

**International benchmarking
of
quality management
in
forensic science drug laboratories**

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**Internasionale maatstaf
van
kwaliteitsbestuur
in
forensiesewetenskap dwelm laboratoriums**

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To HIM who believed in me, more than I did

To HIM who supported me, more than I deserved

To HIM who helped me, more than I can ever repay

To HIM who provided me with knowledge and wisdom

Abstract

Since the early 1980s, laboratory managers in the field of forensic science were introduced to the first international standards for testing and calibration laboratories. Now almost three decades later every laboratory should have some level of quality management system implemented to assure the quality of results. With all the quality standards and requirements in the global arena, proper assessment is necessary to ensure that quality standards are harmonised across laboratories.

The aim of this study was first to establish the extent of quality standards and recommendations within the forensic drug environment and secondly, the level to which they were implemented in forensic drug laboratories globally. A questionnaire was developed to measure quality variables according to five categories in forensic drug laboratories, namely equipment, personnel, quality assurance and quality control, customer relationship as well as productivity. A total of seventy international drug laboratories participated in the study which consisted of laboratories from the United States of America, Canada, Australia, New Zealand, Belgium, Finland, Netherlands, Switzerland, Taiwan and Israel. To make statistical inferences on the greater population of forensic drug laboratories, all data was converted to proportions. These proportions were compared to international quality standards such as ISO 17025 and ASCLD/LAB.

International forensic drug laboratories use similar analytical methodology when analysing drug samples. These techniques comply with ISO standards and can be accepted within any jurisdiction, if operated and maintained correctly. Laboratory managers should however pay more attention to maintenance and procurement plans. All the laboratories appoint qualified scientists and have internal training programs to ensure that technical staff are qualified and competent when performing specialised tasks. More attention should however, be given to mentorship programs to assess and coach new technical staff. The majority of laboratories complied with the technical and managerial ISO requirements on quality control and quality assurance, in spite of a non-standardised sampling scheme. Although laboratories have a good relationship with their customers, staff shortages will lead to extended turn around times which will influence customer satisfaction over time. Furthermore, small drug laboratories, translating to a small staff quotient, were determined to be more productive than larger laboratories. This study ultimately, underscores the fact that an established quality system and an effective

laboratory information management system will contribute to higher productivity in a forensic laboratory environment.

Opsomming

Laboratorium bestuurders in die veld van forensiese wetenskap was sedert die vroeë 1980's blootgestel aan die eerste internasionale standaarde vir toets en kalibrasie laboratoriums. Nou, amper drie dekades later behoort elke laboratorium 'n geïmplimenteerde kwaliteitsbestuursstelsel op 'n sekere vlak te hê om die kwaliteit van resultate te verseker. Met al die kwaliteitstandaarde en aanbevelings in die internasionale arena, is dit nodig om behoorlike evaluasie daarop uit te oefen om te verseker dat kwaliteitstandaarde geharmoniseer is tussen laboratoriums.

Die eerste doel van die studie was om die mate van kwaliteit standaarde en aanbevelings binne die forensiese dwelm omgewing te bepaal en tweedens om die implimenteringsvlak daarvan in forensiese dwelm laboratoriums wêreldwyd te evalueer. 'n Vraelys was opgestel om sodoende kwaliteitsveranderlikes in forensiese dwelm laboratoriums te evalueer onder vyf kategorieë, naamlik toerusting, personeel, kwaliteitsversekering en kwaliteitsbeheer, kliënte verhouding en produktiwiteit. Sewentig internasionale dwelm laboratoriums van die Verenigde State van Amerika, Kanada, Australië, Nieu-Seeland, België, Finland, Nederland, Switserland, Taiwan en Israel het deelgeneem. Om statistiese afleidings te maak van die groter bevolking, was alle data as proporsies uitgedruk. Hierdie proporsies is met internasionale kwaliteitstandaarde soos ISO 17025 en ASCLD/LAB vergelyk.

Internasionale forensiese dwelm laboratoriums gebruik soortgelyke analitiese metodiek in die analisering van dwelm monsters. Die tegnieke voldoen aan die ISO standaarde en behoort deur enige regstelsel aanvaar te word, indien die proses reg toegepas en onderhou word. Laboratorium bestuurders moet egter meer aandag skenk aan formele onderhouds- en aankoop prosedures. Alle laboratoriums stel gekwalifiseerde wetenskaplikes aan en het interne opleidingsprogramme om te verseker dat tegniese personeel gekwalifiseer en bekwaam is om gespesialiseerde take uit te voer. Daar moet egter meer aandag geskenk word aan mentorskap programme om nuwe tegniese personeel op te lei en te evalueer. Ten spyte van 'n nie-gestandardiseerde monsternemings skema, voldoen meerderheid van laboratoriums aan die ISO tegniese- en bestuursvereistes verwysend na kwaliteitsbeheer en kwaliteitsversekering. Alhoewel laboratoriums goeie verhoudinge met hul kliënte het, sal personeel tekorte lei tot verlengde draaitye en sodoende kliënte tevredenheid beïnvloed oor tyd. Daar was vasgestel dat

kleiner dwelm laboratoriums, verwysend na 'n klein personeel hoeveelheid, meer produktief is as groter laboratoriums. Hierdie studie beklemtoon dat 'n gevestigde kwaliteitstelsel en 'n effektiewe laboratoriuminformasiebestuurstelsel bydra tot hoër produktiwiteit in die forensiese dwelm laboratorium omgewing.

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LIST OF ABBREVIATIONS AND SYMBOLS

ABC	American Board of Criminalistics
A.C.S.	American Chemical Society
APLAC	Asian Pacific Laboratory Accreditation Cooperation
AQAP	Allied Quality Assurance Publications
AR	Analytical Reagent
ASCLD	American Society of Crime Laboratory Directors
ASCLD/LAB	American Society of Crime Laboratory Directors/ Laboratory Accreditation Board
BC	Before Christ
BSI	British Standards Institution
CCI	Californian Criminalistic Institute
CI	confidence interval
CITAC	Cooperation on International Traceability in Analytical Chemistry
CLIC	Clandestine Laboratory Investigation for Chemists
CP	chemical pure
CRE	Home Office Central Research Establishment
CRM	certified reference material
CSF's	Critical Success Factors
CSI	crime scene investigation
CTS	Collaborative Testing Services
DNA	deoxyribonucleic acid
DEA	Drug Enforcement Administration
DQ	design qualification
Ed.	Edition
e.g.	for example
EMS	exhibit management system
EN	European Nation
ENFSI	European Network of Forensic Science Institutes
ESR	Environmental Science & Research
ENFSI:DWG	European Network of Forensic Science Institutes Drug Working Group
FCC	Food Chemical Codex
FDA	Food and Drug Administration
FIMS	Forensic Information Management System
FSL	Forensic Science Laboratory
FSS	Forensic Science Services
FTE	Full Time Equivalent
FT-IR	Fourier Transform Infrared Spectroscopy
GC	Gas chromatography
GC/MS	Gas chromatography mass spectrometry
GLP	Good Laboratory Practise
GMP	Good Manufacturing Practise
GR	guaranteed reagent
HPLC	high performance liquid chromatography
ICH	International Conference on Harmonisation
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IO	Investigating Officer
IQ	Installation Qualification
IR	Infrared Spectroscopy
ISA	International Federation of the National Standardising Association
ISO	International Organisation of Standardisation
IUPAC	International Union of Pure and Applied Chemistry
KPI's	key performance indicators
Lab Grade	laboratory grade
LC	liquid chromatography
LGC	Laboratory of the Government Chemist
LIMS	laboratory information management system
LUF	Labour Utilisation Factor
MS	mass spectrometry
MSDS	Material Safety Data Sheets

N	population of forensic drug laboratories represented on CLIC
<i>N</i>	The maximum percent overtime that is deemed acceptable
<i>n</i>	representative sample
<i>n</i>	Total number of laboratories who answered the specific question
NAMAS	National Measurement & Accreditation Service
NAO	National Audit Office
NAS	National Academy of Sciences
NATA	National Association of Testing Authorities
NATO	North Atlantic Treaty Organisation
NDID	National Drug Intelligence Database
NF	National Formulary
NFSTC	National Forensic Science Testing Centre
NMR	nuclear magnetic resonance
OECD	The Organization for Economic Co-operation and Development
OR	organic reagent
ORA	Office of Regulatory Affairs
ONDCP	Office of National Drug Control Policy
OQ	operation qualification
<i>p</i>	proportion of laboratories replied
<i>pp</i>	pages
PQ	performance qualification
PRP	Proficiency Review Program
QA	quality assurance
QAU	quality assurance unit
QC	quality control
QCM	quality control material
QM	quality management
RCMP	Royal Canadian Mounted Police
RM	reference material
SABS	South African Bureau of Standards
SANAS	South African National Accreditation System
SCC	Standard Council of Canada
SD	standard deviation
SEM	scanning electron microscopy
SMANZFL	Senior Managers of Australia and New Zealand Forensic Science Laboratories
SMS	short message service
SOP's	Standard Operating Procedures
SWGDRUG	Scientific Working Group for the analysis of seized drugs
TAT	turn around times
TG06-01	Technical Guide 06-01
T.I.Q.M.S	Technicon Institute of Quality Management and Statistics
TLC	thin-layer chromatography
TQM	Total Quality Management
TWGDRUG	Technical Working Group for the analysis of seized drugs
UN	United Nations
UNDCP	United Nations Drug Control Program
UNODC	United Nations Office of Drug Control
UNSCC	United Nations Standards Co-ordinating Committee
UK	United Kingdom
UKAS	United Kingdom Accreditation System
UPLCMSMS	ultra performance liquid chromatography/mass spectrometry/mass spectrometry
US	United States
USP	United States Pharmacopeia
UV-VIS	ultraviolet-visible
VAM	Valid Analytical Measurement
21CFR	Title 21, Code of Federal Regulations of the United States of America
21 ⁺	More than twenty one days

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CHAPTER ONE

Introduction

Drug manufacturing and dealing are the biggest economical albeit illegal trades in the world. Suppliers believe it is the best return on the investment of any stakeholder. On 26 June 2008, the United Nations Office of Drug Control (UNODC) launched the 2008 World Drug Report and announced that one in every twenty people aged between 15-64 years has tried drugs at least once in the past 12 months globally. Problem drug users (people with severe drug dependence) are approximately one tenth of this percentage i.e. 26 million people, or 0.6% of the adult population (UNDCP World Drug Report, 2008).

With this illegal trade comes the responsibility of governing bodies to combat the manufacturing, dealing and possession of controlled substances. More than one third of the cases submitted to the forensic science laboratories worldwide involve evidence that is related to synthetic and/or naturally occurring illegal drugs (UNDCP, 1995). The average increase in drug related cases in forensic science laboratories is more than 10% per annum which has forced laboratories to hire more personnel and invest in more sophisticated and expensive analytical instrumentation to meet the demand of the forensic community. This is due to the huge pressures placed on forensic science laboratories due to the need for high quality results, low turnaround times as well as constrained budgets. In return, forensic laboratories place enormous pressure on instrument vendors to improve the analytical methodology used in the analysis of controlled substances. This has resulted in fewer time-consuming “wet” methods of analysis and a greater number of faster, more accurate instrumental methods. It is thus important to survey the analytical methods most commonly employed by forensic science laboratories internationally in the analysis of controlled substances, and to determine if they are fit for their purpose.

Laboratory managers are now faced with a number of risks that have increased with the increased demand. As a non-profit organisation, managers within forensic science laboratories of South Africa find it difficult to justify or motivate resources to deal with the heavy drug case loads. The majority of forensic science laboratories are owned by the local, state, federal or national government and are connected to law enforcement

institutions. It is therefore more important for these authorities to appoint two police officials with a visible police vehicle for the community than purchasing one expensive piece of laboratory equipment or to fund the salary of another analyst. Furthermore, efficient laboratory personnel are hard to find and take time to train. Within this environment, it is necessary for forensic drug analysts to develop a philosophy within the laboratory i.e. a set of underlying principles that guides the analyst through the myriad of available tests within the constraints of time, efficiency, quantity of sample and most importantly, the purpose of the analysis. Forensic scientists acquire not only skills in analytical thinking or problem solving, but also the ability to convey the language of science in a court of law in such a way as to ensure that the laymen understand. The second obstacle involved in the forensic laboratory is space utilisation. Often, more analysts are employed however the amount of space does not increase. It is again difficult to justify more space and workbenches, thus supervisors have to employ shifts for effective space and instrumentation use.

A third obstacle is the amount of paperwork that are a burden for any state *laboratory*. Two factors contributing to this are firstly, the lack of an effective laboratory information management system (LIMS) and secondly, the lack or misunderstanding of the concept of total quality management. Little value can be added to any of the previously mentioned risks unless good quality control and/or quality assurance is implemented.

An evolution of quality requirements for testing and calibration in laboratories started in the early 1980's and developed into an industry of quality systems and assessment bodies to ensure every result produced by a forensic science laboratory is not only accurate, but is also assured. To fully comprehend the scope of quality systems, laboratory managers should investigate all the international recommendations related to the concepts of exhibit management, sampling management, personnel management, analytical methodology, quality assurance, customer focused management and performance management. The best way of doing such an investigation is by means of benchmarking laboratories within the same industry. Clear barriers should be set on the outcomes of the survey as operational objectives over a short period of time. A risk assessment plan will help laboratory managers to take the opportunities and proactively eliminate the threats.

Quality control and quality assurance mechanisms should be included in quality management systems and laboratories should gain independent endorsement for their quality management system through an internationally recognised accreditation authority.

This should be backed with a philosophy of quality improvement to produce forensic excellence within the community which they serve.

The background to the evolution and standardization of quality standards in the fields of forensic drug chemistry is presented in Chapter 2. The materials and methods used in this study are outlined in Chapter 3. All the results obtained from the global benchmarking exercise are tabulated and discussed in Chapter 4. Conclusions and future recommendations to achieve quality excellence in forensic drug laboratories are outlined in Chapter 5.

CHAPTER TWO

Evolution and role of quality standards in forensic science

Standards ensure desirable characteristics of products and services such as quality, environmental friendliness, safety, reliability, efficiency and interchangeability at an economical cost. When products and services meet our expectations, one tends to take it for granted and forget about the role of standards. However, when standards are absent, customers soon notice. Customers care when products turn out to be of poor quality, do not fit, are incompatible with equipment purchased earlier, or are unreliable or dangerous. When products, systems, equipment and devices work well and safely, it is often because they meet the standards (ISO, website, 2008).

The concept of quality first emerged out of the Industrial revolution where products were handcrafted by the same person or a team of people. Mass production brought larger teams together to work on specific stages of production. An operative's work would be inspected and a decision made whether to accept or reject it. As companies became larger, full time inspection jobs were created. In the late 1800's Henry Ford emphasised standardisation of design and component standards to ensure a standard product was produced and Frederick Winslow Taylor established quality departments to oversee the quality of production and rectifying of errors (Taylor, 1911).

The attitude towards the concept of quality control in chemical analysis has only had a short history, though the applications of quality control date back to the beginning of the 1900's. In 1908, an amateur of statistics and a professional chemist, published a paper on the error of a mean (Gosset, 1908). He introduced a parameter known as Student's *t*. This quality parameter was the level of probability that two means were equal. Another statistical quality parameter evolved from this publication called standard deviation. After the 1940's, a number of papers were published on the application of statistical techniques in analytical chemistry. In 1963, van der Grinten simplified equations that were derived from the rules of Norbert Wiener on control theory (Kateman and Buydens, 1993). This allowed the quantitative evaluation of the quality of measurements with respect to the object that was measured.

Van der Grinten and Kateman continued to study the possibilities of quality parameter measurability in analytical processes. In the 1972 study by Leeumans it was stated that apart from accuracy and reproducibility, the speed of analysis, the frequency of sampling and their merit for the application of analytical results could be quantified and optimised. In 1972, the Chemometrics Society was founded with the aim of tying together the diverse research in statistical, mathematical, and artificial intelligence techniques in analytical chemistry (Kateman and Buydens, 1993). These developments led to a new view of quality control in chemical analysis.

In 1963, the evolution of engineered products began with the MILQ 9858 standard in the United States of America which spread to the Western countries. Military applications had to be manufactured with high quality and safety requirements. From the MIL 9858, a number of company-specific, trade-specific and eventually national comprehensive quality assurance standards originated. In Germany, the NATO (North Atlantic Treaty Organisation) standard, known as AQAP (Allied Quality Assurance Publications) was derived from MIL 9858 standards and in turn developed into compulsory requirements for quality assurance of military goods deliveries in the NATO countries (T.I.Q.M.S, 1998). These changes were controversial as the European defence contractors used the DEF STAN 05/21 Standards which were a series standard issued by the department now known as the Ministry of Defence in the United Kingdom, but the contractors followed both sets of standards (Hounshell, 1932).

In 1979, the British Standards Institution (BSI) issued the BS 5750 standard for quality management procedures with an added quality assurance system clause. Quality procedures evolved into quality systems, through the combination of technical engineering standards and the managerial process associated with the quality function. The quality profession grew from simple control, to engineering followed by system engineering. Quality became a recognised profession (Smith, 1997).

As a result of the growing interest in quality standards and questionable study reports from research laboratories and equipment manufacturers, two sets of requirements were published in the United States. Good Laboratory Practises (GLP) and Good Manufacturing Practises (GMP) evolved during 1972 to 1974 when the FDA (Food and Drug Administration) discovered that reports submitted by pharmaceutical sponsors to the agency contained inconsistencies in their respective data. On inspection, defects in design, conduct and reporting of studies were discovered. This led to the implementation

of task teams to ensure validity and reliability on new, non-clinical safety studies by research laboratories before submissions to the FDA.

On 19 November 1976, GLP regulations were proposed for assuring validated studies. The final regulations were codified as part 58 of 21CFR (Code of Federal Regulations). GLP regulations were transferred under the umbrella of the OECD (The Organization for Economic Co-operation and Development) as principles of GLP to other countries like Europe and Asia. One of the directives of GLP regulations was a quality assurance unit (QAU) for internal control functions such as facilities, equipment, personnel, methods, practices, records, controls, Standard Operating Procedures (SOP's), final reports and archives. QAU's were independent of the personnel engaged in the direction and conduct of that study.

The FDA identified in the Quality Standard regulations (21CFR), the essential elements that a quality system shall embody for design, production and distribution, without prescribing specific ways to establish these elements. These compulsory regulations refer to non-clinical experimental tests of materials for possible dangers to human beings and the environment. The GLP regulations were needed for non-clinical safety studies of drug development, agricultural pesticide development, development of toxic chemicals, food control and test of substances with regard to explosive hazards. Studies to develop new analytical methods and laboratories conducting tests and calibration were not regulated (Douglas, 2008).

ISO (International Organization for Standardization), the organisation which was started on 23 February 1947 as a result of two organisations that united namely the ISA (International Federation of the National Standardizing Association) which was established in New York in 1926 and the UNSCC (United Nations Standards Co-ordinating Committee) established in 1944, set the tone for the development of quality management systems to direct and control an organisation towards quality improvement with the ISO Guide 25:1990. It was one of three guides that were prominent in the development of testing and calibrating laboratories. EN45001 and NAMAS M10 were the other two guides used. ISO Guide 25 was first issued in 1978, revised in 1982 and further revised in 1990 and was titled, "General requirements for the competence of calibration and testing laboratories". The EN45001 was issued in Europe and superseded any equivalent national standard in the early 1980's. The requirements of NAMAS M10 were consistent with the requirements of ISO Guide 25 and EN45001, and were implemented in the United Kingdom. The purpose

of the guides was for international laboratories to establish a quality management system that defines its commitment to good professional practice and to define specific quality standards. The standards were designed with one goal in mind i.e. excellence and credibility of measurement. The guides provided a mechanism for promoting confidence in testing and calibration laboratories that can demonstrate that they operate in accordance with its requirements. The content of the three guides addressed that which was believed to be the most important aspects of testing which included the following, according to Walsh (1999):

- a. Personnel
- b. Equipment
- c. Environment (testing)
- d. Methods
- e. Measurements
- f. Control

During the 1980's, more national standards evolved for trade specific products and services. There were no fundamental differences between these two types of standards and both generated a considerable amount of paperwork and organisation in some companies with generic technical and managerial regulations. Economic stakeholders agreed on specifications and criteria to be applied consistently in the classification of materials, in the manufacture and supply of products, in testing and analysis, in terminology and in the provision of services. International standardisation was needed to address the problem of uniform engineering or technical specifications, criteria, methods, processes or practices. This led to international standards which provided a reference framework between suppliers and their customers, thus facilitating trade and technology transfer (T.I.Q.M.S., 1998).

2.1 INTERNATIONAL STANDARDISATION

A consequence of the developments mentioned above was the growing interest in the development and application of quality control and quality assurance programs in all industries that did not fall under the GLP or GMP regulations. The idea was to organise the industry in such a way that the number of errors and mistakes were reduced to a minimum. Goods and services had to be delivered internationally in the correct manner, at the correct time. Thorough quality systems had to be established for accomplishing quality products and services.

At this point ISO had already produced a substantial number of quality management and quality assurance standards all over the world. They tasked the ISO Committee TG 176 in drawing up standards differentiating between:

- a. Guidelines for quality management and the necessary quality components, and
- b. Demonstration standards for a quality management system

They first published a series of standards for quality management and quality assurance in 1987 (revised in 1994). These standards became known as the ISO9000 standards which are indicated in Table 2.1 and were a written set of standards that defined the basic elements of a management system that an organisation should use to ensure that its products and services meet or exceed customer needs and expectations (T.I.Q.M.S, 1998).

Table 2.1 The ISO9000 standard series

ISO9000 series	Heading of Standard	Differentiation
ISO 9000	Quality Management and Quality Assurance standards – Guidelines for selection and use.	Guidelines for the use of standards
ISO 9001	Quality Systems – Model for quality assurance in design/development, production, installation and servicing	Three models for demonstration of the Quality Management System
ISO 9002	Quality Systems – Model for quality assurance in production and installation	
ISO 9003	Quality Systems – Model for quality assurance in final inspection and test	
ISO 9004	Quality Management and quality system elements – Guidelines	Standards for Quality Management and for elements of a Quality Management Systems

The table is derived from ISO9000 review, T.I.Q.M.S.

Although a vast majority of ISO standards were highly specific to a particular product, material or process, the ISO9000 and ISO9001 series are generic management system standards. Since their first publication in 1987, these standards have been adopted by most ISO member countries into their national standards structures. Due to the generality of ISO9000 as a generic management system on quality, the need for a more specific standard was necessary in testing and calibration laboratories, but with the same managerial and technical principles. A number of quality guides existed for testing laboratories e.g. ISO Guide 25:1990, EN45000, NAMAS10 etc., but did not have all the management requirements that were outlined in ISO9001.

Reflecting the increasing global importance of the general requirements for testing and calibration laboratories, Guide 25 had to be revised. More than 123 pages of comments were received from interested parties around the world and this led to seven draft versions of ISO17025 (Hoolihan, 1998). On 15 December 1999, the first edition of ISO/IEC17025:1999 standard was published. The first edition of the International standard entitled, "General requirements for the competence of testing and calibration laboratories," was produced as the result of the extensive experience in the implementation of ISO/IEC Guide 25:1990 and EN45001 standards, both of which it replaced. It contained all the requirements that testing and calibration laboratories had to meet if they wanted to demonstrate that their organisation or laboratory operated a management system. They are technically competent and are able to generate technically valid results. The ISO17025 Quality Management System Model provided structure using the industry standard ISO9001 approach. It embraced trusted methods and frameworks in the establishment of a stable quality environment. (ISO17025:1999)

The first edition of ISO/IEC17025:1999 for testing and calibration laboratories had direct references to ISO9001:1994 and ISO9002:1994. In 2000, the 1994 ISO9000 series standards were rewritten with the withdrawal of ISO9002 and ISO9003 and furthermore included small managerial changes. The ISO9000 changes made an alignment of ISO/IEC17025:1999 necessary. On 15 May 2005, the second edition of ISO/IEC17025 was published with amended clauses or clauses added only when considered necessary in the light of ISO9001:2000 standard.

ISO17025 is divided into two principle parts namely:

- a. Management requirements (section 4) of which most of the requirements were new but similar to ISO9001 and ISO9002
- b. Technical requirements (section 5) of which most of the requirements came from ISO Guide 25. There were also new requirements added, the most important was to "report measurement uncertainty"

Table 2.2 ISO 17025 Requirements

Management requirements	Technical requirements
Organisation and management (4.1)	General information (5.1)
Quality System (4.2)	Personnel (5.2)
Document control (4.3)	Accommodation and environmental conditions (5.3)
Review of request, tenders and contracts (4.4)	Tests and calibration methods including sampling (5.4)
Subcontracting of tests and calibrations (4.5)	Equipment (5.5)
Purchasing services and supplies (4.6)	Measurement traceability (5.6)
Service to the customer (4.7)	Sampling (5.7)
Complaints (4.8)	Handling of test and calibration items (5.8)
Control of non-conformity testing and/or calibration work (4.9)	Assuring the quality of tests and calibration results (5.9)
Improvement (4.10)	Reporting the results (5.10)
Corrective action (4.11)	---
Preventive action (4.12)	---
Control of record (4.13)	---
Internal audits (4.14)	---
Management reviews (4.15)	---

Requirements according to ISO/IEC17025:2005.

2.2 QUALITY IN FORENSIC SCIENCE LABORATORIES

Forensic science has a long history of deliberating the truth in public. Scientists had to answer questions of interest to the legal system. The Eureka legend of Archimedes (287-212BC) can be considered an early account of the use of forensic science. Archimedes determined that a crown his friend King Heiro II had ordered was not completely made of gold, as it was fraudulently claimed. He determined the density of the crown by placing the crown into water and measured the displacement of the water level. He then took the weight of the crown and divided the volume of water displacement therein. The density value calculated in this process differed from the known density of an equal amount of pure gold. He informed his friend, the king, that he has been cheated, and cheaper, less expensive metals were added to the crown to cut costs on the part of the goldsmith. The method of density determination is still used in liquid dynamics and the same principles are used in forensic sciences today (Heckert, 1998). In 1784, in Lancaster, England and later in 1816, Warwick, England, forensic scientists first demonstrated the increasing use of logic and procedure in criminal investigations. Practitioners started to specialise in different disciplines in forensic science and it became necessary for quality organisations to protect individual forensic scientists, to ensure, that the highest possible standards were maintained. It was discovered that the fundamental requirements of achieving a high standard of performance and accuracy in forensic science were and still are a good general scientific education coupled with specialised

training in the subject and a constant monitoring of performance. The first trials were conducted around blood and urine alcohol in 1969, by the Home Office Central Research Establishment (CRE) in the United Kingdom. They were extended to other aspects of forensic science in 1978. A quality assurance organisational system was developed under the wing of the Forensic Science Service of the home office. Quality audits were performed to examine the standards. It made no recommendations regarding detailed procedures but demanded the preparation of methods manuals, describing approved departmental techniques which should have been available for use by all staff. In 1979, the first recognised quality guide for forensic science was produced and entitled "A Guide to Quality Assurance in Forensic Science."

The document summarised quality assurance in forensic science as follows:

- a. The promotion of a uniformly high standard of performance by all concerned in situations which ranged from the examination of crime scenes to the presentation of evidence in courts.
- b. The identification and correction of problems which arise.
- c. A continuing review of analytical methods, procedures, equipment and data currently in use in order to determine the best available.
- d. The education and encouragement of all staff, thereby ensuring an efficient and effective program.

Quality control as a requirement was the confirmation of all scientific findings by an appropriate member of staff. This and other quality measures were the start of forensic science laboratories in the United Kingdom. It later became the NAMAS standard in NIS46 (April 1992).

During isolation from the world in the 1970's and 1980's, forensic scientists in South Africa had to rely on limited resources and outdated instrumentation to achieve high levels of discrimination in criminal investigations. The South African courts sentenced suspects based on confessions made by them rather than scientifically proven results. With the lifting of sanctions, forensic scientists faced new challenges in an ever-changing environment with new legislation, new drug types, shortage of expert personnel and the lack of sufficient instrumentation. Developed countries designed highly sophisticated instrumentation and local scientists had to adapt to these developments and implement it in the laboratory. Table 2.3 indicates quality contributors in forensic drug laboratories globally and the entrance of the forensic science laboratory of South Africa in the quality arena.

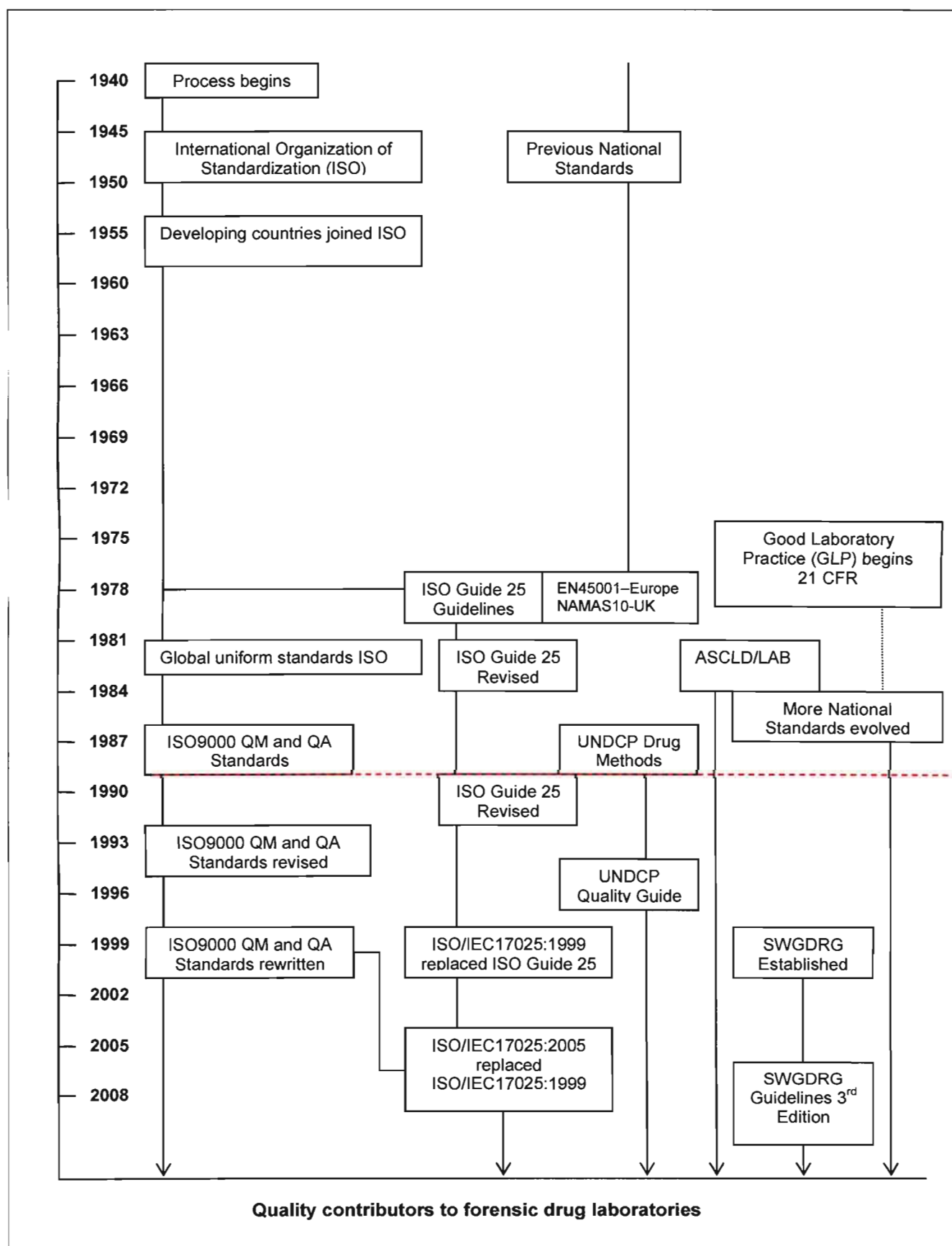
In 1990, the South African forensic science drug laboratory received its first set of standards from the United Nations Drug Control Program (UNDCP). It consisted of a number of recommended methods for testing controlled substances. The manuals dated back to 1984 when international law enforcement authorities had to be notified of new trends and analytical data from drug discoveries. The exchange of analytical data internationally required internationally acceptable methods of testing to achieve these objectives.

In February 1984, the Commission on Narcotic Drugs requested the secretary-General of the United Nations "to investigate the possibility of reaching agreement at the regional and interregional levels of recommended methods of analysis of drugs seized from the traffic". In response to the Commission's request, a group of fifteen experts was convened in October 1985 by the Division of Narcotic Drugs in Wiesbaden, Germany, to develop recommended methods for testing controlled substances (UN, ST/NAR/6, 1986). These recommendations only prescribed methods and procedures to be followed from sampling until confirmatory testing and made use of techniques such as colour tests, thin layer chromatography and infra-red spectrometry for qualitative analysis and gas liquid chromatography for quantitative analysis.

The concept of quality assurance and quality control in forensic science laboratories in South Africa only started in 1993, when the SABS (South African Bureau of Standards) provided the first document called "SABS0259:1990-General requirements for the competence of calibration and testing laboratories". SABS0259 was prepared from NIS46, a document published by NAMAS in April 1992 and titled "Accreditation for Forensic Analysis and Examination."

Key elements for testing included:

- a. Quality control
- b. Staff
- c. Equipment
- d. Calibration
- e. Reference materials
- f. Reagents
- g. Methods and procedures for calibration and tests
- h. Environment
- i. Handling of items to be tested or analysed

Flow chart 2.1 Quality timeline in forensic drug laboratories

The red dotted line indicates the entrance of the South African forensic science drug section to the global quality arena.

Later in the 1990's, the National Calibration Service took over from SABS and is now incorporated under the South African National Accreditation System (SANAS). In 1997, SANAS and the American Society of Crime Laboratory Directors (ASCLD) published a joint guide in South Africa entitled "Forensic Science Laboratory Accreditation Criteria".

On 07 January 1999, a more comprehensive quality document namely TG06-01 was published by SANAS titled "Criteria for laboratory accreditation in the field of forensics". The document described all managerial and technical requirements for laboratories accredited under the SANAS forensic science laboratory accreditation program. TG06-01 was a combination of requirements from the following sources:

- a. ISO/IEC Guide 25 – General requirements for the competence of testing and calibration laboratories
- b. NATA Accreditation Criteria for Forensic Science Laboratories
- c. ASCLD/LAB Accreditation Criteria
- d. SANAS Specialist Technical Committee for Forensic Science

The document was rewritten and issued as R08-01 on 23 July 2004 with the necessary transformation of ISO/IEC Guide 25 to ISO/IEC17025:1999. On 15 February 2008, it was replaced with TG01-01 with the new requirements of ISO/IEC17025:2005.

2.3 SUPPLEMENTARY GUIDES TO IMPROVE QUALITY IN FORENSIC DRUG LABORATORIES

The United Nations Drug Control Program (UNDCP) was the first organisation that realised the extent and diversity of drug abuse and that this has placed increasing demands on nations to intensify their regulatory efforts. Results produced by governing laboratories have serious consequences for the individual charged with drug possession or drug dealing. With the enormous increase in the production and supply of controlled substances as well as the rate of abuse, laboratories performing analytical tests on these substances were placed under greater pressure to detect drug abuse by analysing biological specimens. Some governing authorities further required quantitative results for more severe sentencing of abusers and dealers.

Forensic laboratories had to increase their personnel and equipment to be able to deal with the increase in seized controlled substances, and they also had to use methods of detection and analysis that would decrease turnaround times but were more accurate and specific. In central, eastern and south eastern Europe, the UNDCP operations focused on

developing cross border co-operation between themselves and eastern Europe, the Baltic states and the Commonwealth of independent states. The UNDCP published guidelines in 1995 titled "Recommended Guidelines for Quality Assurance and Good Laboratory Practices" with 14 recommendations for laboratories analysing controlled substances on effective quality assurance procedures, thus stimulating the use of good laboratory practices and participation in proficiency testing programs. These issues were addressed in three UNDCP meetings held in 1984, 1986 and 1992 respectively. They were intended to guide national authorities and analysts in the implementation of internal quality assurance programs.

The procedures described in the guidelines were based on the experience of international scientists in the same field. The guide was intended to promote and harmonise national efforts by providing internationally accepted standards.

