SCIENTIFIC WORKING GROUP FOR THE ANALYSIS OF SEIZED DRUGS (SWGDRUG) RECOMMENDATIONS

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RECOMMENDATIONS INCLUDE:

CODE OF PROFESSIONAL PRACTICE

EDUCATION and TRAINING

METHODS OF ANALYSIS

QUALITY ASSURANCE

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
COUNTERDRUG TECHNOLOGY ASSESMENT CENTER

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Foreword

This publication contains recommendations from the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG). These recommendations are intended to assist forensic analysts and managers in the development of analytical techniques, protocols and policies. They are recognized to be minimum standards that may be modified to address unique jurisdictional requirements. SWGDRUG seeks to have these recommendations internationally accepted as the foundation for good laboratory practice. These recommendations encompass Code of Professional Practice, Education and Training, Methods of Analysis and Quality Assurance. The SWGDRUG Core Committee strongly urges the adoption of these recommendations by any laboratory involved in the analysis of seized drugs.

Since 1997, SWGDRUG has been working to provide useful and practical recommendations for the analysis of seized drugs. SWGDRUG recognizes that over time these recommendations may need to be updated as a result of advances in technology, changes in accreditation requirements and/or the emergence of new requirements. To this end, SWGDRUG relies heavily of the input of the forensic community to ensure that all recommendations remain useful and current. This synergetic approach is a key component of the SWGDRUG process. I encourage everyone to continue supporting the mission of SWGDRUG.

Finally, as the Chairman of SWGDRUG, I would be remiss if I did not single out several individuals within whom SWGDRUG would not exist. Benjamin A. Perillo, former Deputy Assistant Administrator, DEA Office of Forensic Sciences, who conceived this working group and made it a reality. Thomas J. Janovsky, Deputy Assistant Administrator, DEA Office of Forensic Sciences and former Chairman of SWDRUG who promoted and enhanced SWGDRUG's prominence in the Forensic Community. Joseph P. Bono, former Quality Assurance Manager, DEA Office of Forensic Sciences who served as SWGDRUG secretariat from the beginning and handled all of the behind the scene activities that made SWGDRUG a success. Lastly, Scott R. Oulton, Laboratory Director, DEA Southwest Laboratory, for his untiring efforts in coordinating and facilitating the SWGDRUG meetings.

I would also like to make special mention to the Office of National Drug Control Policy, Counterdrug Technology Assessment Center and the National Institute of Standards and Technology, which over the years have provided the financial resources for SWGDRUG to operate.

Nelson Santos

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Introduction

SWGDRUG is comprised of a core committee of more than 20 forensic scientists from around the world. The mission of SWGDRUG is to recommend minimum standards for the forensic examination of seized drugs and to seek their international acceptance. SWGDRUG seeks to achieve this mission through the following objectives:

- specifying requirements for practitioners' knowledge, skills and abilities,
- promoting professional development,
- providing a means of information exchange within the forensic science community,
- promoting ethical standards of practitioners,
- providing minimum standards for examinations and reporting,
- establishing quality assurance requirements,
- considering relevant international standards, and
- seeking international acceptance of SWGDRUG recommendations.

Drug abuse and trafficking in controlled substances are global problems, and in recent years law enforcement has looked to international solutions for these problems. In 1997 the U.S. Drug Enforcement Administration (DEA) and the Office of National Drug Control Policy (ONDCP) co-sponsored the formation of the Technical Working Group for the Analysis of Seized Drugs (TWGDRUG). Forensic scientists from the United States, England, Canada, Australia, Japan, Germany and the Netherlands, as well as representatives of the United Nations, several international forensic organizations and academia were invited to meet in Washington, DC. This group, with input from around the world, developed recommendations for educational standards and professional development for forensic practitioners. They also recommended quality assurance standards for the analysis of seized drugs and minimum standards for their identification. The name Scientific Working Group for the Analysis of Seized Drugs was adopted in 1999.

SWGDRUG has received input from many forensic scientists in its standards development process. It has used various methods of communication including its Internet site (www.swgdrug.org), MICROGRAM, presentations at numerous local, national and international meetings, and personal contacts. The Methods and Reports subcommittee received over 300 responses to an international survey. Following each meeting of the Core Committee, updates are published and distributed.

SWGDRUG sought and considered comments from the forensic science community on all its proposals. In order for a recommendation to be adopted, there must be a quorum of at least 3/4 of the membership and acceptance vote of 2/3 of the attending members is required. Please refer to SWGDRUG's bylaws, which can be found on the internet at www.swgdrug.org/bylaws.htm for additional details.

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In January 2005 the leadership of SWGDRUG was transferred to Nelson A. Santos, Chair and Scott R. Oulton, Secretariat, after the many years of service from Mr. Janovsky and Mr. Bono. The various sub-committees continue to research and develop proposals for additional recommendations with several members completing their service to the group and others replacing them by invitation. The following chart details those persons who have rendered service as members of the core committee over the years. For a list of current members, please reference the SWGDRUG website.

Core Committee

Ms. Susan Ballou Office of Law Enforcement Standards National Institute of Standards and Technology Gaithersburg, Maryland	Dr. Suzanne Bell West Virginia University Morgantown, West Virginia
Mr. Robert Bianchi Drug Enforcement Administration McLean, Virginia	Mr. Joseph Bono (Secretariat) Drug Enforcement Administration Washington, DC
Dr. Michael Bovens Wissenschaftlicher Dienst Zurich, Switzerland	Dr. Bob Bramley Forensic Science Service Birmingham, England
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Mr. Alan B. Clark Drug Enforcement Administration Washington, DC	Mr. Jeffrey H. Comparin (Secretariat) Drug Enforcement Administration Dulles, VA
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Mr. Richard Gervasoni Montgomery County Police Department Lab Rockville, Maryland	Ms. Jo Ann Given Naval Criminal Investigative Service Norfolk, Virginia
Mr. Garth Glassburg Northeastern Illinois Regional Crime Laboratory Vernon Hills, Illinois	Ms. Dorothy Gordimer Union County Prosecutor's Office Laboratory Westfield, New Jersey
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Dr. Takako Inoue National Research Institute of Police Science Tokyo, Japan	Ms. Linda Jackson Department of Forensic Science Richmond, Virginia
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Mr. Marc LeBeau Federal Bureau of Investigation Washington, DC	Mr. John Lentini Applied Technical Services, Inc. Marietta, Georgia
Dr. Bruce Lodge Health Canada Ottawa, Ontario Canada	Mr. David Martin Department of Forensic Science Richmond, Virginia
Mr. Jack Mario Suffolk County Crime Laboratory Hauppauge, New York	Dr. Yoshiteru Maruno National Research Institute of Police Science Chiba, Japan
Mr. Jerry Massetti California Department of Justice California Criminalistics Institute Sacramento, California	Mr. Christian Matchett Georgia Bureau of Investigation Decatur, Georgia
Dr. Iphigenia Naidis United Nations Office on Drugs and Crime Vienna Austria	Dr. Helmut Neuman Bundeskriminalamt Forensic Science Institute Wiesbaden, Germany
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Mr. Scott R. Oulton (Secretariat) Drug Enforcement Administration Vista, California	Mr. Richard A. Paulas Illinois State Police Forensic Sciences Command Chicago, Illinois
Mr. Benjamin Perillo Drug Enforcement Administration Washington, DC	Dr. Robert Powers Connecticut Department of Public Safety Hartford, Connecticut
Ms. Cate Quinn Victoria Police Forensic Services Department Melbourne, Australia	Dr. Conrad Roberson Georgia Bureau of Investigation Decatur, Georgia
Mr. Nelson A. Santos (Chair) Drug Enforcement Administration Washington, DC	Mr. Tshepo Shole National Forensic Science Laboratory Pretoria, South Africa
Dr. Jay Siegel Michigan State University School of Criminal Justice East Lansing, Michigan	Dr. Erkki Sippola National Bureau of Investigation Crime Laboratory Vantaa, Finland
Mr. Zoran Skopec Australian Forensic Drug Laboratory Pymble, NSW, Australia	Dr. Howard Stead United Nations International Drug Control Programme Vienna, Austria

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Mr. Etienne van Zyl National Forensic Science Laboratory Pretoria, South Africa	Ms. Eileen Waninger Federal Bureau of Investigation Laboratory Quantico, Virginia
Mr. Jaco Westraat National Forensic Science Laboratory Pretoria, South Africa	Dr. Udo Zerell Bundeskriminalamt Forensic Science Institute Wiesbaden, Germany

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PART I

A CODE OF PROFESSIONAL PRACTICE FOR DRUG ANALYSTS

PREFACE

This Code of Professional Practice has been written specifically for analysts. However, it is important that their managers and the technicians and others who assist them in their work are equally aware of its provisions, and they support the analyst in adhering to these. Where appropriate, the provisions are also equally applicable to the technicians in the approach to their own work.

