- Recycling of glassware after sterilization and washing. Plastic ware is preferably incinerated;
- Removal of solid tissue specimens from glass containers, bagging (preferably in heat-sealed bags) and incineration; samples in plastic containers may be incinerated directly.

Just as it is essential to record the delivery of specimens on reception, it is necessary to log their disposal. If specimens are collected from the laboratory for delivery to a subsequent destination (for example, to a court for exhibit), the details of when the specimen was handed over, and to whom, should be recorded in a logbook, which should be signed by the recipient.

IV. Reference standards, materials and reagents

A. General

The laboratory should document the standards, controls and calibration steps that are necessary in the various analytical procedures and methods it uses to ensure that the results are reliable (see also chapter IX.B, on external supplies). The traceability of reference standards, by which standards in the laboratory can be directly related to national or international standards, is highly desirable and in some situations, necessary. A certified reference material is a reference standard (normally) obtained commercially: one or more of its property values have been certified by a technical procedure, and it is accompanied by, or traceable to, a certificate or other documentation that is issued by a certifying body.

Laboratories that have no independent access to reference standards for drug substances may obtain small quantities of them from UNDCP.

B. Reference standards

Standards should be appropriate for the test being performed, and documentation should be maintained describing their source and the date of acquisition. Reference standards should be stored under conditions that ensure stability and integrity. If a reference standard is prepared in the laboratory, the sources of the chemical reagents, the method of preparation and the verification of the final product should be recorded and kept on file.

Purchased reference standards are generally accompanied by an authentication of their chemical identity, quality and concentration. However, it is recommended that the laboratory should independently verify their identity and purity (or concentration) before putting them to use. This is often done by a quantitative comparison with a previously used reference standard.

Labelling should be uniform for all standards. The date of acquisition or preparation and the initials of the individual responsible for their preparation should appear on the label, as should the expiration date. An expiration date furnished by a vendor/manufacturer determines the useful lifetime of the standard/control unless it can be verified beyond that date.

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

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

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 non-official reference standards procured from various outside sources, as well as all secondary reference standards prepared at the laboratory (working standards).

C. Materials and reagents

Reagents should be of analytical grade unless otherwise specified. Reagents and materials should be matched against the specifications of quality required by the method, by regulation or by good laboratory practices. Upon receipt, all reagents should be properly labelled with the following information: date received, expiration date (if applicable) and date opened. The initials of the analyst should also be added. A reagent solution prepared in the laboratory should be labelled with the date of preparation, the concentration of active ingredients, an expiration date and the initials of the person who prepared it.

It is important to note that problems with reagents can arise after they have been received in the laboratory. As soon as a container is opened, contamination becomes a possibility. 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 with a contaminated spatula or pipette, especially by untrained technicians, who often do not understand the extreme care needed to prevent contamination. All personnel involved in this work require adequate training and need to be fully informed of quality requirements (chapter II.C.4).

The practice of pouring unused portions of solutions back into reagent bottles should be vigorously discouraged. Similarly, the practice of inserting pipettes into the stock bottle of solvent or other reagent could lead to contamination. It is recommended that solvents should be decanted into 500-millilitre or, at most, 1-litre bottles for use in the laboratory. Solvents used for rinsing (for example of the microlitre syringes used in gas chromatography) should be changed frequently.

Every laboratory should have a reagent solution preparation notebook that is kept in a suitable location. When a reagent solution is prepared, the person responsible for the preparation should record in that notebook 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.

V. Equipment

A. *General*

A key factor for laboratories undertaking the analysis of seized or biological materials is the reliability and performance of the equipment that is used. To control this it is essential that there is an inventory of the equipment and that records are kept concerning location, date of purchase, servicing history and maintenance.

Staff should be trained to use the equipment and only then authorized to use it. Current philosophy in this area, incorporated into quality standards in some jurisdictions, is that personnel should only be asked to undertake tasks for which they have been trained and in which they have proved to be competent. Each staff member should have such training documented in the personnel records (chapter II.C.5).

