PART II QUALITY ASSURANCE

SECTION 1: INTRODUCTION

Recommendations in PART II involving the analysis of seized drugs are limited to qualitative analysis only. Issues involving quantitative analysis will be taken up in a later version.

It is the goal of a laboratory's drug analysis program to provide the customers of the laboratory's services access to quality drug analysis. It is the goal of these guidelines PART II to provide a quality framework for management the processing of drug casework, including handling of evidentiary material, management practices, analysis and reporting. These are minimum recommendations for practice.

The term “evidence” has many meanings throughout the international community. In this document it is used to describe drug exhibits which enter a laboratory system.

1.1 QUALITY MANAGEMENT SYSTEM

A documented quality management system must be established and maintained. Personnel responsible for this must be clearly designated and shall have direct access to the highest level of management concerning laboratory policy.

1.1.1 The quality management system must cover all procedures and reports associated with drug analysis.

SECTION 2: PERSONNEL

2.1 JOB DESCRIPTION

The Job descriptions for all personnel should include responsibilities, duties and required skills.

2.2 DESIGNATED PERSONNEL AND RESPONSIBILITIES

An individual (however titled) may be responsible for one or more of the following duties:

2.2.1 Quality Assurance Manager: A designated person who is responsible for maintaining the quality management system (including an annual review of the program) and who monitors compliance with the program.

2.2.2 Health & Safety Manager: A designated person who is responsible for maintaining the Laboratory Health and Safety

program (including an annual review of the program) and who monitors compliance with the program.

2.2.3 Technical Support Personnel: Individuals who perform basic laboratory duties, but do not analyze evidence.

2.2.4 Technician/Assistant Analyst: A person who analyzes evidence, but does not issue reports for court purposes.

2.2.5 Analyst: A designated person who

2.2.5.1 Examines and analyzes seized drugs or related materials, or directs such examinations to be done

2.2.5.2 Independently has access to unsealed evidence in order to remove samples from the evidentiary material for examination AND

2.2.5.3 As a consequence of such examinations, signs reports for court or other purposes.

2.2.6 Supervisor: A designated person who has the overall responsibility and authority for the technical operations of the drug analysis section. Technical operations include, but are not limited to protocols, analytical methodology, and technical review of reports.

2.3 QUALIFICATIONS/EDUCATION

2.3.1 Technical Support Personnel will

2.3.1.1 Have education, skills and abilities commensurate with their responsibilities AND

2.3.1.2 Have on-the-job training specific to their position.

2.3.2 Technicians/Assistant Analysts will

2.3.2.1 Have education, skills and abilities commensurate with their responsibilities AND

2.3.2.2 Have on-the-job training specific to their position.

2.3.3 Analysts will have

2.3.3.1 a bachelor's degree (or equivalent, generally a three to four year post-secondary or tertiary degree) in a natural science or in other sciences relevant to the analysis of seized drugs. The degree program shall include lecture and associated laboratory classes in general, organic and analytical chemistry

or

2.3.3.2 by January 1, 2005, a minimum of five (5) years practical experience in the area of seized drug analysis, and have demonstrated competency following the completion of a formal, documented training program and post training competency assessment.

2.3.4 Supervisors will

2.3.4.1 Meet all the requirements of an analyst (2.3.3),

2.3.4.2 Have a minimum of two (2) years of experience as an analyst in the forensic analysis of drugs and

2.3.4.3 Demonstrate knowledge necessary to evaluate analytical results and conclusions.

2.4 SECTION 2: INITIAL TRAINING REQUIREMENTS

2.4.1 These minimum requirements allow individual laboratories to structure their training program to meet their needs as it relates to type of casework encountered, analytical techniques, available instrumentation and level of preparedness of trainees.

2.4.2 There must be a documented training program, approved by laboratory management, which focuses on the development of theoretical and practical knowledge, skills and abilities necessary to examine seized drug samples and related materials. The training program must include the following:

2.4.2.1 documented standards of performance and a plan for assessing theoretical and practical competency against these standards (e.g. written and oral examinations, critical reviews,

analysis of unknown samples and mock casework per topic area)

2.4.2.2 a training syllabus providing descriptions of the required knowledge and skills in specific topic areas in which the analyst is to be trained, milestones of achievement, and methods of testing or evaluating competency

2.4.2.3 a period of supervised casework representative of the type the analyst will be required to perform

2.4.2.4 a verification document demonstrating that the analyst has achieved the required competence.