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1 Introduction

1.1 A Code of Professional Practice is intended to provide the framework of ethical values and scientific and legal obligations within which the analyst should operate. Details are also usually provided on how alleged breaches of the Code will be investigated, what sanctions are available and how appeals should be pursued.

1.2 A Code of Professional Practice is essential to analysts and their managers in helping them carry out their duties in a proper manner and in making appropriate decisions when questions of ethics arise.

1.3 A Code of Professional Practice that is enforced and publicly available is also a powerful means of demonstrating the professional expectations of analysts and the reliability of their findings to others in the criminal justice system and the public at large.

1.4 SWGDRUG recommends that all employers of analysts develop a Code of Professional Practice and the means of dealing with breaches of the Code.

1.5 SWGDRUG further recommends that all Codes of Professional Practice for analysts should include, as a minimum, provisions relating to their professional conduct, their casework and the reporting of their results, as provided in Section 2. For further information, see supplemental document S1 (Examples for Part I A Code of Professional Practice for Drug Analysts).

2 Code of professional practice

2.1 Professional conduct

Analysts should:

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a) act with honesty, integrity and objectivity;

b) work only within the bounds of their professional competence;

c) take reasonable steps to maintain their competence;

d) recognize that their overriding duty is to criminal justice;

e) declare to their employer any prior contact or personal involvement, which may give rise to conflict of interest, real or perceived;

f) declare to their employer or other appropriate authority any pressure intended to influence the result of an examination.

2.2 Casework

Analysts should:

a) ensure and be able to demonstrate that the integrity and security of evidential materials and the information derived from their analysis have been maintained while in their possession;

b) ensure that they have a clear understanding of what the customer needs and all the necessary information, relevant evidential materials and facilities available to reach a meaningful conclusion in an appropriate timeframe;

c) employ an appropriate analytical approach, using the facilities available;

d) make and retain full, contemporaneous, clear and accurate records of all examinations and tests conducted, and conclusions drawn, in sufficient detail to allow meaningful review and assessment of the conclusions by an independent person competent in the field;

e) accept responsibility for all casework done by themselves and under their direction;

f) conduct all professional activities in a way that protects the health and safety of themselves, co-workers, the public and the environment.

2.3 Reporting

Analysts should:

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a) present advice and testimony, whether written or oral, in a clear and objective manner;

b) be prepared to reconsider and, if necessary, change their conclusions, advice or testimony in light of new information or developments, and take the initiative in informing their employer and customers promptly of any such changes that need to be made;

c) take appropriate action if there is potential for, or there has been, a miscarriage of justice due to new circumstances that have come to light, incompetent practice or malpractice;

d) preserve customer confidentiality unless officially authorized to do otherwise.

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PART II

EDUCATION AND TRAINING

1 Introduction

Part II recommends minimum education, training and experience for analysts practicing in laboratories that conduct seized drug analyses. It describes the types of activities necessary to continue professional development and reference literature required in laboratories where they practice.

1.1 Recommendations listed in Part II are intended to apply to any analyst who:

a) independently has access to unsealed evidential material in order to remove samples for examination;

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

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

2 Education and experience for analysts

2.1 The aim of this recommendation is that all analysts recruited in the future should have at least a bachelor's degree, while allowing existing analysts without degrees to be retained as analysts. The minimum educational requirements for analysts are EITHER

a) 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

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

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3 Continuing professional development

All forensic scientists have an ongoing responsibility to remain current in their field. In addition, laboratories should provide support and opportunities for continuing professional development. Minimum continuing professional development requirements for a laboratory analyst are:

3.1 Twenty contact hours of training every year. Contact is defined as face-to-face interaction with an instructor or trainer in a classroom or laboratory setting. It does not include self-paced learning or distance education where the instructor has no active interaction with the student.

3.2 Training shall be relevant to the laboratory's mission. This statement is purposely broad to embrace the laboratory's broader needs such as ancillary duty assignments and supervision/management.

3.3 Training completed shall be documented.

3.4 Training can be provided from a variety of sources, including, but not limited to the following:

- chemistry or instrumental courses taught at the post-secondary educational level
- instrument operation or maintenance courses taught by vendors
- in-service classes conducted by the employer
- in-service training taught by external providers
- participation in relevant scientific meetings or conferences (e.g., presenting a paper, attending a workshop, providing reports on conferences).

4 Initial training requirements

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.

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

a) documented standards of performance and a plan for assessing theoretical and practical competency against these standards (e.g., written

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and oral examinations, critical reviews, analysis of unknown samples and mock casework per topic area);

b) 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;

c) a period of supervised casework representative of the type the analyst will be required to perform;

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

4.2 Topic areas in the training program will include, as a minimum, the following:

- relevant background information on drugs of abuse (e.g., status of control and chemical and physical characteristics)
- techniques, methodologies and instrumentation utilized in the examination of seized drug samples and related materials
- quality assurance
- expert /Court testimony and legal requirements
- laboratory policy and procedures (e.g., sampling, evidence handling, safety and security) as they relate to the examination of seized drug samples and related materials.

4.3 An individual qualified to provide instruction shall have demonstrated competence in the subject area and in the delivery of training.

5 References and documents

The following references and documents shall be available and accessible to analysts.

a) college/university level textbooks for reference to theory and practice in key subject areas, e.g., general chemistry, organic chemistry and analytical chemistry

b) reference literature containing physical, chemical and analytical data. Such references include the *Merck Index*, *Clarke's Analysis of Drugs and Poisons*, laboratory manuals of the United Nations Drug Control Program, in-house produced spectra and published standard spectra, (e.g., Mills and Roberson's *Instrumental Data For Drug Analysis*, or compendia from Pfleger or Wiley)

c) operation and maintenance manuals for each analytical instrument

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d) relevant periodicals (e.g., *Journal of Forensic Sciences*, *Forensic Science International*, *Microgram*, *Journal of Canadian Society of Forensic Science*, *Japanese Journal of Forensic Science and Technology*)

e) laboratory quality manual, standard operating procedures, and method validation and verification documents

f) relevant jurisdictional legislation (e.g., statutes and case law relating to controlled substances, and health and safety legislation)

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PART III A

METHODS OF ANALYSIS/SAMPLING SEIZED DRUGS FOR QUALITATIVE ANALYSIS

1 Introduction

This document addresses minimum recommendations for sampling of seized drugs for qualitative analysis; quantitative analyses will be addressed at a later time.

NOTE For the purpose of this document the use of the term "statistical" refers to "probability-based."

1.1 The principal purpose of sampling in the context of this recommendation is to answer relevant questions about a population by examination of a portion of the population (e.g., What is the net weight of the population? What portion of the units of a population can be said to contain a given drug at a given level of confidence?)

1.2 By developing a sampling strategy and implementing appropriate sampling schemes, as illustrated in Figure 1, a laboratory will minimize the total number of required analytical determinations, while assuring that all relevant legal and scientific requirements are met.