The recommendations included were:

- a. Quality assurance and good laboratory practices
- b. Policy, organisation and management
- c. Handling of specimens
- d. Reference standards, materials and reagents
- e. Equipment
- f. Laboratory accommodation, environment and safety
- g. Methods and procedures
- h. Reporting
- i. The laboratory and external organisations

Two other recommendations included participation in an international drug proficiency testing program and a glossary of quality assurance terms.

In 1997, the United States Drug Enforcement Administration (DEA) and the Office of National Control Policy (ONDCP) co-sponsored the formation of the Technical Working Group for the analysis of seized drugs (TWGDRUG) now known as the Scientific Working Group for the analysis of seized drugs (SWGDRUG). Forensic scientists around the globe, representatives of the United Nations, several international organisations and academics met in 1999 in Washington DC to develop recommendations for educating forensic practitioners in the analysis of seized drugs. In 2001, new recommendations were adopted to enhance quality assurance and to define methods for the analysis and the identification of seized clandestine laboratories. SWGDRUG has established a core committee meeting annually to discuss the newest developments in technology and quality

standards. The 3rd edition of the “Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG) Recommendations” was published on 09 August 2007 and is a product of continuous deliberation and consultation with the international forensic drug community and includes the recommendations presented in Table 2.3.

Table 2.3 SWGDRUG recommendations for the analysis of seized drugs

Part I	A Code of Professional Practice for Drug Analysis
Part II	Education and Training
Part IIIA	Methods of Analysis/Sampling Seized Drugs for Qualitative Analysis
Part IIIB	Methods of Analysis/Drug Identification
Part IVA	Quality Assurance/General Practices
Part IVB	Quality Assurance/Validation of Analytical Methods

Adopted from SWGDRUG recommendations for the analysis of seized drugs (2007).

2.4 THE VALUE OF QUALITY SYSTEMS IN FORENSIC SCIENCE

Internationally recognised quality standards are essential to the drug analysis workplace. The evidence submitted to forensic laboratories should be analysed accurately and precisely, followed by objective reporting based on the results obtained. The ultimate judge of the quality of work in a forensic drug laboratory ought to be the court of law, where these results are contested by the defence. The judges of the criminal justice system rely on the integrity of the scientists that work in forensic science laboratories (FSL) as well as the management of these laboratories to ensure that the highest standards are maintained. Scientists working in the FSL should use techniques and equipment that are applied globally. These techniques should generally be accepted within the appropriate scientific community, have been peer reviewed and the theory upon which the technique is based should have been tested or should be testable. Lastly, but most importantly, standards should exist for controlling the application of the technique used. Incorrect test results in court could severely damage the credibility of the laboratory, as well as that of the international forensic community (St. Clair, 2003). For international forensic drug laboratories to assure and maintain quality, a system should be established wherein its commitment to good laboratory practices and laboratory specific standards are documented and subsequently implemented.

A quality system should also ensure that all the examination procedures are operating within established performance criteria, that the validity of the analytical data is maintained and that problems are anticipated and prevented. When forensic science drug laboratories operate under a well functioning quality system, a number of skills will be developed by the

scientists performing analytical work. These skills may include continuous improvement of managerial and technical skills, self discipline, analytical thinking and problem solving. With a functional quality system, all activities and processes in the laboratory are managed in such a controlled manner, which in turn would constantly improve the effectiveness and efficiency of the laboratory's performance.

The establishment of a quality control department, the recruitment of a quality manager, increased quality standards and employment of more quality staff and inspectors, however important that may be, will not spontaneously improve the quality of services. All this investment may have little or no impact if a quality framework is not in place.

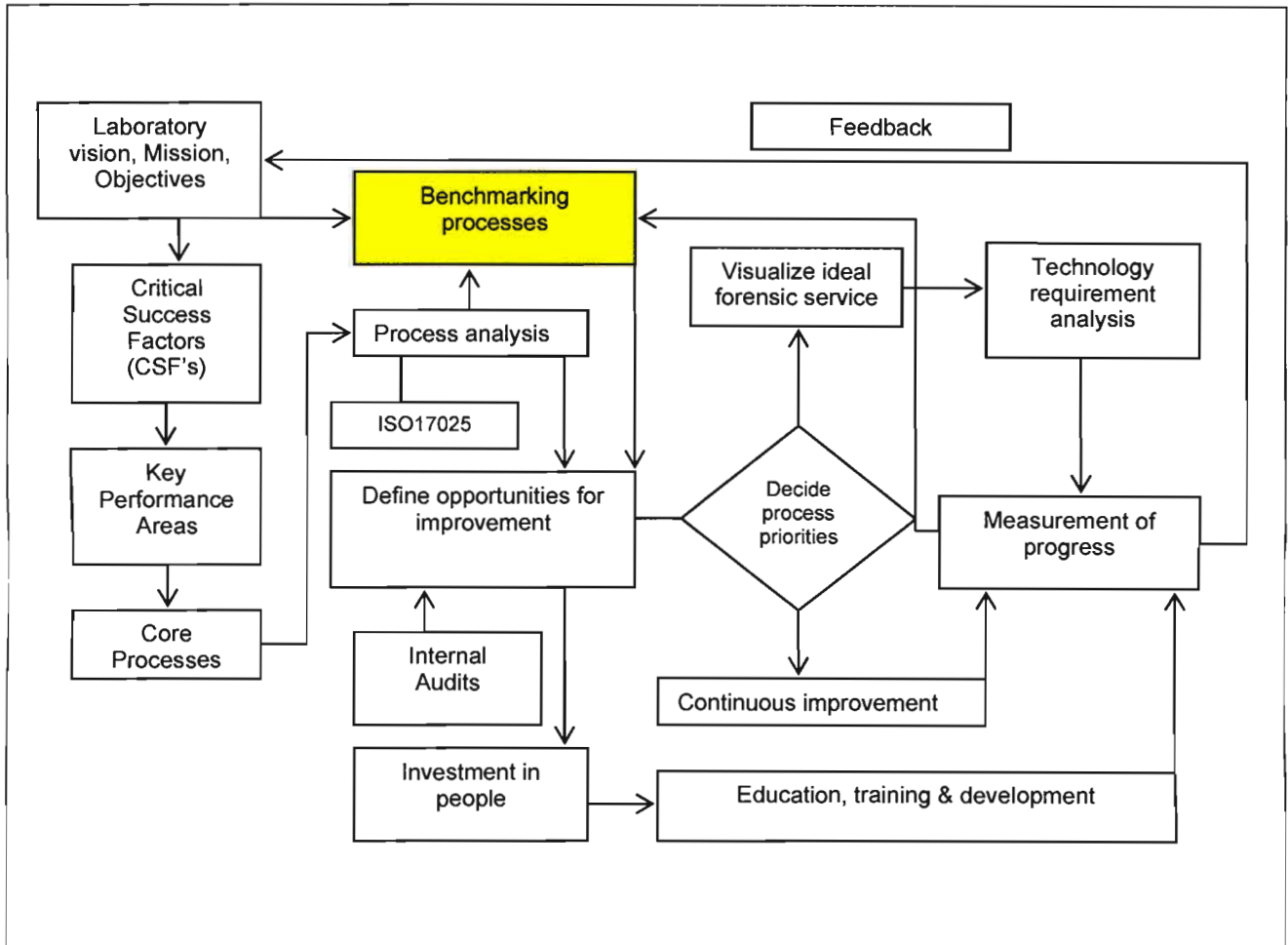
It is therefore important to implement a quality framework as a building block towards putting together all ideas to achieve organisational excellence. This framework should include TQM (Total Quality Management), processes, tools and techniques, people development, teamwork, management systems, performance measurement and self assessment in the form of benchmarking. An example of a framework model to achieve organisational excellence can be seen in Flow chart 2.2.

A laboratory manager, who wishes to be successful, needs to establish a philosophy of quality excellence in the laboratory. The philosophy starts with mission statements including the primary function of analysing physical evidence objectively. These statements stipulate direction and the role of any FSL in the community it serves, as well as forming the basis of continuing success. These statements, if not an entity on their own, should be clearly understood by the senior management of the organisation and laboratory staff.

A documented mission statement alone is not enough to ensure its implementation. It must be developed into its building blocks i.e. strategic objectives. The objectives should be a written statement by the laboratory director in consultation with a higher authority i.e., if not a single entity, setting directions as to what are believed to be the appropriate functions of the laboratory and the direction in which the laboratory should move. The objectives will be the basis for a sound management philosophy. The contributing factors in creating objectives are the size, the range of services provided, the nature of the parent organisation, the size of the population served and the nature of the area served. The objectives should always be understood and supported by the staff (ISO17025:2005 4.1;

ASCLAD:2005 1.1.1; TG01-01 6.1.2). Many laboratories fail from the start, due to misconceptions or wrong interpretations of objective statements.

Flow chart 2.2 Framework for achieving laboratory excellence



Adapted from Department of Trade and Industry, UK, (2003).

Typical statements could include:

- The implementation and maintenance of a quality management system.
- The continuous empowerment of personnel and clients through training.
- The assurance that facilities are secured and security for personnel is provided.
- The provision of accommodation and ensuring the efficient utilisation thereof.
- To live and communicate a value system.
- The achievement of case work goals set for the respective units.
- The optimal utilisation of the laboratory's management system.
- The implementation of systems that will enable the laboratory to function autonomously within set standards.

Once strategy is implemented, a system of follow-up, evaluation and control is essential to ensure that the results agree with those expected at the time that the strategy was formulated.

It is good practice to establish Critical Success Factors (CSF's) from the objectives. These factors should be evaluated quarterly and redesigned annually. CSF's are the integral requirements to achieve the objectives. The CSF's should not consist of more than eight factors, e.g.:

- a. We must have motivated, skilled employees
- b. We need a safe environment for all employees
- c. We need to satisfy our client's needs

Each of these CSF's should have a responsible individual, and the laboratory director should delegate authority to those people to establish accountability. These individuals should form part of the senior management team.

For any strategic plan there should be a responsible person to accomplish strategic goals. A good supporting measure is by means of key performance indicators (KPI's), which are accompanied by clear targets. The monitoring process is a senior management control system used as evidence of success for the laboratory.

2.5 CORE PROCESSES

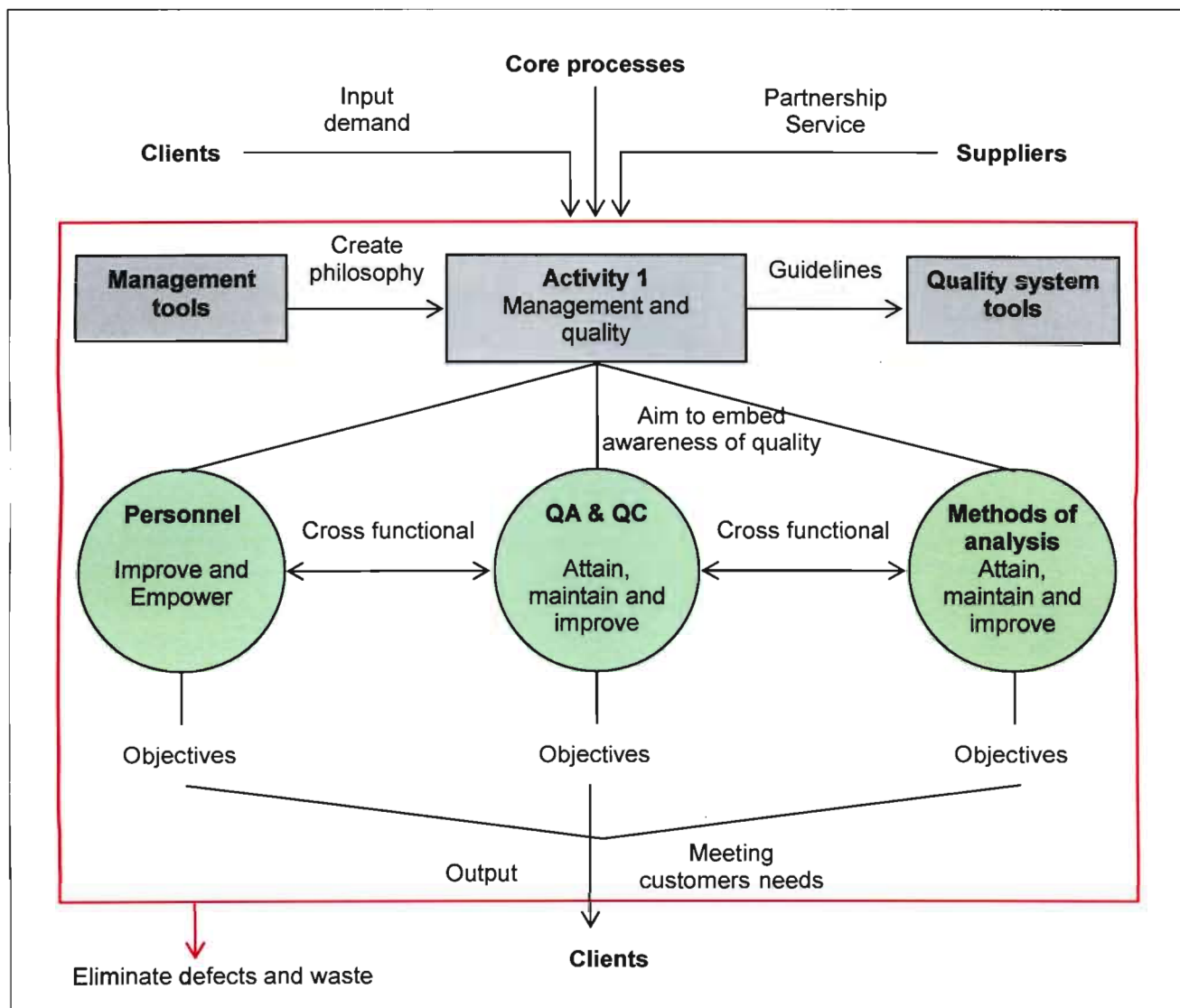
Core processes indicate the processes that should be managed within the laboratory and too which a responsible person should be allocated, e.g.:

- a. Human resources
- b. Quality
- c. Suppliers (supply chain management)
- d. Case flow
- e. Skills development
- f. Health and safety in the laboratory environment
- g. Exhibit reception
- h. The management of an activity or a group of activities

Two concepts that need to be documented within these core processes are a laboratory structure and the delegation of authority, which must be covered in the quality management system (ISO17025:2005 4.1; ASCLAD:2005 1.2; TG01-01 6.1). The core

processes describe what is, or needs to be, done to deliver the CSF's. The core processes should be prioritised and mapped as sub-processes, activities and tasks. Flow Chart 2.3 indicates a process analysis of activities implemented in the forensic science laboratory.

Flow chart 2.3 Process analysis for continuous quality improvement



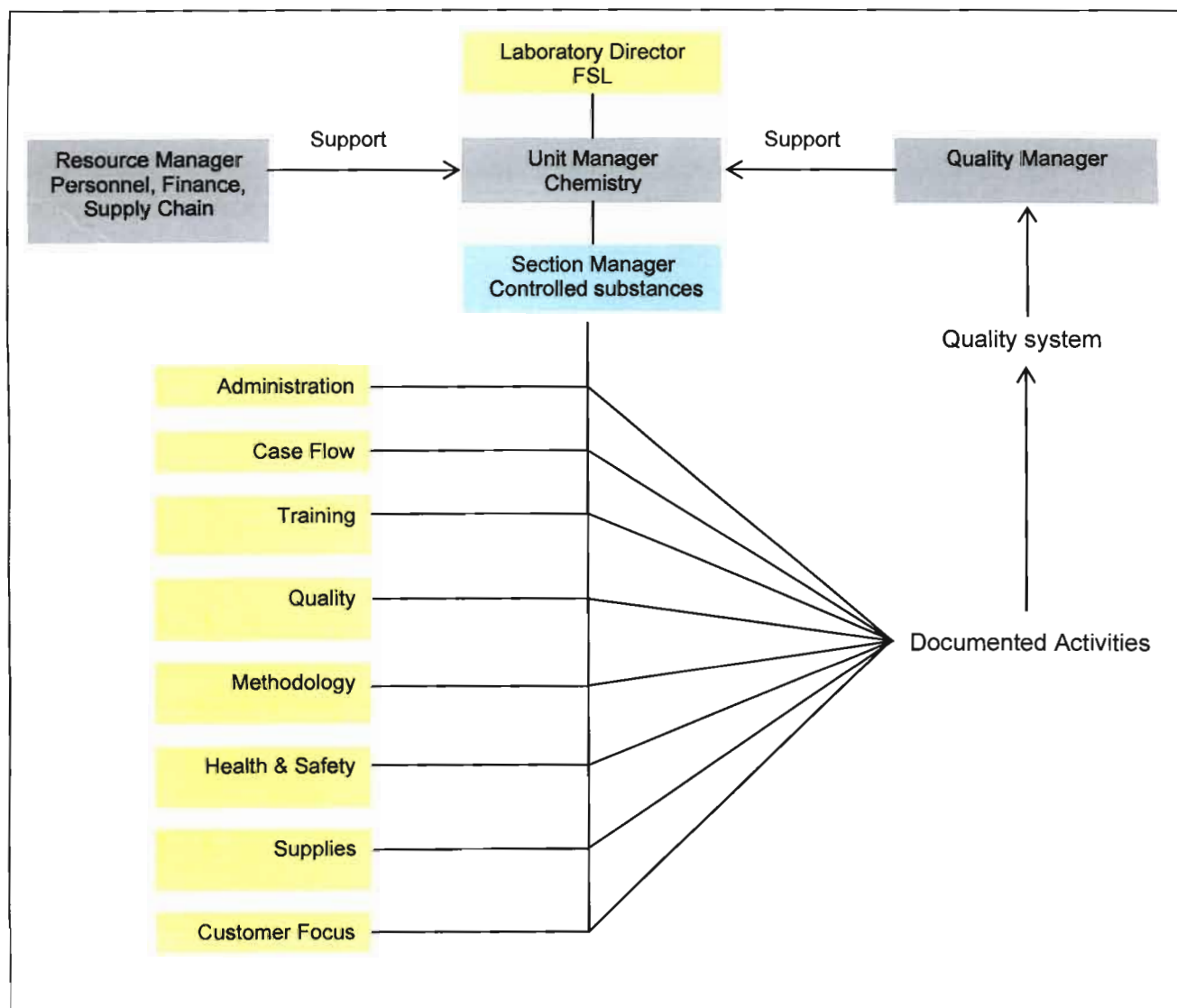
It may be required in a laboratory that a few co-ordinated activities are performed in order to constantly improve the overall effectiveness and efficiency. A critical control point analysis performed by Goldschmidt in 2001 revealed that a particular laboratory had up to 64 activities. Identification and analysis of controlled substances can lead to a number of sub-processes in the laboratory e.g.:

- Qualitative analysis of drugs
- Quantitative analysis of drugs
- Identification of controlled medicines
- Quantitative analysis of controlled medicines

- e. Analysis of biological specimens for controlled substances
- f. Investigation and analysis of clandestine (illegal) laboratories, manufacturing controlled substances.

Each sub-process must be documented and should have a title, purpose, scope inputs, outputs, controls and resources. The sub-processes will lead to a number of activities that will take into consideration both managerial and quality tools. Each of these activities will need resources and guidelines in the form of qualified and administrative people, accommodation, laboratory equipment, methods of analysis as well as an appropriate quality system. Daily activities require tasks to be performed and controlled and will include exhibit management, case flow management, training management, quality management, information technology management, administration management, health and safety management, crime scene management and financial management. "Owners" should again be allocated to specific activities. Certain "owners" will have more than one activity to manage and should perform these activities on a supervisory level.

Flow chart 2.4 Tasks to be performed, planned and controlled



This set of activities and the associated managerial responsibilities form the basis of any quality management system. Quality systems are important for every member in the organisation and thus it requires total commitment from top management to administrative staff. These activities can not be isolated for the purpose of understanding the quality management system, but may be used through internal audits and benchmarking to evaluate the effectiveness within the quality system and identifying opportunities for improvement.

Prior to internal audits or benchmarking of the activities within the forensic drug environment, the same language should be spoken within quality systems. Great emphasis has been placed on managerial requirements in the literature; however it is the language of technical requirements that are constantly misinterpreted by forensic laboratories. The managerial requirements include the elements of ISO9001:2000, whereas the technical requirements deal with factors that can influence the quality of test results. Factors that determine correctness and reliability of results include:

- a. Method validation
- b. Equipment
- c. Test and calibration methods
- d. Human factors
- e. Accommodation and environmental conditions
- f. Measurement traceability
- g. Sampling
- h. Handling of test and calibration items

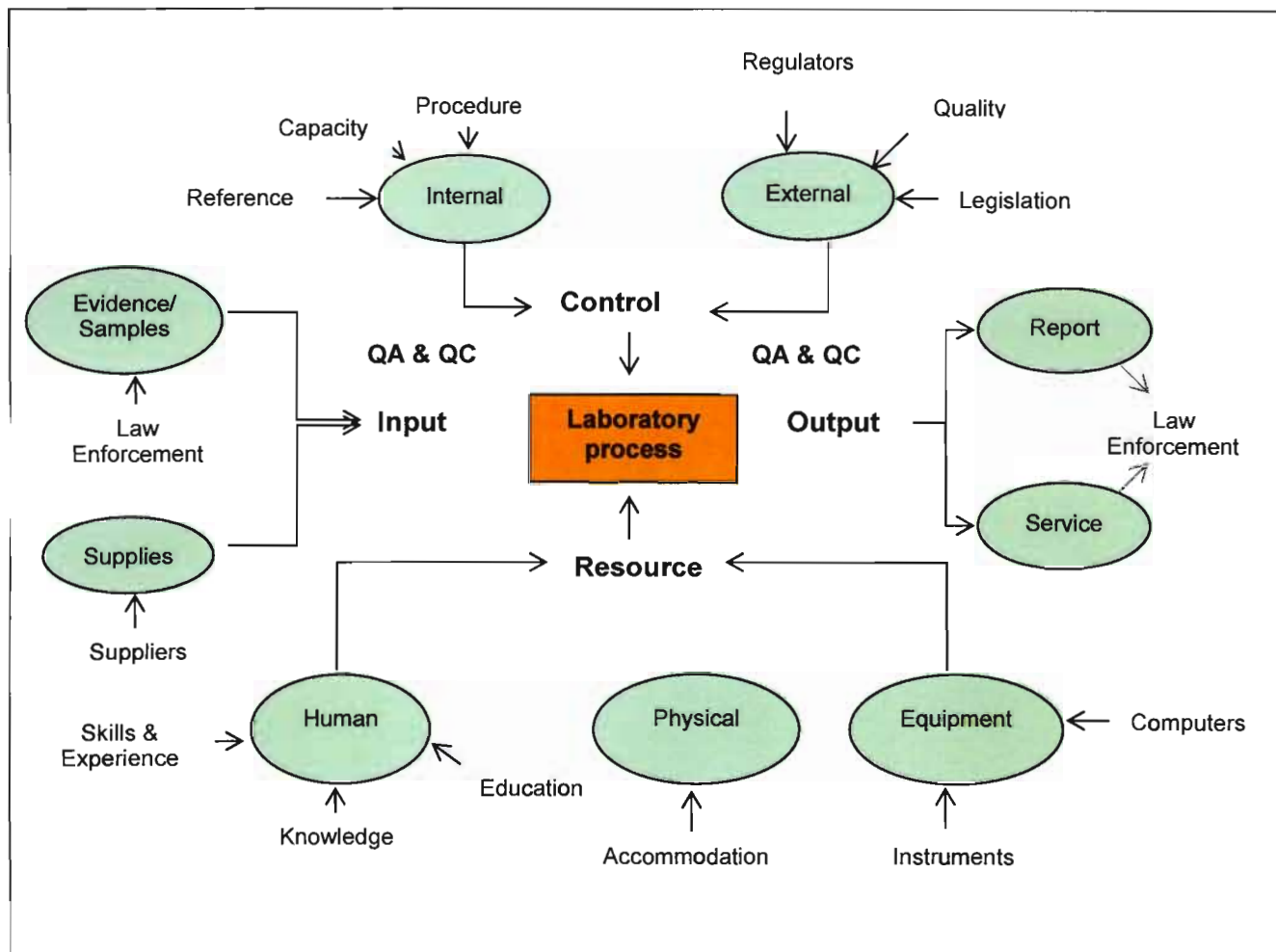
The scope of this study is first to identify the elements that influence these factors, explain their objectives and suggest best practices.

Table 2.4 Elements of interest in forensic drug laboratories

Management requirement	Technical requirement
Exhibit management	--
--	Sampling
--	Equipment suitability
--	Methods of analysis
--	Personnel
Quality assurance	Quality assurance
Customer expectations	--
Productivity	Productivity

Flow Chart 2.5 illustrates the position of the above mentioned elements in a well defined forensic drug laboratory process. For continuous improvement of quality assurance and quality control, a forensic drug laboratory should constantly evaluate and benchmark the elements indicated in green.

Flow chart 2.5 Elements in a Forensic Drug Laboratory process



2.6 EVIDENCE/SAMPLE CONTROL SYSTEM

The quality of any result starts with the quality of the exhibits/samples received for analysis. Factors that influence the quality of the exhibit collected at crime scenes are sample contamination, illegal searches, sample switching, incorrect sample identification, inadequate sample sealing etc. Although sample collection is outside the scope of laboratory quality management systems, it stays the responsibility of the forensic laboratory to empower and sensitise law enforcement officers towards ensuring sample integrity. Law enforcement officers are the first custodians of the evidence recovery process and should protect and secure it by placing exhibits immediately in forensic seal bags or evidence bags/containers followed by subsequent marking and sealing. Certain

evidence bags might have a unique number printed on the bag. This will serve as a tracking system for the exhibits collected at the scene. The officer will take responsibility for the exhibit and must be able to distinguish it from other exhibits also collected at the same scene or from other scenes. The term chain of evidence or chain of custody has been adopted in crime laboratories internationally to describe the flow of evidence from one individual to another.

Exhibit management is unique to forensic science laboratories and differs from other industries where terms such as parts- or item tracking are used. Quality guides such as TG01-01 and ASCLD:2005 covers an enormous amount of detail on the subject. According to these guides, forensic science laboratories must have a system that ensures the integrity of all the evidence under their control. The policy should as minimum requirements include procedures that explain receipt, handling, protection and storage of evidence. There is no single control system that will cover all forensic science laboratories, but the principles of exhibit management will be the same internationally. Certain laboratories only receive controlled substances whereas others receive a range of exhibits. Control systems that may be implemented can include a paper system or an electronic system as long as all principles of receipt, handling, protection and storage of evidence ensure exhibit integrity.

Evidence submissions to the forensic laboratory must be acknowledged by means of a signature, initials or a secure electronic equivalent. Policies should clearly state when to “accept” or “reject” evidence material and any discrepancy should be explained to investigating officers at the case or evidence reception at the laboratory. Submitted evidence should be accompanied by a covering letter/submission form indicating a description of the offence e.g. dealing in controlled substances, the case reference and seal numbers as well as the analyses expected from the laboratory. Once accepted, it becomes evidence under the laboratory’s control (TG01-01 6.4.1.2; ASCLAD 1.4.1.1).

Certain forensic laboratories receive hundreds of exhibits per day and often the only means to discriminate between the exhibits is through proper markings on the bags and/or containers. The markings should be traceable to an enforcement authority and investigating officer for future consultation if deemed necessary. The evidence should be retained in the sealed bag or container until it reaches the analyst who is going to conduct the analysis. Additional identifiers can be applied to the bag or container in the form of a laboratory generated number or bar coding sticker (TG01-01 6.4.1.3; ASCLAD 1.4.1.2).

Any discrepancies should be recorded and the investigating officer should be contacted to rectify the discrepancy. Many recipients are confused with this requirement, however if an abnormality exists, the evidence should be “rejected”. Quality requirements can not prescribe common sense. It might be a small mistake that can be rectified immediately on site or evidence may have travelled from a long distance and the problem can only be corrected through a fax or e-mail. All communication should be noted and dated, for future reference (TG01-01 6.4.1.4).

“Properly sealed” or “tamper proof” is a difficult concept to explain if the wrong types of evidence bags or containers are used. The sealing of evidence in envelopes with a waxed seal number is outdated and not in use anymore. Commercial evidence bags are available with proper characteristics to indicate obvious damage/alteration to the bag or its seal. The seal itself must be sufficient to prevent the possibility of the item(s) being lost or removed without noticing any alteration to the seal or being contaminated by outside sources so as to compromise the integrity of the evidence. Vacuum sealing is risky due to the possibility of opening and resealing it without obvious signs of alteration. Bags and containers that are sealed should at all time be inspected thoroughly by all recipients during the laboratory process until the seals are broken for analysis of the evidence (TG01-01 6.4.1.5; ASCLAD 1.4.1.3). When forensic evidence is kept within the laboratory, a few factors need to be considered to ensure evidence integrity. All evidence received should be within evidence bags/containers which are properly marked and sealed. These evidence bags/containers should be kept safe in access controlled areas under specified environmental conditions. Proper control measures should be in place to monitor, maintain and record these conditions. Investigating officers should also be trained to preserve wet plant materials according to prescribed methods. A typical example is the active component in the *Catha Edulis* plant. Cathinone (a controlled stimulant) changes in molecular structure, 72 hours after harvesting, if not kept under cool, dry conditions (TG01-01 6.4.1.6; ASCLAD 1.4.1.4).

Evidence should at all times be securely stored before, during and after analysis, to maintain the integrity thereof. Evidence that is not immediately allocated to an analyst should be stored in a secure area, which is compliant with strict security requirements. Access to these areas should be limited to authorised personnel only. Analysts should have their own safes or lockable storage facilities to keep evidence safe when the process of examining that evidence extends over a period of time. On completion of examinations, the remaining exhibits should be sealed again to maintain their integrity. Evidence might

be needed by analysts working for the defence to conduct their own examinations. In the case of bulk evidence, photographs should be taken and appropriate representative samples kept for defence disputes. The remaining evidence may be destroyed to ensure laboratory safety. Pre-destruction of evidence should only be performed after consulting with prosecuting authorities (TG01-01 6.4.1.7, ASCLAD 1.4.1.5).

A Laboratory Information Management System (LIMS) or an Evidence Management System (EMS) could be implemented that is able to control the flow of evidence through different processes in a laboratory. Computerised evidence tracking systems are faster and replace written systems. It is however important to implement and maintain a proper system, that is secure and generates hard copies when needed.

2.7 SAMPLING

Sampling is an internal procedural contributor to quality in forensic drug laboratories. The importance of appropriate sampling in analytical testing can never be overemphasised and has a long history in forensic science. Choosing suitable test samples from a laboratory sample is the beginning of the analytical process and plays an important role in chemical analysis. The selection process is, however, seldom straightforward. Selection of a proper sampling plan in forensic drug laboratories is never easy, especially when working with diverse sample populations. Controlled substances and chemicals from illicit clandestine laboratories differ in physical appearances. Sample types can be described in terms of the physical state i.e. gasses, liquids or solids. Where appropriate these can be further subdivided into homogeneous or heterogeneous materials i.e. tablets, powders, capsules or paper motives. This may be in terms of the ability to separate the sample into more than one phase or in the case of a solid, one that consists of a mixture of materials with varying particle sizes.

For most analysts in the forensic drug environment, sampling is simple i.e. you take a sample from the laboratory sample which has been submitted for analysis, analyse it and report the results. The number of samples to be taken is typically indicated in a table or procedure prepared by more senior staff. However it is often not that simplistic and analysts need to be made aware of the importance of sampling. It is necessary to have a certain level of statistical background to understand the terminology and definitions associated with sampling. IUPAC published a paper in 1990, clarifying the definitions and guidelines on sampling.

"Sampling is the process of selecting a portion of material, in some manner, to represent or provide information about a larger body of material."

Reference E7 of IUPAC describes the terms used in the sampling of bulk goods or packaged batches, increments, primary or gross samples, composite or aggregate samples, sub samples or secondary samples and compare these to a laboratory sample. If the laboratory sample is heterogeneous, the analyst may need to further prepare or separate samples before test sampling takes place. The laboratory sample or the test sample should be the end of the sampling procedure.

NAMAS defines sampling as a defined procedure where a portion of the substance that might be captured in a specific matrix or material, is taken for analytical testing and the result of such testing represents the whole sample (Crosby *et.al*, 1995). This definition indicates that the implications of the analysis have to be considered before taking the sample or devising a sampling scheme. It is the responsibility of the forensic chemist, through discussions with competent colleagues, to establish the real nature of the problem. Questions should be asked on the net weight of the population or the portion of the units to be taken to represent the population. The answers affect the sampling plan, and the analytical method chosen depends on the precision required.

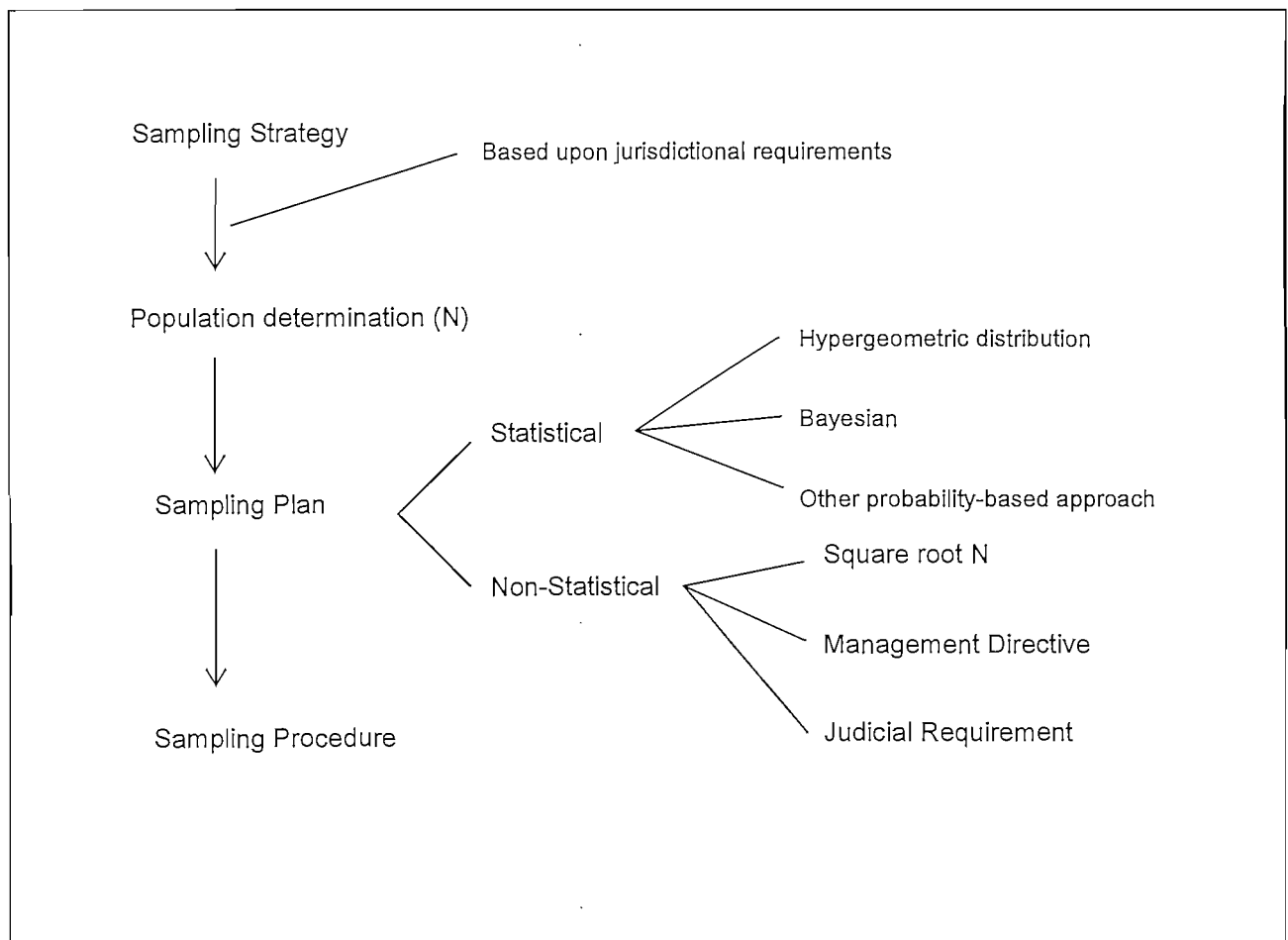
If the test sample is not representative of the original sample population received, it will not be possible to make any inferences on the original sample population, no matter the analytical methodology followed. Various sources exist regarding sampling approaches in analytical laboratories (Motulsky H, 1995; UNDCP, 1995; ENFSI, 2003). While the pharmaceutical industry were flooded with requirements for sampling (Mendes, 2001; Timmerman, 2001), the forensic drug industry could not decide on a single defined sampling method due to the diversity of laboratory samples received (Tzidony, 1992; Colón, 1993; Coulson, 2001), varying legal requirements and the costs associated (SWGDRUG, 2007).

