GENERAL NOTICE

NOTICE 452 OF 2012

DEPARTMENT OF ENVIRONMENTAL AFFAIRS

NATIONAL ENVIRONMENTAL MANAGEMENT: WASTE ACT, 2008

(ACT NO. 59 OF 2008)

DRAFT HEALTH CARE RISK WASTE MANAGEMENT REGULATIONS

I, Bomo Edith Edna Molewa, Minister of Water and Environmental Affairs, hereby give notice of my intention, under section 69(1)(b), (g), (h), (q), (r), (s), (dd), and (ee) read with section 73 of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), to make regulations regarding Health Care Risk Waste Management in the Schedule hereto.

Members of the public are invited to submit to the Minister, within 60 days of publication of this notice in the *Gazette*, written representations on or objections on the Regulations to the following addresses:

By post to: The Director-General
Department of Environmental Affairs
Attention: Dr Shauna Costley
Private Bag X447
Pretoria
0001

By fax to: (012) 320 0024;

By e-mail to: scostley@environment.gov.za; or

Hand delivered at: 315 Pretorius Street, Pretoria, Fedsure Forum Building, North Tower, 2nd Floor (Reception).

The Regulations can also be accessed at www.sawic.org.za.

Any enquiries in connection with the regulations can be directed to Dr Shauna Costley at (012) 310 3330.

Comments received after the closing date may not be considered.

BOMO EDITH EDNA MOLEWA

MINISTER OF WATER AND ENVIRONMENTAL AFFAIRS

SCHEDULE

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PART 1

DEFINITIONS, INTERPRETATION AND PURPOSE

Definitions

1. (1) In these Regulations any word or expression to which a meaning has been assigned in the Act has the same meaning, and unless the context requires otherwise –

'Act' means the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008);

'anatomical or pathological waste' means-

(a) human and animal tissues, organs, body parts, blood and blood products and body fluids;

(b) non-viable foetus;

(c) deceased animals or animal parts infected with potential infectious agents and includes animals maintained for biological or scientific research and testing,

but excludes human teeth, hair and nails and animal carcasses;

'competent person' means a person that is generally recognised within the scientific community as having the capability of conducting in conformance with generally recognised scientific principles, microbiological assessments and independent analyses or assessments;

'cytotoxic waste' means waste that contains agents that are toxic to cells and that can lead to cell death;

'decontamination' means the process of reducing or eliminating the presence of harmful substances such as infectious agents so as to reduce the likelihood of disease transmission from those substances;

'Department of Health' means the national Department of Health

'device' means the treatment technology used to treat health care risk waste;

'disinfect' means to render non-viable potential human and animal pathogens, but not necessarily all microbial forms to the level presented in the Standard for Validation of the Treatment Efficacy of a Non-combustion Health Care Risk Waste Treatment Facility published in terms of section 7 of the Act;

'domestic generator' means-

(a) a household generator; or

(b) other generators who generate less than 150 grams (excluding the container) per day of health care risk waste (excluding nappy waste), or less than 10 (ten) kilograms (excluding the container) per day of nappy waste, calculated monthly as a daily average;

but excludes households or facilities which generate any sharps waste and who shall be considered a minor generator;

'generator' means a person, whose actions, or activities result in health care risk waste and includes-

(a) households;

(b) home based care givers and organisations;

(c) health care practitioners and health care facilities;

(d) veterinary practitioners, animal clinics, and animal hospitals;

(e) mortuaries, funeral parlours, undertakers and embalmers;

(f) emergency medical services;

(g) traditional healers; and

(h) tattoo artists and body piercers;

'genotoxic waste' means waste that contains agents that are capable of interacting with living cells to cause genetic damage;

'health care facility' means the place or site where health care services are dispensed to human or animal patients or where research relevant to medical care is carried out, including-

(a) hospitals;

(b) clinics;

(c) laboratories;

(d) rehabilitation centres;

(e) old age homes;

(f) hospice;

(g) funeral homes;

(h) day clinics; and

(i) mobile units;

'health care general waste' means the non-hazardous component of waste generated by a health care facility and includes the domestic waste generated by the facility;

