A South African perspective on prohibited substance testing in humans: A proposed regulatory framework

by

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The complexity of the "obvious solution" never cease to astonish me.

One of the lessons in life that I learn over and over again is to think and think, ... and to think again before arriving at the "obvious solution", ... to discover that it may not be the correct one.

Tim Laurens

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ABSTRACT

Substances have been used for medicinal, recreational, and enhancement purposes by numerous population groups since ancient times. This practice is as old as humankind itself with alcohol use in South Africa for instance dating back 70 000 years. Regulation of some substances has now become standard practice due to their harmful and deleterious effects, increasing the risk to the user and society, which includes the educational, workplace and sports environment. Regulation involves enlisting of substances and testing for these prohibited substances in humans to assess compliance. Such a program has to be ethically sound, legally correct and scientifically accurate.

Prohibited substance regulation and testing in humans can be seen as a biomedical intervention on an individual which may violate the right to privacy, dignity, autonomy and freedom to use substances for medicinal, recreational and enhancement purposes. The field is flawed with ethical dilemmas that can be solved by employing the principalism approach, which involves respect for autonomy, nonmaleficence, beneficence and justice. The obtainment of voluntary free informed consent, as a prerequisite for respect for autonomy is essential before a prohibited substance test on an individual is initiated.

The author suggests that ethical oversight be instituted by statute, at a standard equivalent to that of ethical clinical research which is aligned with the Nuremberg code. It was also suggested that the professionals involved in the administration of prohibited substance regulation and testing programs should be registered with a professional council to comply with minimum standards of education and professionalism.

International prohibited substance regulation and testing programmes related to the workplace as an example of foreign law (SAMHSA), and sports doping (WADA) as an example of international law, were studied and evaluated against the relevant provisions of the Constitution of the Republic of South Africa (CSA) and statutes such as the Occupational Health and Safety Act and the Protection of Personal Information Act. The relevant sections in the CSA revolved mainly around respect for privacy, dignity, autonomy, freedom and equality. It was found that the prohibited substance regulation and testing policy was essential in all settings to provide legal certainty for subjects and administrators. The constitutional right to just administrative action is of vital importance for these policies which have to function in a quasi-judicial environment, also based on the principle of “separation of powers”.

The legal implications of the recent legalisation of cannabis on the workplace and other safety-sensitive environments were assessed and it was concluded that organisations still had an obligation to regulate, and to test for the active constituent (Δ^9-tetrahydrocannabinol or THC) in their employees, due to its impairment potential that increases the risk to the health and safety of others. It was also suggested that the relevant legislation, such as the Occupational Health Act be changed to include threshold concentrations or cut-off concentrations in biofluids which mark the onset of impairment. A cut-off concentration of 2 ng/mL in blood was suggested for THC, and the use of oral fluid and urine as matrices for testing was discussed due to the invasiveness of blood sampling.

Current issues in South Africa is addressed from a forensic toxicology perspective. The use of the hypergeometric distribution, based on sampling without replacement was suggested as a means to obtain the minimum number of subjects to be selected from a group within a specified level of confidence. Observational and chemical strategies to identify drug users were reviewed. A strategy to evaluate drug screening devices was proposed and applied to typical devices currently on the market in South Africa.

CHAPTER 1:

INTRODUCTION TO PROHIBITED SUBSTANCE REGULATION AND TESTING IN HUMANS

1.1 INTRODUCTION AND BACKGROUND

1.1.1 Background

This work was initiated during a postgraduate MPhil programme on Medical Law and Ethics at the University of Pretoria. The author, who also has a forensic toxicology background, realised that the legal, ethical and scientific approaches related to prohibited substance testing in South Africa is not well understood and respected by administrators of prohibited substance regulation and testing programmes.

The general sensitivity and urge within the medical law and ethics environment to respect human rights such privacy, dignity and bodily integrity led to the realisation that a similar approach has to be followed when a regulatory framework for prohibited substance regulation and testing programmes is proposed. Although a prohibited substance test has the intent of monitoring compliance instead of a medical diagnostic aim, it is essential to recognise that it is still a biomedical intervention on a human, which requires an ethical and legal approach similar to that applied by the medical fraternity as far as respect for human rights is concerned.

Prohibited substance regulation and testing programmes in the Republic of South Africa are in most instances overseen by individuals who do not have the necessary legal, ethical and scientific backgrounds, which may result in the infringement of the human rights of the individuals or test subjects.

The unique contribution of this study lies in the multi-disciplinary approach striving to highlight the legal, ethical and scientific aspects of prohibited substance regulation and testing programmes, as well their "interconnectedness" in the South African context for the first time. The author suggests that a regulatory framework can only be fair and just if it is legally correct and ethically sound and informed by the principles of forensic toxicology and science.

1.1.2 Problem statement

The main aim of this study is to propose a regulatory framework for prohibited substance regulation and testing in humans, which complies with the Constitution of the Republic of

South Africa and other relevant legislation. This will be approached from ethical, professional, legal and scientific perspectives and by comparing the approaches followed internationally. Prohibited substance regulation and testing in humans in South Africa will also be assessed with the proposed regulatory framework in mind.

1.1.3 Origin of drug use by humans

Drugs are part of the evolution of life. Fungi and plants have developed the ability to synthesise chemical compounds to manipulate the behaviour of insects and higher animals to assist them with survival, which was achieved by either deterring the insects and animals from consuming the plant or by them assisting the plants in reproducing.[1] Animals, in turn, developed the ability not to be poisoned by the plant and sometimes even became addicted to the plant chemicals due to an overload of their neural systems, which is still evident in modern-day animals.[2]

Modern-day humans, who are also part of the animal kingdom, still use drugs that originate from plants for recreational, medicinal and enhancement reasons. We have also developed the scientific ability to modify these plant chemicals to suit our needs or to synthesise these compounds *de novo* in a laboratory. Being curious and having the ability to reason and remember, we have (and still are) developed ingenious ways to deliver the drugs to the brain more effectively on our journey to extract more pleasure and other advantages form drugs. We became aware of the fact that the dose plays a role in achieving the effect and also, that the "dose makes the poison" as was claimed by Paracelsus who is credited as the "father of Toxicology"[3] and one of his contributions relates to the following statement:

> "Alle Dinge sind Gift, und nichts ist ohne Gift, allein die Dosis macht dass ein Ding kein Gift ist"
>
> ***Paracelsus***

This means: "All things are poison, and nothing is without poison, the dosage alone makes it so a thing is not a poison."

The effect of drugs on the human brain is facilitated by a change in the neurotransmitter concentrations in the synapses between nerve endings in our brain. The function of

[1] D Nutt *Drugs without the Hot Air: Minimising the harms of legal and illegal drugs* (2012) 51UIT Cambridge.
[2] For example: Goats eating coffee beans, elephants indulging in fermented fruit containing alcohol (ethanol).
[3] 'Die dritte Defension wegen des Schreibens der neuen Rezepte' (1965) *Septem Defensiones* 1538. Werke Bd. 2, Darmstadt 510.

neurotransmitters is to regulate the brain by turning it "on/off" by increasing, for instance, glutamate and gamma-aminobutyric acid (GABA).[4] Examples of other neurotransmitters are endocannabinoids, serotonin, noradrenaline, dopamine, adenosine, and endorphins, each with its effect on the human brain.[5,6]

The chemical influence on the human brain is not the only reason why humans take drugs since there is also a "reward" in the fact that we choose to administer a drug. The way a drug is administered may even be part of our identity or social image; for instance, smoking of a specific type of tobacco product, drinking of certain alcoholic beverages and the use of selected marijuana formulations. People may experience peer pressure for refusing to take drugs, of which tobacco and alcohol are prime examples. Drugs are sometimes part of religious ceremonies like the use of cannabis by members of the Rastafarian religion,[7] or the use of alcohol by Christians in some of their religious ceremonies,[8] or the use of peyote cactus by the Native American Church.[9] The use of alcohol has become a trend amongst young people, and binge-drinking is practised to manifest themselves in their social groups.

Alcohol is also not only used as a self-medication for people to wind down and relax, but also for enjoying the company of others. In general, humans enjoy pleasurable experiences and have an urge to repeat these. Humans still consume drugs either for the sake of pleasure (recreational) or to relieve suffering (medicinal).

Humans also use drugs to enhance their performance, which includes not only physical ability but also enhanced cognitive ability, emotional stability, as well as for longevity. The use of enhancement drugs has come to the point where it is the order of the day to take a pill for nearly every aspect of our existence. A cosmetic bodybuilding culture has taken off in South Africa (and internationally) where a large number of people divert to these substances as a quick fix to a beautiful body.

Athletes take enhancement drugs to improve their performance, which may aid them in achieving success, resulting in big rewards and fame. The rewards and fame have the potential of skewing their ability to remain objective in their decision to (or not to) administer the drugs

[4] Glutamate turns the brain on by its effect on alertness, sensation and mood, while GABA turns the brain off with an effect of sleep, relaxation, anxiety.

[5] Nutt (n 1) 54.

[6] Endocannabinoids regulate pain, coordination, and appetite; Serotonin regulates mood, anxiety, mood, and sleep cycle; Noradrenaline increases alertness, attention, concentration, blood pressure and anxiety; Dopamine creates feelings of pleasure, attention, liking, and enjoyment; Endorphins create feelings of pleasure and reward.

[7] 'Rastafari religious movement' https://en.wikipedia.org/wiki/Rastafari (accessed 29 October 2017)

[8] 'Religion and alcohol' https://en.wikipedia.org/wiki/Religion_and_alcohol (accessed 29 October 2017)

[9] American Indian Religious Freedom Act, URL-25, 1996.

which may result in severe physical damage to the individual. In many instances, these athletes are regarded as role models for the younger generation who may also make use of these substances to become like the role model. Minors in schools also sometimes use performance-enhancement substances due to pressure on them by coaches to perform; especially in highly competitive sports requiring power and endurance.

1.1.4 History of human drug use

1.1.4.1 General

Human beings are programmed for pleasure and tend to repeat a pleasurable encounter which is perceived as healthy and in the interest of survival based on evolution. Drug taking can be regarded as a natural phenomenon and, historically, was used mostly in religious and cultural settings.

The use of plants for medicinal, recreational or religious purposes is entwined with mythology.[10] The medicinal, toxic and mind-altering properties of the plants were restricted to a few medicine men and magicians. Some of the active constituents have been converted into safe drugs still in use today.

Mind-altering plant use varied from mild stimulants (*Coffee Arabica*), khat (*Catha Edulis*), Kanna (*Mesembryanthemum tortuosum*), aphrodisiacs and euphoriants (Bluewater lily, *Nymphaea nouchali*), potent sedatives (wild yam or *Tabernanthe iboga*) and hallucinogens (poison bulb or *Boophone disticha*).[11]

Nutt provides typical examples of historical drugs that were used. [12] Some of these are:

- Ayahuasca, mushrooms, coca leaf, cacao and beer in South America
- Tobacco and peyote in North America
- Ibogaine in West-Africa
- Beer in South-Africa
- Beer and wine in North-Europe
- Coffee and Khat in the Middle-East
- Cannabis and Beatle nuts in South-Asia
- Fly agaric mushrooms in North-Asia

[10] The god of medicine and therapy was Asclepias, holding the characteristic snake, which is still used today as an emblem.
[11] M Wink & BE van Wyk *Mind-altering and poisonous plants of the world* (2008) 19 Briza Publications, Pretoria, South Africa.
[12] Nutt (n 1) 62.

- Opium in central Asia
- Tea and ephedra in West-Asia
- Rice wine in the Far-East.
- Kawa in the Pacific region

These formulations were sometimes viewed as food. Beer, for instance, was part of the diets in Europe because the water was not always safe to drink. As time went by, the compounds were spread over the world and it was adopted by other cultures.

The poppy plant had a peculiar influence on human history. The dried latex (or opium) from the unripe fruit contains morphinan alkaloids such as morphine and codeine, amongst others, and was used by the ancient Sumerians, 400BC, and also by the Egyptians, Persians, Africans and Grecians. Its medicinal, pain-killing and sedating effects were well known. Opium, in combination with tropane-containing plants like Erythroxylum Coca, was the most abundant narcotic during the Middle Ages.[13] Opium smoking was introduced in China in the 17th century where it became a problem as wars were initiated to keep the free trade of opium. The misuse of opium and its active constituents like heroin and morphine is still a problem today, even after being declared an illicit compound worldwide.

The use of the coca plant, with cocaine as the active constituent, also has an intriguing history. The properties of the coca plant have been known since ancient times. A Peruvian king was found buried with a few bags of coca leaves during 500 AD. The use of coca leaves was well established by the Incas during the 10th century to silence hunger and "uplift" one's spirit. It was part of religious ceremonies and was used by the priests to enter a transcendental state which enabled them to communicate with the gods.

The Spaniards brought coca to Europe after conquering the Incas. During the 1880s, Angelo Mariani invented "Vin Mariani" which contains extracts from coca and the aphrodisiac Damiana (*Turnera diffusa*). This wine was viewed as the "elixir of life" and officially approved by Pope Leo XIII.

Two similar products were sold in the USA; the first went by the name "Peruvian wine of Coca" and the other by "Coca-Cola". The latter originally contained extracts from

[13] Wink & Van Wyk (n 11) 21.

Erythroxylum coca and caffeine from *Cola nitida* and wine. The wine was later replaced by sugar syrup, and the cocaine extracts removed in 1904.[14,15]

The advances in chemistry since the 1800s enabled the isolation of the active ingredients of plants, which initiated a whole new era in the interaction of humans with drugs. The chemical structure of the pure compounds was unravelled, and new synthetic routes were discovered on how to make these compounds in a laboratory. The synthesis of designer drugs soon followed.[16] In the late 1800s, drugs were on sale in pharmacies, and medication contained cannabis, heroin and cocaine.[17] It was virtually a "free-for-all" scenario in terms of drug use and with no regulation. The purified drugs and their synthetic analogues became very potent and more harmful. Pharmaceutical companies generated enormous profits with many people at risk of becoming dependent or being overdosed. The effects of the purified drugs were vastly different from those consumed historically in the natural plant formulations. Humans furthermore found ingenious ways of delivering these compounds to the brain (intravenous injection, snorting, inhalation).

1.1.4.2 Drug use in South African society

The use of alcohol can be traced back to ancient times during which indigenous people used it as a part of social gatherings and rituals. Very few of the ancient drug use customs of Africa, with human cultures dating back more than 70 000 years, were documented. However, *Boophone* bulb scales were used to embalm the dead in the Khoisan culture and in rituals like the "trance dance" which was performed for healing and divination.

Alcohol was used as a currency in colonial times.[18] The "dop" system[19] was used to exercise undue influence over farmworkers by supplying them with a brew from a crude extract of grape skins which contained alcohol, as part of their remuneration. Alcohol use also has an extensive history in the South African mining industry.[20]

[14] Wink & Van Wyk (n 11) 23.
[15] Sugar is currently also viewed to be an addictive compound.
[16] Heroin is a synthetic analogue of morphine that occurs naturally in the opium poppy; Amphetamines can be regarded as the derivatives of ephedra occurring in ephedra plants; Mephedrone is a derivative of cathinone found in khat plants (Khata Edulis).
[17] L Grinspoon & JB Bakalar *Marihuana: The forbidden Medicine* (1997) New Haven, CT, Yale University Press,
[18] CDH Parry 'SA: Alcohol today' (2005) 100 *Addiction* at 426-429.
[19] The term "doping" originates from the word "dop".
[20] A Mager 'White liquor hits black livers: meanings of excessive liquor consumption in South Africa in the second half of the twentieth century' (2004) 59 *Social Science & Medicine* at 735-751.

Surveys indicate that approximately 50% of men and 20% of women in South Africa drink alcohol, establishing alcohol as an essential component of the South African economy.[21,22] According to Schneider et al.[23], alcohol use contributed 7.1% to all deaths and 7% to deaths and disability-adjusted life years (DALY). It ranked at the top for the overall attributable burden for interpersonal violence (39.0%), neuropsychiatric conditions (18.4%) and road-traffic injuries (14.3%). Interpersonal violence accounted for 42.8% of the injury DALYs attributable to alcohol in males and 25.9% in females. In terms of alcohol-attributable disability, alcohol use disorders ranked first (44.6%), interpersonal violence second (23.2%), and fetal alcohol syndrome (FAS) third (18.1%).

Drug use and abuse have been part of the South African society for many years and have become increasingly common.[24] The collapse of traditional family structures, in combination with pressures on individuals due to rapid modernisation and high unemployment, is a contributing factor to the increase in drug abuse.[25] South Africa is no different from any other country and being part of the global community makes it easier to import illegal drugs, increasing supply and therefore, also illicit drug use/abuse. The United Nations Office of Drugs and Crime (UNODC) claimed in 2011 that South Africa is one of the largest synthetic drug consumers and producers in Africa.[26]

There is a general lack of accurate national statistics on illicit drug use as well as on the misuse (inappropriate use) of over-the-counter medication in South Africa. The lack of accurate information may be due to the country's lack of infrastructure, amongst others. Some information does come from ad hoc, cross-sectional and intervention studies conducted in specific geographic locations.[27] There is consensus in the literature that illicit drug use is on the increase. Pick et al. found that alcohol and cannabis are the most prevalent of illicit drugs

[21] Department of Health, Medical Research Council, Macro International. *South African Demographic and Health Survey 1998*. Full report (2001) Pretoria: DOH.

[22] A Demers, R Room & C Bourgault. *Surveys of drinking patterns and problems in seven developing countries* (2001). Geneva: Department of Mental Health and Substance Dependence, World Health Organisation http://www.unicri.it/min.san.bollettino/dati/AlcBrochur.pdf (accessed 14 May 2007).

[23] M Schneider et al 'Estimating the burden of disease attributable to alcohol use in South Africa in 2000' (2007) 97 *South African Medical Journal* at 672.

[24] South African Community Epidemiology Network on Drug Use (SACENDU) http://www.mrc.ac.za/adarg/sacendu.htm (accessed 18 August 2017).

[25] United Nations Office of Drugs and Crime (UNODC), South Africa, Regional Office for Southern Africa, 2002.

[26] UNODC *World drug report* (2011) New York, United Nations. http://www.un.org/wdr (accessed 31 August 2017).

[27] BJ Meyers *Access to substance abuse treatment for historically underserved communities in the Cape Town metropole* (2007) Cape Town: Medical Research Council; http:/wwwsahealthinfo.org/admodule/accessreport (accessed 1 September 2017).

used for coping, socialisation and relaxation in the mining sector.[28] Pick et al. furthermore held that approximately 6-16% of the average worker might experience an alcohol-dependence problem, and 20% will have drug problems. The South African Community Epidemiology Network on Drug Use (SACENDU) estimated the percentage of workers referred for substance abuse treatment by their employers to be between 5% and 20%.[29]

Alcohol has a high rate of admissions into primary healthcare facilities, compared to other drugs, since alcohol is legal and freely available, contrary to cannabis, which was illegal in South Africa at the time. Admission figures may change after the decriminalisation of cannabis. It may also be that in order to prevent stigmatisation, individuals abusing other illegal drugs do not submit themselves for admission.[30,31] It is reasonable to expect that the legalisation of cannabis will impact on future drug use trends.

Misuse of over-the-counter medication for recreational purposes, of which codeine use is a prime example, is a cause for increasing concern in South Africa. The pattern of misuse of codeine varies between individuals who use it within the recommended dose, but have to use it regularly to avoid the withdrawal-associated headaches, as opposed to those who exceed the dosage regimen to become intoxicated.[32]

It is essential to consider the socio-economic background of a drug abuser in exercising his decision regarding drug abuse; however, other reasons also contribute to the individual's decision, such as religious, traditional, and experimental use.[33] The use of methamphetamine (TIK) is the most commonly used drug in the Cape Town region.[34] Parry held that socio-economic background influences the drug of choice.[35]

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[28] W Pick et al 'Prevalence of alcohol and cannabis use and reported knowledge, attitudes and practice regarding its relationship with health'(2003). Safety in the Mines Research Advisory Committee Project *Health* (1) at 712.

[29] SACENDU http://www.mrc.ac.za/adarg/sacendu.htm (accessed 18 August 2017).

[30] CDH Parry & BJ Myers 'Legalising medical use of cannabis in South Africa: Is the empirical evidence sufficient to support policy shifts in this direction?' (2014) 104 *South African Medical Journal* at 399-400 http://dx.doi.org/10.7196/SAMJ.8135.

[31] R Fellingham et al 'The 'war on drugs' has failed: Is decriminalisation of drug use a solution to the problem in South Africa?' (2012) 5 *The South African Journal of Bioethics and the Law* at 78-82. Also available at http://www.sajbl.org.za/index.php/sajbl/article/view/219/228 (accessed 31 August 2017).

[32] S Dada et al 'Codeine misuse and dependence in South Africa – learning from substance abuse treatment admissions' (2015) 105 *South African Medical Journal* at 776.

[33] The high rate of violent crime, gangsterism and drug abuse in the "Cape-flats" may be attributed to the socio-economic deprivation of these unfortunate individuals.

[34] C Parry et al 'Drug policy for methamphetamine use urgently needed' (2004) 94 *South African Medical Journal* (SAMJ) at 964-965.

[35] 'Substance abuse in South Africa: Country report focussing on young persons' Paper prepared for the regional consultation - Global Initiative on Primary Prevention of Substance Abuse Among Young People, Harare, February 1998. http://www.sahealthinfo.org/admodule/countryreport.pdf (accessed 31 August 2017).

It is clear that South Africa has a drug-abuse problem which places an enormous burden on the health, social development and economic sectors of the country. The country is ranked second highest for the prevalence of substance-abuse disorders amongst 14 other countries.[36]

There are several sectors in South Africa where people use drugs for various reasons. Examples are as follows:

Workplace: Drug use in the workplace mimics that of society in general. Alcohol is the most used and abused drug, and therefore policies should prohibit the use of alcohol on-site and prevent impaired employees from entering safety- and risk-sensitive areas. Other drugs also need to be covered by the policy since humankind will resort to the use of other drugs if these are not regulated. There are, however, no formal regulations in South Africa regarding prohibited substance testing in the workplace.

Mining industry: Beta-blockers obtained illegally are consumed by underground workers to lower their heart rate for fitness tests during annual medical examinations. The individual's heart rate has to be below a certain threshold while exercising to be allowed to work underground. Beta-blockers can only be obtained legally on prescription after a medical examination.[37,38]

Transport industry: Drivers on long-haul routes divert to stimulants to stay alert and awake. In addition to caffeine, it is common to find drivers taking drugs from the amphetamine group of compounds. This practice is illegal since an individual may not drive a vehicle under the influence of an intoxicating substance.[39]

Students sometimes resort to pharmaceuticals to enhance their cognitive ability.[40] These compounds are obtained legally as well as illegally. A trend has developed in South Africa by which students can obtain a legal prescription relatively easy from some doctors who are prepared to act unethically. Alcohol is the compound being used most by students, which sometimes results in severe intoxication due to binge drinking, with other negative consequences like poor academic performance, drug-facilitated sexual assault (commonly referred to as "date-rape") and confrontations with the authorities.

[36] DJ Stein et al 'Findings from the first South African Stress and Health Study' MRC Policy brief (2007).
[37] Medicines and Related Substances Control Act Schedules 101 of 1965.
[38] Medicines and related Substances Amendment Act 72 of 2008.
[39] National Road Traffic Act 93 of 1996.
[40] Methylphenidate is the active constituent of Ritalin™ and Concerta™.

Minors in schools, due to their exploratory nature, experiment with pharmaceuticals ranging from illicit compounds to legal over-the-counter medication and dietary supplements. The legal age for purchasing alcohol and tobacco is 18 years, but the substances are in many instances sold illegally to mature minors, which sometimes end up in misfortune with disastrous outcomes. One of the concerns currently in South Africa is the use of anabolic steroids by minors in schools to reach success in power-driven sports like rugby where larger body size is to the benefit of the player and the team. The fierce competition encouraged by coaches and parents, as well as peer pressure, sometimes directs these minors to engage in this dangerous practice.

1.1.4.3 Drug use and sport

Mottram provided a short history of drug use in sport.[41] Sports events were organised by the ancient Greek society, of which religion and culture were an integral part. The Roman Empire maintained this tradition until the mid-19th century, after which sport became a recreational activity. By the end of the 19th century, sport became more structured with the onset of game rules, clubs and institutions as a result of urbanisation and industrialisation. The number of spectators and participants increased during the 20th century, which resulted in commercial interests. After World War II, a multitude of drugs came on the market and athletes started to use these drugs to enhance their physical ability and performance.[42]

The ancient Olympic Games began in 776 BC which comprised running only, with the addition of other sports as time went by. Huge rewards and fame resulted from a win, and there is evidence that athletes resorted to cheating to obtain these prizes. [43]

By the end of the 19th century, industrial development had a positive influence on sport, with some types of sports becoming professional. Enhancement drugs were extracted from plants and animal sourcesand used in all sorts of formulations and cocktails. [44] It is widely accepted that the term "doping" originates from the word "dop" which was the word used for a beverage made from grape skins in South Africa and exported to the Netherlands in the 19th century. Drugs enhancement for cycle events already took place during this early time.

The first case of drug enhancement occurred during the Olympic Games in 1904, which involved a marathon runner taking alcohol and strychnine at the end stages of the race.

[41] D Mottram (ed) *Drugs in Sport* 5th ed (2011) 21 Routledge, Taylor and Frances, London.
[42] As above.
[43] As above.
[44] Such as caffeine from tea and coffee, strychnine from the seeds of *Strychnos nux vomica*, cocaine from the Coca plant, morphine from the opium poppy and alcohol from brewing practices.

Amphetamine came on the market in 1920 with no formal regulations in sport prohibiting the use of pharmaceuticals for enhancement purposes.[45] In 1928, the use of doping stimulants was banned by the International Amateur Athletic Federation without testing, which rendered the ban ineffective.[46] The non-medicinal use of amphetamine in the Second World War to delay fatigue in soldiers was copied in athletic circles to enhance performance.[47] Steroid use (testosterone) dates back to 1954 at a world Weightlifting Championship by the Soviet team,[48] with a similar incident by the American team in 1962 which used Dianabol.

During the 1960s, several new drug classes were developed which was experimented with extensively in sports and resulted in many deaths of athletes.[49] Doping tests were introduced in 1966 by both the international governing bodies of football (FIFA) and cycling (ICU). The first mandatory tests by the International Olympic Committee (IOC) started in 1968 with a corresponding list of prohibited substances.[50] State-controlled doping was performed in Germany in the late 1970s and research focused on the use of anabolic steroids by women.[51,52] Once a reliable method for anabolic steroid testing became available, the steroid class was added to the prohibited list in 1976. Blood doping also started during the 1970s and is still practised today. EPO use started during the 1990s.

The culture of taking pharmaceuticals to enhance performance encourages athletes to take legal supplements (until today), which mostly have a dietary function. These contain proteins, vitamins and other ergogenic supplements, leaving the door open for manufacturers to illegally spike their dietary formulations to improve the efficacy of their products.[53]

The World Anti-Doping Association (WADA) was established by the IOC in 1999 to standardise prohibited substance lists, doping rules and to coordinate research.

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[45] AJ George 'CNS stimulants' in DR Mottram (n 41).

[46] AD Fraser 'Doping control from a global and national perspective' (2004) 26 *Therapeutic Drug Monitoring* at 171-174.

[47] M Verroken 'Drug use and abuse in sport' (2005) in DR Mottram *Drugs in Sport* 4th ed (2005).

[48] JM Hoberman 'Faster, higher and stronger. A history of doping in sport' (1992) in JM Hoberman (ed) *Mortal engines: The science of performance and dehumanization of sport* Maxwell MacMillan Canada, Toronto. In Mottram (n 41) ch 2.

[49] George (n 45) ch 2.

[50] Fraser (n 46) 171-174.

[51] WW Franke & B Berendonk 'Hormonal doping and androgenisation of athletes: A secret program of the German Democratic government'(1997) 43 *Clinical Chemistry* at 1262-1279. In Mottram (n 41) ch 2.

[52] L Wang 'C&EN Talks with John W Huffman - Organic Chemist invented a compound in 1955 that is now the centre of a controversy brewing over synthetic marijuana (2010) *Chemical and Engineering News (C&EN)* at 43.

[53] H Geyer et al 'Analysis of non-hormonal nutritional supplements for anabolic-androgenic steroids – results of an international study' (2004) 25 *International Journal of Sports Medicine* at 124-129. In Mottram (n 41) ch 2.

1.1.5 Future of drug use in South African society

Taking drugs to enhance one's physical and mental performance no longer bears the negative stigma it has in the past. A culture of "lifestyle medicine" has emerged in a moral milieu where individuals feel it their right to enhance critical aspects of their existence to reach idealised goals. This trend does not only apply to pharmaceutical enhancements such as steroids and hormones, but also the rise of cosmetic surgery, diet aids, body-building devices, and sexual augmentation and anti-ageing remedies.

"Designer drugs" are developed on an ongoing basis. These are structural analogues of the original drug with the same (or sometimes more potent) pharmacological action. The illicit drug suppliers produce these in clandestine laboratories in a race against the sensitivity and robustness of current analytical detection techniques and claim them to be undetectable. These drugs are available over the internet from websites,[54] which decreases the possibility of prosecution.[55] Typical examples of these are analogues of Cannabinoids,[56] Opioids,[57] Amphetamines,[58] and Benzodiazepines.[59] See Figure 1:1 for an illustration of the formulations.[60] Advanced gene technology to design more effective drugs for medical conditions is employed to design new drugs that will enhance human performance more effectively.

Dietary supplements are of great concern since pharmaceutical companies and scientists in the field continuously explore new avenues of enhancing human performance. Plant and animal products are extracted and purified far beyond the concentrations that an average individual will consume as part of a regular diet. These products are registered as "dietary supplements", without making therapeutic claims, with the result that the formulation complies with South African legislation. It should be remembered that most drugs have a plant/animal origin. The concentrations of the particular pharmaceuticals (or the combinations of pharmaceuticals) in

[54] D Feyerick, 'Drugs sold as bath salts easy to buy' CNN, (http://edition.cnn.com/2011/US/02/16/us.bath.salts.methadrone/index.html) (accessed 19 June 2019).
[55] As above.
[56] AM Kemp 'Top ten facts you need to know about synthetic cannabinoids: Not so spice' (2016) 129(3) *American Journal of Medicine* at 240.
[57] N Qin et al. 'Application of a validated UHPLC-MS/MS method for 28 fentanyl-analogue and novel synthetic opiods in whole blood in authentic forensic cases' (2019) 1124 *Journal of Chromatography B: Analytical; Technologies in the Biomedical and Life Sciences* at 82.
[58] J Morland 'Toxicity of drug abuse-amphetamine designer drugs (ecstacy): mental effects and consequences of single dose use' (2000) 112-113, *Toxicology Letters* at 147.
[59] JB Zawilska 'An expanding world of new psychoactive substances-designer benzodiazepines' (2019) 73 *Neurotoxicology* at 8.
[60] D Feyerick, 'Drugs sold as bath salts easy to buy' CNN, (http://edition.cnn.com/2011/US/02/16/us.bath.salts.methadrone/index.html) (accessed 19 June 2019).

the natural formulation are vastly lower than those in the commercial dietary supplement (sometimes up to 10 times). These formulations influence the human endocrine system, which, amongst others, stimulates the synthesis of testosterone in the body. Even though there are no therapeutic claims on the labels of these products, the models and graphics on the label advertise "extreme muscle growth". It is the opinion of the author that the ancient wisdom by Paracelsus that: "The dose makes the poison", will proof to be right again and will have to be revisited soon.[61]

The use of cannabis and its many formulations is also a matter of severe concern. One exemplary aspect is the legitimate use of cannabis oil for medicinal purposes. With cannabis legalised for personal use in South Africa, interest in the medicinal use of cannabis oil has increased drastically by individuals as well as companies trying to pursue the commercial aspects thereof.[62] Many of these oil formulations contain THC which is not entirely removed during the extraction process, resulting in these formulations being used by unsuspecting individuals who are under the impression that all the THC has been removed.

Another aspect of concern is the fact that the concentration of Δ^9-tetrahydrocannabinol (Δ^9-THC) has been increased from 3% to 40% by the application of horticultural techniques. Because cannabis is a plant, it is viewed by some people as "natural". These plants with such high Δ^9-THC concentrations are certainly not natural because these were genetically modified to produce such high levels of the active constituent.

The new Medicines and Related Substances Amendment Act[63] will have an impact on the marketing and selling of these products.[64] The definition of medicine has been changed to: "(a) any substance or mixture of substances used or ***purporting*** to be suitable for use or manufactured or sold for use in…(ii)... ***modifying any somatic*** or psychic or organic function in humans…". This all-inclusive definition seems to cover dietary supplements which will then

[61] This means that a seemingly innocent substance can produce a harmful effect associated with its toxic properties only if it reaches a susceptible biological system within the body in a high enough concentration. Even water and oxygen can be toxic if too much is eaten, drunk, or absorbed. This finding provides also the basis for public health standards, which specify maximum acceptable concentrations of various contaminants in food, public drinking water, and the environment.
There is also not always a linear relationship between the dose and the response/effect. Relatively low doses of contaminants in water, food, and environment can have significant chronic effects if there is long-term exposure. Many pollutants, drugs, and natural substances adhere to this principle by causing different effects at different levels, which could, as a result, lead to health standards that are either too strong or too weak.

[62] F Grotenheim 'Review of therapeutic effects' (2008) in F Grotenheim (ed) *Cannabis and Cannabinoids* (Pharmacology, Toxicology and Therapeutic Potential), Taylor and Francis Group, London. In ch 2 at 123.

[63] Medicines and Related Substances Amendment Act 72 of 2008.

[64] N Kirby 'A new regulatory regime for medicines comes into force in SA' *Times Live* https://www.timeslive.co.za/news/2017-06-15-a-new-regulatory-br-regime-for-medicines-br-comes-into-force-in-sa/ (accessed 31 August 2017).

be regulated by the newly formed South African Health Products Regulatory Authority (SAHPRA) by enforcing product registration first before selling. The chemical analysis and characterisation of the formulations surely is a daunting task which requires that an enormous infrastructure and funding have to be made available by the government. Hopefully, the legislation will be in place soon since these formulations are currently sold on the market with virtually no testing by either the manufacturers or the traders.

Enhancement pharmaceuticals can be classified into physical, cognitive, emotional, and anti-ageing. Most attention, in terms of prohibited substance testing, is currently focused on the sports arena where the number of pharmaceuticals is growing by the day. Consuming drugs that enhance athletic performance, including various steroids like testosterone, erythropoietin (EPO), and human growth hormone (HGH), is common.

Figure 1:1: Photo of the designer drug formulations that can be purchased via the internet.

Taking of drugs such as tea, coffee, tobacco and coca to enhance performance was also part of older civilisations; however, the potency of the current drugs is much higher, and self-administration of these drugs can result in serious harm to the individual. EPO can increase the

red-blood-cell count to a level that is dangerous to the athlete. It has become a common phenomenon to hear and see how athletes are forced to retire from competitive sport in the race between regulatory bodies and manufacturers of illicit drugs. As a result, a realm of suspicion has entered the entire domain of competitive athletics, which forced our current civilisation to question the integrity of sports and also ponder the philosophical question of, "What is sport really about?" This question has no clear-cut answer, but it is clear that the use of pharmaceuticals to enhance physical ability had a tremendous impact on one of the most ancient practices of humankind.[65]

1.2 DEFINITION OF A DRUG OR PROHIBITED SUBSTANCE

There are many approaches to define a prohibited substance. The most prominent approach is to define a drug as an exogenous compound that can alter the biochemical systems in the body by interaction with biological targets. Interactions can take place in several target organ systems in the body and drugs can cross the blood-brain barrier and influence on the brain by changing the abundance of neurotransmitters in the brain, either by blocking neurotransmitter re-uptake or by mimicking neurotransmitter behaviour.[66] Drugs included in this category are usually those that are highly regulated by statute due to their potential effect on brain chemistry.

A prohibited substance can also be defined as a chemical compound/pharmaceutical of which the use is restricted by the law and which can be used to achieve a desired effect on the body by targeting specific organs/systems like the central nervous system. The effect sought by the individual may vary from a "high/low" to an enhancement of physical abilities. These compounds can be prohibited by law or by policies and regulations depending on the requirements of the specific setting, whether it be roadside, workplace, and school drug testing or testing to dope control.

The National Drug Master Plan (2013 - 2017) of South Africa defines a drug as follows:[67]

"A term of varied usage. In medicine, it refers to any substance with the potential to prevent or cure disease or enhance physical or mental well-being, and in pharmacology to any chemical agent that alters the biochemical or physiological processes of tissues or organisms. In common

[65] M Bess *Make way for superhumans* (2015) 15 Icon Books, London.

[66] For instance, ephedrine can increase the heartbeat rate; Amphetamines can give more energy and change mood and behaviour; Insulin can interact with the metabolic process involving the transfer of glucose across cells throughout the body.

[67] Department of Social development & Central Drug Authority Republic of South Africa *National Drug Master Plan 2013 – 2017* http://www.dsd.gov.za/index2.php?option=com_docman&task=doc_view&gid=414&Itemid=3 (accessed 10 December 2017).

usage, the term refers to psychoactive or dependence-producing substances and often, more specifically, to those that are illicit." (See also "dependence", "drug or substance of abuse", "illicit drug" and "psychoactive substances or drugs").

1.3 APPROACHES TO THE PROHIBITION OF SUBSTANCES

Before a substance is used in a medical setting, a risk/benefit analysis has to be performed and only if the benefits outweigh the risks of the drug can it be used.[68] The risk-benefit analysis is usually performed through the combined input from pharmaceutical companies, clinicians and regulatory bodies to minimise harm.[69]

In the case of recreational drug use, two entirely different approaches can be followed:

The *first approach* has to do with regulation of compounds that do not have any recognised medicinal purposes and have an element of harm to an individual or society (however, the medicinal value of some compounds is sometimes overlooked).[70] This is the approach mostly followed by governments and which is sometimes forced upon their citizens by them signing international agreements.[71] International treaties have been initiated which strive to divide the compounds for recreational and medicinal use legally.[72] This division seems to be quite blurry since a compound like cannabis, classified as illegal in many countries, and perceived by authorities as for recreational use only, also has well-known medicinal properties.[73]

Substance abuse has been a mainstay of humankind for millennia. The number of euphoric substances has grown and their distribution greatly enhanced due to the globalisation effect of the internet. The magnitude of the problem has intensified over the past decade due to enhanced internet access yielding information on the synthetic routes used to manufacture prohibited substances in clandestine laboratories.[74] The South African government has prohibited designer drugs as the analogues of the scheduled compounds.

[68] Nutt (n 1) 68.
[69] Prevention of and Treatment for Substance Abuse Act 70 of 2008 ch 2 sec 3(1)(b).
[70] JT O'Donnel 'Pharmacology of Marijuana' in *JM Tiftickjian (Ed) Medicolegal Aspects of Marijuana*, Colorado edition (2015) 9 Lawyers and Judges Company, Tuscon, Arizona.
[71] *Single convention on Narcotic Drugs*, UN, URL-22, 1961 (amended in 1972).
[72] As above.
[73] JT O'Donnel 'Pharmacology of Marijuana' in *JM Tiftickjian (Ed) Medicolegal Aspects of Marijuana*, Colorado edition (2015) 9 Lawyers and Judges Company, Tuscon, Arizona.
[74] UNODC https://www.unodc.org/ (accessed 18 August 2017).

The declaration of war on drugs by US President Nixon (1971) does not seem to have had the desired consequences.[75,76] Not only has misuse of drugs increased,[77] but other negative consequences also followed, like an increase in the number of prisoners,[78] and corruption of politicians, police and other institutions as a result of the enormous profit margins of the trade. Thousands of individuals were harmed and died in this war on drugs. In recognition of this, national drug policy reviews were initiated internationally and tended toward the legalisation of previously illicit compounds,[79] for example, in Portugal,[80] The Netherlands[81], the USA[82] as well as in South Africa. Parry and Meyers recommend that South Africa should start implementing an evidence-based drug policy and learn from the experience of other countries in their processes of drug decriminalisation.[83,84] This approach took into account the harm caused by the drug classes.[85,86,87] For instance, it was claimed that marijuana is less harmful than the two most often used legal drugs, [88] alcohol and tobacco, and may even have medical benefits.[89]

The *second approach* has to do with accepting the natural tendencies and freedom of choice (**autonomy**) of an individual and minimising harm in other ways within the setting where the drug is consumed. For instance, harm can be minimised effectively by education to create an entirely new culture regarding the use of drugs and a renewed social perception thereof (which includes alcohol). Increasing the price of alcoholic drinks and decreasing the price of non-alcoholic drinks also proved to be an effective deterrent.

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[75] JP de V van Niekerk 'The drug dilemmas' (2012) 30 *CME* editors comment.
[76] JP van Niekerk 'Medical Marijuana and beyond' (2014) 104 *South African Medical Journal* at 387.
[77] SACENDU http://www.mrc.ac.za/adarg/sacendu.htm (accessed 18 August 2017).
[78] International Centre for Prison Studies http://www.prisonstudies.org/highest-to-lowest (accessed 6 April 2014).
[79] *Report of the Global Commission on Drug Policy* (2011) http://www.globalcommissionondrugs.org (accessed 8 April 2014).
[80] CATO Institute. *Drug decriminalization in Portugal: Lessons for creating fair and successful drug policies* http://www.cato.org/publications/white-paper/drug-decriminalization-portugal-lessons-creating-fair-successful-drug-policies (accessed 10 April 2014).
[81] J-P Grund & J Breeksma *Coffee shops and compromise: Separated illicit drug markets in the Netherlands* http://www.opensocietyfoundations.org/about/programs/global-drug-policy-program (accessed 12 April 2014).
[82] Parry & Myers (n 30) 399-400.
[83] C Parry & B Myers 'Beyond the rhetoric: Towards a more effective and humane drug policy framework in South Africa' (2011) 101 *South African Medical Journal* 704-706.
[84] Parry & Myers (n 30) 399-400.
[85] D Nutt et al 'Development of a rational scale to assess the harm of drugs of potential misuse' (2007) 369 *The Lancet* 1047.
[86] Nutt (n 1).
[87] DJ Nutt, LA King & LD Phillips 'Drug harms in the UK: A multicriteria decision analysis' (2010) 376 *The Lancet* at 1558–1565.
[88] SACENDU http://www.mrc.ac.za/adarg/sacendu.htm (accessed 18 August 2017).
[89] L Degenhardt & W Hall 'Extent of illicit drug use and dependence, and their contribution to the global burden of disease' (2012) 379 *The Lancet* at 56.

The autonomy of an individual to exercise freedom of choice is of prime importance to the South African population, and it is worthwhile pondering this for a moment. Freedom of choice to use drugs for recreational purposes relates to autonomy enshrined in the CSA.[90] The limitation of rights clause should always be kept in mind as the other side of the proverbial the coin.[91] David Nutt[92] highlighted the following prime aspect that should be taken into account when the issue of freedom of choice is raised:

"… one is only free to exercise freedom of choice if the correct information is portrayed."

The tobacco and alcohol industry is a typical example of a case where the dangers of consumption are hidden behind extremely effective advertisements, portraying smoking and alcohol abuse as something highly sought after with suggestions of freedom and happiness. The consequences of smoking, like lung cancer and other illnesses, are never highlighted in the advertisements. Alcoholic drinks are also never advertised without making use of "alcohol stars". Freedom of choice needs to be respected by ensuring that the consumer does not have thwarted information. *An addict cannot make a free choice* since addiction impairs our ability and limits our capacity to make an informed decision.[93] The protection of freedom of choice should include action to avoid addiction.

The use of drugs is also not an isolated personal matter. It may influence someone else. The responsibility to safeguard the health and safety of others is not always respected by those who have a quest to exercise their freedom of choice related to drug-taking. This personal freedom may affect the safety of others on the roads, schools and other safety- and risk-sensitive environments, which applies directly to the use of alcohol and other drugs that impair our abilities. The ability to impair should also be borne in mind with the current effort by libertarian groups to have cannabis and other drugs legalised.

There are many more aspects to take into account when a drug is regulated. Nutt et al. identified 16 harm criteria, which can be divided into two categories, namely: "harm to others" and "harm to users". These were clustered under physical, psychological and social effects. An overall harm score (0-100) was assigned as indicated in

Table 1:1. The data was estimated and summarised by the author from an article by Nutt et al.[94]

[90] The Constitution of the Republic of South Africa (CSA) 1996 secs 12(1)(a) & 12(2)(b).
[91] As above sec 36.
[92] Nutt (n 1) 206.
[93] This aspect is also applicable for athletes since their free choice is also limited in their desire for success.
[94] Nutt et al (n 88) 1558-1565.

Table 1:1: Multiple harm criteria as summarised from Nutt et al. [95]

	Harm to users		Harm to others	Overall harm score
	Sum of dependence and drug specific impairment on mental functioning	**Total harm to users**		
Alcohol	5	24	48	72
Heroin	6	33	22	55
Crack cocaine	12	36	18	54
Methamphetamine	9	31	2	33
Cocaine	6	19	8	27
Tobacco	5	17	9	26
Amphetamine	5	19	4	23
Cannabis	3	11	9	20
GHB	5	17	2	19
Benzodiazepines	7	12	3	15
Ketamine	6	13	2	15
Methadone	4	11	3	14
Mephedrone	6	12	1	13
Butane	4	10	1	11
Khat	2	8	1	9
Anabolic steroids	2	8	2	10
Ecstasy	3	8	1	9
LSD	6	7	0	7
Buprenorphine	3	5	2	7
Mushrooms	5	6	0	6

[95] As above.

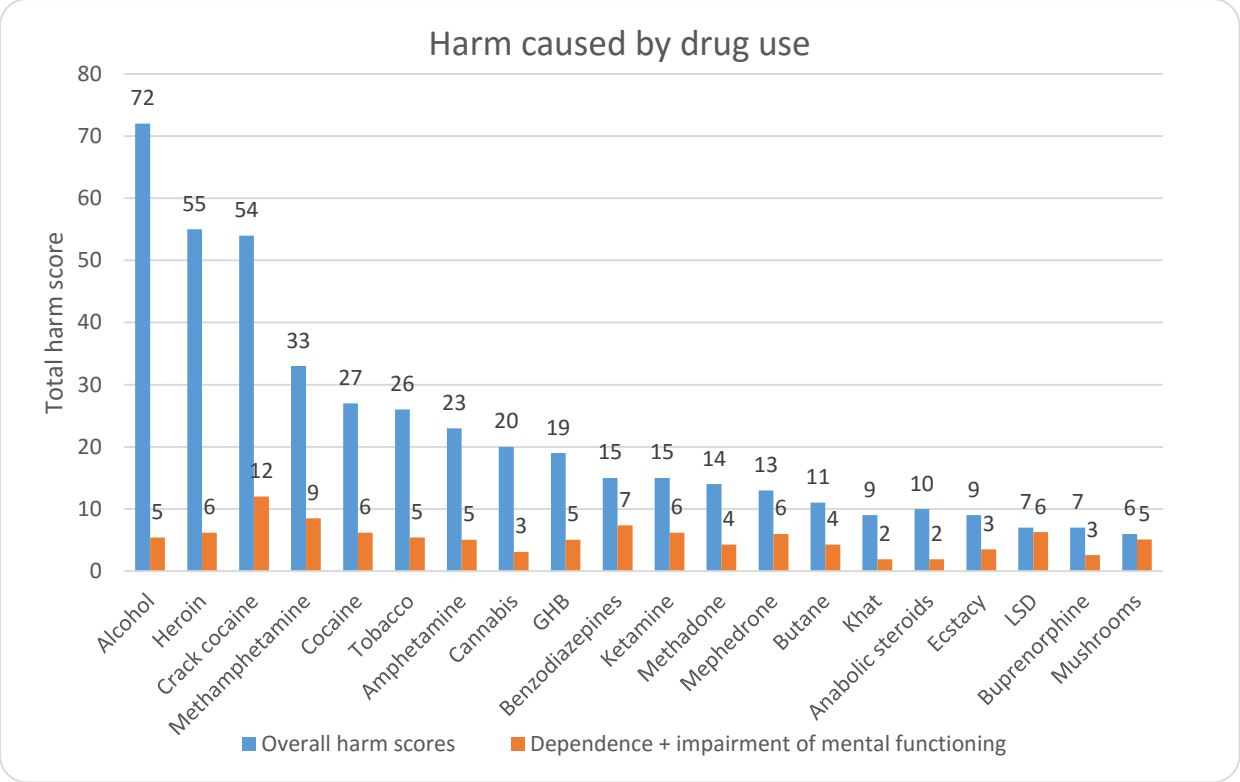

Figure 1:2: Harm caused by drug use

The data in Table 1:1 as summarised in Figure 1:2 graphically portrays the overall harm scores as well as a combination of two other harm criteria, namely drug-specific impairment on mental functioning and dependence. The combination of the two may provide some motivation for drug testing in a safety- and risk-sensitive environment.

Figure 1:2 illustrates that alcohol consumption has the highest overall harm, followed by heroin and crack cocaine. It is also important to note that the harm scores for cannabis are lower than those for alcohol and tobacco, with cannabis use illegal and the use of alcohol and tobacco legal. Benzodiazepines are not illegal substances in South Africa; however, it requires a legal prescription before purchase, making it not as freely available as alcohol and tobacco. This group of compounds has fairly high addiction potential.

The data on harm provided by Nutt did not take into account the availability and legal status of drugs, which will influence many of the harms. This model also did not distinguish between harms resulting from the use and those due to the control system, since control and policing of prohibited compounds also have a financial impact on society. The monetary benefits from tax offset the harm to some extent and were also not taken into account.

Tobacco is legal, but it has a score of zero for the drug-specific impairment on mental functioning category. However, its addiction potential is significant, with a score of 5.0

Cannabis, on the other hand, is illegal but have approximately equal contributions from the "drug-specific impairment on mental functioning" (1.5) and "dependence categories" (1.5).

The legalisation of cannabis will put this drug on equal footing with alcohol and tobacco in terms of availability, which may lead to an increase in use, which in turn can result in an increase of overall harm to society due to cannabis-related impairment, especially in safety-sensitive environments. This may also become critical to the prevention of drug use in schools by minors.[96]

1.4 LEGALISATION OF DRUGS

It would be impossible to tell in advance if the legalisation (decriminalisation) of drugs will result in less harm or more harm. The legalisation of a compound will increase its use by society since there will be no risk of prosecution, which may result in more harm. The prohibition of alcohol in the USA is a prime example of the outcome of the criminalisation of a drug. In the USA, the legal regulation of alcohol was abandoned in favour of total prohibition during the 1920s, only to be reintroduced 13 years later. The prohibition allowed the criminal syndicates to capitalise on the situation, and they made huge profits, the mafia became very powerful, and corruption amongst law enforcement officers and politicians soared.[97] In addition, contaminated alcohol products killed many people due to poor quality control by the illegal manufacturers.

The legalisation of drugs and the form the legalisation might take on are a current conversation, and the debates include ideas like:[98]

- The selling of drugs should be allowed on registered premises only (pharmacies).
- Personal possession should be decriminalised (with no intention of supply).
- Possession of drugs manufactured under government supply should be legal, but not from illicit sources.
- Supply to registered users via registered clinics should be legal.
- Legislation should be limited to certain drugs only.

[96] Parry & Myers (n 30) 399.
[97] J Hari *Chasing the scream: The first and last days of the war on drugs* (2015) London: Bloomsbury.
[98] S Wills *Drugs of abuse* (2005) Pharmaceutical Press, London ch 1 14.

1.4.1 Arguments in favour of legalisation

Wills raised the following arguments:[99]

- ***Freedom of choice and autonomy***: The choice of whether to use a drug belongs to the individual. It has been custom since prehistoric times for humans to self-medicate. The use of alcohol and tobacco are legal and used by free will, why not the same for other compounds also?
- ***Quality control***: The drug purity and also its possible toxic impurities can then be certified. The user will be able to estimate the risk connected to a specific dose. The drugs will also then be supplied in sterile containers preventing contamination with the human immunodeficiency (HI) and hepatitis B viruses.
- ***Reduction in crime rate***: Crime rate will decrease since the purchasing of drugs will be legal and available at affordable prices from registered suppliers.
- ***Reduced profits for criminal organisations***: The illegal drug trade industry is a multi-billion-dollar industry scrambling for the market within which numerous people are paying with their lives. The profits and power of these syndicates will be reduced since there will be no need for the clandestine supply anymore.
- ***Lower workload on the law enforcers***: Drug regulation and policing form a large part of the duties of police, customs, government prosecution lawyers and courts. Legalisation will decrease the pressure on resources in this area.
- ***The current laws have not affected drug abuse***: The war on drugs has failed in most democratic societies.[100] It is time to be more liberal in our approach since people will always use drugs, even if it is illegal.

1.4.2 Arguments against legalisation

Wills furthermore holds the following:[101]

- ***Impossible to predict the outcome***: It is complicated to predict the outcome of the legalisation of drugs since we have very little research to predict the possible adverse effects of drugs. Research in this area has been hampered due to a general refusal by ethics committees to perform research related to the effect of illicit compounds on the human body. Reversing the decision of legalisation will be impossible.

[99] Wills (n 98) 14-16.
[100] https://www.globalcommissionondrugs.org/reports/ (accessed 1 September 2017).
[101] Wills (n 98) 14-16.

- ***Increase in use***: Legalisation of drugs may, in general lead to an increase in use since it will be more available. Ethanol, the most misused drug, is a prime example of how a legal drug can be misused by society.
- ***Safety concerns due to adverse effects***: The current illegal drugs have never been subjected to clinical trials, which makes it impossible to predict the adverse effects. Little information is available on long-term toxicity and psychiatric effects. The adverse effects may also be extended to the rest of society due to accidents and other societal impacts. The effort to warn individuals against the use of other drugs will have to be much larger than the current effort made for alcohol and tobacco. This will also come with a tremendous financial implication.
- ***Loss of control***: Legalisation of more drugs may result in increased use, which may end in anarchy. The current system has at least some control that can be exerted by the government.
- ***The most vulnerable may be exposed***: The most vulnerable individuals may suffer disproportionately as a result of legalising new drugs. These may include individuals who are: minors, psychiatrically ill, in financial difficulty, poorly educated.
- ***The financial expense of regulation***: Non-regulation may have a more significant expense due to increased healthcare and quality control.
- ***Philosophy of life***: Humankind should not find happiness in general from a bottle or by taking tablets. There are more sustainable ways of finding happiness in real-life experience.

There is currently a big drive to re-think the criminalisation of cannabis in the South African community.[102] Calabrese holds that similar to life insurers, many financial, pharmaceutical and other businesses, drafters of public policy on substance regulation should use risk-analysis-based on realistic data in risk modelling to calculate the possibilities of risk, harm, benefits, and costs by gathering as much useful real-world data as possible. [103] The failure of regulatory agencies during the past few decades to gain insight into the uncertainties related to the risks has led to a **protectionist public health philosophy** in which conservative assumptions became the norm in the risk assessment process. This stance has resulted in increasingly stringent standards preventing the accurate estimation of the benefits and risks, often with extraordinarily high costs. Decoupling the potential risks from the financial cost differentiates

[102] Fellingham et al (n 31) (accessed 31 August 2017).

[103] JE Calabrese 'Hormesis: A revolution in toxicology, risk assessment and medicine, reframing the dose-response relationship' (2004) 5 *European Molecular Biology Organisation* (EMBO) **S**37.

the field of substance abuse risk assessment from the rest of the healthcare world, resulting in a continuous burden on public finances. There is also not much evidence of progress, despite numerous scientific studies by many professionals.

This dubious practise has a tremendous effect on the standards for prohibited substance regulation, the communication of risks to the public and the establishment of priorities related to substance abuse. It resulted in an intuitive decision-making process as opposed to a more scientific stance and is therefore more susceptible to political manipulation by interested parties. If only zero risks are acceptable to the public, then it is easy to call for the complete ban of a substance, which sometimes may have little associated risks, regardless of the costs or benefits.[104]

1.5 THE RATIONALE FOR DRUG AND ALCOHOL TESTING

The UNODC reported "An estimated 250 million people, ca 5% of the adult population aged 15-64 years, used drugs at least once in 2015. Globally, approximately 29.5 million people are estimated to suffer from drug-use disorders, which is harmful to the extent that they require treatment. Moreover, around 17 million "healthy" years of life lost (disability-adjusted life years or DALYs) were attributable to drug use disorders in 2015."[105] These statistics highlight the need for prohibited substance testing.

Drug and alcohol testing is usually performed where there is a risk of harm to a natural or juristic entity's interests. The nature of the interest may be related to the health and safety of an individual and others in his or her environment like co-workers or the public. It may also be related to the protection of an organisation's property, financial and public image. The need for drug and alcohol testing may also have a morally driven component. The rationale for drug testing in some sectors is discussed below:

1.5.1 Safety- and risk-sensitive environments like the workplace and public roads

The deleterious effects of drugs on human performance is well known because of their acute effects and impairment due to chronic use and withdrawal. Experimental studies, evaluating the psychomotor and cognitive functions of volunteers after the administration of a drug, are usually employed to obtain knowledge about the effects of drugs, alcohol included. Various

[104] Parry & Myers (n 30) 399-400.

[105] UNODC 'Global overview of drug demand and supply' *World Drug Report Booklet 2* (2017) http://www.unodc.org/wdr2017/field/Booklet_2_HEALTH.pdf (accessed 12 December 2017).

types of tests are conducted on the volunteers to provide information on the performance of the individual.[106,107,108] These tests typically involve attention, vigilance, auditory and visual ability, reaction time, cognitive tests, critical flicker fusion, visual-motor coordination, body sway, physiological measurements.[109] Drugs can affect human performance due to their primary effects, as well as their side effects, for instance, the hallucinogenic effect of LSD and cannabis, the sedative effect of heroin, and tremor as a side effect in amphetamine users. Verstraete et al. lay claim to the following effects of drugs on human performance:[110]

- Alcohol is a psychoactive (mind-altering) compound that depresses the central nervous system (CNS). It is very efficient in the reduction of short-term anxiety, but it affects the part of the brain that controls inhibitions, which manifests in drinkers being more talkative, having more self-confidence, becoming foolish, and a general loss of self-constraint. The effects of alcohol are dose-related and as a result, the brain's communication with nerves and muscles are suppressed, the higher the level of alcohol in the body becomes. Alcohol use results in slurred speech, staggering, and loss of emotional control. Alcohol may become extremely dangerous and use at higher levels can lead to stupor from which recovery is difficult, severe respiratory depression, coma, and possible death.[111] The dose-related effects of ethyl alcohol are the best understood of all drugs since its consumption is legal, which allowed for research in this area as opposed to other illegal drugs.

  The stages of alcohol impairment are summarised by Garriott as in table 1:2.[112]

[106] SD Ferrara, R Giorgetti R & S Zancaner 'Psychoactive substances and driving: State of the art and methodology' (1994) 10 *Alcohol Drugs Driving* at 1-55.

[107] RC Baselt *Drug effects on psychomotor performance* (2001) Foster City, CA, Biomedical Publications.

[108] A Irving & W Jones 'Methods for testing impairment of driving due to drugs' (1992) 43 *European Journal of Clinical Pharmacology* at 61-66.

[109] E Raes & A Verstraete 'Effects on human performance' in A Verstraete (ed) *Workplace drug testing* (2011) Pharmaceutical Press, London 35.

[110] As above.

[111] AW Jones 'Alcohol' in S Karch (ed) *Drug abuse handbook* (1998) CRC Press, Taylor and Frances Group ch 5 313.

[112] JC Gariott & JEM Monna 'Pharmacology and toxicology of ethyl alcohol' in JC Garriott (ed) *Gorriot's medicolegal aspects of alcohol* 5th ed (2009) 28 Lawyers and Judges Company, Tuscon, Arizona.

Table 1:2: The stages of alcohol impairment as summarised by Garriott

Blood-alcohol concentration (grams/100mL)	**Clinical signs and symptoms**
0.01 – 0.05	Subclinical: Slight euphoria and loss of inhibition
0.03 – 0.12	Euphoria: Mild euphoria, attention, judgement, control and some sensory impairment inhibited. Loss of performance in critical performance tests.
0.09 – 0.25	Excitement: Impairment of perception, memory, and comprehension, increased reaction time, reduced peripheral vision, sensory-motor incoordination, impaired balance and drowsiness.
0.18 – 0.3	Confusion: Disorientation, mental confusion, dizziness. Disturbances of vision and perception of colour, motion, and form. Increased muscle incoordination and unsteady gait.
0.25 – 0.4	Stupor: Unable to control movement by loss of motor functions, unstable while walking and standing, impaired consciousness, sleep or stupor.
0.35 – 0.4	Coma: Unconsciousness, coma and anaesthesia, subnormal temperature, impairment of cardio-respiratory function and possible death.
0.45+	Death due to respiratory dysfunction.

- Methamphetamine use has an inhibitory effect on signalling performance, reaction time, i.e. failure to stop at red traffic lights and increased reaction times.
- MDMA (Ecstasy) decreases attention, short- and long-term memory, verbal memory, visual-spatial skills and prediction of object movement under divided attention.[113] It also

[113] HV Curran & RA Travil 'Mood and cognitive effects of ±3,4-methylenedioxymethamphetamine (MDMA, 'ecstasy'): Week-end 'high' followed by mid-week low' (1997) 92 *Addiction* at 821-831.

timulates impulsive behaviour.[114,115,116,117] The duration of the primary acute effects was less than 24 hours.

- Cannabis, the most-used illicit drug next to alcohol, has dose-dependent effects involving impairment of cognitive and psychomotor functions (learning, equilibrium, coordination, tracking ability, memory, impulsivity and vigilance) and with the user unaware of the impairment, he or she can also only partially compensate for the impairment.[118,119,120] The effects also include changes in time-, sensory-, auditory-, and visual perception. The effects can last up to 24 hours. Chronic use has longer-term effects on individuals in occupations requiring high cognitive capacity, and heavy use may result in a decrease of neurocognitive performance even after abstinence for 28 days. Breitstadt and Kauert state that the use of cannabis can result in indecisiveness, misinterpretation of colour and acoustic signals. It was also proposed that insufficient psychomotor capacities might be dangerous when operating machines in the workplace.[121]
- Chronic cocaine consumption can influence work performance negatively by leading to cognitive defects, impaired psychomotor performance, impulsiveness and psychosis.[122,123]
- The concomitant use of alcohol complicates the prediction of the effects. Cocaine users sometimes co-administers alcohol to extend the duration of the effects, due to the formation of a coca-ethylene metabolite in the body with a longer half-life.[124]

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[114] FJ Couper & BK Logan *Drugs and human performance fact sheets* (2004) Report no. DOT HS 809 725, National Highway Traffic Safety Administration (NHTSA).

[115] AC Parrot & J Lasky 'Ecstacy (MDMA) effects upon mood and cognition: Before, during and after Saturday night dance' (1998) 139 *Psychopharmacology* at 261-268.

[116] CTJ Lamers et al 'Dissociable effects of a single dose of ecstasy (MDMA) on psychomotor skills and attentional performance' (2003) 17 *Journal of Psychopharmacology* at 379-387.

[117] RM Smith et al 'Apparent transient effects of recent 'ecstasy' use on cognitive performance and extrapyramidal signs in human subjects' (2006) 19 *Cognitive Behavioral Neurology* at 157-164.

[118] RV Fant et al 'Acute an residual effects of marijuana in humans' (1998) 60 *Pharmacology Biochemistry Behavior* at 777-784.

[119] CL Hart et al 'Effects of acute smoked marijuana on complex cognitive performance' (2001) 25 *Neuropsychopharmacology* at 757-765.

[120] SJ Heisman et al 'Acute residual effects of marijuana: Profiles of plasma THC levels, physiological, subjective and performance measures' (1990) 37 *Pharmacology Biochemistry Behavior* at 561-565.

[121] R Breitstadt & G Kauert G *Der mensch als risiko und sicherheitsreserve* (2004) Aachen, Germany, Shaker Verlag GmbH.

[122] AL Hoff et al 'Effects of crack cocaine on neurocognitive function' (1996) 60 *Psychiatry Research* at 167-176.

[123] DA Smelson & A Roy 'Neuropsychological deficits in withdrawn cocaine-dependent males**'** (1999) 25 *American Journal of Drug Alcohol Abuse* at p377-381.

[124] GJ Dumont et al 'Acute neurophysiological effects of MDMA and ethanol (co-)administration in healthy volunteers' (2008) 197 *Psychopharmacology* at 465-474.

- The hallucinogenic effects of LSD and its resulting perceptual distortions result in an individual not being able to perform any work during intoxication.[125] The recurrence of these states may take place for a period of up to five years after a single dose.[126]
- The acute effects of heroin depend on the dose and the route of administration. It was found that heroin use may result in decreased psychomotor performance[127] and increased reaction time, which may last up to six hours.[128]

The residual effects of drugs on an individual will impair his or her performance in the workplace since the acute and chronic effects may last longer than the timespan from the evening before until the next day when he or she reports for work. There is more than sufficient evidence to show that the decreased psychomotor and cognitive performance, which results from drug and alcohol impairment, leads to the conclusion that a person under the influence of drugs has an inhibited ability to perform safety- and risk-sensitive tasks. There is also abundant evidence that prolonged use of drugs and alcohol leads to ill health, which is detrimental to the user.[129]

1.5.2 Educational environments (schools and universities)

Drug use in schools and other educational institutions where the interests of minors and other young people need protection also requires drug prohibition and regulation. The use of drugs in South Africa is an ongoing problem affecting the broader school community and leading to absenteeism, academic failure and an increased dropout rate. According to the Department of Basic Education (DBE), drug testing should be performed to enhance the safety, and emotional and psychological well-being of learners: however, testing should be the last option for a learner who appears to have a drug or alcohol problem. Safety of the youth in schools (ca 12 million children) is of prime importance, and many of these children are subjected to poverty, abuse, and insufficient adult supervision. Identification of children who use drugs at an early stage enhances the probability of them being assisted effectively.

[125] AM Hartman & LE Hollister 'Effect of mescaline, lysergic acid diethyl amide and psilocybin on color perception' (1963) 65 *Psychopharmacology* at 441-451.
[126] HD Abraham & AM Aldridge 'Adverse consequences of lysergic-acid diethylamide' (1993) 88 *Addiction* at 1327-1334.
[127] EJ Cone et al 'Pharmacokinetics and pharmacodynamics of intranasal 'snorted' heroin' (1993) 17 *Journal of Analytical Toxicology* at 327-337.
[128] AJ Jenkins et al 'Pharmacokinetics and pharmacodynamics of smoked heroin' (1994) 18 *Journal of Analytical Toxicology* at 317-330.
[129] N Liu, DM Zhou, B Li, et al 'Gender related effects of heroin abuse on simple reaction time task' (2006) 31(1) *Addicton Behavior* at 187-190.

The use of drugs by learners is of concern. According to the DBE's guide to drug testing in South African Schools, more than 10% of all learners nationally have used dagga or heroine.[130] A similar percentage of grade 8 learners (ca 13 years of age) have used cocaine, and more than 33% of secondary school children knew others who had come to school drunk or under the influence of drugs. The DBE claims that the proportion of South African patients reporting to drug treatment centres, younger than 20 years, has increased to 25%.

The consequences of drug use/abuse for learners are as follows:

- Health problems typical of drug abuse are heart disease, cancer, and respiratory diseases.
- Poor academic performance, which increases the chances of them leaving school prematurely.
- Depression and other mental health disturbances.
- Increased risky behaviour that may lead to unprotected sex, unintended pregnancy and an increased risk of acquiring sexually transmitted infections, like HIV.
- Involvement in violence and crime.
- Higher risk of injury and involvement in traffic accidents, as either a driver or a pedestrian.
- Increased financial liability to governmental resources for treatment and medical care.

It is also suggested that a preventative approach should be followed by educating learners on the dangers of drug and alcohol abuse, and all South African Schools were declared drug-free zones.[131]

1.5.3 Sport environment

The sports arena is another setting where the use of drugs by individuals is highly regulated and controlled. Drug testing in the sports community is performed for two main reasons, namely to (1) protect individuals from the harm of drug use and (2) encourage fair play.[132]

Athletes for various reasons use drugs in sport, such as legitimate therapeutic use, sports injuries, recreational or social use and for performance enhancement. WADA tightly regulates the use of drugs with a strict liability on the athlete. Performance enhancement due to drug use involves deliberate, prohibited use of drugs to gain a competitive edge over fellow competitors.

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[130] Department of Basic Education *Guide to drug testing in South African Schools* https://www.education.gov.za/Portals/0/Documents/Publications/Drug%20Testing%20Guide_FINAL_PRINT.pdf?ver=2014-07-18-150102-000 (accessed 8 December 2017).

[131] Regulations for safety measures at public schools (2001) GG 22754 of 12 October 2001.

[132] World Anti-Doping Agency (WADA) https://www.wada-ama.org/ (accessed 20 February 2017).

This type of cheating is widely recognised as a severe threat to the integrity and credibility of competitive sport.

The number of adverse analytical findings of WADA prohibited substances between 2003 and 2008 has increased by 109% from 2634 to 5523 of which anabolic agents, which are at the top of the list, showed a 273% increase.[133]

Anabolic agents are mainly used by athletes to increase lean body mass, reduce fat and enhance performance. Administration of these compounds assists the athlete to sustain prolonged periods of intense training and enhance body appearance.[134] Testosterone is the anabolic agent most often used due to its androgenic and anabolic effects. Anabolic effects involve the enhancement of protein synthesis and muscle growth.[135,136] The side effects of anabolic steroids are typically related to the following:

- *Cardiovascular function*: By increasing blood volume, the effect on salt and water retention, hypertension, ventricular function, the effect on blood lipids and lipoproteins, blood clotting.
- *Carcinomas*: An association has been established between anabolic steroid administration and tumour formation (liver and kidney).[137,138]
- *Sex-related effects* on fertility, effects on libido, gynecomastia, specific actions in female athletes like the drastic increase in muscle mass and permanent masculinisation,[139] deepening of the voice, unwanted facial hair, menstrual problems and clitoral enlargement.[140] Loss of hair (boldness), testicular atrophy and reduced sperm production are also part of the side effects.
- Increased incidence of *tendon damage.* [141]

[133] Mottram (n 41) 375.
[134] F Hartgens & H Kuipers 'Effects of androgenic anabolic steroids in athletes' (2004) 34 *Sports Medicine* at 513-554.
[135] Mottram (n 41) 375.
[136] HM Perry, D Wright & BN Littlepage 'Dying to be big: A review of anabolic steroid use' (1992) 26 *British Journal of Sports Medicine* at 259-261.
[137] M. Pärssinen et al 'Increased premature mortality of competitive power lifters suspected to have used anabolic agents' (2000) 21 *International Journal of Sports Medicine* at 225-227.
[138] M Pärssinen & T Seppälä 'Steroid use and long-term health risks in former athletes' (2002) 32 *Sports Medicine* at 83-94.
[139] PYL Choi 'Illicit anabolic androgenic steroid use in women: A case of pseudo-hermaphroditism' (1998) 2 *Journal of Performance Enhancing Drugs* at 24-26.
[140] P Korkia, P Lenehan & J Mcveigh 'Medicinal use of androgens among women' (1996) 1 *Journal of Performance Enhancing Drugs* at 71-76.
[141] JT Laseter & JA Russel 'Anabolic steroid-induced tendon pathology: A review of the literature' (1991) 23 *Medicine and Science in Sports and Exercise* at 1-3.

- *Behavioural effects, such as increased aggression and violent behaviour*.[142]

See appendix 5 for a more extensive list of compounds enlisted by WADA. Mottram has provided an excellent overview of the physiological effects and side effects of performance enhancement drugs.[143]

1.5.4 Other environments where drug testing is performed

1.5.4.1 Horseracing industry

The horse racing industry in South Africa is an integral part of gambling activities in South Africa and falls under the National Gambling Board of South Africa (NGBSA).[144] The NGBSA fulfils an important function in ensuring that gambling activities are aligned with the provincial licensing authorities' requirements to ensure the protection and integrity of the sport. The National Horseracing Authority (NHRA), through the application of its rules and disciplinary processes, uphold and protect the integrity of the sport of thoroughbred horseracing and ensure the safety and welfare of both the *human* and *equine* participants.[145] A part of this function is the responsibility to screen and to be in a position to prosecute for numerous prohibited, forbidden and banned substances in compliance with international racing and quality requirements, policies and guidelines.

In addition to the screening for prohibited substances in the horses, the jockeys are also tested at random for prohibited substances.[146] The prohibited substances in this case are different compared to other sports where the emphasis is on mostly on human performance enhancement. Urine of riders are analysed by focussing on substances that may impair the judgment of the jockeys on the track, which may endanger both riders and horses. This type of prohibited substance regulation may be viewed as a type of "workplace prohibited" substance regulation programme with the emphasis on safety sensitivity.

[142] KB Kashin & HD Kleber 'Hooked on Hormone? An anabolic steroid addiction hypothesis' (1989) 262 *Journal of the American Medical Association* at 3166-3170.
[143] Mottram (n 41) 386.
[144] The National Gambling Board of South Africa http://www.ngb.org.za/organisational-areas/gambling-sectors/racing-and-betting.aspx (accessed 16 December 2017).
[145] The National Horse Racing Authority http://www.nhra.co.za/ (accessed 16 December 2017).
[146] National Horse Racing Authority of South Africa (NHRA) 'Rider banned substances guidelines' http://www.nhra.co.za/index.php/laboratory/rider-banned-substances/rider-banned-substances-guidelines (accessed 16 December 2017).

Banned substances for the riders fall into two broad categories, namely recreational drugs and therapeutic substances. Some of these substances may have similar effects to that of alcohol that may be detrimental to the judgment and performance of the rider.

1.5.4.2 Statutory or public environment for law enforcement purposes

There are two other scenarios where prohibited substance testing is called for in South Africa, namely in child custody court battles and in drug-facilitated sexual assault cases.

1.6 REGULATION AND TESTING FOR PROHIBITED SUBSTANCES

A prime example of prohibited substance regulation is in the USA's Federal Drug-Free Workplace drug testing programme overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA) and which is the custodian of the regulatory guidelines.[147,148] These guidelines intend to ensure legal certainty and testing at a forensically acceptable standard, with simultaneous protection privacy of the test subjects. The following requirements are recommended for a drug-free programme:

- a formal written policy which explains all the rules, protocols and list of prohibited substances
- employee education regarding the dangers of drug-use as well as supervisor training on the administration of their part of the programme
- an employee assistance programme (EAP)
- strategies for the identification of employees abusing drugs including analytical testing
- several types of tests may be performed for risk sensitive positions in the federal environment such as pre-employment, post-incident, reasonable suspicion, rehabilitation follow-up, random and voluntary drug testing.

The essentials of these guidelines, designed for prohibited substance regulation in the workplace, can be extracted and applied to the other settings where prohibited substances are regulated and tested. The starting point for the regulation of prohibited substances is an overarching written policy that communicates all the information required by individuals and administrators to ensure compliance:

[147] Mandatory guidelines for Federal Workplace Drug-Testing Programs FR 63(219) 63483-63484 1998-11-14 http://workplace.samhsa.gov (accessed 17 January 2017).

[148] Mandatory Guidelines and Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 69(71) 19644-19673 2004-04-13 http://workplace.samhsa.gov (accessed 17 January 2017).

- ***Policy***
  - should explain why regulation is required.[149,150]
  - should list the prohibited substances.
  - should explain the rules and delineate the detail of the whole illicit substance-free programme.
- ***Training and education*** on the dangers of drug use and administration of the programme.[151] (also minimum standards for professionals)
- ***Testing*****:** Identification of individuals abusing drugs, which may include drug testing by paying due respect to the individual and the accuracy of the testing procedure.
- ***Decisive action*** in the case of confirmed and validated non-compliance by an individual.
- ***Assistance*** to individuals who have an abuse problem.

1.7 ETHICS OF PROHIBITED SUBSTANCE REGULATION AND TESTING

The focus of this study is on ethical and scientific issues related to the legal framework within which a prohibited substance testing regime has to comply with the law. There are a few themes that recur when theories are discussed to categorise different schools of thought. A regulatory approach for prohibited substances may be based on the four standard principles of ethical decision-making employed in the medical field, as advocated by Beauchamp and Childress[152]. The four principles are (1) Respect for autonomy, (2) Beneficence, (3) Nonmaleficence and (4) Justice. [153]

- ***Respect for autonomy***: Encompass respect for the ability of an autonomous individual to make decisions on his behalf. This overlaps with the legal approach to autonomy in the CSA.
- ***Beneficence***: The regulator/administrator/professional needs to balance the risks and benefits to ensure that whatever is done is to the benefit of the individual and society.
- ***Nonmaleficence***: The regulator/administrator/professional must cause no harm to the individual/society. This has to do with minimisation of harm and also that harm must not be disproportionate.

[149] Explanation important for them to "consent" to the regulation, which, in private law domain, is covered by the law of contract and by statute in the statutory environment.
[150] Policy can either be a national policy or a private policy in the workplace.
[151] Training and communication should take place on a continuous basis.
[152] T Beauchamp & J Childress *Principles of biomedical ethics* 7th ed (2012) Oxford University Press, New York.
[153] As above.

- ***Justice***: Refers to fairness and equality. Everybody should be treated equally, and rules should be applied in a fair fashion across individuals in a specific setting.

Respect for autonomy will be highlighted throughout this work. Beneficence and nonmaleficence will also be encountered; for instance, in decisions regarding the prohibition and listing of compounds, for example, cannabis. Justice will be discussed in relation to aspects such as resource allocation for the regulation of prohibited substances and is particularly important when individuals have to deal with each other or have differing bargaining power. Subject-organisation relationships are by its very nature asymmetrical or skewed due to the position of power a regulator has. A regulator can be an entity like the management of a company, a government or a school body.

It becomes interesting when some of these principles are potentially in conflict with one another – where beneficence to society or a specific group may result in harm to others, or where consent is overruled in order to be just, for instance in a criminal setting.[154]

1.8 SECTORS WHERE TESTING FOR PROHIBITED SUBSTANCES TAKES PLACE

Drug and alcohol tests are conducted in public and private domains. The private domains where drug and alcohol testing is usually performed can involve both private and governmental organisations. A list of the various sectors and settings where drug testing is and should typically be performed is provided in Table 1:2.

- In terms of legal capacity, the sectors can be classified into two groups, namely those where the test subject has full capacity such as the workplace and sports testing[155] and those where the test subject may have diminished capacity such as schools and some medical environments (drug and alcohol rehabilitation centres [156] and psychiatric and mental institutions).[157]

[154] N Hoppe & J Miola *Medical law and medical ethics* (2014) 12-14 Cambridge University Press.
[155] R Heltsley et al 'Prevalence of synthetic cannabinoids in US athletes: Initial findings' (2012) 36 *Journal of Analytical Toxicology* at 588-593.
[156] MA Dada & DJ McQuid-Mason 'Legal aspects of medical malpractice, doctor patient relationship' in *Introduction to medico-legal practice* (2001) at 12.
[157] Mental Health Care Act 17 of 2002.

Table 1:2: Sectors and settings where prohibited substance regulation can be performed

Domain	Sector/environment	Industry	Example
Private domain	Workplace environment	Transport industry	Buses and taxi industry, railway, maritime, aviation [158]
	Other industries	Professional fraternities police, military and intelligence Manufacturing and (refining) industry[159,160] Mining industry Nuclear industry	Law, medical and teaching professions.[161]
	Educational environment	Minors in schools Students in universities	
	Sport environment	Olympic Committee (WADA) National Horse Racing Authority (NHRA of SA)	Athletes (professional and amateur)[162,163] Jockeys in horse racing
	Medical/clinical setting	Diagnostic	Emergency treatment Drug and alcohol rehabilitation centres and psychiatric and mental institutions[164,165]
	Research environment	Clinical trials	Trials involving prohibited substances[166]
Public domain	Criminal justice system		Road and traffic offences[167]

[158] Civil Aviation Act 13 of 2009.
[159] SAMHSA website http://workplace.samhsa.gov (accessed 20 February 2017).
[160] Code of the Federal Register 608(2004), Title 49, Subtitle A, Part 40.
[161] Employment of Educators Act 76 of 1998.
[162] World Anti-Doping Agency (WADA) https://www.wada-ama.org/ (accessed 20 February 2017).
[163] Heltsley et al (n 155) 588-593.
[164] Mental Health Care Act 17 of 2002.
[165] National Health Act 61 of 2003.
[166] J Herring *Medical Law and ethics* 2016 6th ed 614.
[167] National Road Traffic Act 93 of 1996.

			Drug-facilitated assault-related offences Testing to obtain evidence of drug abuse offences Testing of detainees
	Child custody battles	Parents tested in child custody battles (voluntarily or on a court order)[168]	

1.9 CONCLUSIONS

From times immemorial, humankind has used substances for medicinal, recreational, and enhancement purposes. The use of alcohol in South Africa dates back 70 000 years as part of the Khoisan culture. Regulation of some substances has now become standard practice due to their harmful effects and the deleterious effect, which also increase the risk to the users and society at large.

Substances are regulated in the criminal justice setting as well as in the private setting, such as the workplace, sports and education, and other environments. The regulation also involves testing for these prohibited substances in humans to assess compliance. The regulation and testing of prohibited substances have to be purpose-driven in order not to infringe on the individual's rights such as the right to privacy, freedom and autonomy. Prohibited substance testing serves mostly as a deterrent but may sometimes also be employed as part of a diagnostic paradigm in a medical setting.

The principalism approach, as suggested by Beauchamp and Childress, is an ideal ethical framework within which interventions on humans should be performed. The four principles of respect for autonomy, beneficence, nonmaleficence and justice each find application in their own right in the regulation and testing of prohibited substances in humans. Prohibited substance regulation and testing have to be performed within a legal framework which requires reliable scientific information.

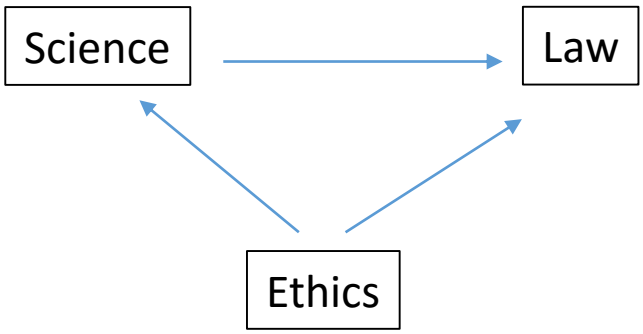
[168] Children's Act 38 of 2005.

CHAPTER 2:

ETHICAL ASPECTS RELATED TO PROHIBITED SUBSTANCE REGULATION AND TESTING IN HUMANS

2.1 INTRODUCTION TO ETHICAL ASPECTS OF A PROHIBITED SUBSTANCE REGULATION AND TESTING PROGRAMME

A prohibited substance regulation and testing programme has to be ethically sound, scientifically accurate and legally correct to be legally defensible and therefore requires careful consideration. The role of ethics cannot be overestimated due to its supportive role in both science and law. Science has to be practised ethically, and it is generally accepted that where there is no law, ethics becomes the law. Sound ethics act as a good foundation for a well-designed prohibited substance regulation and testing programme in the interest of natural justice. Science, on the other hand, informs the law.



The possible concerns that an individual may have regarding a drug test, as indicated below, should all be addressed by due consideration of the legal, ethical, and scientific aspects, to eventually arrive at a fair outcome for all parties involved in the prohibited substance regulation programme (individual and the organisation).[1] The three aspects are accross the different phases of the regulatory programme; these aspects also define each other's boundaries since there is an interdependence amongst them.

Common involuntary questions that may arise from an individual subjected to a regulation and testing programme are:

[1] The state, employer, WADA, NHRA, schools, etc.

- Why do we have a drug-testing programme, am I suspected of substance abuse? (invasion of privacy and dignity)
- How did the organisation arrive at this particular policy? (four principles of ethical decision making namely: respect for autonomy; beneficence; nonmaleficence; and justice, as discussed in sections 1.7 and 2.2
- What was the basis used to decide which substances should be included in the prohibited list, since I have the right to self-medicate? (autonomy)
- The policy is too difficult for me to understand. (right to information and justice)
- Am I going to get fired and lose my livelihood? (justice)
- Is the testing officer (security/sister) going to tell my superior and will they not influence each other? (are the professionals/testing officers truly objective and independent; separation of powers)
- The testing sequence is usually triggered by ***selecting*** an individual to submit for a prohibited substance test. Several critical issues are at stake in the selection process like:
  - In which way and why was I selected, am I suspected of drug abuse? (privacy, discrimination)
  - What about false accusations? (discrimination, scientific inaccuracy and fairness)
- **Specimen donation** can be regarded as an invasion of the individuals' privacy, dignity and autonomy. The following issues may arise during this step:
  - I did not want to donate a specimen, or I was forced to donate the specimen. Should the specimen not have been collected with my consent? (privacy and consent/autonomy)
  - Was the collector trained and qualified to collect the specimen? (professionalism, accurate results produced by professionally qualified personnel)
  - Why dit the collection not allow for visual and auditory privacy? (privacy and confidentiality)
  - Why was an observed specimen collection required? (privacy)
  - Is the integrity of the specimen that was submitted for testing guaranteed? (scientific accuracy, testing protocol, tampering, contamination, secured access to specimen)
  - What type of specimen would serve the purpose/reason for the test (blood/hair, urine, saliva)? (invasion of privacy, unethical to collect the incorrect type of specimen/matrix since it will not serve the purpose)

- The **specimen analysis/testing** of the specimen is a critical step since the outcome will determine if the individual had the substance in his or her body. The critical questions that arise here are:
  - Was the result accurate? (scientific accuracy, accurate testing protocol followed by professional, scientific personnel in accredited laboratories)
  - A second chance for analysis? (justice, fair and just administration)
  - Were the individuals involved in the analytical procedure qualified and trained to live up to the task? (professionalism, qualifications, registration at professional boards and accreditation of laboratories)
  - Were the equipment and devices used in the testing process in good working order? (scientific accuracy and accreditation)
  - How was the specimen transported to the confirmation laboratory, and what is the turn-around time? (scientific accuracy, a guaranteed chain of evidence, just administrative action)
  - Was the data interpreted correctly by medical personnel and scientists? (scientific accuracy and professionalism)
- Besides the generation of the test result, the ***reporting*** is also critical since the following issues may arise:
  - Who will receive the result and who may have insight into the results? (privacy, confidentiality and autonomy)
  - How will the result be communicated? (email/fax/telephone) (privacy, confidentiality)
  - Will I have access to the information? (autonomy, privacy and confidentiality)
  - What information will appear on the report? (privacy and confidentiality and scientific accuracy)
- The last step involves the ***decision*** as to whether the person transgressed the rules of the policy.
  - Will I have a chance to explain the confirmed test result? (justice)
  - What are the criteria and rules used for the decision? (justice and scientific accuracy)
  - By whom was the decision made? (discrimination, justice)
  - What will be the result of the decision? (justice)
- Assistance to the individual if he or she has a drug problem.
  - I have a real drug abuse problem/dependency problem. Can you help me, please? (justice and duty of care)

2.2 ETHICS AND THE PROHIBITED SUBSTANCE REGULATION AND TESTING PROGRAMME

2.2.1 Theories of ethics

"Ethics is the activity of man directed to secure the inner perfection of his own personality"

Albert Schweitzer

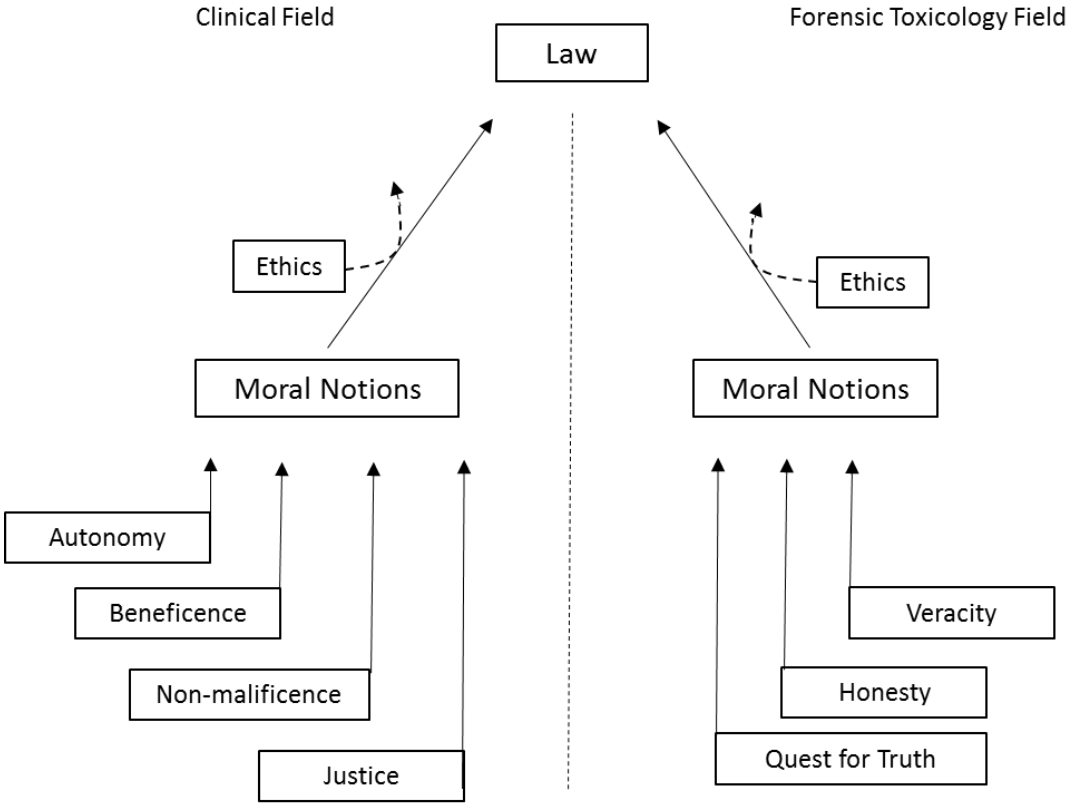


Figure 2:1 Aspects of ethics in the fields of medicine and forensic toxicology

At a fundamental level, "law" is a framework of rules that were developed, codified and enforced by society. "Morals" refer to a set of shared values and norms which enables us to decide what is right and wrong. Ethics is the systematic method of reflecting, arguing and justifying what a right or wrong decision might be and use moral notions to develop an argument.[2]

A *legal obligation* is one that is prescribed by law as a statutory duty, by precedent or by guidelines that may have a binding character, typically that specific behaviour by a medical

[2] N Hoppe & J *Miola Medical law and medical ethics* (2014).

practitioner or medical scientist is demanded or prohibited by law. The law is mostly aimed at protecting the privacy, autonomy and confidentiality of a drug test subject.

A *moral obligation* is one that an individual has towards others in society, and may or may not be a legal obligation. All morals are not always law; however, the law encompasses the moral obligations that are regarded as most essential to maintain societal cohesion.[3] This allows the professional practitioner/scientist to opt-out if the treatment or action requested by the patient is against his or her moral values.[4]

In law, a man is guilty when he violates the rights of another. In ethics, he is guilty if he only thinks of doing so.

Immanuel Kant

Ethical resolution in business, medicine, government, and science requires an ethical framework to address the question of "What is right?" in an "all-inclusive" manner, striving for the greater good. In the prohibited substance regulation and testing environment ethics finally comes down to the notion of treating others like you would like to be treated. No standard treatment will satisfy us all; however, as commanded by the CSA, treating each other with the utmost respect for autonomy, dignity, privacy and confidentiality will go a long way towards solving ethical dilemmas.[5,6]

Law and ethics (as the arbiter of morals) are in a constant interplay in the biomedical field. This can be observed from the multitude of regulations in the medical field, from primary law to standard operating procedures (SOPs) in laboratories and hospitals. It is also well known that where there is no law, ethics become the law.[7]

[3] Hoppe & Miola (n 2) 3.
[4] Hoppe & Miola (n 2) 6.
[5] TL Beauchamp et al (eds) *Contemporary issues in bioethics* 8th ed 1978 1.
[6] K Moodley (ed) *Medical ethics, law and human rights: A South African perspective* (2011)ch 1, 2 & 3 at 3, 7 & 19 Van Schaik Publishers.
[7] Hoppe & Miola (n 2) 7.