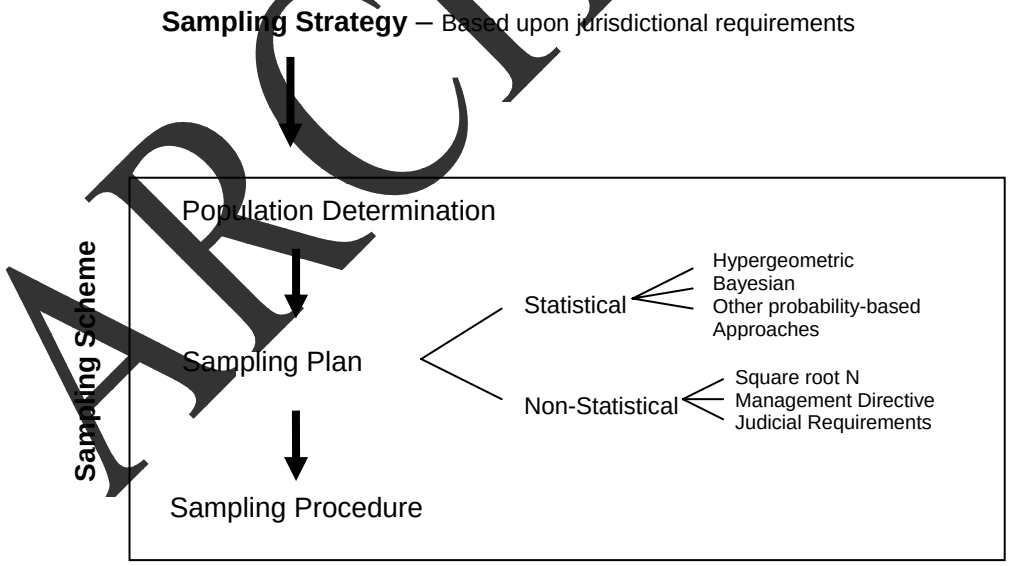

Figure 1: Relationship of the Various Levels Required in Sampling

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2 Sampling strategy

A sampling strategy is highly dependent on the purpose of the investigation, the original question, and the ultimate use of the results. Laws and legal practices form the foundation of most strategies and shall be taken into account when designing a sampling scheme. Therefore, specific sampling strategies are not defined in this document.

2.1 The laboratory has the responsibility to develop its own strategies consistent with these recommendations. SWGDRUG recommends attention to the following key points:

2.1.1 Sampling may be statistical or non-statistical.

2.1.1.1 In many cases, a non-statistical approach may suffice. The sampling plan shall provide an adequate basis for answering questions of applicable law (e.g., Is there a drug present in the population? Are statutory enhancement levels satisfied by the analysis of a specified number of units?)

2.1.1.2 If an inference about the whole population is to be drawn from a sample, then the plan shall be statistically based and limits of the inference shall be documented (see supplemental document SD-1, 2.3 Reporting).

2.1.2 Statistically selected units shall be analyzed to meet the SWGDRUG minimum recommendations (see Part III B) for forensic drug identification if statistical inferences are to be made about the whole population.

3 Sampling scheme

The sampling scheme is an overall approach which includes population determination, selection of the sampling plan and procedure and, when appropriate, sample reduction prior to analysis (Figure 2).

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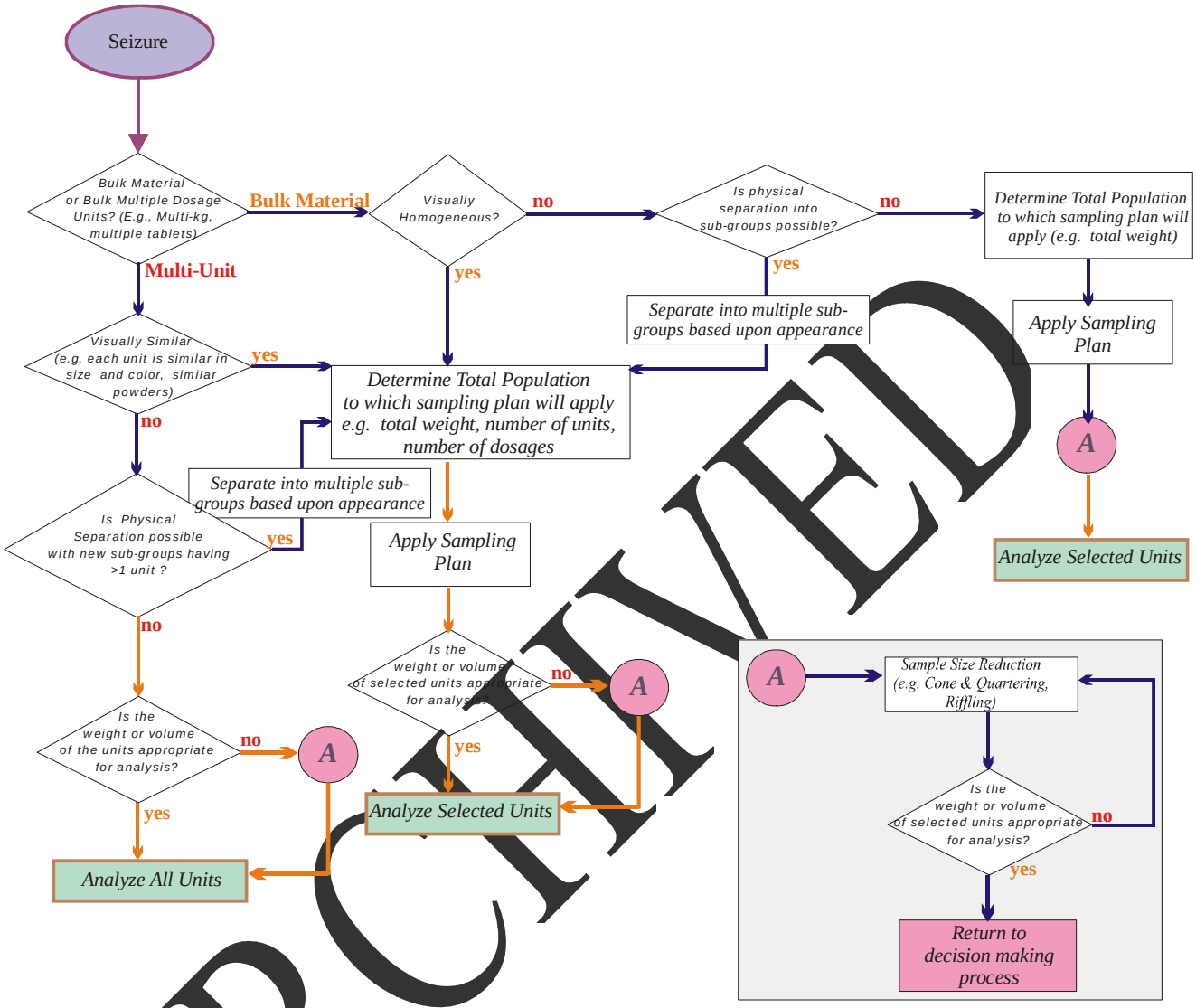

Figure 2: Example of a Sampling Scheme - A Decision Flowchart

3.1 Population determination

3.1.1 The population determination shall take into account all typical forms and quantities in which exhibits may appear.

3.1.2 A population can consist of a single unit or multiple units.

3.1.3 A multiple unit population shall consist of items, which are similar in relevant visual characteristics.

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3.2 Sampling plan

There are numerous sampling plans used in the forensic analysis of drugs, which are applicable to single and multiple unit populations.

3.2.1 When a single unit or bulk population is to be analyzed the issue of homogeneity shall be addressed within the sampling plan.

3.2.1.1 One sample is sufficient if the bulk material is homogeneous, or if it is made so by the analyst.

3.2.1.2 If the bulk material is not homogeneous, several samples from different locations may be necessary to ensure that the test results are representative of the bulk material and to avoid false negative results.

