Cape Peninsula University of Technology

THESIS:

"An environmental impact perspective of the management, treatment, and disposal of hazardous pharmaceutical compounds generated as medical waste at selected hospitals in Cape Town, South Africa"

by

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DECLARATION

I, **Mohamed Shaheen Sattar**, declare that the contents of this thesis represents my own unaided, work and that this thesis has not previously been submitted for academic examination towards any qualification. Furthermore, it represents my own opinions and not necessarily those of the Cape Peninsula University of Technology.

……. ……..

Signed Date

ABSTRACT

Pharmaceuticals have been formulated to influence physiological systems in humans, animals, and microbes but have never been considered as potential environmental pollutants by healthcare professionals. The human body is not a barrier to chemicals, but is permeable to it. Thus after performing their *in-vivo* functions, pharmaceutical compound introduced into the body, exit mainly via urine and faeces. Sewage therefore contains highly complex mixtures of chemicals in various degrees of biological potency. Sewage treatment works including those in South Africa, on the other hand, are known to be inefficient in removing drugs from sewage and consequently either the unmetabolised pharmaceutical compounds or their metabolites emerge in the environment as pollutants via several trajectories. In the environment, the excreted metabolites may even undergo regeneration to the original parent molecule under bacterial influence, resulting in "trans-*vivo*-pharmaceutical-pollution-cycles".

Although all incinerators are known to generate toxins such dioxins and furans from the drugs they incinerate, all the medicines disposed by the hospitals under research, were incinerated, as the preferred option of disposal. The incineration process employed was found to be environmentally unsafe.

Expired and unused medicines which the general public discard as municipal solid waste become landfilled. Because many landfill sites are not appropriately engineered, the unwanted drugs landfilled therein, leach into the surrounding ground water, which is the influent source of water treatment plants. Water treatment plants, including those in South Africa, are also inefficient in eliminating pharmaceutical compounds, releasing them in sub-therapeutic concentrations into potable tap water as pollutants, the full effects of which are yet to be determined.

The research targeted doctors, pharmacists, and nurses, since medicines are one of the tools of their professions. A total of 742 questionnaires were distributed amongst them at three state and three private hospitals in Cape Town, South Africa, to determine the level of their knowledge and awareness with regard to:

1) the management, collection, treatment, and disposal of pharmaceutical waste, and
2) the potential and actual environmental pollution caused by the pharmaceutical waste, they generated.

Photographic evidence was obtained of the pharmaceutical waste and of its intermediate storage facilities within the hospital precincts before final disposal. The results of the questionnaires were then compared with the observed conditions of the pharmaceutical waste. The research exposed mismanagement of pharmaceutical waste by the hospitals which is the precursor of environmental pollution.

Interviews were conducted with the three tertiary academic institutions which produce healthcare professionals in Cape Town. All confirmed gaps in their curricula, in respect of pharmaceutical waste management.

The operations of the contracted transporter and disposer of the hospitals' pharmaceutical waste, were surveyed and evidence was found of direct environmental pollution caused by the incineration activities.

With regard to the various aspects of pharmaceutical waste, including legislation and future research, recommendations were thus made.

ACKNOWLEDGEMENTS

In sincere appreciation and gratitude, I would like to thank

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- The superintendents of the three state hospitals for their support and co-operation.
- The respondents for their participation in completing the questionnaires.
- My wife, my son and daughter for their support and accepting the reduction of family time which this research demanded.

DEDICATION

As a result of this research I became aware of the eternal

truth in the declarations by Almighty God:

"…We made from water every living thing…"

Quran 21.30

"And Allah has created every animal from water…"

Quran 24.45

"And it is He who has created man from water…"

Quran 25.54

I consequently conclude that

Protecting the integrity of our water resources will remain the

Quintessential environmental issue for all living species for all time.

In humble submission I therefore

Dedicate this research to the glory of God and

Pray that He be pleased with it.

LIST of ABBREVIATIONS

ASTM:	American Society for Testing Materials
BCL MWM:	BCL Medical Waste Management
BFR:	Brominated flame retardants
CHC:	Community Health Centre
CPUT:	Cape Peninsula University of Technology
DDT:	Dichlorodiphenyltrichloroethane
DEAT:	Department of Environmental Affairs and Tourism
DWAF:	Department of Water Affairs and Forestry
EEC:	Estimated Environmental Concentration
EIA:	Environmental Impact assessment
EPA:	Environmental Protection Agency
EU:	European Union
GPP:	Good Pharmacy Practice
HCS:	Hazardous Chemical Substances
HPW:	Hazardous Pharmaceutical Waste
IMDG:	International Maritime Dangerous Goods
MCC:	Medicine Control Council
MRA:	Medicine Regulatory Authority
MRC:	Medical Research Council
ng/l:	nanograms per litre
OHSA:	Occupational Health and Safety Act 85 of 1993 as amended
PCBs:	polychlorinated biphenyls
PhACs:	Pharmaceutically Active Compounds
PMU :	Premarin Mares' Urine
ppb:	parts per billion (equivalent to microgram/l)
ppm:	parts per million (equivalent to milligram/l)
ppt:	parts per trillion (equivalent to nanogram/l)
PVC	Polyvinyl Chloride
SANS:	South African National Standard
SAPS:	South African Police Services
STP:	Sewerage Treatment Plant
TCDD:	2,3,7,8-tetrachlorinated dibenzo-p-dioxin
TCDF:	2,3,7,8-tetrachlorinated dibenzo-p-furan
TCLP:	Toxicity Characteristic Leaching Procedure
TEQ/g:	Toxic Equivalency Quantity per gram
UNEP:	United Nations Environment Program
UCT	University of Cape Town
US:	University of Stellenbosch
US EPA:	United States Environmental Protection Agency
USP:	United States Pharmacopoea
UWC:	University Western Cape
WCHCWM:	Western Cape Healthcare Waste Management
WHO:	World Health Organisation
WWTW:	Wastewater Treatment Work
WWTP:	Wastewater Treatment Plant

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CHAPTER ONE: INTRODUCTION

1.1 Background

The scientific community's attention to toxic chemicals in the environment was stimulated in 1962 when "Silent Spring" by Rachel Carson was first published in which she highlighted the damage to fauna and flora by the use of dichlorodiphenyltrichloroethane (DDT) in the battle against mosquitoes and malaria. This subsequently initiated the shift of attention to the presence of pharmaceuticals as environmental pollutants.

Forty years later in 2002, the United States Geological Survey completed the most comprehensive target-monitoring study of pharmaceuticals, hormones, and other organic wastewater contaminants (OWCs) in surface water, ever performed in the world. One hundred and thirty nine rivers across the country were surveyed for 95 (ninety five) different OWCs. One or more contaminants were found in 80% (eighty percent) of the samples which included pharmaceuticals (Kolpin et al., 2002).

Hospitals produce large amounts of waste of which only 15% could be considered infectious or hazardous medical waste. The balance (composed of food, paper etc) is no different to normal household municipal solid waste (Fisher, 1996).

The environment, can be defined as:

> "the surroundings within which humans exist made up of:
> (i) the land, water and atmosphere of the earth;
> (ii) micro-organisms, plant and animal life;
> (iii) any part or combination of (i) and (ii);
> (iv) the interrelationships among between (i) and (ii); and
> (v) the physical, chemical, aesthetic, cultural properties and conditions of the foregoing that influence human health and well-being", (South Africa, 1998a).

From the above definition it can be seen that the impact of pharmaceuticals on the environment can be very extensive, and since hospitals are sites where the pharmaceutical waste is generated, hospitals become initiators of environmental pollution if the pharmaceutical waste is not properly managed.

Contrary to common perceptions the WHO states that:
"…between 76% and 90% of the waste produced by healthcare providers is non-risk or general healthcare waste, comparable to domestic waste, which is derived mainly from the administrative and housekeeping functions of the healthcare institutions. Only the remaining 10-25% of healthcare waste is regarded as hazardous and may create a variety of health risks" (Pruss et al., 1999a). For this reason medical waste is generally regarded as special waste because, although produced in relatively small quantities compared to domestic solid waste, it has a very high potential for infection and environmental pollution. Proper management of such dangerous substances, like radioactive therapeutics, thus require technical skills, effective administration, enforceable legislation, funding, and most of all commitment from trained personnel.

Pharmaceuticals which are commonly known as "medicines", are chemicals which have been specifically engineered to influence physiological systems whether they occur in man, animal, or microbes. Lilly et al., (2007) therefore succinctly defines a "drug" as "any chemical that affects the physiological processes of a living organism".

For decades medicines were never considered as environmental pollutants and were not recognised as being of consequence beyond the patient, especially by healthcare professionals. Safety of the patient was regarded as a higher priority than safety of the environment. But even if drugs were acknowledged as environmental pollutants, it would not have been possible to detect them, until the late 1990s when the technology became available to separate and identify pharmaceuticals from the galaxy of other chemicals amongst which they were abounding in such low concentrations as nanograms per litre (ng/l), equivalent to parts per trillion (ppt) (Daughton and Ternes, 1999).

Chemicals in the human body are not locked within the boundaries of the skin. Medicines, after performing their *in-vivo* functions for which they were engineered, exit the human body via urine, faeces, exhaled breath, hair, nails, breast milk and sweat, either as a mixture of metabolites, as unchanged original compounds, or conjugated to an inactivating molecule (Dollery, 1991; Lennernäs et al., 1996; Rang et al., 2003). Eventually via a complex of possible trajectories, exogenous pharmaceuticals, as well as endogenous organic compounds such as natural enzymes, exits the body and emerge in the environment as pollutants, triggering a cascade of ecotoxic consequences.

1.2 Pharmaceutical Trajectories into the Environment

Human therapeutics enters the sewerage system having been excreted by patients in their urine and faeces and will attend the sewage treatment works (STWs). Expired and unused medicines are also

disposed of via household toilets. Sewage emanating from hospitals contains the most complex mixtures of chemicals which are still biologically active. These compounds are constantly interacting thereby reducing even further the ability and efficiency of the STWs to eliminate them. As a result large amounts of these xenobiotics are delivered to the environment (Nunes, 2005), where their ultimate fate may be one of the following:

i) mineralization to carbon dioxide and water;

ii) if lipophilic they will not be degraded but retained in the sewage sludge;

iii) if hydrophyllic they will pass through the STWs into rivers (Halling-Sorensen et al., 1988). Other gateways into the environment are via landfill sites, incineration of pharmaceutical waste and graveyards.

1.2.1 Synergistic Interactions of a Mixture of Pollutants

Generally the impact of chemical pollution on the environment in the past has been limited to single chemicals. However, chemical pollutants can react with each other in the environment to produce new compounds of unknown composition, resulting in consequences never expected from the original pollutants. Similarly a mixture of pollutants can bring about synergistic responses in the human body wherein the toxicity of the mixture is greater than the sum of their individual toxicities.

1.2.2 Human Medicines

Human medicines which are the subject of this study, emerges in the environment via a complex of trajectories summarised in figure 1.3. A significant amount is delivered to the environment via the disposal of household waste which is then landfilled. Unwanted or expired medicines (figure 1.3; G1, and G2), may also be disposed via the kitchen sink, or toilet (figure 1.3; G3, and G4A) (Bound and Voulvoulis, 2005) *en route* to the STWs.

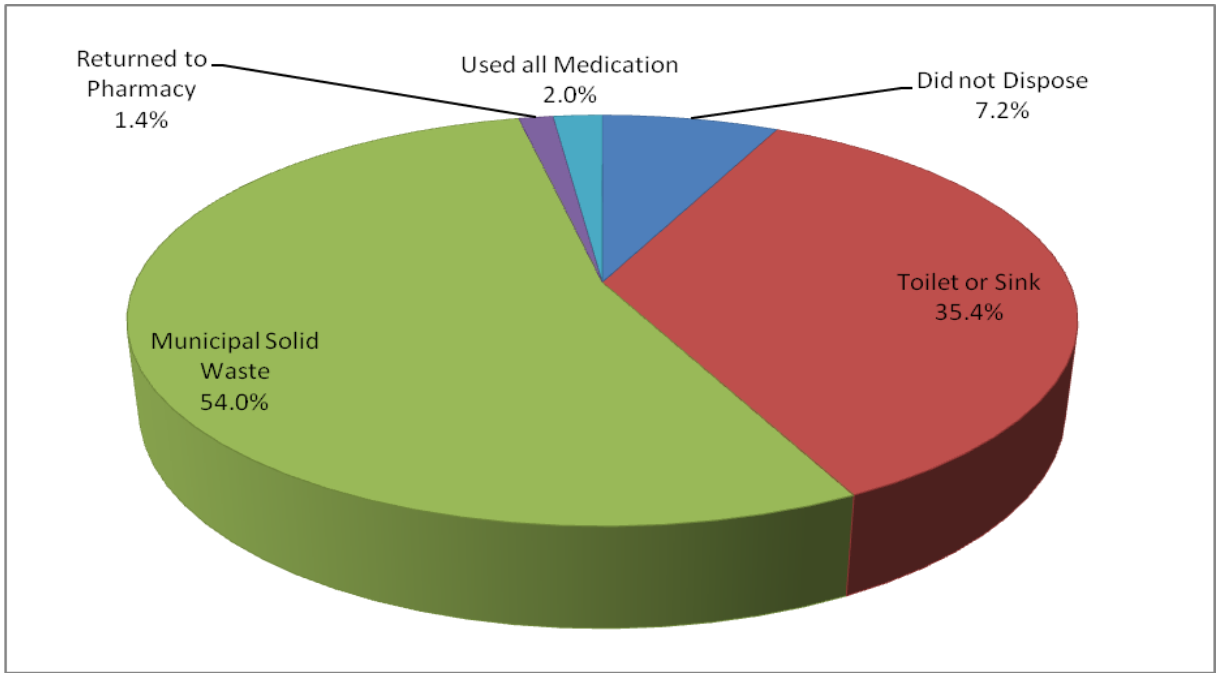

Figure 1.0: Survey of unused medication disposal practices (Source: Glassmeyer et al., 2009)

Figure 1.0 illustrates the results of a survey by Columbia University in which it was revealed that in America only 1.4% of patients returned unwanted medications to a pharmacy; 54% disposed of it in household waste; and 35.4% flushed it down the toilet (Glassmeyer et al., 2009).
Medicines administered to patients are metabolically decomposed as the body attempts to inactivate any exogenous chemical entering it. These chemicals, having varying physiological potencies will later be excreted in the urine and faeces (figure 1.3; G3) as metabolites (Pérez and Barceló, 2007). Table 1.1 gives the excretion rates of some toxic oncology drugs used in South Africa (Adapted from Baxton 2001).

As a result, a plethora of pharmaceuticals and their metabolites are discharged into the sewers (Ternes et al., 2001; Miao et al., 2002; Heberer, 2002b). However, research has established that STWs are not efficient and that pharmaceuticals are not entirely eliminated (Stan and Heberer 1997, Hirsch et al.,1998, Ternes 1998, Hirsch et al.,1999, Daughton and Ternes 1999, Stumpf et al., 1999, Ollers et al., 2001, Kolpin et al, 2002, Jones-Lepp et al., 2004).The municipal STWs in Germany, at best, were able to recover only 70% of estrogens from the raw influent (Ternes et al., 1999), while large amounts of clofibric acid for example, could not be removed (Nunes, 2005). In Spain ibuprofen and naproxen have been identified in both influent and effluent waters of a sewage plant (Rodriques et al., 2003).

Table 1.1: Excretion rates of various drugs (Adapted from Baxton 2001**)**

Drug	Method of Excretion		Duration of excretion
Bleomycin	Urine		72 hours. 50% in 1st day
Carmustine	Urine		96 hours
Cisplatin	Urine		7 days
Cyclophosphamide	Urine		72 hours
Methotrexate	Urine		72 hours
Dacarbazine	Urine		30-46% within 6 hours
Doxorubicin	Urine		6 days
		Faeces	7 days
Vincristine sulphate	Urine		4 days
Vinblastine sulphate	Urine		4 days
Epirubicin	Urine		7 days
		Faeces	5 days

All unused and expired medicines, disposed of by the hospitals researched in this study, were dispatched for incineration (figure 1.3; A1). No other disposal method was used. Medicines which the general public discard in their household waste, are disposed for landfilling (figure1.3; L1) and if the landfill is not properly engineered, hazardous pharmaceuticals will leach into ground water (figure 1.3; L2). For example ibuprofen, carbamazepine and naproxen were found in the leachates from Norwegian municipal landfills, proving that these medicines were disposed as municipal solid waste (Eggen et al., 2003).

STWs effluent and surface waters of the lower river Tyne were analysed for the presence of 13 pharmaceuticals (acetyl-sulphamethoxazole; clofibric acid; clotrimazole; dextropropoxyphene; diclofenac, erythromycin; ibuprofen; mefenamic acid; paracetamol; propanolol; sulphamethoxazole; tamoxifen and trimethoprim) selected from priority lists of the UK Environmental Agency and the Oslo and Paris Commission. Of the samples retrieved, all except sulphamethoxazole and acetyl-sulphamethoxazole were detected in concentrations ranging from 11 to 69,570 ng/l. The surface water from the river Tyne revealed the presence of trimethoprim in concentrations ranging from 4 to 2370 ng/l (Roberts and Thomas, 2006).

Most pharmaceuticals excreted by humans or animals are only slightly metabolised (chemically transformed). Some are often conjugated to polar molecules such as glucuronides, which are easily cleaved during the sewage treatment, liberating the original pharmaceutical compound (PhAC)

which is then discharged from the STWs into the receiving waters (Herberer, 2002a), (figure 1.3; G6).

Drugs which are lipophilic are not easily degradable by the STWs. They become adsorbed onto the sludge (figure 1.3; G5), which will later be dispersed on gardens and farms where they impact on plants.(figure 1.3; G7). Elvers and Wright (1995) demonstrated that ibuprofen which is an analgesic, anti-inflammatory and an anti-pyretic, also inhibits the growth of *Staphylococcus aureus* at concentrations of 150µg/ml. Batchelder (1981) demonstrated that oxytetracycline and chlortetracycline, although indicated as antibiotics bactericidal for humans and animals, can influence plants as well. Similarly Harris, et al., (1985), showed that Streptomycin inhibited the growth of blue-green algae. The emergence thus of antibiotics in the terrestrial and aquatic environment also lead to the development of resistance among naturally occurring bacteria (figure 1.3; G6 to G9). Studies have shown that STWs only removes at least 38% and at most 83% of natural steroids and synthetic hormones (Fisher and Borland, 2003).

The City of Cape Town concedes that: "...many Wastewater Treatment Works (WWTWs) operate beyond capacity or use older technology and thus do not have the ability to meet the required standards effectively..." The only pollutants monitored in the city's WWTWs are: ammonia, chemical oxygen demand, *Escherichia coli*, suspended solids, and orthophosphate (City of Cape Town, 2009). From figure 1.3 it can be seen that ground water is the fulcrum to which pharmaceutical compounds in the environment navigate, and on which their environmental impact pivots.

This unwanted exposure to sewage effluent containing estrogenic chemicals resulted in inter-sexuality of some of the river population e.g. feminizing of the male fish, has been observed amongst the Wild Roach (*Rutilus rutilus*), (Trevor et al., 2001), (figure 1.3; G11).

Hayes et al 2001, (figure 1.1) demonstrated the hermaphroditic demasculinization of male frog *Xenopus laevis* under the influence of an endocrine disruptor atrazine at concentrations of > 1.0 ppb,

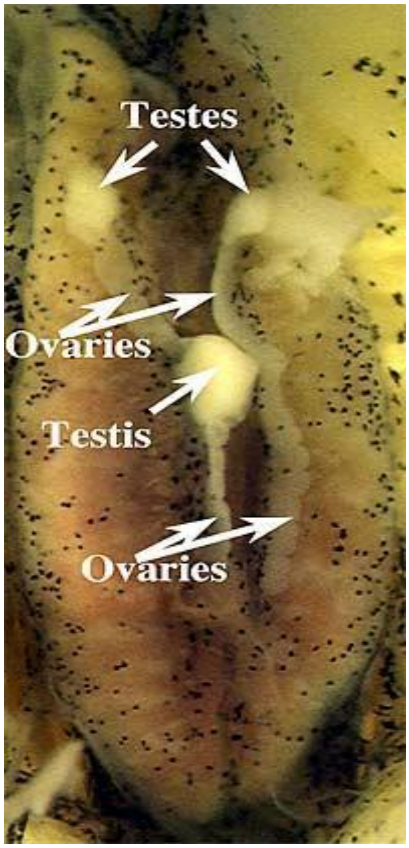

Figure 1.1: Demasculinization of the male frog *Xenopus laevis* (Hayes et al.,2001)

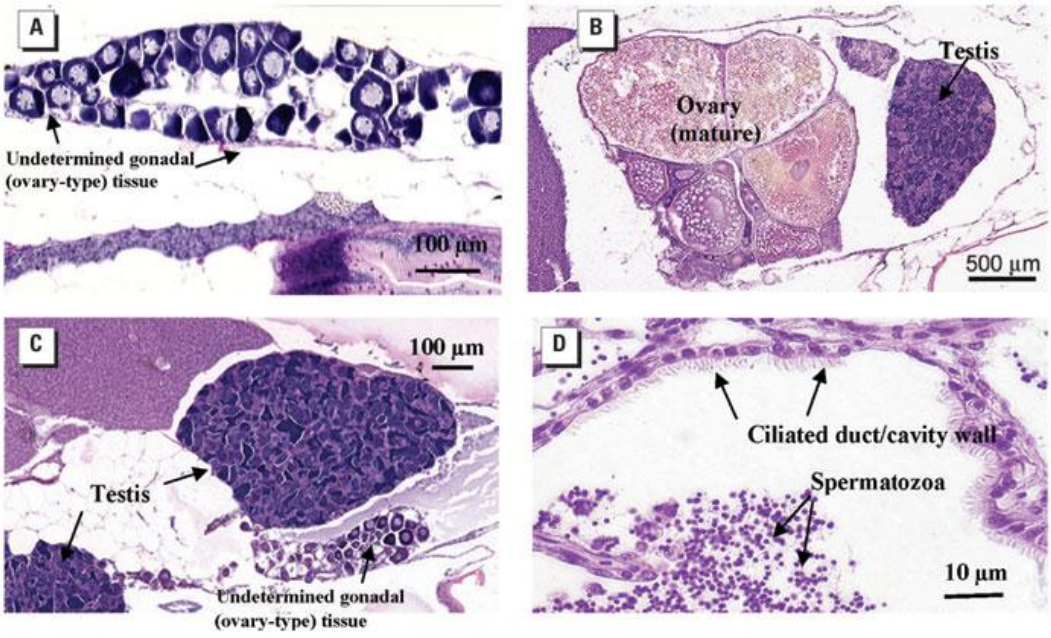

Figure 1.2: Female egg cells in testes of Smallmouth male bass (Blazer et al.,2007)

while Blazer et al.,2007, (fig.1.2) exposed immature female egg cells developing in the testes of male smallmouth bass found in the Potomac river as a result of environmental endocrine disrupting compounds polluting the rivers. Although very little is known about the effects of pharmaceutical pollutants on aquatic photosynthetic organisms, it was demonstrated that the antibiotics

erythromycin and tetracycline and the anti-inflammatory ibuprofen had an effect on the growth of environmental bacteria (Pomati et al., 2004), (fig.1.3; G9). Fruit and vegetables can become contaminated as a result of the farms being irrigated with polluted waters (figure 1.3; G10), (Biyase, 2010).

Fluoxetine a selective serotonin reuptake inhibitor (SSRI), indicated for depression, compulsive behaviour, eating and other personality disorders, are extensively used in South Africa under the trade names: Prozac ®, A-Lennon Fluoxetine ®, Lilly fluoxetine ®, Lorlen ®, Nuzak®, ProHexal ®, Ranfloc ®, Sandoz Fluoxetine ®. Notwithstanding that very little data on environmental fluoxetine exposure and hazard to aquatic life, are currently available in the literature, recent studies by Brooks et al., (2003) indicated that Fluoxetine discharged from STWs into surface waters, stimulated the reproduction of invertebrates and adversely influenced the behaviour of the estuary-dwelling shrimp *Echinogammarus marinus* (Winder et al., 2012) (figure 1.3; G11). Untreated ground and surface water are consumed by millions of indigent communities in the rural areas of South Africa (figure 1.3; G12). Surface water (rivers) is also the influent source for water treatment plants (WTPs) (figure 1.3; G13), producing potable water.

Considerable concern has been expressed regarding the presence of pharmaceuticals in the environment, but there has been very few studies on the potential of these substances to enter potable water supplies. This is surprising because drinking water would provide direct access to the human body for any drug that might be present in the water that is consumed. Water treatment plants if not efficient in eliminating pharmaceutical pollutants, release them into the potable water supplies which are reticulated in towns and cities, with the potential to impact on every citizen that consumes the tap water (figure 1.3; G14). In the famous study conducted by the US Geological Survey and the Centre for Disease Control and Prevention, 24 water samples were collected at selected locations within WTPs to evaluate the potential for wastewater-related organic contaminants to survive a conventional treatment process and to emerge in the potable water supplies. No less than forty pollutant drugs were detected in one or more of the samples (Stakelberg et al., 2004).

When the STWs discharges the metabolites into rivers, they easily penetrate the membranes of aquatic micro-organisms (figure 1.3; G9). If the organism is capable of metabolising it to a hydrophilic compound it will in turn be excreted by them. If not then a reservoir of novel toxins builds up within them and thus within the aquatic environment. Persistence of such toxins is thus not limited to the aqueous solubility in the river water but also to storage within micro-organisms populating the river. For instance cyclophosphamide, a highly potent cytotoxic drug used in

oncology, and diethylstilboestrol used *inter-alia* to induce labour in cows, each has an environmental persistence of at least 1 year (Fisher and Borland, 2003).

In the past the attention of environmental toxicologists was mainly focused on singular pollutants. However drug-drug interaction is common in the human body especially in the case of poly-pharmacy. This analogy can be equally applied to the environment, where exposure to sub-therapeutic levels of pharmaceuticals synergize or potentiate each other in surface water (Jones et al., 2004; Biradar and Rayburn, 1995), and in tap water (Stackelberg et al.,2001, Squillace et al., 2002), with the potential for human-health consequences (figure 1.3; G14). Jones et al., (2002) suggested that if drugs are present in drinking water, then the focus should be on their cumulative and synergistic effects over an extended period of approximately 80 years.

If one apply the international findings with regard to the efficiencies of STWs as a yardstick (Stan and Heberer 1997; Hirsch et al.,1998; Hirsch et al.,1999; Ternes 1998; Daughton and Ternes 1999; Stumpf et al., 1999; Ollers et al., 2001, Kolpin et al., 2002; Jones-Lepp et al., 2004), then the STWs managed by the City of Cape Town, are inefficient. In 2009 the City of Cape Town State of the Environment Report (Anon., 2010b), revealed that only a few of the STWs were 95% compliant:

1) Average compliance with ammonia standard (1998-2009)
   Out of the 21 STWs only 8 achieved over 95% compliance,
2) Chemical Oxygen Demand
   Out of the 21 STWs only 11 achieved over 95% compliance
3) Suspended Solid Standard (2009)
   Out of 21 STWs only 9 achieved over 95% compliance
4) *E.coli* Standard (2009)
   Out of the 21 STWs only 2 achieved 95% compliance
5) Orthophosphate Standard (2009)
   Out of the 21 STWs zero achieved compliance with the proposed orthophosphate standard.

From the above it is clear that the City of Cape Town has not identified pharmaceuticals as environmental pollutants which have to be eliminated from the effluent of STWs.

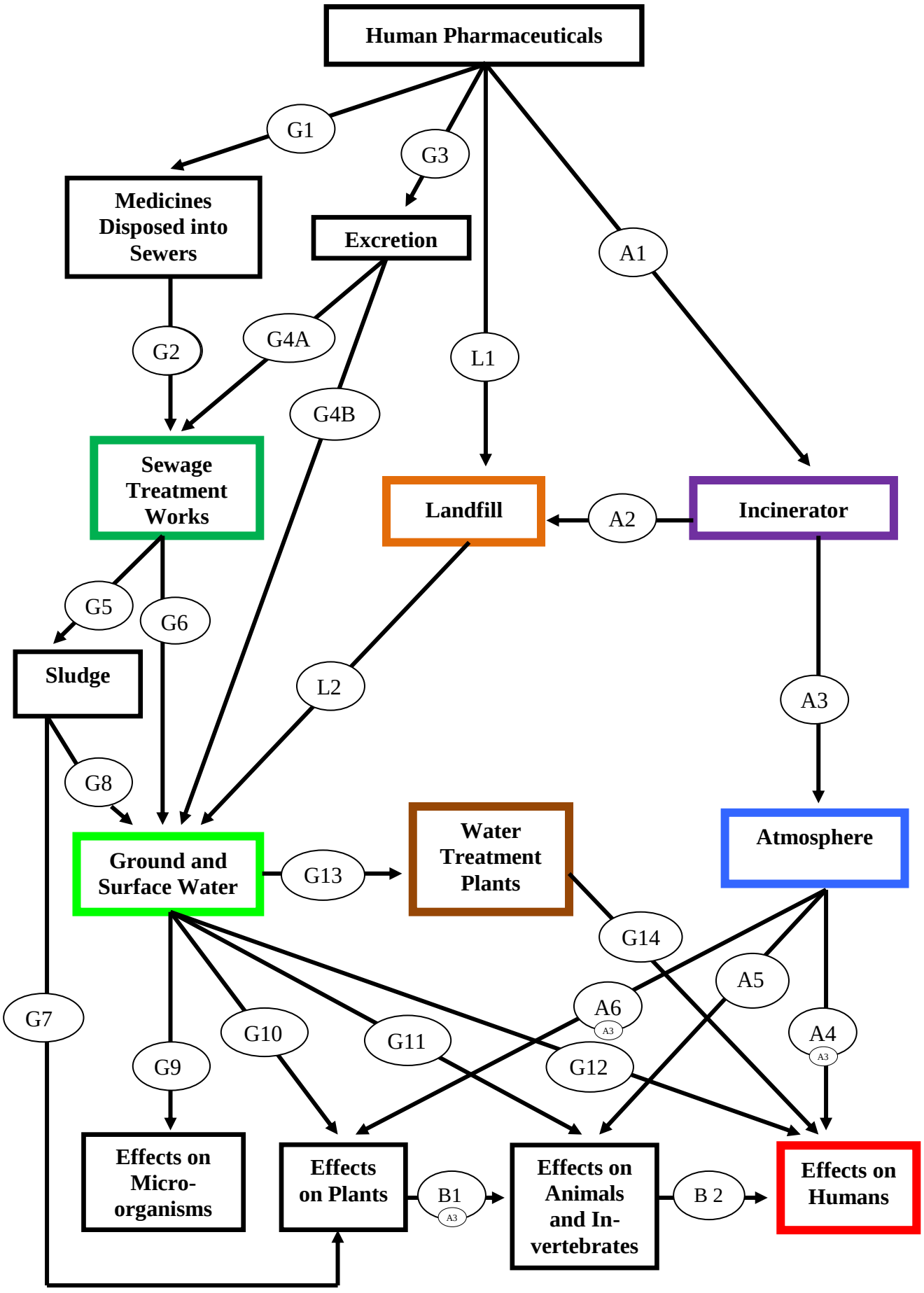

Figure 1.3: Trajectories of human pharmaceuticals into the environment (Adapted from Halling-Sorenson 1998).

When the intake of persistent pollutants exceeds the organism's ability to excrete them, bioaccumulation occurs within the organism. This can occur in micro-organisms, plants, animals, and humans. The pollutants which incinerators release directly into the air become diluted to concentrations of nanograms per litre (i.e. parts per trillion) or micrograms per litre (i.e. parts per billion), and dispersed over vast spaces thereby evading initial detection.

However this results in a slow but gradual accumulation of the pollutants in the food chain and in the human body, the consequences of which only manifests after a long latency period (Hens et al., 2000). Concentrations becomes magnified exponentially as the contaminants move up the food chain via B1 to B2 in fig.1.3. PCDDs and PCDFs have been detected in the chicken flesh and eggs derived from the soil on which the chickens were foraging, in higher concentrations than in the soil. The same bioaccumulation was found in cows (Stephens, 1990). Other studies demonstrated that the concentration of dioxins and furans were higher in cow's milk obtained from cows grazing near incinerators than elsewhere (figure 1.3; A5). The same researcher concluded that the source of human intake (figure 1.3; A4) of dioxins and furans originated from the incinerators (Rowat, 1999).

In the United States of America more than 90% of the dioxins responsible for environmental pollution are emitted to the atmosphere (figure 1.3; A3) and then transported by air currents for many kilometres *e.g.*: dioxins released in California have been identified in the Arctic Circle (Anon., 2003a). In one of the most detailed study of organochlorides in the African air, several endocrine disrupting chemicals such as chlordane, hexachlorobenzene, dieldrin and long-banned aldrin, were detected the ambient air of Durban (eThekwini Municipality), South Africa, (Batterman, Chernyak, Gounden, Matooane, and Naidoo, 2008). It has also been shown that residents who resided within a 5km radius of an industrial waste incinerator in the city of Pyongtaek, Korea, had high levels of dioxins in their blood (Leem et al., 2006).

When waste has been generated then the immediate and critical step is its segregation. Segregation means separating waste into its different component not only at the point of generation but also maintaining the separation until disposal. The separation allows appropriate
recovery and recycling techniques to be applied to each separate waste stream. When healthcare waste is not properly segregated at the point of generation there are severe implications of costs, and environmental impacts.

Medical waste handling procedures are designed to protect individuals from the potential of infection by disease–carrying pathogens transmitted via the medical waste. For pathogens to enter,

proliferate and infect an individual, there must be sufficient quantity of and virulence in the pathogenic organism, a portal of entry, including inhalation, direct contact or oral transmission, and a targeted host. Proper handling practices seek to avoid a portal of entry. Pharmaceutical waste differs in that the damage that it causes to the environment including humans, is not dependent on pathogenic interaction. Only in some cases the interaction with microbes lead to a secondary impact on human life e.g. the development of bacterial resistance (Costanzo et al.,2005).

1.3 Incineration

Incineration is not a panacea for waste disposal. Contrary to common perception, waste of whatever nature, cannot be destroyed, in accordance with the Law of the Conservation of Matter (Stavy, 1990). When incinerated, matter does not disappear, but becomes transformed into different physical phases. The products of the combustion (an oxidation process) in the incinerator are exhaust gases released to the atmosphere; ash on the floor of the incinerator (bottom ash), and fly ash trapped in the incinerator filters. Regardless of whatever emission control technology is applied, all incinerators will emit three types of toxic pollutants to the environment: heavy metals, partially combusted chemicals and entirely new chemicals synthesized during the incineration process in the combustion chamber (Allsopp et al., 2001). Bottom ash, containing the toxic end-products of the combustion, landfilled and eventually leach to ground water (figure 1.3; L2). South Africa has traditionally employed incineration as the preferred means of disposal of healthcare risk waste, but all the incinerators are of the type designed without air pollution control systems, and causes environmental pollution (Anon. , 2003b).