Operational manuals should be readily available and adjacent to the equipment. Staff members should be made responsible for the various pieces of equipment, and regular, documented checks, calibrations and blanks should be run to ensure that specifications are being met. It is important that records are kept of all calibrations. These individuals should also be responsible for ensuring that the equipment is adequately maintained and that servicing is carried out according to a predetermined schedule, by either in-house personnel or an outside agency. Performance of the maintenance must also be documented.

If a fault is identified it must immediately be brought to the attention of the person responsible for the equipment and for taking corrective actions. The equipment should be withdrawn from service until the problem has been rectified. The manner in which the problem is resolved and the time and date should be documented in the logbook for the equipment.

B. *Specific requirements of some types of equipment*

Some of the commonly used pieces of equipment and their specific requirements with respect to good laboratory practices and quality control are described in the following paragraphs. For equipment not covered here, reference should be made to the operating manuals.

1. Balances

The need for balances to be calibrated regularly is one of the most easily understood examples of the requirements of good laboratory practice and quality control. Errors in weighing affect all standards and reagents and the trueness of the analytical data obtained using them.

The current requirement for accreditation purposes in some jurisdictions is that balances should be calibrated annually by a certifying body with a traceable primary standard, i.e. using certified reference weights traceable to an international standard.

Routine calibration on a day-to-day basis may be carried out within the laboratory using a set of reference weights that in turn must have a calibration certificate. Such reference weights (for example, those for a microbalance used to weigh drug standards) are very easily damaged by careless handling or even by using the wrong type of forceps (for example, forceps with serrated points), so all personnel should be trained in using them.

The use of balances that provide a printout of the weighings is recommended in general and indeed is necessary in some circumstances, for example, if laboratories have to meet accreditation requirements. At the very least, all weighings should be recorded in a hard-backed, bound laboratory notebook and not on pieces of paper.

2. *Glassware*

The glassware used in an analytical laboratory is an integral part of the analytical method. Three important considerations need to be taken into account in the quality manual and laboratory policy:

- The grade of glassware used, i.e. the properties of the glass (soda glass, borosilicate glass);
- The specification of the volumetric glassware (Class A or B). Class A is more accurate than Class B but also much more expensive;
- The cleaning and handling procedures. Using hot water to wash volumetric glassware causes an irreversible loss of accuracy.

3. *Automatic pipettes*

Like balances, pipettes must be calibrated regularly, either in-house or by an external agency and their calibration recorded in a logbook.

4. *Chromatographs*

The operating parameters of these instruments (temperatures, pressures, flow rates, etc.) need to be calibrated, particularly if a laboratory must conform to specified protocols. For example, a reference analytical method using gas chromatography may specify injector and column oven temperatures: the analyst must verify that the temperatures obtained are in fact what is set on the oven controllers. In some circumstances it may be necessary to calibrate instrumental parameters independently. However, most chromatographers rely on the regular use of a test mixture to verify the correct operation of the instrument.

5. *Integrators and microprocessor-based data systems*

It is important to check that the measurement of peak areas or heights and any subsequent data manipulation (calibration curves, calculation of concentrations etc.) are carried out accurately. While electronic devices are available to generate test chromatograms for this purpose, most chromatographers rely on the regular use of a test mixture to verify the correct operation of the instrument.

The use of computers for data acquisition and processing gives rise to the possibility of tampering with the data and the subsequent analytical results. The current trend in this area is to incorporate security measures into the software that

record any access or changes to data files (an "audit trail"). When data files must legitimately be changed because of transcription errors etc., these must be authorized by the laboratory manager or analytical supervisor (see chapter II.C), who should note any changes in the printouts or other documentation associated with the sample.

6. *Spectrometers*

Ultraviolet/visible spectrometers

Wavelength calibration is normally carried out by recording the spectra of standards. Some spectrometers incorporate an internal calibration procedure using a reference filter.

Mass spectrometers

Correct operation of mass spectrometers and gas chromatography-mass spectrometer combinations requires routine tuning to maintain sensitivity and optimize operating parameters. Most bench-top quadrupole instruments perform this function automatically on request by the user. The minimum frequency is once per day, but this may be modified according to experience with the instrument. The critical factor is that modifications to standard operating practice must be authorized by the laboratory manager, documented and validated using empirical data to support the changes.