'health care risk waste' means the portion of the health care waste that is hazardous and including-

(a) laboratory waste;

(b) anatomical waste;

(c) genotoxic/cytotoxic waste;

(d) infectious waste;

(e) sharps waste;

(f) sanitary waste;

(g) nappy waste;

(h) low-level radioactive waste; and

(i) pharmaceutical waste;

'health care waste' is health care general waste and health care risk waste;

'incineration' means any method, technique or process to convert waste to flue gases and residues by means of oxidation;

'infectious agent' means microorganisms including bacteria, mycobacterium, fungi, parasites, or viruses which normally causes, or significantly contributes to infectious diseases and result in an increased morbidity or mortality of humans or animals;

'infectious waste' means waste which contains or may be reasonably presumed to contain infectious agents in sufficient concentrations or quantities to cause disease in susceptible hosts and includes isolation waste;

'isolation waste' means waste containing discarded materials contaminated with excretion, exudates, or secretions or materials generated in the treatment and diagnosis of humans or animals who or which are required to be isolated from the general population due to the pathogenicity or transmissibility of the suspected etiologic agents and includes health care general waste, health care risk waste and the containers of such waste from isolation wards;

'laboratory waste' means-

(a) laboratory generated cultures of human or animal specimens;

(b) cultures and stocks of infectious agents maintained in laboratories;

(c) wastes from the production of cultures of bacteria, fungi and viruses or in the production of spore sand vaccines or instruments used to transfer, inoculate and mix cultures; and

(d) specimens sent to a laboratory for analysis;

'low-level radioactive waste' means waste with a specific activity less than 74Bq/g (0.002µCi/g) or a surface dose rate of not more than 5µSv/h;

'major generator' means a generator of health care risk waste that generates more than 20 kilograms (excluding the weight of the container) per day calculated monthly as a daily average and includes nappy waste

'Minister' means the Minister responsible for environmental affairs;

'minor generator' means a generator of health care risk waste that generates more than 150 grams and less than 20 kilograms (excluding the weight of the container) per day calculated monthly as a daily

average and includes nappy waste above 10 kilograms (excluding the weight of the container) per day calculated monthly as a daily average;

'nappy waste' means discarded soiled nappies including soiled adult nappies;

'non-combustion treatment' means any method, technique or process which results in the inactivation of potential microbial pathogens within health care risk waste by methods or procedures other than incineration of the health care risk waste;

'pathogen' means a virus, bacterium, prion, parasite or fungus that causes disease in humans or animals;

'non-viable foetus' means a foetus that is not capable of living or developing successfully outside the uterus;

'pharmaceutical waste' means expired, unused, spilt or contaminated drugs, medicines and vaccines which are no longer usable and includes their packaging materials;

'residue' means material remaining after treatment of health care risk waste and includes ash from incineration or residue for non-burn technology;

'rigid' means physically inflexible such that the container is not pliable or flexible;

'sanitary bin' means the reusable container used to store sanitary waste;

'sanitary waste' means tampons, sanitary towels and incontinence pads;

'SANS 10248-1' means the South African National Standard for the Management of Health care Waste, Part 1: Management of Health Care Risk Waste from a Health Care Facility;

'SANS 452' means the South African National Standard for Non-reusable and Reusable Sharps Containers;

'sealed' means tightly or completely closed containers that cannot be reopened without major structural damage to the container;

'segregated' means to separate or isolate the health care risk waste from other waste types;

'sharps waste' means waste having acute rigid corners, edges, or protuberances capable of cutting or piercing, including:

(a) hypodermic needles, syringes with attached needles, blades, needles and lancets with or without attached tubing;

(b) broken clinical glass items, such as Pasteur pipettes and blood vials used in the diagnosis and treatment of patients and animals; and

(c) culture slides and exposed ends of dental wires;

'third party protection' means protection of persons who may come into contact with or who handle health care risk waste after generation;

'treatment facility' means a premises licensed to treat health care risk waste;

'waste manager' means any person that supervises the treatment and/or disposal of health care risk waste, including the waste generator itself or those persons acting on behalf of the waste generator;

'waste manifest system' means a system of control documentation containing the information specified in the Waste Classification and Management Regulations, 2011;

Purpose of Regulations

2. (1) The purpose of these Regulations is to:

(a) regulate the management of health care risk waste by providing a regulatory framework for its management;

(b) prescribe requirements for the management of health care risk waste such that this waste no longer constitutes a threat to humans, animals or the environment;

(c) prescribe requirements for management of health care risk waste that ensures the protection of third parties; and

(d) establish a timeframe to bring all health care risk waste management treatment facilities in compliance with the operational requirements for health care treatment facilities.