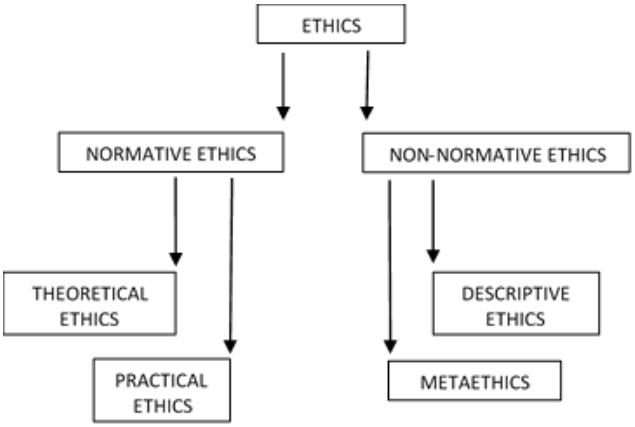


Figure 2:2 Different fields of ethics

"Ethics" is a generic term for the different approaches to examine or "obey" moral life, according to Beauchamp and Childress.[8] The approaches can be either *normative* or *non-normative*. Normative ethics enquires about which moral norms apply to a situation during the evaluation of ethical conduct and why in order to justify the use of these norms in a specific situation. It enquires about how people ought to act.[9] ***Practical ethics (applied ethics)***, the complement of ***theoretical ethics***, uses these general norms as a starting point to address ethical problems in practice, policies in professions, institutions and public policy.[10,11,12] ***Practical ethics*** poses questions regarding how people ought to implement moral knowledge and apply ethical theory in practical situations. It employs ethics with the intention to solve ethical dilemmas in real life.

> "The importance of applied ethics became obvious first in the medical context, wherein the aftermath of World War II and the expanding interest in human rights, developments in technology gave rise to challenging ethical issues such as the use of transparent technology and the allocation of scarce resources such as kidney dialysis." [13]

The objective of non-normative ethics is to establish whether the case is factual or conceptual. Two types of *non-normative* ethics exist, namely, *descriptive ethics* and *meta-ethics*. ***Descriptive ethics*** is the study of what people claim and believe is right. It uses facts obtained from scientific investigations by anthropologists, sociologists, psychologists and historians to

[8] TL Beauchamp & JF Childress *Principles of biomedical ethics* 7th ed (2013) 2 Oxford University Press.
[9] These norms are often referred to as "principles".
[10] In the fields of medicine and science in this instance.
[11] Beauchamp & Childress (n 8) 2.
[12] http://www.iep.utm.edu/ethics/ (accessed 22 September 2017).
[13] R Chadwick *Encyclopedia of applied ethics* xxxv.

determine which moral norms are employed in professional practices and codes, institutional mission statements and rules, and in public policies. One of the objects of this discipline is the study of the nature of consent. ***Meta-ethics*** is concerned with the epistemology of ethics and poses conceptual questions to study the origins and limitations of ethical statements. It has to do with the language, concepts and reasoning in normative ethics.[14] It enquires about "What do right and wrong mean?" and tries to obtain an understanding of the nature of moral concepts. Other objectives of this field are to study the theory of moral knowledge and the possibility of nature and moral truth, amongst others.

2.2.2 Principalism: A framework for biomedical moral decision-making

The principalism approach, as described by Beauchamp and Childress is a pronounced applied ethical theory, claiming that individuals have a common morality based mainly on four norms which they also call principles. This study proposes the use of the *Principalism model* as an ethical framework to solve ethical dilemmas imposed on individuals who are subjects of a prohibited substance regulation programme.

A prohibited substance regulation and testing programme is in essence an infringement on the autonomy of an individual who has the right to self-medicate and to privacy. Therefore, a prohibited substance regulation and testing programme can be viewed in the same light as any other biomedical intervention or decision. Even though there are procedural differences between the decision-making process for medical intervention and that for a prohibited substance regulation programme, the ethical aspects and treatment of the two demonstrates a tremendous amount of overlap.

Common morality: Beauchamp claims that morality has different facets varying from common morality having to do with right/wrong conduct in general, to moral norms applicable to specific communities and groups of people like physicians, scientists, nurses, and public health officials. The *common morality*[15] entails vital moral principles, rules, obligations, ideals and rights, which are obligatory norms shared by all society with which some moral character traits are associated.[16] The vital moral obligations and common morality also endorse basic "human rights".

[14] It addresses concepts like obligation, virtue, justification, morality and responsibility.

[15] Some of the basic principles of common morality are: (1) Do not kill, (2) Do not cause pain and suffering to others, (3) Prevent evil/harm from occurring, (4) Tell the truth, (5) Do not steal, (6) Nurture the young, (7) Do not punish the innocent. (8) Obey just laws.

[16] These are: nonmalevolence, (2) honesty, (3) integrity, (4) conscientiousness, (5) trustworthiness, (6) fidelity, (7) gratitude, (8) truthfulness, (9) lovingness, and (10) kindness.

Particular moralities apply to specific communities/groups as opposed to common morality, which applies to all morally abiding individuals. Particular moralities are more specific and are aimed at behaviour in specific situations, such as the medical and scientific fields. However, it should still obey the common morality. Beauchamp further holds that specific moralities include: "responsibilities, aspirations, ideas, sentiments, attitudes, and sensitivities found in diverse cultural traditions, religious traditions, professional practice standards, and institutional guides."[17]

Professional morality is specifically aimed at standards of conduct required by all in the profession. Professionals from learned professions are different from other professions in their level of specialised knowledge and training, as well as their level of commitment to provide services to consumers. Their knowledge is partly obtained by working under close supervision during training and their acceptance by the professional organisations is based on a minimum obligatory level of qualifications and competence as well as ethical standards they have to live up to. Affiliation with such a professional organisation then implies that the professional is competent and trustworthy.

A professional society usually delineates the obligations in the form of a code which specifies the code of conduct and sometimes also the etiquette of the profession.[18] Typical examples of professional societies applicable in the regulation of and testing for prohibited substances are the Health Professions Council of South Africa (HPCSA)[19] and the South African Council of Natural Scientists (SACNASP).[20]

In addition to that of the professional body, health professionals and scientists are also morally and legally guided by public and private policies in the form of regulations and guidelines. Public policies are guidelines and regulations promulgated and enforced by the government, i.e. from an agency of government or by legislature such as WADA in the form of the South African Institute for Drug-free Sport Act (SAIDS) in South Africa. Private policy can be regulations coming forth from private organisations such as hospitals, trade groups, professional societies, companies, and other organisations like universities and schools.

Biomedical decision-making spans over all the phases of substance regulation and testing, from policy formulation, testing individuals for prohibited substances, up to the final decisive action

[17] Beauchamp & Childress (n 8) 5.
[18] For instance: "Do not criticize colleagues who have been previously involved in a specific case".
[19] HPCSA professional conduct and ethics, https://www.hpcsa.co.za/conduct, (accessed 19 June 2019).
[20] SACNASP Code of Conduct, https://www.sacnasp.org.za/code-of-conduct, (accessed 19 June 2019).

that is taken when an individual did not comply with the policy. The following principles were suggested by Beauchamp and Childress to act as a framework for biomedical moral decision-making when ethical dilemmas arise.[21]

Table 2:1 Four principles of biomedical moral decision making according to the principalism approach

Respect for autonomy: A norm of respecting an individual's autonomous decisions
Nonmaleficence: A norm of avoiding harm (unlimited)
Beneficence: A group of norms related to relieving, minimising or preventing harm, and providing benefits and balancing benefits against risks and costs (limited)
Justice: A group of norms for fair distribution of benefits, risks, and costs

Only those who respect the personality of others can be of real use to them.

Albert Schweitzer

Respect for a fellow human being's autonomy means respecting the individual's entitlement to self-rule or self-governance if he or she is free from controlling interference and limitations that will inhibit a rational choice, which implies that consent must be *informed*. Respect for autonomy has two essential aspects, namely:[22] (1) liberty – independence from controlling influences, and (2) agency – capacity for internal action. Respect for autonomy should be realised actively as opposed to a respectful *attitude which* "allows only the individual to choose". It involves the dedicated provision of information, aimed at enhancing the capacity of an individual, to enable him or her to act autonomously and to take an informed decision after he or she has internalised the information that relates to the capacity of the individual. Autonomy should be exercised voluntarily and competently, meaning that the individual must have the necessary capacity (or competence) to exercise a decision.

The signing of an informed consent form by an individual without reading just because he or she trusts the specimen collection officer is, therefore, in principle, not consent due to a lack of information. A typical example of this occurs when an individual signs the consent form

[21] Beauchamp & Childress (n 8) 13.
[22] Beauchamp & Childress (n 8) 102.

without obtaining or reading the information on the form before he or she submits for a drug test.

Dworkin proposes a definition of consent in terms of a "second-order capacity of an individual to reflect critically upon his first-order preferences, desires, wishes, and the capacity to accept or attempt to change these in light of higher-order preferences and values".[23] For example, an employee feels that his or her privacy is invaded by a drug test but has a second-order desire to comply with the prohibited substances regulation policy for the sake of safety and in order not to be disciplined for refusing the test to keep his or her affiliation to the organisation intact. Dworkin claims that this higher-order capacity to abandon the first-order desire constitutes autonomy.

Our first-order preferences may also be influenced by our second-order preferences, as in the case of a drug addict who has an urge to use drugs, but has a higher-order realisation that he should stop using drugs. Strong second-order desires from a condition such as drug abuse can cause a first-order desire. Failure to comply with a higher-order desire does not amount to non-autonomy since numerous typical human actions will then be considered as non-autonomous due to the fallibility of humankind. Dworkin's theory of autonomy is, therefore not consistent with all the possible scenarios wherein ordinary human beings have to make decisions as competent agents.[24]

2.2.2.1 Conditions for autonomy

According to Beauchamp and Childress, a decision made by an individual can be regarded as autonomous if it complies with the three conditions of (1) intentionality, (2) with understanding, and (3) without controlling influences or interferences that determine his or her action.[25]

(1) *Intentionality*: An act is regarded as intentional if the actions of the individual are in line with his or her plan; this also includes actions that one wishes one did not have to perform.
(2) *Understanding*: An individual has to understand his or her action as completely as possible for the action to be autonomous. Limitations (irrationality or immaturity) in understanding and poor communication may inhibit understanding. Full understanding is an ideal since it cannot be expected of an ordinary person in the real world to exhibit equal expert knowledge about a procedure that is highly technical.

[23] G Dworkin *The theory and practice of autonomy* (1988) 20 Cambridge University Press, Cambridge.
[24] Beauchamp & Childress (n 8) 104.
[25] Beauchamp & Childress (n 8) 104.

(3) *Without controlling influences or interferences that determine his or her action* means that there should be no external (by another individual) or internal controls (mental illness, immaturity, or irrationality) that will diminish the individual's self-directedness.

The second and third conditions of autonomy above both exhibit a range of degrees of compliance; for instance, in the case of children who may have limited understanding and control at a young age, which improves when getting older, resulting in increased resistance against external control. The thresholds of understanding and being in control should depend on the specific objective of the decision. By law, the age of consent is 12 years. More mature young individuals have an increased capacity to make autonomous decisions by carefully providing information. A parent or guardian should also assist the minor to comply with the conditions of understanding and elimination of controlling influences.

This aspect becomes crucial when minors are tested for drug use in South African schools. The parent or guardian is usually not present and is most of the time contacted after the preliminary drug test was performed, and the concerned teacher wants to discuss the matter with them. It is difficult to accept that the minor was free from coercion when asked to provide consent. This situation is even more critical when the parent wants to test his or her child in the privacy of the family home with a drug-testing device obtained from a pharmacy. The parent or guardian now becomes the proverbial judge and jury with a limited sense of independence and ability to judge the situation.

2.2.2.2 Autonomy and authority

It may be reasoned that an individual's autonomy is compromised when he or she submits to the authority of an organisation, government or institution.[26] However, even in an unsymmetrical relationship as far as power is concerned, autonomy still exists if the individual voluntarily chooses to comply with the rules of an organisation which he or she regards as a legitimate source of direction or authority. Choosing to belong to an institution like WADA, NHRA, various industries, and even to subscribe to a legitimate democratically elected government are typical examples. The voluntariness lies in the fact that an individual has a free choice whether he or she wants to subscribe to the rules of the organisation. Conflict can usually be attributed to the fact that authority has not been unequivocally introduced and accepted by

[26] A Kuflik 'The inalienability of autonomy' (1984) 13 *Philosophy and Public Affairs* 271-198; J Raz 'Authority and justification' (1985) 14 *Philosophy and Public Affairs* 3-29; C McMahon 'Autonomy and authority' (1987) 16 *Philosophy and Public Affairs* 303-328.

the individual. For example, the drug regulation policy should be brought to the attention of an individual before he or she voluntarily chooses to subscribe to the rules of the organisation.

In a substance regulation environment, respect for autonomy implies that a competent individual has the right to make an informed decision regarding substance use, whether it be for recreational or medicinal purposes after all the relevant information was considered and understood. (Policy drafters, therefore, must be able to defend the prohibition of a substance on a rational basis).

Furthermore, respect for autonomy implies that an individual has the right to make the decision not to subject herself or /himself to a test for prohibited substances or to withdraw from the substance regulation process at any stage. In the real world, withdrawal from a prohibited substance test will have severe consequences for the individual (typically the same as for a validated positive test result); however, he or she has the right to make such a decision, and it should not be regarded as an acknowledgement of guilt.

The following rules result from "respect for autonomy": (1) Tell the truth, (2) Respect the privacy of others, (3) Protect confidential information, (4) Obtain consent for interventions with an individual, (5) Help the individual to make an informed decision if required through effective communication.[27,28]

2.2.2.3 Informed consent

Informed consent is not a process that requires a "yes" or "no" from the individual only. It is a process that requires time to allow the individual to exercise his or her autonomy and to weigh the options. Consent is also a legal requirement.[29,30,31,32,33]

Two different approaches to obtain informed consent also exist, the first is autonomous authorisation by the individual and the second has to do with institutionalised and legally correct authorisation. The second approach is not necessarily autonomous and meaningful. A typical example would be when a learner older than 12 years provides informed authorisation according to law; however, his or her decision may not necessarily be informed and free from coercion.

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[27] Beauchamp & Childress (n 8) 107.
[28] K Moodley (ed) *Medical ethics, law and human rights: A South African perspective* (2014) 4 Van Schaik Publishers.
[29] Health Professions Act 56 of 1974 ch 2 sec 27(A) subsec (g).
[30] National Health Act 61 of 2003 (NHA) ch 2 secs 6-8.
[31] HPCSA General ethical guidelines for good practice in healthcare professions Booklet 1 (2016) sec 5.3.
[32] HPCSA Guidelines for good practice in healthcare professions. Seeking Patient's informed consent: The ethical considerations, Booklet 4 (2016).
[33] Protection of Personal Information Act 4 of 2013 (POPI Act) ch 3 Part A Condition 2 Processing limitation sec 11(1).

It is also important to realise that when an individual is subjected to a prohibited substance regulation, he or she has to provide consent for the whole process of drug regulation and testing due to the infringement on his autonomy, beginning with the acknowledgement of the policy up to the final decision. He or she can withdraw from the process at any stage due to the voluntary nature of his or her part taking in the regulation programme.

The consent process has three elements, namely: (1) Threshold, (2) Information, and (3) Consent elements.[34,35]

2.2.2.3.1 Threshold elements

- **Competence in understanding and to decide**

Beauchamp and Childress hold that the assessment of competency in the biomedical setting should be "focussed on whether the individual is capable, cognitively, psychologically and legally of adequate decision making".[36] Someone is regarded as competent if he or she understands a medical procedure, appreciate the risks and benefits, and can make a decision in view of his understanding. This is echoed by Moodley who claims that an individual is competent to provide consent if he or she (1) is competent to communicate his or her decision, (2) is able to reason about the potential risks and benefits of the intervention, (3) understands the nature of his or her situation, (4) expresses a choice.[37]

In a law environment, standards of competence are mostly focused on the ability to understand and process information with a concomitant ability to reason about the consequences of one's actions.

It is the opinion of the author that seeking consent from an individual in a compliance drug test (such as for workplace or sports doping testing), requires a hybrid approach combining a biomedical decision-making process, which has an element of active enhancement of capacity to decide, with information on the consequences that may result from a drug test.

Competency judgement should serve the purpose of enabling the physician or drug-testing official to distinguish individuals with full capacity from those with limited capacity. Individuals with limited capacity due to immaturity, ignorance, and incapacitation or forced

[34] A Meisel & L Roth 'What do we know about Informed consent' (1981) 246 *Journal of the American Medical Association* at 2473-77; Presidents' Commission *Making health care decisions*, Vol II at 317-410 (particularly 318 and Vol I ch 1, particularly 38-39; National Commission for the protection of human subjects of biomedical and behavioural research *The Belmont Report* (1978) (Washington DC: DHEW Publications OS 78-0012 at 10.; Dieter Giesen *International Medical Malpractice Law A Comparative Law study of Civil Liability Arising from Medical care* (1988) 309-340 Kluwer Academic Publishers Group, United Kingdom; wherein the scope of disclosure and general requirements is discussed.

[35] Beauchamp & Childress (n 8) 124.

[36] Beauchamp & Childress (n 8) 114.

[37] Moodley (n 28) 44.

into a situation can be regarded as having *diminished* autonomy, in which case a more paternalistic approach may be followed. Surrogate decision-makers must be consulted in cases of diminished autonomy or where lack of capacity is evident. Examples of these in the field of drug regulation are: testing of learners in schools, testing of cognitively challenged individuals in mental institutions, testing of prisoners in correctional services in a situation of coercive institutionalised constraint or where a court has established legal incompetence and appointed a surrogate decision-maker with partial/full authority over the incompetent individual.

Age is traditionally usually used as a criterion for providing valid consent to medical interventions, which provides a standard of competence related to the experience, maturity, and responsibility of an individual.[38] The consent age currently in South Africa is 12 years for medical treatment, operations, HIV testing, and access to contraceptives. The consent age for male circumcision is 16 years, and consent for termination of pregnancy can be provided at any age. There is no legal age specified by law for consent to take part in research, [39] and specifically no consent age for a drug test.[40]

A balance needs to be struck between autonomy and protection, with the initial equilibrium lying more to the side of autonomy (rebuttable presumption of autonomy). Factors such as (1) the individual's mental abilities and (2) the probable gain due to the intervention may then be considered in favour of protection. If a high level of physical harm/risk exists due to the intervention, then the requirements for assessing competence (or the level of evidence required as proof of competence) must be stringent and vice versa.[41] For example, a drug test in the case of a minor may prove to hold great benefits and strong reasons exist for protecting the minor against unsustainable drug-taking behaviour (that can affect him or her and others in a school for instance). Such a test also has a low level of physical harm. Therefore, it may be justified to have a more relaxed approach in assessing his or her decision-making ability or competence (or be satisfied with less evidence of competency). However, it should be kept in mind that harm may also be caused to the individual's emotions since he or she may experience mistrust by the authorities that instruct the drug test (for instance his or her parent or teachers).

[38] A Strode, C Slack & Z Essack 'Child consent in South African law: Implications for researchers, service providers and policy makers' (2010) 100 *South African Medical Journal* at 247.

[39] A Strode, C Slack & Z Essack 'Child consent in South African law: Implications for researchers, service providers and policy makers' (2010) 101 *South African Medical Journal* at 604.

[40] The minimum legal age for leaving school is 14 years.

[41] Beauchamp & Childress (n 8) 120.

- **Voluntariness in deciding**

Voluntary consent involves that a competent individual is not forced or coerced into consent by another person or condition. Coercion involves the intentional use of a threat to harm or force to control an individual.[42] An example of such a threat is where an employee threatens a worker to submit for a drug test or otherwise be "fired". This aspect can be challenged when a competent individual is instructed according to policy to submit himself for a prohibited substance test where the element of "voluntariness" is diminished. Few individuals will submit themselves voluntarily for such a test; however, it can be reasoned that the *voluntary* element is embedded in the fact that the individual voluntarily chooses to associate himself or herself with the specific organisation continuously.

A threat has to be *real* to count as coercion and the fact that the worker may *feel* threatened when requested to undergo a drug test according to policy does not amount to a real threat. It is, therefore, a reasonable instruction that does not count as a threat or coercion. Institutional needs for safety and order are sometimes legitimately invoked and can sometimes exert pressure on the autonomy of an individual. However, coercion can be justified in a law enforcement environment (the civil domain of law) but not in a private law domain.

Choices and preferences also change over time with the result that an individual may change his mind at any stage during the regulation process or drug test, even if it is in conflict with a previous choice or contradicts the organisation's policy which the individual has agreed to previously. There may be consequences for him or her, but a refusal to give consent should not be regarded as an acknowledgement of guilt.

2.2.2.3.2 Information elements

- **Disclosure of information, recommendations and understanding before the intervention**

It is assumed that it is general knowledge that informed consent has to be obtained before a medical intervention to demonstrate respect for autonomy and to prevent deception and coercion and to ensure proper understanding. Beauchamp argues that sharing of information should not be equated to shared decision-making since it can be seen as a continuation of paternalism. There should be a clear distinction between the two processes of information sharing and the individual's act of authorising the intervention.[43]

[42] Beauchamp & Childress (n 8) 148.
[43] Beauchamp & Childress (n 8) 122.

The professional must disclose (1) the facts considered material in the decision, (2) the purpose of seeking consent and (3) the nature and limits of consent and authorisation, and (4) the subjects' right to withdraw without it such withdrawal being regarded as an acknowledgement of guilt in the case of a drug test for compliance.[44,45]

Three standards of disclosure exist, namely (1) the professional standard, (2) the reasonable person standard and (3) the subjective standard. The professional community's common practice determines the first standard and, as a result, only the professionals of the specific profession can testify as to the violation of an individual's rights. There may be some bias in the profession regarding the correct procedures, which may render the standard inaccurate. The reasonable person standard places the individual central in terms of authorising the intervention; however, it is difficult to define a *reasonable person*. The subjective model proposes that the information be shared on the needs of the individual. It is viewed as a more workable model since the information disclosure is adjusted according to the needs of an individual.[46]

However, the difficulty of obtaining consent according to the stringent standards of the autonomy-based model in real life under all circumstances should be appreciated since it may be almost impossible to implement. A workable, realistic model has to be obtained to be fair to all involved in the process, individuals and professionals alike, without compromising the stringent requirements of the autonomy-based model. A typical example where extensive information sharing may become a problem is when a large number of individuals have to be tested in a short period, and a balance needs to be struck between the detail of the information to be communicated and the time it requires to provide the necessary information. Workplace drug testing is a typical example of where time constraints impose pressure on the consent process.

All the information applicable to the intervention (a drug test in this case) must be provided to the individual, preferably in his or her native language, or by someone that can translate the information clearly and reliably. The risks and benefits must be explained, and a recommendation should be made, after which the individual must be allowed the opportunity to ask questions to ensure that he or she understands the information and recommendation

[44] Beauchamp & Childress (n 8) 125.
[45] Carstens P & Pearmain D *Foundational Principles of South African Medical Law* (2007) Lexis Nexis Cape Town, South Africa at 875.
[46] Beauchamp & Childress (n 8) 126

(instruction). Care must be taken that the individual is not exploited for financial gain when the recommendation is made.

In a prohibited substance regulation and testing environment, information on a prohibited substance test must be specific. Typical information required is: (1) Who will perform the test? (2) What does the test involve and what substances will be tested for? (3) To whom will the test results be disclosed, and (4) In which manner will the results be communicated? The testing officer may also not alter the list of compounds to be tested for, after the specimen was collected, without the explicit consent of the individual.

The individual should also be informed that he or she may refuse or withdraw from the test at any stage and that he or she has the right to designate an individual whom he consents to for receiving the result. He or she may also designate himself or herself as the only person who may receive the test result; however, in terms of his contractual obligations with the organisation, he or she must communicate the result to the appointed medical review officer (MRO) within a predetermined time.

2.2.2.3.3 Consent elements

- **A decision in favour or against the authorisation of the intervention**[47,48]

Finally, the individual who may be against or in favour of the intervention, which is a drug test in this case, should make a decision. The decision then needs to be formalised in the form of written consent and must be respected regardless of what the recommendation and expectations were. The decision may invoke ethical conflict when it conflicts with the organisation's policy, which subscribes to the principles of beneficence and nonmaleficence, which have the intention of doing good and to prevent harm.

The consent provided by the individual can be regarded as an "agreement/contract" with the organisation, which should be respected. The decision may not be disregarded or unilaterally altered by the organisation and its officials afterwards without the consent of the individual.

In the regulation of prohibited substances, consent is also provided at various levels. Typically, when the individual decides to commit herself or himself to, or join the organisation at the acceptance of the policy, and before or during a prohibited substance test. Consent is a can be withdrawn at any stage of the process since it is a continuous process. It can be withdrawn even

[47] An informed refusal should also be tolerated whenever informed consent is requested.

[48] A Nienaber and KN Bailey 'The right to physical integrity and informed refusal: Just how far does a patient's right to refuse medical treatment go? ' (2016) 9(2), *The South African Journal of Bioethics & Law* at 73-77.

after a biological specimen was donated for a prohibited substance test during the stages of laboratory analysis and reporting.

Consent should be *specific,* and "umbrella" consent is not acceptable. In the drug-testing environment, for instance, the individual has to consent for each specific drug he or she is going to be tested for. The collection officer/doctor, for instance, cannot add more substances later via a telephonic request to the confirmatory laboratory without obtaining the written consent from the individual.

A typical example of the process of obtaining voluntary informed consent is the HIV pre-test counselling protocol.[49]

2.2.2.4 Confidentiality

Confidentiality is one of the prime elements spreading from the doctor-patient relationship, which is one of trust. It is on this basis that an individual will divulge private information.[50,51] Confidentiality has a longstanding relationship with medical practice as far back as the Hippocratic Oath, stating that:

"Whatsoever things I shall see or hear concerning the life of men, in my attendance on the sick or even part therefrom, which ought not to be noised abroad, I will keep silence thereon, counting such things to be as sacred secrets."[52,53]

Confidentiality was also captured as an element of the Declaration of Geneva declaring that: "I will respect the secrets that are confided in me, even after the patient has died". [54] More recently also in the International Code of Medical Ethics, as adopted by the General Assembly of the World Medical Association (1968, 1983 and 2006) which states that: "A physician shall respect a patient's right to confidentiality".[55]

Confidentiality is also a legal obligation according to the National Health Act 61 of 2003 (NHA) stating that:[56,57,58,59]

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[49] Moodley (n 28) 43.
[50] HPCSA (n 31) sec 5.4.
[51] HPCSA General Ethical Guidelines for good practice in healthcare professions, Confidentiality: Protecting and providing information Booklet 5 (2016).
[52] J Herring *Medical Law and ethics* 2016 6th ed, Oxford University Press 232.
[53] https://en.wikipedia.org/wiki/Hippocratic_Oath (accessed 2 September 2017).
[54] https://en.wikipedia.org/wiki/Declaration_of_Geneva (accessed 2 September 2017).
[55] https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/
[56] Moodley (n 28) 48.
[57] NHA ch 2 sec 14.
[58] Health Professions Act 56 of 1974 ch 2 sec 13.
[59] POPI Act ch 3 Part A Condition 2 secs 10-11.

"(1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential and (2) no person may disclose any information contemplated in subsection (1) unless -

(a) the user consents to that disclosure in writing;

(b) a court order or any law requires that disclosure; or

(c) non-disclosure of the information represents a serious threat to public health".

There is also an obligation to keep record according to the NHA[60] and to protect information and personal information by setting up control measures to prevent unauthorised access to the records and to the storage facility in which, or by which, records are kept.[61] The inevitable increase in the use of computer technology for the storage and transferral of reports to those who need to know makes the protection of confidentiality more complex.

"Subject to National Archives of South Africa Act, 1996 (Act No. 43 of 1996), and the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), the person in charge of a health establishment must ensure that a health record containing such information as may be prescribed is created and maintained at that health establishment for every user of health services".

In the prohibited substance testing environment, this implies that the MRO, testing officers and the confirmatory laboratories must keep and store test results which may only be released with the authorisation of the individual. It may also only be released for other purposes like study, teaching, or research with the consent of the individual, the head of the establishment concerned and a relevant research ethics committee.[62]

Laboratory results reporting also has the risk that confidentiality could be compromised if the test result reporting line is not secured. Delivery by hand is the most secure option, but this is not always practical. Telephonic transferral of test results has a risk of compromising personal information unless the person receiving the results has been adequately identified. Electronic mailing to the designated person, as indicated on the consent form with an accompanying secure password is the preferred option. The amount of information that is processed or

[60] NHA ch 2 sec 13.
[61] As above at sec 17.
[62] As above sec 14.

disclosed must be kept to a minimum[63] and must also not be retained for longer than necessary to achieve the purpose for which the information was collected.[64,65]

Respect for privacy and dignity is also related to the confidential nature of a physical intervention on an individual.[66] The individual requires auditory and visual privacy during the testing process as a minimum, which is a critical aspect to consider in a workplace setting where large numbers of employees have to enter secured premises in a limited time. It is sometimes inevitable that the privacy of the worker and confidentiality of the testing process are compromised when it comes to the testing for alcohol in large worker groups due to the layout of the security gates where screening for alcohol takes place most of the time without visual and auditory privacy. It is of prime importance that the employer must pay extra attention to the architectural design to protect the privacy of the worker and the confidentiality of the process.

The random selection procedure and reporting for testing by an individual also have an element of confidentiality since there is a stigma to the use/abuse of illegal drugs. The stigma of drug abuse should be countered actively by the organisation by providing education on the prohibited substance regulation and testing protocols for the individuals to appreciate the fact that a positive (or non-negative) preliminary test result should not be viewed as a confirmed positive and validated test result.[67]

Preliminary, as well as for the confirmation, test results should be communicated to the individual in privacy and in a confidential manner.

2.2.2.5 Truth-telling

Truth-telling is an integral part of respect for autonomy and is the basis for a relationship of trust. It is a fundamental attribute of common morality and applies to all phases of the prohibited substance regulation process, namely:

- Policy drafting should be performed truthfully.
- Consent should be obtained openly and honestly.

[63] POPI Act ch 3 Part A Condition 2 Processing limitation sec 10.
[64] As above Condition 3 sec 14.
[65] As above Condition 2 sec 11(1)(a) "Personal information may only be processed if: Processing is necessary to carry out actions for the conclusion or performance of a contract to which the data subject is party;"
[66] HPCSA (n 31) sec 5.2.
[67] Note: An individual's diet or medication may be the reason for a non-negative test result.

- Test results must be reported honestly (precise and accurate) and truthfully. The test result is part of the truth, and there must be no doubt about the reliability of the result, which should be a product of a truthful testing process.
- The individual subjected to the prohibited substance test must be allowed to be open an honest (if he wishes to).
- The professionals involved, such as the collection officers, MRO, breath alcohol technician (BAT), laboratory scientists, and designated employee representative, must be honest and truthful in their assessments. Professional organisations demand a high level of honesty and truthfulness. The MRO must be truthful and honest in his decisions regarding drug use by the individual. Similarly, forensic scientists who perform the analyses on biospecimens must ensure accurate results since all decisive action hinges on accurate test results.
- The nature of decisive action can only be decided upon if the whole process of regulation was truthful and just.

2.2.2.6 Effective communication

Effective communication of information to the individual by the administrators of the substance regulation and testing programme and a clear understanding of the policy and procedures by an individual are prerequisites in a prohibited substance regulation and testing programme. Good communication is not only an ethical requirement but will also enhance the individual's perception of justice. All procedures have to be communicated to the individual, in any of the official languages, since he or she has to understand what is expected of him or her to comply with the programme.

The policy, consent forms, and other documentation should be available in all the official languages. The testing officers must be able to communicate instructions clearly and in a compassionate manner, suitable to respect the dignity of the individual, which will enhance his or her trust in the process. The confirmation laboratory must report the test result in an unambiguous fashion in the form of a test report.

The MRO must communicate his or her findings clearly to the individual and must also clarify scientific jargon that may be an obstacle in the understanding of the test result. The MRO also has to explain the validated test result and findings to the individual. The test result has to be explained to the designated employer representative (DER) who has an obligation towards the management of the organisation to convey the information clearly before a decision is made

on the outcome of the test. Eventual decisive action must be explained to the individual at a level at which he or she can understand the information.

2.2.3 Nonmaleficence

2.2.3.1 Nonmaleficence vs beneficence

The Hippocratic Oath states the following: "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing".[68,69.] The first part of the phrase refers to *beneficence,* and the last part of the phrase refers to *nonmaleficence.* This was also confirmed in writings of the Hippocratic school, stating that: "Practice two things in your dealings with disease: either help or do not harm the patient."[70]

It is of prime importance to keep in mind that both parties in a prohibited substance regulation programme have rights and obligations. The subject should co-operate with the organisation and respect the interests of the organisation, which encompass its goals, whether it be profit, property, image or safety of other members of the organisation. The organisation or the management thereof, on the other hand, should respect the rights of the individual. The principles of nonmaleficence and beneficence, therefore, should impose a moral obligation on both the organisation and the subject.

Nonmaleficence has to do with the *intentional* avoidance of actions that may inflict harm or evil,[71] while beneficence has to do with: (1) preventing harm, (2) removing harm and, (3) promoting good.[72] Acts like dishonesty, intentional disclosure without permission, intended use of prohibited substances, and incorrect drug test result reporting can all be viewed as a way of inflicting harm or evil during the drug regulatory process.

Beneficence is the complement of nonmaleficence in the process of minimising harm to the benefit of the individual, fellowmen and the organisation. Acts that can promote beneficence in the drug regulatory environment are, for instance: (1) respect for autonomy, (2) responsible listing of prohibited substances as opposed to indiscriminate enlisting of "all" suspect substances, (3) drafting of a policy in such a manner that it protects the interests of all and

[68] https://en.wikipedia.org/wiki/Hippocratic_Oath (accessed 27 October 2017).

[69] It is often said that the phrase "First do no harm" (Latin: Primum non nocere) is a part of the Hippocratic oath. The phrase as such does not appear in the oath, although the oath does contain Latin: "... noxamvero et maleficium propulsabo" (Also ... I will utterly reject harm and mischief). The phrase "primum non nocere" is believed to date back to the 17th century.

[70] G Lloyd ed. (1983) *Hippocratic writings* 2nd ed. 94 London: Penguin Books.

[71] Rules of nonmaleficence usually constitutes: "Do not do X".

[72] Beauchamp & Childress (n 8) 152.

promote health and safety, (4) compliance with the policy, (5) ensuring accurate drug testing results, and providing assistance to a drug addict or alcoholic.

The criteria for nonmaleficence are usually more stringent than those for beneficence, which means that even in the case where the benefit may be high for some, an intervention should not happen if it is morally indefensible and where wrong is performed intentionally. Nonmaleficence is therefore said to be limited and beneficence unlimited. However, care must be taken not to prioritise the two at all costs since the equilibrium position may sometimes depend on the specific circumstances.[73]

Nonmaleficence can also be viewed as a skewing, prevention or diminishing of someone's rights or interest. "Harmful" action may sometimes be justified, for instance, fair disciplining of employees or athletes who did not comply with a drug regulation policy, and fair punishment of professionals due to incompetence or negligence. These harmful actions should be justified by ensuring that they are not contributing to nonmaleficence themselves and are outweighed by other ethical principles. Significant bodily harm (like death, injury, disability, suffering assault or risk thereof) and damage to vital interests (like mental or financial harms) are typical examples of harm with a serious impact on others.

For example, the drawing of blood in the prohibited substance setting for alcohol testing may be viewed as the infliction of unnecessary harm if the same result can be achieved by way of a non-invasive breathalyser alcohol test. Another example will be if blood is sampled for a drug test where the same outcome could have been achieved with a urine or saliva test. The same situation applies for a blood test for drugs for which there are no therapeutic ranges available, which implies that no conclusion can be made on the level of intoxication and that the blood specimen collection was not necessary.

2.2.3.2 Rules for nonmaleficence in a prohibited substance regulation programme

Rules of nonmaleficence typically apply to all involved in a drug regulation environment and typically constitute: "Do not do X", for instance:

- Do not have an unethical or scientifically or legally incorrect prohibited substance regulation programme or policy.
- Do not enlist a compound with medicinal benefits if it does not suit the purpose of the regulation programme.

[73] As above.

- Do not be intoxicated in safety- or risk-sensitive environments.
- Do not use performance-enhancing substances when you are an athlete under the WADA regulations.
- Do not tamper with a urine specimen designated for a confirmatory test.
- Do not maliciously disclose personal information without consent from the owner of the information.
- Do not deny an individual the opportunity to explain his or her positive drug test to mitigate the severity of the outcome.
- The forensic scientist should not disrespect the autonomy of a court/tribunal by not telling the *full truth*, especially if he withholds information or is aware of the truth. A typical example of this would be where a forensic scientist provides only selective information to suit the case of the defence or that of the prosecution. For instance, in addition to an accurate result, the measurement uncertainty (limitations) of the result should also be reported to enhance the capacity of the court to make an informed decision.
- A professional involved in a drug prohibited substance and testing programme should not be negligent.

2.2.3.3 Negligence and the standard of care

In addition to 'not to inflict harm', nonmaleficence also includes obligations not to impose risks that may lead to harm; for instance, if a subject consumes a substance with full knowledge that the organisation's policy prohibits it which may harm to others or the interests of the organisation. The standard of due care requires adequate care to avoid causing harm as is demanded from a reasonable person under the circumstances that require that the goals in the prevention of harm may justify the risks and that the goals and risks must be in proportion. For instance, a prohibited substance regulation and testing programme in the workplace or schools which infringe on the autonomy of an individual is justifiable due to the physical danger inflicted on others by the use of mind-altering drugs. An ethically and scientifically sound testing protocol does not violate moral or legal rules even if it poses the risk of invasion of privacy and restricts autonomy. Another example of the standard of due care is the disclosure of an individual's drug-taking habits by a doctor to the individual's employer when others in the workplace may be in danger or to the parents in the case of a child whose life may be endangered.

Ignorance regarding the standard of due care is viewed as negligence, which can be either intentional (attentively or knowingly) or unintentional (inattentively).[74] An example of the first is to disclose a drug test result to the employer without the individual's consent or to force an individual into donating a specimen without his or her consent, or a forensic scientist to report an incorrect result knowingly or negligently. An employer/organisation in an environment where serious harm can be inflicted due to the working conditions without a prohibited substance policy or ignoring the policy also falls in this category.

Examples of the second category of unintentionally or inattentively causing harm is (1) where a forensic scientist does not take due care to prevent the reporting of incorrect test results, or (2) where adequately validated methods according to professional standards and scientific principles are not used, or (3) where a collection officer does not take due care to prevent contamination of the specimen during the collection process.

Professional malpractice can be defined as follows: "The professional must have had a duty to the affected party which was breached. The affected party must experience harm caused the breach of duty".[75] By subscribing to the rules when entering a professional organisation like the HPCSA or the SACNASP, the professional confirms that he or she will comply with the standards specific to the profession. Non-compliance with these standards then will imply negligence. When a professional initiates an intervention/action in the absence of a specific agreement, it can be assumed that he or she possesses the qualifications required from his profession. It can also be assumed that he or she will exercise the skill required, care and diligence in the execution of the interventions and actions unless the individual excuses him or if the professional, upon due notice, refuses to be involved any further.

For instance, a forensic laboratory should practice due care by using validated methods that can produce accurate and precise results. The scientists should have the necessary qualifications and expertise to perform the analyses with due diligence. Acting negligently by losing a urine specimen, or by not using a validated method (without prior arrangement with a client), or by reporting an incorrect result, or by disclosing the result to the wrong person will be viewed as not practising the standard of due care. Furthermore, the scientist responsible for signing off the result must be available afterwards if there are uncertainties or if more

[74] This applies not only to professionals involved in the regulation process, but also to the individuals who are subjects in the regulation process.

[75] Beauchamp & Childress (n 8) 155.

information is required about the test result. This *after-care* service should be performed at the same standard of due care as was expected during the initial phase of reporting the test result.

Collection of a biospecimen from an individual where the collection officer does not follow an ethically and scientifically sound protocol, or even utilising an incorrect analytical protocol which is not capable of providing a final and correct result also falls short of the standard of due care.

The same standard of care also applies to the subjects of a prohibited substance regulation and testing programme. A prime example would be the case where an athlete consumes performance-enhancing substances, also referred to as "doping". The obligation of nonmaleficence does not only include the athlete's obligation to take part in a manner that does not inflict harm in terms of safety to fellow participants but also not to impose risks that may lead to harm related to the interests of others. In the case of anabolic steroid use, which does not pose life-threatening harm to fellow competitors, harm (or risk of harm) is imposed on the interests of fellow athletes who have seriously and honestly invested in winning, with concomitant monetary compensation. Besides being dishonest, the use of performance enhancement drugs diminishes fellow athletes' interest.

2.2.3.4 Protection of incompetent individuals: surrogate decision-making

When an incompetent person or an individual with diminished capacity has to submit for a prohibited substance test, a surrogate decision-maker should provide consent. Beauchamp and Childress propose that surrogate decision-makers should have the following qualifications:[76,77] They must: (1) be able to make rational decisions (competent), (2) be emotionally stable, (3) have the interest of the incompetent person at heart and (4) be free from conflicts of interest, controlling influence.

Substance testing in schools requires careful consideration in this regard. In the ideal situation, a school will have a sound policy, with sufficient separation of powers or independence by the role players and that will be based on sound ethical, scientific and legal principles for the minor not be treated unfairly. In such a case, the parent or legal guardian will act as a surrogate to provide consent. The confirmation test result should be forwarded to the designated person

[76] Beauchamp & Childress (n 8) 190.
[77] Carstens P & Pearmain D *Foundational Principles of South African Medical Law* (2007) Lexis Nexis Cape Town, South Africa at 897.

who will submit it to the MRO. The MRO, in turn, will provide an answer to the headmaster of the school who will decide on the way forward.[78]

An ethical dilemma arises when a parent "tests" his or her child himself or herself with a preliminary testing device purchased from pharmacies for home testing or when the parent takes the child to a confirmatory laboratory to donate and submit a specimen for analysis. It is the opinion of the author that parents are not always free of conflict of interest and sometimes forces the minor to donate a specimen. Parents are not always well informed and may behave emotionally when they receive the test result to the disadvantage of the child. The author proposes that the parent must make rational and objective decisions by seeking the assistance of a qualified social worker or psychologist to act as a buffer between the minor and the parent and to view the situation objectively.

There are mainly two surrogate decision-making standards applicable to incompetent individuals in a prohibited substance regulation environment, namely: (1) the substituted judgement standard and (2) the best interests standard.

The substituted judgement standard is typically invoked when individuals who could make autonomous decisions in the past now lack capacity. A surrogate decision-maker can then decide on what the incompetent individual would have wanted had he or she been competent on the basis that he or she knows the incompetent individual well. This standard should be applied when an individual is unconscious after an accident, and a biospecimen is required for a forensic investigation. A physician or a family member may take such a decision in the interest of justice.

In the case of the best interest standard, the surrogate decision-maker protects the incompetent individual by following a rational path of reasoning and by weighing the benefits and the risks imposed by the intervention. This standard also applies when a minor has to be tested for drugs and consent is provided by parents or guardians who have the best interests of the child at heart.

2.2.4 Beneficence

Beneficence implies that we must contribute to the welfare of the individual and usually requires a more substantial effort than not to inflict harm, as is the case for nonmaleficence. Beneficence is an unlimited principle, and it is held that positive beneficence has some *prima*

[78] The decision should be taken in close collaboration with a social worker or psychologist.

facie rules, namely:[79] (1) protect and defend the rights of others, (2) prevent harm from occurring to others, (3) remove conditions that will cause harm to others, (4) help persons with disabilities (for instance, assist an individual with drug-abusing tendencies) and (5) rescue persons in danger (for instance, take serious action if a person is dependent on drugs).

All of the above find direct application in the prohibited substance regulation and testing policy which states that the organisation has to make sure that the rights of the individuals are protected and that harm is prevented from occurring with a sound testing protocol. The organisation also has to make use of professionals that can execute their duties accurately and responsibly. The policy has to comply with ethical principles, legal obligations and scientifically correct procedures.

The provision of information and education on the effects of the prohibited substances is also a benevolent action in a prohibited substance regulation and testing programme, since a positive and proactive action that will remove and prevent harm over a longer time, as opposed to drug testing which is a benevolent action with an immediate deterrent effect.

A substance regulation and testing programme usually requires specific beneficence to be provided by the professional as an obligation as part of his or her contract with the organisation, which requires the professional to administer the policy in a way that (1) prevents harm, (2) removes harm and, (3) promotes good.

The rules of beneficence are in general less strict than those of nonmaleficence in the sense that it: (1) requires positive types of action, (2) does not always have to be followed impartially and (3) does not provide legal grounds for punishment when a professional does not comply with them.[80] Positive action is to be followed impartially because we are obligated, for instance, to rescue an individual if the risks imposed are low. Positive action finds application in the principle that the organisation's policy should accommodate individuals with a substance abuse problem through a formal assistance programme where he or she can receive help. The programme must also be designed in such a fashion that an individual who is under the influence of intoxicating substances, is prevented from inflicting harm to himself, others and the organisation. From this perspective, an occupational health doctor should disclose a patient's drug-taking habits after the patient was informed of the disclosure and did not do so himself voluntarily, even if there is a competing obligation such as protection of privacy and

[79] Beauchamp & Childress (n 8) 204.
[80] Beauchamp & Childress (n 8) 205.

confidentiality. It is the opinion of the author that a professional or educator has a *prima facie* obligation of beneficence to act, in the form of duty to rescue, when a minor is dependent on substances or abuse it.

The criteria that can act as guideline as to when to intervene are: (1) the individual is at risk of serious harm to health and safety, or some other essential interests,[81] (2) action is required to prevent the harm from taking place and has a good chance of preventing the harm, (3) will not impose severe risk/burdens on the professional and, (4) the benefits to the individual that follows the action will outweigh the risks imposed on the professional.[82]

The third guideline pertains to the fact that beneficence has limits for both professionals and organisations as part of the prohibited substance regulation programme. The limits of beneficence are a grey area in some instances; however, when applied to an organisation that wants to institute a prohibited substance regulation and testing programme in the act of beneficence, the benefits of the programme must outweigh the financial burden imposed by it. The substance regulation programme must be affordable for the organisation within its financial constraints, which is a debatable topic since the loss of even one life cannot be measured in monetary terms. A prohibited substance regulatory programme in a safety-sensitive environment is, therefore, an impartial rule of beneficence, making a substance regulation an obligation on an ethical basis.[83]

An interesting dilemma arises when considering the liability for payment for drug tests. The obligation to institute and maintain a prohibited substance regulation programme in the interest of the safety of fellow employees, as well as in the interests of the organisation requires the organisation to foot the bill. The reciprocal obligation of beneficence by the members or subjects of the regulation programme may provide sufficient grounds for the individual to carry the cost incurred due to non-compliance with the policy that he or she undertook to observe when he or she entered the organisation. If the individual was selected randomly to submit for a drug test and the test result indicates that he or she complied with the policy, the costs should be for the account of the organisation. This is also supported by the Occupational Health and Safety Act.[84]

[81] This justifies the act of whi+stle-blowing or anonymous tip-offs where a person has information that an individual may endanger the life of others while under the influence of mind-altering substances.
[82] Beauchamp & Childress (n 8) 207.
[83] This is also a legal obligation. See the Legal chapter ch 3.
[84] Occupational Health and Safety Act 85 of 1993 (OHSA).

2.2.4.1 Reciprocity as an obligation of beneficence

David Hume holds that: "All our obligations to do good to society seem to imply something reciprocal. I receive the benefits of society, and therefore ought to promote its interests."[85] Reciprocity is the practice of exchanging things with others for mutual benefit, for instance, when the organisation takes decisive action against an individual who transgresses the rules of the policy and thereby poses a risk to the safety and interests of fellow individuals who may be (or not be) part of the organisation. The organisation thereby returns the favour to its members who observe and respect the rules of the policy.[86,87]

There is also a benevolent obligation imposed on the members of the organisation. An organisation cannot minimise harm and exercise due care, whether it be physical harm or risk of harm to vital interests if it does not have the dedicated co-operation of its members. The success in minimising harm is not only based on the philanthropic, altruistic and commitment of the organisation, but also on the reciprocal obligation of the members to co-operate and respect the policy.

An exciting development in medicine and health-care, based on the obligation of reciprocity that can also be extended to a drug regulation programme is that of a learning health-care system. [88] This system rewards patients who contribute to the body of knowledge by providing information to enhance the learning in the health-care system, which improves the quality of treatment provided by the health-care system for other patients. A variation of this model is where patients who agree to become organ donors reciprocally obtain preferred status when requiring access to health-care services. This model may very well be extended to the substance regulation environment where individuals are rewarded (monetary or some other form of reward like special leave) if they comply with the policy when tested randomly on the initiative of the organisation.

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[85] D Hume 'Of Suicide' in E Miller (ed) *Essays moral, political, and literary* (1985) 577-589 Indianapolis: Liberty Classics.

[86] Beauchamp & Childress (n 8) 213.

[87] WF May 'Code, covenant, contract or philanthropy' in *The Hastings Centre Report, 1975* (50)6 at 29-38; WF May 'The healer's covenant: Images of the healer in medical ethics' 2nd ed (2000) Louisville, KY: Westminister-John Knox Press.

[88] Beauchamp & Childress (n 8) 213; LifeSharers at https://en.wikipedia.org/wiki/LifeSharers (accessed 28 October 2017); G Siegal & R Bonnie 'Closing the organ donation gap: A reciprocity-based social contract approach' (2006) 34 *Journal of Law, Medicine & Ethics* at 415-23; D Ofri 'In Israel, a new approach to organ donation' *New York Times* 17 February 2012 (obtained from B&C ref 16 at 243).

2.2.4.2 Paternalism as a means of providing beneficence

2.2.4.2.1 Definition of paternalism

Dworkin defines paternalism as: "Interference with a person's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests, or values of the person being coerced." [89]

Beauchamp and Childress, in turn, define paternalism as:

> The intentional overriding of one person's preferences or actions by another person, where the person who over-rides justifies this action by appeal to the goal of benefiting or of preventing or mitigating harm to the person whose preferences or actions are overridden.[90]

Paternalism involves the restriction of an autonomous and free choice. It also includes treating others as means to our goals as opposed to treating them as means to their ends. It can be divided into two categories, namely "hard" or "soft" paternalism. Hard paternalism can be defined as mitigation of harm to the benefit of an individual despite wrong decisions even when they are fully voluntary. Soft paternalism applies to individuals that are not competent where a paternalistic action protects the patient from harm due to a decision he or she could not make competently.[91] Examples of soft paternalism are where a professional informs a minor's parents without the consent of the minor or where a school headmaster instructs a learner to submit for a drug test without his or her consent or prevents an individual under the influence of a hallucinogenic drug from killing himself.

2.2.4.2.2 Paternalism in prohibited substance regulation

Paternalism is highly prominent in public policy on substance regulation where the policymakers take decisions that a certain percentage of the population will not agree with due to a restriction on their autonomous choice about the use of the prohibited substances. Both hard and soft paternalism is at work in public policy since the autonomy of intended beneficiaries lies on a continuum from full autonomy to limited autonomy as in the case of minors. It involves individuals that do not agree with the restriction of their autonomy as well as those who need to be protected due to inadequate voluntariness, commitment, or self-control, such as limited autonomy.

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[89] Dworkin (n 23) 121.
[90] Beauchamp & Childress (n 8) 215.
[91] Dworkin (n 23) 124.

A soft paternalistic approach can be followed by a government to educate individuals who may have limited capacity to make an informed decision on substance use due to psychological bias or limited understanding. Information can be distributed to enhance the capacity of its citizens. Showing television programmes highlighting the dangers inflicted by the use of dangerous substances cannot be viewed as a violation of an individual's autonomy.[92] Such a libertarian paternalistic approach is based on the assumption that all autonomous individuals will prefer health above ill health caused by the use of dangerous substances.

Soft paternalistic approaches to correct cognitive biases may sometimes stigmatise individuals (drug abusers) instead of the act (drug abuse). Stigmatising individuals will also have a psycho-social cost, such as preventing a drug abuser from seeking help due to feelings of guilt and rejection by society. Drug abuse is more common among the lower socio-economic groups in real life and stigmatisation then targets these vulnerable individuals.

A campaign against drug abuse may include interventions that may vary from providing information to giving sharp warnings on the danger and other soft paternalistic acts, such as the inclusion of a warning sign on cigarette boxes, the prohibition of advertising on national media or a significant increase in sin tax. Hard paternalistic acts such as or the initiation of a random drug testing programme will infringe on the autonomy of the individual.[93]

2.2.4.2.3 Justification of paternalism in the regulation of substances

The extent of paternalistic actions may be justified by balancing an individual's demand for autonomy and the benefits due to the paternalistic action. If the benefits outweigh an individual's demand for autonomy, paternalistic action may be justified, as opposed to when the individual has a high demand for autonomy compared to the little benefits. If the risk of serious harm increases, the plausibility of paternalistic action also increases.

Beauchamp argues that "when a person's actions are substantially autonomous and create the risk of harm to himself or herself, without imposing significant harms or burdens on others or the society, we should not act paternalistically beyond the use of modest means such as persuasion". [94] Therefore, the harm and concomitant risk that the use of mind-altering substances may pose to an individual as well as to society can, in general, justify a stronger form of paternalism such as regulating and prohibiting these substances. This regulatory approach can be viewed as a hard paternalistic act or intervention that restricts an individual's

[92] C Jolls & CR Sunstein 'Debiasing through Law' (2006) 35 *Journal of Legal Studies* at 199-242.
[93] WK Viscusi 'The new cigarette paternalism' (2002) 58 *Regulation* at 58-64.
[94] Beauchamp & Childress (n 8) 244.

autonomy to the benefit of society. Hard paternalistic interventions can be justified when the criteria, as discussed under the section of beneficence above, are met.

In a drug regulation environment, the criteria for hard paternalistic interventions like drug regulation can be as follows:

(1) Individuals or members of society are at risk of harm to health and safety or their interests.

(2) Paternalistic intervention or action is required to prevent the harm from taking place and has a good chance of preventing the harm

(3) It will not impose severe risk/burdens on the organisation/state

(4) The benefits to the members of society that follows the intervention will outweigh the risks imposed on the individual whose autonomy is violated by the intervention.

An additional criterion can be added not to cause a substantial infringement of autonomy interests, such as the deep religious convictions by the Rastafari religious group, which spiritually uses cannabis.[95] Preventing the individuals belonging to this group from consuming cannabis during their spiritual ceremonies would be seen as an infringement of their autonomy. However, if the necessary precautions are taken, like instituting random roadside testing to prevent driving under the influence of an intoxicating substance such as cannabis, harm to others in society can be minimised.[96] The same can be said of alcohol, which is a legal drug with minimal regulation in South Africa, where roadside testing is performed under the National Road Traffic Act.[97]

2.2.5 Justice

Aristotle said: "Equals must be treated equally and unequals must be treated unequally". In its contemporary form, this principle is sometimes expressed as follows: "Individuals should be treated the same unless they differ in ways that are relevant to the situation in which they are involved."[98]

Aristotle's statement, however, does not specify who are regarded as equals and also not what is meant by "equal treatment". In a prohibited substance regulatory programme, it may be interpreted as "Everybody subjected to a prohibited substance policy is expected to comply

[95] Rastafari religious movement: https://en.wikipedia.org/wiki/Rastafari (accessed 29 October 2017).
[96] National Road Traffic Act 93 of 1996 ch XI sec 65.
[97] As above.
[98] Justice and Fairness https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/justice-and-fairness/, (accessed 1 November 2017.)

with the policy, regardless of his or her status in the organisation; however, the policy may discriminate between various activities which are grouped according to risk". An example illustrating this is the vast difference in safety sensitivity between the operations of a gardener working at an airline and those of a pilot in the organisation. Even if both are employees of the airline, the rules for substance use may be less stringent for the gardener than those that apply to the pilot.

Justice refers to the principle of fairness and in prohibited substance regulation, more specifically, to the fair treatment of the individuals subjected to the policy of the organisation. The obligations of justice in a prohibited substance regulation programme are: (1) legal justice, (2) rights-based justice, (3) distributive justice, and (4) procedural justice.

2.2.5.1 Legal justice

The law is an essential factor in resolving ethical dilemmas where individuals believe that they have been mistreated. Respecting morally sound laws is an essential ethical requirement in complying with the principle of justice. Chapter 5 describes the aspects of laws and statutes related to prohibited substance regulation in more detail.

2.2.5.2 Rights-based justice

Rights are entitlements that protect individuals from state or organisational power. Examples of rights include the right to equality, dignity, life, and the security of the person, which includes autonomy and privacy. These rights are provided for in chapter 2 of the Bill of Rights of the CSA.[99] Rights also have a reciprocal relationship with obligations in the sense that the compliance of an organisation with the specific right of an individual, creates an obligation for the individual to respect the effort of the organisation. For example, if an organisation has a policy that respects autonomy and that prohibits the use of dangerous mind-altering drugs for the sake of safety or to minimise harm, the individual should respect the policy of the organisation by avoiding the consumption of such compounds in a manner that is forbidden by the policy.

2.2.5.3 Distributive justice

This type of justice refers to treatment that is owed to persons with a "fair, equitable, and appropriate distribution of benefits and burdens determined by norms that structure the terms of social co-operation".[100] It has to do with how fairly the outcomes of a prohibited substance

[99] The CSA ch 2.
[100] Beauchamp & Childress (n 8) 250.

regulation policy are distributed. A question that may be asked to assess distributive justice in a prohibited substance regulation programme is: "Are everybody treated equally and without unfair discrimination?" [101,102,103]

2.2.5.4 Procedural justice

Procedural justice focuses on the fairness of the outcome of a procedure or intervention.[104,105] Fair procedural justice in a prohibited substance regulatory intervention requires the process itself to be fair. A prohibited substance policy should be examined from both a distributive and procedural justice perspective.[106,107,108,109,110] Leventhal claimed that a policy has to comply with the following four principles of distributive justice: (1) Consistency, (2) ethicality, (3) accuracy, and (4) correctability.[111] These are all related to the fairness and "distribution of the outcome".

A prohibited substance testing programme is ***consistent*** if it applies to all members of the organisation equitably, which means that the policy should not be applied for specific groups or individuals in the organisation only, for instance when management is not tested, but everybody else is. ***Ethicality,*** in this instance, refers to the notion that the punishment must be in proportion to the violation. ***Accuracy*** refers to the reliability with which the procedure can detect prohibited substance use. False-positive (FP) detections must be at a minimum to be confirmed accurate. ***Correctability*** refers to the inclusion of rehabilitation or assistance programme to correct the individual's behaviour, also if the violation will be "forgotten/forgiven" and deleted from his or her record.

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[101] J Brockner, CL Martin & BM Weisen 'Decision frame, procedural justice, and supervisor's reactions to layoffs' (1995) 63 *Organisational Behaviour and Human Decision Processes* at 59-68.

[102] J Greenberg 'Equity and workplace status: A field experiment' (1998) 73 *Journal of Applied Psychology* at 606-613.

[103] GS Leventhal 'What should be done with equity theory?' in KJ Greenbergh, MS Greenberg & RH Willis (eds) *Social exchange: Advances in theory and research* (1980) 27-55 New York: Plenum.

[104] K Wagner & LJ Moriarty 'Perceived fairness of drug-testing policies: An application of Leventhal's Principles of Procedural Justice' (2002) 26 *American Journal of Criminal Justice* at 219-233.

[105] GC Homans *Social behaviour: Its elementary forms* (1961) New York: Harcourt Brace.

[106] L Barrille 'Drug testing: At odds with public opinion' in A Trebach & K Zeese (eds) *New frontiers in drug policy* (1991) 323-332 Washington DC: Drug Policy Foundation.

[107] J Crant & T Bateman 'A model of employee responses to drug testing programs' (1989) 2 *Employee Responsibilities and Rights Journal* at 173- 190.

[108] R Cropanzo & M Konovsky 'Resolving the ethical dilemma by improving the outcomes: The case of employee drug screening' (1995) 10 *Journal of Business and Psychology* at 221-227.

[109] B Raciot & K Williams 'Perceived invasiveness and fairness of drug testing procedures for current employees' (1993) 23 *Journal of Applied Social Psychology* at 1878-1891.

[110] D Stone & D Kotch 'Individuals' attitudes toward organisational drug testing policies and practices' (1989) 74 *Journal of Applied Psychology* at 518-521.

[111] GS Leventhal 'The distribution of rewards and resources in groups and organisations' in L Berkowitz and E Walster (eds) (1976) 9 *Advances in Experimental Social Psychology* 91-131 New York: Academic Press.

The author proposes a new principle to be included, bearing relation to small variations in the policy called **robustness**. A policy can be referred to as robust if small variations in the procedure do not result in unfairness. Small variations, for instance, may occur in the sampling and testing protocol. The order of events should not have an impact on the final result, as long as the privacy and dignity of an individual are respected. The time that the specimen is in transit also counts as such a small variation.

The areas in a prohibited substance policy that are of importance for procedural justice, according to Wagner and Moriarty are (1) notice, (2) consequences and (3) confidentiality.[112] These principles are related to the four stages of prohibited substance regulation, namely the (1) selection, (2) testing, (3) review and (4) decisive action stages with an overarching respect for privacy, dignity and autonomy.

Selecting/nominating individuals for random unannounced testing may be perceived as unfair since it can be regarded as an invasion of privacy and loss of control; however, this should be judged with the health and safety or risk others in mind.[113] In the safety-sensitive environment like the workplace, public roads, prisons, and even schools, unannounced testing is an effective deterrent. In addition to the safety aspect in schools, unannounced drug testing in schools in general adds to the upbringing of the minor and deters harm to other minors. In the sports environment, the use of prohibited substances may infringe on the rights of other competitors in terms of safety, fair competition and monetary rewards. Random testing is in principle a risk management strategy which controls drug-taking behaviour of the individuals in their private life, and it is therefore not uncommon for individuals to report and perceive this as unfair and invasive to their privacy.

The ***testing*** protocol should guarantee the accuracy of the test result from the sample donation stage, preliminary testing up to the final reporting of the confirmed result to the individual's designated person. If the sampling officer is not independent (not on the same payroll) of the organisation, the individual may perceive it as unjust. If the integrity of the specimen and the chain of custody cannot be guaranteed, doubt is cast on the test result, which may be perceived as unfair. The time an individual has to wait for the test result (turn-around time) is also of prime importance for the administration of justice to be fair in a prohibited substance testing environment.

[112] Wagner & Moriarty (n 101) 219-233.
[113] Stone & Kotch (n 107) 518-521.

The ***review*** procedure whereby the MRO validates the confirmed test result must provide the individual with a fair chance to declare the use of medication to a qualified and professional MRO operating independently from the organisation. The on-site occupational health doctor should preferably not be involved due to his or her duty-of-care relationship with the individual.

The ***decisive action*** stage relating to the consequence of termination are usually perceived fairer if it defaults to a rehabilitation procedure rather than to immediate disciplinary action like the termination of with the individual; however, this must again be evaluated against the risk to the safety of others in safety-sensitive environments.[114,115,116,117]

2.2.5.5 Social justice

Perceptions of fairness should also be viewed in terms of the social context within which prohibited substance testing is performed. Situational variables such as interpersonal treatment, organisational reputation, and testing context also affect the perception of procedural fairness. The quality of treatment of the individual and others, as well as the context of substance testing, contribute to the perception of organisational fairness in prohibited substance testing.

Interpersonal treatment contributes to *interactional justice*, which was initially thought to be a formal form of procedural justice, but is now viewed to be a social aspect of procedural fairness.[118,119,120,121] Interactional justice relates to the quality of the interpersonal treatment the individual receives from a superior. Human beings require treatment that confirms dignity and respect before, during, and after a prohibited substance test. The ***voice effect*** is also a long-standing issue in the perception of fairness.[122] In addition to politeness which is a prerequisite, Bies also indicates that the individual perceives the testing procedure fairer when he or she understood that the test is a result of the organisational programme instead of a superior's decision that may target him or her. A proven record of providing fair treatment to individuals

[114] Barrille (n 103) 323-332.
[115] Crant & Bateman (n 104) 173-190.
[116] Stone & Kotch (n 107) 518-521.
[117] Raciot & Williams (n 106) 1891-1897, 1993.
[118] J Brockner & BM Wiesenfeld 'An integrative framework for explaining reactions to decisions: The interactive effects of outcomes and procedures' (1996) 120 *Psychological Bulletin* at 189-208.
[119] R Cropanzo & J Greenberg 'Progress in organisational justice: Tunnelling through the maze in LT Robertson & CL Cooper (eds) *International Review of Industrial and Organisational Psychology* (1997) New York, John Wiley and Sons.
[120] R Folger & RJ Bies 'Managerial responsibilities and procedural justice' (1989) 2 *Employee Responsibilities and Rights Journal* at 79-90.
[121] TR Tyler & RJ Bies 'Beyond formal procedures: The interpersonal context of procedural justice' in JS Carrol (ed) *Applied social psychology in organisational settings* (1990) Hillsdale, NJ, Erlbaum at 77-98.
[122] EA Lind, R Kanfer & P Early 'Voice, control, and procedural justice: Instrumental and non-instrumental concerns in fairness judgements' (1990) 59 *Journal of Personality and Social Psychology* at 952-959.

by the organisation also contributes to a positive perception of fair treatment.[123] The context within which substance testing takes place relates to the reason that triggers the nomination for an individual to submit for a prohibited substance test. These may be random testing, testing for cause (after an incident, rehabilitation) and, periodic testing as part of annual medical examinations. Random testing is perceived to be the least favourable.[124]

2.3 MORAL DILEMMAS IN PROHIBITED SUBSTANCE REGULATION AND TESTING

The principles are not absolute, but should instead be viewed as *prima facie* rules that have to be complied with unless they conflict with an equally essential or stronger rule.

Moral dilemmas often arise, in which case practical ethics are employed to decide the outcome. These dilemmas typically arise when moral obligations demand that an individual has to adopt either of two incompatible outcomes which may, or may not be mutually exclusive.[125] Complying with one obligation may imply overriding of the other. Ethical dilemmas arise in all phases of substance regulation, from policy formulation to the decisive action and assistance of an individual with a substance abuse problem. Typical examples of such dilemmas are:

- A medical practitioner has to disclose a patient's illicit drug use or abuse to an employer or organisation to which the individual is accountable. If the practitioner discloses the information, the relationship of trust and the individual's right to privacy are compromised. If the disclosure is not done, the interests of others may be at stake (safety, prize money).
- An individual has to use peyote cactus or cannabis as part of a religious ceremony. Abstinence may indicate disregard in religious circles as opposed to using the prohibited substance, which constitutes a transgression of the policy of an organisation/society.
- The father of an unborn child requests a forensic laboratory to analyse the hair on his partner's hairbrush for heroin without her knowing since she refuses to submit for a drug test. By performing the analysis without her consent, her autonomy and privacy will be disrespected; however, without the information, the father cannot act in the interest of the unborn child.

[123] ML Ambrose 'Drug testing and procedural fairness: The influence of situational variables' (2000) 13 *Social Justice Research.*

[124] KR Murphy, GC Thornton & DH Reynolds 'College students' attitudes toward employee drug testing programmes' (1990) 43 *Personal Psychology* at 615 – 631.

[125] Confusion between moral dilemmas and self-interest sometimes arise, which dilemmas require careful balancing and consideration since the moral obligation does not always have to take precedent, especially if advancing self-interest in the interest of others.

The scope of the four principles of the Principalism approach is broad and provides only a framework for reasoning on ethical dilemmas. These dilemmas can be solved either by *specification* or by *balancing,* with the result a *weighted* one. Specification is a process of narrowing the scope of the four principles to create a rule for a specific situation as opposed to weighing and balancing, which the process of reasoning to motivate support for certain norms. Specification has a perspective of scope and balancing one of relative weight placed on the four principles.[126]

Typical examples of rules created within the respect for autonomy principle, generated by the author are:

- An emergency room doctor is requested to obtain a blood sample from an unconscious patient for a drug test, but obtaining informed consent is an imperative of medical ethics.
- An on-duty state pathologist is requested to draw blood from an arrested person suspected to be under the influence of an intoxicating substance.

A specific rule designed to address this problem can be formulated as follows: "Respect the autonomy of an individual by obtaining written informed consent for prohibited substance tests with competent individuals, except in emergencies and forensic examinations, or in the case where the patient has waived their right of autonomy". This norm will require further qualification as to what constitutes informed consent, an emergency, and a forensic examination.

Balancing the four norms usually has some constraints when taking an ethical decision. Beauchamp proposes six conditions to arise at a reasonable conclusion in case of ethical dilemmas.[127] These are:

[126] Beauchamp & Childress (n 8) 70.
[127] Beauchamp & Childress (n 8) 23.

Table 2:2 Constraints in ethical decision-making

1. There must be sufficient reason to act on a norm which is viewed to have a higher priority in the specific case.
2. The objective of the norm to be followed must have a good chance of achievement.
3. There are no other morally acceptable alternatives available.
4. The lowest level of infringement, in line with the infringement, has been selected.
5. The minimisation of harm principle has been applied to all parties.
6. All parties involved have been treated impartially.

Typical scenarios where the balancing of norms in the regulation and testing of prohibited substances comes into play are:

- Disclosures by private doctors regarding a patient's substance abuse to an employer.
- The decision about whether an organisation should introduce random testing for prohibited substances before taking part in the organisation's activities.
- The nature of a prohibited substance regulation policy in general.

Scenario one: A private doctor obtains information that a patient abuses alcohol and drugs while performing safety- or risk-sensitive tasks daily. Two principles to balance here is the privacy of the patient against the safety of others.[128] The doctor now has to follow a line of reasoning, which involves the following:

The doctor has to decide if the safety of others provides sufficient reason to disclose the patient's drug abuse. Before the disclosure, the doctors must decide if the moral objective of disclosure, which justifies the infringement on the patient's privacy, has a realistic prospect of achievement; typically, if the safety of the individual's colleagues will be enhanced. The doctor must also consider any other alternative actions that can have the same effect as enhancing the safety of others, for instance, voluntary treatment for addiction without the organisation's knowledge. If the doctor then decides to disclose the information, he has to do it in a way that will cause the minimum level of infringement to achieve the goal of safety enhancement and on a need-to-know basis only. Lastly, he should strive towards the principle of "minimisation

[128] *Tarasoff v Regents of the University of California* 17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14 (Cal. 1976) was a case in which the Supreme Court of California held that mental health professionals have a duty to protect individuals who are being threatened for bodily harm inflicted by a patient.

of harm", for instance, that the individual will not be labelled as a drug abuser and be discriminated against and perhaps be terminated by the organisation. All parties affected should also be treated impartially.

Scenario two: An organisation (company, school, sporting body) has to decide if a random substance testing programme has to be instituted for the individuals in the organisation. The principles of autonomy and privacy have to be balanced against the interest of others like safety and financial interests. The organisation may reason as follows:

The organisation has to decide if there is sufficient reason to infringe on the autonomy and privacy of individuals belonging to the organisation. The risk to the health and safety of others or financial interests may constitute sufficient reason to perform random prohibited substance testing. Random testing has been proven to act as an effective deterrent for prohibited substance abuse and, therefore, will achieve the objective of enhancing the health and safety of the individuals and others. There is no other morally acceptable alternative available to ensure that a person does not participate in the organisation's activities after consuming a prohibited substance.

Educational programmes will be a long-term deterrent; however, the organisation has to guarantee the safety of others daily. Performing the random testing in urine or saliva in private with due respect and sensitivity for the individual's dignity will display a minimum level of infringement. Harm may be minimised with a sound scientific testing protocol, reporting procedure and just decisive action. The fact that the interest of all parties (the individual, and the organisation) has to be treated impartially and free of bias speaks for itself.

Scenario three: Confidentiality is central to trust between medical personnel (doctors/sisters and other healthcare workers) and patients. Patients may be reluctant to seek medical assistance if they are not convinced that their information will be treated as confidential. It is for this reason that the clinician responsible for the healthcare of the members in an organisation or company should not be involved in drug tests that may result in punitive action, which may harm the relationship of trust.

2.4 ETHICS APPLICABLE TO PUBLIC POLICY FORMULATION

Laws and public policy are usually related. All laws are considered public policies; however, the reverse is not always true. Suitable policy formulation always requires a moral base to protect the rights of individuals affected by the policy and this also applies to the prohibition of substances where an individual has the right to self-medicate, which is related to autonomy

and right to life. An individual has the right to decide whether he or she wants to consume a substance or not.[129] The relevance of ethics in public policy is well recognised and was illustrated in a recent case in South Africa related to the legalisation of cannabis whereby the Constitutional Court instructed that legislation be brought in line with the notion of autonomy under the CSA.[130]

Public policy often addresses social disagreements, uncertainties and differing interpretations of history. Public policy formulation must take into account the moral norms and should balance aspects such as feasibility, efficiency, cultural pluralism, administrative procedures, legal requirements and uncertainty about risk and non-compliance by the public. Policies should also draw on empirical data and information from fields such as medicine, nursing, public health, veterinary science, natural sciences, economics, law, biotechnology and psychology.

A prohibited substance regulation policy has to take into account the right of an individual to self-medicate, which is related to the 'right to life', but also to the right of others that may be affected by the individual's substance use. It has to be argued based on sound epidemiological and scientific evidence that a policy (statute or private policy) will assist in the decrease of harm to others (and the individual). This should be aimed at the level of the individual as well as a collective level in the form of harm to the organisation or society in general due to financial implications for an organisation (companies, sports organisations) or to healthcare at a national level. Educational programmes and provision of information are also morally viable alternatives to minimise the harm caused by the use of substances, and a balance has to be struck between the lowest level of infringement of the right of individuals to self-medicate and harm caused by substance use/abuse. Policymakers should include only the substances that have been proven to cause harm after all the parameters of harm qualification were taken into account.

The question of the ethical basis of the inclusion of substances in substance prohibition policies has merit, primarily if law and international treaties enforce it. The question can be asked whether it is morally justifiable to prohibit a substance if sufficient evidence does not exist that

[129] It should be kept in mind that an individual's rights are not absolute since rights are limited when the rights of others are compromised, especially their safety.

[130] In the High Court of South Africa (Western Cape Division, CT), Case No: 8760/2013, in the matter between Gareth Prince and Minister of Justice and Constitutional Development, and Case No: 7295/2013, in the matter between JD Rubin and the National Director of Public Prosecution, and Case No: 4153/2012, in the matter between JD Acton and the National Director of Public Prosecution, Judgement: 31 March 2017 by Judge Davis.

the substance poses harm to an individual and society in the Republic of South Africa (RSA), but is listed as a prohibited substance due to international treaties and law. It can be reasoned that since the RSA is part of the global community and has a responsibility towards other countries, the basis of the prohibition of such compounds needs to be assessed.

Another typical example is the prohibition of substances by organisations (companies and sports associations) to enlist a compound based on its legal status. Cannabis, for example, has no ergogenic (enhancement) properties in most sports but are indeed ergolytic; however, cannabis is on the WADA list for all sports for in-competition use. It does pose a threat to fellow competitors in driving-related sports since it impairs alertness and reflexes, which may serve as motivation for the prohibition of cannabis in high-risk sports like motorsport and ski-jumping. Therefore, it may be ethical to prohibit cannabis for specific events or actions but not for all sports. This illustrates the principle that a substance may be prohibited by an organisation only if it is based on a rational ethical decision.

A further moral consideration is the prohibition of substances without providing information on the reasons for its inclusion on prohibition lists. Proactive steps also need to be taken by the organisation in the form of training and education, and information sharing are undoubtedly a valid complementary moral option which will enhance minimisation of harm.

2.5 ETHICAL CLEARANCE AND APPROVAL FOR PROHIBITED SUBSTANCE REGULATION AND TESTING POLICIES

2.5.1 Testing for prohibited substances for compliance purposes vs medical diagnostic tests

The RSA does not have mandatory guidelines for prohibited substance control and testing programmes as opposed to the United States of America[131] and some European countries,[132] The country requires a regulatory framework and guidance on a legally defensible prohibited substance testing protocol that can be applied across all sectors.[133] Testing for the presence of prohibited substances in an individual infringes on his or her fundamental human rights of

[131] Executive Order 12564 Drug-Free Federal Workplace Federal Register 32889-32893 15 September 1986 available at http://workplace.samhsa.gov (Acessed on 15 March 2018).

[132] International Labour Organisation (ILO) 'Appendix V: Guiding principles on drug and alcohol testing' in *Management of alcohol-drug-related issues in the workplace* (1996) Geneva: ILO.

[133] National policy on the management of drug abuse by learners in public and independent schools and further education and training institutions published under GN 3427 in GG 24172 of 13 December 2002.

autonomy, privacy, and bodily integrity. It is also the opinion of the author that false accusations may result in unfair discrimination and injustice.

Prohibited substance tests are not always performed for medical diagnostic purposes with the intention of medical diagnosis and emergency treatment, but is most often performed to ensure that the individual's body and mind are fit for the specific activity to be pursued, for instance in the workplace, sports arena and to prevent harm. Prohibited substance tests performed with the aim of compliance testing may be perceived as related to the medical-clinical diagnostic field due to the overlap of the technology used in both fields, which are also are both performed in bio-matrices or body fluids. It should be kept in mind that in the instance of compliance testing, there is no primary intention to treat the individual medically and that the result does not necessarily contribute to a medical diagnostic paradigm.

A prohibited substance test for regulatory compliance may result in disciplinary action, as opposed to a medical test which will result in the medical treatment of the individual. In compliance testing, it can also be said that there is no doctor-patient relationship as would be the case if there is a prospect of medical treatment. The prohibited substance regulation and testing process as a whole should be approached as a "non-diagnostic bio-intervention", which impacts on the autonomy and privacy of an individual with an "organisation-individual" relationship of trust in addition to the relationship of trust between the individual and professionals and administrators relating to the accurate and fair execution of the policy.[134]

The individual subjected to the prohibited substance regulation and testing programme should first and foremost be considered an autonomous human being and treated with respect to preserving dignity as required by the CSA and as summarised in the ethical guidelines of the HPCSA.

The actions of most individuals involved in practice in the administration of the prohibited substance regulation and testing programme do not fall within the ambit of the NHA and the Health Professions Act [135] that prescribe the ethical and legal requirements of medical interventions on a person in detail. However, the whole body of knowledge pertaining to the ethical and legal aspects in the medical field, as accumulated over many years can be applied to the setting of prohibited substance regulation and testing in humans. The ethical and legal

[134] Reference on the doctor-patient relationship which is one of trust (It is advisable for treating doctors not to perform drug tests for regulatory compliance on a patient due the confidential nature of medical treatment in the doctor-patient medical diagnostic test relationship, which is one of trust.

[135] Health Professions Act 56 of 1974 (HPA).

aspects of medical interventions are well developed and documented to comply with the requirements of the law. Prohibited substance regulation and testing are also an infringement on an individual's basic human rights such as privacy, dignity, and autonomy.

Prohibited substance tests, in general, can be grouped into three categories in terms of its intention or goal with the impact on others. Please see the table below. Medical diagnostic tests have a direct impact on the specific individual to add information to the diagnostic paradigm to benefit the individual patient. On the other hand, tests performed for research purposes have the goal of scientific progress to the benefit of humankind. Prohibited substance regulation and testing are positioned in the middle and have the aim of identifying individuals whose drug-taking behaviour poses a risk in order to minimise the risk that may result in harm to others, the organisation as well as the individual himself.

Type of test	Expected outcome and purpose	Ethical oversight
Diagnostic tests	Diagnostic outcome to the benefit of the patient	HPCSA
Prohibited substances; Regulation compliance testing	Identification and prevention of possible harm/risk to others, organisation and the individual	No ethical oversight currently in South Africa
Research	Scientific progress to the benefit of humankind	Declaration of Helsinki

2.5.2 Medical diagnostic tests and ethical compliance

The ethics of **medical diagnostic** tests are overseen by the HPCSA,[136] to which all professionals in medical fraternity is obliged to be affiliated to by law.[137] Affiliation to this body implies compliance with minimum requirements in terms of education and training, professional conduct and ethical behaviour as well as fostering compliance with standards of the HPSCA.

[136] HPA 56 of 1974.
[137] NHA

2.5.3 Health research tests and experiments and ethical compliance

Health research is performed to improve our knowledge of diseases (current and new) and to find new ways of treating them. The ethical principles for conducting research on humans are primarily based on the Nuremberg Code,[138] which was adopted by the World Medical Association General Assembly in Helsinki, Finland, in 1964 and updated several times by the World Health Organisation (WHO) during 2000 in the form of the Declaration of Helsinki. It has been amended on many occasions, amongst others, during the 48th World Medical Association General assembly in Somerset West in the Republic of South Africa in 1996.[139,140] Please see appendix 7 for the Declaration of Helsinki.

1. "The voluntary, informed, non-coerced consent of a human subject is of prime essence.
2. The experiment should be conducted and designed in such a manner as to yield fruitful results for the good of society, that cannot be obtained by any other means of study and also should also not be conducted at random and be unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

[138] *Nuremberg Code*: https://history.nih.gov/research/downloads/nuremberg.pdf (accessed 16 January 2019).
[139] Declaration of Helsinki: World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects https://www.who.int/bulletin/archives/79(4)373.pdf (accessed 16 January 2019).
[140] EJ Emmanuel, D Wendler & C Grady C 'What makes clinical research ethical?' (2000) 283 *Journal of the American Medical Association* at 2701-2711.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject."

Figure 2:3 Nuremberg Code, 1947

There is a constant need for new medicines or to replace the old ones such as antibiotics in order to counter mutated microbes that have built up resistance to the old antibiotics, for instance. Research concerning the discovery of new medication has the aim of obtaining health information from human beings and animals in the process of testing the safety and efficacy of new medicines. Health research is defined by the NHA not only as medically related research such as the development of new medicines, pathology, causes of disease, but also as research into social and psychological matters of humankind. [141]

Health research may impose risk and harm to the individuals subjected to the research, which imposes an obligation on the researchers to plan the study carefully and to involve a research ethics committee to clear the study before it may commence. Special precautions need to be taken to ensure that vulnerable groups, such as children are not abused. An inability to understand the language while consent is obtained may render even an adult person vulnerable. The research may then be conducted with the written informed consent of the individual.[142]

The danger of personal interest in research is always present due to the burden of duty of care to the research subjects, on the one hand, and the responsibility to humankind, in general, to contribute to human kind's knowledge on the topic being researched, on the other. The interest of society is not always synchronised with the best interest of the participant. Conflict of interest requires special consideration and guard, for instance, researchers may have a self-interest in the form of academic qualifications, or a pharmaceutical manufacturer may have a commercial interest in the study. The fundamental principles of health research are respect for autonomy, beneficence, nonmaleficence, and justice.

[141] NHA sec 69.
[142] NHA sec 71.

2.5.3.1 Minimum requirements for ethical clinical research

Emanuel et al. suggest seven universal principles for ethical research that have to be adapted for the economic, cultural and technological conditions in which clinical research is conducted.[143,144] Howard and Bogle also summarise the factors to be considered in a research application, which are mostly similar to the principles of Emanuel et al.[145] A discussion on the typical requirements of a research protocol was also published by Deutch. [146]

2.5.3.1.1 Social or scientific value

- **"Enhancements of health or knowledge must be derived from the research."**

Ethical clinical research has to be of relevance in the sense that it will contribute to the scientific understanding of the disease and the treatment thereof. It should have a clearly defined outcome and not merely be an end in itself effecting a waste of valuable resources in the form of public money and the exploitation of research subjects. The judgement of relevance will require in-depth scientific knowledge in addition to an understanding of social priorities.

Typical examples of pitfalls for ethical clinical research are: (1) An insufficient review of the relevant literature, (2) the research problem not clearly defined, (3) The prospected results for the study have already been proven by previous research, making the current study not really useful as far as a contribution to society's pool of knowledge related to the research problem.

Any factors that might put the completion of the study at risk, such as patient numbers, costs, and the equipment have to be taken note of, as well as of the outcomes of pilot studies to assess feasibility. Indemnification by no-fault compensation is also a matter that is often overlooked.

2.5.3.1.2 Scientific validity

- **"The research must be methodologically rigorous"**

Sound scientific principles must be applied and validated methods and protocols employed. This also applies to the proper use of statistics to produce reliable and valid results and outcomes. Scientific validity will ensure that scarce resources and public money are not wasted and that the individuals taking part in the programme are not exploited. The researcher has to have an understanding of the application of statistics, and knowledge of the condition that is researched and the population to assess feasibility.

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[143] Emmanuel et al (n 138) 2701-2711.
[144] Moodley (n 28) ch 20 at 329.
[145] P Howard & J Bogle *Medical Law and Ethics, Lecture Notes* (2005) Blackwell Publishing ch 13 at 143.
[146] E Deutsch Medical experimentation: International rules and practice in *Essays in honour of SA Strauss*, (1995) 69 Interpack, Pietermaritzburg.

A scientific study of poor quality does not have a reasonable prospect of producing meaningful results and therefore is unethical. The hypothesis and alternative hypothesis needs to be clearly defined, and the decision criteria must impose sufficient statistical power to give meaningful results. The study design must be applicable, for instance, an interventional, observational, double-blind placebo trial. The inclusion and exclusion criteria are also of prime importance to make a study feasible.

2.5.3.1.3 Fair subject selection

- **"Scientific objectives and the potential for the distribution of risks and benefits should determine communities selected as study sites and the inclusion criteria for individual subjects."**

Selection should be performed in a way that not only prevents the exploitation of vulnerable persons, but that also limits benefits to the socially powerful. This principle is in line with the concept of "justice" of the principalism approach. Compliance with this principle is underpinned by scientific, ethics, and legal knowledge. The researcher should employ expert scientific knowledge and demonstrate a citizen's understanding of social values. Patients may typically be recruited by use of patient databases or public advertisements.

2.5.3.1.4 Favourable risk-benefit ratio

- **"Risks must be minimised, and the potential benefits to individuals and knowledge gained for society must outweigh the risks."**

Nonmaleficence and beneficence should be applied by minimising risks to research subjects to be proportionately small compared to the benefits for both the research subjects and society. A favourable risk-benefit ratio will also contribute to non-exploitation. For example: Is the opportunity to use/or not use any beneficial treatment made clear to the patients, for example, by the continuation of a drug on a named patient basis?

2.5.3.1.5 Independent review

- **"Unaffiliated individuals must review the research and approve, amend, or terminate it."**

This involves an independent review of the study design, risk-benefit ratio, and the intended purpose of the study by independent individuals to ensure public accountability and to avoid conflict of interests. The independent reviewers should have the intellectual ability, financial background, scientific knowledge and knowledge of ethics as part of their skills set.

2.5.3.1.6 Informed consent

- **"Individuals must be informed about the research and provide their voluntary consent."**

Unforced informed consent is of prime importance to respect the autonomy of an individual who has the right to physical integrity and informed refusal.[147] The research subject must have full knowledge of the aim, potential risks and benefits of the research to make an informed decision to take part in the research. A certain amount of scientific knowledge is required to understand the information communicated to the research subject as well as ethics and legal knowledge. The expertise for the evaluation of the aspect of informed consent also requires knowledge of ethics and law. Informed consent is enhanced by (1) clear patient information leaflets, (2) declaring any possibility of undue influence or conflict of interest during the recruitment of the patient and (3) informing the patients of the results of the study.

2.5.3.1.7 Respect for participants

- **"Subjects should have their privacy protected, the opportunity to withdraw and their well-being monitored."**

Respect for research subjects' autonomy can take on various forms, such as: (1) permitting withdrawal from the programme, (2) protection of privacy by abiding to confidentiality, (3) continuous communication with the subjects regarding newly discovered risks and benefits, (4) informing subjects of the results of the research, (5) assisting in their welfare and (6) taking adequate precautions to store the research data for an extended period of time (normally, research data should be made available for reference or verification purposes for at least ten years after the study, or longer if required by a research body.)

2.5.3.1.8 Patient safety

The risks to the patient's safety should be carefully assessed and monitored in accordance with the interventions and treatments employed in the study. Protocols must be in place to contact the investigators in the event of adverse events or, if it is necessary, to break randomisation codes or discontinue treatment as well as for contacting the patient's GP.

2.5.3.1.9 Action policy and publication

Human research ought to be of such a standard that it is publishable.

[147] A Nienaber & KN Bailey 'The right to physical integrity and informed refusal: Just how far does a patient's right to refuse medical treatment go?' (2016) 9(2), *The South African Journal of Bioethics & Law* at 73-77; EJ Emmanuel, D Wendler & C Grady 'What makes clinical research ethical?' (2000) 283 *Journal of the American Medical Association* at 2701-2711.

2.5.3.1.10 Legal compliance

It is a requirement for the research to comply with relevant laws and regulations of a country which is usually in line with that of international treaties such as the Declaration of Helsinki above.

2.5.3.2 Legal framework for health research in the Republic of South Africa

A combination of ethics, human rights and the law are employed to protect individuals from harmful research and from being abused in the process. The CSA, which is the overarching law of the land, instructs respect for human dignity, privacy, autonomy, and other rights. One of the prime sections for research is section 12 on the freedom and security of the person, which protects people from unlawful and abusive research. This section implies that individuals have the right to make their own decisions about their bodies and by implication, also to what extent they want to take part in the research. Informed consent as part of autonomy and, by implication also privacy, is of prime importance for the research subjects to exercise this right.

Research is also directed by statutes, common law, and the CSA. Three cases are employed as common law for a doctor to obtain informed consent for medical treatment, namely *Stoffberg v Elliot,*[148] *Castell v D Greef* [149] and *C v Minister of Correctional Services*.[150] Consent has also been addressed in the NHA which stipulates that a person must be informed of the possible risks, benefits and procedures during the process of obtaining consent, a full disclosure.[151]

The NHA has brought into life the National Health Research Committee (NHRC) and the National Research Ethics Council (NHREC). The NHREC has the authority to prescribe guidelines regarding the functioning of research ethics committees, may register and audit health research ethics committees, set norms for conducting research on humans and animals, adjudicate complaints about health research ethics, and institute disciplinary action against any person who is found to be in violation of the norms and guidelines for conducting research, amongst others.[152] The NHA also makes provision for the establishment of health research ethics committees at institutions, health agencies and establishments which also have to be registered formally with the NHREC.[153]

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[148] Stoffberg v Elliot 1923 CPD 128.
[149] *Castell v D Greef* 1994 (4) SA 408 (C).
[150] *C v Minister of Correctional Services* 1996 (4) SA 292 (T).
[151] FWW van Oosten 'The law and ethics of information and consent in medical research' (2000) *Tydskrif vir die hedendaagse Romeins Hollandse Reg* at 5-31.
[152] NHA sec 69(6).
[153] NHA sec 73.

The NHA also addresses the issue of research to be conducted on minors, which calls for the best interest of the minor, consent of the parent or guardian of the child and whether the minor is capable of understanding that he or she has to provide consent.[154]

2.5.4 Prohibited substance regulation and testing ethical compliance

There is no formal body or ethical committees for prohibited substance regulation and testing with the aim of ethical clearance and oversight in the RSA. Ethical aspects outside the medical/clinical setting are not always respected and understood by non-medical people who are responsible for the administration of prohibited substance regulation and testing programmes. The medical professions have set the bar for the minimum standard of ethics to be complied with by non-medical people in prohibited substance testing programmes. The basic principles of medical ethics and research are directly applicable to prohibited substance testing programmes as a whole, which is not part of the medical diagnostic/emergency testing regime.

The administrators and support personnel of such a programme also have to comply with ethical principles similar to those of biomedical intervention. A prohibited substance regulation and testing policy have much in common with the minimum requirements for research experiments and proposals which require ethical clearance by law, as discussed above.

*The author proposes that **ethical clearance** for prohibited substance regulation and testing programmes in South Africa should be instituted or enacted for all organisations involved as a non-negotiable requirement before the onset of testing. The policy should be based on the four principles of autonomy, beneficence, nonmaleficence, and justice.*

2.5.4.1 Minimum requirements for prohibited substance regulation and testing

The author furthermore suggests that the ***universal*** principles of ethical clinical research discussed above can be directly applied in a prohibited substance regulation and testing programme. It should also be kept in mind that the requirements for each industry may differ and therefore adaptation of the principles may be required, A "one-size-fits-all" approach may not be suitable to ensure a suitable ethical approach in all the different types of sectors and settings.

[154] NHA sec 71(2)

2.5.4.1.1 Social or scientific value

"Enhancements of health and safety, risk minimisation and useful information must result from the prohibited substance regulation and testing program."

A prohibited substance regulation and testing programme must contribute to risk minimisation and must have a clear objective of improving health and safety in an organisation. The enlisting of substances to be prohibited and the testing thereof should be in line with this goal to prevent wasting of an organisation's valuable resources and prevent the exploitation of subjects in the programme and eventually cause more harm than good to all involved.