The combustion of sulphur and chlorine containing material *e.g.* PVC a common component of catheters and syringes, results in the formation of acidic gases (sulphur dioxide) and hydrochloric acid. In well designed incinerators these are removed from the gas stream before discharge to the atmosphere, by scrubbers built into the incinerator. Hazardous waste (which includes pharmaceutical) requires a very high incineration temperature of approximately 1250 ºC and a

long residence time of between 1 to 2 seconds, essential for the complete thermal destruction of PCBs, dioxins and furans (South Africa, 1998).

The WHO confirms that all types of incinerators, if operated properly will eliminate pathogens from waste and reduce the waste to ashes. However, it warns that certain types of healthcare waste e.g. pharmaceutical waste, requires higher temperatures for complete destruction and stipulates the types of waste that may not be incinerated *viz.:*

- pressurised gas containers
- large amounts of reactive chemical
- silver salts, photographic or radiographic chemicals
- halogenated plastics such as polyvinyl chloride (PVC)
- mercury and cadmium compounds
- sealed ampoules or ampoules containing heavy metals (Pruss et al., 1999f).

When the combustion temperature is too low, or the residence time of the molecule in the combustion chamber is too short, (a consequence of poor design) totally new molecules synthesized within the combustion chamber of the incinerator. For example, when poly chlorinated biphenyls (PCBs) are incompletely combusted, dioxins and furans such as polychlorinated dibenzo-dioxins and polychlorinated dibenzo-furans, are generated as novel waste, which are far more toxic than their PCB precursors,. These dioxins and furans did not exist in the medical waste prior to incineration (Rowat, 1999; Allsopp et al., 2001).

Dioxins have the general molecular structure given in figure 1.4 and are the chlorinated structure *e.g.* 2,3,7,8-tetrachlorinted dibenzo-p-dioxin (TCDD) given in figure 1.5.

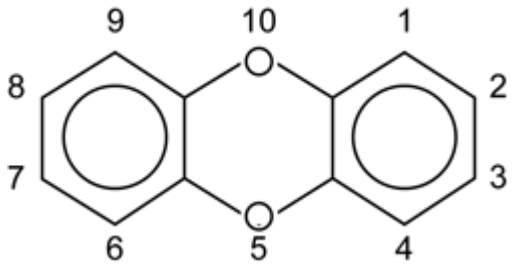

Figure 1.4: Dibenzo-p-dioxin molecule
(source Cancer Ass.):[http://www.cansa.org.za/unique/cansa/documents/dioxin.pdf]

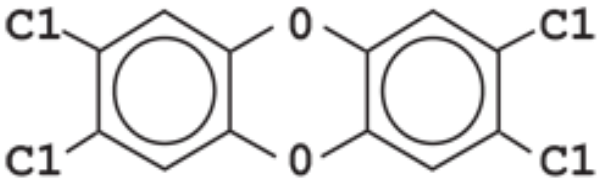

Figure 1.5: Molecular structure of TCDD (2,3,7,8-tetrachloro-para-dibenzodioxin)
(source :Centre for Environmental Research and Children's Health)
http://cerch.org/research-programs/seveso/

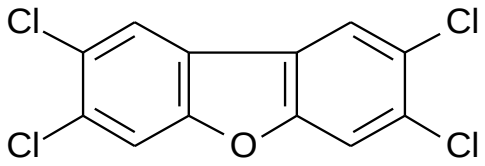

Figure 1.6: Molecular structure of TCDF (2,3,7,8-tetrachlorinatedibenzofuran)
(source: United Nations Industrial Development corporation: Environmental Impact
http://www.unido.org/index.php?id=5529

Figure 1.6 shows the chemical structure of a typical furan 2,3,7,8-tetrachlorinatedibenzofuran.

1.3.1 Environmental Pollution by Incineration

Besides the stack gases, fly ash, bottom ash, and scrubber water filter cake, distributing a diversity of pollutants, incinerators also emit fugitive emissions. Fugitive emissions being vapours or particles that escape during incineration, and the handling of ash *e.g*., fugitive dusts can be released from bottom ash and fly ash hoppers during its transfer from transport vehicles to their final repositories such as landfills (Anon., 2011).

Some pollutants, such as particulate matter, semi-volatile organic compounds (dioxins, and PCBs), and volatile chemicals may be transported vast distances by air currents. Lorber et al., (1988), showed that 2% of dioxins emissions to the air are deposited in soil near to the incinerator. Particulate matter of ten microns (PM_{10}) and less in dimensions has been implicated in respiratory diseases (Tony et al., 2010). Schuhmacher et al., (1999); Ohata et al., (1997); Domingo et al., (1998), demonstrated how dioxin contamination of the soil can be detected in plants and how this can be used to prove pollution of the atmosphere (figure 1.3; A6).

With regard to vegetation, dioxins are deposited on the leaves of grass and crops, are absorbed through the stomata (Bache et al., 1992). Elimination of metabolites is the final step in the pharmacokinetic process. In the case of cattle, elimination via their milk is a route for bovine excretion. Cattle grazing in areas subjected to dioxin deposition, ingest the pollutants deposited on the leaves of the vegetation, then transfer the dioxins to their milk which humans in turn consume (figure 1.3; B1 to B2). In the Netherlands cows' milk obtained from cattle grazing in the vicinity of municipal waste incinerators, were found to be contaminated with dioxins (Liem et al., 1991). Similar discoveries of contaminated cow's milk were also reported in Switzerland (Schmid and Schlatter, 1992), and in France (Durand, 2008). This transfer process is called "Bioaccumulation" or "biomagnifications" which is the condition where an organism's intake of a resistant contaminant exceeds the organism's ability to metabolise or excrete the substance, resulting in the accumulation of the chemical in its tissues. Although the concentration of a contaminant may be virtually undetectable in water, it can be magnified exponentially as the contaminant passes along a food

chain. As an example polychlorinated biphenyls (PCBs) found in the Great lakes of North America, where the biomagnification for this substance in the food chain, (beginning with phytoplankton and ended in the Herring Gull), became magnified nearly 50 000 times. Domesticated animals and humans consume the fish (members in the same food chain) from the Great Lakes, resulting in PCBs poisoning (Gabriels, 2007).

Dioxin poisoning was uncovered in the Akwesasne Mohawk Reservation in the Great lakes Basin of Canada, where a study undertaken on the lactating women of a reservation, revealed elevated levels of dioxins in their breast milk, which they inadvertently passed on to their breastfeeding babies. The reservation was located downwind of a motor vehicle manufacturing plant owned by General Motors (Smith, 1995). In Spain breast milk of mothers living around a hazardous waste incinerator was analysed for dioxins and positive results were obtained (Schuhmacher et al., 2004). Figure 1.7 illustrates the dioxin intake by humans via different foodstuffs.

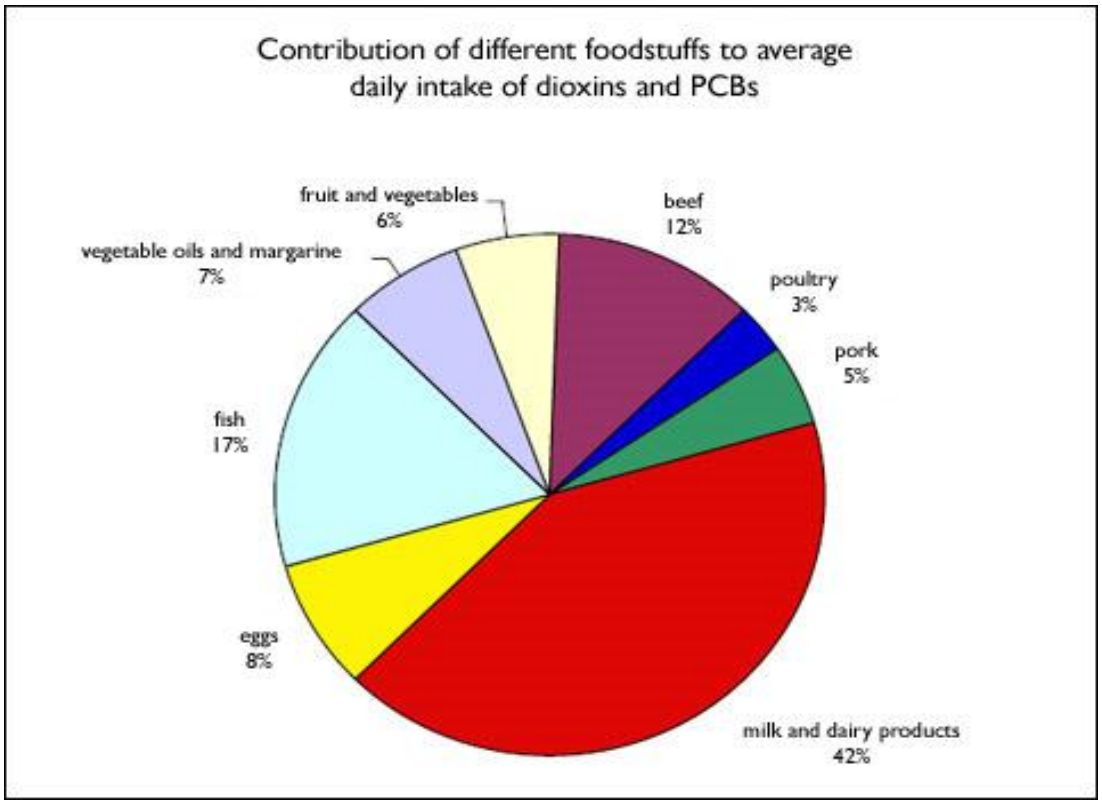

Figure 1.7: Dioxins in foods (Source: www.bmu.de/.../doc/41969.php)

1.4 Statement of the Research Problem

Internationally it has been found that only in the developed countries such as the United States of America, Canada, and some European countries, pharmaceutical waste has been recognised as a

distinct waste stream subset, and is consequently managed differently from general medical waste. The purpose of the present research was to prove:

a) that there exist a similar need in South Africa to characterise pharmaceutical waste as a distinct waste stream, and
b) that the mismanagement of pharmaceutical waste contributes to environmental pollution.

1.5 Objectives of the Study

The objectives of the research were:

a) To determine the extent of the prevailing knowledge by the healthcare professionals with regard to the management of the pharmaceutical waste which they generated,
b) To determine whether the incineration of the pharmaceutical waste generated at the selected sites contributed to environmental pollution.

1.6 Hypotheses

The research project set out to validate the following:

1.6.1 Hypothesis One

"That hazardous pharmaceuticals will be found unsegregated amongst non-hazardous pharmaceutical waste at the sites of generation".

1.6.2 Hypothesis Two

"That pharmaceutical waste would not be considered a distinctly different waste stream by hospital healthcare professionals at the sites of generation".

1.6.3 Hypothesis Three

"That the incineration of pharmaceutical waste generated at the selected hospitals in Cape Town, contributes to environmental pollution".

CHAPTER TWO (A): LITERATURE REVIEW

2A 1 Introduction

This chapter provides an overview of existing empirical literature on pharmaceutical compounds as environmental pollutants, and also deals with the complexity of the terminology used in these publications.

Clofibric acid was the first prescription drug reported to be present in sewage influent in Kansas City, as far back as 1976 (Hignite and Azaznoff, 1977). Today it is the most commonly discovered drug in tap water, groundwater, sewage effluents and rivers in all the countries where it was used, despite the fact that the drug was discontinued in those countries (Koutsouba et al., 2003; Stumpf et al., 1999). Clofibric acid is the main active metabolite of clofibrate. Table 2.1 lists some fibrates currently marketed in South Africa and the companies that produce them. These would be metabolised to clofibric acid compounding the presence of resident clofibric acid which were deposited years ago, extending its presence well into the next two decades. Environmental persistence of clofibric acid is estimated to be 21 years in water (Buser et al., 1998). Unfortunately South Africa's waters have not been analysed for the presence of clofibrate as a pollutant and as a biomarker for other pharmaceutical pollution.

Circa 1984, the idea of environmental risk assessment (ERA) for toxic chemicals, was mooted and ERAs became compulsory for all new chemicals sold in the European Union. Attempts were simultaneously made to develop ERAs for the plethora chemicals already circulating in the market at the time, although it was agreed that this would take many years to complete. It is this latter group of unchartered chemicals, of which pharmaceuticals constitute the majority, that forms the basis of our present day problems. Drugs *per se* were not discussed in this context before the early nineties. Jorgensen and Halling-Sorensen (2000) revealed that the drugs investigated for environmental impacts, at the time, were primarily:

1) the antibiotics (eight papers);
2) the anti-parasitic agents (four papers); and
3) hormones (three papers).

Table 2.1: Fibrates currently used in South Africa

Fibrate	Trade name	Dosage form	Pharmaceutical company
Gemfibrozil	Lopid®	600mg tablet	(Pharmacia) Pfizer
Bezafibrate	Bezalip®	200mg tablet 400mg retard tablet	(Thebe Pharma) Roche
	Bezachole®	400mg slow release tablet	Aspen Pharmacare
	Dyna-Bezafibrate®	400mg slow release tablet	Pharma Dynamics
	Sandoz-Bezafibrate®	400mg tablet	Sandoz
Fenofibrate	Lipanthyl®	200mg capsule	Solvay

There has been relatively little research into the potential of pharmaceuticals entering potable water supplies. One of the very first studies into the ability of pharmaceuticals to evade capturing by the conventional water treatment processes and emerge in the civilian potable water supplies was conducted by Stackelberg and his cohorts (Stackelberg, 2001).

2A 2 Terminologies

For the last three decades, research into the effects of chemical pollution in the environment, focussed mainly on conventional high production volume chemicals, such as pesticides, and heavy metals, petro-chemicals and ignored pharmaceuticals which are also anthropogenic substances. This void was reflected in the literature, until recent advances in gas and liquid chromatography (linked to mass spectrometry), made its advent and was applied to expose the presence of pharmaceutical compounds, lurking in the aquatic environment.

Humans are inexorably intertwined with the environment. David Rapport, by linking medicines to the environment, introduced the concept of “ecological health” and the “health of the ecology” in 2002. By “health of the ecology” he referred to the condition of the ecosystem and by “ecology of health” he referred to the state human health as influenced by the ecosystem within which we live (Daughton, 2003).

The difficulties associated with identifying pollutants were further compounded in the literature by the use of terminologies, definitions and acronyms which are often the bane of scientists; at best unnecessarily confusing or at worst obfuscating communications between the scientific disciplines. To simplify this complexity and to highlight the significance of the problem which also confounded my literature search, I list some of the important terminologies below.

2A 2.1 Medical Waste

The WHO has opted to use the term "Health-care Waste" instead of "Medical Waste", and defines the former as:

> "Health-care Waste" includes all the waste generated by healthcare establishments, research facilities, and laboratories. In addition it includes the waste originating from "minor" or "scattered" sources such as that produced in the course of health care, undertaken in the home (dialysis and insulin injections, *etc*)", (Pruss et al., 1999a).

2A 2.2 Pharmaceutical Waste

"Pharmaceutical", the Concise Oxford English Dictionary defines as "…of or engaged in pharmacy, the use or the sale of medicinal drugs" (OED, 1992). The use of the term "pharmaceuticals" in this research, refers to human medicines.

The WHO expands the term "Pharmaceutical" by linking it to "pharmaceutical waste" and defining the latter as:

> "Pharmaceutical waste includes expired, unused, spilt, and contaminated pharmaceutical products, drugs, vaccines, and sera that are no longer required and need to be disposed of appropriately. The category also includes discarded items used in the handling of pharmaceuticals, such as bottles or boxes with gloves, masks, connecting tubing, and drug vials" (Pruss et al., 1999b).

2A 2.3 Genotoxic Waste

Genotoxic waste is highly hazardous and may have mutagenic, teratogenic, or carcinogenic properties. It raises serious safety problems, both inside and outside the hospitals, and should be given special attention. Genotoxic waste may include cytotstatic drugs, vomit, urine, or faeces

from patients treated with cytostatic drugs, chemicals, and radioactive material. Cytotoxic (or antineoplastic) drugs, have the ability to kill or stop the growth of certain living cells and are used in the chemotherapy of cancer. but are also finding wider application as immunosuppressive agents in organ transplantation and in treatment of various immunological diseases. Cytotoxic drugs are most often used in specialised departments such as oncology and radiotherapy units. However, their use in other hospital departments is increasing and they may also be used outside the hospital setting (Pruss et al., 1999c).

The Department of Water Affairs and Forestry under Appendix 5.3 of the Minimum Requirements for Handling, Classification and Disposal of Hazardous Waste, lists mutagens and carcinogens under four classes. Class A contains well known carcinogens and teratogens like arsenic, asbestos, benzene and mustard gas. However many chemicals listed here as mutagens and carcinogens are used therapeutically, and only a few common drugs from this Appendix 5.3 are listed in Table 2.2 to underscore the point (South Africa. Department of water Affairs and Forestry, 1998b). However, in pharmacies these listed drugs are not segregated from other drugs in order to dispose of it appropriately when required.

The Department of Water Affairs and Forestry's, Minimum Requirements for Handling, Classification and Disposal of Hazardous Waste, under its Appendix 5.2, lists a number of chemicals as teratogenic (South Africa. Department of water Affairs and Forestry, 1998).

2A 2.4 Chemical Waste

Chemical waste consists of discarded solid, liquid, and gaseous chemicals, for example from diagnostic and experimental work and from cleaning, housekeeping, and disinfecting procedures. Chemical waste from health care may be hazardous or nonhazardous. In the context of protecting health, it is considered to be hazardous if it has at least one of the following properties: toxic; corrosive; flammable; reactive and genotoxic, (Pruss et al., 1999d). The WHO does not link the concept of chemical hazard to pharmaceuticals, as a separate waste stream. The process of establishing pharmaceutical waste as a specific waste stream has become the major challenge facing pharmacists throughout the world. Only a few countries like the United States of America (USA), have developed systems that bridges this gap**.**

Table 2.2: Mutagens and carcinogens currently used in South Africa

	Generic Name	Trade Name
Class A	Ciclosporin	Sandimum®, CicloHexal®
	Cyclophosphamide	Endoxan®
	Tamoxifen	Kessar®;Nolvadex®; Neophedan®; tamoplex®
Class B	Chloramphenicol	Chlorphen®
	Griseofulvin	Microcidal®
	Metronidazole	Flagyl®; Trichazole®
	Phenobarbital	Lethyl®
	Phenytoin	Epanutin®
Class C & D	Ampicillin	Ampicillin-Fresenius® Be-ampicillin®
	Cimetidine	Cimlock®; Lenamet®; Hexamet®
	Diazepam	Valium®;Pax®; Betapam®
	Disulfiram	Antabuse®
	Furosemide	Lasix®;Puresis®; Beuresis®
	Paracetamol	Panado®; Tylenol®; Dolorol®
	Prednisone	Meticorten®; Panafcort®
	Reserpine	Reserpine®
	Rifampicin	Rimactane®; R-Cin®
	Theophylline	Nuelin®; Alcophyllin®; Euphyllin Retard®
	Vinblastine	Vinblastine PCH®; Vinblastine-Faulding®

2A 2.5 Hazardous Waste

The definition of Hazardous Waste is very broad, since wastes can vary substantially in nature, composition, size, volume, appearance and degree of harmfulness. The National Environmental Management: Waste Act, 2008 (Act 59 of 2008), defines "General Waste" as:

> "…waste that does not pose an immediate hazard or threat to health or the environment, and includes-
>
> (a) domestic waste:
>
> (b) building and demolition waste:
>
> (c) business waste: and
>
> (d) inert waste".

The same Act (Act 59 of 2008) defines "hazardous waste" as:

> "...any waste that contains organic or in organic elements or compounds that may, owing to the inherent physical, chemical or toxicological characteristics of that waste, have detrimental impact on health and the environment".

2A 3 International Benchmarking for Healthcare Waste

In 1976 the USA enacted The Resource Conservation and Recovery Act (RCRA), as a direct response to escalating environmental disasters occurring throughout the country. The objective of RCRA was to encourage waste minimisation, and define hazardous waste, but it also laid the basis for the stewardship and the tracking of hazardous waste. RCRA and its amendments up till today are considered as the international benchmark for waste management (Bezdek and Wendling, 2006). In tandem to this development, the Environmental Protection Agency of the USA (US EPA) developed definitions for the four characteristics of hazardous waste, viz., ignitability, toxicity, corrosivity, and reactivity, which could also be applied to pharmaceuticals:

2A 3.1 Ignitability-

Applies to aqueous liquids containing less than 24 % alcohol by volume and has flash point less than 60 °C (140 °F) *e.g.* Dalacin-T ®, a Schedule 4 drug, containing clindamycin in isopropyl alcohol 50% and propylene glycol 5% (Rossiter, 2010). The ignitability property of a chemical has tremendous impact on pharmaceuticals since many medicines contain alcohol. Certain volatile topical applications such as collodion flexible will ignite below 60 ºC, yet it is commonly found on the shelves of dispensaries and not in a flameproof cupboard (Smith, 2002).

2A 3.2 Toxicity

Any chemical in the USA which meets certain specific leaching concentrations are classified as potential toxic pharmaceuticals (Smith, 2002):

e.g 1. Selenium. In South Africa selenium is the active ingredient in Selsun ® Shampoo which is unscheduled, and can freely be sold over the counter without a prescription.

*e.g.2.*Silver. In South Africa the following medicine contain silver but are not considered toxic:

Flamazine® Cream (Schedule 4)

Silbercor® Cream (Schedule 4)

e.g.3 Mercury. In South Africa the following medicine contain mercury but are not considered toxic:

Methiolate ® Tincture (unscheduled)

Mercurochrome ® Solution (unscheduled)

2A 3.3 Corrosivity

Applies to aqueous liquids which has a pH of less than or equal to 2 or greater than or equal to 12.5, including liquid waste capable of corroding steel at a rate greater than 0.250 inches per year. Examples of such chemicals used in pharmaceutical manufacturing are glacial acetic acid, and sodium hydroxide (Smith, 2002).

2A 3.4 Reactivity

Any chemical or solid waste exhibits the characteristic of reactivity if it has the following properties:

(1) It is normally unstable and readily undergoes violent change without detonating,

(2) It reacts violently with water,

(3) It forms potentially explosive mixtures with water,

(4) When mixed with water, it generates toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment,

(5) It is a cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment,

(6) It is capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement,

(7) It is readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure (Smith, 2002).

Aerosol therapeutics commonly used for lung diseases also fall in this category. They are pressurised metallic containers which explodes when incinerated, even if it is empty. They are thus more than ignitable since they explode inside the incinerator damaging the combustion chamber, even if the container is empty. A solid waste that exhibits the characteristic of reactivity receives the US EPA Hazardous Waste Number of D003 (Hari and Lewis, 1994).

The RCRA also publishes three continuously updated lists of hazardous chemicals viz., P-listed, U-listed, and D-listed chemicals. Since pharmaceuticals are chemicals *per se*, some of these compounds classified as "chemicals" are in fact pharmaceuticals (USA 2009). In the USA pharmacists constantly have to check whether chemicals on this ever-expanding list contains pharmaceuticals in order to subject it to "P", "U" and "D" priority handling that it legislatively commands (Smith, 2002). A similar procedure is not applied in South Africa.

2A 3.5 P-Listed Chemicals

P-listed chemicals are considered by the US EPA as "acutely hazardous", constituting the most dangerous chemicals for acute exposure. Each of these chemicals carry a unique "P" number by which they are identified as "acutely hazardous". Any institution that generates 2.2 lb (1kg) of P-listed hazardous waste in one month becomes subject to special regulations as a "large quantity" hazardous waste generator. Table 2.3 gives a few examples of such drugs (Smith 2002).

Table 2.3: P-listed chemicals

P-listed number (USA)	Pharmaceutical	Schedule (South Africa)
P042	Epinephrine	S4
P075	Nicotine	S2
P081	Glyceryl trinitrate	S3

2A 3.6 U-Listed Chemicals

This list covers a broader range of lesser toxic chemicals than those on the P-list, and if they are the sole active ingredient in a product, they would be listed as "U-listed" hazardous pharmaceutical waste, and assigned a "U" number. Table 2.4 gives a few examples of such drugs (Smith 2002).

Table 2.4: U-listed chemicals

U-listed number (USA)	Pharmaceutical	Schedule (South Africa)
U058	Cyclophosphamide	S4
U200	Reserpine	S3
U202	Saccharine	Unscheduled
U205	Selenium	Unscheduled
U122	Formaldehyde	Unscheduled
U010	Mitomycin	S4
U150	Melphalan	S4

2A 3.7 D-listed Chemicals

The USEPA has defined four characteristics viz., ignitability, toxicity, corrosivity, and reactivity (q.v. above), which if possessed by any pharmaceutical waste, would be classified as a D-Listed hazardous waste, and assigned a "D" number (Anon., 2010c). Table 2.5 gives a few examples of such drugs (Smith 2002).

Table 2.5: D-listed chemicals

D-listed number (USA)	Pharmaceutical	Schedule (South Africa)
D005	Barium 100 mg/L	S2
D022	Chloroform 6 mg/L	Unscheduled
D013	Lindane 0.4 mg/L	S1

2A 4 New Drug Development

During the development of new drugs, the selected chemical compound destined to become a pharmaceutical, has to meet specific performance criteria before being allowed to progress in the registration process. Live animal studies, during the preclinical-safety and toxicity-testing stages, are generally necessary to determine the effect of the proposed drug on organ systems and disease models. Subsequent to this stage, drugs then undergo substantial pharmacological investigations and clinical trials on human subjects, prior to registration and release into the market for therapeutic purposes. However, it was only until very recently that data with regard to their ecotoxicity was required by US authorities, before the final registration of a new drug. (Berkowitz, 2007). However this criterion is non-existent for most of the drugs currently in use in the USA.

2A 5 The Chemical Milieu of Daily Living

Humans live in an envelope of chemicals which we inhale, ingest, or absorb through the skin, and the manner in which they influence our bodies and the environment is described by different terms. "Toxicology" is concerned with the deleterious effects these chemicals have on

all living systems. “Environmental Toxicology” deals with the potentially harmful effects chemicals, present as pollutants in the environment, have on specific living organisms. “Ecotoxicology” is concerned with the toxic effects of chemicals on populations and communities of living organisms within a defined ecosystem, including the transfer pathways of the chemicals within the system and their interactions with the environment. The terms environmental toxicology and ecotoxicology are thus not interchangeable (Gabriel, 2007).

Drug residues in human excreta are transported to the coast, primarily by municipal and industrial sewage effluents as well as by run-offs from farmlands and golf courses irrigated by sewage water. The pharmaceuticals most commonly found in estuaries are antibiotics, hormones, and cytotoxic drugs (Benotti and Brownawell, 2009). The condition of our local surface waters (rivers, lakes, and coasts) have continued to decline to the extent that an advisory warning was given to the general public that the acceptability of the inland waters has dropped from 80% to 58%. Furthermore, of the waters along the False Bay coastline, only 55% is suitable for human use (Anon., 2010a).

The acronym PPCP (pharmaceuticals and personal care products) was originally coined by Daughton and Ternes in 1999. PPCPs comprise a very diverse collection of thousands of chemical, including prescription, veterinary, and over-the-counter (OTC) therapeutic drugs, fragrances, cosmetics, sun-screen agents, diagnostic agents, nutraceuticals, biopharmaceuticals, growth enhancing chemicals used in livestock operations, and many others. The mass of chemical compounds captured under the abbreviation of PPCPs has become generally accepted to refer to any product used by individuals for personal health or cosmetic reasons. Since its introduction in 1999, the acronym PPCPs has not only become the most frequently adopted term in both the technical and popular literature but has become an extremely useful keyword when performing literature searches on the internet.

Giger (1999) reviewed the research done on the environmental pollution of pharmaceuticals, but surveyed only that done in Europe. Daughton and Ternes (1999), in their landmark publication on the other hand, gives a more comprehensive review of the prevailing international research literature with regards to the environmental occurrences, distribution, and effects of PPCPs, providing a chemical-by-chemical listing of information on structure, use, origin, environmental occurrence, and toxicity. The chemicals identified by them as being of potential environmental

concern, were lipid regulators, analgesics, anti-inflammatories, anti-epileptics, anti-depressants (e.g. fluoxetine), anti-neoplastics (e.g. vinblastine), fragrances (e.g. musks), x-ray media (e.g. diatrizoate), oral contraceptives (ethenyl estradiol), impotence drugs (e.g. Viagra®), and sunscreen agents (e.g. methylbenzylidene camphor).

2A 5.1 Xenobiotics

The term encompasses all anthropogenic chemicals existing in the environment, such as pharmaceutical and personal care products (PPCPs); organic wastewater contaminants (OWCs); endocrine disrupting chemicals (EDCs); pharmaceutically active compounds (PhACs or (PCs as used below)); industrial chemicals (ICs); all of which are schematically represented below in figure 2.1.

The acronym PhACs (pharmaceutically active compounds), is a subset of PPCPs. PhACs as expounded by Daughton and Ternes, (1999), included veterinary medicines. However I have reduced this range even further by limiting the PhACs to human therapeutically active compounds (HPhACs).

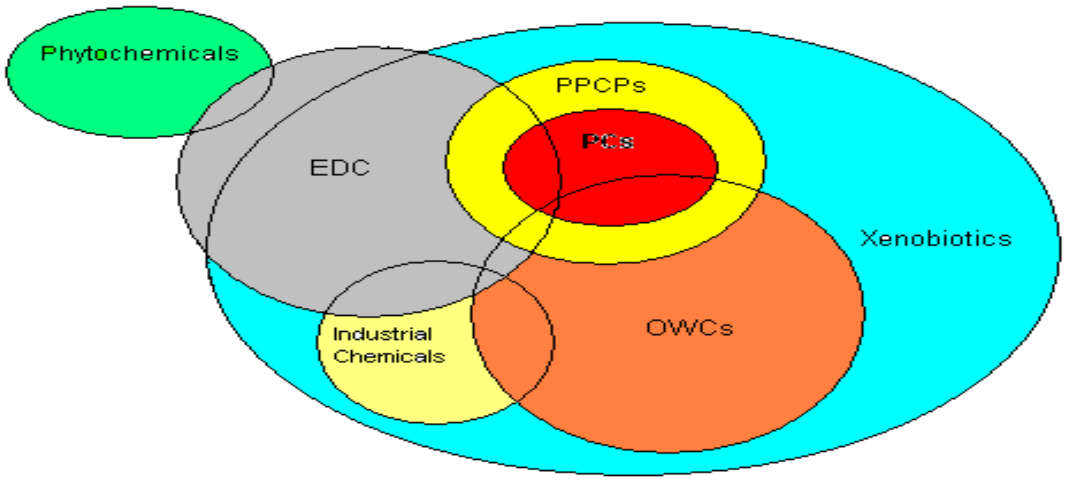

Figure 2.1: Xenobiotics nomenclature (adapted from Jean Debroux, 2007)

Sub-therapeutic concentrations of pharmaceuticals were detected in many countries in the effluents from STWs, surface waters, seawaters, groundwater and some drinking waters. Only in the case of some of these compounds, have their physiological effects on aquatic organisms been

investigated for acute toxicity. An overview of this topic, further showed that very little is known and recorded about the chronic effects of pharmaceuticals on aquatic organisms, in particular with respect to their biological targets (Fent et al., 2006).

However, chronic effects are always insidious and the impact on the environment is always on a larger scale than the acute affects referred to by them. This view was substantiated by the surprise discoveries of the unusually high death rate of three complete species of vultures in India and Pakistan, reported in 2004 to be caused by diclofenac, an analgesic, anti-inflammatory used in animal husbandry (Fent et al., 2006). Diclofenac is still widely used in South Africa, but no research has been undertaken on its environmental toxicity.

Many environmental analyses have been performed in various countries, which were summarized by Halling-Sorensen (1998); Daughton and Ternes (1999); and Kummer (2004). These monitoring studies demonstrated that drug residues in ground and surface water are very widespread. In contrast to the mere monitoring for their presence, little is known about their ecotoxicological effects on aquatic, terrestrial organisms and wildlife. A comprehensive overview of their ecotoxicity is lacking (Fent et al., 2006).

2A 6 Obligations of Healthcare Professionals

Healthcare professionals (doctors, pharmacists, and nurses) like all other citizens also have a moral obligation towards sustaining a healthy environment. However very little has appeared in the medical literature to demonstrate that they subscribe to this principle (Daughton, 2002).

Although there is consensus that the ultimate responsibility for the environmental stewardship of pharmaceuticals, rests with the healthcare professionals, (who uses pharmaceuticals as the tools of their profession), there is almost no discussion of the overall issue in South African medical literature. For this reason, the present research has *inter alia* targeted medical doctors, pharmacists, and nurses, at selected hospitals, to gauge their perspective on the management of pharmaceutical waste.

Pharmaceutical pollutants are often described in the literature as “emerging pollutants” (Barcelo, 2004; Knepper, 2004) which is a misnomer because they were probably present long before their discovery and their presence only came to light with the advent of improved analytical methods

in the 1990s. In South Africa no thesis was registered on the acute or chronic effects of pharmaceuticals [as a specific waste stream] on the environment.

CHAPTER TWO (B): THE SOUTH AFRICAN LEGISLATIVE ENVIRONMENT

2B 1 Introduction

In 1994 South Africa became a democracy, which brought about unprecedented changes in every aspect of life in this country. In 1996 a new constitution was promulgated for the newborn democracy, which included the environment. For the first time in South Africa's history the environment received juristic rights and the citizens of the country received *locus standi*.

The inclusion of an environmental clause in Section 24 of the Bill of Rights of the Constitution, has been followed by the rapid development of South Africa's environmental legal framework. Responsibility for the safeguarding of the environment was formerly distributed between many different national departments, and provincial authorities. Although this picture has not changed much since 1994, the Department of Environmental Affairs and Tourism took the lead in coordinating the attempts to merge the various pieces of fragmented environmental legislation. Environmental issues in South Africa are largely prompted by law, but regrettably not by the social responsibilities of its citizens. However, it is agreed that although superlative laws are enshrined in our statutes, law enforcement is sadly lacking. Environmental law is no exception.

2B 2 The Complexity of Legal Definitions

A review of the South African environmental legislation was confounded by several definitions of the different types of waste. Because this thesis focuses of the environmental impact of hazardous pharmaceutical waste, it behoved the researcher to clearly understand the definition of "hazardous waste".

The Department of Water Affairs and Forestry (DWAF) in 1998 published the Minimum Requirements for the Handling, Classification, and Disposal of Hazardous Waste, as a systematic framework for identifying a hazardous waste and classifying it in accordance with the degree of risk that it poses. It defines and describes "hazardous waste" as:

> "an inorganic or organic element or compound that, because of its toxicological, physical, chemical or persistent properties, may exercise detrimental acute or chronic impacts on human health and the environment. It can be generated from a wide range of commercial,

industrial, agricultural and domestic activities and may take the form of liquid, sludge or solid. These characteristics contribute not only to the degree of hazard, but are also of great importance in the ultimate choice of a safe and environmentally acceptable method of disposal.

Further to this, a hazardous waste can be defined as that directly or indirectly represents a threat to human health or the environment by introducing one or more of the following risks:

- Explosion or fire ,
- Infection, pathogens, parasites or their vectors,
- Chemical instability, reactions or corrosion,
- Acute or chronic toxicity,
- Cancer, mutations, or birth defects,
- Toxicity, or damage to the ecosystem or natural resources, and
- Accumulation in biological food chains, persistence in the environment, or multiple effects to the extent that it requires special attention and cannot be released into the environment or be added to sewage or be stored in a situation which is either open to air or from which aqueous leachate could emanate" (South Africa, 1998d).