3.2.2 Depending upon the inference to be drawn from the analysis for a multiple unit population, the sampling plan may be statistical or non-statistical.

3.2.2.1 Statistical approaches are applicable when inferences are made about the whole population. For example:

a) The probability that a given percentage of the population contains the drug of interest or is positive for a given characteristic.

b) The total net weight of the population is to be extrapolated from the weight of a sample.

Published examples are provided below:

- Hypergeometric
  - Frank *et al*., *Journal of Forensic Sciences*, 1991, 36(2) 350-357
  - *Guidelines on Representative Drug Sampling*, European Network of Forensic Science Institutes (ENFSI), 2004, www.enfsi.org
  - American Society for Testing and Materials (ASTM) E-2334-03

- Bayesian
  - Coulson *et al., Journal of Forensic Sciences*, 2001, 46(6) 1456-1461
  - *Guidelines on Representative Drug Sampling*, ENFSI, 2004, www.enfsi.org

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- Other probability based approaches
  - ASTM E105-04 “Standard Practice for Probability Sampling of Materials”
  - ASTM E122-00 “Standard Practice for Calculating Sample Size to Estimate, With a Specified Tolerable Error, the Average for a Characteristic of a Lot or Process”
  - *Guidelines on Representative Drug Sampling*, ENFSI, 2004, www.enfsi.org

3.2.2.2 Non-statistical approaches are appropriate if no inference is to be made about the whole population.

Examples are provided below:

- The “square root” method
  - *Recommended Methods for testing Opium, Morphine and Heroin: Manual for use by National Drug Testing Laboratories*, United Nations Office on Drugs and Crime, 1998
- *Guidelines on Representative Drug Sampling*, ENFSI, 2004, www.enfsi.org
- Selection of a single unit from a multiple unit population. This may be appropriate under certain circumstances (e.g., management directives, legislative and/or judicial requirements).

3.3 Sampling procedure

3.3.1 Establish the procedure for selecting the number of units that will comprise the sample.

3.3.1.1 For non-statistical approaches select a sample appropriate for the analytical objectives.

3.3.1.2 For statistical approaches SWGDRUG recommends that a random sampling be conducted.

3.3.2 Select a random sample.

3.3.2.1 A random sample is one selected without bias. Computer generated random numbers or random number tables are commonly employed for such tasks and these should be included in the sampling plan.

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3.3.2.2 Random sampling of items using random number tables may not be practical in all cases. In these instances, an alternate sampling plan shall be designed and documented to approach random selection. A practical solution involves a "black box" method, which refers to one that will prevent the sampler from consciously selecting a specific item from the population (e.g., all units are placed in a box and the samples for testing are selected without bias). Random sampling is discussed in the following references:

- ASTM E105-04 "Standard Practice for Probability Sampling of Materials"
- *Guidelines on Representative Drug Sampling*, ENFSI, "Chapter 3: Representative Sampling Techniques", pages 10-11; www.enfsi.org

3.4 Sample reduction

Sample reduction may be applied in cases where the weight or volume of the selected units is too large for laboratory analysis (Figure 2, insert A).

4 Analysis

4.1 Statistically selected sample(s)

SWGDRUG recommends that each unit comprising the sample shall be analyzed to meet the SWGDRUG minimum recommendations (Part III B) for forensic drug identification, if statistical inferences are to be made about the whole population.

4.2 Non-statistically selected sample(s)

SWGDRUG minimum recommendations for forensic drug identification shall be applied to at least one unit of the sample.

5 Documentation

Inferences drawn from the sampling plan and analyses shall be documented.

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PART III B

METHODS OF ANALYSIS/DRUG IDENTIFICATION

1 Introduction

The purpose of PART III B is to recommend minimum standards for the forensic identification of commonly seized drugs. It is recognized that the correct identification of a drug or chemical depends on the use of an analytical scheme based on validated methods and the competence of the analyst. SWGDRUG requires the use of multiple uncorrelated techniques. It does not discourage the use of any particular method within an analytical scheme and it is accepted that unique requirements in different jurisdictions may dictate the actual practices followed by a particular laboratory.

2 Categorizing analytical techniques

Techniques for the analysis of drug samples may be classified into three categories based on their discriminating power. Table 1 provides examples of these techniques listed in order of decreasing discriminating power from A to C.

Table 1: Categories of Analytical Techniques

Category A	Category B	Category C
Infrared Spectroscopy	Capillary Electrophoresis	Color Tests
Mass Spectrometry	Gas Chromatography	Fluorescence Spectroscopy
Nuclear Magnetic Resonance Spectroscopy	Ion Mobility Spectrometry	Immunoassay
Raman Spectroscopy	Liquid Chromatography	Melting Point
	Microcrystalline Tests	Ultraviolet Spectroscopy
	Pharmaceutical Identifiers	
	Thin Layer Chromatography	
	Cannabis only: Macroscopic Examination Microscopic Examination	

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3 Identification criteria

SWGDRUG recommends that laboratories adhere to the following minimum standards:

3.1 When a validated Category A technique is incorporated into an analytical scheme, then at least one other technique (from either Category A, B or C) shall be used.

3.1.1 This combination shall identify the specific drug present and shall preclude a false positive identification.

3.1.2 When sample size allows, the second technique should be applied on a separate sampling for quality assurance reasons. When sample size is limited, additional measures should be taken to assure that the results correspond to the correct sample.

3.1.3 All Category A techniques shall have data that are reviewable.

3.2 When a Category A technique is not used, then at least three different validated methods shall be employed.

3.2.1 These in combination shall demonstrate the identity of the specific drug present and shall preclude a false positive identification.

3.2.2 Two of the three methods shall be based on uncorrelated techniques from Category B.

3.2.3 A minimum of two separate samplings should be used in these three tests. When sample size is limited, additional measures should be taken to assure that the results correspond to the correct sample.

3.2.4 All Category B techniques shall have reviewable data.

3.3 For the use of any method to be considered of value, test results shall be considered "positive." While "negative" test results provide useful information for ruling out the presence of a particular drug or drug class, these results have no value toward establishing the forensic identification of a drug.

3.4 In cases where hyphenated techniques are used (e.g. gas chromatography-mass spectrometry, liquid chromatography-diode array ultraviolet spectroscopy), they will be considered as separate techniques provided that the results from each are used.

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3.5 Cannabis exhibits tend to have characteristics that are visually recognizable. Macroscopic and microscopic examinations of cannabis will be considered, exceptionally, as uncorrelated techniques from Category B when observations include documented details of botanical features. Additional testing shall follow the scheme outlined in sections 3.1 or 3.2.

3.5.1 For exhibits of cannabis that lack sufficient observable macroscopic and microscopic botanical detail (e.g. extracts or residues), Δ^9-tetrahydrocannabinol (THC) or other cannabinoids shall be identified utilizing the principles set forth in sections 3.1 and 3.2.

3.6 An identification of botanical material may be made utilizing morphological characteristics **alone** provided sufficient botanical features appropriate for identification are observed. Such examinations shall be made by analysts competent in botanical identifications. In this context botanical competence applies to those examiners recognized as professional botanists or those assessed to be competent by such. Identifications of chemical components contained in botanicals (mescaline, opiates, psilocin, etc.) should rely on principles of chemical identification set down in Table 1.

3.7 Examples of reviewable data are:

- printed spectra, chromatograms and photographs or photocopies of TLC plates
- contemporaneous documented peer review for microcrystalline tests
- reference to published data for pharmaceutical identifiers
- recording of detailed descriptions of morphological characteristics for cannabis (only).

4 Comment

These recommendations are minimum standards for the forensic identification of commonly seized drugs. However, it should be recognized that they may not be sufficient for the identification of all drugs in all circumstances. Within these recommendations, it is up to the individual laboratory's management to determine which combination of analytical techniques best satisfies the requirements of its jurisdiction.