(a) Factors to consider in the assessment of social and scientific value in an ethical application

- Has the phenomenon of prohibited substance regulation and testing been systematically reviewed from literature?
- Does the organisation have a formal policy that has been accepted by the subjects and the organisation?
- Why is a prohibited substance regulation and testing programme required?
- What are the aims of such a programme in the organisation?
- Will the prohibition of substances and the testing thereof in the subjects genuinely contribute to the aims of the programme?
- Are there less invasive procedures available to obtain the same information?

2.5.4.1.2 Scientific validity

"The prohibited substance regulation and testing program must be methodologically and scientifically rigorous."

The null hypothesis, from an ethical point of view, is that an individual is not guilty until the contrary is proved. This approach will endorse the fact that a prohibited substance regulation and testing programme is not a policing exercise, but rather one of risk minimisation and rehabilitation. The notion of disciplinary action will act as a deterrent; however, this should be the last option. The study can be classified as an observational study since the subjects will be tested for compliance. The duration of the study will be infinite due to the ongoing nature of a prohibited substance regulation and testing programme.

The inclusion criteria should typically address those individuals in safety-sensitive or risk-sensitive positions who may pose a possible risk to the organisation's goals such as health and

safety, organisational image or brand, or other interests of the organisation. Those who do not pose a threat to the organisational goals may be excluded.

The substances that are prohibited and the rate of subject testing have to be of such a nature that it will lower the risk to acceptable and realistic levels. The incidence of drug use, as well as the type of substances used, may be obtained from a pilot study. Statistical calculations will aid in the calculation of the testing frequency and the number of subjects to be tested to obtain a required level of statistical significance or statistical power. A statistical power of P = 0.05 will imply that 95% of the individuals, each posing an equal risk to the organisation, will not have prohibited substances above be allowed threshold concentrations and will be allowed to take part in the organisation's activities. It should be kept in mind that 5% of the test population will escape detection, for instance, will be "false negatives" (FN) at a statistical significance of 95%.[155]

An increase in statistical power is an inevitable result if the risk to the organisation's interests is high. For example, if more individuals with a history of drug abuse is employed, testing will have to be perfomed more frequently before they will be allowed to take part in the organisation's activities. In such an instance, the statistical power will become typically P = 0.01 (99%) or P = 0.001 (99.9%). It is important to note that the uncertainty has its origin in both the subject selection and the testing protocol.

Subject allocation to testing groups may be a result of risk assessment, with those groups in risk-sensitive, risk-sensitive positions the highest priority, with the highest frequency of testing. Allocation of groups selected for testing may also be a result of information that was obtained which indicates the high incidence of use of specific substances by the test population, such as ethanol and cannabis.

It is essential to have sufficient resources in terms of funds and instrumentation allocated to the prohibited substance regulation and testing programme. Insufficient resources and funds may result in inadequate testing and the exploitation of individuals. Unrealisable test results and conclusions may be one of the consequences of inadequate funding and may lead to false accusations, amongst others.

It is also an ethical requirement that the information regarding prohibited substance use cannot be obtained in any reliable and less invasive way. In a prohibited substance testing

[155] JN Miller & JC Miller *Statistics and chemometrics for analytical chemistry* 6th ed (2010) 26 Pearson Hall.

environment, this aspect becomes applicable; for instance, when a compliance test can be performed in urine as opposed to blood, which is much more intimate and invasive.

Scientific correctness is of the utmost importance to obtain reliable and accurate test results.[156] Sound decisions and decisive actions cannot be taken if the programme does not comply with scientific correctness. This bares relation to all aspects of a prohibited substance regulation and the testing programme should be scientifically correct. Enlistment of substances, sampling, analytical testing and reporting, interpretation and validation of test results should all be performed in a scientifically correct fashion to prevent the test subjects from being exploited and treated unethically and unfairly.

(a) Factors to consider for scientific validity in an ethical application

- What is the hypothesis to be tested?
- What type of study is involved?
- What is the duration of the programme?
- What are the inclusion and exclusion criteria?
- Does the programme have sufficient statistical power to provide meaningful results and has statistical advice been sought during the design of the programme?
- How will the participants be allocated to testing groups? What are the randomisation procedures?
- Will there be any factors that might put the programme at risk? For instance, costs or equipment? Was there a pilot study to assess feasibility?
- Are there viable alternatives to obtain the same information?
- Are all phases of the programme scientifically correct?

2.5.4.1.3 Fair subject selection

"Subject selection must be based on risk sensitivity."

Objectives should be directed to risk sensitivity and the advancement health and the distribution of risks and benefits should determine which groups should be selected according to the inclusion criteria for selection of individual subjects. Selection of subjects has to be fair, which requires that equals should be treated similarly and that both the benefits and burdens should

[156] *Twine and Another v Naidoo and Another* 2018 (1) All SA 297 (GJ).

be distributed fairly.[157] Vulnerable individuals should not be exploited, and the more influential individuals should not be advantaged. Test subjects selection should be based on a random basis instead of a management's decision. Individuals posing a higher risk, such as rehabilitated drug abusers and alcoholics, may be selected for testing more often with the necessary sensitivity for their dignity and privacy. A discriminatory subject selection must be eliminated such as individuals who use the prohibited substances for religious rituals; however, risk minimisation is of prime importance.

(a) Factors to consider for fair subject selection in an ethical application

- How will the test subjects be selected and allocated to testing groups?
- Has the possibility of discrimination against vulnerable groups been eliminated?
- What are the randomisation procedures?
- What is the expected testing rate?

2.5.4.1.4 Favourable benefit-risk ratio

"Benefit in risk minimisation for the subject as well as for the organisation must outweigh the potential risks of no substance regulation and testing program."

The potential benefits from a prohibited substance regulation and testing programme for both the individuals and the organisation should outweigh the risks. Risks to the individuals involve the invasion of their rights such as privacy, dignity and autonomy. The benefits should be centred around on the minimisation of the risk to the individual as well as for the organisation in terms of health and safety. The principles of beneficence and nonmaleficence should guide the maximisation of the benefit-risk ratio.

(a) Factors to be considered to enhance the benefit-risk ratio in an ethical application

- What are the actions taken to prevent the invasion of human rights?
- What are the risks to the individuals and the organisation?
- What are the benefits to both the individuals and the organisation?
- Do the benefits outweigh the risks?

[157] Emmanuel et al (n 138) 2701-2711.

2.5.4.1.5 Independent review

"Unaffiliated individuals must have the authority to review the prohibited substance regulation and testing program policy and approve, amend, or terminate it."

The relationship between the organisation and the individuals subjected to a prohibited substance regulation and testing programme is unsymmetrical since the organisation is in a position of power. Conflicts of interest, therefore, should be guarded against by a sound policy which fosters sufficient independence between the various role players, such as by separating the powers of the administrators involved in the various stages of the regulation and testing programme.

Independent review by an ethical committee for prohibited substance regulation and testing programmes will also be an effective way to enforce ethical compliance. Such a committee, consisting of individuals with a range of expertise, should have the authority to approve, amend or terminate a study.

2.5.4.1.6 Informed consent

"Individuals must be informed about the prohibited substance regulation and testing program and provide their voluntary consent."

The Nuremberg Code refers to the requirement of voluntary informed consent that should be obtained in a non-coerced fashion.[158] Informed consent ensures that individuals submit to the programme when it is in alignment with their own values, interests and preferences.[159,160,161,162,163,164] Individuals have to be accurately informed of the purpose and protocols of the prohibited substance test, and also have a certain understanding of the information before making a voluntary, un-coerced decision to submit to the prohibited substance regulation and testing programme. The concept of informed consent was discussed in Chapter 2 under the principle of autonomy.

(a) Factors to be considered when obtaining informed consent in an ethical application

- Was the policy explained and accepted by the subject?

[158] *Nuremberg Code* https://history.nih.gov/research/downloads/nuremberg.pdf (accessed 16 January 2018).
[159] Dworkin (n 23).
[160] Beauchamp & Childress (n 8) ch 3.
[161] RD Troug, W et al 'Is informed consent always necessary for randomized controlled trials? (1999) 340 *New England Journal of Medicine* at 804-807.
[162] GJ Annas 'The changing landscape of human experimentation' (1992) 2 *Health Matrix* at 119-140.
[163] Council for International Organisations of Medical Research Involving Human Subjects, Geneva, Switzerland 1993.
[164] The Nuremberg Code (1996) 276 *Journal of the American Medical Association* at 1691.

- When will informed consent be obtained?
- Will it be obtained in a voluntary and non-coerced fashion?
- Will the individual's consent be recorded in writing?
- Will the information be understandably explained to the individual?
- How will consent be obtained from minors and other vulnerable individuals? (Discretion proxies.)
- Will the individual provide consent as to who may receive the test results? (Designated persons.)
- Will the participants be informed of the results?
- Is there any possibility of undue influence or conflict of interest in the selection of the test subject?

2.5.4.1.7 Respect for the prohibited substance testing program participants

"Test subjects should have their privacy protected, have the opportunity to withdraw and their well-being monitored"

Respect for participants involves respect for their fundamental, human rights such a dignity, freedom, autonomy and privacy. Test subjects must voluntarily submit for a drug test by providing consent, and they may withdraw at any stage of the process since consent is a continuous process. Test results should be kept confidential and disclosed on a need-to-know basis only and with the consent of the individual involved. Obeying the rules of obtaining consent, keeping test results confidential and respect for the individual's privacy all relate to respect for the individual's autonomy. Respect for autonomy should also be exercised even if the individual refuses to provide consent for a prohibited substance test.

(a) Factors to be considered when assessing respect for prohibited substance regulation and testing participants in an ethical application

- Will the subjects have visual and auditory privacy during the process of specimen donation and the MRO interview?
- How is participant confidentiality protected?
- How is data stored and transmitted?
- How long will data be stored?

- Will there be an opportunity for the participant to seek help without penalty?

2.5.4.2 Action policy, expertise and professionalism, participant safety and legal compliance

2.5.4.2.1 Action policy

"Action against prohibited substance use should take the form of a "zero tolerance" stance for validated and illegitimate (knowingly) prohibited substance use that poses a risk to health and safety"

A formal stand-down policy is required when a subject's preliminary test result is non-negative. A non-negative preliminary test result can be viewed as a reasonable objective suspicion that the threshold concentration for a specific substance in an individual's bodily fluid may have been exceeded. Allowing the individual to take part in the organisation's activities may increase risk, which requires the individual to be temporarily removed from the risk-sensitive task until the confirmation test result becomes available and is validated by the MRO. No decisive action should be taken based on a non-negative test result other than removing the individual from the risk-sensitive task.

A zero-tolerance stance should be applied for all validated, illegitimate prohibited substance use, which poses a risk to the activities of the organisation. Decisive action should be taken according to a documented policy.

(a) Factors to be considered for an action policy in an ethical application

- How will the test results be used?
- Does the organisation have a written stand-down policy?

2.5.4.2.2 Necessary expertise and professionalism

All the professionals involved, such as the specimen collection officer, BAT, DER, forensic confirmation laboratory and personnel, and MROs, should be fully qualified to comply with the professional standards of corresponding regulatory bodies.

(a) Factors to be considered to evaluate expertise and professionalism in an ethical application

- What are the qualifications and the professional attributes of all the persons involved in the administration of the program?
- Are the professionals all registered at a professional regulating body?

- Are there suitable arrangements for no-fault compensation?
- How are the investigators indemnified?

2.5.4.2.3 Participant safety

Safety of participants is always of prime importance.

(a) Factors to be considered for participant safety in an ethical application

- What are the safety issues for participants?
- Are the facilities for specimen collection of such a standard that it complies with hygienic clinical standards?
- Is there a formal medical-waste disposal programme?

2.5.4.2.4 Legal compliance

"The prohibited substance regulation and testing program and policy should comply with the legal framework of the Republic of South Africa."

Table 2:3 Factors to be considered in a prohibited substance regulation and testing programme ethical application. [165]

Principle	Justifying ethical values	Expertise required for evaluation
Social or scientific value	Scarce financial resources and non-exploitation	Scientific knowledge; understanding of the organisation's priorities
Scientific validity	Scarce financial resources and non-exploitation	Scientific and statistical knowledge; understanding of prohibited substance use and regulation
Fair subject selection	Justice	Scientific, ethical and legal knowledge
Favourable risk-benefit ratio	Nonmaleficence, beneficence, and non-exploitation	Scientific knowledge; understanding of the organisation's priorities
Independent review	Accountability and minimisation of potential conflicts of interest.	Intellectual, financial, independent experts, scientific, ethical and legal knowledge
Informed consent	Respect for subject autonomy	Scientific, ethical and legal knowledge
Respect for participants	Respect for subject autonomy and welfare	Scientific, ethical and legal knowledge; an understanding of the subject population

[165] Emmanuel et al (n 138) 2701-2711.

2.6 CONCLUSIONS: ETHICAL ASPECTS OF PROHIBITED SUBSTANCE REGULATION AND TESTING IN HUMANS

Prohibited substance regulation and testing in humans can be seen as a biomedical intervention on an individual which may violate his or her right to privacy, dignity, autonomy and freedom to use substances for medicinal, recreational and enhancement purposes. The field is flawed with ethical dilemmas which can be solved by employing the principalism approach, as suggested by Beauchamp and Childress, which involves respect for autonomy, nonmaleficence, beneficence and justice.

Informed consent, as one of the conditions for autonomy, is of prime importance for prohibited substance regulation and testing in humans. It is therefore also required that the threshold elements, competence, and voluntariness are met before an individual is subjected to a prohibited substance test. Confidentiality is a prime element of the complete process, as well as truth-telling and effective communication with the test subjects.

Nonmaleficence should be in balance with beneficence as required by the Hippocratic Oath, and the rules of nonmaleficence must be stated unambiguously in a prohibited substance regulation and testing programme. All role players have a duty of care, and negligence should be avoided at all cost, in the interest of both the individual and the organisation. Individuals who are incompetent to make autonomous decisions, such as children, maybe assisted by surrogate decision-makers when providing consent for a prohibited substance test; however, care must be taken that the surrogate is not biased or subjective or acts paternalistically.

Justice, which finds application in the forms of legal justice, rights-based justice, distributive justice, procedural justice and social justice is essential for the programme to be regarded as ethical.

A prohibited substance test on an individual infringes on his or her fundamental human rights of autonomy, privacy, bodily integrity and may result in false accusations, discrimination and injustice. Prohibited substance tests are mostly performed to monitor compliance, although it may be perceived as related to the medical-clinical diagnostic field due to the overlap of the technology and also since bodily fluids are employed for both. Compliance tests do not necessarily contribute to a diagnostic paradigm, and therefore, is strictly speaking not a “medical diagnostic” test with a health worker-patient relationship. Random prohibited substance tests are often performed to ensure that the individuals’ body and mind are fit for the specific activity to be pursued, for instance, in the workplace and sports arena to prevent harm.

A prohibited substance test for regulatory compliance may result in disciplinary action as opposed to a medical test which will result in the medical treatment of the individual.

The tests are also not always performed by individuals and organisations that are skilled and sensitive to treat an individual in the correct ethical fashion.

It was suggested by the author that ethical oversight is instituted by statute, at a standard equivalent to that of ethical clinical research which is aligned with the Nuremberg Code. The minimum requirements for ethical clinical research were reviewed and employed to draft minimum ethical standards for prohibited substance regulation and testing. Ethical principles, corresponding ethical values and required expertise to evaluate ethical compliance of organisations were proposed.

CHAPTER 3:

PROFESSIONAL ASPECTS RELATED TO PROHIBITED SUBSTANCE REGULATION AND TESTING IN HUMANS

3.1 PROFESSIONALISM APPLICABLE TO PROHIBITED SUBSTANCE REGULATION

The principles of respect for autonomy, beneficence, nonmaleficence and justice find application in relationships between professionals/administrators and individuals as subjects in a prohibited substance regulation and testing programme by the rules of veracity, privacy, confidentiality, and fidelity.[1] The professional services in a prohibited substance regulation programme include the MRO and his or her assistants, specimen collection officer, forensic scientists and laboratories, BAT and DER.

3.1.1 Veracity

Veracity can be defined as the: "accurate, timely, objective, and comprehensive transmission of information, as well as to how the professional fosters the subject's "understanding" throughout and after the intervention."[2] Veracity is a premise that needs to be maintained due to its central role in the relationship of trust between a professional and a subject of a prohibited substance regulation programme. It stems from respect for autonomy, promise-keeping, and contract, which is invoked when the professional enters into a relationship of trust that is initiated by communication with an individual. The individual then has a right to truthful information regarding results and analytical procedures. Similarly, the professional (MRO) has the right to honest disclosures from the individual. In the field of compliance drug testing, truthful disclosure is not *prima facie*, but binding and absolute if the individual is voluntarily committed to the programme policy. All the professionals involved (and the organisation) should ensure that the result of a drug test is available timeously, with objective and proper analytical procedures and protocols. The results need to be communicated and explained to the individual in an understandable way.

If an incorrect test result is uncovered that resulted in an incorrect decision by the MRO/forensic scientist/BAT, he or she has to disclose the error to the individual even after

[1] TL Beauchamp & JF Childress *Principles of biomedical ethics* (2013) Oxford University Press at 302.
[2] Beauchamp & Childress (n 1) 302.

decisive/disciplinary action may have been taken in order to foster transparency, respect, and accountability. A significant non-conformance in the forensic laboratory, which is defined as "a deviation of any parameter from the normal range within which the analytical method was validated in the laboratory that may have affected the test result" needs to be treated similarly.

If a doctor is in the service of an organisation/third party that provides healthcare, the boundaries of the doctor's duty of care may become diffuse. If a company, for instance, has contracted a doctor to perform pre-employment medical screening to provide information related to the individual's fitness for duty, drug testing is sometimes performed. With the moral of veracity requiring accurate information such as correct test results, in this case, the doctor should ensure that the results of the tests are accurate. If the analyses were performed in-house with preliminary screening tests, which are prone to cross-reactivity (which means that some other compound may cause an FP result), an unreliable non-negative test result should not be offered as a reason for declaring the applicant unfit for duty. The doctor has to ensure accurate and reliable test results by sending the specimen for further confirmatory analysis.

3.1.2 Privacy

Privacy and confidentiality are deeply rooted in the principle of respect for autonomy and are prime elements of compliance testing in a prohibited substance regulation programme and its administration. Confidentiality is, in principle, effected by respect for privacy. The concept of privacy implies that the subject has the right to controlled access. A number of forms of privacy exist, namely: (1) informational privacy (2) physical privacy (personal space/locational privacy), (3) decisional privacy (personal choices), (4) propriety privacy (property interests like person's image), and (5) relational/associational privacy. [3]

With this wide range of different types of privacy, a prohibited substance regulation policy should comply with the limits of privacy or the specific type of privacies that has to be respected and not violated. In this setting, privacy as limited access to information usually involves bodily information like private substance use, drug test results, and other private information like prescription medication and chronic illnesses like HIV. The policy has to delineate the rules of what will be viewed as a loss of privacy and whatnot. A drug testing policy has to acknowledge the right to private drug use; however, an individual may be tested with his or her consent, and disclosures may also be made only to third parties with his or her consent. Based on respect for autonomy, it is unethical for the MRO or forensic scientist to

[3] Beauchamp & Childress (n 1) 312.

disclose the result to the employer without prior consent and agreement by the individual. The individual should always be allowed the opportunity to *opt-out* of the regulatory process at any stage before disclosure of test results takes place.

It has to be kept in mind that the right to privacy is not absolute and has to be balanced with other relevant factors such as the safety of others. Disclosure of a drug test report by an MRO or occupational health doctor without the consent of the individual may be a proportionate and justifiable measure to protect the health and safety of others.

Violations of an individual's privacy may also be caused by the extent of access to test reports, who has access, through which means, and about which aspect of an individual.[4] An example of such a violation in drug testing that takes place in South Africa quite often is the case where a pathology company would act as a third party for a prohibited substance compliance test by overseeing the urine specimen collection in a private company. The specimen is then shipped to their laboratory from where it is sent to a forensic laboratory for a confirmation test, which then sends the test result back to the pathology company where the test result is transcribed into their report format and made available to the company's occupational health representative. The violation of privacy occurs if the subject has not provided consent for the data transmission process that took place in the pathology laboratory whereby a third party gained access to the private information on the drug testing report.

3.1.3 Confidentiality

The right to confidentiality is violated if the confidant fails to protect or deliberately disclose information that the confider confidently disclosed to him and had a reasonable expectation that the information would be kept confidential. In the example involving the pathology company above, privacy is violated by the person performing the data transcription onto the pathology company's report, but the company violated the right to confidentiality since they failed to keep the information confidential. A further example of breach of confidentiality involves the sharing of passwords to gain illegitimate access to laboratory test results by persons who are authorised and designated by the subject to receive the test results from a confirmation laboratory.

Confidentiality is continuously under siege in modern-day practice since it is common for institutions to store confidential information electronically. Drug test reports are stored and

[4] F Charles 'Privacy: A rational context' (1968) 77 *Yale Law Journal* at 475-493.

transmitted electronically from the confirmation laboratories to the MRO or institutions, during which unwanted access may violate the right to confidentiality.

Legal rules may define the limits to confidentiality, typically when the life of others are endangered in a safety-sensitive environment due to the drug-taking behaviour of an individual. In this instance, disclosure to a third party is not regarded as a breach of confidentiality due to the original intention with which the information was gathered. If the context was to ensure that the interests of fellow athletes and the International Athletic Organisation are protected, then the disclosure of drug testing results are not regarded as a breach of confidentiality. The limits of confidentiality can also be established by contract, which should spell out the limitations to confidentiality. In the case of an athlete, the contract will be the policy as prescribed by WADA that is agreed upon by the individual and the International Association of Athletics Federations (IAAF).

3.1.4 Fidelity

Fidelity is an essential norm in the relationship between the professional and the individual if the individual is a patient where a doctor-patient relationship of trust evolved with a concomitant duty of care. Compliance with the obligation of fidelity requires the doctor to remove self-interest that may be in conflict with the patient's interests and that he prioritises the patient's interests over that of a third party. In a prohibited substance regulatory environment, this implies that the professional sampling officer (sister), the MRO and his assistants may not be in the service of the organisation to which they also owe loyalty. This conflict of interest manifests itself in South Africa in abundance where the occupational health sister and doctor fulfil the roles of collection officer and MRO. The HPCSA requires that the conflict of interest be declared to the patient, which may result in the patient choosing another doctor. In a workplace drug regulation environment, the employee then has no other option than to submit to the request of the occupational health doctor/sister, which constitutes an unwanted coercive situation from the perspective of the employee.

The duty-of-care and fiduciary relationships become less defined for doctors in the service of an organisation that does not provide healthcare. A typical example would be where the doctor is contracted to provide medical information about applicants after a pre-employment medical examination or for an insurance company to assess their risks. The patient must be informed of the doctor's third-party relationship, and the patient has to give consent concerning the information that will be disclosed to the third party or company. Drug testing for compliance

has an inherent potential of violating fidelity, since the disclosure may end up in disciplinary action, as opposed to medical treatment.

3.2 PROFESSIONAL STANDARDS: ETHICAL STANDARDS, QUALIFICATIONS AND REGISTRATION

Professional councils usually aim to regulate a specific profession or a group of related professions in aspects about registration, education and training, professional conduct and **ethical behaviour**, ensuring continuing professional development, and fostering compliance with standards of the occupation. It is of prime importance to realise that professional registration at one of these councils is in principle a certification process which ***excludes*** individuals who do not comply with a minimum set of criteria. This should not be confused with an ***all-inclusive*** philosophy of organisations aiming to advance the interest of a specific occupation only. Professional registration requirements in principle aim to be exclusive rather than inclusive. A professional council may also strive to advance the interest of the occupation; however; the end goal differs in principle from other learned organisations.

The Substance Abuse and Mental Health Services Administration of the USA's (SAMHSA), mandatory guidelines for the USA, prescribe the following professionals to be involved in a prohibited substance regulation and testing programme for workplaces. These professionals are directly involved with the individual during the pre-testing, testing and post-testing phases and fulfil the following functions: (1) collection officers, (2) forensic toxicologists and scientists, (3) BAT, (4) MRO and assistants, and (5) DER.[5] It is a requirement for all these professionals to comply with professional standards that dictate respect for autonomy, including consent, privacy, confidentiality, and dignity, amongst others, as discussed above as well as to have the required minimum level of training.

The figure below illustrates the role of the professionals in the sequence of events during a prohibited substance test.

[5] Substance Abuse and Mental Health Services Administration (SAMHSA), https://www.samhsa.gov/workplace/workplace-programs (accessed 17 April 2019).

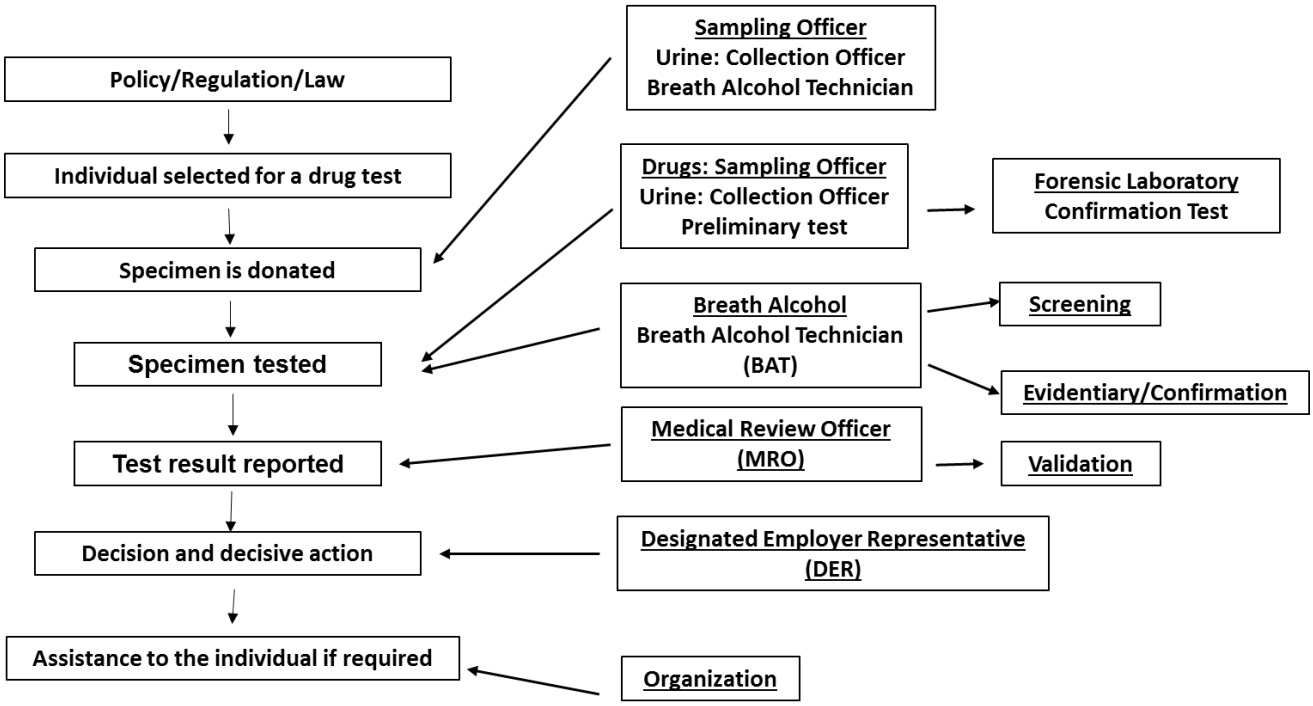

Figure 3:1 The sequence of events during a prohibited substance test

3.2.1 The ideal ethical code

According to Upshaw Downs, the ideal ethical code should accommodate the following:[6]

- Accepted and validated ethical norms should be published in codes of conduct that should be enforceable and binding on all parties.
- A continuing education programme is requiring the members to stay current with their knowledge that is enforceable.
- The code must be available to all the practitioners and other interested parties.
- A mechanism to pre-emptively and pro-actively judge ethical decision-making and conflicts in the profession, for example, by way of an ombudsman.
- The code must comply with the applicable laws and should mandate reporting of criminal violations, with reasonable suspicion.
- Disciplinary processes and investigations should be open, fair and neutral with reasonable respect for confidentiality to not allow the professional to be trialled by the public in advance, and that allows for the trial of fact and not opinion. There must be a separation of powers, which implies that the investigator should not be allowed to be the

[6] JC Upshaw Downs & AR Swienton 'Ethics codes in other organisations: Structures and enforcement' in JC Upshaw Downs & AR Swienton (eds) *Ethics in forensic science* (2012) 189 Elsevier.

judge and the executioner simultaneously. The person who settles a dispute or has ultimate authority in a matter should be someone who is involved in the management the professional reports to.

- Notice of disciplinary action should be given to the accused professional for him or her to respond accordingly and to prepare a possible hearing where both parties present the facts.
- An appeal mechanism to an independent authority in case of a breach of the code finding.
- If the breach of conduct is serious, it should be dealt with accordingly.

3.3 COLLECTION OFFICERS

3.3.1 General role of a collecting officer

The primary function of a collection officer in a prohibited substance testing programme is to collect a specimen in a *legally defensible* fashion by assuring the integrity of the specimen and collection process.[7] This individual has direct face-to-face contact with the subjects of the programme and must follow a protocol that guarantees the integrity of the specimen and that is consistent with ethical, scientific and legal principles. The collection official also has to be alert to possible tampering with the specimen. After the specimen was donated, the official has to perform a preliminary onsite screening test, after which a confirmation test is required. The official also has to understand and appreciate the chain-of-custody protocols to support a sound chain of evidence.

3.3.2 Ethical and professional standards for collection officers

The ***biomedical*** ethical and moral obligations related to the specimen collection officer involve veracity, respect for privacy, confidentiality and fidelity, as discussed in section 3.1 above. Without the collector's sensitivity to an employee's privacy and dignity, the entire testing programme may be subject to criticism. The official must address the individual in a kind and friendly manner that is consistent with respect for dignity while obtaining voluntary informed consent and explaining the procedure to the subject. All communication must be in an environment that allows for visual and auditory privacy. The donor's privacy must be respected by allowing him or her to donate the specimen in private, but still sufficient to detect any efforts

[7] https://www.transportation.gov/sites/dot.gov/files/docs/Urine_Specimen_Collection_Guidelines_July3_2014_A.pdf (accessed 23 August 2018).

of tampering by the donor. Observed specimen collection is an invasive strategy; however, it can be motivated if the donor was found to have tampered with a specimen.

The specimen collector has to keep in mind that the donor can withdraw from the process due to his or her right to autonomy. In such a case, the officer must record the event and report it to the organisation's representative (DER) who in turn will convey the information to the management of the organisation.

3.3.3 Educational and training requirements

The specimen collection official must be skilled in all the aspects of a legally defensible specimen collection.[8,9] He or she must have a basic overall knowledge of the prohibited substance policy and, more specifically, knowledge regarding the collection of biological specimens for drug testing and preliminary onsite testing. He or she must understand best practice principles to ensure privacy and confidentiality as well as respectful communication about the activities and non-negative preliminary test results. Proper record-keeping is imperative. The practice of specimen collection must comply with internationally recognised standards and precautions in healthcare settings to ensure that the health and safety of the subjects and specimen collection officials are not compromised.[10,11] The specimen collection officer who will be using screening devices must demonstrate as part of a mock test, that he or she can discern changes, contrasts, or readings correctly.

3.3.4 Professional councils for specimen collection officers

There are currently no professional boards that regulate the registration, education and training of collection officials for prohibited substance testing in South Africa. It is the opinion of the author that this profession should be regulated by the HPCSA due to the direct and intimate contact these individuals have with the subjects and the concomitant ethical standards they have to live up to.

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[8] *Urine specimen collection handbook for federal agency workplace drug testing programs* 14 May 2014 https://www.samhsa.gov/sites/default/files/specimen-collection-handbook-2014.pdf (accessed 9 November 2017).

[9] World Anti-Doping Agency *ISTI urine sample collection guidelines* https://www.wada-ama.org/sites/default/files/resources/files/wada _guidelines_urine_sample_collection_2014_v1.0_en.pdf (accessed 9 November 2017).

[10] *Sample collection personnel: Recruitment, training, accreditation and re-accreditation guideline, Version 2.0* July 2006 https://www.wada-ama.org/sites/default/files/resources/files/WADA_Guidelines_SampleCollectionPersonnel_EN.pdf, (accessed 9 November 2017).

[11] US Department of Transportation *DOT's 10 steps to collection site security and integrity* https://www.transportation.gov/odapc/dot-10-steps-collection-site-security-and-integrity-english (accessed 2 December 2017).

HPCSA registered occupational health sisters may fulfil this function, but they may have an established trust relationship with the individual, resulting in a conflict of interest. The same rules apply to an occupational health sister as for a doctor in terms of declaring the conflict of interest regarding third-party interest.

The fact that the urine specimen is not collected for purely diagnostic purposes may imply that officials, other than HPCSA registered phlebotomists, may collect a less intimate biospecimen, like urine. The collection official has to be bound by some form of ethical code of conduct which will prescribe ethical behaviour in the course of his or her duties. Such ethical code may be part of the collection official's employment contract.

3.4 ANALYTICAL TOXICOLOGY SERVICES

3.4.1 Forensic toxicologist/scientist

3.4.1.1 General role of the forensic toxicologist/scientist in a prohibited drug regulation programme

The National Academy of Science summarises the role of a forensic scientist as follows:

> "Forensic professions involve the examination or scientific analysis of evidence and related testimony. They apply principles, techniques, and methods of science, to determine the facts and formation of opinions that may be significant in legal cases. In fulfilling these duties, forensic scientists should use all of the means at their command to ascertain the facts relevant to the matters under investigation. Having made factual determinations, forensic scientists may then interpret and evaluate those facts. Forensic scientists should practice within the limitations of their knowledge, skills, and abilities. The forensic scientist should be guided by those practices and procedures that are generally recognised within the profession to be consistent with a high level of professional ethics." [12]

The field of analytical toxicology involves the detection, identification and quantification of drugs and xenobiotics (and metabolites) in biological fluids. In prohibited substance regulatory testing, the array of drugs is narrowed down to the substances that are enlisted and prohibited by policy. The forensic toxicologist must have the ability to communicate effectively with his or her clients, which may vary from clinicians, MROs, police, forensic pathologists. This

[12] American National Academy of Sciences *A model code of professional conduct in the forensic sciences* http://www.cacnews.org/policies/Model_for_NCPC.pdf (accessed 17 November 2017).

professional must also be able to provide competent and professional testimony in court regarding the analytical procedures and protocols that were followed as well as the validity of the results obtained. It may also be expected that he or she should provide expert opinion on the effect that drugs may have on the human body.

3.4.1.2 Ethical and professional standards for the forensic toxicologist/scientist

The ethical standards that the analytical toxicologist have to comply with are diverse and can be divided into two categories, namely, biomedical and scientific ethics.

3.4.1.2.1 Biomedical ethics applicable to the analytical toxicologist

The ***biomedical*** ethical/moral obligations revolve around veracity, respect for privacy and confidentiality, and fidelity, as discussed in section 3.1 above. The forensic scientist should also have a sound knowledge of the relevant legislation and guidelines of the professional body that regulates the profession. The forensic toxicologist must ensure accurate, truthful, timely, objective, and comprehensive transmission of laboratory test results to the designated person, as per the consent form. If an incorrect test result is detected and it was released to the donor/MRO/designated person, the forensic toxicologist has to disclose the error even after decisive/disciplinary action has been taken to foster transparency, respect, and accountability. If the result has not been released, the matter needs to be investigated internally according to scientific principles and protocols.

Respect for privacy involves operating within the limits of the informed consent form of the donor to comply with the details thereof. He or she has to make sure that only the analyses that the donor consented to are performed and reported. The report has to be forwarded to the individual designated by the donor only and must be password protected in the case of electronic transmission. Confidentiality has to be maintained by not providing test results telephonically. If the donor wants to have access to the test results, for instance, the analyst must verify his contact details on the consent form first before he or she release test results.

In terms of fidelity, the forensic toxicologist has to remove all self-interest that may conflict with his duties to act ethically and legally correct. In a prohibited substance regulatory environment, this implies that the forensic toxicologist may not be employed by the organisation connected to the specimens or another third party. This conflict of interest can manifest in the South African private sector where the forensic analyst or forensic laboratory is contracted by organisations from which the specimens originated. The HPCSA requires that the conflict of interest be declared to the patient, which will respect the autonomy of the donor

and allow him the freedom to choose another confirmation service. This may become a controversial issue if the confirmation laboratory is not specified in the policy and on the consent form, which would have implied that there is an official agreement between the donor and the organisation on which specific laboratory is going to be used.

Truth is one forever absolute, but opinion is truth filtered through the moods, the blood, the disposition of the spectator.

Wendell Phillips

3.4.1.2.2 S*cience ethics applicable to the analytical toxicologist*

The forensic toxicologist should have an innate quest for truth itself and, amid an environment characterised by opposition, maintain his truth-telling nature by investigations and communication for the truth to be discovered, shared and honoured. The original Greek word for "truth" is *Aletheia*, which means "the state of not being hidden or the state of being evident", also related to "openness" or "disclosure", which requires paying attention, perceptional accuracy, comprehension of detail, and understanding of the context, and never to be intentionally careless, ignore facts, and bring to light in a proactive fashion.[13]

Truth in the laboratory starts with ensuring that the procedures executed by the forensic toxicologist produce reliable test results that are accurate and precise. He or she must function in such a manner that they can be held accountable. He or she should follow internationally recognised best practice and be open and honest in the reporting of results. The results must be consistent and obtained in an objective and unbiased fashion. Precise record-keeping is a requirement from the moment the forensic toxicologist takes custody of the specimen, and the raw data of all observations has to be secured. The forensic toxicologist should preserve the integrity of the specimen by restricting access. A split-specimen has to be frozen away for second independent analysis in case the donor wants to challenge the test result.

Professional codes of conduct usually require that professionals "do not undertake work for which their education, experience or background have not rendered them competent to perform" and "not knowingly misrepresent their academic or professional qualifications".[14]

[13] W Willoughby, E Thompson & JC Upshaw Downs 'The forensic practitioner's quest for truth' in JC Upshaw Downs & AR Swienton (eds) *Ethics in forensic science* (2012) 39 Elsevier.

[14] South African Council for Natural Scientific Professions (SACNASP) http://www.sacnasp.org.za/about-us/code-of-conduct.html (accessed 10 November 2017).

The HPCSA prescribes that a health professional must "Acknowledge the limits of their professional knowledge and competence. They should not pretend to know everything."[15] The Health and Care Professions Council of the United Kingdom states that: "You must keep within your scope of practice by only practising in the areas you have appropriate knowledge, skills and experience for".[16]

The knowledge of every human being has limits which apply not only horizontally, but also vertically. Horizontal limitations limit the forensic toxicologist not to function outside his field of study, for instance, chemistry or microbiology. The vertical limits have to do with the depth of knowledge in the specific field. It is also essential to observe the various subsections in each field due to the highly specialised nature of the various scientific fields. A forensic toxicologist requires knowledge in several areas to be able to obtain, report and defend a test result (see Figure 3:2.

The Criminal Procedure Act[17] requires an expert witness to have skills in chemistry and toxicology to be able to testify in court; however, the forensic toxicologist has to disclose to the court his or her academic level of training and experience in the specific discipline. He or she should disclose not only the limitations of his knowledge but also the limitations of the test results, like the measurement uncertainty. He or she may have to refer some questions to the laboratory's reporting officer, or technical and quality manager.

He or she should explain the results/procedures logically and understandably and must disclose all the information relevant to the case for the presiding officer to make an informed decision. The well-known maxim which requires "the truth, the whole truth, and nothing but the truth" to be disclosed is highly appropriate for the forensic toxicologist. Withholding information would constitute paternalism on the side of the forensic toxicologist and disrespect for the court's autonomy to make an informed decision. A prime example of this is when the "measurement uncertainty" related to the test result is not indicated on the analytical report, or in a limited fashion sometimes referred to as "available on request". The expert witness has to

[15] HPCSA *Guidelines for good practice in the health care professions general ethical guidelines for the health care professions* http://www.hpcsa.co.za/downloads/conduct_ethics/rules/generic_ethical_rules/booklet_1_guidelines_good_prac.pdf (accessed 9 November 2017).

[16] Health and Care Professions Council United Kingdom *Standards of conduct, performance and ethics* http://www.hcpc-uk.org/assets/documents/10004EE2Ourrulesforhowhealthandcareprofessionalsbehave.pdf (accessed 9 November 2017).

[17] Criminal Procedure Act 51 of 1977 Art 212 subsec (4)(a).

proactively make the court aware of this information even if he or she was not asked for it explicitly.[18]

3.4.1.3 International standards for ethics applicable to the forensic toxicologist

The American National Academy of Sciences issued a report that describes the standards of practice in a model code of professional conduct for the forensic sciences in general. The parts of the code applicable to the forensic toxicologists are summarised below:[19,20]

The Code of Ethics of the American Board of Criminalistics requires that everybody in the forensic laboratory take responsibility, from the leaders up to the routine analysts.[21] Ethics related to the scientific method of investigation, opinion and conclusions, court presentations and the general practice and responsibilities towards the profession are covered in this code of ethics, which is enforceable.[22,23]

3.4.1.3.1 Standards of practice in the model code of the American National Academy of Science applicable to the forensic toxicologist

A summary of the standards of practice in the model code of the American National Academy of Science is available in Appendix 6.[24] Table 3.1 lists the principles of the code of ethics of the California Association of Criminalistics.[25]

[18] A complete analytical result consists of the mean of replicate analyses as well as an indication of the measurement uncertainty. For instance, a blood-alcohol result must be reported as (0.07 ± 0.01) g/100 mL. It is critical to consider the measurement uncertainty of a test result, especially in borderline cases where the measurement uncertainty will assist in deciding if the test result is increased significantly above the threshold concentration. For example, if the threshold concentration for blood alcohol is 0.050 g/100 mL and the measurement uncertainty is ± 0.010 g/100mL, it implies that the test result may be between 0.040 - 0.060 g/100mL. In this case, significant elevation above the threshold can only be indicated for results higher than 0.060 g/mL. A test result of 0.054 g/100mL can in this instance not be regarded as significantly above the threshold of 0.050 g/100mL.

[19] *Strengthening forensic science in the United States: A path forward* https://www.nap.edu/catalog/12589/strengthening-forensic-science-in-the-united-states-a-path-forward (accessed 17 November 2017).

[20] American National Academy of Sciences *A model code of professional conduct in the forensic sciences* http://www.cacnews.org/policies/Model_for_NCPC.pdf (accessed 17 November 2017).

[21] *Code of ethics of the Californian Association of Criminalist* http://www.cacnews.org/membership/California-Association-of-Criminalists-Code-of-Ethics-09-23-2015.pdf (accessed 13 November 2017).

[22] *Code of ethics enforcement of the California Association of Criminalistics* http://www.cacnews.org/membership/California-Association-of-Criminalists-Code-of-Ethics-Enforcement-Procedure-09-23-2015.pdf (accessed 13 November 2017).

[23] Californian Association of Criminalist *Summary of the forensic science ethics documents* http://www.cacnews.org/ethics/summary.pdf. (accessed 13 November 2017).

[24] American National Academy of Sciences *A model code of professional conduct in the forensic sciences* http://www.cacnews.org/policies/Model_for_NCPC.pdf (accessed 17 November 2017).

[25] California Association of Criminalist *Summary of the forensic science ethics documents* http://www.cacnews.org/ethics/summary.pdf (accessed 13 November 2017).

Table 3:1 Code of ethical principles of the California Association of Criminalistics[26]

Be objective in analyses and in reporting of results and by avoiding potential conflicts of interest
Be honest about qualifications, in reports and regarding association business
Be forthcoming regarding scrutiny of work
Be conservative
Be current
Be fair
Communicate precisely, accurately, and clearly
Do proper tests and use suitable methods, equipment and facilities and perform verification and review of results
Be confidential
Be responsible and promote ethical conduct to the association and support the profession

3.4.1.4 General ethical dilemmas confronting the forensic toxicologist

Siegel summarises the general ethical dilemmas that may occur in all facets of the forensic scientist's work.[27] In addition to the usual ethical dilemmas that scientists in other occupations also experience, there are some dilemmas they experience that are a result of the forensic part of their work. These are mostly related to the fact that they serve the criminal justice system and have to communicate their results to law professionals in court proceedings. The ethical dilemmas in the general forensic field are similar to those that arise in the field of forensic toxicology.

The ethical dilemmas can be categorised as follows:[28]

- ***Professional credentials***: Forensic scientist misrepresent themselves sometimes by inflating their CVs. The aim of this may improve their chances of being declared an "expert witness" by the judge and also to ward off challenges by the defence or impress their clients. Some may even go so far as to deliberately claim false credentials, degrees and certifications from professional boards.

[26] As above.
[27] JA Siegel 'General forensic ethical dilemmas' in *Ethics in forensic science* (2012) 59 JC Upshaw Downs & AR Swienton Elsevier.
[28] Siegel (n 27) at 60.

- ***Laboratory analytical procedures***: The forensic scientist may perform insufficient analyses by deviating from a fixed scheme or by exercising his discretion. An example of this is where the scientist performs only a preliminary drug screening test, which is not followed by a confirmation test. Confidence in the results is higher when two techniques were applied to arrive at the final result. The scientist can decide not to perform a preliminary test but, instead, opt for the confirmation test directly. The confirmation test, set up in a specific manner, may then yield misleading results by not detecting substances that the screening test would have. Peer review of the analytical results will be efficient to deter such unethical behaviour.
- It is also unethical to perform analyses indiscriminately by over-analysing or practicing defensive science to create the impression that all the options are covered, where the reality was that no logical plan was followed to investigate the case and to come to a rational decision.
- Preconceived notions that may result in biased results should be eliminated. A typical example of this can be found in a blood-alcohol analytical result reporting with a result at or near the legal threshold concentration of 0.05 g/100mL. If the result is 0.045 g/100mL, it can be rounded up to 0.05 g/100mL or truncated to 0.04 g/100mL. Rounding up, in this case, will imply that the legal threshold was exceeded and truncation will imply that the individual's blood-alcohol level was below the threshold and he or she may not be found guilty. The analyst should follow the laboratory's protocol in this regard. Usually, test results are truncated to the benefit of the accused. The number of decimal figures should be reported according to the measurement uncertainty to be reported, together with the test result.
- Dry-labbing occurs where the analyst does not perform an analysis on the exhibit and manufacture a test result that either benefits the defence or the prosecution. Another form of this dubious practice is where a scientist dishonestly reports that he or she has received an "insufficient sample" to perform a complete analysis and discard the specimen to destroy the evidence. There is no excuse for this practice, and it amounts to fraud.
- ***Interpretation of analytical data and presentation of testimony in court***: Bias of opinion has to be avoided at all costs. There are two types of bias, namely: *contextual bias* and *conformational* bias. The first may typically occur when the information around a specific case is made known to the analyst; for instance, he or she knows that the urine specimen originates from a known methamphetamine user. The information may influence the

analyst. Confirmational bias can occur when there is a peer review of analytical data of a drug test, and the reviewer knows what the findings of the first analysts were, which may bias his opinion, especially if they are colleagues. Blind verification may be employed fruitfully as a solution to conformational bias.

Imprecise terminology and scientific jargon plague forensic testimony. Some terms used in forensic toxicology and analytical chemistry may have a different meaning in their everyday use. Typical examples of terms used to declare a notion of "equal to" are: *consistent with, similar to, could not be distinguished from, cannot be excluded* and *match*. The statement of "equal to" can only be used in a scientifically correct context in relation to statistical hypothesis testing. A more correct statement would be that: "the evidence indicated that there is no ***significant*** difference on a 95% probability". Another example can be found in the use of the word "calibration curve" to indicate that the instrument's response was obtained with certified calibration solutions. Individuals who are not trained in analytical chemistry may interpret that the instrument was calibrated. The use of the term "calibration standard" should also be avoided since "standard" can be interpreted in terms of a minimum level of quality or attainment.

Laboratory reports that are improperly written present a serious ethical dilemma. An analytical report in forensic toxicology aims to report the "full truth and nothing but the truth". The answer to the question as to what constitutes a proper laboratory report depends on the nature of the investigation. In the forensic toxicology environment, it is suggested by the author that the report should contain at least the following information:

- An **introduction** that explains what tests were performed, by which methods and why these methods were selected. It should also specify the date on which the specimen was received in the laboratory and by whom.
- An **experimental** section that delineates the exact experimental procedure.
- A **results** reporting section that provides detailed results. Raw data can be included in an appendix.
- A **conclusions** section that allows for data interpretation and a conclusion.
- The **limitations** to the tests are essential to put the analytical investigation into perspective. The expanded measurement uncertainty and the level of probability should be reported in this section.

In the opinion of the author, court testimony delivered in a biased fashion is one of the ultimate sins that can be performed by a forensic toxicologist. Bias can manifest by either overstating or understating the facts selectively to suit the case of either the prosecution or the defence. Attorneys and judges find it extremely difficult to follow specialised scientific reasoning since they are not skilled scientists by training. Scientists can also withhold parts of the truth without the attorneys and judges knowing. Evidence must be presented in an unbiased, logical and rational fashion, in a way that laypeople can understand, without compromising the quality of the evidence and in an accountable fashion.

- ***Privately employed forensic toxicologists*** face numerous ethical difficulties by their status as private examiners. Claims of contextual bias may take the forefront, and confirmational bias is a more significant problem if the privately-owned business is too small to hire additional scientists that can objectively confirm their results.

  A privately employed forensic toxicologist should never work on a contingency fee basis with the promise that if the client wins the case, the toxicologist's remuneration would be more, which creates a suspicion of bias and subjectivity. Fees should be negotiated upfront and it is ethically permissible to ask for a certain percentage of the payment upfront. The mere fact that the defence pays a private forensic toxicologist may initiate claims of favouritism towards the defence. A perception of bias can also be created when a privately owned forensic toxicology laboratory always testifies for the defence only.

  Most of the forensic toxicology work in South Africa is performed by national laboratories which, according to the policy, are not allowed to perform work for private individuals, even if they are willing to pay for the investigation. There are currently only two forensic toxicology laboratories who service the private sector, creating a perception that the experts from these laboratories testify for the defence only.

- ***Publicly employed forensic toxicologists*** are subjected to the classical "state-employee stigma" due to the nature of their employer. They may be biased by the responsibility perceived to serve justice by "getting rid of the criminals". It should be kept in mind that a scientist never convicts anyone, but the court does, which may or may not use the evidence provided by him or her. Publicly employed scientists in term may be accused of always testifying for the state or prosecution.

- ***Obligations to the profession of forensic science and maintenance of professional skills*** apply to all scientists and not only to the forensic scientist. According to Siegel, there are three categories of ethical dilemmas in this group, namely:[29]
  - Failure to keep up with the latest technology and developments.
  - Improper use of proficiency tests.
  - Improper continuing education practices.

  A laboratory that employs forensic scientists should allow them to keep up with the latest technology and developments to remain current in their field by providing sufficient funds and time off to attend lectures and conferences and to have access to scientific journals. Proficiency testing is also an excellent way to prove that the forensic toxicologist is competent and should mimic casework and should be performed blind. Continuing education should be taken seriously when attending conferences and lectures away from work.

3.4.1.5 Educational and training requirements for forensic toxicologists

The forensic toxicologist has interdisciplinary expertise and has skills in chemistry (analytical and organic chemistry), pharmacology (pharmacokinetics) and the relevant ethics and laws in his or her profession. The sub-fields in which expertise is required is indicated in Figure 3:2. The subfield in which he or she should have a higher level of training depends on the specific case, for example:

- If a drug metabolite were identified and quantitated in a bio-matrix, the specific skill set required would be analytical-organic chemistry with the emphasis on instrumental analytical techniques such as chromatography and mass spectrometry. Reliable quantitation would also require skill in chemometrics and analytical quality control.
- In the case of back extrapolation calculations, for instance, where the amount of alcohol consumed before a specific point in time has to be calculated, skill in pharmacokinetics is a requirement.
- It may also be expected that the forensic toxicologist provides expert opinion regarding the effect that drugs may have on the human body, which would require skill in pharmacology.

[29] Siegel (n 27) 76.

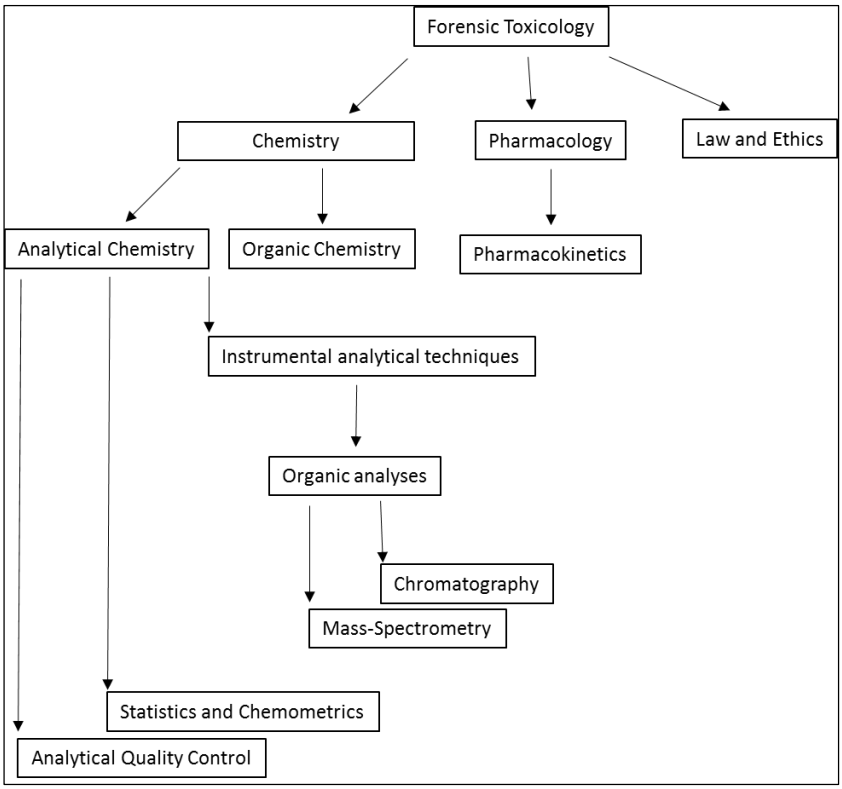

Figure 3:2 Disciplines which apply to the field of forensic toxicology

The forensic toxicologist is required to maintain and improve the level of his/her professional skills[30] and observe and keep up to date with the laws that affect professional knowledge and skills.[31] The Health and Care Professions Council, United Kingdom, summarises this aspect as follows: "You must keep your knowledge and skills up to date and relevant to your scope of practice through continuing professional development. You must keep up to date with and follow the law, our guidance and other requirements relevant to your practice."[32]

The third important aspect of a forensic toxicologist's training involves knowledge of ethics and laws applicable to the profession. Training in professional ethics will provide an understanding of acceptable behaviour in the profession and appreciation of the standards of ethical behaviour in the practice of forensic toxicology. Ethics training programmes should address aspects such as professional requirements, educational requirements, organisational structures, collegial relationships, managerial philosophies and examples of unethical

[30] HPCSA (n 14) sec 8.1.1.
[31] As above sec 8.1.3.
[32] Health and Care Professions Council (n 15).

behaviour.[33] Most of the ethics in forensic toxicology revolves around honesty. The guiding principles are as follows:

- A forensic scientist must be technically competent and employ reliable scientific methodologies.
- A forensic scientist must be honest about their qualifications, acknowledge his or her limitations and must not operate outside his or her field of expertise.
- A forensic scientist must be honest about the data, conclusions and opinions.
- A forensic scientist must be objective when giving evidence about a case.

3.4.1.6 Professional councils for forensic toxicologists in South Africa

There is no professional body in South Africa regulating the occupation of forensic toxicology per se. The two regulating bodies closest to the daily practice of a forensic toxicologist are the HPCSA with registration as a medical-biological scientist[34] or the SACNASP with registration as a professional natural scientist.[35]

3.4.1.6.1 The Health Professions Council of South Africa registration

All the health professions in South Africa is regulated by the HPCSA with registration a requirement to practice as a medical scientist. Almost all aspects of the occupation are regulated, including registration requirements, standards for theoretical and practical training, ethical conduct and behaviour,[36] compliance with scientific and healthcare standards, and requirements for continuous professional development (CPD).[37] Persons training to qualify as medical scientists are required to register with the HPCSA while they are students and remain registered while training and working.

The HPCSA defines the scope of practice for medical scientists as the "development, evaluation and practice of scientific procedures involving **humans, *human biological material*** or medical equipment emphasising that acts performed by medical scientists will lead to or impact on the treatment, ***diagnosis*** and counselling of humans (in the case of Genetic Councillors) and where appropriate, interpretation, quality management, patient genetic

[33] MM Houck & RT Bowen 'Teaching ethics' in JC Upshaw Downs & AR Swienton (eds) *Ethics in forensic science* (2012) 201 Elsevier.

[34] Medical Scientist (Occupation Code: 213110) Department of Higher Education and training http://ncap.careerhelp.org.za/occupation/9e3813a2-02ac-4184-bc8a-40163f6b20ba (accessed 27 February 2019).

[35] file:///C:/Users/u02412969/Downloads/Code%20of%20Conduct%20(2).pdf (accessed 27 February 2019).

[36] HPCSA (n 14).

[37] HPCSA *Revised scope of profession for medical scientists – guidelines* (2009) http://www.hpcsa.co.za/downloads/medical_dental/medical_scientists/medical_scientists_letter.pdf (accessed 9 November 2017).

counselling and ***consultation with other registered and appropriately qualified health practitioners***."

Health professionals working within the scope of the medical science profession are registerable under the disciplines of medical-biological science, genetic counselling or medical physics and must be registered with the HPCSA as stipulated by the Health Professions Act.[38]

The HPCSA has specific training requirements for medical, biological scientists at accredited training facilities which involve mostly clinical chemistry. The training is not explicitly applicable to the field of forensic toxicology.[39]

3.4.1.6.2 The South African Council for Natural Scientific Professions registration

The SACNASP defines the scope of practice of an analytical chemist's field of practice in the chemical sciences as: "work in ***any branch*** of chemistry to determine which chemical substances and the amount of each is present in a specific composition". The scope of practice of a forensic chemist is defined as "any of the disciplines for the express purpose of presenting evidence in a court of law. Knowledge of the legal requirements for expert testimony is required and work experience should be gained after the completion of the highest qualification."

The requirements for work experience are:[40] "After completing a BSc. Honours or recognised B.Tech. Degree, three years' work experience is required, two years after completing an appropriate and recognised M.Sc. degree, and one year after completing a PhD".

There are two levels of registration, the first as a *certificated natural scientist*, which applies to individuals who mainly perform routine laboratory work. The second level of registration is that of a *professional natural scientist* who applies to individuals in more senior positions with an advanced career.

3.4.1.6.3 HPCSA or SACNASP registration for a forensic toxicologist?

South Africa needs a professional body to regulate the occupation of forensic toxicology since the scope of practice by both the HPCSA and the SACNASP does not include the field of forensic toxicology specifically. The SACNASP scope of practice is not specific as to whether it includes interaction with humans or the analyses of human biological material as opposed to the HPCSA scope of practice for a medical-biological scientist.[41,42] Although a prohibited

[38] HPA 56 of 1974.
[39] HPCSA *Education and training* http://www.hpcsa.co.za/PBMedicalDental/Education (accessed 11 November 2017).
[40] SACNASP *Work experience requirements* http://www.sacnasp.org.za/new-submissions/work-experience-requirements.html (accessed 11 November 2017).
[41] SACNASP http://www.sacnasp.org.za/about-us/code-of-conduct.html (accessed 9 November 2017).
[42] HPCSA (n 14).

substance test is a test for compliance and not a medical diagnostic test, the HPCSA seems to be a better route to follow in terms of registration since its regulatory requirements are more specifically aimed at humans regarding the ethical and legal requirements.

3.4.1.6.4 Discrepancies legal requirements at the HPCSA and SACNASP professional councils

The Health Professions Act[43] regulates the registration of professionals at the HPCSA. It specifies that "Registration a pre-requisite for practising -(1) No person shall be entitled to practise within the Republic, (a) any health profession registrable in terms of this Act;…"[44]

The Natural Scientific Professions Act[45] that regulates SACNASP registration requires that "Only a registered person may practise in a consulting capacity".[46] It furthermore states that "This Act binds the State, except in so far as the State provides forensic science services". This includes the forensic toxicologists employed by the national Department of Health.[47]

Registration at the HPCSA is much more critical for professional scientists to be allowed by law to practice than at the SACNASP. A medical-biological scientist may not practice if he or she is not registered; however, a professional natural scientist has to be registered if he acts in a consultative capacity only. In the opinion of the author, exemption of the government's employees seems irrational since providing expert testimony to court is one of the ultimate forms of a consultation capacity.

This relaxed standard that applies to the government's forensic scientist implies that they may perform scientific forensic investigations and give expert testimony in court with effectively no ethical code of conduct to comply with.

Another implication of this is that a scientist with a lesser qualification may issue a report/certificate which is regarded as *prima facie* evidence and may give expert testimony in court as opposed to forensic scientists that function in the private sector. In principle, the Natural Scientific Professions Act allows for a lower standard of professionalism in the state than the private sector. It is also important to note that the government currently employs most forensic scientists in South Africa. This can be seen as discriminatory against the private forensic scientists who have a legal obligation to register with the SACNASP.

[43] HPA 56 of 1974.
[44] HPA 56 of 1974 ch II Education, training and registration sec 17.
[45] National Scientific Professions Act 27 of 2003 (NSPA).
[46] As above sec 20.
[47] As above secs 20 & 43.

Counter-arguments that may be offered for this discriminatory statute may relate to limited state resources and that the state does not have the funds to remunerate better-qualified scientists. Another argument may be that it is the court's prerogative to declare a scientist an "expert" and to accept or ignore the testimony, which implies that professional registration of the forensic scientist will in principle not affect how the court will view the evidence. Regardless of the reasons for the relaxed standard of registration for the government's forensic services, it is the opinion of the author that this will ultimately impact on the citizens of South Africa's right to safety. Forensic science fulfils a vital function in the criminal justice system and for the South African nation as a whole.[48]

A recent incident related to scientific and ethical malpractice, or so-called "dry-labbing", by a forensic toxicologist employed by the national Department of Health, highlights the importance of professional registration where, according to allegation, the analyst poured 60 blood samples in a row down the drain before fraudulently claiming that the "amount of blood was not sufficient for analysis". The direct superiors who verified the laboratory reports also did not detect this. The analyst was also praised in a staff meeting for "completing so many cases in such a short time". She was allegedly given a merit award and a day off.[49,50,51] The enormous backlog of ca 3 000 post-mortem blood-alcohol cases can partly be attributed to the poorly qualified individuals employed by the state.[52]

It can be concluded from the discussion above that South Africa does not have a suitable professional board to regulate the profession of forensic toxicology effectively. Neither the HPCSA nor the SACNASP code of conduct accommodates the forensic part of the forensic toxicologist's unique interactions with the legal professionals and court testimony part. A professional body for the forensic sciences, in general, is desperately called for in South Africa to regulate the profession and set minimum standards of scientific and ethical conduct.

[48] CSA ch 2 Bill of Rights sec 12.

[49] SA News, South African Government News Agency 'Health forensic analyst put on suspension' http://www.sanews.gov.za/south-africa/health-forensic-analyst-put-suspension (accessed 12 November 2017).

[50] 'Forensics official suspended over blood samples, criminal case opened' *Times Live* https://www.timeslive.co.za/news/south-africa/2017-09-22-forensics-official-suspended-over-blood-samples-criminal-case-opened/ (accessed 11 November 2017).

[51] 'Hawks investigate faked Pretoria forensic lab results' Medical Brief https://www.medicalbrief.co.za/archives/hawks-investigate-faked-pretoria-forensic-lab-results/ (accessed 11 November 2017).

[52] 'Forensic backlogs reduced, but still too high' *News 24* https://www.news24.com/SouthAfrica/News/forensic-backlogs-reduced-but-still-too-high-20160406 (accessed 11 November 2017).

3.4.2 Forensic toxicology laboratory

3.4.2.1 The general role of the forensic laboratory

A forensic laboratory is a laboratory where the science of analytical toxicology and other toxicology-related scientific investigations are performed which pertain to the justice (criminal and private) system. Forensic toxicologists analyse and interpret evidence found in biological specimens that include urine, blood, saliva, breath, hair, nails, intestines and other body parts to assess which compound and how much of it was administered. A forensic laboratory can serve both the prosecution and the defence; however, current public forensic laboratories are mostly exclusively maintained for the state. Private forensic laboratories, on the other hand, perform mostly toxicology investigations related to the private law domain, like workplaces, sports doping and schools in South Africa.

The forensic toxicology laboratories of the national Department of Health in South Africa are mandated to provide forensic toxicology services related to post-mortem toxicology and blood-alcohol analyses for both post- and antemortem cases, with no service related to antemortem toxicology testing.

3.4.2.2 Ethical and professional standards for forensic laboratories

The ethical/moral obligations of prime importance in the management of a forensic toxicology laboratory are veracity, respect for privacy and confidentiality, and fidelity, as discussed in section 3.1 above. The laboratory management also should observe the ethics applicable to the scientific aspects, which are all about finding and reporting the "truth". The unique position that forensic laboratories enjoy in society, which is based on public trust, necessitates that a forensic toxicology laboratory's operation must be *fair* and must be *seen* and *perceived* to be fair.

It is advisable for a forensic laboratory to have an "ethics officer" who is responsible for scrutinising the daily activities and for assisting in ethical decision-making related to the laboratory's activities. Such a person should have direct access to laboratory management, similar to a quality officer in the organisation.

A forensic toxicology laboratory should apply principles, techniques, and methods of science with the primary objective of determining the facts that may be significant in forensic toxicology cases, interpret and evaluate those facts and form opinions. Forensic laboratories must comply with protocols and practices that are generally recognised within the fraternity to achieve a high level of professional ethics. Forensic scientists should stay current with new

developments in the profession, and their professional actions should be consistent with ethical conduct described in the specific organisation's code of conduct. Failure to meet or maintain these standards may cast doubt upon both the forensic toxicologist and the forensic laboratory. Responsibility should be taken for work done and managers should be aware of the code of professional conduct and should act in a way that is aligned with it.

The American National Academy of Sciences has issued a report that describes the standards of practice in the model code of professional conduct in the forensic sciences. The managerial part of the code is summarised below:[53]

- "Laboratory managers and supervisors must promote an environment conducive to ethical conduct. Violations of the code of professional conduct should not be tolerated or concealed, and severe or repeated violations must be reported to the relevant association.
- Laboratory managers should make sure that laboratory services are provided to the maximum of the organisation's financial ability while maintaining necessary quality standards.
- Laboratory managers and supervisors must employ scientists with sufficient academic qualifications, experience, knowledge, and training to within their areas of expertise and operate under the code of professional conduct.
- Laboratory managers and supervisors must institute and maintain a suitable quality assurance system.
- Laboratory managers and supervisors shall promote and support participation in professional associations, certification programmes, and technical working groups.
- Laboratory managers and supervisors shall not allow employees to be pressured to perform substandard work, take technical shortcuts, or arrive at conclusions not supported by scientific data."

The aspects of providing suitable laboratory services, employing employees with suitable qualifications, establishing and maintaining a quality system are all part of the ISO17025 guidelines for testing laboratories.[54] The South African National Accreditation System (SANAS), under the national Department of Trade and Industry, is the accreditation body that is mandated to assess testing labs for compliance with the ISO17025 standard. Accreditation means third-party attestation related to conformity assessment bodies (laboratories in this case)

[53] American National Academy of Science *A model code of professional conduct in the forensic sciences* http://www.cacnews.org/policies/Model_for_NCPC.pdf (accessed 17 November 2017).

[54] General requirements for the competence of testing and calibration laboratories ISO/IEC 17025: 2005.

conveying formal demonstration of their competence to carry out specific conformity assessment tasks. Laboratories testing for performance enhancement substances like WADA, for instance, have additional specifications for accreditation, which typically involves proficiency testing specific to the industry. Accredited laboratories are required to take action when errors are discovered or when protocols are not followed. Corrective action logs wherein the non-compliances should be documented can only contribute to the openness of the forensic toxicologist's testimony.

SANAS is mandated through the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act [55] and laboratories have a responsibility to maintain its accreditation by complying with the accreditation standards, which includes the specific products as specified in their accreditation certificate. Misuse of accreditation, including misrepresentation of data from an accredited body or misuse of the accreditation symbol, is an offence.[56] The implication of this is that a laboratory may not use the SANAS logo for test methods not specified on their accreditation schedule, even if they are accredited for other test methods. The results that a forensic toxicologist will present in court remain the responsibility of the scientist and the laboratory, even if he or she is certified as a technical signatory in the accredited laboratory.[57]

The Act also states that it is an offence if any person who knowingly makes or assists in making a report that contains any untrue statement of a material fact to be sent to any other person; or omits to state a material fact in a document as such. Any person contravening the act or failing to comply with this is guilty of an offence and upon conviction is liable to a fine or to imprisonment for a period not exceeding 24 months or to both a fine and such imprisonment.[58]

Although laboratory accreditation is a noble goal to strive for, it is ***not a legal obligation*** for forensic laboratories in South Africa. In the end, it is the prerogative of the judges and magistrates to accept the evidence produced in the specific forensic laboratory as provided by the forensic toxicologist, even if he or she is not certified and the laboratory he or she works for is not accredited.

The laboratory must have a system in place that creates a unique laboratory identification number for a specimen from the moment it is received in the laboratory so it can be treated and

[55] Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act 19 of 2006.
[56] As above sec 24(1) & (2).
[57] As above sec 25.
[58] As above sec 27(1) and (2).

investigated anonymously. Treating specimens anonymously will contribute to respect for privacy, confidentiality and fidelity. All personal information, results and communications must be confidential and should be delivered to the individual or designated person confidentially. Management must have a system in place that secures exhibits and data. The building and the custody of data should have security controls in place and rooms where exhibits are stored should have restricted and documented access. Electronic data must be archived and secured from accidental changes or malignant tampering.

Sufficient storage must be available to keep split specimens frozen for the period that was specified in the organisation's policy, with the consent of the individual, in case he or she wants to have it reanalysed by another laboratory.

The laboratory should have procedures in place for maintenance of the instrumentation to be performed regularly, calibration of equipment, and replacement of equipment on an ongoing basis. The requirement that the latest and most reliable technology has to be used for analyses comes at a high price and requires proper budgets and planning. Cleaning of the laboratory and prevention of contamination require a constant and conscious effort.

3.4.2.3 Typical ethical dilemmas in private forensic toxicology laboratories

- Ethical conundrums may occur in a forensic toxicology laboratory with walk-in clients, for instance, where a parent accompanies his or her child to undergo a drug test. It must be kept in mind that the parent has to give consent if the child is a minor with limited capacity. Some parents may act in a coercive manner by "forcing" the minor to donate a specimen. Such a situation is undesirable for the specimen collection officer who has to collect the specimen from the minor, knowing that the child did not provide voluntary free consent. A possible solution may be to refer the parent to a registered social worker first who can supervise the process. It is also problematic to release the results to the parent since he or she may not be qualified to perform a medical review of the test result and thereby validate the result. It is advisable to ask the parent's consent for the laboratory to release the report to their family doctor.
- Pathology laboratories providing routine medical testing services to the industry for routine medical surveillance present a unique ethical dilemma if the laboratory also includes regulatory drug testing as part of their service offering. Prohibited substance testing is a regulatory test to ensure that an individual complies with policy and these tests may result in punitive action, which may impact on the doctor-patient relationship of trust.

A further problem that presents with pathology laboratories in South Africa is when they offer to act as a service provider for prohibited substance testing and refer some of the drug tests to a third party laboratory without the consent of the individual undergoing the drug test. Confidentiality is then breached when the company transfers the test results into their format before releasing the test results.

3.4.3 Alcohol testing services

3.4.3.1 Breath alcohol technician and screening test technician

3.4.2.1.1 The general role of the breath alcohol technician

Breath alcohol should be tested onsite within half an hour after a non-negative breath alcohol test result. The technician who performs the confirmation test is termed a "breath alcohol technician" (BAT), and it is his or her responsibility to conduct the test in a legally defensible way.[59] A BAT and a screening test technician (STT) may perform preliminary assays only and not confirmatory breath alcohol tests.[60]

3.4.2.1.2 Ethical standards for the breath alcohol technician

The BAT has to ensure that the test is performed with the necessary visual and auditory privacy and also that confidentiality of the test result is maintained. The BAT has to obtain consent from the donor before the test and avoid making degrading statements and politely address the individual with due respect for human dignity. In the instance where the immediate supervisor of an individual is a qualified BAT or STT, he or she should not perform the test to avoid a conflict of interest, unless there is no other option.

3.4.2.1.3 Educational and training requirements for the breath alcohol technician

The BATs and STTs should have a detailed knowledge of the organisation's prohibited substance regulation policy and proven proficiency in the breath alcohol testing devices that are employed.[61] The training must emphasise that he or she is responsible for maintaining the integrity of the testing process, and the qualification should include proficiency testing in the alcohol screening test as well as the evidentiary testing device. He or she should have a sound knowledge of the internal workings of the testing device at a level that he or she can explain the scientific principles in a hearing or a court.

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[59] US Department of transportation *Breath alcohol technician and screening test technician* https://www.transportation.gov/odapc/alcohol-technicians (accessed 2 December 2017).

[60] The task of the SST is mostly fulfilled by security officers in South Africa.

[61] US Department of Transportation Subpart J – Alcohol testing personnel DOT Rule 49 CFR Part 40 sec 40.213 (accessed 2 December 2017).

The instrument has to be maintained, calibrated and regularly certified, and control specimens must be analysed to prove that the device was fully operational and operated within tolerance at the time the confirmation test was performed. The BAT should therefore, also know quality control practices similar to that of a forensic laboratory. Furthermore, the BAT must be able to explain the concept of measurement uncertainty and its impacts on the test result. The breath alcohol testing facility should be viewed as an onsite laboratory, which must comply, with good laboratory practice as per ISO17025 guidelines for testing laboratories.[62] The STT who will be using an alcohol screening device (ASD) that indicates readings by changes, contrasts, or other readings in colour, must demonstrate as part of the mock test that he or she can discern changes, contrasts, or readings correctly.

3.4.2.1.4 Professional councils for the breath alcohol technician

There are no professional boards or councils that regulate the occupation of a BAT or an STT in South Africa. It is the opinion of the author that the HPCSA would be a suitable council to regulate this profession due to the ethical sensitivity related to the breath alcohol testing procedure.

3.5 MEDICAL PROFESSIONALS

3.5.1 Occupational health doctor (HPCSA)[63]

3.5.1.1 General role and professional standards of the occupational health doctor

Occupational health doctors are fully qualified clinicians duly registered with the HPCSA. These professionals have to comply with a code of ethics and should have all the professional attributes required for registration.[64,65]

Medical review officers

3.5.2.1 The general role of the MRO

The role of the MRO was created in the American federal environment for physicians to receive and review drug testing results in workplace drug testing.[66,67] The MRO acts as a gatekeeper in the drug testing process by validating laboratory confirmed test results, since a positive result

[62] General requirements for the competence of testing and calibration laboratories ISO/IEC 17025: 2005
[63] HPCSA (n 14).
[64] A Dhai & D McQuoid-Mason Bioethics, human rights and health law, principles and practice (2011) 3 & 16.
[65] HPCSA (n 14).
[66] DR Smith & JL Ferguson 'Medical review officer interpretation of workplace drug test results' in JD Ropero-Miller & BA Goldberger (eds) *Handbook of workplace drug testing* 2nd ed (2009) 407 AACC Press, Washington.
[67] H Vangikar 'Interpretation of urine drug test results by the medical review officer' in A Verstraete (ed) *Workplace drug testing* (2011) 293 Pharmaceutical Press.

does not necessarily imply that an individual has a drug misuse issue. The MRO must interview the donor to obtain information in order to decide about possible drug misuse before giving the result through to the organisation's representative who in turn will convey the information to management. (Refer to section 5.4.7.2.4 later in this document regarding the gatekeeping role of the MRO in the legal setting)

The European Workplace Drug Testing Society (EWDTS)[68,69] defines an MRO as "a medical physician responsible for receiving laboratory results from the drug-testing laboratory. The MRO must have knowledge of substance abuse and also have appropriate training or experience to interpret and evaluate an individual's positive test results, in light of declared information", which indicates that a positive result may be a due to the consumption of substances other than illicit drugs (i.e. prescribed or over-the-counter medication or dietary causes). It requires interpretation that is best carried out by the laboratory toxicologist in conjunction with a qualified medical practitioner who can consult both with the donor and the donor's medical practitioner.

An MRO is not only required by workplace drug testing programmes, but also by other testing programmes such as sport, rehabilitation and prisons, each having its standard legal and technical requirements.

The role of an MRO is also defined as "a licensed physician responsible for receiving laboratory results generated by an agency's drug-testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result with his or her medical history and any other relevant biomedical information."[70]

The MRO must be independent of the confirmation laboratory and cannot be employed by, contracted by or have a financial interest in the confirmation laboratory responsible for the test result he or she reviews. An independent MRO may manage a laboratory contract on behalf of an employer/organisation. The MRO must act as an advocate for the accuracy and integrity of the drug testing process and the organisation's safety and aspirations.

[68] UK Workplace Drug Testing Forum *United Kingdom laboratory guidelines for legally defensible workplace drug testing version 1.0* (2001) http://www.ewdts.org/data/uploads/documents/ewdts-urine-guideline-2015-05-29-v02.pdf (accessed 1 December 2017).

[69] European Workplace Drug Testing Society (EWDTS) European guidelines for the collection part for urine and oral fluid and the entire procedure for hair for feedback version 2.0 http://www.ewdts.org/ewdts-guidelines.html (accessed 1 December 2017).

[70] TF Schultz *Medical review officers handbook* 8th ed (2002) London, Quadrangle Research.

The UK's guidelines also define a toxicology review officer (TRO) whose role is defined as "a person responsible for interpreting a positive analytical result for the customer or the customer's designated MRO." Making use of a TRO may allow the organisation to obtain a limited review of the test results without having to carry the costs of an MRO.[71]

3.5.2.2 Ethical standards for the MRO

As a registered physician in South Africa, the MRO should comply with the code of healthcare ethics of the HPCSA. Even though a prohibited substance test is not a medical diagnostic test, the MRO should inform the donor if he obtained information that can result in harm to the donor and refer him to his own or the organisation's doctor.[72]

The American Medical Review Officer Certification Council Board of Directors has established an MRO code of ethics as follows:[73]

" The MRO shall:

- behave professionally as befits all activities of a physician, *regardless of whether a real physician-patient relationship exists*.
- maintain the highest standards of practice and perform all professional functions with honesty and integrity.
- handle and transmit laboratory results in an accurate, direct, precise and confidential manner and strive for objectivity in dealing with all aspects of the drug-testing system.
- maintain scientific standards and appropriate application of science in the review process and refrain from any misrepresentation of the laboratory evidence or the scientific or technical basis of drug testing.
- demonstrate a commitment to the development and maintenance of professional competence and personal scientific knowledge.
- refrain from misuse of private information as may come to light in an interview with the donor. Employee or donor confidentiality is to be protected as much as possible in all cases.

[71] EWDTS (n 68) sec 4.6.
[72] HPCSA (n 14).
[73] Medical Review Officer Certification Council Board of Directors *MRO Code of Ethics* https://www.mrocc.org/code_of_ethics.pdf (accessed 7 November 2017).

- not currently misuse/abuse or be dependent on illegal drugs or alcohol, and not misuse/abuse prescription medications."[74]

Doctor-patient relationship: Reviewing a drug test result of a donor who is also a patient of the physician may result in a conflict of interest. The reviewing physician should then respect the doctor-patient relationship of trust and refer the interpretation of drug test results to another qualified MRO, since this may place him or her in an adversarial role against his patient.[75]

The MRO should maintain absolute confidentiality of the test results, which is of prime importance when the MRO has to interview a donor telephonically, and a third party answers the phone. The MRO should continuously reassure the donor of confidentiality of the conversation and also of the circumstances under which the confidentiality is no longer valid; for instance when the lives of others are in danger due to a medical condition brought to the attention of the MRO during the conversation. If the MRO requires information from the donor's physician, it may be obtained with the explicit written consent of the donor only.

3.5.2.3 Educational and training requirements for the MRO

A physician that acts as an MRO must know the legal, medical and toxicological aspects of drug testing. The American Federal Regulations require specialised training and examination by a nationally recognised MRO certification board, or sub-speciality board for medical practitioners in the field of medical review.[76]

The American Federal regulations prescribe the following qualification criteria for MROs:[77]

- A qualified and registered medical doctor
- Knowledge of the pharmacology and toxicology of illicit drugs
- Knowledge and experience regarding controlled substance abuse disorders
- Detailed knowledge of the organisation's prohibited substance regulation policy
- Must have completed a written examination as administered by a recognised MRO certification board

[74] Medical Review Officer Certification Council Board of Directors *MRO Code of Ethics* https://www.mrocc.org/code_of_ethics.pdf (accessed 7 November 2017).
[75] RB Swotinski & DR Smith *The medical review officer's manual, MROCC's guide to drug testing* 4th ed (2010) 10 OEM Press.
[76] 49 CFR Part 40: Procedures for transportation workplace drug- and alcohol-testing programs (Updated 27 September 2011) https://www.transportation.gov/sites/dot.dev/files/docs/PART40.pdf (accessed 1 December 2017).
[77] Swotinsky & Smith (n 75) 4.

An MRO must also have training in specimen collection procedures, chain-of-custody procedures, reporting, recordkeeping and interpretation of test results.

3.5.2.4 Professional councils for the MRO

There are no sub-speciality board currently in South Africa that regulates MROs other than the HPCSA regulations for medical practitioners.

Occupational health sister

3.5.2.1 General role and professional standards for the occupational health sister

Occupational health sisters are fully qualified healthcare workers and nurses duly registered at the South African Nursing Council. These professionals have to comply with a code of ethics and should have all the professional attributes required for registration.[78]

3.5.4 MRO assistant

3.5.4.1 The general role of the MRO assistant

MRO's may employ assistants to perform administrative tasks, but may not be involved in the interpretation of the results. In American federally regulated testing, the assistant may:

- Receive, review and report negative results
- Compile information and forms for the MRO to perform the review
- Schedule interviews and verify phone numbers with donors
- Advise donors to speak to the MRO and also explain the consequences of not doing so
- Assist with the evidence which confirms or supports a medical explanation
- Report validated test results in a summary report to the employer

The MRO assistant must have training in:

- Specimen collection procedures
- Chain-of-custody procedures, reporting, and recordkeeping

3.5.4.2 Ethical standards for the MRO assistant

The MRO assistant should maintain absolute confidentiality regarding the test results of patients and must be detail orientated, well organised and reliable.

[78] Nursing Council of South Africa http://www.sanc.co.za/ (accessed 11 January 2019).

3.5.4.3 Educational and training requirements for the MRO assistant

There are no formal education and training requirements for MRO assistants in South Africa. An occupational health sister who has to comply with the ethical guidelines of the HPCSA may also fulfil this role.

3.5.4.4 Professional councils for the MRO assistant

No professional councils are regulating the occupation of MRO assistant in South Africa.

Designated employer representative

This individual acts as the primary point of contact between the MRO and the organisation. The DER must have the authority to make disciplinary and safety decisions on behalf of the employer and must be well informed about the employer's/organisation's policy under which he or she operates. He or she must convey the communication from the MRO to the company and must orchestrate the testing programme in general. A thorough understanding and respect for the test subjects' human rights are of prime importance.

3.6 CONCLUSIONS: PROFESSIONALISM IN PROHIBITED SUBSTANCE REGULATION AND TESTING

The rules of respect for veracity, privacy, confidentiality and fidelity, which apply to the professionals involved in a prohibited substance regulation and testing programme, were reviewed. There are no professional councils currently in South Africa with a mandate to regulate the group of professions involved in the prohibited substance testing process in terms of registration, education and training, professional conduct and ethical behaviour, continuing professional development, and to promote compliance with standards of the occupations. These councils should allow only individuals who comply with a minimum set of criteria and should not be ***all-inclusive,*** as opposed to organisations that advance the interest of a specific occupation only.

The general role, ethical and professional standards, and minimum educational requirements for each of the prohibited substance professionals were reviewed, and possible professional councils currently available in South Africa were assessed to act as professional bodies for these professions.

It is suggested that these professionals be registered at the HPCSA, under newly created categories due to the intimacy and "ethical overlap" that exist between these professions and

the medical professions. Forensic toxicologists, for instance, currently have to register at the SACNASP with very vague ethical guidelines and oversight.

The general role of a forensic laboratory in a prohibited substance regulation and testing programme was reviewed, and ethical and professional standards were discussed. It was found that ISO 17025 accreditation is not a legal requirement currently in South Africa, which makes the quality management of forensic laboratories problematic. It is suggested that all forensic toxicology laboratories must be accredited by the ISO17025 standard for testing laboratories, as is required by WADA, for instance.

CHAPTER 4:

INTERNATIONAL AND FOREIGN LAW RELATED TO PROHIBITED SUBSTANCE REGULATION AND TESTING IN HUMANS: CAPITA SELECTA

4.1 INTRODUCTION

The Constitution of the Republic of South Africa specifies that when interpreting the Bill of Rights[1], the values that underlie an open and democratic society based on human dignity, equality and freedom must be promoted,[2] in addition, international law *must* be considered and that foreign law *may* be considered. It is therefore essential to take note of, and to study, international- and foreign law related to prohibited substance testing procedures and protocols to assess its applicability in the South African context. A prime example of international- and foreign law related to prohibited substance testing programmes are the (1) mandatory guidelines for workplace drug testing in the US,[3] as an example of foreign law and (2) rules on anti-doping of the World Anti-Doping Association (WADA), as an example of international law.[4]

4.2 PROHIBITED SUBSTANCE TESTING IN THE WORKPLACE

4.2.1 Foreign Law: Overview of the United States of America legal framework and mandatory guidelines for the American federal drug- and alcohol-free workplace programme

(This section was submitted as part of a postgraduate study by the author and is summarised below:)[5]

[1] CSA sec 39(1)(b) and (c).
[2] CSA sec 39(1)(a).
[3] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 53(69) pars 11970-11989, 11 April 1988 http://workplace.samhsa.gov (accessed 17 January 2017).
[4] WADA *World anti-doping code* (2015) Art 3.1 at 25 https://www.wada-ama.org/sites/default/ files/resources/files/wada-2015-world-anti-doping-code.pdf (accessed 1 January 2018).
[5] JB Laurens *Validation of the mandatory guidelines for the American Federal Workplace Drug Testing Program within the context of the South African Constitution* (2017) University of Pretoria.

4.2.1.1 United States of America regulatory framework for a prohibited substance-free workplace

4.2.1.1.1 Regulated testing: Mandatory Guidelines for the American Federal Drug- and Alcohol-Free Workplace Program

The USA Federal Drug-Free Workplace Program was launched in 1986 by President Reagan[6] under the auspices of the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA is also responsible for the certification of laboratories to perform drug testing in accordance with the Mandatory Guidelines for Federal Drug and Alcohol-Free Workplace Programs.[7,8,9,10] The Department of Trade drug-testing rules and its procedures were captured in the commonly referred to "Part 40".[11,12] The testing that started in the US military environment during the 1970's has evolved to what is known as the HHS Mandatory Guidelines administered by SAMHSA.[13] Six federal agencies have to comply with the DOT procedures currently[14] and the Departments of Defence, Energy, and Nuclear Regulatory Commission all have to comply with the guidelines, with minor deviations to fit their specific needs. These guidelines intend to ensure legal certainty and testing at a forensically acceptable standard, with simultaneous protection privacy of the test subjects. The following requirements are recommended for a drug-free programme:

- a formal written policy which explains all the rules, protocols and list of prohibited substances
- employee education regarding the dangers of drug use as well as supervisor training on the administration of their part of the programme
- an employee assistance programme (EAP) is required

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[6] Executive Order 12564 Drug-Free Federal Workplace FR 32889-32893 15 September 1986 http://workplace.samhsa.gov (accessed 17 January 2017).

[7] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 53(69) pars 11970-11989, 11 April 1988 http://workplace.samhsa.gov (accessed 17 January 2017).

[8] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 59(110) pars 29908-29931 9 June 1994 http://workplace.samhsa.gov (accessed 17 January 2017).

[9] Mandatory guidelines for Federal Workplace Drug-Testing Programs FR 63(219) pars 63483-63484 14 November 1998 http://workplace.samhsa.gov. (accessed 17 January 2017).

[10] Mandatory Guidelines and Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 69(71) 19644-19673 13 April 2004 http://workplace.samhsa.gov (accessed 17 January 2017).

[11] 49 CFR part 40: DOT Drug Testing Rule Commonly referred to as "Part 40".

[12] Procedures for Transportation Workplace Drug-Testing Programs FR 54 par 49855.

[13] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 53(69) pars 11970-11989, 11 April 1988 http://workplace.samhsa.gov (accessed 17 January 2017).

[14] Commercial motor carriers (Federal Motor Carrier Safety Administration, FMCSA); Aviation (Federal Aviation Administration, FAA); Railroad (Federal Railroad Administration, FRA); Public Transportation (Federal Transit Administration, FTA); Pipeline (Pipeline and Hazardous Materials Safety Administration, PHMSA); Maritime (United Sates Coast Guard, USCG).

- strategies for the identification of employees abusing drugs including analytical testing
- several types of tests may be performed for risk-sensitive positions in the federal environment such as pre-employment, post-incident, reasonable suspicion, rehabilitation follow-up, random and voluntary drug testing.
- A drug- and alcohol-free workplace programme should apply to everybody in the organisation and must be applied consistently in a non-discriminatory fashion.

4.2.1.1.2 State drug and alcohol testing laws

All workers have to comply with prohibited substance regulation and testing in some states while others offer incentives such as decreased worker's compensation insurance premiums to enhance compliance with the laws. The commonalities in state laws relating to prohibited substance regulation and testing related to the type of tests, procedures and policies and the denial of worker's compensation benefits. [15]

Test types:

- Random testing may be performed only on specific groups of workers
- Post-incident testing may be performed only if reasonable suspicion exists
- return-to-duty testing is not performed if an individual acknowledged his abuse problem and voluntarily sought help
- Pre-employment testing may take place only after a job offer on the basis that the drug test is negative.

Procedures and policies:

- Only HHS accredited laboratories are allowed to perform the analytical work, and the cost is for the account of the employer.
- The only matrices allowed are urine, oral fluid and hair, (no blood).
- No observed specimen collection is allowed either.
- All test results have to be reviewed by an MRO and the test subject must have access to the test result
- Employees may not be dismissed after the first positive, validated test

Worker's compensation and unemployment benefits:

[15] RB Swotinsky & DR Smith *The medical review officer's manual, MROCC's guide to drug testing* 4th ed (2010) 84 OEM Press.

- Worker's compensation benefits are forfeited if an injury occurs as a result of intoxication with a positive drug test viewed as rebuttable evidence of the cause of injury.
- *If an employee's contract is terminated as a result of a positive test result,* unemployment benefits may be denied.

4.2.1.1.3 Non-regulated testing

Non-regulated testing programmes also employ the mandatory federal SAMHSA drug testing guidelines even though different types of tests, concentration threshold values, bio-matrices may be used. State and city laws also command the non-regulated drug-testing programmes in the US. Some programmes allow for the immediate removal of the employee from duty after a reasonable suspicion until the MRO report has been received. This is however not in agreement with the stand-down policy of the mandatory guidelines, as discussed in section 4.2.1.12 below. The Americans with Disabilities Act (ADA) has an indirect influence on drug- and alcohol-free workplace programmes in the non-regulated environment [16] Collective bargaining agreements have a direct effect on drug and alcohol-free workplace programmes in unionised environments.

4.2.1.1.4 American Acts that influence drug-free workplace programmes

- ***Americans with Disabilities Act (ADA)***[17,18]

The ADA protects individuals from being discriminated against if they are qualified to perform a specific job. A disabled person is defined as someone who "has a physical or mental impairment that substantially limits one or more life activities" which includes someone who "has a record of impairment, or is regarded as having such an impairment". *Current* drug abuse or the use of a prohibited substance is not in the scope of a disability if the individual does not have a drug dependency problem. The employer may inquire about a prospective employee's drug use but only after a firm job offer which may be based on the fact that the drug test is negative. An individual with a drug-abuse history may be refused employment if it is based on the company policy and requirements of the job, such as compromising safety.