It must be noted that the definition omits health care facilities as possible generators of hazardous waste. The DWAF refers to the above definition as the "The South African definition of hazardous waste and states that it complies with the United Nations Environment Program definition, primarily because of its content and scope, but also to obtain international acceptance for South African waste management legislation and management practices (South Africa, 1998d).

The definition of terms such as "pollution", "waste", and "hazardous waste" is problematic. Not only is it conceptually difficult to distinguish between "waste" as a resource, or a pollutant, but the nature of the receiving environment is also crucial. For example, the medical waste generated by hospitals can become a valuable resource and fuel when incinerated. A new technology has been developed for the co-incineration of waste in cement kilns as replacement fuels, especially those wastes which has sufficiently constant composition such as oils. Kilns are well suited for toxic organic waste incineration (*e.g.*

cytotoxic medicines) because of the high temperatures and longer residence times (5 seconds between 1500 ºC and 2000ºC) than in conventional incinerators (2 seconds at 1200ºC) (Rabl and Spadaro, 2001).

Waste according to the Genetically Modified Organisms Act (Act 15 of 1997), defines waste as:

"... means any matter, whether gaseous, liquid or solid or any combination thereof, which is in the *opinion of the person* in whose possession or under whose control it is, an undesirable or superfluous by–product, emission, residue or remainder of any process or activity in connection with genetically modified organisms".

The problem becomes still more perplexing since the National Environmental Management Act (Act 107 of 1998) contains the following convoluted definition of "pollution":

> "…any change in the environment caused by
>
> i. Substances,
> ii. Radioactive or other waves or
> iii. Noise, odour, dust, or heat
>
> emitted from any activity, including the storage or treatment of waste or substances, construction and the provision of services, whether engaged in by any person or organ of state, where that change has an adverse effect on human health or well-being, or on the composition, resilience and productivity of natural or managed ecosystems, or on material useful to people, or will have such an effect in the future" (South Africa, 1998).

The WHO does not use the term "Medical Waste", but instead uses "Health-care Waste" which it defines as:

> "Health-care waste includes all the waste generated by health-care establishments, research facilities, and laboratories. In addition it includes the waste originating from "minor" or "scattered" sources such as that produced in the course of health care undertaken in the home (dialysis, insulin injections, etc)"(Pruss et al., 1999a).

The WHO further defines Hazardous Pharmaceutical waste as:

"Pharmaceutical waste includes expired, unused, spilt, and contaminated pharmaceutical products, drugs vaccines, and sera that are no longer required and need to be disposed of appropriately. The category also includes discarded items used in the handling of pharmaceuticals, such as bottles or boxes with gloves, masks, connecting tubing, and drug vials."(Pruss, et al., 1999b).

In the light of the many "legal" definitions for hazardous waste, and the general confusion that results there from, the DWAF declares that

"South Africa has decided that the most practical method of identifying and classifying hazardous substances is by

- Inclusion of a list of substances
- Incorporation of a degree of hazard approach, not only to designate a waste as hazardous or not, but also to differentiate between degree of hazard regarding disposal methods and sites;
- Use of concentration levels and "total loading", or the assimilation capacity of sites, to guard against future detrimental effects on the environment;
- The use of "acceptably low risk" levels to allow for the delisting or reclassification of a hazardous waste as a general waste for waste disposal, if it can be shown that the risk posed to the environment is acceptably low (South Africa, 2000).

The salient features of South Africa's legislation currently applicable to the environment, from a pharmaceutical waste perspective, are:

2B 3 The South African Constitution

Section 24 of the constitution provides that every one has the right to

a) an environment that is not harmful to their health or well-being; and

b) have the environment protected, for the benefit of present and future generations, through reasonable legislative and other measures that

i. prevent pollution and ecological degradation;

ii. promote conservation; and

iii. secure ecologically sustainable development and use of natural resources while promoting justifiable economic and social development.

This entrenched right is secured by two anchors, firstly the right to a clean and healthy environment and then by a commitment to promulgate legislation to bring this about. All the organs of state are subject to the Constitution and section 7 and 8 of the constitution provides the basis for this obligation.

Waste management *per se* is not dealt with in our Constitution in any detail, but the constitution determines in Schedule 4 and 5, which tiers of government shall be responsible for the different aspects of waste management. Schedule 4 lays down the areas of both national and provincial competence, while Schedule 5 determines the activities for which provincial and local government are exclusively responsible for *inter alia*: cleansing, refuse removal, landfills and solid waste disposal.

Glazewski (2009) indicated that the meaning of the words "health" and "well-being", as used in the constitution, is not defined and it will ultimately rest with the courts to clarify its meaning. Until the courts decide, he contends that the most likely interpretation of the words would be:

- "Protection of our "health" includes protection from pollution, whether in the air, water, food or soil. It includes protection from dangers in the workplace, and from less obvious dangers to health such as noise.
- Protection of our "well-being" is wider than the protection of health. It includes protection from nuisances and invasions of privacy and dignity. The European Court of Human Rights recently ruled that a bad smell from a tannery that offended neighbouring residents was a violation of their right to privacy. In our [South African] law this would probably qualify as a violation of the right to well-being. So we can say that something affect our well-being if it affects our ability to enjoy our life".

2B 4 The National Environmental Management Act (Act 107 of 1998) (NEMA)

The NEMA serves as the basic framework for environmental management legislation and came into operation in January 1999. The principles enshrined in NEMA, guides the interpretation, administration and implementation of all other laws concerned with the protection of the environment.

The central theme of NEMA in relation to waste is encapsulated in section 2 (4) (a) (iv):

"…that waste is avoided, or where it cannot be altogether avoided, minimised and reused or recycled where possible and otherwise disposed in a responsible manner…".

2B 4.1 Sustainable Development

Pharmaceutical waste, because of its persistence, pervasiveness, and unknown inherent hazard, is internationally considered to be the new frontier of environmental pollution.

The NEMA defines sustainable development as "the integration of social, economic and environmental factors in decision-making so that development serves present and future generations". This founding principle in the NEMA is thus very pertinent.

2B 4.2 Polluter-Pays Principle

Section 28 of the Constitution of the Republic of South Africa gives effect to the "Polluter Pays Principle" and provides for a "duty of care" and for the remediation of any environmental damage by the polluter. Any person who is guilty of causing, or may cause serious pollution of the environment is simultaneously obligated under this Act, to take reasonable precaution to prevent this from recurring.

This principle has been adopted in South Africa in a number of policy documents including:

1) The White Paper on Environmental Management in South Africa, which states:

"Those responsible for environmental damage must pay the repair costs both to the environment and human health, and the costs of preventive measures to reduce or prevent further pollution and environmental damage" (South Africa, 1998d).

2) NEMA includes the polluter pays principle in the following terms:

"The cost of remedying pollution, environmental degradation and consequent adverse health effects and of preventing, controlling or minimising further pollution, environmental damage or adverse health effects must be paid for by those responsible for harming the environment" (South Africa, 1998e).

Section 19 of the National Water Act (Act 36 of 1998) also legislates into effect the "Polluter Pays Principle" by making the owner, controller, occupier or user of land responsible for preventing the pollution of the water resources on the land in question.

2B 4.3 Principle 16 of the Rio Declaration

The negative cost of industrial production, pollution and waste management, are often borne by the environment rather than by the generator of the pollution. The idea behind the polluter pays principle attempts to reverse this so that the actual cost of the pollution is borne by the generator. This concept is also encapsulated in Principle 16 of the Rio Declaration which states:

> "National authorities should endeavour to promote the internalization of environmental costs and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution, with due regard to the public interest and without distorting international trade and investment" (Anon. 1992).

2B 4.4 Legal Violations

Every doctor, nurse, or pharmacist, whether employed in the private or public sector, is classified as a generator of medical waste in terms of the Western Cape Healthcare Waste Management Act (Act 7 of 2007). If it can be shown that the medicines that they administered, prescribed or dispensed in the course of their normal duty, were the cause of environmental pollution, then they would be culpable under this provincial act as well as under NEMA.

Although there were agreements between CPUT and the superintendents of the hospitals, that the findings of this research is purely of academic interest, the hospitals were made aware, in discussions with them, of the legal implications and of the *locus standi* of the general public in the matter of environmental pollution. It should not be overlooked by the hospital managements that the Promotion of the Access to Information Act (Act 2 of 2000), gives every citizen the right to access information with regard to medical waste and to process such information in whatever manner the receiver deems fit.

2B 4.4.1 Vicarious Liability of Hospital Staff, Management, and Provincial Authority

Vicarious liability refers to a person being liable for someone else's unlawful action even if there is no fault by the first person.

The hospitals involved in the research and others may therefore be held vicariously liable for the unlawful acts of the healthcare professionals employed by the hospital, who engage in any wrongful act or omission during the course and scope of their normal practice. The case of Esterhuizen v Administrator, Tvl.1957 (3) SA 710 (T), became a landmark in South African law,

where successful action for damages was instituted against the Provincial Administrator and the hospital management that employed the doctor (Naidoo, 2004).

More recently in March 2011, the Western Cape premier, Helen Zille, and a Tygerberg Hospital surgeon, lost their appeal against a Western Cape High Court ruling that held them responsible for the damages suffered by a women, after a botched sterilization operation, which left her suffering from dementia, poor memory, cognitive disability, virtually blind, paraplegic and unable to talk, after childbirth (Schroeder, 2011).

Hospitals could be liable despite having warned their employees against using certain procedures, or when the acts or omissions of the employees, amount to intentional wrongdoing, provided that their action fall within the course and scope of the employees. The of case of Cf Zungu v Administrator, Natal 1971 (1) SA 284 D) provides a legal precedent.

The regional Department of Health may also not escape vicarious liability for the conduct of the hospital employees. The doctors, pharmacists, and nurses may be held directly or vicariously liable for the conduct of the waste disposer. The case of Cf Feldman (Pty Ltd) v Mall 1945 AD 733 provides a legal precedent.

If one considers the above together with many other laws spearheaded by the Constitution, it is clear that should there be litigation against any of the hospital healthcare professionals, I anticipate that the rights of the environment would prevail.

2B 5 The National Environmental Management: Air Quality Act (Act 39 of 2004)

The old Atmospheric Pollution Prevention Act (Act 45 of 1965), (APPA), has been entirely replaced by the National Environment Management: Air Quality Act (Act 39 of 2004), (Air Quality Act). The Air Quality Act was promulgated following the President's signature on 24th February 2005, and most of its provisions came into force on 11th September 2005. In the past APPA largely governed point-source emission control, which does not take into consideration the cumulative impact of air pollution in areas where the concentration of emissions of harmful substances into the atmosphere is substantial. However, at present there are no legally binding

guidelines or standards in South Africa for the efficient and safe operations of incinerators nor for other healthcare waste treatment technologies (Molefe et al., 2006).

2B 6 The National Environmental Management: Waste Act (Act 59 of 2008)

Democratic South Africa in 1994 inherited a mosaic of fragmented environmental laws. This Act is the most recent national waste management act promulgated in South Africa and is seen as the single piece of legislation that addresses waste management in a holistic and integrated manner. It includes the National Waste Management Strategy and Norms and Standards, Institutional and Planning requirements for government, waste management measures or things to do when handling reduction, reuse and recycling of waste. It also covers processes or direction on how to deal with polluted land, develop industry waste management plans, the licensing of waste management activities, waste information, compliance and consequences for non-compliances as well as general issues, (South Africa, 2011).

Generally this Act gives effect to section 24 of the Constitution in order to secure an environment that is not harmful to health and well-being.

2B 6.1 Environmental Impact Assessment (EIA) Regulations

On 02 August 2010 the Minister of Water and Environment Affairs, Buyelwa Sonjica**,** published the Listing Notice 2 of the activities that requires an environmental authorisation prior to the commencement of that activity and which identifies the competent authorities in terms of section 24(2) and 24D of the National Environmental Management Act 107 of 1998. This listing notice is called the Environmental Impact Assessment Regulations Listing Notice 2 of 2010. It describes activity no.5 as:

> "The construction of facilities or infrastructure for any process or activity which requires a permit or licence in terms of emissions, pollution or effluent and which is not identified in Notice No.544 of 2010 or included in the list of waste management activities published in terms of section 19 of the National Environmental Management: Waste Act 2008 (Act No.59 of 2008), in which case that Act will apply"(South Africa, 2010).
>
> Clearly this applies to hospitals, waste water treatment works, incinerators, landfill sites, and water treatment plants.

2B 7 Department of Water Affairs and Forestry (DWAF)

In order to control and manage the many aspects of waste, DWAF published in 1998 the "Minimum Requirement" Series of standards and procedures. These requirements have not been legislated into law, but are strongly recommended guidelines. The three volumes comprise:

1. **Minimum Requirements for Handling, Classification and Disposal of Hazardous Waste**.

   This document sets out a waste classification system, the requirements for the pre-treatment and disposal of hazardous waste according to this classification, the prevention, minimization, handling, transportation, and storage of such waste.

2. **Minimum Requirements for Waste Disposal by landfill**.

   This document deals with landfill sites, investigation, design, operation and monitoring of landfill sites.

3. **Minimum Requirements for monitoring of Water Quality at Waste Management Facilities**.

   This document addresses monitoring of water quality at and around the waste disposal site.

2B 8 The National Water Act (Act 36 of 1998) (NWA)

The NWA acknowledges that all water in South Africa is a natural resource that belongs to all its citizens. The Act regulates the manner in which a person acquires this legislated right to use water and it provides for a just and equitable utilisation of the water resources. This Act restricts in section 1, the definition of waste to water and defines waste as:

"…any solid material or material that is suspended, dissolved or transported in water (including sediment) and which is spilled or deposited on land or into a water resource in such volume, composition or manner as to cause, or to be reasonably likely to cause, the water to be polluted"

The Act refers to water where it is used to transport waste and where water is, or may be polluted by waste. In terms of pharmaceutical waste this would be applicable where pharmaceuticals which leached into ground water from landfills, and where pharmaceuticals excreted by patients are not removed from the sewage by the sewage treatment plant and expelled as effluent.

The uses of water are set out in section 21 and include the following uses which are relevant to waste:

"The uses of water relevant to pharmaceutical waste are-

- "Engaging in an activity controlled under section 37 which includes:
  - Irrigation of any land with waste or water containing waste generated through any industrial activity or waterworks and
  - intentionally recharging an aquifer with any waste or water containing waste
- Discharging waste into water resources or in a manner which may detrimentally impact on a water resource".

2B 9 Western Cape Health Care Waste Management Act (Act 7 of 2007) (WCHCWM Act)

Since all the research sites are located in the Western Cape Province it is incumbent to review relevant legislation applicable to this province. In 2007 the Premier of the Western Cape assented to the WCHCWM Act, which thus becomes the most recent provincial legislation, against which the activities of the research sites (hospitals) will be evaluated for compliance.

The Act lays down the following definitions *inter alia*:

" ***disposal****"* means the intentional release or discharge, or burial, deposit, or placing of any waste material into air or water or onto land, and the words "dispose" , "disposes", have corresponding meanings.

" ***generator***: means any person or any agent of a person that generates health care waste, but does not include a household generator of health care waste".

"*health care waste management:* means the environmentally safe handling, storage, collection, transportation, treatment and disposal of health care waste, and the words "manage" and "managed" have corresponding meanings".

"***health care waste mismanagement:*** means the unsafe or negligent handling, storage, collection, transportation, treatment or disposal of health care waste that has the potential to harm the environment or compromise human health, and the word "mismanage" has a corresponding meaning".

"*health care risk waste:* means that portion of health care waste that is hazardous and includes infectious waste, pathological waste, sharp waste, pharmaceutical waste,

genotoxic waste, chemical waste, waste with heavy metals, radioactive waste, and any other health care waste which is defined as hazardous in terms of the Waste Management Series: Document 1: Minimum Requirements for the Handling, Classification and Disposal of Hazardous Waste, as published by the Department of Water Affairs and Forestry".

"transport: means the movement of health care risk waste from the point of generation to a temporary or permanent point of storage, treatment, or disposal".

"transporter: means any person or agent acting on behalf of a person that transports health care risk waste from the point of generation to a temporary or permanent point of storage, treatment or disposal.

"treater: means any person or any agent acting on behalf of a person or an institution, involved in the treatment of health care risk waste prior to the final disposal of such health care risk waste."

"treatment facility: means a facility permitted in terms of section 20 of the Environmental Conservation Act for the treatment of health care risk waste"

"treatment: means the manipulation of health care risk waste to completely eliminate all infection risk or potential and to render the waste non-recognizable as health care risk waste, and the words "treat" and treated have corresponding meanings"

The Act is linked to the National Environmental Management Act (Act 107 of 1998) in the following way by stating:

"Principles of interpretation

This Act must be interpreted and applied in accordance with the principles set out in Section 2 of the National Environmental Management Act (Act 107 of 1998)".

Section 6 of the WCHCWM Act states:

(1) A generator, transporter, treater or disposer of health care risk waste has a duty of care to implement reasonable measures to ensure, in accordance with this Act and any other relevant legislation, that all health care risk waste is minimised,

separated at source, packaged, stored, transported, treated and disposed of, where applicable, in a safe manner that poses no threat to human health or the environment.

(2) Without limiting the generality of the responsibility imposed by subsection (1), a generator, transporter, treater or disposer of health care waste must comply with the following requirements, where applicable:

(a) A generator of health care waste must ensure that the generation of health care waste is as far as possible minimised at source.

(b) A generator must segregate different categories of health care waste at the point of generation and put reasonable measures in place to maintain this segregation at all times thereafter.

(c) Only a generator, treater, transporter or disposer registered in terms of section 6 (2) (n) may store health care risk waste.

(d) A generator, transporter, treater or disposer of health care risk waste must at all times store health care risk waste in appropriate, clearly labelled containers, as prescribed by the Provincial Minister.

(e) A generator, transporter, treater or disposer of health care risk waste must prevent public access to health care risk waste containers and storage facilities.

(f) A generator, transporter, treater or disposer of health care risk waste must ensure that his or her storage area for health care risk waste is clearly demarcated and includes appropriate signage.

(g) A generator, transporter, treater or disposer of health care risk waste must ensure that all health care risk waste is treated at a treatment facility before disposal.

(h) A generator, transporter, treater or disposer of health care waste must ensure that all health care waste is disposed of at a disposal site.

(i) A generator, transporter, treater or disposer of health care risk waste must ensure that radioactive waste for which he or she is responsible is managed in terms of the provisions of the Hazardous Substances Act, (Act 15 of 1973).

(j) A generator, transporter, treater or disposer of health care risk waste must maintain up-to-date written or electronic records of the health care risk waste that he, she or it generated, treated, transported or disposed of.

(k) A generator, transporter, treater and disposer of health care risk waste must keep the written or electronic records referred to in subsection 2 (j) for a period prescribed by the Provincial Minister.

(l) A generator, transporter, treater or disposer of health care risk waste must make these records available to the public, if requested, in terms of the Promotion of Access to Information Act, (Act 2 of 2000).

(m) A generator, transporter, treater or disposer of health care risk waste must submit all the information contemplated in subsection (2)(j) to the Department at a frequency to be prescribed by the Provincial Minister, and the Provincial Minister may stipulate the format and the specific dates for submission of such information.

(n) A generator, transporter, treater or disposer of health care risk waste must, within a prescribed period after the promulgation of this Act, register with the Department by submitting to the Department a duly completed registration form that is available from the Department.

(o) A generator, transporter, treater or disposer of health care risk waste must perform and record internal audits at a frequency to be prescribed by the Provincial Minister, and must make them available to inspectors on request".

2B 10 Medicine and Related Substances Act (Act101 of 1965) and its Regulations

This Act is the overarching act that controls every aspect of scheduled substances used as medicines in South Africa, from its initial registration as a medicine to its ultimate disposal. With regard to waste disposal this Act incorporates the following regulations.

2B 10.1 Regulation 27

This regulation deals with the protocols for the disposal of pharmaceutical waste but does not specify the exact method for the destruction of the different schedules of medicines and dosage forms. It states:

"**(1)** A medicine or scheduled substance may be destroyed as follows:

(a) A medicine containing a Schedule 5, 6,7 or 8 substance may only be destroyed in the presence of an inspector, an officer of the South African Police Services or any other person authorized by the Director-General. Such inspector, person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of an officer, the case number must be entered in the register;

(b) notwithstanding paragraph (a), the Council may authorize the destruction of Schedule 5 or 6 substance by a manufacturer of such substances in the absence of an inspector;

(c) in the case of Schedule 1, 2, 3 and 4 substance or medicine, a pharmacist or an authorized person in charge of a place where medicines or substances are kept may destroy such medicines or substances. Such pharmacist or authorized person shall certify such destruction.

(2) No medicines may be disposed of into municipal sewerage systems.

(3) The destruction or disposal of medicines or scheduled substances must be conducted in such a manner as determined by the Council to ensure that they are not retrievable".

2B 10.2 Guidelines for the Destruction of Schedule 5 Medicines and Substances

The Medicine Control Council (MCC) which is an organ of the National Department of Health, (the supreme authority with regard to all aspects of any substance used in South Africa as a medicine), published the "Guidelines for the Destruction of Schedule 5 Medicines and Substances" which should be read in conjunction with Regulation 27. The guidelines describes the treatment and disposal protocols for Schedule 5 medicines under the following headings:

2B 10.2.1 Destruction authorized by an inspector

"The destruction of Schedule 5 medicines and substances that have been entered into a register, may take place under the supervision of an inspector designated in terms of Section 40 (1) of the Act, an officer of the South African Police Services (SAPS) or other person authorized in terms of the legislation to supervise this action.

- All destruction must take place in accordance with local municipal regulations regarding the disposal of chemical or medicinal waste. The applicant (person

requesting destruction) may be requested to prove that the method of destruction is in accordance with such regulations.

- All medicines or substances must be destroyed in such a manner that does not allow recovery.
- The inspector must on behalf of the Medicine Regulatory Authority (MRA), provide a certificate of destruction and in the case of an officer of the SAPS, a case number must be provided which must be kept with the register for a period of 5 years.
- All quantities destroyed must be indicated in the relevant register on the date of destruction and signed by the applicant, indicating the reference to the destruction certificate or case number.

2B 10.2.2 Method of Destruction

Potent or large quantities of medicines and substances

- Depending on the municipal regulations regarding the disposal of chemical or medicinal waste, the applicant may choose an appropriate method of destruction such as incineration or destruction by a reliable contractor who specialize in waste disposal.
- If a contractor is not used (e.g. incineration), two pharmacists employed by the applicant must witness the removal and destruction of the correct quantities of the medicines or substances authorized for destruction, regardless of where the destruction will take place.
- In the case of a contractor, where destruction does not take place at the premises of the applicant, and a certificate of destruction will be provided, two pharmacists employed by the applicant must witness the removal from the stock of the correct quantities of medicines or substances authorized for destruction and at least one of the pharmacist should accompany the goods to the place of destruction, to witness that these have actually been destroyed or disposed of in such a manner that precludes their recovery.
- In the case of a contractor a valid certificate of destruction must be obtained".

2B 10.2.3 Schedule 5 Register

- The quantities of any medicines or substances destroyed must be entered into the register on the date of destruction.
- The inscription in the register must be signed by the two pharmacists employed by the company who witnessed their removal from the stock for destruction. The Managing Director must co-sign, unless the Managing Director was one of the pharmacists involved with the removal and destruction.
- The letter of authorization and destruction certificate (if applicable) must be referenced in or attached to schedule 5 register and retained for a period of 5 years".

2B 10.3 Labeling of dispensed medicines

Regulation 8.4(c) of Act 101 of 1965 lays down the requirements for a label on a dispensed medicine, and is of relevance here. It states:

"Any medicine sold by a pharmacist, a person authorised to compound and dispense, or in a hospital pharmacy in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient: Provided that such medicine shall be sold in a package to which is attached a label containing the following information-

i. the proprietary name, approved name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine;
ii. the name of the person for whose treatment such medicine is sold;
iii. the directions in regard to the manner in which such medicine should be used;
iv. the name and business address of the person authorised to sell such a medicine;
v. date of dispensing; and
vi. reference number".

It must be noted that the above regulation does not stipulate that the schedule number of the dispensed medicine must be stated on the label. Should a dispensed Schedule 5 medicine be returned to a pharmacy by a member of the public, for appropriate disposal, the dispenser would not be able to tell immediately from the label to what schedule the medicine belong until this has been established by him. Should the discarded medicine belong to Schedule 5, the necessary entry into the Schedule 5 register must be made in terms of disposal. Similarly a member of the

South African Police Services would not be able to properly supervise the destruction of a Schedule 5 medicine if the schedule to which the medicine belong was not stated of the label of the dispensed medicine. A recommendation in this regard has thus been made in Chapter 6.

It is important to understand the extent of the term "dispense" which is defined under the Definitions of the General Regulations to this Act *viz*.:

"Dispense:..

(b) in the case of a medical practitioner, dentist, practitioner, nurse or any authorised prescriber to dispense medicines, means-

i) the interpretation and evaluation of a prescription;

ii) the selection, reconstitution, dilution, labelling, recording and supply of the medicine in an appropriate container;

iii) the provision of information and instruction to ensure safe and effective use of the medicine by a patient".

2B 11 The Pharmacy Act (Act 53 of 1974)

Regulation 2.7.1 (Minimum Standards for Services provided in a Pharmacy) of the Pharmacy Act describe the dispensing procedures as follows:

"The dispensing process is divided into three phases namely-

Phase 1: Interpretation and evaluation of the prescription.

Phase 2: Preparation and labelling of the prescribed medicine.

Phase 3: Provision of information and instructions to the patient to ensure the sale and effective use of medicine".

The above activities are the prescribed activities for which professional registration with the South African Pharmacy Council is required. The dispensing of the radioactive medicine by the radiation officer (figure 4.7) is therefore a violation of the Pharmacy Act.

2B 11.1 Good Pharmacy Practice

All pharmacists providing a pharmaceutical service must ensure that such a service is of the highest standard possible in South Africa. This expected level of quality is prescribed in "Good

Pharmacy Practice in South Africa" (GPP), a standard published by the South African Pharmacy Council (SAPC) with which pharmacists are expected to comply, in order to meet the ethical and professional requirements of the profession.

Compliance with GPP is obligatory in terms of:

i) Section 35A of the Pharmacy Act;

ii) Regulation 20 (1) of the Regulations Relating to the Practice of Pharmacy , and Regulation 7(a) of the Regulations Relating to the Ownership and Licensing of Pharmacies, published in terms of the Pharmacy Act; and

iii) Regulation 18 (7) (b) of the General Regulations published in terms of the Medicines and Related Substances Act (Act 101 of 1965), as amended (Masango, 2010).

Non-compliance with GPP will result in disciplinary action taken by the SAPC against any professional on its registers. With regards to waste disposal, GPP only states the following:

A) Waste Disposal (Minimum Standards for Pharmacy Premises, Facilities and Equipment)

"(a) A suitable and adequate means of waste disposal must be available and in use

(b) Waste material must not be allowed to accumulate and must be collected in suitable covered (as applicable) receptacles for removal to collection points.

(c) Written sanitation procedures must be available detailing schedules, methods, materials and equipment available. Responsibility must be assigned in writing.

(d) Under no circumstances must substances be disposed of down surface water drains e.g. storm water drains.

(e) In all situations, a pharmacist must use his pharmaceutical knowledge and skill, together with any necessary expert advice from Local Authority/Provincial Department of Health, to segregate and dispose of materials, and bio-medical waste safely and in accordance with regulations".

B) Waste Disposal (Minimum Standards for Cholesterol monitoring Service)

(a) **"**Dressings, swabs and other contaminated waste from treatment areas should be placed in a suitable clinical waste storage bag or bin with suitable plastic liner at the point of generation.

(b) Liner bags should be removed at least daily or when three-quarters full. They should be securely fastened with adhesive plastic tape before removal and deposited in a clinical waste storage bag-which should be securely fastened. The waste should then be sent for incineration.

(c) Syringes, needles and cartridges should be discarded in tact and placed in suitable 'sharps container', which when full should be sealed and placed into chemical waste bag for storage prior to removal and disposal by incineration."

It is clear from the above that the South African Pharmacy Council in setting out the standards for waste disposal, does not make clear the distinctions between the different types of wastes which can be generated in pharmacies.

Recommendation in this regard has been made under Chapter Six herein.

2B 12 The Hazardous Substances Act (Act 15 of 1973)

Substances liable of causing injury or ill-health by reason of their toxicity, corrosivity, flammability, or other inherent hazardous properties are largely controlled by the Hazardous Substances Act (Act 15 of 1973).

2B 13 Occupational Health and Safety Act (OHSA) (Act 85 of 1993)

The Act empowers the Minister to make regulations as to any matter which, in terms of the Act, shall or may be prescribed. The regulations pertinent to this research are the following:

2B 13.1 Hazardous Chemical Substances Regulations

The relevant sub-regulations under this section are:

- **"Regulation 3: Information and Training**

  (1) An employer shall, before any employee is exposed, or may be exposed, after consultation with the health and safety committee established for that

section of the workplace, ensure that the employee is adequately and comprehensively informed and trained, as well as thereafter informed and trained at intervals as may be recommend by that health and safety committee, …

(j) the safe working procedures regarding the use, handling, storage, and labelling of Hazardous chemical substances (HCS) at the workplace;

(k) procedures be followed in the event of spillages, leakages or any similar emergency situation which could take place by accident.

(2) An employer or self-employed person shall give written instructions of procedures contemplated in paragraph (k) of sub-regulation (1) to the drivers of vehicles carrying HCS.

(3) An employer or a self-employed person shall ensure that he himself or she herself or any person who in any manner assists him or her in the carrying out or the conducting of his or her business, have the necessary information and has undergone sufficient training in order for him or her to identify risks and the precautions which should be taken".

- **"Regulation 14: Labelling, Packaging, Transportation and Storage**

An employer shall, in order to avoid the spread of contamination of an HCS, take steps, as far as is reasonably practicable, to ensure-

(a) that the HCS in storage or distributed are properly identified, classified and handled in accordance with SABS 072 and SANS 10228

(b) that a container or vehicle in which an HCS is transported, is clearly identified, classified and packed in accordance with SANS 10228, and SABS 0229

(c) that any container into which a HCS is decanted, is clearly labelled with regard to the contents thereof".

- **"Regulation 15: Disposal of hazardous chemical substances.**

An employer shall as far as is reasonably practicable-

(a) recycle all HCS;

(b) ensure that all collected HCS waste is placed into containers that will prevent the likelihood of exposure during handling;

(c) ensure that all vehicles, re-useable containers and covers which have been in contact with HCS waste are cleaned and decontaminated after use in such a way that the vehicles, containers or covers do not cause a hazard inside or outside the premises concerned;

(d) ensure that all HCS waste which can cause exposure, is disposed of only on sites specifically designated for the purpose in terms of the Environmental Conservation Act 73 of 1989, in such a manner that it does not cause a hazard inside or outside the site concerned;

(e) ensure that all employees occupied in the collection, transport and disposal of HCS waste, who may be exposed to that waste, are provided with suitable personal protective equipment; and

(f) ensure that if the services of a waste disposal contractor are used, a provision is incorporated into the contract stating that the contractor shall comply with provisions of these regulations".

The Act also provides under an Annexure 1, comprehensive guidelines to protect employees from HCS and also provide lists of different HCS and their occupational exposure limits. The Act is linked to the South African National Standard 10228:2006, and this was one of the standards which was used in the evaluation of the research sites.

2B 14 South African National Standard Codes

The following are the relevant Codes.

2B 14.1 SANS 10228:2006

- A list of industries and processes has been published, to identify processes that are likely to generate hazardous waste. Waste from these processes, are classified as potentially hazardous requiring it to be controlled.
- The list is a table of Hazardous Waste. It is incomplete and has to be updated periodically.
- Identification and Classification of Dangerous Goods for Transport, is used as an exclusive Hazard Waste list; and explicitly identifies hazardous substances. The presence of a substance on the list automatically brings the waste into the regulatory

control system. (Note: the absence of a substance from this list does not necessary imply that the substance is not hazardous).

Degree of Hazard:

- SANS 10228 is derived from the International Maritime Dangerous Goods (IMDG) Code. This is a United Nations based system for the classification of dangerous goods to be transported by sea. The IMDG Code was adopted by South Africa in 1986 (RSA-IMDG Code), to provide a uniform and internationally acceptable system for the identification and classification of hazardous substances.

- SANS 10228 groups substances into 9 classes, according to characteristics such as flammability, corrosivity, reactivity, or toxicity. These characteristics are defined by means of limiting parameters determined by standard test protocols.

- Wastes that fall within class 6 of SANS 10228 are given a Hazard Rating for disposal. The Hazard Rating is derived from the inherent mammalian and ecological toxicity of the compounds, including environmental fate and the Estimated Environmental Concentration (EEC) principle.

Concentration Levels*:*

- The EEC is used to provide an exposure level and assimilation capacity approach. In this approach, chemical compounds are regarded as being hazardous above a threshold concentration. The EEC includes environmental fate and allows prediction of the fate of a waste contaminant.

- The SANS 10228 is to be expanded to include a “no effect” or “acceptable low risk” level. This will provide a list of substances that in certain quantities or concentrations will not pose an unacceptable risk to health and/or to the environment.

2B 14.2 SANS 10248:2004

SANS 10248 read together with the Western Cape Healthcare Waste Management Act 7 of 2007 also provided the criteria by which the six research sites were evaluated for compliance.

This standard presents the basic elements of the management of healthcare waste and deals with:

- Identification of healthcare waste
- Responsibilities
- The waste management plan
- Training, supervision and workplace hygiene
- Waste storage
- Waste minimization, segregation, and packaging
- Collection and transport of healthcare waste
- Spillage of hazardous healthcare waste
- Treatment and disposal methods
- Disposal by small-scale healthcare waste generators
- Minimal programmes for healthcare waste management

2B 15 International Acceptability of South Africa's Environmental Standards

International acceptability in terms of environmental policy and practices are closely related to South Africa's acceptability as a trading partner and to South Africa's ability to participate in international affairs. It is thus important that the regulation of waste, and hence the Minimum Requirements, be internationally acceptable. South Africa therefore takes full cognisance of international efforts to address the control of waste, and in particular, Hazardous Waste. Of relevance to this document are the United Nations Environment Program's Code of Practice (1993), the Cairo Guidelines (1985), the International Register of Potentially Toxic Chemicals (1985) and the Guidelines for Hazardous Waste Management in Asia and the Pacific (1986), (South Africa, 1998b).

2B 16 Convention on the Control of Trans-boundary Movements of Hazardous Waste and their Disposal ("Basel Convention")

This convention was conceived to control the trans-boundary movement of hazardous waste globally. South Africa acceded to it and became a signatory to the convention on 03 August 1994, by so doing it accepted the international protocols contained therein. Some lawmakers consider this to be "the single most important step in South Africa's quest towards implementing a waste management regime designed to function on a global scale".

