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GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF ENVIRONMENTAL AFFAIRS

NO. 463 **30 APRIL 2018**

NATIONAL ENVIRONMENTAL MANAGEMENT: WASTE ACT, 2008 (ACT NO. 59 OF 2008)

PROPOSED NATIONAL HEALTH CARE RISK WASTE MANAGEMENT REGULATIONS

I, Bomo Edna Edith Molewa, Minister Environmental Affairs, hereby give notice of my intention to make regulations regarding health care risk waste, in terms of section 69(1)(b), (g), (h), (q), (r), (s), (dd), and (ee) read with sections 72 and 73 of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), set out in the Schedule hereto.

Members of the public are invited to submit to the Minister, within 30 days of the publication of this notice in the *Gazette*, written representations or inputs to the following addresses:

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

By hand at: Reception, Environment House, 473 Steve Biko Road, Arcadia, Pretoria, 0083.
By e-mail: scostley@environment.gov.za

The draft Regulations on Health Care Risk Waste can also be accessed at [illegible] under "Draft documents for comment".

Any inquiries in connection with the Regulations and Norms and Standards can be directed to Dr Shauna Costley at 012 399 9775.

Comments received after the closing date may not be considered.

BOMO EDNA EDITH MOLEWA
MINISTER OF ENVIRONMENTAL AFFAIRS

SCHEDULE

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CHAPTER 1

DEFINITIONS, PURPOSE AND APPLICATION

Definitions

1. In these Regulations, unless the context indicates otherwise, any word or expression that is defined in the Act has the same meaning in these Regulations, and in addition—

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

'body fluids' means liquid emanating or derived from humans and includes—

(a) blood and blood components;

(b) cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, dialysate and amniotic fluid, semen, pus, drainage, vaginal secretion; or

(c) body fluids that are contaminated with blood, that are in containers or that drip freely or could be released in a liquid or semi-liquid state from soaked solid wastes items;

but excludes faeces, urine, nasal secretions, sputum, sweat, tears, semen, vaginal secretion, vomitus, saliva and breast milk unless such excluded substances contain visible blood or is isolation waste;

'chemical waste' means discarded solid, liquid and gaseous chemicals used in providing a health care service and includes but is not limited to—

(a) pharmaceutical waste;

(b) hazardous waste from diagnostic and experimental work; and

(c) hazardous waste used in cleaning, housekeeping and disinfecting;

'competent authority' means a local, provincial or national authority responsible for the management of waste;

'container' means a disposable or reusable vessel in which health care risk waste is placed for the purpose of storing, accumulating, handling, transporting, treating or disposing of that waste;

'crime or accident scene clean-up waste' means health care risk waste generated by commercial entities hired to clean up crime or accident scenes;

'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 and **'decontaminated'** has the corresponding meaning;

'domestic generator' means—

(a) a household generator; or

(b) other generator;

who generates less than one kilogram per day of health care risk waste calculated monthly as a daily average;

'genotoxic waste' means hazardous waste that may have mutagenic, teratogenic or carcinogenic properties and includes but is not limited to certain cytostatic drugs as well as vomit, urine, or faeces from patients treated with cytostatic drugs, chemicals and radioactive material;

'generator' means a person, whose actions, or activities result in the generation of health care risk waste and includes but is not limited to—

(a) home based care givers or organisations;

(b) medical and dental practitioners;

(c) alternative health practitioners;

(d) clinics, hospitals or surgery centres;

(e) medical laboratories and tertiary medical institutions;

(f) pharmacies;

(g) rehabilitation centres;

(h) veterinary practitioners, animal clinics and hospitals;

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

(j) emergency medical services;

(k) crime or accident scene clean-up contractors;

(l) frail care centres;

(m) facilities catering for the disabled; and

(n) tattoo artists and body piercers;

but does not include a domestic generator;

'health care risk waste' means any waste which is produced in the diagnosis, treatment or immunization of human beings or animals, or waste that has been in contact with blood, body fluids or tissues from humans, or infected animals from veterinary practices and includes but is not limited to the following categories—

(a) infectious waste;

(b) pathological waste;

(c) laboratory waste;

(d) genotoxic waste;