The first recommendations for sampling in forensic drug laboratories came from the recommended guidelines for testing controlled substances that were published by the United Nations Drug Control Program in 1986 (UN;ST/NAR/6-11,1986). These recommendations were revised in 1992 and a new document published in 1995 (UN;ST/NAR/26,1995). The new recommendation stated that 10% of all analytical samples in a batch should correspond to calibrator and control samples. This applied to all types of

analyses. The sampling plan carried no statistical value towards the population of the samples received, but there were few other alternatives that would suit drug laboratories.

The ISO/IEC17025; 1999 guideline was published with the requirement that sampling plans within an analytical laboratory should, whenever possible, be based on recognised statistical approaches. In South Africa, management of the forensic science laboratory of the South African Police Service decided that this guideline be interpreted to allow the laboratory to decide whether or not to use a statistical method, for example, looking at the magnitude of the case, costs on analysis and expected sentence, the sampling method would either be non-statistical for misdemeanour cases or statistical for dealing and manufacturing cases.

Flow chart 2.6 Statistical strategy plan



Adopted from SWGDRUG recommendations "Method analysis/Sampling seized drug for qualitative analysis" (2003).

In short, no universally prescribed sampling plan, for example ISO Standard, exists for forensic drug laboratories. Inspection and jurisdictional authorities leave the choice of an appropriate sampling strategy to the discretion of the laboratory for implementation. A preferred practice for any forensic laboratory is to rely on experience within the laboratory

or adapt statistical approaches from laboratories conducting similar testing (Coulson, 2001). SWGDRUG developed a sampling strategy that will minimise the total number of required analytical determinations, while assuring that all relevant legal and scientific requirements are met. A typical example of such a strategy is indicated in Flow Chart 2.6 and is derived from SWGDRUG recommendations.

The purpose of the investigation, the original question on sampling and the use of the analytical results will determine the sampling strategy. An external contributor to a sampling scheme is the national or local legislation and this should be taken into account when defining a procedure. The laboratory has the responsibility to develop its own strategies consistent with these recommendations. Attention should be paid to population determination, the sampling plan (i.e. statistical or non-statistical) and the sampling procedures used.

2.7.1 Non-statistical sampling plans

Non-statistical approaches may be used if it satisfies the basis for answering the questions of applicable law e.g. is there a controlled substance present in the evidence submitted to the laboratory? No statistical conclusion may be drawn on the total population of samples when using a non-statistical plan. In possession cases, non-statistical plans will be appropriate, especially if the accused will only be sent for drug rehabilitation. It is however important for the forensic scientist to indicate in the forensic report on the nature of the sampling plan.

2.7.2 Square root of the population

In the quest for the determination of the appropriate sample size, different sampling plans were proposed by governing bodies and private laboratories around the world. Sampling proposals were obtained and evaluated (UN;ST/NAR/6-11), and the majority of forensic science laboratories started with a representative sample (n) of a population (N) based on Equation 2.1 a or b.

Equation 2.1 Non-statistical formulas to calculate sample size for analytical testing

$$(a) \quad n = \sqrt{N}$$

$$(b) \quad n = 10\%N$$

$$(c) \quad n = \sqrt{N} + 1$$

Representative sample (n) of a population (N).

These laboratories selected representative samples based on no more than 10% of the whole population, especially in cases in which a random sample was taken from a population containing more than 100 individual units. Considering the findings mentioned by the United Nations Drug Control Program, the South African FSL adopted an approach which started with the selection and evaluation of a sample size that was equal to or larger than the one used by the requirements in 1989. It was decided to evaluate a sampling formula based on Equation 2.1 c, for the selection of sample units to be analysed. Initially a visual examination was conducted to evaluate the physical characteristics of all units in the population. The analysts took into consideration the type of container, material, colour, approximate size, label or stamp and the physical appearance of the contents, whenever possible. If all units (containers with powdered material) were similar in appearance, the population was preliminarily considered homogeneous. Alternatively, if the units were different, all of those presenting the same visual characteristics were grouped together obtaining various sub-populations independent from one another. Once a homogeneous population was obtained, the units were counted. The formula was applied to determine the representative sample upon which qualitative analysis of controlled substances would be performed. The units were randomly selected from the population under consideration. After counting the units or tablets it was placed back into a container and tablets or units were randomly drawn from the bag. In this way, each unit had the same opportunity or probability of being chosen. The selected samples were screened by means of preliminary analytical tests such as colour tests or thin layer chromatography and thereafter a single sample would be taken for confirmatory testing on an FTIR or GCMS. This conservative approach increased productivity, while at the same time sustaining the forensic drug analysis with an acceptable level of scientific certainty. In other words, the sample scheme maintained the analytical methodology and defensibility necessary to comply with the legal definition of proof in the South African criminal justice system. With the implementation of ISO17025:1999 the forensic science laboratory of South Africa decided to adopt the hypergeometric approach in combination with Equation 2.1 c. This approach allowed the laboratory to use smaller amounts of test samples for analysis when the population size was large, but when the population size was small the number of test samples were also similarly small. The combination of the two approaches was not ideal and it was decided to remove the latter approach 2.1 c from the quality documents.

2.7.3 Statistical sampling plans

Non-statistical selection of samples from drug evidence have been and are still accepted by many courts, however, these methods do not allow for the use of pre-established standard and statistical probabilities. The hypergeometric distribution and Bayesian method both provide such standards in the form of confidence levels. Accordingly, these methods permit strong probability statements to be made regarding the portion of the exhibit that contains a controlled substance (Tzidony, 1992; Colón, 1993; Coulson, 2001).

The initial consideration is to determine what confidence level or levels should be employed in the sampling. For the composition of the entire exhibit, it should be sufficient to demonstrate with good probability that most of the exhibit contains the controlled substance. An inference, made at the 95% confidence level, that 90% or more of the packages in an exhibit contain the controlled substance, should be accepted as sufficient proof in such cases. The combination of these principles and the experience of the forensic scientist should enable a conclusion to be made with reasonable scientific certainty about the contents of the entire exhibit.

A single measured test sample either lies within the calculated 95% confidence interval or not, but the scientist will not know beforehand to which category the test sample belongs. If the forensic scientist calculates the 95% confidence interval from randomly selected test samples, the population proportion of the seized drugs will be included in the confidence interval in 95% of the samples, but will be outside of the confidence interval in the other 5% of samples (Motulsky, 1995).

The measurement of uncertainty should also be taken into consideration when choosing a sampling method. Analytical methodology has improved over the last decades and requires reduced test portions for analysis, e.g. , much larger powder samples were used during colour testing methods than the amount required for GCMS analysis today (LGC/VAM/063, 1998; LGC/VAM/085, 2000). In other words, the more sensitive the analytical methods became, the less sample was required for a positive identification. This in turn increased the total uncertainty of the analytical process due to the risk of contamination factors in the sub-sampling and sample preparation processes (LGC/VAM/048, 1999). It is therefore necessary to include the uncertainty measurement during sub-sampling in the total uncertainty measurement of the analytical result whereas

the uncertainty measurement during the basic sampling process was usually treated separately (EURACHEM/CITAC Guide, 2007).

Bayesian logic can be used to combine the result of the analytical test with prior probabilities to determine the probability that a sample contained a controlled substance. The Bayesian approach in qualitative analytical tests, where test samples are either positive or negative can be expressed in terms of sensitivity and specificity. The objective results of tests are combined with prior analytical suspicions to calculate probabilities that controlled substances are present. Bayesian logic in qualitative and quantitative tests integrates the result of one laboratory test into the entire analytical picture. The Bayesian approach within the forensic drug environment is based on previous assumptions made as well as results obtained within the laboratory. The scientist using this approach should incorporate some knowledge of the seizure on hand as well as previous experience of similar evidence received by the laboratory. With this information the scientist will be able to establish a mathematical sampling process (ENFSI: DWG 1993; Coulson, 2001). Once the population is defined, a suitable sampling plan is developed or adopted and sampling procedures are documented. A decision flowchart of a sampling scheme could be developed and placed in analytical laboratories where case opening takes place.

2.8 EQUIPMENT SUITABILITY

It is the responsibility of the user of the analytical equipment to provide evidence that the equipment is appropriate for its intended purpose. Equipment is not restricted to instrumental equipment for the performance of analytical measurements, as it includes all items necessary to perform sampling, sample preparation, measurement, test equipment and calibration. Items and equipment not available at the laboratory must comply with international standards (ISO17025:2005 5.5.1; TG01-01 6.7.1.1; ASCLD;2005 1.1.2.6). Whether performing a wet chemical analysis or a sophisticated instrumental experiment, a history of results must be documented with regard to repeatability and reliability which should lead to equipment qualification. The equipment qualification enables the user and manufacturers of analytical equipment to provide evidence and quality assurance on the fitness of the equipment for its intended purpose.

In 1984, the United Nations Division of Narcotic Drugs published basic requirements which provided assistance to national authorities with regards to skills, equipment and reference materials which were needed to operate a narcotics laboratory (UN ST/NAR/2, 1986). It

was also a guide to allow national authorities to access existing resources in government and university laboratories. Provision had to be made for a confirmatory analytical method by means of either ultraviolet-visible or infra-red spectroscopy for qualitative analysis and gas-liquid chromatography for quantitative analysis. Other equipment recommended by the guide included:

- a. Volumetric measurement equipment e.g. graduated cylinders, pipettes, etc.
- b. General glassware e.g. beakers, test tubes, Erlenmeyer flasks, etc.
- c. General equipment and material e.g. melting point apparatus, wide field microscope, etc.
- d. Weight measurement equipment e.g. analytical balances, top loading balances, etc.
- e. Extraction and separation equipment e.g. mechanical shaker, centrifuge, filter paper, etc.
- f. pH estimation equipment e.g. pH paper 0-14
- g. Distillation and evaporation equipment e.g. rotary evaporator, condenser, laboratory jacks, etc.
- h. Thin-layer chromatography (TLC) e.g. silica plated glass plates, developing tanks, etc.

Reference books and informative material were recommended to support the instrumentation and interpretation of data generated. It was only in the late 1980's-early 1990's when the South African FSL was exposed to more sophisticated instrumentation for the analysis of controlled substances. The first integrated instrument, a gas chromatograph mass spectrometer (GCMS), was received in 1988 and was only used by one experienced analyst for samples that could not be identified via infra-red spectroscopy. In 1993, a second GCMS was purchased for the identification of unknown substances. In 1995 all representative samples were analysed on GCMS as a confirmatory test requirement.

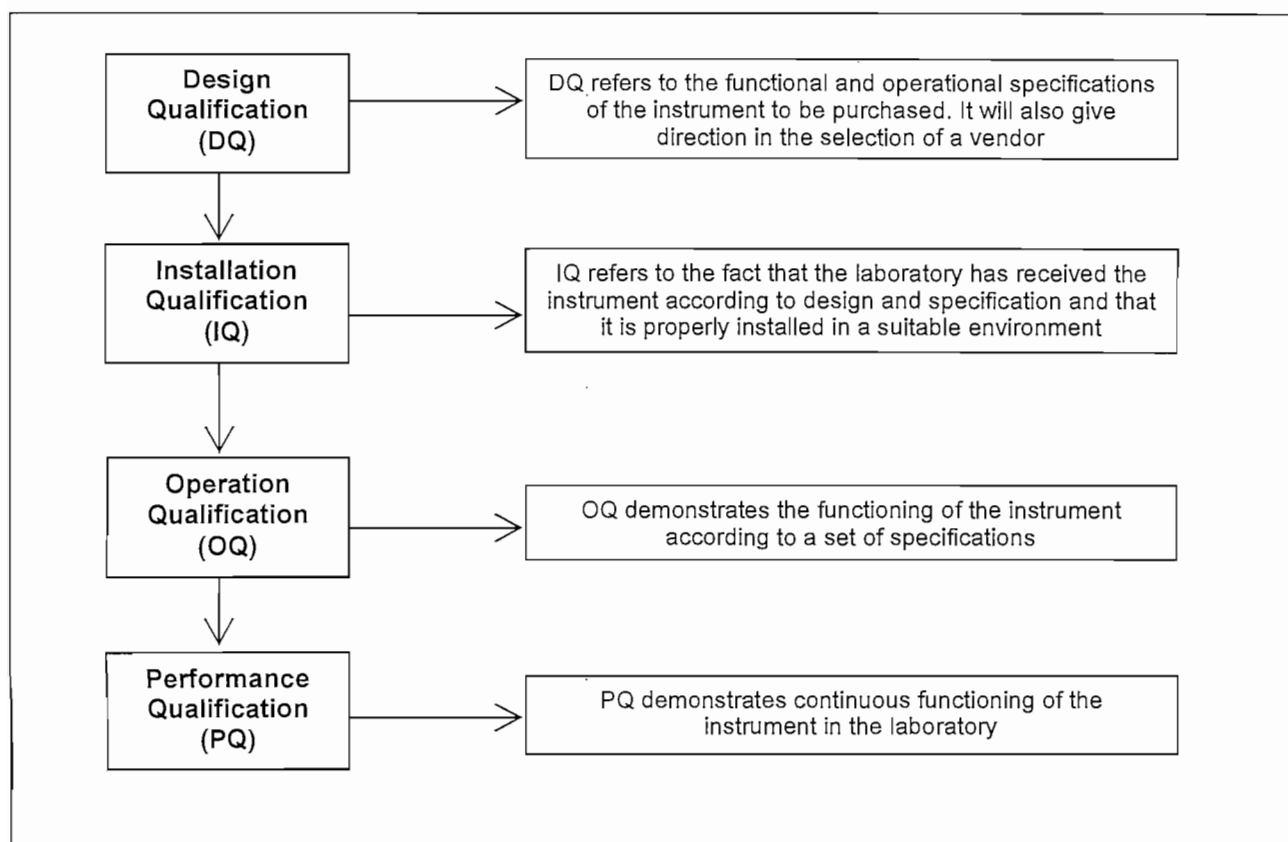
In the early 1990's, forensic science laboratories were introduced to the quality assurance of equipment. Quality standards stipulated that calibration and testing laboratories are required to implement a policy for the maintenance, calibration and testing of equipment utilised in the laboratory (Huber *et al.*, 1996). Quality standards categorised equipment into:

- a. General laboratory equipment not used for making measurements e.g. non-volumetric glassware, hot plates, stirrers, cameras, etc.
- b. Volumetric glassware

- c. Measuring instruments e.g. thermometers, balances, pH-meters, spectrometers, chromatographs, refractometers, etc.
- d. Microscopes including attachments
- e. Computers and data processors

General laboratory equipment had to be maintained by visual examination, safety inspections and cleaning as necessary. Calibrations or performance inspections were necessary as equipment settings could significantly affect the test or analytical results. In 1992, specific guidance was given for the use of volumetric equipment in NIS46. However, it was not enough just to service instruments periodically, or to clean and calibrate them, but periodic performance inspections had to be carried out and limits of acceptability had to be set in advance. The frequency of such performance inspections was determined by past equipment history and was based on the need, type and previous performance of the equipment. Performance inspections had to be documented and had to be completed before equipment was used or before results were accepted (ISO Guide 25:1990; EN45001:1989, NIS 46:1992). Furthermore, regulations, principles and directives concerning laboratory work, such as good laboratory practice (GLP:1992) principles and regulations and good manufacturing practice (GMP:1992) directives and regulations, all included chapters that specifically dealt with equipment (Huber, 1995). Most of the statements made during this time, had one common goal in mind, i.e. to use validated methods and standardised equipment when making analytical measurements (VAM Principle 2:1996). Unfortunately, all these quality standards and regulations were not specific enough to give clear guidelines as to what is actually required or how it should be achieved. The standards were written in broad terms to be widely applicable in analytical laboratories.

In 1995, Huber published a paper on the selection of a vendor, installation and operation of equipment, qualification of software and computer systems, routine maintenance and ongoing performance control as well as handling of defective instruments (Huber, 1995). An instrumentation working group under the aid of Eurachem-UK developed guidance for users and vendors of analytical instruments with a clear and consistent approach for the qualification of analytical instruments. The equipment qualification process described in the document is summarised in Flow Chart 2.7 and is based on four stages of "qualification" i.e. design qualification, installation qualification, operational qualification and performance qualifications (Bedson *et al.*, 1996).

Flow chart 2.7 The equipment qualification process

Adopted from Bedson *et al.* (1996).

The interaction of vendors and end stage users brought a new dimension of standards to the global forensic field. New requirements dealt with capacity and quality of equipment and ensured that the analytical instruments being used were suitable to perform selected analytical tests. The equipment purchased had to comply with specifications relevant to the analytical tests. Before equipment can be used for analytical measurements, it should be calibrated to ensure that it meets the analytical requirements stipulated by the laboratory, as stipulated in the operational qualification (ISO17025:2005 5.5; TG01-01 6.7.2; ASCLD2005 1.4.2.11/12/13).

Quality control should be performed by means of record keeping which includes:

- a. The type of equipment and its software.
- b. The name, model and serial numbers as specified by manufacturers.
- c. Verification that the equipment complies with specifications.
- d. Where it is located.
- e. The manufacturer's instructions.
- f. The dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and the due date of the next calibration.
- g. The maintenance plan and history of maintenance carried out.

- h. Any damage, malfunction, modification or repair to the equipment (ISO17025:2005 5.5; TG01-01 6.7.1.3/4/5).

Instrument suitability testing is part of a validated method process. It requires that the operational parameters of the analytical instrument meet the requirements of the analytical method. The instrumentation used in drug testing laboratories should have an appropriate performance for a given task. SWGDRUG defined analytical techniques as belonging to one of three different categories, (see table 2.1), according to technique strengths and limitations that could affect the design of a validation plan. A laboratory's need should determine the analytical approach.

Table 2.5 Categories of analytical techniques

Category A	Category B		Category C
Infrared spectroscopy	Capillary electrophoresis	Microcrystalline tests	Colour tests
Mass spectrometry	Gas chromatography	Pharmaceutical identifiers	Fluorescence spectroscopy
Nuclear magnetic resonance spectroscopy	Ion mobility spectrometry	Thin layer chromatography	Immunoassay
Raman spectroscopy	Liquid chromatography	Cannabis-macroscopic/microscopic examinations	Melting points
---	---	---	Ultraviolet spectroscopy

Adapted from SWGDRUG Analytical Techniques (2003).

In an analytical scheme performed by any forensic drug laboratory, a category A technique is compulsory. This technique is normally the confirmatory analysis to identify a control substance or a mixture of substances. Any confirmatory analysis should be preceded with a preliminary test or tests to provide direction to rule out false positive identifications. Category B or C techniques are normally used for this purpose. Exceptions exist when hyphenated techniques are used e.g. GCMS. In such cases only one analysis is needed when both retention time and ion fragmentation spectra are compared to a reference standard. All equipment used in any of the categories should be properly maintained. Where calibration is needed, calibration intervals should be documented, performance inspections conducted and records kept.

2.9 METHODS OF ANALYSIS

The quality systems require that analytical measurements used in the forensic drug laboratories should be "fit for purpose". Both system suitability and equipment qualification

should address this problem, but in different ways and with different terms of reference. In this context, the “*system*” includes all equipment used in the process, and is not restricted to the core analytical instrument. Once a system is determined to be suitable and an instrument is qualified; methods can be developed that are fit for its intended purpose. Method of analysis can be defined as the analytical technique employed to obtain a result that either describes the sample in terms of the identity of its elemental parts e.g. atoms or molecules, or the quantities of each of the constituent parts of the sample. Forensic scientists need a profound knowledge and understanding of the fundamental principles upon which modern measuring devices are based before choosing an analytical instrument. Only then can intelligent choices be made from the several possible ways of solving an analytical problem.

In the early years of forensic science, qualitative analyses entailed the separation of controlled substances in a laboratory sample by precipitation, extraction or distillation (Skoog & Leary, 1992). The separated substance was in turn treated with reagents that yielded products that could be recognised by their odour, colour, boiling or melting points, solubility in a series of solvents, optical activities or refractive indices (Skoog & Leary, 1992). Particular processes that demonstrated repeatability for years and indicated continuously specific results changed suddenly when the same results appeared for different analytes while using a specific method. For example, colour tests indicated repeatable colour reactions for a specific analyte and convictions resulted mostly based on confessions from the accused, however similar colour reactions have recently been produced from starches and foot powders.

Gravimetric or titrimetric measurements to determine the concentration of a controlled substance in a sample were used during quantitative analyses (Skoog & Leary, 1992). These classical methods for separating and determining analytes still have a use in many forensic laboratories, but the extent of their applicability has decreased over time. With the evolution of instrumental methods, as described in the previous section, forensic scientists were exposed to more sophisticated analytical techniques for identifying analytes and determining concentrations. Although many of the principles on which analytical methods were based have been identified for more than a century, their applications by most chemists were delayed by the lack of reliable and “simple” instrumentation.

Due to an alarming increase both in the frequency and volume of seized controlled narcotic substances such as opiates, cocaine, cannabis and other synthetic drugs, the

technical and scientific staff of forensic laboratories are confronted with enormous challenges. Innovative chemists continuously produced illicit narcotic drugs or combinations of drugs and placed these products on the illicit market. The increase in illicit substances required rapid and adequate action as well as ingenuity on the part of forensic scientists. With the scheduling of more and more substances, additional pressure was placed on forensic scientists internationally to use faster, more accurate and more specific methods of identification and analysis. National and international law enforcement authorities had to be notified on new trends and analytical data had to be provided soon after the discoveries were determined. The exchange of analytical data internationally required internationally acceptable methods of testing to achieve these objectives.

In February 1984, the Commission on Narcotic Drugs requested the Secretary-General of the United Nations "to investigate the possibility of reaching agreement at the regional and interregional levels of recommended methods of analysis of drugs seized from the traffic". In response to the Commission's request, a group of fifteen experts was convened in October 1985 by the Division of Narcotic Drugs in Wiesbaden, Germany, to develop recommended methods for testing controlled substances (UN, ST/NAR/6,1986). The first manual on recommended methods for testing heroin was published by the United Nations in 1986 (UN, ST/NAR/6, 1986). Followed by a series of recommended methods for other controlled substances such as cocaine, opium/crude morphine, illicit ring-substituted amphetamine derivatives, etc. (UN, ST/NAR/7, 9, 10,11, 1987 etc.) These recommendations only prescribed methods and procedures to be followed from sampling until confirmatory testing, and used techniques such as colour tests, thin layer chromatography, UV-VIS and infrared spectrometry for qualitative analysis and gas liquid chromatography for quantitative analysis.

Analytical accuracy became more important because the traditional use and abuse of controlled substances were not confined to developed countries, but spilled over to developing countries as well. After their meeting in November 1992, the United Nations Drug Control Program published new recommendations to be implemented by international laboratories to increase quality assurance and GLP on analytical procedures (UNDCP:ST/NAR/26:1995).

For the first time, forensic drug laboratories had to define the methods and procedures used in the analysis of seized materials. The details had to be compiled in standard operating procedures. The working methods were either developed internally or were

adopted from published scientific literature. Those developed internally had to be documented with regard to content, format, standards to be run, special requirements for handling reagents, etc. These documents were only developed for standard routine methods and excluded non-standard methods. Early developments introduced the first parameters for method validation:

- a. Sensitivity (limit of detection)
- b. Specificity (freedom from interference)
- c. Repeatability (ability to provide consistent results for qualitative analysis)
- d. Precision
- e. Accuracy
- f. Dynamic range of the assay for quantitative analysis.

For comparison between two methods e.g. an old and a new method, a suitable statistical procedure had to be used to test if there was a significant difference between the two methods with either a one-tailed test of significance or a two-tailed test of significance.

For each of the analytical methods used, a document had to be developed for the SOP manual which included:

- a. The theory and principle of the method.
- b. The instructions for preparation of the substance.
- c. The instructions for preparation of calibrators and controls.
- d. The details of the analytical procedure and its validation.
- e. Information about any special requirements for handling reagents and ensuring safety.
- f. The references to the relevant literature.

Three types of methodologies are used in forensic drug laboratories namely immunoassays, qualitative analysis and quantitative analysis. Regardless of the sample type or methodology followed, the basic principles stay the same dependent on the structure of the analytical procedure. The majority of analytical procedures consist of six distinguishable steps:

- a. Sampling
- b. Sample preparation
- c. Measuring
- d. Data processing
- e. Testing, controlling and correcting
- f. Establishing a quality merit

No analytical procedure is complete without a proper validation of each of these stages and of the final result. Since 1995, considerable attention from literature, the pharmaceutical industry and regulatory agencies, has been given to method validation (U.S FDA CGMP section 211.165(e); ISO Guide 25 section 5.3; ICH; EUROCHEM Guide; ISO17025:1999 section 5.4; ASCLAD section 1.4.2.6; VAM Guide; USP chapter 1225). Working groups of International committees defined a number of parameters for method validation. Many variations were developed and implemented until an attempt by the ICH was made to harmonise pharmaceutical applications (ICH1996). Representatives from different countries not only define these parameters, but also to some extent prescribe the methodology for analytical method validation. A summary of the parameters and a brief description is given in Table 2.2.

Table 2.6 Brief description of parameters for analytical method validation

Parameter	Description
Specificity	Method applicable for a single analyte only
Selectivity	Method applicable for a number of analytes that may or may not be distinguished from each other
Precision	Method where a series of standards are injected and the test results compared to an acceptable extent. The standard deviation can be subdivided into three categories: repeatability, intermediate precision and reproducibility.
Repeatability	Method where the analysis is carried out by an operator using an instrument over a short period of time
Intermediate precision	Method where test results of an analytical process are compared within a single laboratory over a long period of time
Reproducibility	Method where the precision was obtained between different laboratories
Accuracy and recovery	Method where the test results obtained from the method and the true value agree or the extent to which the analytical value determined compares to the accepted reference value
Linearity	A method to produce test results that are directly proportional to the concentration of analytes in test samples within a given range
Range	The method to determine with precision, accuracy and linearity, the interval between the upper and the lower levels that have been demonstrated
Limit of detection	The point at which a measured value is larger than the uncertainty associated with it
Limit of quantitation	Method to determine the minimum injection amount that produces quantitative results in a target sample with acceptable precision in chromatography, typically requiring peak heights 10 to 20 times higher than the baseline noise
Robustness	The effect that operational parameters have on the analysis results
Ruggedness	The degree of reproducibility of results obtained under a variety of conditions such as different laboratories, analysts, instruments, environmental conditions, operators and materials

Derived from Eurachem, A laboratory guide to method validation (1998).

The selection of an analytical method can be determined by either mapping all available procedures in a multi-dimensional space, where the number of criteria equals the number of dimensions or mapping the method space on the problem space to see if the problem is positioned within the method boundaries. Since 1970, a number of improvements were made in solving this crisis of selection. Today, vendors are partners in method selection and they know that measurements made in forensic drug laboratories are expensive and additional financial implications will evolve from decisions made based on analytical results. For example, analytical results confirming the presence of controlled substances results in criminal prosecution of offenders, the penalty of which may range from a fine in one country to execution in some countries.

Good science, well presented, can be an invaluable aide to a court's deliberations. For this reason, forensic scientists entering the courtroom to offer expert evidence on their analytical test results are accorded a privileged position. With this privilege however comes responsibility. When law enforcement officers submit evidence to forensic laboratories they assume that the laboratory has qualified forensic experts, which will provide assured results. The only way that a forensic scientist can trust that a result is sufficiently reliable, is if he/she has confidence in the instrument and the analytical method that was used, because a validated method describes the use of a valid technique to analyse samples using a validated instrument. Confidence can only be achieved through continuously repeatable results from the method employed. Once the validity of an analytical method is scientifically accepted it will be employed in international laboratories.

2.10 REAGENTS AND STANDARDS

The quality of reagents and standards are important in forensic drug analysis. Forensic scientists must have a comprehensive knowledge of chemical compounds and their reactivities in organic and inorganic reactions. Solvents are used to separate compounds from their matrix and it is therefore important to understand the solubility strengths of the solvents used. The polarity of the analyte and the solvent both play a role in the extraction of the analyte from its matrix.

A variety of chemical grades exists for reagents and should be evaluated according to the requirements of the laboratory. Table 2.2 outlines the different grades of chemicals that are available for analytical laboratories. It is important for the forensic analyst to decide which grade is necessary for a specific function. The higher the quality of the reagent the more expensive it becomes.

Table 2.7 Categories of reagents for laboratory use

Categories	Explanation
Reagent A.C.S	A reagent that meets the specifications of American Chemical Society (A.C.S.)
Guaranteed Reagent GR	Reagents meet or exceed A.C.S requirements and are suitable for laboratory use
AR Grade	The standard Mallinckrodt grade of analytical reagents. It is suitable for laboratory and general use.
Primary standard	Analytical reagent with exceptional purity that is manufactured for standardising volumetric solutions and preparing reference material
Reagent	The highest quality commercially available
OR	Organic Reagents that are suitable for research applications
Purified	Good quality reagents for which there is no official standard. It is limited to inorganic chemicals
Practical	Also for reagents with no official standard which may contain small amounts of isomers or intermediates
Lab Grade	A series of solvents for general laboratory use
USP Grade	Chemicals manufactured under Good Manufacturing Practices which meet the requirements of the US Pharmacopeia
USP/GenAR	A line of chemicals manufactured under GMP, which meet the requirements of the 1995 USP 23, meet European Pharmacopeia, British Pharmacopeia and are endotoxin tested
NF Grade	Chemicals meet the requirements of the National Formulary
FCC Grade	Chemicals meet the requirements of the Food Chemical Codex
CP (Chemical Pure)	Products of purity suitable for the use in general applications
Technical Grade	Reagents for general industrial use

Derived from internet www.Americanchemicalsociety.com, www.aldrich.com, www.merck.co.za (2009).

Procurement of reagents is difficult when a new laboratory starts as it must go through the process of selecting the right chemical supplier and building a relationship of trust, as well as setting up systems for receiving the reagents and the correct storage thereof. In the past, procurement of goods and services in the South African forensic science laboratory were difficult due to the requirements of getting three quotations before any purchase. This resulted in the dependence of the FSL on a number of companies who supplied the laboratory with low quality reagents. In the 1980's and early 1990's all solvents that were used in the Forensic Chemistry Unit had to be distilled to eliminate the possibility of contaminants in purchased solvents. The majority of reagents were cleaned as they were used for wet chemical analysis, colour tests and thin layer chromatographic analysis in forensic drug testing. With the acquisition of the new analytical equipment in 1994, AR grade reagents were motivated for instrumental use. In 1995, the first requirements for the use of reliable reagents and standards in critical measurements were published in ISO Guide 25 and implemented in the forensic laboratory which emphasised the importance of analytical grade reagents. For the first time, laboratory managers had the opportunity to motivate and purchase higher grades of chemicals which would in return comply with

quality standards. All reagents and materials had to be matched according to the specifications of quality required by the method, by regulation or by good laboratory practise (UNDCP STR/NAR/25:1995 ISO Guide 25, par 8.1). The reagents had to be labelled upon receipt with the date received, the expiration date and the date opened. The same requirements were set for chemical preparations made for colour testing and thin layer chromatographic developments.

Registers had to be implemented to demonstrate the date of preparation, the ratio of chemicals used, the analyst or laboratory assistant who prepared the solution and the expiration date. Laboratory assistants were trained in the possibility of contamination when bottles are not properly sealed and the content exposed to air. They were also trained to follow good laboratory practices when removing smaller amounts of powders and liquids from larger containers during reagent preparations. Material Safety Data Sheets (MSDS) were prepared to indicate hazardous properties of chemicals used in the laboratory and the medical treatments to be implemented upon exposure to these chemicals. The quality of analytical results increased once the quality of the critical reagents and standards were upgraded. More requirements on reagents have evolved since 1999, which required that all reagents be routinely tested for their reliability, that the recording of lot or batch numbers of all critical reagents are made and storage conditions and hazardous warnings be indicated on labels (ASCLD/LAB:1999 par 1.4.2.10 and TG01-01, par 6.5.5). The newly adopted requirements set by ISO17025:1999 quality system, enable laboratory managers to demonstrate the importance of buying from accredited chemical companies only. Suppliers of goods and services have to comply with quality requirements. Today, the South African forensic science laboratories have purchase contracts with reliable chemical suppliers which are revised once a year.

The laboratory placed more emphasis on reference standards in analytical methods from the beginning of the process. Traceable reference materials were received from the UNDCP in the late 1980's. Due to the low quantities of reference standards received, the laboratory was forced to clean samples from completed case exhibits that were extracted and compare them to UNDCP reference standards. The samples were then re-crystallised and used as reference standards on thin layer chromatographic plates next to laboratory test samples for comparison. They were also used as reference standards for FT-IR analysis.

The importance of reference material was emphasised in EN45001 and ISO Guide 25 in 1989 as these materials provide traceability in analytical measurements and demonstrate

the accuracy of results. A number of uses for reference materials were encouraged including the calibration of equipment, monitoring laboratory performance and validating methods by comparing methods. Two classes of material were recognised by ISO, namely reference materials (RM's) and certified reference materials (CRM's). Both were defined in ISO/IEC Guide 30:

- a. "A reference material (RM) is a material or substance 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."
- b. "A certified reference material (CRM) is a reference material whose property values are certified by a technically valid procedure, traceable to a certificate or other documentation which is issued by a certified body."

There are no technical differences in the production of CRM's and RM's. It is only the certified value and the uncertainty associated with it that differs (ISO Guide 34). Reference materials produced prior to the early 1990's did not indicate any level of uncertainty. A number of publications followed in the late 1990's to define the different classes of reference material and their associated uncertainty levels (De Bièvre *et al.* 1996; Pan, 1997; Eurachem/CITAC, 2000).

An internationally harmonised quality system to assure the competence of reference material producers was necessary and ILAC Guide G 12:2000 set the tone followed shortly by ISO Guide 34:2000. International laboratories, producing a range of pure organic substance reference materials can seek accreditation through ISO Guides 31, 34 and 35 today. ISO17025 specifies that reference materials should be traceable to certified reference material and intermediate checks should be performed on the reference materials to maintain their confidence (ISO17025:2005, paragraph 5.6.3).

Laboratory of the Government Chemist (LGC) published a number of papers on the production of in-house RM's (LGC/VAM/1998/040; LGC/VAM/2001/009 and 010). Several considerations should be taken into account before engaging in in-house RM productions. In-house production of RM's can be costly and time-constraining if scientists are not properly trained on RM production. If done correctly, a lot of money can be saved, however in-house productions always end up in legal issues having to defend their reliability (Venelinov and Sahuquillo, 2006). It is therefore advisable for crime laboratory managers to purchase reference materials from accredited suppliers, when possible.

However, a larger range of reference material is needed from suppliers due to a continuous production of illicit drugs or new designer combinations that appear on the illicit market internationally. Due to the low quality control on the side of the illicit producers, each new preparation contains not only the controlled substance but also two to three intermediates or by-products. With more than two hundred controlled substances, excluding salts, isomers and esters in the South African Drug and Drug Trafficking Act (Act 140 of 1992) and many more in the Medicine and Related Substances Act (Act 101 of 1965) it is impossible to keep reference material for all of these in the laboratory. CRM's and RM's are purchased according to the changes in fashion of controlled substances on the illicit market. It is however still a concern to identify or verify intermediates or by-products in the forensic drug laboratory.

In 2004, Cordeiro published a paper on analytical requirements and the improvement of the quality of measurement results. In the paper, it was recommended that quality improvement of a measurement result should not only rely on more sophisticated instrumentation, but also on the quality of the reference standards used as *calibrants*. The paper recommended that RM's should also be declared with confidence interval values. This enables scientists to conduct method validation studies, whereby scientific and statistical principles are followed.