The Constitution of the Republic of South Africa in section 231(4) states:
"Any international agreement becomes law in the Republic when it is enacted into law by national legislation". The Basel Convention has not yet been domesticated into law and thus it is not legally binding on the citizens of South Africa.
However as a prominent signatory to the Basel Convention, South Africa is obligated to adopt legislation to prevent and punish illegal trafficking in hazardous waste. The fundamental principles of the Basel Convention incorporates:

- Minimization of the generation of hazardous waste
- Disposal of hazardous waste as close as possible to its source of generation
- Limiting the transposition of hazardous waste immediately after its generation by prohibiting its export
- Permitting the trans-boundary movement of hazardous waste, in special cases
- Prior informed consent for importation or transit of hazardous waste
- The return of illegally exported waste to the state of origin

http://www.basel.int/convention/basics.html
http://www.dfa.gov.za/foreign/Multilateral/inter/basel.htm.

2B 17 The Ban of the Import into Africa and the Control of Trans-Boundary Movement of Hazardous Waste (Bamako Convention)

The principles of the Bamako Convention are virtually identical to that of the Basel Convention except that it imposes stricter conditions of monitoring and notification to its secretariat, than the Basel Convention. It is also much more specific than the Basel Convention, in that it places a total ban on the importation of waste from outside Africa, and it would thus be far more

appropriate if South Africa become a signatory to this convention and legislate it into South African law.

2B 18 Promotion of Access to Information Act (Act 2 of 2000)

The constitution of South Africa endows every citizen with environmental rights. To give effect to this constitutional right, of access to any information held by the State and any information that is held by another person and that is required for the exercise or protection of any rights; and to provide for matters connected therewith, this Act was promulgated. In terms of access to this set of legislation all the hospitals and the disposal companies are obligated to provide any relevant information about their operations which is requested by the general public.

2B 19 Criminal Offences

Mismanagement of pharmaceutical waste is punishable under the following Acts:

2B 19.1 The Western Cape Health Care Waste Management Act (Act 7 of 2009)

Section 11 of the Act states:

"(1) A person who contravenes or fails to comply with

(a) any provision of section 5, 6 or 7(1); or `

(b) a compliance notice issued in terms of section 10(3),

is guilty of an offence and upon conviction is liable to a fine or imprisonment not exceeding five years.

(2) In the event of a continuing or repeated offence, an additional fine or imprisonment for a period not exceeding ten years for every subsequent occasion on which the offence is so continued or repeated may be imposed**"**.

2B 19.2 Medicine and Related Substances Act (Act 101 of 1965)

Section 42 of the Act 101 of 1965 lays down that:

"… any person who fails to comply with, contravenes the provisions of or willfully furnish incorrect information in respect of Regulation 27 of this Act , shall be guilty of an offence and upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years".

2B 19.3 Occupational Health and Safety (OHSA) Act (Act 85 of 1993)

Section 16 of OHSA states:

“Any person who contravenes or fails to comply with any provision of regulation 3, 14, and 15, shall be guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding six months and in the case of a continuous offence, to an additional fine of R200 for each day on which the offence continues or additional imprisonment of one day for each day on which the offence continues: Provided that the period of such additional imprisonment shall in no case exceed 90 days”

CHAPTER THREE: MATERIALS AND METHODS

3.1 The Research Design

The research study was designed to be a qualitative cross-sectional study using self-administered questionnaires, corroborated by photographic evidence, direct observations, and interviews.

3.2 The Research Sites

Hospitals being healthcare institutions were selected as the research sites because the targeted professionals perform at these venues simultaneously and their activities are inter-related.

3.2.1 The Public Hospitals

The following three state hospitals selected are integrated to form the backbone of the healthcare services of the Provincial Administration of the Western Cape, South Africa.

3.2.1.1 Groote Schuur Hospital

Groote Schuur Hospital forms part of the Associated Academic Hospitals group, serving mainly the Cape Flats and the southern suburbs of Cape Town, providing tertiary care and formal teaching in all the major branches of medicine. It is the main academic hospital for the University of Cape Town's medical school, employing over 467 doctors, 1679 nurses, 28 pharmacists and 250 allied health professionals. Groote Schuur Hospital made history when Professor Christian Barnard performed the world's first human heart transplant on the 3rd December 1967. Today it is still highly regarded internationally, as a world class academic hospital,
http://www.capegateway.gov.za/eng/pubs/public_info/C/99478.

3.2.1.2 Tygerberg Hospital

Tygerberg Hospital is not only the largest tertiary hospital located in the Western Cape Province, but is also the second largest in South Africa. It was specifically commissioned to be the academic hospital of the University of Stellenbosch Medical School,
http://www.capegateway.gov.za/eng/your_gov/5987.
It also serves as the teaching hospital for the Dental Faculty of the University of the Western Cape and for the Department of Nursing and Radiography of the Cape Peninsula University of the Technology. The hospital carries a complement of 420 doctors, 1500 nurses, and 25

pharmacists, and like Groote Schuur Hospital, it is internationally regarded as a world class academic hospital.

3.2.1.3 Red Cross War Memorial Children's Hospital

The Red Cross War Memorial Children's Hospital is acclaimed as the only specialist paediatric hospital in South Africa and is regarded as the leading institution for specialist paediatric post-graduate training in Southern Africa. It proudly lays claim to several world firsts such as the first open-heart surgery performed on a child in 1959, http://www.turtlesa.com/ezine60b.html. It has a complement of 182 doctors, 522 nurses, and 11 pharmacists.

3.2.2 The Private Hospitals

The three private hospitals that agreed to partake in the research belong to the Melomed Hospital Holdings Ltd., which is the largest Black-owned private hospital group in the Western Cape. The group prides itself by providing a world class service to mainly the disadvantaged blacks of the Cape Flats area of the Western Cape. The three hospitals were:

3.2.2.1 Mitchells Plain Medical Centre

The Mitchells Plain Medical Centre is situated in the heart of the township of Mitchells Plain on the False Bay coast. In October 2009 the hospital launched its Melomed Renal Care Unit which became the first and only of its kind in the disadvantaged townships of Cape Town, http://www.melomed.co.za/news.asp?ID=17. It has on board 17 doctors, 95 nurses, and 3 pharmacists.

3.2.2.2 Bellville Medical Centre

This hospital was functional at the time of the research project. It has subsequently closed and relocated. At the time of the research it had 18 doctors, 66 nurses, and 2 pharmacists on its complement of staff. It has been replaced by the new Melomed Bellville Hospital.

3.2.2.3 Gatesville Medical Centre

Gatesville Medical Centre is a private hospital located in the township of Athlone about 10km from the Red Cross War Memorial Children's Hospital. The hospital like the other hospitals in its group of private hospitals, has been approved by the South African Nursing Council for the training of nurses since 1998. Its professional complement consists of 33 doctors, 153 nurses, and 4 pharmacists.

3.3 The Pilot Questionnaire

A pilot questionnaire was distributed prior to the main data collection phase, to test the responses to the research questionnaire (Appendix M1). Ten respondents from each of the professional categories were randomly selected to participate. The objective of the pilot questionnaire was to anticipate confounders and difficulties which may be encountered by the respondents during the completion of the research questionnaire.

For identification purposes the pilot questionnaires were indexed as: “PP” for pharmacists, “PD” for doctors, “PN” for Nurses.

3.4 The Research Questionnaire

The research questionnaire (Appendix M2) was designed to gauge the level of awareness of the healthcare professionals employed in hospitals with regard to pharmaceutical waste, was based on the “Programme for the implementation of the national waste management strategy” of the DEAT (South Africa, 2000).

Although the WHO (Pruss et al.,1999a) recommends that all hospital personnel should be conscious of health, safety and environmental issues as it relates to hazardous medical waste, the questionnaire was directed only at medical doctors, nurses, and pharmacists. Pharmacists were not listed in the WHO recommendations. The questions adapted from the WHO questionnaire, comprised 68 short questions in the form of a tick list with instructions to the participant to tick the most appropriate answer. Only one question, Q7 (b), with regard to problems encountered with pharmaceutical waste disposal was open-ended. Table 3.1 lists the different aspects covered by the questionnaire.

Table 3.1: Composition of Questionnaire

Question Number	Aspect Covered
1	Type of hospital (private or state)
2 (a)	Departmental assignment of responsibility
(b)	Provision of training in medical waste management including pharmaceutical
3	Waste audit, legislation and procedures
4	Job description of waste personnel
5	Disposal via sewerage system
6 (a)	Segregation of pharmaceutical waste at point of generation
(b)	Segregation of pharmaceutical waste before removal from hospital
7 (a)	Pharmaceutical waste problems encountered
(b)	Description of problems encountered
8	Perceptions of the efficiency of different disposal methods
9	Question deleted
10	Agreement /disagreement with various statements of disposal
11	Generation and segregation of pharmaceutical waste by hospital departments

3.4.1 Distribution of the Questionnaire and Data Collection

Distribution of the questionnaire to the following healthcare professionals were as follows:

a) Doctors

Randomly distributed by myself to the doctors who attended the weekly departmental meetings at the three state hospitals, and was completed immediately. At the private hospitals the Quality Assurance Manageress, distributed the questionnaires to all doctors employed and collected them after completion. In the private hospitals there was 100% doctor response.

b) Pharmacists

Every pharmacist (because their numbers were relatively the smallest) in both the state and private hospitals, was issued a questionnaire by the responsible pharmacist (RP) for each of the hospital pharmacies, and was collected by the RP after completion.

c) Nurses

The CPUT nursing mentors at the state hospitals randomly distributed the questionnaire to senior nurses in different wards, and collected them after completion.

At the private hospitals the distribution was randomly distributed and collected by the Quality Assurance Manageress.

All respondents were not required to identify themselves nor their profession, in order to encourage them to answer the questions freely and without inhibitions. However for statistical purposes each questionnaire carried an encrypted number. A copy of the questionnaire is attached as Appendix M.

3.5 The Sample

The composition and sample size is given in table 3.2

Table 3.2: Sample size

	Doctors		**Nurses**		**Pharmacists**	
	Employed at hospital	**Sample**	**Employed at Hospital**	**Sample**	**Employed at hospital**	**Sample**
Private	69	**69**	314	**96**	11	**11**
State	1069	**175**	3701	**350**	64	**45**
Subtotals	1138	**244**	4015	**446**	75	**56**
Total sample	**746**					

3.6 Observations

The observed results for the different aspects of the pharmaceutical waste management were photographically recorded for each hospital accompanied by a brief qualitative evaluation.

3.7 Interviews

"Unstandardised" also referred to as "unstructured open-ended" interviews were held by myself with the key role players at the following universities:

1. School of Pharmacy, University of the Western Cape;
2. Medical School, University of Stellenbosch; and
3. Department of Nursing and Radiography, Cape Peninsula University of Technology.

Because the participants were not homogenous, with very different points of references, and hailing from three very different disciplines the "focus group" approach was not adopted (Krueger, 1988).

These tertiary academic institutions were selected because they train pharmacists, medical doctors, and nurses respectively. An unstandardised protocol was employed because it does not involve a set of predetermined questions, thereby allowing the participants the opportunity to express their opinions freely. It also allows the interviewer to establish a cordial relationship with the participant (Fontana and Frey, 1994). Another advantage of this method was that it allowed follow-up interviews if necessary, which in this study there was no need.

3.8 Statistical Analysis of Data

The data captured from the questionnaires was entered into Microsoft Excel spreadsheets and analysed using Statistical Package for Social Sciences (SPSS) version 17, 18, and 19. Closed ended questions were analysed using the SPSS version 19 and are presented as descriptive statistics. The correct title for the software used, is actually IBM SPSS after the product was bought by International Business Machines (IBM).

3.8.1 Methodology Used to Perform the Analyses

- **Descriptive statistics**

The purpose for having used descriptive statistics was to describe the sample. We used crosstabulation (contingency table) to show the distribution between two variables measured categorically. In the crosstabluation we showed the number of participants as well as the percentage out of the total of the row. The purpose of the row percentage provided is to show the relation of the column variable (awareness of waste management legislation) within each level of row variable (profession).

- **Inferential (analytical) statistics**

The purpose for having used inferential statistics was to generalize the findings of the sample to the whole population of which the sample is drawn. To test whether the association shown by the sample was significant or not, we used Chi-square test of independence (association) because we were testing the association between two categorical variables. The decision to say the association was significant or not was based on p-value. A p-value of less than 0.05 indicates a significant association. The small p-value indicates that the probability that the observed association due to chance alone was small.

3.9 Ethics Approval

The following ethical approvals were obtained:

3.9.1 CPUT Approval

Ethics approval for undertaking this research was obtained from the Research Ethics Committee of the Cape Peninsula University of Technology (Appendix K).

3.9.2 Hospital Approvals

Although the research did not involve any patient, or staff member, ethical approvals to perform the research at the hospitals were still considered essential and were applied for. The Research Ethics Committees of the state hospitals, granted permission to undertake the study at Groote Schuur Hospital (Appendix L1), Tygerberg Hospital (Appendix L2), and at Red Cross War Memorial Childrens Hospital (Appendix L3). The Research Ethics Committee for the Melomed Group also granted permission to perform the research at the three private hospitals (Appendix L4).

3.9.3 Government Approval

Support for this research was also received from the Deputy Director, Waste Management, Department of Environmental Affairs and Development Planning, of the Western Cape Provincial Government (Appendix L5).

CHAPTER FOUR: RESULTS

4.1 Introduction

It is accepted that the results of any good research always create more questions. Throughout this research, unanswered questions emerged as a consequence of the discoveries made. Further research is required in order to dispel or confirm new hypotheses that now suddenly stand unanswered. Such conditions of uncertainty create unhappiness in the minds of people searching for the truth, and become the basis for human progress.

4.2 Observed Results

The observed results which can be considered as qualitative primary data, was categorised under the following headings:

- Waste generation,
- Waste segregation,
- Storage within the hospital,
- Transport,
- Treatment and
- Disposal by incineration.

4.2.1 Waste Generation

It was discovered that all the hospitals researched, do not maintain accurate records of the different schedules of pharmaceutical waste generated and disposed. The pharmaceutical waste is weighed and the mass presented to the hospitals for payment by the transporter/disposer *e.g*. BCL Waste Management's Manifest Document 099272 [Appendix A (i), and Appendix A (ii)].

4.2.2 Waste Segregation

Waste segregation is the very first step in the process of reducing the volume of hazardous waste and involves the identification of hazardous substances. For example, medicines which are cytotoxic, in whatever quantity, remains hazardous. If it is co-disposed with solid waste, the total quantity must be considered cytotoxic. The lack of segregation was observed to be perpetuated throughout the passage of the pharmaceutical waste from the point of generation

to its final disposal by incineration. Not only was the hazardous pharmaceutical waste unsegregated from non-hazardous pharmaceutical waste, it was even found mixed with anatomical waste and placed in red bags (figures 4.16; 4.34; and 4.35), constituting a violation of section 6 (2) b of the WCHCWM Act.

4.2.3 On-Site Storage Within the Hospitals

Nurses are responsible for collecting the pharmaceutical waste which is generated in their wards and they have a duty to accumulate it in dedicated areas in the ward. All the wards however were found not to have such dedicated waste storage areas. As a result, an array of unacceptable interim measures were used for temporary storage, which included sluice rooms, unlocked nameless storerooms, dispensary corners, public corridors, *etc*.. These practices exposed not only the hospital staff but also the general public to dangerous contamination. Because, neither dedicated nor secured areas were set aside in the wards, accidents such as hazardous spills and contaminations could occur. Such environmental pollution have probably occurred, unbeknown to the staff, treated as trivial and went unrecorded. The results of the questionnaire confirmed this suspicion in that 91.7 % of doctors, 85.5 % of pharmacists, and 90.4 % of nurses stated they have never encountered pharmaceutical waste problems (Table 4.4 and 4.5) where n=number of respondents).

4.2.3.1 Tygerberg Hospital

The hospital has two independent pharmacies; one in the general hospital and the other in the oncology wing.

4.2.3.1.1 The General Pharmacy

Pharmaceutical waste which was generated elsewhere in the hospital was transported to this pharmacy for temporary storage and later disposal. The waste was observed to be in the following states:

4.2.3.1.1a Non-segregated Pharmaceutical Waste

Proper waste segregation consists of placing waste materials in their appropriate disposal containers and relies on the generators (doctors and nurses in the wards) to perform this step at the point of generation, even if it is at the patient's bedside. The process includes separating the package inserts and secondary containers (composed of paper and cardboard) and transferring these to the normal municipal solid waste stream. The primary containers, usually glass, together with its contents, which are in contact with the actual PhACs, constitute the

pharmaceutical waste. No segregation was observed. Figure 4.1 shows pharmaceutical waste with primary containers (glass) and secondary containers (cardboard) unsegregated. Sharps were disposed amongst tablets, in violation of Section 6(2) (b) of the WCHCWM Act 7 of 2007 (Figure 4.4b and figure 4.4c).

Figure 4.1: Unsegragated pharmaceutical waste: non-hazardous cardboard and hazardous liquids

4.2.3.1.1b Mixed Liquid Pharmaceutical Waste

Small volumes of different liquid medicines were poured into large 20 litre containers mixing them into a brew in which reactions probably take place, generating new chemicals of unknown molecular composition and thus of unknown ecotoxicity. The mixtures were not labelled by the pharmacists. The container did not contain formalin 4%.

Figure 4.2: Unlabelled liquid medicine mixture

This activity constitutes non-compliance with Regulation 14 of the Hazardous Chemical Substances Regulations of the Occupational Health and Safety Act 85 of 1993, and translates

into a criminal offence. Furthermore the regulations to this Act, lists formaldehyde as a hazardous chemical compound and lays down occupational exposure limits. Whether these limits have been exceeded have not been tested in this research.

4.2.3.1.1c Incorrectly Stored Pharmaceutical Waste

The storage facility for pharmaceutical waste in the main hospital was a small room opposite the chief pharmacist's office. It had no outside signage indicating its dedicated purpose and becomes a violation Section 6 (2) (f) of the WCHCWM Act (figure 4.3). Non-pharmaceutical waste such as metal and wooden shelving were also found to be stored therein (figure 4.4a).

Figure 4.3: Pharmaceutical store without signage

Figure 4.4a: Non-Pharmaceuticals stored with medicines

Figure 4.4b: Unsegregated pharmaceutical waste

Figure 4.4c: Unsegregated pharmaceutical waste

4.2.3.1.1d Incorrectly Identified Hazardous Pharmaceuticals

In the main pharmacy of the general hospital, methotrexate (4-amno-10-methyl-folic acid) tablets were found packed on a dispensary shelf, amongst other tablets without recognising and affording it the dangerous cytotoxic status it inherently possesses. The drug is extremely hazardous and is classified as “toxic” in Europe and “very toxic” in the U.S.A (Henschel et al.,1917). Furthermore expired methotrexate (plus that returned by patients as unwanted) was disposed of as normal pharmaceutical waste, when it should have been packed separately as cytotoxic waste, with the prescribed labels in special containers as per (SANS 10248, 2004), and disposed of with other cytotoxic waste. This example of methotrexate disposal, epitomizes the need for pharmaceutical waste to be classified as a specific waste stream. It is only an understanding of the pharmacology of methotrexate that will influence its proper treatment and disposal.

4.2.3.1.2 The Oncology Pharmacy

The oncology wing of the hospital had no dedicated storage area for the extremely dangerous cytotoxic waste generated by this unit. Sharps which were used in the preparation of the oncology medicine and in the treatment of the cancer patients, were packed in the corridor of the hospital nearest the backdoor, awaiting removal by the waste disposer. The cardboard box next to the sharps containers, (Figure 4.5), was filled with a mixture of cytotoxic waste including the contaminated protective gear used in the preparation and administration of the cytotoxic medicines.

This area in the general passage acted as a temporary storage position for the hazardous waste which was a violation Section 6 (2) (e) of the WCHCWM Act, and subjected the general public and the hospital staff to hazardous cytotoxic exposure.

Figure 4.5: Cytotoxic pharmaceutical waste in public exposure

4.2.3.1.3 The Radiotherapy Unit

The radioactive procedures, employed by the radiotherapy unit of this hospital, has been approved by the Department of Health under authority no. M/0014/06/0567 (dated 19 June 2006, expiring on 30 June 2010), in compliance with Section 3A of the Hazardous Substances Act 15 of 1973 [Appendix B(i)]. The two isolation rooms opposite each other (figure 4.6a and figure 4.6b) has been approved under "Condition 90" of the certificate of authority which states: "Activities only to be administered in isolation wards that have already been approved by the Director for this purpose" [Appendix B(ii)].

However, it was found that proper isolation of the radioactive procedures were not fulfilled in that a public corridor between the two radioactive rooms (figure 4.6a) exists. Radioactive warnings, mounted on both doors, and the general public walking in the corridor, can clearly be seen (figure 4.6b). It is clear that the approval under "condition 90" need to be reviewed.

Figure 4.6a: Public passage crossed by radioactive patients

Figure 4.6b further illustrates contaminated gowns, disposed into a black bin containing a transparent plastic bag, in the public corridor. The green bin next to it, was used for the collection of cytotoxic waste, generated in this isolation room, exposing the general public (seen here walking past it unaware) and the hospital staff to cytotoxic danger. This also constituted a violation of Section 6(2)(i) of the WCHCWM Act.

Figure 4.6b: Radioactive contaminated garments in public exposure

Figure 4.7 shows the medicine in the dosage form of a capsule of radioactive iodine I^{131} , being removed from its protective lead container which in turn was stored inside a lead lined cupboard. The Radiation Officer (not a pharmacist, doctor, nurse or licensed dispenser) removes the Schedule 4 medicine through a hatch in the lead-lined cupboard, but his arms and body were exposed to radiation from the radionuclide being manipulated.

Figure 4.7: Unqualified radiation officer dispensing radioactive medicines

After the capsule was placed on the tissue he retreated and instructed the patient how to approach the lead-lined cabinet, retrieve the capsule and how to swallow it. This procedure is in accordance with the 2nd and 3rd stage of the dispensing process and is restricted to the scope of practice of a pharmacist, pharmacist assistant or a licensed dispenser. The radiation officer does not have this prerequisite qualification to dispense medicines and is thus committing a criminal offence by violating Section 22 C of the Medicine and Related Substances Act 101 of 1965.

4.2.3.1.4 The Radio-pharmaceutical Laboratory

The WHO recommends that for safety reasons the medical use of radioactive isotopes should be restricted to teaching hospitals which are attached to a medical university (Pruss et al., 1999b). Nuclear medicine facilities are therefore only available at two of the six hospitals under research *viz*. Groote Schuur Hospital and Tygerberg Hospital. This laboratory was situated on the uppermost floor of the general hospital. The pharmaceutical waste produced here was radioactive and the principle of segregation should have been applied even more diligently because of the very high hazardous nature of this specific pharmaceutical waste. However, the following was discovered. Syringes were not disposed in the special sharps container but were disposed together with latex gloves, (Figure 4.8). This constituted a violation of Section 6 (2) (b) of the WCHCWM Act.

Figure 4.8: Unsegregated radioactive pharmaceutical waste

Radioactive pharmaceutical waste was found to be improperly stored, while waiting for its radioactivity to subside to manageable levels before it could be safely removed from the hospital for disposal. This door of the store room did not exhibit a prominent warning notice. Instead the notices on the door read "Helix II Gammakamera, Danger, Nuclear Medicine", referring to the past when the room housed a gamma ray camera. This constituted a violation of section 6 (2) (f) of the WCHCWM Act (figure 4.9).

Figure 4.9: Radioactive waste storeroom without proper signage

4.2.3.2 Gatesville Medical Centre

a) The dispensary did not have a dedicated storage area for pharmaceutical waste. A corner near the taps in the dispensary was used for this purpose. This area was also the area for the dispensary waste bin, and was juxtapositioned to the crockery used by the dispensary staff, during their lunch and tea-breaks (figure 4.10).The pharmacy also did not have a dedicated area where the staff could relax during their off-duty periods.

b) A red bag was placed inside a red bin (figure 4.10) marked "Bio-Hazardous" into which all pharmaceutical waste was deposited without segregation. The use of the red bag for pharmaceutical waste was in direct contravention of the Section 4.3.3 of the South African National Standard 10248:2004, which prescribes dark green as the correct colour code for pharmaceutical waste. The recommended green is in alignment with international standards. The indiscriminate use of red bags for the collection and temporary storage for

all the hospital's pathological waste (figure 4.13), together with pharmaceutical waste further demonstrated the absence of mandatory segregation.

Figure 4.10: Pharmaceutical waste in kitchen area

Figure 4.11: Unsegregated pharmaceutical waste

c) The red bags containing the pharmaceutical waste was removed manually by a general hospital cleaner and transferred to the general waste store marked "Medical Waste Room",

situated outside the main hospital, in which all the hospital's pathological and hazardous waste were temporarily retained, awaiting removal by the dedicated waste disposer (figure 4.12).

Figure 4.12: Pharmaceutical waste storeroom without proper signage

Figure 4.13: Unlabelled pharmaceutical waste stored with anatomical waste

d) The sharps containers should at all times be stored vertically to prevent the liquid contents of the syringes and catheters from leaking onto the floor of the storeroom. On the day of

visit, the sharps containers were not packed vertically but in a disorganised manner. Some were found flat with the containers leaking and contaminating the floor and the environment (fig. 4.13).

The room with its contents presented an extremely hazardous threat to all the waste personnel that entered the room and constituted a violation of Section 6 (1) of the WCHCWM Act.

Figure 4.14: Waste stored in hazardous pharmaceutical intensive care ward

e) Figure 4.14 shows hazardous pharmaceutical waste exposed in the general sluice room of the intensive care ward. There was no dedicated area where the hazardous waste could have been safely secured until collection and removal to the "medical waste store" constituting a violation of section 6 (2) (f) of the WCHCWM Act. The container was open and its position was such that it obstructed access to the wash basins and could easily have been knocked over causing a hazardous spill.

4.2.3.3 Bellville Medical Centre

a) The store room for medical waste was found unlocked and in easy access to the general public. Figure 4.15 shows a member of the general public walking pass the unlocked door, constituting a violation Section 6 (2) (e) of the WCHCWM Act.

b) Pharmaceutical waste was not segregated from other human pathological waste and was stored in red bags making it indistinguishable from other types of medical waste. Sharps

containers, were found lying flat. The floor of the room was also stained (figure 4.16) from previous contamination as in the case of Gatesville Medical Centre.

Figure 4.15: Unlocked pharmaceutical store accessible to general public

Figure 4.16: Leaking and unlabelled medical and pharmaceutical waste containers

c) Fragile glass intravenous fluid containers half-filled (contents unknown) were found unsealed on a shelf in the general waste storeroom (figure 4.16).

d) Overfilled sharps container which could not close properly, were found in the same storeroom (figure 4.17).

Figure 4.17: Overfilled sharps container with unlabelled medical waste

4.2.3.4 Groote Schuur Hospital

a) The hospital does not have a dedicated store for the pharmaceutical waste which was generated at various wards in the hospital. Instead the waste was stored in the dispensary next to in-dated stock (figure 4.18). Figure 4.19 is a view of the Bulk Store, illustrating the unacceptable storage of pharmaceutical waste, below a table on which dispensing was performed. The bulk store is also the room in which automated pre-packing of medicines were done. These activities were violations of sections 6 (2) (d), and (f) of the WCHCWM Act.

b) Mandatory segregation of waste was also not performed by this generator of hazardous waste, as prescribed by section 6 (2) (b) of WCHCWM Act, (figure 4.20).

Figure 4.18: Pharmaceutical waste stored in busy dispensary

Figure 4.19: Pharmaceutical waste stored in busy bulk store

Figure 4.20: Pharmaceutical waste from bulk store in figure 4.19

4.2.3.5 Red Cross War Memorial Children's Hospital

a) This hospital did not have a dedicated store for the storage of pharmaceutical waste, in violation of section 6 (2) (f) of WCHCWM Act. Instead the hazardous pharmaceutical waste which was not segregated (figure 4.22) was stored in the pharmacy, in a corridor leading to the rear entrance (figure 4.21), in violation of Section 6 (2) (b) and section 6 (2) (f) of WCHCWM Act. The drums were also improperly sealed; (red plastic bag exposed).

Figure 4.21: Hazardous pharmaceutical waste stored in dispensary corridor

Figure 4.22: Pharmaceutical waste containing mainly cardboard

The waste was also not stored in the correct containers and should have been properly colour coded as prescribed in Section 4.3.3 of the South African National Standard 10248:2004, which prescribes a dark green container as the correct colour for pharmaceutical waste.

b) Figure 4.23 and figure 4.24 illustrates the incorrect management of cytotoxic waste, which was not stored in the special dark green containers and which were not correctly labelled (violation of Section 4.4.2 of SANS:10248:2004). Figure 4.24 shows a small label designed for dispensed medicines being used on the waste container. Provisions for the patient's name and folder number was still clearly visible.

Figure 4.23: Cytotoxic caste in stored in incorrectly coloured drum

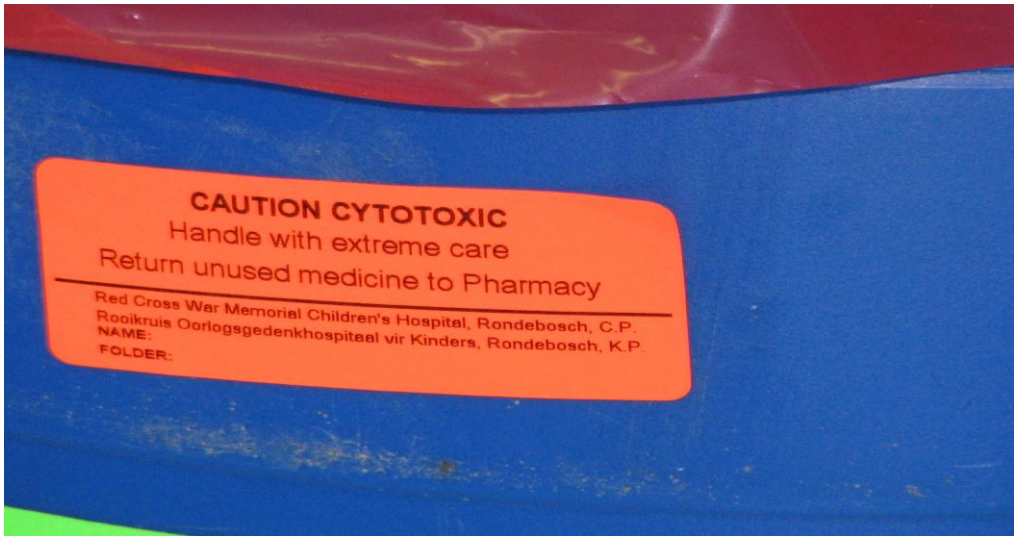

Figure 4.24: Cytotoxic waste incorrectly labelled

c) This cytotoxic section of the pharmacy did not have a dedicated area for pharmaceutical waste. Instead it was also using the sluice room of the aseptic production area which is frequented by the staff, increasing the risk of hazardous spills or accidents, in violation of Section 6 (2) (b) and section 6 (2) (f) of the WCHCWM Act.

4.2.3.6 Mitchells Plain Medical Centre

The mismanagement of pharmaceutical waste at this hospital was no different to that observed at the five other hospitals: sharps containers were over-filled (figure 4.25) and pharmaceutical waste was unsegregated (figures 4.26; 4.27 and 4.28).

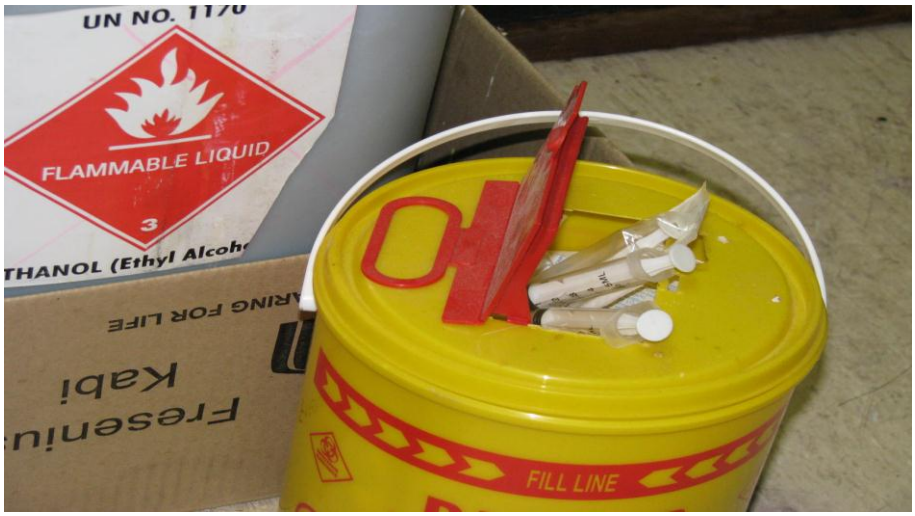

Figure 4.25: Overfilled sharps containers and flammable waste stored together

Figure 4.26: Unsegregated pharmaceutical waste in drum for cytotoxic waste

Figure 4.27: Hazardous pharmaceutical waste in cardboard container

Figure 4.28: Unsegregated pharmaceutical waste

4.2.4 Transport of Pharmaceutical Waste

The pharmaceutical waste was removed from the private hospitals by BCL Medical Waste Management Pty Ltd (BCL MWM) and transported to their incinerator by a fleet of vehicles registered to BCL MWM as an approved transporter of medical waste. In the case of the state hospitals, the pharmaceutical waste was collected by Hlumani Wasteman Pty Ltd and transported to their incinerator outside the Western Cape Province.

4.2.4.1 Private Hospitals' Pharmaceutical Waste Transportation

The certificate of registration issued by the City of Cape Town in terms of by-law no.13333 P.G.E No. 6041, was not dated and the vehicle fleet has changed *e.g.* vehicle registration number CF103988, was no longer part of the fleet, and has been replaced by a vehicle registration CF102550. However, there was no registration certificate for the new addition to the fleet. Any transport of medical waste in this unregistered vehicle was thus illegal. The extent of environmental pollution which the unregistered vehicle caused was not investigated. This violation makes BCL MWM liable to a fine and /or imprisonment for a period not exceeding two years. (Appendix C). The director of the company acknowledged this violation in his correspondence (Appendix N).

No Certificates of Safe Disposal were issued by BCL MWM for the removals and the disposals of pharmaceutical waste from the all three private hospitals, as confirmed by the Quality Assurance Manager of the Melomed Hospital Group.

4.2.4.2 State Hospitals' Pharmaceutical Waste Transportation

In the case of Hlumani Wasteman Pty Ltd it could not be established whether the vehicles used in their transport fleet were properly registered *e.g*. CY297768 which transported 5x 50L of pharmaceutical waste from Tygerberg Hospital, on transport document 26534 [Appendix D(i)], may have been an unregistered vehicle.

4.2.5 Treatment and Disposal of Pharmaceutical Waste

The only disposal method for all the medical waste (including pharmaceutical) generated by the six hospitals researched was and still is incineration. The three private hospitals have contracted BCL MWM to do the disposal, while the three state hospitals have contracted Hlumani Wasteman Pty Ltd, to do the disposal including the transportation.

On the 11th March 2011 the BCL MWM incineration plant was visited. It was explained to company that the brief survey of their incineration plant is the final stage of this research project, which involved the three state hospitals and three private hospitals (Appendix N). Permission was granted that the incineration facility may be surveyed and photographs taken. The chief executive officer himself conducted the tour of the plant. He further stated that BCL MWM was in the process of upgrading and that a new incinerator is hoped to be installed in the near future. The company, Resource Management Services, has been commissioned by BCL MWM to facilitate the Scoping/Environmental Impact Assessment process for the proposed upgrade of the existing incineration technology currently being used by BCL MWM and that all the relevant information which was required may be obtained on the company's website: www.rmsenviro.co.za.The website posted the following documents dated January 2011 with regard to BCL MWM:

1) A Draft Environmental Impact Assessment Report;
2) Air Quality Impact Assessment Due to the Current and Proposed Operations at the BCL MWM Incinerator near Cape Town International Airport,
3) Draft Environmental Management Plan, and
4) Public Participation Report.