The normal approach to verifying the performance of a mass spectrometer is to check on mass assignments for fragment ions in the mass spectrum of a calibration substance, for example perfluorokerosene or heptafluorotributylamine, i.e. mass calibration, and to measure ion abundances and ion ratios in the mass spectrum, to verify that the ionization and fragmentation reactions are proceeding normally.

7. *Biological safety cabinets*

The correct operation of biological safety cabinets ensures the safety of laboratory personnel working with biologically hazardous materials. Normally located within a part of the laboratory designated for the handling of biological materials, the filters and air flows must be regularly checked as part of the normal maintenance schedule.

VI. Laboratory accommodation, environment and safety

A. General

This section of the quality manual should set out the laboratory policy for providing safe and healthy offices, laboratories and other amenities. Laboratories must comply with the applicable provisions of national requirements.

There should be reference to any special requirements for specific tests and to the records needed to demonstrate that these requirements, as well as general good-housekeeping requirements, are being satisfied. Laboratories must have the facility and capability of performing tests for each drug or metabolite for which a service is offered, including appropriate security systems and areas as well as laboratory safety facilities.

B. Design of the laboratory

The quality of work produced by a laboratory is affected by the details of the laboratory accommodation and organization [10]. Some of the following factors should be considered within the quality system specification:

Purpose. The types of sample analysed in the laboratory—seized materials or biological specimens, or both—will affect the requirements for space, storage and security. Also affected will be the number of staff and the associated requirements for work space, changing rooms, offices etc. The projected workload of the laboratory should be related to the facilities and staffing available: overloading with work and understaffing adversely affect quality or else result in long turn-around times for the samples;

Movement of samples through the laboratory. Some consideration should be given to the flow of samples through the laboratory when the accommodation is designed. The sequence of sample reception, storage, pretreatment, analysis, disposal and reporting should, if possible, be reflected in the physical layout of the facilities. It is also important to segregate different types of activity to minimize the possibilities of contamination, for example, glassware for the analysis of seized materials involving high concentrations of drugs should not be mixed with glassware used for trace analysis in biological specimens. Opened biologically hazardous specimens and dirty glassware should not be transported through unprotected areas. Environmentally sensitive equipment should be in low-access areas; for example, microbalances should be protected from vibration and chemical corrosion;

Provision of laboratory services. Laboratories need adequate supplies of electricity and water, telephone lines and special equipment and supplies such as gases (especially for gas chromatography), fume hoods, safety cupboards, refrigerators and freezers.

C. *Safety*

Safety policy should be defined in the quality manual. Details of the following need to be contained in the manual or in other laboratory documentation:

Normal laboratory hygiene requirements. Typical of these are prohibiting the consumption of food and drink in the laboratory and requiring the wearing of gloves, laboratory coats and protective eye-wear;

Fire hazard. Due regard must be given to local regulations on fire safety, including the storage of flammable solvents and reactive chemicals, the provision of suitable fire-fighting equipment (together with its routine inspection and the training of staff in its use), the designation of laboratory fire safety officers and the scheduling of fire safety drills;

Biological hazard. The potential hazard of biological specimens was mentioned above and in chapter III. As the risk of infection for specimens of blood and autopsy tissue is higher than that for urine specimens, the use of biological safety cabinets is recommended for their processing;

Radioactivity hazard. Hazards may arise from the practice of radioimmunoassay (iodine isotope ^{127}I or tritium) or from electron capture detectors in gas chromatography (commonly ^{63}Ni). Local regulations for the use of radioactive material and the disposal of radioactive waste should be observed. Personnel exposed to radiation should wear radiological exposure monitoring badges.

D. *Site security*

This section of the manual should describe the person responsible for site security and the procedures that have been adopted to maintain that security and the integrity of the exhibits, documents and other records and to provide a secure working environment for the employees.