Application of Regulations

3.(1) These Regulations apply uniformly throughout the Republic of South Africa.

(2) These Regulations do not apply to domestic generators.

(3) Subject to sub-regulation (2) these Regulations apply to all generators, transporters and waste managers of health care risk waste.

PART 2

GENERAL PROHIBITIONS

General Prohibitions

4. (1) No person may—

(a) manage health care risk waste other than in accordance with these Regulations;

(b) mix health care risk waste with health care general waste or any other waste stream at the point of generation;

(c) dispose of untreated health care risk waste to land unless authorised to do so by the Minister;

(d) separate, sort or remove any item of health care risk waste once containerised unless to open a reusable container to load the health care risk waste into a device for treatment or to open a sanitary bin for cleaning;

(e) transport health care risk waste unless in accordance with the National Road Traffic Act, Act 93 of 1996 and the relevant regulations;

(f) fill a container with health care risk waste to weigh in excess of 15 kilograms including the container;

(g) transport health care risk waste for a distance exceeding 100m unless the container is mobile or on a mobile application suitable for the purpose;

(h) leave health care risk waste unattended in a place where unauthorised personnel or the public have unrestricted access;

(i) release health care risk waste from a major generator unless weighed and recorded, or

(j) release health care risk waste for storage, treatment or disposal without a waste manifest document.

PART 3

SEGREGATION, PACKAGING, LABELLING AND STORAGE

Segregation

5.(1) Health care risk waste must be segregated and containerised at the point of generation.

(2) Containers must be colour coded in accordance with SANS 10248-1 (as amended).

Packaging

6.(1) No health care risk waste must leave a generator unless containerised in rigid, leak proof and puncture resistant containers.

(2) Any health care risk waste containers must be packaged in accordance with SANS 10248-1 (as amended).

(3) Packaging for health care risk waste shall be filled to no more than three-quarters capacity of the container.

(4) All sharps waste must be packaged in sharps containers manufactured in accordance with SANS 452 (as amended).

(5) Plastic bags used as an interim storage container supported in a rigid frame must be in accordance with SANS 10248-1 (as amended).

(6) Plastic bags used as liners which form an integral part of a rigid container must be in accordance with SANS 10248-1 (as amended).

(7) All plastic bags used for the packaging of health care risk waste must be managed as health care risk waste and must not be reused.

(8) All plastic bags shall be closed by means of non-PVC plastics ties, non-PVC plastics sealing tags of the self-locking type or heat sealers purpose-made for health care risk waste.

(9) Anatomical waste not suitable for containerisation must be double bagged, sealed and placed in a single-use container.

(10) Isolation waste must be double bagged, sealed and placed in a single-use container.

(11) Reusable containers, excluding sanitary waste bins, must be cleaned and decontaminated after each use in accordance with the standards as set out in Annexure 1 to these Regulations.

Labelling

7. (1) All health care risk waste containers excluding interim storage containers must be sealed and labelled, bar coded or micro chipped to reflect the following:

(a) the date container is sealed; and

(b) the generator's registration number issued in terms of the Waste Information Regulations, 2011 for major generators, or

(c) that the waste is from a minor generator.

Storage

8.(1) Health care risk waste must be stored in a designated area that—

(a) is inaccessible to unauthorised personnel and members of the public;

(b) is secured by means of suitable locks;

(c) is under cover and protected against the elements;

(d) is appropriately ventilated;

(e) has adequate pest control measures;

(f) has access to running water and is linked to sewer;

(g) is capable of storing clean and dirty containers separately;

(h) is clearly signposted with warning signs as to the nature of the health care risk waste being stored; and

(i) is clearly signposted with the contact details of the person in charge of the designated area.

