PART IV A

QUALITY ASSURANCE/GENERAL PRACTICES

IVA.1 Introduction

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 recommendations in PART IV A to provide a quality framework for management of the processing of drug casework, including handling of evidentiary material, management practices, qualitative and quantitative 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 that enter a laboratory system.

IVA.2 Quality management system

A documented quality management system shall be established and maintained. The quality management system shall consider the risks and opportunities of the laboratory activities to reduce potential failures and achieve improvements.

IVA.2.1 Personnel responsible for this shall be clearly designated and shall have direct access to the highest level of management concerning laboratory policy.

IVA.2.2 The quality management system shall cover all procedures and reports associated with drug analysis.

IVA.3 Personnel

IVA.3.1 Job description

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

IVA.3.2 Designated personnel and responsibilities

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

IVA.3.2.1 Technical Support Personnel: Individuals who perform basic laboratory duties, but do not analyze evidence.

IVA.3.2.2 Technician/Assistant Analyst: A person who analyzes evidence, but does not issue reports for court purposes.

IVA.3.2.3 Analyst: A designated person who:

a) examines and analyzes seized drugs or related materials, or directs such examinations to be done

b) independently has access to unsealed evidence in order to remove samples from the evidentiary material for examination AND

c) as a consequence of such examinations, signs reports for court or other purposes.

IVA.3.2.4 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.

IVA.3.2.5 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.

IVA.3.2.6 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 monitors compliance with the program.

IVA.3.3 Qualifications/Education

IVA.3.3.1 Technical Support Personnel shall

a) have education, skills and abilities commensurate with their responsibilities AND

b) have on-the-job training specific to their position.

IVA.3.3.2 Technicians/Assistant Analysts shall

a) have education, skills and abilities commensurate with their responsibilities AND

b) have on-the-job training specific to their position.

IVA.3.3.3 Analysts shall meet educational requirements stated in PART II – Education and Training (Section 2).

IVA.3.3.4 Supervisors shall

a) meet all the requirements of an analyst (3.3.3),

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

c) demonstrate knowledge necessary to evaluate analytical results and conclusions.

IVA.3.4 Initial training requirements

Initial training requirements for analysts are defined in PART II – Education and Training (Section 4).

IVA.3.5 Maintaining competence

Continuing professional development for analysts is defined in PART II – Education and Training (Section 3).

IVA.4 Physical plant

IVA.4.1 Laboratories shall provide a healthy, safe and secure environment for its personnel and operations.

IVA.4.2 Laboratories shall contain adequate space to perform required analytical functions and prevent contamination.

IVA.4.3 Chemical fume hoods shall be provided. They shall be properly maintained and monitored according to an established schedule.

IVA.4.4 A laboratory cleaning schedule should be established and implemented.

IVA.4.5 Adequate facilities shall be provided to ensure the proper safekeeping of evidence, standards and records.

IVA.4.6 Appropriately secured storage shall be provided to prevent contamination of chemicals and reagents.

IVA.5 Evidence control

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

IVA.5.1 Receiving and identifying evidence

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

- submission documents or copies
- identity of party requesting analysis and the date of request
- description of items of evidence submitted for analysis
- identity of the person who delivers the evidence, along with date of submission
- for evidence not delivered in person, descriptive information regarding mode of delivery and tracking information
- chain of custody record
- unique case identifier.

IVA.5.2 Integrity of evidence

Evidence shall 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 shall be safeguarded against loss or contamination. Any alteration of the evidence (e.g. repackaging) shall be documented. Procedures shall be implemented to assure that samples are and remain properly labeled throughout the analytical process.

IVA.5.3 Storage of evidence

Access to the evidence storage area shall 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.

IVA.5.4 Disposition of evidence

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

IVA.5.5 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.

IVA.6 Analytical procedures

IVA.6.1 Analytical procedures for drug analysis

IVA.6.1.1 Laboratories shall have and follow documented analytical procedures.

IVA.6.1.2 Laboratories shall have in place protocols for the sampling of evidence (see PART III A – Sampling).

IVA.6.1.3 Work practices shall be established to prevent contamination of evidence during analysis.