2.5 MAINTAINING COMPETENCE

2.5.1 Minimum annual training required for continuing professional development of analysts is twenty (20) contact hours.

2.5.1.1 Training must be relevant to the laboratory's mission.

2.5.1.2 Training completed must be documented.

SECTION 3: PHYSICAL PLANT

3.1 PHYSICAL PLANT REQUIREMENTS

3.1.1 Laboratories shall provide a healthy, safe and secure environment for its personnel and operations.

3.1.2 Laboratories must contain adequate space to perform required analytical functions and prevent contamination.

3.1.3 Chemical fume hoods must be provided. They must be properly maintained and monitored according to an established schedule.

3.1.4 A laboratory cleaning schedule must be established and implemented.

3.1.5 Adequate facilities must be provided to ensure the proper safekeeping of evidence, standards and records.

3.1.6 Appropriately secured storage must be provided to prevent contamination of chemicals and reagents.

SECTION 4: EVIDENCE CONTROL

Laboratories shall have and follow a documented evidence control system to ensure the integrity of physical evidence.

4.1 RECEIVING AND IDENTIFYING EVIDENCE

Laboratories must maintain records of requests for analysis and of the respective items of evidence. A unique identifier must be assigned to each case file or record. For chain-of-custody purposes, the evidence shall be compared to the submission documentation, any significant observations of irregularity should be documented in the case file or record, and the submitter informed promptly. This file or record must include, at least, the following:

4.1.1 submission documents or copies

4.1.2 identity of party requesting analysis and the date of request

4.1.3 description of items of evidence submitted for analysis

4.1.4 identity of the person who delivers the evidence, along with date of submission

4.1.4.1 For evidence not delivered in person, descriptive information regarding mode of delivery and tracking information

4.1.5 chain of custody record

4.1.6 unique case identifier

4.2 INTEGRITY OF EVIDENCE

Evidence must be properly secured (e.g., sealed). Appropriate storage conditions shall ensure that, insofar as possible, the composition of the seized material is not altered. All items must be safeguarded against loss or contamination. Any alteration of the evidence (e.g. repackaging) must be documented. Procedures

should be implemented to assure that samples are and remain properly labeled throughout the analytical process.

4.3 STORAGE OF EVIDENCE

Access to the evidence storage area must be granted only to persons with authorization and access shall be controlled. A system shall be established to document a chain of custody for evidence in the laboratory.

4.4 DISPOSITION OF EVIDENCE

Records must be kept regarding the disposition (e.g., return, destruction, conversion to another use) of all items of evidence.

4.5 DOCUMENTATION RETENTION PROCEDURES

All laboratory records such as analytical results, measurements, notes, calibrations, chromatograms, spectra and reports shall be retained in a secure fashion in accordance with jurisdictional requirements.

SECTION 5: ANALYTICAL PROCEDURES

5.1 ANALYTICAL PROCEDURES FOR DRUG ANALYSIS

5.1.1 Laboratories shall have and follow DOCUMENTED analytical procedures.

5.1.2 Laboratories shall have in place protocols for the sampling of evidence.

5.1.3 Work practices shall be established to prevent contamination of evidence during analysis.

5.1.4 Laboratories shall monitor the analytical processes using appropriate controls and traceable standards.

5.1.5 Laboratories shall have and follow documented guidelines for the acceptance and interpretation of data.

5.1.6 Analytical procedures must be validated in compliance with Section 10.

5.1.7 The analyst shall determine the identity of a drug in a sample, and ensure that the result relates to the right submission. This is best established by the use of at least two appropriate techniques based on different principles and two independent samplings.

5.2 VERIFICATION OF DRUG REFERENCE MATERIALS

5.2.1 The identity of certified reference materials must be verified prior to their first use.

5.2.2 The identity of uncertified reference materials must be authenticated prior to use by methods such as mixed melting point determination, Mass Spectrometry, Infrared Spectroscopy, or Nuclear Magnetic Resonance Spectroscopy.