(2) All health care risk waste excluding anatomical waste, sharps, pharmaceutical waste, and isolation waste must not be stored for longer than 14 days from the date the container is sealed to the date of treatment.

(3) Isolation waste must be stored inside the isolation ward and must be treated immediately on arrival at the treatment facility.

(4) All anatomical waste must be treated within 24 hours of generation unless stored at a minimum temperature of –4°C, in which case the waste must be treated within 90 days from the date the container is sealed.

(5) Sharps waste must be stored for no longer than 90 days from the date the container is sealed to the date of treatment.

(6) Pharmaceutical waste must be stored for no longer than 90 days from the date the container is sealed to the date of final disposal.

(7) Notwithstanding anything contained in these Regulations, if the odour from health care risk waste poses a nuisance that health care risk waste must be treated immediately.

PART 4

DUTIES OF GENERATORS, TRANSPORTERS AND WASTE MANAGERS

General Duties

9. (1) Every holder of health care risk waste must be in possession of a waste manifest document issued in accordance with the Waste Classification and Management Regulations, 2011.

(2) Every holder of health care risk waste must keep accurate and up-to-date records of the management of health care risk waste relevant to that facility.

(3) Every holder of health care risk waste must keep the records as contemplated in sub-regulation (2) for a minimum of 5 (five) years.

(4) Every holder of health care risk waste must make the records as contemplated in sub-regulation (2) available to the Department on request.

(5) The analysis of effective cleaning and decontamination of reusable sharps and health care risk waste containers are subject to sub-regulations (2), (3) and (4) and must be made available to the generator on request.

Duties of Generators

10. (1) A generator must—

(a) provide designated areas for the segregation of health care risk waste from other waste streams at the point of generation;

(b) demonstrate the safe management of the health care risk waste generated through on-site treatment records or written agreement with a waste contractor licenced in terms of the Act to treat health care risk waste;

(c) not release health care risk waste for treatment unless that waste is packaged and labelled in accordance with the requirements set out in Part 3 of these Regulations;

(d) not release health care risk waste from a major generator for treatment unless that health care risk waste is weighed;

(e) not release health care risk waste without initiating the waste manifest documentation as contemplated in Regulation 9(1) of these Regulations.

Duties of Transporters

11. (1) A transporter must —

(a) not accept health care risk waste from a major generator, unless that health care risk waste has been segregated, packaged, labelled and weighed in accordance with the requirements set out in Part 3 of these Regulations;

(b) not accept health care risk waste from a minor generator unless that waste has been segregated, packaged and labelled in accordance with the requirements set out in Part 3 of these Regulations;

(c) not accept health care risk waste for transport unless the manifest document accompanies the waste; and

(d) only transport health care risk waste to a storage or treatment facility licensed in terms of the Act.

Duties of Waste Managers

12.(1) A waste manager must—

(a) not accept health care risk waste that is not packaged, weighed and labelled in accordance with the requirements set out in Regulation 5, 6 and 7 of these Regulations;

(b) comply with the waste manifest system requirements set out in the Waste Classification and Management Regulations, 2011;

(c) operate a non-combustion treatment in accordance with the Standard for Validation of the Treatment Efficacy and Operation of a Non-combustion Health Care Risk Waste Treatment Facility published in terms of section 7 of the Act; and

(d) operate an incinerator in accordance with the requirements of section 21 of the National Environmental Management: Air Quality Act, 2004 (Act No 39 of 2004);

(e) not manually load the devise with health care risk waste for treatment;

(f) treat human anatomical waste and suction canisters by incineration;

(g) treat low-level radioactive waste by incineration that, in addition to the relevant environmental authorisations, has the relevant approval from the Department of Health;

(h) release effluent from the premises into sewer unless authorised to do so by the competent authority;

(2) Any residue from a health care risk waste treatment process must be-

(a) smaller than 80mm with no particle exceeding 80mm in any dimension; and

(b) disposed of through a waste disposal facility licensed in terms of the Act.