IVA.6.1.4 Laboratories shall have and follow documented guidelines for the acceptance and interpretation of data.

IVA.6.1.5 Laboratories shall monitor the analytical processes using appropriate blanks, controls and reference materials.

IVA.6.1.6 Reference materials and reference data are critical to demonstrating the validity of quantitative and qualitative test results. A positive test result shall meet the acceptance criteria defined in the method validation and operating protocol. In descending order of preference SWGDRUG recommends that the acceptance criteria should be based on:

IVA.6.1.6.1 Comparison to data obtained from a suitable drug reference material analyzed under the same analytical conditions as the test/case sample. If reference material data are collected on a different instrument than the test/case sample, it must be demonstrated that both instruments produce comparable data.

The reference material may be analyzed:

- contemporaneously with test/case sample (e.g. same sequence/batch)
- as part of routine quality control (e.g. daily check solutions)
- at a previous date (e.g. method validation, internal reference collection)

IVA.6.1.6.2 Comparisons to external reference data may be used where a reference material is unavailable. External reference data shall be assessed and demonstrated to be fit for purpose. Factors to consider include

- Origin of the data
- Validation of the data
- Peer review of the data
- Comparability of analytical conditions

IVA.6.1.6.3 When neither reference materials nor external reference data are available, structural elucidation techniques may be employed providing the analyst has the appropriate skills for their interpretation. Such interpretations shall be made only by analysts competent in structural elucidation interpretation.

IVA.6.1.7 Analytical procedures shall be validated in compliance with PART IV B - Validation.

IVA.6.1.8 When analysts determine the identity of a drug in a sample, they shall employ quality practices to ensure the results correspond to the sample tested. (see Part III B – Drug Identification)

IVA.6.2 Assessment of drug reference materials

ISO/IEC 17025 specifies that reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials (CRM). For seized drugs this requirement is difficult to fulfil because the concept of traceability for drug standards is not internationally established and CRM's for drug analysis are not readily available or affordable.

Note: A certificate does not necessarily define a material as a CRM.

IVA.6.2.1 SWGDRUG recommends laboratories have a process for assessing that reference materials are fit for purpose.

IVA.6.2.1.1 The assessment and purpose of a reference material shall be documented. The documentation shall include the name of the individual who performed the assessment, the date of assessment, verification test data, and details of all reference materials and reference data used.

IVA.6.2.2 To be fit for purpose, the reference material must meet the minimum specification defined in the validation (see Part IV B - Reference Materials).

IVA.6.2.2.1 The assessment shall be done on each lot of reference material.

IVA.6.2.2.2 This assessment shall be completed prior to or alongside casework analysis as appropriate.

IVA.6.2.2.3 Reference materials shall only be used for the purpose defined by the laboratory. For example a reference material may be deemed suitable for qualitative but not quantitative determinations.

IVA.6.2.3 Fit for purpose for qualitative work requires an assessment of chemical identity.

IVA.6.2.4 Fit for purpose for quantitative work requires an assessment of purity and/or concentration, as appropriate to the application and its associated uncertainty of measurement in addition to the parameters in 6.2.3.

IVA.6.2.4.1 For quantitative determinations, different sources of reference material should be used for calibration and quality control. Where this is not feasible, two different lots of the same source may be used or lastly a single source of reference material can be sub-divided and each part assigned a specific purpose.

IVA.6.2.5 These parameters in Sections 6.2.3 and 6.2.4 may be described in a certificate, statement of analysis, data sheet or label supplied with the material or may be determined by in-house analysis or reference to published literature.

IVA.6.2.6 The laboratory shall assess the reliability of the information supplied with a reference material even if the material meets the definition of a CRM.

IVA.6.2.6.1 For reference materials obtained from a provider accredited under ISO 17034, the information contained in the accompanying certificate is considered reliable and can be accepted as correct if the material is stored and used in accordance with the manufacturer's instructions. In these circumstances the assessment need not include analysis.