The first discrepancy that was observed, was that the permit to conduct an offensive trade, was made out on 05 November 1999 to "MRC Delft Centre" *i.e*. The Medical Research Council, and not to BCL MWM (Appendix E). On the 05 April 2011, I consulted the Department of Environmental Health of the City of Cape Town (Eastern District), whose records show that the BCL MWM was never assessed for compliance. The City of Cape Town officials could not explain the anomalies that was discovered on its original permit issued to BCL MWM, 12 years ago. BCL MWM currently operates on this 1999 permit. There exists the very real possibility that the incinerator is operating illegally. This was not investigated in the research, and presented one of the ethical dilemmas encountered.

Furthermore the permit stated that a "Berco Waste Incinerator" was used (Appendix E). No information with regard to a "Berco Waste Incinerator" could be obtained, only for a "Single Chamber Lucifer Model 450 LA" which is the one presently used.

4.2.5.1 Treatment and Disposal by BCL MWM

On the 18th March 2011 another visit to the plant was made to witness the actual segregation and the incineration of the pharmaceutical waste. This tour was again conducted by the chief executive officer of the company. The following were the findings:

- All the bags were red and the workers could not distinguish between pharmaceutical waste and other types of medical waste, except by opening them. The likelihood of the wrong bag being opened was great, exposing the workers to severe health risks such as needle stick injuries and exposure to pathogens.
- No internal audits were available where such injuries have been recorded.

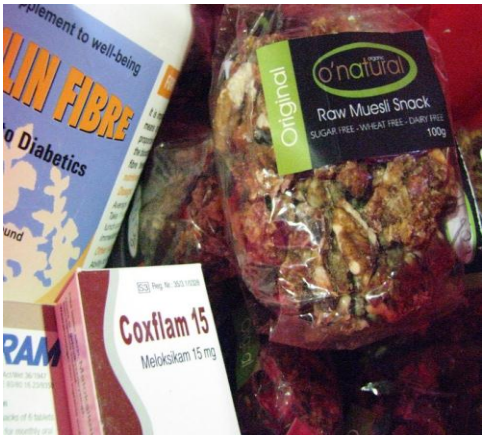

Figure 4.29a

Figure 4.29b

Figures 4.29a: and Figure 4.29b: Uunsegregated pharmaceutical waste about to be incinerated

- Figure 4.29a shows Raw Muesli Snack which belongs to municipal solid waste, being mixed with Coxflam 15® a Schedule 3 medicine, about to be incinerated. Figure 4.29b shows lozenges (Schedule 0) also belonging to municipal solid waste, mixed with pre-filled syringes and needles, which should have been disposed into a sharps bin.

- The workers did not wear proper protective clothing while segregating the pharmaceutical waste, nor during the transfer of the bags and sharps containers into the incinerator, and the removal of hot bottom ash (figures 4.30a, 4.30b, and 4.30c). Their bodies were dangerously exposed and the thin latex gloves served no protection against needle stick injuries. This was a violation of Regulation 11 of the Hazardous Chemical Substances Regulations, of Occupational Health and Safety Act 85 0f 1993.

- The Certificate of Good Standing no. 773244 dated 01-09-2010 issued by the Dpt. of Labour in terms of the Compensation for Occupational Injuries and Diseases Act 1993 (Appendix I) was expired.

Figure 4.30a: Dangerous manual segregation of hazardous pharmaceutical waste

Figure 4.30b.

Figure 4.30c

Figures 4.30b: and Figure 4.30c: Dangerous manual segregation of hazardous pharmaceutical waste

Whether the certificate was renewed and the operators were sufficiently covered in case of occupational injuries, was unlikely, because on the 11th March 2011, I was presented with a current brochure of the company's profile, in which this expired certificate was found.

- The BCL MWM incinerator is located on Portion 67 of Erf 544, Brentwood Park on a property belonging to the Medical Research Council (MRC), surrounded by the residential areas of Delft, Silversands, Mfuleni, Khayelitsha. The nearest township to the incinerator Eindehoven, is about 500m north of the incinerator.

Figure 4.31a: Eindehoven residences within 500m: engulfed in incinerator smoke

Figure 4.31b: BCL MWM incinerator emitting black smoke

With regard to the incineration process the following conditions were found:

a) During every day that the research was conducted at the incinerator, thick black smoke was observed to be emitted from the chimney stack (fig. 4.31b). A haze of offensive smoke (figure 4.31a) which originated from the incinerator and could clearly be seen to engulf the surrounding residences. However the emissions from the stack were stated to be within the accepted emission standards (Petzer and Breitenbach, 2011). Figure 4.31b shows the incinerator emitting black smoke, indicating incomplete combustion.

b) The current incinerator operated by BCL MWM was a single chamber Lucifer Model 450 LA. The technology which it uses (single chamber, excess air) is considered very old and such models are no longer available on the open market. This antiquated incinerator cannot reach temperatures above 800ºC, and thus operates at temperatures much lower. Because of the high proportion of materials with high calorific value it is inevitable that products partially combusted, will be formed in the combustion chamber, even if the incinerator, was designed to operate under excess air (Anon., 2011). In order to eliminate unwanted by-products, modern incinerators have built-in after-burners which contain the primary chamber gases at a minimum temperature of 1100 ºC , to destroy the products of incomplete combustion. Polyvinyl chloride (PVC) plastics (in this case, the catheters containing pharmaceutical waste), is composed of 45% chlorine by weight, will be

converted into hydrogen chloride, chlorine gas, together with dioxins and furans and other chlorinated products of incomplete combustion (Green, 1992).

Independent tests done by a company Poltech Earth and Occupational Health Sciences, commissioned by BCL MWM in 2007, determined the emission stack temperature to between 258 ºC and 272 ºC (Appendix O). The incinerator of BCL MWM does not have a stack scrubber (to remove fly ash and water soluble gases) nor a secondary or tertiary combustion chamber in which the combustion temperatures can rise to the required minimum for complete combustion, nor provide sufficient residence time of two to three seconds. On the day of the visit the incineration temperature was observed to be 333 ºC (figure 4.33). Any temperature much higher than 333 ºC can only be obtained by overloading and by manually trying to convert it to a continuous batch incinerator. This was dangerously attempted by the staff as can be seen in figure 4.34 and figure 4.35, where the bottom ash of the first load (still burning) was being removed, while several bags of a new batch were waiting to be inserted.

The only stack emission analysis available was that done on 30 October 2007 and it only measured the amount of a few heavy metals released in "Normal milligrams per cubic metre" (Appendix F). These results were not complete and accurate as it did not measure dioxins and furans emitted, which is standard practice internationally.

Figure 4.32a: External view of the Incinerator

Figure 4.32b: Internal view

Figure 4.33: Incineration temperature

c) The incineration of medical or pharmaceutical waste does not make it disappear, but only reduce it to ash and atmospheric emissions. The heavy metals found in medical waste either end up as fly ash in the stack emissions or bottom ash at the bottom of the combustion chamber. Properly designed incinerators should not only combust the medical waste completely, resulting in minimal ash, but should also incorporate scrubbers which trap the toxic air pollutants and fly ash. A great amount of ash and gases are generated when there is partial combustion, which are then dispersed to the surrounding communities, near and far, depending on wind strength and direction, resulting in numerous lung diseases (Mato and Kasenga, 1997).

Bottom ash is more toxic than the hazardous medical waste it originated from, because the heavy metals it contain are now much more concentrated. Because it is classified as hazardous, it has to be landfilled in a H:H engineered landfill. The bottom ash in the case of the BCL MWM incinerator was manually removed by unprotected labourers (figure 4.35) and placed in an open-lidded skip exposed to the weather and wind, for many days until it was collected by a different medical waste transporter, Wasteman Western Cape a division of Wasteman Holdings (Pty) Ltd, and taken by the latter to the only H:H engineered landfill site at Vissershok Waste Management Landfill Facility (Appendix Q). The exposure to the wind contributed to air pollution and is a violation of Regulation 10 and 15 of the Hazardous Chemical Substances Regulations of the Occupational Health and Safety Act 85 of 1993.

Figure 4.34: Hot bottom ash removed manually and escaping to the atmosphere

Figure 4.35: Improperly clad workers removing bottom ash

Figure 4.36: Fugitive bottom ash blown into the environment

Figure 4. 37: Hot bottom ash cooling off while blown into atmosphere

Figures 4.34 and 4.36 shows fugitive bottom ash escaping into the atmosphere while being loaded into drums. The hot ash was placed into metal drums in the open, exposed to wind

while cooling off and before being transferred to the skip (figure 4.37) continuing the environmental pollution.

Figure 4.38: Open-lidded skip containing cold bottom ash

Figure 4.39: Bottom ash partially combusted

Figures 4.40 shows glass bottles being emptied and figure 4.30c shows glass bottles being segregated from pharmaceutical waste by hand. The reason for BCL MWM undertaking this procedure was because the incinerator was incapable of volatilizing the glass into vapour because of its low operating temperatures. The glass liquefies instead and collects at the bottom where it later solidifies damaging the grid and interfering with bottom ash collection. Figure 4.39 shows an intact glass vial that were not incinerated into vapour, in the extracted bottom ash.

Figure 4.40: Indiscriminate mixing of liquid pharmaceutical waste prior to incineration

Figure 4.41: Segregated hazardous glass containers not incinerated

Liquid pharmaceuticals were emptied into a large container, creating a cauldron of unknown chemicals and medicines, which was then disposed of into the waste water drains (figure 4.40), destined for the onsite STWs. The glass bottles so emptied (irrespective of its hazardous contents or not) were then collected in an open skip (figure 4.41) and landfilled at Vissershok, having been transported there by Wasteman Western Cape, who issued a Certificate of Safe Dispoal, no.15291, dated 02/03/2011 (Appendix P). This certificate was

inadequate in that it did not indicate the method of "Safe Disposal" as in Appendix Q. The glass bottles and mutidose vials contained varying amounts of hazardous pharmaceutical and cytotoxic drugs.

On 06-07-2011 at 16h30, the technical officer at the Vissershok Waste Managment Facility, situated near the town of Atlantis on the west coast, informed me telephonically after consulting their records that the said vials were co-disposed with normal municipal solid waste. This load, like the others, should have been landfilled in an H:H engineered landfill site, with documentation to verify it. There's thus every possibility that this method of pharmaceutical waste disposal is causing extensive environmental pollution especially ground water in the Vissershok area.

The skip containing the glass vials is stationed in the wash bay area. While it is filling up over a period of days, rain falls into it and wash out the contents of the vials which entered the sewer drains, as can be seen in figure 4.38 showing the wet ground below the skip.

The transport vehicles of BCL MWM are washed daily in the dedicated area, in front of the entrance door to the incinerator (figure 4.36). The contaminated water from the vehicles is disposed into the waste water drains. The re-usable plastic containers used to transport the medical waste and the hazardous pharmaceutical waste, are washed in a special wash bay and the washing water therefrom was also discharged into the waste water drains.

All the waste water described above, together with the sewerage from BCL MWM, are disposed into an on-site sewerage system which serves Erf 544 only. Portions of Erf 544 were sublet to several private commercial enterprises such as light engineering, whose effluent waters and human sewerage are also discharged into the same on-site sewers. Erf 544 is owned by the Medical Research Council (MRC) of South Africa and located on the site are the South African Forensic Laboratories, which houses dozens of cages for animals varying from monkeys to horses. The excretions of the animals and that of the technical staff plus the MRC chemical waste from the forensic laboratories are also disposed into the same sewers found on this Erf. The sewers converge and the accumulated waste waters from these activities, are treated by a MRC STWs (figure 4.42).

Figure 4.42: MRC Sewage Treatment Works (STWs)

This sewage treatment works is not a true treatment facility like other municipal STWs. According to the MRC maintenance manager on site, the only chemical treatment that is performed on the waste water is the addition of approximately 2kg of a commercial swimming pool chlorinator "HTH" on Friday mornings. After this chlorination step the effluent is pumped into the first of three consecutive retention ponds (fig. 4.43). From the final pond (figure 4.43), the effluent is released into a "French Drain" from where it discharges into the surrounding ground of the adjacent Driftsands Nature Reserve. There's thus every possibility that the groundwater has become polluted.

Although the MRC STWs has been operating for many years it has not been evaluated by the Department of Water Affairs in terms of the National Water Act 36 of 1998. The plant does not have a General Authorisation Licence to operate as a provincial STWs. STWs in South Africa, was not designed to eliminate pharmaceuticals. On 06-05-2010, the MRC commissioned K. Pontac Pty Ltd., to analyse the sewage effluent. The results given in Appendix S shows that no test for the pharmaceuticals were done, even though there were evidence of pharmaceuticals having been discharged into the STWs.

A non-governmental organisation (NGO) is active on the site growing vegetables which are supplied to a "soup kitchen" feeding the indigent of the surrounding areas. The crops are watered from a bore-hole situated at the end of the last pond.

Figure 4.43: Final effluent retention pond of the MRC STWs

4.2.5.2 Treatment and Disposal by Hlumani Wasteman (Pty) Ltd.

In the case of Hlumani Wasteman (Pty) Ltd., the actual incineration process could not be witnessed as the company's incinerator is situated out of Cape Town. However, the incorrect documentation issued by the company was noted and is discussed under chapter six.

4.3 Interviews

The outcomes of the interviews indicated that the curricula of the health professionals, which the tertiary institutions produced, did not cover pharmaceutical waste in sufficient depth, and were thus inadequate in preparing the new graduates for the management thereof.

4.3.1 Interview with Director of School of Pharmacy, University of the Western Cape

With regards to pharmaceutical waste management in the curriculum of the Bachelor of Pharmacy degree offered by the University of the Western Cape, the Director of the School of Pharmacy agreed that although the course incorporates a module, referred to as "Waste disposal and environmental health care", the course does not cover pharmaceutical waste sufficiently to prepare the graduate to correctly and legally manage pharmaceutical waste in the hospitals nor in community pharmacies. These challenges were also superficially addressed in one or two lectures in the subject "Applied Pharmaceutical Microbiology". Furthermore, although the Medicine and Related Substances Act [Act 101 of 1965] is included in "Basic Pharmacy Practice" module of the course, only the sale of scheduled medicines were covered. The essential aspects of disposal and destruction of medicines were

not significantly covered in undergraduate studies, nor in post-graduate pharmacy courses. The interviewee requested anonymity, but gave a verbal undertaking that the curriculum gap will be addressed.

4.3.2 Interview with Head of Department of Pharmacology, University of Stellenbosch

In terms of circularisation of the M.B. Ch. B. degrees at the University of Stellenbosch Medical School, it was confirmed that the combined degree of Bachelor of Medicine and Bachelor of Surgery, which is the basic qualification for all medical practitioners, does not cover the subject of pharmaceutical waste management at all. It was suggested that a module with regard to pharmaceutical waste management be introduced either in the 4th year of study under Forensic Medicine or the 5th year of study under the subject Health Management. The interviewee requested anonymity, but gave a verbal undertaking that the curriculum gap will be addressed.

4.3.3 Interview with Head of Nursing Programs, Cape Peninsula University of Technology.

It was agreed by the Head of Post–Basic Nursing Training Programme that the B.Tech (nursing) curriculum does not cover the management of pharmaceutical waste. It was further emphasized that nurses who are in charge of the hospital wards where the pharmaceutical waste is generated, should be skilled in the management of pharmaceutical waste. It also suggested that a module with regard to waste management be introduced at under- and post-graduate level dealing with medical waste management including pharmaceutical waste. The interviewee requested anonymity, but gave a verbal undertaking that the curriculum gap will be addressed.

4.4 Pilot Questionnaire Results

After each questionnaire was completed, verbal comments were solicited from the respondents, and these were used as a basis for modifying the questionnaire. Based on their replies the following amendments were consequently made to facilitate the completion of the final questionnaire:

a) The questions and statements were shaded to highlight them and to make the format appear less intimidating and complex,
b) Questions that require written statements by the respondents [3(c) and 5] were deleted in order to reduce the time required to complete the questionnaire. This had a ripple

effect in the numbering sequence with the result that question 9 did inadvertently not appear in the final questionnaire.

c) The following questions were deleted and or amended (table 4.1):

Table 4.1 Amendments to pilot questionnaire

Question	Pilot questionnaire	Action	Reason	Final questionnaire
Q7	Is pharmaceutical waste segregated (divided into different types and schedules) before disposal	Replaced	New questions were more focussed.	Q6.(a) Is pharmaceutical waste segregated... Q6 (b) Is pharmaceutical waste segregated...
Q9	Cement kilns	Deleted	Outside scope of this research.	
Q9	Commercial incineration	Amended	Amended question were more specific.	Q8.Incineration of pharmaceutical waste
Q10	Hospitals should employ waste companies to dispose of their hazardous waste	Deleted	Irrelevant. Implies outsourcing, and privatisation of the function. Outside scope.	
Q10	There are clearly defined procedures for the handling of different types of waste from different departments in the hospital	deleted	Question duplicated.	
Q10	Training courses are provided by the hospital for all personnel involved with waste.	Amended	Emphasize the need for proper training.	Formal training in medical waste management should be provided by the hospital for all its healthcare professionals.
Q10	This hospital has a waste management policy	Deleted	A Labour concern. Outside scope of this research.	

Question	Pilot questionnaire	Action	Reason	Final questionnaire
Q10	Hospital policy addresses the identification of risk to personnel involved in handling of waste	deleted	A Labour concern. Outside scope of this research.	
Q10	Hospital policy addresses quantification of risk to personnel involved in handling of waste	deleted	A Labour concern. Outside scope of this research.	
Q10		Inserted	Sewage treatment identified in fig.1.3	Sewage treatment personnel should have certificates of competency
Q10		Inserted	Landfills are destinations for pharmaceutical waste.	Landfill personnel should have certificated competency

4.5 Questionnaire Results

The objectives of the questionnaire were:

- To determine the level of knowledge amongst doctors, pharmacists, and nurses on different aspects of the management, collection, treatment and disposal of pharmaceutical waste as undertaken in the respective hospitals;
- To determine the level of awareness of the potential environmental impact of pharmaceutical waste;
- To correlate the results of the questionnaire with the actual practice as observed;
- To evaluate the findings in terms of the WCHCWM Act.

The questionnaire extracted information with regard to the following aspects of pharmaceutical waste management at the selected hospitals.

4.5.1 Knowledge of Departmental Assignment of Medical Waste Disposal Responsibility. Refer Q2(a).

Figure 4.44 shows that 73.4% of nurses are aware of existence of a dedicated waste management department in the hospital compared to only 46.4% of pharmacist and 44.7% of doctors. With regards to "Don't know" answers (uncertain of the existence of a waste management department), 50.4% of doctors said they do not know versus 39.3% of pharmacist and 18% of nurses. These results indicated an association between the profession and the awareness of a waste management department, with doctors being the least aware of such an existence. When the Chi-square test was applied to this result the association was found to be significant (p-value<0.05).

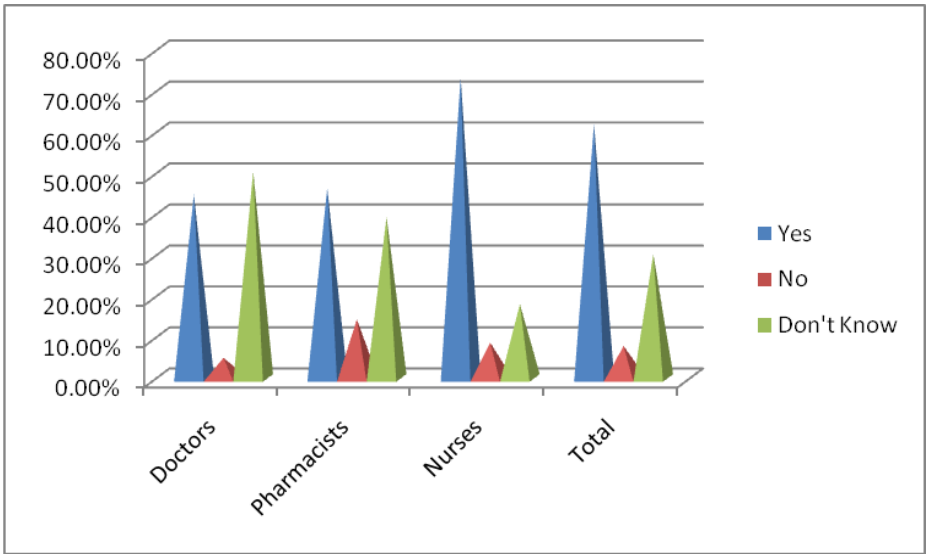

Fig.4.44: Knowledge of a specific department assigned to the management of medical waste disposal

4.5.2 Provision of Professional Training in Medical (including Pharmaceutical) Waste Management. Refer Q2(b).

One of the most critical questions was Q2(b) which revealed the following results.

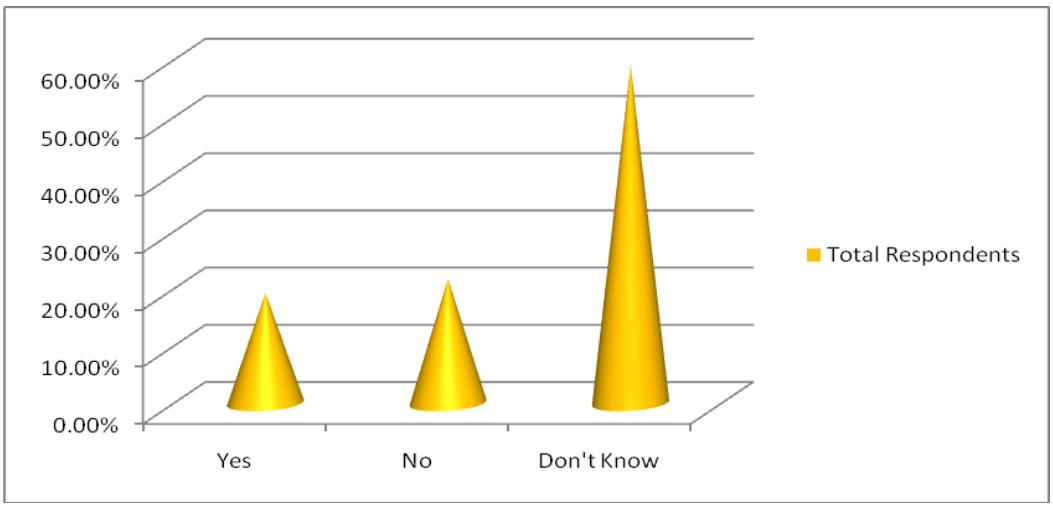

Figure 4.45a: Provision of training in medical (including Pharmaceutical) waste management: all professionals combined

Fig.4.45a shows that only 19.2% of the all participants said they received training in medical waste management; 21.7% said they did not, while 59.1% answered that they do not know, indicating a very low level of training overall.

When analysing the results in terms of professions, the lowest level of training (Yes answer) was the pharmacist with only 3.6% declaring that they received training, followed by doctors with 11.5% and nurses with 25,4% (fig.4.45b). The association between profession and the receipt of training, was found to be significant (p-value<0.05). It was difficult to interpret the "Don't Know" results. Either it meant that the respondents did receive the prerequisite training but have forgotten it or they cannot remember whether they did receive the training in the first place.

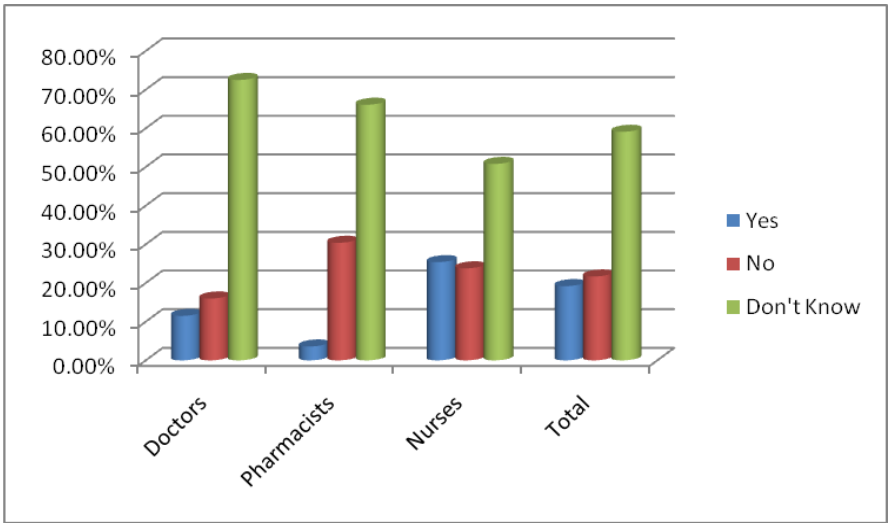

Fig.4.45b: Provision of training in medical (including pharmaceutical) waste management by profession

4.5.3 Awareness of Audits, Legislation, and Waste Management Protocols. Refer Q3.

Audits are important assessment tools for evaluating hospitals standards. Figure 4.46 illustrates the results of the question Q3 which demonstrated that the awareness of waste audits having been done in the hospitals, were very low.

Hospital waste audits are routinely carried out at hospitals and fulfils several functions such as analysis of the composition of the waste generated (Mohee, 2005), but also provide a strategic tool to manage the waste effectively (Woolridge et al., 2005).

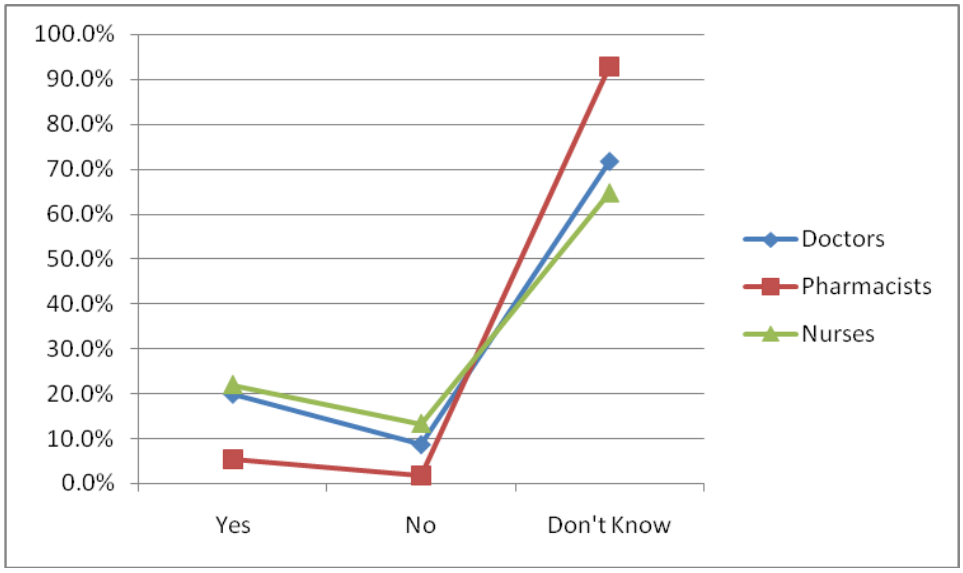

Fig. 4.46: Awareness of hospital audits done in the last 3 years

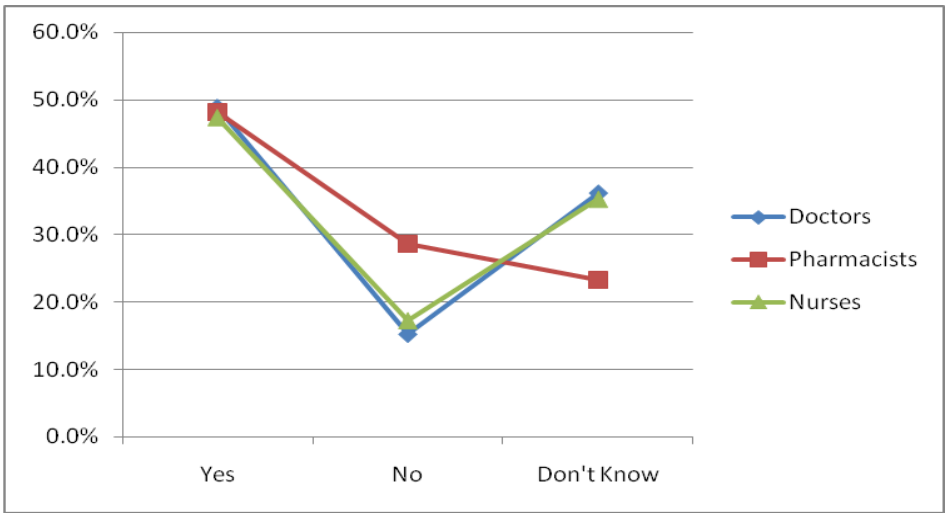

Fig. 4.47: Awareness of legislation applicable to hospital waste management

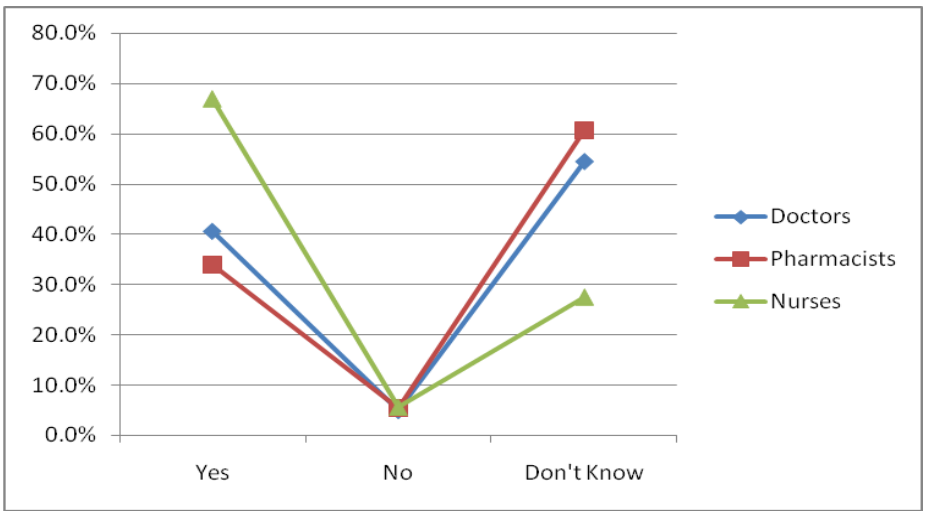

Fig.4.48: Awareness of hospital waste management policy and procedures

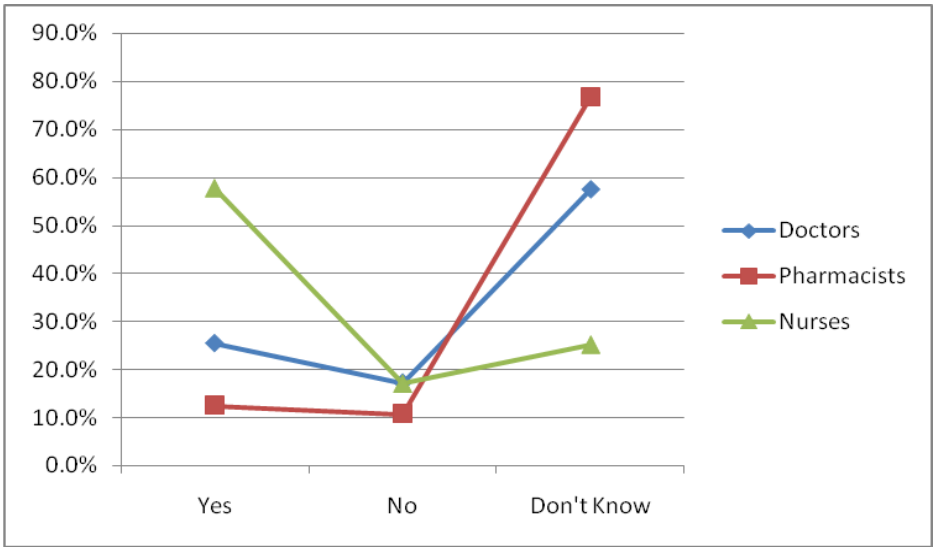

Fig.4.49: Awareness that the policies and procedures have been distributed to all wards and departments

Table 4.2: Pearson Chi-Square tests for Q3 Results are based on nonempty rows and columns in each innermost sub-table. chi-square statistic showed significance at 0.05.

		Hospital Type
Q3 Waste audit done in last 3 years	Chi-square	21.062
	df	2
	Sig.	.000*
Q3 Waste management legislation Awareness	Chi-square	10.047
	df	2
	Sig.	.007*
Q3 Hospital has waste management policy	Chi-square	3.463
	df	2
	Sig.	.177

		Hospital Type
Q3 Policy distributed to all wards`	Chi-square	.724
	df	2
	Sig.	.696

The results revealed (fig. 4.46) that 71.6 % of doctors, 92.9 % of pharmacists, and 64.7 % of nurses were not aware that audits have been done in the last three years at the hospitals where they practiced. A lack of knowledge with regard to the hospital's waste management policies and procedures (fig.4.47) were also extensive in that 54.5% of doctors, 60.7% of pharmacists, and 27.5% of nurses had no such knowledge.