PART 5
GENERAL MATTERS

Implementation and Transitional Provisions

13.(1) New and existing incinerators must comply with the new plant emission standards published in terms of section 21 of the National Environment Management: Air Quality Act, 2004 (Act No 39 of 2004) within 3 (three) years from the date of coming into operation these Regulations.

(2) New non-combustion health care risk waste treatment facilities must comply with the Standard for Validation of the Treatment Efficacy and Operation of a Non-combustion Health Care Risk Waste Treatment Facility published in terms of section 7 of the Act on the date of coming into operation of these Regulations.

(3) Existing non-combustion health care risk waste treatment facilities must comply with the Standard for Validation of the Treatment Efficacy and Operation of a Non-combustion Health Care Risk Waste Treatment Facility published in terms of section 7 of the Act within 3 (three) months from the date of coming into operation of these regulations.

(4) The automated loading requirements as set out in regulation 12(1)(e) shall come into operation 2 (two) years after the date of coming into operation of these Regulations.

(5) The shredder requirements as set out in regulation 12(2), (3) and (4) shall come into operation 1 (one) year after the date of coming into operation of these Regulations.

Offences and Penalties

14.(1) A person is committing an offence if that person

(a) contravenes or fails to comply with the provisions of Regulations 4, 5, 6, 7, 8, 9, 10, 11, 12 and 13.

(b) provides incorrect or misleading information in any record or document required or submitted in terms of these Regulations.

(2) A person who commits an offence referred to in sub-regulation (1) is liable on conviction to-

(a) imprisonment for a period not exceeding 15 years;

(b) an appropriate fine; or

(c) both a fine and imprisonment.

(3) A fine contemplated in sub-regulation (2), must be determined with due consideration of—

(a) the severity of the offence in terms of its impact or potential impact on health, well-being, safety and the environment; and

(b) the monetary or other benefits that accrued to the convicted person through the commission of the offence.

Short Title and Commencement

15.(1) These Regulations shall be called National Health Care Risk Waste Management Regulations, 2012 and take effect on a date determined by the Minister by notice in the Government Gazette.

ANNEXURE-1

STANDARDS FOR THE OPENING, CLEANING AND DECONTAMINATION OF REUSABLE CONTAINERS

1. Decontamination standard

(1) As a minimum decontamination standards must equal:

(a) total coli form count less than 100 colony forming units; and

(b) *Staphylococcus aureus* and *Escherichia coli* not detected

2. Preparation of an operating protocol

(1) A written operating protocol must be developed by an independent competent person for the cleaning and decontamination of reusable containers used for the storage or transportation of health care risk waste and must include the details of:

(a) the cleaning methodologies to be used;

(b) the monitoring protocol to be followed;

(c) training of relevant personnel to ensure effective cleaning and safe working procedures to prevent injuries from sharps or biohazards; and

(d) actions to be taken when cleaning fails to meet the decontamination standard.

(2) The cleaning of associated vehicle and handling equipment is to be included in the operating protocol to ensure the cleanliness of reusable containers is maintained.

3. Procedures for opening reusable containers

(1) Reusable containers used for the storage or transportation of health care risk waste must be opened, using methods which:

(a) protect operators and handlers from injuries or disease risks; and

(b) ensure the integrity and functionality of the container before they are re-used.

(2) Reusable sharps containers must be opened using methods which are mechanical and in no way require manual handling;

4. Minimum requirements for monitoring

(1) Sampling and analysis of the efficiency of the cleaning and decontamination procedures for reusable sharps and health care risk waste containers and vehicles used to transport the waste must be undertaken as follows:

(a) swab testing must be undertaken by an independent competent person, randomly once per quarter;

(b) swab testing must be undertaken on at least 5% of the reusable containers cleaned within a hour, based on a monthly average;

(c) swab testing must be undertaken on at least 3 (three) trucks used to transport the waste;

(d) by taking a minimum of 3 (three) swab samples per container and per truck after decontamination; and

(e) swab samples must be sent to an independent laboratory for analysis.