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PART IV A

QUALITY ASSURANCE/GENERAL PRACTICES

1 Introduction

Recommendations in PART IV A 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 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, 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.

2 Quality management system

A documented quality management system shall be established and maintained.

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

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

3 Personnel

3.1 Job description

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

3.2 Designated personnel and responsibilities

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

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3.2.1 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.

3.2.2 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 monitors compliance with the program.

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

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

3.2.5 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.

3.2.6 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.

3.3 Qualifications/Education

3.3.1 Technical Support Personnel will

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

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

3.3.2 Technicians/Assistant Analysts will

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

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

3.3.3 Analysts will have EITHER

a) 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

b) 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.

3.3.4 Supervisors will

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.

3.4 Initial training requirements

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.

3.4.1 There shall 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.

3.4.2 The training program shall include the following:

a) documented standards of performance and a plan for assessing theoretical and practical competency against these standards (e.g.

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written and oral examinations, critical reviews, analysis of unknown samples and mock casework per topic area);

b) 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;

c) a period of supervised casework representative of the type the analyst will be required to perform;

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

3.5 Maintaining competence

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

3.5.1 Training shall be relevant to the laboratory's mission.

3.5.2 Training completed shall be documented.

4 Physical plant

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

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

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

4.4 A laboratory cleaning schedule shall be established and implemented.

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

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

5 Evidence control

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

5.1 Receiving and identifying evidence

Laboratories shall maintain records of requests for analysis and of the respective items of evidence. A unique identifier shall 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 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.

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

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.

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.

5.5 Documentation retention procedures

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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.

6 Analytical procedures

6.1 Analytical procedures for drug analysis

6.1.1 Laboratories shall have and follow documented analytical procedures.

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

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

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

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

6.1.6 Analytical procedures shall be validated in compliance with Section 11.

6.1.7 When analysts determine the identity of a drug in a sample, they shall 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.

6.2 Verification of drug reference materials

6.2.1 The identity of certified reference materials shall be verified prior to their first use.

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

6.2.3 Verification shall be performed on each new lot of drug reference material.

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

7 Instrument/Equipment performance

7.1 Instrument performance

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

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

7.1.2 Instrument performance monitoring shall be documented.

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

7.2 Equipment

7.2.1 Only suitable and properly operating equipment shall be employed.

7.2.2 Equipment performance parameters should be routinely monitored and documented.

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

8 Chemicals and reagents

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

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

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 and the expiration date (if appropriate).

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

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

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

9 Casework documentation, report writing and review

9.1 Casework documentation

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

9.1.2 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.

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.

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

9.2 Report writing

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

- identity of the testing laboratory
- case identifier
- submitting agency
- date of receipt
- date of report
- descriptive list of submitted evidence
- identity of analyst
- analytical techniques employed
- results
- conclusions.

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9.3 Case review

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

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

10 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.

10.1 Proficiency testing

10.1.1 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.

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

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

10.2 Competency testing

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

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

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

11 Analytical method validation and verification

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

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

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

11.1.3 Validation documentation is required.

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

12 Laboratory audits

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

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

13 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 shall have a documented policy to address such deficiencies.

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.

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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 may have had on other activities of the individual or other analysts;

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.

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14 Health and safety

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

14.1 Health and safety requirements

14.1.1 All personnel should receive appropriate health and safety training.

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

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

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

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

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

15 Additional documentation

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

- test methods/procedures for drug analysis
- reference standards (including source and verification)
- preparation and testing of reagents
- evidence handling protocols
- instrument and equipment calibration and maintenance
- instrument and 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.

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PART IV B

QUALITY ASSURANCE/VALIDATION OF ANALYTICAL METHODS

1 Introduction

1.1 Definition and purpose of validation

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. There are numerous documents that address the topic of validation but there are few validation protocols for methods specific to seized drug analysis.

1.2 Analytical scheme

An analytical scheme shall be comprised of validated methods that are appropriate for the analyte.

1.2.1 The combinations of methods chosen for a particular analytical scheme shall identify the specific drug of interest, preclude a false positive and minimize false negatives.

1.2.2 For quantification the method should reliably determine the amount of analyte present.

1.2.3 If validated methods are used from published literature or another laboratory's protocols, then the methods shall be verified within each laboratory.

1.2.4 If non-routine validated methods are used, then the method shall be verified prior to use.

1.2.5 Verification should, at a minimum, demonstrate that a representative set of reference materials has been carried through the process and yielded the expected results.

1.3 Individual laboratory responsibility

Each laboratory should determine whether their current standard operating procedures have been validated, verified or require further validation/verification.

1.4 Operational environment

All methods shall be validated or verified to demonstrate that they will perform in the normal operational environment when used by individuals expected to utilize the methods on casework.

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1.5 Documentation

The entire validation/verification process shall be documented and the documentation shall be retained. Documentation shall include, but is not limited to the following:

- personnel involved
- dates
- observations from the process
- analytical data
- a statement of conclusions and/or recommendations
- authorization approval signature.

1.6 Recommendation

To meet the above requirements, SWGDRUG recommends that laboratories follow the applicable provisions of Section 2 [General Validation Plan] when validating seized drug analytical methods. For further information, see supplemental document SD-2 (Preparing Validation Plans, Section I: Analytical Techniques – Elements to Consider and Section II: Example Validation Plan for GC/MS Identification and Quantitation of Heroin).

2 General validation plan

2.1 Purpose/scope

This is an introductory statement that will specify what is being tested, the purpose of the testing and the result(s) required for acceptance.

2.1.1 Performance specification

A list of specific objectives (e.g., trueness and precision) should be determined prior to the validation process.

2.1.2 Process review

After completion of the validation process the objectives should be revisited to ensure that they have been satisfactorily met.

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2.2 Analytical method

State exactly the method to be validated. It is essential that each step in the method be demonstrated to perform satisfactorily. Steps that constitute a method for the identification and/or quantification of seized drugs may include:

- visual characterization (e.g., macroscopic examination)
- determination of quantity of sample, which may include:
  - weight
  - volume
  - item count
- sampling (representative or random, dry, homogenized, etc.)
- stability of analyte
- sample preparation
  - extraction method
  - dissolution
  - derivatization
  - crystallization
  - techniques for introducing sample into instrumentation
- instrumental parameters and specifications
  - list the instruments and equipment (e.g., balance and glassware) utilized
  - instrument conditions
- software applications (e.g., software version, macros)
- calculations
  - equation(s) to be used
  - unit specification
  - number of measurements required
  - reference values
  - significant figure conventions
  - conditions for data rejection
  - uncertainty determination.

2.3 Reference materials

Appropriate reference material(s) shall be used for qualitative and quantitative procedures. Traceability of the reference material is required.

2.4 Performance characteristics

2.4.1 Selectivity

Assess the capability of the method to identify/quantify the analyte(s) of interest, whether pure or in a mixture.

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2.4.2 Matrix effects

Assess the impact of any interfering components and demonstrate that the method works in the presence of substances that are commonly encountered in seized drug samples (e.g. cutting agents, impurities, by-products, precursors).

2.4.3 Recovery

May be determined for quantitative analysis.

2.4.4 Accuracy

2.4.4.1 Precision (Repeatability/Reproducibility)

Determine the repeatability and reproducibility of all routine methods. Conditions under which these determinations are made shall be specified.

NOTE Reproducibility determination may be limited to studies within the same laboratory.

2.4.4.1.1 Within the scope of the validation, determine acceptable limits for repeatability and reproducibility.

2.4.4.1.2 For qualitative analysis, run the qualitative method a minimum of ten times.

2.4.4.1.3 For quantitative analysis run the quantitative method a minimum of ten times.

2.4.4.1.4 Validation criteria for non-routine methods may differ from what is stated above.

2.4.4.2 Trueness

Trueness shall be determined for quantitative methods to assess systematic error. Trueness can be assessed through various methods such as:

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- comparison of a method-generated value for the reference material with its known value using replicate measurements at different concentrations
- performance of a standard addition method
- comparison to proficiency test results
- comparison with a different validated analytical method.