Venelinov and Sahuquillo published a paper in 2006 in which they describe the optimisation of the uses and costs of RM's in analytical laboratories. They also differentiated between CRM's and RM's, but they referred to RM's as quality control materials (QCM's). The study recommended CRM's to be used with method validation, measurement uncertainty and instrument calibration, which should contribute to internal quality control. QCM's should alternatively be used with statistical control schemes for internal quality control and proficiency testing schemes for external quality control. Even though CRM's and QCM's are expensive to purchase from accredited production laboratories, it prevents frustration and allows these laboratories to focus on their core business of analysis and comparison.

2.11 PERSONNEL

Personnel are the most valuable asset to any organisation, but also the most difficult resource to manage. Appointing new personnel in public agencies is a rigorous and long process that might take six months to a year to finalise. It consists of many steps that an

applicant must successfully pass in order to be considered for a position. Other than a basic appointment, forensic scientists could be faced with submitting a resume, completing an application, passing a written knowledge examination, undergo a personal history background investigation, passing a polygraph examination, passing a pre-employment drug screen and participation in one or more interviews with various staff members. If treated well, after appointment, the lifespan of a staff member can be more than 20 years which is more than any other resource in a laboratory. It is therefore important to employ individuals according to the long term vision of the laboratory and not merely for filling gaps. The process starts with clear qualification requirements for the position. The position qualification should define the quality, knowledge, ability, experience and acquired attributes needed. The interview should include an explanation of the job description and tasks to be performed after appointment. It should also cover a walk-through of the direct environment wherein the new staff member will work (St. Clair, 2003). Derek Mengel, managing director of CHART DBM South Africa, career management specialists, published an article within the "Recruitment update" that 90% of staff resignation is caused by poor hiring decisions which will have expensive consequences.

After appointment, a thorough orientation program should exist whereby a new employee will learn more about the laboratory, working conditions, pay days, personnel policies, benefits, daily routine, safety requirements etc. Handing a new employee a big package of material and leaving the person alone to read should be avoided. It is also important to start with the quality philosophy of the laboratory at this stage. On completion, an internal training program should commence.

The laboratory should have a well defined training program for technical as well as administrative staff. This study will only focus on technical staff performing drug analysis. Three categories of training should exist:

- a. Training for the new analyst.
- b. Training for the present analysts whose performance is insufficient.
- c. Long term training, called development training.

As staff members build experience and tenure within the laboratory, further training should be offered in recognition of their growth. Quality guides have recommended since the early 1990's that forensic drug analysts should have a baccalaureate degree, diploma or equivalent qualification in the field of natural sciences, criminalistics or *in a closely related field* as the basis for employment (ISO/SANAS Guide 25, TG01-01, ASCLAD/LAB2005).

This is however not enough to be regarded as a forensic drug expert, but only serves as the foundation for a comprehensive internal or external drug training program. It is the responsibility of the laboratory manager to provide opportunities for forensic drug scientists to receive training that is adequate for the performance of the tests and operation of equipment. Before examiners are exposed to or have access to unsealed evidence material to allow for the removal of samples for examination, they should have completed a training program which should include the following:

- a. Documented standards of performance with assessment on the theoretical and practical competency against the standards.
- b. A training syllabus providing information on drug classes, their origin, status of control, chemical characteristics and methods of sampling, extraction/isolation and identification. It should also include the uses and limitations of analytical techniques, methodologies and instrumentation for reliable qualitative and quantitative analyses of controlled substances.
- c. Quality assurance.
- d. Expert witness testimony and legal requirements.
- e. Laboratory policies and procedures.

On completion of the above, forensic drug analysts should work under the supervision of an experienced analyst until they demonstrate the required competence in the field in which they were trained. An internal proficiency test or tests will serve as verification, demonstrating that the analyst has achieved the required competence to work independently. Authorisation can be given by the laboratory director or his designate for the analysts to perform casework independently.

Any quality system should include a portfolio of evidence on the training progress of the analyst. The portfolio of evidence should include a statement of qualification, statement of internal training, internal proficiency test results, specialised training received and a developmental program in the laboratory. The purpose of these records is to demonstrate specialised internal and external training were received, that an individual analyst is competent to carry out specified analytical tests and proper assessment during this time was conducted by superiors. Additional authorisation should be given to analysts performing specialised tasks within the laboratory, for example, operators performing maintenance on instrumentation. Specialised training by vendors or experienced staff should be documented and recorded in portfolio files.

A key objective of any laboratory should be to continuously empower staff through professional training. The ongoing responsibility to remain current in the specialised forensic disciplines lies with the forensic scientist performing analytical work. Laboratory managers should provide financial support and opportunities for continued professional development. During performance evaluations and appraisals, prospects for advances in the work situation should be discussed in the form of further training and development. The training should include a number of contact hours of training every year relevant to the laboratory's mission to improve service delivery. Training interventions may include chemistry or instrumentation courses from tertiary institutions, instrument operation or maintenance courses presented by vendors, in-service training and participation in relevant scientific meetings or conferences nationally or internationally (SWGDRUG, 2003). The irony in retaining good scientists is that the more they feel that they are able to grow and become more marketable, the more likely they are to stay (Mengel, 2000).

2.12 QUALITY ASSURANCE

ISO defines quality assurance as the process where an entity provides adequate confidence in its fulfilment of quality requirements through the demonstration of a quality system that includes all activities within the entity (ISO8402). Until 1984, little attention has been paid to quality assurance in forensic science laboratories. In 1984, Pereira, discussed quality assurance in forensic science in the United Kingdom and summarised quality assurance as follows:

- a. Promoting standardised performance by all role players in the process of evidence collection, examination of evidence and court presentations.
- b. Identification and rectification of problems arising in the process.
- c. Continual technical revision of methods, procedures, equipment and analytical data.
- d. Empowerment of all staff and law enforcement agents through training and education.

In the early 1990's, quality control became the first measuring tool for quality assurance and was soon followed by good laboratory practice. Quality Control (QC) schemes were set up to monitor certain activities in forensic science laboratories related to analytical testing (NIS46, NAMAS). As part of a quality system in testing laboratories, laboratories had to develop a level of QC depending on the type of the analysis, frequency of analysis, sample size, equipment needed and skills required. It was also recommended for analytical laboratories to participate regularly in proficiency testing or inter-laboratory comparisons as an integral part of their quality assurance protocols (SABS0259:1990). At

the time, ISO had already published a number of recommendations on participation in proficiency testing with ISO/IEC Guide 43 and ISO5725.

More attention was given on this topic with the publication of "Recommended guidelines for quality assurance and good laboratory practices" by the UNDCP in 1995 (ST/NAR/25; UNDCP). Again emphasis was placed on QC measures to make sure that results released by the laboratory were reliable. A number of new concepts were incorporated under the heading of quality assurance that included quality control, proficiency testing, case record review and court testimony monitoring as well as corrective and preventative actions (ISO Guide 25 and SANAS, 1997).

The quality assurance program should provide evidence of satisfactory operations through careful documentation. The quality assurance should lie in the quality system which covers the entire operation of the laboratory and its intended quality service. The quality control system should cover internal control that covers specific samples and batches of samples through the analysis of reference material / measurement standards, quality control samples, analysis of blanks between every sample and analysis of spiked samples. The quality control system adopted must be sufficient to ensure the validity of analytical results. The laboratory should perform continuous risk assessments to determine uncertainty levels during analytical tasks. The risk level should determine the level and frequency of QC. For external QC, it is recommended that participation in proficiency testing schemes be undertaken to establish the accuracy of a laboratory's work by comparison with an external reference to demonstrate that the laboratory has a commitment to quality. Comparison between the performances of different laboratories then provides feedback assurance about the continuing performance of individual laboratories. Proficiency testing can also be performed internally or intra-laboratory testing can be undertaken to ensure an individual in the laboratory is fit to perform analytical work. In 1999, a study by Levy *et al.* indicated that quality assurance in forensic science laboratories is beyond quality control, proficiency testing, review etc. The study indicated that quality assurance should also include exhibit collection which should include sample loss or degradation during evidence collection, examination techniques, forensic expertise and testimony in court.

Quality assurance programs should be able to determine poor performance within the laboratory throughout the entire process of collection, examination and presentation, in order to continuously improve procedures and to strive for zero defects. All errors and their

associated corrections should be documented to add value to quality improvement and to indicate the level of assurance by the laboratory.

SWGDRUG included measurements of uncertainty under quality assurance in their 2003 recommendations. The benefits of determining and understanding uncertainty will:

- a. Enhance confidence
- b. Provide a way of expressing reliable results
- c. Evaluate fitness for the purpose of results
- d. Identify limitations of procedures and provide a basis for improvement and
- e. Comply with quality requirements for accreditation

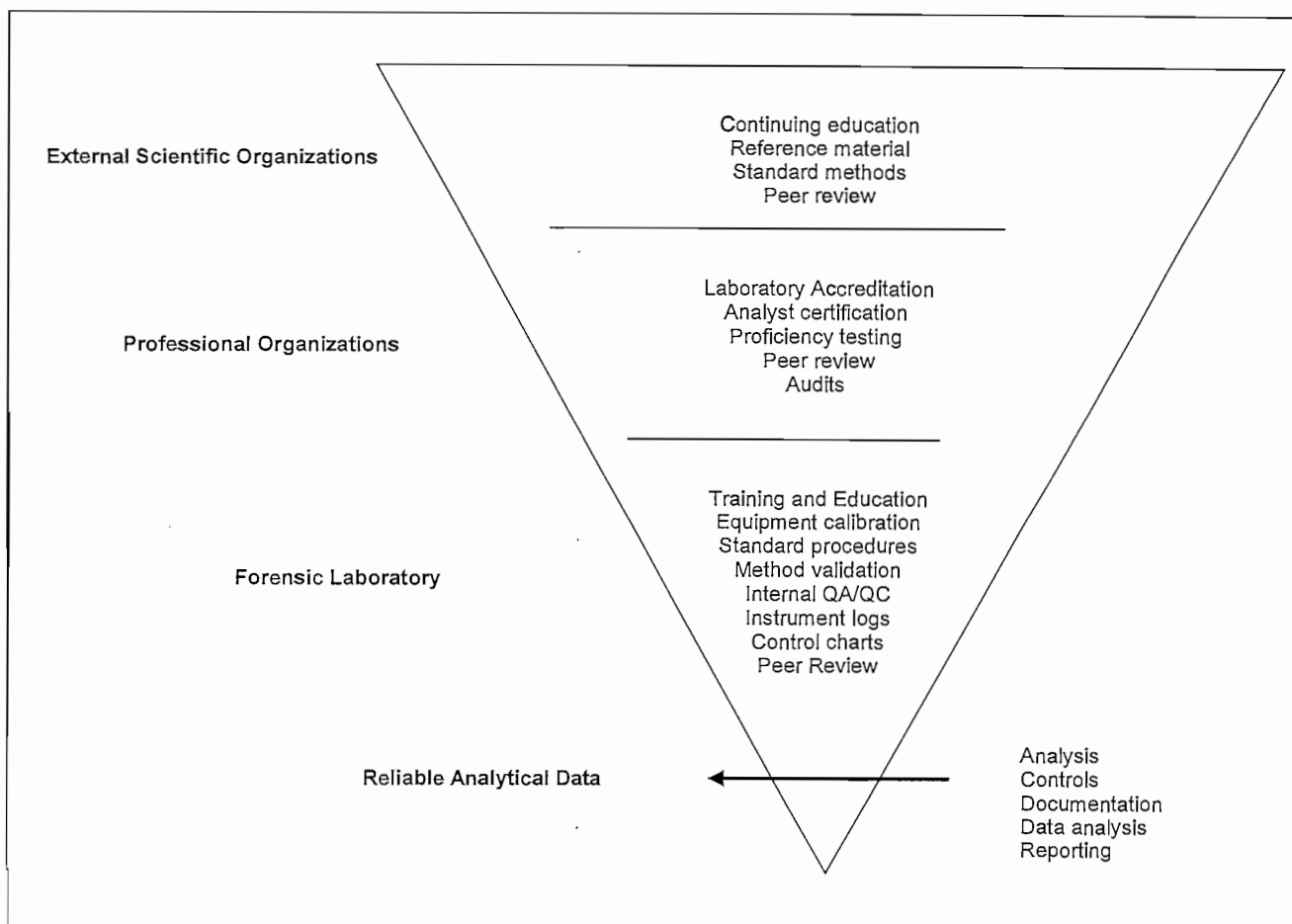
A clear distinction is made between uncertainty measurement in qualitative analysis and quantitative analysis. ISO17025 and other quality systems treat estimation of uncertainty of analytical measurements as an entity on its own under technical requirements. A number of studies have been published over the years since uncertainty of measurements was first introduced (ISO/TAG4/WG3:1993; Haesselbarth, 2004; EURACHEM/CITAC Guide, 2007). For qualitative analytical measurements, an uncertainty of zero in an analytical procedure would indicate an appropriate validated method, however, scientists are aware of all the limitations of analytical techniques. These limitations and their associated uncertainties in qualitative analysis of controlled substances should be documented in the quality system and may need to be included in reports, as for example, isomer differentiation on GCMS.

For quantitative measurements, a more rigorous, metrological and statistical valid measurement of uncertainty is needed for the analysis of controlled substances. Uncertainty begins with correct metrological determinations of drug samples with expressed uncertainty levels, followed by reasonable estimation of uncertainty in the methods employed, based on previous experience and data generated during method validation. The key is to determine uncertainty for all calibrations and types of calibrations. The variants contributing to the uncertainty should include:

- a. Reference standards and reference material used
- b. Methods and equipment used
- c. Environmental conditions
- d. Properties and condition of the samples being tested and
- e. The operator's competency

In summary, quality assurance is an all-encompassing “entry to exit” system that controls data generation. Quality control has to do with the procedures, policies and practices designed to assure data quality. Flow Chart 2.8 illustrates the relationship of quality assurance and quality control, where QA defines the triangle and QC populates it.

Flow chart 2.8 The layered nature of quality assurance



Adapted from Bell (2005).

2.13 CUSTOMER EXPECTATIONS

Until recently most focus has been placed on the core processes in the forensic laboratory and the factors influencing the standard of quality in the laboratory. The crime laboratory manager should ask whether the services which the laboratory renders meet client expectations and if it is relevant to government institutions providing a forensic service as well as exactly whose expectations the forensic laboratories need to satisfy.

During the last decade, more and more criminal activities have evolved across the world. The community expects law enforcement agencies, the criminal justice system and governments to clamp down on these criminal activities in order to provide a safe haven for all. Legislation requires proof before convictions can take place i.e. a person is innocent

until proven guilty. Thus, investigating officers need to gather enough evidence for state prosecutors before charging a person of an offence in a court of law. Forensic scientists have to accumulate more knowledge through discovery and experience to provide evidential value that satisfies expectations of investigating officers, while staying impartial throughout the criminal process. Demands have increased over the last few years on that which can be analysed and the time in which it can be processed. In return, the field of forensic science has experienced numerous advances due to improving technology that has increased capabilities to use forensic evidence. Questions regarding the effectiveness of forensic evidence being used to identify and prosecute offenders and the impact of these advances on the criminal justice system however still remain.

The author of the book "Managing expectations" (Karten, 2003) described expectations as wondrous creatures, which grow, shrink and change shape and direction. These creatures also shift constantly and easily. The performance of laboratories in meeting these expectations will determine the level of customer satisfaction (or dissatisfaction). That means both customer expectations and the laboratories performance play a role in customer satisfaction, and forensic laboratories have to pay attention to both. Quality systems incorporate a management requirement for complaints and anomalies whereby laboratories have to document their policies and procedures for the resolution of complaints or anomalies pointed out by customers. Records should be maintained on the complaints themselves, their investigation and the corrective action taken (ISO Guide 25 par 2.7.2; ISO17025:2005 par 4.8; TG 01-01 par 6.2.6). Nel (2000) refers to customers needs as the voice of the customer, which means the manager of the forensic drug laboratory should have continuous quarterly meetings with law enforcement supervisors and senior prosecutors to listen to their complaints and ideas. This will form a two way channel, one that satisfies the needs (voice) of the customer and another that satisfies the requirements of the quality management system with regard to client feedback.

Forensic drug laboratories should consider two elements of customer satisfaction, namely the technical element and the human element. Generally, few complaints or feedback will be received regarding technical elements as law enforcement and the law has little knowledge of the technical concepts in the specialised field of forensic drug analysis. Law enforcement officers and prosecutors rely on the expertise of the forensic expert to translate the language of science into the language of law in the courtroom. It is only when opposing counsel gain knowledge in the same field that it can be used to challenge the

credibility, conclusions, methods and/or qualifications of the forensic witness (Saferstein, 1988).

The human element produces more complaints, as investigating officers and prosecutors require continuous feedback from the laboratory on the progress of evidence submitted to the laboratory. In the report "Improving Service Delivery, The Forensic Science Service" published by the National Audit Office in 2003, a number of recommendations were mentioned dealing with technical as well as human elements to improve customer satisfaction i.e.

To reduce turnaround times in completing forensic analysis, focusing on:

- a. Sufficient and skilled staff to meet demand for its service.
- b. Police should understand presentation of forensic evidence so that its quality is not impaired and that supporting information is complete.
- c. Equal and appropriate distribution of casework across all laboratories.
- d. Send casework to the laboratory with the best capacity to analyse it.
- e. To have more consistent performance across laboratories.
- f. To notify law enforcement agencies when a deadline is not going to be met.
- g. To assess the effectiveness of casework whether it provides conclusive evidence in support of an investigation.
- h. To introduce a new operations management system.
- i. The justice department should routinely inform the laboratory on the outcomes of cases in which it has been involved.

Forensic science drug laboratories should implement the recommendations reported as this is an international problem. The Forensic Science Service (FSS), one of the largest independent forensic services in the United Kingdom, responded to these recommendations by ensuring successful delivery of criminal justice through science and technology and by providing impartial forensic scientific analysis in aid of the investigation of crimes. The laboratory should have a good relationship with the police service and the Department of Justice in the criminal justice system to ensure successful prosecution in criminal cases. Laboratory management should constantly evaluate the skills levels of their scientists and when necessary encourage them to stay abreast of internationally relevant technologies and methodologies. Documented objectives should address evidential turnaround times and these targets should be communicated to law enforcement officials and the justice department.

Laboratories should also communicate their core processes to the law authorities which they serve thus indicating the abilities present in that specific laboratory. It would be a complete waste if a laboratory purchased expensive sophisticated equipment but it only received two exhibits for analysis a year that could be analysed with that specific piece of equipment. The primary level of performance of any laboratory will be determined by skilled staff, quality control and sufficient scientific equipment. The combination of the three should lead to a productive laboratory.

2.14 PRODUCTIVITY

Productivity in forensic drug laboratories can be defined as a measurement of the number of reports dispatched as output in direct relation to the number of cases submitted as input. Flow chart 2.5 presents the elements within a forensic drug laboratory that contributes to productivity. The three major contributors are human, physical and equipment resources. Productivity measurements should be in place in all areas where these contributors are operational. Without measurements, it will be difficult to determine how the laboratory measures up to productivity standards. It will be important to identify critical processes that can influence the whole process negatively. These areas are normally where bottlenecks occur, for example, sample backlogs on GCMS instruments, insufficient sample preparation space in the laboratory or getting reports back from typists. By ignoring critical processes, poor turnaround times evolve which in turn leads to poor service delivery. Productivity, like the other sciences, requires specified measurement skills.

Quality systems include management requirements and technical requirements. Working with people and motivating them to perform optimally is a management skill and not a requirement. Every manager and supervisor in the laboratory should therefore acquire these skills. A lot of productive time is lost every year due to conflicts pertaining to poor measurement caused by the inexperience of managers and the misconception of employees. Managers and supervisors should attain the skills pertaining to productivity and related concepts and employees must also be empowered to learn productivity concepts and measures along with time- and self-management. Supervisors should also determine the capacity of employees and establish a reasonable standard of productivity within the department. Job descriptions for every promotional level as well as performance programs should be a measuring tool for supervisors.

When referring back to Flow Chart 2.5, two categories of factors that influence productivity exist in any laboratory, namely external factors and internal factors. Management has to work within the framework of external factors, e.g., legislation and quality requirements. Most forensic drug laboratories form part of a larger organisation and are under obligation of human resource management policies, work ethics and the financial management of the organisation. To attempt to change these factors, the essence of the laboratory will have to be changed. The second set of factors i.e. internal factors, are within the power of management to change e.g. by motivating the purchase of more GCMS instruments to deal with the heavy load of samples, hiring more administrative personnel to deal with administrative functions or providing more space in laboratories for every analyst to have his own workspace. This will not only improve productivity, but also produce better quality. When management introduces new equipment or appoints more personnel, the improvement must be measured and the results published for employees to monitor their productivity.

An article published in 2001 by the National Productivity Institute ranked South Africa poorly on values and habits that support productivity and competitiveness. Bad habits that inhibit productivity are absenteeism, injuries, lack of motivation and high labour turnover (Venter, 2001). These habits are normally anticipated by an individual who cannot see what value they are adding through their work causing them to feel unwanted, resulting in them being more inclined to look for other employment options. Forensic laboratories can only have satisfied customers if they have satisfied personnel. Strategies in human resource planning, recruiting and retention should be implemented by the laboratory. A number of strategies are published in the literature internationally on employee motivation and valuable asset retention (Becker and Dale, 2003; Becker and Dale, 2004; HR Future, 2001 and 2002; Mengel, 2001).

CHAPTER THREE

Benchmarking Methodology

In the previous chapter, a historical study of the quality concepts which determine the successes of forensic drug laboratories internationally was presented. However knowing all the quality requirements and actually employing them in the laboratory are two different undertakings. In this regard, a benchmarking exercise which could indicate the current state of quality management in forensic drug laboratories and give a better understanding of the quality standards in the international forensic drug laboratories was undertaken. Forensic laboratories tend to adopt a quality system without knowing all the concepts and requirements specified within the system or they are unable to be accredited due to wrong approaches in implementing quality systems in the laboratory.

A benchmarking approach should be a continuous process to identify, understand and adapt the best practices and processes that will lead to organisational excellence. Four basic types of benchmarking practices exist, namely:

- a. Internal benchmarking where a comparison of internal operations and processes are made.
- b. Competitive benchmarking where competitor to competitor comparisons for a specific function are made.
- c. Functional benchmarking where comparisons of similar functions within the same industry are made.
- d. Generic benchmarking where comparison of organisational functions are very similar, but in different industries.

A functional benchmarking approach was followed in this study by comparing quality systems within the global forensic drug industry (dti, 2003). The first step was to determine the sample population i.e. this would be the entire set of laboratories which is the object of research from where qualitative and quantitative data characteristics will be generated by the researcher (Bless and Higson-Smith, 1995).

3.1 SAMPLE POPULATION

A sampling plan should be determined, where statistical calculations would allow researchers to make inferences on the larger population with limited data. The second process would be to select representative samples from laboratories performing the same analysis within the population. This would be possible by means of written surveys, interviews or practical evaluations. The resulting data can be used to make inferences on the larger population.

3.1.1 Determination of the sample population

Forensic drug laboratories are in existence on all six continents globally. A number of these laboratories function as entities on their own, while others function under the auspices of a larger forensic or law enforcement organisation. A study conducted in 2003 by the National Audit office in the United Kingdom revealed the following information on forensic science services in other countries:

- a. There are more than 250 forensic services in the 51 States of America.
- b. One national laboratory and five regional laboratories in Canada.
- c. There are more than 50 registered forensic laboratories in Europe.
- d. Each of Australia's six states and its two territories has its own forensic science provider.
- e. One national and three regional laboratories exist in New Zealand.

From the little information that does exist on forensic drug laboratories globally, the size of the population was unknown and a sampling plan was necessary that would represent the largest number of forensic drug laboratories. It was necessary to select a sample from the greater population as the characteristics of this subset would be generalised to the entire population (Bless & Higson-Smith, 1995).

3.1.2 Selection of the sample from the population

Due to practical reasons, a judgemental sampling plan was chosen. This is classified as a non-probability procedure and is used when small samples have to be drawn from heterogeneous populations. The judgemental sampling method is left to a person who is familiar with the relevant population characteristics, and elements are selected that would represent the population (Pretorius, 2004). The researcher in this study has been employed as a forensic scientist for twenty years in a forensic drug laboratory; thus has

the required capacity for following such a sampling strategy. The strategy involved a questionnaire that was distributed in a convenient setting to reach as many participants in the same forensic drug environment. The first set of questionnaires were distributed via e-mail to twenty laboratories for participation, but a number of problems arose upon the feedback and data received from eleven of the twenty laboratories collected. The format and size of the questionnaire influenced effective feedback thus the questionnaire was reformatted for ease of use as discussed in Chapter 4.

Participants were targeted at the International Technical Training Seminar for Clandestine Laboratory Investigation for Chemists (CLIC) in Vancouver in 2006 and Las Vegas in 2007. CLIC has more than 300 members, who are all scientists working in forensic drug laboratories internationally, performing drug analysis. Every year more than 150 members, mostly from state laboratories in the United States of America and some from other international laboratories, participate in this annual training seminar. The seminar was a convenient setting for the distribution of one hundred questionnaires in 2006 and another ten in 2007. Due to the high level of participation of laboratories within the United States, other laboratories on the CLIC e-mail list were also contacted for participation.

3.2 QUESTIONNAIRE

A preliminary questionnaire was developed in 2004 and after an initial pilot study; problems regarding the layout of the questionnaire were detected. Certain questions were not clearly stated and limited conclusions could be drawn from the answers received. The questionnaire was sent to the director of the Psychological Behavioural Sciences of the North-West University for experienced and professional input on the structure of the questionnaire. It was revised in 2006 to allow for the determination of a set of categorical data points that could be transformed to functional data. Quality variables that were included in the questionnaire were:

- | | |
|-------------------------------------|---------------------------------|
| a. Quality system and accreditation | f. Quality assurance |
| b. Technology/Instrumentation | g. Access control |
| c. Personnel | h. Customer/Client relationship |
| d. Standards and reagents | i. Productivity |
| e. Sampling | |

The questionnaire resulted in 62 categorical questions that covered all of the above mentioned variables on quality and productivity management. The first objective was to evaluate quality recommendations and guides developed during the evolution of quality, and to determine at which level they are currently being implemented by international drug laboratories. The second objective was to determine if a well implemented quality system was conducive to a productive laboratory i.e. is there a relationship between quality and productivity in the forensic drug laboratory. Annexure A is a template of the final questionnaire.

3.3 STATISTICAL ANALYSES

After a 3 year period, responses were received from 70 international laboratories which included twenty seven of the fifty two states of the United States of America (51), DEA federal laboratories (3), Canada (8), Australia (1), New Zealand (1), Belgium (1), Finland (1), the Netherlands (1), Switzerland (1), Taiwan (1) and Israel (1). All categorical data were captured using the Excel database program from Microsoft^{®1}. Data was entered on two separate occasions by two different individuals. The two sets of data were later merged and verified for their authenticity. Laboratory numbers were allocated to each participating laboratory to anonymise the samples. To make statistical inferences on the greater population of forensic drug laboratories, all data had to be converted to a statistical value. The resulting values were calculated and compared to international quality standards such as ISO17025:2005 to evaluate the current status of quality variables in forensic drug laboratories. Firstly the percentages of participating laboratories were calculated for comparison. Thereafter a 95% CI was calculated to measure the range of possible proportions that will occur in 95% of all the possible samples that could have theoretically been collected. The 95% CI will allow for a margin of error, which means the researcher can be 95% certain that the 95% CI calculated from the samples will include the actual population proportion. By making the interval wider the confidence that the population is within the calculated interval will increase. Equation 3.1 was used to determine the 95% CI. The equation is a reasonable approximation for calculating the 95% CI of a proportion p assessed in a sample with N subjects (Motulsky, 1995).

¹ Microsoft[®] office Excel 2003, Part of Microsoft office professional edition 2003, copyright © 1985-2003 Microsoft corporation, WA, USA.

Equation 3.1 Calculation of the 95% confidence Interval (CI)

$$(p - 1.96\sqrt{p(1-p)/N}) \text{ to } (p + 1.96\sqrt{p(1-p)/N})$$

p = proportion of participating laboratories who answered " yes" on each question. N = number of laboratories completed the questionnaire. Motulsky (1995).

The letter p is used to indicate the proportion of laboratories who answered "yes" on each question, whereas N represents the number participants who completed the questionnaire in the study. The confidence interval values were tabulated under each variable for discussion. Statistica^{®2} version 8.0 software was used to calculate and demonstrate the 95% CI in a graphical format by means of box plot graphs as indicated in Chapter 4.

3.4 THE RIGHT TO CONFIDENTIALITY

The guidelines on ethics for medical research, prescribed by the Medical Research Council (MRC) of South Africa were followed (MRC, 1993). The prescribed guidelines were derived from the Belmont report and the Helsinki declaration (Helsinki, Finland, June 1964; Belmont report, 1979). One of the major ethical codes is the right of the confidentiality of personal information which should always be honoured.

The following steps were taken to protect confidential information of each laboratory who participated:

- a. The questionnaire did not require any names of the person completing the survey.
- b. Questionnaires will be destroyed at the end of the study.
- c. Respondents were given the option of whether the information should be held confidential or published in this format.
- d. The names of the laboratories who participated would not be published or handed over to anybody to question their standards employed.
- e. All data will be protected with security passwords on all the spreadsheets.

The study was approved by the Ethics Committee of the North-West University. The ethics approval number NWU-00038-07-S8 was assigned to it.

² Statistica[®] version 8.0 software: StatSoft Inc: STATISTICA, version 8 [data analysis software system], 2004, OK, USA.

CHAPTER FOUR

Results and Discussion

To achieve quality excellence and to improve service delivery, forensic drug laboratories should not only benchmark quality systems for implementation, but also compare themselves against other laboratories with the same core business. Forensic drug laboratories internationally have one common goal i.e. to provide valid analytical results which will be used by law enforcement officers in legal proceedings. If the results are not according to an accepted scientific standard, it will harm not only the individual that will be prosecuted unfairly, but also the forensic community as a whole. The questions in the survey used in this investigation were based on variables in forensic drug laboratories that contribute to both reliable and credible results. The outcome of the survey indicates on which level forensic drug laboratories that participated, comply with quality systems such as ISO17025:2005 and ASCLD/LAB:2005. The mentioned quality systems are currently followed in most of the forensic drug laboratories surveyed and will be used as parameters for laboratory conformance. Secondly, the productivity in forensic drug laboratories is evaluated using indicators of productivity improvement which will contribute to quality management improvement. The guidelines of the two quality systems mentioned above were used as the quality and management tools and were added to the survey to evaluate the service excellence in the forensic drug laboratories globally. A total of 62 questions were included in the questionnaire related to the categories as mentioned in paragraph 3.2. Questions had to be answered by ticking in the following boxes i.e. "yes", "no" or "I don't know" (See Annexure A for questionnaire layout).

With limited data or publications on the population size of the global forensic drug laboratory community, it can not be assumed from the current information published that the sample size of laboratories participating in the current investigation represents the total population of forensic drug laboratories worldwide. However, it does represent all the laboratories that have affiliated members on CLIC. One of the studies that were conducted in 2003 by the National Audit office in the United Kingdom revealed the following information on forensic science services in other countries:

- a. In the United States of America there are more than 250 forensic science laboratories which consist of a mixture of state, county and private sector

laboratories. The specific services rendered by each laboratory are not published and it is therefore unclear the exact amount of forensic drug laboratories in the United States.

- b. In Canada, forensic science laboratories are controlled nationally by the Royal Canadian Mounted Police (RCMP). There are five regional laboratories and one nationwide headquarters in Ottawa. Each laboratory performs forensic chemistry analysis which might include forensic drug analysis.
- c. Dutch forensic science laboratories are operational under the Netherlands Forensic Institute (NFI) which is aiming to become a government agency, at the time of the publication. It is unknown how many laboratories perform drug analyses.
- d. The European Network of Forensic Science Institutes (ENFSI) provides a forum where the directors of Western European forensic laboratories can discuss research and develop techniques in the field of forensics. It is unclear, the amount of laboratories that exist in Europe which perform drug analyses.
- e. Each of Australia's six states and its two territories have their own forensic science provider and the system is different in each. In some states, forensic services are highly integrated and in others they are more fragmented, for example, in Western Australia forensic chemistry is performed by the Minister of Mines laboratories. The interaction of forensic services is controlled by the Senior Managers of Australia and New Zealand Forensic Science Laboratories (SMANZFL). Again there is no indication of the number of drug laboratories in Australia.
- f. In New Zealand, forensic science services are managed by two organisations namely the New Zealand police and Environmental Science and Research (ESR) departments. Both organisations are part of SMANZFL.

Another study conducted by Malkoc and Neuteboom in 2007, revealed that 53 forensic science laboratories are members of the European Network of Forensic Science Institutes (ENFSI). The studies did not have any information on forensic drug laboratories in Asia, Russia, Africa or South America. This might be due to a number of reasons which includes language barriers, individualization of laboratory managers, non-participation in surveys, no publications of laboratory data in recognisable international journals or the limitation on infrastructure that is unable to maintain forensic laboratory services thus making the sampling process more challenging.

Attempts were made to contact laboratories from the United Kingdom as well as forensic drug laboratories from the Asian continent without any success. Laboratories in the United

Kingdom are private laboratories and their quality information is confidential. Revealing any information on their quality system could lead to a competitor's advantage for future contracts. Most of the Asian laboratories are protected or served by the UNDCP laboratory and an attempt to contact these laboratories through the UNDCP was denied due to the absence of or the current development of sufficient quality systems at these laboratories.

Another consideration that had to be made of the person(s) who completed the questionnaire was that the knowledge that the individual had of the quality system in his/her laboratory would determine the answer chosen e.g. answers would be different if a person in management completed the form versus a member of the technical staff. In the study it was assumed that the respondent had enough knowledge of the existing quality system in their laboratory to make the correct choices and if the respondent was not sure the "I don't know" box would have been chosen.

For the purpose of this study, the term population will refer to those laboratories that have representatives/membership at the CLIC organisation. It was the most convenient process to include a large number of laboratories with a core function of drug analysis internationally. The number of laboratories that responded to the questionnaire was therefore taken as the number of subjects.

The questions on the survey used in this investigation were primarily aimed at evaluating the resources employed in international laboratories as this is one of the critical elements for any laboratory process (Refer to Flow chart 2.5 in Chapter 2). Three types of resources exist in forensic drug laboratories namely equipment, human and physical resources.

4.1 EVALUATION OF EQUIPMENT

According to the second principle of VAM, analytical measurements should be made using methods and equipment which have been tested to ensure that they are fit for their purpose. Various methodologies exist in forensic drug laboratories internationally, some are generic and others differ depending on legislation requirements and the quality system employed (Mills *et al.*, 1993; UNDCP, 1995). In one laboratory, qualitative analysis would be sufficient for prosecution, but in another laboratory quantitative analysis must be conducted. These requirements are normally stipulated through the criminal justice system, for example, in South Africa, the requirements on prosecution were proclaimed in the criminal procedure act, Act 51 of 1977, which only requires qualitative analysis. The

purpose of the analytical method will determine the analytical technique and therefore the equipment to be used. Paragraph 5.5.1 of ISO17025:2005 served as the baseline requirement for evaluating the international drug laboratories. The requirement states that the laboratory will be furnished with equipment and software that will be able to correctly perform analytical measurements for drug analysis and meet international standards. It is therefore important to choose a working group that have already tested and evaluated the international forensic drug community on analytical techniques employed internationally.

4.1.1 Analytical techniques

In the current survey, analytical techniques were selected that are “fit for purpose” in forensic drug analysis according to SWGDRUG recommendations. The categories of analytical techniques are indicated in Table 2.1 of Chapter 2. The analytical techniques employed by forensic drug laboratories internationally, their purpose in analytical measurements, and their selectivity are presented in Table 4.1. The order of techniques indicates their increasing discrimination value from top to bottom. In each Table presented in this chapter the column marked “A” lists the number of laboratories indicating yes on the questionnaire of this study with the “n” denoting the total number of laboratories which answered the specific question. The percentages indicated in column B of these Tables are based on a 95% CI, which was calculated as discussed in Chapter 3.