VII. Methods and procedures

A. General

The laboratory should define the methods or procedures that will be used for the analysis of seized and biological material. The details need not be included in the quality manual but there should be a reference to where the working documents may be found, and these should be readily available to those undertaking the analyses. Usually the laboratory compiles these documents into an SOP manual.

The working methods may be local methods or internationally approved or documented ones such as those issued by UNDCP or those appearing in the scientific literature. If local methods are used, the quality manual should specify the way in which they should be written with regard to content, format, standards to be run, special requirements for handling reagents etc. and the validation and authorization procedures necessary before they are adopted and used. There will be situations for which no documented technical procedures exist or those that do exist are not exactly appropriate. In those situations it will be necessary to record what was undertaken in sufficient detail to make it possible for another suitably qualified individual to understand the method used and the results obtained. The authorization necessary to carry out non-standard methods needs to be defined in the quality manual.

B. Selection and validation of methods

Generally applicable criteria for methodology used for the analysis of biological specimens have been reviewed in previous United Nations publications [11], [12].

Before an analytical procedure can be used to analyse submitted specimens, it must be fully validated in terms of sensitivity (limit of detection), specificity (freedom from interferences) and repeatability (ability to provide consistent results). If the procedure is used for quantitative determinations, the precision, accuracy and dynamic range of the assay should be demonstrated and documented. When two methods are to be compared (for example, if the analyst wishes to compare a new method with an old one), a suitable statistical procedure should be used to test if there is a significant difference between the two methods. Such significance tests can determine if the new method is better than the old one ("one-tailed test of significance") or if it is either better or worse ("two-tailed test of significance"). Reference should be made to standard texts on statistics for analytical chemistry [10], [14]-[20].

It should not be assumed that the analytical capabilities reported by the laboratory that developed an assay are easily achieved in a different laboratory.

C. Standard operating procedures manual

Each analytical method must be fully described in the SOP manual, which should be readily available to all personnel who are performing the analyses and

which is subject to the same sort of constraints with respect to format, individual numbering, amendments, etc. as the quality manual (see chapter I.B). When significant changes are made to the SOP manual by personnel authorized to do so (and who are defined as such in the quality manual), a new manual, individually numbered and labelled with the edition number and date of issue, should be distributed to each member of the analytical staff. Earlier editions should be retained for reference purposes in the event that analytical results are subsequently reviewed for scientific or legal purposes. It is essential that every analytical report can be related to the precise methods used to obtain the data on which it is based, and the best way to achieve this is to reference the SOP manual, including its edition number, in the documentation associated with each specimen.

As the SOP manual should include detailed descriptions of procedures for sample reception, accessioning, chain of custody, choice of reagents, analysis, quality assurance and quality control, review of data and criteria for acceptance, and reporting, it may duplicate some of the contents of the wider-ranging quality manual. It is essential that the SOP manual should be kept up to date with respect to improvements in methods, new equipment, new literature references and interpretative guidelines based on current scientific knowledge or legal practice in the region in which the laboratory operates.

For each analytical method the SOP manual should include the following:

- The theory and principle of the method
- Instructions for the preparation of the specimen
- Instructions for the preparation of calibrators and controls
- Details of the analytical procedure and its validation
- Information about any special requirements for handling reagents and ensuring safety
- References to the relevant literature

D. Sample batch composition

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, 10 per cent of all samples in a batch should correspond to calibrator and control samples. This applies to all types of analysis.

1. Immunoassays (for biological specimens)

Each immunoassay batch must contain at least one negative control sample (such as a drug-free urine sample), a calibrator sample containing the analyte at the cut-off concentration (if a cut-off has been adopted, see chapter VIII) and at least one positive control sample.

2. 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 under the same conditions. For this reason, sample batches for qualitative analysis should include reference standards for each of the anticipated drug analytes.

3. *Quantitative analyses*

Each sample batch should contain a calibrator plus two controls, or at least two additional calibrators. If a single calibrator is used, its concentration should be generally near the mid-point of the expected range of drug concentrations, or at the cut-off if this concentration has been established. For accurate quantitation, the concentrations of calibrators and/or control samples must encompass the measured concentration range of the analyte in the submitted specimens. If the concentration of a specimen falls outside the concentration range encompassed by the calibrators and controls, the specimen may be appropriately diluted and reanalysed, or additional calibrators and/or controls may be run in order to encompass the concentration of the analyte in the specimen.