IVA.6.2.6.1.1 For reference materials obtained from a provider not accredited under ISO 17034 the identity and purity information supplied by the provider shall be verified by analysis. When verification by

analysis is not possible, this shall be documented and where applicable the limitation expressed within the report. Other information may be evaluated as needed.

IVA.6.2.6.1.2 Examples of verification of chemical identity by analysis:

- Analysis and comparison of the results to peer-reviewed published data, data produced by a laboratory accredited under ISO/IEC 17025, or to data produced from a previously verified reference material.

- Evaluation of data from in-house structural elucidation analysis of the material.

IVA.6.2.6.1.3 Examples of verification of purity by analysis utilizing validated methods:

- Quantitative NMR Spectroscopy
- Quantitative UV-Visible Spectroscopy
- Comparison to previously verified material

IVA.6.2.6.2 Where a reference material has no or limited supporting documentation or is produced in-house (by synthesis or from a case sample), then the chemical identity shall be determined in sufficient detail to demonstrate that it is fit for purpose. In addition, for quantitative work the purity and associated uncertainty of measurement shall also be determined.

IVA.6.2.7 Reference materials should have an expiration/retest date.

IVA.6.2.7.1 If the material is not supplied with an expiration date, one should be assigned at the first assessment (section 6.2.3, 6.2.4). If the expiration date passes before the material is fully used, then the material can be re-assessed and the expiration date extended. The laboratory protocol for extending expiration dates shall be documented and should include analysis of the material.

IVA.6.2.7.2 If expiration dates are not assigned to reference materials, the laboratory must have a documented

protocol for assessing the validity of the reference material each time it is used.

IVA.7 Instrument/Equipment performance

IVA.7.1 Instrument performance

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

IVA.7.1.1 Monitoring shall include, at least, the use of blanks and reference materials, test mixtures, or calibration standards.

IVA.7.1.2 Instrument performance monitoring shall be documented.

IVA.7.1.3 The manufacturer's operation manual and other relevant documentation for instrumentation should be readily available.

IVA.7.2 Equipment

IVA.7.2.1 Only suitable and properly operating equipment shall be employed.

IVA.7.2.2 Equipment performance parameters should be routinely monitored and documented.

IVA.7.2.3 The manufacturer's operation manual and other relevant documentation for each piece of equipment should be readily available.

IVA.8 Chemicals and reagents

IVA.8.1 Chemicals and reagents used in drug testing shall be of appropriate grade for the tests performed.

IVA.8.2 There shall be documented formulations for all chemical reagents produced within the laboratory.

IVA.8.3 Documentation for reagents prepared within the laboratory shall include identity, concentration (when appropriate), date of preparation, identity of the individual preparing the reagents, storage conditions (if appropriate) and the expiration date (if appropriate).

IVA.8.4 The efficacy of all reagents shall be checked prior to or concurrent with their use in casework. Results of these tests shall be documented.

IVA.8.5 The received and opened date(s) shall be recorded for chemicals and reagents, where relevant to testing results.

IVA.8.6 Chemical and reagent containers shall be labeled as to their contents.

IVA.9 Casework documentation, report writing and review

IVA.9.1 Casework documentation

IVA.9.1.1 Documentation shall contain sufficient information to allow a peer to evaluate case notes and interpret the data.

IVA.9.1.2 Evidence handling documentation shall include chain of custody, information regarding packaging of the evidence upon receipt, the initial weight/count of evidence to be examined (upon opening), a description of the evidence and communications regarding the case.

IVA.9.1.3 Analytical documentation should include procedures, standards, blanks, observations, test results and supporting documentation including charts, graphs and spectra generated during an analysis.

IVA.9.1.4 Casework documentation shall be preserved according to documented laboratory policy.

IVA.9.2 Report writing

Reports issued by laboratories shall be accurate, clear, objective, and meet the requirements of the jurisdictions served.