4.5.4 Opinions on whether selected categories of pharmaceuticals may be sewered. Refer Q5

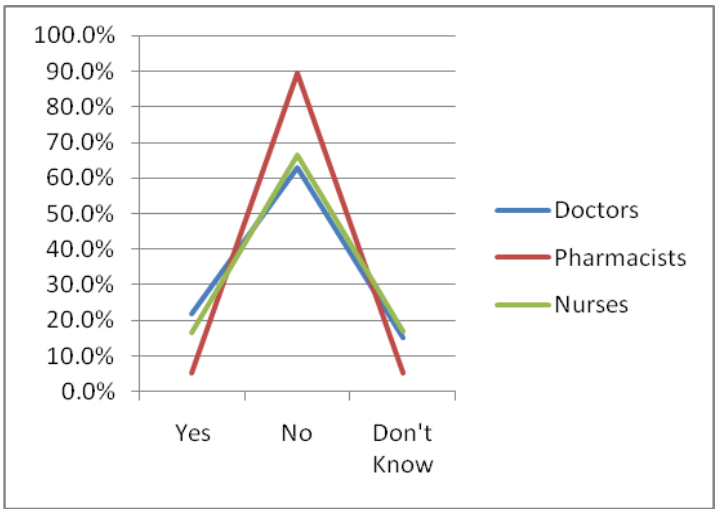

Figure 4.50: Organic solvents may be sewered

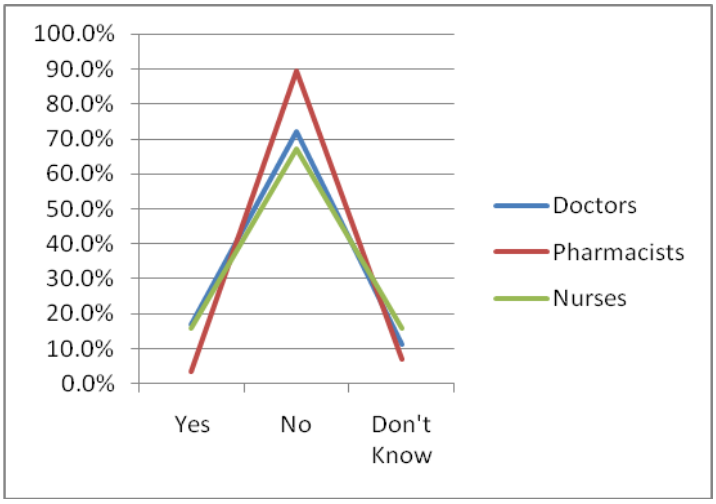

Figure 4.51: Antibiotics may be sewered

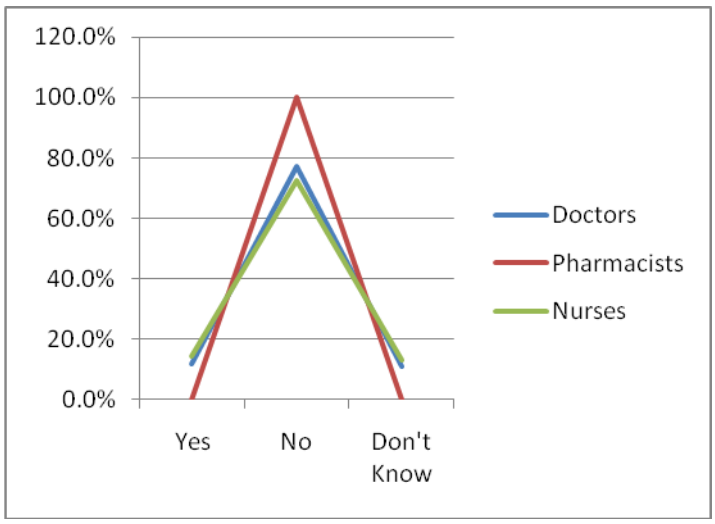

Figure 4.52: Cytotoxics may be sewered

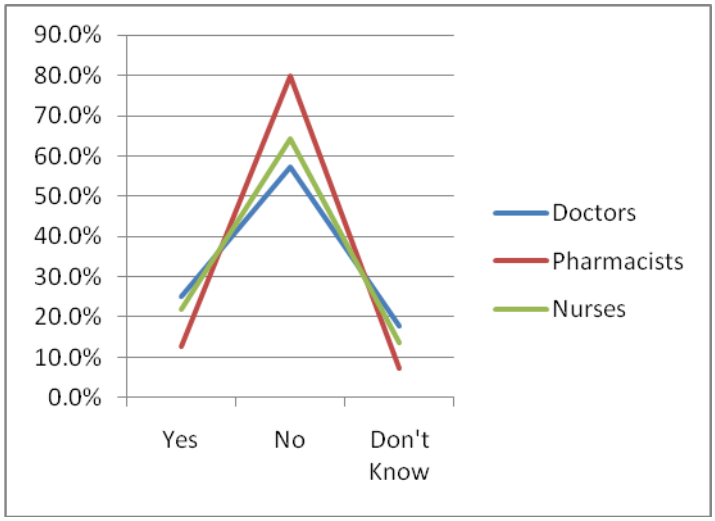

Figure 4.53: Multivitamins may be sewered

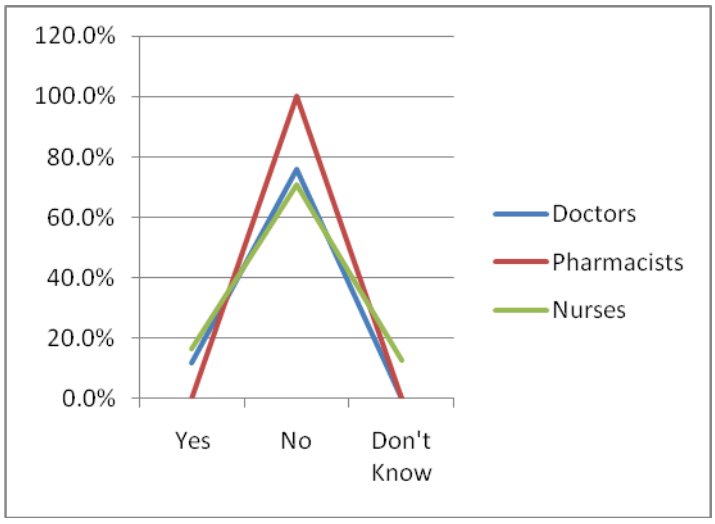

Figure 4.54: Expired medicines may be sewered

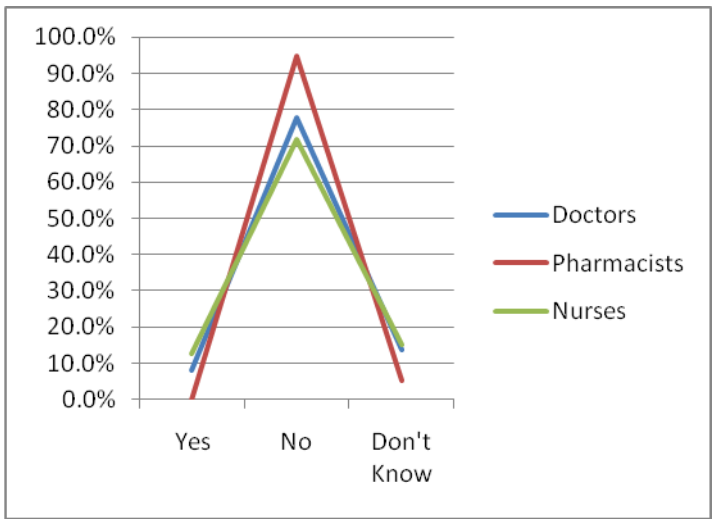

Figure 4.55: All unused medicines may be sewered

Regulation 27 (2) of Act 101 of 1965, is quite explicit in stating that: "No medicines may be disposed into municipal sewerage systems". One of the objectives of this research was to guage the opinions of healthcare professionals in this regard. Figures 4.50 to 4.55 reflects this perspective on the "sewerability" of selected pharmaceutical compounds, which is further discussed in Chapter Five.

4.5.5 Segregation of pharmaceutical waste. Refer Q6

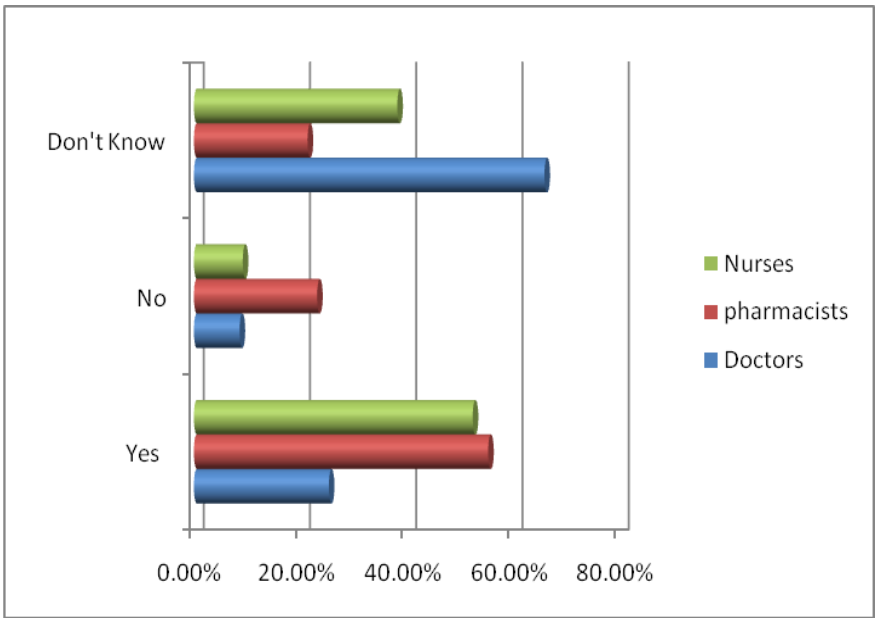

Figure 4.56: Response to segregation of pharmaceutical waste at point of generation by profession

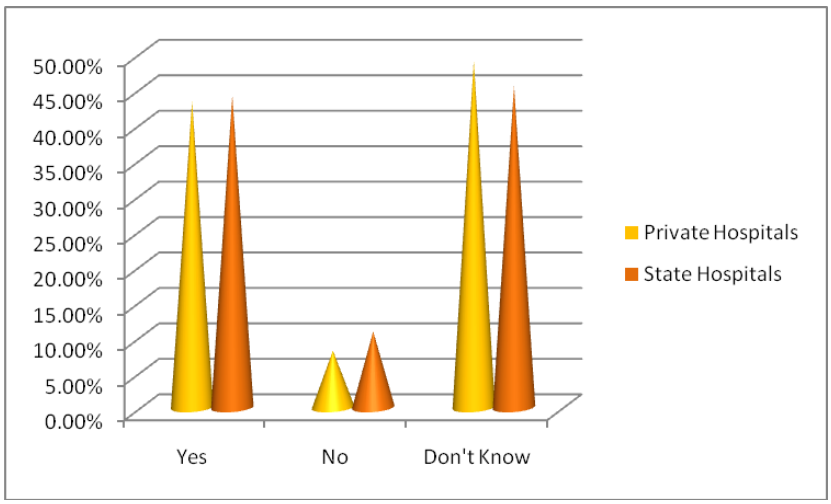

Figure 4.57: Response to segregation of pharmaceutical waste at the point of generation by hospital type

Table 4.3 Pearson Chi-Square tests for Q6a and Q6b. Results are based on nonempty rows and columns in each innermost sub-table of the questionnaire

		Hospital Type
q6a Pharmaceutical waste segregated at the point of generation	Chi-square	1.410
	df	2
	Sig.	.494
q6b Pharmaceutical waste segregated before final removal from hospital for disposal	Chi-square	2.107
	df	2
	Sig.	.349

.

Nearly half of the professionals questioned (48.9% in the private hospitals, 45.3% in the state hospitals) did not know whether the pharmaceutical waste was segregated at the point of generation (fig.4.57). Of them 66.0% were doctors; 21.4% were pharmacists; and 38.3% were nurses (fig. 4.56). The unsegregated condition of the pharmaceutical waste observed (figures 4.1; 4.2; 4.4b; 4.4c; 4.8; 4.11; 4.14; 4.18; 4.20; 4.22; 4.26; 4.27; 4.28; 4.29a; 4.29b; 4.30b; and 4.30c), was thus indicative of and reflected this lack of knowledge.

4.5.6 Pharmaceutical waste problems encountered by profession. Refer Q7

A very high percentage of professionals (91.7% doctors, 85% pharmacists, and 90% nurses) stated that they never encountered a pharmaceutical waste problem (table 4.4) with a reported Chi-Square test result of 0.363 (table 4.5).

Table 4.4: Pharmaceutical waste problems encountered by profession

		Profession					
		Doctor		Pharmacist		Nurse	
		n	%	n	%	n	%
Q7.a Encountered pharmaceutical waste problems	**Yes**	20	8.3%	8	14.5%	43	9.6%
	No	221	91.7%	47	85.5%	403	90.4%
	Total	241	100.0%	55	100.0%	446	100.0%

Where n = number of respondents

Table 4.5: Pearson Chi-Square Tests Results are based on nonempty rows and columns in each innermost subtable.

			Profession
q7.a Encountered pharmaceutical waste problems		Chi-square	2.026
		Df	2
		Sig.	.363

4.5.7 Perceptions of Efficiency of Existing Disposal Methods by professions. Refer Q8

The results in figure 4.59, reflected the perceived efficiencies for the different disposal methods applied to hazardous pharmaceutical waste, on a scale of 1 (inefficient) to 10 (efficient).

a) Disposal of Medical Waste by Private Company

Disposal of medical waste by private companies received the highest aceptance (6.8), by pharmacists.

b) Disposal of Medical Waste by the Municipality

It appeared that the healthcare professionals did not have a clear opinion as whether the municipal disposal of medical waste was good or bad (score between 4.8- 5.5). This could be explained because the municipality was not involved in the disposal of hospital medical waste.

c) Disposal of Medical Waste by Incineration

Perception of the efficiency of incineration was scored between 6-7. Nurses and medical doctors scored equally 6.2 while pharmacists scored 6.4.

d) Disposal of Medical Waste by Landfilling

As a process landfilling scored between 4-6, with pharmacists displaying the lowest score of 4.3. This was probably because municipal landfilling was generally perceived not to be an acceptable method for medical waste disposal. The score was therefore expected to have been much lower.

e) Efficiency of Sewage Treatment Works

The perception of the efficiency of sewage treatment works in the removal of pharmaceutical compounds scored between 5-6 which showed that the respondents did not have any strong views.

f) Efficiency of Water Treatment Plants

The acceptance of the purity of Cape Town's tap water (pharmaceutically free) was reflected in the perception of the efficiency of the water treatment plants 5.6 to 5.9 (where the inlet sources are dam water, fed by rivers, as in the case of Cape Town).

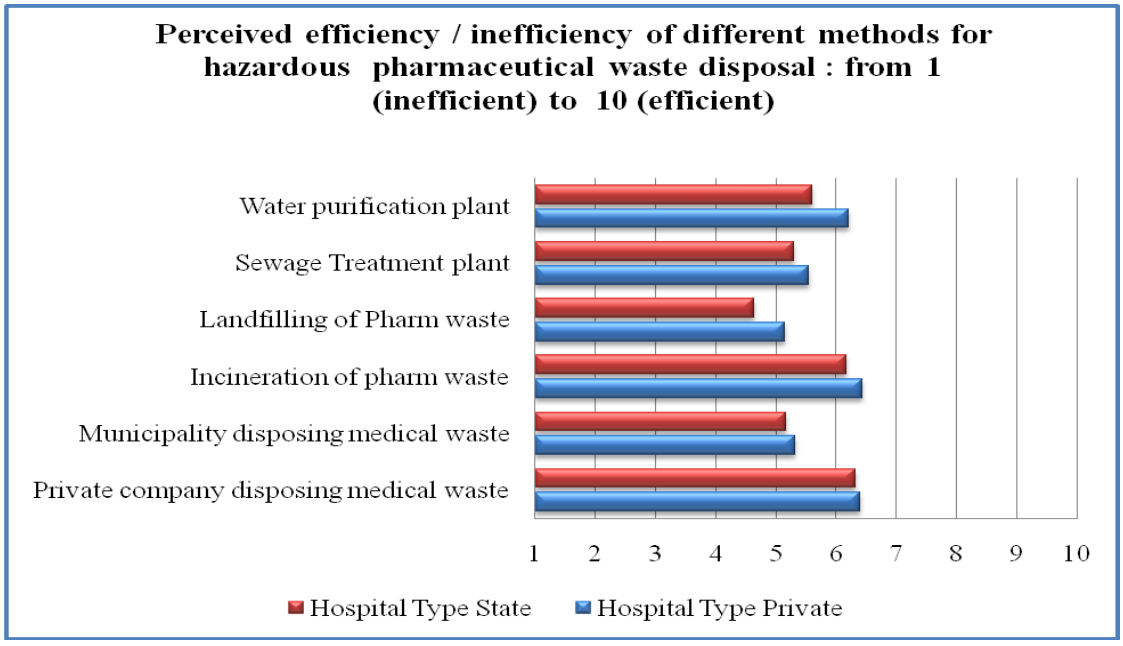

Figure 4.58: Perceived efficiency of different methods of hazardous waste disposal by hosptial type

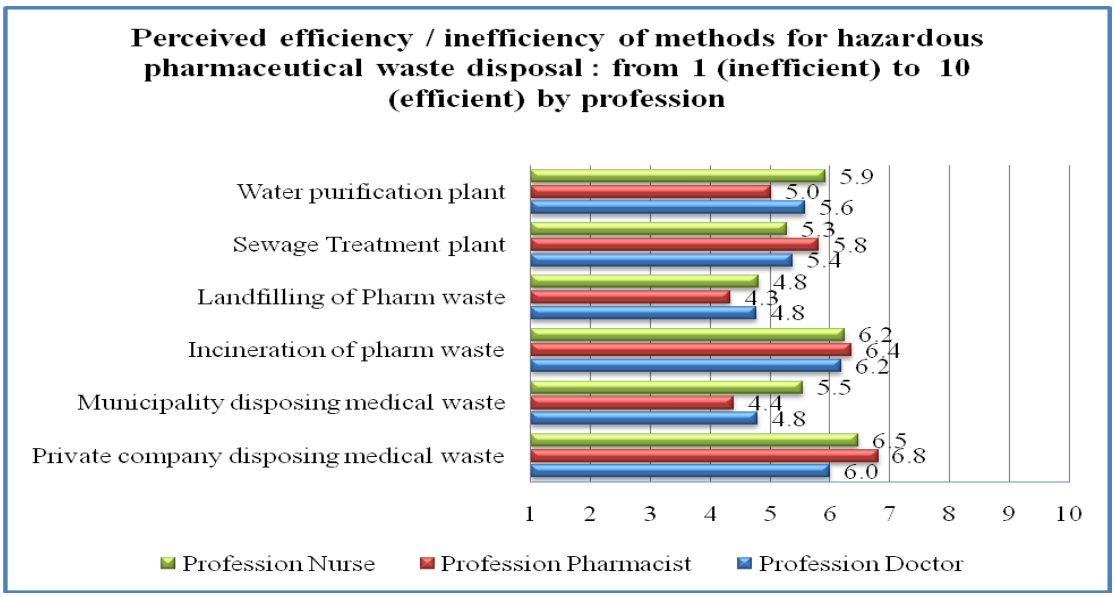

Figure 4.59: Perceived efficiency of the different methods of hazardous waste disposal by profession

The above perceptions of the health care profesionals in state employ when compared to those in private practice were fairly consistent and did not differ by more than one unit (figure 4.58). The origins of these perceptions were not interrogated.

4.5.8 Levels of Expectation With Regard to Disposal Processes. Refer Q10

Strong views of agreement as to whether incinerators should be certified, were expressed by doctors [(91.3% private), (93.2% state)], pharmacists [(100% private), (88.6% state)], and nurses [(94.8 % private), (92.4% state)], table 4.6.

Table 4.6: Profession * The incinerator Should Be Certified * Hospital Type Cross tabulation *

Hospital Type			Incinerators Should Be Certified						Total
			Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Don't know	
Private	Doctor	Count	44	19	3	0	1	2	69
		% within Profession	63.8%	27.5%	4.3%	.0%	1.4%	2.9%	100 %
	Pharmacist	Count	7	4	0	0	0	0	11
		% within Profession	63.6%	36.4%	.0%	.0%	.0%	.0%	100 %
	Nurse	Count	51	40	1	1	1	2	96
		% within Profession	53.1%	41.7%	1.0%	1.0%	1.0%	2.1%	100 %
	Total	Count	102	63	4	1	2	4	176
		% within Profession	58.0%	35.8%	2.3%	.6%	1.1%	2.3%	100 %
State	Doctor	Count	109	54	10	0	1	1	175
		% within Profession	62.3%	30.9%	5.7%	.0%	.6%	.6%	100 %
	Pharmacist	Count	25	14	2	0	0	3	44
		% within Profession	56.8%	31.8%	4.5%	.0%	.0%	6.8%	100 %
	Nurse	Count	205	107	11	2	4	9	338
		% within Profession	60.7%	31.7%	3.3%	.6%	1.2%	2.7%	100 %
	Total	Count	339	175	23	2	5	13	557
		% within Profession	60.9%	31.4%	4.1%	.4%	.9%	2.3%	100 %
Total	Doctor	Count	153	73	13	0	2	3	244
		% within Profession	62.7%	29.9%	5.3%	.0%	.8%	1.2%	100 %
	Pharmacist	Count	32	18	2	0	0	3	55
		% within Profession	58.2%	32.7%	3.6%	.0%	.0%	5.5%	100 %
	Nurse	Count	256	147	12	3	5	11	434
		% within Profession	59.0%	33.9%	2.8%	.7%	1.2%	2.5%	100 %
	Total	Count	441	238	27	3	7	17	733
		% within Profession	60.2%	32.5%	3.7%	.4%	1.0%	2.3%	100 %

Strong views of agreement as to whether incinerator staff should be certified as competent, were expressed by doctors [(92.8% private), (94.3% state)], pharmacists [(91% private), (81.4% state)], and nurses [(93.7 % private), (77.7% state)], table 4.7.

Table 4.7: Profession * Incinerator Staff Should Be Certified Competent * Hospital Type Crosstabulation

Hospital Type			Incinerator staff should be certified competent						Total
			Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Don't know	
Private	Doctor	Count	38	26	2	0	1	2	69
		% within Profession	55.1%	37.7%	2.9%	.0%	1.4%	2.9%	100 %
	Pharmacist	Count	5	5	1	0	0	0	11
		% within Profession	45.5%	45.5%	9.1%	.0%	.0%	.0%	100 %
	Nurse	Count	46	44	2	1	1	2	96
		% within Profession	47.9%	45.8%	2.1%	1.0%	1.0%	2.1%	100 %
	Total	Count	89	75	5	1	2	4	176
		% within Profession	50.6%	42.6%	2.8%	.6%	1.1%	2.3%	100 %
State	Doctor	Count	102	63	8	0	1	1	175
		% within Profession	58.3%	36.0%	4.6%	.0%	.6%	.6%	100 %
	Pharmacist	Count	22	13	1	1	1	5	43
		% within Profession	51.2%	30.2%	2.3%	2.3%	2.3%	11.6 %	100 %
	Nurse	Count	149	116	63	2	3	8	341
		% within Profession	43.7%	34.0%	18.5%	.6%	.9%	2.3%	100 %
	Total	Count	273	192	72	3	5	14	559
		% within Profession	48.8%	34.3%	12.9%	.5%	.9%	2.5%	100 %
Total	Doctor	Count	140	89	10	0	2	3	244
		% within Profession	57.4%	36.5%	4.1%	.0%	.8%	1.2%	100 %
	Pharmacist	Count	27	18	2	1	1	5	54
		% within Profession	50.0%	33.3%	3.7%	1.9%	1.9%	9.3%	100 %
	Nurse	Count	195	160	65	3	4	10	437
		% within Profession	44.6%	36.6%	14.9%	.7%	.9%	2.3%	100 %
	Total	Count	362	267	77	4	7	18	735
		% within Profession	49.3%	36.3%	10.5%	.5%	1.0%	2.4%	100 %

Strong views of agreement as to whether sewage treatment staff should be certified competent, were expressed by doctors [(92.7% private), (94.2% state)], pharmacists [(90.9% private), (84% state)], and nurses [(93.7% private), (74.3% state)], table 4.8.

Table 4.8: Profession * Sewage treatment staff should be certified competent * Hospital Type Crosstabulation

Hospital Type			Sewage treatment staff should be certified competent						Total
			Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Don't know	
Private	Doctor	Count	35	29	3	0	0	2	69
		% within Profession	50.7%	42.0%	4.3%	.0%	.0%	2.9%	100 %
	Pharmacist	Count	4	6	1	0	0	0	11
		% within Profession	36.4%	54.5%	9.1%	.0%	.0%	.0%	100 %
	Nurse	Count	49	41	2	3	1	0	96
		% within Profession	51.0%	42.7%	2.1%	3.1%	1.0%	.0%	100 %
	Total	Count	88	76	6	3	1	2	176
		% within Profession	50.0%	43.2%	3.4%	1.7%	.6%	1.1%	100 %
State	Doctor	Count	93	72	7	0	0	3	175
		% within Profession	53.1%	41.1%	4.0%	.0%	.0%	1.7%	100 %
	Pharmacist	Count	24	13	3	0	0	4	44
		% within Profession	54.5%	29.5%	6.8%	.0%	.0%	9.1%	100 %
	Nurse	Count	153	98	68	6	3	10	338
		% within Profession	45.3%	29.0%	20.1%	1.8%	.9%	3.0%	100 %
	Total	Count	270	183	78	6	3	17	557
		% within Profession	48.5%	32.9%	14.0%	1.1%	.5%	3.1%	100 %
Total	Doctor	Count	128	101	10	0	0	5	244
		% within Profession	52.5%	41.4%	4.1%	.0%	.0%	2.0%	100 %
	Pharmacist	Count	28	19	4	0	0	4	55
		% within Profession	50.9%	34.5%	7.3%	.0%	.0%	7.3%	100 %
	Nurse	Count	202	139	70	9	4	10	434
		% within Profession	46.5%	32.0%	16.1%	2.1%	.9%	2.3%	100 %
	Total	Count	358	259	84	9	4	19	733
		% within Profession	48.8%	35.3%	11.5%	1.2%	.5%	2.6%	100 %

4.5.9 Overall Levels of Expectation. Refer Q10

Table 4.9: Overall Levels of Expectation With Regard to Waste Management Processes

		Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Don't know	Total
Incinerator staff should be certified competent	Count	362	267	77	4	7	18	735
	Row %	49.3%	36.3%	10.5%	.5%	1.0%	2.4%	100%
Incinerators should be certified	Count	441	238	27	3	7	17	733
	Row %	60.2%	32.5%	3.7%	.4%	1.0%	2.3%	100%
Sewage treatment personnel should be certified competent	Count	358	259	84	9	4	19	733
	Row %	48.8%	35.3%	11.5%	1.2%	.5%	2.6%	100%
Landfill personnel should be certified competent	Count	313	266	109	5	7	29	729
	Row %	42.9%	36.5%	15.0%	.7%	1.0%	4.0%	100%
Healthcare professionals should be more environmentally aware	Count	438	212	31	1	45	9	736
	Row %	59.5%	28.8%	4.2%	.1%	6.1%	1.2%	100%
Formal training in medical waste management should be provided by the hospitals	Count	307	171	73	27	75	80	733
	Row %	41.9%	23.3%	10.0%	3.7%	10.2%	10.9%	100%
Waste management responsibilities should be included in job descriptions of the professionals	Count	286	310	81	26	20	11	734
	Row %	39.0%	42.2%	11.0%	3.5%	2.7%	1.5%	100%
Hospital staff should be protected from hazardous waste	Count	464	227	21	3	5	7	727
	Row %	63.8%	31.2%	2.9%	.4%	.7%	1.0%	100%

The results of table 4.9 revealed strong views of agreement by all the respondents that :

a) Incinerator staff should be certified competent,
   [49.3% strongly agree + 36.3% agree = 85.6%]

b) Incinerators should be certified,
   [60.2 % strongly agree + 32.5 % agree = 92.7%]

c) Sewage treatment personnel should be certified competent,
   [48.8% strongly agree + 35.3% agree = 84.1%]

d) Landfill staff should be certified competent,
   [42.9% strongly agree + 36.5% agree = 79.4%]

e) Healthcare professionals should be more environmentally aware,
   [59.5% strongly agree + 28.8% agree = 88.3%]

f) Formal training in medical waste management should be provided by the hospitals,
   [41.9 % strongly agree + 23.3% agree = 65.2%]

g) Waste management responsibilities should be included in job descriptions of the professionals,
   [39.0% strongly agree + 42.2% agree = 81.2%]

h) Hospital staff should be protected from hazardous waste,
   [63.8% strongly agree + 31.2% agree = 95.0%]

CHAPTER FIVE: DISCUSSION

5.1 Introduction

This research established that pharmaceutical waste, from the time of its generation at the selected hospitals:

a) Polluted the hospital environment,
b) Endangered the health of patients, healthcare professionals, and other hospital staff,
c) Endangered the health of the general public and the environment during its transportation to the incinerator,
d) Polluted the atmosphere during its incineration, and
e) Polluted the ground water during its incineration.

5.2 Disposal Problems of Dispensed Medicines

All regulated drugs in South Africa, are classified by the Medicine Control Council (MCC) under schedules ranging from 1-8, which are printed on all the original medicine containers under the "S" symbol when packed by the manufacturers. Pharmacists, when dispensing medicines in South Africa are not obliged to state the schedule number of the medicine on the label when issuing medicines to patients, because it is not a requirements under Regulation 8(4)c of Act 101 of 1965. This poses a problem to healthcare professionals, and the waste personnel, since the absence of the schedules on the package of the dispensed medicine, makes it very difficult to identify the category of waste to which it belong and consequently the prescribed processing of the documentation and method of disposal when such unwanted medicine is disposed.

However, it would be easy for a pharmacist to categorise any dispensed drug by its generic or trade name, into its prescribed schedule after it was discarded as pharmaceutical waste. On the contrary, this step would be impossible for an officer of the South African Police Services, or the waste disposal personnel to do, as required by the official guidelines of the MCC, since they never had the relevant training. A recommendation in this regards is made in of Chapter Six hereof.

5.3 Protocols at State Hospitals

All the state hospitals participating in the research were contracted to "Hlumani Wasteman (Pty) Ltd", to remove medical waste from the hospitals and to deliver it to the disposer for final disposal. Observations and the documentation issued to the hospitals by Hlumani Wasteman Pty Ltd, illustrated violations of the MCC guidelines for the destruction of Schedule 5 medicines, as well as the WCHCWM Act 7 of 2007, in that the transporter issued the following certificates at the state hospitals, time that the waste was removed from the hospital stating that the waste had already been disposed by incineration.

5.3.1 Groote Schuur Hospital

a) On the 12th March 2009 a certificate no. 32053 was issued by Hlumani Wasteman to the effect that 2 x 90 litre boxes containing pharmaceutical waste was removed by them from the premises of the Hospital (Appendix G).

b) Before leaving the hospital premises in Cape Town the hospital was also issued with a second certificate no.112 to the effect that they confirm that the pharmaceutical waste, which was collected on the certificate 32053 "was disposed of via high temperature incineration" at their incineration plant in the town of Klerksdorp in the province of Gauteng, situated nearly one and a half thousand kilometres out of Cape Town (Appendix H).

5.3.2 Tygerberg Hospital

a) On the 30th October 2008 certificate no 26534 was issued by Hlumani Wasteman (Pty) Ltd to the effect that 5 x 90 litre boxes containing pharmaceutical waste was removed by them from the premises of hospital [Appendix D(i)].

b) On the same date 30th October 2008, and at the same time, a similar Certificate of Safe Disposal no. 0102 was issued [Appendix D(ii)], stating that waste was safely disposed.

5.3.3 Red Cross War Memorial Children's Hospital

Several similar "Certificates of Safe Disposal" from Hlumani Wasteman (Pty) Ltd were accepted by the responsible pharmacist of the hospital over a period of several years from the time that this transporter was officially commissioned by the state.

It can be construed that the acceptance of the "Certificates of Safe Disposal" by the responsible pharmacists of the hospitals over a period of several years, was unethical conduct, in that the responsible pharmacist who is ultimately accountable for all activities in the pharmacy, did not verify the validity of the certificates. It may also have been that the pharmaceutical waste generated in these pharmacies, were improperly disposed (dumped on open fields) and have caused serious environmental pollution or human harm. Examples of such incidences have already been reported in the newspapers (Makinana, 2009).

5.4 Protocols at the Private Hospitals

In terms of documentation the following were observed:

5.4.1 Bellville Medical Centre

It can be seen from the results of the research that the hospital did not practice the prescribed segregation of pharmaceutical waste. Proper documentation was not used. The transporter was also the disposer. Thus the violations of transportations, compounded the violations of disposal (Section 6(2)(j) of the WCHCWM Act), *e.g*: Service Manifest Document no. 082826 dated 02-09-10 and Service Manifest Document no. 083524 dated 09-09-10. The list did not detail the pharmaceutical waste that was uplifted from the hospital [Appendix R(i)].

5.4.2 Mitchell's Plain Medical Centre

An examples of improper documentation is:

Service Manifest Document no 077397 dated 28-06-10, [Appendix R(ii)] representing non-compliance with Section 6(2)(j) of the WCHCWM Act.

5.4.3 Gatesville Medical Centre

Examples of improper documentation are:

Service Manifest Document no 082485 dated 03-09-10 and

Service Manifest Document no 083171 dated 07-09-10 [Appendix R(iii)], representing non-compliance with Section 6(2)(j) of the WCHCWM Act, but also evidence of the unregistered transport vehicle, CF 102550, having being used.

5.5 Improper Documentation for the Destruction of Medicines

All the hospitals researched did not comply with the legal requirements in terms of documentation for the destruction of Scheduled medicines *viz.*;

5.5.1 Absence of Records for the Hazardous Pharmaceutical Waste

Records of the names, quantities and schedules of the medicines generated as waste by all the hospitals were not kept, in violation of Section 6(2)(j) of the WCHCWM Act *e.g*. Phenobarbitone 30mg tablets [Appendix J(i)) and Phenobarbitone 200mg/ml ampoules Appendix J(ii)] were recorded in the Specified Schedule 5 register of Groote Schuur Hospital as expired, but no other record of its proper disposal could be obtained, in violation also of the MCC guidelines for the destruction Schedule 5 medicines.

The existence of Phenobarbitone, (Specified Schedule 5 drug with high potential for abuse and addiction), disposed as pharmaceutical waste, indicates that the drug is still widely used by the hospital contrary to general international trends to eliminate its use. It also indicated that because the drug was dispensed by the hospital, the drug is circulating in the communities which the hospital serve. There is thus every possibility that the drug would be incorrectly disposed into household waste and is entering the aquatic environment, as it did in Germany (Schaefer, 2006).

5.5.2 Absence of Internal Audits

Internal audits with regard to waste management were not done at any of the private hospitals. This is in violation of Section 6(2)(o) of the WCHCWM Act.

5.5.3 Improper Management of Schedule 5 Pharmaceutical Waste according to Department of Health Guidelines

The national Department of Health issued a set of guidelines to be complied with for the disposal of pharmaceutical waste (Chapter 2B.10.1 Regulation 27). None of the hospitals complied.

5.5.3.1 Application for Authorised Destruction

None of the hospitals applied to the Medicine Regulatory Authority (MRA) for permission to destroy Schedule 5 medicines, as prescribed in the MCC guidelines (South Africa, 2003):

i) Written authority to destroy schedule 5 medicines was not obtained before releasing the specific waste to the waste transporter for destruction;
ii) Two pharmacists employed by each hospital did not sign the register to confirm that they witnessed, the removal of the schedule 5 medicines;
iii) Consequently no certificate of destruction was received from the MRA.

5.6 The Questionnaire

It is generally accepted that medical waste will be an inevitable result of the normal activities of a hospital. However the mismanagement of the pharmaceutical waste, as an integral component of medical waste, clearly reflected an attitude of disregard by the generators. Consequently pharmaceutical waste was not afforded the same significance as the other types of medical waste. This re-enforced the need to characterise pharmaceutical waste as a specific waste stream.

With regard to the "sewerability" of selected categories of pharmaceutical waste (figures 4.50 to 4.55), the overwhelming percentage of the professionals stated "No". However it remains of great concern that:

- 21.9% of doctors, 5.4% of pharmacists, and 16.6% of nurses stated that organic solvents may be sewered (table 4.6),
- 16.9% of doctors, 3.6% of pharmacists, and 16.9% nurses stated that antibiotics may be sewered (table 4.7),
- 11.9% of doctors, 0.0% of pharmacists, and 14.4% of nurses stated that cytotoxic drugs may be sewered (table 4.8),
- 25.1% of doctors, 12.7% of pharmacist, and 22.0% of nurses stated that multivitamins may be sewered (table 4.9),
- 11.9% of doctors, 0.0% of pharmacists, and 16.6% of nurses stated that expired medicines may be sewered (table 4.10), and
- 8.2% of doctors, 0.0% of pharmacists, and 12.8% of nurses stated that all unused medicines may be sewered (table 4.11).