E. Acceptance of analytical results

Before a specimen can be reported positive for one or more drugs of abuse, it should be subjected to two independent tests using separate aliquots of the specimen. If feasible, the two tests should involve different analytical techniques. Specific criteria for what constitutes a positive test should be established and clearly stated in the SOP manual. The criteria should include requirements for acceptable results for quality control samples.

Also, before a specimen can be reported positive, the test results should be thoroughly reviewed by at least two individuals who are familiar with the analytical methods. The reviews should include examination of the test results, acceptability of all quality control results, proper and complete documentation of specimen handling (chain of custody), correct calculation of quantitative measurements and absence of clerical errors.

F. Statistical control of analytical methods

An analytical method is in statistical control when results consistently fall within established control limits, that is, when there is constant mean and variance. Compliance with statistical control should be monitored graphically with control charts such as the 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 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:

Warning limit. Corresponds to ±2 standard deviations of the analytical method from the mean. Even if the method is under statistical control, approximately 5 per cent of results may be expected to fall outside the warning limits;

Action limit. Corresponds to ±3 standard deviations of the analytical method from the mean. If an observed value falls outside the action limit, immediate measures must be taken to identify the cause and to take remedial action.

A typical example would be a graph of the measured concentrations of control standards 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. 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.

VIII. Reporting

This section of the manual should define the format and content of the reports and the procedure for authorizing their release and transmission from the laboratory.

A. Contents of the analytical report

In the forensic context, the results of the analysis of seized and biological material are likely to be used in courts of law. The following items should be considered the absolute minimum for inclusion in a report of analysis:

- The name and unique identification number of the report, as well as identifiers for the individual pages of the report
- The laboratory's unique identification number for the specimen
- The name of the submitting agency or individual
- The unique identification number assigned by the submitting agency or individual to the specimen
- The date the specimen was received by the laboratory
- The date the report was prepared
- Description and unambiguous identification of the item tested
- The test results
- The signature and title, or equivalent identification, of the person(s) accepting responsibility for the content of the report

B. Terminology

"Positive" indicates that a particular substance has been identified in accordance with the laboratory protocols. "Negative", "not detected" or "none detected" are all generally used to indicate the absence of an analyte or analytes. "None detected" is preferable: it indicates that particular substances were absent within the limitations of the test or tests performed.

Results should be indicated by naming the testing method followed by the terms "positive" or "none detected". For screening (presumptive tests), any result below the designated cut-off should be reported as "not detected" and those above this cut-off reported as positive.

For other types of forensic sample, trace amounts may be mentioned if the substance is detected above the limit of detection of the assay but below the limit of quantitation of the assay (generally considered to be the lowest point on the calibration curve) or the designated cut-off.

All units used in the report should comply with national or international recommendations.

C. *Reporting procedure*

Generally a single written report on an assay or batch of assays is the appropriate form of reporting. In exceptional circumstances, it may be appropriate for an authorized individual in the laboratory to provide an oral report on a specimen. In such cases, it is important to follow the oral report with a written and signed report as soon as possible.

In other, special circumstances where supplemental assays are performed on the sample or corrections must be made to the report, these should be specifically noted and so labelled and placed in the original case report file for the sample. Similarly, if it becomes necessary to refer the sample to another laboratory for analysis, this information should also be noted on the original sample along with the date and place of referral. The results of the analysis carried out at the referral laboratory will be on a record maintained at that laboratory (see also chapter IX).

D. *Retention of records*

This section of the manual should define the extent of any documentation and length of time it is kept to allow the work to be reviewed later on, sources of error to be identified, etc.

It is desirable to retain copies of the report, request and custody forms, worksheets, laboratory data, quality control and proficiency testing records. Retention requirements need to comply with national legislation, and the records should be retained as locally prescribed.