An employer is allowed to discipline employees in safety-sensitive positions for the prohibited use of drugs and alcohol and may also remove an employee from a safety-sensitive position for legitimate use of prescription medication.

[16] 29 CFR part 126 Labor.
[17] 29 CFR part 1630.
[18] Liska (n23) 406.

Drug tests may be performed under the ADA since these are not viewed as medical tests however, interestingly alcohol tests are regarded as medical tests and are therefore restricted under the ADA. Alcohol tests as a post-offer test may be requested if it is a requirement for the job.

- ***Clinical Laboratory Improvement Amendments***[19]

The Clinical Laboratory Improvement Amendments Act (CLIAA) applies for clinical testing and not to workplace drug tests since these are regarded as forensic tests which are not included in the scope of the CLIAA.[20] Screening tests are also not included under the CLIAA due to its inherent simplicity.[21]

- ***Emergency Medical Treatment and Active Labour Act*** [22]

The Emergency Medical Treatment and Active Labour Act **(**EMTALA) bares relation to emergency medical treatment which includes the requirement adequate screening, which may include drug and alcohol tests.

- ***Food and Drug Administration Regulations***

Diagnostic medical devices are regulated by the Food and Drug Administration **(**FDA). This includes the clearance of point-of-collection drug testing (POCT) kits which may not be marketed unless the FDA clears it after evaluating the performance and labelling. [23] Labelling clearance involves the evaluation of the instructions of use that should be clear and that important information is communicated, such as the requirement for confirmatory testing after a non-negative result.

- ***Health Insurance Portability and Accountability Act***[24]

The Health Insurance Portability and Accountability Act (HIPAA) the protection of the privacy of individuals in the manner that health information is treated. It regulates access to healthcare

[19] Clinical Laboratory Improvement Amendments of 1988 (CLIA).
[20] Not a medical test
[21] 42 CFR ch IV subch G part 493 par 3(b)(3): Laboratory requirements
[22] Emergency Medical Treatment and Labor Act (EMTALA) of 1986; 42 USC par 1395dd: Examination and treatment for emergency medical conditions and woman in labor.
[23] US Food and Drug Administration (FDA) Draft guidance for industry and FDA staff: Premarket submission and labelling recommendations for drugs of abuse screening tests (2003) 2.
[24] Health Insurance Portability and Accountability Act (HIPAA) 45 CFR 45 part 164 subtitle A subch C part 164: Security and Privacy.

information and medical records. It makes provision for the release of information **without** written consent.[25]

4.2.1.2 Workplace drug testing flow-chart

A workplace drug testing flow chart as suggested by SAMHSA is shown in appendix 1. The stages involve (1) the initial request by the employer for the drug test, (2) specimen collection, (3) laboratory receipt, analyses and reporting (4) MRO involvement and (5) the final actions by the employer. The sequence of events is indicated in figure 4:1 below.

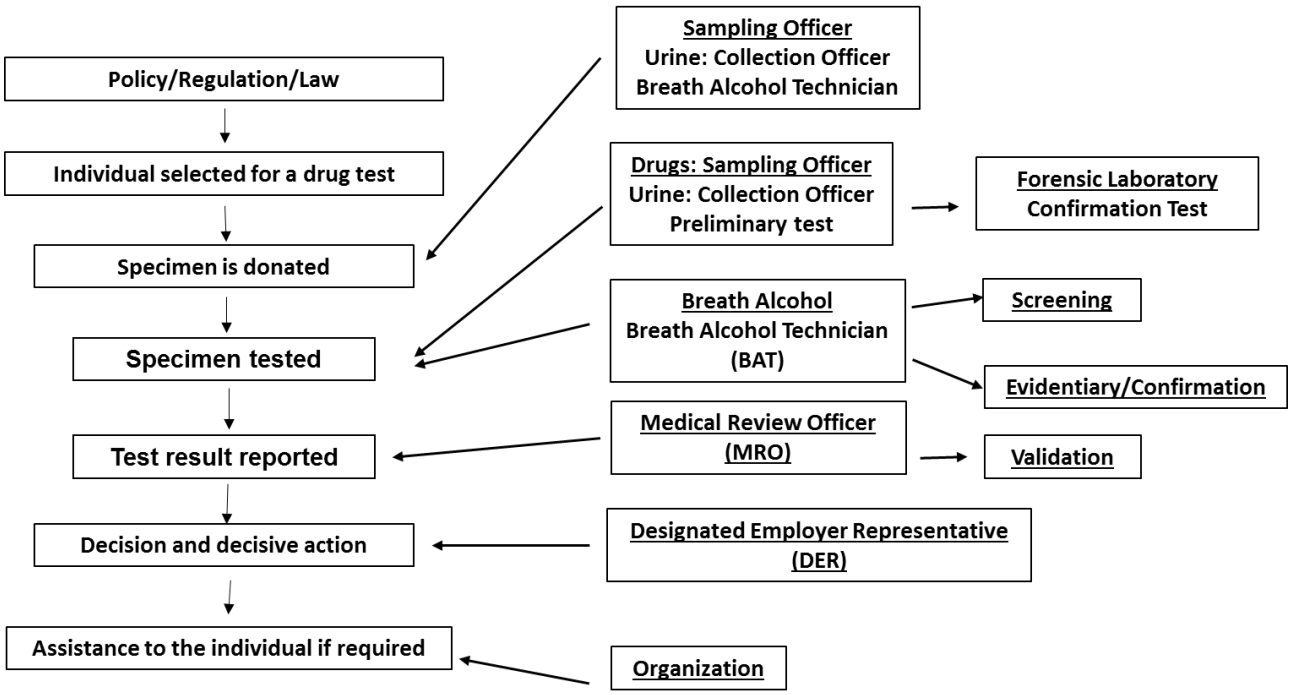

Figure 4:1 The sequence of events during a prohibited substance test

4.2.1.3 Drug- and alcohol-free workplace policy

The key aspects of a drug- and alcohol-free workplace policy can be summarised as follows.[26,27]

- responsibilities of both the employer and employee:

The employer's responsibilities revolve mainly around the design and maintenance of the programme by ensuring that it complies with high ethical, legal and scientific standards. The

[25] Not in line with the CSA.
[26] See DOT SAMHSA website at http://workplace.samhsa.gov for a model workplace drug testing policy.
[27] Swotinsky & Smith (n 15).

employer has to guarantee the confidentiality and the accuracy of the test results and also that the results are validated before any decisive action is initiated. The following aspects are important to provide accurate and reliable test results:

- correct specimen collection protocols
- integrity of the specimen should be preserved during the collection step and transport to the confirmation laboratory. The chain of evidence must be beyond any doubt, i.e. the specimen should have a unique number to link the specimen unequivocally to the test subject.
- professional services and well qualified professional must be used for the administration of the programme.
- suitable collection and preliminary testing apparatus must be obtained and maintained.

The employee's responsibilities involve mainly respect for the rules of the policy and to make sure that the prohibited substance levels are below the concentration threshold values. The programme should not be obstructed and no tampering with the specimens should take place.

- *Training:*

Employee training should have the intent that test subjects must understand the complete drug-free workplace programme in detail. They must know whom to approach if there is any doubt and also be informed about their responsibilities towards the programme. Information about the complete process, from test subject selection up to possible disciplinary action, as well as the role of the professionals executing the programme must be explained understandably to all employees to provide certainty about the rules. Please refer to figure 4:1. They must know under which circumstances they will be tested and how they will be tested and what they will be tested for. A refusal-to-test must be defined and the resulting consequences explained (see below). The complete workforce must be trained on the effects of prohibited substance abuse. In addition to information on the prohibited list, which must be freely available, the employees must understand how to go about when they are prescription medication and the consequences of borrowing medicine should be highlighted. The contact details of a drugs abuse professional must be provided and possible access to treatment programmes.

Supervisors must also receive training on the effects of drugs, the recognition of drug users and the managerial aspects of the programme such as the initiation of a drug test.

- *Recordkeeping* of test results
- Administration of the return-to-duty process
- *Designated employer representative (DER)*

This individual has the responsibility to relay test results from the MRO and BAT to management. The DER must have a clear understanding of the prohibited substance testing programme including the testing protocols. He has the authority to command a reasonable suspicion or post-accident test as well as the removal of an employee from a safety-sensitive position. The DER also has the authority to decide on the outcome of refusal –to-test, adulteration and insufficient urine- and breath donation. It is also part of his responsibility to communicate with a substance abuse professional about an employee who has completed treatment after a test violation.

- *Self-referrals and voluntary drug testing:*[28]

Voluntary testing and self-referrals should be an integral part of the programme since an employee is expected to give his full cooperation in the interest of safety. Voluntary testing will allow the employee to be tested before he enters the safety-sensitive environment without consequences.

- *Who will be tested, when will they be tested and how will they be tested*.

Designated positions for testing has to be specified with risk sensitivity of prime importance. The type of tests may vary from: pre-employment, periodic medical, random testing, reasonable cause or suspicion, post-accident/incident, return-to-duty, follow-up testing or other possible reasons that may depend on the specific industry. The type of bio-matrices to be employed must be captured in the policy such as urine, oral fluid, sweat, hair, blood. It must also be clear which compounds will be tested for and the concentration threshold (cut-off) concentrations must be provided in writing. The detail on the analytical testing protocols and techniques also has to be provided.

- *Employer actions after receiving test results:*

The actions and removal from a safety-sensitive position after notice of a violation was received should be stipulated. A violation may involve a (1) non-negative preliminary drug test result (2) confirmed positive drug test result (positive dilute results as well), (3) preliminary

[28] If an employee voluntarily submits himself frequently, it should be followed up since this option may be misused to avoid the consequences of an "over-the-limit" test result.

breath test[29] (4) confirmed positive alcohol test result, (5) alcohol and drug-use on duty (6) Consumption of alcohol within two hours after an incident knowing that a drug and alcohol test will be required.

- Consequences of non-compliance should be addressed.[30]
- After a drug test violation, the employee must be provided with the contact details of an SAP who will provide feedback to the employer, via the DER, with a report.
- *The roles of the* MRO and the BAT must be explained.
- *The functions of an Employee Assistance Programme (EAP)* should be detailed should an employee have a drug-abuse problem. (please see the discussion below)
- *A written stand-down policy (*please see the discussion below)
- *Disciplinary action*:
  - Decisive action must follow if there is no legitimate explanation for the confirmed positive and validated test result and in terms of the organisation's policy.
  - Consequences for a refusal-to-test. (please see definition of refusal to test below)

4.2.1.4 Background checks[31,32]

The US mandatory guidelines require that an applicant's background regarding drug violations at employers, for the previous two years, be verified for risk-and safety-sensitive positions applications. This has to take place with the consent of the applicant; however, if "voluntary" consent is not provided, the applicant may not be hired. If confirmation of a drug violation is received, then the applicant may not be employed in the position. This also applies when an applicant has not completed the return-to-duty process at the previous employer. If the applicant admits to a drug violation at a previous employer, he or she has to provide proof that the return-to-duty process has been completed or he employer may communicate with the SAP directly with the consent of the applicant. [33]

[29] The SAMHSA guidelines define the limit for alcohol as 0.04. If the test result is between 0.02 and 0.039, the employee is removed from safety-sensitive duties for a defined period or until re-tested below 0.02. If the test result is confirmed to be above 0.04, he/she is not reinstated to a safety-sensitive duty until he has met with return-to-duty requirements.

[30] It is the prerogative of the employer to decide the fate of an employee after a drug test violation in terms of company policy. Some employers dismiss the employee after a first violation, others after a second violation or by treating the decision on a case-by-case basis. However, the latter exposes the employer to the risk of being discriminatory. Some employers respond by sending the employee for a second test, which will typically be negative due to the extra time the body had to metabolise and break down the ethanol or drug. This practice should be prohibited since it undermines the foundations of a workplace drug-free programme.

[31] 49 CFR part 40: Procedures for Transportation Workplace Drug and Alcohol Testing Programs (DOT Procedures).

[32] 49 CFR part 40 par 391.23: DOT Procedures.

[33] Records of this process have to be kept for up to three years.

4.2.1.5 Release and consent form[34]

Documented voluntary informed consent is required before a test is conducted. This includes the designation of individuals to whom the test results may be disclosed in terms of confidentiality. Consent forms or "release and consent forms (RCF)" to document consent is a requirement after the HIPAA was promulgated but the HIPAA does not apply to urine workplace drug testing since this is not regarded as a medical test. [35, 36]

The HIPAA describes the requirement of consent as follows:[37]

- Disclosure is prohibited without the written consent of the donor, which is implicit or assumed when the donor signs the RCF.
- A specimen may not be withdrawn or the result prevented from being reported to the employer after it was submitted for analysis.
- Consent forms **cannot** be used to (1) indemnify the organisation and its administrators, (2) obtain "umbrella consent", (3) obtain information regarding medication used before the test. Enquiring about medication is classified as a medical enquiry which is prohibited under the ADA.[38]
- Drug test results may not be released by following Part 40, which requires the donor's written consent.[39,40] Certain legal proceedings such as a court order, lawsuits (wrongful discharge action), grievance, and administrative proceedings (e.g. an unemployment compensation hearing resulting from a positive test or a refusal-to-test result) are regarded as a defence for release without consent. The donor has to be informed in writing before his or her test result is released without his or her consent. (Please see the section on the role of the MRO below where the release of test results is discussed.)

4.2.1.6 Testing of minors in the workplace

Medical procedures with inherently low risk may be consented to or "informed refused" by "mature minors" (age 12-15) with the right to confidentially. However, a workplace drug test not viewed as a medical test, allowing a minor to consent (or refuse) to a federally mandated

[34] Swotinsky & Smith (n 15) 66.
[35] HIPAA (n 25).
[36] 49 CFR part 40 par 123(d): DOT Procedures.
[37] In analogy to the NHA ch 2 sec 14.
[38] ADA: 42 CFR part 126.12114(d)(1): Illegal use of drugs and alcohol.
[39] 49 CFR part 40: DOT Procedures.
[40] A third party is any person or organisation that the rule (part 40) does not explicitly authorise.

drug test without parental consent. Since the law is not clear on this matter, it should be considered carefully.[41,42]

4.2.1.7 Specimen collection

4.2.1.7.1 Drug testing

Collection of a urine specimen should be performed in a manner that preserves the integrity of the specimen by preventing tampering and simultaneously respect the privacy of the donor. The donor must be unequivocally linked to the specimen, and a chain-of-custody must be observed from collection till the final result is released. The issues can be avoided with a sound legally defensible collection protocol which involves specific documentation to be completed to document the process. [43,44,45,46,47,48]

4.2.1.8 Refusal-to-test

A donor may commit a "refusal to test" violation if he or she does not (1) appear within two hours after the instruction of the DER, (2) complete the collection procedure, (3) refuses an observed specimen collection, (4) cooperate with the collection officer, (5) provide a second specimen on request of the collection officer, (6) provide a specimen after the MRO evaluated him or her medically and concluded that there is no legitimate reason for not being able to donate a urine specimen. [49] An adultered specimen is regarded as a "refusal to test".

4.2.1.9 Specimen testing and reporting

4.2.1.9.1 Drug testing in urine

The SAMHSA guidelines require that a preliminary test, as well as a confirmation test, be performed. The preliminary screening test involves an on-site immunoassay for the specific

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[41] Alerting the parent of a drug test can be advantageous, especially if the minor has a confirmed positive test result since he/she may not have information on the medication that the minor took prior to collection of the specimen. This may result in a dilemma for the MRO if the parent demands that the MRO reveals the child's test result, which may then be viewed as a breach of confidentiality.

[42] School-imposed drug tests in the USA does require parental consent.

[43] Department of Health & SAMHSA Urine specimen collection handbook for federal workplace drug testing programs (Urine specimen handbook) http://workplace.samhsa.gov (accessed 13 January 2019).

[44] JB Laurens *Validation of the mandatory guidelines for the American Federal Workplace Drug Testing Program within the context of the South African Constitution* (2017) University of Pretoria.

[45] Typically, he/she should wash his/her hands before entering the donation cubicle and he/she should not wear unnecessary garments or take bags into the donation cubicle. This is to prevent persons from hiding adulteration agents.

[46] The specimen collection container should be a certified clean and sterile, sealed container. It must also be possible to obtain the certificate of analysis, certifying the batch as clean from the supplier.

[47] No direct contact tests are allowed due to the possibility of contamination like: submerging of a thermometer, "dip-stick" immunoassay preliminary tests. Contact thermometers are a better alternative for temperature measurements.

[48] A part specimen should be retained in the specimen collection container after emptying the bulk into a specimen bottle. This will nullify any claims of contamination while preliminary/validity testing is performed, since the bulk specimen has then been secured for confirmatory testing should the preliminary assay result come out non-negative.

[49] Swotinsky & Smith (n 15).

drug class in combination with urine validity testing such as for creatinine, pH and oxidising adulterants. A second test is to be performed if any of the preliminary parameters and tests are outside the norm. Please see appendix 2 for a summary of the type of tests required for drugs and alcohol for preliminary and confirmatory testing. The preliminary- and confirmation cut-off (threshold) concentrations for urine and oral fluid are summarised in appendix 3.[50,51,52]

4.2.1.9.2 Breath alcohol testing

Breathalysing tests should also follow the route of a preliminary test first, followed by a confirmation test in the case of a non-negative preliminary test result. The proposed breath alcohol testing protocol is shown in appendix 4.[53]

4.2.1.10 Medical review of test results

4.2.1.10.1 Drug testing

The test results from accredited SAMHSA confirmation laboratories are forwarded to a medical review officer, who is a licensed medical doctor with specialised knowledge on drug and alcohol use. Confirmed positive analytical results have to be validated by the MRO to assess if the drug was consumed negligently or wilfully by the employee to establish "culpability" which can be excluded by interviewing the employee. The employee is afforded the chance to explain the confirmed positive result by offering reasons such as the use of prescription medication, diet, herbal products, or even self-medication without legal prescription or by borrowed prescription medicine. A legitimate explanation for the presence

[50] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 53(69) par 119701, 11 April 1988 http://workplace.samhsa.gov. (accessed 23 October 2018).

[51] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 53(69) par 119701, 11 April 1988 FR 80(94), 15 May 2015/Notices (http://workplace.samhsa.gov) (accessed 13 January 2019).

[52] It is essential to keep in mind that the preliminary testing device technology can only be employed to raise "objectively reasonable suspicion". These devices are not selective enough to unequivocally confirm the presence of a drug residue in the urine specimen. All non-negative results should be referred for confirmatory testing. Specimens suspected of being tampered with should also be shipped to a confirmatory laboratory.

[53] It is of vital importance that the first step is performed promptly and accurately, as this is the link between the result and the donor. The observation period is part of the protocol to counter all claims of residual alcohol in the buccal cavity (cough syrup and mouth wash). Air blanks are performed between each alcohol test to ensure that there is no chance of carry-over from the previous analysis. The first air blank provides proof that the air in the room does not contain alcohol. Two breath alcohol test results are recorded, and the mean value reported. The quality control process is critical (besides the high standard of training required for the BAT). Firstly, the two individual test results may not differ by more than a certain percentage. Secondly, the control test result must provide proof that the evidentiary breathalyser provided a result within the tolerance of the certified control gas control specimen. Proof that the instrument was functioning at the specific time the testing took place is required and not only the usual periodic calibration by a calibration laboratory. An evidentiary breathalyser operates on the principle of a simultaneous measurement by two independent techniques which can be either fuel cell or infra-red techniques – sufficient selectivity to prevent interference of metabolic substances that occur in the breath naturally will then be guaranteed

of the drug in urine specimen allows the MRO toy report the result to the employer as *negative*. If there is no alternative explanation, the MRO reports the result to the employer as *positive*

4.2.1.10.2 Alcohol testing

An alcohol testing result generally requires no medical review since the result can stand on its own. An exception to this would be in the case of a "shy lung" when the donor could not supply a sufficient volume of breath, and the MRO has to confirm the medical condition.

4.2.1.10.3 MRO report

The validated and verified outcome of the drug test is communicated to the Designated Employer Representative (DER) confidentially with limited comments and information to protect the individual. The possible verification outcomes that may be indicated in the MRO report are the following (1) *Negative:* if the test result is negative or changed to negative by the MRO, (2) *Positive*: if the laboratory result is confirmed positive with no legitimate excuse. Drugs/metabolites information is included with no reference to drug concentration levels.[54] (3) *Refusal to test*: the result is reported as a refusal to test, and a reason is provided. Please refer to section 4.1.2.9 above for a summary on "refusal to test", (5) *Cancelled*: if the test is cancelled with a reason, (6) *Dilute:* with following two possible options *Positive dilute*: The employer should treat this as a positive and *Negative dilute*: Creatinine concentration will direct the MRO on what to do next [55], (6) *Retest*: for instance, because of a problematic collection, (7) *Safety risk or medical disqualification*: If the MRO identified a safety risk other than drug use or medical disqualification concern, it could be indicated as a safety risk. The details can then be communicated to the occupational health doctor or health care professional, making the determination of fitness for duty.

4.2.1.11 Standing down an employee

Removing an employee from a safety-sensitive position is referred to as "Stand-down". An employee is stand-down on the basis of a drug violation from the moment of a non-negative screening test up until the MRO report is issued. Stand-down may compromise the confidentiality of the employee's information, however, the right to confidentiality of the individual needs to be balanced against the safety of others. The SAMHSA guidelines require that permission be obtained from the Department of Trade to stand-down an employee. [56]

[54] The drug concentration levels can be reported later if the test is challenged or as part of an administrative process.

[55] Creatinine 2-5 mg/L: MRO informs the DER to retest immediately under direct observation. If negative again and found to be negative, the test is accepted as negative. If creatinine is higher than 5 mg/L, the employer is informed that the employee may be re-tested once, but not under direct supervision.

[56] Ethical committee or DTI in SA.

A written stand-down policy should (1) be non-discriminatory, (2) be confidential, (3) provide for continued pay to a maximum of five days, (4) instruct the removal of all records if the MRO verifies the result as negative.

4.2.1.12 Employee assistance programme

An EAP provides confidential assistance concerning problem identification, counselling, referral to treatment, support and guidance through treatment and rehabilitation.[57] The EAP also assists with the training and education related to drug dependency matters.

4.2.1.13 Service agents

Third-party drug and alcohol programme administrators may be utilised by an employer; however, he remains responsible for all aspects of the programme. These services include specimen collection, laboratory testing, random selections, background checks, supervisor/employee training, MRO review, record maintenance and assistance with audits by the government. The service providers are also liable in terms of the Public Interest Exclusion Act (PIEA) whereby a service provider can be barred from providing services to any government agency.[58]

4.3 INTERNATIONAL LAW: PROHIBITED SUBSTANCE TESTING IN SPORT

4.3.1 Introduction

Governments signalled their intention to formally recognise and implement the World Anti-Doping Code (WADA Code) through an international treaty named the Copenhagen Declaration on Anti-Doping in Sport (Copenhagen Declaration). The fact that governments cannot be legally bound by a non-governmental document such as the WADA Code[59] led to the Copenhagen Declaration according to the WADA Code.[60] Governments subsequently drafted the International Convention against Doping in Sport under the auspices of the United Nations body responsible for education, science, and culture (UNESCO) to allow formal acceptance of WADA and the WADA Code. The Copenhagen Declaration was drafted and agreed to by governments at the Second World Conference on Doping in Sport held in Copenhagen, Denmark, in March 2003. South Africa is a signatory to the Copenhagen

[57] RB Swotinsky (ed) *The medical review officer's guide to drug testing* (1992) 10, 47, 141.

[58] 49 CFR part 29: Government-wide debarment and suspension (non-procurement) and government-wide requirements for drug-free workplace (grants).

[59] WADA *World anti-doping code 2015* https://www.wada-ama.org/sites/default/files/resources/files/wada-2015-world-anti-doping-code.pdf (accessed 1 January 2018).

[60] WADA *Copenhagen Declaration* (2003) https://www.wada-ama.org/en/governments#CopenhagenDeclaration (accessed 15 December 2017).

Declaration. The Copenhagen Declaration specified the criteria as to how countries should support the code. In short, these were as follows:

- The participants and signatories had to respect the WADA Code as the foundation of the worldwide fight against doping in sport.
- Participants had to progressively adjust their anti-doping rules and policies to be in line with the WADA Code and encourage other countries to become signatories to the code.
- The specific country's government should not financially support athletes who are not compliant with the WADA Code.
- Signatories had to agree to the coordinative, harmonisation and standardisation role of WADA regarding anti-doping efforts.

Each country furthermore had to ensure that regulations and legislative measures were in place to control the availability of prohibited substances[61] and had to provide financial support for a national anti-doping programme within their means, which involved doping control, education, research and information activities.[62] Each country was to test its athletes with no advance notice, after which the specimen had to be transported to an accredited testing laboratory promptly, and WADA reserved the right to monitor compliance on an ongoing basis.

The fundamental rationale for the WADA Code is the preservation of the intrinsic values of sport which can be described as "the spirit of sport which pursues human excellence through the dedicated perfection of each person's natural talents" and thereby declares doping to be contrary to the spirit of sport.[63]

The main aim of WADA is to harmonise anti-doping efforts around the world, which are based on six international standards that are mandatory for all signatories of the WADA Code. The standards relate to:[64]

- Prohibited list of substances and methods
- Testing and investigations
- Laboratories
- Therapeutic use exemptions (TUEs)

[61] As above sec 5.
[62] As above sec 6.
[63] WADA (n 59) 14.
[64] WADA *WADA International standards* https://www.wada-ama.org/en/international-standards (accessed 1 January 2018).

- Protection of privacy and personal information[65]
- Code compliance by signatories

The medical commission of the International Olympic Commission (IOC) drafted a list of prohibited substances and doping methods that were absorbed into the WADA Code. Doping control analyses are performed by a network of IOC-accredited laboratories, designated to analyse urine specimens taken directly after and out of competition.

4.3.2 The anti-doping rules apply to the following individuals and organisations

The anti-doping rules apply to all national sports federations who should incorporate the rules into their governing documents and policies, and as a condition for receiving financial and/or other assistance from their governments. They must accept and abide by the spirit of the anti-doping rules by applying its sanctions to individuals in order to co-operate with WADA in anti-doping matters.[66] It also states that the anti-doping rules apply to athletes and their support personnel, in all events organised, convened, authorised by any national federation as well as other national events not affiliated to a national federation. As such, these persons are deemed to have submitted to the anti-doping rules of WADA as a condition of their membership, accreditation and participation in their chosen sport, with particular reference to national-level athletes.

4.3.3 Definition of anti-doping rule violations.

The definition of anti-doping rule violations is summarised in table 4.1[67]

Table 4.1: Definition of doping – anti-doping rule violations[68]

▪ Presence of a prohibited substance or its metabolites or markers in an athlete's specimen
▪ Use or attempted use by an athlete of a prohibited substance or method
▪ Evading, refusing or failing to submit to specimen collection
▪ Whereabouts failures
▪ Tampering or attempted tampering with any part of doping control
▪ Possession of a prohibited substance or a prohibited method
▪ Trafficking or attempted trafficking in any prohibited substance or prohibited method
▪ Complicity

[65] WADA *Protection of privacy and personal information* January 2015 https://www.wada-ama.org/sites/default/files/resources/files/WADA-2015-ISPPPI-Final-EN.pdf (accessed 1 January 2018).
[66] WADA (n 59).
[67] As above art 1.
[68] As above art 2. Directly adapted from the WADA rules.

- Prohibited association

Strict liability: It is the athlete's responsibility to ensure that no prohibited substances (including metabolites and markers) are detected in his or her body and, accordingly, it is not necessary that intent, fault, negligence or intentional use on the athlete's part be demonstrated in order to establish a doping violation. An athlete's fault is taken into consideration in determining the consequences of the anti-doping rule violation.

This analytical *detection rule*[69] applies for prohibited substances, except for those substances for which a quantitative threshold concentration[70] is set in the prohibited list. In the case of administration of endogenous substance administration, like testosterone, other criteria will be employed to prove a doping violation. Strict liability standard of proof also applies to the use of prohibited methods (such as red-blood-cell doping) regardless of whether the use of such a method was successful.

Intentional avoidance of a doping control official to evade notification or testing will be regarded as "evading specimen collection", which may be viewed as intentional conduct. Refusal or failure to submit to specimen collection by the athlete without a reasonable explanation is also considered an anti-doping violation, namely "failing to submit to specimen collection" and may be regarded as negligent conduct.

4.3.4 Proof of doping

The burden of proof rests with the anti-doping organisation to establish that an anti-doping rule has been violated to the comfortable satisfaction of the hearing panel.[71] The standard of proof is more than a mere balance of probability but less than a proof of beyond reasonable doubt. In the case where the anti-doping rules place the burden of proof upon the athlete to rebut a presumption or to establish facts, the standard of proof becomes the balance of probability.

The methods of establishing facts and presumptions are:[72]

a. Analytical methods with decision and detection limits decided upon during consultation with the scientific community are presumed to be scientifically valid. These can be rebutted at a balance of probabilities standard of proof.

[69] "Detection rule" must have a detection limit and the sensitivity and specificity therefore has to be established.
[70] Uncertainty of measurement important.
[71] WADA (n 59) art 3.
[72] This evidence is accepted on a *prima facie* basis.

b. It is also presumed that the specimen transport, custody and analytical procedures were compliant with the WADA International Standard for Laboratories.[73] Deviation from these standards may serve as a defence if it could have reasonably caused the adverse analytical finding. The SAIDS will then have the burden to prove that the deviation did not cause the adverse analytical finding.
c. The evidence established by a competent court, a professional disciplinary tribunal of competent jurisdiction, will be irrefutable unless it can be proven that the decision was incorrect.
d. An adverse finding might be made against an athlete who was supposed to attend a hearing if due notice was given within a reasonable time.

4.3.5 List of prohibited substances

The criteria for including substances and methods on the prohibited list are explained unequivocally as follows.[74,75] A substance or method will be included on the list if any two of the following criteria are met.

Firstly, if sufficient medical and pharmacological evidence or experience exists that:

a) a compound (on its own or in combination with another substance) has the potential to enhance sports performance or
b) the use of a substance or method poses a potential health risk to the athlete or
c) the use of a compound or method violates the spirit of sport.

Secondly, if sufficient medical and pharmacological evidence or experience exists that a substance or method has the potential to mask the use of other prohibited substances or methods.

Thirdly, it is stated that WADA's enlisting of substances and classification thereof is final and should not be subject to challenges regarding enhancement and masking properties.

A distinction between the classes of compounds is also made in terms of the decisive action to be taken such as preliminary suspension.

- ***Substances prohibited at all times – in and out of competition:***

[73] WADA (n 64).
[74] WADA (n 59) art 4.
[75] As above art 4.3.

- S0: Non-approved substances that are not indicated in the rest of the sections of the list. Compounds with no current regulatory approval for human therapeutic use such as drugs under pre-clinical or clinical development or discontinued, designer drugs and substances approved only for veterinary use are included.
- S1: Anabolic-Androgenic substances (AAS) which include (1)(a) exogenous and (1)(b) endogenous AAS when administered exogenously as well as (2) other anabolic agents. It is significant to note that the list also makes provision for "other substances with a similar chemical structure or similar biological effects."[76]
- S2: Peptide hormones, growth factors, related substances, and mimetics.
- S3: Beta-2 Agonists
- S4: Hormone and metabolic modulators
- S5: Diuretics and masking agents

- ***Prohibited methods at all times –in and out of competition:***
  - M1: Manipulation of blood and blood components.
  - M2: Chemical and physical manipulation, which includes (1) Tampering (or attempting to tamper, altering the integrity and validity of specimens collected during doping control. Also included are urine substitution and adulteration, for instance, proteases (2) Intravenous infusions of more than 100 mL per 12-hour period (except if legitimately received as part of medical treatment).
  - M3: Gene doping
- ***Substances prohibited in competition***
  - S6: Stimulants
  - S7: Narcotics
  - S8: Cannabinoids from natural as well as cannabimimetics of synthetic origin, excluding Cannabidiol (CBD)
  - S9: Glucocorticoids
- ***Substances prohibited in particular sports***
  - P1: Beta-blockers for sports like archery, automobile and darts.
- ***Therapeutic use exemptions (TUEs)*** imply that the use of prohibited substances will not be seen as an anti-doping violation if its use was granted by WADA within the framework

[76] The inclusion of structural and effect analogues addresses the continued development of new designer compounds that may come onto the market sooner than the list can be updated yearly.

of the WADA International Standard for therapeutic use exemptions and was considered by an expert panel from WADA.[77]

- ***Specified substances***: A distinction between the classes of compounds is also made in terms of the decisive action to be taken, such as mandatory preliminary suspension. For this purpose, substances in classes S1, S2, S4.4, S4.5, and S6A, and prohibited methods M1, M2, and M3 of the prohibited list are regarded as specified substances. This classification has to do with the seriousness and risk associated with the use of these compounds and methods. The prohibited methods include tampering.

4.3.5.1 Testing and investigations

Testing will be conducted with the sole purpose of anti-doping investigations, in line with the International Standard for Testing and Investigations, to obtain analytical evidence as to the athlete's compliance.[78]

The following activities performed by national anti-doping bodies have to be in line with the testing and investigations international standard:

- Test distribution planning, testing itself and post-testing activities.
- The number of tests as well as the type of tests, such as random and targeted tests according to specific criteria also described in the international standard for testing and investigations.

Investigations will be initiated into atypical findings to obtain information and evidence (analytical) to assess if an anti-doping violation has occurred. Investigations will also be performed when other non-analytical information may indicate that an anti-doping violation had taken place, such as when an anonymous tip-off was received.

The national anti-doping body will have the authority over all athletes in its scope (in and out of competition) to conduct testing and to provide a specimen at any time and any place. The relevant body, such as the SAIDS in South Africa, will also have a test distribution plan that may prioritise between disciplines, categories of athletes, types of testing, specimens collected and types of specimen analysis.

Athletes, who have been notified that they are included in a testing pool has to provide whereabouts information so that they can be reached with no advance notice, with particular reference to the collection of the minimum amount of information to arrange for the test by the

[77] WADA (n 64).
[78] WADA (n 59) art 5.

collection official with due respect for the protection of personal information and confidentiality.[79] A combination of three missed tests within 12 months is regarded as an anti-doping rule violation.

If an athlete returns from retirement or suspension due to a doping violation, he or she has to give the anti-doping organisation due notice of the intention to start competing again six months in advance so that athlete can be tested during this period.

4.3.6 Procedures and protocols related to specimen transport, analyses and reporting of results

WADA-accredited/approved laboratories may only analyse specimens for prohibited substances, and the anti-doping organisation responsible for the results management has the right to decide which laboratory to engage for the analyses.[80] Specimens may also be collected and analysed for future use, in line with the Protection of Personal Information International Standard, but no specimen may be analysed for research without the consent of the donor, and this should be done in such a fashion that the result cannot be traced back to the donor.

Specimen analyses should conform with the WADA International Standard for Laboratories and analyses should be aimed at the substances or group of substances as determined by WADA and listed in a technical document that was composed based on a risk assessment for the different types of sports.[81] The number of analyses may be decreased or increased on request of the anti-doping organisation. The laboratories also have the authority to change the type of substances to be analysed at their initiative. A specimen may be stored for ten years and analysed at any time.

4.3.7 Management of test results

The SAIDS will have the responsibility for results management and will appoint a Doping Control Review Commission (review commission) to conduct a review, which may or may not seek the assistance of experts to conclude on an anti-doping rule violation.[82]

- ***Review of an atypical finding***

[79] World anti-doping code international standard, testing and investigations sec 5.6.
[80] WADA (n 59) art 6.
[81] As above art 5.4.1.
[82] As above art 7.

The results must be communicated by the laboratory representative to the review commission confidentially. The review committee will then assess the report to determine if: (1) an applicable TUE has been granted and (2) there were deviations from the International Standard for Testing and Investigations or International Standard for Laboratories that caused the ***atypical finding***. If neither of these was the case, the atypical finding would be brought forward as an ***adverse analytical finding*** only after the review committee has released its conclusion.[83] The athlete will be notified unless it is decided by the review committee to analyse the B-specimen to conclude the possible anti-doping rule violation.

If it is found that there was a deviation from one of the international standards (testing and investigations or laboratories), the entire test will be considered negative, and the athlete will be informed as such – the same applies to the case where that of the B-specimen does not confirm the A-specimen result.

- ***Review of other anti-doping rule violations***

The SAIDS will conduct follow-up investigations into possible anti-doping rule violations other than prohibited substance-related cases and will inform the athlete on the outcome promptly. The athlete will be informed by the anti-doping organisation simultaneously with the athlete's international and national federation in a way that includes the following information:

- The adverse analytical finding
- The anti-doping rule violated
- The athlete's right to request a B-specimen analysis under his or her supervision (or a representative) on a scheduled date and time. If he or she do not take up the opportunity, it will imply that the A-specimen results are accepted.
- The athlete's right to request copies of the laboratory documentation package.

- ***Provisional suspensions***
  - *Mandatory provisional suspension* should take place after the review of an adverse analytical finding which indicated the administration of a specified substance. In the case of prohibited methods like tampering or if it was not a *legitimate* TUE, the athlete will be allowed to have a provisional hearing, and if he or she can prove that the violation

[83] This is in analogy to a "confirmed positive" test result from the analytical laboratory that has to be validated by an MRO who will report the test result as "positive" drug test.

was due to a contaminated product, the mandatory provisional suspension may be lifted.[84]

- Temporary suspension may also be lifted if the B-specimen test result does not confirm the A-specimen test result.
- *Optional provisional suspension* may apply in the case where the adverse analytical finding involves a ***specified substance,*** and the default suspension may be set aside by the anti-doping organisation at any time before the final hearing.

- ***Resolution without a hearing***
  - An athlete may admit the anti-doping rule violation at any time, waive the right to a hearing and accept the consequences. If he or she fails to dispute the assertion within a specified time, he or she will be viewed as having admitted to the violation and waive the right to a hearing and accept the consequences.
  - In such a case, the athlete will be provided with written notice of rule violation and the consequences. The athlete will still have the right to appeal.
- ***Retirement from sport***

If an athlete retires from the sport before or after the results management process has begun, the anti-doping organisation will have the right to complete the results management process.

4.3.8 Right to a fair hearing

- ***Hearings following the SAIDS results management process:***[85]

An independent doping hearing panel with no prior exposure to the case would be appointed to hear the case if the athlete did not waive the right to a hearing.[86] The principles of natural justice will be applicable, which include the rights to: (1) have access to the evidence that will be presented at the hearing, (2) be heard and be represented by a competent person, (3) produce evidence, (4) be judged by impartial and independent adjudicators, and (5) call witnesses and to cross-examine witnesses.

[84] Suspension with certain provisions, which may allow the athlete to compete under certain provisions.
[85] WADA (n 59) art 8.
[86] The independent doping hearing panel should consist of at least a (1) legal practitioner as chairperson, (2) a medical practitioner and/or a person with analytical and/or forensic pharmacology or endocrinology and (3) another member from either of the two former categories or a previous sports administrator or athlete.

- ***Principles of a fair hearing:***

The hearing should be concluded in a reasonable time and the independent hearing panel, who should be impartial, may decide on the procedure to be followed at the hearing,

- ***Decisions of the independent doping hearing panel***:

After the conclusion of the hearing, the athlete will receive a written decision on the majority decision, which will contain the information regarding the reasons for the decision as well as the period of ineligibility decided upon. The reasons for not imposing the maximum potential consequences should also be provided. If the doping rule violation decision is not appealed, it should be publicly disclosed, and if there was no anti-doping rule violation, consent from the athlete is required before public disclosure.

- In the case of a national-level and international-level athlete, the Court of Arbitration in Sport (CAS) may hear the case directly with prior consent from the athlete who will then not have the right to appeal the ***single hearing*** decision of the CAS.

4.3.9 What the consequences are for a doping-anti-doping rule violation for:

- ***Sanctions***:[87]
  - All results and medals obtained in the event during which the anti-doping rule violation occurred will be disqualified. The presence, use or attempted use, possession of a prohibited substance or prohibited method will result in four years of ineligibility if the (1) substance is not a specified substance (unless the athlete can prove that the violation was not intentional) or (2) in case of a specified substance if the violation was intentional. Intentionality is regarded as "the athlete knew and understood that the conduct constituted an anti-doping rule violation or that his conduct could lead to an anti-doping rule violation, but disregarded this by employing the prohibited substance or method". In short, he or she cheated intentionally.
  - If the assertion relates to evading, refusing, failing to submit or tampering with a specimen, the period of ineligibility will be four years unless it was not intentional, in which case it will be two years.
  - A whereabouts violation will result in a sanction of two years with a minimum of one year, depending on the degree of fault by the athlete.

[87] WADA (n 59) art 10.

- Violations related to trafficking on prohibited substances or methods, administration to any athlete (in or out of competition) will result in a minimum penalty of four years up to lifetime ineligibility and is viewed in harsh light in case of a minor.
- Complicity may result in a sanction of between two to four years, depending on the seriousness of the violation.
- Prohibited association with an athlete support person who is under a doping violation sanction, will result in a sanction of between one and two years for the athlete.

- Where there is no fault or negligence on the part of the athlete, the period of ineligibility shall be eliminated.
- Sanctions enforced on athletes will be published publically after informing the athlete. The publication will be on the anti-doping organisation website for a minimum of one month.
- ***Reduction of the sanction based on no significant fault or negligence:***
  - In the case of specified substance use, the sanction may decrease to two years or even a reprimand with no period of ineligibility, depending on the degree of fault by the athlete.
  - The same applies to the use of a contaminated product.
  - Assistance in discovering anti-doping rule violations by other athletes and prompt admission of an anti-doping rule violation is encouraged and may serve as a reason to reduce the sanction imposed on an athlete from four to two years.
- If an athlete is ineligible, he or she may not take part in any competitions/events organised by his or her member organisation in any capacity.

4.3.10 Importance of result confidentiality and privacy

***Information related to adverse analytical findings, atypical findings and other anti-doping rule violations*:**[88] Athletes may be notified of an anti-doping rule violation through his or her national federation or sporting body in writing, which contains all the relevant information regarding the anti-doping rule violation.

The recipient organisation should not disclose this information beyond those individuals with a need to know until the anti-doping organisation has made a public disclosure. It is the responsibility of the anti-doping organisation to maintain confidentiality by contracting with its employees, contractors and consultants for protecting confidential information.

[88] As above art 14.

Data privacy: The anti-doping organisation may collect, store, process or disclose personal information relating to athletes as required to conduct anti-doping activities under the WADA Code and the international standards, more specifically the International Standard for the Protection of Privacy and Personal Information. It is furthermore assumed that "any participant who submits information, including personal data to any person, shall in accordance with the anti-doping rules be deemed to have agreed, pursuant to applicable data protection laws and otherwise, that such information may be collected, processed, disclosed and used by such person for implementation of the anti-doping rules…"[89]

4.3.11 Statute of limitations

It is stated that no anti-doping rule violation proceeding may commence without an athlete being notified of the anti-doping rule violation within ten years from the date of the violation.[90]

4.3.12 The necessity of education

The anti-doping organisation should implement education and prevention programmes for doping-free sport and should encourage active participation by athletes and their support personnel in such programmes.[91]

4.3.13 Additional roles and responsibilities of athletes and other persons

- ***Roles and responsibilities of athletes***:[92]
  - To ensure that they understand and obey the anti-doping rules
  - To be available for specimen collection at all times
  - To act responsibly about what they ingest and use
  - To inform medical personnel of their obligation not to use prohibited substances to ensure that the medical treatment does not violate the anti-doping rules as far as possible
  - To co-operate with anti-doping organisations to investigate anti-doping rule violations
- The WADA Code applies to all athletes and authorises the national anti-doping organisation to request an athlete to provide a sample for doping control
- adopts the international standards as required by the WADA Code

[89] As above art 14.6.2.
[90] As above art 17.
[91] As above art 19.
[92] As above art 22.

- requires the institute to enter the name of an athlete or another person in the doping register when the athlete or other person is found guilty of violating an anti-doping rule
- requires the institute to communicate with the relevant sports federation regarding an athlete's doping violation, provided that the information communicated complies with the provisions of the Promotion of Access to Information International Standard[93]
- authorises the institute to disclose to the police and customs service information on any use, possession, trafficking by a person of a prohibited substance (any substance on the list). The institute may furthermore disclose information regarding the return of an athlete after an adverse analytical finding, or an anti-doping rule violation to the public.[94]

4.4 CONCLUSIONS

Examples of foreign law and international law on prohibited substance regulation and testing programmes were reviewed, namely, the "Mandatory guidelines on workplace drug testing in the USA" and the rules for anti-doping of the "World Anti-Doping Association (WADA)".

A summary of the USA statutes applicable to these guidelines is provided and the elements of a drug- and alcohol-free program listed. The importance of a written policy is stressed in the interest of legal certainty for the test subjects and also the administrators/professionals in the organisation. The independence of the different phases was noted, meaning the separation of powers principle is applied in the testing process.

The guidelines also prescribe that the consent of the test subject is essential; however, it is unclear how the information on test results are treated when an employee moves to another department within the USA government where a possibility of breach of confidentiality may exist.

The WADA prohibited substance regulation and testing programme are in the opinion of the author, the best system currently in the world. It has due consideration for ethical, legal and scientific aspects. A concern may also be raised regarding the privacy of an athlete as the athlete has to inform the authorities of his whereabouts, who may test the athlete even when on vacation. Another concern is the principle of strict liability, which may conflict with the CSA in terms of which a person has the right to be presumed innocent.[95] The separation of powers

[93] WADA (n 65).
[94] South African Institute for Drug-Free Sport Act 14 of 1997 (SAIDS Act) sec 11A(g)(ii).
[95] CSA sec 35(3)(h).

principle is, in the opinion of the author, also not well applied in the WADA prohibited substance regulation and testing system.

CHAPTER 5:

LEGAL FRAMEWORK FOR PROHIBITED SUBSTANCE REGULATION AND TESTING IN SOUTH AFRICA

5.1 STATUS QUO OF THE REGULATORY FRAMEWORK FOR PROHIBITED SUBSTANCE TESTING IN SOUTH AFRICA

South Africa does not have mandatory guidelines for prohibited substance abuse testing programmes as in the United States of America[1] and some European Countries [2] and needs legally defensible prohibited substance control and testing regulations that can be applied across all sectors. Testing for the presence of prohibited substances in an individual may infringe on fundamental human rights such as privacy, dignity, bodily integrity and freedom, and false accusations have the potential to result in unfair discrimination and injustice.

Ethical aspects of prohibited substance testing outside the medical/clinical setting are not always respected and understood by non-medical people who are responsible for the administration of prohibited substance testing programmes. The medical professions have set the bar for the level of ethics to which non-medical people in prohibited substance regulation and testing programmes should be accountable. The principles of medical ethics can be directly applied to testing programmes outside the medical sector, as discussed in Chapter 2.

South Africa does have broader legislation related to the use and possession of drugs and alcohol, but clear guidelines on prohibited substance regulation and testing are not enacted that will allow for prohibited substance regulation and testing to be performed in an ethically sound, legally correct and scientifically correct fashion. The following statues and policies may serve as examples that may be related directly or indirectly:

- Possession and use of prohibited substances are regulated by the Schedules of the Medicines and Related Substances Act [3] and the Drug and Drug Trafficking Act, [4] respectively.
- Medicines and Related Substances Control Act[5]

[1] Executive Order 12564 Drug-Free Federal Workplace Federal Register 32889-32893 15 September 1986 available at http://workplace.samhsa.gov (accessed 16 December 2017).
[2] International Labour Organisation (ILO) 'Appendix V: Guiding principles on drug and alcohol testing' in *Management of Alcohol-Drug-related Issues in the Workplace* (1996) Geneva: ILO.
[3] Schedules of the Medicines and Related Substances Act 101 of 1965.
[4] Drug and Drug Trafficking Act 140 of 1992.
[5] Medicines and Related Substances Control Act 72 of 2008.

- Prevention of and Treatment for Substance Abuse Act.[6]
- The National Road Traffic Act that prohibits drivers on public roads to drive under the influence of alcohol and intoxicating substances.[7]
- The South African Schools Act[8,9,10,11] allows the school principal (or their delegate) in the absence of a police officer, without a warrant, to search any person on school premises if they have **reasonable** suspicion that illegal drugs may be present. A drug test may then be conducted on the learner, and his parent or guardian should be contacted. It is also required that drug testing must be supported by a school code of conduct and policy that can be enforced should anyone be found to be breaking the rules of the school regarding drug use.
- The South African Civil Aviation Authority (SACAA) also has strict rules which employees in the aviation sectors have to comply with,[12,13] and the Department of Transport has a substance abuse policy which is extremely broad and provides no legal certainty.[14]
- South African Institute for Drug-free Sports Act, which provides the SAIDS with the mandate to promote participation in sport, free from the use of prohibited substances or methods intended to enhance performance artificially.[15]
- The NHRA has a prohibited substance testing programme for both jockeys and horses.[16]

[6] Prevention of and Treatment for Substance Abuse Act 70 of 2008
[7] National Road Traffic Act 93 of 1996.
[8] South African Schools Act 84 of 1996 (SASA).
[9] Department of Basic Education *Guide to drug testing in South African Schools* https://www.education.gov.za/Portals/0/Documents/Publications/Drug%20Testing%20Guide_FINAL_PRINT.pdf?ver=2014-07-18-150102-000 (accessed 8 December 2017).
[10] Regulations for safety measures at public schools (2001) GG 22754 of 12 October 2012.
[11] Department of Education South African Schools Act 84 of 1996 Devices to be used for drug testing and the procedure to be followed GN 1140 in GG 31217 of 19 September 2008.
[12] South African Civil Aviation Authority Drug and substance abuse in the aviation maintenance environment, revised cross-functional accident reduction plan 2016/17 – 2018/19, Implementation Plan http://www.caa.co.za/Airworthiness%20Documents/Drug%20an%20Substance%20Abuse%20in%20the%20Aviation%20Maintenance%20Environment.pdf (accessed 9 December 2017).
[13] South African Civil Aviation Authority 'South African Civil Aviation Technical Standard 67 (SACATS 67) Medical Requirements South African civil aviation technical standards relating to medical requirements sec 67.00.13 (2017)' http://www.caa.co.za/Pages/default.aspx (accessed 9 December 2017).
[14] Limpopo Department of Roads and Transport *Substance abuse policy 2011*, http://policyresearch.limpopo.gov.za/bitstream/handle/123456789/250/SUBSTANCE%20ABUSE%20POLICY.pdf?sequence=1 (accessed 8 December 2017)
[15] South African Institute for Drug-free Sport (SAIDS) Act 14 of 1997.
[16] NHRA, April 2018 http://www.nhra.co.za/pubs/docs/rules/Rules_2018.pdf. (accessed 12 March 2018).

5.2 LEGAL ASPECTS OF PROHIBITED SUBSTANCE TESTING

5.2.1 Overview of the South African legal system

Members of a society adhering to rules created by their government are known as the "rule-of-law", which is founded in a social contract amongst the members to the benefit of all. According to Thomas Hobbes, an individual in its original state is someone living without rules and with self-interest, which has the potential to disrupt harmony and may harm society. According to the social contract (agreement) with each other, each person will then have to give up his unlimited freedom to make co-existence possible.

The government lays down the legal rules which citizens must obey since they have agreed to the authority and gave up their freedom to the government (state).[17] To determine whether socially deviant or unacceptable behaviour should be regulated, "harm to others" should be used as a criterion. Regulation can only be enforced if harm to others can be prevented, but not to enforce good behaviour and morality.[17] The relationship between the state and an individual can be regarded as paternalistic if the state enforces proper behaviour and morality. In the case of children, it may be acceptable if the state is paternalistic since they cannot understand the consequences of their actions and to make informed choices.

The South African courts provide for justice in the following ways:

- "The system of precedent is the judicial instrument which ensures that like cases be treated alike
- Criminal procedure regards an accused person is innocent until proven guilty. The process requires that both sides be heard, that a person must appear before a court within a reasonable time and that no force or undue influence may be used to induce an accused to confess to a crime."[17]

The outcome is decided on the *beyond reasonable doubt* standard of proof in criminal cases and based on a *balance of probabilities* in civil cases.

The adjudication of justice takes place by a combination of two different philosophical approaches, namely legal positivism and natural law. The first relates to the *letter-of-the-law*, ignoring the moral dimension of the law. The latter approaches justice not only to *letter-of-the-law* but also to what *ought to be*. This approach connects a higher set of moral principles to the law against which positive law can be judged. Natural law has its foundations in human nature,

[17] D Kleyn & F Viljoen *Beginners guide for law students* 4th ed (2010) 7 Juta.

can be found by human reason and apply universally. These are the inalienable rights such as equality, human dignity, right to life, freedom and security of the person as captured in the Bill of Rights in the Constitution of the Republic of South Africa.[18]

5.2.1.1 A general classification of the law that regulates the aspects of prohibited substance testing in South Africa

The legal aspects of prohibited substance testing in South Africa can be found in substantive[19] and adjective law[20]. Substantive law is divided into public, and private law and adjective law has to do with the procedural aspects of the law. Public law prescribes the extent of the state's authority and regulates, amongst others, the relationship between the state and its subjects. In this domain, the state acts with authority and dictates that criminal offences must be punished. The Criminal Procedure Act describes the procedure of prosecution and punishment.[21]

The private law domain regulates the relationships between legal subjects and defines the rights and duties of persons originating typically from contracts and ownership. The relationship between the legal subjects in the private law domain is an equal one (as opposed to the public domain). When an individual wants to enforce her or her rights against another person, the law of civil procedure applies. The category of private law that regulates the relationship between persons concerning their means (assets and liabilities) is the law of patrimony under which the law of obligations falls. Prohibited substance regulation and testing programmes in the workplace testing typically fall in the private law domain.

The law of obligations prescribes the relationship between a *creditor* who has the right to performance by a *debtor*. This performance is termed an *obligation*. Contracts describe the rights of a creditor and corresponding duty to perform by a debtor. The employee-employer relationship is typically based on a contract whereby the employee should perform his work safely, whereas the employer should ensure a safe work environment.

A delict is an unlawful act which causes damage to someone else who has the right to restitution. There will then also be an obligation to pay damages to the creditor. Legal subjects should respect each other's property, personalities, privacy and personalities. The prohibited

[18] CSA ch 2 secs 7 to 39.

[19] Substantive law is also called material law. This determines the content and meaning of the different legal rules and principles in Kleyn & Viljoen (n 17) 7.

[20] Adjective law regulated the enforcement of material law. It prescribes the procedure in which a case must be handled in case of a violation of a legal rule in Kleyn & Viljoen (n 17) 7.

[21] Criminal Procedure Act 51 of 1977.

substance regulation and testing environment certainly have the potential for instances where privacy, personality (dignity) and property may be disrespected.

A legal subject can be an individual human being (natural person) and also a juristic person who is an abstract person like a company, organisation, trade union or the state. Legal subjects stand in a relationship not only to each other but also to legal objects that have a monetary value. Legal objects may, amongst others, be things (property), performances and aspects of personality (sense of honour, dignity, reputation and privacy).

Performance can be defined as an act of giving, doing or refraining from doing something and usually relates to the law of contract and delict. A typical example is where an employee has an obligation towards an employer to perform according to his contract of service, or an employer must guarantee the safety of others in the workplace. A breach of contract (or delict) may result in the paying of damages.

A legal subject must have the ability to take part in law activities. This ability is referred to as "capacity" and encompasses the capacity to act and being held accountable. The capacity to act has to do with the legal subject to be able to envisage the consequences of his or her acts. Not all legal subjects have full capacity to act because age and mental health may diminish a subject's capacity to act. There are three categories of capacities to act, namely:

- Full capacity to act: People over the age of 18 years and who are not insane are assumed to have this capacity. Legal subjects in this category usually are held accountable for juristic acts.
- Limited capacity: Minors between the ages of 7 and 18 years may perform individual juristic acts without the consent of their guardian. There is a rebuttable assumption that these individuals can be held accountable for their juristic acts.
- No capacity to act: Children under the age of 7 years and an insane person has no capacity to act. All acts have to be consented to by their guardians on their behalf. This group of individuals cannot be held accountable for their juristic acts

5.3 LEGAL FRAMEWORK FOR PROHIBITED DRUG TESTING, WORKPLACE, SCHOOLS, SPORT AND OTHER OCCUPATIONS IN SOUTH AFRICA

This study focuses on prohibited substance testing in the educational, workplace and sport environments. The selection is based on the level of capacity that the test subjects have in each.

Individuals in the workplace environment usually have full capacity, and those in schools usually are minors with limited capacity.

The medico-legal questions raised in this study will be portrayed in an integrative fashion, "founded in the provisions of the Constitution; the applicable principles of common law; relevant legislation (often articulated in terms of the Constitution); interpretative case law, professional policy guidelines and considerations of medical ethics" as stated by Carstens.[22] The principle that the legal rule follows the medical ethical value originates from the fact that the most important ethical values (life, bodily integrity, dignity, privacy and equality), as incorporated into and articulated in medical ethical codes/instruments, have been elevated to legal *rights* into the South African legal system and the CSA or human rights legislation.

5.3.1 The Constitution of the Republic of South Africa, 1996

In the founding provisions of the CSA, it is stated that: "the Constitution is the supreme law of the Republic and law or conduct inconsistent with it is invalid and the obligations imposed must be fulfilled."[23] The CSA finds application in many aspects of a prohibited substance regulation and testing programme. The HHS Guidelines for a drug- and alcohol-free workplace programme (as discussed in Chapter 2 of this work) will be tested against the Bill of Rights[24] and discussed in this chapter.

A fundamental doctrine of the CSA, whereby powers and responsibilities are divided among the legislative branch, executive branch, and the judicial branch is called the "Separation of Powers" principle**.**[25] Separation of powers, which is intrinsic to the CSA, ensures that there is no abuse of powers and that the three branches are unable to interfere with one another to ensure that no one of the three branches can become too powerful and in effect destroy the democratic governing system.

- A prohibited substance regulation and testing programme can only benefit by adopting this doctrine into the policy to achieve sufficient independence between the (1) organisation,

[22] Carstens P & Pearmain D *Foundational Principles of South African Medical Law* (2007) Lexis Nexis Cape Town, South Africa.

[23] CSA ch 1 sec 2. See Curry I & De Waal J *The Bill of Rights Handbook* 6th ed (2014) 8 Juta, Claremont, South Africa, where the supremacy of the CSA is discussed. It implies that the rules and principles of the CSA are binding and take priority over all other rules and statutes.

[24] CSA ch 2. Chapter 2 encompasses the Bill of Rights, which has supremacy over all forms law and binds all branches of government as well as, private individuals.

[25] Curry & De Waal (n 23). The principle of *Separation of Powers* requires that the functioning of government be based on three entities, namely, the legislature, executive and the judiciary. The three entities should function separately and should be overseen by different institutions and persons.

(2) the confirmation off-site forensic laboratory, (3) independent off-site review and validation of the test result by the MRO and (4) the part of the organisation that will initiate decisive action.

The following sections in the CSA bear relation to a prohibited substance regulation and testing programme:

***Section 8**: Application - The Bill of Rights binds not only the legislature, the executive, the judiciary and all organs of state but also natural and juristic persons to the extent that the right is applicable with cognisance of the right and the duty imposed by the right.* [26]

- Section 8 specifies that the Bill of Rights applies horizontally to natural and juristic persons as well in a vertical fashion between the state and natural/juristic persons. Private individuals are regarded as natural persons, and juristic persons can, for instance, be a company or private organisation, sports organisations and schools.

***Section 9**: Equality – Everyone is equal before the law"*,[27] *and no unfair discrimination is allowed.*

- Section 9 directs that everyone is equal before the law and has the right to equal protection and benefit of the law and neither the state nor any other person may discriminate directly or indirectly against anyone on grounds such as race, gender, religion, disability, religion, belief and culture. In a prohibited substance regulation and testing environment, this may typically have the implication of, for instance, forbidding discrimination against individuals that belong to a religious group that employs the use of cannabis as part of their rituals,

[26] CSA ch 2 sec 8. See Curry & De Waal (n 23) 34 for an interpretation on the beneficiaries of the Bill of Rights. Most of the rights apply to natural persons, which can be interpreted as "everyone". A juristic person does not necessarily have all the rights of a private individual such as right to dignity, freedom and privacy, however, a company may have some rights which are similar to that of an individual such a property rights, right to a fair trial and right to just administrative action. A juristic person is entitled to the rights "to the extent required by the nature of the rights and the nature of the juristic person". Fair labour relations (section 23) is such a right which is applicable when a company wish to institute a prohibited substance regulation and testing policy to enhance the health and safety and to minimize the risk of harm to individuals as well as to the company. A company could also rely on the right of just administrative action (section 33) when there is a dispute regarding the prohibited substance regulation and testing policy. The horizontal application refers to the relationship between the organization and the individual with due respect for each other's rights. The vertical relationship has to do with the interactions between the state and the organization, of which a typical example would be where the state will enforce a prohibited substance regulation and testing program upon a company. If the rights of the company are infringed in the process Constitutional remedy may be sought.

[27] CSA ch 2 sec 9(1)-(4). See Curry & De Waal (n 23) 209 for an interpretation on the right to equality as well as the stages of enquiry which range from the first principle of equality conferring the right to equal protection of the law to everyone, affirmative action, prohibition of unfair discrimination on certain listed grounds. The right to equality is very much connected to the limitation clause of the CSA (section 36) as far as the limitation of unfair discrimination is concerned. In certain instances, it may be regarded as fair discrimination if a specific group is more often tested for prohibited substances than others due to the inherent risks of their safety sensitivity of their jobs which may impose a risk to the health and safety of others. Fair discrimination has to be performed in a rational manner however.

testing for the use of cannabis only, testing only certain groups without justification that the discrimination is fair.

- Equality is enacted by the Promotion of Equality and Prevention of Unfair Discrimination Act.[28]

***Section 10**: Human dignity – Everyone has inherent dignity and the right to have their dignity respected and protected.* [29, 30, 31]

- In the prohibited substance regulation and testing environment, human dignity is typically invoked during the testing process whereby the individual needs to be treated with sensitivity and respect, and care should be taken not to invoke emotions by the way the individual is addressed and requested to donate a specimen. Specimen collection should be performed in privacy and information should be treated as confidential. The nomination/ selection for a prohibited substance test should also be performed in a fashion that does no humiliate an individual or perhaps makes him, or her feel that he or she is already suspected to be a drug abuser.

***Section 11**: Everyone has a right to life.* [32]

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[28] Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000.

[29] CSA ch 2 sec 10. See Curry & De Waal (n 23) 250 for a discussion on "dignity" by Temba Ngcukaitobi. Section 1 of the CSA is based on human dignity as a founding value, amongst others, however, the concept is not clearly defined in the Constitution. It has a wide meaning and involves a number of different values. See further *Le Roux v Dey* 2011 (3) SA 274 (CC) [138]. From a Kantian moral perspective, it can be viewed as a value that refers to a human's worth and also the origin of inherent rights such as freedom and physical or body integrity. See *Dawood v Minister of home affairs* 2000 (3) SA 936 (CC) [35]. According to Curry & De Waal, dignity and punishment are related in different ways, one of which is related to the common law principle of "*actio iniuriarum"*. This relates to the remedy due to injury to the person, dignity or reputation and requires the individual to prove that the conduct was subjectively and objectively insulting. According to Curry & De Waal, an infringement of the Constitutional principle of "dignity" has a wider meaning namely that 'the *actio iniuriarum* is related to the person's feeling of self-worth' which relates to the individual's self-respect. With the above reasoning in mind, it is the opinion of the author that defamation caused by a faulty drug tests or by an inhuman or undignifying testing protocol is very much related to the Constitutional value of human dignity.

[30] L Ackermann *HUMAN DIGNITY: Loadstar for equality in South Africa* (2012) 95 Juta, Claremont, South Africa: wherein it is stated that human dignity is a categorical imperative proclamated by the Consitution about the 'essence of the natural person and about what he or she already is without the invocation of human dignity as a right under the Constitution. According to Ackermann, section 10 should be read with section 7(2) holding that 'the state must respect, protect and promote and fullfill the rights in the bill of Rights.

[31] A Chascalson 'Human dignity as a foundational value of our Constitutional Order' (2000) 16 *SAJHR* 193, 196.

[32] CSA ch 2 sec 11. See Curry & De Waal (n 23) 250 for an extensive discussion on the "right to life" which is unqualified as referred to by the judges in the case *S v Makwanyane* 1995 (3) SA 391 (CC). The right to life may not be deprived arbitrarily. It is the opinion of the author that an individual who performs safety sensitive tasks, and who is impaired because of substance abuse, has the potential to deprive someone of his or life arbitrarily. The state has a duty either to protect life, through the enforcement of criminal law to the best of its ability, or to enforce legislation to enhance the health and safety of individuals in the workplace through the Occupational Health and Safety act. This place the responsibility on an employer to have procedures and policies in place to comply with health and safety. A prohibited substance regulation and testing program should therefore be in place to respect the life of others. The unqualified respect for life obligates not only the authorities, but also fellow humans. In the prohibited substance regulation and control environment the right to life requires respect for life by all, not only the authorities but also individuals involved in safety sensitive activities of the organization.

- An individual also has the right to self-medication, which is in line with his or her right to life. It is therefore of prime importance to respect self-medication practices, within the context of safety and minimisation of risk and harm to others and the interests of the organisation.
- Enlisting of substances on the prohibited list also related to this since a compound must be enlisted based on its risk to the organisation and not merely copied from the official government list of prohibited substances. The enlisting of substances by an organisation has to be purpose-driven and aimed at the pharmacological impairment effect of a substance.

***Section 12**: Freedom and security of the person which includes the right (1) Not to be deprived from freedom arbitrarily or without just cause*[33] *and (2) Everyone has the right to bodily and psychological integrity, which includes the right to security in and control over their body and not to be subjected to medical or scientific experiments without their informed consent*.

- Prohibited substance regulation testing should not be performed arbitrarily by simply enlisting substances without just reasons and, similarly, should a prohibited substance test not be performed without a just cause. It should be performed only with the individual's voluntary, non-coerced informed specific consent, which will respect his or her autonomy. The subjects should also have access to the test results and may withdraw consent at any stage of the process. Matters such, as to whom the information and test results will be communicated, how this will be done and when this will be done also strike at the individual's autonomy

***Section 14**: Privacy – Everyone has the right to privacy, which include the right not to have their person or property searched, be searched*.[34]

[33] CSA ch 2 sec 12(1)(a). See Curry & De Waal (n 23) 270 for a discussion on "freedom and security of the person". Section 12 has a dual purpose, namely to protect the right to freedom and security of a person and also the right to bodily and psychological integrity. As to the first part regarding freedom, a question can be raised about its interpretation. A narrow interpretation of freedom may refer to deprivation of physical freedom (unfair detention), but in Ferreira v Levin NO cited by Ackerman proposed a broader interpretation of freedom which entails 'not to have obstacles to possible choices and activities...placed in their way...by the state.' In a prohibited substance regulation and testing setting this can be interpreted that an organisation may not restrict the freedom of an individual irrationally by enlisting substances that pose no danger to the specific industry. It has a further implication in that the organisation may not restrict the use of legal substances, such as alcohol and cannabis, without accommodating the freedom of legitimate use rationally. Concentration threshold values of "zero" does not support legitimate substance use. The right to bodily and psychological integrity, according to Curry & De Waal, relates to the personal autonomy in respect of medical treatment. The phrase "...and control over one's body" points to bodily autonomy or self-determination against interference. This is very much applicable to the requirement that "voluntary informed consent" has to be obtained before bio-medical interventions such a drug test.

[34] CSA ch 2 sec 14. See Curry & De Waal (n 23) 270 for a discussion on the Constitutional right to privacy. The first part refers to the general right to privacy and the second specifies specific types of infringements. The common law

- The right to privacy is applicable from the onset of initial nomination to submit for the prohibited substance test until the final result reporting. One of the instruments to protect privacy is to respect confidentiality and to communicate information to third parties on a need-to-know basis only, with the consent of the individual. The individual has the right to donate his specimen within an environment where visual and auditory privacy is ensured.
- The individual furthermore has the right for his private life to be respected as far as his substance use is involved. Information on the individual's chronic medication is a private matter and should not be requested should he or she not wish to provide the information. The individual should be made aware of the fact that he or she does not have to disclose the information if he or she does not want to. He or she may if he or she voluntarily chooses to, disclose the information to the MRO to mitigate a confirmed positive test result to the MRO. Matters such as to whom the information and test results will be communicated to, how this will be done, and when this will be done also strike at the individual's privacy.
- Section 14 is enacted by the Protection of Personal Information Act (POPI Act).[35]

***Section 15**: Freedom of religion, belief and opinion*[36]

- Prohibited substances are sometimes part of religious ceremonies like the use of cannabis by members of the Rastafarian religion,[37] or the use of alcohol by Christians in some of their religious ceremonies,[38] or the use of peyote cactus by the Native American Church.[39]

***Section 23**: Labour relations – Everyone has the right to fair labour practices*[40]

interpretation of a breach of a person's right to privacy constitutes *iniuria,* according to Curry & De Waal, which involves an "unlawful and intentional acquaintance with private facts by outsiders contrary to the determination and will of the person by intrusion or disclosure". Privacy may be limited in the interest of society. Examples in the drug testing setting will involve breach of confidentiality of test results, disclosure of chronic medication, etc.

[35] The Protection of Personal Information Act (POPI) 4 of 2013.

[36] CSA ch 2 sec 15. See Curry & De Waal (n 23) 270 for a discussion on the Constitutional right to freedom of religion. This right incorporates the freedom to exercise religion and "an equal treatment" component, according to Curry & De Waal. The horizontal application of this right is implicit and prohibits unfair discrimination on grounds of religion by not only the state but also by private individuals. The Rastafarian religion for example therefor needs to be accommodated in a rational fashion if they wish to pursue the legal use of cannabis.

[37] 'Rastafari religious movement' https://en.wikipedia.org/wiki/Rastafari (accessed 29 October 2017).

[38] 'Religion and alcohol' https://en.wikipedia.org/wiki/Religion_and_alcohol (accessed 29 October 2017).

[39] American Indian Religious Freedom Act URL-25 (1996).

[40] CSA ch 2 sec 23(1). See Curry & De Waal (n 23) 270 for a discussion on section 23 involving the right to fair labour relations. Section 23 applies directly to the law at work, however, there are other sections in the Bill of Rights that impacts on 'fair labour relations', such as the equality, privacy clause, dignity, life and freedom and security of the person and right to fair administrative action. Curry & De Waal holds that the term "everyone" points in the direction that fair labour practices should extend beyond the common law definition of 'employee' which is defined as a party to the contract which entails the provision of personal services in turn for remuneration". Section 23 also applies to applicants for employment, who may have been unfairly overlooked. The latter category of individuals therefor has to be treated fairly, similar to a formal employee, as far as prohibited substance testing for employment purposes is concerned.

- This section speaks to the heart of a prohibited substance regulation and testing programme in that due process has to be followed and that the rules must be fair. A prohibited substance policy must be exercised fairly and consistently without discrimination to any individuals or groups. It must be based on sound scientific principles and protocols to serve as a basis for informed decisions for decisive action. The prohibited substance programme must be fair and just based on the principles of natural justice.
- Section 23 is enacted by the Labour Relations Act 66 of 1995 (LRA).[41]

***Section 24**: Environment – Everyone has the right to an environment that is not harmful to their health or wellbeing*.[42]

- Everyone has the right to a safe environment free from risk, which should be minimised as will be the case where a sound and just prohibited substance and testing policy is executed punctually and respected by all involved.

***Section 28**: Children – Every child has the right …(c) basic health care services and social services and (d) to be protected from maltreatment, neglect, abuse or degradation. A child's best interests are of paramount importance in every matter concerning a child, i.e. a person under the age of 18 years*.[43]

- Section 28 is enacted by two kinds of Acts as far as prohibited substances regulation, and use are concerned, namely: (1) the Children's Act[44] and (2) Acts related to schools and governance, namely: The South African Schools Act[45] and the National Education Policy Act.[46]

Administrative, legal aspects: The CSA addresses the constitutional right to fair administrative justice in a multi-faceted fashion. The prominent sections in the CSA are section

[41] Labour Relations Act 66 of (1995).

[42] CSA ch 2 sec 24(a). See Curry & De Waal (n 23) 520. The right to an environment that is not harmful to their "health" refers to physical needs. Humans must not be subjected to physical harm. Curry & De Waal refer to "autonomous needs of humans to make informed choices to achieve conscious goals". Doyal & Gouch identified intermediate needs to enable autonomous needs, one of which refers to a non-hazardous work environment. An individual cannot make an autonomous decision regarding his or her safety if a co-worker would be intoxicated or under the influence. A prohibited substance regulation and testing program will enhance the ability of individuals to make autonomous decisions regarding their own safety.

[43] CSA ch 2 sec 28 (2 & 3). See Curry & De Waal (n 23) 520. "A child's best interests are of paramount importance in every matter concerning a child, i.e. a person under the age of 18 years" requires reflection on children's autonomy and protection which is highly applicable when a child consumes illegal substances and has to be tested. It is a difficult issue to resolve since children can also rely on basic human rights such as privacy, bodily integrity and the right to refuse to provide consent. Skelton claims that a balance has to be struck between a child's need for autonomy and need for protection. This becomes more challenging as the child becomes more mature the parent's rights diminish.

[44] Children's Act 38 of 2005.

[45] SASA.

[46] National Education Policy Act 27 of 1996 (NEPA).

34, which specifies the right to have disputes settled by a court or independent forum or tribunal;[47] section 32, which confers the right to access to information held by the state or by another person, and that is required to exercise or protect any rights;[48] section 38 of the CSA, which empowers "anyone" who alleges that a right has been infringed or threatened, to approach a competent court who has the authority to grant appropriate relief, including a declaration of rights; section 33, which contains the right to just administrative action, which is described as the heart of our transition to constitutional democracy.[49]

The relationship between the constitution and administrative law was elegantly described by Holland whereby constitutional law was referred to as "the state at rest" and the administrative law as "the state in motion", which refer to the *structural* and *functional* aspects of the two, respectively.[50] Both constitutional law and administrative law have to do with the distribution of power in a system", meaning how power is distributed in a constitutional democracy and how it is brought into effect, both having a different perspective.[51]

Separation of powers:

The principle of separation of powers is inherent in modern constitutionalism.[52, 53] The application of the doctrine has the result of functional independence amongst the three branches of government to prevent each from accumulating too much power, for example, the legislature,[54] executive[55] and the judiciary.[56] Policymaking is the function of the highest-ranking political officials while the legislative branch gives effect to the policy by enacting legislation that complies with the CSA; and the judicial branch, the courts, resolve disputes regarding the meaning and effect of the law.

[47] Section 34 reads as follows: "Everyone has the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum".

[48] CSA sec 33.

[49] *Joseph v City of Johannesburg* 2010 (4) SA 55 (CC) para 55 (Skweyiya J)

[50] Sir Thomas Holland *Elements of Jurisprudence* 13th ed (1924) 374.

[51] C Hoexter Administrative Law in South Africa 2nd ed (2016) 23-24.

[52] The doctrine of separation of powers forms part of the final constitution and has been explained in several Constitutional Court cases., See Judge PM Mojapelo, Deputy Judge President of the Southern Gauteng High Court 'The doctrine of separation of powers (A South African perspective) *Advocate* April 2013.

[53] Constitutional Principle VI in the interim constitution provided: "There shall be a separation of powers between the legislature, Executive and Judiciary, with appropriate checks and balances to ensure accountability, responsiveness and openness". The principle is not expressly included in the 1996 constitution, but underpins the South African constitutional order.

[54] CSA sec 45 provides for legislative authority by Parliament.

[55] CSA secs 85 and 125 provide for executive authority by the President at national level and Premiers at provincial level.

[56] CSA sec 165 provides for judicial authority by the courts.

- The doctrine of separation of powers can be applied analogously to prohibited substance regulation and testing by organisations with the management of the organisation being the equivalent of the legislature as the generator of a prohibited substance regulation and testing policy. The prohibited substance regulation and testing team include the administrators[57] (the "government" of the programme and the human resources department) who can be seen as the final arbiters of a prohibited substance transgression. The MRO is the equivalent of the National Prosecuting Authority (NPA) who determines if there is a *prima facie* case against the individual.

Section 32*: Access to information – Everyone has the right of access to any information that is held by the state or another person, and that is required for the exercise or protection of any rights".*[58]

- Enacted by the Promotion of Access to Information Act (PAIA)[59]
- "Access to information" bears a direct relationship to the fact that an individual must have access to his or her test results, which should not be kept from the individual to obscure possible errors in the protocols.

Section 33: *Just administrative action – Everyone (1) has the right to administrative action that is lawful, reasonable and procedurally fair and (2) everyone whose rights have been adversely affected by the administrative action has the right to be given written reasons and (3) national legislation must be enacted to give effect to these rights which amongst others must provide for the review of administrative action by a court or, where appropriate, an independent and impartial tribunal.*[60]

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[57] Sampling officers, breath alcohol technician, designated employer representative, the forensic toxicologist in the laboratory.

[58] CSA ch 2 sec 32(b). See Curry & De Waal (n 23) 691 for a discussion on section 32 of the Constitution of the Republic of South Africa. The right to freedom of information is based on the principle that an individual is entitled to request information held by the state, or any other person that impact on him or her the exercise of power arbitrarily, without reasons or explanation is not in the spirit of openness and transparency in a democratic society and the decision makers can be held accountable by the right to access of information. This impacts on a prohibited substance regulations and testing program in number of ways. The procedures and testing protocols, qualifications of the professionals and validity of test results are for instance important information that may affect the other rights of a test subject. He or she has the right to enquire about any matter in the regulation ans testing of substances that affects his rights.

[59] Promotion of Access to Information Act 2 of 2000.

[60] CSA ch 2 sec 33(1, 2 & 3). See Curry & De Waal (n 23) 639 for a discussion on section 33 by Cora Hoexter. "One of the aims of this section is to prevent abuse of power by government and other parties by protecting the judicial review and enable individuals to claim relief from the effects of unlawful administrative action." Administrative action has to be fair, reasonable and also according to fundamental principles of justice. In light of the fact that prohibited substance regulation and testing is performed in a semi-judicial environment the same principles of procedural fairness, reasonableness applies. A test subject may exercise his or her constitutional rights by taking a prohibited substance regulation and testing policy on review.

- The Promotion of Administrative Justice Act (PAJA), which gives effect to the right of administrative action that is lawful, reasonable and procedurally fair.[61] This section bears relation to procedurally fair and just treatment in the execution of a prohibited substance regulation and testing policy, which has to be fair and just.

***Section 34**: **Access to courts** – Everyone has the right to have any dispute that can be resolved by the application of law decided in a fair public hearing before a court or, where appropriate, another independent and impartial tribunal or forum.*[62]

***Section 36**: **Limitation of rights** – Rights in the Bill of Rights may be limited by a law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all the relevant factors, including (a) the nature of the right, (b) the importance of the purpose of the limitation, (c) the nature and extent of the limitation, (d) the relation between the limitation and its purpose and (e) less restrictive means to achieve the purpose.*

- This section advocates that our rights are <u>not</u> unlimited and may become limited if harm may be caused to others during the exercising of our rights. Prohibited substances are regulated and tested for due to the risk imposed on the safety of others.
- The abovementioned rights are not absolute and may be limited in the context of section 39 (Interpretation clause).

***Section 38**: **Enforcement of Rights** – Anyone has the right to approach a competent court which may grant appropriate relief when a right in the Bill has been infringed or threatened such as (a) anyone acting in their own interest, (b) on behalf of another person, (c) member of an interest group, (d) acting in public interest and (e) an association acting in the interest of its members.*

- Any individual who is part of a prohibited substance regulation and testing programme may approach a competent court to grant an appropriate relief if they believe that the policy has infringed on a right in the Bill of Rights. "Any individual" may be an administrator, medical personnel, scientists and employees, for instance, or someone related to the test subject.

[61] Promotion of Administrative Justice Act 3 of 2000.

[62] See Curry & De Waal (n 23) 639 for a discussion on the "right to access to courts". This right is central for a constitutional democracy which is founded on the rule of law. Anyone may challenge the legality of conduct or any law. The rule of law enhance resolution of disputes in a civilised non-arbitrarily manner. The independence of impartial tribunals and forums is also a prerequisite in the dispute resolution.

Section 39*: *Interpretation of the Bill of Rights *– When interpreting the Bill of Rights, a court, tribunal or forum:* (a) *must promote the values that underlie an open and democratic society based on human dignity, equality and freedom, (b) must consider international law and (c) may consider foreign law. Furthermore, when developing the common law or customary law, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights. The Bill of Rights does not deny the existence of any other rights or freedoms that are recognised or conferred by common law, customary law or legislation, to the extent that they are consistent with the Bill.*

- Foreign law that may be considered when interpreting the rights in the Bill of Rights is the SAMHSA Federal Mandatory Guidelines employed in the USA for workplace drug testing.[63] The policies of the World Anti-Doping Association (WADA) may serve as an example of international law.[64] The International Labour Organisation (ILO) regulations on drug testing are also a credible reference for prohibited substance regulation and testing in humans.

Section 233*: *Application of international law *– When interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law*.

5.3.2 Drugs and Drug Trafficking Act

5.3.2.1 Summary of the Act

The aim of the Drugs and Drug Trafficking Act 140 of 1992 (Drugs Act) is to address the problem of drug use, abuse and trafficking in South Africa. It proclaims the use or possession of or dealing in drugs, and in some instances, the manufacture or supply substances related to the drug trade as illegal.[65,66] *It also obligates the report of certain information to the police related to drug offences* and prescribes how the police may use its mandate to handle drug offences.

The following actions are considered illegal under this act:

[63] SAMHSA https://www.samhsa.gov/ (accessed 18 April 2019).
[64] WADA https://www.wada-ama.org/ (accessed 18 April 2019).
[65] Drugs and Drug Trafficking Act 140 of 1992.
[66] Summary of the Drugs and drug Trafficking Act 140 of 1992 http://ossafrica.com/esst/index.php?title=Summary_of_the_Drugs_and_Drug_trafficking_Act,_no._140_of_1992 (accessed 31 august 2017).

- The *manufacture and supply of scheduled substances*, which are substances used in the unlawful manufacture of drugs.[67]
- The *use or possession* of any substance which produces a dependency:[68]
- *dealing in scheduled substances*, or *any substance* that produces a dependency or
- *Provision of false information* to the police related to a drug offence or *hinder* in any way a police investigation into a drug-related offence.

The Act allows for some exceptions such as when the person:

- is a patient with a legitimate medical prescription from a medical practitioner or
- is an employed by someone legally entitled to use or deal in such substances, and therefore does so as part of his professional duties.

A person has a legal obligation to provide information to a legal authority related to a drug offence. This obligation overrides any rule of law which prohibits him or her from providing information about the affairs of another individual.[69] The same principle applies to the owners or managers of places of entertainment.[70]

If a police officer has reason to suspect that a drug-related offence has been committed, he has the authority to search any premises, vehicle, vessel or aircraft which is suspected of containing the illegal substance, at any time.[71] In addition, if a police officer suspects that any person has committed a drug-related offence, he has the power to search that person and to examine anything in that person's possession. (A woman, however, may only be searched by a woman.)

A police officer has the authority to question any person who might be able to provide information about a drug-related offence and examine any register, record or document and to make a copy of it, in the course of investigating a drug-related offence.[72]

If a magistrate receives information may issue a warrant of arrest for a person if he is convinced that information related to a drug offence. Such a person will then be sent to a place of interrogation where they will be detained until the magistrate permits his or her release.[73]

The penalties for drug-related offences are:[74]

[67] Drugs and Drug Trafficking Act 140 of 1992, sec 3.
[68] As above subsec 4(a) and (b).
[69] As above subsec 9 (a) and (b).
[70] As above subsec 10 (1) (a) and (b).
[71] As above subsec 11 (1)(a)(i) and (ii).
[72] As above subsec 11 (f).
[73] As above subsec 12.
[74] As above subsec 17.

Any person who:

- *Obstructs or fails to co-operate* with a police investigation into a drug-related offence shall be liable to imprisonment for no longer than **12 months** or a fine, or to both a fine and imprisonment.
- *Uses or possesses* an illegal substance or tries to frame another person by placing such a substance in their vehicle or premises, is liable to a fine or to imprisonment for no longer than **five years**, or a fine and imprisonment.
- Deals in an illegal drug are liable to a fine or imprisonment for no longer than **ten years**, or to a fine and imprisonment.
- Illegally manufactures a scheduled substance, or uses or possesses a dangerous dependence-producing substance, is liable to a fine or to imprisonment for no longer than **15 years**, or both a fine and imprisonment.

It will be presumed that:

- When prosecuting a drug-related offence, it will be assumed that the person charged is not a health professional or wholesale dealer in, or manufacturer of, pharmaceutical products, unless proven otherwise.
- If a person was found in possession of an illegal substance while on school grounds or within 100 metres of such grounds, it will be assumed that the person dealt in dagga or the substance in question unless proven otherwise.[75]
- If a drug offence were committed at a place of entertainment, it would be assumed that the manager, occupier or owner of that place had reason to suspect that such an offence had occurred, unless he has proven otherwise.

5.3.2.2 Implications of the Drugs Act for prohibited substance regulation and testing in South Africa

The use of drugs can be proved by the presence of the drug in an individual's body, which is the main aim of testing for drugs in the workplace, schools or sports environment. If an illegal drug (or its corresponding metabolites) is detected in an individual's body, it implies that he or she has consumed the illegal drug and has, therefore, contravened the provisions of the Drugs and Drug Trafficking Act. The individual may be liable to a possible sentence of no longer than

[75] The requirement of the possession of dagga exceeding 115 grams is now obsolete after the Constitutional Court decriminalised the cultivation, possession for private use of cannabis.

five years, or a fine and imprisonment.[76] This legislation may influence drug testing in a non-statutory environment like the workplace, Olympic sports testing or a school where a drug test is carried out confidentially and privately since:

- if a police officer has reason to suspect that drug-related offence has been committed, he has the authority to search any premises, vehicle, vessel or aircraft which is suspected of containing the illegal substance, at any time[77]
- The officer has the authority to question any person who might be able to provide information about a drug-related offence and also has the power to examine any register, which includes the confidential drug testing medical records held by the organisation.
- The organisational representative furthermore has a legal obligation to inform the authorities that an offence related to drug use has been committed, regardless of laws such as the POPI Act, which prohibits him or her from revealing information related to the business or affairs of another person.[78]

5.3.2.3 Schedules of the Drugs and Drugs Trafficking Act

The scheduled substances are listed in two schedules, which categorise the substances as follows:

- Schedule 1 lists the substances that are useful for the manufacture of drugs in part I and II
- Schedule 2
  - Part I: "Dependence-producing substances", the use/possession of which may result in imprisonment for no longer than five years, or to a fine and imprisonment.
  - Part II: "Dangerous dependence-producing substances", the use/possession of which may result in imprisonment for no longer than 15 years, or to a fine and imprisonment.
  - Part III: "Undesirable dependence-producing substances", the use/possession of which may result in imprisonment for no longer than 15 years, or to a fine and imprisonment. For instance, Tetrahydrocannabinol (Δ^9-THC), the active constituent of cannabis was listed in Part III of the schedules.

It is essential to take note that the use and possession of homologues of listed compounds are also illegal. Homologues of the listed substances are defined as "any chemically related substances that incorporate a structural fragment into their chemical structures that are similar

[76] Drugs and Drug Trafficking Act 140 of 1992 sec 17.
[77] As above sec 11(1)(a)(i) and (ii).
[78] As above subsecs 9 (a) and (b).

to the structure of a listed substance or exhibit pharmacodynamic properties similar to the listed substances".[79] Homologues are typically designer drugs that can be purchased over the internet. There are endless structural homologues for the cannabinoids, opiates, amphetamines, and the other drug classes, making it impossible to screen for all these substances.

5.3.3 Medicines and Related Substances Control Act

5.3.3.1 Summary of the Act

The Medicines and Related Substances Control Act (Medicines Act) provides, amongst others, for the:[80]

- registration of medicines and related substances intended for human and animal use.
- control of medicines and scheduled substances and medical devices.
- regulation of the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licenced to dispense medicines.

The provisions that deal with the control of medicines and scheduled substances are included in section 22A, which states that:

- no person may sell, possess, or manufacture any medicine or scheduled substance, except per the prescribed conditions[81]
- schedule 0 substances may be sold in open shops [82]
- schedule 1 – 6 substances may only be sold by [83]
  - licensed pharmacists.
  - manufacturers/wholesaler dealers to any person who may lawfully possess such a substance.
  - medical practitioners, dentists, nurses or persons registered under the Health Professions Act, who may prescribe such a substance.

There are three main categories for the schedules of medication and substances, namely:[84]

- Schedule 0 medicines that can be purchased from the shelves at pharmacies, supermarkets, and health shops.

[79] As above schedule 2part I (2)(c), part II (2)(e) and part III (2)(e).
[80] Medicines and Related Substances Control Act (Medicines Act) 101 of 1965 sec 22A(9)(i).
[81] Medicines Act 101 of 1965 sec 22A(1).
[82] As above sec 22A(4).
[83] As above sec 22A(5).
[84] As above schedules.

- Schedule 1 and 2 medicines, which are also referred to as over-the-counter medicines (or OTC medicines), are medicines that can be made available over the counter without a prescription. Even though a prescription is not required for schedule 1 and 2 medicines, it can only be obtained from a pharmacy and must be provided by a pharmacist. These include cold and flu remedies, antihistamines and anti-inflammatories.
- Schedule 3 and 4 medicine requires a legitimate prescription from a doctor, dentist, or allied health professional. These include medication for hypertension, diabetes, antibiotics and antivirals.
- Schedule 5 and 6 medicine is habit-forming and has potentially harmful side effects – pharmacists keep a record of all sales and repeat prescriptions are limited or not given and need to be renewed. These include psychoactive medication (sedatives, anti-depressants) and narcotic painkillers.
- Schedules 7 and 8 substances are the "controlled substances" and "strictly controlled substances", respectively. These include compounds like heroin, amphetamines, methamphetamine, cathinone, LSD, methcathinone, gamma-hydroxybutyrate (GHB), nabilone (Synthetic THC), cannabis (of which personal use is now decriminalised), synthetic cannabinoids, psilocin, and psilocybin, amongst others.

Section 22A furthermore provides that: "No person may acquire, use, possess, manufacture, or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture, or supply…" [85]

5.3.3.2 Implications of the Medicines and Related Substances Control Act for prohibited substance regulation and testing in South Africa

It should be noted from the information provided above, medication in Schedules 3 to 6 requires a legitimate prescription and the possession and use of substances in Schedules 7 and 8 are completely prohibited and may not even be prescribed by medical practitioners as remedies.

Prohibited drug-testing policies should distinguish between the "use of illegal substances" and the "illegal use of substances". The "use of illegal substances" refers to highly scheduled substances (Schedules 7 and 8) which may not be used or purchased. The use of these substances is illegal by default. The "illegal use of substances" involves the illegal use of

[85] As above sec 22A(9)(a)(i).

substances that require a legitimate prescription according to the schedules of the Medicines Act. The use of scheduled substances without a prescription is also illegal (Schedules 3 to 6).

Reading the Drugs Act together with the Medicines Act shows that there is a dilemma between an individual's constitutional right to privacy regarding his or her private drug use and the resulting outcome of drug tests, and the obligation of an employer to report the offence of illegal substance use to the authorities. It is the opinion of the author that the solution to the problem would be the legal control of all the substances in Schedules 7 and 8, which should follow the same route as cannabis decriminalisation in South Africa *en-route* to legal regulation, similar to alcohol and tobacco. Current drug legislation ignores the constitutional right to autonomy of adults (who should have the authority to choose psychoactive drugs of their choice) as a basic human right. (Please see section 5.3.8.1 below.)

5.3.4 Protection of Personal Information Act

5.3.4.1 Summary of the Act

The POPI Act enacts the right to privacy as enshrined in the CSA which provides that "everyone has the right to privacy", including the right to protection against the unlawful collection, retention, dissemination and use of personal information.[86,87] The aim of the POPI Act is not to inhibit the flow of information, but to see that it takes place securely and responsibly to ensure that all South African institutions and individuals responsibly conduct themselves when collecting, processing, storing and sharing an entity's personal information. Therefore, they are accountable should they abuse or compromise personal information in any way.

The POPI Act considers an individual's personal information to be private and therefore aims to provide the individual with certain rights of protection with the ability to exercise control over when and how to allow sharing of information. The individual must provide ***consent*** before the collection and processing of private information (or as soon as is reasonably practicable after the collection of information).

Personal information is defined as information that relates to an identifiable living natural person (and existing juristic person). The following are typical:

[86] Protection of Personal Information (POPI) Act 4 of 2013.
[87] CSA sec 14.