2.4.5 Range

Determine the concentration or sample amount limits for which the method is applicable.

2.4.5.1 Limit of detection (LOD)

Limit of detection shall be determined for all qualitative methods.

2.4.5.1.1 Determine the lowest amount of analyte that will be detected and can be identified.

2.4.5.1.2 The results obtained at the LOD are not necessarily quantitatively accurate.

2.4.5.2 Limit of quantitation (LOQ)

Limit of Quantitation shall be determined for all quantitative methods. Determine the lowest concentration that has an acceptable level of uncertainty.

2.4.5.3 Linearity

Linearity shall be determined for all quantitative methods.

2.4.5.3.1 Determine the mathematical relationship (calibration curve) that exists between concentration and response over a selected range of concentrations.

2.4.5.3.2 The LOQ effectively forms the lower end of the working range.

2.4.5.3.3 Determine the level of acceptable variation from the calibration curve at various concentrations.

2.4.5.3.4 Determine the upper limits of the working range.

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2.4.6 Robustness

Robustness shall be determined for either qualitative or quantitative methods. Alter method parameters individually and determine any changes to accuracy.

2.4.7 Ruggedness

Ruggedness may be determined for either qualitative or quantitative methods. Ruggedness should assess the factors external to the method.

2.4.8 Uncertainty

The contribution of random and systematic errors to method result uncertainty shall be assessed and the expanded uncertainty derived for quantitative methods.

3 Quality control

Acceptance criteria for quality control parameters should be adopted prior to implementation of the method.

4 References

a) *The Fitness for Purpose of Analytical Methods, A Laboratory Guide to Method Validation and Related Topics*, EURACHEM Guide, 1998.

b) *Federal Register, Part VIII*, Department of Health and Human Services, March 1995, pages 11259-62.

c) "Validating Analytical Chemistry Methods", Enigma Analytical Training Course (Version 2000-1), Breckenridge, CO, 2000, pages 8-4, 8-5.

d) "Guidelines for Forensic Science Laboratories", ILAC-G19:2002, page 10.

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PART IV C

Quality Assurance/Uncertainty

1 Introduction

This recommendation provides guidance on the concept of uncertainty and its application to the qualitative and quantitative analysis of seized drugs. In this context, uncertainty encompasses limitations of qualitative methods as well as numerical ranges as applied to quantitative analyses.

1.1 SWGDRUG considers an understanding of uncertainty to be fundamental to the interpretation and reporting of results.

1.2 The term “uncertainty” does not imply doubt; rather, its consideration provides assurance that results and conclusions from methods and analytical schemes are fit for purpose.

1.3 SWGDRUG recommends the concept of uncertainty be considered for all analytical results.

1.4 Laboratory management shall ensure that uncertainty be addressed through the provision of training, procedures and documentation.

1.5 Laboratory management should consider customer requirements which influence the application of uncertainty.

1.6 Benefits

The benefits of determining and understanding uncertainty include:

- Enhancing confidence through increased understanding of results
- Providing a mechanism to express the reliability of results
- Enabling the laboratory and customer to evaluate the fitness for purpose of results
- Facilitating the identification of procedural limitations and providing a basis for improvement
- Complying with accreditation requirements

1.7 Application of uncertainty

Qualitative and quantitative analyses require different approaches. Analysts shall understand the limitations of qualitative and quantitative determinations and have tools to estimate a value for measurement uncertainty of relevant, but not necessarily all, numerical results. In this regard, efforts should be made to use the vocabulary, symbols, and

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formatting expressed in documents published by international standardizing organizations such as ISO and ASTM-International.

2 Qualitative Analysis

The identification of seized drugs requires the combination of methods to form an analytical scheme (see PART III B - Methods of Analysis/Drug Identification).

2.1 Individual methods have limitations and, consequently, uncertainty. Uncertainty of qualitative methods is not typically expressed in numerical terms.

2.2 Understanding these limitations enables the laboratory or analyst to build an appropriate analytical scheme to correctly identify a drug or chemical.

2.2.1 It is expected that an appropriate analytical scheme will result in, effectively, no uncertainty in reported identifications.

2.2.2 Relevant limitations of an analytical scheme (e.g., inability to differentiate isomers, unavailability of reference standard) should be documented and may need to be included in the report (see reporting examples).

3 Quantitative Measurements

3.1 Quantitative measurements have an associated uncertainty, which is defined as "an estimate attached to a test result which characterizes the range of values within which the true value is asserted to lie" (see Glossary).

3.2 A precise calculation of measurement uncertainty is not always required.

3.2.1 A laboratory shall understand the contributing factors of measurement uncertainty for each analytical procedure and evaluate them with respect to customer, accreditation or jurisdictional requirements.

3.2.2 Where a value is critical, such as a weight or purity level close to a statutory threshold, an appropriate measurement uncertainty determination shall be applied.

3.3 Primary numerical values reported in the analysis of seized drugs are weight and purity. Where other values are measured (e.g., size, volume, estimated tablet numbers), the same principles stated herein apply.

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4 Estimation of measurement uncertainty for quantitative determinations

4.1 Sources of uncertainty for weight determination

4.1.1 The uncertainty of a reported value is dependant on the weighing process. Factors for consideration include:

- Single versus multiple items (number of weighing operations)
- Tare function as a separate weighing operation
- Extrapolation of population weight from limited sampling of multiple items
- Aggregate weighings
- Incomplete recovery of material from the packaging
- Balance selection (e.g., readability, capacity)
- Balance operation (e.g., sample placement on pan, environmental conditions)

4.2 Sources of uncertainty for purity determination

The uncertainty of a reported purity value is dependant upon the entire quantitation process. Factors for consideration include:

- Sampling plan (e.g., handling of multiple exhibits)
  - Sample homogeneity
- Analytical method
  - Sample preparation (e.g., sample size, matrix effects, solubility)
  - Analytical technique
  - Reference material (e.g., purity of standard)
  - Equipment and instrument properties (e.g., glassware, pipetters, balances, chromatographs)
  - Concentration of analyte
  - Environmental conditions

4.3 Factors relevant to estimation of measurement uncertainty

4.3.1 When estimating measurement uncertainty, the following sources of error shall be considered:

4.3.1.1 Analytical Error: Systematic and random error both contribute to measurement uncertainty and shall be addressed through method validation and quality assurance practices (Part IV B). SWGDRUG recommends that for all validated procedures, systematic error is characterized and minimized.

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4.3.1.2 Sampling Error: The sample and sampling procedure are often the greatest contributors to measurement uncertainty.

4.3.2 Where appropriate, confidence levels (e.g., 95% or 99.7%) shall be selected based on considerations relevant to the analytical context.

4.3.3 Uncertainty information shall be recorded in validation documents and/or case records.

4.4 Approaches for estimating measurement uncertainty

4.4.2 Uncertainty budget approach

4.4.2.1 In this approach all sources of error are separately identified and tabulated.

4.4.2.2 A value is assigned to each source of error (collectively or individually) using either:

- empirical data (e.g., from validation process, historical performance data, control chart data, proficiency tests)
- published data (e.g., volumetric glassware tolerances)
- combination of empirical and published data

4.4.2.3 Where a source has an uncertainty which is insignificant compared to other sources, it can be excluded.

4.4.2.4 The remaining significant values are used to calculate the combined standard uncertainty and expanded uncertainty.

4.4.3 Non-budget approaches

4.4.3.1 The sources of uncertainty that are separately assessed in the budget method are collectively assessed by experimental measurement. In this approach data obtained from a statistically significant number of replicate analyses utilizing a validated method with an appropriate sampling plan may be utilized to calculate the standard or expanded uncertainty.

4.4.3.2 An alternate approach involves the use of two standard deviations (2σ) of the test method results from reproducibility data from the validation studies. This

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provides an approximation of the measurement uncertainty for non-critical values.