Table 4.1 Analytical techniques used in forensic drug laboratories

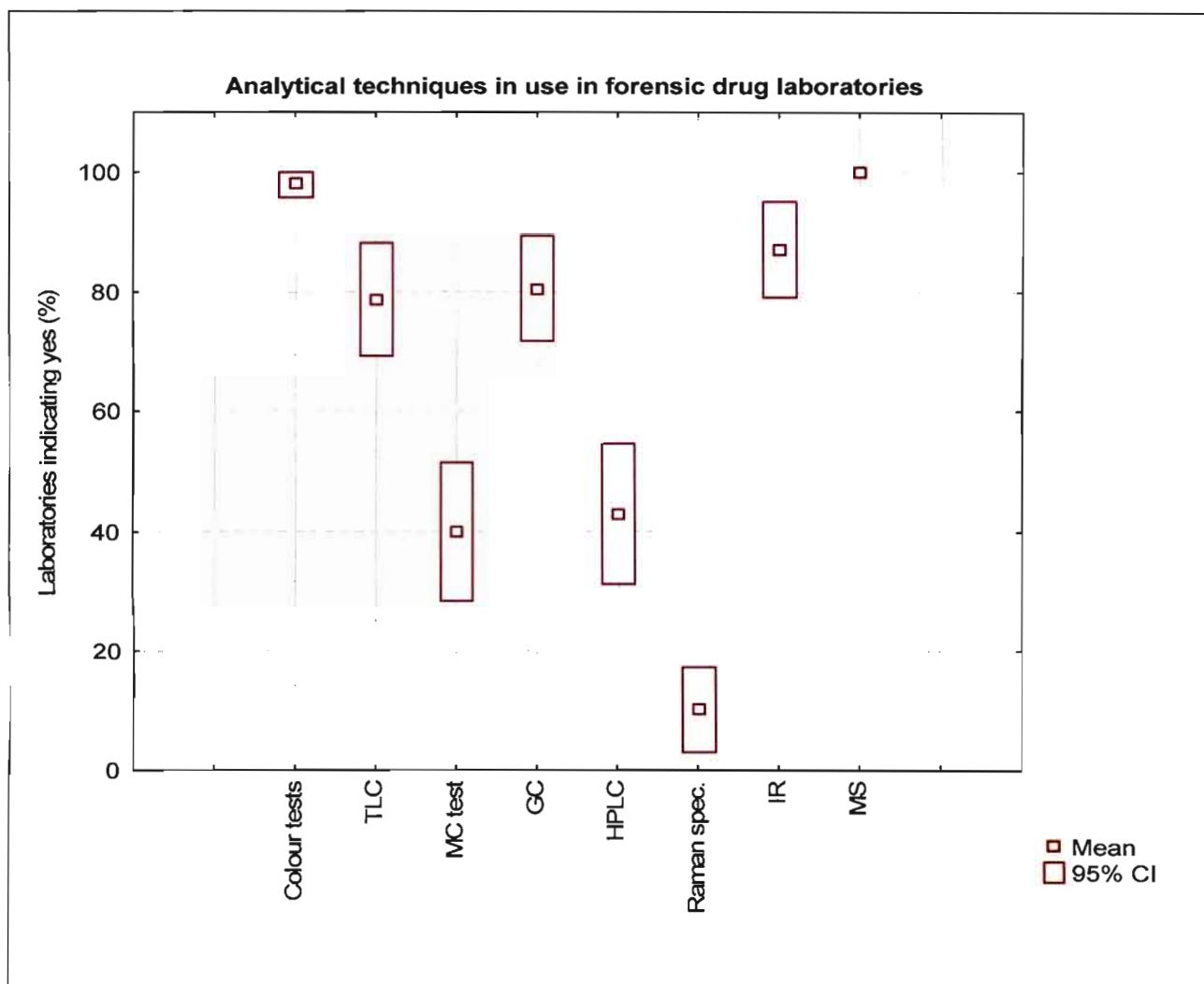
Technique	Purpose summary	A - (%) Laboratories indicating yes	B - 95% CI ^a
Colour tests	- Indicates presence or absence of a certain drug type in a non-extracted sample. - Positive result indicates a certain class of drugs.	98.6 (n = 70)	95.8 – 100.0
Thin layer chromatography (TLC)	- Quick separation and comparison technique - Indicates probable identity of analyte and probable presence of additional compounds - Also useful as a preparative method	78.6 (n = 70)	69.0 - 88.2
Microcrystalline tests	- Determining the presence of many chemicals including both controlled and other related compounds - Differentiation of closely related analogues	40.0 (n = 70)	38.5 – 51.5
Gas chromatography (GC)	- The same as TLC but with a higher level of discrimination. - Quantitative analysis of known compounds.	80.0 (n = 70)	71.6 – 89.4

Technique	Purpose summary	A - (%) Laboratories indicating yes	B - 95% CI ^a
Liquid chromatography (HPLC)	• The same as GC but a non-destructive method • Terminal labile drugs can be analysed • Non-volatile drugs can be analysed without derivatisation • Quantitative analysis with great selectivity • Separate enantiomers by using chiral columns	42.9 (<i>n</i> = 70)	31.3 – 54.5
Raman spectroscopy	• Yields structural information that provides sufficient selectivity • High purity substances and concentrations are necessary • Isomer discrimination ability	10.0 (<i>n</i> = 70)	3.0 – 17.0
Infrared spectroscopy (IR)	• The same as Raman but with a higher discrimination • Discriminates between diastereomers, free base/acid and salt forms • Non-destructive method	87.1 (<i>n</i> = 70)	79.2 – 95.0
Mass spectrometry (MS)	• Discrimination between diastereomers • Mass spectrum yield structural information with high discrimination capability • Hyphenation with GC and LC able to identify several compounds in the same sample • Also multidimensional MS techniques	100.0 (<i>n</i> = 70)	100.0

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

The calculated data of analytical techniques used in forensic drug laboratories from Table 4.1 are graphically displayed in Graph 4.1. The graph illustrates the techniques of preference used by forensic drug laboratories.

Table 4.1 indicates that colour tests and TLC are still currently used as the methods of choice in forensic drug laboratories for the preliminary inclusion or exclusion of drug groups, according to the current survey. These methods are quick and inexpensive with a valuable contribution. Colour tests and TLC have a low level of uncertainty, during sample preparation, due to the larger amounts of the samples used. If the presence of components with the same characteristics of a specific drug type is determined by these preliminary techniques the analyst will know which solvent and technique to use to confirm results with high accuracy. The confirmatory tests of choice in forensic drug laboratories are Fourier transform infrared (FTIR) spectroscopy and gas chromatography mass spectrometry (GCMS), according to the survey. Both have a high discrimination capability and, with the correct sample preparation, most organic compounds can be structurally identified. With more sophisticated instrumentation, less sample amounts are necessary, which in turn increases the uncertainty levels during sample preparation.

Graph 4.1 Box plot of distribution of analytical techniques used in forensic drug laboratories

95% CI = 95% confidence interval, TLC = Thin Layer Chromatography; MC = Micro Crystalline; GC = Gas Chromatography; HPLC = High Performance Liquid Chromatography; Raman spec = Raman Spectroscopy; IR = Infra-Red; MS = Mass Spectrometry.

The combination of GCMS from Agilent® with the HP® Chemstation software has been in use in South African laboratories since the early 1990's with minor changes having occurred over the years. The software is supported by two powerful libraries (Wiley, 1998; Nist, 2002 and 2005) that enable the analyst to screen through thousands of compounds in seconds for possible similarities in the fragmentation patterns. GCMS has solved more than 95% of unknown samples received by South African laboratories in the past (National Drug Intelligence Database, NDID; FSL, 2005 and 2006). This was determined by evaluating all the cases received over two years and the results reported on the database versus cases with a negative result on the GCMS. Most of the remaining 5% of samples were solved using FTIR spectroscopy. The addition of an ultra performance liquid chromatography tandem mass spectrometer (UPLCMSMS) in 2007, enabled analysts are now able to identify drug metabolites, alkaloids in plants, thermally unstable pharmaceuticals etc. It is important for forensic drug scientists to think analytically,

especially when a problem arises during pre-phase examinations. Some samples are unambiguous with an immediate indication or result after the first analytical method is employed, whereas other samples are more difficult to analyse. Ambiguous samples are generally frequently associated with inorganic properties and require a different analytical approach.

In the past, ambiguous samples of organic and inorganic nature were sent to other forensic chemical departments within the South African forensic laboratory for analysis via techniques such as nuclear magnetic resonance (NMR) spectroscopy, x-ray spectroscopy, scanning electron microscopy (SEM) etc. In many laboratories, the frequency of samples for these types of analyses does not justify the purchase of such expensive instrumentation. In many instances the purpose of such analyses is only for interest sake and no evidential value can be added to the results. In certain cases, it might be a problem and value might be added to the evidence at hand and in such cases, the samples should be outsourced to universities or laboratories with the necessary expertise and analytical equipment for identifying the unknown sample, until such time that the amount of samples to be identified justifies the purchasing of the analytical instrument.

The management of the South African forensic drug laboratories decided that, according to National legislation, more than 99% of controlled substances can be identified with the above mentioned techniques and only if the investigating officer requests more information regarding adulterants, diluents or other unknown compounds in samples, will it be submitted for further analysis. Negative end-point protocols were developed, that are followed if a sample appears to be negative, with a clearly defined termination point, whereafter no more analyses are performed. For quantitative analysis of controlled substances, GC and HPLC will be used. Although the concentration of the controlled analyte in the sample is not mandated by legislation in South Africa, it is sometimes used in aggravating circumstances when large quantities of controlled drugs have been imported (Drug and Drug Trafficking Act, Act 140 of 1992).

According to the survey, 100% of international laboratories included in this evaluation have adequate instrumentation and equipment for the methods and procedures used. This complies with the quality standards, ISO17025:2005 paragraph 5.4.1 and ASCLD/LAB:2005 paragraph 1.4.2.11. It is however important that every laboratory in the forensic drug industry commit themselves to protecting the credibility of instrument

performance internationally and the only way of doing so is through proper quality control and quality assurance.

4.1.2 The procurement plan

The concern however, from a management point of view, is that only 64.3% of the laboratories which participated in the survey, have a procurement management plan. The main reason for the lower than expected percentage of laboratories complying with good procurement management practice, can be attributed to the placement of forensic laboratories under the control of law enforcement agencies. Laboratories such as these have limited control over their budgets and have to rely on another agency for a comprehensive budget that specifically addresses forensic needs (Koussiafes, 2004). The South African forensic laboratory is on par with other laboratories in the field, as it too has no national procurement plan. Over the last few years the perceived absence of a procurement plan was not problematic, due to an abundant source of funds from the Ministry of Safety and Security, (Vote 23 National Assembly, Vote 25 Independent Complaints Directorate, June 2004). Overspending on equipment may however lead to unused instruments being stored in storerooms, due to the limited bench space in laboratories. These problems can be overcome if external evaluation committees are included as part of the procurement management plan.

According to the ISO standard, policies and procedures should exist for selection and purchasing of the services and supplies that the laboratory uses that may have an influence on the quality of analytical results (paragraph 4.6.1, ISO17025:2005). Policy and procedures should also include inspections and/or verifications of reagents and chemicals purchased (paragraph 4.6.2, ISO17025:2005). These policies and procedures should all form part of the procurement management plan of the laboratory. A procurement plan should include the current instrumentation on hand, their operational capabilities, depreciation status and future requirements. Management of equipment maintenance, which is discussed later in this chapter, allows an organisation to plan ahead for procurement of equipment that is no longer cost effective to maintain. Short term and long term procurement plans should exist for annual and five year evaluations respectively (Bartle & Korosec, 2000; Bartle, 2002; St. Clair, 2003). In paragraph 4.4.1b of the ISO17025:2005 guideline, a requirement is placed on laboratories to ensure that they have all the resources necessary to meet the demands of the customer. Under the procurement plan, evaluation charts or logbooks should exist to evaluate not only downtime of

instrumentation but also consumable costs, e.g. cost of the replacement of liners, gold base seals, filaments, helium and columns for the GCMS. These costs are not taken into consideration by laboratories without a proper procurement management system and contribute to skeleton savings close to financial year ends. The after-effect on cost savings are poor maintenance and the shortening of instrument lifespan. In Table 4.2, the current period of use of instrumentation used in forensic drug laboratories included in the study are expressed.

Table 4.2 Instrument lifespan in forensic drug laboratories

Duration in use	A - Laboratories indicating yes (%)	B - 95% CI ^a
One year	1.4 (n=70)	0.0 – 2.8
Two to three years	1.4 (n=70)	0.0 – 2.8
More than three years	54.3 (n=70)	42.6 – 66.0
Until results fail standard	47.1 (n=70)	35.4 – 58.8
Determined by the number of runs	1.4 (n=70)	0.0 – 2.8

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

According to the data presented in Table 4.2, most laboratories should make provision in a procurement plan for instrumentation replacement every three years. However, it is not always necessary to replace instruments after three years, because some can last for more than 10 years, if effective maintenance management was employed. Of the laboratories who participated in the current survey, 47.1% use instruments until results fail standards. In general laboratory managers will agree that the majority of instruments have a life cycle that is longer than three years if maintained properly. Maintenance plans form part of any laboratory's quality assurance program to prevent, detect, and correct problems with instrumentation. The purpose is to ensure that the results are generated at an acceptable quality level. The plan may include preventative maintenance, performance verification, calibration, system suitability testing and other factors. The international standard, paragraph 5.5.3 of ISO17025:2005 requires that all instructions on the use and maintenance of equipment should be up to date in the laboratory. Preventative maintenance should be an orderly program of positive actions for preventing failure of equipment and ensuring that instruments are operating reliably in order to ensure quality results.

4.1.3 Equipment maintenance management

The results of the survey indicated that between 62.5% and 83.3% of forensic drug laboratories will have a maintenance management system in place to ensure reduction in

the variation of test results, fewer interruptions in instrument runtime, elimination of premature replacement and greater confidence in the reliability of the results. A laboratory that has a maintenance plan also complies with paragraph 5.5.6 of ISO17025:2005 which states that a maintenance plan for measuring equipment should be established to prevent deterioration. All the laboratories in the survey use self-employed maintenance plans after supplier contracts have expired. If the problem exceeds the knowledge of the self-employed maintenance operator, maintenance contracts should be in place for the timely recovery of the instrument with a minimum amount of downtime. The South African forensic laboratory has maintenance contracts with major instrument suppliers. If the repair is minor it will be fixed in-house, whereas if it is an unknown problem, a call centre will try to identify the problem via modem communication and send a technician to attend to the problem. According to paragraph 5.5.7 of ISO17025:2005 the instrument should be taken out of service or it should be clearly indicated that it is out of order until it has been repaired and demonstrated by calibration that it is "fit to perform" analytical measurements. Quality systems do not prescribe by whom it must be corrected, as long as it passes the calibration tests. Maintenance management comes into effect when an instrument does not perform according to standards, whereas calibration intervals are determined by a laboratory or supplier based on the past history of the specific instrument. According to the survey, all the international laboratories will comply with this standard of documented calibration intervals and Table 14.3 demonstrates the relevance of documented calibration and verification programs of instruments in these forensic laboratories.

Table 4.3 Documented calibration and verification programs of instruments

Content of program	A - Laboratories indicating yes (%)	B - 95% CI ^a
Nature of calibration	81.4 (n=70)	72.3 - 90.5
Maximum interval between calibration based on history	68.6 (n=70)	57.7 - 79.5
The acceptable performance criteria where appropriate	87.1 (n=70)	79.3 - 94.9

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

Calibration intervals form part of quality control in the quality system and maintain confidence in the calibration status of the equipment (paragraph 5.5.10, ISO17025:2005). Calibration intervals can be supported with performance qualifications. According to the survey, 81.4% of laboratories document the nature of calibration on analytical instruments. The nature of calibration is normally prescribed in the vendor's instruction manual and the calibration should start before the instrument or equipment is placed into service. Thereafter, it should form part of the maintenance plan of the laboratory (paragraph 5.6.1,

ISO17025:2005). The percentage of participating laboratories which indicated that the maximum interval between calibrations based on history was 68.6%. More experienced instrument operators may deviate from the prescribed calibration intervals by extending calibration intervals to a maximum based on instrument history. This will result in a longer operational time for analytical measurements, but may shorten the instrument lifespan. Newer instruments are equipped with a series of internal performance qualification tests that can automatically be performed every morning, every week or every month. If the instrument fails one performance qualification test, the analyst will not be able to proceed with any analysis until the problem is corrected. Records are automatically stored to build a performance history of the instrument. This will enable the laboratory to demonstrate reliability and assurance of the instrument.

4.1.4 Disposal management

Disposal management criteria should be documented to clearly state when to withdraw an instrument or piece of equipment from the laboratory. The disposal management system should be based on the past documented history of the equipment, its repair costs and the downtime of instruments. The combination of these factors will indicate low capability which will contribute to decreased productivity if disposal is not managed. The actual disposal of instrumentation may be executed via different avenues. Table 4.4 display some responses from international laboratories that were polled in this survey.

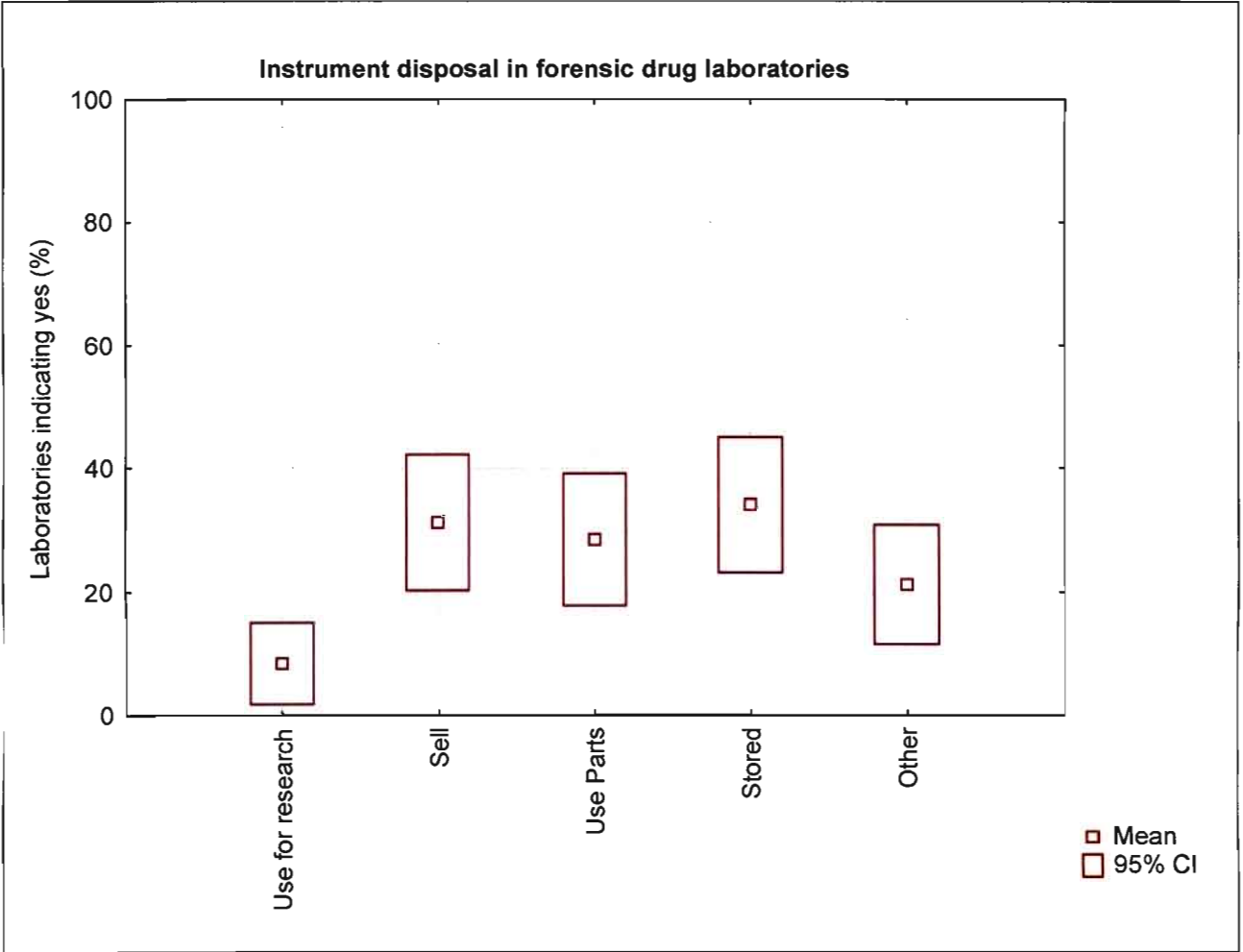
Table 4.4 Instrument disposal in forensic drug laboratories

Method of disposal	A - Laboratories indicating yes (%)	B - 95% CI ^a
Use for research projects	8.6 (n = 70)	2.0 - 15.2
Sell on auctions/other laboratories	31.4 (n = 70)	20.5 - 42.3
Use for parts in new instruments	28.6 (n = 70)	18.0 - 39.2
End up in storerooms	34.3 (n = 70)	23.4 - 45.2
Other	23.4 (n = 70)	11.8 - 31.0

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

The calculated data of instrument disposal from Table 4.4 are graphically displayed in Graph 4.2. The graph illustrates various ways in which majority of forensic drug laboratories dispose of old instruments on hand.

Graph 4.2 Box plot of instrument disposal in forensic drug laboratories



95% CI = 95% confidence interval.

Certain laboratories in the United States dispose of their instruments by means of donation to universities, colleges or schools or through the Government Services Administration as surplus equipment according to the survey. Also according to the survey, laboratories often perform dealer trade-ins upon the purchase of the new instrumentation. In the South African forensic drug laboratories, pieces of equipment will end up in storerooms after they have been stripped of their old parts that can be used in the new instruments. A good practice to follow is to use the instruments for training purposes of new analysts either to familiarise them with the software and hardware or for basic in-house maintenance procedures. Forensic drug analysts are trained in-house (see Section 4.1.7 on internal training), which means analysts are trained in the laboratory environment. Practical training forms part of the internal training program, thus analysis and software training must be conducted on instruments employed in the laboratory (Internal drug training program, FSL, 2007). If the trainers/instructors can use instruments that are not fit for quality purposes, but good enough for training of new analysts, then operational

instruments do not need to be withdrawn from performing real case work for training purposes. Training officials and mentors will be able to run training samples and present instrument software training on terminated instruments without interruptions and delays from instrument operators. If the instrument is not taking up unnecessary bench space after operational service termination it can serve as an efficient training tool for new analysts until proper disposal or permanent termination can be arranged.

Disposal management is however not limited to instrumentation, but will also include disposal of chemicals, used consumables, exhibit material and other calibration items. Paragraph 5.8.1 of ISO17025:2005 requires procedures for the transportation, handling, protection, storage, retention and/or disposal of test and/or calibration items. Separate disposal procedures might exist for different items used in the laboratory, for example, disposal of glassware will be in a dedicated container that is clearly marked "Danger, contaminated sharps" and chemical waste will be removed by a designated waste removal company. Continuous measures should be taken to evaluate the environmental conditions to ensure good housekeeping in the laboratory. Health and safety officers can be appointed in the laboratory to perform inspections and provide feedback to management for the proper disposal of test and calibration items and to ensure good housekeeping (paragraph 5.3.5, ISO17025:2005).

4.1.5 Information Management Systems

Instrumentation and laboratory equipment are not the only resources required in forensic drug laboratories. Modern forensic laboratories rely on Laboratory Information Management Systems (LIMS), also referred to as Forensic Information Management Systems (FIMS) to control and monitor exhibit receipt, handling and storage, instrument usage, bar coding of evidence, analytical results, reports, management reports and/or connection to external investigating entities. New FIMS software provides the forensic administration personnel, forensic scientist and management with search functions that eliminate tedious paper handling tasks as well as the loss or misfiling of hard copy data at the desk. Other advantages include higher accuracy with drop-down menus and error-free printed labels, interfaces with other departments, tracking productivity, enhanced quality control with graphs as well as reports. Modern laboratories are now able to operate in a paperless environment, which saves costs on printers, copiers, toners, file storage boxes and shelf space. From the study, 80.0% of forensic drug laboratories have a LIMS in place. Table 4.5 indicates the coverage of LIMS in the respective global laboratories.

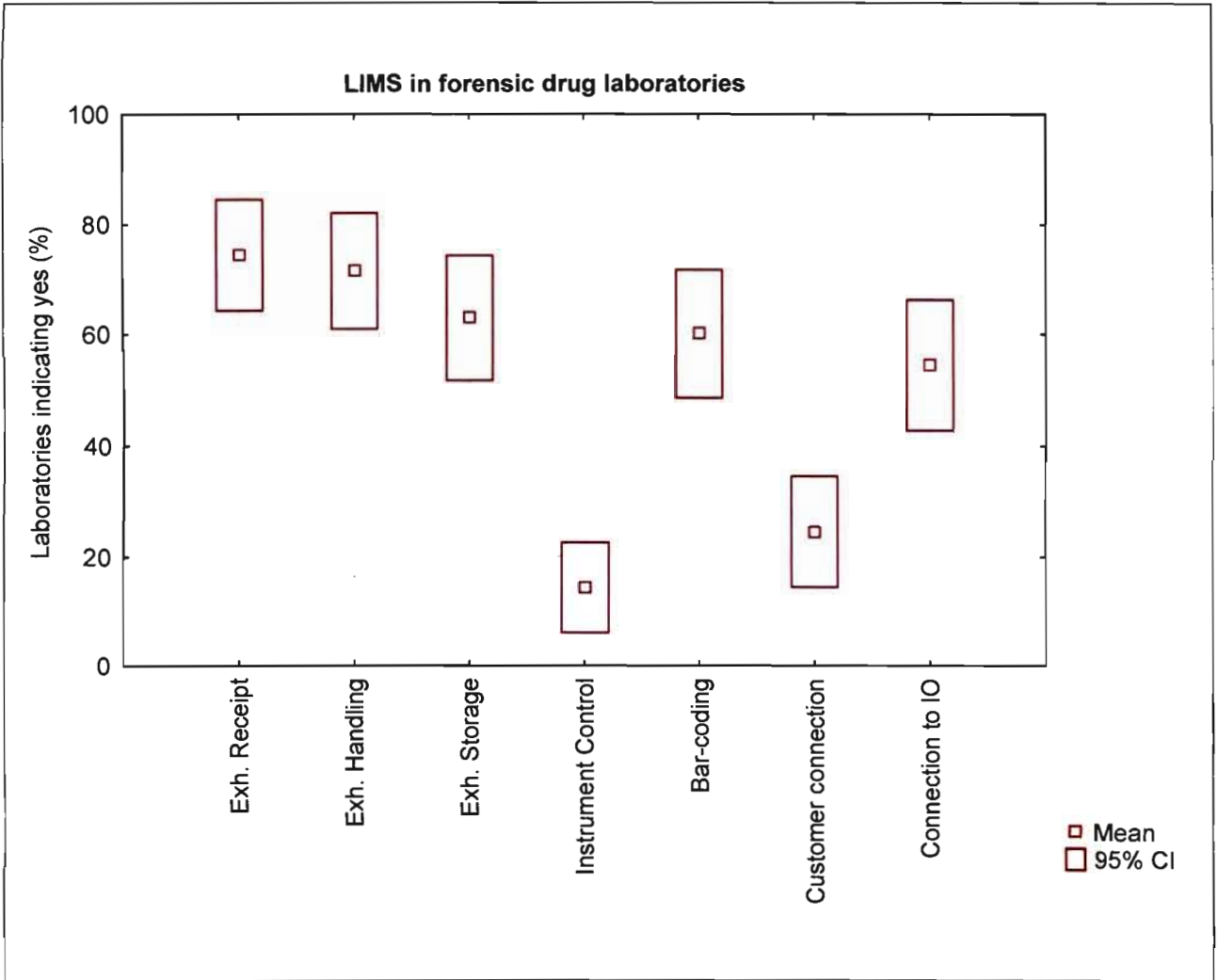
Table 4.5 Laboratory Information Management Systems (LIMS)

LIMS Coverage	A - Laboratories indicating yes (%)	B - 95% CI ^a
Exhibit receipt	74.3 (n=70)	64.1 - 84.5
Exhibit handling	71.4 (n=70)	60.8 - 82.0
Exhibit storage	62.9 (n=70)	51.6 - 74.2
Instrument control	14.3 (n=70)	6.1- 22.5
Bar-coding of evidence	60.0 (n=70)	48.5 - 71.5
Connection to customers	24.3 (n=70)	14.2 - 34.4
Connection to investigating officers	54.3 (n=70)	42.6 - 66.0

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

The calculated data of exhibit and report flow from Table 4.5 are graphically displayed in Graph 4.3. The graph illustrates the level in which exhibit control and reports are covered by a LIMS in forensic drug laboratories.

Graph 4.3 Box plot of Laboratory Information Management System (LIMS) used in forensic drug laboratories



95% CI =95% confidence interval; IO = Investigating Officer.

LIMS or FIMS are not direct quality requirements, but paragraphs 5.4.7.2 and 4.13.1.4 of ISO17025:2005 prescribe requirements to follow when using computers or automated equipment for acquisition, processing, recording, reporting, storage or retrieval of test or calibration data. According to this survey, more than sixty percent of participating laboratories use LIMS for exhibit management and control, indicating the importance of an automated computer system for the receipt, handling and storage of exhibit material. Furthermore, a way to meet today's challenges that the modern society place on forensic laboratories to operate effectively is the acquisition of a LIMS. Selection, installation and implementation of a LIMS require careful consideration based on goals, resources, computer literacy of staff, and other factors. Different laboratories have different requirements and the more complex a laboratory becomes the more difficult and expensive the implementation of the analysis system. The South African forensic laboratories started in 1998 with the implementation of a LIMS in the four respective laboratories. Top management strategically terminated the implementation two years later due to its complexity as it had to serve more than nine hundred people in seven separate units in four different laboratories. The laboratory opted to hire consultants, which in itself is inherently more of a risk and also brings with it additional expenses (*Executive board meeting, FSL Pretoria, 2001*). Since the termination of the project, smaller systems have been implemented to cover exhibit control from receipt, handling and storage by means of bar-coding. The implementation of the Exhibit Management System (EMS) in 2003 caused problems and lowered productivity due to its inability to handle large numbers of data entries simultaneously as well as the transfer of large amounts of data through the old data lines. Staff members have to capture data twice due to the time-out mechanisms of the software, causing handover transactions to fail and resulting in the transactions having to be repeated with less handovers at a given time. When implementing a LIMS system, external communication network lines should be able to deal with high level of data transfers.

There is however a debate on the inclusion of instrumentation in LIMS, due to potential problems associated with system downtime and electronic data loss. The low percentage of participating laboratories who implemented instrument control systems as indicated in Table 4.5 is a consequence of the international debate as laboratory managers are not confident in the integration of instrumentation into LIMS or FIMS.

According to the current survey, 54.3% of forensic drug laboratories investigated have web based interaction with investigating officers. This function allows laboratories to save on turnaround times (TAT) as results are available on-line immediately upon verification and

directly thereafter via automated email, fax, export or SMS. With the absence of this level of efficiency in South African laboratories, administrative staff spends hours in filing rooms searching for duplicate reports to fax to investigating officers. Unfortunately, this cannot change unless South African legislation is changed with regard to the submission of reports. According to legislation, all forensic reports must be affirmed or attested to by a Commissioner of Oaths, which means reports must be printed out and signed in the presence of a Commissioner of Oaths before submission to courts (Section 212, Criminal procedure act, Act 51 of 1977). Other advantages of a web-based function in the laboratory is higher client satisfaction, central web content management, lowered systems administration costs, lower hardware requirements, ease of access and geographically distributed deployment. South Africa is a developing country with a lot of rural and under-developed infrastructure, which creates economical challenges for the government with regards to service delivery. With internet-based function administration, functions can be co-ordinated in cities and larger town areas, while law enforcement officers situated in remote areas can capture and receive information via the World Wide Web. Through this process forensic results will reach the officers in remote areas as soon as the examination results are determined in the laboratory. The function will decrease travel time to and from cities by law enforcement officers and will allow for cost saving on service delivery.

There is however security risks involved, such as unauthorised access in order to tamper, steal or destroy data on the system. A security hierarchy should be defined and depending on the user's level in the hierarchy, access will be granted to specific levels or areas within the system. Safekeeping of passwords plays a vital role. Another risk is staff members or investigating officers placing virus contaminated objects such as mobile phones or flash drives into computers linked to the internal web on which the system is operating. A network management policy must be in place to prohibit unauthorised use of programs or hardware devices other than those specifically authorised by management or information technology personnel.

LIMS programs should be chosen carefully and should be able to integrate with the quality system that is already present in the laboratory. The implemented LIMS or FIMS should be validated regularly to demonstrate that all software is functioning properly. Making use of reputable, internationally recognised suppliers that are able to assist in after-sales problems and employee training is essential.

In summary, more than 95% of the forensic drug laboratories internationally will comply with the requirement that instrumentation and equipment are “fit for their intended purpose”. This means that analytical measurements made in most of the forensic drug laboratories investigated in this study, comply with ISO international quality standards and in turn can be accepted by any jurisdiction, if operated and maintained correctly and if proper sampling and exhibit management procedures are followed. Laboratory managers should however implement a proper procurement plan to enable them to meet customer demands and avoid resource shortages. More attention should also be paid to maintenance management to minimise instrument downtimes and prolong instrument life span. Furthermore, laboratory managers should stay abreast of technological changes globally and look for new analytical techniques and methods that are able to minimise turn around times as well as lower costs. They should also ensure the protection of the credibility of the instruments currently employed in forensic drug laboratories. When replacing older equipment with newer versions, procedures should be put in place to ensure the termination date of the former does not influence the installation date of the latter. Disposal management of equipment can be done as described in paragraph 4.1.4 as long as the equipment does not take up unnecessary bench space or end up not being used. More publications on efficient LIMS programs in forensic drug laboratories should be published for laboratory managers to evaluate and decide on the best system to implement.

Equipment can however not function on its own and will require skilled and trained staff for proper operation. It is therefore important to appoint or train suitable laboratory members to operate and maintain equipment in the drug laboratories. It should also be kept in mind if an analyst presents a contaminated sample to a validated instrument, the results would be invalid.

4.2 EVALUATION OF PERSONNEL

Equipment can however not function on its own and will require skilled and trained staff for proper operation. It is therefore important to appoint or train suitable laboratory members to operate and maintain equipment in the drug laboratories (paragraph 5.2.1, ISO17025:2005).

4.2.1 Qualifications of personnel

The third VAM principle requires staff making analytical measurements to be both qualified and competent to perform specialised tasks within the laboratory. According to paragraph 2.2.1 of ASCLDLAB:2005 and paragraph 6.3.1.2 of TG01-01:2008 examiners working in

the field of controlled substances should have a baccalaureate or advanced degree in the natural sciences, criminalistics or in a closely related field, have experience/training to perform analytical measurements on controlled substances and to be able to defend findings made in a court of law. Table 4.6 indicates the distribution of the level of qualifications required by members of the forensic drug laboratories.

Table 4.6 Qualification and competence of forensic drug scientists

Statement of qualification/internal training	A - Laboratories indicating yes (%)	B - 95% CI ^a
Bachelor's degree, college degree or 3 year qualification	100.0 (<i>n</i> = 70)	100.0
Internal training program	100.0 (<i>n</i> = 70)	100.0
Trained by the DEA	42.9 (<i>n</i> = 70)	31.3 – 54.5
Trained by private institutions	17.1 (<i>n</i> = 70)	8.3 – 25.9

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

From Table 4.6 it is clear that laboratory managers are serious in appointing qualified scientists to perform analytical work within the forensic drug laboratory. They all believe that a 3 year related qualification (with chemistry until the final year) provides analysts with a sound knowledge to begin in the forensic drug laboratory. A concern in South African laboratories is however the standard of new scientists coming from tertiary institutions. With the revolution of instrumentation and computers over the past years, sound chemical principles have been neglected by these institutions providing scientists with insufficient skills in problem solving and analytical thinking. Some new scientists try to solve all their analytical problems in the laboratory with computer software, but there are cases where only simple grass roots solutions, such as wet chemical analysis, will solve the problem. Although new analytical instrumentation has resulted in a lower work load, it is the sound chemical principles of recognising samples by their odour, colour, solubility in a range of solvents, optical activities or refractive indexes that are required to evaluate problematic samples in the laboratory. It is therefore important for tertiary institutions to not only focus on sound analytical principles in their curriculum, but also to stress the limitations and replacements of these principles over the years. During practical interviews conducted by the FSL in 2006 and 2007, on scientists coming from tertiary institutions, shortcomings were immediately detected related to problem solving and analytical thinking skills. These shortcomings make target selection difficult for laboratory managers, because the short list of possible candidates for a specialised position within the laboratory has decreased during the past few years. Laboratory managers have adopted a process of selecting target personnel that begins with neatness and accuracy in completing paperwork,

focusing on the number of mistakes made on a resume, setting up an interview panel that is diverse in personality, practical interviewing and evaluating candidates with a balance between detail-orientation and creativity (St Claire, 2003). It is advisable to rather re-advertise a position than to fill it with a candidate who did not perform during an interview.