- Information relating to sex, gender, colour, sexual orientation, language, the birth of a person, criminal, ***medical***, or employment history of an individual.
- Information found in records of schools, universities, hospitals, human resource departments and criminal records (background checks) as well as information related to previous drug use.
- Correspondence sent by the person that is private, or further correspondence that contains the original information sent by the person (such as email replies and email forwarding).
- A person's view of another person as well as the views and opinions of another person about the person.

The amount of information to be collected should be limited to the purpose for which the information is collected. The collection of additional information would require consent from the subject. Consent means a ***voluntary, specific and informed*** expression of will in terms of which the person to the processing of personal information related to him or her.

- "Voluntary" means that an individual cannot be forced or coerced into providing consent.
- "Specific" means that consent cannot be provided in a general or umbrella fashion, a precise and detailed description of what the person provides consent form must accompany the consent. This should include a clear description of the purpose for which the information will be used as well as with whom, and in what manner the information will be shared.
- "Informed" means that the person should be informed of what he or she agrees to and what the information will be used for.
- "Expression of will" implies that the person has to indicate that he or she agrees. It is essential to obtain the consent in writing or in the presence of a witness since the onus of proof that consent was obtained will be on the entity, which determines the purpose and means of collection and processing of personal information.

An individual has to be provided with a copy of his or her personal information upon request, according to the POPI Act, read together with the PAIA Act.[88] It is mandatory for his or her privacy to be protected if a third party requires the unreasonable disclosure of his or her information,[89] except if the personal information is required by state bodies to maintain the

[88] PAIA ch 2 sec 14.
[89] PAIA 2 of 2000 ch 2 secs 37 & 65.

law, for example, the prevention, detection, investigation, prosecution and punishment of offences, as well as for court proceedings.[90]

The conditions that need to be complied with under the POPI Act are [91] accountability,[92] processing[93] and further processing limitation[94], purpose specification,[95] information quality,[96] openness,[97] security safeguards,[98] data subject participation.[99] Personal information of a child (below the age of 18) without the consent of the parent/guardian is also not allowed.[100]

5.3.4.2 Implications of the POPI Act for prohibited substance regulation and testing in South Africa

It is of prime importance to obtain consent from a subject before collection of personal information, such as recording of personal information before conducting a specimen collection and preliminary screening test and only information relevant to the test may be collected. The information should be transferred to others on a need-to-know basis only and with the consent of the subject which was obtained in advance. Two types of consent are required for this; the first consent for the specimen collection and the second for to the processing of information related to the individual.

In addition to not obtaining adequate consent, the POPI Act can typically also be breached in various other ways, such as:

- when personal information is made known to others due to inadequate security safeguards such as throwing documents into a rubbish bin without being shredded or not having back-up protocols in place to secure electronic information.
- sending personal information recorded on drug test reports to people who are not supposed to receive it, for instance, by copying the wrong people into an email containing a drug test report.
- hacking of an organisation's computer and the processing of information without following correct prescribed protocols.

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[90] POPI Act 4 of 2013 sec 6.
[91] D Taylor & F Cronje 101 Questions and answers about the Protection of Personal Information Act (2014) Juta and Company (Pty) Ltd, Claremont.
[92] POPI Act ch 2 sec 8.
[93] As above ch 2 secs 9-12.
[94] As above ch 2 sec 15.
[95] As above ch 2 secs 13&14.
[96] As above ch 2 sec 16.
[97] As above ch 2 secs 17&18.
[98] As above ch 2 secs 19-22.
[99] As above ch secs 23-25.
[100] As above secs 34 & 35.

- non-compliance with the POPI Act can result in an R10 million fine, and civil actions for damages can also be instituted for actual losses and aggravated damages.

5.3.5 Promotion of Equality and Prevention of Unfair Discrimination Act

5.3.5.1 Summary of the Act

"To give effect to section 9 read with item 23(1) of Schedule 6 to the Constitution of the Republic of South Africa, 1996, so as to prevent and prohibit unfair discrimination and harassment; to promote equality and eliminate unfair discrimination; to prevent and prohibit hate speech; and to provide for matters connected therewith."

- The object of the act is to: [101]

  "(a) Enact legislation required by section 9 of the Constitution

  (b) Give effect to the letter and spirit of the Constitution in particular-

  (i) The *equal enjoyment of all rights and freedoms* by every person

  (ii) The promotion of equality.

  (iii) The prevention of *unfair discrimination* and *protection of human dignity* as contemplated in sections 9 and 10 of the Constitution."

- "equality includes the ***full and equal enjoyment of rights and freedoms*** as contemplated in the Constitution and includes de jure and de facto equality and also equality in terms of the outcomes".[102]
- "discrimination means any act or omission, included in policy, law, rule, practice, condition or situation which directly or indirectly by imposing burdens, obligations and disadvantage on, or withholds benefits, opportunities and advantages from any person on one or more of the prohibited grounds". The prohibited grounds are race, gender, sex, ...disability, ***religion, belief, and culture,*** amongst others. Other grounds also involve instances that (i) causes systematic disadvantages, (ii) ***undermines human dignity***, or (iii) ***adversely affects the equal enjoyment of a person's rights and freedoms*** in a serious manner that is comparable to discrimination on the grounds mentioned above.
- The burden of proof follows the reasoning:[103]

[101] Promotion of Equality and Prevention of Unfair Discrimination Act 4 of 2000.
[102] As above sec 1.
[103] As above sec 13.

(1) If a complainant makes out a *prima facie* case of discrimination, the respondent must prove that discrimination did not take place as alleged or that the conduct was not based on one or more of the prohibited grounds.
(2) If discrimination did take place on any of the grounds, then the respondent must prove that the discrimination was fair.

5.3.5.2 Implications of the Promotion of Equality and Prevention of Unfair Discrimination Act for prohibited substance regulation and testing in South Africa

The use of alcohol and cannabis is a typical example of substances that can be used freely by the adult population of South Africa. A user of these substances may claim that a prohibited substance regulation and testing policy restricts his or her full and equal enjoyment of rights and freedoms. Rastafarians may also have a claim that the prohibition involves discrimination on one of the prohibited grounds, which is religion in this case.

An organisation with interest in health, safety and a general interest in minimisation of risks will have to prove that the discrimination, such as prohibition and testing, was fair based on context and whether the discrimination reasonably and justifiably differentiates between persons according to objectively determined criteria intrinsic to the activity concerned.[104] The reason and context for the prohibition and testing will then have to be related to the fact that these substances impair one's faculties, which is a threat to health and safety, and increase risk in general. The fact that these substances are legal also allows more individuals to have access to them, which may serve as a motivation for an increased testing rate.

Singling out individuals who have a higher chance of using these substances, such as Rastafarians, will be unjustifiable and may be seen as unfair discrimination. A tendency or confirmed history of addiction can also serve as a legitimate reason and defence for testing specific individuals more than others.

The factors to take into account in the evaluation of the fairness of the possible discrimination also include enquiries into impairment of dignity and whether discrimination has a legitimate purpose and achieves its purpose, whether there are less restrictive and less disadvantageous means to achieve the purpose, and whether reasonable steps were taken to address the disadvantage and accommodate diversity.[105]

[104] As above sec 14(2).
[105] As above sec 14(3).

Diversity can be accommodated typically by the use of threshold concentration values, which will give the individual the freedom to enjoy his or her rights but will also respect the organisation's interest in minimisation of risk.

Factors that may impair dignity are, for instance, where individuals do not have auditory and visual privacy while a breathalyser test is performed or where the 'standing-down' of an employee is not performed with sensitivity and on a need-to-know basis. How subjects are treated is also an example of how dignity should be protected.[106]

5.3.6 Promotion of Administrative Justice Act

5.3.6.1 Summary of the Act[107]

The PAJA enacts the right to just administrative action as specified in the CSA.[108] The act aims to guarantee that administrative actions will be reasonable, lawful and procedurally fair. The act also provides for people to have the right to ask for written reasons when administrative action harms them. It furthermore gives citizens the right to have administrative action reviewed by the courts.

"Administrative action is the decisions taken (or failure to make a decision) by (a) an organ of state when exercising power in terms of the Constitution (or a provincial constitution) or when exercising a public power (or performing), a public function in terms of an empowering provision or (b) a natural or juristic person, other than an organ of state, when exercising a public power or performing a public function in terms of an empowering provision."[109]

For administrative action to be "procedurally fair" an individual must be given: (i) an adequate notice of the nature and purpose of the proposed administrative action, (ii) a reasonable opportunity to make representations, (iii) a clear statement of the administrative action, (iv) adequate notice of any right of review or internal appeal and (v) adequate notice of the right to request reasons.

Administrators must follow a fair procedure when making a decision and is obliged to explain the decisions taken. The PAJA has the aim of: (1) promoting an efficient administration and good governance and (2) creating a culture of accountability, openness and transparency in the

[106] As above sec 14(2).
[107] Promotion of Administrative Justice Act (PAJA) 3 of 2000.
[108] CSA sec 33.
[109] PAJA sec 1(a) and (b).

public administration or the exercise of a public power …giving effect to the right to just administrative action.

5.3.6.2 Implications of the PAJA for prohibited substance regulation and testing in South Africa

Judicial review is the specific method whereby maladministration can be prevented and is not so much concerned with the merits of a decision, but rather with the process of how the final decision was arrived at. A review is different from an *appeal* where the initial decision can be overruled based on the merits.[110] A decision that was based on merits can even be turned over if the process which led to the decision was not procedurally sound.

The fact that the power of administrators is limited to what is conferred to them by law gives rise to different grounds of review in administrative law. In addition to the CSA as the prime empowering provision, original and delegated legislation and the common law is also empowering provisions.[111] Most administrative power has its origins in legislation, delegated legislation as well as quasi-legislation (standards), which are less formal. Standards are used by administrators to make policy determinations, guidelines, directives, circulars and manuals which direct the administrator's decisions and actions.[112] It is also of importance that these standards are published and readily accessible for the individuals who are affected by the standards.

The PAJA definition of an empowering provision refers to "a law, a rule of common law, an agreement, instrument or other documents in terms of which administrative action was purportedly taken". These include standards such as policy statements, directives and guidelines. Standards also have variable administrative authority in the sense that if the original legislation appears to anticipate their creation, it is afforded legal recognition and enforceability as opposed to when they interfere with the common law or statutory law rights where they will have no legal authority.[113]

Administrative power is vested in the administrators of South African schools by the South African Schools Act[114] in terms of random searches and drug testing on learners. The South

[110] C Hoexter *Administrative law in South Africa* 2nd ed (2011) 108 Juta.
[111] PAJA sec 1 defines administrative action as a decision made under an empowering provision as well as action taken by a natural or juristic person under an empowering provision.
[112] Hoexter (n 110) 32.
[113] Hoexter (n 110) 33.
[114] South African Schools Act 84 of 1996 sec 8A, related to random search and seizure and drug testing at schools.

African Institute for Drug-Free Sport Act (SAIDS Act)[115] is the equivalent legislation governing the use of prohibited substances and testing in sports.

Administrative review of decisions related to disciplinary matters by private bodies, such as the workplace, churches and clubs, has been done by the courts in the past in terms of principles of common law rather than the direct application of section 33.[116] J Claasen held that the:[117]

> "extension of judicial review to domestic tribunals exercising public powers does not mean that judicial review is limited to such instances. Such extension did not, in my view, extinguish the courts' powers of judicial review in instances where coercive actions of domestic tribunals not exercising public powers are at stake… To my mind the Constitution makes no pronouncements in respect of this branch of private administrative law. Thus, continuing to apply the principles of natural justice to the coercive actions of private tribunals exercising no public powers will in no way be abhorrent to the spirit and purport of the Constitution".

From a constitutional perspective, private power can also possibly be reviewed based on section 8(2) of the CSA, which invokes the direct horizontal application of rights in the private sphere.[118] Therefore, the authority for control of private power can be found in the horizontal application of section 33 of the CSA.[119] The more general approach by the South African courts to provide constitutional justification for the review of private administrative action, is to apply section 33 of the CSA indirectly, in combination with section 39(2), which applies to all other rights as well.[120] This provides the constitutional authority to establish public-law standards for private administrators to abide by in cases where coercive power is exercised or where the relationship is unsymmetrical or unequal.[121] The power exercised in these private environments mimics the power that is controlled by rights to administrative justice to promote the spirit, purport and objects of section 33 in a private setting, such as the workplace.[122]

The arbitration proceedings of the CCMA have also been confirmed as administrative action under section 33 of the CSA by the Constitutional Court in *Sidumo v Rustenburg Platinum*

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[115] SAIDS Act.

[116] *Turner v Jockey Club of South Africa* 1974 (3) SA 633 (A) related to a disciplinary decision of the professional body; *Theron v Ring van Wellington van die NG sendingkerk in Suid-Afrika* 1976 (2) SA (1) (A) related to disciplinary action by a church body.

[117] *Klein v Dainfern College* 2006 (3) SA 73 (T) para 24.

[118] Section 8(2) "A provision of the Bill of Rights binds a natural or a juristic person if, and to the extent that, it is applicable, taking into account the nature of the right and the nature of any duty imposed by the right."

[119] Hoexter (n 110) 127.

[120] Hoexter (n 110) 128.

[121] Hoexter (n 110) 130.

[122] Claasen J in *Klein v Dainfern College* 2006 (3) SA 73 (T) para 24.

Mines, despite notable differences between a tribunal such as the CCMA and a court of law. The absence of a binding system of precedent, the relative informality of the CCMA proceedings and the less secure tenure by its presiding officers did not influence the ruling.[123] It was held that the PAJA did not apply to the review of such arbitrations, but instead, the LRA had to be regarded as the empowering provision giving rise to administrative justice rights in the sphere of labour law. [124]

Prohibited substance regulation and testing policies in the ***workplace*** is a typical example of a **guideline** that can be taken on review if it is procedurally wrong. A review of the complete prohibited substance regulation and testing policies, which prescribe the complete testing procedure and protocols, for example, can be justified on the following basis:[125]

- If the administrator who took action was not authorised, was biased or reasonably suspected of bias
- If a mandatory and material procedure prescribed by the empowering provision was not complied with
- If the action was procedurally unfair
- If an error of law influenced the action
- If the action was taken in bad faith or arbitrarily or capriciously
- If the action itself contravenes the law or is not rationally connected to the purpose for which it was taken, the purpose of the empowering provision, information before the administrator, and the reasons given for it by the administrator
- If the exercise of the power in the performance of the function in pursuance of the administrative action is so unreasonable that no reasonable person could have exercised power or performed the function
- If the action is otherwise unconstitutional and unlawful

The need for the fair, just and reasonable exercise of power by an organisation in terms of a prohibited substance control and testing policy is clearly illustrated by the provisions of section 6(2) of the PAJA above. Some of the relevant aspects of a workplace drug testing setting are listed below:

- The officials and administrators have to be skilled, duly authorised and not be biased.

[123] Sidumo v Rustenburg Platinum Mines Ltd 2008 (2) SA 24 (CC).
[124] *Sidumo v Rustenburg Platinum Mines Ltd* 2008 (2) SA 24 (CC) para 89 as discussed by Hoexter (n 110) 128.
[125] PAJA 3 of 2000 sec 6(2).

- The protocol has to be followed carefully from the specimen collection stage to the final reporting and validation stage.
- The complete process must be fair, from policy drafting to testing.
- No decisions may be taken arbitrarily or in bad faith.
- The decision to test an individual must fulfil the intention of the policy, which is to minimise risk and possible harm to the organisation's interests. The question of testing to incriminate individuals is also not in line with the purpose of prohibited substance regulation and testing for the sake of minimising harm.
- Managers and professionals involved in the process should not assist in discrimination against the individual by targeting him or her unfairly.
- The type of specimen selected for the prohibited substance test must be suitable for the purpose.
- The procedure and action must be constitutional and lawful.

5.3.6.3 The doctrine of separation of powers

A typical roadside blood alcohol investigation within the criminal justice system may serve as an example of a typical protocol for alcohol testing. The protocol and order of events of a typical roadside blood alcohol testing case are as follows: (a) A law was enacted by the democratically elected Parliament of South Africa (**legislator**), which in this case specifies that a person may not drive a vehicle under the influence of an intoxicating substance;[126] (b) the law/rule is enforced by the government (**executive**) by way of a police officer (SAPS) who has the authority to select individuals on the roads randomly and who may, on reasonable suspicion, take further action by arresting the suspect to undergo a blood-alcohol test; (c) the blood is then sampled by venepuncture by a trained and registered phlebotomist, who will draw the blood in a way that will preserve the integrity of the specimen; (d) the investigating officer from the SAPS will then hand the blood specimen to a forensic laboratory where; (e) the blood-alcohol analysis will be performed by skilled scientists in a forensic laboratory who will send the test result to the investigating officer; And (f) after a thorough investigation, the investigation officer will hand the report/facts over to the national prosecuting authority (NPA) (**executive**) which, after due consideration, may institute prosecution of the suspect in a court according to a lawful procedure under the supervision of a magistrate/judge who is employed by the **judiciary**.

[126] National Road Traffic Act 93 of 1996.

Please note that all three arms of government are employed to achieve the highly valued principle of the **separation of powers**.[127] This is one of the first principles of fair justice in a democratic society with a human rights-based constitution, like South Africa.[128,129] The main objective of this principle is to prevent abuse of power within the different spheres of government.[130] Simply put, the aim is to install checks and balances to limit power.[131]

The principle is usually applied in constitutions, but it should also be employed in the regulation and testing for prohibited substances in humans. It involves a separation of the three spheres of government, namely legislative, executive and judiciary. Within the constitutional framework, it has the following meaning: (a) *Legislative authority* means the power to make, amend and repeal the rules of law; (b) *Executive authority* means the power to execute and enforce rules of law; (c) *Judiciary authority* means the power, if there is a dispute, to determine what the law is and how it should be applied in the dispute.[132] This concept implies that the same person may not be part of more than one of the organs of government, that an organ of government may not control/interfere with the work of another and that an organ should not perform the functions of another.[133]

In the example above, the authority to enforce the legal rule is conferred to the government (state), and the police officer has the authority to arrest an individual based on reasonable suspicion and command a blood specimen from the suspect, limiting the rights of the individual such as freedom.

In contrast to the criminal investigative approach in the example above as is part of the public law domain, prohibited substance regulation and testing in the workplace are part of the private law domain where an employer does not have the authority to arrest an individual for the use of illegal or prohibited substances. However, the employer does have the authority to stop the employee from engaging in safety-sensitive activities. The employer has to obtain voluntary informed consent from the employee in a non-coerced fashion with due respect for the subject's

[127] n 51.
[128] Interim Constitution 200 of 1993 schedule 4 "There shall be a separation of powers between the Legislature, Executive and Judiciary, with appropriate checks and balances to ensure accountability, responsiveness and openness".
[129] CSA sec 8 lists the elements of the structures that are bound by the Bill of Rights, namely the legislature, the executive, the judiciary and all organs of state.
[130] Judge Phineas M Mojapelo, Deputy Judge President of the Southern Gauteng High Court 'The doctrine of separation of powers (A South African perspective)' (2013) *Advocate* April 2013 at 37.
[131] Mojapelo (n 130) 40.
[132] EFJ Malherbe & IM Rautenbach *Constitutional law* 4 ed (2004) 78.
[133] AW Bradley & KD Ewing, *Constitutional and administrative law* 13th ed (2001) 84, Harlow: Longman.

dignity, freedom and security of the person, privacy and other human rights such as fair labour practice.

The diagram in figure 5:1 is a typical protocol followed by many employers in South Africa currently (in the experience of the author).

Prohibited substance regulation and testing can be seen as an invasion of an individual's private life in general, and the following questions may be raised by the individual who is the subject of the prohibited substance regulation and testing. All the concerns that an individual may have must be answered from an ethically sound, scientifically accurate and legally correct perspective.

The possible concerns that an individual may have regarding a drug test, as indicated, should all be addressed by due consideration of the legal, ethical, and scientific aspects, amongst which there are also an interplay and interdependence. The three aspects are intertwined and can be viewed as the fabric that binds the different phases of the prohibited substance regulation and testing programme and which also define each other's boundaries.

The principle of separation of powers will be better served by a protocol as illustrated in figure 5:2 where it is indicated that some of the functions in the process of prohibited substance regulation should be divided into entities that are independent in decision-making power. The organisation should be responsible for the programme up to where a preliminary drug test is performed (A), and if the outcome is a non-negative[134] test result (which can be regarded as a reasonable suspicion), a confirmatory analysis should be performed by an off-site facility (B).

[134] A non-negative test result cannot be classified "positive" before a confirmation analysis was performed and the presence of a drug was confirmed.

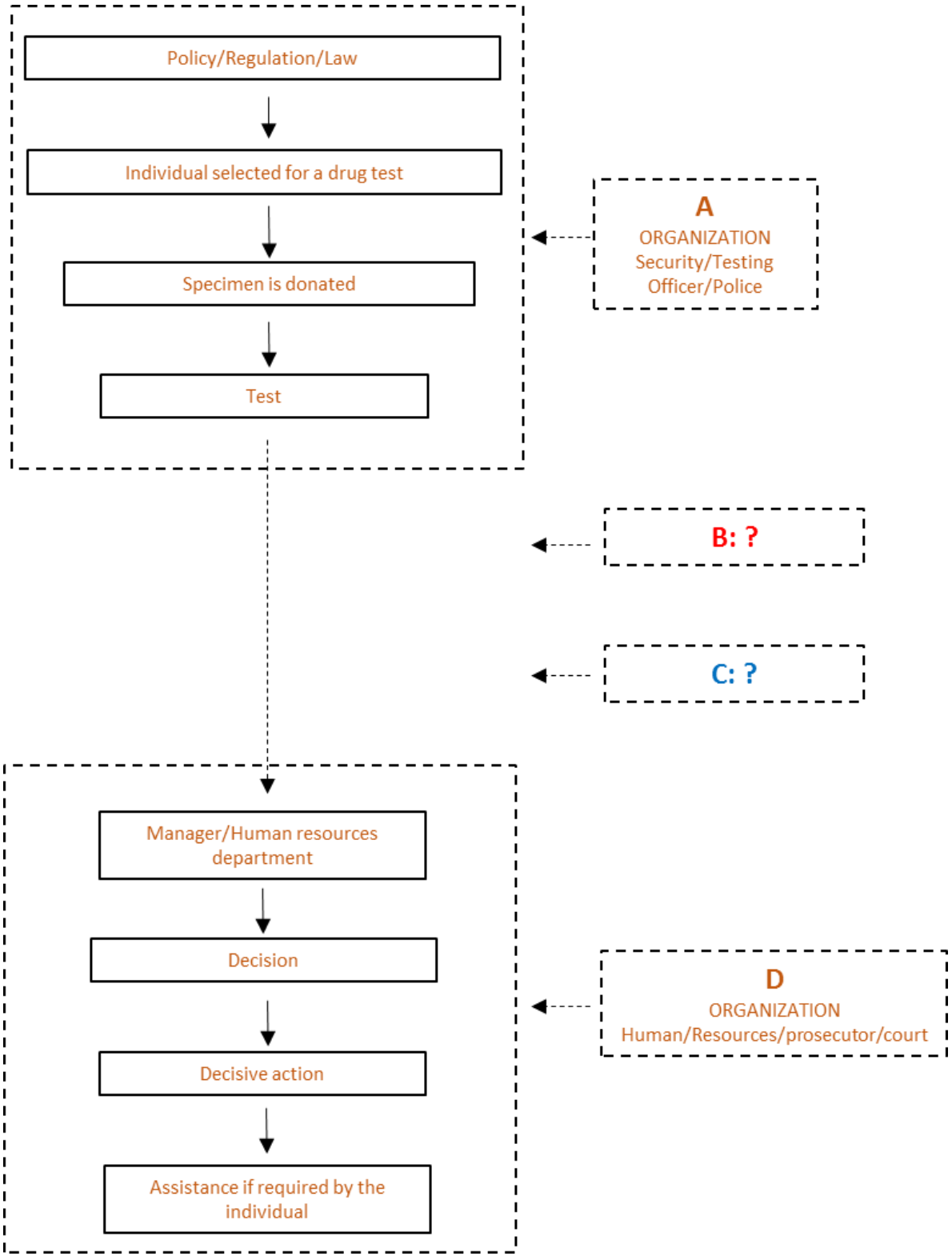

Figure 5:1 Flow diagram of the order of events in a prohibited substance-free programme

After the confirmation analysis, the confirmed test result should be subjected to a review process (C), also independent of the organisation, who will review and validate the confirmed positive test result and report the validated result to the organisation's representative (D). This person will then present the validated positive test result to the authorities in the organisation to make a decision and initiate possible decisive action. It is also imperative that the personnel of the organisation in the two phases (A) and (D) are functioning independently; however, complete separation is not achievable because the officers in phases A and D form part of the same organisation.[135]

The function and powers of phase A can be compared to that of the legislative authority, phases B and C to that of the executive authority, and phase D with that of the judicial authority.

The same entity cannot fulfil all the functions simultaneously, namely: draft the policy, select the individuals for testing, perform the drug tests, report the results, decide and take decisive action, since this may result in a conflict of interest.

[135] Mojapelo (n 130). Judge Mojapelo held that: "It should however, be kept in mind that complete separation of powers is not possible – neither in theory nor in practice. Some overlapping is unavoidable; given the fact that we talk here of spheres of what is in fact one government".

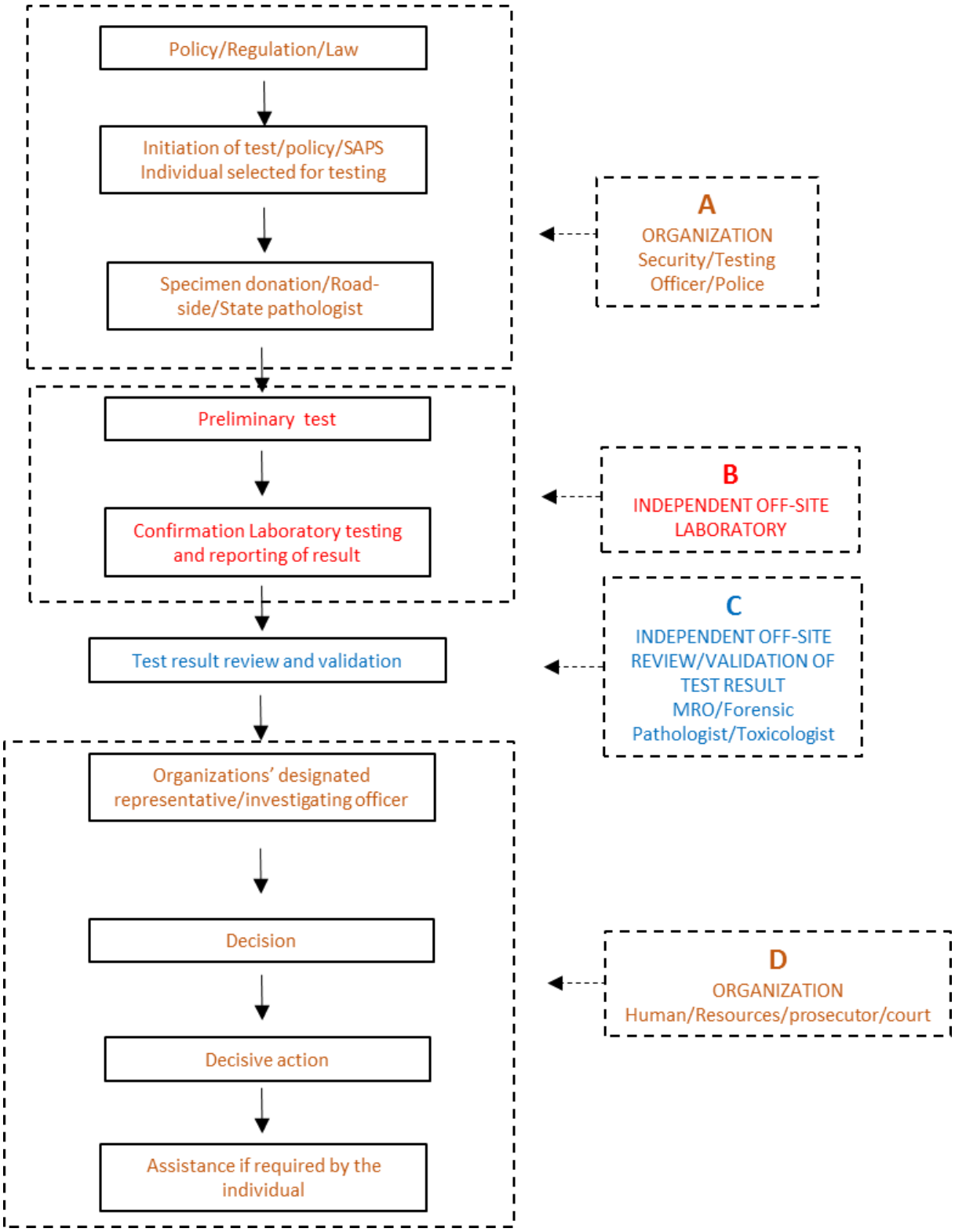

Figure 5:2 Flow diagram of the order of events when the principle of separation of powers is applied

5.3.7 Promotion of Access to Information Act

5.3.7.1 Summary of the Act

This Act gives effect to the constitutional right of access to information held by the state as well as to information held by any other person, and that is required for the exercise or protection of any rights.[136,137] Access to information is limited to the reasonable protection of privacy amongst others.

5.3.7.2 Implications of the PAIA for prohibited substance regulation and testing in South Africa

Section 50 of the PAIA holds that a requester must be given access to any record of a private body if the record is required for the exercise or protection of any rights.[138] Requests for making available prohibited substance tests of individuals who are suspected of having a history in substance abuse or involvement in criminal activities may also be put forward. However, section 65 specifies "mandatory protection of certain confidential information of third parties" if its disclosure would constitute an action for breach of duty of confidence owed to a third party in terms of an agreement, such as the confidentiality agreement between an employer and an employee in the case of workplace drug testing. The safety of others and public interest may be regarded as sufficient defence to disclose confidential information.[139]

Therefore, an organisation should include a clause in the prohibited substance regulation and testing policy which states the organisational obligation to allow investigating officers to gain access to test results in a legal fashion such as by court order in terms of the Drugs Act.[140]

5.3.8 Decriminalisation of drugs

5.3.8.1 Decriminalisation as against legal regulation of drugs

The term "decriminalisation" refers to the removal of criminal sanctions for personal use as well as the possession of limited amounts of a drug. It furthermore implies the intentional ignoring of current drug laws without altering them. It does not, however, allow users to obtain drugs legally with certified purity and potency.[141]

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[136] CSA sec 32.
[137] PAIA 2 of 2000 sec 9.
[138] As above sec 50.
[139] As above sec 70.
[140] Drugs and Drug Trafficking Act 140 of 1992 subsecs 4(a) and (b).
[141] K Scott 'Comment on the Central Drug Authority's position statement on cannabis' (2016) 106 *South African Medical Journal* at 545-546.

Legal regulation, as opposed to legalisation, is not a complete hand-over to international drug syndicates by making the illegal use, manufacture and trade of drugs legal. Instead, it requires a legal framework to govern the production, supply and use of drugs as held by Scott.[142] The advantages of legal regulation include the following:

- Better alignment with the *status quo* on managing health and social risks in other risk-sensitive areas such as dangerous sports, road safety and sexually transmitted infections where an individual can estimate his or her risk.
- Dangerous drugs and the formulations thereof will be safer to the extent that quality control during manufacture may eliminate other harmful impurities.
- It is more in line with the current tobacco and alcohol legislation, which is also legally regulated.[143]

5.3.8.2 Decriminalisation of possession of cannabis for personal use in South Africa

In a ground-breaking High Court decision, the prohibition on the use of cannabis by an adult in a private dwelling, as well as the purchase and cultivation thereof, was suspended for 24 months commencing 31 March 2017, to allow Parliament sufficient time to adjust the laws in dispute accordingly.[144]

The matter originated by a combination of three different court proceedings instituted in the High Court, which were consolidated and heard as one matter as they were all based on the same principle. The applicants claimed that certain sections of the Drugs Act and the Medicines Act were constitutionally invalid.

- Section 4(b) of the Drugs Act prohibits the use or possession of any dangerous dependence-producing substance or any undesirable dependence-producing substance unless exceptions listed in the provision apply.
- Section 5(b) of the Drugs Act prohibits dealing in any dangerous dependence-producing substance or any undesirable dependence-producing substance unless exceptions listed in the provision apply.

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[142] As above.

[143] The prohibition of alcohol products in the USA in 1920 and its reintroduction 13 years later constitute the most graphic demonstration that legal regulation of even a highly toxic psychoactive drug like alcohol is far better than its prohibition according to Hari in Hari (n 98); S Taylor, J Buchanan & T Ayres 'Prohibition, privilege and the drug apartheid: The failure of drug policy reform to address the underlying fallacies of drug prohibition' (2016) *Criminology and Criminal Justice* (accessed 30 December 2016).

[144] In the High Court of South Africa (Western Cape Division, CT) Case 8760/2013 in the matter between Gareth Prince and Minister of Justice and Constitutional Development, and Case 7295/2013 in the matter between JD Rubin and the National Director of Public Prosecution, and Case 4153/2012 in the matter between JD Acton and the National Director of Public Prosecution, Judgement: 31 March 2017 by Judge Davis J.

- Section 22A(9)(a)(i) of the Medicines Act, read with schedule 7 of the Medicines Act, prohibits the acquisition, use, possession, manufacture or supply of cannabis.
- Section 22A(10) of the Medicines Act, read with schedule 7, prohibits the sale or administration of cannabis other than for medicinal purposes.

The High Court declared sections 4(b) and 5(b) of the Drugs Act, read with Part III of Schedule 2 to the Drugs Act, and sections 22A(9)(a)(i) and 22A(10) of the Medicines Act, read with Schedule 7 of the Medicines Act, inconsistent with the ***right to privacy*** of the CSA, but only to the extent that they ***prohibit the use, possession, purchase or cultivation of cannabis by an adult person in a private dwelling for his or her consumption***.

Interim relief was granted by ordering that individuals should not be charged if the use, possession, purchase or cultivation of cannabis in a private dwelling was for the personal consumption of the adult accused, pending the amendment of the relevant legislation by Parliament. 24 months from 31 March 2017 to cure the constitutional defects in the statutory provisions concerned was allowed to Parliament by the High Court.

The High Court's order of constitutional invalidity was then referred to the Constitutional Court for confirmation as required by the CSA. The state applied for leave to appeal against the order of the High Court and opposed its confirmation. The applicants in the High Court applied for leave to cross-appeal against the High Court's failure to conclude that the statutory provisions also infringed on the other rights they had relied upon, such as freedom and dignity, which are also entrenched in the CSA. They also sought leave to cross-appeal against the High Court's decision to confine its order to the use or possession or purchase or cultivation of cannabis in a private dwelling. However, they contended that if the High Court was right to confine its order of invalidity to the infringement of the right to privacy, it should not have confined this to a home or private dwelling because the right to privacy extends beyond the boundaries of a home.

In a unanimous judgment written by Zondo, the Constitutional Court declared that: [145]

- section 4(b) of the Drugs Act was unconstitutional and therefore invalid to the extent that it prohibits the use or possession of cannabis by an adult in private for that adult's consumption in private

[145] Minister of Justice and Constitutional Development v Prince 2018 30 ZACC CCT 108/17.

- section 5(b) of the Drugs Act was constitutionally invalid to the extent that it prohibits the cultivation of cannabis by an adult in a private place for that adult's consumption in private
- section 22A(9)(a)(i) of the Medicines Act was constitutionally invalid to the extent that it renders the use or possession of cannabis by an adult in private for that adult's personal consumption in private a criminal offence.

The Constitutional Court held these statutory provisions to be constitutionally invalid to the extent indicated because they infringed on the right to privacy entrenched in section 14 of the CSA. The Constitutional Court dispensed with the High Court's limitation of its order to the use, cultivation or possession of cannabis at home or in a private dwelling. It held that the right to privacy extends beyond the boundaries of a home.

The effect of the judgment is two-fold: (a) it decriminalises the use or possession of cannabis by an adult in private for that adult person's consumption in private, and (b) it decriminalises the cultivation of cannabis by an adult in a private place for that adult's personal consumption in private. However, the use or possession of cannabis by a child anywhere, or by an adult in public, is not decriminalised.

The Constitutional Court suspended its order of invalidity for 24 months to allow Parliament to correct the constitutional defects in the two Acts. The court also granted interim relief by way of a reading-in of the two Acts to ensure that, during the period of suspension of invalidity, it would not be a criminal offence for an adult person:

- to use or be in possession of cannabis in private for his or her consumption in private
- to cultivate cannabis in a private place for his or her consumption in private.

5.3.8.3 Foreign law and trends on decriminalisation of cannabis and other drugs

According to the CSA, the interpretation of a human right, such as privacy and autonomy, which is at stake in the criminalisation of possession of cannabis for personal use, foreign law must be considered.[146]

Comparative law from other open and democratic societies based on freedom, equality and dignity is summarised below:

- **Canada**: In a Canadian Supreme Court decision, after two police officers arrested an individual in possession of 0.5 grams of cannabis, it was decided to appeal the conviction.

[146] CSA sec 39 subsec 1(b).

The court had to decide if the provision of the Narcotics Control Act (NCA),[147] prohibiting the possession of marihuana for personal use, was unconstitutional under the Canadian Charter of Rights and Freedoms. "Everyone has the freedom to life, liberty and security of the person and the right not to be deprived thereof except under the principles of fundamental justice."[148]

- The majority decision was that it is up the Canadian Parliament to take the decisions in a rational manner related to the possibility of harm which may be caused by the use of cannabis. The minority judgement took the contrary position and engaged in the examination of the harm principle. The judge noted that the costs incurred by the use of cannabis were negligible compared to that incurred due to the use of alcohol and tobacco. The cost to society in the process of preventing harm to society compared to that imposed through the use of cannabis was higher. It was concluded that the specific section in the Narcotics Control Act prohibiting possession for personal use, violated the right in the individual's liberty in a manner that was not consistent with the harm principle, which is a principle of fundamental justice in the Canadian Charter of Rights.[149]
- **Argentina**: In the "Arriola case" the Argentinian Supreme Court of Justice declared the provision of the Argentinian Drug Control Legislation, [150] which criminalised the possession of drugs for personal consumption, bearing prison sentences of between one month and two years unconstitutional in 2009. It was concluded that the specific article invaded the personal sphere of liberty and that the incrimination regarding possession of drugs for personal use was unconstitutional in terms of the right to privacy under

[147] Narcotic Control Act sec 3 prohibits the possession of a narcotic. A person is authorised to have a narcotic in his or her possession if he or she requires the narcotic for his or her business or profession and is a licenced dealer, a pharmacist, or a practitioner who is registered and entitled to practice in the province in which he has such possession. The maximum penalty for possession of narcotics is seven years imprisonment https://en.wikipedia.org/wiki/Narcotic_Control_Act (accessed 30 December 2017); Narcotic Controlled Substances Act, Narcotic Control Regulations CRC, C 1041 http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/FullText.html (accessed 30 December 2017).

[148] *R v Malmo-Levine* (2003) SCC 74.

[149] Section 7 of the Canadian Charter of Rights provides that an individual's autonomy and personal legal rights are protected from actions of the government in Canada. The three types of rights specified in this section are the right to life, liberty, and security of the person. Denials of these rights are constitutional only if the denials do not breach what is referred to as fundamental justice https://en.wikipedia.org/wiki/Section_7_of_the_Canadian_Charter_of_Rights_and_Freedoms (accessed 30 December 2017).

[150] Article 14 of Law No. 23.737.

circumstances that do not bring any concrete danger or harm to others.[151,152] The court also found that Argentina was not obliged to punish drug possession for personal consumption according to the United Nations Drug Control Conventions.[153]

- **Alaska**: In *Ravin v State* of Alaska, the Alaskan Supreme court found that the citizens of the state of Alaska have a fundamental right to privacy in their homes under Alaska's Constitution. This right to privacy included the possession and use of substances such as marijuana in a purely personal and non-commercial context. The court also concluded that it found no real danger to the user or others in the consumption of marijuana or conclusive evidence that it is harmless. [154]
- **Jurisdictions that have decriminalised the possession of cannabis in small quantities for personal use include:** Australia, Austria, Chile, Czech Republic, Estonia, Jamaica, Portugal, Spain, Switzerland, and 13 states of the United States of America (Connecticut, Delaware, Illinois, Maryland, Minnesota, Mississippi, Missouri, New York, North Carolina, Ohio, Rhode Island and Vermont).[155]

From the above information, it can be summarised that the criminalisation of cannabis for personal use is no longer effective in preventing harm and that there is a trend towards moving away from the criminalisation of cannabis for personal private and non-commercial use.

5.3.8.4 International treaties and conventions

South Africa is a signatory to drug control treaties, and once they have been signed and tabled in Parliament for approval, the legislation is binding in the Republic of South Africa.[156,157]

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[151] Reference adopted from: In the High Court of South Africa (Western Cape Division, CT) Case No: 8760/2013, In the matter between Gareth Prince and Minister of Justice and Constitutional Development, and Case No: 7295/2013 In the matter between JD Rubin and the National Director of Public Prosecution, and Case No: 4153/2012 In the matter between JD Acton and the National Director of Public Prosecution, Judgement: 31 March 2017 by Judge J Davis para 75; A. 891. XLIV. RECURSO DE HECHO Arriola, Sebastián y otros s/ causa n° 9080 (Available in Spanish only) http://www.druglawreform.info/en/country-information/latin-america/argentina/item/235-the-arriola-ruling-of-the-supreme-court-of-argentina (accessed 30 December 2017).

[152] Argentine National Constitution, Art 19: "Private actions that offend in no way order and public morals, or damage a third party, are exclusively reserved to God, and are exempt from the authority of judges. No inhabitant of the Nation will be obliged to do that which the law does not order, nor deprived of that which it does not prohibit."

[153] Reference adopted from: In the High Court of South Africa (Western Cape Division, CT), Case No: 8760/2013, In the matter between Gareth Prince and Minister of Justice and Constitutional Development, and Case No: 7295/2013 In the matter between JD Rubin and the National Director of Public Prosecution, and Case No: 4153/2012 In the matter between JD Acton and the National Director of Public Prosecution, Judgement: 31 March 2017 by Judge J Davis para 75.

[154] *Ravin v State of Alaska* (27 May 1975) para 11.

[155] Reference adopted from: In the High Court of South Africa (Western Cape Division, CT), Case No: 8760/2013, In the matter between Gareth Prince and Minister of Justice and Constitutional Development and Case No: 7295/2013 In the matter between JD Rubin and the National Director of Public Prosecution, and Case No: 4153/2012 In the matter between JD Acton and the National Director of Public Prosecution, Judgement: 31 March 2017 by Judge J Davis para 88.

[156] CSA sec 231.

[157] In *Glenister v President of the RSA & others* 2011 (7) BCLR 651 (CC) at para 189 the Constitutional Court observed that such legislation is not only binding on the Republic, but also has domestic constitutional effect through sec 7(2) whereby the state must respect, promote and fulfil the rights in the Bill of Rights. This provision imposes a positive obligation on

Although the treaties allow countries to decide how to deal with their laws related to drug use, it forbids the production and trade in those drugs deemed illicit by the United Nations (UN).

The treaties are as follows:

- **Single Convention on Narcotic Drugs (1961)**[158] (Single Convention)
- **Convention on Psychotropic Substances (1971)**[159,160]
- **United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)**, which came into force in 1990.[161] (1998 Convention)

  The purpose of the 1998 Convention was to more effectively enhance cooperation among governments to address illicit traffic in narcotic drugs and psychotropic substances having an international dimension. Governments should take necessary measures, including legislative and administrative measures, in conformity with the basic provisions of their respective domestic legislative systems. The 1998 Convention distinguishes between possession associated with manufacturing, distribution and dealing [162] and possession for personal use.[163] Article 3(2) of the convention addresses personal use as follows:

  "Subject to its constitutional principles and the basic concepts of its legal system, each party shall adopt such measures as may be necessary to establish as a criminal offence under its domestic law, when committed intentionally, the possession, purchase or cultivation of narcotic drugs or psychotropic substances for **personal consumption** contrary to the provisions of the 1961 Convention, the 1961 Convention as amended or the 1971 Convention."

  In terms of the CSA, this leaves the door open to interpretation regarding the decriminalisation of personal drug use in so far as the right to autonomy and privacy is concerned. Judge Davis held that there is "a multitude of options available to fight the drug use problem, as opposed to the blunt use of criminal law".[164] The Central Drug Authority's

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the state and its organs to provide appropriate protection in an effective and reasonable manner to everyone through laws and structures designed to afford such protection.

[158] Single Convention on Narcotic Drugs (1961) https://www.unodc.org/pdf/convention_1961_en.pdf (accessed 30 December 2017).

[159] The Convention on Psychotropic Substances (1971) https://www.unodc.org/pdf/convention_1971_en.pdf (accessed 30 December 2017).

[160] The Convention on Psychotropic Substances does not apply to cannabis.

[161] United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988) https://www.unodc.org/pdf/convention_1988_en.pdf (accessed 30 December 2017); https://en.wikisource.org/wiki/United_Nations_Convention_Against_Illicit_Traffic_in_Narcotic_Drugs_and_Psychotropic_Substances#Article_3:_OFFENCES_AND_SANCTIONS (accessed 30 December 2017).

[162] United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988) Art 3(1)(a).

[163] As above Art 3(2).

[164] In the High Court of South Africa (Western Cape Division, CT), Case No: 8760/2013, In the matter between Gareth Prince and Minister of Justice and Constitutional Development and Case No: 7295/2013 In the matter between JD Rubin and the

(CDA) strategy of an evidence-based approach to reducing supply, harm, and demand concurs with this judgement. The CDA also has other strategies for harm reduction and for combating alcohol, tobacco, cannabis, and other psychoactive substance use and abuse in SA.[165,166] Parliament in South Africa has the authority to pass legislation to decriminalise or legally regulate the possession and private use of drugs.

- **Southern African Development Community Protocol on Combating Illicit Drugs (2006)**[167] (Southern African Drugs Protocol)

Scott holds that the treaties mentioned above are outdated and did not serve their purpose to contain drug use and the simultaneous global trade in illicit drugs.[168] Scott also makes further claims that should be accepted in the process to legal regulation of drugs, namely that:

- the 'war on drugs' has failed as a result of criminalisation instead of legal regulation.
- humans have and always will have the urge to experiment with psychoactive substances, which makes a drug-free society unattainable.
- The majority (over 80%) of people who use licit/illicit drugs do not develop substance use disorders. The rest of the people (less than 20%) who do develop drug-use disorders, have significant psychological disorders and may be forced into dismay due to drug use, which is currently criminalised.
- Current drug legislation ignores the autonomy of adults as a basic human right who should have the authority to choose psychoactive drugs of their choice.

5.3.8.5 Implications of cannabis legalisation on prohibited substance regulation and testing in South Africa

The legalisation does not imply that the impairment potential does not exist anymore. An organisation may, and should still, test for cannabis in individuals, due to its impairment potential on psychomotor and cognitive functions, similar to alcohol. The legalisation of cannabis has placed the use of this substance on equal footing with alcohol, which is also a

National Director of Public Prosecution, and Case No: 4153/2012 In the matter between JD Acton and the National Director of Public Prosecution, Judgement: 31 March 2017 by Judge J Davis at para 107.

[165] DJ Stein for the Executive Committee of the Central Drug Authority 'Position statement on cannabis' (2016) 106 *South African Medical Journal* at 569-570.

[166] Scott (n 141).

[167] Southern African Development Community Protocol on Combating Illicit Drugs (2006). http://www.sadc.int/files/1213/5340/4708/Protocol_on_Combating_Illicit_Drug_Trafficking_1996_.pdf.pdf (accessed 30 December 2017).

[168] Scott (n 141).

prohibited substance in most risk-sensitive environments and the employer should still ensure the safety of others and, therefore, should enlist cannabis as a prohibited substance.

An organisation has to define its stance regarding private use since there may be some discrepancy as to the interpretation of "private use" on its premises. For instance, an office may also be regarded as private. The organisation should prohibit the possession of cannabis on-site, similar to alcohol.

The legalisation does have some interesting implications in the pre-employment setting. Refusing individuals access to work because they are cannabis users inflicts negatively on the individual's right to freedom to use cannabis. A "fitness for work" decision should instead be based on a risk assessment by the doctor who should have the same approach as he would have in the case of alcohol users. The current practice of making use of THC cut-off concentration values in a "fitness for work examination" during pre-employment consultations similar to random screening practices and declaring an applicant not fit to be employed by the organisation is in principle therefore not correct.

The legalisation of possession and private use of cannabis implies that the obligation to report the use of cannabis to the authorities is put on hold. The constitutional right to privacy trumped the provisions related to the criminalisation of cannabis use and possession for private use. However, this does not apply for the other illegal compounds and, according to the Drugs Act, the organisation should report the use of illegal compounds.

Another exciting aspect relating to the medicinal use of cannabis oils by individuals subjected to a prohibited substance regulation and testing programme has emerged since the legalisation of cannabis. Commercial products containing Cannabidiol (CBD) oil has become increasingly available as Cannabidiol is claimed to have anti-inflammatory properties, amongst others. These commercial products have been shown to contain high levels of THC, which will also lead to impairment. THC will be absorbed by the human body, even if it is applied topically. Therefore, an organisation has to insist on a legal prescription similar as for other medications.

It remains to be seen if the other illegal compounds will follow the same route as cannabis in that personal use will be decriminalised due to the overriding right to freedom and privacy.

5.3.9 Health Professions Council of South Africa

Guidelines for Good Practice in the Healthcare Professions of South Africa, seeking patients' informed consent: The ethical considerations (Booklet 9) and *Health Professions Council of*

South Africa (HPCSA): Guidelines for Good Practice in the Healthcare Professions of South Africa.[169]

Being registered with the HPCSA gives healthcare practitioners certain rights and privileges. In return, they have to meet the standards of competence, care and conduct set by the HPCSA and its professional boards. Healthcare practitioners hold information about patients that information is private and sensitive. The NHA provides that this information may not be given to others unless the patient consents or the disclosure can be justified by the healthcare practitioner. Practitioners have to take responsibility for their staff to respect confidentiality in the performance of their duties.

5.3.10 Registration of preliminary drug-testing devices

On-site preliminary drug screening test devices have to be registered. The Medicines and Related Substances Amendment Act[170] came into force on 1 June 2017, together with a further amendment act, namely the Medicines and Related Substances Amendment Act.[171] These amendment acts are significant since they fundamentally changed the medicines regulatory regime in South Africa, and altered the Medicines Act.[172]

Both amendment acts came into force simultaneously and gave effect to numerous amendments to the Medicines Act. The amendments to the Medicines Act attempt to reconcile various general regulations promulgated under the Medicines Act, dealing with issues such as complementary medicines and the registration and licensing of medical devices.

The most prominent change brought about by the amendment act is the change in the regulatory authority, which is now the South African Health Products Regulatory Authority (SAHPRA) and which is outside of the public service. The Medicines Control Council, which is an organ of state, was previously in charge of the regulatory oversight of medicines, medical devices, complementary medicines, foodstuffs, cosmetics and in vitro diagnostic medical devices.

The SAHPRA has the mandate to register products such as medicine, medical devices, and cosmetics and in vitro diagnostic medical devices, amongst others. Amendments have been made to section 14 of the Medicines Act, which requires that only registered products are allowed to be on the commercial market in South Africa.

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[169] UNODC Confidentiality: Protecting and Providing Information, Booklet 10, May 2008, Pretoria.
[170] Medicines and Related Substances Amendment Act 72 of 2008.
[171] Medicines and Related Substances Amendment Act 14 of 2015.
[172] Medicines and Related Substances Control Act 101 of 1965.

In terms of the amendment act,[173] specific fundamental definitions changed in respect of how one identifies a medical device in order to determine what must be registered in terms of the Medicines Act. Medical devices are now subject to the regulatory restrictions imposed by the Medicines Act, as amended, and the definition of "medical device" has been modified and expanded, and now means the following:

"Means any instrument, apparatus, implement, machine, appliance, implant, a reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act.

(a) Intended by the manufacturer to be used, alone or in combination, for humans or animals, for amongst others, the provision of information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) Which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in human- or animal bodies, but which may be assisted in its intended function by such means." [174]

5.4 SOUTH AFRICAN STATUTES RELATED TO A DRUG- AND ALCOHOL-FREE WORKPLACE

5.4.1 Common-law criteria related to a prohibited substance regulation and testing program towards a drug- and alcohol-free workplace

Employee: The employee must conduct himself in such a manner to perform duties effectively and efficiently according to his or her contract. Noncompliance may result in the termination of the contract of employment based on misconduct/incapacity or may claim damages contractually. If an employee reports for duty in an impaired/intoxicated state, he is in breach of contract with the employer and may not be allowed onto the premises without payment due to non-performance. The employer may approach this from an "*incapacity" or "misconduct"* perspective. Disciplinary action can be taken in the case of misconduct, and the employee may be terminated. Damages can also be claimed from the employee due to harm that may have been caused due to the employee not competently performing his duty, as per the contract.

[173] Act 14 of 2015.
[174] Hazardous Substances Act 15 of 1973.

Employer: Employees, contractors and the public who may be exposed have the right to safety which imposes an obligation on the employer to establish safe working conditions.[175] Reasonable suspicion of a possibly harmful situation due to prohibited substance use is sufficient to request the employee to undergo a drug test to the effect the employee is satisfied that the employee is not "under the influence" of drugs or alcohol. And also not to allow the employee to enter the workplace or safety-sensitive environment.

There is a reciprocal contractual duty and responsibility on both employees and employers to treat each other with respect and dignity not to destroy the relationship of trust and confidence.[176,177] This responsibility applies not only to the provision of safe machinery and safety clothing and equipment but also to the use of prohibited substances that may cause an employee to under the influence or intoxicated and possibly harm fellow employees and the public. Harm or injury to an employee or a member of public due to negligence by the employer can be deemed as a breach of contract, and the employee may claim for damages.

It is advisable for all in the organisation to respect the prohibited substance regulation and testing programme as part of the contract of employment. Prospective employees should also be informed of the prohibited substance regulation testing programme in advance that drug- and alcohol testing will be conducted in the interest of health and safety.

5.4.2 Statutory recognition and incorporation of International Labour Organisation standards

The ILO's support for a drug- and alcohol-free workplace programme is expressed in the European Guidelines for Workplace Drug Testing.[178] Alcohol and drug abuse as one of the conducts justifying dismissal according to the ILO code.[179] Incapacity, such as drug dependence, is approached more sympathetically than misconduct such as negligent and irresponsible use of drugs and alcohol. The latter may result in severe disciplinary action such as dismissal. The LRA[180] recognises the international law obligations of South Africa under its

[175] Van Niekerk et al *Law @ Work* (2015) 93.
[176] C Bosch 'The implied term of trust and confidence in South African Labour Law' (2006) 27 *International Law Journal*.
[177] Van Niekerk et al (n 175) 94.
[178] European Workplace Drug Testing Society *European Guidelines for Workplace Drug Testing in Urine, Saliva and Hair* www.ewdts.org (accessed 2 January 2017).
[179] Van Niekerk et al (n 175) 276.
[180] Labour Relations Act 66 of 1995.

membership of the ILO explicitly.[181] The Employment Equity Act 55 of 1998 (EEA) also provides for this in relation to the ILO convention.[182]

5.4.3 The Labour Relations Act

5.4.3.1 Summary of the Act

The LRA[183] is the main statute regarding the collective and individual rights of employees and protects employees against unfair dismissal and labour practices. Its regulations apply to trade unions and allow for dispute resolution organisations such as the CCMA and labour courts. The LRA[184] provides possible reasons for unfair dismissal in section 188, which are per the ILO requirements.[185] *Misconduct* and *incapacity*, within the operational requirement of the establishment, is included in these requirements as well as the opportunity for the individual defend himself against the allegations, according to the principles of natural justice.

5.4.4 The Occupational Health and Safety Act

5.4.4.1 Summary of the Occupational Health and Safety Act

The Occupational Health and Safety Act (OHSA) "provides for the health and safety of persons at work and the health and safety of persons in connection with the use of plant and machinery; the protection of persons other than persons at work against hazards to health and safety arising out of or in connection with the activities of persons at work..."[186]

The relevant sections of the Act related to prohibited substance regulation and testing in the workplace are summarised and discussed below:

Section 8 of the act holds that as part of its general duties of employers to their employees:

(1) "Every employer should provide and maintain, as far as is reasonably practicable, a working environment that is safe and without risk to the health of employees.
(2) The duties of employers also include:

[181] Secs 1(b) & 3(a), (b) & (c) of the LRA.
[182] Employment Equity Act 55 of 1998 sec 3: Interpretation of the Act.
[183] Labour Relations Act 66 of 1995.
[184] LRA sec 188.
[185] International Labour Organisation Convention on the Termination of Employment at the Initiative of the Employer 158 of 1982 Art 4 states that: a worker shall not be terminated unless there is a valid reason related to capacity/conduct of the worker or based on the operational requirements of the undertaking.
[186] Occupational Health and Safety Act 85 of 1993 (OHSA).

a. taking all necessary measures to ensure that the requirements of the Act are complied with by every person in his employment or on the premises under his control where plant machinery is used.[187]
b. enforcing such measures as may be necessary for the interest of health and safety."[188]

Section 9 relates to persons other than employees whereby the employer should conduct his undertaking in such a manner that persons other than employees are not exposed to the hazards to their health and safety.[189]

Section 14 on the general duties of employees at work involves:[190]

(a) "To take reasonable care for the health and safety of himself and of other persons who may be affected by his acts or omissions.
(b) ...shall cooperate with the employer to enable a duty or requirement to be performed or complied with.
(c) carry out a lawful order given to him, and obey the health and safety rules and procedures laid down by his employer or by anyone authorised to it by his employer, in the interest of health and safety.
(d) If any situation which is unsafe or unhealthy comes to his attention, as soon as practicable report such situation to his employer or to the health and safety representative for his workplace who shall report it to the employer."

Section 23 holds that: "No employer shall in respect of anything which he is in terms of this Act required to provide or to do in the interest of the health and safety of an employee, make any deduction from an employee's remuneration or require or permit any employee to make any payment to him or any other person."

Section 2 of the Regulations in terms of the Health and Safety Act address intoxication and admittance of persons as follows:

- "**Section 2A**: Intoxication: (1) ...an employer or user, ..., shall not permit any person ***who is or appears to be under the influence of intoxicating liquor or drugs***, to enter or remain at a workplace; (2) ...no person at a workplace shall be under the influence of or have in his possession or partake of or offer any other person intoxicating liquor or drugs."

[187] OHSA sec 8(2)(g).
[188] As above sec 8(2)(h).
[189] As above sec 9(1-2).
[190] As above sec 8(2)(a-e).

- "**Section 2C**: Admittance of persons: ...an employer or user...shall not permit a person to enter a workplace where the health and safety of such a person is at risk or may be at risk, unless such person enters such workplace with the express or implied permission of and subject to the conditions laid down by such employer or user."

5.4.5 General Safety Regulations of the Machinery and Occupational Safety Act

5.4.5.1 Summary of this Act

(This Act has been repealed, but the regulations are still applicable).[191]

Regulation 12(2) of the Machinery and Occupational Safety Act 6 of 1983 (MOSA) states: "At a workplace or on premises where machinery is used, no person shall have in his possession or partake of or offer any other person intoxicating liquor or drugs, except with the express permission of the employer…" The General Administrative Regulations of the MOSA (Regulation 6) holds that: "…every employee shall: carry out any lawful order given to him and shall obey the safety rules and procedures laid down by his employer or by anyone authorised thereto by his employer, in accordance with or for the proper observance of the provisions of the Act or the regulations or in the interest of safety; and where a situation which is unsafe at or near his workplace comes to his attention, as soon as possible report such a situation to a safety representative or his employer." The regulation in the MOSA dealing specifically with intoxication states the following: "An employer shall not permit any person ***who is or who appears to be drunk or under the influence of drugs***, to enter or remain at a workplace or on the premises where machinery is used if such person's presence constitutes a threat to the safety of himself or other persons at such workplace or on such premises".

5.4.5.2 Implications of the OHSA and MOSA for prohibited substance regulation and testing in South Africa

Obligations of the employer: An employer has to provide and maintain a safe and risk-free working environment in the interest of the health of his employees. [192] Sufficient measures to ensure compliance with the requirements of the Act must be taken by everybody employed on his premises where plant or machinery is used.[193] These measures should be exercised to the extent that is required in the interest of health and safety.[194]

[191] General Safety Regulations of the Machinery and Occupational Safety Act 6 of 1983 (MOSA).
[192] OHSA sec 8(1).
[193] As above sec 8(2)(b).
[194] As above sec 8(2)(h).

Obligations of the employee: All employees must take responsibility and cooperate by taking reasonable care for himself and others' health and safety who may be exposed due to his actions or omissions.[195] Lawful orders by the employer must be obeyed in terms of the health and safety rules and procedures.[196] Harmful and unsafe situations should be reported to the employer or health and safety representative.[197] All incidents which may have an effect on health and safety, which may have caused injury must be reported as soon as possible.

The Act also holds that it is the responsibility of the employer to cover the costs for prohibited substance testing related to the workplace health and safety under section 23.

Section 2A of the General Safety Regulations[198] of the OHSA prohibits access to the workplace by any individual who is (or appears to be) **under the influence of intoxicating liquor or drugs**.[199] "No person may be under the influence in the workplace or possess intoxicating substances or offer intoxicating substances to another person, or take part in the offering".[200] "An employee may not be allowed to perform duties in the workplace if the side effects of medication taken by the employee impose a threat to the health or safety of himself or other persons in the workplace." [201]

5.4.5.3 "Under the influence" of "intoxicating" liquor or drugs

The concept of "under the influence of intoxicating liquor or drugs" has been addressed in the criminal law setting for driving under the influence of alcohol and drugs cases (DUI), which is prohibited under the National Road Traffic Act.[202] A driver is under the influence of intoxicating liquor if: "the skill and judgement normally required in the manipulation of a motor car is obviously diminished or impaired as a result of the consumption of alcohol".[203] It should be kept in mind that an individual's faculties and ability to drive can be impaired long before it becomes evident since the indicators of impairment lie on a continuum with various degrees of severity. It may require a skilled person to judge these levels of impairment which may range from less severe to more severe, contributing to a state of intoxication.[204] It can also be viewed as a process that involves various degrees of impairment, leading to intoxication.

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[195] As above sec 14(a).
[196] As above sec 1(4)(b)(c).
[197] As above sec 14(d).
[198] GN R1031 GG 10252 of 1986-05-30 s 2A.
[199] As above sec 2A(1).
[200] As above sec 2A(2).
[201] As above sec 2A(3).
[202] National Road Traffic Act 93 of 1996 sec 65(1).
[203] Lloyd 1992 EDL 270 in J Burchell *Principles of criminal law* (2014) 787 Juta.
[204] See ch 6 on "sobriety testing"

The use of the words “appears to be under the influence” and “under the influence of intoxicating liquor or drugs” intuitively leads the organisations to interpret the relevant sections to the “letter of the law”, resulting in the inclusion of the wording that “the individual may not be intoxicated” in their prohibited substance regulation and testing policies. This surely is a noble goal, but problematic to defend in a medico-legal setting, since no clear point exists beyond which an individual can be regarded as intoxicated. Various degrees of intoxication can be achieved by an individual who depends on the dose, the rate of consumption and other factors.

In their strive to comply with the law, organisations, therefore, enforce a stance of zero tolerance for prohibited substance use by way of a prohibited substance regulation and testing policy, which may then serve as a guideline in the legal setting. The intention is that the individual has to be drug and alcohol-free, which implies that drugs and alcohol whatsoever should not impair him and that no level of impairment will be tolerated. The concept of zero tolerance and intoxication is misunderstood by numerous organisations in South Africa currently. The stance of zero tolerance should not be interpreted as “zero-concentration levels”, which is not defensible from a scientific perspective. Implementation of low threshold concentration levels is more scientifically sound.

Proof of driving under the influence (DUI) cases is presented by following a two-tier approach to proving that the transgression complies with the definitional element of the DUI case. The first part involves evidence of impairment, and the other part involves that the legal threshold of alcohol in the blood has been exceeded. Proof of impairment evidence is usually introduced to complement the forensic laboratory blood-alcohol test results.

Proof of impairment requires observational recognition of impairment indicators, which has an inherent risk of non-selectivity due to observational error and even discrimination or biasedness against the employee. It may also be difficult for the officials to recognise the effects, which may be obscured due to learned behaviour by the test subject, resulting in the individual entering the risk-sensitive premises. This approach has the potential to result in a large number of FP and FN identifications, meaning the diagnostic sensitivity and specificity of observational recognition of impairment indicators for prohibited substance use are not favourable.

The law of contract applies in the labour setting, where the prohibited substance regulation and testing policy can be viewed as an agreement between the employer and employee. The prohibited substance regulation and testing policy, therefore, may use cut-off levels that are

different from that in the criminal justice setting discussed above relating to proof of impairment and BAC levels. Both elements might not have to be proved in combination, but rather separately.

The author suggests the following remedy by either an Act of Parliament or by reading the following phrase into the current OHSA: the concentration of a prohibited substance in a biological fluid specimen (such as blood, urine, saliva) from an individual's body must be less (or lower) than a predetermined threshold concentration value and as specified in the policy.

The act, therefore, should read as follows:

"...namely that the individual shall not be allowed to enter or remain at the workplace while:

(1) "he or she *appears to be* under the influence."

OR

(2) "the concentration of a prohibited substance in a biological fluid specimen (such as blood, urine, saliva) from his or her body is not less than a predetermined threshold concentration value and as specified in the policy/guideline".

Such an addition to the OSHA will accommodate the prohibited substance chemical testing similar to roadside DUI testing, in addition to sobriety testing, which also has the aim of compliance testing and has a diagnostic slant. The threshold or cut-off concentration levels may then be obtained from predetermined mandatory statutory guidelines, in which case liability will be based on the fact that the threshold concentration was exceeded, which can be viewed a is a breach of contract. The specification of a threshold concentration level also counters all the claims related to between-individual metabolic differences, which are sometimes used as a defence against evidence of impairment.[205]

The statutory threshold concentration levels for BAC in DUI in South Africa is 0.05 gram per 100 mL for the general public and 0.02 gram per 100 mL for professional drivers. These are well-established values that will prevent an individual from functioning in an impaired state. These values are regarded as subclinical since the influence or effects are not apparent or obvious, the behaviour is normal by ordinary observation, and impairment is detectable only

[205] For instance genetic make-up, sex, age, metabolic rates, rates of absorption.

by special tests.[206] (See the table in chapter 1 on the stages of alcohol impairment.) The equivalent threshold concentrations for ethanol in breath is 0.24 mg per 1000 mL of breath, and in the case of professional drivers 0.10 mg per 1000 mL of breath. The concentration ranges for other drugs have not been well established compared to alcohol due to the ethical restrictions on research involving illegal drugs. Cannabis was also subjected to this restriction, which is now decriminalised in South Africa for private use and cultivation.

5.4.6 The Compensation for Occupational Injuries and Diseases Act

5.4.6.1 Summary of the Compensation for Occupational Injuries and Diseases Act

Intoxication is classified as a "serious and willful misconduct" by the Compensation for Occupational Injuries and Diseases Act 130 of 1993 (COIDA) which holds that no compensation will be provided in such a case. Section 35(1) of the COIDA provides immunity to employers against claims of delict under these circumstances.[207] A statutory insurance scheme was brought into life by this act for employees to claim compensation for occupational injuries and diseases from the commissioner.[208] Injuries or harm caused to co-workers as a result of drug use is not in the scope of the work contract which makes the employer liable in terms of breach of his common-law contractual relationship with the injured employee.[209]

5.4.7 Foreign Law: Validation of the HHS Mandatory Workplace Drug Testing Guidelines within the South African legal framework

5.4.7.1 Background

Validation of the HHS Mandatory Workplace Drug Testing Guidelines refers to the assessment of the suitability of the guidelines to function within the South African legal framework. No mandatory guidelines currently exist in South Africa for the regulation and testing of prohibited substances in the workplace. Implementing a workplace drug- and alcohol-free programme, which is legally defensible, scientifically accurate and ethically sound involves several critical stages where legal tension may arise. These are:

- a formal written policy which explains all the rules, protocols and list of prohibited substances which is primarily aimed at health and safety but simultaneously respect private

[206] JC Garriott (ed) *Medical-legal aspects of alcohol* 4th ed (2003) 27 Lawyers and Judges Company Inc.
[207] Compensation for Occupational Injuries and Diseases Act (COIDA) 130 of 1993.
[208] COIDA does not cover all harms that may be caused in the workplace.
[209] Media24 Ltd and another v Grobler 2005 (7) BLLR 649 (SCA).

drug use by the institution of concentration threshold levels that ensures safety and accommodate private drug use as far as possible.

- The *specimen collection* stage may be perceived as invasive by compromising privacy, dignity and autonomy if the donation process is not treated with the necessary sensitivity and the donor's voluntary informed consent is not obtained.
- The *analytical testing* of the specimen for detection of intoxicating substances is also a crucial part of the process since the test result must be a reliable reflection of the individual's drug use.
- *Reporting* of the test result with respect to confidentiality which impacts on the donor's privacy.
- *The validation/verification and interpretation of a positive confirmed test result* is seen as the "gate-keeping" stage before decisive action is initiated. This needs to be performed by a professional doctor with the necessary experience.
- *Action that follows* from the confirmed presence of an intoxicating substance.

The following are typically legal, ethical and scientific concerns:

- The compliance of the policy with a due process will have a direct effect the fair and justness of the programme
- Prohibited substance testing is by its very nature invasive on an individual's human rights.
- False accusations may be raised if the testing protocol is not carried out scientifically correct and accurately
- Discrimination may arise as a result of the labelling of an employee as a "drug-abuser"
- Injustice may result due to incorrect and unreliable testing protocols.
- The reasons for testing and the way individuals are selected for testing.
- Confidentiality of private drug of the individual may be compromised.
- Drug test results cannot always directly be employed as an indicator of impairment utilising some matrices like urine, saliva and hair.
- Doctor-patient relationship of trust may be compromised.
- The reliability of the preliminary assays and laboratory confirmatory assays is of critical importance.
- The type of information about the employee that will be communicated to the employer by the doctor.
- A prospective employee's access to his or her test results.

5.4.7.2 Legal aspects of critical stages of a drug- and alcohol-free workplace programme

The HHS Mandatory Guidelines of a workplace drug- and alcohol-testing programme can be evaluated by grouping the testing regime into a pre-testing, testing and post-testing phase, each requiring careful consideration before the implementation of the guidelines in the South African setting from a legal, scientific and ethical perspective.

5.4.7.2.1 Pre-testing phase: Policy drafting, specimen collection and onsite preliminary analytical testing

(a) Policy

The SAMHSA mandatory guidelines are in line with the South African legal framework to a large extent.

The policy should list the responsibilities of both parties (employer and employee) and allow for workforce training and education of supervisors and employees. A rehabilitative stance should be taken as opposed to a punitive one which may involve the "policing" of the workers. Disciplinary action for a validated positive test result should be detailed as a very last option/solution to act as a deterrent, and a refusal to test should be defined as well as the consequences thereof. Self-referrals, voluntary testing should be accommodated as well as an employee assistance programme (EAP).

The policy should address and explain the type of tests (and frequency) as well as the type of specimen (matrices) that will be employed and collected for prohibited substance testing. The threshold concentration levels that will be used to prevent a worker from entering the site to perform safety- and risk-sensitive duties should be agreed upon. The procedures, protocols of specimen collection, transport and laboratory testing should be covered in detail. The result reporting process and the eventual communication thereof, in the case of a non-compliant test result, should also be included. A stand-down policy involving its procedures and requirements should also be detailed. Information on the EAP to assist an employee with a drug-abuse problem should be provided.

The South African prohibited substance regulation and testing scenario can be compared to the US "non-regulated" setting. Drafting of a drug- and alcohol-free workplace policy in the South African setting should involve the inputs of the employees (or their representatives in an unionised environment), management, health and safety officials. Inputs from the security and human resource departments are also required.

All parties must accept the prohibited substance regulation and testing policy after a collective bargaining process, which will establish the rules of a drug- and alcohol-free workplace programme. Scrutiny of the policy should be welcomed as this will improve the outcomes and achievement of the ultimate aim namely, improved health and safety of the workforce

- **South African constitutional perspective**

The rights as specified in the CSA are intertwined in a workplace drug- and alcohol-free programme – defiance of one may affect others. An organisation should implement a prohibited substance regulation and testing programme on the authority of the CSA, common law and relevant statutes, within the guidelines of good scientific practice and ethics. A prohibited substance regulation and testing policy should be tested for compliance against these criteria.

A *documented* policy must be *understood by everybody* involved to provide legal certainty and must also be available in all official languages of South Africa. The policy must comply with due process as required by sections 32 and 33 of the CSA, which state that everybody has the right to access any information that is required to protect his or her rights and also that everybody has the right to just administrative action.[210] The policy must ensure that due respect will be paid respect for dignity, privacy, bodily integrity and must also comply with due process and the right to fair labour practice.

Employee and supervisor training is required to comply with the right to access to information and to ensure that due process is followed. It should be highlighted which prohibited substances should not be used as well as how to approach the prescription medications that may result in impairment of the individual's faculties.

Traditional medication and herbal medication should also be accommodated if it is legally prescribed by a **registered** health worker or doctor, however, if the medication has an impairment effect the organisation has the right to remove the individual from a safety-sensitive position in the interest of health and safety.

The reasons for testing such as for pre-employment, periodic, random testing and selection of employees must be motivated from a risk- or "safety-sensitive" perspective *without*

[210] *President of the Republic of South Africa and others v M &G Media Ltd* 2012 (2) SA 50 (CC): Ngcobo CJ said "everyone has the right to access to any information held by the state. It gives effect to accountability, responsiveness and openness as founding values of our constitutional democracy. It is impossible to hold accountable a government that operates in secrecy…"

discrimination against anyone (race religion, day shift/night shift, site, position in the organisation) as per the right to equality (section 9 of the CSA).

Post-incident testing requires some careful consideration in a non-regulated setting like South Africa, since it may have an element of criminal liability and negligence associated with it. The other types of tests may be viewed as preventative tests to maintain the drug- and alcohol-free workplace.[211] If a prohibited substance test of an employee would be confirmed positive for an illegal substance after an incident, the employer has an obligation to inform the authorities not to be criminally liable himself. If the individual does not have the capacity to provide consent, *necessity* will be the defence for disclosure without the consent of the employee.

- **Common law perspective**

From the Common law perspective, acceptance of the policy is a contract that binds both the employee and the employer according to the prohibited substance regulation and testing policy. Reasonable suspicion is sufficient for the employer to request that the employee submits for a prohibited substance test to prevent harm to the individual and other employees. The employee may not be present at the workplace in a state of intoxication.

- **Statutory perspective**

The LRA allows for the collective rights of individuals in the workplace as far as prohibited substance regulation and testing programmes are concerned. The LRA distinguish between misconduct and incapacity within the operational requirements of the organisation. Non-compliance with the prohibited substance regulation and testing policy will be regarded as misconduct in the case of intoxication if a history of drug dependency does not exist. Intoxication, in the case of drug dependency, will be treated as incapacity resulting in the employee be referred for treatment and by having to give full co-operation.

The LRA also holds that the services of the employee may not be terminated without the employee having the opportunity to defend himself. The MRO review process, providing the employee with a fair opportunity to explain his confirmed positive test result, concurs with this.[212]

[211] Sec 2.4 of this document: pre-employment testing, periodic medical testing, random testing, return-to-duty testing and follow-up testing.

[212] In the South African context, this requires extra caution since the use of herbal medication, laced with western medication is a phenomenon that occurs often.

The EEA prohibits unfair discrimination against an employee with regard to policies and procedures, placing a high premium on a legally correct, ethically sound and scientifically accurate prohibited substance regulation and testing policy.

The OHSA also requires a workplace prohibited substance regulation and testing programme and enforce obligations on both the employer and the employee relating to health and safety in the workplace. The employee should report an unhealthy or unsafe workplace, including colleagues who are under the influence of intoxicating substances. The employer has to maintain safe working conditions and therefore, may perform workplace prohibited substance testing to this extent.

Section 2A of the General Safety Regulations[213] of the OHSA provides explicitly for the prohibition of access to the workplace of any person who is (or appears to be) "under the influence of intoxicating liquor or drugs".[214] It is a requirement that no person may be under the influence in the workplace or have "intoxicating substances in his possession or offer intoxicating substances to another person, or take part in offering".[215] An employer may not allow an employee to perform duties in the workplace if the side effects of medication that is taken by the employee constitute a threat to health or safety to the employee or other persons in the workplace.[216]

(b) Specimen collection

The integrity of the specimen needs to be supported by a collection protocol that complies with respect for autonomy, dignity and privacy. Voluntary informed consent, the provision of suitable privacy during the donation process and by treating the test subject in a sensitive manner is, therefore, a requirement. The type of specimen collected (urine, breath, blood, hair, saliva) also relates to respect for the *dignity, bodily integrity and privacy* of the employee in the sense that the information to be obtained must be aligned with the purpose of the testing. Scientific correctness is also part of a fair process since science informs the law. Section 33 of the CSA *requires just administration that is lawful, reasonable and procedurally fair*.

Judging a person's degree of intoxication by observation is problematic since the level of "intoxication" can be viewed as a continuum of levels of impairment. The level of intoxication is problematic to gauge by mere observation, and it can be challenging (and carries a risk of

[213] GN R1031 GG 10252 of 30 May 1986 sec 2A.
[214] As above sec 2A(1).
[215] As above sec 2A(2).
[216] As above sec 2A(3).

subjectivity) to identify an intoxicated person[217] who sometimes requires extensive medical observations.[218] The selection of a worker based on reasonable suspicion of intoxication may also not go unchallenged. A preliminary analytical test for prohibited substances can assist in avoiding subjectivity as an objective means of requiring a reasonable suspicion to have a confirmation analysis performed.

The selection of the bio-matrix is quite essential when relying on the test results as a measure of intoxication. The bio-matrices available in the human body for drug and alcohol testing are blood, saliva, urine, sweat and hair. The HHS guidelines recommended the use of urine initially; however, oral fluid testing is now also included in the mandatory guidelines.

From a forensic perspective, blood, urine and hair may provide proof that the drug was part of the internal environment of the body. The buccal cavity, however, is not considered to be part of the internal environment of the human body from a physiological perspective and, therefore, may be subjected to external contamination, which may result in inaccurate conclusions regarding impairment status. Blood will be of most value to obtain information on a person's impairment status. Oral fluid will provide relatively recent information regarding drug consumption since it mimics blood concentrations to a certain extent, typically up to three hours. Drug detection times for urine varies from hours to weeks for a frequent user and detection of drugs in hair is possible for up to years. The longer the detection time, the least efficient drug test result becomes in predicting current intoxication status. The decision regarding the specimen matrix that will be collected for prohibited substance testing will have to be a contractually agreed upon by striking a balance between the information required, invasion of privacy, respect for dignity and scientific reliability.[219]

Private drug use (licit and illicit) will be allowed and tolerated to a large extent by setting concentration threshold levels in a specific matrix. This will be the "zero-tolerance" concentration levels, above which a *stance of zero tolerance* will be initiated, and the action should be taken.[220] The Substance Abuse and Mental Health Services Administration

[217] The term "intoxication" is used regularly to refer to a person who is drunk or under the influence of drugs.

[218] In the industrial environment where workers work shifts, it is difficult to perform these observations within the limited time available as they enter the premises.

[219] It is the opinion of the author that urine is the matrix of choice since it strikes a balance between sampling privacy and scientific viability.

[220] It is important to note that the zero-tolerance approach should not be confused with one of zero-concentration levels. The first is a stance or approach that "action will be taken" if the cut-off concentration is exceeded. The latter refers to the total absence of drugs and alcohol in the human body, which is impossible from a scientific point of view; R Capler & D Bilsker et al Cannabis use and Driving Evidence review, Canadian Drug Policy Coalition (CDPC), Simon Frazer University (2017) 34; JC Cone et al 'Non-smoker exposure to second-hand Cannabis smoke. Urine screening and confirmation results' *Journal of Analytical Toxicology* (2015) 39 (1-12).

(SAMHSA), cut-off concentrations are set at a level that ensures that the employee is not in a state of intoxication, but that also accommodates private use within time limits before the employee enters the organisation's premises.[221]

Employing a urine matrix as opposed to saliva may impose more restrictions on the private life of the individual since he has to abstain earlier, but may also allow the company to manage long-term risk more effectively. Urine drug testing may be regarded as paternalistic due to the long half-life of drugs like cannabis, which, requires the individual to abstain from cannabis use much sooner before entering the premises of the organisation. This emphasises the need for a negotiated decision regarding the bio-matrices for specimen selection for prohibited substance testing. The concentration of THC in urine is not an indicator of current impairment and, therefore, may restrict an individual's freedom to consume cannabis.

Blood may be regarded as more invasive and intimate with a concomitant risk of infection to the worker. Hair specimen analysis may provide information on the worker's past, which may be regarded as private. Breath is a suitable matrix for alcohol testing since it will indicate the current impairment status and is not as invasive as blood collection. Breath alcohol concentrations also mimic blood-alcohol concentrations reliably.

In the non-regulated environment of South Africa, the employer has to supply consumables for specimen collection, which can also be extended to the purchasing of reliable testing equipment for preliminary drug and alcohol tests. This also includes confirmatory testing equipment for alcohol testing in breath.[222] The employer also has a responsibility to ensure the contracting of competent professional drug-testing services, collection officers, MROs and external service providers.

- **Constitutional requirements for specimen collection**

Section 12 of the CSA holds that "everyone has the right to bodily and psychological integrity, which includes the right to security in and control over their body". By viewing the concept of "physiological integrity" from a pure physiological/medical perspective, the physiological integrity of a human is disturbed when homeostatic mechanisms are disrupted. A wound or penetration of the body (drawing blood) can strictly be seen as a disruption of homeostasis, although to a limited extent. The collection of a urine/saliva specimen, where the collector does

[221] Substance Abuse and Mental Health Services Administration (SAMHSA), https://www.samhsa.gov/workplace/workplace-programs (accessed 17 April 2019).
[222] Regulations in terms of the OHSA sec 2(3)(g).

not even touch an employee, cannot be viewed as a compromise to bodily integrity from a physiological point of view. Blood collection, however, would be the most invasive of all matrices.

Section 10 of the CSA also applies to the collection of bio-specimens, since it may invoke the dignity clause whereby human dignity may be compromised in the case of urine donation, especially in for an observed specimen collection. Dignity may also be diminished during the selection process, whereby the employer selects employees to undergo a drug or alcohol test. If the approach is not sensitive towards the person, he or she may feel offended or even labelled. It should be kept in mind that the bulk of the workforce consists of honest and hardworking individuals.

Section 14 of the CSA holds that "everyone has the right to privacy" which may be compromised during the collection process if an employee is not allowed the required privacy to donate the specimen or if the collector is not of the same gender.

The doctrine of voluntary informed consent is of prime importance and is a paradigm shift away from medical paternalism towards the autonomy of the person, which accords with the Bill of Rights.[223,224] Patient autonomy is a concept that was addressed in 1923 already in the case of *Stoffberg v Elliott*,[225] where the judge stated that:

> "In the eyes of the law, every person has absolute rights which the law protects. They are not dependent on statute or contract, but they are rights to be respected, and one of the rights is absolute security to the person… any bodily interference or restraint of man's person which is not justified in law, or excused in law or consented to is a wrong, and for that wrong, the person whose body has been interfered with has the right to claim such damages as he can prove he has suffered owing to that inference."[226]

[223] Carstens & Pearmain (n 22) 877.
[224] CSA sec 12: Freedom and security of the person.
[225] Stoffberg v Elliott 1923 CP 148.
[226] Carstens & Pearmain (n 22) 879.

Consent must be informed, and it is the prerogative of the individual to permit or refuse the procedure.[227,228,229,230,231] Voluntary, free, informed consent in terms of prohibited substance testing has the following requirements:

- Consent should be voluntary and free.
- Submission for the specimen collection does not imply consent.
- Consent must be explained to the worker in his native language.[232]
- The individual should be informed of the nature of the test.
- The intention and type of tests that will be carried out should be explained in a procedure-specific way.[233]
- What the consequences of a positive test result would be.
- What the results would be used for.
- Consent should be given in writing.
- Consent may be withdrawn during the process, from specimen collection stage to the test result reporting to management.
- Refusal of consent should not be seen as an acknowledgement of guilt, but should instead be treated as a refusal-to-test, with its accompanying consequences.
- The donor may declare the use of any medication afterwards during the MRO review and interview with the donor. (The donor may, however, declare his personal medication use should he or she wish to so voluntarily).
- Consent is a continuous process and may be withdrawn at any stage

Consent is typically obtained at different stages and levels, namely:

- when the policy is accepted by the worker.
- before sampling and testing can proceed.
- before the laboratory release results.
- before the MRO release any result to human resources/management.

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[227] NHA.

[228] Howard & Bogle (n 146) 25.

[229] Beauchamp & Childress *Principles of Biomedical Ethics* (2013) 120.

[230] K Moodley (ed) *Medical ethics, law and human rights: A South African perspective* (2014) 4 Van Schaik Publishers 43.

[231] J Herring *Medical Law and ethics* 2016 6th ed, Oxford University Press 232 155.

[232] In *Lymbery v Jefferies* 1925 AD 236 Wessels referred to the fact that there is a distinction between what the patient should have understood as opposed to what he really understood.

[233] Carstens & Pearmain (n 22) 876.

The following comments and observations regarding the consent and release form (CRF) of the HHS applies:

- Consent and Release Form (CRF)

Observation the completion of the CRF by the collector and signing by the donor of his or her initials on the seals and labels after the collection, cannot be viewed as voluntary informed consent, submission to a test is not regarded as consent. There is also no indication o the CRF where it can be indicated that consent was provided voluntarily and freely. The request for a drug test is also not procedure-specific and also not specific as to whom the donor will allow to receive the test result. Consent to release the test result to the MRO is requested in an "umbrella" and generic fashion and no specific person involved in the testing process designated to receive the test result; for example, the MRO, DER, the appropriate laboratories.

The completion of the CRF also does not indicate that the test subject may withdraw consent after the specimen was submitted since it becomes part of the "mandatory process". Therefore, it can be deduced that the level of consent in the US Mandatory Guidelines do not comply with the South African legislative framework and level of consent to be obtained.

Refusal to submit for a prohibited substance test should **not** be viewed as an admission of guilt and should **not** be treated in the same way as a validated positive test result. It should instead be addressed as non-compliance in terms of the contract of employment, which may have the same outcome as a validated positive test result would have had.

The HHS Mandatory Guidelines also prescribe *background checks* for new employees who have been employed in the regulated system previously. In South Africa, this would raise critique in terms of the right to privacy.

- **Statutory requirements for specimen collection**

The POPI Act: The purpose of the POPI Act is to ensure that all South African institutions conduct themselves responsibly when collecting, processing, storing and sharing another entity's personal information and hold them accountable in the case of abuse or compromise of personal information.

HPA: Health Professions Ethical Rules of Conduct for Registered Health Professionals provide prescriptive guidelines for obtaining consent from a person and also holds that all patients have a right to confidentiality, which is included in the right to privacy.[234] The NHA Regulations

[234] NHA.

(Regulation No. 375) relating to Health Care Waste Management in Health Establishments require safe disposal of human waste which applies to the safe disposal of biospecimens such urine, blood or oral fluid after a negative screening test. [235]

- **Ethical guidelines related to obtaining voluntary informed consent before specimen collection**

The following sources provide information on the obtainment of consent from a patient before a medical intervention:

- The Medical Protection Society of South Africa's guide to "*Consent to medical treatment in South Africa."*[236]
- The HPCSA: "*Guidelines for good practice in the health care professions. Seeking patients' informed consent: The ethical considerations", Booklet 9*
- The HPCSA: "*Guidelines for good practice in the health care professions. Confidentiality: Protecting and providing information", Booklet 10.* [237]

- **Urine specimen collection for drug testing**

In the US, a collection officer has to be a qualified and certified professional, but there is no specific regulatory body in South Africa for this profession. Blood collection requires HPCSA-registration in South Africa however, and only a trained phlebotomist may collect blood. The case for urine and oral fluid collection is less clear since a test for prohibited substance has the purpose of "compliance" monitoring as opposed to a medical diagnostic test, which will require a collector to be registered at the HPCSA. If the test is performed for medical or diagnostic purposes, the specimen collector has to be registered.[238] Collecting a urine or saliva specimen in the interest of safety and security or compliance is not to be regarded as part of a medical test. The collector will require training, which must include instruction on:

- the collection process
- chain of custody procedures

[235] NHA.

[236] www.medicalprotection.org/southafrica (accessed 7 January 2017).

[237] Being registered under the HPA gives healthcare practitioners certain rights and privileges. In return, they have the duty to meet the standards of competence, care and conduct set by the HPCSA and its professional boards. Healthcare practitioners hold information about patients that is private and sensitive. The NHA provides that this information must not be given to others, unless the patient consents or the healthcare practitioner can justify the disclosure. Practitioners are responsible for ensuring that clerks, receptionists and other staff respect confidentiality in their performance of their duties.

[238] HPA sec 39.

- processes involved with problem collections ("shy bladder" and out of range temperature observations)
- the respect for donor privacy, the confidentiality of the information and specimen integrity
- defending the collection protocol in a disciplinary hearing or a court of law.
- The collector should be evaluated to verify his understanding of the issues which should include mock collections to assess his or her proficiency after having received training

It is the opinion of the author that the criteria mentioned above should be included in the job description of a specimen collector if he or she is not registered at the HPCSA. This will provide some accountability to obey ethical guidelines.

- **On-site preliminary testing**

The collection officer must perform urine validity testing before the preliminary drug test, which functions on the principle of lateral-flow immunoassay (generally with an integrated split cup configuration). The same reasoning regarding professional registration applies to the collection officer regarding the performance of a preliminary urine test. If the test is not a medical or pathology test, the collector may be exempted from professional registration. The collection officer should be trained in the use of these testing devices, even though they are relatively simple to use. In terms of section 32 of the CSA, it is the right of the donor to have access to his preliminary test result, and a positive test result should not be used to exclude a prospective employee from employment. Drug testing should be performed as part of a post-offer testing regime, with the prerequisite that the person must pass the drug test. If the test result is non-negative, the specimen should also be referred to the confirmatory laboratory for further testing, similar to a drug test performed on an employee of the organisation.[239] An often forgotten aspect of urine preliminary testing is the safe disposal of urine specimens where the collector must dispose of the urine specimen safely, as prescribed in the specific regulation of the NHA.[240]

5.4.7.2.2 Drug testing and reporting phase

Confirmatory laboratories in South Africa are not required by law to have accreditation, as is the case in the US where the testing laboratories must be SAMHSA accredited. Laboratories can comply voluntarily with the ISO 17025 international guidelines, after certification by the

[239] In the experience of the author, most organisations fall short in the way in which pre-employment drug testing is performed.

[240] Reg 375 of the NHA relating to Health Care Waste Management in Health Establishments requires safe disposal of human waste.

South African National Accreditation Service (SANAS) who also monitor the maintenance of the quality system implemented by the laboratory regularly.

The ISO17025 guidelines require well-trained personnel to perform the analyses and who should be certified as technical signatories by SANAS as an indication of their competence. [241] All test methods have to be thoroughly validated, and it is a requirement that an ISO17025-accredited laboratory should take part in external quality control programmes in addition to routine internal quality control protocols. The forensic scientists have to be registered with their professional bodies, which, in this case, is the HPCSA or the South African Council for Natural and Associated Professions (SACNASP). All confirmation drug tests should be performed by a certified scientist using a forensically acceptable technique and results has to be verified by a senior colleague in the role of a "verifying scientist". After the drug test results become available, the report is sent to the designated person as designed on the voluntary informed consent form.

5.4.7.2.3 Alcohol testing and reporting phase

The profession of Breath Alcohol Technician (BAT) does not have full recognition in South Africa compared to the US, and formal training programmes do not exist either. Breath alcohol testing is regarded as a non-medical test which exempts the South African BAT's from HPCSA registration. The BAT, however, will undoubtedly require training, which must include instruction on:

- the collection process
- chain of custody procedures
- processes involved with problem collections ("shy lung")
- the obtaining of informed consent and maintaining donor privacy, the confidentiality of information and specimen integrity
- the scientific principles of the breathalyser instrumentation and the collection protocol to enable the BAT to explain this to the level of satisfaction that will be required in a disciplinary hearing or a court.