(e) sharps waste;

(f) chemical waste;

(g) pharmaceutical waste; and

(h) radioactive waste;

but does not include nappy and sanitary wastes unless such wastes are isolation waste;

'infectious agent' means microorganisms including bacteria, mycobacterium, fungi, parasites, or viruses which normally cause, or significantly contribute 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 vomit, urine, or faeces from patients treated with cytostatic drugs; genotoxic substances or chemicals which have mutagenic, tetrogenic or carcinogenic properties; discarded bedding contaminated with blood or any body fluid; crime or accident scene clean-up waste; laboratory waste and isolation waste but excludes pathological waste;

'interim storage container' means a plastic bag in direct contact with, holding or securing health care risk waste and includes double bagged health care risk waste;

'isolation waste' means waste containing discarded materials contaminated with excreta, exudates, or secretions or materials generated in the treatment and diagnosis of humans or animals who are required to be isolated (by the infection control staff, the attending doctor, the attending veterinarian or the local health practitioner), in order to protect others from highly communicable or zoonotic diseases and includes nappy waste or sanitary waste from such sources;

'labelled' means the appearance or attachment of any brand, mark or imprint or any written, pictorial or other descriptive matter to a container;

'labelling' means the process of attaching any brand, mark or imprint or any written, pictorial or other descriptive matter to a container;

'laboratory waste' means waste generated from laboratory work that contains or may be reasonably presumed to contain infectious agents in sufficient concentrations or quantities to cause disease in susceptible hosts and includes, but is not limited to—

(a) discarded human or animal specimen cultures from health care and pathological laboratories;

(b) discarded cultures and stocks of infectious agents from research and industrial laboratories;

(c) wastes from the production of bacteria, viruses, or the use of spores, discarded, live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate and mix cultures; and

(d) waste containing any microbiological specimens sent to a laboratory for analysis;

'liner' means a disposable plastic bag that forms an integral part of a rigid container;

'major generator' means a generator of health care risk waste that generates in excess of 20 kilograms (including the weight of the container) per day calculated monthly as a daily average;

'minor generator' means a generator of health care risk waste that generates up to 20 kilograms (including the weight of the container) per day calculated monthly as a daily average but does not include a domestic generator;

'nappy waste' means soiled nappies or incontinence products;

'National Environmental Management: Air Quality Act' means the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004);

'National Waste Information Regulations' means the National Waste Information Regulations, 2012, published under Government Notice No. R. 625 in *Gazette* No. 35583 of 13 August 2012, as amended or replaced from time to time;

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

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

'packaged' means enclosed in a container;

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

'pathological waste' means—

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

(b) recognisable human body parts also known as anatomical waste;

(c) non-viable foetus; and

(d) deceased animals or animal body parts infected with zoonotic disease;

but excludes hair, nails and teeth;

'pharmaceutical waste' means expired, unused, spilt or contaminated pharmaceutical products, drugs, vaccines and sera which are no longer usable in human or animal treatment and includes items contaminated by or items contaminated with cytotoxic drugs;

'radioactive waste' means solid, liquid, and gaseous materials contaminated with radionuclides, including waste produced as a result of procedures such as *in-vitro* analysis of body tissue and fluid, *in-vivo* organ imaging and tumour localization, and various investigative and therapeutic practices;

'rigid' means, with respect to containers, unable to bend or to be forced out of shape;

'sanitary waste' means soiled napkins, towels, pads and tampons;

'SANS 10248-1' means the latest edition of 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 latest edition of the South African National Standard for Non-reusable and Reusable Sharps Containers;

'sealed' means, with respect to containers, securely closed to minimise the risk of contamination or pollution of the environment or to prevent uncontrolled access to the waste and that cannot be reopened without major structural damage to the container;

'segregated' means to separate the health care risk waste into designated categories at the point of generation;

'sharps waste' means health care risk waste having acute rigid corners, edges or protuberances capable of cutting, piercing or puncturing, including but not limited to—

(a) human teeth;

(b) needles;

(c) surgical, scalpel and razor blades;

(d) pasteur pipettes, capillary tubes;

(e) slides and cover slips;