4.2.2 Internal training

According to the survey all the laboratories are using in-house self-developed training courses for their new analysts. A variety of internal and external courses for drug identification in forensic laboratories exist globally. Besides the internal drug training programs used in drug laboratories, 42.9% of participating laboratories are also using the standardised program developed and presented by the Drug Enforcement Administration (DEA) in the United States (DEA Training, 2000). The program is however restricted to national laboratories in the United States. According to the survey 17.1% of laboratories use private institutions for the training of technical staff. These institutions included the Californian Criminalistics Institute (CCI) and The National Forensic Science Testing Centre (NFSTC). Paragraph 5.2.2 of ISO17025:2005 require a training program that is relevant to the anticipated tasks of the laboratory, meaning that the content of the program should be relevant to the identification and analysis of controlled substances. Items in the drug training program should include, but are not limited to, procedures routinely used, principles of methods and instrumentation, prescribed literature to be read, practicals to perform, legislation pertaining to controlled substances, competency tests to demonstrate competency and mock trails (St Claire, 2003). The ISO standard also requires proper assessment to demonstrate the effectiveness of the training intervention. Training courses should be documented with assessment criteria that stimulate the intended outcomes. The successful completion of the internal drug training program will serve as evidence of the competence of the forensic drug analyst. A statement of internal training, statement of qualification, relevant training, workshops and seminars attended and competent testing results should be filed in a quality training file in building up a "portfolio of evidence" for the analyst (paragraph 5.2.5, ISO17025:2005). The portfolio of evidence will allow the laboratory director or his designate to authorise the analyst to perform casework independently. Internal drug training courses are not standardised internationally and it would be difficult to do so due to the variation of substances from laboratory to laboratory. For example, for years the South African laboratories received methaqualone and related substances in the majority of their cases. For this reason more emphasis had to be placed

on quanaazolinones and related substances. Currently, the DEA's training course on controlled substances are customised to the South African national legislation and registered as an official training program in the South African Police Service (DRG001M, Physical identification of Controlled substances; DRG002M-DRG010M, Analytical identification of Controlled substances, 2006).

4.2.3 Mentorship programs

The success of any training program does not lay in the content of the course or in the total marks the analyst scores on the assessment, but how the analyst implements the knowledge gained. Paragraph 5.2.2 of ISO17025:2005 requires the evaluation on the effectiveness of training interventions. It is therefore necessary for laboratories to have mentorship programs in place to continuously measure outputs and coach new staff in the laboratory. In paragraph 5.2.1 of ISO17025:2005 it is required that trainees be appropriately supervised during the training program. Information is shared directly from expert to trainee, as and when problem situations arise. According to the survey only 30% of the laboratories have formal mentorship programs to measure the output of trained personnel. The percentage is surprisingly low, due to the importance of mentoring and coaching. This means that newly appointed technical staff is performing in a trail and error environment, without effective supervision, guidance or assistance. Mentors are the link between laboratory management and new staff and mentors are there to ensure assistance when problems arise, provide feedback to the laboratory manager on progress made and to determine the competency status of the new scientist (St Clair, 2003). Forensic drug laboratories in South Africa that did not have a mentorship program in place had much more non-conformances in their casework than those who had implemented mentorship programs. With a well defined mentorship program quality defects were detected within the laboratory and were able to be corrected before the submission of reports to the investigating officer, thus preventing serious non-conformances.

On the completion of the internal drug training program, the newly appointed analyst should perform a competency test or tests to demonstrate their ability to perform casework in the speciality field of drug analysis. The laboratory manager might go one step further and certify the drug analyst with an independent certification body such as the American Board of Criminalistics (ABC). The level of certification should be determined by the laboratory manager (St Clair, 2003). In South Africa, the Natural Scientific Professions Act, Act 27 of 2003, was published on the 28th November 2003, requiring registration of

scientists at a council as either a professional natural scientist, candidate natural scientist or certified natural scientist to practice in a specialised forensic field. The scientists working at government institutions are currently exempted from registration and registration is only mandatory to individuals working in private laboratories and practice. The exemption of forensic scientists in government laboratories however creates doubt in the forensic community on the ability and assurance of the standard of expertise in the forensic laboratory. This issue will be discussed later in the final conclusions of this study.

4.2.4 Skills development program

As important as their original qualifications are, the continued development and honing of skills of members in the forensic science laboratory is more important. Technical staff needs to be empowered continuously through training interventions and exposure to conferences, seminars and vendor workshops. A skills development program will help laboratory managers to budget and plan continuous development of staff each year. According to paragraph 1.3.3 of ASCLDLAB:2005, laboratory managers should allow analysts a number of developmental hours per year to stay abreast with new developments in the field of forensic drugs. The level of training should change proportionally to the various degrees of ability and attitude of the scientist and laboratory managers should also change their own leadership style towards the scientist during the developmental phases of the employee (St Clair, 2003). Table 4.7 is an indication of the total number of days that were spent on training per analyst per year according to the survey.

Table 4.7 Skills development of analysts in forensic drug laboratories

Number of contact days	A - Laboratories indicating yes (%)	B - 95% CI ^a
1 to 5 days	32.9 (n = 70)	21.9 - 43.9
6 to 10 days	24.3 (n = 70)	14.2 - 34.4
More than 10 days	38.6 (n = 70)	27.4 - 50.0

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

According to the survey most of the participating laboratories comply with the ASCLDLAB:2005 recommendations on allowing continuous training for technical staff. The concern however is the ever increasing cost of training interventions. Governing bodies approve more and more appointments, but laboratory managers have to work with curtailed budgets. Due to budget constraints, laboratory managers have to think of new ideas to meet quality requirements and therefore should develop internal courses using

experienced analysts or past training interventions in which the laboratory participated. Another way in saving costs is to share the costs between regional laboratories or to make use of onsite training facilities, therefore saving travelling costs. Laboratory managers may also include training in the purchase of expensive instrumentation. Some vendors also provide maintenance workshops at their facilities free of charge ensuring future relationships with the laboratory. Managers may also negotiate packages with local colleges and universities through lecture exchange programs. The laboratory provides an experienced scientist as a guest speaker to the training provider in exchange for a skills development course presented by the institution at the laboratory.

The level to which scientists are exposed to trends and developments in their field is presented in Table 4.8. This indicates the percentage of laboratories that develop their analysts via exposure to national and international conferences and seminars.

Table 4.8 Development via conferences and seminars

Exposure to conferences	A - Laboratories indicating yes (%)	B - 95% CI ^a
National conferences and seminars	95.7 (n = 70)	90.9 - 100.0
International conferences and seminars	47.1 (n = 70)	35.4 - 58.8

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

Table 4.8 is a reflection on the method laboratories follow to expose trained technical staff to comply with ASCLD/LAB:2005 standards. Technical staff exchanges knowledge and experiences gained through their work or studies at national and international conferences. Presenters and participants both benefit from the conferences as experienced scientists receive recognition on their achievements and less experienced scientists adopt the new knowledge gained in their respective laboratories. The laboratory manager may benefit through technical staff receiving information from scientists working in the same field of expertise, rather than someone teaching only the theoretical knowledge. Managers should however evaluate the content of conferences and decide in which way the laboratory may benefit. It might be in the laboratory's interest to rather send a new analyst on an instrument operating course, than sending a less experienced scientist to a conference where various papers are presented with no value added to the laboratory.

The reason for the high percentage of participants not being exposed to international conferences, according to Table 4.8, might be due to the fact that a large number of laboratories participating in the survey were from the United States. They are the world leader in providing staff with exposure to regional and national conferences and seminars.

A lot of emphasis is placed on information sharing and development. The United States satisfies their own training and development needs through conferences and seminars whereas smaller countries with one or two national laboratories fail to attract scientists to participate in local conferences and seminars at the level that the USA is able to do. It is more difficult for smaller countries to get the same type of exposure unless they participate in conferences and seminars internationally. It is therefore necessary for scientists from smaller countries to travel abroad to the United States for similar exposure levels. Due to budget constraints on training and international exposure only two experienced clandestine laboratory investigating scientists from South Africa were allowed to participate in the Technical Training Seminar of Clandestine Laboratory Investigating Chemists (CLIC) over recent years. Tremendous successes have arisen from participation in these seminars. The literature obtained at the CLIC meeting and the scientific knowledge that was shared at that level has contributed greatly to subsequent efforts in legal proceedings. Clandestine laboratory investigators are able to defend their findings with greater confidence and assurance due to their participation at CLIC since 1998.

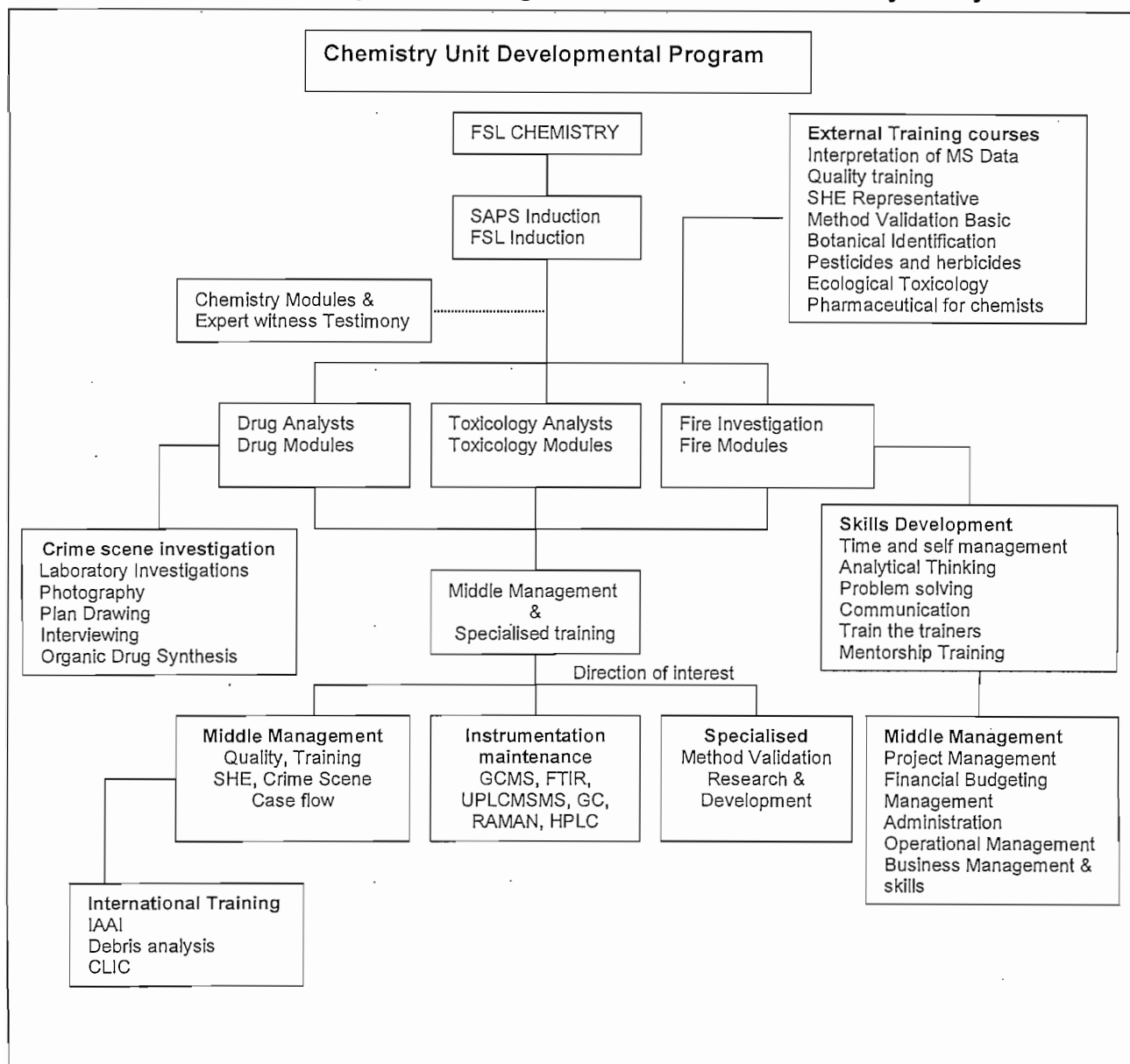
According to the survey, 97.2% of participants were satisfied with the sources of information in forensic drug laboratories. This means analysts have adequate sources of information and are able to stay abreast with technological changes and new drug trends. With most of the forensic journals available through the internet, laboratory managers have no excuse other than budget constraints to not be on par with international trends. In paragraph 4.2 of ISO17025:2005, laboratory managers are required to commit themselves to providing the necessary sources of information to ensure continuous improvement in the laboratory's effectiveness.

4.2.5 Research and capacity development

Forensic science laboratories are not renowned for their research capabilities, but rather the ability to solve mysterious crimes. Most of these laboratories have to rely on past achievements in other laboratories for the same level of success. This is all well if it was achieved and published, but with illicit producers and promoters of new illicit drugs or combinations of drugs that appear on the market, rapid and adequate actions as well as ingenuity on the part of the forensic chemist are required. Exhibit material that has an unknown origin and result is not limited to those laboratories with research capacity and need special attention in solving the crime. This can only be achieved through research and capacity development. As assessed during the survey, only 22.9% of drug

laboratories which participated have research and development programs in place. Although it is not an absolute requirement for a laboratory to have a research and development department, paragraph 5.4.4 of ISO17025:2005 requires method validation of the non-standard methods prior to the analysis being performed. This requires research and capacity development from the laboratory and can only be achieved if the scientist in possession of the exhibit material has the necessary access to such a facility. Shortcomings in terms of seized illegal manufactured samples are listed on the CLIC website, where international scientists post their problematic analytical spectra in the hope of a possible answer. Access to a research facility would have helped to solve many of these problems directly. National or state authorities should facilitate access to at least one research facility that can assist with the analyses of unknown samples received by laboratories under their jurisdiction.

In summary, employees are a valued asset to any organisation. No foolproof technique exists for hiring the perfect employee. Laboratory managers must look for basic character traits such as their approach towards casework and cooperation with existing staff, rather than immediate performance on casework. The international standard in appointing forensic drug chemists, although not an ISO17025:2005 standard, is a relevant 3 year tertiary qualification. Once appointed, a senior scientist should be allocated to the new staff member in mentoring and coaching them. According to the survey, formal mentorship programs are lacking in forensic drug laboratories and need serious revision. Internal training programs should be formalised and ready before commencement of the training program, so that the new scientists can familiarise themselves with the goals, measures, actions and assistance placed in front of them to meet the performance objectives. All the forensic drug laboratories have internal drug training programs available, but there is no international standard on the content of such training programs, only recommendations from SWGDRUG. The successes of the training presented should be evaluated and monitored to determine if the new staff members are competent to perform casework. This can be achieved through certification of the individual through an independent certification body. According to the survey, laboratory managers are continuously developing staff to a level of high competence and high commitment. It is done by allowing each individual to be exposed to national and international conferences and seminars as well as a number of contact training days per year. Laboratory managers are doing well by constantly seeking opportunities to develop technical staff in the most cost effective ways. Flow chart 4.1 illustrates the developmental program used by management in the forensic science laboratory chemistry unit, South Africa.

Flow Chart 4.1 Developmental Program for Forensic Chemistry Analysts

FSL=Forensic Science Laboratory, SAPS=South African Police Service, MS=Mass Spectrometry, SHE=Safety Health and Environment, GCMS=Gas chromatography Mass spectrometry, FTIR=Fourier Transform Infrared Spectroscopy, UPLC=Ultra Performance Liquid Chromatography, GC=Gas Chromatography, HPLC=High Performance Liquid Chromatography, IAAI=International Association of Arson Investigations, CLIC=Clandestine Laboratory Investigating Chemists. Adopted from chemistry developmental program, Quality Training, FSL South Africa (2007).

Through the developmental program managers are able to perform a skills development audit, to evaluate staff skills shortages, before submitting an annual work place skills plan. This will ensure continuous technical and administrative skills development within the laboratory. The developmental path of an individual can be evaluated during performance evaluations annually that are conducted by supervisors. Scientists will be able to develop on each level according to the level's requirements, through internal training programs, external training courses and international exposure.

4.3 ANALYTICAL ENVIRONMENT

Another resource of importance that did not receive the attention that it deserves in this study is the environment wherein analytical work has to be performed. This aspect is addressed in full in Section 4.6 in the discussion related to productivity, due to its importance in the wellbeing of personnel at the workplace. Sufficient space and correct layout of the laboratories are two main contributors to productivity.

From the results presented in paragraphs 4.1.1 to 4.1.11, it is evident that the majority of forensic drug laboratories globally comply with the recommended standards of ISO17025:2005 related to critical resources namely equipment, personnel and environment. This is however not enough to ensure quality results within the forensic community, as it is the control mechanisms and assurances which are provided with these resources that are most important to the community. Continuous pressure has been placed on forensic laboratories to strengthen quality control and quality assurance while performing analytical tests. In the next section of the survey, the aspects of quality control and quality assurance were benchmarked against the recommendations stipulated by ISO17025:2005 and other related standards.

4.4 EVALUATION OF QUALITY ASSURANCE AND QUALITY CONTROL

The sixth principle of VAM recommends that laboratories making analytical measurements should have well defined quality control and quality assurance procedures. According to the VAM principle, quality assurance starts with documented control procedures on all processes within the drug laboratory to evaluate exhibit receipt, exhibit handover, exhibit counting and/or weighing, sampling, solvent extraction, method validation, proficiency testing, access control, instrument calibrations, uncertainty levels and report writing (Hardcastle, 1998). Quality assurance programs are a preventative action in bringing non-conformances to light before they culminate in adverse events. Procedural manuals, safety manuals, training manuals and other related documents will contribute to a quality manual, which in turn will ease the accreditation, certification and competency testing processes within the drug laboratory (St Clair, 2003). The questionnaire covered some of the critical control procedures for compliance to the ISO17025:2005 international standard.

According to the study all the international drug laboratories have implemented documented quality control procedures. According to paragraph 4.3.1 of ISO17025:2005,

laboratories shall establish and maintain procedures to control all documents that form part of the quality management system. The standard also covers data control in paragraph 5.4.7 and record control in paragraph 4.13. The level and magnitude of these control procedures will differ from laboratory to laboratory. Laboratory managers may use the principle of “measure and manage”, where quality programmes are evaluated (measured) in such a manner that it can be managed. The programmes can either be managed directly, through physical observation and time measurement by the supervisor or indirectly, through a pre-established detailed description of the task given to the scientist and the time measured without direct supervision. It is an old business principle, but highly effective if applied correctly even in the public service (de JCronje *et al.*, 1987).

4.4.1 Record keeping and testing of standards and reagents

In Section 2.10 of Chapter 2 the importance of quality control on standards and reagents were discussed. Table 4.9 presents the importance of the record keeping of standards and reagents in global drug laboratories.

Table 4.9 Record keeping and testing of standards and reagents

Status of standards and reagents	A - Laboratories indicating yes (%)	B - 95% CI ^a
Lot/Batch numbers of standards and critical reagents are recorded	92.9 (<i>n</i> = 70)	86.9 - 98.9
Critical reagents are routinely tested for their reliability	92.9 (<i>n</i> = 70)	86.9 - 98.9

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

The results from Table 4.9 are another indication that laboratory managers are serious about traceability, not only on samples the laboratory receives, but also critical reagents and standards used within the laboratory. In paragraph 5.6.3 of ISO17025:2005 the traceability of reference standards/materials to SI units are emphasised. Standards and reagents play an integral part in calibration, testing and traceability in forensic drug laboratories. The calibration activities determine and monitor any deviations in the measuring instruments and the “true” value of the measured and required standards that are traceable to national and international standards. The testing operation is a direct comparison of characteristics between the known standard and unknown samples received by the laboratory under the same environmental conditions. Lastly, the traceability process to compare results obtained from the analytical instrument with a national or international reference standard, purchased from an accredited laboratory. The purpose of requiring traceability is to ensure that the standards used in analytical

measurements are accurate and fall within the uncertainty levels of national and international standards. An advantage of a well documented control system is that defence attorneys in legal proceedings can be presented with historical records of lot/batch numbers as well as analytical results for their reliability and traceability, when standards and reagents are disputed. Routine practices and empirical studies determine critical reagents which require routine testing before their use on evidentiary laboratory samples. No international standard prescribes the intervals for the routine testing of critical reagents and standards. Although not prescribed, according to the survey, 92.9% of laboratories implemented the routine testing of critical reagents for their reliability.

According to the Office of Regulatory Affairs (ORA) from the U.S Food and Drug Administration (FDA), analytical grade reagents, solvents and gases should meet the required standards for most analyses. ORA standards recommend that reagents should be ordered in quantities which will be consumed within the supplier's expiration date or five years, whichever is first. The standard also recommends the proper storage of chemicals according to manufacturer's specifications and that reagents should be regularly inspected for signs of deterioration. Once chemicals and reagents are not fit for the intended purpose, laboratory procedures should exist for proper disposal according to health and safety regulations (ORA-LAB.5.6, 2006). Although not specifically defined in the ISO17025:2005 quality documents, laboratory managers should adopt the above mentioned recommendations from ORA to ensure good laboratory practices.

4.4.2 Sampling

The sampling of exhibit material from submitted test samples is an important part in the forensic drug process. The scientist should first confirm that the drug evidence received was unaltered, since collection and the seals holding the drug samples are intact, for example, the chain of evidence has been certified (Hardcastle, 1998). Once confirmed, sub-sampling can proceed. The most controversial data sampled in this study was with regard to the topic of sampling. Due to the complexity and diversity of samples that laboratories receive, standardisation may influence critical aspects such as turn around times and cost. Table 4.10 presents the manner in which samples are received by laboratories globally.

Table 4.10 Manner in which samples are received at the laboratory

Status of sample receipt	A - Laboratories indicating yes (%)	B - 95% CI ^a
All physical drugs seized	37.1 (<i>n</i> = 70)	25.8 – 48.4
Representative sample of drugs seized	22.9 (<i>n</i> = 70)	13.1 – 32.7
Both	40.0 (<i>n</i> = 70)	28.5 – 51.5

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

According to the survey 22.9% of forensic drug laboratories only receive a representative sample for testing. The concern however is that the law enforcement officer performing the sampling may not be properly trained in statistical sampling methods. If the officers are not properly trained, no inferences can be made by the analyst on the bulk of the drugs seized. Certain agencies might decide only to send a representative sample, while others submit all drugs collected regardless of the size. It is a matter of laboratory capacity and safeguarding the samples collected. To overcome this, certain laboratories serve as storage facilities as well, while others can only handle small amounts. It is however, important that whatever sample is received, it should represent the total sample population for which an accused will stand trial. In the South African laboratories, as in many other drug laboratories, it is not always possible to receive all the drugs seized on crime scenes. Cannabis plantations, for example, may be numerous hectares in size and it would be impossible to seize it all. The same applies to truck loads of dried cannabis discovered in road blocks. In this case, the investigating officer should take the vehicle to a weighing bridge to do a weight determination. Photographs should be taken of the bulk after which a representative sample should be taken and sent to the laboratory. Those officers are all trained and work at regional organised crime units. With regard to clandestine laboratories, the amount and type of samples to take for the analysis is entirely the decision of the investigating chemist, whereas the rest will be left for destruction by a chemical waste removal contractor. Emphasis is placed on the competence of scientists, and the training of staff in these activities is therefore of prime importance. In the majority of large sample cases received by the South African laboratories, pre-trial destructions are performed, with only a representative sample being kept for possible defence analysis. This procedure also ensures the health and safety of all personnel working in the laboratory, thus managing the risk with regard to potential attacks or burglaries.

4.4.3 Sampling schemes

Regardless of the size of exhibits received, the analyst must be able to use the laboratory's sampling strategy to achieve the aim of the investigation. An important factor

in sampling strategies is that all the analysts working in the same laboratory or laboratories under the same national or regional jurisdiction should use the same strategy. If not, defence attorneys will attack the quality control of that laboratory during court procedures. Scientists in the same laboratory should agree on the sampling strategy and feel comfortable to defend it on the scientific and forensic levels. The ISO standard requires a strategy for sampling of substances for analytical testing in paragraph 5.7.1 of the international standard. It also states the sampling strategy should be based on statistical principles, whenever reasonable. In paragraph 2.7 Chapter 2 the differences between statistical and non-statistical sampling strategies were explained. Given the wording “whenever reasonable” in the ISO standard, laboratory managers or experienced scientists should clearly distinguish which circumstances are reasonable and which are not possible in the science context. If the laboratory is not using a statistical methodology, management directives should be documented for a clear understanding on the methodology to be followed (SWGDRG, 2003). Table 4.11 presents the diversity of sampling strategies implemented by global drug laboratories.

Table 4.11 Sampling schemes used in forensic drug laboratories

Sampling plan	A - Laboratories indicating yes (%)	B - 95% CI ^a
Hyper-geometric distribution	28.6 (<i>n</i> = 70)	18.6 - 39.2
$\sqrt{N}$	21.4 (<i>n</i> = 70)	11.8 - 31.0
10% $\sqrt{N}$	5.7 (<i>n</i> = 70)	0.3 - 11.1
10%	4.3 (<i>n</i> = 70)	0.0 - 9.1
Other	40.0 (<i>n</i> = 70)	28.5 - 51.5

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

According to the survey only two statistical methods are used in forensic drug laboratories, namely the hyper geometric distribution method (28.6%) and the Bayesian method (1.4%). The remaining drug laboratories (70%) are using non-statistical methods. The other schemes that were reported on the survey by participating laboratories include $\sqrt{N} + 1$; square root only; Bayesian and the DEA sampling plan. According to other laboratories participating on the survey, management directives are followed and are determined by their respective justice departments. The laboratories in South Africa changed over to the hyper-geometric distribution method with a 90% proportion level in 2002, but soon after realised the impact on increased turn around times and high analytical costs. With caseload increases of more than 40% in three consecutive years, management had to re-evaluate the impact of sample size and lower the proportion level to 50%. In the beginning of 2008 it was revised again, due to large case backlogs. A managerial directive strategy

was implemented where the offence determines the number of samples taken for analysis. The hyper-geometric distribution approach is still followed in dealing and manufacturing cases, but single sample analysis is performed on possession cases with homogenous exhibits. The representative sample will still be taken and sealed for further analysis upon request of the state prosecutor or defence attorney. It has not been challenged in court as yet and case turn around times has decreased for the first time in years.

Although 70% of the drug laboratories use non-statistical approaches, 94.3% (n=70) of the laboratories believe their statistical scheme is suitable for the purpose. Laboratory managers believe that because it has been accepted by the prosecuting attorney's office and the defence community, it is suitable for the judicial system.

Sampling schemes in forensic drug laboratories are difficult to define and laboratory management should monitor their respective laboratory's situation at regular intervals. A balance should exist between the costs, of turn around times, scientific proof and judicial acceptance. Laboratory managers should however emphasise that scientific proof always weighs the heaviest of the three, when inferences are to be made on the total population of sample material. When non-statistical methods are used it should be documented in reports, not to mislead the courts on the content of the total sample population. Scientists should refrain from making any inferences on the population of drugs received if they did not follow a scientifically validated statistical method.

Defence attorneys on a regular basis request scientific proof or peer reviewed literature on sampling methods used in the South African Forensic Sciences Laboratories. It is therefore important to have such information on hand to answer their request. Various literatures exist on sampling and statistical approaches on forensic drugs (Richard, 1991; Tzidony, 1992; Colon, 1993; SWGDRG/Sampling, 2003 and ENFSI Working Group Drugs, 2003) that could serve as authority in this regard. It is however concerning that only 57.1% of forensic drug laboratories that participated in the current survey have scientific proof or literature, on the sampling scheme implemented in their laboratories, as proof of its validity. From the survey, 32.9% of participants do not have any scientific proof or literature and the remaining 10% don't know if such documentation exists. Laboratory managers in these laboratories should obtain relevant peer reviewed literature on the sampling strategies that were followed or change to a validated statistical approach which would prove its validity in courts. Laboratory managers should validate the statistical method for

these types of samples, for it to be scientifically valid, and fit for purpose, and therefore allowing for its use in court.

4.4.4 Method verification and validation

The sampling strategy should be followed with the sound analytical methods used in forensic drug laboratories globally. This means analysts should use analytical measurements that are validated for the purpose of qualitative and quantitative analyses of drugs. According to ORA-LAB.5.4.5 when a laboratory uses standard methods in analytical measurements, verification is needed to ensure that the laboratory is capable of performing such analyses. The verification process will demonstrate that a specific laboratory is capable of replicating a standard analytical method with an acceptable level of performance. Various performance characteristics can be used to accomplish verification such as blanks to assess contamination, control samples to assess accuracy, duplicate analysis to assess precision, periodic analysis of calibration standards to assess quantitative analyses and control charts to monitor quality control samples.

In paragraph 5.4.2 of ISO17025:2005 it is recommended that a laboratory should be able to demonstrate that it can properly operate standard methods before implementing the analytical method. These standard methods should be selected from published international or national standards and if the standard method changes, the verification should be repeated.

For non-standard or laboratory developed methods, validation of the method is required (Paragraph 5.4.4, ISO17025:2005) prior to declaring the method fit for purpose. In such processes specific performance characteristics such as accuracy, precision, specificity, detection limit, limit of quantitation, linearity, range and ruggedness/robustness should be validated based on the intended use of the analytical method (ORA-LAB5.4.5, version 1.4, 2009). According to paragraph 5.4.5.2 of ISO17025:2005 non-standard methods, laboratory designed/developed methods, standard methods used outside their intended scope and modification of standard methods to confirm that the method are fit for the intended purpose should be validated. The study revealed that 90.0% of global drug laboratories participated, have documented validated methods. This indicates compliance with paragraphs 5.4.2; 5.4.5 and 5.9 of ISO17025:2005 in assuring the quality of analytical drug tests and calibration results. The rest of the laboratories surveyed were not aware if the validated methods were documented. Forensic drug laboratories in South Africa make

use of internationally accepted and validated methods, but they are not formally documented or verified. A history of performance characteristics does exist, but are not formulated in quality documents. This is not enough because the laboratory should be able to demonstrate that the methods in use can achieve the same level of performance claimed to be possible with this method. This will determine if the analysts are competent and if the equipment and facilities are adequate to analyse controlled substances. The level of validated methods has improved over the last decade with uncertainty of measurement levels now associated with increased credibility. However, it is dangerous to assume that just because a method is standard, that its published validation is adequate. Each method must be verified in-house within the local laboratory environment, prior to analysis of case samples. The document titled, "The fitness for purpose of analytical methods," published by EURACHEM in 2003 provides enough information on how to validate and document validated methods.

4.4.5 Proficiency testing

One of the most appropriate ways to evaluate not only equipment suitability in forensic drug laboratories but also analyst competence is by means of both external and internal participation in proficiency testing. These independent assessments will demonstrate to the forensic community, the laboratory's commitment to, and achievement of, quality. Principle four of VAM recommends regular independent assessments of the technical performance of a laboratory. LGC/VAM/026 was a document published by the LGC in 1999 and posed the following question: "Do we need to accredit proficiency testing schemes?" Here a lot of emphasis has been placed on suitable proficiency testing schemes as a quality assurance tool for external assessment. Certain accreditation bodies such as ASCLD/LAB have even developed requirements for proficiency test providers and their respective manufacturers to apply for approval from this body before participation in any program (ASCLD/LAB Proficiency Test Provider Program, March 2007). They also developed the Proficiency Review Program (PRP) that outlines the roles and responsibilities of accredited laboratories, Proficiency Review Committees, approved test providers, the ASCLD/LAB Quality manager and other systems in carrying out the elements of the proficiency review process. The various approaches have been brought together in the ILAC document, "Guidelines for the requirements for the competence of the providers of proficiency testing schemes," that has been adopted by many proficiency test providers (ILAC G13:08/2007, 2007). The status of international drug laboratories participating on different proficiency testing schemes is listed in Table 4.12.

Table 4.12 Proficiency testing in global forensic drug laboratories

Status of proficiency tests	A - Laboratories indicating yes (%)	B - 95% CI ^a
Internal tests	2.8 (<i>n</i> = 70)	0.0 – 6.7
External tests	30.0 (<i>n</i> = 70)	19.3 – 40.7
Both	65.7 (<i>n</i> = 70)	54.6 – 76.8

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

From Table 4.12 it is evident that 95.7% of forensic drug laboratories participate in either external or both internal and external proficiency testing schemes ensuring compliance with paragraph 5.9 of ISO17025:2005. Regardless of the route that is followed, laboratories that seek accreditation status and want to demonstrate the comparability of its measurements, should participate in proficiency testing. It is a laboratory manager's duty to demonstrate the efficacy of the actions taken after evaluation of the laboratory's own performance.

Besides internal proficiency testing programs within the South African forensic drug laboratory, the laboratory also participates in external collaborative programs such as the Collaborative Testing Services (CTS) tests. CTS provides two proficiency tests in the discipline of drug chemistry and each test is issued once per year and allows nine weeks, from shipment to the due date of the data, for analysis. With these collaborative tests forensic drug laboratories do not just monitor their performance against their own requirements, but also against the norms of other laboratories.

False negative analytical results indicate limitations on the side of the laboratory, which means that the instrumentation used could not determine the analyte of interest, the method employed was incorrect or the analyst followed the wrong procedures. Generally if the analyte of interest is of a low concentration, accreditation authorities see it as a minor non-conformance, but if the result is a false positive, where an analyte is detected that does not exist, the credibility of the laboratory and the analyst are brought into question. This will result in a serious non-conformance, due to poor laboratory performance and a laboratory failure. In a study by Nichols in 1997, the results of seventeen proficiency tests and seven years of CTS test results were surveyed and a total of sixty-three errors were reported. Fifty-six percent of the respondents who reported false positives used GCMS and IR in their analytical scheme. Upon investigation it was determined that it was not the methodology that resulted in the errors, but the lack of critical thought on the part of the analysts. The correct methodology was used but the analysts interpreted the results incorrectly due to insufficient knowledge on deviated results. Nicols (1997) made an

analogy between sophisticated instruments employed in forensic laboratories and finely crafted musical instruments stating that a skilled musician will play magnificently on the musical instrument whereas an unskilled musician will not. Accreditation bodies recognise the benefit of these schemes as objective evidence of competence of the forensic drug laboratory, its scientists and the assessment process itself (ASCLD/LAB:2005; SANAS R01-01, 2007).

4.4.6 Access control

Another quality control process is to assure the integrity of exhibit material while under the possession of laboratory operations. The best way that this can be done is via controlled access to key areas in the analytical laboratory. Methods in employing limited access vary from laboratory to laboratory, depending on budget restraints and the commitment of management. The first control point starts at sample reception and processing, where sample transfer is taking place between the law enforcement officer and the laboratory. Responsible administration staff will receive the samples and allocate a laboratory number to it. Proper secure storage facilities should exist until sample transfer to the analyst can take place. Exhibit material might be kept here for long periods of time, depending on the backlog of cases within the laboratory. Defence attorneys generally question access control to such storage facilities when disputing the integrity of sample material. The second point of interest is sample storage during analysis. Each forensic scientist in the SA forensic laboratories has its own standalone safe for exhibit storage during analyses. On completion of the analysis, samples are transferred to sample reserve storage points for safekeeping for the duration of court proceedings. The last point of control is the disposal of samples, when samples are separated and destroyed upon completion of court proceedings. All of these points should be properly controlled and access monitored accordingly. Table 4.13 lists data that is an indication of the commitment of laboratory managers to protect and assure exhibit integrity.