With alcohol being the most often used drug in South Africa, breath-alcohol testing is performed regularly in South Africa. Preliminary breath-alcohol testing is performed mostly, and confirmatory or evidentiary testing less often (or sometimes never). The requirement for

[241] South African National Standard ISO/IEC 17025:2005: General requirements for the competence of testing and calibration laboratories.

privacy is similar to that of drug testing for both the preliminary and confirmatory tests in terms of the CSA. Section 33 also applies for breath testing, requiring just administration, and that should be reasonable and procedurally fair, and it is of essence to prevent infringement of the donor's dignity and privacy.[242]

Breathalyser testing equipment has to be calibrated regularly and must be proven to operate within tolerance close to the time at which the confirmatory breath test is performed. This should involve quality control procedures and statistical interpretation similar to that performed in an ISO17025 accredited laboratory. It is the opinion of the author that a breath alcohol testing facility should be regarded as a testing facility that should be accredited according to the ISO17025 guidelines. [243]

After a breath alcohol test result was obtained in duplicate, the result should be communicated to the DER to communicate the non-compliant breath alcohol test results to management in a confidential manner, since a breath alcohol testing results do not require medical review.

It is again recommended that HPCSA registration is not required for the BAT, but the aspects mentioned above should be part of the job description, ensuring that he or she obeys the ethical and scientific guidelines that would have been set out by the HPCSA.

Many organisations in South Africa take decisive action on a preliminary breathalyser test result and sometimes even perform a "confirmation" analysis with a second preliminary breathalyser test. This practice is scientifically unreliable since the preliminary result has to be confirmed with an evidentiary breathalyser as part of a validated test method. The ISO17025 guidelines for testing laboratories should be applied, and an evidentiary breath testing facility should be managed as such.

5.4.7.2.4 Drugs post-testing phase

(a) Medical review officer

Once the confirmation drug test result becomes available, it should be submitted to a knowledgeable, and a professionally trained person called a Medical Review Officer (MRO)

[242] From the experience of the author, the South African industry falls short regarding the provision of privacy during alcohol testing. Most South African organisations do not provide any privacy, implying disrespect for human dignity and privacy.

[243] It is the opinion of the author that most (if not all) organisations in South Africa falls short in the aspect of accurate and reliable breath-alcohol testing. The reasons being that periodic calibration of a breathalyser does not guarantee correct results between calibrations, since all electronic equipment is subject to drift that will not be noticed with periodic calibrations by a certified calibration laboratory. Furthermore, of great concern is: What if the breathalyser had to be adjusted by the calibration facility during its periodic calibration? How would the employees who suffered unfair and irreparable damage to their reputation be traced? It is therefore unacceptable practice that does not comply with sections 35 and 23 of the CSA.

to verify or validate the result (NOT a member of the Human Resource Department). Validation concerns the extent to which the test accurately provides information as to the purpose of the test, which in this case was to detect negligent or intentional prohibited substance use in a voluntary fashion which is culpable.

The validation should be performed by way of a personal interview with the subject who may offer some possible reasons as reasons for the presence of the prohibited substance in his or her body. The act of validation is in principle to establish whether the individual has a justified reason for the presence of the prohibited substance in his or her body. If the prohibited substance was consumed intentionally by the subject, it should be regarded as a marker for risk to the organisation's health and safety and other interests. Unintentional consumption would be a legitimate reason for the MRO to ignore the confirmed positive test result since *prima facie* evidence of risk-enhancing drug-taking behaviour did not exist. If there is evidence of *prima facie* risk-enhanced drug-taking behaviour, the DER has to be informed confirmed and validated positive drug test result who will communicate the result to management for further possible decisive action.

The formal occupation of a professionally qualified MRO does not exist in South Africa, and current practice involves the review and validation by the on-site occupational health clinician who attends to the health and safety of the workers. This practice may result in a conflict of interest which is a threat to the ethical duty-of-care and trust relationship between the doctor and the patient since the prohibited substance test may end up in punitive action. It is the opinion of the author that the organisation should contract an independent service provider to perform the task of medical reviewing. If the MRO is employed by an external service provider administrating the drug-testing programme, the MRO should not have any business interests in a particular company.

Current practice in many South African organisations requires the employee to be cleared after a non-negative preliminary test result by the on-site occupational health clinician to be "not intoxicated". This practice will not only override and undermine the policy but will create president. The threshold concentration levels should be obeyed as part of the contract between the employee and the organisation.

Many organisations in South Africa currently make use of a preliminary immunoassay testing technique only for testing. Decisive disciplinary action is then incorrectly and unfairly based on the result of a preliminary test. This dubious practice is sometimes aggravated by

"confirming" the first preliminary test by a second immunoassay test on-site or at a pathology laboratory. This is an incorrect approach since neither of these tests was based on a result obtained by a forensically acceptable analytical technique such as Mass Spectrometry-Gas chromatography (GC-MS).

The employee (prospective employee) should have access to his or her testing results based on the PAIA.[244]

(b) The sequence of events and the role of a medical review officer

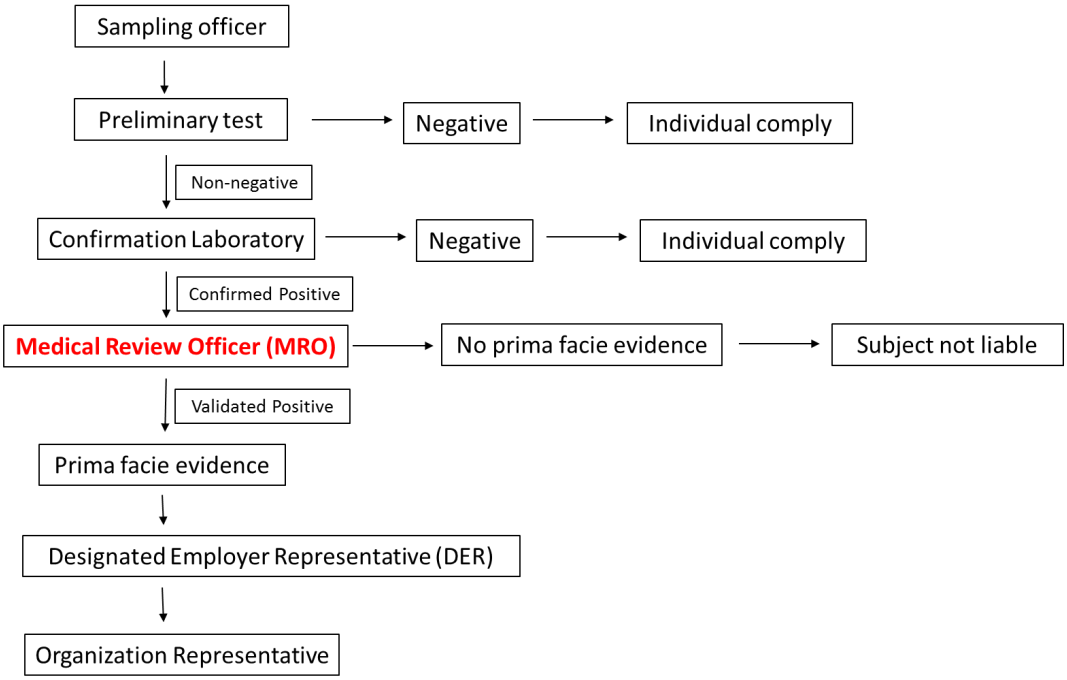

Figure 5:3 The sequence of events and the role of the medical review officer (MRO)

(c) Liability due to prohibited substance policy transgressions

The adjudication of a prohibited substance case requires the MRO to establish whether there is a *prima facie* case before the information is disclosed to the organisation's management. In analogy to the requirements for criminal liability, requirements for prohibited substance policy transgressions can be summarised as follows:[245]

Non-compliance: The first aspect to address is whether the organisation recognises the consumption of a prohibited substance forming the basis of the investigation as a transgression

[244] PAIA sec 9.
[245] CR Snyman *Criminal law* 6th ed (2014) 29 Lexis Nexis.

according to a formal prohibited substance regulation and testing policy. The subject may not merely be disciplined because the organisation believes that his or her drug-taking behaviour is immoral, or that he or she in general "deserves" to be punished. Prohibited substance consumption must be recognised by the organisation as a transgression as indicated by the prohibited substance regulation and testing policy.

Voluntary substance consumption: In terms of liability to a prohibited substance regulation policy, the action of substance consumption must have been voluntary. Consumption is regarded as voluntary if the individual subjected his or her body movements to his or her will or intellect; for instance, he or she consumed the substance by voluntary inhalation, smoking or swallowing.

Substance consumption must comply with the definitional elements of the transgression: This implies that the substance must be included in the prohibited substance list as per the organisation's policy for prohibited substance regulation and testing. Specifications related to the methods of administration and even "seasonal" consumption may also be specified. Threshold concentration levels for certain compounds may also be included.[246]

Unjustified substance consumption: The mere fact that an individual has consumed an enlisted prohibited substance voluntarily, such as codeine for a migraine, contrary to the prohibited substance policy still does not imply that the individual has transgressed the rules of the prohibited substance policy. "Unjustified" in this case refers to "against the rules". However, the totality of the "rules" also includes rules in which particular circumstances would allow an individual to consume certain compounds that are regarded as unjustified to the "letter" of the prohibition.[247] These circumstances can be approached as grounds for justification, which include "necessity". A medical prescription also belongs to this category. Before the consumption of a substance can be declared as unjustified, it must be sure that there was no justification for the conduct.

Culpability: This aspect refers to the fact that there must be grounds upon which the individual personally can be blamed for his unjustified prohibited substance consumption. Culpability involves two requirements, namely, *capacity* and *intention/negligence*.

[246] WADA prohibited substance list.
[247] Snyman (n 245) 30.

Capacity refers, firstly, to the ability to distinguish between right or wrong and, secondly, to acting according to this appreciation. A child may not be able to distinguish between right or wrong and therefore lacks capacity.

If an individual consumed a prohibited substance with ***intent,*** it means that he understood the definitional elements of the transgression, and knowingly and willfully consumed the prohibited substance unjustifiably. “Intent” can be regarded as a *marker* for risk in drug-taking behaviour. It is also a possibility that a prohibited substance was consumed unintentionally by passive administration, such as in the case of passive inhalation of cannabis or crack-cocaine, unintentional consumption of alcohol in foodstuffs and medication, unintentional consumption of prohibited substances laced into herbal medication, and so forth. In short, an individual transgresses a prohibited substance regulation and testing policy if he or she knowingly consumes an enlisted prohibited substance voluntarily with intent.

If the prohibited substance was consumed with intent, the subject realised that his drug-taking behaviour was a transgression of the rules of the policy, which may result in disciplinary action. On the contrary, if the individual did not know or foresaw that wrongful, intentional consumption might result in punishment, his ignorance or mistake excludes intention. This may be the case when the organisation did not have a formal policy or if the policy was not communicated and accepted by the members of the organisation.

Prohibited substance use in workplaces and other environments is usually adjudicated on the basis that does not presume culpability

The sequence of requirements in the process of deciding on liability is indicated in the figure below.

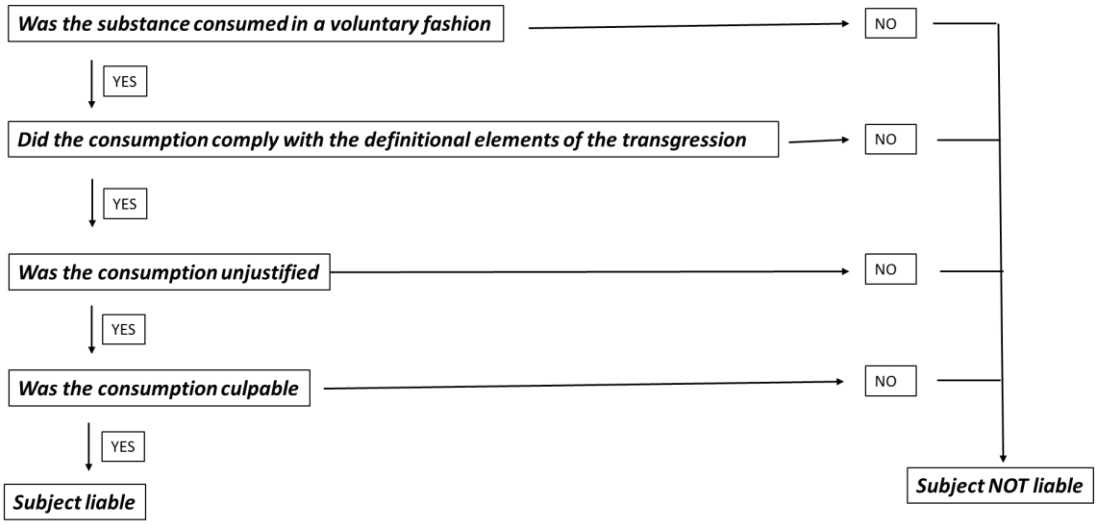

Figure 5:4 Flow diagram for liability determination

Strict liability: The second form of liability also exists in the law of South Africa, namely "strict liability", which is not so often applied. Intentional action is also referred to as "fault", which is one of the criteria in the adjudication of criminal and civil matters related to the consumption of intoxicating substances (alcohol and drugs), in addition to the second criterion of wrongful consumption, under ***the definitional elements of the transgression***.[248] This dual basis for liability is also termed "fault liability" which stands in contrast with "no-fault liability" which applies for doping control in the WADA regulations.

No-fault liability is commonly referred to as a strict liability, which is applied when public welfare is said to outweigh the welfare of the individual by excluding culpability as a vital ingredient of liability. A typical example of this is the sports environment where public trust in the fairness of sport is viewed as sufficiently sacrosanct not to be eroded by doping. Strict liability is applicable in the adjudication of the WADA transgressions due to the ease with which "doping" may be evaded if culpability were required. The presumption of culpability applies if it would be difficult to prove intent, such as when an athlete may have consumed the prohibited substance as part of a food supplement unknowingly.[249] It is the opinion of the author, that it is questionable that all doping cases should be judged on a strict liability basis because, in the case of an athlete applying a prohibited method such as blood doping, the intent is not as difficult to prove as in the case of the administration of an anabolic steroid.

[248] Snyman (n 245) 33.
[249] Snyman (n 245) 239.

Strict liability may be unconstitutional in South Africa in two ways. The first being the right to a fair trial as provided for in section 35(2) of the CSA and the second applies to the right to freedom and security of the person as specified in section 12(1) of the CSA.[250]

5.5 NATIONAL POLICY ON THE MANAGEMENT OF DRUG ABUSE BY LEARNERS IN PUBLIC AND INDEPENDENT SCHOOLS AND FURTHER EDUCATION AND TRAINING INSTITUTIONS IN SOUTH AFRICA

5.5.1 Introduction

National policy on the management of drug abuse by learners in public and independent schools and further education and training institutions,[251] in terms of the National Education Policy Act,[252] prescribes the stance of the national Department of Education against drug usage in schools. The policy framework has the aim of contributing to effective prevention, management and treatment of drug use/misuse and dependency in public, independent schools as well as further education and training institutions.[253] It furthermore aims to be consistent with the National Drug Master Plan (1999 – 2004)[254] and in line with the CSA. The provisions in the CSA with which the national policy aims to align itself are: (1) the right to basic education, (2) not to be unfairly discriminated against, (3) the right to life, (4) right to privacy, and (5) bodily and psychological integrity with reference to the limitation of rights clause.[255]

A high premium is placed on a safe and disciplined learning environment as a crucial element for delivering quality education, which is hampered by drug use.[256] The Ministry claims that punitive approaches, which are sometimes required, can only solve the problem partially. Drug abuse is detrimental to humans on social, physical, emotional and psychological levels. Drug use can be initiated by peer pressure, which may lead to dependency.[257]

It is furthermore acknowledged that there is a difference between habitual use of drugs, drug dealing and experimentation/peer group-led abuse, and each of these should be treated on its own merits. Habitual use should be addressed in a rehabilitative manner, while drug dealing

[250] Snyman (n 245) 238.
[251] National policy on the management of drug abuse by learners in public and independent schools and further education and training institutions published under GN 3427 in GG 24172 of 13 December 2002.
[252] NEPA sec 8A.
[253] GN 3427 in GG 24172 of 13 December 2002 sec 10.
[254] *National drug masterplan* https://extranet.who.int/ncdccs/Data/ZAF_B10_National%20drug%20masterplan.pdf (accessed 18 April 2019).
[255] CSA sec 36.
[256] GN 3427 in GG 24172 of 13 December 2002 sec 1-3.
[257] As above sec 8.

should be dealt with according to the requirements of the law. Peer group-led drug use should be addressed in the context of restorative justice.[258]

It is stated that evidence indicates an increase in drug use across the socio-economic continuum in schools, which correlates with other anti-social and high-risk behaviour such as violence, sexual violence, gangsterism, theft, as well as the prevalence levels of HIV/AIDS, which results in early death.

The main aim of the policy is to assist learners with an abuse problem as well as fellow learners affected by this. The learners will be assisted as long as they are prepared to co-operate with educators and other professionals involved in the treatment and rehabilitation.

The policy has the intention of complementing related policies on the management of drug abuse in schools such as:

- *Regulations for Safety Measures at Public Schools*, which declared all public schools drug-free zones.[259]
- Policies such as the *United Nations Convention on the Rights of the Child*,[260] which address the fundamental human rights of children (below the age of 18).
- *Guidelines for the Consideration of Governing Bodies in Adopting a Code of Conduct for Learners*, which prescribes how a principal or educator, or reasonable suspicion may search for drugs, harmful and dangerous substances.[261]

The regulation of drug use and abuse by educators is dealt with in the Employment of Educators Act which "calls for mandatory dismissal for an educator found in possession of any intoxicating, illegal or stupefying substance while at work."[262]

5.5.2 Guiding principles

South African schools were declared tobacco-, alcohol- and drug-free zones and should be respected as such. Therefore, it is required for all learning institutions to have a clear policy regarding the prevention and intervention with the aim of restoration and rehabilitation. The

[258] As above secs 1-3.

[259]' Regulations for safety measures at public schools (2001)' GG 22754 of 12 October 2001 as amended by GN R1128 in GG 29376 of 10 November 2006 sec 4(2)(d) and (e) and sec 4(4)(a) and (b).

[260] FACT SHEET: A summary of the rights under the Convention on the Rights of the Child https://www.unicef.org/crc/files/Rights_overview.pdf (accessed 31 December 2017); The convention defines a "child" as a person below the age of 18.

[261] SASA Guidelines for the consideration of governing bodies in adopting a Code of Conduct for learners, GN in GG 18900 of 15 May 1998 sec 3(3.8).

[262] Employment of Educators Act 76 of 1998 sec 17(1)(e).

policies should be clearly communicated to the school community and should highlight the: (1) development of a safe and supportive environment where innocent young people are educated, (2) need for education on drug use and abuse as well as the adverse effects thereof for learners and educators,[263] (3) response to drug use and abuse with respect for confidentiality and by taking into account the nature of the incident and the learner's circumstances, and (4) regular review of the policy.

The information related to a learner's drug use/misuse or dependency should be kept confidential, and his or her parents or guardians should be informed immediately. The learner's consent is required to obtain reports from professionals involved in his or her rehabilitation and should be reviewed in the presence of the parent/guardian in the case of a minor. If the learner refuses to co-operate, it is recommended that disciplinary action be invoked.[264,265]

5.5.3 Drug screening/testing and searches

Due to the invasive nature of a drug test, it is recommended that drug testing should not be performed randomly. It should instead only be employed if reasonable suspicion exists that a learner is using drugs and also for monitoring relapse in a way that respects the child's basic human rights such as confidentiality of test results and dignity.[266]

The testing devices that are allowed to be used for drug testing are also prescribed by the Department of Education in the notice titled, "Devices to be used and procedure to be followed for drug testing."[267,268] The Minister has listed ten devices, ranging from devices claiming to detect traces of drugs in solid form on surfaces, to testing devices that can detect parent and drug metabolites in urine and saliva, and information is provided on how to use each device to conduct a drug test. [269]

5.5.4 Conclusions and implications for drug testing in South Africa

It is significant to note that the Act does not prescribe the actual testing procedure and protocol adequately and also does not comply with the CSA for the following reasons:

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[263] 'National policy on the management of drug abuse by learners in public and independent schools and further education and training institutions' published under GN 3427 in GG 24172 on 13 December 2002 secs 22-26.
[264] GN 3427 in GG 24172 on 13 December 2002 secs 13-18.
[265] It is important to keep in mind that if the learner refuses to provide consent, it should not be regarded as an acknowledgement of guilt.
[266] GN 3427 in GG 24172 on 13 December 2002 secs 19-20.
[267] NEPA sec 8A(11).
[268] 'Devices to be used and procedure to be followed for drug testing' GN 1140 in GG 31417 of 19 September 2008.
[269] As above secs 2-5.

- The Act states that: "A learner who is about to be tested must first be asked whether he or she has taken any medicine" before the test commences.[270] This may infringe on the individual's right to privacy and the confidentiality of his or her personal medicine use. In the case of a negative screening test result, an HIV patient may have declared his HIV status and thereby compromised his or her right to privacy. The individual may declare his personal and chronic medication use at such time he or she is offered an opportunity to explain a confirmed positive test result after a confirmation analysis. It is essential that this action, during which the individual may declare his or her personal and chronic medication use, should be performed by a qualified professional clinician who can interpret and validate the confirmed test result.
- It is significant to note that the Act also does not prescribe that a **confirmation analysis** should be performed by default after the onsite testing device has indicated a positive test result (which should instead be referred to a non-negative test result in scientific terms). It should be kept in mind that these devices can, at most, help raise only a reasonable suspicion regarding the presence of drugs in the human body and for this reason, they are referred to more correctly as screening devices. These devices are subject to cross-interference by other substances which may, or may not, even be related to the drug's chemical structure. (Please refer to the section on testing in Chapter 5)
- The package insert of one of the devices does mention that "GC-MS is the preferred confirmatory method".[271] A second also referred to the fact that a "secondary analytical method can be used to obtain a confirmed result";[272] however, the requirement of a confirmation test that should follow after a non-negative screening test result, is not explicitly mentioned in the Act where the procedures to be followed for a drug test are explained.[273]

  The mere fact that the act makes no mention of confirmatory analyses purports that the initial screening test provides a final answer as to the presence of drugs in the individual's body.
- The use of a preliminary detection device in the educational setting that "allows for the testing of solid surfaces such a hand, on the inside of a lined pocket, tabletop, computer keyboard or a cell phone keypad"[274] for drug residue is also questionable. It has been

[270] As above sec 4(3).
[271] As above sec 5.3(5)(c).
[272] As above sec 5.1(4)(c).
[273] As above sec 4.
[274] As above sec 5.1.

proven that drug residues are present in virtually all areas and surfaces in our environment; and with such a questionable chain of evidence, it can only be to the disadvantage of the individual against whom reasonable suspicion is raised by this procedure.

5.6 SOUTH AFRICAN STATUTES RELATED TO TESTING FOR SPORTS DOPING

5.6.1 South African Institute for Drug-Free Sport Act

5.6.1.1 Summary of the Act

The SAIDS Act aims to "promote the participation in sport, free from the use of prohibited substances or methods intended to artificially enhance performance, thereby rendering impermissible doping practices which are contrary to the principles of fair play and medical ethics, in the interest of the health and well-being of sportspersons; and to provide for matters connected therewith." [275]

The objectives of the SAIDS are aligned with those of the Copenhagen convention:

- To promote drug-free sport
- To encourage development programmes in sport with education regarding the dangers of doping in sport
- To adopt a centralised doping control programme which may test any athlete (with or without warning, both in and out of competition)
- To ensure that national sports federations and other sports organisations comply with the code
- To ensure, as far as reasonably possible, the establishment and maintenance of a WADA-accredited laboratory in SA.[276]

As far as its duties and powers are concerned, the Institute has to adopt the WADA Code with the WADA list of prohibited substances, establish and maintain a register of notifiable events, disseminate information on possible sanctions, select athletes for doping control testing, and transfer the specimens in a tamper-free fashion to the testing laboratory, amongst others.[277]

The SAIDS has the authority and responsibility, amongst others to: "Vigorously pursuing all potential anti-doping rule violations within its jurisdiction, including investigating whether

[275] SAIDS Act.
[276] As above sec 10(f).
[277] As above sec 11.

Athlete Support Personnel or other persons may have been involved in each case of doping, and ensuring proper enforcement of Consequences." Investigations of athlete support personnel in cases of a doping rule violation by a minor will take place automatically.[278]

5.6.1.2 SAIDS Anti-doping rules

In the opinion of the author, the WADA-SAIDS anti-doping rules is a model policy, with a few exceptions. It states the scope of application of the anti-doping rules unambiguously as summarised below. The SAIDS anti-doping rules mimic those of WADA carefully, as described in section 4.3.

The anti-doping rules have to be enforced by all national sports federations as a prerequisite for receiving governmental funds and who have to abide by the spirit of the anti-doping rules. All athletes (including their support personnel) have to comply in all events organised, convened, and authorised by any national federation in South Africa as well as other national events not affiliated to a national federation. An athlete's membership will signify submission to the anti-doping rules of SAIDS. [279]

Anti-doping rule violations are defined similarly to the definition of WADA, and the strict liability rule is employed.[280] The standard of proof is that of "to the comfortable satisfaction" of the SAIDS hearing panel that a doping violation has been committed with that of "balance of probability" upon an athlete to rebut a presumption.[281] Methods of establishing facts involve analytical chemistry methods, and specimen transport, custody and analytical procedures are presumed to be compliant with the WADA International Standard for Laboratories.[282]

The prohibited substance and methods list prescribed by the SAIDS is similar to that of WADA[283] and testing and investigations will be conducted under the International Standard for Testing and Investigations, to obtain analytical evidence of the athlete's compliance.[284] The procedures and protocols related to specimen transport, analysis and reporting of results[285] should also be in line with this international standard.

[278] South African Institute for Drug-Free Sport (SAIDS) *Anti-doping rules* (2016) 5 http://www.drugfreesport.org.za/wp-content/uploads/2014/09/SAIDS-Anti-Doping-Rules-2016.pdf (accessed 10 January 2018).
[279] As above Art 1.
[280] As above Art 2.
[281] As above Art 3.
[284] As above Art 3.
[283] As above Art 4.
[284] As above Art 5.
[285] As above Art 6.

Doping analyses should be guided by those substances or groups of substances listed in technical documents composed by WADA based on a risk assessment for the different types of sports[286] according to the International Standard for Laboratories.[287] The SAIDS will manage the results and appoint a Doping Control Review Commission (review commission) to perform a review and which is permitted to request the assistance of experts to conclude an anti-doping rule violation.[288] Atypical findings will be reviewed and validated before being reported as an adverse analytical finding, which will be used as a basis to assert an athlete.[289]

Temporary suspensions may or may not take place depending on the type of prohibited substance that was administered by the athlete,[290] and an athlete may be found guilty of a rule violation if he or she does not dispute the adverse finding by waiving his or her right to a fair hearing. If an athlete retires from sport before or after the results management process has begun, the SAIDS will have the right to complete the results management process.

Athletes have a right to a fair hearing by an independent doping hearing panel after the results management process[291,292] according to the principles of natural justice, which include the rights to: (1) have access to the evidence that will be presented at the hearing, (2) to be heard and to be represented by a competent person, (3) to produce evidence, (4) to be judged by impartial and independent adjudicators, and (5) to call witnesses and cross-examine witnesses. The hearing should be finalised in a reasonable time where after the athlete will receive a written document containing the majority decision and the reasons for the decision, as well as the period of ineligibility decided upon. If the doping rule violation decision is not appealed, it should be publicly disclosed; however, if there was no anti-doping rule violation, consent from the athlete is required before public disclosure.

The sanctions for a doping violation are similar to those prescribed by WADA, [293] and if there was no fault or negligence on the part of the athlete, the period of ineligibility should be eliminated. Sanctions enforced on athletes will be published publically on the SAIDS website for a minimum of one month after informing the athlete. The protection of result confidentiality

[286] WADA CODE, Article 5.4.1.
[287] SAIDS Act Art 6.
[288] As above Art 7.
[289] Similar to laboratory-confirmed positive test results in the SAMHSA workplace drug testing guidelines.
[290] Suspension with certain provisions which may allow the athlete to compete under certain provisions.
[291] SAIDS Act Art 8.
[292] The independent doping hearing panel should consist of at least a (1) legal practitioner as Chairperson, (2) A medical practitioner and/or a person with analytical and/or forensic pharmacology or endocrinology and (3) another member from either of the two former categories or a previous sports administrator or athlete.
[293] SAIDS Act Art 10.

and privacy is of prime importance, and the SAIDS should not disclose this information beyond those individuals with a need to know until the SAIDS has made a public disclosure. The SAIDS has the onus to maintain confidentiality by contract with its employees, contractors and consultants for protection of confidential information.[294]

The SAIDS may collect, store, process or disclose personal information relating to athletes in its line of duty to conduct anti-doping activities under the WADA Code and the international standards (specifically the International Standard for the Protection of Privacy and Personal Information). It is furthermore assumed that any participant who submits information, including personal data, to any person, will under the anti-doping rules be deemed to have agreed, according to applicable data protection laws and otherwise, that such information may be collected, processed, disclosed and used by such person for implementation of the anti-doping rules.[295]

The SAIDS has a responsibility to initiate education and prevention programmes for doping-free sport and should encourage active participation by athletes and their support personnel in such programmes.[296]

The SAIDS also assigns some additional roles and responsibilities to athletes, which involve (1) the responsibility of the athlete to understand and obey the anti-doping rules, (2) to be available for specimen collection at all times, (3) to act responsibly with regard to what they ingest and use, (4) to inform medical personnel of their obligation not to use prohibited substance, (5) to ensure that their medical treatment does not violate the anti-doping rules as far as is possible and (6) to co-operate with anti-doping organisations to investigate anti-doping rule violations.[297]

5.6.2 International law: Validation of the WADA Code for prohibited substance testing (anti-doping testing) within the South African legal framework

5.6.2.1 Background

South Africa should comply with the Copenhagen agreement as enacted by the SAIDS Act.[298] The latter conforms entirely with the WADA Code and its corresponding international standards. Typical aspects that are critical for a prohibited substance regulation policy include

[294] As above Art 14.
[295] As above Art 14.6.2
[296] As above Art 19.
[297] As above Art 22.
[298] As above .

the following: (1) Private drug use must be respected for legitimate medical reasons as well as other drugs, which may be illegal according to statute, by setting cut-off concentration levels that will prevent workers from coming on-site in a state of intoxication, (2) S*pecimen collection* requires voluntary informed consent from the donor, (3) The *analytical testing* of the specimen for the presence of prohibited substances, (4) *Reporting, interpretation and management of* test results, and (5) *Actions after the* confirmed and validated presence of a prohibited substance as per the prohibited list.

The concerns that are generated by prohibited substance testing can be grouped into legal, ethical and scientific classes. The question of who will have access to the test results is of importance when providing consent. Testing may initiate discrimination and false accusations if not performed accurately. An athlete may be unfairly labelled if the protocol is not managed confidentially and may suffer reputational damage in the public domain. Private information on a medicinal substance used by an individual may have to be disclosed, which is critical in the South African environment with a high incidence of HIV. The type of information that will be communicated to the national organisation and the accuracy and reliability of analytical testing methods must be entirely above board.

5.6.2.2 Pre-testing phase: Policy, specimen collection

5.6.2.2.1 Policy

From a constitutional perspective, the SAIDS Act may be unconstitutional for the following reasons:

- The separation of powers doctrine is not strictly followed due to insufficient independence between the different "arms", which involve the Olympic testing laboratory in Bloemfontein financed by the SAIDS and the hearing panels, which are appointed and paid by the SAIDS.
- The strict liability burden of proof [299] may be inconsistent with the CSA on the following basis:
  - The right to a fair trial as provided for in section 35(2) of the CSA, which involves being innocent until proven guilty.

[299] WADA *World anti-doping code* (2015) Art 3.1 at 25 https://www.wada-ama.org/sites/default/files/resources/files/wada-2015-world-anti-doping-code.pdf (accessed 1 January 2018).

- The right to freedom and security of the person provided for in section 12(1) of the CSA.[300]

5.6.2.2.2 Specimen collection

International Standard for Testing and Investigations and the International Standard for the Protection of Privacy and Personal Information.

(a) Constitutional perspective

- Athletes who have been notified that they are included in a testing pool have to provide whereabouts information so he or she can be reached with no advance notice, with reference to the collection of the minimum amount of information to arrange for the test by the collection official with due respect for the protection of personal information and confidentiality.[301] A combination of three missed tests within twelve months is regarded as an anti-doping rule violation.
- The SAIDS will have the authority over all athletes in its scope (in and out of competition) to conduct testing and to provide a specimen at any time and any place. The SAIDS will also have a test distribution plan that may prioritise between disciplines, categories of athletes, types of testing, specimens collected and types of specimen analysis. This implies an athlete's right to privacy and freedom.

  The SAIDS may collect, store, process or disclose personal information relating to athletes in its line of duty to conduct anti-doping activities under the WADA Code and the international standards (specifically the International Standard for the Protection of Privacy and Personal Information). It is furthermore assumed that "any participant who submits information including personal data to any person shall in accordance with the anti-doping rules be deemed to have agreed, pursuant to applicable data protection laws and otherwise, that such information may be collected, processed, disclosed and used by such person for implementation of the anti-doping rules".[302]

  To be reached without advanced notice and to provide a specimen, any time and any place are undoubtedly an infringement on the athlete's privacy and autonomy. To assume that information may be disclosed is also infringing on a person's autonomy and bypasses the issue of consent.

[300] *Coetzee* 1997 1 SACR 379 (CC) 414-422 O'Reagan stated that strict liability may be unconstitutional: "As a general rule people who are not at fault should not be deprived of their freedom by the State…Deprivation of liberty, without established culpability, is a breach of this established rule" (442 h-i).

[301] WADA Code International Standard, Testing and Investigations sec 5.6.

[302] SAIDS Act Art 14.6.2.

5.6.2.2.3 Prohibited substance testing and reporting phase

(a) Constitutional perspective

- The laboratories also have the authority to change the type of substances to be analysed at their initiative. A specimen may be stored for ten years and analysed at any time.
- If an athlete retires from sport before or after the results management process has begun, the SAIDS will have the right to complete the results management process.

(b) Statutory perspective

- Specimens may be collected and analysed for future use, but no specimen may be analysed for research without the consent of the donor and analysis should be done in such a fashion that the result cannot be traced back to the donor. Collection and storage of personal information should be done under the International Standard for Protection of Privacy and Personal Information, but more specifically in line with the South African POPI Act.

5.6.2.2.4 Post-testing phase

(a) Constitutional perspective

- If the doping rule violation decision is not appealed, it will be publicly disclosed; however, if there was no anti-doping rule violation, consent from the athlete is required before public disclosure, to respect the autonomy of an athlete.
- All results and medals obtained in the event, during which the anti-doping rule violation occurred will be disqualified. The presence, use or attempted use, or possession of a prohibited substance or prohibited method will result in four years of ineligibility if the substance is not a specified substance (unless the athlete can prove that the violation was not intentional) or, in case of a specified substance if the violation was intentional. Intentionality is regarded as: "the athlete knew and understood that the conduct constituted an anti-doping rule violation or that his conduct could lead to an anti-doping rule violation, but disregarded this by employing the prohibited substance or method". In short, he or she cheated intentionally.

5.7 THE ANALOGY BETWEEN A CRIMINAL AND CIVIL APPROACH TO PROHIBITED SUBSTANCE REGULATION AND TESTING: STANDARDS OF PROOF

The common law of contract regulates a prohibited substance regulation and testing programme in the workplace in the private domain. The execution thereof is analogous to

regulations imposed on individuals in the public sphere where the behaviour is regulated and enforced based on a social contract. If an individual does not comply with the rules of the societal contract, disciplinary action will be enforced due to criminal liability. Similarly, if an individual does not comply with the rules of an organisation in the private domain, to which he or she is contractually liable, disciplinary action may result in lawful, reasonable, fair and rational execution of power.

Disciplinary action in the private domain does not result in the criminal prosecution of the individual. The consequences of the irresponsible and intentional use of prohibited substances have an equivalent impact on the individual in the civil and private domains where he may be criminally liable or may be terminated, however.

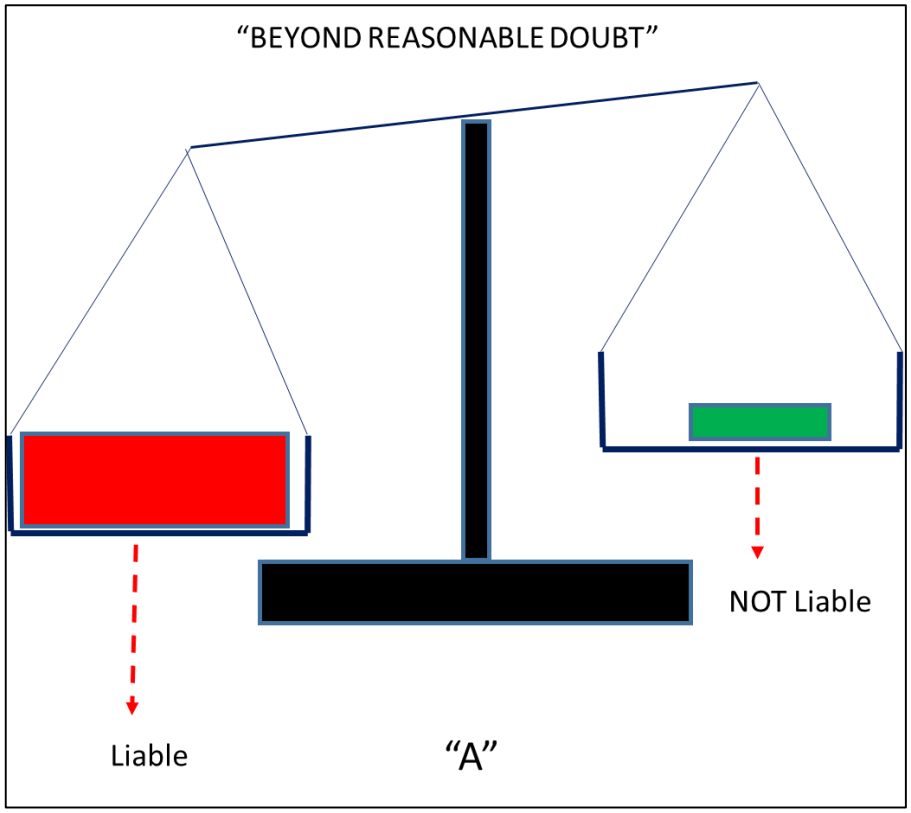
Liability for prohibited substance consumption by an individual in the private domain is decided analogously to criminal liability and culpability. The intentional and voluntary use of a prohibited substance also has an element of culpability similar to the criminal environment. The intent in the form of negligent or intentional use of a prohibited substance can be used as an indicator of drug-taking behaviour of an individual, which increases the risk to the organisation's interests.

Legal decisions regarding prohibited substance consumption in the private law domain are adjudicated on the ***balance of probabilities*** (Figure B) as opposed to those of ***beyond reasonable doubt*** (Figure A) in the criminal domain. The assessment of liability is, in principle the same, such as liability related to culpability.

The difference in the standard of proof between the civil and public domain also does not imply that lowered standards of reliability for scientific evidence, related to prohibited substance analytical chemical identification and quantification, is acceptable. Scientific evidence needs to be as accurate and reliable as possible since this informs the law. Prohibited substance testing is adjudicated in the private domain on a balance of probabilities. The balance of probabilities adjudication is, in principle, a weighing process whereby weights or priorities are assigned to each element of the evidence in total (Figure C).

The process of assigning weights to the elements of evidence and markers of impairment from sobriety testing, slurred speech and unsteady gait should typically be applied when assessing a subject's level of impairment,[303] intoxication or being under the influence.[304]

[303] From a scientific perspective, there are no threshold concentrations beyond which an individual can be claimed to be "intoxicated". The concepts of "intoxication" and "under the influence" are incorrectly used as a substitute for "impairment". Various degrees of impairment exist, which can be supported by a number of indicators each having its own range of intensities. The level of intoxication correlates with the level of impairment which has some indicators.
[304] AW Jones in S Karch (ed) *Drug abuse handbook* 2nd ed (2006) 324.


"BEYOND REASONABLE DOUBT"
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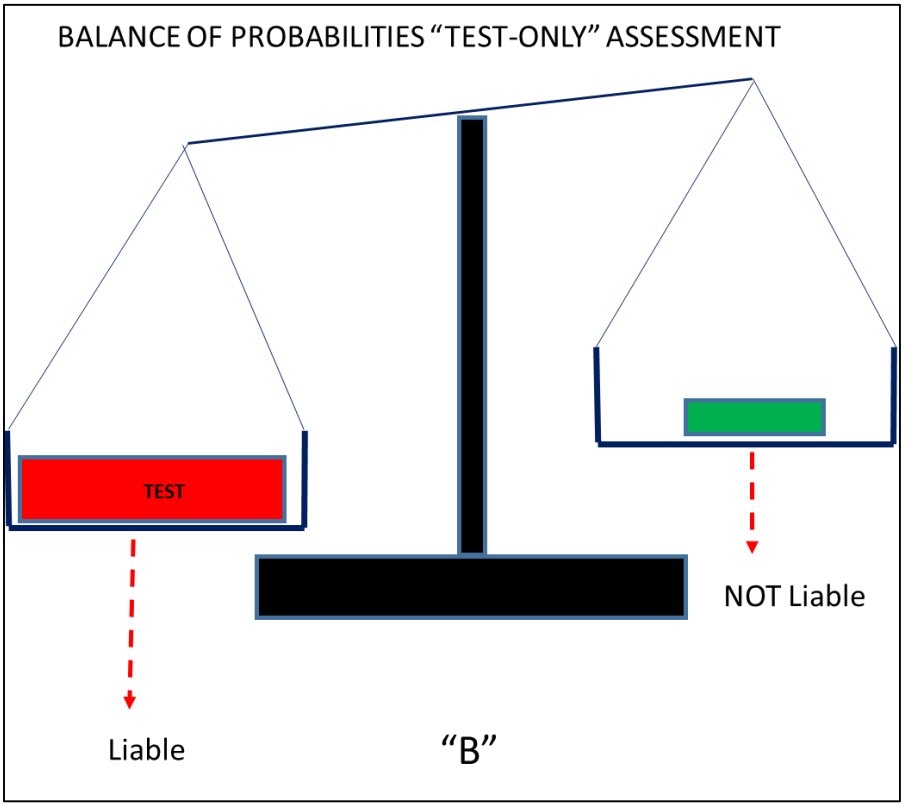
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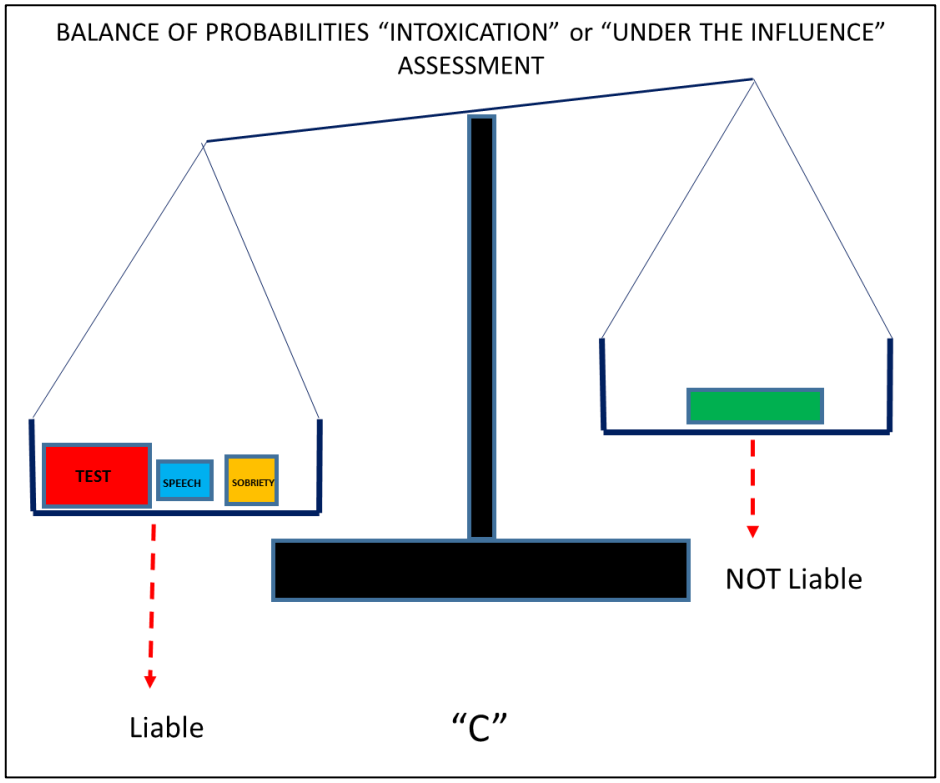


Figure 5:5 Standards of proof in the public and civil domain, i.e. "beyond reasonable doubt" vs "balance of probabilities."

If the chemical test result bears the most weight, it is a matter of prime importance for the result to be extremely accurate and precise and will require a confirmatory test, on a forensically acceptable standard, in addition to the initial preliminary screening test. Confirmation is also a standard required by the professional, scientific community. On the other hand, if additional evidence for the impairment exists, culpability may be proved by the use of a screening test, in combination with a medical practitioner's observations and conclusions regarding the level of impairment of the individual.

Science informs the law by assisting jurists to make informed, autonomous, just decisions, and it is for this reason that the quality of a test result should not be compromised in any way. In the case of the balance of probabilities standard, the analytical test result can be regarded as one of the principal elements contributing to the weight, in addition to other elements or facts that may tip the scale on the balance of probabilities. If the test result is less reliable as in the case where the official performs a screening test only, he or she should have additional evidence to be employed in the decision as to the level of impairment of the test subject.

Proof of the presence of a prohibited substance in an individual's bodily fluid is the most reliable way to confirm the definitional element of prohibited substance consumption liability,

namely that the individual consumed the prohibited substance and that the concentration is above the threshold. A reliable test result, therefore, makes an essential contribution to the balance of probabilities, and it is vital to employ the current gold standards for the analyses to offer the court or tribunal the highest quality test result that can be offered by the scientific industry.

5.8 CONCLUSIONS

The relevant provisions of the CSA have been reviewed and their application in a prohibited substance regulation and testing programme delineated. These include equality, human dignity, right to life, freedom and security of the person, privacy, freedom of belief and opinion, labour relations and children's rights. The importance of constitutional administrative rights such as access to information, just administrative action, and access to courts was also highlighted keeping the separation of powers principle in mind. It was also concluded that an individual's right to the use of substances for medicinal purposes are not absolute and can be limited if harm may be caused to another individual or his interests or the organisation's property.

It is also essential to consider foreign and international law when the Bill of Rights is interpreted. The foreign law that was applied in this study is the mandatory guidelines of the USA which are administered by SAMHSA, and the international law is the policies and protocols related to sports doping administered by the World Anti-doping Association (WADA).

It is also important to note that the criminalisation of drugs always has the potential to create tension between an individual's right to autonomy and the responsibility of the state to protect society from harm by the use of drugs. The implications of prohibited substance regulation and testing enforced by statutes such as the Drugs and Drug Trafficking Act and the Medicines and Related Substances Control Act were reviewed. The legal obligation of the organisational representative to inform the authorities that an offence related to drug use has been committed regardless of laws, such as the POPI Act, which prohibit him or her from revealing information related to the business or affairs of another person, was highlighted.

The protection of personal information is enacted by the POPI Act, which specifies the framework within which the personal information of an individual has to be treated as confidential. This also applies to the complete process of prohibited substance testing.

The Promotion of Equality and Prevention of Unfair Discrimination Act also requires that there may be no discrimination towards individuals on specific grounds and also in general that

diminishes human dignity, and adversely affects the equal enjoyment of a person's rights and freedom. This is also the case with the use of cannabis that was recently decriminalised. Singling out individuals who have a higher tendency of using these substances, such as Rastafarians, will be unjustifiable and, therefore, may be seen as unfair discrimination. A tendency or confirmed history of addiction can also serve as a legitimate reason and defence for testing specific individuals more than others.

The Promotion of Administrative Justice Act requires the prohibited substance regulation and testing programme to be procedurally fair and allows for the review of such a programme if this is not the case. The programmes have to be based on the separation of powers, which requires the separate entities of the process to be independent.

The implications of the recent decriminalisation of cannabis in the workplace were discussed, and it was found that organisations with risk-sensitive environments still should enlist cannabis as a prohibited substance due to the resulting impairment when used. The statutes that regulate this requirement are the Occupational Health and Safety Act and the General Safety Regulations of the Machinery and Occupational Safety Act. Both of these statutes employ the word "intoxication". It was concluded that "intoxication" should be interpreted as different levels of impairment of which the lowest level will allow an individual to have residual THC in his or her system at concentration levels where the individual is not impaired. This is especially important if one takes the relatively long half-life of THC in the human body into account. A chronic user will not be able to exercise his right of freedom to use cannabis responsibly.

The author also suggested that the wording of the OHSA and MOSA should be changed by reading adding the accommodation of a threshold concentration of the prohibited substance in the bodily fluid matrix. For THC, this should typically be 2ng/ml THC in blood/oral fluid.

The mandatory workplace drug testing guidelines and those of WADA were furthermore validated against the CSA and relevant legislation for the different phases of a prohibited substance test. The role of the MRO was also highlighted as the professional who has to validate the confirmed test results and inquire about the drug use habits of an individual to assess culpability. If the individual is found to have used the prohibited substance intentionally or negligently, a *prima facie* case exists, and the MRO should refer the case to the organisation's management.

The national policy on the management of drug abuse by learners in schools and further education and training institutions in South Africa was reviewed, and it was found that due process is not correctly prescribed. It was found that some matured learners' autonomy may be infringed by the prescribed procedure and also that privacy may be affected negatively by the requirement to declare chronic medication use even before the screening test. The procedure is also not scientifically correct and reliable if a confirmation test is not performed before any action against the child.

The WADA prohibited substance testing and regulation programme was found to be mostly in line with the CSA. However, the protocols may give rise to the infringements on privacy and autonomy.

CHAPTER 6:

SCIENTIFIC AND MEDICAL RELATED ASPECTS OF PROHIBITED SUBSTANCE REGULATION AND TESTING IN HUMANS: CAPITA SELECTA

6.1 INTRODUCTION: DETECTION OF PROHIBITED SUBSTANCE USE

This chapter is aimed at providing information on current issues regarding prohibited substance regulation and testing in South Africa since it is an impossible task to provide an exhaustive and complete treatise of the scientific and medical aspects of prohibited substance testing in this document. The supportive role that science plays, more specifically, forensic toxicology, to inform the law by providing complete and accurate information will be illustrated. The adversarial approach resulting from prohibited substance testing positions prohibited substance testing entirely within the domain of forensic toxicology. Prohibited substance detection protocols also have to be extremely reliable to comply with the ethical aspects of prohibited substance regulation and testing.

The identification of prohibited substance users usually starts with the selection of individuals, where after the testing procedures commence. The identification can involve observation or chemical detection, but the observational strategy is subject to bias. Chemical detection is based on a two-tier approach involving preliminary testing (or screening) followed by confirmatory testing at a forensically acceptable level.

The low concentration levels classify this type of analysis as trace analysis, which is sometimes also referred to as ultra-trace level analysis. The recognition of individuals, with prohibited substances in their bodies, requires specialised sampling strategies and chemical analysis. Reliable sampling or selection of individuals will allow for reliable inferences related to the drug-free status of individuals in the group. The selection process must ensure that the individuals chosen are representative of the group or population. In a prohibited substance regulation and testing setup, one would typically want to select the individuals in a way that conclusions can be made on a specific level of confidence.

The concept of correct sampling should also be extended to the sampling of bio-matrices in humans, where the choice of the bio-matrices to be analysed is of prime importance to assess the level of impairment in an individual. A typical question that refers to the suitability of the

matrix (blood, saliva, hair, urine, breath) sampling which is often asked is: "Is a threshold value of x ng/mL in saliva, for instance, a suitable indicator of impairment?"

There will always be a certain extent of uncertainty in recognition of a prohibited substance user which arises from the sampling and the chemical analytical procedure. Quantification of the uncertainty may then be interpreted as the level of confidence in the sampling and chemical analytical test result. Uncertainties always have to be quantified to assess the statistical confidence relating to the power of the outcome.

Zero tolerance: Organisations usually have a *zero-tolerance* stance against prohibited substance use, mainly if the substance was used negligently and intentionally. Liability resulting from a zero-tolerance stance should, therefore, originate from: "the negligent or intentional use of a prohibited substance which will not be tolerated". The concept of zero tolerance, however, should not be incorrectly interpreted that "the policy demands zero concentration" levels. Some organisations intentionally set the threshold level for blood alcohol at 0.00 gram per 100 millilitres of blood. Zero tolerance intends to ensure that the individual is not impaired while performing the risk-sensitive task or that the individual is drug-free, but zero concentration is dependent on the sensitivity of the detection technique. A more sensitive detection technique will demonstrate a lower zero concentration level. A cut-off concentration equal to zero will result in the detection of random noise, which is not significant and is difficult to defend from a scientific perspective.[1] A more scientific and legally defensible approach would be to set the threshold concentrations sufficiently low to prevent an individual from performing the risk-sensitive tasks as required by the organisation, in an impaired state.

Science informs the law by supplying accurate and reliable information, which enables courts and tribunals to take autonomous and just decisions. Ethics and, more specifically, the notions of *honesty* and *complete knowledge* are driving forces in the natural sciences. Prohibited substance detection or recognition methods also aim to investigate prohibited substance use accurately and precisely. Reliable detection is a prerequisite for respect for dignity, privacy, autonomy and other human rights. "Accurate", in this instance, refers to the minimisation of FP and FN test results, which may have a devastating effect on the individual and the organisation.

[1] R Capler and D Bilsker et al, *Cannabis use and Driving Evidence review, Canadian Drug Policy Coalition* (CDPC), Simon Frazer University (2017) 34.

The reliability of a detection method, which can be observational or chemical detection, is based on its *accuracy* and its *precision*, with accuracy having to do with non-biasedness and precision with the repeatability of the detection. The practical implication thereof is that the detection method will not allow for biasedness and will prevent false accusations (false positive) to be levelled against an individual. FNs on the other hand may increase the risk to the organisation unknowingly allows an individual to perform a risk-sentitve task. The precision of detection relates to the consistency with which a prohibited substance user will be detected given the same circumstances.

Prohibited substance testing is mostly carried out with the intention of compliance testing. Test results are employed in disciplinary proceedings, and therefore the results can be expected to be challenged in a formal arbitration, litigation and other adversarial proceedings and hearings. The tests are regarded as a forensic toxicology activity and should be performed on a forensically acceptable level of test quality assurance to serve the purpose of a legally defensible forensic analysis.

6.2 RISK MANAGEMENT BY PROHIBITED SUBSTANCE REGULATION AND TESTING

The goal of a prohibited substance regulation and the testing programme should be clearly understood in that such a programme aims to minimise risk and not to prosecute individuals who have used a prohibited substance. The impossible task of detecting every single individual who is impaired or has consumed a prohibited substance is supported by the notion that disciplinary action will always be a strong deterrent. Even if the protocols from a carefully designed prohibited substance regulation and testing policy is followed to the letter, some individuals will still not be identified by the system. Any risk detection system is only partially effective in screening out the individuals that pose a risk due to their drug-taking behaviour.

Example: Assume that a company has a rule of testing 30 employees per day, which is about 10% of the total workforce of 300 employees. The 30 individuals will be randomly selected/nominated to submit for a prohibited substance test before entering the organisation's premises. Assuming furthermore that these individuals have a total disregard for the prohibited substance regulation and testing policy and all have an oral fluid THC concentration at the threshold concentration specified by the policy (ca 50 ng/mL). A typical commercially available screening device will identify 20 individuals as positive and 10 individuals as negative at this concentration level. This implies that the 10 employees will be allowed to

proceed with their daily tasks, while the specimens of 20 employees will be subjected to further confirmation testing. The 10 employees that tested negative are said to be false negative (FN) since their oral fluid THC concentration was at the cut-off concentration. The 20 positive test results are said to be true positive (TP).[2]

It is a general challenge for all risk identification instruments to discriminate correctly between real risk and false alarms, whether it be with the help of a specific protocol aimed at risk detection, analytical instrument or simple observation. The ability to identify a risk correctly is termed the "diagnostic sensitivity" as opposed to the "diagnostic specificity", which involves the correct identification of false alarms. The diagnostic sensitivity relates to the number of positives, which includes not only the TP detections, but also the FN detections, and the diagnostic specificity bears relation to the negatives, which includes both the TN and FP detections.

From the example above, there will be individuals who have disregarded the policy and therefore posed a risk to the organisation, namely those with the TP and the FN test results. The individuals with the TP test results will be dealt with according to the policy, which usually involves a stance of zero tolerance by the organisation. Any technique applied to limit risk will always have a possibility of not detecting the "guilty".

Other ways to lower the number of positives (TP and FN), and therefore the concomitant risk, will be to educate the individuals on the dangers of the use of prohibited substances in the workplace. An increase in the testing rate for safety-sensitive positions in combination with the possibility of disciplinary action may decrease the use of prohibited substances. Pre-employment, post-incident, reasonable suspicion, rehabilitation follow-up, and random and voluntary drug testing will also contribute to the decrease in prohibited substance use an in effect decrease the number of FN test results.

The scenario described in the example above is valid for all risk-detection devices since all detection devices will produce a test result with an unavoidable uncertainty. This includes alcohol breathalysers. In the ideal case, *all* the TP individuals will be screened out, and all the TN individuals will be allowed onto the premises to take care of their daily activities.

Keeping in mind that only 10% of the workforce was randomly selected in the example above and in combination with the uncertainty regarding the actual rate of cannabis use by the workforce, it is impossible to guarantee that no person will be allowed on site who does not

[2] TP = True positive; FP = False positive; TN = True negative; FN = False negative.

have an oral fluid THC concentration at or above 50 ng/mL. This example serves as an indication that it is problematic to screen out all TP individuals and to allow still all the TN individuals to proceed with their daily duties due to the nature of detection devices.

6.3 RANDOM SELECTION OF INDIVIDUALS

The selection of individuals can be based on either *for cause* selection (annual medical, after the incident, return from leave, rehabilitated drug user) or *random* selection. The random selection procedure has two prerequisites to be ethically, legally and scientifically defensible, namely: (1) the selection must be truly random, and (2) the number of individuals selected must be of a sufficient number to represent the broader population. A population, in this case, refers to a group of individuals such as a group of workers on a shift at a specific site. It is also an ethical requirement to select a statistically correct number of individuals to ensure that the testing of humans will be effective in managing risk and not to 'over-select' and thereby perform drug tests on humans unnecessarily.

6.3.1 Random sampling of individuals

In practice, individuals who are selected for a chemical drug test will not be sent back to the group from which they were selected before the next individual is selected. The selection method is termed "sampling without replacement", and the statistical distribution that enables the random selection in this fashion is called the hypergeometric sample distribution. The population is furthermore divided into two groups, namely prohibited substance ***users*** and **non-users.**

6.3.1.1 Hypergeometric distribution

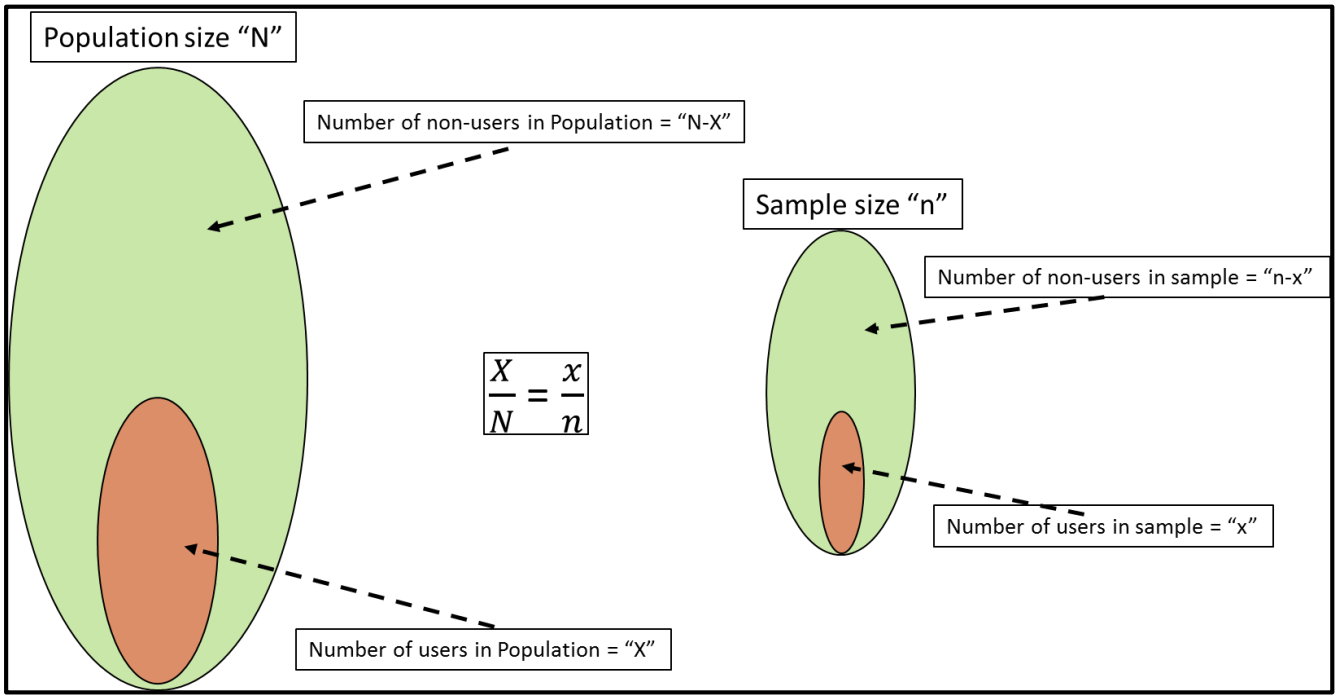
The following equation gives the probability function of the hypergeometric distribution:[3]

$$Pr_X(X) = \Pr(X = x) = \frac{\binom{X}{x}\binom{N-X}{n-x}}{\binom{N}{n}}$$

- K number of (drug users) in the population
- N is the total number of individuals in the population
- n is the sample size or the number of individuals to be selected from the group
- X is the number of positives in the population

[3] Scientific Working Group for the Analysis of Seized Drugs *Guidance on sampling of illicit drugs for qualitative analysis* http://www.swgdrug.org/tools.htm; http://enfsi.eu/wpcontent/uploads/2017/05/guidelines_on_sampling_of_illicit_drugs_for_qualitative_analysis_enfsi_dwg_2nd_edition.pdf (accessed 5 March 2019).

- x is the number of positives in the selected group
- $\binom{a}{b}$ is the binomial coefficient = $\frac{a!}{b!(a-b)!}$



The null hypothesis (H_o) will be accepted if the value of "n" does not allow for an x-value with a corresponding $\Pr(x) > 0.9999$ for the 99.99% confidence level (or 0.99 for the 99% confidence level). It means that n is too small for the corresponding x-value to result in a $\Pr(x) > 0.9999$.

The alternative hypothesis (H_1) will be accepted if the value of "n" does allow for an x-value with a corresponding $\Pr(x) > 0.9999$ for the 99.99% confidence level (or 0.99 for the 99% confidence level). It means that n is large enough for the corresponding x-value to result in a $\Pr(x) > 0.9999$.

The number of individuals selected (n) should be chosen such that it is not *too large*, but be *just large* enough to reach the minimum requirement for $\Pr(x)$ to be more than 0.999. The hypergeometric distribution in effect enables the calculation of the smallest "n" that will result in a probability $\Pr(x)$ that will exceed the minimum expectation of $\Pr(x) = 0.9999$ for an exact "x".

It allows for the calculation of an "n" value to be used in the following equation which reflects that the ratio of drug users in the population (k) is equal to the ratio of drug users in the sample in the ideal case

$$k = \frac{X}{N} = \frac{x}{n}$$

If the number of individuals selected (n) is too large, then the chosen level of incidence of drug users in the population (k) will be smaller than $\frac{x}{n}$ i.e. $k < \frac{x}{n}$, which implies that the number of samples selected is more than sufficient to reach the minimum requirement of, for instance, $\Pr(x) > 0.9999$. For the sample size to be not unnecessarily large, the n-value should be just large enough to reach the requirement for k to be smaller than $\frac{x}{n}$. This will imply that the ratio $\frac{x}{n}$ in the sample is just larger than the ratio $\frac{X}{N}$ of the population (N), which can be interpreted that the number (n) of samples selected is sufficient to represent and reflect the ratio (k) or the number of drug users in the total population (N). The alternative hypothesis (H_1) will be accepted if $k < \frac{x}{n}$ and the null hypothesis (H_o) will be accepted if $k \geq \frac{x}{n}$.

It is also important to note from the equation of the probability function that n must be the next integer larger than x (n>x) for $\Pr(x) > 0.9999$ for the function to be defined.

Each drug will have a unique incidence of use in a population, for example, $k_{alcohol} \neq k_{cannabis} \neq k_{extacy}$. However, it would be reasonable to assume that employing the incidence of use ratio for the substance used most in a population will serve the purpose of calculating the number of individuals to be selected if all the prohibited substances are tested for simultaneously, which is enabled by immunoassay technology. The number of users selected will then automatically be more than sufficient for the prohibited substances with a lower incidence of use (k).

6.3.1.2 Sample size (n) calculations

The minimum sample size on 99% and 99.99% confidence levels is shown in the tables below and is also graphically illustrated in Figures 6.1 and 6.2. Referring to a 99% confidence level implies that if one were to sample for 100 days, the sample would be an accurate reflection or representation of the population. Thus, **one** day out of the **one hundred** days the organisation may be at risk, even if the correct number of individuals were selected. If the confidence level is 99.99%, it implies that 1 out of every 10 000 days, the organisation may be at risk. (This amounts to one in 27 years approximately!) With the small difference in the number of individuals to be selected and the seriousness of putting the organisation at risk, it is worth functioning on a 99.99% confidence interval. The number of individuals to be selected varies from typically two individuals to be selected (k = 0.1, N <2000, 99% confidence) to eleven individuals (k = 0.4, N <2000, 99.99% confidence).

The ratio of incidence of use (k) may either be estimated from the literature on drug use of by a pre-trial performed by the organisation to estimate the number of prohibited substance users in the total workforce or a subpopulation of the organisation. This will be the most reliable way to proceed, compared to an estimation from literature.

The selection of a few individuals does not bear relation to the number of drug-free individuals. The hypergeometric sampling procedure, as used in this instance provides information on the number of subjects to be selected to enhance the scientifical correctness of the selection of individuals.

	N	25	50	75	100	200	300	400	500	600	700	800	900	1000	2000
k															
0,1		2	2	2	2	2	2	2	2	2	2	2	2	2	2
0,15		3	3	3	3	3	3	3	3	3	3	3	3	3	3
0,2		3	3	3	3	3	3	3	3	3	3	3	3	3	3
0,3		4	4	4	4	4	4	4	4	4	4	4	4	4	4
0,4		4	5	5	5	5	5	5	5	5	5	5	5	5	6

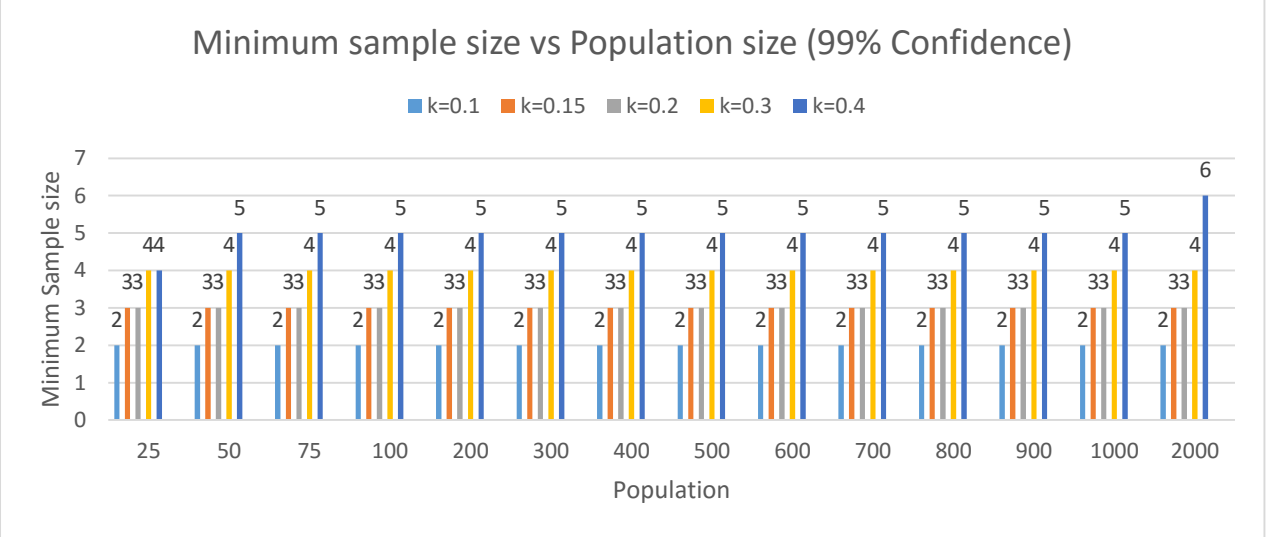


Figure 6:1 Minimum required number of individuals (n) to be selected at various levels of drug use incidence (k) and different sizes of populations (N) at a 99 % confidence level

	N	25	50	75	100	200	300	400	500	600	700	800	900	1000	2000
k															
0,1		3	4	4	4	4	4	4	4	4	4	4	4	4	4
0,15		4	5	5	5	5	5	5	5	5	5	5	5	5	5
0,2		4	5	6	6	6	6	6	6	6	6	6	6	6	6
0,3		6	7	7	7	8	8	8	8	8	8	8	8	8	8
0,4		7	8	10	10	10	10	10	10	10	10	10	10	10	11

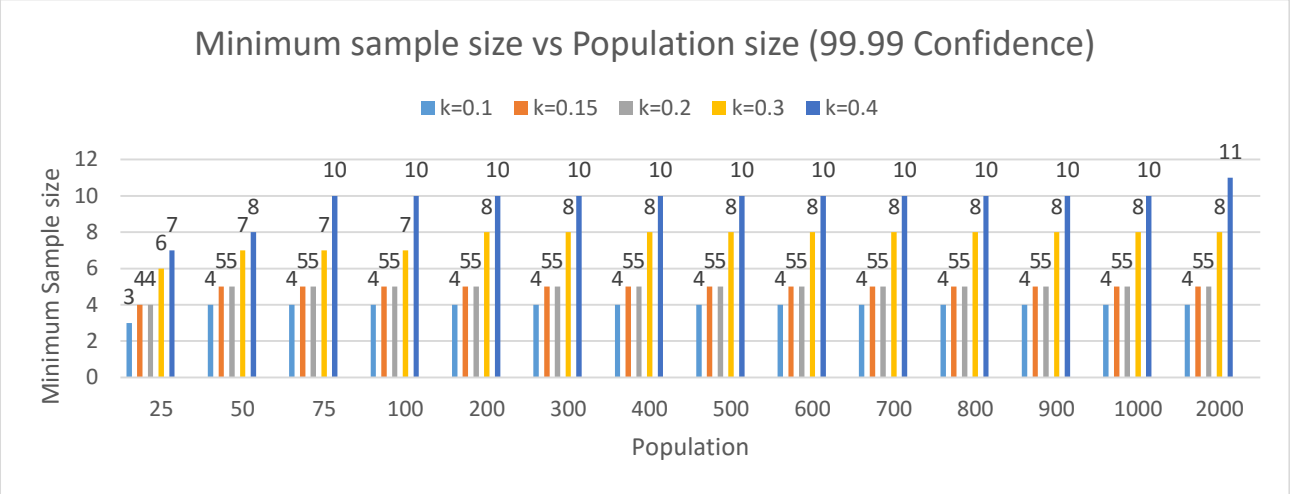


Figure 6:2 Minimum required number of individuals (n) to be selected at various levels of drug use incidence (k) and different sizes of populations (N) at a 99.99 % confidence level

6.4 OBSERVATIONAL IDENTIFICATION

The current wording of the OHSA of South Africa which refers to "...under the influence of intoxicating liquor or drugs..." necessitates specific attention to be paid to the sobriety testing, which is mostly observational testing. Sobriety testing will complement prohibited substance recognition (or identification) such as analytical chemical testing since the prohibited substance concentration in an individual's body does not always correlate with the level of impairment. The laboratory analysis will contribute most significantly to the final decision made by the trier of fact. An abundance of research on the correlation between alcohol concentrations and impairment has also been performed regarding behavioural toxicology aspects as opposed to other substances such as for drugs-of-abuse due to ethical restrictions imposed by research committees.

6.4.1 Lay witness observation of objective signs of impairment

A lay witness can observe signs of impairment by comparing normal behaviour with that of the individual suspected of being impaired. Typical signs of impairment are shown in the

accompanying table below:[4] Laypersons may detect some of these, but others should be used by a skilled person/clinician after a medical diagnostic investigation.

- Difficulty with balance which may manifest in swaying, staggering and stumbling
- Poor coordination
- Speech indicators such as slurring words, fast/slow-talking
- Bloodshot eyes, watery eyes, abnormal pupil size
- The odour of beverage which contained alcohol or marijuana
- Untidy/messy clothing, clothes inside out, general untidy appearance, an odour of urine or vomit on clothes
- Skin colour abnormal
- Slow reaction, response or general lack of awareness
- Insensitive to heat or cold
- Strange demeanour
- Abnormal respiration, blood pressure, and temperature
- Injection sites

6.4.2 Behavioural observation

6.4.2.1 Sobriety testing

The long history of recognition of impaired drivers, mostly for alcohol use on the roadside, can serve as a source of information when performing observational recognition tests in the workplace. Field sobriety testing consists of a battery of tests to recognise impairment in an individual's ability to function normally in a specific environment that is risk-sensitive. The tests can be classified in categories relating to:[5]

(1) ***Motor control and cognitive function*** – Alcohol, for instance, has an effect on fine motoric control as well as on cognitive control of behavioural functioning, for instance, the performance of multiple tasks simultaneously. Reaction time and dual-task performance tests are standard tests in this category.

(2) ***Speech*** – Alcohol induces changes in the speech, which may sound like "slurred speech" since the lips and tongue and vocal cords require fine motoric control and coordination as well

[4] J Landau in JC Garriott *Medical-legal aspects of alcohol* (2003) 4th ed 365, Lawyers and Judges Publishing Company.
[5] CS Martin in SB Karch (ed) *Forensic issues in alcohol testing* (2008) 2-7 CRC Press, Taylor and Francis.

as timing. Recitation of the alphabet at a fast rate is a well-known sobriety test.[6] The overall rate of reading also slows down with alcohol consumption.[7,8] .

(3) ***Vestibular function*** – The vestibular system in the inner ear assists with the maintenance of spatial orientation and balance, which are also supported by eye movements. The effect of alcohol on the vestibular system precipitates in poor ocular-motor control, causing jerkiness (nystagmus) in eye movements related to the effectiveness of eye movements under different conditions, such as when:

- The head is placed in a sideways position for the Positional Alcohol Nystagmus (PAN). The onset of this type of nystagmus starts at approximately 0.04 g alcohol per 100 mL blood.[9,10]
- The head is placed in the upright position for the Horizontal Gaze Nystagmus (HGN). The onset is at approximately 0.08 g alcohol /100 mL blood.[11]

Validated sobriety tests such as the walk and turn, one-leg stand, and horizontal gaze nystagmus tests are not applied in South Africa on a routine basis and will surely aid in and contribute to the recognition and detection of individuals who have administered prohibited substances.[12]

It is essential to take note that there are differences in the level of impairment individuals may experience due to the following reasons:

- Some individuals drink more often than others and, therefore, may experience a lower level of impairment due to their increased rate of metabolism due to the development of tolerance for alcohol.[13]
- Gender differences also exist. A woman will achieve higher blood-alcohol concentrations compared to their male counterparts when consuming an equivalent amount of alcohol due

[6] Keep in mind that the individual has to be literate to site the alphabet fast.
[7] LC Sobell, MB Sobell & RF Coleman 'Alcohol induced dysfluency in non-alcoholics' (1982) 34 *Folia Phoniatrica* at 316.
[8] DB Pisoni & CS Martin 'Effects of alcohol on the acoustic-phonetic properties of speech: perceptual and acoustic analyses' (1989) 13 *Alcoholism: Clinical and Experimental Research* at 577.
[9] KE Money, WH Johnson & WH Corlett 'Role of semi-circular canals in positional alcohol nystagmus' (1965) 208 *American Journal of Physiology* at 1065.
[10] Y Nito et al 'The non-auditory labyrinth and positional alcohol nystagmus' (1964) 58 *Acta Otolarnygology* at 65.
[11] D Ashan 'Different types of alcohol nystagmus' (1958) 40 *Acta Otolarnygology* at 69.
[12] National Highway Traffic Safety Administration 'DUI detection and standardized field sobriety testing: administration guide' DOT-HS-178/RI/90 National Highway Traffic Safety Administration, Washington, C.C.
[13] TR Liscomb & PE Nathan 'Effect of family history of alcoholism, drinking pattern, and tolerance on blood alcohol level discrimination' (1980) 37 *Archives of General Psychiatry* at 576.

to the difference in body weight, body fat, and lower levels of gastric dehydrogenase, as well as the effect of the menstrual cycle.[14,15,16,17]

- Age was also demonstrated to play a role in the level of alcohol impairment.[18,19]

Since there are differences in the level of impairment that individuals may experience, a more objective means is required to recognise and identify individuals that are not drug-free before performing a risk-sensitive task. The alternative to visual detection, is analytical chemical testing of biological fluids, which has an inherently smaller potential for errors. This premise is based on the fact that the analytical methods are adequately validated and also that the analyses are carried out within the constraints that were set by the validation process.

6.4.2.2 Clinical observations

Clinical recognition resorts under the category of diagnostic tests as opposed to compliance tests. A healthcare provider can assist with the recognition of an employee who has a drug problem by direct observation of his or her behaviour as well as by observation of specific medical conditions related to substance abuse. Medical screening programmes may also assist in recognising such an employee. Suspected substance abusers should be sent to a healthcare provider if there is any suspicion that he or she has problematic substance use behaviour.[20]

6.5 CHEMICAL RECOGNITION AND DETECTION IN BIO-MATRICES

The discussion in this document will be focused on cannabis due to its recent legalisation and its abundant use, compared to other drugs. Cannabis, with its active constituent called tetrahydrocannabinol (THC), has a definite potential for impairment and is abundantly available. There is currently widespread uncertainty on the prohibition and regulation of cannabis in South Africa as well as on the approach to be followed in substance regulation and testing programmes. The study may serve as an example as to how the prohibition and regulation of other substances can be approached.

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[14] M Frezza et al 'High blood alcohol levels in women: the role of decreased gastric alcohol dehydrogenase activity and first pass metabolism' (1990) 322 *New England Journal of Medicine* at 95.

[15] PB Sutker, K Goist & A King 'Acute alcohol intoxication in women: relationship to dose and menstrual cycle phase' (1986) 11 *Alcoholism: Clinical and Experimental Research* at 74.

[16] J Brick et al 'The effect of menstrual cycle on blood alcohol levels and behaviour' (1986) 47 *Journal of Studies on Alcohol* at 472.

[17] BM Jones & MK Jones 'Alcohol effects in women during the menstrual cycle (1976) 273 *Annals of the New York Academy of Sciences* at 576.

[18] ES Parker & EP Noble 'Alcohol and the aging process in social drinkers' (1980) 41 *Journal of Studies on Alcohol* at 170.

[19] M Linnoila et al 'Effects of age on alcohol and psychomotor performance of men' (1980) 41 *Journal of Studies on Alcohol* at 488.

[20] KG MsAndrew, G Zimbardy and M Burns (ed) *Medical-legal aspects of drugs* 2nd ed (2007) 146, Lawyers and Judges Publishing Company.

6.5.1 Ideal marker/matrix

The relationship between alcohol concentration in body fluids, such as blood and breath, and level of impairment or intoxication status is well established and understood compared to other drugs-of-abuse.[21] The ideal marker-matrix combination would allow for a direct dose-response relationship. The level of impairment could then be directly deduced from the concentration in the specific matrix as obtained by chemical analysis. The ideal matrix is blood since it comes into direct contact with the brain and other organs where the drug exerts its effect. The invasiveness of blood sampling is a valid ethical concern, especially if other matrices can also be employed to achieve the same result of identifying irresponsible drug use. The use of other less ideal but less invasive matrices and corresponding markers therein usually has to serve the purpose.

6.5.2 Matrices for prohibited substance testing

The consumption of a substance results in the absorption, distribution, metabolism, and elimination of the substance as part of the detoxification mechanism in the human body.[22] After absorption and distribution of a substance, the detoxification process starts with the metabolism of the substance by the various organs such as the liver, which is aimed at increasing the aqueous solubility of the substance by adding more polar functional groups via enzymatic oxidation. The metabolites are then eliminated by excretion in the urine, faeces, saliva, breath, and hair, in specific ratios that depend on the properties of the metabolites, which also determines its excretion half-life. Table 6-1 below illustrates the typical time for detection after substance use in the various matrices.

The time of detection since the last use of drugs for parent compounds and metabolites in biological matrices may vary from hours to weeks (and even years for hair), depending on the type of specimen to be tested. The detection times are generally arranged as follows: blood < breath< oral fluid < urine < sweat < hair. [23]

[21] KM Dubowski & YH Caplan in Garriott (n 4) 418.
[22] The acronym ADME is often used to describe the process of detoxification by the human body.
[23] EJ Cone, A Sampson-Cone & MA Huestis 'Interpretating alternative matrix test results' in SB Karch (ed) *Workplace drug testing* (2008) 108.

Table 6:1 Detection times for drugs in various biological matrices[24]

Matrix	Detection time	Comments
Blood and oral fluid	1 – 3 days	
Breath alcohol	Immediately	Similar to blood for ethanol detection
Urine (most drugs)-single dose	1 - 3 days	Initial time-lag of typically 4 hours
Urine (most drugs)-multiple dose	1 - 5 days	Initial time-lag of typically 4 hours
Urine (cannabis)-multiple dose	Up to 27 days [25]	Initial time-lag of typically 4 hours
Sweat	Up to 7 days	Initial time-lag of typically 2-8 hours
Hair	Up to years	Initial time-lag of typically 3-5 days

6.5.3 Cannabis

More than 60 cannabinoids have been identified as part of the approximately 400 other compounds that have been identified in the plant.[26] The pharmacokinetics of cannabis entails the absorption of cannabinoids after exposure via one of the possible the routes of administration (inhalation, oral ingestion), distribution of the compounds in the body, metabolism by the organs and elimination through the faeces, urine, sweat, oral fluid, hair, and nails.

6.5.3.1 Absorption and distribution of cannabinoids

The preferred route of administration of cannabis and its active compounds is smoking. Inhalation is preferred above oral consumption due to the rapid absorption of the active constituent (**Δ^9-THC**) through the lungs into the bloodstream with a resultant quick effect on the brain and onset of the euphoric effects. The rate of smoking dramatically contributes to the dose of THC that is absorbed from the smoke. The plant also contains variable concentrations of **Δ^9-THC** of between 9.6% and 16%, in plants and up to between 50 and 80% THC in cannabis oils.[27] THC is absorbed rapidly by the blood after smoking, and plasma THC levels are detectable after the first puff from a cannabis cigarette with a 3.5% THC content. Plasma

[24] As above 111.

[25] A Smith-Kielland et al 'Urinary excretion of 11-nr-9-carboxy-delta-9-tetrahydrocannabinol and cannabinoids in frequent and infrequent users' (1999) 23 *Journal of Analytical Toxicology* at 323-332.

[26] CE Turner et al 'Constituents of cannabis sativa L, XVII. A review of the natural constituents' (1980) 43 *Journal of National Products* at 169.

[27] National Institute on Drug Abuse *A rise in Marijuana's THC levels* https://archives.drugabuse.gov/rise-in-marijuanas-THC-levels (accessed 18 March 2019).

concentrations may increase to 160 ng/mL with peak concentrations occurring at approximately nine minutes.[28, 29] The blood concentration then rapidly declines to approximately 10% within 1-2 hours due to a rapid distribution to the lipophilic tissues such as the brain, fat and muscle. THC distributes rapidly into the more perfused organs such as the brain and less rapidly into less perfused tissues such as fat. The initial distribution is followed by the second phase of slow redistribution of **Δ^9-THC** back into the bloodstream, which is followed by hepatic elimination.[30]

Absorption is slower when taken orally with the peak concentration delayed depending on the bioavailability and rate of release from the matrix (foodstuff).[31] Peak plasma THC concentrations ranged from 4 – 11 ng/mL within 1-5 hours after ingestion of 20 mg THC in a cookie.[32]

6.5.3.2 Metabolism of THC

Metabolism is the primary route of elimination of THC from the body, and the elimination half-life of **Δ^9-THC** is approximately one day in casual smokers and three to five days in chronic smokers.[33, 34] The peak psychoactive effects of THC lag behind the peak blood concentration by 20-30 minutes.[35] The hepatic cytochrome P450 liver enzyme system is responsible for the metabolism of THC to enhance water solubility of the drug metabolites, which contributes to excretion in urine and other biological matrices.[36] **Δ^9-THC** is metabolised to the 11-hydroxy- Δ^9-THC (**11-OH- Δ^9-THC**) metabolite which is also biologically active and which in turn is metabolised to the biologically inactive metabolite 11-nor-carboxy- Δ^9-THC (**THC-COOH**). Figure 6:3 illustrates the metabolic pathway of **Δ^9-THC.**

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[28] MA Huestis et al 'Characterization of the absorption phase of marijuana smoking' (1992) 52 *Clinical Pharmacology & Therapeutics* at 31-41.

[29] MA Huestis et al 'Blood cannabinoids. I Absorption of THC and formation of 11-OH-THC and THC-COOH during and after smoking marijuana' (1992) 16 *Journal of Analytical Toxicology* at 276.

[30] WH Porter et al 'Clinical Toxicology' ch 25 at 1197 in CA Burtis & ER Ashwood (eds) *Tietz Textbook of Clinical Chemistry* (1994).

[31] RS Goodwin et al 'Delto-9-tetrahydrocannabinol, 11-hydroxy-delta-9-tetrahydrocannabinol and 11-nor-9-carboxy-delta-9-tetrahydrocannabinol in human plasma after controlled oral administration of cannabinoids' (2006) 28 *Therapeutic Drug Monitoring* at 545.

[32] A Ohlsson et al 'Plasma delta-9-tetrahydrocannabinol concentrations and clinical effects after oral and intravenous administration and smoking' (1980) 28 *Clinical Pharmacology & Therapeutics* at 409.

[33] E Johansson et al 'Prolonged apparent half-life of delta-9-tetrahydrocannabinol in plasma of chronic marijuana users' (1988) 40 *Journal of Pharmacy and Pharmacology* at 374.

[34] RT Jones 'Drug abuse profile: Cannabis' (1987) 33 *Clinical Chemistry*.

[35] LE Domino 'Relation of delta-9-THC concentrations to subjective "high" marijuana users: A review and reanalysis' in S Agurell (ed) *The cannabinoids: Chemical, Pharmacologic, and therapeutic aspects* (1984) 245-261 Orlando, Academic Press.

[36] T Matsunaga et al 'Metabolism of delta-9-tetrahydrocannabinol by cytochrome P450 enzymes purified from hepatic microsomes of monkeys' (1995) 56 *Life Sciences* at 2089.

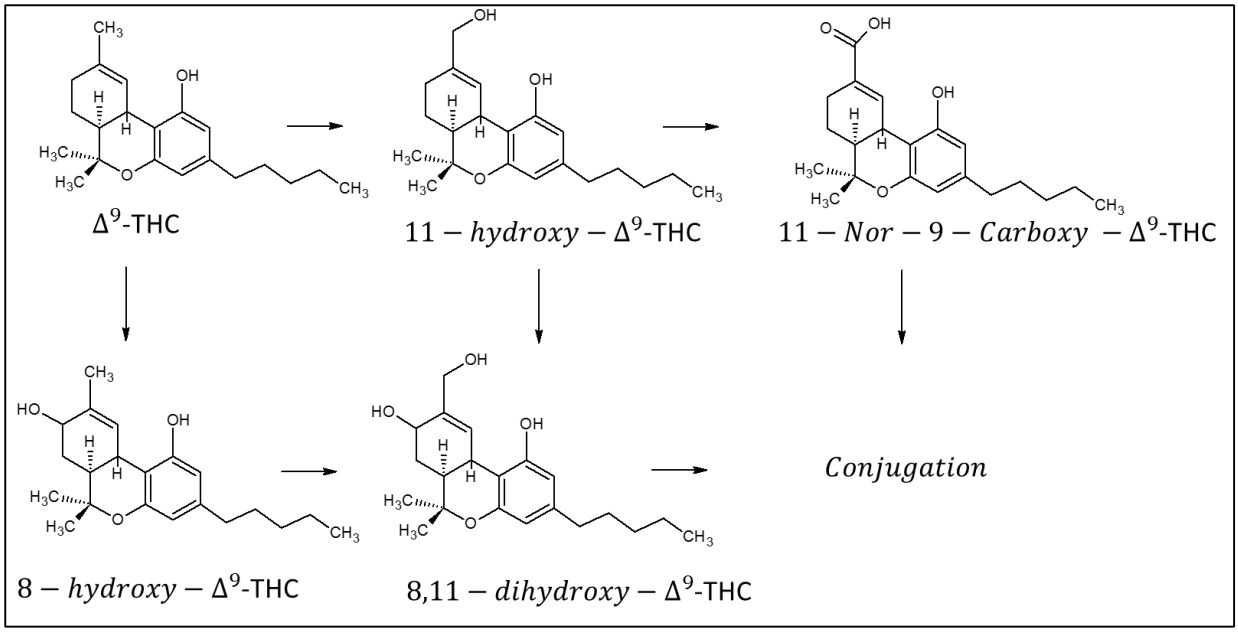


Figure 6:3 Major metabolites of delta-9-tetrahydrocannabinol (Δ^9-THC) in human bodily fluids. [37,38]

6.5.3.3 Elimination of THC

Urine: Most of the THC dose is excreted within five days (80-90%) with approximately 65% in the faeces and 20% in the urine.[39] Urinary THC-COOH glucuronide conjugates are the most abundant metabolites excreted in urine and its concentrations decrease rapidly to approximately 50 ng/mL, after which the concentration decreases at a much slower rate.[40,41] Cannabinoid detection in urine can serve only as an indication that drug exposure did take place and provides no information regarding the route of administration, amount of drug exposure (dose), time of the exposure and the degree of impairment.[42]

Drug detection time is dependent on pharmacological factors such as drug dose, route of administration, rates of metabolism and excretion, and also on analytical factors such as assay sensitivity, specificity and accuracy.[43] As the THC-COOH concentration approaches the cut-

[37] MA Huestis 'Cannabinoids' in JD Ropero-Miler & BA Goldberger (eds) *Handbook of workplace drug testing* 2nd edition (2009) 355 AACC Press, Washington.
[38] Porter (n 30) 1197.
[39] DJ Harvey 'Absorption, distribution, and biotransformation of the cannabinoids' in GG Nahas et al (eds) *Marijuana and Medicine* (2001) 91-103.
[40] Johansson & MM Halldin 'Urinary excretion half-life of delta-9-tetrahydrocannabinol-7-oic acid in heavy marijuana users after smoking' (1980) 13 *Journal of Nala Toxicology* at 218-223.
[41] PL Williams & AC Moffat AC 'Identification in human urine of delta-9-tetrahydtocannabinol-11-oic glucuronide: a tetrahydrocannabinol metabolite' (1980) 32 *Journal of Pharmacy and Pharmacology* at 445.
[42] DR Smith & JL Ferguson 'Medical review officer interpretation of workplace drug test results' in JD Ropero-Miller & BA Goldberger (eds) *Handbook of workplace drug testing* 2nd ed (2009) 407.
[42] Ropero-Miller & Goldberger (n 37) 355.
[43] Smith & Ferguson (n 42) 407.
[43] Ropero-Miller & Goldberger (n 37) 355.

off concentrations (15 ng THC/mL urine), the test result may fluctuate between positive and negative. It was found that the THC-COOH concentration was above 15 ng /mL for 33.7 (± 9.2) hours after smoking a cannabis cigarette with THC content equal to 1.75% and 88.6% (± 23.2 hours) for a 3.55% THC cannabis cigarette.