E. *Confidentiality of records*

This section should also document the arrangements made to ensure that individual records are maintained with the highest regard for individual privacy and confidentiality. Any information relating to the donor of the specimen and the results of the assay on a specimen should be kept in a high security area to which only authorized individuals have access.

F. *Retrieval of records*

A system should be established and described in the SOP manual that allows rapid and complete retrieval of the following:

- All data and documentation associated with a specific sample, including personnel files on all individuals authorized to have access to specimens
- Chain-of-custody documents
- Quality assurance/quality control records
- Procedure manuals
- All test data, including calibration curves and any calculations used in determining test results
- Reports
- Performance records on proficiency testing
- Performance on certification inspections
- Hard copies of computer-generated data

IX. The laboratory and external organizations

A. Subcontracting of analytical work

If it uses other parties to undertake analytical work on its behalf, a laboratory will need to formulate and document policies to satisfy itself that the quality of the subcontracted work meets the required standard (see also chapter VIII.C).

B. Outside support services and supplies

The quality of outside support services and supplies such as reagents can have a marked effect on the quality of the work carried out by laboratories that analyse seized and biological materials, and it will be necessary to formulate and document policies to ensure that the standards of these outside support services and supplies are adequate for the purposes for which they will be used (see also chapter IV). The practice adopted will include recording dates of receipt and the necessary checks or calibrations to demonstrate that they meet the specifications.

C. Complaints and anomalies

When a complaint is made or an anomaly pointed out, this should be taken as an opportunity to improve the quality system in a laboratory. The manual should therefore describe how these complaints or comments are to be recorded and handled. It should be the responsibility of the quality manager and system review process to audit the complaints and anomalies periodically and ensure that the lessons learned from them have been incorporated into revisions of the existing quality procedures.

D. Quality audit and quality system review

The quality policy and procedures of the laboratory are drawn up to assure management and staff, as well as clients and authorities, that the results obtained are fit for their intended purpose and that the required standards are being maintained. It is necessary to have a system of periodic checks or audits to demonstrate that all the technical and administrative processes in place to achieve quality are actually being implemented and followed. It should be the responsibility of one trained and qualified member of the laboratory staff, in the laboratory, often designated as the quality manager, to carry out this task. Such audits should be carried out, whenever possible, independent of the activity to be audited. All activities should be reviewed at least annually, and the quality manager should have direct access to the head of the laboratory to report his/her findings.

Audits, customer complaints, issues identified by staff, etc. may indicate problems or opportunities for improving practices or procedures. There must be a system review process involving senior management so that the problems can be considered, corrective actions approved, and the quality manual and quality system amended and updated. Valuable information on the reliability of the work of the laboratory is provided by internal quality control systems, participation in proficiency testing schemes (see below), repeat analyses of samples, collaborative exercises, etc., so the laboratory should have an agreed policy and documented programme for these.

E. Proficiency testing and interlaboratory comparisons

One good way for a forensic science laboratory to monitor its performance and for it to be externally assessed, both against its own requirements and those of peer laboratories, is for it to take part in proficiency testing schemes and interlaboratory comparisons. Forensic science may involve the destructive testing of small samples and usually involves the interpretation of results. It also often relies heavily on the initial recovery stages of examination. For these reasons, undeclared or "blind" proficiency testing (where samples are submitted to a laboratory without being identified as proficiency testing samples) is particularly valuable.

The International Proficiency Testing (IPT) programme of UNDCP is to be published shortly.

F. Accreditation and certification

Accreditation is the procedure by which an accreditation body, such as a national or international organization or professional body, formally recognizes that a laboratory or person is competent to carry out specific tasks. Certification is the procedure by which a certifying body formally recognizes that a person or product complies with given specifications. Several countries have established accreditation procedures for at least some aspects of controlled substance analysis, and the current trend is for such procedures to be established where possible. External accreditation and certification are appropriate goals in the development of a quality assurance programme. While they may require a significant investment of resources, they will provide the highest level of confidence in the work of the laboratory.

As the IPT programme of UNDCP develops, it may become possible to accredit participating laboratories.

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