There thus exists a strong possibility that a small percentage of these professionals may be responsible unintentionally for environmental pollution via the sewerage systems.

A dichotomy was found between the observed evidence and the declarations by the healthcare professionals. The observed evidence contradicted the declarations in the questionnaire, by all three professionals of not having encountered pharmaceutical waste problems (table 4.4). This was particularly significant in the case of pharmacists in that large amounts of pharmaceutical waste was stored within the dispensing area of the pharmacy, where it was not supposed to be. In the case of doctors, they also stated that pharmaceutical waste problems were not encountered. I am of the opinion that this was not a deliberate attempt not to state the truth in the questionnaire, but merely a lack of knowledge.

Clearly the questionnaire revealed a critical lack of knowledge amongst doctors, pharmacists and nurses regarding waste management in general and pharmaceutical waste in particular. This deficiency of essential knowledge may be ascribed to:

a) a gap in their undergraduate curriculum;
b) a lack of formal post graduate training;
c) a lack of experience during practices.

5.7 Validation of Hypotheses

The results, substantiated by *prima facie* evidence, validated the hypotheses postulated at the commencement of the research.

5.7.1 Hypothesis One

"*That hazardous pharmaceuticals will be found unsegregated amongst non-hazardous pharmaceuticals at the sites of generation*".

Segregation of pharmaceutical waste from other waste generated in the wards were not strictly adhered to. Dosage forms such syringes with needles, and pressurised aerosol containers were found amongst tablets. The same occurred during the storage of the pharmaceutical waste. Overwhelming evidence was found that validated this hypothesis.

5.7.2 Hypothesis Two

"That pharmaceutical waste would not be considered a distinctly different waste stream by hospital healthcare professionals at the sites of generation".

From the time the pharmaceutical waste was generated, followed by its handling in the hospital, and during transportation to the final incineration, it was evident that pharmaceutical waste was not considered a distinct waste stream, and was managed no differently from medical waste. The results of this research validated this hypothesis.

5.7.3 Hypothesis Three

"*That the incineration of pharmaceutical waste generated at the selected hospitals in Cape Town, contributes to environmental pollution".*

Convincing evidence was obtained indicating that the incineration of pharmaceutical waste generated by the selected private hospitals, and incinerated at the BCL Waste Management incinerator at Delft, Cape Town, contributed to environmental pollution.

5.8 Ethical Dilemmas in Respect of the Hospitals

The research presented the following ethical dilemmas:

a) should the identity of the hospitals and the disposers be divulged if they were found to be non-compliant with the required standards and in violation of the legislation, and
b) where infringements of the law occurred, what option should be adopted.

5.9 Ethical Dilemmas in Respect of the Transporters and Disposers

Where the transporters and disposers of the pharmaceutical waste *viz*. BCL Medical Waste Management (Pty) Ltd (BCL MWM) and Hlumani Wasteman (Pty) Ltd are concerned, CPUT had no formal nor informal agreement. What should be the approach of the researchers under these circumstances since CPUT were under no obligations to these two companies, in terms of the findings of the research?

5.10 Ethical Dilemmas Resolved

During the site visits, to all the parties involved in the research (*i.e*. the hospitals and the disposers), it was explained that my brief review of their management, treatment and disposal of hazardous pharmaceutical waste, including any information gleaned would be purely of academic interest. This was accepted by them without reservations.

Although it was never mentioned in discussions with all the parties, it must be remembered that every citizen in South Africa has *locus standi* with regard to the environment, in terms of the section 24 of our constitution. Thus all the information about any generator, transporter, treater, or disposer of hazardous pharmaceutical cannot be withheld from the general public. This is further re-enforced in section 6 (2) (l) of the WCHCWM Act, which states:

> "A generator, transporter, treater, or disposer of health care risk waste must make these records available to the public, if required, in terms of the Promotion of Access to Information Act (Act 2 of 2000)".

a) The Public Hospitals

Although the three state hospitals involved in this research, are tertiary academic institutions, and were obligated in terms of their mandate from the Department of Higher Education, to partake in medical research, it was decided not to inform any regulatory authority or professional councils of my findings as the research project is purely academic in nature and not a law enforcement exercise. Each hospital requested a copy of the final thesis, with the objective of implementing the recommendations where applicable and possible.

b) The Private Hospitals

The Executive Chairman of Melomed Hospital Holdings, requested a copy of the findings of this research, which could be used as a basis for improving their management of pharmaceutical waste.

c) BCL MWM

Since all the pharmaceutical waste generated by the private hospitals researched, was incinerated by BCL MWM, the incineration process was of critical importance, and the concerns of the Melomed Hospital Holdings as to whether the hospital comply with all the legal requirements, were reasonable.

It must further be remembered that in the case of BCL MWM, the company is in the process of upgrading its facilities and has appointed Resources Management Services (RMS) to facilitate the Scoping and the Environmental Impact Assessment (EIA). Every detail of the operations of BCL MWM, including the public participation process, is on their website: www.rmsenviro.co.za., and

thus in the public domain. In correspondence to them, requesting further information, it was made clear that this research is purely for academic purposes. The BCL MWM obliged (Appendix N).

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1 Outcomes of the Research

From observations of the waste generated at the hospitals and the general discussions (not recorded as part of the research) with healthcare professionals employed at these hospitals, one can conclude that the same ethos of "environmental non-significance" exists in South Africa today as it did in the USA prior to 1999. The subject of this research is multidisciplinary, bridging the gap between pharmacy and environmental toxicology.

It contributed to:

i) Creating more awareness amongst healthcare professionals (doctors, pharmacists, and nurses) of the disposition of the pharmaceuticals in the environment. Healthcare professionals have traditionally limited their spheres of influence to their patients while being totally oblivious to the potential influence their activities have on the environment,

ii) Stimulating, greater awareness amongst the professionals above for role of STWs, incinerators and landfill sites in pharmaceutical waste management,

iii) Promoting the acceptance of "cradle-to-grave" responsibility for the pharmaceutical waste which results from the execution of their normal duties and by doing so encourage healthcare professionals to take more responsibility for the consequence of:

a) pharmaceutical pollutants in surface, ground, and the potable water,

b) the toxic fallouts from the incineration of unwanted and expired medicines,

iv) Motivating for the inclusion in the curricula of pharmacists, medical doctors, and nurses of a module on pharmaceutical waste management,

v) Developing a closer co-operation between CPUT [which offers waste management courses] and UWC, UCT and US [which trains healthcare professionals],

vi) Avoiding possible prosecution of healthcare professionals,

vii) Creating greater awareness for the need to establish pharmaceutical waste as a specific waste stream.

6.2 Offences, Penalties and Consequences

This research has clearly demonstrated a dissonance between the proclaimed commitment and understanding of the management of hospital-generated pharmaceutical waste and the actual practice in the hospitals. It can be concluded from the results that healthcare professionals who depend *inter alia* on pharmaceuticals in the execution of their duties, are oblivious to the fact they are culpable and may be liable for prosecution, under the acts listed in section 2B 19 hereof.

6.3 Recommendations

I believe that more than a scientific debate on the topic of the occurrence of pharmaceuticals in sewage effluent, ground water, surface waters, and the incineration of pharmaceutical waste, is warranted in South Africa. The recommendations below not only serve as guidelines for better planning and action programs at the hospitals, but also focuses on the need for further research in several areas where pharmaceuticals impact on the environment.

6.3.1 Problems of Definitions

Before specific improvements can be implemented, a standard scientifically derived definition must be established for HPW. Only after this has been done would solutions to the existing problem be forthcoming. HPW should be defined as a specific subset of pharmaceutical waste, which in turn is a subset of medical waste. Such defined waste streams have already been developed in the United States of America and in some European countries (Smith, 2002).

6.3.2 Initiation and Maintenance of Waste Segregation

It is universally accepted that segregation of hazardous pharmaceutical waste is the most critical step in the entire process of pharmaceutical waste management, and underpins every aspect of waste management. Because segregation remains the responsibility of the waste generator until the waste is finally disposed, the process should commence at the point of generation, and be maintained thereafter.

I therefore propose that:

a) All containers including plastic bags destined to contain HPW should be colour-coded dark green in compliance with SANS 10248:2004. Currently red plastic bags are used.

b) Spilled, contaminated, or packaging containing residues of HPW should not be returned to the hospital pharmacy because of the risk of general pollution during transit within the hospital. It should be deposited in the dark green colour-coded containers at the point of generation, and then be transferred directly to the holding area for hospital waste until collected for disposal. Currently all pharmaceutical waste is returned unsegregated to the hospital pharmacy as the first stop.

c) Pharmaceutical aerosol containers (metal or glass) that are completely or partially empty should be encapsulated and not be sent for normal landfilling, because the human "harvesters" on the landfill sites may attempt to compact the metal, for later resale, damaging the aerosol containers, releasing some of the pharmaceutical contents to the atmosphere, or the container could explode during the compaction. The safest option that remains for waste aerosol pharmaceuticals is encapsulation in irretrievable drums and then landfilling in H:H engineered landfill sites (South Africa, 1998g).

d) All hospital personnel should never attempt to correct errors of segregation by manually removing the HPW from a wrong bag. If the HPW and general waste are accidentally mixed, the mixed bag must immediately be sealed and placed inside a new HPW green colour-coded bag.

6.3.3 Safety Through Education and Training

The training of healthcare professionals and waste personnel is essential if a waste management program is to be successful. The overall aim of the training should be to develop awareness of health, safety, and environmental issues relating to pharmaceutical waste. All hospital personnel, including doctors, pharmacists, and nurses should be convinced of the need for comprehensive healthcare waste management training. I recommend that appropriate training programs should be designed and provided, to the following categories of personnel.

a) Hospital managers and all personnel involved with waste care

It can safely be concluded from this research, that the lack of knowledge, awareness and the absence of mandatory segregation of the pharmaceutical waste, by the healthcare professionals, was a precursor to environmental pollution. This lack of knowledge influenced the manner in which pharmaceutical waste was handled and

the significance it was afforded. Should proper waste segregation have been implemented, a large amount of the non-hazardous pharmaceutical waste need not have been incinerated. Furthermore, if efficient incineration of the hazardous pharmaceutical waste was thereafter performed, the environmental pollution would have been reduced.

b) Medical doctors

The research established that there exists a need to train medical doctors in the management of pharmaceutical waste.

c) Nurses

Because nurses control most of the activities in the hospital wards on a 24 hour basis, there is great need for them to be skilled in the management of pharmaceutical waste, and thus the need to constantly upgrade their existing knowledge and the handling of it.

a) Pharmacists

This research has demonstrated that there is also a need to constantly upgrade the academic training of the pharmacists with regard to pharmaceutical waste management.

e) Incinerator Operators

The results of the research demonstrated beyond doubt that mismanagement and incineration of pharmaceutical waste by BCL MWM contributed to the pollution of the atmosphere, surface and ground water. I therefore propose, in line with WHO recommendations (Pruss et al., 1999e), that all incinerator operators undergo proper training by an accredited service provider.

6.3.3.1 Amendments to WCHCWM Act 7 of 2007

The above recommendation are in line with Section 8 of the WCHCWM Act, which states:
"A generator, transporter, treater, or disposer of health care waste must comply with the Occupational Health and Safety Act 1993 (Act 85 of 1993) in respect of staff safety and training regarding health care waste, and as prescribed by the Provincial Minister". Although the Act makes training mandatory, it appears from Section 11 of the Act that non-compliance with its requirement does not constitute an offence. I therefore recommend that the

WCHCWM Act, be amended so that non-compliance in respect of the provision of training, also constitute a criminal offence.

6.3.3.2 CPUT Waste Management Courses

The waste management courses offered by CPUT are generic. I therefore recommend that these course include pharmaceutical waste as a specific waste stream.

6.3.4 Collection, Storage and On-site Transport of Pharmaceutical Waste

This aspect of the management of pharmaceutical waste is the responsibility of the provincial government in the case of the state hospitals and that of Melomed Hospital Holdings Ltd., in the case of the private hospitals they own.

a) If the benefits of waste segregation are to be realized, then there must be secure internal collection, external collection, and transportation systems in place. If the pharmaceutical waste is segregated, only to be mixed later by the wastecare personnel on site and transporters off site, then the value of the segregation will be lost. Pharmaceutical waste should be stored in a designated room for hazardous waste, separate from other hospital waste. Such a storeroom should be locked and be accessible only to authorised personnel.

b) With regard to on-site transport**,** pharmaceutical waste are moved within the hospitals to a storage areas to await collection and disposal. To prevent unintentional exposure and cross-contamination, specific routes to the storage areas must be specified and adhered to, so as to minimise their passage through patient-care areas and other uncontaminated areas.

c) The trolleys used for the purpose of transporting pharmaceutical waste should be used exclusively for this purpose.

6.3.5 Collection of Sharps and Medicines from Residential Areas

In South Africa, systems are already in place for the private commercial supply of medicines for chronic diseases, from a central dispensary, to the homes of private patients, to their places of employment or to the post offices nearest their residences.
(http://www.directmedicines.co.za/ and http://www.pharmacydirect.co.za/).

A private-public partnership is also operational in Cape Town for the supply of chronic medication to state hospital patients from a private pharmacy. The "Chronic Dispensing Unit" is contracted to the state, to supply chronic medicines to state patients. The medicines, after the prescriptions was evaluated by pharmacists (the 1st stage of the dispensing process) in the "Chronic Dispensing Unit", and after preparation by post-basic pharmacists assistants (the second stage of the dispensing process), are sent to the Community Health Centres (CHCs) throughout the Cape Peninsula, from where the medicines are finally handed over to the hospital patient, by post-basic pharmacist's assistants (the third stage of the dispensing process).

a) I propose that the reverse procedure be instituted where unwanted medicines can be returned via private pharmacies called a "reverse distributor" whose responsibility it would be to dispose of it properly. Such systems are already in existence in the United States of America (Henningsen, 2003; Chi, 2003).

b) I propose further that programs be developed to encourage state patients to return unwanted medicines, used needles and syringes to their nearest CHC from where it could be retuned to the "Chronic Dispensing Unit" whose responsibility it would then be to dispose of it properly. When implemented this recommended procedure would become the first Private-Public-Partnership in waste management involving state patients in South Africa.

6.3.6 Amendments to existing legislation and professional standards

Notwithstanding the fact that individuals cannot change legislation on their own, I propose that representations be made to the national Department of Health to change the following legislation.

6.3.6.1. Amendments to Regulation 27 of the Medicine and Related Substances Act (Act 101 of 1965)

This regulation deals with the destruction of medicines, but

i) is silent with regards to the method of destruction;

ii) does not cover the destruction of schedule 0 medicines, which form a large percentage of non-prescription medicines, available in pharmacies and non-pharmacies. These medicines are available in supermarkets and as such are considered by the general public no different to other household consumables.

Consequently it would be disposed as general municipal solid waste and landfilled together with other household waste. I therefore recommend that a clause be added to the effect that all "medicines" as defined in the Medicine and Related Substances Act 101 of 1965 as amended, may not be disposed of in municipal solid waste, including schedule 0 medicines;

iii) only insist that the destruction of the medicine must be such that the medicine is not "retrievable", ignoring reference to the environment. I thus recommend that an additional sub-clause be added to the regulation which ensures that the method of destruction or disposal ensures no harm to the environment.

6.3.6.2 Amendments to "Good Pharmacy Practice" (GPP)

Because GPP is silent on clearly defined types of waste generated in the pharmacy, I recommend that GPP be amended as follows:

i) Definitions of different types of waste generated in a pharmacy be included;

ii) Pharmaceutical waste including subsets, be characterised as a distinct waste stream;

iii) Clear instructions be published with regard to the exact methods of disposal for the subsets of pharmaceutical waste.

iv) Facilities to be prescribed in pharmacies for the proper management of pharmaceutical waste. It became obvious during the research that the hospitals were not designed to take into account the demands of pharmaceutical waste, and the layout plans of the pharmacies [although approved by the SAPC], did not make provision for the management of pharmaceutical waste.

6.3.6.3 Amendments to Regulation 8 (4) c of Act 101 of 1965

The omission of a scheduling requirement for the label of dispensed medicine in Regulation 8(4)c of Act 101 of 1965, as explained in Chapter Two (B), does not facilitate its disposal when it becomes unwanted and expired. I therefore recommend that the regulation be amended to make it a mandatory requirement for the schedule of a medicine dispensed to be stated on the label of such a medicine.

6.3.6.4 Amendments to Good Manufacturing Practice (GMP)

I recommend that GMP and Act 101 of 1965, be amended so that only pharmaceuticals that would bio-transform *in-vivo* or bio-degrade spontaneously *in-vitro* into metabolites that are environmentally safe, be registered in South Africa.

6.3.7 Future Pharmaceutical Research

This research has drawn attention to the contribution that the hospitals and the waste disposer made to environmental pollution, as a result of their mismanagement of pharmaceutical waste. In terms of future research the following are proposed:

a) Identifying the most common prescribed medicine in South Africa and its environmental fate,

b) Testing for the presence of pharmaceuticals in the groundwater around old municipal landfill sites in Cape Town,

c) Testing the communities living in the close proximity to the only incinerator in Cape Town *viz.* the BCL MWM incinerator in Delft, for presence of endocrine disruptors in their bodies,

d) Investigating the suitability of using the cement kiln in the town of Piketberg for the co-processing of medical waste, including pharmaceutical waste, instead of BCL MWM,

e) Analysis of the soil, and the vegetables cultivated on the premises of the Delft incinerator for the presence of endocrine disruptors,

f) Analysis of the effluent from STWs in Cape Town for the presence of pharmaceuticals and

g) Analysis of the tap water from WTPs in Cape Town for the presence of pharmaceuticals.

CHAPTER SEVEN
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Appendix A (i)

Pharmaceuticals by mass

Gatesville Medical Centre

BCL MEDICAL WASTE MANAGEMENT

P.O. Box 2637, Clareinch 7740
Tel: 021 955 2447 Fax: 021 955 0283
Email: info@bclmedicalwaste.co.za
sales@bclmedicalwaste.co.za

CERTIFICATION OF SAFE DISPOSAL

Date 15 March 2011

Manifest Doc. 099272

Cert No. EGA 002

This document serves to confirm the following :

Generator Gatesville Medical Centre

Address 1 Temple Road
Gatesville

Waste Type Expired Pharmaceuticals

Volume 1 x 100L Bin (31.2 Kgs)

Collection & Transportation The above was collected from the above premises by BCL Medical Waste Management and transported to the incinerator facility in Delft.

Destruction date The above was destroyed by high temperature incineration at the licenced BCL Medical Waste incinerator facility in Delft, so as to meet regulatory legislation as laid down by Governing Authorities And Health Department.

Date: 18.3.11. Time: 12.30.

Supervision the above destruction was carried out under the supervision of the BCL Incinerator Operator.

P.P.

MARTIN EVERTS
Operations Supervisor

Appendix A (ii)

Pharmaceuticals by mass

Bellville Medical Centre

BCL MEDICAL WASTE MANAGEMENT

P.O. Box 2637, Clareinch 7740
Tel: 021 955 2447 Fax: 021 955 0283
Email: info@bclmedicalwaste.co.za
sales@bclmedicalwaste.co.za

CERTIFICATION OF SAFE DISPOSAL

FEBRUARY 2010

BELLVILLE MEDICAL CENTRE

This letter serves to confirm the following :

the contaminated medical waste as itemised below, was contained in specific labeled containers and was collected by BCL Medical Waste Management from

Bellville Medical Centre

during the month of FEBRUARY 2010. This contaminated waste was disposed of via high temperature incineration at the licenced BCL Medical Waste Management incineration facility in Delft, so as to meet all regulations and legislation as set out by the governing relevant Authorities and Health Department.

Non-Sharp Medical Waste	**Quantity**	
140 litre liners	0	
70 litre liners	216	**1,498.40 Kg**
50 litre liners	0	
25 litre liners	0	
Foetus Buckets	7	**12.00 Kg**

Sharp Medical Waste	**Quantity**
5 litre sharps container	1
7 litre sharps container	85
20 litre sharps container	0
25 litre buckets	26
Trochar container	0

26 FEB 2010

Signed

Anjé Britz
Office Administrator

Appendix B (i)

Tygerberg Hospital Radiotherapy Approval

Condition 41

The holder of the authority must have access to the services of a qualified medical physicist, who should provide guidance, where necessary, on matters pertaining to radiation protection, and who should be available for consultation in the event of an emergency.

Condition 90

Activities only to be administered in isolation wards that have already been approved by the Directorate for this purpose.

Condition 91

A radiation dose rate meter, as well as a contamination monitor must be available for monitoring the patient, as well as possible contamination.

Condition 92

Compliance with the requirements of the Directorate's most recent Code of Practice for the Safe Use of Unsealed Radioactive Nuclides, and the Internal Rules drawn up by the Authority Holder, and approved by the Directorate.

ppDIRECTOR GENERAL: HEALTH

Appendix B (ii)

Tygerberg Hospital Isolation Ward Approval

DEPARTMENT OF HEALTH

Directorate: Radiation Control
Private Bag X62
BELLVILLE
7535

Tel: (021) 9486162
Fax: (021) 9461589

Page: 0861005050
Code: T64701/T64702

ISOA01

WA GROENEWALD
TYGERBERG HOSPITAL - GENE LOUW BUILDING
MEDICAL PHYSICS DEPARTMENT
PRIVATE BAG X3
TYGERBERG
7505

Enquiries: Radionuclides
Reference: M/0014
Date: 19 June 2006
Email: isotope@health.gov.za

Attention: GROENEWALDT WA

AUTHORITY TO POSSESS AND USE RADIOACTIVE NUCLIDES IN TERMS OF THE REGULATIONS RELATING TO GROUP IV HAZARDOUS SUBSTANCES

Receipt is hereby acknowledged, with thanks, of your letter/application RN787 dated 26-MAY-2006.

Enclosed please find authority number M/0014/06/0567 which replaces your old authority number M/0014/05/1091.

All holders are required to keep copies of:

1. the Regulations
2. their authority
3. their internal rules, together with any amendments in a place accessible to all employees, or their information.

PLEASE NOTE that copies of the above must be issued to the Radiation Protection Officer (RPO) or the Acting Radiation Protection Officer (ARPO).

Inform us if the email address(es) of wag@pawc.pgwc.gov.za and/or efssnym@pgwc.gov.za are incorrect, or when no longer valid.

PLEASE QUOTE OUR REFERENCE NUMBER IN YOUR CORRESPONDENCE TO AVOID DELAYS.
PLEASE NOTIFY US IF YOUR POSTAL ADDRESS HAS CHANGED.

DIRECTOR: RADIATION CONTROL

Appendix C

BCL MWM Registration as Medical Waste Transporter

CITY OF CAPE TOWN | ISIXEKO SASEKAPA | STAD KAAPSTAD

CITY OF CAPE TOWN
ISIXEKO SASEKAPA
STAD KAAPSTAD

Director: City Health
PO Box 2815
CAPE TOWN
8000

REGISTRATION AS A MEDICAL WASTE TRANSPORTER AS PRESCRIBED IN TERMS OF THE CITY OF CAPE TOWN : ENVIRONMENTAL HEALTH BY – LAW , NO. 13333, P.G.E. NO 6041 DATED 30 JUNE 2003, PART 3 (Medical Waste Management),

NAME OF APPLICANT : BCL Medical Waste Management TEL NO : 021 955 2447

E-MAIL ADDRESS: info@bclmedicalwaste.co.za

POSTAL ADDRESS OF APPLICANT: P.O Box 19070, Tygerberg, 7505

ADDRESS OF PREMISES - (where medical waste will be stored / treated prior to disposal.)

MRC Premeises , Off Hindle Road, Brentwood Park, Delft.

NAME AND ADDRESS OF PREMISES (where medical waste will be disposed.)

MRC Premises , Off Hindle Road, Brentwood Park, Delft.

REGISTRATION NUMBER AND DESCRIPTION OF VEHICLES:

Registration Number	Description of vehicle
CF 128 414	Toyota Box Body (BCL 1)
CF 103 988	VW Ct TDI Panel Van (BCL 2)
CF 140 715	Toyota Box Body (BCL 3)
CA 660 737	Toyota Box Body (BCL 4)
CF 144 574	Toyota Box Body (BCL 5)
CF 110 735	Toyota Box Body (BCL 6)
RI PETS- WP	VW Transporter 1.9 TDI (RIP 1)

CERTIFICATION

It is hereby certified that the abovementioned Medical Waste Transporter at the date of inspection complies with the provisions of the City of Cape Town: Environmental Health By – Law No 13333,P.G.E. No. 6041 dated 30 June 2003, Part 3 (Medical Waste Management). Should the aforementioned transporter contravene any provisions of Part 3 of the Environmental Health By - Law or fails to comply with any notice lawfully given there - under he/she commits an offence and will liable to a fine and/or imprisonment for a period not exceeding two years.

Yours faithfully

FOR EXECUTIVE DIRECTOR: CITY HEALTH

Appendix D (i)

Hlumani Wasteman Transport Document

HLUMANI WASTEMAN (PTY) LTD
Co Reg. No 2000/011876/07 VAT Reg. No. 4580192203
WINGFIELD HOUSE, MOBILE ROAD AIRPORT INDUSTRIA
PO BOX 219 EPPINDUST 7475
TEL (+27) 021 380-3000 FAX: (+27) 021 380-3030
E-MAIL: service@wasteman.co.za

HLUMANI WASTEMAN
(FORMERLY WASTEMAN CAPE (PTY) LTD)
YOUR PARTNER IN TOTAL WASTE MANAGEMENT

DOCUMENT No. 26534

MEDICAL WASTE DIVISION - HEALTH CARE RISK WASTE MANIFEST

CUST. NAME / GENERATOR: TYGERBERG PHARMACY ✓ ACCOUNT NUMBER:

ADDRESS:

CONTACT: TEL No.: ORDER NUMBER:

TRANSPORTER: HLUMANI WASTEMAN • DRIVER: ERIC • VEHICLE REG No.: CA977[illegible]

DELIVERY / COLLECTION ADVICE / DETAILS OF SERVICE

ITEMS / DESCRIPTION	UNIT	CONSUMABLES PLACED	WASTE REMOVED
50 ℓ BOX SET	EACH	UNITS	UNITS
90 ℓ BOX SET	EACH	UNITS	UNITS
142 ℓ BOX SET	EACH	UNITS	UNITS
5 ℓ SHARPS CONTAINER	EACH	UNITS	UNITS
20 ℓ SHARPS CONTAINER	EACH	UNITS	UNITS
10 ℓ PLACENTA CONTAINER	EACH	UNITS	UNITS
20 ℓ PLACENTA CONTAINER	EACH	UNITS	UNITS
50 ℓ PHARMACEUTICALS CONTAINER	EACH	UNITS	5 UNITS
TROCHAR SHARPS CONTAINER	EACH	UNITS	UNITS
BUFF TAPE	EACH	UNITS	UNITS
CABLE TIES	PACK/100	UNITS	UNITS

DELIVERY • GOODS RECEIVED / ACCEPTED (CONSUMABLES PLACED)

PRINT NAME | SIGNATURE | DATE

GENERATOR CERTIFICATION (WASTE REMOVED)

I hereby declare that the contents are properly described, packaged, marked and labled prior to transportation according to all relevant registration

PRINT NAME | SIGNATURE | DATE: 30/10/23

TRANSPORTERS ACKNOWLEDGMENT OF RECEIPT OF MATERIALS

ERIC | SIGNATURE | DATE: 30-10-23

PRINT NAME

COMMENTS:

WHITE	GREEN	PINK	YELLOW
CUSTOMER COPY	ACCOUNTS COPY	INVOICE	FILE COPY

Appendix D (ii)

Hlumani Wasteman Certificate of Safe Disposal

Hlumani Wasteman (Pty) Ltd

Mobile Road, Airport Industria P.O. Box 219, Eppindust, 7475
Tel: (+27) 21 380-3000 Fax: (+27) 21 380 3030 Email: info@hlumaniwasteman.co.za

"Your Partner in Total Waste Management Solutions"

CERTIFICATE OF SAFE DISPOSAL

This is to confirm that Hlumani Wasteman (Pty) Ltd collected Pharmaceutical Waste with a total mass of 158.5 Kg from Tygerberg Hospital, Tygerberg Premises on 30 October 2008.

We further confirm that the abovementioned Pharmaceutical waste was disposed of via high temperature incineration at our North West Medical Waste facility, so as to meet all regulatory requirements as set out by the governing Authorities and Health Department.

Authorised Official : .....

Reference: Collection Docket No 26534
Certificate No. 0102

Appendix E

BCL MWM Certificate for Offensive Trade

Community Services

DIREKTORAAT • ISEBE • DIRECTORATE
Environmental Health

Afdeling • Icandelo • Section

Mr Petersen
Vra vir • Buza u • Ask for

952-7640
Telefoon • Ifoni • Telephone

952-5904
Faks • Fax

E-Mail

Cnr St Vincent & Belhar Drives
Adres • Idilesi • Address
BELHAR (7490)

TYGERBERG
STAD • ISIXEKO • CITY

5 November 1999
Datum • Umhla • Date

Eastern District
Dienskring • Inginqi yenkonzo • Service area

HS/18/2/5/1/4
Verwysing • Isalathiso • Reference

PERMIT NO: 18/2/5/1/4/1/0T/BH

PERMIT TO CONDUCT AN OFFENSIVE TRADE

NAME : MRC Delft Centre

ADDRESS : P O Box 19070
TYGERBERG
7505

PREMISES : PTN. 61 (A PTN of PTN 1) of the farm Driftsands No 544
Brentwood Park
Delft

PROCESS : incineration of Medical Waste

PLANT : Berco Waste Incinerator

CAPACITY : 125 kg of Medical waste per hour

pp

DIRECTOR: COMMUNITY SERVICES

Appendix F

BCL MWM Stack Emission Analysis

TABLE I: MEDICAL WASTE INCINERATOR STACK EMISSION CONCENTRATIONS. BCL MEDICAL WASTE MANAGEMENT. 30 OCTOBER 2007.

Sample No.	Substance Monitored	Emission Concentration (Nmg/m^3)	Emission Limit (Nmg/m^3)	Mass Flow (Nkg/h)
THB 184	Total Particulates (1st sampling run)	42.93	120	0.61
THB 185	Total Particulates (2nd sampling run)	32.84	120	0.45
	Mercury	BDL	0.05	-
	Thallium	BDL	0.05	-
	Chromium	<0.01	0.5	<0.01
	Beryllium	BDL	0.5	-
	Arsenic	BDL	0.5	-
	Antimony	BDL	0.5	-
	Barium	0.18	0.5	<0.01
	Lead	0.15	0.5	<0.01
	Silver	<0.01	0.5	<0.01
	Cobalt	<0.01	0.5	<0.01
	Copper	0.12	0.5	<0.01
	Manganese	<0.01	0.5	<0.01
	Tin	0.03	0.5	<0.01
	Nickel	0.01	0.5	<0.01
	Vanadium	BDL	0.5	-
	Total Metals	0.44	5	<0.01
MIS 1008	Chloride (as HCL)	1.68	30	0.07

$Nmg/^3m$: Normal milligrams per cubic metre

Nkg/h: Normal kilograms per hour

Appendix G

Hlumani Wasteman: Collection Manifests

HLUMANI WASTEMAN
(FORMERLY WASTEMAN CAPE (PTY) LTD)
YOUR PARTNER IN TOTAL WASTE MANAGEMENT

HLUMANI WASTEMAN (PTY) LTD
Co. Reg. No. 2000/011876/07 VAT Reg. No. 4580192203
WINGFIELD HOUSE, MOBILE ROAD AIRPORT INDUSTRIA
PO BOX 219 EPPINDUST 7475
TEL (+27) 021 380-3000 FAX: (+27) 021 380-3030
E-MAIL: service@wasteman.co.za

DOCUMENT No. 32053

MEDICAL WASTE DIVISION - HEALTH CARE RISK WASTE MANIFEST

CUST. NAME / GENERATOR: EIO PHARMACY ACCOUNT NUMBER:

ADDRESS:

CONTACT: TEL No.: ORDER NUMBER:

TRANSPORTER: HLUMANI WASTEMAN • DRIVER: M. ZUNGU VEHICLE REG No.: DEP 55 GP

DELIVERY / COLLECTION ADVICE • DETAILS OF SERVICE

ITEMS / DESCRIPTION	UNIT	CONSUMABLES PLACED	WASTE REMOVED
50 ℓ BOX SET	EACH	UNITS	UNITS
90 ℓ BOX SET PHARMACEUTICAL	EACH	UNITS	2 UNITS
142 ℓ BOX SET	EACH	UNITS	UNITS
5 ℓ SHARPS CONTAINER	EACH	UNITS	UNITS
20 ℓ SHARPS CONTAINER	EACH	UNITS	UNITS
10 ℓ PLACENTA CONTAINER	EACH	UNITS	UNITS
20 ℓ PLACENTA CONTAINER	EACH	UNITS	UNITS
50 ℓ PHARMACEUTICALS CONTAINER	EACH	UNITS	UNITS
TROCHAR SHARPS CONTAINER	EACH	UNITS	UNITS
BUFF TAPE	EACH	UNITS	UNITS
CABLE TIES	PACK/100	UNITS	UNITS

DELIVERY • GOODS RECEIVED / ACCEPTED (CONSUMABLES PLACED)

F Mathambo (PRINT NAME) (SIGNATURE) 12/3/09 (DATE)

GENERATOR CERTIFICATION (WASTE REMOVED)

I hereby declare that the contents are properly described, packaged, marked and labled prior to transportation according to all relevant registration.

(PRINT NAME) (SIGNATURE) 12-03-09 (DATE)

TRANSPORTERS ACKNOWLEDGMENT OF RECEIPT OF MATERIALS

M. ZUNGU (PRINT NAME) (SIGNATURE) 12-03-09 (DATE)

PROUDLY SOUTH AFRICAN

COMMENTS:

DISTRIBUTION	WHITE *CUSTOMER COPY*	GREEN *ACCOUNTS COPY*	PINK *INVOICE*	YELLOW *FILE / POD*

Appendix H

Certificates of Safe Disposal

Hlumani Wasteman (Pty) Ltd

Mobile Road, Airport Industria P.O. Box 219, Eppindust. 7475
Tel: (+27) 21 380-3000 Fax: (+27) 21 380 3030 Email: info@hlumaniwasteman.co.za

"Your Partner in Total Waste Management Solutions"

CERTIFICATE OF SAFE DISPOSAL

This is to confirm that Hlumani Wasteman (Pty) Ltd collected Pharmaceutical Waste with a total mass of 47.6 Kg from E10 Pharmacy, Grooteschuur Hospital Premises on 12 March 2009 .

We further confirm that the abovementioned Pharmaceutical waste was disposed of via high temperature incineration at our North West Medical Waste facility, so as to meet all regulatory requirements as set out by the governing Authorities and Health Department.

Authorised Official : .....