Oral fluid:[44, 45]

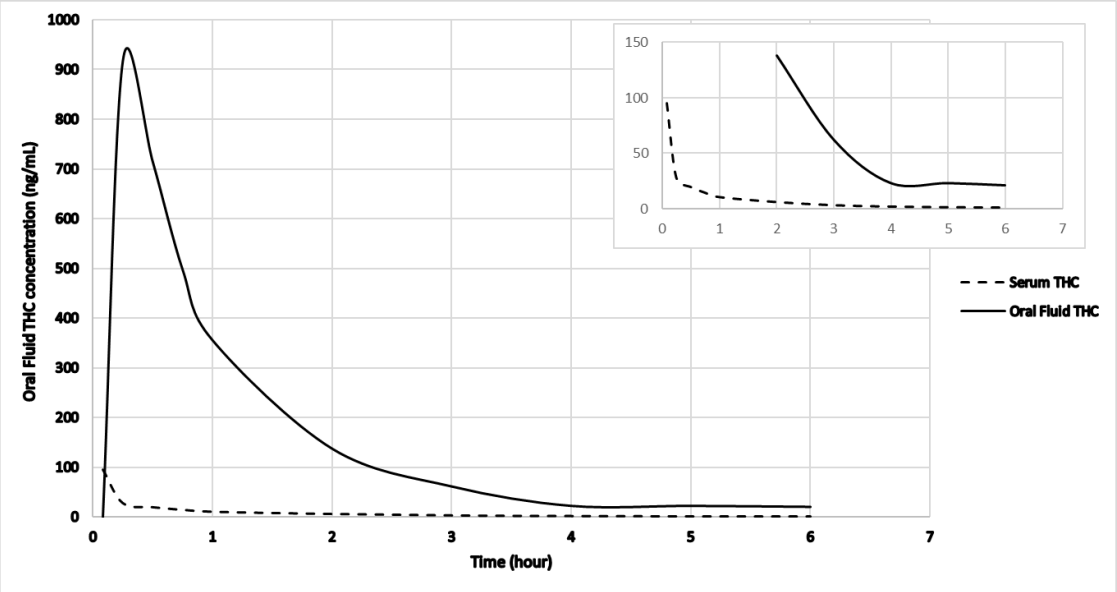


Figure 6:4 Oral fluid THC concentration vs time (Data from Raemakers et al.) [46]

A dose of 500 mg THC administered to volunteers who smoked a cannabis cigarette, resulting in oral fluid (OF) concentration equal to 95 ng/mL serum within five minutes after administration, which decreased to 1-2 ng/ml serum after three to five hours.[47] Serum THC concentration was shown to correlate fairly well with the oral fluid (r=0.84) which, according to Ramaekers, leads to the possible use of oral fluid THC as a valid biomarker for recent cannabis exposure due to the ease of use in qualitative roadside drug tests.[48,49,50]

[44] P Kintz et al 'Analytical approaches for drugs in biological matrices other than urine' in SB Karch (ed) *Workplace drug testing* (2008) 81 CRC Press.
[45] Ropero-Miller & Goldberger (n 37) 369.
[46] JG Ramaekers et al 'Cognition and motor control as a function of delta-9-THC concentration in serum and oral fluid: limits of impairment' (2006) 85 *Drug and Alcohol Dependence* at 114-122.
[47] As above.
[48] As above
[49] MA Huestis & EJ Cone 'Relationship of delta-9-Tetrahydrocannabinol concentrations in oral fluid and plasma after controlled administration of smoked cannabis' *Journal of Analytical Toxicology* (2004) 28.
[50] N Samyn & C Haeren 'On-site testing of saliva and sweat with drug-wipe and determination of concentration of drugs of abuse in saliva, plasma and urine in suspected users' (2000) 113 *International Journal Legal Medicine* at 150-154.

A linear correlation was found between serum log[THC] and oral fluid log[THC] with a correlation coefficient of 0.84 with a significance of below p=0.001.[51] The linear regression equation was:

$$log[THC]_{Oral\ fluid} = 0.94 + 1.47\log[THC]_{Serum}$$

The oral fluid concentration values of the serum concentrations referred to above are indicated in the table below.

Serum THC (ng/mL)	**Blood THC (ng/mL)**	**Oral fluid THC (ng/ml)**
1	2	9
2	4	24
5	10	93
10	20	257
30	60	1292

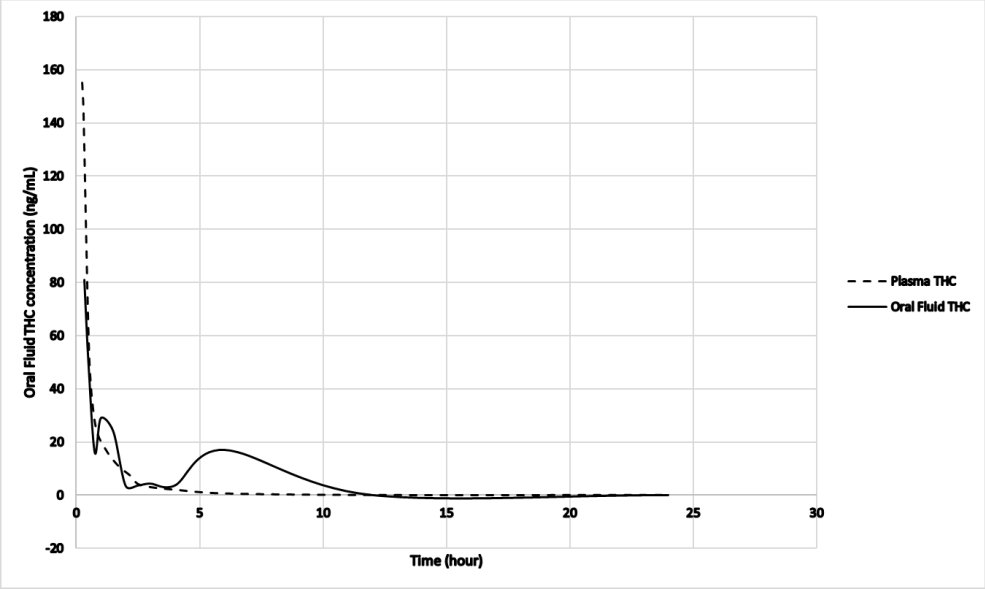


Figure 6:5 Oral Fluid THC concentration vs time. Data from Huestis et al [52]

[51] Ramaekers et al (n 46) 114-122.
[52] Huestis & Cone (n 49).

In a study of a similar nature, Huestis[53] et al found a serum-to-oral fluid ratio of between 0.5-2, as opposed to the study by Ramaekers, who found a serum-to-oral fluid ratio of between 12-33. The significant difference between serum-to-oral fluid ratios of the two studies is attributable to the difference in oral fluid collection methods. The lower-ratio study was obtained by a stimulated collection of oral fluid (by the use of citric acid on the collection device) while the non-stimulated sampling of oral fluid obtained the higher-ratio study. Stimulation of oral fluid excretion may also dilute the THC concentration.[54] This is a concern since inconsistent sampling may give rise to reasonable doubt about the real THC concentration in oral fluid. Furthermore, if the individual is allowed to sample the oral fluid himself even more doubt may be raised.

It was recommended that oral fluid testing be employed primarily to obtain a first indication of recent cannabis use until methods for collection have been standardised. Ramaekers further advises that further confirmatory analysis be performed to establish the quantitative levels of serum THC.[55]

Oral fluid testing appears to have several confounding variables and is suceptable to interindividual variability.[56] The significant influence that buccal cavity contamination has on oral fluid THC concentration indicates that caution must be exercised when a correlation between oral fluid and blood (serum or plasma) concentrations is sought. It is documented in the literature that the oral fluid: blood ratios has large inter-individual variability, making it impossible to predict blood THC concentrations from oral fluid THC concentrations. The OF-to-blood-ratios documented in literature are: 0.2-3.1 (n=6);[57] mean = 1.2 (0.5-2.2, n=6);[58] mean = 8.2 (0.4-41.5, n=11);[59] (0.01-568.9, n=277);[60] mean = 16.5 (0.3-425);[61] mean = 0.3 (0.03-12.0).[62] Blood THC concentration levels used as an indication of impairment level are typically

[53] Huestis & Cone (n 49).
[54] OH Drummer 'Review: pharmacokinetics of illicit drugs in oral fluid' (2005) 150 *Forensic Science International* at 133-142.
[55] Ramaekers et al (n 46) 114-122.
[56] GS Yacouban and Wish ED A comparison between instant and laboratory oral fluid analysis among arrestees *Journal of psychoactive drugs* (2006) 38(2) 143-50.; D Lee and Huestis MA, Current knowledge on cannabinoids in oral fluid Drug testing and analysis (2014) 6(1-2: 88-111.
[57] Samyn & Haeren (n 50) 150.
[58] Huestis & Cone (n 49) 394).
[59] H Gjerde et al 'Comparison of drug concentrations in blood and oral fluid collected with intercept sampling device' (2010) 34 *Journal of Analytical Toxicology* at 204.
[60] SM Wille et al 'Relationship between oral fluid and blood concentrations of drugs of abuse in drivers suspected of driving under the influence of drugs' (2009) 31 *Therapeutic Drug Monitoring* at 511.
[61] SW Toennes et al 'Pharmacokinetic properties of delta-9-tetrahydrocannabinol in oral fluid of occasional and chronic users' *Journal of Analytical Toxicology* (2010) (34) 216.
[62] G Milman et al 'Oral fluid and plasma cannabinoid ratios after around-the-clock controlled oral delta-9-tetrahydrocannabinol administration' (2011) 57 *Clinical Chemistry* at 1597.

in the order of 2 ng THC/mL blood. This large variation, therefore, serves as motivation to specify threshold concentration levels for THC in each matrix such as saliva and urine (*as per the law of contracts in the policy*). The large variation in oral fluid-blood THC concentration ratios renders it impossible to predict the level of impairment of a subject that consumed cannabis based on an oral fluid THC concentration test result.

Prediction of plasma THC concentration from THC oral fluid concentration or THC-COOH urinary concentrations is not scientifically accurate due to significant variations observed. The results of a study by Marsot et al. support the hypothesis that a positive oral fluid THC or positive urine THC result is indicative of recent cannabis exposure and not as an indication of impairment.[63]

"There is no real evidence that was found by research suggesting that THC concentrations in OF can be extrapolated to blood concentrations."[64]

Millman et al summarised the findings as follows:

"Dose, route, and frequency of cannabis exposure; smoking topography; time since last use; and OF-collection method also influence cannabinoid OF concentrations. Because of the high inter-individual variation, the required equilibration time for cannabinoids in plasma and OF, and the differences in cannabinoid disposition in these 2 matrices, predicting plasma cannabinoid concentrations from OF concentrations cannot be scientifically supported" [65,66]

If an individual is destined to perform safety-sensitive tasks, it would be wise to use the lowest possible concentration level in a matrix that was obtained from reliable pharmacokinetic and performance-behavioural effect studies of cannabis in humans. This will prevent an individual from taking part in risk-sensitive tasks while impaired.

Oral fluid vs urine: The collection of oral fluid is less invasive than urine and also requires less specialised facilities for the collection process than urine. Oral fluid collection can be performed under the direct supervision of the collection officer, which minimises the probability of sample adulteration. The disadvantages of oral fluid include the limited specimen volume as well as the need for lower analytical detection limits.

[63] A Marsot et al 'Comparison of cannabinoid concentrations in plasma, oral fluid and urine in occasional cannabis smokers after smoking cannabis cigarette' (2016) 19 *Journal of Pharmacology and Pharmacology Science* (www.capsCanada.org) at 411-422.
[64] R Capler and D Bilsker et al (n1).
[65] As above.
[66] G Millman (n 62).

Buccal cavity contamination from the oral mucosa of the sample during collection is also a complexing factor in its use to estimate levels of impairment. With oral fluid having a shorter detection window, it can be used as an indication of recent cannabis exposure as opposed to urine cannabis detection. The latter can be used to manage long-term risks imposed by cannabis use. Inconsistent oral fluid sampling may give rise to reasonable doubt about the real THC concentration in oral fluid, which may be more pronounced if the individual is allowed to sample the oral fluid himself.

The analytical challenges for the detection of THC at low concentrations stem from its lipophilicity, which results in absorption of the THC into the collection devices as well as into the plastic during storage and transport.

6.5.3.4 Performance-behavioural effects of cannabis and threshold concentration levels

The effects of THC start rapidly during smoking, with its peak after 30-60 minutes. The duration of the acute effects lasts between two to four hours in a dose-dependent fashion. The euphoria effect is sometimes connected to anxiety, tension and confusion. Several effects result from acute consumption, such as impairment of psychometric tasks, memory, sense of time, motor coordination and reaction speed. All the studies discussed in this section relate to driving impairment due to the use of cannabis.[67] Caution should be exercised when extrapolating behavioural performance related to driving of a vehicle to settings in the workplace.

Several experimental studies were conducted on individual physiological functions and skills related to driver performance. Robbe shows that THC concentrations of between 40-300 µg/kg demonstrated a reduction in laboratory performance tasks related to attention, reaction time, tracking and motor control.[68] Driving simulator task studies surprisingly illustrated that THC doses of up to 250 µg/kg did not result in severe effects.[69] Differences in the effects of alcohol and THC existed in that the consumption of THC decreased the driving speed, as opposed to alcohol that increased the driving speed. Drivers who consumed THC were more careful by increasing following distances and also passed less often. The standard deviation of lateral position (SDLP) did increase in the case of THC use, which is a measure of weaving. The reaction time also increased in these studies, but no indication of alcohol-THC interaction was

[67] AJ Smitt et al 'Performance and behavioural effects of illicit drugs' in Burns et al (n 20) 74.

[68] HWJ Robbe 'Marijuana's impairing effects on driving are moderate when taking alone, but severe when combined with alcohol' (1998) 13 *Human Psychopharmacology* secs 70-78.

[69] DA Attwood et al Cannabis alcohol and driving: Effect on selected close-course tasks. Alcohol Drugs and Traffic Safety (1981) Almqvist and Witsell International: Stockholm.

found.[70,71] THC did produce a dose-related response for SLDP decrease in real driving situations such as a road-tracking test, but a relationship between reaction time and dose in car-following tests was not proved in the presence of a low dose of alcohol (BAC< 0.05 g/100 mL)[72,73] The effects of THC on SDLP were comparable to that of a blood-alcohol concentration of 0.05 g/100 mL. Severe impairment resulted from THC in combination with a low dose of alcohol (BAC< 0.05 g/100 mL) in a road-tracking test.

A correlation was found between recent use of THC and odds ratios of crash risk with THC blood concentrations, which is the best indicator of recent use.[74] Drummer shows that individuals with THC in their blood were two to six times more likely to be responsible for the accident than the control population.[75] The odds ratios are shown in the accompanying table below.

Odds ratio (OR)	**THC <u>whole blood</u> concentration (ng/mL)[76]**	**THC <u>serum</u> concentration (ng/mL)**
	1-2.5 ng/mL blood	Impairment of critical tracking task for serum THC concentration 2 – 5 ng/mL[77]
Mean = 6.6 95% CI (1.5-28.0)[78]	Larger than 5 ng/mL blood	Similar to blood alcohol level of 0.15 g/dL[79, 80]

Ramaekers et al. confirm the findings in an experimental study and found that slight selective impairment was present for perceptual-motor control, motor impulse control and cognition at serum THC concentration levels between 2-5 ng/mL and that impairment became prominent

[70] As above.
[71] AM Smiley et al 'Driving simulator studies of marijuana alone and in combination with alcohol' 25th Conference of the American Association of Automotive Medicine (1981) 107-116.
[72] Robbe (n 68).
[73] JG Ramaekers et al 'Marijuana, alcohol and actual driving performance' (2000) 15 *Human Psychopharmacology* at 551-558.
[74] B Laumon et al 'Cannabis intoxication and fatal road crashes in France: Population based case-control study' (2005) 331 *BMJ* at 1371.
[75] OH Drummer et al 'The involvement of drugs in drivers of motor vehicles killed in Australian road traffic crashes' (2004) 36, *Accident Analysis and Prevention* at 239-248.
[76] The conversion factor from blood to serum/plasma is in the order of 2.
[77] Ramaekers et al (n 46) 114-122
[78] Drummer et al (n 75) 239-248
[79] As above.
[80] R Capler and D Bilsker et al *Cannabis use and Driving Evidence review, Canadian Drug Policy Coalition* (CDPC), Simon Frazer University (2017) 32; RL Hartman and Huestis MA 'Cannabis effects on driving skills *Clinical Chemuistry* (2013) 59(3) 478-92.

at concentrations between serum THC concentration levels between 5-10 ng/mL. [81] Epidemiological data also indicated that a THC serum concentration level of between 2 and 5 ng/mL blood is the range for general impairment above which drivers will be at risk. [82] A concentration of 5-10 ng/mL blood was found to be significant in terms of impairment and an upper limit above which total impairment was evident is a serum concentration >30 ng/mL blood. [83] The concentration ranges of 2-5 ng/mL serum indicated 75-90% of the observations to be positive, meaning there was no indication of impairment in 10-30% of the tests. It should be kept in mind that these levels were proposed for driving impairment.

There was no performance impairment below 2 ng/mL serum (equivqlent to 1 ng/mL blood), which is an indication that this concentration level may be used as a threshold for THC in users in countries where cannabis is legalised. This threshold concentration value will also comply with ethical and human rights related to respect for an individual's privacy and freedom, which means that an individual may use cannabis, but the concentration in blood/serum has to be below 2 ng/mL. Passive exposure investigations also did not increase THC values above 2 ng/mL serum.[84]

THC was found to impair cognitively as well as motor performance for between two and six hours after smoking in critical–thinking, stop-signal, and Tower-of-London tasks. THC-induced performance impairment was similar to that of blood-alcohol concentrations (BAC) larger than 0.1 g Ethanol / 100 mL blood for critical tracking tasks.[85] Similarly, THC tracking-induced impairment was similar to that observed in the stop-signal tracking and Tower-of-London tasks at BAC larger than 0.05 g/100 mL blood. These tasks were not affected at BAC = 0.05 g/100 mL blood.[86, 87]

6.5.3.5 Threshold concentration levels for THC by international organisations

Table 6:2 Threshold concentration levels proposed by international organisations [88]

[81] Ramaekers et al (n 46) 114-122.
[82] G Berghaus et al Effects of cannabis on psychomotoric skills and driving performance – a meta analysis of experimental studies. In Kloeden CN and McLean (Eds), Alcohol, Drugs and Traffic Safety, University of Adelaide, Adelaide.
[83] Ramaekers et al (n 46) 114-122.
[84] EJ Cone et al 'Passive inhalation of marijuana smoke: urinalysis and room air levels of delta-9-tetrahydrocannabinol' (1987) 11 *Journal of Analytical Toxicology* at 89-96.
[85] JG Remaekers et al 'A study of the pharmacodynamics interaction between befloxatone and ethanol on performance and mood in healthy volunteers' (1996) 10 *Journal of Psychopharmacology* at 288-294.
[86] CTJ Lamers et al 'Dissociable effects of a single dose of ecstasy (MDMA) on psychomotor skills and attentional performance' (2003) 17 *Journal of Psychopharmacology* at 379-387.
[87] JG Raemakers & KPC Kuypers 'Acute effects of 3,4 methylenedioxymethamphetamine (MDMA) on behavioural measures of impulsivity: alone and in combination with alcohol' (2006) 31 *Neuropsychpharmacology* at 1048-1055.
[88] D Lee & MA Huestis 'Current knowledge on cannabinoids in oral fluid' (2014) 6 *Drug Testing and Analysis* at 88-111.

Agency	Purpose	Screening Threshold (ng/mL Oral fluid)	Confirmatory Threshold
Australia	DUID	30 (DrugWipe™) 50 (RapiScan™)	2
Belgium	DUID	25	10
Canada[89]			2
DRUID[90]	DUID		1
France[91]	DUID	15	
Talloires	DUID		2
AS4760[92]	Workplace	25	10
EWDTS[93]	Workplace	10	2
SAMHSA[94]	Workplace	4	2

The threshold concentration values prescribed by some authoritative international organisations are indicated in Table 6.2. It is interesting to note the following:

The threshold concentration values of the different organisations are not similar: This aspect may lead to the questioning of the reliability of any specific threshold value scientifically. Scientific literature is not in consensus about these threshold values; however, it will be in the interest of health and safety to err to the side of which will complement safety and lower risk, meaning the lowest possible value should be prescribed that will prevent an individual from taking part in risk-sensitive tasks. If the individual's test result is below this value, he or she should be regarded as drug-free. On the other hand, it is imperative to respect the constitutional right to freedom of the individual. If the threshold value is too low, he or she may end up in a position of not ever being allowed to consume legal cannabis, similar to alcohol. Please see the discussion on "zero-tollerance in section 6.1 above.

[89] Confirmation in blood.
[90] Driving under the influence of drugs, alcohols and medicines.
[91] Confirmation in blood.
[92] Australian Standard 4760-2006.
[93] European Workplace Drug Testing Society (EWDTS) European guidelines for the collection part for urine and oral fluid and the entire procedure for hair for feedback version 2.0 http://www.ewdts.org/ewdts-guidelines.html, (accessed 1 December 2017).
[94] Substance Abuse and Mental Health Services Administration, USA.

Summary:[95]

A threshold THC concentration of 0.00 ng/mL may be challenged since it will restrict the freedom of an individual to the extent that he or she may never consume cannabis while being subjected to the prohibited substance and regulation policy. Zero-concentration approach may target individuals passively exposed to cannabis smoke and will treat all cannabis use as illegal which is in contradiction to the legalszation of theuse of cannabis.

The author, therefore, suggests a threshold of 2 ng THC/mL blood, which was well researched, as the concentration level for the onset of impairment. The relationship between the blood THC concentration and oral fluid THC concentrations is a matter of some uncertainty due to the contribution of residual THC in the buccal cavity. Based on the assumption that the stimulated THC oral fluid concentration mimics THC blood concentration in a 1:1 ratio, a confirmation threshold in oral fluid of 2 ng/mL seems reasonable from a safety and risk point of view and also strikes a balance between safety and the constitutional right to freedom of the individual. This level will also accommodate prescription medical cannabis use

It is the opinion of the author that chemical detection of THC in oral fluid should be performed in combination with observational identification (See section 6.4) until scientifically sound *per se* THC oral fluid concentration levels is agreed upon by the scientific community. This will however, not solve the dilemma of possible buccal cavity contamination of an oral fluid specimen due to residual THC in the mouth. The importance of a written policy, wherein the threshold concentration levels of THC (in the specific matix) to be sampled and tested, is specified cannot be overstated since this will be regarded as the *guideline* as part of the employer-employee contract.

- ***Confirmatory threshold concentration values are lower than the initial screening test**:* This relates to the ability and quality of preliminary testing (screening) devices to produce correct test results at the impairment concentration, which is usually the confirmation cut-off. The aim of employing preliminary testing is to screen out all the TN individuals and to

[95] R Capler and D Bilsker (n 1)

retain the non-negative individuals objectively. Screening devices should have the ability to distinguish between the "negatives" and the "positives". The difference between the screening cut-off and the confirmation cut-off must be high enough to prevent the generation of too many false-positive test results (SFP) from innocent individuals who are drug-free. If the difference between the screening cut-off and the confirmation cut-off is too large on the other hand, some individuals with THC concentrations above the impairment concentration may be allowed to proceed with their safety-sensitive tasks.

Some of the individuals who are not drug-free may be missed and not correctly identified, even though they may have a THC concentration level above the threshold. This is due to the inability of screening devices to identify drug users and non-drug users at or near the screening cut-off concentrations correctly. These test results are referred to as FN, which has the possibility of allowing an impaired individual to engage in risk-related activities due to the inherent shortcomings of the preliminary (screening) technology. The FN rate of screening devices is higher at or near the screening cut-off concentrations and becomes less at higher concentrations, which will result in fewer FN test results at higher THC concentrations.

Setting the screening threshold higher than the confirmatory threshold implies a first approximation that a non-negative test (or "screening positive") is sufficient to raise reasonable suspicion not to allow the individual to engage in risk and safety-sensitive activities. This implies that there is a good chance that the subject will have THC in his system and that the biomedical intervention, with the aim of risk minimisation, has a good chance of success. This is also aligned with the ethical principle of *fair subject selection* and *favourable risk-benefit ratio.*

- ***The screening threshold concentrations are specified as obtained by specific devices***: The Australian DUID screening threshold concentration limit is specified at two different threshold concentrations, the first as 30 ng THC/mL oral fluid with a DrugWipe™ screening device, and the second as 50 ng THC/mL oral fluid with the RapiScan™ screening device.

  This illustrates the fact that it is important to standardise on a specific sampling and testing device that was validated and found to be scientifically suitable for screening at a specific threshold concentration. It is also important to standardise on the technology of sample collection and confirmation strategies. Standardisation will also enhance compliance with

the constitutional principle of everybody is equal before the law, and that discrimination is not acceptable.

- ***The international organisations prescribe confirmation analysis:*** The adversarial nature of prohibited substance testing places a high demand on scientific reliability and that the final test result must be accurate and precise. The preliminary test is merely an objective means of raising an *objective reasonable suspicion* to prevent the subject from engaging in safety- and risk-sensitive activities while a more reliable test on a forensically acceptable standard is performed to confirm the preliminary assay or screening test result before any decisive action.

  There are a few reasons why confirmatory analysis, which is also regarded as the industry standard, should be performed and therefore also recommended by the manufacturers of these devices. The ***first*** relates to the inadequate diagnostic sensitivity and specificity of screening devices, which result in FP test results at or near the cut-off concentration of the device as discussed above. The ***second*** reason for confirmation analysis has to do with the potential of these devices for cross-reactivity towards other substances which may trigger FP test results. Substances originating from medication and even the diet may exhibit cross-reactivity and result in FP screening results. The ***third*** reason why confirmatory analysis should be performed has to do with the constitutional requirement that "international law must be considered and foreign law may be considered...to the extent that they are consistent with the Bill of Rights..."[96] This also complies with the principle of legal precedent or "*stare decises*" which requires that later cases with similar issues and facts are to be decided similarly.

Please note that the Canadian agency requires confirmation for Δ^9-THC in blood after screening in oral fluid was performed.

6.5.4 Preliminary drug testing (screening)

6.5.4.1 Introduction

Chemical analysis, as part of the drug user identification strategy, has been employed internationally and is based on a preliminary assay (screening test) followed by a confirmation test on those specimens that resulted in non-negative readings with the screening test. The success of screening tests is debatable, and each test has to be evaluated individually. An

[96] CSA sec 39(b).

understanding of the limitations of each device contributes significantly to its valid and scientifically correct use. The initial screening test is used to screen out all the negatives, at a predetermined policy screening threshold concentration, and to serve as a way to raise an objectively reasonable suspicion to attend to the non-negatives by way of a confirmation analysis which should be much more reliable.

These preliminary assays must enable the users to distinguish between negatives (drug-free individuals) and non-negatives (possible or not drug-free individuals). The results of the screening assay are used to determine if an additional confirmation analysis should be performed. The confirmation assay is performed in a forensic laboratory on a forensically acceptable standard to confirm the presence and concentration level of the prohibited substance in the biological fluid specimen that was sampled and shipped securely to the laboratory by the collection officer.

The preliminary assay is usually performed on-site to assist with an immediate objective decision related to the safety and risk of the organisation. A non-negative test result may be used to motivate a "stand-down" by the test subject until the confirmation test result is available. The screening assay has an essential function and must be designed to distinguish between the screening true negatives (STN) and screening true positives (STP) and also to strike a balance between screening false-positive (SFP) and screening false-negative (SFN) test results. FP and FN results are an inevitable part of the all chemical assays involving thresholds, and it is essential to be aware of this and to eliminate the detrimental effects thereof by employing better technology.

SFP test results may result in false accusations and labelling of the test subject, and an SFN test result is a risk to the organisation's interests. Form a biomedical ethical perspective it is unethical if the proportion SFP assays result is to large and the screening test may on the other hand not be useful in the identification of drug users if the proportion of SFN results are too high.[97]

6.5.4.2 Preliminary drug testing technologies

Drug screening tests are performed by the use of many different technologies, each having unique requirements which are dependent on the complexity of the assay and its associated instrumentation. The technologies are Radioimmunoassay (RIA), Enzyme immunoassay

[97] L Rivier 'Laboratory technology' in Burns et al (n 20) 55.

(EIA), Fluoroimmunoassay (FIA), Kinetic Microparticle Immunoassay (KIMS) and Lateral Flow Immunoassay (LFIA).[98]

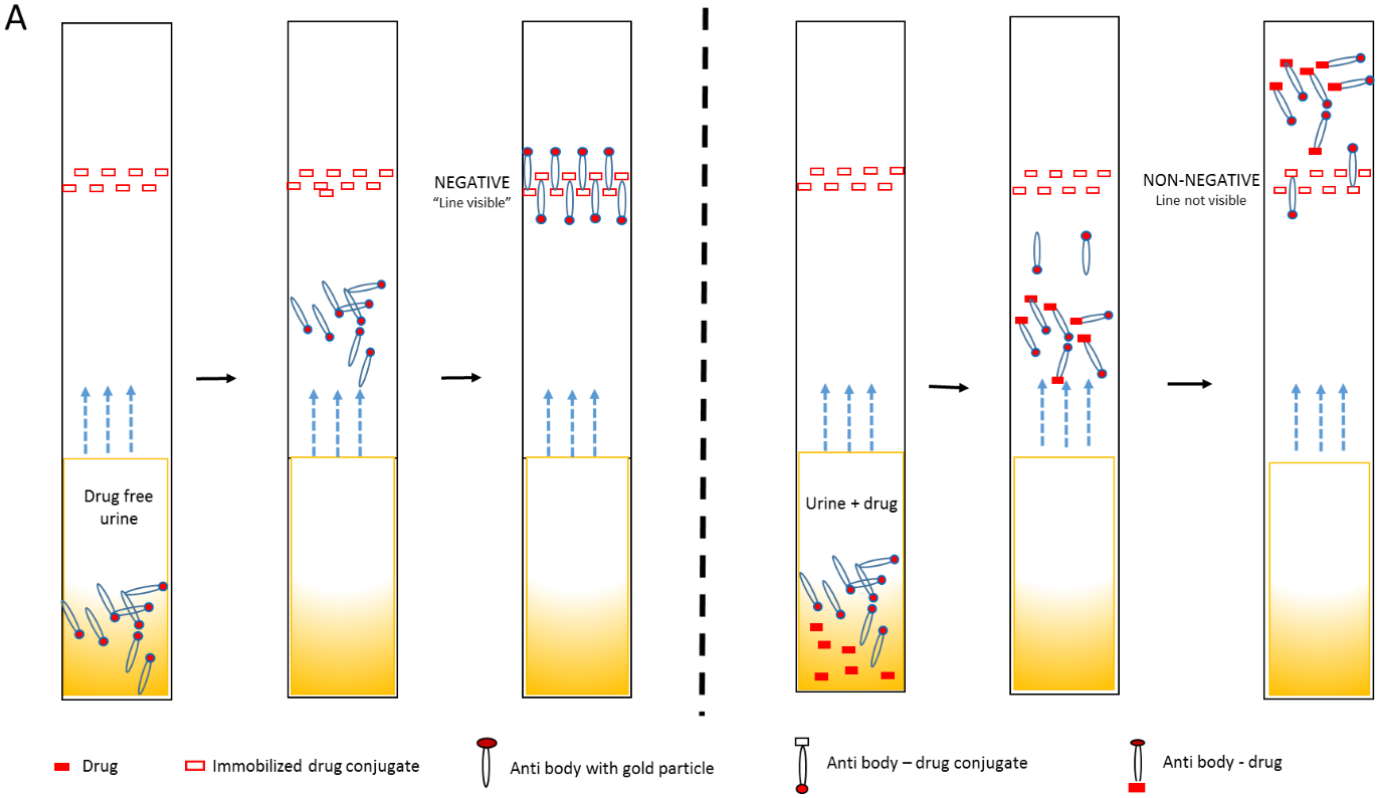


Figure 6:6 Lateral Flow immunoassay: A = Negative test on drug-free urine; B = Positive test on urine containing a drug

6.5.4.2.1 Lateral flow immunoassay

Lateral flow immunoassay screening devices are currently the method of choice in South Africa since these devices are relatively inexpensive, simple to use, have the analytical selectivity to enable detection of the drugs of interest and allow for use at the point of collection for many substances simultaneously.[99, 100] The test result involves the disappearance of a visible line on a test strip which is evaluated by an operator with the naked eye. The line is also known as the analytical line or the detection line. A shortfall of this type of assays is the ability of the operator to recognise the disappearance of the magenta-coloured line, which may result in inaccuracies and imprecision.

[98] JA Collins in *Screening immunoassays in handbook of workplace drug testing* 2nd ed JD Ropero-Miller & BA Goldberger (eds) (2009) 15-25 AACC Press.
[99] DJ Crouch 'Point of collection testing' in B Karch (ed) *Drug abuse handbook* (2007) 895CRC Press, Taylor Francis.
[100] Collins (n 98) 15.

The operational principle of a lateral flow immunoassay is illustrated in Figure 6.6. LFIA is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine (or bio-fluid) specimen compete against their respective drug conjugate for binding sites on a specific antibody. During testing, a urine specimen migrates upward by capillary action and a drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug conjugate (which is applied in the detection line region during the manufacturing process), and a visible coloured line will show up in the test line region of the strip if the test is negative. A non-negative test will show no visible line. The rapid disappearance of the visible line for a non-negative specimen at the threshold (cut-off) concentration will enhance the separation between negatives and non-negatives.

The effectiveness of an LFIA test to distinguish between the negatives and the non-negatives hinges on the disappearance of the visible line, which depends on in a diagnostic sensitivity and diagnostic specificity at the cut-off screening concentration of the assay. (Please refer to the equation section 6.5.7.1).

6.5.4.2.2 Limitations of the LFIA

An appreciation of the limitations of LFIA technology will enhance the correct use of these devices, which will eventually have a positive impact on legal and ethical compliance. Limitations result in inaccurate detection due to uncertainty around the presence of the analytical line which can cause FP and FN test results in the following ways:

(a) Reading of the line

Bias in the reading of the disappearing line, which indicates indicating the absence or possible presence of a drug above the cut-off concentration, may be due to differences between the individual's (operator's) ability to detect colour change or just uncertainty regarding the change in colour. Please see the discussion later in this work related to the uncertainty in the reading of the line.

(b) Chemical interferences

The characteristics of the LFIA devices vary between different manufacturers due to the difference in the type of antibody employed and consequently its affinity (selectivity), which

impacts on the diagnostic sensitivity and diagnostic specificity of the assay in many ways. Chemical interferences can be attributed to: [101]

- Changes in reagents by manufacturers which may influence cross-reactivity (analytical selectivity)
- Structurally similar or structurally unrelated endogenous substances: One way to obtain information on cross-reactivity of the device is to study the information on the package inserts that are made available with each device.[102,103] Care should be taken that this information relates mostly to the parent compounds and not the corresponding metabolites.
- Specimen matrix characteristics: Factors such as urine pH, ionic strength, and viscosity are well known to influence an immunoassay test.
- Collection methodology: This is critical in the case of oral fluid due to residual cannabis (THC) remaining in the buccal cavity after smoking, insufflation and oral ingestion. [104]
- Adulterants which are chemicals added on purpose by the drug test subject to obscure a non-negative test result. These vary from household products such as bleach, vinegar to "kits for cheating", a drug test that can be purchased over the internet.[105]

6.5.5 Confirmatory drug testing

Confirmatory drug testing techniques are laboratory-based and should be performed by competent forensic analysts with a sufficient level of training and professionalism. The forensic toxicology laboratory should have at least ISO 17025 accreditation to ensure that the quality of the test results is accurate and precise. This work will not focus on the extensive detail of the confirmatory techniques, which is a vast science in its own right, but it will suffice to mention that the confirmation techniques have the aim of unequivocal identification and quantification of drugs that are possibly present in the non-negative specimens originating from the screening analysis. The accuracy and precision of the confirmation techniques are superior to those of the screening assays and have enhanced analytical selectivity obtained by the correct use of analytical sound chemometrics techniques. The analytical confirmation procedures need

[101] L Rivier 'Laboratory technology' in Burns et al (n 20) 65.
[102] A Dasgupta et. al 'Analytical performance evaluation of emit II monoclonal amphetamine/ methamphetamine assay: more specificity than emit d.a.u. monoclonal amphetamine/methamphetamine assay' (1993) 39 *Clinical Chemistry* at 104-108.
[103] JD Nicola et al 'Evaluation of six commercial amphetamine and methamphetamine immunoassays for cross reactivity to phenylpropanolamine and ephedrine in urine' (1992) 16 *Journal of Analytical Toxicology* at 211-313.
[104] DJ Crouch 'Oral fluid collection. The neglected variable in oral fluid testing' (2005) 250 *Forensic Science International* at 165-173.
[105] A Dasgupta *Beating a drug tests and defending positive results: A toxicologist's perspective* (2010) Humana Press.

to be adequately validated. The analyses are performed by hyphenated techniques such as Gas chromatography-Mass spectrometry (GC-MS) and Liquid chromatography-Mass spectrometry (LC-MS).

6.5.6 The relationship between drug screening cut-off concentration levels and confirmation cut-off concentration levels

The approach to establishing prohibited substance screening and concentration threshold levels is a rather intricate process that has the aim of recognising prohibited substance users by screening the negatives out in order to attend to the non-negatives (or screening positives) that may eventually end up as confirmed positives. The correlation between the non-negatives and the confirmation test results is important to uphold the integrity of the process and the technology employed in the screening test is mostly the dominant factor that influences this correlation.

It is common practice to have a higher screening cut-off concentration and a lower confirmation cut-off concentration. (Please refer to Table 6.2). Regulatory authorities have to take many factors into account in the determination of screening cut-off concentration levels, depending on the potential application of the results.[106] The applications range from the clinical diagnostic setting to the workplace. Administrative cut-off concentrations are determined by the technology that is available and also by what concentrations are relevant, depending on the intended application for the result. It is also essential to keep the sampling technology in mind since the devices for sampling and transport to the forensic laboratory for confirmation may significantly influence the test result and may also bring a concomitant discrepancy between the screening and confirmation results.

If the intended use is aimed at minimising risk and preventing harm in a safety-sensitive environment, the lowest possible confirmation and screening cut-off combination must be employed to ensure that the test subject's faculties and abilities are not impaired when taking part in risk-sensitive activities. If the screening test is intended to identify drug abusers in the pre-employment or diagnostic setting, different cut-off concentrations may be used since the information obtained will supplement the diagnostic paradigm. This is especially the case with legal substances such as alcohol and cannabis.

[106] SAMHSA; CLIA; CAP: College of American Pathologists.

Cross-reactivity between target compounds, such as amphetamine and methamphetamine, may serve as motivation to increase the screening threshold to improve the correlation between the screening and confirmation tests. A similar type of reasoning can be applied, for instance, in the case of morphine where the ingestion of poppy seed foodstuffs may cause an FP test result, which will complicate the interpretation of the test result. [107] The cut-off screening concentration for opiates was later revised and increased from 300 ng/mL up to 2000 ng/mL as a result of this interference complication.[108]

The organisation must determine the type of compounds to be tested for, but the most common drug classes/substances that are tested for currently in South Africa are opiates, amphetamines (methamphetamine and ecstasy), cannabis and benzodiazepines. The type of matrix is also open for decision in a non-regulated environment, such as in South Africa currently. Blood sampling may be viewed as too invasive if there is another alternative matrix that will achieve the same effect which is for the drug test to act as a deterrent as well as to identify dug users. The enlisting of a substance has to be purpose-driven at the least, with the intention of a scientific reliable, ethically sound and legally correct approach.

The confirmation and screening cut-off concentrations are also related to the type of specimens such as urine or oral fluid, and the same markers are not necessarily employed in the various matrices. In the case of cannabis, [THC] is employed in oral fluid and [THC-COOH] for urine. The SAMHSA cut-off concentrations are shown in Table 6:3 below.[109]

Table 6:3 SAMHSA cut-off concentrations for cannabis in the workplace

	Screening cut-off	**Confirmation cut-off**
Oral fluid (THC)	4 ng/mL	2 ng/mL
Urine (THC-COOH)	50 ng/mL	15 ng/mL

Cut-off concentrations, therefore, are not solely influenced by the concentration, which marks the onset of impairment. It would be ideal, however, to have the cut-off screening concentration as close as possible to the confirmation cut-off concentration, which should be aimed at concentration levels that are below the concentration marking the onset of impairment. The ideal screening method should also correlate with the confirmation method in terms of

[107] MA ElSohly 'Morphine and codeine in biological fluids: approaches to source differentiation' (1989) 1 *Forensic Science Review* at 13-22.
[108] Collins (n 98) 39.
[109] SAMHSA website http://workplace.samhsa.gov (accessed 20 February 2017).

diagnostic sensitivity and specificity. The next section will illustrate that the correlation is strongly dependent on the available technology.

6.5.7 An experimental study to establish the relationship between screening and confirmation thresholds for THC LFIA oral fluid screening tests commercially available in South Africa

An experimental study was conducted by the author on commercial THC-LFIA screening tests currently on the market in South Africa to assess its correlation between the screening and confirmation cut-off levels regarding the diagnostic sensitivity and specificity. One should be cognisant of the ethical requirement of scientific validity as one of the minimum requirements for prohibited substance testing (see section 2.5.4.1.2), to obtain accurate information before decisive action is enforced on an individual by exercising a due standard of care and not to act unintentionally or inattentively (see section 2.2.3.3). The use of drug testing technology that does not provide reliable test results is unethical and therefore will not serve the purpose for which its use is intended.

The generation of unnecessary FP test results may impact on the individual in the form of false accusations, and FN test results may impact on the organisation's risk since these individuals will be incorrectly deemed negative and will be allowed to proceed with their risk-sensitive tasks. It is therefore essential to minimise both the number of FP (from the drug-free popupation) and FN (from the drug-user popupation) results, not only relative to the screening cut-off concentration, but also relative to the confirmation cut-off concentration. With the multitude of screening devices commercially available, with a considerable variation in quality, it has become increasingly important to evaluate the LFIA screening devices before being used for prohibited substance screening on human beings.

6.5.7.1 Experimental data on oral fluid (OF) THC LFIA screening devices commercially available in South Africa

Response data indicating the number of positive and negative readings of four different commercial LFIA products for THC screening in oral fluid (OF) was obtained from package inserts that come with the devices. The data is usually generated by the supplier through the analysis of spiked OF specimens at different discreet concentrations by performing several replicate tests (N). The operator classifies the test result as positive or negative by judging the extent to which the analytical line (detection line) on the device has disappeared. The disappearance of the line, which is regarded as positive, will indicate the presence of THC. If

the operator can still observe the analytical line, the test result is negative, and the test subject will be allowed to commence with his or her risk-sensitive tasks.

The data is mostly recorded by the manufacturer under repeatability conditions, for example, the same OF matrix and a limited number of operators are utilised to minimise variation in test results. The ideal would be to perform the tests under reproducibility conditions, which encompass more than 30 replicates at each concentration, by more than three operators, and to use different OF matrices from 30 different individuals separately, instead of one pooled OF specimen. Reproducibility conditions will provide a much more realistic perspective as to how these devices will perform in real practice.

The concentrations at which device A was tested was indicated as: cut-off – 50%, cut-off – 25%, cut-off, cut-off + 25% and cut-off + 50%", (i.e. at 25, 37.5, 50, 62.5 and 75 ng/mL THC in OF.

The response data for LFIA THC screening test in oral fluid (OF), obtained at different spiked oral fluid THC concentrations, as per the package inserts of four typical commercial THC LFIA oral fluid screening test products currently available in South Africa is shown in Figure 6.7.

DEVICE A					
THC test concentration range	ng/mL	Number of negatives Package insert	Number of positives Package insert	Diagnostic specificity	Diagnostic sensitivity
N = 30					
Negative	0	30	0	1,000	0,000
- 50% Cut-off	25	30	0	1,000	0,000
- 25% Cut-off	37,5	30	0	1,000	0,000
Cut-off (50)	50	10	20	0,333	0,667
+ 25 Cut-off	62,5	4	26	0,133	0,867
+ 50% Cut-off	75	0	30	0,000	1,000

DEVICE B					
THC test concentration range	ng/mL	Number of negatives Package insert	Number of positives Package insert	Diagnostic specificity	Diagnostic sensitivity
N = 50					
Negative	0	50	0	1,000	0,000
- 50% Cut-off	25	50	0	1,000	0,000
- 25% Cut-off	37,5	49	1	0,980	0,020
Cut-off (50)	50	22	28	0,440	0,560
+ 25 Cut-off	62,5	4	46	0,080	0,920
+ 50% Cut-off	75	1	49	0,020	0,980

DEVICE C					
THC test concentration range	ng/mL	Number of negatives Package insert	Number of positives Package insert	Diagnostic specificity	Diagnostic sensitivity
N = 60					
Negative	0	60	0	1,000	0,000
- 50% Cut-off	20	60	0	1,000	0,000
- 25% Cut-off	30	54	6	0,900	0,100
Cut-off (40)	40	10	50	0,167	0,833
+ 25 Cut-off	50	5	55	0,083	0,917
+ 50% Cut-off	60	0	60	0,000	1,000

DEVICE D					
THC test concentration range	ng/mL	Number of negatives Package insert	Number of positives Package insert	Diagnostic specificity	Diagnostic sensitivity
N = 10					
Negative	0	10	0	1,000	0,000
- 40% Cut-off	3	10	0	1,000	0,000
- 20% Cut-off	4	9	1	0,900	0,100
Cut-off (5)	5	4	6	0,400	0,600
+ 20 Cut-off	6	2	8	0,200	0,800
+ 40% Cut-off	7	0	10	0,000	1,000

Figure 6:7 Response data on the number of negative- and positive THC test results in oral fluid (OF), obtained at different spiked oral fluid THC concentrations, as per the package inserts of four typical commercial THC LFIA oral fluid screening test products currently available in South Africa

The response data is usually listed in the package inserts under the heading "Analytical sensitivity" or sometimes only as "Sensitivity" to indicate the responses at various THC concentrations. The diagnostic sensitivity and diagnostic specificity data, which is very important for the evaluation of these devices, is usually not indicated. The extraction of this information from the response data needs some more in-depth calculations by the user to evaluate the ability of the product to correctly identify positives and negatives, which is the primary goal of prohibited substance screening, as well as its inherent deterrent effect. The

ability to identify the positives correctly is termed the "diagnostic sensitivity", and the ability to identify the negatives correctly is termed the "diagnostic specificity".[110]

The values of these two characteristics can be calculated with the following two equations:

$$Diagnostic\ screening\ specificity\ = \frac{STN}{STN + SFP}$$

$$Diagnostic\ screening\ sensitivity = \frac{STP}{TSP + SFN}$$
$$= (1 - Diagnostic\ screening\ specificity)$$

The response data for device A will be employed in a worked example to illustrate the approach and reasoning to be followed when evaluating the performance of a typical LFIA THC screening test device. Calculation of the diagnostic screening sensitivity and specificity for device A at a concentration level of 50 ng/mL THC, which is also the cut-off screening concentration for device A, yielded the following values:

$$Diagnostic\ screening\ specificity\ = \frac{STN}{STN + SFP} = \frac{20}{30} = 0.667\ @\ 50\frac{ng}{mL}THC$$

$$Diagnostic\ screening\ specificity\ = \frac{STN}{STN + SFP} = \frac{10}{30} = 0.333\ @\ 50\frac{ng}{mL}THC$$

The value for the diagnostic screening sensitivity of 0.667 @ 50 ng/mL THC implies that the operator will identify 66.7% individuals at a THC oral fluid screening cut-off concentration of 50 ng/mL correctly as above the cut-off screening concentration when using device A. This group of test results are referred to as the STP test results. This implies that 33.3 out of 100 individuals will be incorrectly identified as below the cut-off and will be allowed to proceed with possible risk- and safety-sensitive tasks since they are falsely regarded as negative. The results of the 33.3% of individuals are referred to as false negative (SFN) test rate. The SFN test rate has an implication on the safety and risk of the organisation since this group of individuals goes undetected.

The diagnostic specificity of 0.333 implies that device A will identify 33.3% individuals at a THC oral fluid screening concentration of just below the screening cut-off of 50 ng/mL correctly as negative and therefore below the cut-off concentration. These test results are referred to as the STN test results. This implies that 66.7 out of 100 individuals with an oral fluid THC concentration just **below** the screening cut-off will not be allowed to proceed with

[110] K Linnet & JC Boyd 'Selection and analytical evaluation of methods' in Tietz, CA Burtis, ER Ashwood & D Bruns (eds) *Textbook of clinical chemistry and molecular diagnostics* (2006) 4 Elsevier Saunders.

risk- and safety-sensitive task; they will be channelled into a stand-down procedure since they are falsely regarded as positive. The results of the 66.7% of individuals are referred to as false positive (SFP) test rate.

It can be depicted from Figure 6.7 that the diagnostic screening sensitivity increases and the diagnostic screening specificity decrease with an increase in concentration, which will result in more effective discrimination between the positives and the negatives as the THC concentration increase. The opposite is true with a decrease in concentration, namely that the diagnostic screening sensitivity decrease and the diagnostic screening specificity increase, resulting in more effective discrimination between the negative and positives with decreasing THC concentration.

It is important that the diagnostic screening sensitivity and screening specificity of the device at the confirmation cut-off concentration level (ca 2 ng/mL) is also calculated since this will enable the operator to estimate the SFN test rate at the confirmation cut-off in the interest of risk management for the organisation. The SFP rate should also be attended to in the interest of ethical behaviour towards the individual to avoid unnecessary false accusations and possible labelling. If the diagnostic sensitivity is not high enough at the confirmation cut-off, the probability for SFN tests will be too high, which may compromise health and safety. Too many SFN results for the drug-free specimens at the confirmation cut-off will result in too many SFP results. Too many SFP and SFN results may also lead to claims that the testing procedure is unreliable, unfair and ineffective to distinguish irresponsible, intentionally prohibited substance users from responsible users (or non-users).

Unfortunately, the devices are typically tested only at spiked concentration levels indicated in the package inserts as: “cut-off – 50%, cut-off – 25%, cut-off, cut-off + 25% and cut-off + 50%” (i.e. at 25, 37.5, 50, 62.5 and 75 ng/mL THC for device A) which does not include the low confirmation cut-off levels.

The calculation of diagnostic screening sensitivity and specificity at the confirmation cut-off will have to be performed by extrapolation after extracting the relevant information from the response data as provided in the inserts by following a detailed statistical approach and calculations. This will be delineated in the next section.

6.5.7.2 A practical statistical approach to obtain the confirmation diagnostic sensitivity and specificity

6.5.7.2.1 Gaussian distribution (normal distribution)

Device A will be subjected to the evaluation procedure to serve as an example.

The manufacturer performed a total of 30 replicate tests per concentration level at five different fixed THC concentration levels for device A. The response data at each THC concentration level is provided in the form of negative-to-positive test responses at only the specific THC oral fluid concentrations, R_X, at the fixed concentrations (X ng/mL THC). X ng/mL, without an indication of the spread or distribution of the data. The probability of the response, (R_X), to occur can also be deduced from the negative-to-positive test responses; for example, an $R_{62.5}$ response of 4 negatives: 26 positives will have a probability $\Pr(R_X) = \frac{4}{30} = 0.133$ to occur (@ X=62.5 ng/mL). It is important to keep in mind that each R_X response will have a unique corresponding concentration value.

If it is assumed that the probabilities of occurrence for the responses, $\Pr(R_X)$, can be mimicked with a **Gaussian distribution** (also termed a "normal distribution"), then the R_X that will have the highest frequency of occurrence, will have a concentration equal to the nominal concentration value (X) of the spiked THC solutions. Each concentration will have a maximum if replicate analyses are performed, which will occur at the nominal concentration value at the centre of the distribution. Every concentration value will also have its own distribution of responses and not only the five discrete concentration values for which the response data is provided by the manufacturer.

Figure 6.8 illustrates a Gaussian distribution of responses around the central or nominal concentration value of 50 ng/mL THC, each with a corresponding concentration value. The Gaussian distribution of responses is, in essence, an indication of the spread (uncertainty) in the reading of the analytical line by the operator when analysing an oral fluid specimen with a nominal concentration of 50 ng/mL.

The Gaussian distribution can be interpreted as follows:

The same operator may randomly classify a test result for a specimen with a nominal concentration of 50 ng/mL THC as positive. A range of responses will be randomly generated around a central concentration of 50 ng/mL THC. Therefore, it is possible to find a response

that corresponds to a concentration of 80 ng/mL THC with a probability of at least 0.0485 amongst the other responses generated by the operator. This amounts to a positive rate of at least 4.85%, which implies that the operator will call a positive response which corresponds to 80 ng/mL THC, for 1.5 analyses out of the total of 30 replicate analyses. The 50 ng/mL THC solution will be read as if it is an 80 ng/mL solution 4.85% of the time. Response at 35 ng/mL THC will be called as positive at a rate of least 23.2%, implying that the operator will call a positive response which corresponds to 80 ng/mL THC, for 6.96 analyses out of a total of 30 replicate analyses. The 50 ng/mL THC solution will be read as if it is an 80 ng/mL solution 23.2% of the time. The 50 ng/mL THC specimen will be nominated as positive at a rate of 50% since it is the concentration at the centre of the distribution of the nominal concentration.

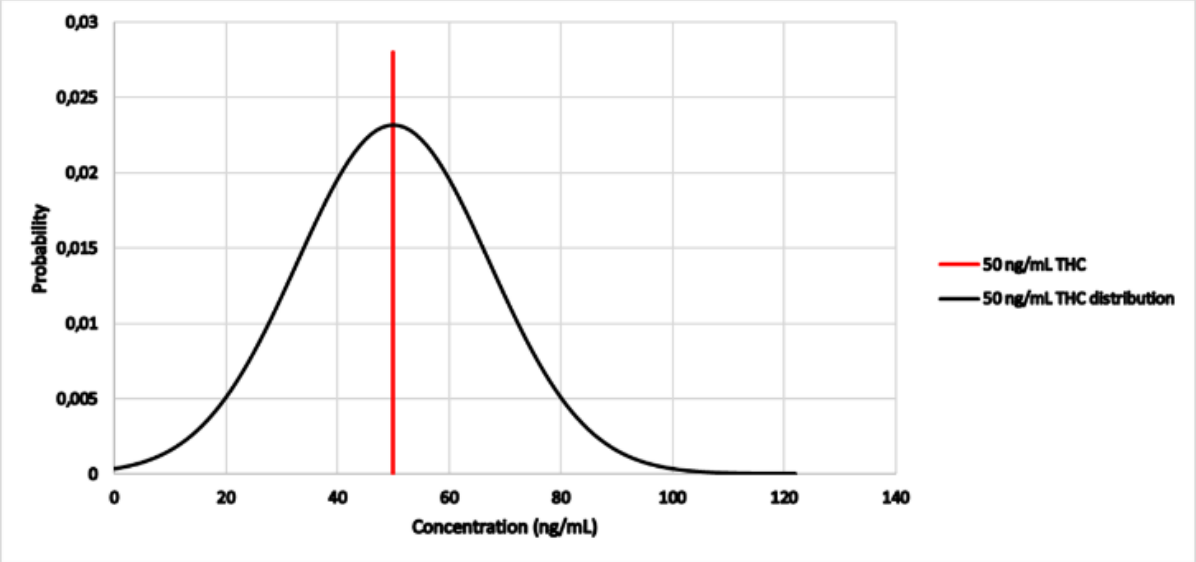


Figure 6:8 Gaussian distribution around a nominal concentration of 50 ng/mL THC

The spread in the responses around a nominal concentration is an indication of the uncertainty in the response reading of the analytical or detection line of the screening device.

The choice of the distribution model needs careful consideration. A normal distribution was chosen in this case due to the random nature of replicate observations, which do not have the same frequency of occurrence. In the case of LFIA screening tests, there is uncertainty in the line intensity (or disappearance), making it impossible to make the same judgement every time even in the absence of bias. Bias will result in unreliable test results, for instance, if the operator may have a preconceived notion of what the result ought to be. Other distributions may also be utilised, such as a triangular, or a log-normal distribution but more experimental data will be

required to choose a suitable distribution that will mimic the probabilities of these devices more accurately.[111]

6.5.7.2.2 The standard deviation of the screening normal distribution

The two most critical parameters to have complete knowledge or predict the "shape" of a Gaussian distribution are the **nominal value (mean or central value) and the standard deviation, σ_{screen},** in this case. The screening standard deviation (σ_{screen}) is a measure of the spread of the data around the centre or mean value (X), which is the nominal concentration value. The probability of a response value to fall within ± 1σ is 68.3 % and within ± 2σ is 95.4 % as indicated in figure 6-10.

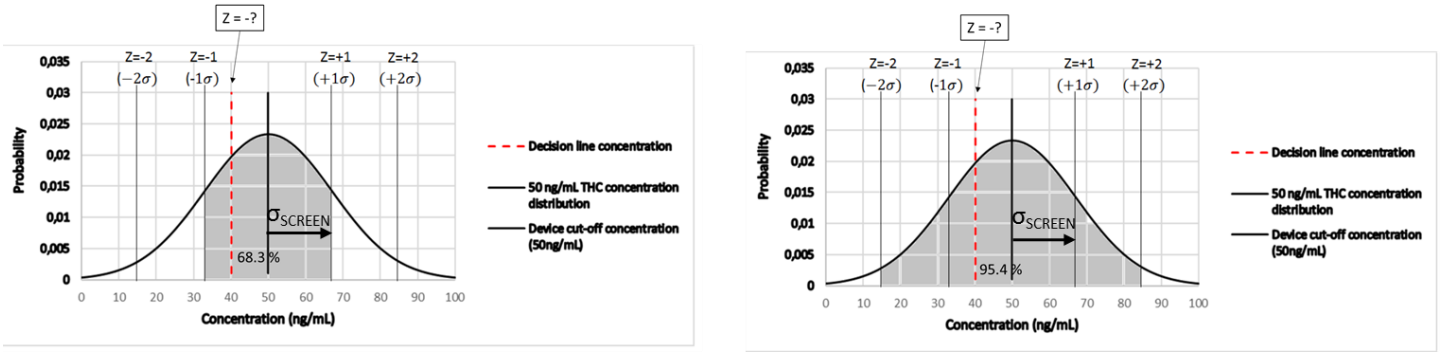
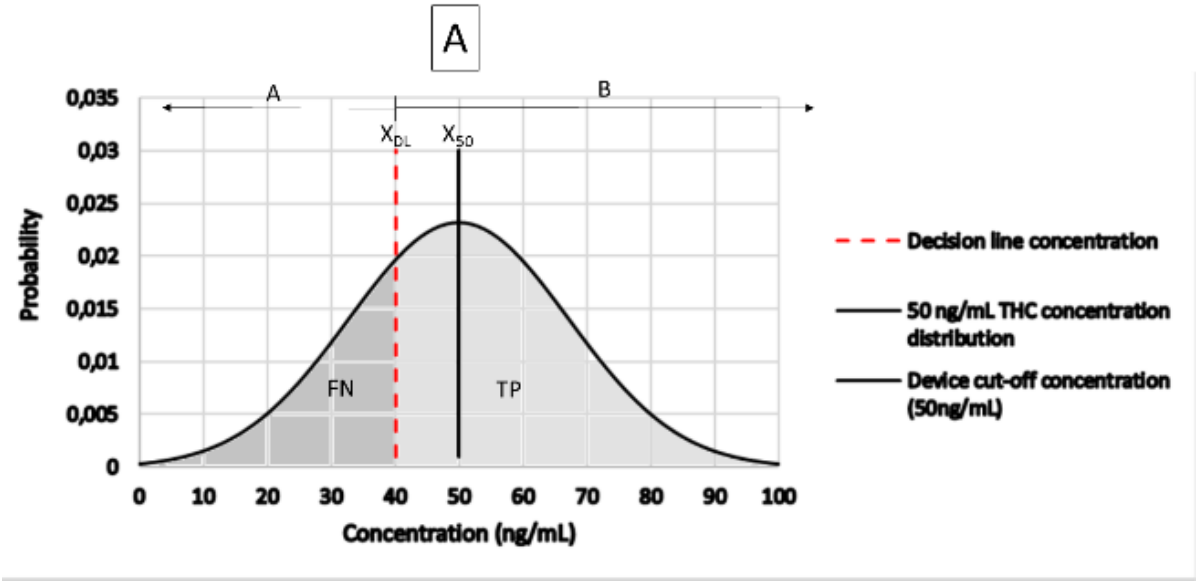


Figure 6:9 Standard deviation of the normal distribution around the nominal concentration value of 50 ng/mL THC with the 95% confidence interval indicated as the area ± 2σ_{SCREEN}.

6.5.7.2.3 Areas under the Gaussian curve: sensitivity and specificity

The probability for a R_X response to occur can also be calculated from the areas under the curve for a Gaussian distribution. The diagnostic screening sensitivity and specificity relative to a concentration of 40 ng/mL (decision line concentration, X_{DL}, for device A), with a screening cut-off equal to X=50 ng/mL THC, is indicated as the areas under the curve in figure 6.9. The diagnostic screening sensitivity is equal to the fraction $1 - \Pr(R_{40})$ (or area under the curve to the right of X_{DL}), (B) of the total area under the curve. The diagnostic screening specificity is equal to fraction $\Pr(R_{40})$ (or area under the curve to the left of X_{DL}, (A) of the total area under the curve.

[111] DA Skoog et al *Fundamentals of analytical chemistry* (2002) 144 8th ed, Brooks/Cole.



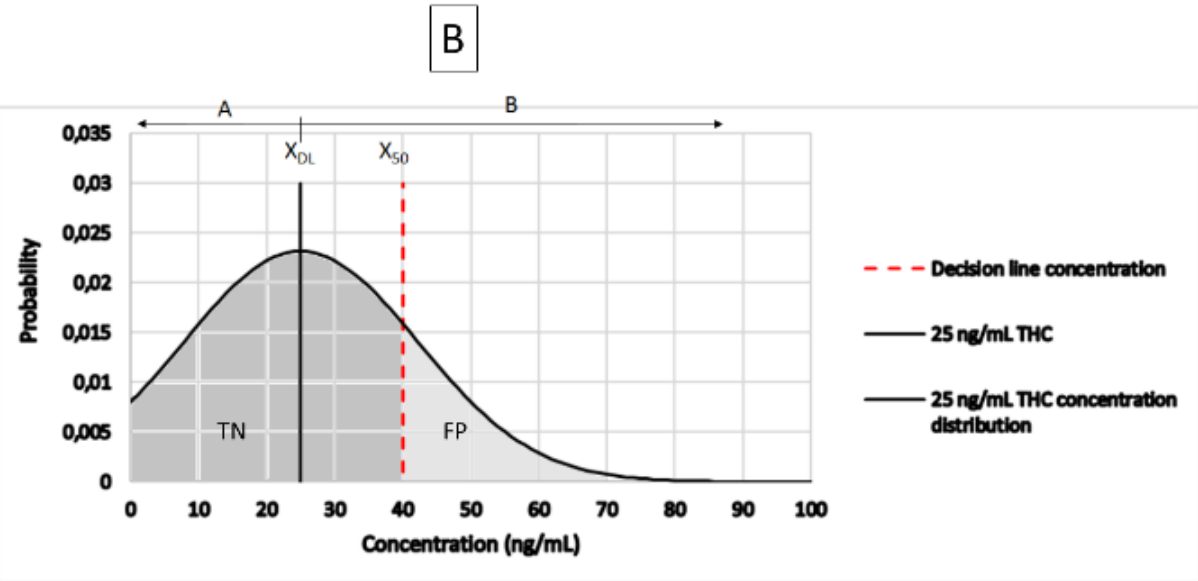


Figure 6:10 (A)The diagnostic screening sensitivity for a 50 ng/mL THC oral fluid solution is equal to the fraction 1-Pr (R_{40}) of the total area under the curve. (B)The diagnostic screening specificity for a 50 ng/mL THC oral fluid solution is equal to the fraction Pr (R_{40}) of the total area under the curve.

$$Diagnostic\ screening\ sensitivity\ = \frac{STP}{STP + SFN}$$

$$= 1 - \Pr\ (R_{40}) = \frac{Area\ under\ the\ curve\ to\ the\ right\ (B)}{Total\ area\ under\ the\ curve\ (A + B)}$$

$$Diagnostic\ screening\ specificity\ = \frac{STN}{STN + SFP}$$

$$= \Pr\ (R_{40}) = \frac{Area\ under\ the\ curve\ to\ the\ left\ (A)}{Total\ area\ under\ the\ curve\ (A + B)}$$

In Figure 6.9 (A), the diagnostic sensitivity will correspond to the light-shaded portion of the total area under the curve, which is equal to 0.72 (or 72%) and the diagnostic specificity will correspond with the dark-shaded area, which is equal to 1- 0.72 = 0.28 (or 28%) of the total area under the curve for an oral fluid specimen with a THC concentration of 50 ng/mL THC.

The diagnostic sensitivity and specificity of device A will be changed according to the relative concentration for which it is calculated, which was 40 ng/mL THC in this case. In Figure 6.9(B), the diagnostic sensitivity will correspond to the light-shaded portion of the total area under the curve, which is equal to 0.192 (or 19.2%) and the diagnostic specificity will correspond with the dark-shaded area, which is equal to 1- 0.808 = 0.28 (or 80.8%) of the total area under the curve for an oral fluid specimen with a THC concentration of 50 ng/mL THC.

The diagnostic sensitivity and specificity relative to a cut-off concentration of 2.2 ng/mL are graphically portrayed in Figure 6.11 after calculation of the areas under the curve (or probabilities) according to the equations shown above. The values for both the diagnostic sensitivity and specificity for device A with a detection line concentration of 40.1 ng/mL and $\sigma_{SCREEN} = 17.2$ can be depicted at any concentration, as indicated in the figure.

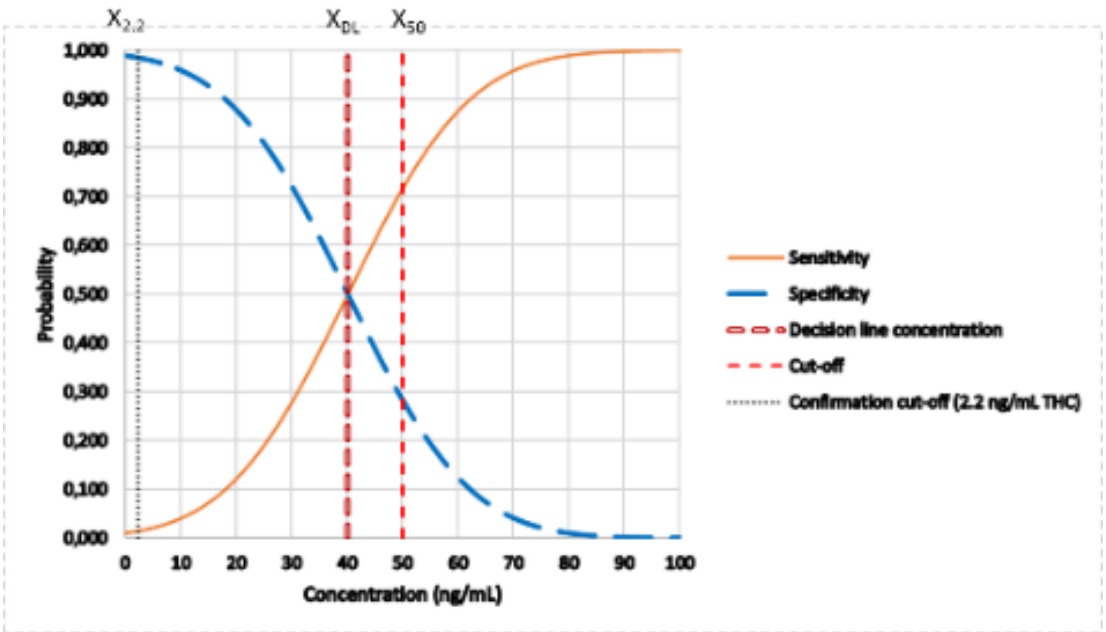


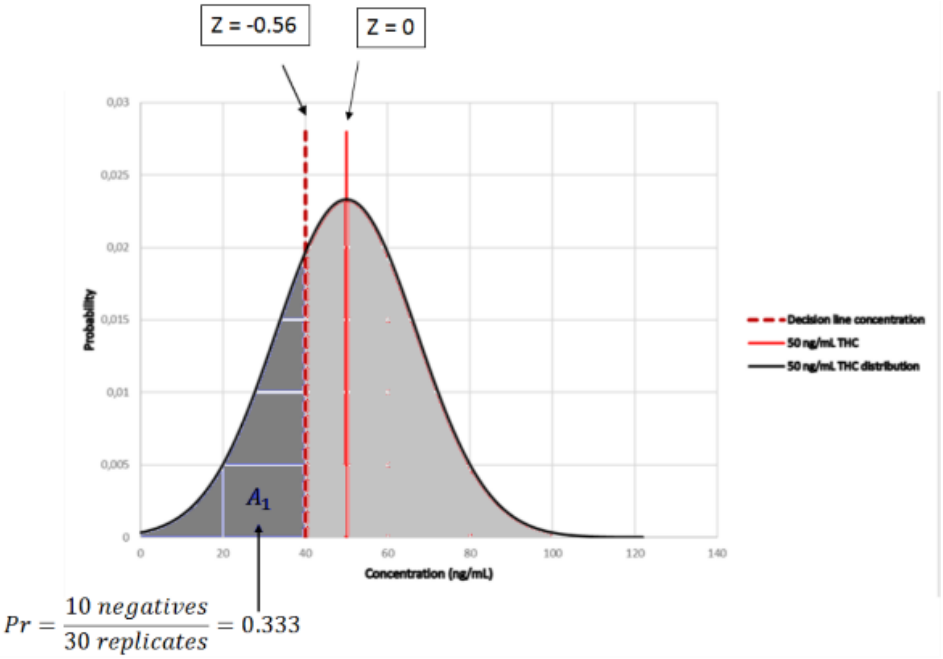
Figure 6:11 (A) The diagnostic sensitivity and specificity of device A at different concentrations after calculation of the areas under the curve (or probabilities)

6.5.7.3 A practical approach to calculate the standard deviation of the normal distribution of ratios

Statistical prediction of the diagnostic sensitivity and specificity at a specific concentration requires knowledge of the standard deviation of the normal distribution. This information is not readily available from the product package inserts and requires some basic statistics knowledge, which will be explained below. The test results shown in Figure 6.7 for device A will be used to illustrate the approach for the calculation of the standard deviation of the ratio distribution.

The approach is as follows:

- The probability or area under the curve A_1 and A_2 are calculated from the test results obtained by replicate testing of the manufacturer-spiked solution.
- The z-score is obtained for the two probabilities. (The z-score for a specific probability can be obtained from a z-table which appears in most basic statistics texts.)[112]
- The z-equation is used to calculate σ_{screen} and X
- With X = decision concentration which is unknown to the reader of the package insert
- μ = concentration of the spiked test solution with which the test result was generated (50 and 62.5 ng/mL in this case)



[112] SLR Ellison, VL Barwick & TJ Farrant *Practical statistics for the analytical scientist, A Bench Guide* 2nd ed (2009) RSC Publishing.

Figure 6:12 (A) Distribution deduced from the probability data for device A at the device cut-off (50 ng/mL THC).

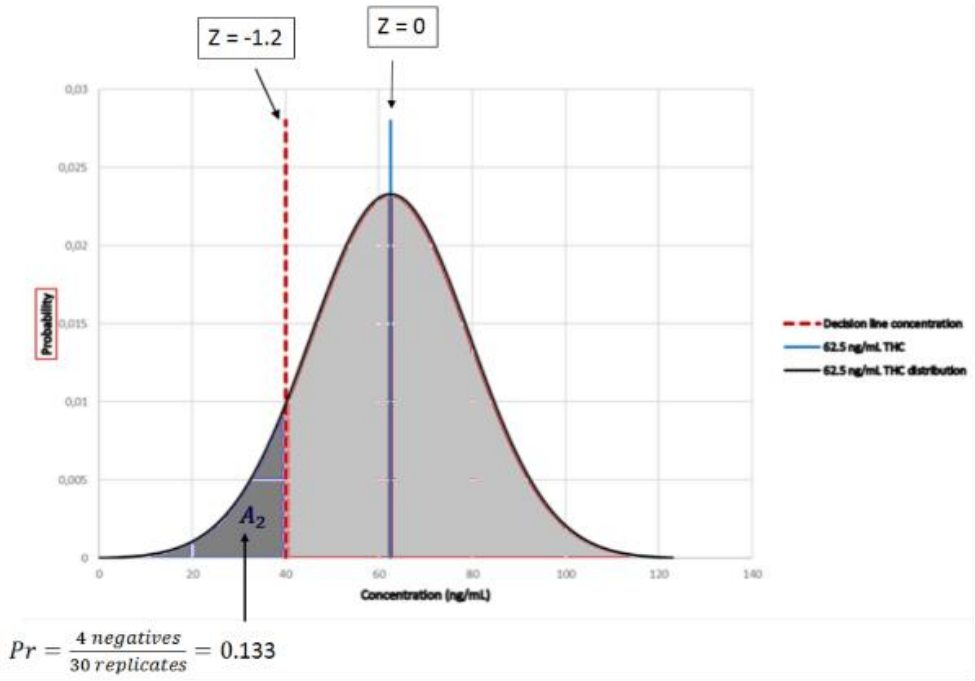


Figure 6:12 (B) Distributions deduced from the probability data for device A at the device cut-off + 25% (62.5 ng/mL THC).

The equation for the z-value is as follows:

$$z = \frac{X - \mu}{\sigma_{screen}}$$

It then follows that:

$$z_1 = \frac{X-\mu_1}{\sigma_{screen}} = \frac{X-50}{\sigma_{screen}} = -0.56 \quad \dots(Eq1) \qquad z_2 = \frac{X-\mu_2}{\sigma_{screen}} = \frac{X-62.5}{\sigma_{screen}} = -1.2 \quad \dots(Eq2)$$

$$\therefore X = z_1\sigma_{screen} + 50 \qquad \therefore X = z_2\sigma_{screen} + 62.5$$

By solving the two equations with two unknowns, it follows that:

$$\sigma_{screen} = 17.12\ \frac{ng}{mL} \quad and \quad X = 40.1\ \frac{ng}{mL}$$

If σ_{screen} may vary with concentration (heteroscedastic), which means that it may be smaller at higher concentration levels due to a clearer disappearance of the line. At lower concentrations, it may be larger due to more uncertainty in recognising the disappearance of

the analytical line. The distribution is centred around the detection line concentration of 40.1 ng/mL THC. The device cut-off of 50 ng/mL THC was prescribed by the manufacturer. (Please see the discussion above under section 6.5.7.3.2). If σ_{screen} does not vary with concentration (homoscedastic); it can be assumed that the spread of the distribution is independent of concentration. It was assumed in this study that the data is homoscedastic.

6.5.7.4 Screening false-positive (SFP) and screening false-negative (SFN) test rate

The dark-shaded area in Figure 6.9 (A) above can also be referred to as the **false-negative rate (FN)** and the light-shaded area can be referred to as the **true-positive rate (TP)** for device A when analysing a 50 ng/mL oral fluid solution (which is also given as the cut-off for device A). The dark-shaded area in Figure 6.9(B) can be referred to as the **true-negative rate (TN),** and the light-shaded area can be referred to as the **false-positive rate (FP)** for device A if a 25 ng/mL THC oral fluid solution is tested.

6.5.7.5 Evaluation of an oral fluid LFIA screening device, figures of merit

During an evaluation of a screening device, the following aspects, also referred to as "figures-of-merit", need due consideration to:

- ***Diagnostic false-positive screening rate (SFP):***

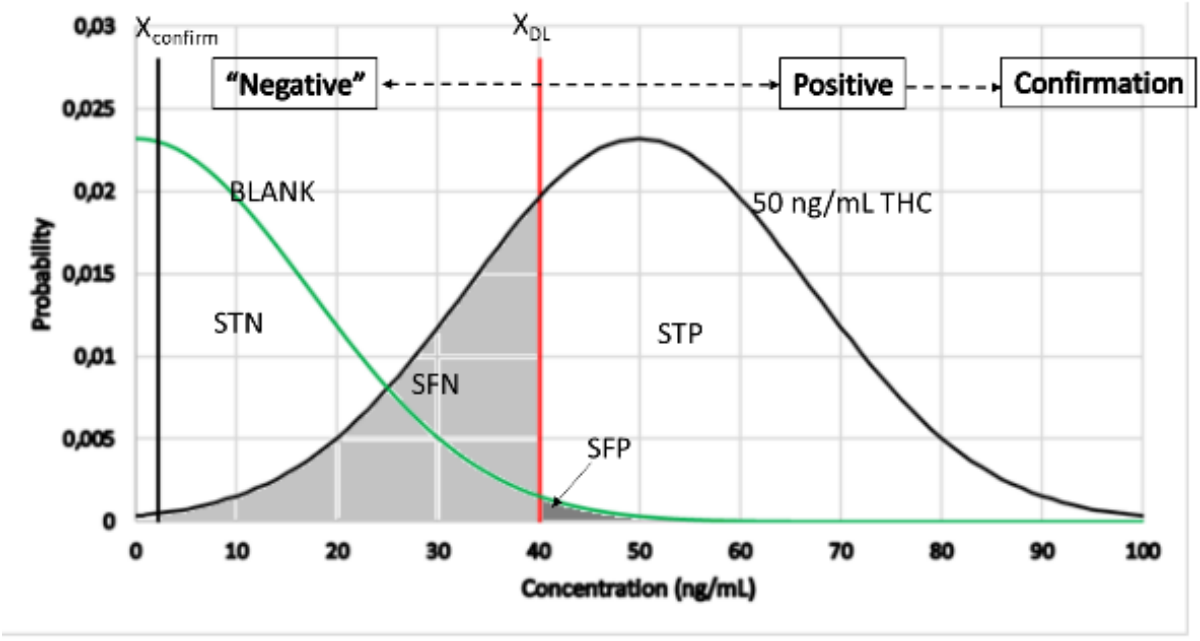


Figure 6:13 (A) Negative (or blank) group distribution about a 50 ng/mL screening cut-off concentration for device A

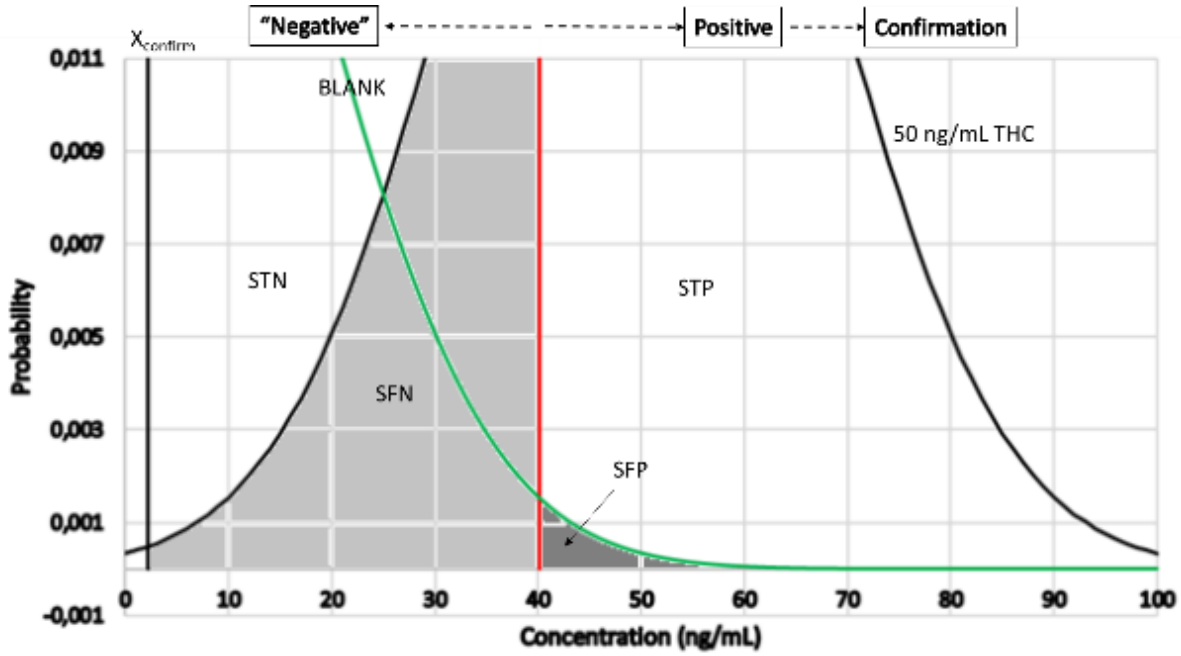


Figure 6:13 (B) Negative (or blank) group distribution about a 50 ng/mL screening cut-off concentration for device A

The ability to separate the positives from the negatives is the primary purpose of screening devices. Therefore, it is essential to assess the performance of the device for these "innocent and responsible drug users" group. Figure 6.12 indicates the negative (or blank, drug-free) group normal distribution about a 50 ng/mL screening cut-off concentration. Close inspection of the distribution curves reveals that there is a chance for these individuals to be falsely nominated as positive, (FP) and, therefore, they will be diverted into a stand-down procedure. The SFP rate can be viewed as the diagnostic screening sensitivity for the blank group at the analytical line concentration (X_{DL}), and in the interest of ethics, the SFP rate must be kept as low as possible. The SFP rate is dependent on the detection line (analytical line) concentration (X_{DL}), as well as the size of σ_{SCREEN}, or the width of the distribution. Lowering the analytical line concentration will require a simultaneous decrease in the width of the distribution (σ_{SCREEN}) not to increase the SFP rate automatically. The SFP rate is equal to $1 - \Pr(R_{40})$ (for a 0 ng/mL THC solution) and is dependent on the analytical line concentration (X_{DL}) and on σ_{SCREEN}. *The SFP rate is equal to the diagnostic sensitivity of the device for the blank (THC-free) samples.* The SFP probability for device A can be obtained as follows: $z_{SFP} = \frac{X_{DL}-0}{\sigma_{screen}} = \frac{40.1-0}{17.2} = +2.33$, which corresponds with a probability of 0.990. This implies that there is a (1-

0.99) = 0.01 probability (or 1% chance) for a test result of a specimen in this drug-free group to be nominated as non-negative for device A.

- ***Diagnostic false-negative screening rate (SFN):***

If correct scientific principles are followed, all the screening positives (STP & SFP) are sent for confirmation analysis. The negatives (STN & SFN) are regarded as compliant and therefore, not attended to any further. It can be depicted from Figure 6.12 that the SFN rate can constitute quite a large portion of the negatives; however, these individuals go unnoticed even though they impose a risk to the health and safety of the organisation. The SFN rate is also dependent on the detection line (analytical line) concentration (X_{DL}), as well as the size of σ_{SCREEN}, or the width of the distribution. Lowering the analytical line concentration will require a simultaneous decrease in the width of the distribution (σ_{SCREEN}) not to increase the SFN rate automatically. *The SFN rate is equal to the diagnostic specificity, Pr (R_{40}), of the device at its cut-off concentration*. The diagnostic screening specificity for device A is equal to 0.28 (or 28%) for an oral fluid specimen with a THC concentration of 50 ng/mL THC.

- **Positive predictive value (PPV) and negative predictive value (NPV)**

The PPV is defined as the rate at which individuals who are above the screening cut-off are indeed identified as positive.

$$PPV = \left[\frac{(STP)}{(STP + SFP)}\right] X100$$

$$\text{With : } STP = 1 - SFP - SFN$$

$$\text{and } STN = 0.5 - SFP$$

The NPV is defined as the rate at which individuals who are below the screening cut-off are indeed identified as negative

$$NPV = \left[\frac{(STN)}{(STN + SFN)}\right] X100$$

- **The overall efficiency of an LFIA THC oral fluid test:[113, 114]**

The overall efficiency of the screening test can be defined as the percentage of individuals classified as drug-free and drug users correctly above the screening cut-off is given by the following relationship:

[113] SS Deshpande *Enzyme immunoassays, From concept to product development* (1996) 346 Chapman & Hall.

[114] EA Sasse 'Reference intervals and clinical decision limits' in LA Caplan & A Pesce (eds) *Clinical Chemistry, Theory, Analysis and Correlation* 3rd ed (1996) 376 Mosby.

$$Efficiency = \left[\frac{(STP + STN)}{(STP + SFN + STN + SFP)}\right] X100$$

The probability figures for device A are as follows:

- $SFP = 0.01$
- $SFN = 0.28$
- $STN = 0.5 - SFP = 0.5 - 0.01 = 0.49$
- $STP = 1 - SFP - SFN = 0.71$

The efficiency for device A is, therefore equal to:

$$Efficiency = \left[\frac{(STP + STN)}{(STP + SFN + STN + SFP)}\right] X100$$
$$= \left[\frac{(0.719 + 0.499)}{(0.719 + 0.28 + 0.499 + 0.001)}\right] X100 = 80.49\%$$

The ideal value for a screening test's efficiency would be close to 100% if the SFN and SFP rates were small.

- ***Width of the negative concentration range and minimum requirements for the screening standard deviation*:**

The following equation can describe the detection line concentration:

$$X_{DL} = X_{BLANK} + z(\sigma_{SCREEN})$$
$$\sigma_{SCREEN} = \frac{X_{DL} - X_{BLANK}}{z}$$

With z=1.64 (95% Confidence); 2.36 (99% Confidence); 3.08 (99.9% Confidence).

The minimum value for σ_{SCREEN} of device A therefore should be equal to: 24.45 (95% Confidence); 16.99 (99% Confidence); 13.01 (99.9% Confidence). The value of σ_{SCREEN} of device A is equal to 17.1, which indicates a confidence level of between 99% an 99.9%.

The detection line concentration depends on the number of antibodies immobilised on the analytical line position on the test strip and indirectly on the width of the normal distribution for the blank sample. The visualisation technology is of importance for the reduction in (σ_{SCREEN}) to reduce the uncertainty in the reading of the analytical line by the operator. With the aim of reducing the analytical line concentration, to detect THC in oral fluid at a lower concentration as close as possible to the confirmation cut-off (2.2 ng/mL THC), it would be required of the manufacturer to attend to these two parameters and to enhance the colour

recognition of the line disappearance and to increase the number of immune bodies in the analytical line on the test strip.

- **Statistically predicted device cut-off concentration at a confidence level:**

This is the concentration level where the SFP rate is as low as possible, typically at a 99.99% confidence level, which implies that there is a chance of $\frac{1}{10000}$ for a drug-free specimen to be called positive (or non-negative) by the operator.

$$X_{SCREEN\ CUT-OFF\ (99.99\%)} = X_{BLANK} + z(\sigma_{SCREEN})$$

$$X_{SCREEN\ CUT-OFF\ (99.99\%)} = 0 + 3.10(17.2) = 53.01 \text{ ng/mL THC}$$

6.5.7.6 Evaluation comparison of four commercial LFIA THC screening test devices available in South Africa

The distributions for all four devices at their cut-off concentrations are shown in Figure 6.14. Each has its combination of screening cut-off, detection line concentration and σ_{screen}. The screening cut-off concentrations for each, as well as the response data, are provided in Figure 6.7.

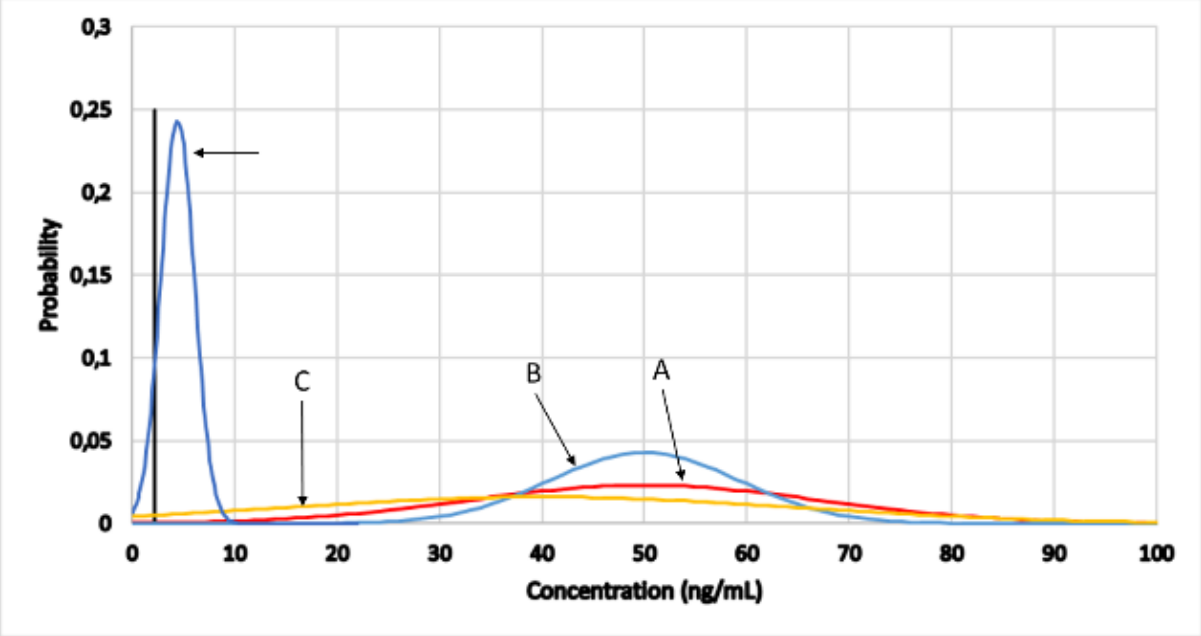


Figure 6:14 (A) Gaussian distributions for all four devices, each with its combination of screening cut-off, detection line concentration and σ_{screen}. (Note the change in scale in the B part)

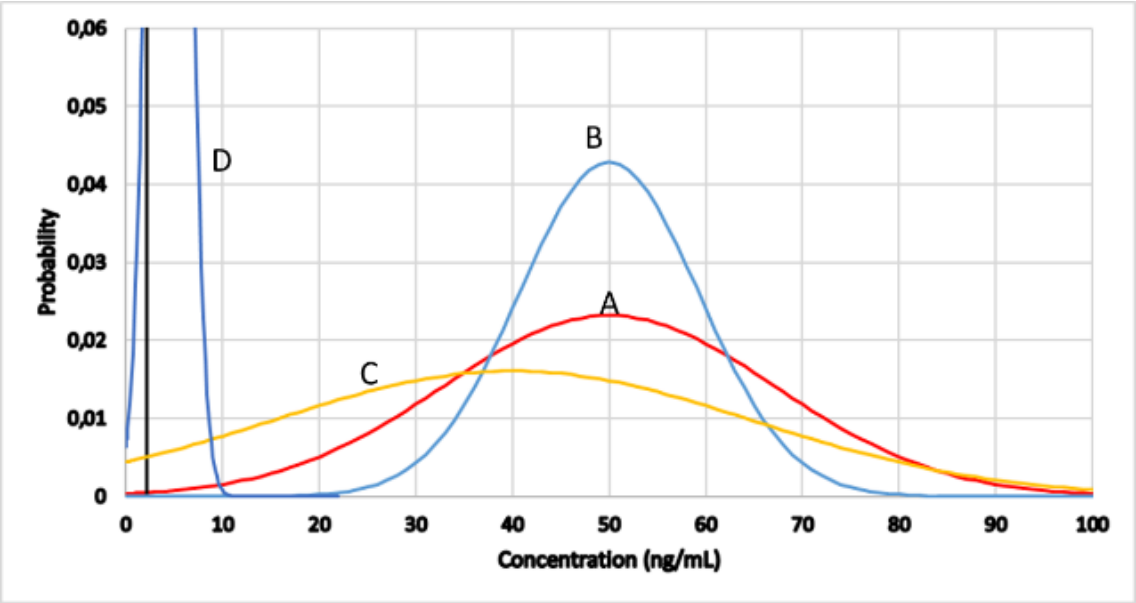


Figure 6:14 (B) Gaussian distributions for all four devices, each with its combination of screening cut-off, detection line concentration and σ_{screen}. (Note the change in scale in the B part)

The detection line concentration and value for σ_{screen} for each was calculated from the response data as per section 6.5.7.3 above. The important parameters, as discussed in section 6.5.7.2.5 were also calculated and are shown in Figure 6.15. Inspection of the distributions in Figure 6.14 indicates that the spread increase in the following order:

$$(\sigma_{SCREEN_D}) < (\sigma_{SCREEN_B}) < (\sigma_{SCREEN_A}) < (\sigma_{SCREEN_C})$$

The cut-off concentrations for device A and device B are set at 50 ng/mL by the manufacturer, and those of device C is set at 40 ng/mL THC in oral fluid. Note that the cut-off concentration of device D, 5 ng/mL, is close to the oral fluid level that marks the onset of impairment (ca 2 ng/mL). The narrow distribution of device D, in combination with its low cut-off, will allow fewer screening negatives for individuals with concentrations below the detection line that will go unnoticed, compared to the other devices.