Table 4.13 Access control in forensic drug laboratories

Access control	A - Laboratories indicating yes (%)	B - 95% CI ^a
Secure access control	98.6 (n = 70)	95.6 – 100.0
Keys and/or other devices of security doors limited to authorised personnel	98.6 (n = 70)	95.6 – 100.0

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

Again it is clear that laboratory managers of global drug laboratories have realised the importance of secure access to critical areas with 98.6% of laboratories denying unauthorised personnel access to controlled and sensitive analytical areas with proper security devices. Laboratory managers in the South African forensic laboratories have implemented access control to the laboratories by means of biometric fingerprinting as well as electronic card devices connected to a central access control server. Laboratories and walkways are also covered with camera surveillance to monitor and detect unauthorised people in the building. The total system ensures limited access to critical areas and prevents any person from wandering around in restricted areas without being detected and removed. It also ensures evidence integrity when under the control of the forensic laboratory.

4.4.7 Accreditation

Management of forensic drug laboratories may decide to design their own quality assurance procedures as part of a quality management system or they may follow an established protocol or standard such as ASCLAD/LAB or ISO17025:2005. If a laboratory chooses the latter it may claim informal compliance against the protocol or ideally undergo independent assessment from a mandated expert body. All the forensic drug laboratories have ownership of a documented quality management system, but to date not all of them have gained independent endorsement of their quality systems. The importance of gaining independent endorsement is that the testing body accepts responsibility for the laboratory by demonstrating competence to perform specific types of testing, measurement, inspection and calibration. Many of the accreditation bodies do more than just independent inspections. They also provide testing facilities with technical advice, online resources, discounts on various training courses and publications.

For many state laboratories it is mandatory to be accredited. Commonwealth Government laboratories are required, under a Memorandum of Understanding between The National Association of Testing Authorities (NATA) and the Australian Government, to obtain and maintain NATA accreditation (NATA website, 2008).

In South Africa, the South African National Accreditation System (SANAS) was appointed on 20 March 2007 as the only accreditation body in South Africa according to Act No. 19 of 2006: "Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice". SANAS follows the ISO17025:2005 requirements for Testing and Calibration

laboratories and recommends the use of TG01-01 as a guide for forensic laboratories (Government Gazette, Vol. 501, 6 March 2007, No. 29712). None of the forensic science drug laboratories in South Africa are currently accredited, as they represent only one forensic discipline within a larger national forensic science laboratory. The management recently requested all forensic disciplines within the laboratory to comply with the ISO17025:2005 requirements before seeking accreditation from SANAS. For now, each discipline should use and maintain the required quality management system implemented within the forensic science laboratory, given by SANAS for the preparation of accreditation.

The status of forensic science laboratories in Europe are supervised by the European Network of Forensic Science Institutes (ENFSI). ENFSI amended its framework of membership in 2004 and stated that for laboratories to be eligible applicants, they should establish a clear plan towards accreditation in the near future. A study conducted by Malkoc and Neuteboom in 2007, on the current status of forensic science laboratory accreditation in Europe, revealed that only 32.7% (N=52) of the 53 ENFSI registered forensic science laboratories were accredited (Malkoc and Neuteboom, 2007). Laboratories in the United Kingdom seek ISO17025 accreditation through the United Kingdom Accreditation System (UKAS). The Asian Pacific Laboratory Accreditation Cooperation (APLAC) also provides accreditation and quality assistance to many forensic laboratories in the East (St Clair, 2003).

In Canada the Canadian Society of Forensic Science established the Standard Council of Canada (SCC) to overlook accreditation of Canadian forensic science laboratories. In 1999 CAN-P-1578 termed "Guidelines for the accreditation of Forensic Testing Laboratories" was published. The CAN-P-1578 publication meets all the requirements of ISO17025:2005 (St Clair, 2003).

Although a number of registered bodies do exist in the United States, forensic drug laboratories generally seek accreditation through ASCLD/LAB. The legacy of ASCLD/LAB began with accrediting crime laboratories in 1982, but it was only in 2004 that the implemented accreditation according to international standards was implemented. Both programs i.e. ASCLD/LAB legacy and the international accreditation are currently implemented, however, the legacy program will not be supported after April 2014 (Keaton, 2008, ASCLD/LAB, Newsletter, 2008). The international program is based on ISO17025 and supplemented with requirements of ASCLD/LAB legacy and ILAC G-19. In September 2005 the ASCLD/LAB program had 301 forensic laboratories accredited (13 under

ASCLD/LAB international and 289 under ASCLD/LAB legacy) this included nine international laboratories (ASCLD/LAB, 2008).

Most of the accreditation bodies mentioned above are signatories to the International Laboratory Accreditation Cooperation (ILAC) and by a Multilateral Recognition Arrangement, constantly need to demonstrate the technical competence of their accredited calibration and testing laboratories to sign or maintain their status as signatories. Table 4.14 indicates the status of accredited forensic drug laboratories globally.

Table 4.14 Accreditation status of forensic drug laboratories

Accreditation status	A - Laboratories indicating yes (%)	B - 95% CI ^a
Total number of laboratories accredited	68.6 (<i>n</i> = 70)	57.7 - 79.5
Number of laboratories accredited by ASCLD/LAB	58.5 (<i>n</i> = 70)	46.9 - 70.1
Number of laboratories accredited by other accreditation bodies	10.0 (<i>n</i> = 70)	3.0 – 17.0

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

As listed in Table 4.14, 68.6% of the 70 forensic drug laboratories who participated were already accredited. The concern however is that only 10.0% of the laboratories which are accredited, were accredited by other accreditation bodies than ASCLD. The data reveals ASCLD/LAB dominance and this can be attributed to the geographic make-up of the study group of the questionnaire. Responses were received from twenty seven of the fifty two states in the United States (51 laboratories), DEA federal laboratories (3 laboratories), Canada (8 laboratories), Australia (1), New Zealand (1), Belgium (1), Finland (1), Netherlands (1), Switzerland (1), Taiwan (1) and Israel (1). In the study, 77.1% of participating laboratories were from North America, with ASCLD/LAB legacy as the accreditation body of choice since 1982.

In 2006, the National Academy of Science established a committee to assess the status of forensic laboratories in the United States. The independent assessment led to a report published in January, 2009, entitled “Strengthening Forensic Science in the United States: The path forward.” One of the recommendations of that report is that laboratory accreditation and individual certification of forensic science professionals should be mandatory. The committee further recommended that the National Institute of Forensic Science should take into account established and recognised international standards, such as ISO17025:2005 in the accreditation and certification processes (National Academies Press, 2009).

Accreditation according to international standards is not always cheap or easy. The South African forensic drug laboratories are not only scattered over four regions, but are also attached to larger forensic entities. For this section to become accredited would mean all other disciplines need to be ready for independent quality assessments, a process that has been ongoing for more than a decade now. The organisation consists of more than a thousand employees situated in nine different laboratory locations and several more offices, making independent assessment very difficult. However, a well established quality assurance program does currently exist.

4.4.8 Summary of quality assurance and quality control

For any kind of forensic evidence to play a useful role in court proceedings, the evidence must be admissible and reliable. When forensic evidence relies on analytical results, a number of quality control and quality assurance principles become important. A well defined quality control program will enable management and supervisors to monitor various aspects of the quality data generated on a routine basis. With the exception of a standardised sampling scheme, the majority of laboratories which participated complied with ISO standards on critical standards and reagents, method validation/verification, proficiency testing and proper access control. The management of drug laboratories in South Africa have implemented the following quality control mechanisms to ensure mistakes are minimised and the quality of results are assured:

- a. Analysts control markings and seals before accepting forensic evidence.
- b. Every analyst has his/her own safe for safekeeping evidence during analytical time to ensure evidence integrity.
- c. Analysts are only allowed to open one case file on the bench at a time to eliminate the possibility of cross-contamination or sample switching.
- d. Working procedures are placed in laboratories to remind analysts constantly of GLP.
- e. Blanks are prepared for every case file and extraction type. When more than five samples are extracted with the same procedure a second blank needs to be prepared. This is to measure contamination and interferences.
- f. Certified reference standards are run every 48 hours to evaluate repeatability, instrument performance and sample comparisons.
- g. Every case file will be reviewed technically and administratively by an experienced scientist before reports are distributed to investigating officers to ensure that the results released are accurate and precise.

Regardless of all the quality control mechanisms in place in any laboratory, laboratory members, customers and the forensic community should realise that quality assurance cannot guarantee that 100% of the individual results will be correct. Mistakes and errors do occur, even in a well-run laboratory. An example would be where two samples might have been switched. With a well defined quality assurance program these mistakes will be small, but not zero. Random and systematic errors will lead to uncertainty in the analytical data. The confidence levels employed by the laboratory will determine the uncertainty range for analytical measurements, but deviant results will still occasionally appear regardless of the efficiency of the laboratory. The role of quality assurance is to manage the frequency of quality failures and the amount of the effort implemented will determine the number of non-conformances. Three publications mentioned in Chapter 2 covers the principles of quality assurance in laboratories namely:

- a. ISO17025:2005 – addressing the technical competence of laboratories.
- b. ISO9001/2000 – relating to quality management.
- c. OECD Principles of Good Laboratory Practice (GLP):1998 – guidelines concerned with organisational processes and laboratory conditions.

Compliance to a combination of all three documents will ensure quality assurance excellence. Accreditation bodies and laboratory managers should consider the above principles and recommendations when establishing quality assurance programs for independent assessment.

4.5 EVALUATION OF CUSTOMER/CLIENT RELATIONSHIP

VAM Principle 1 indicates that analytical measurements should be performed with an appropriate analytical strategy which will satisfy the needs of the investigating officer/customer. It is therefore important for any forensic drug laboratory, before conducting any analysis, to define the problem to be solved. The objective of any government and especially safety and security agencies is to provide a safe and secure environment for all and therefore the key objective of the associated forensic laboratory is to operate in a manner that supports the government objective. Private forensic laboratories should also commit themselves to government objectives to ensure a secure environment and future contracts. If they do not comply with national standards, contracts will not be renewed and jobs will be lost. Paragraph 4.7 of ISO17025:2005 deals with services to the customer. One of the most important aspects that is emphasised in the international standard is the effective communication between the laboratory and its customers. Effective communication should include, but is not limited to:

- a. Proper feedback, either negative or positive
- b. Guidance in technical matters, for example, clandestine laboratory assistance
- c. Customer training on technical aspects and
- d. Opinions and interpretations based on results obtained (Paragraphs 4.7.1 and 4.7.2 of ISO17025:2005).

4.5.1 Customer training

It is important to convey analytical methods to investigating officers, so that they can understand the balance between costs, turn around times and quality requirements. Customers of forensic drug laboratories should be part of the quality philosophy of the laboratory. According to the survey, 82.9% of forensic drug laboratories provide training to their customers. Analysts performing training for customers should have an understanding of the investigating officer's working environment and their need to strengthen customer/provider relationship. Relationships and training should be in place on all levels in both organisations. Often good relationships exist on management level, but no communication takes place on the ground level and *vice versa*.

Forensic science laboratories are a supporting aid to the legal system, but it is the investigating officer that needs to present a sound case for the state prosecutor to prosecute. It is therefore important that forensic drug laboratories satisfy the needs of the investigating officer through proper training and good communication structures. The training will also ensure the quality of exhibits that are seized on crime scenes by law enforcement officers. Topics that are covered during training, workshops or information sessions by the Forensic Science Laboratory in South Africa include:

- a. Physical identity and history of various drugs in their respective nature and matrixes
- b. Classification of drugs
- c. Importance and evidential value of analyte identity in the sample
- d. Additional information needed by the investigating officer
- e. Critical nature of results
- f. Cost and time constraints
- g. Quality assurance and quality control measures in place at the laboratory
- h. Regulatory/legislative constraints

4.5.2 Identifying customer expectations

The survey revealed that 98.6% of the laboratories know they have a good relationship with customers, but only 72.9% of the laboratories know what their customers expect from them by means of a survey measurement tool. Forensic drug laboratories should conduct a client satisfaction survey annually to measure its success as a service provider. This will contribute to the total quality management and compliance as outlined in paragraphs 4.7 and 4.8 of ISO17025:2005.

4.5.3 Balance based on customer relationships

Less than 4.2% of forensic drug laboratories are privately owned whereas more than 90.9% of laboratories are state or government controlled. The laboratories owned by states or governments are more likely not to expand services as they serve a specific community and their customers are directed by the authorities of that state or government. Only 21.4% of drug laboratories consider expanding to new markets and new customers. Where privately owned laboratories determine their resources according to state contracts and the number of private analytical measurements expected, managers of state owned laboratories need to consider case increase, cost, turn around times as well as equipment utilisation rates, when motivating new equipment, laboratory space and staff. Available resources, service cost, productivity, safety and quality are interrelated and the lack of any leads to customer dissatisfaction. One of the concerning factors discovered by the committee of the National Institute of Forensic Science, is the alarming shortage of forensic experts in forensic laboratories. A recommendation was made to assess and fund more jobs in forensic science laboratories in the United States (National Academies Press, 2009). South Africa is experiencing the same problem in that there is a shortage of forensic experts, with more than 447 of the 1,098 forensic expert posts vacant in the forensic science laboratory (Steenkamp, 2009).

4.6 EVALUATION OF PRODUCTIVITY

Although quality provides a snapshot of the performance of portions of the system, laboratory managers need insight into the interdependent laboratory relationships that may produce unexpected changes during the operational process. A service model needs to be developed to constantly evaluate the available resources, service satisfaction, cost, productivity, safety and quality, as they are all interrelated.

In the preceding discussion, the focus has been the resources and quality system supporting the effective use of resources. In this part of the study, focus is shifted to the operational performances of individual drug laboratories. Attention is given to personnel capacity and service output ratios as well as personnel well-being in the forensic drug industry.

4.6.1 Time component spent on analyses

Minimum staff levels in the forensic drug laboratory should exceed the demand for the analyses requested over a one year period in order to comply with customer needs. The variety of services rendered, the size and extent of the client base and the speed at which the legal system requires analytical reports will determine the magnitude of analyses requested. Forensic drug laboratory managers should therefore consider the following:

- a. Determine the analytical demand through calculating the number of cases received the previous year and number of analyses performed.
- b. Add an average expected caseload increase.
- c. Determine the number of working hours per year per analyst (full time equivalent).
- d. Maximum overtime allowed according to legislation.
- e. Negotiate a reasonable turn around time with the customers.

4.6.2 Analytical demand

The staffing level should be based on labour supply or analytical demand. The analytical demand is the input of cases from law enforcement agencies. Statistical data of cases received and analytical tests performed can be used as an indicator when determining analytical demands. Table 4.15 indicates the analytical demands per month in forensic drug laboratories.

Table 4.15 Analytical demands to forensic drug laboratories

Average number of samples analysed per month per laboratory	A - Laboratories indicating yes (%)	B - 95% CI ^a
0 to 100 samples	5.7 (n = 70)	0.3 - 11.1
100 to 1000 samples	54.3 (n = 70)	43.0 - 65.6
1000 to 3000 samples	27.6 (n = 70)	16.7 - 38.5
3000+ samples	12.9 (n = 70)	5.1 - 20.7

a = the percentages indicated in the last column are based on a 95% confidence interval. n = total number of laboratories who answered the specific question.

According to the data presented in Table 4.15, more than half of forensic drug laboratories have an analytical demand of between 1,200 to 12,000 samples per year. The second highest demand is laboratories with between 12,000 to 36,000 samples per year. The forensic drug laboratory in the Western Cape, South Africa has an analytical demand of more than 36,000 samples per year. Higher analytical demands require more analysts and bigger or more forensic laboratories.

The next investigation is to determine case load increases in forensic drug laboratories globally. The combination of the analytical demand and case load increase will determine minimum scientist requirements. In Table 4.16 the case load increases in global drug laboratories are demonstrated.

Table 4.16 Case load increase in global drug laboratories every year

Percentage case load increase	A - Laboratories indicating yes (%)	B - 95% CI ^a
No increase	4.5 (<i>n</i> = 70)	0.0 - 9.1
0% to 10% per year	68.6 (<i>n</i> = 70)	57.7 - 79.5
10% to 20% per year	21.4 (<i>n</i> = 70)	11.8 - 31.0

^a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

Table 4.16 indicates the increases of drug related cases in global laboratories, with 68.6% of laboratories undergoing a 10% increase in cases per year. Only 4.5% of laboratories that participated in the survey did not receive any increases. The remaining 21.4% of the laboratories presented with case load increases of between 10% and 20% per year. The high case load increases experienced in South Africa and globally has contributed to staff skill shortages globally. One would expect staff increase to correlate with the case increase, but forensic laboratories find it difficult to convince higher authorities and the human resource departments to employ new staff. Appointment of new staff does not always solve the problem immediately as it requires time and further costs to train them. Laboratories should make provision for the increase of drug cases and train new staff in a proactive way and not reactively, which will lead to backlogs that are again difficult to normalise.

On the question of analyst shortages in global laboratories, 44.1% to 67.3% of global laboratories with representation on CLIC would require more analysts to exceed the total labour demand. One way to convince higher authorities and Human Resource departments to employ more analytical staff is to perform a benchmarking exercise, comparing analytical demands with staff levels. This will require a better understanding of

the concept of the full time equivalent (FTE). In forensic drug laboratories operating under governing bodies, an FTE is based on human time resource rather than labour cost. The majority of the laboratories which indicate staff shortages are also the laboratories with turn around times of more than 21 days, indicating the impact of too little analysts on the performance of analytical casework. Equation 4.1 can be used to calculate the FTE per analyst in the laboratory.

Equation 4.1 FTE in the analytical laboratory per year

$$\text{FTE (Full Time Equivalent)} = \text{Hours per week} \times 52 \text{ weeks per year}$$

Collins (1998).

Labour hours are hours set by the basic conditions of employment and may differ from jurisdiction of states and countries. The South African legislation for government employees requires a 40 hour labour week per analyst, which provides one FTE of 2,080 hours per staff member working in the forensic drug laboratory. Table 4.16 shows the average FTE per analyst per week in global forensic drug laboratories.

Table 4.17 Full time equivalent per analyst per week

Number of working hours per week per analyst	A - Laboratories indicating yes (%)	B - 95% CI ^a
1 to 20 hours	0.0 (<i>n</i> = 70)	-
21 to 40 hours	67.1 (<i>n</i> = 70)	56.1 - 78.1
41 to 70 hours	31.4 (<i>n</i> = 70)	20.5 - 42.3
71+ hours	1.4 (<i>n</i> = 70)	0.0 - 4.2

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

According to Table 4.15, 67.1% of forensic drug laboratories are working on an FTE of 21 to 40 hours per week, whereas 31.4% of laboratories have a FTE of 41 to 70 hours per week. The one laboratory indicating a 71+ working hours is thus the exception to the rule and this may contribute to analytical mistakes due to fatigue. The FTE alone cannot be used to determine the actual staff level, since task differentiation exists for every member of staff. Secondary tasks, vacation leave, sick leave, public holidays, meetings (safety, team, department and quality), training, breaks, housekeeping and filing, will all contribute to non-analytical time spent in the laboratory. The laboratory manager and human resource manager should keep this in mind and ensure that the FTE is greater than the labour needed to perform all analytical tests. To accommodate the loss of analytical time, a labour utilisation factor (LUF) should be determined. Equation 4.2 is used to determine the LUF per analyst performing analytical work.

Equation 4.2 LUF for determining real analytical time per analyst per year

$\text{Labour Utilisation Factor (LUF)} = \text{Total Time} - \text{Non-analytical Time} / \text{Total Time}$

Collins (1998).

Non-analytical Time is the time committed to accomplish secondary tasks, laboratory benefits and other related activities. The total time is the sum of the entire analyst’s time at the laboratory. Countries that lie in the top productivity margin estimate the theoretical upper limit of about 85% of an FTE that may be used for analytical analysis over a long period. The LUF will differ from forensic drug laboratories depending on the non-analytical time factor. The forensic analyst in South Africa has 22 days of leave per annum whereas other countries only allow for 12 days leave per annum. The LUF should only be used to benchmark productivity in the laboratory and should not be set as an operational goal.

4.6.3 Resource requirements

The next step would be to determine the resource requirements for specific tests to indicate standard test times that will cover the total demand of the labour needed. Standard tests must be divided into tasks that require the physical presence of the analyst and calculate the performance for each task to capture a total standard test time. For example, a routine GCMS analysis might include a sample preparation task, an instrument sequential task and an analytical data reduction task, but no time will be added for a GCMS run time due to the fact that the physical presence of the analyst is not required. Different sample classes can be implemented as one set of standards are not always possible, sample preparation time may increase for plant materials with low level analyte content such as *Catha edulis*, as the plant produces two stimulants namely cathine and cathinone, whereas multiple homogenous sample preparations may decrease analysis time. Using accumulated standard test times for all samples submitted over a long period and a reasonable discount factor for non-analytical time, the minimum possible staff level for the drug laboratory can be calculated. With the exclusion of turn around time the labour resource should be equal or exceed the demand over the same estimated period. Equation 4.3 can be used to determine minimum analyst level if the laboratory manager worked out standard test times for analytical functions performed in the laboratory.

Equation 4.3 Minimum analytical staff required without any overtime

$\text{FTE}_{\text{MIN}} = \sum_{1/\text{yr}} (\text{standard test time}) / \text{LUF} / \text{FTE}$
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Collins (1998).

With the above equation, laboratory managers should be able to determine the amount of samples per analyst for a specific period of time: One FTE can however be increased when overtime is allocated to analysts working in the laboratory. Equation 4.4 can be used to adjust the FTE with added overtime.

Equation 4.4 Minimum analytical staff required with overtime

$$\text{Minimum Staff} = \text{FTE}_{\text{MIN}} / (1 + N)$$

N is the maximum percent overtime that is deemed acceptable. Collins (1988).

National legislation might also prescribe the maximum allowed overtime for organisations. Laboratory managers may use this to their advantage where staff shortages are experienced to increase analytical time. Table 4.18 indicates the average amount of overtime per analyst per month in forensic drug laboratories globally.

Table 4.18 The average overtime worked per analyst per month

Overtime/Analyst per month	A - Laboratories indicating yes (%)	B - 95% CI ^a
1 to 10 hours	70.0 (<i>n</i> = 70)	59.3 - 80.7
11 to 20 hours	22.9 (<i>n</i> = 70)	13.1 - 32.7
20 to 50 hours	2.8 (<i>n</i> = 70)	0.0 - 6.5
50+ hours	1.4 (<i>n</i> = 70)	0.0 - 4.2

^a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

Table 4.18 indicates that 70% of participating laboratories work less than 10 hours of overtime per analyst every month. This is less than 3 hours per week. The high percentage of low overtime hours might be due to financial constraints experienced by those laboratories or a managerial decision to limit overtime hours considering employee morale and welfare.

The maximum overtime allowed in the South African Police Service is 39 hours per month, but the preferred amount over long periods of time considering employee morale and welfare is 20 hours. Historical data from the quality system indicated that those analysts working long overtime hours are the biggest contributors to corrective actions taken on analytical and administrative mistakes in casework. It is therefore advisable to limit long overtime hours to project months which do not exceed three months consecutively.

4.6.4 Staff level versus case output

With a known analytical demand, known case load increase and pre-determined overtime hours the laboratory manager would be able to use Equation 4.4 to determine minimum staff levels in the forensic drug laboratory. It is also good for laboratory managers to benchmark work performances in other laboratories performing the same analytical tasks. This enables laboratory managers to set performance standards for analytical staff members. Table 4.19 indicates the amount of drug related samples analysed per analyst per month in global drug laboratories according to the survey.

Table 4.19 The amount of drug related samples analysed per analyst per month

Samples/Analyst per month	A - Laboratories indicating yes (%)	B - 95% CI ^a
0 to 100 samples	35.7 (<i>n</i> = 70)	24.5 - 46.9
100-500 samples	57.1 (<i>n</i> = 70)	45.5 - 68.7
500 ⁺ samples	8.6 (<i>n</i> = 70)	2.0 - 15.2

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

From Table 4.19 it follows that more than half of the analysts process 100-500 samples per month, which equates to approximately 25 to 125 samples per week (given a four week average per month). The minority of analysts (less than approximately 10%) process more than this amount.

A number of factors should be considered when benchmarking forensic drug laboratories in terms of staff level versus case output e.g. the standard tests performed per sample before it is deemed positive or negative, automation of sample preparation and instrumentation and paper trails for record keeping and case record compilations. The forensic drug laboratory in South Africa previously processed 120 to 160 samples on average per analyst per month, but with the managerial change of the sampling scheme resulting in fewer samples to be analysed per case, more cases will be finalised monthly, resulting in lower sample throughput on the instrumentation. This is due to the high percentage of time spent on case record compilation and administration.

4.6.5 Human error

Another issue to consider as a laboratory manager when determining the staff level is human factors in analytical measurements. A study conducted by Hellier *et al.* in 2001 revealed a number of human factor issues contributing to the unreliability of analytical

measurements. A number of these issues are not controlled by quality systems and have a tremendous impact on productivity and service delivery.

The potential errors evaluated were sample collection (counting, weighing and sampling), cleaning and preparation of equipment, sample preparation, calibration of equipment (balances, pH meters and instruments) and result reporting. This means that human error can take place at any stage during analytical measurements. Laboratory managers should investigate and record potential sources of errors in analytical measurements. These sources of errors should also be taken into account when appointing new staff, as they should be suited to working in this specific environment.

Most drug analysis tasks require the mental ability of memory, thinking and concentration that can easily be influenced by high noise levels, laboratory layouts and continuous interruptions. Laboratories should be designed not to host more than four analysts at a specific time within a defined space. The defined space can either be a single laboratory with four analysts, or with larger laboratories, well separated sub-laboratories within the larger laboratory. Laboratory managers should consider laboratory space or time tables and good laboratory layout to prevent unnecessary human errors as well as lowered productivity caused by over-crowding. Table 4.20 indicates the number of analysts employed in forensic drug laboratories to perform casework.

Table 4.20 Number of analysts employed to perform casework

Number of analysts	A - Laboratories indicating yes (%)	B - 95% CI ^a
1 to 5 analysts	38.6 (<i>n</i> = 70)	27.2 - 50.0
6 to 10 analysts	24.3 (<i>n</i> = 70)	14.2 - 34.4
11 to 15 analysts	15.7 (<i>n</i> = 70)	7.2 - 24.2
16+ analysts	21.4 (<i>n</i> = 70)	11.8 - 31.0

^a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

From the table it is evident that 38.6% of global laboratories have small numbers of analysts performing drug analysis. The 21.4% of drug laboratories who employed more than sixteen analysts under one roof might be a challenge to manage. Productivity will always increase proportionally to staff increases up to a point where command and control and personal laboratory space is neglected.

The South African laboratories differ dramatically in size e.g. with one laboratory having six analysts, one with twelve analysts and the other two with more than thirty analysts each.

The smaller laboratory is continuously the more productive one of the four, due to enough space and good command and control, but it has a low level of analyst retention. The laboratory with the twelve analysts was only capacitated with ten new scientists recently and constantly requires mentorship and coaching from the more experienced laboratories. One of the two laboratories with more than thirty drug analysts lacks command and control due to almost all of the middle management personnel resigning over a period of two years, causing a mentorship gap between new appointees and senior management. The last of the four laboratories has enough experience and qualified staff, but struggles with optimal use of laboratory space. It is clear that laboratories with the same functionality has different strengths, weaknesses, opportunities and threats and laboratory managers should be able to do risk assessments covering all of these aspects in getting the best possible solutions to optimise productivity.

4.6.6 Case backlog

The last and most important issue to consider when determining staff levels is the constant backlog supply of cases. Investigating officers and courts apply constant pressure on laboratories to produce analytical reports within short periods of time. The minimum staff level must exceed the total labour demand from drug analyses requested over a period of time. Again, revising historical data will help the laboratory manager to estimate turn around times that can be negotiated with clients and the judiciary. The relationship between standard test times and estimated turn around times will guide the manager to identify the minimum staff level. The average turnaround times in global drug laboratories is listed in Table 4.21.

Table 4.21 The turn around time for an average drug related case in global drug laboratories

Number of days	A - Laboratories indicating yes (%)	B - 95% CI ^a
0 to 7 days	20.0 (<i>n</i> = 70)	10.6 - 29.4
7 to 14 days	15.7 (<i>n</i> = 70)	7.2 - 24.2
14 to 21 days	22.9 (<i>n</i> = 70)	13.1 - 32.7
21 ⁺ days	42.9 (<i>n</i> = 70)	31.3 - 54.5

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

With the significant increase of drug related cases globally, it is not surprising to see turn around times of more than twenty-one days in 42.9% of the global laboratories who participated in the survey. The more fortunate laboratories finalise cases within seven days which is an ideal for every drug laboratory. The impact of case load increases differs from

one laboratory to another and large increases over a short period of time will have a direct impact on turn around times in any laboratory. Such an impact was experienced at the Western Cape laboratory in the South Africa. Escalating figures on drug related seizures of between 40% and 50% were experienced over a three year period, with the same amount of staff and a slight addition of equipment. The management had set turn around times at 35 days while receiving 400 to 500 cases per month, suddenly had to readjust with case loads of 2,500 cases per month. Currently case-backlogs are in the thousands and the turn around times are determined on the basis of priority. Certain other laboratories in the study also reveal turn around times of between three and six months. The challenge however is to overcome the increases and bring turn around times back to a norm of 21 days, to ensure the right of every accused to a speedy trial.

4.6.7 Motivation of staff

Once a balance between minimum staff and labour demand is reached in the laboratory, laboratory managers are faced with the daunting task of keeping them motivated and retaining them. Similar to professionals in other industries, scientists in forensic drug laboratories want to experience growth in the work place. One of the best ways to keep staff motivated is by means of promotion and rewards (Nel, 2000). This creates a feeling that the analyst’s expertise is valued and the service rendered is appreciated. The levels of the amount of promotions in forensic drug laboratories are indicated in Table 4.22.

Table 4.22 The number of promotion levels in forensic drug laboratories

Number of promotion levels	A - Laboratories indicating yes (%)	B - 95% CI ^a
Three	42.9 (<i>n</i> = 70)	31.3 - 54.5
Four	4.3 (<i>n</i> = 70)	6.1 - 22.5
Five	7.1 (<i>n</i> = 70)	1.1 - 13.1
More than five	14.3 (<i>n</i> = 70)	6.1 - 22.5

^a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

Table 4.22 indicates that 42.9% of global laboratories only have three promotional levels. Given the life span of a staff member working in this specialised field of 30 to 40 years, it would mean one promotion every 10 to 13 years. Many variations of position descriptions exist in forensic drug laboratories, but only three working categories actually exist i.e. the analyst that works at the bench and performs the actual analysis, a supervisor and/or the laboratory director. Managers in forensic laboratories have motivated more levels over the years with different titles associated with the post level, but the three categories remain the

same. For bench workers titles such as Criminalist I, II or III or forensic scientist, senior forensic scientist and chief forensic scientist are often used. Regardless of the number of promotional levels analysts should be informed of each level and the responsibilities for each level in the form of a job description. In many laboratories, good scientists are pushed into management, a position they might not like or find difficult to adjust to and in which they do not perform well. Laboratories internationally only provide for promotions into management and oversee the abilities of top scientists to stay current in a laboratory specialised field.

4.6.8 Staff retention

Many forensic scientists in South Africa have resigned, due to the lack of promotional opportunities. Contrary to the belief that laboratories do not retain analytical staff, the results of the average analyst stay in global drug laboratories, as indicated in Table 4.23 would suggest otherwise.

Table 4.23 The average time analysts stay in forensic drug laboratories internationally

Number of years in laboratory	A - Laboratories indicating yes (%)	B - 95% CI ^a
0 to 2 years	4.5 (<i>n</i> = 70)	0.0 - 9.1
2 to 5 years	20.0 (<i>n</i> = 70)	10.6 - 29.4
5 to 10 years	24.3 (<i>n</i> = 70)	14.2 - 34.4
10 ⁺ years	48.6 (<i>n</i> = 70)	36.9 - 60.3

a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

In the group of laboratories that was surveyed, forensic drug analysts are satisfied with the work they perform, with almost 50% of laboratories retaining analysts for more than 10 years. One of the reasons given in the survey is that staff stays in the field due to the diversity of samples and the analytical exposure in the laboratory. Another reason is that the laboratory provides a safe and secure environment with little variation influencing the well-being of staff. The forensic drug laboratories in South Africa have lost most of their scientists within a period of 2 to 5 years and senior management of the South African Police Service are currently busy improving remuneration packages to retain expertise.

4.6.9 Factors leading to increased productivity

In the survey, a list of factors that may increase productivity in forensic drug laboratories was listed. Due to the diversity of participants, the responses were not only one

dimensional and came from both managerial and analyst level. The study revealed the following feedback as presented in Table 4.24.

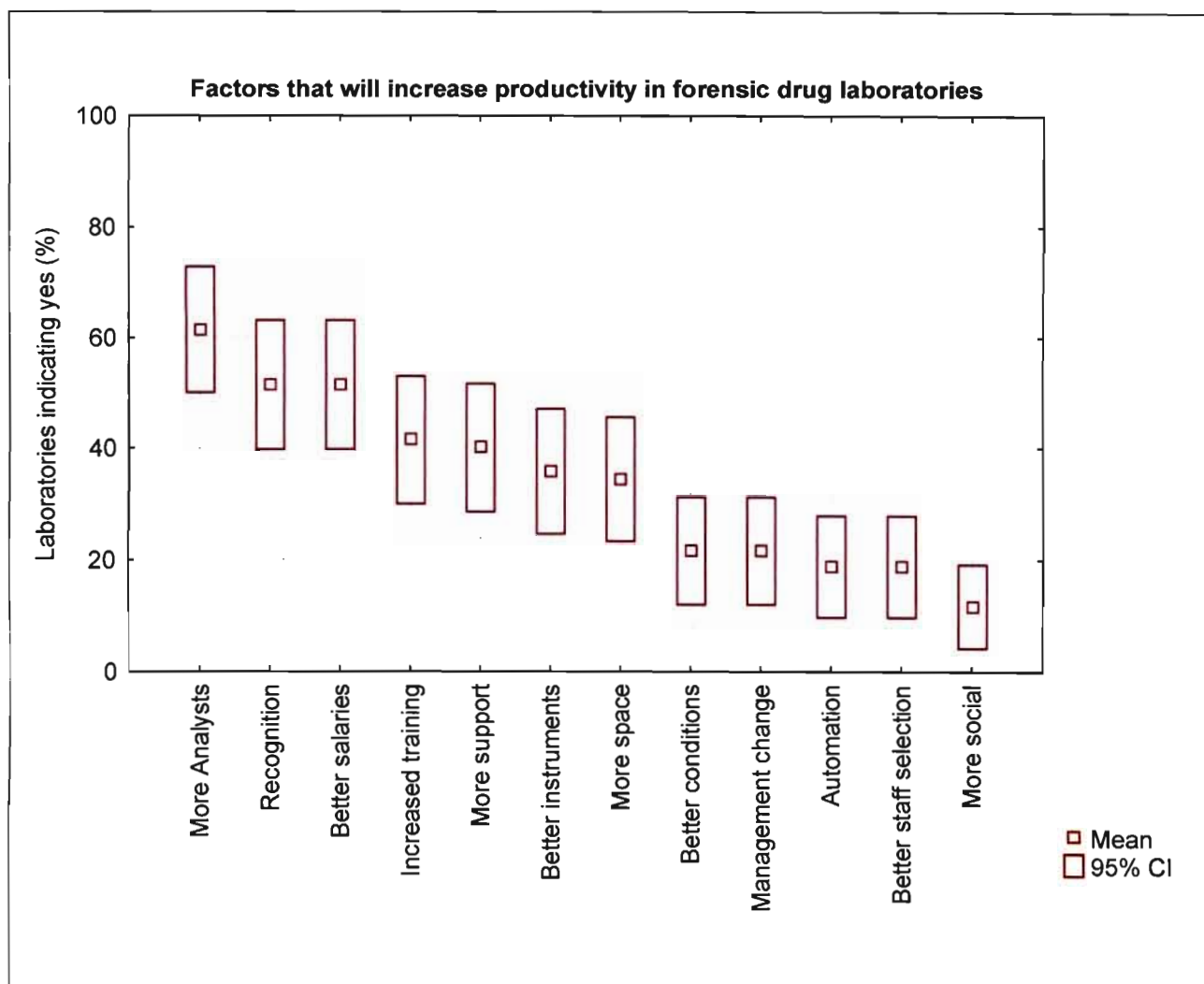
Table 4.24 Factors that will increase productivity in forensic drug laboratories

Factors that will increase productivity	A - Laboratories indicating yes (%)	B - 95% CI ^a
More analysts	61.4 (<i>n</i> = 70)	50.0 - 72.8
Recognition for the work performed	51.4 (<i>n</i> = 70)	39.7 - 63.1
Better salaries	51.4 (<i>n</i> = 70)	39.7 - 63.1
Increased training	41.4 (<i>n</i> = 70)	29.9 - 52.9
More support/administration personnel	40.0 (<i>n</i> = 70)	28.5 - 51.5
More and better instrumentation	35.7 (<i>n</i> = 70)	24.5 - 46.9
More laboratory space	34.3 (<i>n</i> = 70)	23.2 - 45.4
Better working conditions	21.4 (<i>n</i> = 70)	11.8 - 31.0
A change in management	21.4 (<i>n</i> = 70)	11.8 - 31.0
Automation of equipment/instrumentation	18.6 (<i>n</i> = 70)	9.5 - 27.7
Better appointment of new people	18.6 (<i>n</i> = 70)	9.5 - 27.7
More social events at work	11.4 (<i>n</i> = 70)	3.9 - 18.9

^a = the percentages indicated in the last column are based on a 95% confidence interval. *n* = total number of laboratories who answered the specific question.