Reference: Collection Docket No 32053
Certificate No. 112

Appendix I

Certificate of Good Standing:

Department of Labour

THE OFFICE OF THE COMPENSATION COMMISSIONER

COMPENSATION FUND

The Hon., Prof., Dr., Messrs., Mr., Ms

B C L MEDICAL WASTE
PO BOX 2637
CLAREINCH
7740

YOUR REGISTRATION NUMBER:

0109-969-1711

ATTENTION:

YOUR FAX NUMBER: 021 671 6808

DATE ISSUED: 01/09/2010

CERTIFICATE #: 0000773244

LETTER OF GOOD STANDING

COMPENSATION FOR OCCUPATIONAL INJURIES AND DISEASES ACT, 1993

- With reference to Section 89 of the Act, I hereby certify that

B C L MEDICAL WASTE

has complied with the requirements of the above Act and is at present in good standing with the Compensation Fund.

Nature of Business : **WASTE REMOVAL**

Expiry Date : **31/10/2010 (Sunday, Thirty-first of October, Two thousand and Ten)**

- A letter of good standing is hereby issued with expiry date 31/10/2010 (Sunday, Thirty-first of October, Two thousand and Ten), subject to the following:

Your Earnings Return has been received, but has not been processed yet.

IMPORTANT NOTICE:
You make yourself guilty of an offense if you pay any additional fee to obtain this letter.

The Compensation Commissioner shall at his own discretion institute criminal proceedings against perpetrators who unlawfully alter or deface this letter with intent to defraud or misrepresent facts contained therein.

**** TO RENEW THIS LETTER FAX YOUR REQUEST 5 WORKING DAYS PRIOR TO EXPIRY DATE.***

Yours faithfully

L Louwrens

COMPENSATION COMMISSIONER
W.As. 48

DEPT. VAN ARBEID
PROVINSIALE UITVOERENDE BESTUURDER:
WES-KAAP
POSBUS/P.O. BOX 872
2010 -09- 01
KAAPSTAD/CAPE TOWN 8000
PROVINCIAL EXECUTIVE MANAGER:
WESTERN CAPE
DEPT. OF LABOUR

Compensation House, Cnr Hamilton and Soutpansberg Road, P O Box 955, Pretoria, 0001
Fax: (012) 357-1817
Website: http://www.labour.gov.za

Appendix J (i)

Phenobarbitone 30mg tablets

RESTRICTED SCHEDULED
REGISTER VAN BEPERKTE

NAME OF RESTRICTED SCHEDULED SUBSTANCE / NAAM VAN BEPERKTE GESKEDULEERDE STOF: Phenobarbitone
STRENGTH / STERKTE: 30mg

RECEIPTS–ONTVANGSTE				ISSUES	
DATE / DATUM	NAME AND ADDRESS OF SUPPLIER / NAAM EN ADRES VAN LEWERANSIER	Requisition and/or Invoice No. / Rekwisisie en/of Faktuur Nr.	QUANTITY / HOEVEELHEID	DATE / DATUM	Purchaser or Patient NAME/NAAM
			BALANCE BROUGHT FORWARD FROM PAGE N		
6/7/05	D2.	J2599201	11		
6/7/05	E1	J3938980	20½		
14/7/05	B2 (exp 6/05)	J 875722	5		
				21/8/2005	Expired stock destr
18/10/05	D1 Exp: 09/2005	J393693	14		
18/10/05	G1 NIGHT DUTY EXP: 09/2005	J03303	13½		
18/10/05	TRAUMA EXP: 09/2005	J401530	16		
18/10/05	S11 exp: 09/2005	J393567	¼		
26/12/06	Expired 09/05 G1	J00720	9		
25/4/06	Maitland Cottage EXPIRED: 09/05	J210236	4		
2/10/07	E1 expired stock	J052469	15		
8/10/07	B1 expired stock 09/07	J5960	3½		
10/10/07	C1 ICU expiry stock 05/07	J03699	20		
2/1/08	D2 expired stock 12/07	J02913	14		
3/3/08	G1 Night Staff expired stock	J00992	10		
31/3/08	Maitland Cottage Night Staff	J1539953	10		
29/4/08	Emergency cupboard exp stock	09/2008	6		
11/08/08	C1 ICU expired stock	J02450	22		
8/10/08	D1 expired Stock	J03588	12½		
			BALANCE CARRIED FORWARD TO PAGE NO		

Appendix J (ii)

Phenobarbitone 200mg/ml Ampoules

RESTRICTED SCHEDULED
REGISTER VAN BEPERKTE

NAME OF RESTRICTED SCHEDULED SUBSTANCE / NAAM VAN BEPERKTE GESKEDULEERDE STOF: phenobarbitone

STRENGTH / STERKTE: 200mg/ml

RECEIPTS–ONTVANGSTE				ISSUES	
DATE / DATUM	NAME AND ADDRESS OF SUPPLIER / NAAM EN ADRES VAN LEWERANSIER	Requisition and/or Invoice No. / Rekwisisie en/of Faktuur Nr.	QUANTITY / HOEVEELHEID	DATE / DATUM	Purchaser or Patient NAME/NAAM
			BALANCE BROUGHT FORWARD FROM PAGE NO		
6/7/05	~~F 293938~~ G1	J396974	3		
14/7/05	C1	J376492	2		
				21/7/2005	Expired stock destroyed
3/8/05	S11	J393554	3		
3/8/05	C1	J375464	17 + 2 broken		
11/8/05	G1 (expired ~~2006~~ July 05)	J393062	5		
17/8/05	C1 exp July 05	J393060	1		
17/8/05	D1 exp July 05	J393063	5		
17/8/05	G1 exp July 05	J393058	5		
17/8/05	C1 exp. July 05	J393061	2		
17/8/05	Trauma exp July 05	J393521	9		
17/8/05	E2 exp July 05	J393305	7		
14/9/05	G1 exp July 05	J393915	10		
19/9/05	Trauma exp July 05	J393091	1		
18/10/05	E2 exp. July 05	J294650	1		
26/11/05	B2 expired	J033846	1		
			BALANCE CARRIED FORWARD TO PAGE NO		

Appendix K

CPUT Ethics Approval

Cape Peninsula
University of Technology

Mr MS Sattar
Department of Environmental and Occupational Studies
Cape Peninsula University of Technology

09 March 2009

Dear Mr Sattar

AN ENVIRONMENTAL IMPACT PERSPECTIVE ON THE MANAGEMENT , TREATMENT AND DISPOSAL OF HAZARDOUS PHARMACEUTICAL COMPOUNDS GENERATED AS MEDICAL WASTE AT SELECTED HOSPITALS IN CAPE TOWN, SOUTH AFRICA.

Thank you for addressing the issues raised in our correspondence to you regarding the above research project.

Final ethical approved is hereby granted to proceed with the project. The committee wish you success with your research.

Yours sincerely,

Prof AJS Benade
Chairperson
Research Ethics Committee
Faculty of Applied Sciences

PO Box 1906 Bellville 7535 South Africa
086 123 2788

Appendix L1

Research Approval

Groote Schuur Hospital

Dr B Patel

(021) 404-4469

(021) 404-4304

Bpatel@pgwc.gov.za

3 April 2006

PROVINCIAL ADMINISTRATION : WESTERN CAPE
Department of Health

PROVINSIALE ADMINISTRASIE : WES-KAAP
Departement van Gesondheid

ULAWULO LWEPHONDO : INTSHONA KOLONI
Isebe Lezempilo

Mr MS Sattar
CPUT : Department of Health Sciences
(Bellville Campus)
PO Box 1906
BELLVILLE 7535

Dear Mr Sattar

RE : RESEARCH PROJECT : WASTE DISPOSAL

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following :

(a) Your research may not interfere with normal patient care.
(b) Hospital staff may not be asked to assist in the research.
(c) No hospital consumables and stationery may be used.
(d) Please introduce yourselves to the person in charge of an area before commencing.

I would like to wish you every success with your project.

Yours truly,

DR B PATEL
For CHIEF EXECUTIVE OFFICER

BP/yw
Ref.c:l-researchSattar
c.c Chair Research/Ethics Committee – ~~Prof Zabow~~ Dr M Brockerman

Appendix L2

Research Approval

Tygerberg Academic Hospital

Departement van Gesondheid
Department of Health
iSebe lezeMpilo

Verwysing
Reference
Isalathiso

Navrae
Enquiries
Imibuzo
Mr P J Wolfaardt

Telefoon
Telephone
Ifowuni
[021] 938-4138

Tygerberg Akademiese Hospitaal en
Mitchellsplein & Tygerberg Mondgesondheidsentrums

Tygerberg Academic Hospital and
Mitchells Plain & Tygerberg Oral Health Centres

Isibhedlele Sase Tygerberg Kwakunye Ne
Mitchells Plain Neziko Lamazinyo Lase Tygerberg

Privaatsak X3/ Private Bag X3
Tygerberg, 7505

Mr MS Sattar
Department of Health Sciences
PO BOX 1906
Bellville
7535

Facsimile number: 021 959 6015

Dear Mr Sattar

PHARMACEUTICAL WAST RESEARCH PROJECT

Your e-mail dated 26 January 2009 refers.

Your request to undertake the proposed research has been approved subject to:-

- Your research activities not to interfere with patient or operational activities
- No member of staff to be requested to assist in terms of the research
- No hospital equipment, consumables and/or stationery to be used
- Please report to Mrs C Ford or her delegate when commencing
- Confidentiality of staff, patients, suppliers and hospital to be maintained at all times

Your acceptance of the above will be appreciated.

Dr T Carter
CHIEF DIRECTOR
[C: mydoc-wolfaardt2009/sattar – pharm. waste research project

Date: 30 January 2009

Appendix L3

Research Approval

Red Cross War Memorial Children's Hospital

Verwysing
Reference RESEARCH
Isalathiso

Navrae
Enquiries Dr K R Ramiah
Imibuzo

Telefoon
Telephone +27 21 658 5383
Fax +27 21 658 5166

Departement van Gesondheid
Department of Health
iSebe lezeMpilo

15 June 2006

Mr. M.S. Sattar
CPUT – Bellville Campus
P.O. Box 1906
Bellville 7535

Dear Mr. Sattar

Re: Research – Waste Disposal

Your letter dated 13 June 2006 refers.

You are hereby granted permission to proceed with your research.

Please note the following:

1. Your research may not interfere with normal patient care.
2. Hospital staff may not be asked to assist in the research.
3. No hospital consumables and stationery may be used.
4. Please introduce yourselves to the person in charge of an area before commencing.

I would like to wish you every success with your project.

Yours sincerely,

Dr K R Ramiah
Chief Operations Officer

Red Cross War Memorial Children's Hospital
Klipfontein Road / Private Bag
RONDEBOSCH
7700 / 7701

Rooikruis Oorlogsgedenk Kinderhospitaal
Klipfonteinweg / Privaatsak
RONDEBOSCH
7700 / 7701

Appendix L4

Research Approval

Melomed Hospital Group

Clinic Rd. Gatesville, 7764 P.O. Box 94 Gatesville 7766
Legal Department (021) 699 0950

GATESVILLE MEDICAL CENTRE

Telephone: (021) 637 8100 Fax: (021) 637 8111
website: http://www.melomed.co.za
e-mail: melomed@iafrica.com

27 January 2009

Cape Peninsula
University of Technology
Deparatment of Health Sciences
P O Box 1906
BELLVILLE
7530

ATTENTION: MR M.S. STATTAR

Dear Sir

Re: **PHARMACEUTICAL WASTE RESEARCH AT :**
MELOMED GATESVILLE
MELOMED MITCHELLS PLAIN
MELOMED BELLVILLE

We acknowledge receipt of your letter dated the 15th December 2008, the contents of which we have noted and for which we thank you.

With the above in mind, we take this opportunity of giving you permission to undertake to perform the research in respect of the three (3) abovementioned hospitals.

Yours faithfully
MELOMED GATESVILLE

M. Johnson

Per:
MS M JOHNSON

Hospital Manager

Appendix L5

Support from the Western Cape Provincial Government

Verwysing
Reference
Isalathiso E13/2/1/3 HCW Mgmt

Navrae
Enquiries
Imibuzo EP Hanekom

Datum
Date
Umhla 27 January 2006

Departement van Omgewingsake en Ontwikkelingsbeplanning
Department of Environmental Affairs and Development Planning
ISebe leMicimbi yeNdalo esiNgqongileyo noCwangciso loPhuhliso

To Whom It May Concern

LETTER OF SUPPORT FOR M TECH RESEARCH:

" The characterization of medical waste generated by selected major hospitals in Cape Town in order to determine whether "Pharmaceutical Waste" should be considered as a specific waste stream at these and other similar sites in South Africa."

South Africa as in the rest of Africa, is struggling not only with the treatment of diseases but also with the treatment of the medicines after they have been used to treat the diseases. Health Care waste thus has the potential to cause more harm and on a larger scale than the good it can do, if not disposed of properly.

Health Care waste is a term of broad complexity and includes potentially hazardous chemicals such as cytotoxic and nuclear medicines and throughout the developed world it has been found that separating the components of health care waste, facilitates in the treatment of such waste.

The research study of Shaheen Sattar from the Cape Peninsula University of Technology in this regard, will assist South Africa in developing better ways of treating health care waste and is therefore supported by Department of Environmental Affairs and Development Planning.

Yours faithfully

E P Hanekom

DEPUTY DIRECTOR: WASTE MANAGEMENT

4de Vloer
Property Centre Gebou
Utilitasgebou, Dorpstraat 1
Privaatsak X9086
Kaapstad 8000

4th Floor
Property Centre Building
Utilitas Building, 1 Dorp Street
Private Bag X9086
Cape Town 8000

Tel No.: (021) 483 2728
Fax No.: (021) 483 2979
Ifowuni:
Ifaksi:

Appendix M (a)

Pilot Questionnaire

Pilot Questionnaire

Cape Peninsula
University of Technology

Department of Environmental and Occupational Studies

Pharmaceutical Waste Management Questionnaire No.....

The university thanks you sincerely for participating in our research which has been approved by this hospital and by the Department of Environmental Affairs and Planning of the Western Cape Province. Personnel as well as the hospital involved will not be identified. The information derived from this questionnaire will only be used for research into the potential impact of pharmaceuticals on the environment. Your contribution will help towards ensuring a safer environment for all.

1. Name of hospital: .....(Respondent do not complete. For office use only)

2. Research code for the above hospital:.....(Respondent do not complete. For office use only)

For all questions, where applicable, ring the appropriate answer

Type of hospital	
State hospital	1
Private hospital	2

3. (a) Has a department been assigned to the supervision and co-ordination of the hospital waste disposal?

Yes	1
No	2
Don't know	3

(b) Has all the staff of this department received any training in hospital waste management?

Yes	1
No	2
Don't know	3

(c) If yes, briefly describe what kind of training (both certified and uncertified trainings may apply)

Certified by accredited provider	Specify	1
Uncertified	Specify	2

4. Please answer each of the following questions

Question	Yes	No	Don't know	
Has your hospital done a waste audit in the last three years?	1	2	3	
Are you aware of any legislation applicable to hospital waste management?	1	2	3	
Does your hospital have a document outlining the hospital's waste management policy?	1	2	3	
Are you aware of a manual or guideline document on the management of hospital waste issued by any government department?	1	2	3	

5. How are the present waste collection, handling, and disposal responsibilities defined in the job descriptions of the staff involved with waste? (Cite appropriate statement)

.....
.....
.....
.....

6. Should the following waste material be disposed of via the sewage system?

Waste material	Yes	No	Don't know	
Organic solvents (e.g. chloroform, alcohol)	1	2	3	
Antibiotics	1	2	3	
Cytotoxic drugs	1	2	3	
Multivitamins	1	2	3	
All expired medicines	1	2	3	

7. Is the pharmaceutical waste segregated (i.e. divided into different types and schedules) before disposal?

Yes	1
No	2
Don't know	3

8. (a) Have you encountered any problems with pharmaceutical waste disposal in the past?

Yes	1
No	2

(b) If yes, briefly describe the event/s.

.....
.....
.....
.....

9. Indicate on the scale below how efficient or inefficient you consider the following methods of hazardous waste disposal to be?

Technique of disposal	Inefficient → Efficient										
Commercial waste company collecting and disposing	1	2	3	4	5	6	7	8	9	10	
Municipality collecting and disposing	1	2	3	4	5	6	7	8	9	10	
Commercial incineration	1	2	3	4	5	6	7	8	9	10	
Land filling	1	2	3	4	5	6	7	8	9	10	
Cement kilns	1	2	3	4	5	6	7	8	9	10	

10 Indicate to what extent you agree or disagree with the following statements.

Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Don't know	
Incinerator staff should have a certificate of competency	1	2	3	4	5	6	
Incinerators must be certified to dispose of medical waste	1	2	3	4	5	6	
Hospitals should employ waste companies to dispose of their hazardous waste	1	2	3	4	5	6	
Waste generated by hospitals has a serious impact on the environment	1	2	3	4	5	6	
Healthcare professionals should be awareness of environmental issues	1	2	3	4	5	6	
Pharmaceutical waste generated by hospitals has an impact on the environment	1	2	3	4	5	6	
Departments should keep records of hazardous material used.	1	2	3	4	5	6	
There are clearly defined procedures for the collection of different types of wastes from different departments in the hospital	1	2	3	4	5	6	
There are clearly defined procedures for the handling of different types of wastes from different departments in the hospital	1	2	3	4	5	6	
Hospital waste should be incinerated	1	2	3	4	5	6	
The hospital staff involved with waste management are adequately trained to deal with hazardous waste.	1	2	3	4	5	6	
Training courses are provided by the hospital for all personnel involved with waste	1	2	3	4	5	6	
This hospital has a waste management policy	1	2	3	4	5	6	
Waste management responsibilities are included in the job descriptions of the hospital's healthcare professionals	1	2	3	4	5	6	
South Africa has adequate legislation dealing with the safe treatment and disposal of hazardous hospital waste.	1	2	3	4	5	6	
Hospitals should be exempted from pollution control legislation	1	2	3	4	5	6	
Hospital staff should be protected against hazardous waste	1	2	3	4	5	6	
Healthcare professionals need to be more aware of environmental issues	1	2	3	4	5	6	
Hospital policy addresses the identification of risk to personnel involved in the handling of waste	1	2	3	4	5	6	
Hospital policy addresses quantification of risk to personnel involved in the handling of waste	1	2	3	4	5	6	

Appendix M (b)

Research Questionnaire

Cape Peninsula
University of Technology
Department of Environmental and Occupational Studies

Pharmaceutical Waste Management Questionnaire

No.....

Date.....

The Cape Peninsula University of Technology thanks you sincerely for participating in our research that was approved by this hospital and by the Department of Environmental Affairs and Planning of the Western Cape Province. Personnel as well as the hospital involved will not be identified. The information derived from this questionnaire will only be used for research into the potential impact of pharmaceuticals on the environment. Your contribution will help towards ensuring a safer environment in South Africa.

Name of hospital: .....**Do not complete. For office use only**

Research code for the above hospital:.....**Do not complete. For office use only**

For all questions, where applicable, ring the appropriate answer

1) Type of hospital.

Type of hospital	
State hospital	1
Private hospital	2

2. (a) Has a specific department in your hospital been assigned to the management of waste disposal?

Yes	1
No	2
Don't know	3

(b) Has all the staff of this waste department received any formal training (i.e. provided by an accredited provider) in hospital waste management?

Yes	1
No	2
Don't know	3

3.

Question	Yes	No	Don't know	
Has your hospital done a waste audit in the last three years?	1	2	3	
Are you aware of any legislation applicable to hospital waste management?	1	2	3	
Does your hospital have a document outlining the hospital's waste management policy and procedures?	1	2	3	
Has this policy and procedures been distributed to all the wards and departments in the hospital?	1	2	3	

4. Has the waste collection, handling, and disposal procedures been described in the job descriptions of the staff involved with waste management?

Yes	1	
No	2	
Don't know	3	

5. Should the following waste material be disposed via the sewerage system?

Waste material	Yes	No	Don't know	
Organic solvents (e.g. alcohol, ether, acetone, etc)	1	2	3	
Antibiotics	1	2	3	
Cytotoxic drugs	1	2	3	
Multivitamins	1	2	3	
All expired medicines	1	2	3	
Unused medicines	1	2	3	

6.

(a) Is pharmaceutical waste segregated (i.e. divided into different types and medicine schedules) at the point of generation.		
Yes	1	
No	2	
Don't know	3	

(b) Is pharmaceutical waste segregated (i.e. divided into different types and medicine schedules) before final removal from hospital for disposal.		
Yes	1	
No	2	
Don't know	3	

7. (a) Have you encountered any problems with pharmaceutical waste disposal in the past?

Yes	1	
No	2	

(b) If yes, briefly describe the event/s.

.....

.....

8. Indicate on the scale below how efficient or inefficient you consider the following processes to be?

Process	Inefficient → Efficient										
Commercial waste company collecting and disposing of medical waste including pharmaceutical waste	1	2	3	4	5	6	7	8	9	10	
Municipality collecting and disposing of medical waste including pharmaceutical waste	1	2	3	4	5	6	7	8	9	10	
Incineration of pharmaceutical waste	1	2	3	4	5	6	7	8	9	10	
Land filling of pharmaceutical waste	1	2	3	4	5	6	7	8	9	10	
Sewage treatment plants	1	2	3	4	5	6	7	8	9	10	
Water purification plants (tap water)	1	2	3	4	5	6	7	8	9	10	

10 Indicate to what extent you agree or disagree with the following statements.

Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Don't know	
Incinerator staff should have certificates of competency	1	2	3	4	5	6	
Incinerators must be certified to dispose of medical waste	1	2	3	4	5	6	
All waste generated by hospitals has an impact on the environment	1	2	3	4	5	6	
Sewage treatment personnel should have certificates of competency	1	2	3	4	5	6	
Land filling personnel should have certificates of competency	1	2	3	4	5	6	
Healthcare professionals should be more aware of environmental issues	1	2	3	4	5	6	
All pharmaceutical waste generated by hospitals has an impact on the environment	1	2	3	4	5	6	
Each department or ward should keep records of the hazardous waste generated.	1	2	3	4	5	6	
There are clearly defined procedures for the collection of different types of wastes from different departments in the hospital	1	2	3	4	5	6	
All hospital waste should be incinerated	1	2	3	4	5	6	
The hospital staff involved with waste management received adequate training in dealing with hazardous waste.	1	2	3	4	5	6	
Formal training in medical waste management should be provided by the hospital for all its healthcare professionals	1	2	3	4	5	6	
Waste management responsibilities should be included in the job descriptions of all the hospital's healthcare professionals	1	2	3	4	5	6	
South Africa has adequate legislation dealing with the safe treatment and disposal of hazardous medical waste.	1	2	3	4	5	6	
Hospitals should be exempted from pollution control legislation	1	2	3	4	5	6	
Hospital staff should be protected against hazardous waste	1	2	3	4	5	6	

Appendix N

Research Acknowledgment BCL MWM

From: Shaheen Sattar
To: Karin@bclmedicalwaste.co.za
Date: 2011/05/06 08:59
Subject: research information

CC: philipa@malandrinos.co.za

Ms Karin Mathews
Manager
BCL Medical Waste Management

Dear Ms Mathews
Re: Research Information

I would like to place on record my gratitude to you and Mr Philip Malandrinos for all your assistance thus far with my M.Tech. research project, which involves three state hospitals (Groote Schuur, Tygerberg, and Red Cross), three private hospitals (Gatesville Medical Centre, Bellville Medical Centre, and Mitchell's Plain Medical Centre) and reviews the management, treatment and disposal of pharmaceutical waste generated at these hospitals.

In terms of disposal, the state hospitals employs the services of Hlumani Wasteman, and the private hospitals the services of BCL Medical Waste Management. Both are included in the research. During my last visit and walkabout on the premises, conducted by Mr Malandrinos, he informed me of your company's intention to upgrade all the facilities, including the purchase of a modern incinerator and its relocation on the premises, the process being facilitated by Resources Management Services. I was also advised that all your company's details are available on their website.

However the following information could not be found, and I will be thankful if you would provide me copies of the following:
1) Your current permit to conduct an offensive trade. Permit no. 18/2/5/1/4/1/0T/BH dated 05 November 1999 is made out to MRC Delft Centre;
2) A sample of the Certificate of Safe Disposal of the Ash and glass received for landfilling, issued by Vissershok
3) Registration certificate for vehicle CF 102550 as a medical waste transporter, in terms of the City of Cape Town Environmental by-law.

Please note that the information provided is for academic purposes only. Kindly let me know if the above could be collected next week.

Thanking you
Shaheen Sattar. B.Sc. B.Pharm. FPS
Dpt. Nursing and Radiography
Cape Peninsula University of Technology

From: Philip Alexander Malandrinos <philipa@malandrinos.co.za>
To: Shaheen Sattar <sattars@cput.ac.za>, Karin Math...
Date: 2011/05/09 11:40
Subject: Re: research information

Dear Shaheen,

Please find attached the information as requested. The one registration certificate for CF10255o will follow since this is a new vehicle.

Kind regards,

Philip

Philip Alexander Malandrinos
Chief Executive
BCL Medical Waste Management Services
Mobile +2782 567 6000
Office: +2721 955 2447

Appendix O

Incinerator Stack Emission Temperature

TABLE II: MEDICAL WASTE INCINTERATOR STACK DETAILS AND CONDITIONS. BCL MEDICAL WASTE MANAGEMENT. 30 OCTOBER 2007.

Sample No.	Temperature (°C)	Volumetric Flow (Nm^3/s)	Velocity (Nm/s)	Stack Static Pressure (kPa)
THB 184 (First Sampling Run)	258	3.95	12.46	0.0910
THB 185 (Second Sampling Run)	272	3.82	12.06	0.0879

Diameter	:	635mm
℃	:	Degrees Celsius
Nm^3/s	:	Normal cubic meters per second
Nm/s	:	Normal meters per second
KPa	:	kilopascal

6.0. COMMENTS

All measured concentrations were well within the recommended limits. (See Table I).

COMPILED BY : J. JOUBERT

21/12/07
DATE

Appendix P

Certificate of Safe Disposal

By

Wasteman Western Cape

A Division of Wasteman Holdings (Pty) Ltd
Wingfield House, Mobile Road, Airport Industria
P.O. Box 219, Eppindust, 7475
Tel: (+27) 021 380-3000 Fax: (+27) 021 380-3030
E-mail: service@wasteman.co.za

WASTEMAN
WESTERN CAPE

Your Partner in Total Waste Management Solutions

Date: 02/03/2011 No. 15291

Certificate of Safe Disposal

CUSTOMER: BCL MEDICAL WASTE MANAGEMENT (PTY) LTD

DELFT

This is to certify that the following material:

QUANTITY: 1 x 6 CU M SKIP LOAD

WASTE: GLASS VIALS

DISPOSED AT VISSERSHOK WASTE MAN. FACILITY

VH91105

has been responsibly and correctly disposed of in accordance with the provisions of the Environmental Conservation Act No. 73 of 1989 (as amended), the Water Act No. 36 of 1998, the Health Act No. 63 of 1977, the Occupational Health and Safety Act No. 85 of 1993, the Hazardous Substances Act No. 15 of 1973 and the National Environmental Management Act No. 107 of 1998

Authorised Official: .....
for - WASTEMAN

WASTEMAN
GROUP

Appendix Q

Incinerator Ash Disposal

By

Wasteman Western Cape

WASTEMAN
WESTERN CAPE

A Division of Wasteman Holdings (Pty) Ltd

Address: Wingfield House, Mobile Road, Airport Industria
PO Box 219, Eppindust, 7475
Tel: (+27) 21 380 3000
Fax: (+27) 21 380 3030
E-mail: service@wasteman.co.za Website: www.wasteman.co.za

Your Partner in Total Waste Management Solutions

BCL Medical Waste Management
P.O.Box 19001
TYGERBERG
7505

7 September 2010

RE : DISPOSAL OF INCINERATOR ASH

This letter serves to confirm that the Residual Incinerator Ash removed in a lidded skip bin from BCL premises in Delft is disposed of at the Vissershok Waste Management Landfill Facility site which is an H:H permitted site and the disposal of this product is carried out in accordance with the regulations of this permit.

We trust that this is in order.

Yours faithfully

Keith Rowland
Regional Sales and Marketing Manager

Appendix R (i)

Bellville Medical Centre

Service Manifest Document

BCL MEDICAL WASTE MANAGEMENT

SERVICE MANIFEST DOCUMENT No: 0913524

Date: 9/9/10

PO Box 2637, Clareinch, 7740 - Tel: 021 955 2447 - Fax: 021 955 0283 - VAT No.: 4290179896

Generator Name: Bville m'CNT Order Number:

Generator Address: BELLVILLE

Bio-Hazardous Medical Waste:	Stock Delivery / Waste Collection Details	Stocks Placed	Waste Removed
Transport Fee			
50 Litre Bin / Liner			
140 Litre Bin / Liner			
25 Litre Bucket			3
5 | 10 Litre Foetus Bucket			
Reuseable Bins:			
70 Litre Bin		30	44
70 Litre Liners			
Sharps:			
4 | Litre Sharps			
7,6 Litre Sharps			11
20 Litre Sharps			
Trochar Container			2
Other:			
701 BIN PLACENTAS			1

Transporter: BCL Medical Waste Management
Transporter's acknowledgement of receipt of goods as detailed above: Yes ✓ No

Name & Signature:

Disposal: Carried out at the BCL Incineration Facility Yes ✓ No

Gen[illegible]or's: Acceptance of service provided as indicated above and certification that the contents are packaged and labelled so as to comply with all relevant legislation

Generator's Name & Signature:

BCL MEDICAL WASTE MANAGEMENT

SERVICE MANIFEST DOCUMENT No: 0922326

Date: 9/9/10

PO Box 2637, Clareinch, 7740 - Tel: 021 955 2447 - Fax: 021 955 0283 - VAT No.: 4290179896

Generator Name: Bville m/c Order Number:

Generator Address: Bville

Bio-Hazardous Medical Waste:	Stock Delivery / Waste Collection Details	Stocks Placed	Waste Removed
Tr[illegible]port Fee			
50 Litre Bin / Liner			
140 Litre Bin / Liner			
25 Litre Bucket			
5 | 10 Litre Foetus Bucket			
Reuseable Bins:			
70 Litre Bin		30	37
70 Litre Liners			
Sharps:			
4 | 5 Litre Sharps			
7,6 Litre Sharps			6
20 Litre Sharps			
Trochar Container			
Other:			
701 BIN PLACENTAS			1

Transporter: BCL Medical Waste Management
Transporter's acknowledgement of receipt of goods as detailed above: Yes ✓ No

Name & Signature:

Disposal: Carried out at the BCL Incineration Facility Yes ✓ No

Generator's: Acceptance of service provided as indicated above and certification that the contents are packaged and labelled so as to comply with all relevant legislation

Generator's Name & Signature:

Appendix R (ii)

Mitchell's Plain Medical Centre

Service Manifest Document

Ghana-715

MEDICAL WASTE MANAGEMENT

SERVICE MANIFEST DOCUMENT No: 077397

Date 28/6/10

PO Box 2637, Clareinch, 7740 - Tel: 021 955 2447 - Fax: 021 955 0283 - VAT No.: 4290179896

Generator Name: m/Main Hospital M/C	Order Number:
Generator Address:	

Bio-Hazardous Medical Waste:	Stock Delivery / Waste Collection Details	Stocks Placed	Waste Removed
Transport Fee			
50 Litr[illegible] / Liner			13
14[illegible]tre Bin / Liner			2
25 Litre Bucket			
5 | 10 | Litre Foetus Bucket			
Reuseable Bins:			
70 Litre Bin			
70 Litre Liners			
Sharps:			
4 | 5 | Litre Sharps			
7,6 Litre Sharps			3
20 Litre Sharps			
Trochar Container			
Other:			

Transporter: BCL Medical Waste Management
Transporter's acknowledgement of receipt of goods as detailed above: Yes ✓ No

Name & Signature: RAIDD

Disposal: Carried out at the BCL Incineration Facility Yes ✓ No

Generator's: Acceptance of service provided as indicated above and certification that the contents are packaged and labelled so as to comply with all relevant legislation

Appendix R (iii)

Gatesville Medical Centre

Service Manifest Document

CF 102530

MEDICAL WASTE MANAGEMENT

SERVICE MANIFEST DOCUMENT No 082485

Date: 03/09/10

PO Box 2637, Clareinch, 7740 - Tel: 021 955 2447 - Fax: 021 955 0283 - VAT No.: 4290179896

Generator Name: GATESVILLE MEDICAL CENTRE Order Number:

Generator Address: GATESVILLE

Bio-Hazardous Medical Waste:	Stock Delivery / Waste Collection Details	Stocks Placed	Waste Removed
Transport Fee			
50 Litre Bin / Liner			
140 Litre Bin / Liner			
25 Litre Bucket			
5 | 10 Litre Foetus Bucket			
Reuseable Bins:			
70 Litre Bin		20	9
70 Litre Liners			
Sharps:			
4 | 5 Litre Sharps			
7,6 Litre Sharps			8
20 Litre Sharps			
Trochar Container			
Other:			

Transporter: BCL Medical Waste Management
Transporter's acknowledgement of receipt of goods as detailed above: Yes ✓ No

Name & Signature: [signature]

Disposal: Carried out at the BCL Incineration Facility Yes ✓ No

Generator's: Acceptance of service provided as indicated above and certification that the contents are packaged and labelled so as to comply with all relevant legislation

CF 102530

MEDICAL WASTE MANAGEMENT

SERVICE MANIFEST DOCUMENT No: 083171

Date: 07/09/10

PO Box 2637, Clareinch, 7740 - Tel: 021 955 2447 - Fax: 021 955 0283 - VAT No.: 4290179896

Generator Name: GATESVILLE MEDICAL CENTRE Order Number:

Generator Address: GATESVILLE

Bio-Hazardous Medical Waste:	Stock Delivery / Waste Collection Details	Stocks Placed	Waste Removed
Transport Fee			
50 Litre Bin / Liner			
140 Litre Bin / Liner			
25 Litre Bucket			1
5 | 10 Litre Foetus Bucket			
Reuseable Bins:			
70 Litre Bin		10	15
70 Litre Liners			
Sharps:			
4 | 5 Litre Sharps			
7,6 Litre Sharps			3
20 Litre Sharps			
Trochar Container			
Other:			

Transporter: BCL Medical Waste Management
Transporter's acknowledgement of receipt of goods as detailed above: Yes ✓ No

Name & Signature: [signature]

Disposal: Carried out at the BCL Incineration Facility Yes ✓ No

Generator's: Acceptance of service provided as indicated above and certification that the contents are packaged and labelled so as to comply with all relevant legislation

Appendix S

MRC STWs Effluent Analysis

3 RESULTS OF ANALYSIS

DETERMINANDS	METHOD	LAB Ref.	SAMPLE
			CT0680
pH at 25°C	SANS 5011:2005	CPT	9,81
Conductivity at 25°C in mS/m	SANS 7888:2005	CPT	100
Suspended solids at 105°C in mg/l	SANS 6049:2004	CPT	50
Free and saline ammonia as N in mg/L	SANS 5217:2007	CPT	1,1
Nitrate as N in mg/L	SANS 5210:2006	CPT	<0,3
Ortho-phosphate as P in mg/L	SANS 6055:2006	CPT	0,58
Fluoride as F in mg/L	SANS 10359-1:2002	CPT	0,14
Chemical oxygen demand as O2 in mg/L	SANS 6048:2005	CPT	115

NM NDABENI
TEST OFFICER
Water/L4344/mcromey-hawke

N VENA
TEST OFFICER