5 Reporting of uncertainty

5.1 Reporting

Uncertainty should be reported when it may impact the use of a result by the customer. Factors which influence the decision to report uncertainty include:

5.1.1 Jurisdictional

- Prevailing statutory requirement
- Relevant governing body (agency) requirements
- Customer requests
- Potential exculpatory value

5.1.2 Types of Analysis

- Qualitative: Qualitative results where limitations of analytical scheme are known and relevant (e.g., inability to differentiate isomers, unavailability of reference standard)
- Quantitative: Quantitative measurements where a value is critical (e.g., weight or purity level close to a statutory threshold)

5.1.3 Laboratory accreditation requirements

5.2 Reporting Examples

Reporting requirements and styles differ among agencies. The examples listed below are drawn from laboratories with varied requirements.

5.2.1 Qualitative Results

5.2.1.1

Contains ephedrine or pseudoephedrine. Item tested: 5.2 grams net.

5.2.1.2

Visual examination determined that the physical characteristics are consistent with a Schedule IV pharmaceutical preparation containing Diazepam. There was no apparent tampering of the dosage units and no further tests are being conducted.

5.2.1.3

Contains cocaine (salt form not determined)

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5.2.2 Quantitative Results

Factors to be considered when reporting measurement uncertainty include use of significant figures, confidence intervals and rounding/truncating of results.

5.2.2.1 Active drug ingredient (established or common name) methamphetamine hydrochloride
Gross weight: 25.6 grams
Net weight: 5.2 grams
Conc. or purity: 54.7% (± 2.8%)*
Amount of actual drug: 2.8 grams
Reserve weight: 5.1 grams

* This value represents the quantitative uncertainty measurement estimate for the laboratory system.

5.2.2.2 Positive for cocaine in the sample tested
Net weight of total sample: 5.23 grams ± 0.03 grams
Quantitation: 54.7% ± 2.8%

5.2.2.3 Sample tested positive for cocaine
Net weight: 5.23 grams
Purity: 54.7%
Confidence Range: ± 2.8%*
Calculated net weight of drug: 2.8 grams of cocaine

*Confidence range refers to a 95% confidence level.

5.2.2.4 Cocaine was identified in the Item 1 powder at a purity of 65 ± 9% (99.7% confidence level). The Item 1 powder weighed 800 ± 4 mg (99.7% confidence level).

5.2.2.5 White powder: 5.6 grams

The range of heroin concentration identified in the sample was not less than 53.2% and not more than 56.2%.

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6 Training

6.1 Individuals responsible for determining, evaluating and documenting uncertainty in the context of seized-drug analysis shall be capable of competently demonstrating familiarity with foundational concepts and principles of estimating uncertainty.

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6.1.1 Useful topics to review include:

- General metrology to include: terminology, symbols, formulae, publications, international organizations, and global application as related to seized-drug analysis
- The concepts of random and systematic error, accuracy, precision (repeatability, reproducibility, and their conditions), statistical control, standard and expanded uncertainty, and propagation of error
- Reporting conventions including use of significant figures, truncation and rounding
- Basic statistics (descriptive and inferential) to include: measures of central tendency (e.g., median), measures of variation, statistical modeling, sampling, probability, confidence interval, and significance level

6.2 All analysts shall be capable of explaining their laboratory's procedures for evaluating uncertainty of qualitative and quantitative analyses.

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ANNEX A

SWGDRUG GLOSSARY OF TERMS AND DEFINITIONS

A.1 Introduction

This glossary of terms and definitions has been developed and adopted by the SWGDRUG core committee from a variety of sources that are listed in endnotes. In some instances, the core committee modified existing definitions or created definitions where none could be found in standard references.

A.2 Terms and definitions

A.2.1 accuracy

the closeness of agreement between a test result and the accepted reference value

NOTE The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.

[ISO 3534-1:1993 (E/F)]

A.2.2 analyst

a designated person who:

- examines and analyzes seized drugs or related materials, or directs such examinations to be done,
- independently has access to unsealed evidence in order to remove samples from the evidentiary material for examination and,
- as a consequence of such examinations, signs reports for court or other purposes

[SWGDRUG]

A.2.3 analyte

the component of a system to be analyzed

[IUPAC]

A.2.4 audit

systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled

[ISO 9000:2005 (E)]

A.2.5 bias

the difference between the expectation of the test results and an accepted reference value

NOTE Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

[ISO 3534-1:1993 (E/F)]

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A.2.6 blank

specimen or sample not containing the analyte or other interfering substances

[Modified UNDCP Definition]

A.2.7 calibration

set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards

NOTES

1. The result of a calibration permits either the assignment of values of measurands to the indications or the determination of corrections with respect to indications.
2. A calibration may also determine other metrological properties such as the effect of influence quantities.
3. The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.

[ISO VIM]

A.2.8 certified reference material (CRM)

reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence

NOTES

1. The definition of a “reference material certificate” is given in 4.2 (IVIM).
2. CRMs are generally prepared in batches for which the property values are determined within stated uncertainty limits by measurement on samples representative of the whole batch.
3. The certified properties of reference materials are sometimes conveniently and reliably realized when the material is incorporated into a specially fabricated device, e.g. a substance of known triple-point into a triple-point cell; a glass of known optical density into a transmission filter; spheres of uniform particle size mounted on a microscope slide. Such devices may also be considered as CRMs.
4. All CRMs lie within the definition of measurement standards or etalons given in the International vocabulary of basic and general terms in metrology (VIM).
5. Some RMs and CRMs have properties which, because they cannot be correlated with an established chemical structure or for other reasons, cannot be determined by exactly defined physical and chemical measurement methods. Such materials include certain biological materials such as vaccines to which an International unit has been assigned by the World Health Organization.

[ISO GUIDE 30:1992 (E/F), ISO VIM]

A.2.9 chain of custody

procedures and documents that account for the integrity of a specimen or sample by tracking its handling and storage from its point of collection to its final disposition

[UNDCP]

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A.2.10 combined standard uncertainty

standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities

[ISO-GUM]

A.2.11 control

material of established origin that is used to evaluate the performance of a test or comparison

[ASTM E1732-96a]

A.2.12 deficiency of analysis

any erroneous analytical result or interpretation, or any unapproved deviation from an established policy or procedure in an analysis

[SWGDRUG]

A.2.13 detection limit

the lowest concentration of analyte in a sample that can be detected, but not necessarily quantitated under the stated conditions of the test

[EURACHEM, NATA Tech Note #13]

A.2.14 expanded uncertainty (U)

quantity defining an interval about a result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand

NOTES

1. The fraction may be regarded as the coverage probability or level of confidence of the interval.
2. To associate a specific level of confidence with the interval defined by the expanded uncertainty requires explicit or implicit assumptions regarding the probability distribution characterized by the measurement result and its combined standard uncertainty. The level of confidence that may be attributed to this interval can be known only to the extent to which such assumptions can be justified.
3. An expanded uncertainty U is calculated from a combined standard uncertainty u_c and coverage factor k using: $U = k \times u_c$

[EURACHEM, ISO-GUM]

A.2.15 false positive

test result that states that an analyte is present, when, in fact, it is not present or, is present in an amount less than a threshold or designated cut-off concentration

[SWGDRUG]

A.2.16 limit of detection

see A.2.12 *detection limit*

A.2.17 limit of quantitation

the lowest concentration of an analyte that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test

[EURACHEM, NATA technical note #13]

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A.2.18 linearity
defines the ability of the method to obtain test results proportional to the concentration of analyte

NOTE The Linear Range is by inference the range of analyte concentrations over which the method gives test results proportional to the concentration of the analyte.

[EURACHEM, AOAC-PVMC]

A.2.19 pharmaceutical identifiers
physical characteristics of tablets, capsules or packaging indicating the identity, manufacturer, or quantity of substances present

[SWGDRUG]

A.2.20 population
the totality of items or units of material under consideration

NOTE The word “items” may be interpreted in the sense of measurements, or possible measurements, of a single characteristic, or occasionally for multiple characteristics, on all items or units of material being considered. The word “totality” may refer to items not available for inclusion in samples as well as those which are available.