5.2.3 Verification must be performed on each new lot of drug reference material.

5.2.4 All verification testing must be documented. The documentation must include the name of the individual who performed the verification, date of verification, verification test data and reference used in verification.

SECTION 6: INSTRUMENT/EQUIPMENT PERFORMANCE

6.1 INSTRUMENT PERFORMANCE

Instruments must be routinely monitored to ensure that proper performance is maintained.

6.1.1 Monitoring should include the use of reference standards, test mixtures, calibration standards, blanks, etc.

6.1.2 Instrument performance monitoring must be documented.

6.1.3 The manufacturer's operation manual and other relevant documentation for instrumentation should be readily available.

6.2 EQUIPMENT

Only suitable and properly operating equipment shall be employed. Equipment performance parameters should be routinely monitored and documented.

6.2.1 The manufacturer's operation manual and other relevant documentation for each piece of equipment should be readily available.

SECTION 7: CHEMICALS AND REAGENTS

7.1 CHEMICALS AND REAGENTS

7.1.1 Chemicals and reagents used in drug testing must be of appropriate grade for the tests performed.

7.1.2 There must be documented formulations for all chemical reagents produced within the laboratory.

7.1.3 Documentation for reagents prepared within the laboratory must include identity, concentration (when appropriate), date of preparation, identity of the individual preparing the reagents and the expiration date (if appropriate).

7.1.4 The efficacy of all test reagents must be checked prior to their use in casework. Results of these tests should be documented.

7.1.5 Chemical and reagent containers should be dated and initialed when received and also when first opened.

7.1.6 Containers of chemicals or reagents should be labeled as to their contents.

SECTION 8: CASEWORK DOCUMENTATION, REPORT WRITING AND REVIEW

8.1 CASEWORK DOCUMENTATION

8.1.1 Documentation must contain sufficient information to allow a peer to evaluate case notes and interpret the data.

8.1.2 Evidence handling documentation should include chain of custody, the initial weight/count of evidence to be examined (upon receipt by the analyst), information regarding packaging of the evidence upon receipt, a description of the evidence and communications regarding the case.

8.1.3 Analytical documentation should include procedures, standards, blanks, observations, test results and supporting documentation including charts, graphs and spectra generated during an analysis.

8.1.4 Casework documentation must be preserved according to documented laboratory policy.

8.2 REPORT WRITING

8.2.1 Reports issued by laboratories must meet the requirements of the jurisdictions served. These may include:

8.2.1.1 Identity of the testing laboratory

8.2.1.2 Case identifier

8.2.1.3 Submitting agency

8.2.1.4 Date of receipt

8.2.1.5 Date of report

8.2.1.6 Descriptive list of submitted evidence

8.2.1.7 Identity of analyst

8.2.1.8 Analytical techniques employed

8.2.1.9 Results

8.2.1.10 Conclusions

8.3 CASE REVIEW

8.3.1 Laboratories must have documented policies establishing protocols for technical and administrative case review.

8.3.2 Laboratories must have a documented policy for resolving case review disagreements between analysts and reviewers.

SECTION 9: PROFICIENCY AND COMPETENCY TESTING

Note: It is recognized that different jurisdictions may define competency and proficiency testing in a manner other than how they are used here. In this context, competency tests measure the ability of the analyst to produce accurate results. Proficiency tests are an ongoing process in which a series of proficiency samples, the characteristics of which are not known to the participants, are sent to laboratories on a regular basis. Each laboratory is tested for its accuracy in identifying the presence (or concentration) of the drug using its usual procedures.

Each laboratory should participate in, at least, an annual inter-laboratory proficiency- testing program and should have documented protocols for testing the competency of its laboratory analysts.

9.1 PROFICIENCY TESTING

9.1.1 Laboratories shall perform proficiency testing in order to verify the laboratory's performance. The frequency of the proficiency testing should be, at least, annually. Where possible, at least one of these proficiency tests should be from a recognized external proficiency test provider.