The factors that will increase productivity in forensic drug laboratories from Table 4.24 are graphically displayed in Graph 4.4. The graph illustrates plots of important factors that need attention to increase productivity in forensic drug laboratories.

According to the survey, it is evident that a shortage of scientific staff exists in international laboratories. Although staff members will not benefit directly from more analysts, it will decrease case backlogs and turn around times which in turn will decrease managerial pressure. The second and third highest factors are more related to direct benefits to the forensic staff members, with recognition for work performed and better salaries. This is an indication that the work forensic drug analysts perform is not as appreciative or rewarding as one would expect. It might be due to the fact that forensic drug laboratories are operated under government bodies and are therefore not seen as professional scientific services as compared to their counterparts in the private sector. Factors such as more training, more supporting staff, better instrumentation and more laboratory space are again not a direct benefit, but rather factors which will improve the work place conditions. This is an indication of dedicated staff that is looking for improvement in the workplace rather than for their own benefit. According to the survey, the majority of analysts are satisfied with the environment they are working in with only 21.4% of the respondents wanting better working conditions and 18.6% not being satisfied with the co-workers that are appointed.

Graph 4.4 Box plot of factors that will increase productivity in forensic drug laboratories

95% CI = 95% confidence interval.

Other factors that were also mentioned in the survey additional to Table 4.24 which influence productivity may be generic enough to be applicable to many laboratories and include:

- Lack of discipline at work
- Rotation to other chemistry disciplines
- Appointment of people with egos and attitude
- Expertise and interests are ignored
- Legislation changed to analyse only one sample in smaller cases
- Lack of supervision
- Diversity of secondary functions
- Hire analysts to perform administration functions
- Lack of communication
- Unmotivated managers

4.6.10 Summary of productivity in forensic drug laboratories

The majority of global forensic drug laboratories have less than 10 forensic analysts and analyse 100 to 500 samples per month. Smaller laboratories have fewer issues that influence productivity. Depending on the analytical tasks to be performed and sufficient resources, a full time drug analyst should be able to perform not less than 120 to 160 sample analyses per month which includes a preliminary test and confirmatory test. This is based on an optimisation of 65% work bench time versus a 35% non-analytical time, calculated on a 40 hour work week. Laboratory managers should motivate more staff members based on FTE indicators as well as through analytical demand and benchmarking surveys. Command and control by supervisors is however important and performance progress should be discussed once or twice a year (SAPS, performance enhancement process, 2006). During these sessions performance enhancement should be discussed and recognition for performers should be given. Performance measurements should also be used in tracking progress against organisational goals and identifying opportunities for improvement (St Clair, 2003). An acceptable turn around time for a routine drug case should be less than 21 days from entering the laboratory. Productivity enhancement should be a philosophy in the work place and every staff member should contribute to total quality management in achieving quality and productivity excellence.

CHAPTER FIVE

Conclusion

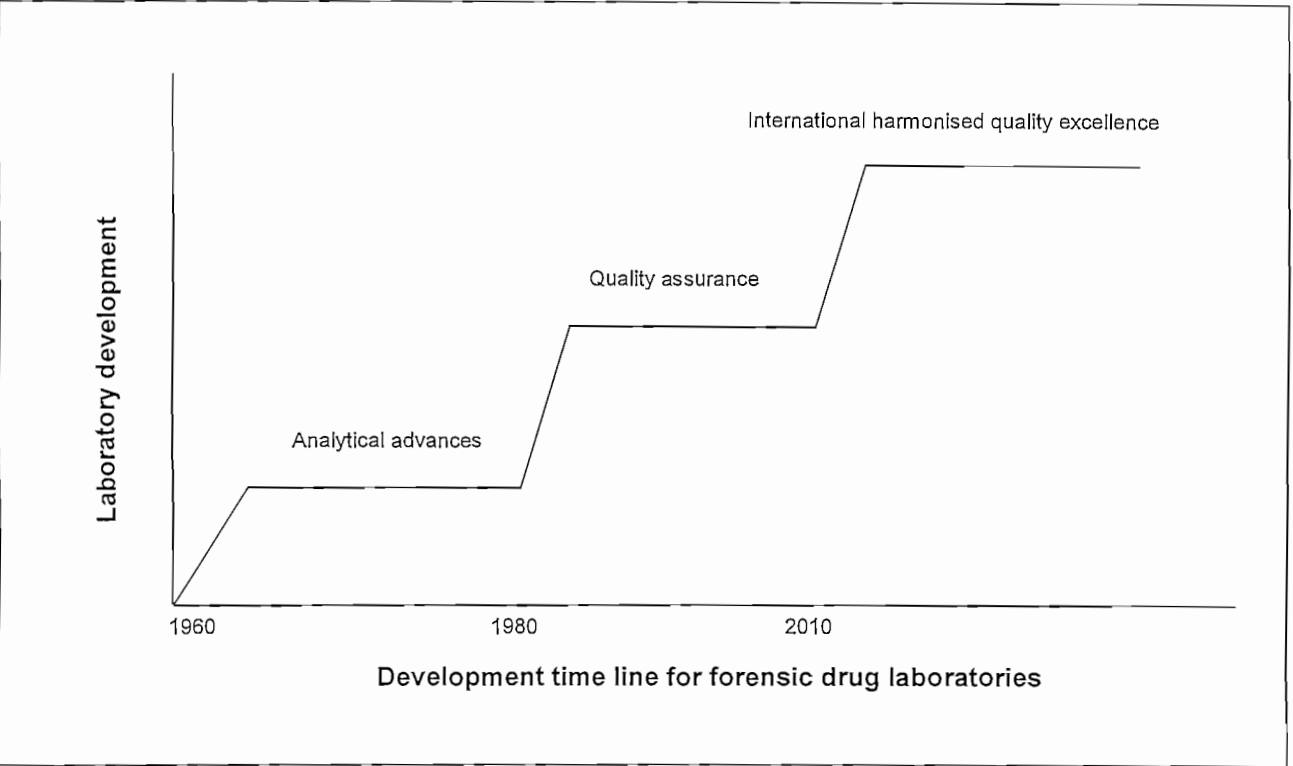
Forensic drug chemistry is only one discipline in forensic sciences with a variety of methods and practices used in both the public and private arenas globally. Over the last three decades, forensic drug laboratories had to overcome a number of challenges. Today, over half of the evidence submitted to forensic science laboratories for evaluation is drug related. The forensic science laboratories in South Africa had to analyse almost 10,000 controlled substance-related cases in the mid-1990, the amount tripled nationally to more than 30,000 cases in 2008. To counteract the tremendous increases, the management of the forensic science laboratory had to appoint more scientists and invest in sophisticated analytical instrumentation to ensure compliance to the National Constitution i.e. the accused had the right to a speedy and fair trial. In this context, forensic drug laboratories have to make an essential contribution to the criminal justice system, keeping three variables in mind, namely rapid results (low case turn around times within the laboratory), cost and fair results (results that are reliable and methods that are fit for purpose). The latter was the focus in the current study.

Over the years managers in forensic drug laboratories have experienced a number of challenges and they will continue to be challenged with new concepts and management strategies. Past, current and future challenges are illustrated in Figure 5.1.

Prior to 1980, the emphasis of forensic drug laboratory development was on methodology and instrumentation development. The laboratory switched from time-consuming “wet” methods of analysis to methods with a higher level of discrimination that are able to produce more accurate and reliable results, faster. These methods included instrumentation connected to stand alone microcomputers which enabled the scientist to gather, store and retrieve analytical data. These accomplishments, published data and reliable results placed a burden of responsibility on forensic scientists when testifying in a court of law. More attention had to be paid to quality assurance and quality control. From the early 1980’s the evolution of quality systems in forensic science started (See Flow chart 2.1 in Chapter 2). It is now almost three decades later and a number of quality

management systems have evolved globally, that has forensic specific standards. These standards are only as good as the implementation and maintenance thereof.

Figure 5.1 Past, current and future challenges with which managers in forensic drug laboratories are faced.



Many independent academics and private forensic scientists accused state owned forensic laboratories of managing a monopoly. Their major complaints were that the state owned forensic laboratories were operating with a poor quality control program, that there was lack of information sharing, the lack of scientific knowledge and the lack of proper science being implemented in the analysis of crime scene evidence (Koppl R., 2005). According to Koppl the error rate of forensic scientists are high and these mistakes are buried within the agency or even rewarded for manipulating expert evidence. More and more similar accusations have been made over the years, requiring government authorities to investigate the overall situation of forensic science services in their respective nations. More attention has been focussed on forensic science due to an increase in fictionalised accounts in television programmes such as CSI Las Vegas, CSI Miami and CSI New York, which illustrate close relationships between forensic science laboratories and the police in the investigation of crime. Furthermore these accounts are not always based in scientific fact, a point which is often lost on the general public. The communities do not discern a difference between the fictionalised television programs and real-life and want the same type of forensic excellence in their regions. In March 2003, the National Audit Office (NAO)

published a report on "Improving Service Delivery, The Forensic Science Service" in the United Kingdom and in February 2009 the National Academy of Sciences (NAS) published a report on "Strengthening Forensic Science in the United States: A path forward". It is however difficult to exclude certain disciplines from others in these reports and all the forensic disciplines, regardless of the forensic work performed or the accomplishments reached, all disciplines will be scrutinised under the same magnifying glass.

Although the forensic profession has many societies that serve the enterprise, most of them are not regulatory authorities and therefore they only contribute to best quality practises in the field of forensic sciences rather than control such practices. Whether managers implement these requirements in their respective quality management systems, can only be determined through quality audits, inspections or bench marking exercises.

5.1 CURRENT SITUATION

In this study, certain quality variables were used to evaluate the current status of quality excellence in the field of forensic drugs, in the global context. Conclusions for these variables are discussed under the following five categories namely equipment, personnel, quality control and assurance, customer relations and productivity.

5.1.1 Evaluation of equipment

Forensic critics accuse forensic scientists of using techniques whereby the analytical data generated can be manipulated to suit a predicted outcome. Quality authorities such as ASCLD/LAB and ISO require analytical techniques that are fit for purpose. In Table 2.1 of Chapter 2, it is indicated that SWGDRUG categorises techniques according to their discrimination value, where a single hyphenated instrument analysis or a combination of "wet" analytical methods needs to be performed before a reliable positive result may be documented. In Table 4.1 of Chapter 4 the results of analytical techniques used in forensic drug laboratories are indicated, with 100% of the participants indicating satisfaction with the instrumentation available to them.

Having adequate instrumentation in the laboratory is however not enough; managers should pay more attention to procedures covering proper maintenance of instrumentation, evaluation of the lifespan of instrumentation and disposal of instruments not performing to standards anymore. Although 32.9% of participants did not have a proper documented procurement plan, laboratory managers should realise that a proper plan will enable them

to meet customer demands and will avoid long turn around times and minimise resource shortages. Between 13.1% and 32.7% of drug laboratory managers do not have a maintenance plan that will, when managed correctly, ensure minimum instrument downtimes and prolong instrument life span.

International quality systems do not require LIMS systems in forensic laboratories, but the results obtained through the study indicated the importance of automated equipment for the acquisition, processing, recording, reporting, storage or retrieval of data; with between 71.6% to 89.4% of forensic drug laboratories having a LIMS in place. More than half of the participating laboratories even have web based interaction with their customers, with automated e-mail, fax, export or SMS on completion of the laboratory report. Through this system they are able to save on turn around times and minimise paperwork. It is not possible in South Africa unless legislation changes, as printing reports and signing them in the presence of a commissioner of oath before submission to court are still necessary.

Equipment cannot function on its own and it requires skilled staff for optimal operation. Laboratory managers should therefore develop technical staff with an interest in instrument control and operations.

5.1.2 Evaluation of personnel

Forensic science laboratories are currently understaffed, due to the large increases of forensic evidence submitted for forensic analysis. Forensic drug chemists are not garnered overnight; it takes time to select them carefully from tertiary institutions with a three year natural sciences background and develop them into forensic drug experts. Laboratory managers in forensic drug laboratories included in this investigation all appointed technical staff qualified to perform analytical work within a scientific environment, with all laboratories appointing technical staff with a three year tertiary scientific based qualification, according to the survey. In all the forensic drug laboratories the proper appointment was followed with internal drug training programs. A concern is however that the majority of the newly appointed scientists coming from tertiary institutions lack problem-solving and analytical thinking skills. This might be due to curriculum changes which result in the neglecting of sound chemical principles. Besides internal training, laboratory managers make use of a variety of external sources to develop technical staff i.e. 31.3% to 54.5% of laboratories make use of the DEA training program and 8.3% to 25.9% of laboratories use private institutions.

The concerning part of all the training interventions is that only 30% of participating laboratories have a mentorship program developed to measure the output of trained personnel. Mentors are the link between management and new staff and the lack of such a system is a broken chain of staff skill development, because managers are unable to determine the competency of new technical staff. Continuous training is also taking place through the exposure to national and international seminars, with 95.7% of participating laboratories attending national seminars and 47.1% attending international seminars. More than 90% of laboratory managers allow more than 5 days per year contact training for staff development.

In a professional field such as forensic science this is still not enough and technical staff must stay abreast with technical changes and new drug trends. The problem currently is the lack of time and interest in reading published articles and journals, although 97.2% of laboratories completing the questionnaire were satisfied with the sources of information in their respective laboratories. Providing the necessary sources of information for continuous improvement of the laboratory's effectiveness is an ISO standard for laboratory managers to comply with.

5.1.3 Evaluation of quality assurance and quality control

For any kind of forensic evidence to play a significant role in court proceedings, the evidence must be admissible and reliable. When forensic evidence relies on analytical results, a number of quality control and quality assurance principles become important. It is therefore important to define quality control programs as a management tool to measure and manage the reliability of results submitted to courts. According to the survey, a majority of forensic drug laboratories have quality control programs covering record-keeping of standards and reagents, sampling strategies, method validation and verification, proficiency testing and controlled access control. The magnitude and detail of these programmes might differ from laboratory to laboratory and recommendations from one authority to another, but the outcomes should be the same i.e. to assure the quality of results. With the exception of a harmonised sampling scheme, more than 95% of participating laboratories are of the opinion that they comply with ISO17025 standards related to quality assurance.

All the participating laboratories had a defined quality assurance program captured in a quality managements system, but only 10% of the laboratories were accredited from a mandated expert body other than ASCLD/LAB. From the survey, 58.5% of forensic drug laboratories gained independent endorsement through ASCLD/LAB. Forensic critics accuse forensic quality control systems as being weak in the US and this is partly due to ACSLD/LAB as the major accreditation agency. According to them ASCLD/LAB is a professional group and not an independent organisation and therefore they are not always in the position to improve quality standards. ASCLD/LAB pays heed to the outcries of critics and are in a process of harmonising quality standards in its effort to move away from the ASCLD legacy standards to ASCLD international, a process where ISO standards are incorporated in future assessments. In Europe, more emphasis is placed on accreditation of forensic science laboratories according to ISO standards. The accreditation status is monitored through an existing European forensic science network, namely ENFSI. Forensic science laboratory accreditation in Australia is monitored through NAMAS and in the UK through UKAS. The SCC overlooks accreditation in Canada, although some of the laboratories are currently accredited through ASCLD. In South Africa, SANAS has been appointed in 2007 as the only accreditation body for endorsing government laboratories and the forensic science laboratories in South Africa are currently aligning its quality management systems for independent endorsement.

5.1.4 Evaluation of customer/client relationship

A quality management system can only be successful if both the organisational needs and customer needs are addressed within such a system. Currently customers in South Africa accept analytical approaches followed by forensic science laboratories when obtaining analytical results. According to the survey, 90.9% of forensic drug laboratories are state or government controlled. Both the laboratory and the customer are controlled under the same authority serving a specific community. Forensic critics do not agree on the current placement of forensic science laboratories and accuses governments of having a monopoly on the evidence they analyse. The placement allows for bias to favour the law enforcement officers working under the same authority rather than giving an independent opinion or result in the court. This is raising the question of who is the real client, the community or the investigating officer. According to ISO standards the investigating officer needs to be satisfied. The community has to rely on the ethical values of the scientist performing the analysis.

Quality results can only be generated from quality evidence being received from investigating officers. It is therefore important to train customers in the collection of quality evidence at crime scenes. From the laboratories participating in the survey, 82.9% provided training to their respective customers. The training ensures effective communication channels between the laboratory and the customer. The survey revealed that 98.6% of the laboratories know they have a good relationship with customers and 72.9% of laboratories measure customer satisfaction by means of client satisfaction surveys, annually.

5.1.5 Evaluation of productivity

The service that is delivered from the forensic science laboratory forms part of a chain of larger services within the criminal justice system. If laboratories fail to meet the demands of the investigating officer, it may have an adverse impact on the delivery of criminal justice, for example, if analytical results are delayed, courts will withdraw criminal charges against an accused. It is therefore important for laboratory managers to know the analytical demand as well as the resources on hand. The analytical demand can be determined through quality control measurement systems, for example, time determination of average case opening and documentation, sample preparation, analytical result generation, interpretation and case record compilation. Laboratory managers will be able to calculate analytical bench optimisation, because a majority of participating laboratories knew the number of samples received, case load increases, working hours per analyst and instrument capacity. In spite of all the information on hand, most laboratories still experience long turn around times, with 42.9% of participating laboratories having turn around times longer than 21 days. With sudden large case load increases the turn around times can rapidly grow to delays of months.

Added pressure from senior management on the case backlogs contribute to lowered motivation and productivity. Although current staff members do not benefit directly from more analysts, they believe it will decrease backlogs on cases which in return will decrease managerial pressure, with 61.4% of laboratories indicating more analysts will improve productivity. Other contributing factors that will increase productivity according to the survey are, recognition for the work performed, better salaries and increased training.

5.2 RECOMMENDATIONS

The results obtained through the questionnaire are indicative of the status of quality management in forensic drug laboratories globally. The majority of these laboratories have a well defined quality management program serving their respective communities. This is

an indication that forensic drug laboratories internationally have grown into the quality generation over the last three decades. Quality contributors to the discipline of forensic drug sciences have to be applauded for all their efforts on setting standards and publishing guidelines internationally. A number of organisations, working groups and committees produced enough guidelines and publications for any laboratory manager to achieve quality excellence. Regardless of all the standards and publications, there will always be some weaknesses which will be uncovered by forensic critics within laboratories. It is therefore important to establish these weaknesses or shortcomings before someone else discovers it, and then act upon it proactively. During the survey a number of shortcomings were detected which require attention within the forensic drug science community, nationally and internationally.

5.2.1 Recommendation 1: Acceptance of ISO17025:2005 as the accreditation standard

Forensic drug laboratories should accept ISO17025:2005 as the accreditation standard internationally. Management should be able to demonstrate its ability to produce reliable and quality assured results. This is only possible when proper measurement and assessment are conducted and compared to other laboratories doing the same business. ISO17025:2005 is currently the international standard of choice within the majority of testing and calibration laboratories. Terms and terminology used in this international standard can also be applied to forensic drug laboratories. Defence attorneys have access to the standards applied internationally and are currently using the information to establish shortcomings within forensic drug laboratories. This does not mean laboratory managers should ignore the requirements established by organisations such as ASCLD/LAB. The combination between these requirements will bring forensic drug laboratories closer to forensic excellence.

The primary advantage of gaining independent endorsement is the acceptance of responsibility by the laboratory management, demonstrating competence to perform specialised tasks within a laboratory environment. Accreditation will ensure regular assessments, picking up non conformances within the laboratory that might have been overseen. Accreditation bodies also provide additional support through technical advice, online resources, training courses and scientific papers published.

5.2.2 Recommendation 2: Empowerment of technical staff

Developmental paths within forensic drug laboratories should be established and annually funded. The path should make provision for managerial development as well as technical development. Not all scientists are or want to be managers and sometimes good scientists are, for the benefit of promotion, forced into a managerial position. Soon after this, the scientist often loses interest in the scientific field and performs poorly as a supervisor as well, therefore a two way career path system will favour both the organisation and the scientists.

According to the results indicated in Table 4.7 the majority of participating laboratories comply with an allocated amount of contact days of training per year, but without a proper developmental path technical staff attends courses that will not promote service delivery. For example the quality manager may attend an instrument maintenance course which is not optimal for the position or career path of the quality manager. Moreover, the training opportunity was lost in terms of the personnel for whom it would have made a significant difference, namely the maintenance staff. One of the advantages in the implementation of a well defined developmental path is giving new technical staff direction within the organisation. Mentors and managers will therefore be able to determine timelines through performance enhancement interviews for the development of new members. Flow chart 4.1 is a typical example of a developmental path to follow with new scientists within a forensic chemistry laboratory.

Mentorship programs should be implemented to ensure training outcomes have been reached and that a link exists between laboratory management and new technical staff. As highlighted in paragraph 4.1.8 the low percentage laboratories (30%) with formal mentorship programs indicate the need for the proper monitoring of new staff to establish scientific or managerial interest early and set direction to the development of the new scientist.

5.2.3 Recommendation 3: Certification of forensic drug analysts

To ensure a high level of expertise within the forensic drug laboratory it is recommended that scientists performing analytical work be certified by an independent entity. The certification should include written examinations, supervised practice, proficiency testing, recertification procedures, adherence to a code of ethics and effective disciplinary

procedures. Supervised practices are referring back to mentorship evaluations after training interventions, to establish competence within the new drug analyst. Proficiency testing should also be conducted by independent entities which are also accredited under ISO standards. Intervals for recertification should be established within the independent entity doing the certification and should consider technical and methodological changes over time. Effective disciplinary procedures should address non compliance to quality control programs and errors made during expert testimony. Reporting and acting on errors made within any laboratory is not a sign of weakness, but rather a well established quality management system reducing error rates. Only after certification should a scientist be allowed to work independently on case dockets or testify as an expert witness.

On the evaluation of personnel in paragraph 4.2 of the survey, many laboratories who participated indicated well developed technical staff. It is however fragmented and individual certification will merge all fragments into one assessment process. Certification of a scientist will provide self confidence to testify with some authority in a court. South Africa does not have any independent entity performing these evaluations for certification and should investigate entities such as the ABC in the US for guidelines in accomplishing the same.

5.2.4 Recommendation 4: Establishment of a research component

Every forensic drug laboratory should have access to a research and development component. As highlighted in paragraph 4.2.5 of the results obtained in the survey only 22.9% of forensic drug laboratories have research and capacity development and indicate the need for such facilities in the laboratory or access to such facility. With the access to such a facility, scientists performing routine analysis will be able to hand over to or engage in a research group solving the analytical problem. The facility can either be an entity outside the laboratory such as a university or within the organisation.

5.2.5 Recommendation 5: Promotion of forensic science profession

Due to the number of professional organisations, entities and working groups within one state or country, government institutions should establish one independent entity to overlook the forensic science profession within their respective states and/or countries. In the field of forensic drug sciences the entity focus should be on:

- a. Establishment and implementation of best practices used in forensic drug laboratories.
- b. Establishment of international standards for mandatory accreditation for the laboratories as well as certification of forensic scientists within the forensic drug discipline.
- c. Ensure efficient allocation of forensic budgets to promote development and research within all forensic disciplines.
- d. National standardisation of methodology and equipment distribution within forensic drug sections.
- e. Establishment of a national education standard for future forensic drug scientists.
- f. Develop training programs to improve the understanding of forensic drug sciences and methodologies within the criminal justice system.
- g. Continuous evaluation and assessment of newly adopted methodologies within the forensic drug community.
- h. Overview forensic drug laboratories and make recommendations to improve on service delivery, for example, turn around times, customer satisfaction surveys, compliance to international standards etc.

The forthcoming advantages from a strategic and well funded independent entity will be:

- a. National standardisation within the criminal justice system, with reliable analytical results.
- b. Prevention of wrongful prosecution.
- c. Higher ethical values within expert testimony.
- d. Improved understanding between state prosecutors, scientists and defence attorneys by avoiding unnecessary questions in courts.
- e. Standardised training of forensic drug chemists.

Currently, South Africa does not have a body that regulates the forensic science profession. Other science professions are registered with the South African Council for Natural Scientific Professions (SACNSP). In the US the National Academy of Sciences performed an overview on forensic science laboratories and in the UK the National Audit Office performed similar audits.

5.3 FUTURE PERSPECTIVE

The new generation laboratory manager will need to study all literature on quality management and quality requirements published internationally, summarise best practices from different laboratories and set new objectives. Through this assessment laboratory managers will be able to implement best practises and get rid of non-optimal practise. Internationally harmonised standards will enable laboratory managers to render services to their clients with reliability and credibility.

Good quality management systems alone are not enough in the twenty first century, laboratory managers are faced with large case load increases that leads to increased turn around times. Law enforcement agencies governing these laboratories do not act immediately on case load increases. They rely on managers and supervisors to deal with it, having personal and equipment on hand. When considering the factors leading to increased productivity it is evident that forensic drug laboratories are understaffed and enforcement agencies should evaluate case load increases quarterly and not over long intervals.

South Africa is a developing country with a lot of rural and under-developed infrastructure, which creates economical challenges for the government with regards to service delivery. With internet-based administration, functions can be co-ordinated in cities and larger town areas, while law enforcement officers situated in remote areas can capture and receive information via the World Wide Web. Through this process forensic results will reach the officers in remote areas as soon as the examination results are determined in the laboratory. The function will decrease travel time to and from cities by law enforcement officers and will allow for cost saving on service delivery. This would only be possible if the criminal procedure act, Act 51 of 1977 is amended, allowing reports to be submitted to court without any affirmation but rather counter signed by a second drug expert. Another solution is the establishment of smaller drug laboratories closer to remote areas to deal with all possession cases, leaving dealing cases and clandestine laboratories to the larger laboratories. The process will lower transport costs, facilitate easy access to a laboratory, reduce the turn around times and pave the way for time efficient trails. It would be possible to establish such laboratories within offices of the criminal record centres that are currently operating closer to communities.

It is imperative that similar research be performed on all disciplines within the forensic science environment. This holds not only for forensic science in South Africa but is equally true for forensic science laboratories internationally. It will enable forensic laboratory directors and managers to determine weaknesses and strengths to enable implementation of solutions to overcome current challenges they may experience within their own environment. Forensic disciplines will be able to learn from one another, as it is often the case that one discipline establishes harmonised standards, while other disciplines can also all benefit from the same standard.

Laboratory directors, managers and supervisors working in either the public or private sector have the responsibility to participate and promote national and international working groups in harmonising quality standards. Failing to comply with the concept of harmonised standards will lead to questionable work ethics within the forensic industry. Given the current challenges faced by South Africa, the forensic science laboratory should strive for excellence in order to fulfil its vision of becoming the world leader in forensic sciences, a process that starts with delivering consistent high quality services.

CHAPTER SIX

References List

References are listed in the following three categories:

- a. General References
- b. Electronic References
- c. International Standards and Guidelines

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APPENDIX A

Quality Questionnaire

1. The name of your laboratory: _____				
INDICATE IN THE BLOCKS PROVIDED				
2. Is your laboratory:		Yes	No	
2.1	owned by the State/Government			
2.2	a private laboratory			
2.3	stakeholders/shareholders			
3. Your laboratory analyse (only drug related):		Yes	No	
3.1	physical drug evidence			
3.2	biological specimen			
QUALITY SYSTEM				
4. Is your laboratory an accredited lab?				
4.1	By whom			
4.2	According to which ISO Standard			
5. Do you make use of a documented quality management system?		Yes		No
TECHNOLOGY / INSTRUMENTATION				
6. Does your laboratory make use of the following analytical techniques?		Yes	No	
6.1	GC/MS			
6.2	GC			
6.3	HPLC			
6.4	FTIR			
6.5	Raman			
6.6	Microcrystal techniques			
6.7	TLC			
6.8	Colour tests			
6.9	Other			
7. Does your lab have an instrument procurement management plan?				
Yes		No	Don't know	
8. Instruments are used longer than:		Yes	No	
8.1	1 year			
8.2	2-3 years			
8.3	3+ years			
8.4	until results fail standard			
8.5	determined by the number of runs			
9. Does your lab have a maintenance management system?				
Yes		No	Don't know	
10. Maintenance takes place through:		Yes	No	
10.1	self employed maintenance			
10.2	maintenance contracts			
10.3	supplier contracts			
10.4	Other:			
11. The instrumentation in your lab are:		Yes	No	
11.1	purchased			
11.2	leased			
11.3	outsource			
11.4	Other:			

12. In what way does disposal of instruments take place?	Yes	No
12.1 use old instruments for research project		
12.2 sell on Auctions / other labs		
12.3 use for parts in new instruments		
12.4 end up in storerooms		
12.5 Other:		
13. Instruments and equipment of your lab are adequate for the procedures used?	Yes	No
	Yes	No
14. Calibration intervals are determined and documented for each instrument and laboratory equipment.	Yes	No
	Yes	No
15. Documented calibration / verification programs of instrumentation used include the following:	Yes	No
15.1 nature of calibration		
15.2 maximum interval between calibration / verification based on the history of previous calibration / verification		
15.3 the acceptable performance criteria where appropriate		
16. All the significant measurement are traceable through certificates of calibration held by the laboratory to National standards of measurement, where applicable.	Yes	No
	Yes	No
17. The lab has a Laboratory Information Management System (LIMS)?	Yes	No
	Yes	No
18. The LIMS covers the following:	Yes	No
18.1 exhibit receipt		
18.2 exhibit handling		
18.3 exhibit storage		
18.4 instrument control		
18.5 bar coding of evidence		
18.6 connection to customers /		
18.7 Investigating officers		
19. All analysts have access to the Internet	Yes	No
	Yes	No
20. Management controls the Internet	Yes	No
	Yes	No
PERSONNEL		
21. Analysts are equipped to perform casework (signatures)through:	Yes	No
21.1 Bachelor's degree, College degree, 3 year qualification		
21.2 Only internal training programs		
21.3 Both 3 year qualification and internal training		
21.4 Other		
22. Training of new specialists in drug related cases take place as follows:	Yes	No
22.1 In-house training		
22.2 Trained by the DEA		
22.3 Trained by Private Institutions		
22.4 Other:		
23. Average total number of days spend on training per analyst per year:	Yes	No
23.1 1-5 days		
23.2 6-10 days		
23.3 10+ days		
24. Your lab has a research and development program.	Yes	No
	Yes	No
25. Your lab has a skills development program (continuous training)	Yes	No
	Yes	No
26. Analysts have adequate sources of information		

Yes		No		Don't know	
27. Analysts in your lab are exposed to conferences and seminars nationally					
Yes		No		Don't know	
28. Analysts are exposed to conferences and seminars internationally					
Yes		No		Don't know	
29. Your lab has mentorship programs to measure output of trained personnel					
Yes		No		Don't know	
STANDARDS AND REAGENTS					
30. Lot/Batch numbers of standards and critical reagents are recorded					
Yes		No		Don't know	
31. Critical reagents are routinely tested for their reliability					
Yes		No		Don't know	
SAMPLING					
32. Your lab receives:			Yes	No	
32.1	All physical drugs seized				
32.2	Representative sample of drugs seized				
33. What sampling scheme do you use in your lab?			Yes	No	
33.1	N				
33.2	10%				
33.3	10% N				
33.4	Hypo geometric distribution				
33.5	Other				
34. The sampling scheme your lab is using is suitable for the purpose					
Yes			No		
Why:					
35. You have scientific proof and/or literature on the sampling scheme that you use to proof its validity.					
Yes		No		Don't know	
PROFICIENCY TESTING					
36. Each analyst performs a proficiency test (external or internal) annually in each class of tests done in casework.					
Yes		No		Don't know	
37. The proficiency tests are:			Yes	No	
37.1	Internal tests				
37.2	External tests				
37.3	Both				
QUALITY ASSURANCE					
38. Quality control procedures are documented.					
Yes		No		Don't know	
39. You make use of documented validated methods in your lab.					
Yes		No		Don't know	
ACCESS CONTROL					
40. Your lab is secure with good access control					
Yes			No		
41. Keys and/or other access devices of security doors are limited to authorised personnel					
Yes			No		
CUSTOMER / CLIENT RELATIONSHIP					
42. Your customers are:			Yes	No	
42.1	Investigating Officers				
42.2	DEA Agents				
42.3	Detectives				
42.4	Specialised Units				
42.5	Private Investigators				
42.6	Other				
43. Your lab provides training to customers.					
Yes		No		Don't know	

44. There are a good relationship between analysts and customers			
Yes		No	Don't know
45. According to surveys do you know what your customers expects form you?			
Yes		No	Don't know
46. Your lab are thinking of expanding services to new markets and new customers			
Yes		No	Don't know
47. The revenue payer is a stakeholder of your lab.			
Yes		No	Don't know

PRODUCTIVITY

48. On average, how many drug related samples do your lab analyse per month?	Yes	No
48.1 0-100		
48.2 100-1000		
48.3 1000-3000		
48.4 3000 ⁺		
49. How many analysts are employed to perform casework?	Yes	No
49.1 1-5		
49.2 6-10		
49.3 11-15		
49.4 16 ⁺		
50. What is the average amount of drug related samples analysed per analyst per month.	Yes	No
50.1 0-100		
50.2 100-500		
50.3 500 ⁺		
51. What is the turn a round time for an average drug related case in your laboratory.	Yes	No
51.1 0-7 days		
51.2 7-14 days		
51.3 14-21 days		
51.4 21 ⁺ days		
52. Your caseload increase every year by:	Yes	No
52.1 0-10% per year		
52.2 10-20% per year		
52.3 No increase		
53. Your lab needs more analysts to perform casework		
Yes	No	
54. What are the average working hours per week per analyst?	Yes	No
54.1 1-20 hours		
54.2 21-40 hours		
54.3 41-70 hours		
54.4 70 ⁺ hours		
55. What is the average overtime worked per analyst per month (Crime scene attendance included)?	Yes	No
55.1 1-10 hours		
55.2 11-20 hours		
55.3 20-50 hours		
55.4 50 ⁺ hours		
56. How many levels of promotions do exist in your lab.	Yes	No
56.1 three		
56.2 four		
56.3 five		
56.4 more than five		
57. How long does the average analyst stay at your lab before changing to another lab?	Yes	No

57.1	0-2 years		
57.2	2-5 years		
57.3	5-10 years		
57.4	10+ years		
58. Your lab has career paths for the analysts.			
Yes		No	
59. How would you rate the productivity of the analysts			
poor		average	
		good	
60. Which of the following will increase productivity in your lab.		Yes	No
60.1	More analysts		
60.2	More support/admin personnel		
60.3	Better salaries		
60.4	Better working conditions		
60.5	Recognition for the work performed		
60.6	More and better instrumentation		
60.7	Automation of equipment/instrumentation		
60.8	More lab space		
60.9	A change in Management		
60.10	Better appointment of new people		
60.11	More social events at work		
60.12	Increased training		
61. What else will increase productivity in your laboratory?			
62. Is there anything else that you would like to know regarding other laboratories to compare it to your own lab concerning quality and productivity?			

Thank you for participating in this questionnaire.
Regards

CASPER VENTER