[ASTM E456-04]

A.2.21 precision
the closeness of agreement between independent test results obtained under stipulated conditions

NOTES
1. Precision depends only on the distribution of random errors and does not relate to the true value or the specified value.
2. The measure of precision usually is expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.
3. “Independent test results” means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme stipulated conditions.

[ISO 3534-1:1993 (E/F)]

A.2.22 procedure
specified way to carry out an activity or process

NOTES
1. Procedures can be documented or not.
2. When a procedure is documented, the term “written procedure” or “documented procedure” is frequently used. The document that contains a procedure can be called a “procedure document.”

[ISO 9000:2005 (E)]

A.2.23 proficiency testing
ongoing process in which a series of proficiency specimens or 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. An accreditation body may

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specify participation in a particular proficiency testing scheme as a requirement of accreditation.

[UNDCP]

A.2.24 qualitative analysis

analysis in which substances are identified or classified on the basis of their chemical or physical properties, such as chemical reactivity, solubility, molecular weight, melting point, radiative properties (emission, absorption), mass spectra, nuclear half-life, etc. See also A.2.28 *quantitative analysis*

[IUPAC]

A.2.25 quality assurance

part of quality management focused on providing confidence that quality requirements will be fulfilled.

[ISO 9000:2005 (E)]

A.2.26 quality management

coordinated activities to direct and control an organization with regard to quality

NOTE Direction and control with regard to quality generally includes establishment of the quality policy and quality objectives, quality planning, quality control, quality assurance and quality improvement.

[ISO 9000:2005 (E)]

A.2.27 quality manual

document specifying the quality management system of an organization

NOTE Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

[ISO 9000:2005 (E)]

A.2.28 quantitative analysis

analyses in which the amount or concentration of an analyte may be determined (estimated) and expressed as a numerical value in appropriate units. Qualitative analysis may take place without quantitative analysis, but quantitative analysis requires the identification (qualification) of the analytes for which numerical estimates are given

[IUPAC]

A.2.29 random sample

the sample so selected that any portion of the population has an equal (or known) chance of being chosen. Haphazard or arbitrary choice of units is generally insufficient to guarantee randomness

[IUPAC]

A.2.30 recovery

term used in analytical and preparative chemistry to denote the fraction of the total quantity of a substance recoverable following a chemical procedure

[IUPAC]

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A.2.31 reference material (RM)

material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials

NOTE – A reference material may be in the form of a pure or mixed gas, liquid or solid. Examples are water for the calibration of viscometers, sapphire as a heat-capacity calibrant in calorimetry, and solutions used to for calibration in chemical analysis.

[ISO GUIDE 30:1992, VIM]

A.2.32 repeatability (of results of measurements)

closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement

NOTES

1. These conditions are called repeatability conditions.
2. Repeatability conditions include:
   - the same measurement procedure
   - the same observer
   - the same measuring instrument, under the same conditions
   - the same location
   - repetition over a short period of time.
3. Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

[VIM]

A.2.33 reproducibility (of results of measurements)

closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement

NOTES

1. A valid statement of reproducibility requires specification of the conditions changed.
2. The changed conditions may include:
   - principle of measurement
   - method of measurement
   - observer
   - measuring instrument
   - reference standard
   - location
   - condition of use
   - time.

[VIM]

A.2.34 robustness

the robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage

[EURACHEM, ICH Q2A, CPMP/CH/381/95]

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A.2.35 ruggedness
The ruggedness of an analytical method is the degree of reproducibility of test results obtained by the analysis of the same samples under a variety of conditions, such as different laboratories, analysts, instruments, lots of reagents, elapsed assay times, assay temperatures, or days. Ruggedness is normally expressed as the lack of influence on test results of operational and environmental variables of the analytical method. Ruggedness is a measure of reproducibility of test results under the variation in conditions normally expected from laboratory to laboratory and from analyst to analyst.

[USP 28: 2005]

A.2.36 sample
one or more sampling units taken from a population and intended to provide information on the population

NOTE A sample may serve as a basis for a decision on the population or on the process which produced it.

[ISO 3534-1:1993 (E/F)]

A.2.37 sampling
the process of drawing or constituting a sample

[ISO 3534-1:1993 (E/F)]

A.2.38 sampling plan
a specific plan which states the sample size(s) to be used and the associated criteria for accepting the lot

NOTES
1. A criterion is, for example, that the number of nonconforming items is less than or equal to the acceptance number.
2. The sampling plan does not contain the rules on how to take the sample.

[ISO 3534-2:1993 (E/F)]

A.2.39 sampling procedure
operational requirements and/or instructions relating to the use of a particular sampling plan; i.e., the planned method of selection, withdrawal and preparation of sample(s) from a lot to yield knowledge of the characteristic(s) of the lot

[ISO 3534-2:1993 (E/F)]

A.2.40 sampling scheme
a combination of sampling plans with rules for changing from one plan to another

NOTE Some schemes have switching rules for automatic change to tightened inspection plans or reduced inspection plans or change to 100 % inspection.

[ISO 3534-2:1993 (E/F)]

A.2.41 selectivity (in analysis)
1. (Qualitative): The extent to which other substances interfere with the determination of a substance according to a given procedure.

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2. (Quantitative): A term used in conjunction with another substantive (e.g. constant, coefficient, index, factor, number) for the quantitative characterization of interferences.

[IUPAC]

A.2.42 standard uncertainty

uncertainty of the result of a measurement expressed as a standard deviation

[ISO-GUM]

A.2.43 traceability

ability to trace the history, application or location of that which is under consideration

NOTES

1. When considering product, traceability can relate to
   - the origin of materials and parts,
   - the processing history, and
   - the distribution and location of the product after delivery.
2. In the field of metrology the definition in VIM:1993, 6.10, is the accepted definition.

[ISO 9000:2005 (E)]

A.2.44 trueness

the closeness of agreement between the average value obtained from a large series of test results and an accepted reference value

NOTES

1. The measure of trueness is usually expressed in terms of bias.
2. Trueness has been referred to as “accuracy of the mean.” This usage is not recommended.

[ISO 3534-1:1993 (E/F)]

A.2.45 uncertainty (measurement)

an estimate attached to a test result which characterizes the range of values within which the true value is asserted to lie

NOTES

1. Uncertainty of measurement comprises, in general, many components. Some of these components may be estimated on the basis of the statistical distribution of the results of a series of measurements and can be characterized by standard deviations. Estimates of other components can only be based on experience or other information.
2. Uncertainty should be distinguished from an estimate attached to a test result which characterizes the range of values within which the expectation is asserted to lie. This latter is a measure of precision rather than of accuracy and should be used only when the true value is not defined. When the expectation is used instead of the true value the expression “random component of uncertainty” should be used.

[ISO 3534-1:1993 (E/F)]

A.2.46 uncorrelated techniques

Uncorrelated techniques are those that yield uncorrelated measurements. In practice this is often achieved by using techniques that have a different fundamental mechanism for characterization. For example, a gas chromatographic test based on a partition

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mechanism and a thin layer chromatographic system based on an adsorption mechanism would be considered uncorrelated techniques, but two gas chromatographic tests based on a partition mechanism would not.

[SWGDRUG]

A.2.47 validation

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTES

1. The term “validated” is used to designate the corresponding status.
2. The use conditions for validation can be real or simulated.

[ISO 9000:2005(E)]

A.2.48 verification

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

NOTES

1. The term “verified” is used to designate the corresponding status.
2. Confirmation can comprise activities such as:
   - performing alternative calculations,
   - comparing a new design specification with a similar proven design specification,
   - undertaking tests and demonstrations, and
   - reviewing documents prior to issue.

[ISO 9000:2005(E)]

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