9.1.2 Proficiency test samples should be representative of the laboratory's normal casework.

9.1.3 The analytical scheme applied to the proficiency test should be in concert with normal laboratory analysis procedures.

9.2 COMPETENCY TESTING

9.2.1 Laboratories must monitor the competency of their analysts. They should do so at least once a year.

9.2.2 If competency test samples are utilized, they should be representative of the laboratory's normal casework.

9.2.3 The analytical scheme applied to the competency test should be in concert with normal laboratory analysis procedures.

SECTION 10: ANALYTICAL METHOD VALIDATION AND VERIFICATION

10.1 Method validation is required to demonstrate that methods are suitable for their intended purpose.

10.1.1 For qualitative analysis, the parameters that need to be checked are selectivity, limit of detection and reproducibility.

10.1.2 Minimum acceptability criteria should be described along with means for demonstrating compliance.

10.1.3 Validation documentation is required.

10.2 Laboratories adopting methods validated elsewhere should verify these methods and establish their own limits of detection and reproducibility.

SECTION 11: LABORATORY AUDITS

11.1 Audits of laboratory operations should be conducted at least once a year.

11.2 Records of each audit must be maintained and should include the scope, date of the audit, name of auditor(s), findings and any necessary corrective actions.

SECTION 12: DEFICIENCY OF ANALYSIS

In the course of examining seized drug samples and related materials, laboratories may expect to encounter some operations or results that are deficient in some manner. Each laboratory must have a documented policy to address such deficiencies.

12.1 This policy must include the following:

12.1.1 A definition of a deficiency as any erroneous analytical result or interpretation, or any unapproved deviation* from an established policy or procedure in an analysis

*Deviations from established policy must have documented management approval.

12.1.2 A requirement for immediate cessation of the activity or work of the individual involved, if warranted by the seriousness of the deficiency, as defined in the documented policy

12.1.3 A requirement for administrative review of the activity or work of the individual involved

12.1.4 A requirement for evaluation of the impact the deficiency may have had on other activities of the individual or other analysts

12.1.5 A requirement for documentation of the follow-up action taken as a result of the review

12.1.6 A requirement for communication to appropriate employees of any confirmed deficiency which may have implications for their work

Comment: It should be recognized that to be effective, the definition for "deficiency of analysis" must be relatively broad. As such, deficiencies may have markedly different degrees of seriousness. For example, a misidentification of a controlled substance would be very serious and perhaps require that either the methodology or the analyst be suspended pending appropriate remedial action, as determined by management. However, other deficiencies might be more clerical in nature, requiring a simple correction at the first line supervisory level, without any suspension of methodology or personnel. Thus, it may well be advantageous to identify the differing levels of seriousness for deficiencies and make the action required be commensurate with the seriousness.

SECTION 13: HEALTH AND SAFETY

Laboratories must have a documented health and safety program in place.

13.1 HEALTH AND SAFETY REQUIREMENTS

13.1.1 All personnel should receive appropriate health and safety training.

13.1.2 Laboratories shall operate in accordance with laboratory policy and comply with any relevant regulations.

13.1.3 Laboratory health and safety manual(s) shall be readily available to all laboratory personnel.

13.1.4 Material Safety Data Sheets (MSDS) shall be readily available to all laboratory personnel.

13.1.5 All chemicals, biohazards and supplies must be stored and disposed of according to applicable government regulations and laboratory policy.

13.1.6 Safety hazards such as syringes, items with sharp edges or noxious substances should be so labeled.

SECTION 14: ADDITIONAL DOCUMENTATION

In addition to casework documentation, laboratories must maintain documentation on the following topics:

14.1 Test methods/procedures for drug analysis

14.2 Reference standards (including source and verification)

14.3 Preparation and testing of reagents

14.4 Evidence handling protocols

14.5 Instrument and equipment calibration and maintenance

14.6 Instrument and equipment inventory (e.g., manufacturer, model, serial number, acquisition date)

14.7 Proficiency testing

14.8 Personnel training and qualifications

14.9 Quality assurance protocols and audits

14.10 Health, safety and security protocols

14.11 Validation data and results.