6.5.7.6.1 Figures of merit for an LFIA THC oral fluid screening device

The figures of merit that were explained in the worked example for the evaluation of device A can be summarised as indicated below and were calculated for each of the devices (A, B, C and D).

- Diagnostic sensitivity (@ cut-off)
- Diagnostic specificity (@ cut-off)
- Screening false-positive probability (SFP)
- Screening false-negative probability (SFN)
- Screening true-positive probability (STP)
- Screening true-negative probability (STN)
- Positive predictive value (PPV) %
- Negative predictive value (NPV) %
- Overall efficiency %
- Predicted screen cut-off (99.99% confidence)

Figure 6:15 Figures of merit applicable to an LFIA THC oral fluid screening device

6.5.7.6.2 Device A

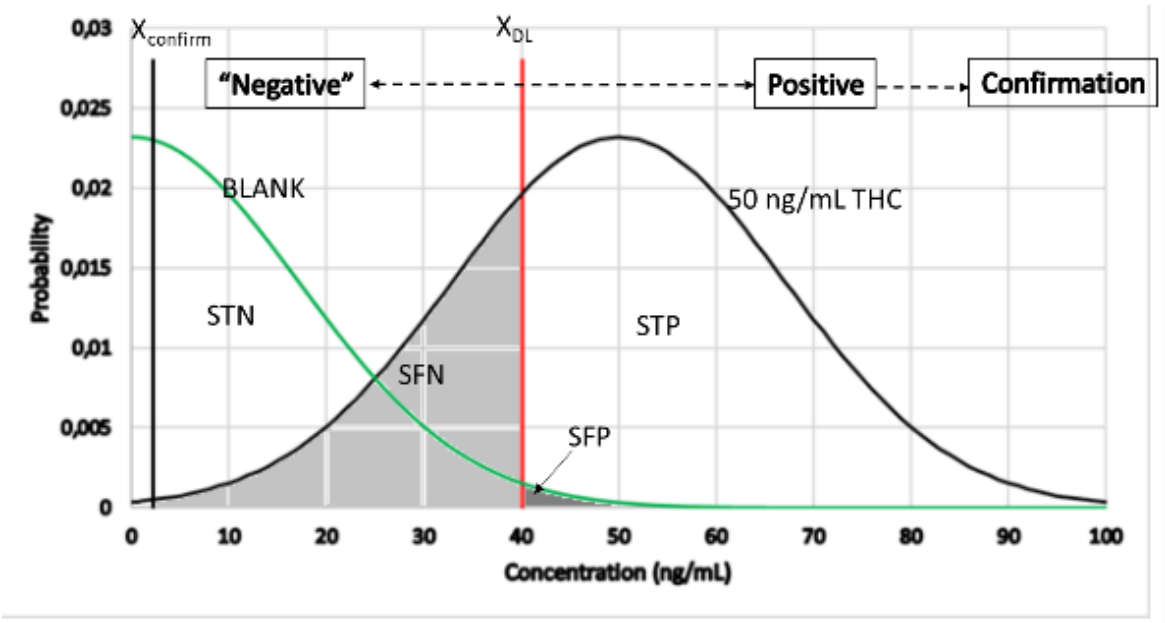


Figure 6:16 (A) Group distribution with a 50 ng/mL screening cut-off concentration for device A

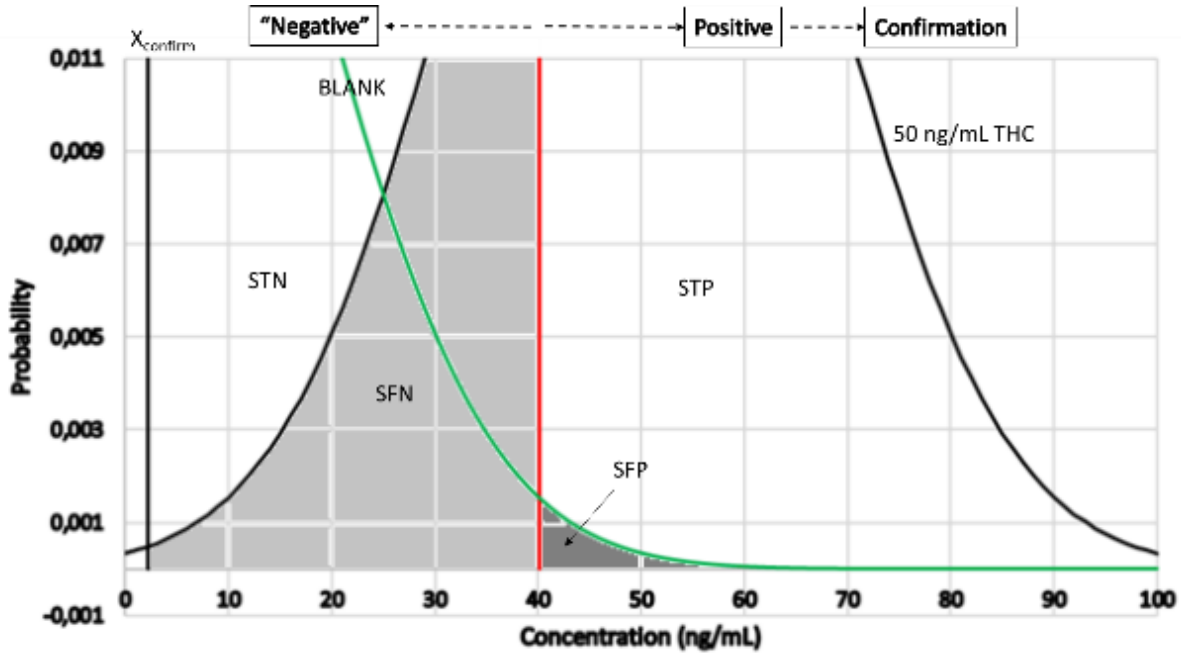


Figure 6:16 (B) Group distribution with a 50 ng/mL screening cut-off concentration for device A

DEVICE A	
	ng/mL
N = 30	
Detection line concentration	40,1
Screening standard deviation	17,1
Confirmation threshold	2,2
Diagnostic specificity @ 2.2 ng/mL THC	0,0026
Negative	0
- 50% Cut-off	25
- 25% Cut-off	37,5
Cut-off (50)	**50**
+ 25 Cut-off	**62,5**
+ 50% Cut-off	75
Diagnostic sensitivity (@ cut-off)	0,7187
Diagnostic specificity (@ cut-off)	0,2813
Screening false-positive probabililty (SFP)	0,0095
Screening false-negative probability (SFN)	0,2813
Screening true-positive probability (STP)	0,7092
Screening true-negative probability (STN)	0,4905
Positive predictive value (PPV) %	98,6764
Negative predictive value (NPV) %	63,5511
Overall efficiency %	**80,4879**
Predicted screen cut-off (99.99% confidence)	53,0100

- The PPV (98.7) > NPV (63.6) is in the interest of safety since the diagnostic specificity (0.72) of this device is higher than the diagnostic specificity (0.28).
- The predicted screen cut-off at 99.99% confidence is equal to 53.0 ng/mL, which is not significantly different from 50 ng/mL cut-off.
- The overall efficiency of 80.5% indicates that the detection line concentration and σ_{SCREEN_A} combination is suitable for a screening cut-off set at 50 ng/mL by the manufacturer.
- The SFP test rate equal to 0.95% will contribute to the fact that fewer innocent individuals will be accused falsely, but the SFN rate of 28.1% serves as proof of the

fact that a large portion of individuals above the cut-off (50 ng/mL) will be allowed to proceed, even if they do not comply with the screening cut-off

6.5.7.6.3 Device B

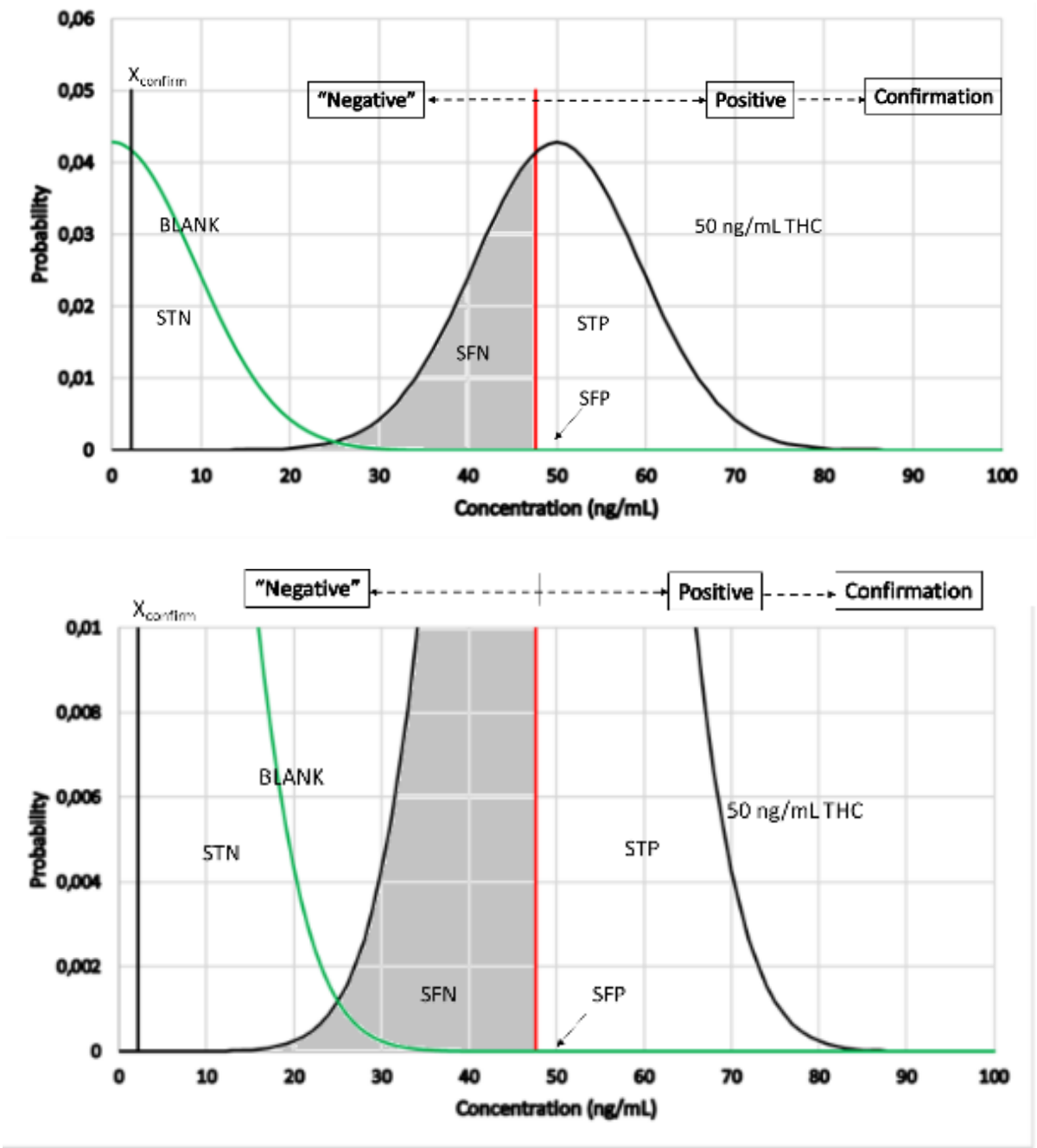


Figure 6:17 Group distribution with a 50 ng/mL screening cut-off concentration for device B

DEVICE B	
	ng/mL
N = 50	
Detection line concentration	47,7
Screening standard deviation	9,32
Confirmation threshold	2,2
Diagnostic specificity @ 2.2 ng/mL THC	0,0000
Negative	0
- 50% Cut-off	25
- 25% Cut-off	37,5
Cut-off (50)	**50**
+ 25 Cut-off	**62,5**
+ 50% Cut-off	75
Diagnostic sensitivity (@ cut-off)	0,5975
Diagnostic specificity (@ cut-off)	0,4025
Screening false-positive probabililty (SFP)	0,0000
Screening false-negative probability (SFN)	0,4025
Screening true-positive probability (STP)	0,5975
Screening true-negative probability (STN)	0,5000
Positive predictive value (PPV) %	100,0000
Negative predictive value (NPV) %	55,3993
Overall efficiency %	**73,1641**
Predicted screen cut-off (99.99% confidence)	28,8920

- Device B has a cut-off concentration of 50 ng/mL THC (equal to that of device A) but with a much lower σ_{SCREEN} (9.32ng/mL) than device A. This reflects in the predicted screen cut-off at 99.99% confidence, which is equal to 28.9 ng/mL compared to the prescribed threshold of 50 ng/mL. However, the detection line is set at 47.7 ng/mL and therefore, will limit a decrease in the cut-off concentration.
- With an SFN rate of 40.25%, a large portion of individuals above the cut-off (50 ng/mL THC) may be allowed to enter the risk-sensitive area. The SFP test rate of 0.000% complies with the ethical notion of not accusing an innocent person falsely.

6.5.7.6.4 Device C

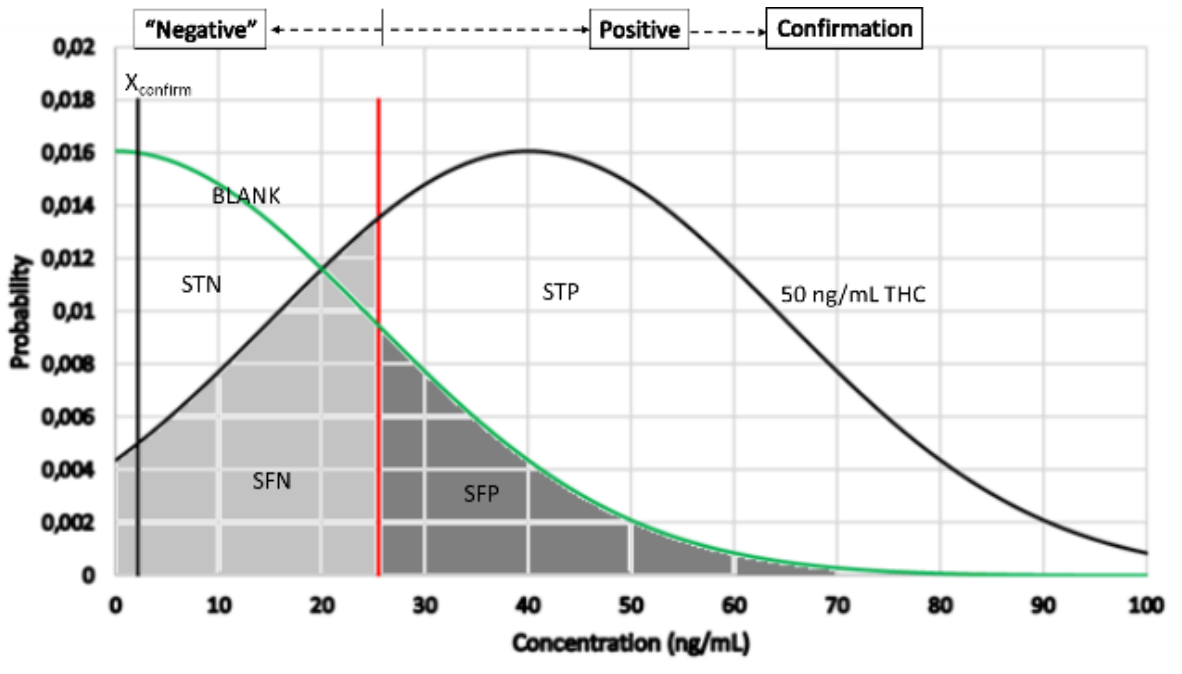


Figure 6:18 Group distribution with a 40 ng/mL screening cut-off concentration for device C

DEVICE C	
	ng/mL
N = 60	
Detection line concentration	25,5
Screening standard deviation	24,8
Confirmation threshold	2,2
Diagnostic specificity @ 2.2 ng/mL THC (%)	0,0637
Negative	0
- 50% Cut-off	20
- 25% Cut-off	**30**
Cut-off (40)	**40**
+ 25 Cut-off	**50**
+ 50% Cut-off	60
Diagnostic sensitivity (@ cutoff)	0,7206
Diagnostic specificity (@ cut-off)	0,2794
Screening false-positive probabililty (SFP)	0,1519
Screening false-negative probability (SFN)	0,2794
Screening true-positive probability (STP)	0,5687
Screening true-negative probability (STN)	0,3481
Positive predictive value (PPV) %	78,9178
Negative predictive value (NPV) %	55,4741
Overall efficiency %	**68,0060**
Predicted screen cut-off (99.99% confidence)	76,8800

- Device C has the largest σ_{SCREEN}, which is reflected in all the parameters. The predicted screen cut-off at 99.99% confidence which is equal to 76.88 ng/mL is also larger than the prescribed threshold of 50 ng/mL; however, the concentration at which THC is detected is fixed at 25.5 ng/mL THC.
- The SFP rate of 15.2% for a test result serves as evidence that all non-negative test results have to be submitted for confirmation analysis at a forensic laboratory. The SFN rate of 27.94% indicates that a large portion of individuals may indeed be proven to be indeed below the cut-off (40 ng/mL THC).
- Also note that the SFN rate is equal to 27.9%, which means that a large portion of individuals, who is above the cut-off (40 ng/mL THC) will be allowed to proceed with their risk-sensitive tasks.

6.5.7.6.5 Device D

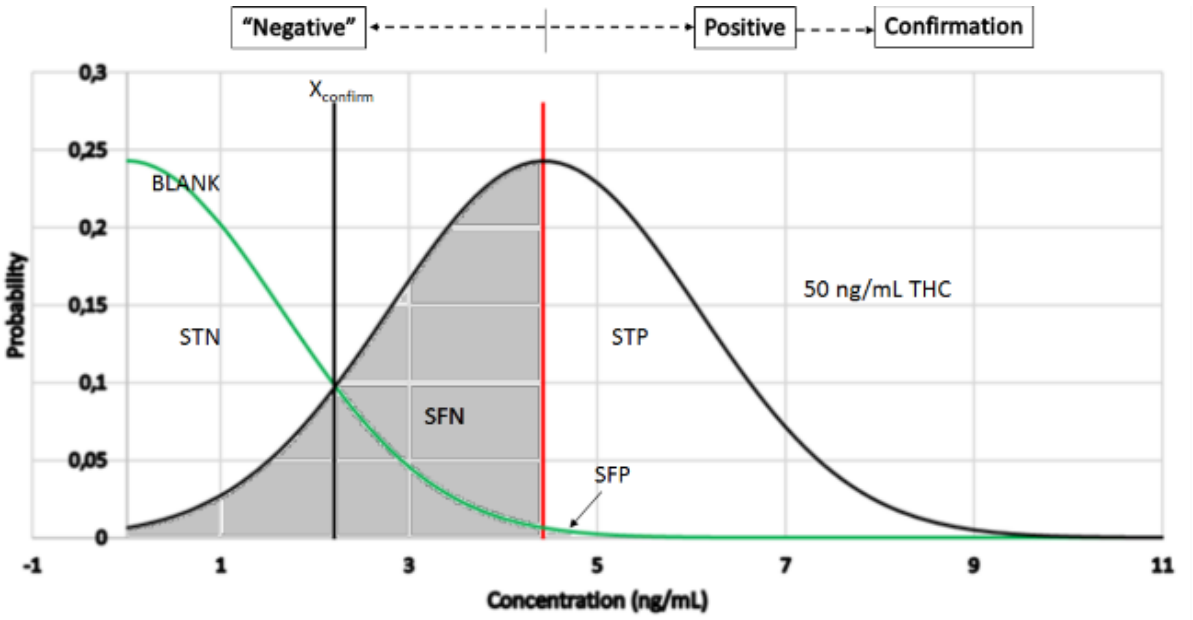


Figure 6:19(A) Group distribution with a 5 ng/mL screening cut-off concentration for device D

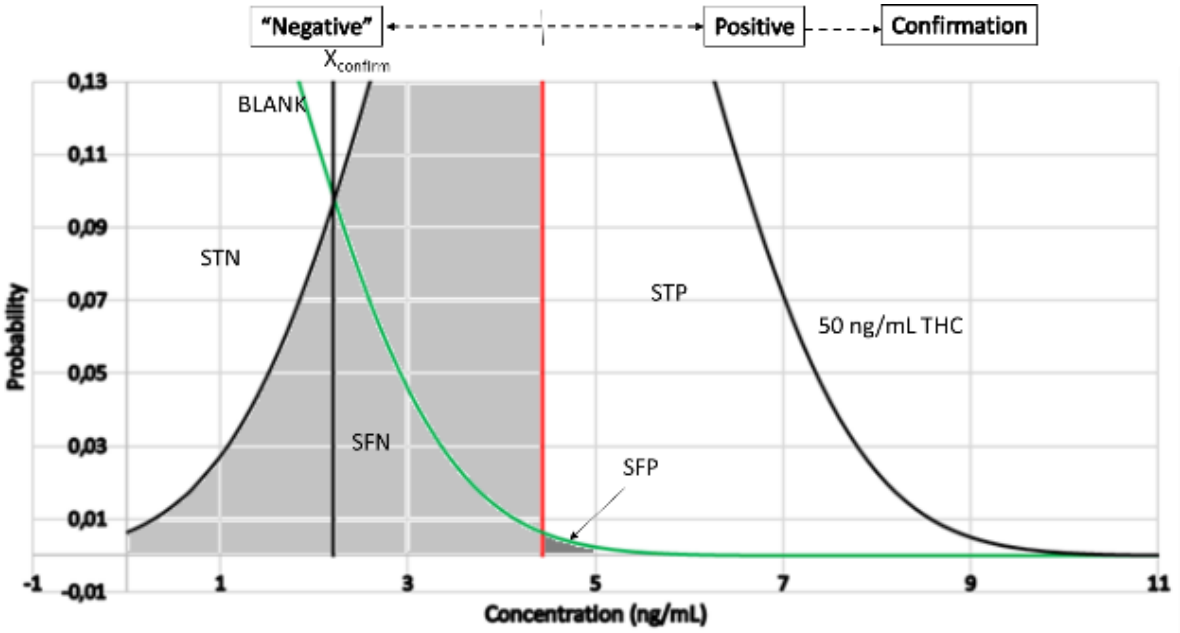


Figure 6:19 (B) Group distribution with a 5 ng/mL screening cut-off concentration for device D

- The statistics for device D are comparable to that of the first two devices (A and B), only it was achieved at a 10 x lower cut-off concentration, which is much closer to the oral fluid impairment level of 2 ng/mL THC. A 10 x decrease in σ_{SCREEN} accommodated the lowering of the cut-off concentration to 5 ng/mL THC compared to device A.
- The predicted screen cut-off (99.99% confidence) corresponds with a cut-off level of 5 ng/mL. The combination of the cut-off at 5 ng/mL and σ_{SCREEN_D} resulted in an overall efficiency of 75.4%.
- At 5 ng/mL THC cut-off, the SFP rate equals 0.35% and the SFN % is equal to 36.41%. The low SFP rate enhances the ethical treatment of innocent individuals; however, an SFN rate of 36.41% may increase the risk for the organisation. Incorrectly or falsely classifying these individuals as below the cut-off will have no further implications on the individual, but may affect the organisation's health and safety.

DEVICE D	
	ng/mL
N = 10	
Detection line concentration	4,43
Screening standard deviation	1,64
Confirmation threshold	2,2
Diagnostic specificity @ 2.2 ng/mL THC	0,0439
Negative	**0**
- 40% Cut-off	**3**
- 20% Cut-off	**4**
Cut-off (5)	**5**
+ 20 Cut-off	**6**
+ 40% Cut-off	**7**
Diagnostic sensitivity (@ cut-off)	0,6359
Diagnostic specificity (@ cut-off)	0,3641
Screening false-positive probabililty (SFP)	0,0035
Screening false-negative probability (SFN)	0,3641
Screening true-positive probability (STP)	0,6325
Screening true-negative probability (STN)	0,4965
Positive predictive value (PPV) %	99,4568
Negative predictive value (NPV) %	57,6956
Overall efficiency %	**75,4408**
Predicted screen cut-off (99.99% confidence)	5,0840

6.5.7.6.6 Summary of the evaluation study

The performance of a screening test is inextricably linked to ethics, and ethical conduct by the organisation and test device operators includes not only the virtue of honesty but also the trueness of analytical results. The combination of σ_{SCREEN} and the screening cut-off is one of the important factors when regulatory thresholds are established. A balance needs to be struck between the technology that is available and the levels of impairment to obey the ethical rule of not accusing a person falsely, or of not performing a medical intervention if there is not a reasonable prospect that the intervention will serve its purpose. By employing the wrong or poor quality drug screening tests, harm may be inflicted on an individual who is in an unsymmetrical relationship with the organisation.

DEVICE A

THC test concentration range	ng/mL	Number of negatives Package insert (Simulation)	Negatives Probability Package insert (Simulation)	z-value	Number of positives Package insert (Simulation)	Positives Probability Package insert (Simulation)
N = 30			Diagnostic specificity			Diagnostic sensitivity
Decision level concentration	40,1					
Screening standard deviation	17,1					
Confirmation threshold	2,2	(29,4)			(0,62)	
Diagnostic sensitivity @ 2.2 ng/mL THC	1,30%					
Negative	0	30			0	
- 50% Cut-off	25	30 (24,3)	1 (0,81)		0 (5,7)	0 (0,19)
- 25% Cut-off	37,5	30 (16,5)	1 (0,55)		0 (13,5)	0 (0,45)
Cut-off (50)	50	10 (8,4)	0,333 (0,282)	-0,56	20 (21,6)	0,667 (0,718)
+ 25 Cut-off	62,5	4 (2,9)	0,133 (0,095)	-1,2	26 (27,1)	0,867 (0,905)
+ 50% Cut-off	75	0 (0,62)	0 (0,021)		30 (29,3)	1 (0,979)
Screening false-positive (SFP) rate						
Screening false-negative (SFN) rate						
Overall efficiency						
Positive predictive rate						
Negative predictive rate						

DEVICE B

THC test concentration range	ng/mL	Number of negatives Package insert (Simulation)	Negatives Probability Package insert (Simulation)	z-value	Number of positives Package insert (Simulation)	Positives Probability Package insert (Simulation)
N = 50			Diagnostic specificity			Diagnostic sensitivity
Decision level concentration	47,7					
Screening standard deviation	9,32					
Confirmation threshold	2,2	(50)			(0)	
Diagnostic sensitivity @ 2.2 ng/mL THC	2,20%					
Negative	0	50				
- 50% Cut-off	25	50 (49,6)	1 (0,992)		0 (0,38)	0 (0,008)
- 25% Cut-off	37,5	49 (42,5)	0,98 (0,85)		1 (7,5)	0,002 (0,15)
Cut-off (50)	50	22 (20,0)	0,44 (0,4)		28 (29,95)	0,56 (0,6)
+ 25 Cut-off	62,5	4 (3,1)	0,08 (0,062)		46 (46,9)	0,92 (0,938)
+ 50% Cut-off	75	1 (0,1)	0,02 (0,002)		49 (49,9)	0,98 (0,998)
Screening false-positive (SFP) rate						
Screening false-negative (SFN) rate						
Overall efficiency						
Positive predictive rate						
Negative predictive rate						

Figure 6:20 Devices A, B response data, z-score, negative, and positive probability. The predicted number of positives and negatives obtained by the simulation, as suggested in this text is given in brackets

DEVICE C							
THC test concentration range	ng/mL		Number of negatives Package insert (Simulation)	Negatives Probability Package insert (Simulation)	z-value	Number of positives Package insert (Simulation)	Positives Probability Package insert (Simulation)
N = 60				Diagnostics pecificity			Diagnostic sensitivity
Decision level concentration	25,5						
Screening standard deviation	24,8						
Confirmation threshold	2,2		(48.5)			(10,4)	
Diagnostics sensitivity @ 2.2 ng/mL THC	17,40%						
Negative	0		60			0	
- 50% Cut-off	20		60 (35,3)	1 (0,589)		0 (24,7)	0 (0,411)
- 25% Cut-off	30		54 (25,6)	0,9 (0,43)		6 (34,3)	0,1 (0,57)
Cut-off (40)	40		10 (16,7)	0,167 (0,278)		50 (42,3)	0,833 (0,722)
+ 25 Cut-off	50		5 (9,6)	0,083 (0,16)		55 (50,3)	0,917 (0,84)
+ 50% Cut-off	60		0 (2,3)	1 (0,038)		60 (53,6)	0,99 (0,962)
Screening false-positive (SFP) rate							
Screening false-negative (SFN) rate							
Overall efficiency							
Positive predictive rate							
Negative predictive rate							

DEVICE D							
THC test concentration range	ng/mL		Number of negatives Package insert (Simulation)	Negatives Probability Package insert (Simulation)	z-value	Number of positives Package insert (Simulation)	Positives Probability Package insert (Simulation)
N = 10				Diagnostics pecificity			Diagnostic sensitivity
Decision level concentration	4,43						
Screening standard deviation	1,64						
Confirmation threshold	2,2		(9,1)			(0,9)	
Diagnostics sensitivity @ 2.2 ng/mL THC	8,70%						
Negative			10			0	
- 40% Cut-off	3		10 (8,1)	1 (0,81)		0 (1,9)	0 (0,19)
- 20% Cut-off	4		9 (6)	0,9 (0,6)		1 (4,1)	0,1 (0,41)
Cut-off (5)	5		4 (3,6)	0,4 (0,36)		6 (6,4)	0,6 (0,64)
+ 20 Cut-off	6		2 (1,7)	0,2 (0,17)		8 (8,3)	0,8 (0,83)
+ 40% Cut-off	7		0 (0,6)	0 (0,06)		10 (9,4)	1 (0,96)
Screening false-positive (SFP) rate							
Screening false-negative (SFN) rate							
Overall efficiency							
Positive predictive rate							
Negative predictive rate							

Figure 6:20 Devices C and D response data, z-score, negative, and positive probability. The predicted number of positives and negatives obtained by the simulation, as suggested in this text is given in brackets.

6.6 CONCLUSIONS

Current scientific issues on prohibited substance regulation and testing in South Africa were addressed.

A study was conducted on the number of test subjects to be sampled randomly to ensure reliable sampling of individuals and to enable reliable inferences to be made about the organization's population drug use. The sampling process must ensure that the number of individuals chosen are representative of the group or population. The hypergeometric distribution was suggested to serve as a means to calculate the minimum number of subjects per group to be selected randomly. "Over-selection" of individuals may be seen as unethical due to the unnecessary biomedical interventions when individuals are subjected to a prohibited substance test. The minimum sample sizes were calculated and provided for different levels of confidence.

It was also concluded that *zero-tolerance* should not be equated to "zero concentration". The former refers to a stance against the use of prohibited substances if the subject's test result is above a certain threshold. The intention is to make sure that the test subjects are drug-free. The latter may not pass legal scrutiny, especially if the concentration levels are below the levels that mark the onset of impairment.

Detection of an impaired drug user can be performed by lay witness observation of objective signs of impairment as well as by behavioural observational techniques such as sobriety testing and clinical observation. The latter two require a higher level of skill.

Chemical recognition and detection in bio-matrices were also reviewed by discussing the applicability of various bio-matrices available for prohibited substance testing and the detection time afforded by these matrices.

Cannabis (THC) was used as an example of how to assess the literature to obtain impairment levels. The absorption, metabolism and elimination of THC in urine and oral fluid were discussed as possible matrices for THC testing in cannabis users. A dose-response relationship was found for THC excretion in oral fluid. However, the sampling process has some difficulties. Sampling can take place by either stimulated or non-stimulated collection. The stimulated collection mimicked blood THC levels more closely, compared to non-stimulated collection methods.

It was found that there was no performance impairment below 2 ng THC/mL blood (4 ng THC/mL serum). This concentration level, therefore, may be used as a threshold for residual

THC in users in countries where cannabis is legalised. This threshold concentration value will also comply with ethical and human rights related to respect for an individual's privacy and freedom. Passive exposure also did not allow for values above 2 ng THC/mL serum.

The ideal matrix for THC testing would be blood, however, due to the invasiveness of blood sampling alternative matrices such as urine or oral fluid may be employed. Both of these matrices have their own "difficulties". The long-halflife of THC in urine is problematic since urinary THC-COOH concentrations is not a proxy for impairment and will also contradict the legalisation of cannabis use.

It is the opinion of the author that oral fluid (OF) may not pass legal scrutiny since the oral fluid collection will always be subjected to potential contamination of residual THC in the buccal cavity. Chemical detection of THC in oral fluid should be performed in combination with observational identification (See section 6.4) until scientifically sound *per se* THC oral fluid concentration levels is agreed upon by the scientific community. This will however, not solve the dilemma of possible buccal cavity contamination of an oral fluid specimen due to residual THC in the mouth. The importance of a written policy, wherein the threshold concentration levels of THC (in the specific matix) to be sampled and tested, is specified cannot be overstated since this will be regarded as the *guideline* as part of the employer-employee contract.

Preliminary drug testing (screening) strategies with lateral flow immunoassay screening devices were discussed, and the author presented a strategy on how to evaluate these devices from the data on package inserts supplied by the manufacturers. It is an ethical obligation to employ the correct technology since poor quality results may impact negatively on a test subject. Four commercial devices on the market in South Africa were used as examples to study the relationship between drug screening and confirmation cut-off concentration levels. A novel approach is suggested to extract the information from the package inserts by the operators of these devices. The figures of merit related to the performance of these devices were calculated and used to make recommendations regarding the performance of these devices.

CHAPTER 7:

REGULATORY FRAMEWORK AND FINAL CONCLUSIONS

7.1 INTRODUCTION

The requirements of an ethically sound, legally correct and scientifically accurate prohibited substance regulation and testing program in humans were studied and highlighted in this document. The requirements were obtained by studying international prohibited substance regulation and testing programs namely the: (1) mandatory guidelines of the USA Federal Drug-Free Workplace drug-testing programme overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA) and (2) World Anti-Doping Association (WADA) programs.

This section will formulate regulations and minimum requirements of each phase, of a prohibited substance regulation and testing program, which comply with the Constitution of the Republic of South Africa and relevant statutes. Ethical principles which need to be obeyed by the professionals as part of the program will also be taken into account. The principles of forensic toxicology and analytical chemistry will also be observed since no justice can prevail if these are not meticulously followed to fulfil the requirement that "Science must inform the law".

The "balance of probabilities" standard of proof also requires an accurate test result similar to a standard of "beyond a reasonable doubt". A test result which is only 51% correct for instance should not be employed as evidence since it will not represent the "full truth" and is, therefore, unreliable to be employed as part of decisive action against an individual.

7.2 REGULATORY APPROACH

The following general aspects need to be addressed in the design of a prohibited substance regulation and testing program namely (1) Prohibited substance control in the organisation by way of a policy that explains the rules (2) Education and sharing of information on prohibited substance use and also the program itself (3) Roles and responsibilities of all parties

In addition to the above outline special attention needs to be paid to the: (1) Prohibited list of substances, (2) Prohibited substance testing and investigations, (3) Laboratories, (4) the therapeutic use of substances included in the list, and (5) protection of privacy and other confidential information.

7.2.1 Policy on prohibited substance control and testing

7.2.1.1 Statement of need and purpose

The main reasons and approach to the program need to be highlighted. The following should be taken into account:

- The highest priority of the program is to minimise risk to the interests of all involved in the activities of the organisation, i.e. the individual, fellow individuals as well as to the organisation.
- The general approach should respect dignity, autonomy, privacy and confidentiality of the test subject's information as far as the interests of others are not compromised. The interests may involve health and safety, property and a learner's development, for instance.
- Rules and laws (statutes) need to be respected.

7.2.1.2 To whom do the prohibited substances rules apply

The rules of the program should apply to individuals to whom there is a risk to health and safety (or other interests), which has to be specified by the organisation. Fair discrimination is acceptable if a clear and sound motivation, in line with the objectives of the program, exist for testing in terms of testing frequency, - methodologies, - protocols and procedures. The policy should be obeyed and respected by everybody in the organisation, regardless of race, position or status in the organisation.

7.2.1.3 Organisation's responsibilities

The organisation is the custodian of the program and has the responsibility to:[1]

- Initiate a prohibited substance regulation and testing program which complies with the Constitution of the Republic of South Africa that is procedurally fair and consistent with relevant statutes (as discussed in this document), ethics, professionalism and reliable scientific principles.
- The programme must be based on the principles of separation of powers and just administrative action to ensure sufficient independence between the organisation, testing – and test validation processes.[2]
- Maintain the prohibited substance regulation and testing programme by regular revisions of the policy and to ensure that the test subjects are informed on the changes.

[1] Refer to section 4.2.1.3 of this document for a discussion on the organisational responsibilities as far as prohibited substance regulation and testing is concerned.

[2] Promotion of Administrative Justice Act as discussed in Section 5.3.6 of this document.

- To provide the resources and infrastructure for the program and also to employ professionally qualified individuals to take part in the execution of the programme.
- Ensure that the program and the rules are executed consistently for all involved in a fair and just fashion in line with the purpose of the programme.
- To disclose the use, possession and trafficking of prohibited substances to the police compliant to the relevant legislation.[3]
- To establish and publish threshold concentrations for the substances enlisted in the prohibited substance list that are safe and scientifically correct and also accommodate the autonomy of an individual to consume of these substances in a legal manner.
- To withdraw an individual from risk-sensitive tasks when using a prescription medication that has impairment potential.
- To accommodate individuals with an addiction problem to the extent that is fair to the organisation and the individual.
- To assist the test subject in making contact with drug abuse professionals in a way compliant with the organisation's policies and legal obligations

7.2.1.4 Subject's responsibilities

Test subjects have the following obligations and responsibilities: [4]

- Subjects have a responsibility to acquaint themselves with the rules of the program
- To be available for specimen collection during the times which is agreed upon and which is reasonable and within the scope of risk minimisation.
- To be responsible with the substances they consume and to inform health practitioners and other medical personnel of the individual's obligations to comply with the programme.
- Prohibited substances should be kept below the threshold concentration levels in biospecimens as specified in the policy.
- To consult with the medical personnel confidentially regarding their personal medication use that may affect their abilities to function in a risk-free manner.

[3] POPI Act as discussed in section 5.3.4 of this document.
[4] Refer to section 4.2.1.4 of this document.

7.2.1.5 Self-referrals and voluntary drug testing

The policy should accommodate self-referrals to provide individuals with the chance to have them tested before entering the events in the interest of honesty and risk minimisation and also to avoid punitive action before entering the testing process.[5]

7.2.1.6 The requirement of consent and privacy and confidentiality

The test subject's voluntary, free, informed written consent has to be obtained at various levels of the process, namely:

- when the subject joins the organisation, he or she will be informed of the prohibited substance regulation and testing program
- when the subject accepts the policy to the extent that he or she understands the contents and willingly and voluntarily submits to the rules of the policy
- before each biomedical intervention such as a prohibited substance testing procedure.

7.2.1.7 Elements of consent involved in prohibited substance testing

The following aspects are threshold elements of informed consent, which involves more than only a "yes/no" answer from a test subject:[6]

- The individual must be competent to understand and decide
- The decision must be voluntary and rational within the abilities of the individual
- Information regarding the intervention has to be disclosed fully.
- The subject must also be informed that he/she may withdraw consent at any stage of the drug testing process; however, this will have consequences.
- Confidentiality, truth-telling and effective communication are principal elements that support consent.
- The individual may designate a person he deems suitable to receive the test result, which can be himself, however, the confirmation laboratory will indicate to the employer that the test report has been released so that the individual has to present the test report to the MRO.

7.2.2 Education and sharing of information

Test subjects, as well as supervisors, require training to support the program.[7]

[5] Refer to section 4.2.1.3 of this document for a discussion on "self-referrals" and "voluntary drug testing".
[6] Please refer to section 2.2.2.3 for a more elaborate discussion on the threshold elements of informed consent.
[7] Refer to section 4.2.1.3 of this document.

7.2.2.1 Test subject training

The test subject should receive training with documented outcomes on the:

- programme and the rules thereof
- roles of all the professionals involved
- collection protocols
- concept and elements of voluntary free and informed consent[8] and that the test is a compliance test.
- how to treat prescription-, and over the counter medication and how to seek advice from the medical personnel involved in the administration of the programme in a responsible manner.

7.2.2.2 Supervisor training

Supervisors should receive training on the following aspects:[9]

- How to recognise drug users, symptoms of "intoxication" and understand the necessary observations to be made objectively for sobriety testing.
- The direct supervisor may not be involved in the testing procedure; the person involved should be at least one level above the direct supervisor.

7.2.3 Definition of violations

A violation regarding a prohibited substance regulation and testing programme should be defined as:

- the individual has the responsibility to ensure that he/she does not consume prohibited substances in a way that can violate the rules of the policy.
- the presence of a prohibited substance or its metabolites in the specimen of an individual above a specified concentration level (threshold level) agreed upon by the organisation and the test subjects as specified in the policy. The specimen, as well as the concentration levels, needs to be specified.
- refusal (or evasion) by the test subject to submit specimen collection. Failing to submit a specimen without a legitimate reason may also be viewed as a violation.[10]

[8] Refer to section 2.2.2.3 of this document
[9] Refer to section 4.2.1.4 of this document
[10] Please refer to section 4.2.1.9 for a more extensive discussion on "refusal-to-test"

- tampering or attempted tampering with any part of prohibited substance regulation and testing programme.
- possession of a prohibited substance on the premises which include illegal substances as well as substances which requires a legitimate prescription by an HPCSA registered medical practitioner or a nurse registered at the South African Nursing Council (SANC).
- the individual will have the right to withdraw his/her consent; however, this will have implications which should be comparable to that of a positive confirmed and validated test result. [11]

7.2.4 Proof of prohibited substance misuse

7.2.4.1 Burden and standard of proof

- The organisation has to establish proof of a violation to the satisfaction of the presiding officer of a court or tribunal. The strict liability on the individual may be rebutted on a balance of probability standard of proof after an interview with the test subject by a Medical Review Officer (MRO) before a hearing is conducted.
- The MRO will establish if the test subject used the prohibited substance negligently or intentionally during the test result validation interviews on the balance of probabilities.
- If the test subject asserts that a departure from a policy rule has caused an adverse finding, the burden of proof will be on the organisation to prove that the adverse finding was not due to the departure on the balance of probabilities. If a departure is confirmed the organisation will have to prove that it did not affect the test result

7.2.4.2 Obtainment of information regarding presumptions

Facts can be established by any reliable means, which may include:

- Interviews with an MRO
- Analytical chemical methods
- Observations by sobriety testing amongst others
- Forensic confirmation laboratories with ISO 17025 accreditation
- Decisions by courts and other professional tribunals
- The hearing panel on the prohibited substance misuse violation

[11] Withdrawal of consent should not be viewed as an acknowledgement of guilt but should have at least the same sanction as a validate positive test result with no legitimate excuse would have.

7.2.5 List of prohibited substances

- Substances must be enlisted in a rational purpose-driven fashion, which respects the autonomy of an individual and his/her constitutional rights such as equal enjoyment of the protection of the law, no discrimination, and right to life, which includes self-medication.
- The purpose of the list is to include substances that may affect the faculties of an individual to the extent that he/she may increase the risk to himself or others or the organisation. A prohibited substance list should also be updated frequently, and the test subjects must be informed on any changes.

The list should at a minimum include the following substances:

- Ethanol (ethyl alcohol) commonly referred to as "alcohol."
- Cannabis with active constituent Δ^9-THC.
- Substances controlled by statute and which are listed in schedules 5 to 8 of the Medicines and Related Substances Control Act[12] of examples are shown in appendix 3.[13] Schedules 5 and 6 medicine is habit-forming and has potentially harmful side effects and require a legitimate prescription for legal possession. These include psychoactive medication (sedatives, anti-depressants) and narcotic painkillers for which a. Schedules 7 and 8 substances are the "controlled substances" and "strictly controlled substances", respectively. These include compounds like heroin, amphetamines, methamphetamine, cathinone, LSD, methcathinone, gamma-hydroxybutyrate (GHB), nabilone (Synthetic THC), synthetic cannabinoids, psilocin, and psilocybin, amongst others.
- Synthetic analogues of prohibited substances, which mimic the effect of the controlled substances and not registered as legitimate medication at the Medicines Control Council of South Africa.
- Over-the-counter medication such as cold and flu remedies and antihistamines amongst others.
- Any other substance that may impair the faculties and neurological function of an individual.

[12] Medicines Act 101 of 1965 sec 22A(1).
[13] Refer to section 5.3.3. of this document.

7.2.6 Ethics "checklist"

The program should be designed with respect for autonomy, nonmaleficence, beneficence and justice,[14] which are crystallised in the minimum requirements for prohibited substance regulation and testing.[15] The program should be evaluated against the following principles or criteria: (1) social value of the program, (2) scientific validity, (3) fair subject selection, (4) favourable benefit-risk ratio, (5) independent review,[16] (6) informed consent, (7) respect for participants.

The program has to be supported by the following:[17]

- ethical clearance by a committee instituted by statute[18]
- an action policy involving a stance of zero-tolerance for validated, illegitimate (knowingly, wilfully or negligent) substance use that pose a risk to health and safety and other interests.[19]
- the necessary expertise and professionalism of all professionals involved in the administration of the program
- participant safety
- compliance with the legal framework of the Republic of South Africa.
- The factors to be considered in the policy needs to be listed in the policy for each of these since all participants need to take note of the ethical aspects to be complied with.

7.2.7 Testing and investigations

The primary purpose of testing is to gather analytical evidence regarding the test subject's compliance with the programme.

The organisation have to plan the following:[20]

- the distribution of tests
- the number of tests according to a statistically viable model.[21]

[14] Refer to section 2.2.2 of this document
[15] Refer to section 2.5.4 of this document
[16] Ethical overview should in the opinion of the author be performed on the authority of a statute, at a standard equivalent to that of clinical research which is aligned with the Nuremberg Code. Please refer to section 2.5.4 of this document.
[17] Refer to section 2.5.4.2 of this document
[18] Refer to section 2.5.4; NHA ch 9.
[19] Refer to section 6.1 and 6.2 of this document.
[20] Refer to section 4.2.1.4 of this document
[21] Please refer to section 6.3 of this document for a discussion on random selection based on the hypergeometric distribution.

- the type of tests such as random, pre-employment, periodic medical, random testing, reasonable cause or suspicion, post-accident/incident, return-to-duty, follow-up testing or other possible reasons that may depend on the specific industry
- What matrices will be used for testing (urine, oral fluid, sweat, hair, blood)
- Which drugs will be tested for (as enlisted in the prohibited list)
- How will the testing be performed (analytical techniques for preliminary and confirmatory testing)
- What type of preliminary testing devices will be employed for testing (commercial brands for alcohol and drugs need to be specified and evaluated) and registered according to the South African Health Products Regulatory Authority Act[22]
- What threshold concentrations will be used to decide an adverse finding for the preliminary assay as well as the confirmatory assay Flow diagram of the prohibited substance testing program
- Flow diagram illustrating the testing sequence of events (see figure 7:2 below)
- A prohibited substance testing flow chart should be included in the policy. The flow chart as suggested by this document represents a sound approach.[23] The following figure will also serve as an additional explanation to highlight the sequence of events, (See figure 7.1 below).

[22] Section 5.3.10

[23] Refer to section 4.2.1.3 which includes table 4:1 and figure 4:1 in this document

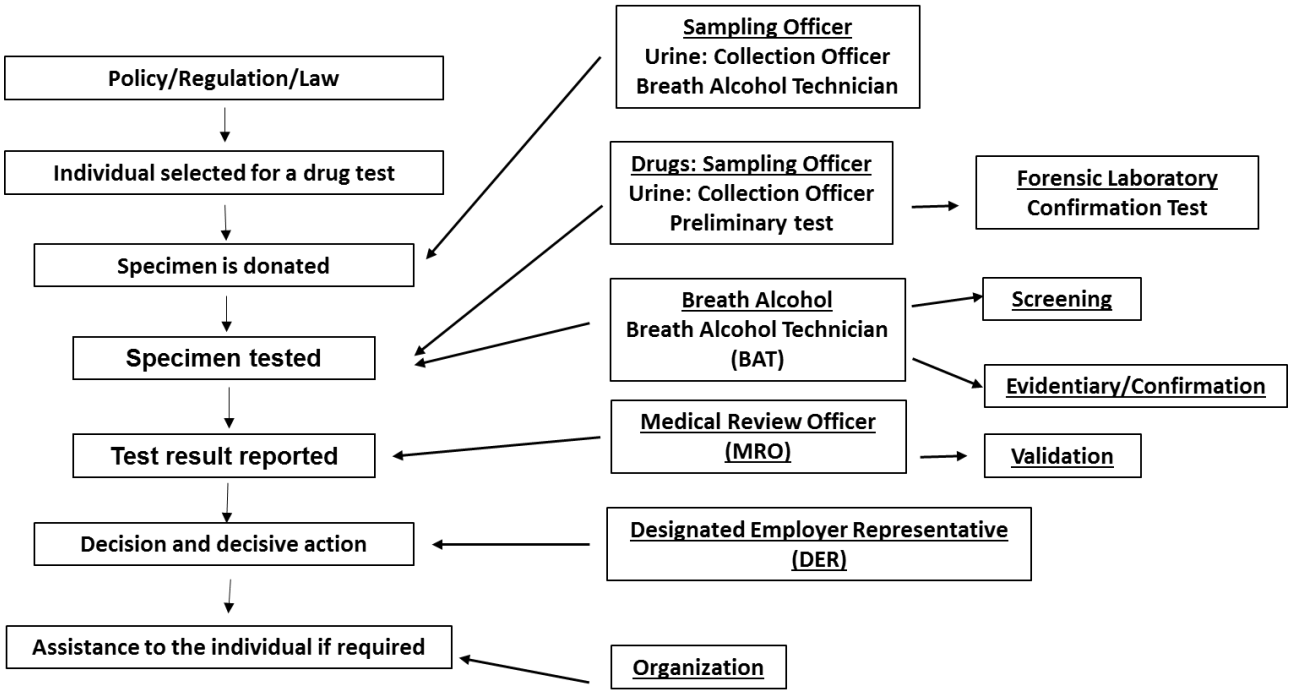


Figure 7:1 The sequence of events during a prohibited substance test indication the various professionals involved in the administration of the programme.

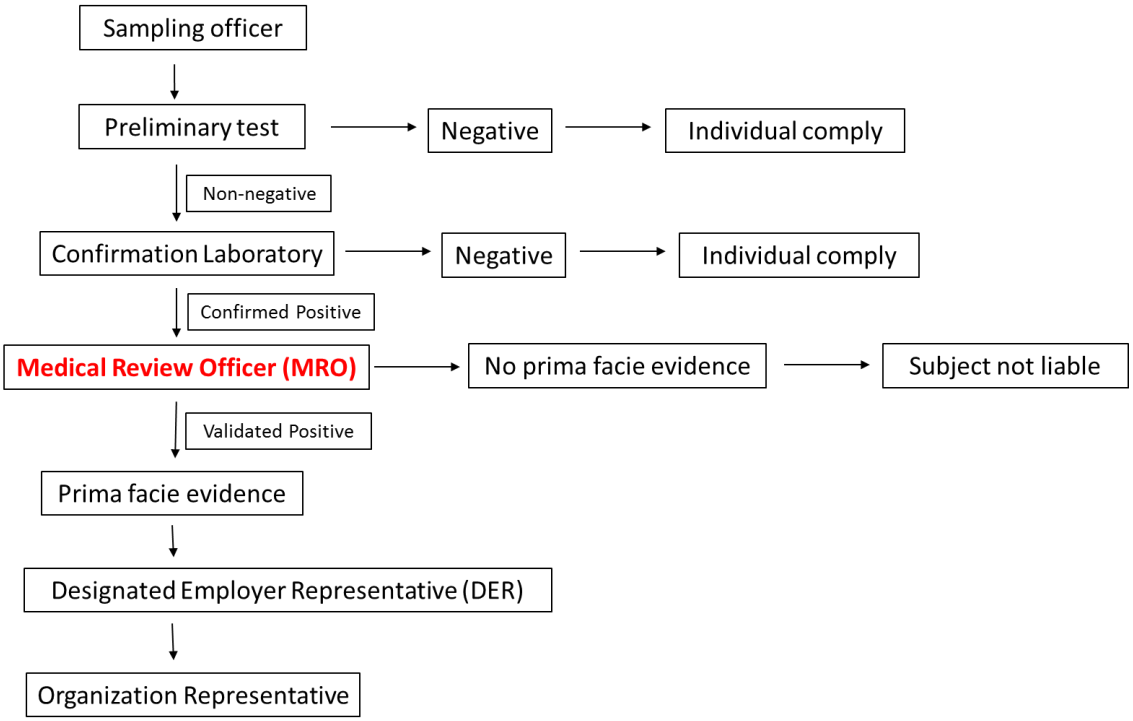


Figure 7:2 Compliance of the test subject concerning the sequence of events

7.2.7.1 Roles, minimum qualifications and professional affiliations of professionals

The organisation is responsible for the policy drafting and nomination of the specific individuals to be tested in an unbiased fashion

Sampling Officer

After the nomination of an individual, he or she has to donate a specimen without unnecessary delays under the guidance of a trained sampling officer who:[24]

- request the individual's written voluntary informed consent before specimen donation,
- supervise the collection procedure in a legally defensible fashion that prevents tampering and preserves the integrity of the specimen in a way that is sensitive to the dignity and privacy of the individual. (observed urine specimen only when a reasonable suspicion was established by previous collections such as proof of tampering)
- conduct the preliminary test with a registered preliminary testing device as specified in the policy in the subject's line of sight [25]
- in the case of a non-negative preliminary test result seal the specimen with the tamperproof seal before making arrangements for the specimen to be shipped to a specific forensic toxicology laboratory as specified in the policy. The confirmation laboratory should have ISO17025 accreditation.
- Typical screening threshold concentration levels have to be documented in the policy.
- The sample collection and preliminary testing procedure should be conducted in a facility that guarantees auditory and visual privacy. The preliminary test includes not only the testing for the prohibited substance but also validity testing, which is performed to prevent tampering with the specimen.
- The sampling officer should then inform the designated employer representative (DER) of the non-negative test result in order to initiate the stand-down protocol while the confirmation test result is awaited.

Forensic Toxicology Laboratory should:[26]

- be specified in the policy as well as contact details provided

[24] Please refer to section 3.3 of this document for a summary of the general role of collection officers and the ethical and professional standards for this profession.
[25] Please refer to section 5.3.10 on the registration of preliminary drug-testing devices.
[26] Refer to section 3.4.2 for a discussion on the general role of the forensic confirmation laboratory and professional requirement in a prohibited substance regulation and testing environment.

- receive the specimen in a sealed fashion and document the integrity of the seal and observe the chain of custody
- have ISO17025 accreditation for the relevant analyses with internationally recognised analytical confirmation techniques such as GC-MS and LC-MS.
- have properly trained professionals who are affiliated to the relevant professional regulatory bodies which required a certain level of academic training and ethical compliance.[27] (SACNASP and/or HPCSA)[28]
- Report the test result to the designated person as per the consent form in a confidential manner.

Breath Alcohol Technician (BAT):[29]

- The breath alcohol technician should conduct the confirmation breath test with an evidentiary breathalyser in a fashion that is equivalent to an ISO17025 accredited test procedure.[30] The test must be performed in a legally defensible manner that is sensitive to human dignity, and that guarantees an accurate test result.[31]
- The BAT should also obtain voluntary written informed consent from the donor before the test is conducted.
- The preliminary and evidentiary testing procedure should be conducted in a facility that guarantees auditory and visual privacy.
- The confirmatory test requires no MRO interpretation except in the case of a 'shy-lung' whereby the donor experience deficiency to donate sufficient breath for the test to be performed.

The Medical Review Officer (MRO):[32]

- The role of an MRO is also defined as "a licensed physician responsible for receiving laboratory results generated by an agency's drug-testing program who has knowledge of

[27] Please refer to section 3.4 for a discussion on the academic training requirements and professional attributes of a Forensic Toxicologist.
[28] It is the opinion of the author that there are no professional body currently in South Africa with a suitable registration category that fits the daily tasks and challenges of a forensic toxicologist. The HPCSA is the closest of the two possible bodies due to the ethical standard it requires when patients are involved.
[29] Please refer to section 3.4.3 for a discussion on alcohol testing services and the general role of a breath alcohol technician.
[30] It is the opinion of the author that the evidentiary breath testing facility should also be ISO17025 accredited in light of the decisive/disciplinary action that may follow in case of a positive confirmed breath test result.
[31] The preliminary breath alcohol screening test should not be confused with an evidentiary test which is performed on a forensically acceptable level.
[32] Refer to section 3.5 for information on the general role of the MRO.

substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result with his or her medical history and any other relevant biomedical information. Please see figure 7:2

- The MRO acts as a gatekeeper in the drug testing process by validating laboratory confirmed test results, since a positive result does not necessarily imply that an individual has a drug misuse issue.
- The MRO must interview the donor to obtain information in order to decide about possible drug misuse before giving the result through to the organisation's representative (DER) who in turn will convey the information to management.[33] Misuse can be defined as intentional or negligent use of a prohibited substance without a legitimate excuse.

Designated employer representative (DER):[34]

- The DER should be formally employed by the organisation and whose responsibilities involve the receiving of test results from the MRO and BAT in a confidential manner
- The DER should communicate test results to management as received from the MRO and BAT.
- The DER should instruct the removal of an individual from a safety-sensitive activity and must be familiar with all the protocols and procedures.[35]

7.2.8 Organisation's actions after receiving confirmed and validated test results

7.2.8.1 Stand-down protocol

A formal stand-down protocol should be documented in the policy. The stand-down protocol is initiated after:

- a non-negative preliminary drug test result or a confirmed positive drug test result (dilute positive results as well).
- preliminary breath test results if the cut-off concentration limit is exceeded.[36]
- confirmed positive alcohol test result.
- alcohol and drug use on duty.

[33] Refer to section 5.4.7.2.4 in this document regarding the gate keeping role of the MRO in the legal setting.

[34] Please refer to section 3.4.3 for a discussion on alcohol testing services and the general role of a breath alcohol technician.

[35] Please refer to section 4.2.1.3 for more information on the responsibilities of the DER.

[36] The SAMHSA guidelines define the limit for alcohol as 0.04. If the test result is between 0.02 and 0.039, the employee is removed from safety-sensitive duties for a defined period or until re-tested below 0.02. If the test result is confirmed to be above 0.04, he/she is not reinstated to a safety-sensitive duty until he has met with return-to-duty requirements.

- using alcohol within two hours after an incident if the employee knows that a drug and alcohol test will be required.

7.2.8.2 Definition of refusal-to-test

A refusal-to-test by the subject constitutes one of the following

- not appearing typically two hours after the instruction of the DER
- not completing the collection procedure
- refuses an observed specimen collection
- not cooperating with the collection officer
- not providing a second specimen on request of the collection officer
- not providing a specimen after the MRO evaluated him or her medically and concluded that there is no legitimate reason for not being able to donate a urine specimen.
- an adultered specimen is regarded as a "refusal to test"[37]

7.2.8.3 Consequences for a "refusal-to-test"

Consequences for a refusal to test should be included to prevent misuse of the freedom and privacy at the cost of health and safety of others.

7.2.8.4 Consequences and sanctions for a confirmed positive, validated test result

Disciplinary action should be the very last resort and should be reserved for cases where the culpability of individuals is such that they have no legitimate excuse for the prohibited substance use, i.e. the prohibited substance was used intentionally or negligently which imposes risk on the fellow individuals in the organisation as well as to the organisation itself.

7.3 FINAL CONCLUSIONS

Introduction: This thesis has reviewed the tendency of humankind to use substances for medicinal and recreational purposes. The deleterious effects of some substances and the possible harm that may be caused to others and society at large necessitate the regulation of substances in many sectors of society. Some of these are the workplace, sports, and educational environments in the criminal justice and private environments.

The extent of the drug-abuse problem in South Africa was reviewed, and it was concluded that the high incidence of drug abuse in South Africa supports prohibited substance regulation and testing in risk-sensitive environments. It should be kept in mind that prohibited substance

[37] Swotinsky & Smith (n 15).

testing for compliance serves mostly as a deterrent, given that only a small fraction of a group is typically selected to undergo prohibited substance testing.

Regulation involves the drafting of policies which explains the rules of the prohibited substance programme as well as testing compliance. Regulation and testing may be viewed as an infringement of the individual's rights to autonomy, privacy, freedom and bodily integrity as well as the right to self-medicate however this has to be balanced against the rights of others such as health and safety for instance. The regulation and testing protocols and rules should, therefore, be designed to be least invasive with due respect for the inalienable rights of the individual.

Ethics: An ***approach was suggested to solve ethical dilemmas in the field of prohibited substance regulation and testing on the basis of the principalism approach***, as suggested by Beauchamp and Childress, and by viewing prohibited substance regulation and testing as a biomedical intervention. The principalism approach involves respect for autonomy, nonmaleficence, beneficence and justice.

Informed consent is of prime importance for prohibited substance regulation and testing in humans as it is one of the conditions for autonomy, and threshold elements such as competence and voluntariness should also be met before a prohibited substance test is performed on an individual. Additional elements such as confidentiality, truth-telling and effective communication with the test subjects have to complement the biomedical intervention.

Nonmaleficence should be balanced with beneficence as required by the Hippocratic Oath, and the rules of nonmaleficence must be stated unambiguously in a prohibited substance regulation and testing programme. An obligatory duty of care exists, and negligence should be avoided in the interest of both parties, i.e. the individual and the organisation. Incompetent individuals such as children should be assisted by surrogate decision-makers when providing consent for a prohibited substance test with special care to be taken by the surrogate not to be biassed or subjective or to act paternalistically.

Justice finds application in the forms of legal justice, rights-based justice and distributive justice. Procedural justice and social justice is essential for the programme to be regarded as ethical.[38]

[38] NHA ch 9

Prohibited substance tests are mostly performed to monitor compliance, although it may be perceived as a medical-clinical diagnostic test, it is strictly speaking not a "medical diagnostic" test within a health worker-patient relationship. In addition, a prohibited substance test may result in disciplinary action as opposed to a medical test, which will result in the medical treatment of the individual.

The fact that prohibited substance test results can be used for decisive action against an individual, and also that the tests are also not always performed by skilled individuals, who should treat an individual in the correct ethical fashion***, prompted the novel suggestion that ethical oversight should be instituted by statute, at a standard equivalent to that of ethical clinical research which is aligned with the Nuremberg Code***. The minimum requirements for ethical clinical research were reviewed and employed to draft minimum ethical standards for prohibited substance regulation and testing. Ethical principles, corresponding ethical values and required expertise to evaluate ethical compliance of organisations were proposed.

***Professionalism*:** It was found that currently in South Africa there are no professional councils with categories suitable for registration of the group of professionals involved in the prohibited substance testing process in terms of education and training, professional conduct and ethical behaviour or continuing professional development. The general role, ethical and professional standards, and minimum educational requirements for each of the prohibited substance professionals were reviewed, and possible professional councils currently available in South Africa were assessed to act as professional bodies for these professions.

It is suggested that these professionals be registered at the HPCSA, under newly created categories due to the intimacy and "ethical overlap" that exist between these professions and the medical professions.

The general role of a forensic laboratory in a prohibited substance regulation and testing programme was reviewed, and ethical and professional standards were discussed. It was found that ISO 17025 accreditation is not a legal requirement currently in South Africa, which makes the quality management of forensic laboratories problematic. It was suggested that all forensic toxicology laboratories must be accredited by the ISO17025 standard for testing laboratories, as is required by WADA, for instance.

***International and foreign law*:** Foreign law and international law on prohibited substance regulation and testing programmes were reviewed, namely, the "Mandatory guidelines on workplace drug testing in the USA" and the rules for anti-doping of the "World Anti-Doping

Association (WADA)". The importance of a written policy was stressed in the interest of legal certainty for the test subjects and the administrators/professionals in the organisation. The independence of the different phases was highlighted in relation to the separation of powers principle, which is to be applied in the testing process.

The WADA prohibited substance regulation and testing programme are in the opinion of the author, the best system currently in the world. It has due consideration for ethical, legal and scientific aspects. A concern may also be raised regarding the privacy of an athlete as he or she has to inform the authorities of his whereabouts. Another concern is the principle of strict liability, which may conflict with the CSA in terms of which a person has the right to be presumed innocent. The separation of powers principle is, in the opinion of the author, also not well applied in the WADA prohibited substance regulation and testing system.

South African Legal Framework: The provisions of the CSA relevant to a prohibited substance regulation and testing programme were reviewed. These include the right to equality, human dignity, right to life, freedom and security of the person, privacy, freedom of belief and opinion, labour relations and children's rights. The importance of constitutional administrative rights such as access to information, just administrative action, and access to courts was also highlighted keeping the separation of powers principle in mind. It was also concluded that an individual's right to the use of substances for medicinal purposes are not absolute and can be limited if harm may be caused to another individual or the organisation's property. It is also essential to consider foreign- and international law when the Bill of Rights is interpreted.

The implications of current statutes on prohibited substance regulation and testing were reviewed. The relevant statutes are the Drugs and Drug Trafficking Act and the Medicines and Related Substances Control Act and POPI Act amongst others. The protection of personal information is enacted by the POPI Act, which provides the framework within which the personal information of an individual has to be treated as confidential. This also applies to the complete process of prohibited substance testing.

The Promotion of Equality and Prevention of Unfair Discrimination Act requires that there may be no discrimination towards individuals on specific grounds and also in general that diminishes human dignity, and adversely affects the equal enjoyment of a person's rights and freedom. Care must be taken not to discriminate against individuals that use cannabis, which was recently decriminalised. Singling out individuals who have a higher tendency to use these substances, such as Rastafarians for instance, will be unjustifiable and, therefore, may be seen

as unfair discrimination. A confirmed history of addiction can also serve as a legitimate reason and defence for testing specific individuals more than others.

The Promotion of Administrative Justice Act requires the prohibited substance regulation and testing programme to be procedurally fair and allows for the review of such a programme. The programmes have to be based on the separation of powers, which requires the separate entities contributing to the administration of the process to be independent.

The implications of the recent decriminalisation of cannabis in the workplace were discussed, and it was found that organisations with risk-sensitive environments should still regulate and test for cannabis due to its impairment potential. The statutes that regulate this requirement are the Occupational Health and Safety Act and the General Safety Regulations of the Machinery and Occupational Safety Act, which both employ the word "intoxication". It was concluded that the concept of "intoxication" should be viewed as the result of different levels of impairment. In a risk-sensitive environment, a threshold THC concentration level in a specific bio-matrices must be specified at which an individual will not be impaired. Specifying threshold concentrations may also accommodate cannabis use to a certain extent. This is especially important if one takes into account the relatively long half-life of THC in the human body. A chronic user will not be able to exercise his right of freedom to use cannabis responsibly if it is required for him to have a concentration of "zero" in his or her system.

It was furthermore suggested that the wording of the OHSA and MOSA should be changed by ***reading in***, a threshold concentration of the prohibited substance in the bodily fluid matrix as an alternative to the prohibition of "intoxication". For THC, this should typically be 2ng/ml THC in blood/oral fluid.

The national policy on the management of drug abuse by learners in schools and further education and training institutions in South Africa was reviewed, and it was found that due process as suggested by the Department of Basic education is not followed. It was found that some matured learners' autonomy may be infringed by the prescribed procedure and also that privacy may be affected negatively by the requirement to declare chronic medication use even before the screening test. The procedure is also not scientifically correct and reliable if a confirmation test is not performed before any action against the child.

***Scientific and medical-related aspects*:** Current scientific issues on prohibited substance regulation and testing in South Africa were addressed. These were related to the:

- Random selection of individuals to undergo a prohibited substance test:

A study was conducted into the number of test subjects to be sampled randomly to ensure reliable sampling of individuals and to enable reliable inferences to be made about the test subjects' drug use. The sampling process must ensure that the individuals chosen are representative of the group or population. The ***hypergeometric distribution was suggested*** to serve as a means to calculate the minimum number of subjects per group to be selected randomly. Over-selection of individuals may be seen as unethical due to the unnecessary biomedical interventions when individuals are subjected to a prohibited substance test. The minimum sample sizes were calculated and provided for different levels of confidence.

- "zero tolerance" versus "zero concentration":

The two concepts should not be equated. The former refers to a stance against the use of prohibited substances if the subject's test result is above a certain threshold. The intention is to make sure that the test subjects are drug-free. The latter may not pass constitutional requirements, especially if the concentration levels are below the levels that mark the onset of impairment. The concept of "zero concentration" is also not a scientifically defendable since the level of "zero" depends on the detection technique.

- Detection of impaired individuals:

Detection of an impaired drug user can be performed by lay witness observation of objective signs of impairment as well as by behavioural observational techniques such as sobriety testing and clinical observation. The latter two require a higher level of skill. Chemical recognition and detection in bio-matrices , as an objective way of detection, was also reviewed in light of the suitability of various bio-matrices available for prohibited substance testing and the detection time.

Cannabis detection study:

- Cannabis (THC) was used as an example of how to assess the literature to obtain impairment levels. The absorption, metabolism and elimination of THC in urine and oral fluid were discussed as possible matrices for THC testing in cannabis users. A dose-response relationship was found for THC excretion in oral fluid. However, the sampling process has some difficulties. Sampling can take place by either stimulated or non-stimulated collection. The stimulated collection mimicked blood THC levels more closely, compared to non-stimulated collection methods.

- There was no performance impairment below 2 ng THC/mL serum. This concentration level, therefore, may be used as a threshold for residual THC in users, in countries where cannabis is legalised. This threshold concentration value will also comply with ethical and human rights related to respect for an individual's privacy and freedom. Passive exposure also does not result in values above 2 ng/mL serum.
- The ideal matrix for THC testing would be blood, however, due to the invasiveness of blood sampling alternative matrices such as urine or oral fluid may be employed. Both of these matrices have their own "difficulties". The long-halflife of THC in urine is problematic since urinary THC-COOH concentrations is not a proxy for impairment and will also contradict the legalisation of cannabis use.
- It is the opinion of the author that oral fluid (OF) may not pass legal scrutiny since the oral fluid collection will always be subjected to potential contamination of residual THC in the buccal cavity. Chemical detection of THC in oral fluid should be performed in combination with observational identification (See section 6.4) until scientifically sound *per se* oral fluid THC concentration levels is agreed upon by the scientific community. This will however, not solve the dilemma of possible buccal cavity contamination of an oral fluid specimen due to residual THC in the mouth. The importance of a written policy, wherein the threshold concentration levels of THC (in the specific matix) to be sampled and tested, is specified cannot be overstated since this will be regarded as the *guideline* as part of the employer-employee contract.
- It is the opinion of the author that oral fluid testing may not pass legal scrutiny since the oral fluid collection will always be subjected to potential contamination of residual THC in the buccal cavity which may cause false-positive results.

Evaluation of preliminary oral fluid cannabis detection devices

- Preliminary drug testing (screening) strategies with lateral flow immune assay screening devices were discussed, and a strategy on how to evaluate these devices from the data on package inserts supplied by the manufacturers was presented. It is an ethical obligation to employ the correct technology since poor quality results may impact negatively on an individual as a test subject.
- Four commercial devices, currently on the market in South Africa, were used as examples to study the relationship between drug screening and confirmation cut-off concentration levels. ***A novel approach*** to extract the information from the package inserts by the

operators of these devices was suggested. The figures of merit related to the performance of these devices were calculated, and recommendations were made regarding the performance of these devices.

Regulatory framework*:** This study proposed a ***first-time novel regulatory framework for prohibited substance regulation and testing in humans, which accords with the Constitution of the Republic of South Africa and relevant legislation. This was approached from ethical, professional, legal and scientific perspectives and by comparing the approaches followed internationally for prohibited substance regulation and testing in humans. Foreign law and international law, namely, the "Mandatory guidelines on workplace drug testing in the USA" and the rules for anti-doping of the "World Anti-Doping Association (WADA)" were reviewed for possible application in the Republic of South Africa with the relevant South African statutes in mind.

CHAPTER 8:

APPENDICES

APPENDIX 1

Workplace drug testing flow chart as suggested by SAMHSA

Employer - Initial request is made for a specific reason.
Specimen collection - Donor reports at the collection site. - Have his or her urine specimen collected and sealed with a unique seal number. - Urine temperature and other preliminary/validity tests are performed. - Chain of custody form is completed. - Urine specimen shipped to the certified confirmation laboratory if the preliminary drug test result is non-negative.[1]
Laboratory receipt - Receipt of the specimen and chain of custody is observed. - Unique internal laboratory identification number assigned to the specimen after registering the specimen on a LIMS. - The specimen is aliquoted (poured off, "no-dip sampling") for analysis and the rest is frozen away.
Laboratory analysis 1. Initial preliminary testing/screening performed with immunoassay: - Validity testing performed (creatinine, pH, specific gravity, adulterants (nitrites, oxidants, etc.) - If the results are negative for all the preliminary immunoassay tests and normal for the validity tests with no adulteration, the testing process ends, and the result is reported as negative. - Urine specimens that screen non-negative or have abnormal validity results are subjected to further testing[2]. 2. Confirmatory testing: - Analysis by a method that is validated for the specific drug class that presented non-negative with preliminary immunoassay analysis. - Confirmation of the drug presence and concentration by a qualified analyst and a certifying scientist. 3. Confirmatory testing:

[1] The specimen is to be kept in a secured environment for temporary storage at the collection facility until it is shipped to the confirmation laboratory.

[2] The term "presumptive positive" is sometimes used synonymous to non-negative. It is the opinion of the author that the use of the former may indicate subjectivity by the confirmatory laboratory. The mainstay of science is objectivity and should not be compromised by any means.

- Specimens that failed the validity testing, implying possible adulteration like dilution (abnormal pH and creatinine) is also subjected to confirmatory testing as explained above.

Laboratory reporting

- All results are reported and verified by a certifying scientist.
- The final report is then sent in a secure fashion (fax, email, mail, courier) to the MRO.
- Results may not be reported by phone.

Medical review officer and blood alcohol technician

- The MRO will review the drug test result if it is **confirmed positive** and will report the final result back to the designated employee representative.
- The role of the MRO is to ensure that the donor has not abused a drug prohibited by the policy or that the donor was not dishonest by obscuring the result through manipulation of the urine during the collection process.
- The MRO may report a drug test result as negative even if the drug was confirmed to be present above the cut-off concentration if there is a legitimate explanation for the drug being present in the employee's body.
- The BAT is responsible for obtaining accurate and reliable alcohol testing according to forensic standards.

Employer

- Decisive action may follow for confirmed positive results with no legitimate explanation.
- No decisive action on preliminary assay results!

APPENDIX 2

Summary of the type of tests required for drugs and alcohol for preliminary and confirmatory testing

	Compounds	Initial tests	Confirmatory tests
Drugs	Drugs as per the CCF form in Appendix A	Immunoassay	Gas Chromatography-Mass Spectrometry (GC-MS)
Specimen validity testing (**SVT)** [3]	Creatinine	Colourimetric testing	Multi-wave spectrophotometer
	pH	Colourimetric testing	pH meter
	Strong oxidising chemicals	Colourimetric testing	ICP-MS [4], AAS [5], capillary electrophoresis
	Alcohol	Preliminary breathalyser, colourimetric test, flashing light, etc.	Evidentiary breathalyser with two independent detection techniques[6]

[3] Specimen validity testing (SVT) is performed on markers that will indicate in-vivo and in-vitro tampering with the specimen during and before the collection of the specimen. There are numerous ways in which tampering can take place; for example, consumption of excessive amounts of fluid; changing of the urine pH by taking lemon juice or vinegar; taking a diuretic will dilute the drug concentration to below the cut-off concentration limit; strong oxidants like swimming pool chlorine under the donor's nail will destroy a drug if he/she dips his finger in the specimen; condoms with "clean" urine from another person are sometimes used unnoticed, pretending that the person urinates.

[4] Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

[5] Atomic-Absorption Spectrophotometry.

[6] A problem in SA with two preliminary breathalysing tests being viewed as a confirmation, a preliminary breathalyser with a result printout is not viewed as confirmatory. A second concern in SA is that all breathalysers and drug testing kits used are not the same across the organisation, which could lead to discrimination towards an employee.

APPENDIX 3

Summary of the initial preliminary assay cut-off concentrations for drugs in urine and alcohol in breath[7]

Drug class	Preliminary cut-off concentration limit (ng/mL)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2000
Phencyclidine	25
Amphetamines	1000
Alcohol	0.10 mg per litre of breath

Summary of the initial preliminary assay cut-off concentrations for drugs in oral fluid[8]

Drug class	Preliminary Cut-off concentration limit (ng/mL)
Marijuana THC	4
Cocaine/Benzoylecgonine	30
Hydrocodone/Hydromorphone	30
Oxycodone/Oxymorphone	30
6-Acetylmorphine	3
Phencyclidine	3
Amphetamines	25
MDMA/MDA/MDEA	25

[7] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 53(69) par 119701, 11 April 1988 http://workplace.samhsa.gov.

[8] Mandatory Guidelines for Federal Workplace Drug-Testing Programs FR 53(69) par 119701, 11 April 1988 FR 80(94), 15 May 2015/Notices (http://workplace.samhsa.gov) (accessed 13 January 2019).

Summary of the confirmatory analysis cut-off concentrations for drugs in urine

Drug	Confirmation cut-off concentration limit (ng/mL)
Marijuana metabolite (delta-9-THC-9-COOH)	15
Cocaine metabolite (Benzoylecgonine)	150
Opiates	
Morphine	2000
Codeine	2000
6-Acetyl morphine (tested when the morphine concentration is higher than 2000 ng/mL)	10
Phencyclidine	25
Amphetamines	
Amphetamine	500
Methamphetamine (Specimen must also contain 200 ng/mL amphetamine)	500
Alcohol	
Breath alcohol	0.10 mg per litre of breath

Summary of the confirmatory analysis cut-off concentrations for drugs in oral fluid

Drug class	Preliminary cut-off concentration limit (ng/mL)
THC	2
Cocaine/	8
Benzoylecgonine	8
Codeine	15
Morphine	15
Hydrocodone	15
Hydromorphone	15

Oxycodone	15
Oxymorphone	15
6-Acetylmorphine	2
Phencyclidine	2
Amphetamines	15
MDMA	15
MDA	15
MDEA	15

APPENDIX 4

Summary of the breath alcohol testing protocol

Step 1: Donor is identified with photographic identification and personal details are recorded.

Step 2: The donor is then subjected to a fifteen-minute observation period during which the BAT actively observes him[9].

Step 3: An air blank analysis is performed first.

Step 4: The donor provides a breath specimen by blowing into the confirmatory breathalyser to register the first alcohol test result.

Step 5: A second air blank analysis is performed.

Step 6: The donor provides a second breath specimen to register a second alcohol test result. The mean of the two alcohol results is calculated.

Step 7: A second air blank analysis is performed.

Step 8: A control gas specimen with a certified alcohol concentration is analysed.

[9] The donor may not smoke or consume any fluids during the observation period. The BAT must also be on the lookout for strange behaviour like regurgitation and belching.

APPENDIX 5

WADA list of prohibited compounds

Schedule	Class	Examples
Schedule 1	Anabolic agents	Exogenous: Boldenone, Drostanolone, Nandrolone, Stanbolone, Stanzolol, (and other substances with a similar chemical structure or similar effect(s). Endogenous: Androstenediol, Androstenediol, Dihydrotestosterone, Testosterone, Epiandosterone, Androsterone, Etiocholanolone
	Other anabolic agents	Clenbuterol, Andarine, Ostarine, Tibolone, Zeranol, Zilpatrol
Schedule 2	Peptide hormones, growth factors, related substances and mimetics	Erythropoietin, Hypoxia-inducible factor stabilizers (HIF) (and activation factors), Chorionic Gonadotropin and Luthenizing hormone (LH) (and releasing factors), Corticotrophins (and releasing factors), Corticotrophins (and releasing factors), Growth hormones (and releasing factors), Growth factors.
Schedule 3	Beta-2-agonists	All beta-2-agonists (please note maximum allowable dose/cut off)
Schedule 4	Hormone and metabolic modulators	Aromatase inhibitors (Anastrozole, Formestane, Testolactone), Selective estrogen receptor modulators (Raloxifene, Tamoxifen, Toremifene), Anti-estrogenic substances (Clomiphene, Cyclofenil, Fulvestrant), Myostatin inhibitors, Metabolic inhibitors (AICAR, GW1516, Insulins, Meldonium, Trimetazine)
Schedule 5	Diuretic and masking agents	Desmopressin; probenecid; plasma expanders, e.g. glycerol and intravenous administration of albumin, dextran, hydroxyethyl starch and mannitol. Acetazolamide; amiloride; bumetanide; canrenone; chlortalidone; etacrynic acid; furosemide; indapamide; metolazone; spironolactone; thiazides, e.g. bendroflumethiazide, chlorothiazide and hydrochlorothiazide; triamterene and vaptans, e.g. tolvaptan

Schedule 6	Stimulants	Cocaine, Modafinil, Selegiline, Sibutramine, Strychnine. Threshold compounds: Cathine, Ephedrine, Adrenaline and Noradrenaline.
Schedule 7	Narcotics	Heroin, Fentanyl, Methadone, Morphine, Oxycodone, Pethidine
Schedule 8	Cannabinoids	Natural, e.g. cannabis, hashish and marijuana, or synthetic Δ9-tetrahydrocannabinol (THC). Cannabimimetics, e.g. "Spice", JWH-018, JWH-073, HU-210.
Schedule 9	Glucocorticoids	All glucocorticoids are prohibited when administered by oral, intravenous, intramuscular or rectal routes
Compounds prohibited in particular sports	Alcohol (Ethyl alcohol)	Alcohol (ethanol) is prohibited in-competition only, and detection will be conducted by analysis of breath and/or blood, in the following sports: Air Sports; Automobile; Archery; Powerboating The doping violation threshold is equivalent to a blood-alcohol concentration of 0.10 g/L.
	Beta-blockers	Beta-blockers are prohibited in-competition only, in the following sports: Skiing/Snowboarding in ski jumping, freestyle aerials/halfpipe. Typical examples are: **A**cebutolol; Alprenolol; Atenolol; Bisoprolol; **N**adolol; **O**xprenolol; **P**indolol; Propranolol; **S**otalol and **T**imolol.

APPENDIX 6

Substances regulated by statute in South Africa

Schedule	Class	Example
Schedule 5	Benzodiazepines and tranquilizers	Alprazolam, Clobazam, Clonazepam, Diazepam, Zolpidem.
	Androgenic Anabolic Steroids	Androstanolone, Androstenediol, Nandrolone, Stenbolone.
Schedule 6	Sedatives/Hypnotics	Amobarbital, Butalbital, Secobarbital, Flunitrazepam.
	Stimulants	Cocaine.
	Opiates	Morphine, Ethylmorphine, Methadone, Methyldihydromorphine, Oxycodone, Hydrocodone.
Schedule 7	Hallucinogens, Cannabinoids, Opioids	Cannabis (and synthetic analogues), Khat, Cathinone, Fentanyl (and analogues), Gamma hydroxybutyrate (GHB), Heroin, Methcathinone, Methaqualone, Phencyclidine.
Schedule 8	Stimulants	Nabilone, Dexamphetamine, Lisdexamphetamine, Amphetamine (and salts).

APPENDIX 7

The Declaration of Helsinki: Basic principles for all medical research

1. It is the duty of the physician in medical research to ***protect life, health, privacy and dignity*** of the human subject.
2. Research should be conducted according to ***accepted scientific principles***, based on ***scientific literature*** and other relevant sources of information and where appropriate on adequate animal experimentation.
3. Research must be conducted in a way that ***respects the environment and animal welfare***
   (a) The design and performance of each experimental procedure should be ***clearly formulated in an experimental protocol*** which should be submitted for ***consideration, comment, guidance*** and where appropriate, approval to a specially appointed ***ethical committee***, which is independent of the investigator, sponsor or any kind of undue influence.
   (b) The independent committee should be in ***conformity with the laws and regulations of the country*** in which the research experiment is performed
   (c) The committee has the ***right to monitor ongoing trials,*** and the ***researcher has an obligation to provide information*** to the committee, especially any serious adverse events.
   (d) The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, ***other potential conflicts of interest*** and incentives for subjects.
4. The research protocol should always ***contain a statement of the ethical considerations involved*** and should indicate that there is compliance with the principles enunciated in this Declaration.
5. Medical research involving human subjects should be conducted only by ***scientifically qualified persons and under the supervision of a clinically competent medical person.*** The responsibility for the human subject must always rest with a ***medically qualified person*** and never rest on the subject of the research, even though the subject has given consent.
6. Every medical research project involving human subjects should be preceded by ***careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others***. This does not preclude the participation of healthy volunteers in medical research. The ***design of all studies should be publicly available***.

7. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the ***risks involved have been adequately assessed and can be satisfactorily managed***. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
8. Medical research involving human subjects should only be conducted if ***the importance of the objective outweighs the inherent risks and burdens to the subject***. This is especially important when human subjects are healthy volunteers.
9. Medical research is only justified if there is a ***reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research***.
10. The subjects must be ***volunteers and informed participants*** in the research project.
11. The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to ***respect the privacy of the subject, the confidentiality of the patient's information*** and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
12. In any research on human beings, each potential subject must be ***adequately informed*** of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail.
13. The subject should be ***informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal***. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.
14. When obtaining ***informed consent*** for the research project, the ***physician should be particularly cautious*** if the subject is in ***a dependent relationship with the physician or may consent under duress***. In that case, the informed consent should be obtained by a ***well-informed physician who is not engaged*** in the investigation and who is entirely independent of this relationship.
15. For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a **legally incompetent minor**, the investigator must obtain informed consent from the ***legally authorized representative in accordance with applicable law***. These groups should not be included in research unless the research is necessary to

promote the health of the population represented and this research cannot instead be performed on legally competent persons.

16. When a subject deemed ***legally incompetent***, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that ***assent in addition to the consent of the legally authorized representative***.
17. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a ***necessary characteristic of the research population***. The specific reasons for involving research ethics and the subjects with the condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.
18. Both authors and publishers have ethical obligations. In the publication of the results of research, the ***investigators are obliged to preserve the accuracy of the results***. Negative as well as positive results, should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible ***conflicts of interest should be declared*** in the publication. Reports of experimentation ***not*** in accordance with the principles laid down in this Declaration ***should not be accepted*** for publication.

APPENDIX 8

Summary of the standards of practice in the model code of the American National Academy of Science[10]

- ***Objectivity***:

Forensic scientists should strive to be objective and unbiased and should design procedures and experiments to address them. The forensic scientist should determine the information required to effectively conduct analyses and examinations and reach reliable conclusions. Whenever possible, examined evidence should be preserved to facilitate reanalysis or re-examination by another expert.

Analyses and Examinations: Reasonable steps shall be taken to obtain all relevant data needed to complete an analysis and all available relevant data shall be assessed. Additional information or evidence which may be relevant to the examination shall be documented, and all observations, examinations, analyses, alterations, results and assumptions shall be documented at the time they are performed. Conclusions or opinions shall be based on the analysis or examination of all available relevant evidence. Reasonable steps must be taken to encourage that all relevant evidence in a case receives appropriate technical analyses.

Conflicts of Interest: All conflicts *of interest with an employer, client, or the justice system shall be documented and disclosed and assignment, where there is a conflict of interest, shall not be accepted. Services shall not be provided on a contingency-fee-basis.

- ***Communication***:

The forensic scientist should be truthful and forthright in all aspects of professional activity. Whenever possible, commonly accepted terminology should be used. Information should not be intentionally obscured by inclusion, omission, or any other means. Scientific and legal principles require that those who utilise or evaluate the conclusions or opinions of the scientist should be able to verify them by the review of data, the replication of experiments, the testing of alternative hypotheses, or by challenging the process used in arriving at the expressed conclusions. For this reason, clear and complete documentation of data and methods used to form a conclusion or opinion should be provided and readily available for evaluation by all who has a legal right to them.

[10] American National Academy of Sciences *A model code of professional conduct in the forensic sciences* http://www.cacnews.org/policies/Model_for_NCPC.pdf (accessed 17 November 2017).

Communication must be precise, accurate, and clear. Stated qualifications shall be accurately represented, including, but not limited to, education, training, experience, areas of expertise, and certification status.

- ***Reports and testimony*:**

The intentionally misleading language shall not be used and the relevant facts, and conclusions and opinions, including qualifications and limitations, shall be fully explained. Yes-or-no answers in testimony shall be explained or qualified when not doing so would be misleading. Data and opinion based on that data shall be clearly differentiated. Court exhibits and tutorials shall accurately reflect the work done. Exhibits used for illustrative purposes not related to the actual evidence that was examined shall be clearly described as such. If the answer to a question is not known, or if that question is outside the forensic scientist's area of expertise, the forensic scientist shall say so. Technically correct statements shall be made in all written and oral reports, testimony, technical publications, and technical presentations. Testimony shall be restricted to matters within the forensic scientist's knowledge, skills, and abilities.

- ***Disclosure*:**

Complete and accurate disclosure of all methods, findings, conclusions, and opinions shall be written into technical records for all work done. When apparent, any errors or omissions shall be documented and disclosed to the employer or client. Any changes in conclusions or opinions shall be documented and disclosed to the employer or client. Additional information or evidence which may be relevant shall be documented in the report. Any attempt by a second party to alter results or improperly influence conclusions shall be documented and disclosed to appropriate statutory or legal authority. The authorized release of material shall not be obstructed nor shall the released material be misrepresented. Confidential information, including information derived from evidence, shall not be inappropriately disclosed. Reports or other records shall not be constructed, and information shall not be withheld, for strategic or tactical litigation advantage.

- ***Professional associations*:**

Information on membership application forms to professional associations shall be accurately represented. Membership status in any professional association shall be accurately represented. In dealing with professional association boards or their representatives, the forensic scientist shall be forthright. Statements or beliefs expressed at professional meetings shall not be repeated without putting them into the context in which they were made.

- ***Procedures:***

The forensic scientist should determine the most appropriate protocol for analyses. While being open to new and novel concepts and methods, the forensic scientist is responsible for evaluating them critically prior to applying them to casework. Novel methods may be used when required. Whenever possible, validated, reliable methods that are generally accepted should be used.

Methods and Materials: Methods used shall have appropriate accuracy and precision and appropriate and reliable reagents, standards, and controls shall be used. Appropriate equipment in adequate facilities shall be used. Superfluous tests shall not be done in an attempt to give a conclusion or opinion more weight.

Sampling: The identity and integrity of evidence shall be confirmed prior to examination. Evidence shall be sampled in a representative manner. Sufficient sample shall be retained for additional testing whenever possible, and evidence shall not be consumed unnecessarily.

- ***Responsibility:***

Forensic scientists should be fair and respectful when interacting with colleagues, clients, attorneys, and the public. Forensic scientists should take responsibility for their own work and for work done under their direction. Each individual should take responsibility for conforming to the Code of Professional Conduct. When a forensic scientist is hired as a consultant by an individual, a confidential relationship is presumed to exist between them. When a forensic scientist is retained by an attorney representing a litigant, an attorney-client relationship is presumed to exist between them. A reasonable fee may be charged for the services of a forensic scientist. On occasion, different conclusions or opinions in a case may be reached by different experts. If aware that there is a difference, the forensic scientist should give due consideration to potential sources of that difference, including acknowledging that differences can be legitimate. The forensic scientist should consider means by which differences of opinions might be resolved. Such means may include the exchange of information, samples, or data; jointly conducting appropriately designed experiments; referral to a third expert; or other means.

Serious or repeated violations of the Code of Professional Conduct shall be reported to the relevant association and v*iolations of the Code of Professional Conduct shall not be tolerated or concealed*:

- ***Responsibilities to the Profession*:**

Conduct detrimental to the profession shall be avoided, including illegal conduct. Forensic scientists shall discourage the association of their names with developments, publications, or organisations to which no significant contributions were made. Forensic scientists shall not engage in plagiarism; work done by others shall be properly credited. When giving advice regarding the questioning of another witness, the purpose shall be to prevent incompetent and misleading testimony and make known facts that are legally relevant. Membership in an association or employment in an agency or company shall not be used to obtain unjustified benefits, privileges, or exemptions.

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