These reports shall include the following information:

- title of report
- identity and location of the testing laboratory
- unique case identifier (on each page)
- clear identification of the end of the report (e.g., Page 3 of 3)
- submitting agency
- date of receipt of evidence
- date of report
- descriptive list and unambiguous identification of submitted evidence
- date(s) of performance of laboratory activity
- identity of analyst
- conclusions / results with, where appropriate, the units of measurement
- a list of analytical techniques employed
- additions to, deviations or exclusions for the method
- sampling plan or method (see Part III A - Reporting)

- a statement to the effect that the result relates only to the items tested or sampled
- uncertainty (see Part IV C - Uncertainty)
- clear identification when results are from external providers
- where relevant, a statement of conformity with requirements or specifications (e.g. statutory regulations)
- where appropriate, opinions and interpretations (e.g. clandestine laboratory synthetic route determination).

If elements listed above are not included on the report, the laboratory shall have documented reasons (i.e. specific accreditation, customer or jurisdictional considerations), for not doing so.

IVA.9.3 Case review

9.1.1 Laboratories shall have documented policies establishing protocols for technical and administrative case review.

9.1.2 Laboratories shall have a documented policy for resolving case review disagreements between analysts and reviewers.

IVA.10 Proficiency and competency testing

Each laboratory shall establish a documented competency testing and proficiency testing program. Each laboratory shall have documented protocols for monitoring the competency and proficiency of its analysts.

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.

IVA.10.1 Proficiency testing

IVA.10.1.1 Laboratories shall perform proficiency testing in order to verify the laboratory's performance. The frequency of the proficiency testing shall be, at least, annually. Where possible, at least one of these proficiency tests should be from an external proficiency test provider.

IVA.10.1.2 Proficiency test samples should be representative of the laboratory's normal casework.

IVA.10.1.3 The analytical scheme applied to the proficiency test should be in concert with normal laboratory analysis procedures.

IVA.10.2 Competency testing

IVA.10.2.1 Laboratories shall monitor the competency of their analysts annually (e.g. proficiency testing, observation of lab activities).

IVA.10.2.2 If competency test samples are utilized, they should be representative of the laboratory's normal casework.

IVA.10.2.3 The analytical scheme applied to the competency test should be in concert with normal laboratory analysis procedures.

IVA.11 Analytical method validation and verification

IVA.11.1 Method validation is required to demonstrate that methods are suitable for their intended purpose (see PART IV B – Validation).

IVA.12 Laboratory audits

IVA.12.1 Internal audits of laboratory operations shall be conducted at least once a year.

IVA.12.2 Records of each audit shall be maintained and include the scope, date of the audit, name of auditor(s), findings and any necessary corrective actions.

IVA.13 Deficiency of analysis

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

IVA.13.1 This policy shall include the following:

a) 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;

NOTE Deviations from established policy shall have documented management approval.

b) 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;

c) a requirement for administrative review of the activity or work of the individual involved;

d) a requirement for evaluation of the impact the deficiency might have had on other operations, equipment, materials, or laboratory personnel;

e) a requirement for documentation of the follow-up action taken as a result of the review;

f) a requirement for communication to appropriate employees of any confirmed deficiency which may have implications for their work.

NOTE It should be recognized that to be effective, the definition for "deficiency of analysis" shall 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.

IVA.14 Health and safety

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

IVA.14.1 Health and safety requirements

IVA.14.1.1 All personnel should receive appropriate health and safety training.

IVA.14.1.2 Laboratories shall operate in accordance with laboratory policy and comply with any relevant regulations.

IVA.14.1.3 Laboratory health and safety manual(s) shall be readily available to all laboratory personnel.

IVA.14.1.4 Safety Data Sheets shall be readily available to all laboratory personnel.

IVA.14.1.5 All chemicals, biohazards and supplies shall be stored and disposed of according to applicable government regulations and laboratory policy.

IVA.14.1.6 Safety hazards such as syringes, items with sharp edges or noxious substances should be so labeled and stored in appropriate containers.

IVA.15 Additional documentation

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

- test methods / procedures for drug analysis
- reference materials (including source and verification)
- preparation and checks of reagents
- evidence handling protocols
- equipment calibration and maintenance
- equipment inventory (e.g., manufacturer, model, serial number, acquisition date)
- proficiency testing
- personnel training and qualifications
- quality assurance protocols and audits
- health, safety and security protocols
- validation data and results
- uncertainty data.