(f) shards of contaminated glass, and any other sharps items derived from human or animal patient care, blood banks, laboratories, mortuaries, research facilities and industrial operations;

(g) sharps used on human beings or animals for other than medical procedures, such as sharps used for cosmetic treatment, training purposes, circumcision or embalming procedures; and

(h) sharps used in the course of injection or physically altering a human including tattooing, ear piercing and any other process where a foreign object is used to cut or piece the skin;

'storage area' means a room, delineated area or designated space used for storage of health care risk waste within a building, or on any permanent structure attached or unattached to a building, prior to treatment;

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

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

'unrecognisable' means waste that is unidentifiable in terms of its medical origin and of its purpose, and is unfit for reuse;

'Waste Classification and Management Regulations' means the Waste Classification and Management Regulations, 2013, published under Government Notice R634 in *Gazette* No. 36784 of 23 August 2013 as amended or replaced from time to time;

'waste manager' means the person who manages the operation of a waste treatment facility;

'waste manifest system' means a system of control documentation in terms of the Waste Classification and Management Regulations, 2013;

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

'waste transporter' means a person who transports health care risk waste from the point of generation to any temporary or permanent point of storage, treatment or disposal;

'zoonotic disease' means an infectious disease of animals that can cause disease when transmitted to humans.

Purpose

2. The purpose of these Regulations is to—

(a) regulate the management of health care risk waste in a manner which supports and implements the provisions of the Act;

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

(d) prescribe general duties of waste generators, waste transporters and waste managers.

Application

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

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

CHAPTER 2

GENERAL PROHIBITIONS

General Prohibitions

4. No person may—

(a) dispose of untreated infectious, laboratory, pathological or sharps waste to land unless authorised to do so by the Minister;

(b) discharge health care risk waste to municipal sewer without approval from the municipality in whose area of jurisdiction the activity is conducted, including the requirements of the National Water Act, 1998 relating to wastewater discharge;

(c) place health care risk waste into a container that does not comply with the packaging requirements of SANS 10248;

(d) manually lift a container of health care risk waste weighing in excess of 15 kilograms including the container;

(e) transport health care risk waste over distances exceeding 50 metres unless it is protected by a rigid container;

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

(g) treat health care risk waste at a waste treatment facility not designed to accept and treat such waste; or

(h) dispose of waste residue to a waste disposal facility not authorised to accept such waste.

CHAPTER 3

SEGREGATION, PACKAGING, LABELLING AND STORAGE

Segregation

5. (1) Health care risk waste must be separated from general waste at the point of generation.

(2) Health care risk waste must be segregated in accordance with SANS 10248-1.

Packaging

6. (1) Health care risk waste must be packaged in containers which are colour coded and marked in accordance with SANS 10248-1.

(2) Internal surfaces of a reusable container, excluding reusable sharps containers, must be protected by a liner.

(3) Liners or interim storage containers used for the packaging of health care risk waste must be managed as health care risk waste and must not be reused.

(4) Non-reusable and reusable sharps containers must be designed and constructed in accordance with SANS 452.

(5) Reusable containers must be thoroughly cleaned and decontaminated prior to reuse.

(6) Reusable sharps containers must be decontaminated in accordance with SANS 452.

Labelling

7. (1) Health care risk waste must be packaged in containers that clearly indicate the contents in accordance with SANS 10248-1.

(2) Containers excluding liners and interim storage containers must be labelled in line with the Waste Classification and Management Regulations.

(3) A major generator must ensure that the labelling contemplated in subregulation (2) indicates the waste information registration number in accordance with the National Waste Information Regulations.

(4) A minor generator must ensure that the labelling contemplated in subregulation (2) indicates that the contents were generated by a minor generator.

Storage

8. A storage area used for storing health care risk waste must as a minimum—

(a) where a separate storage room is used, be inaccessible to unauthorised persons;

(b) be secured by use of locks on entry doors or gates or container lids;

(c) be sheltered from direct sunlight and rain;

(d) be appropriately ventilated;

(e) be vermin proof;

(f) have access to a spill containment and clean-up kit;

(g) have access to water to facilitate cleaning;

(h) have an appropriate wastewater management system;

(i) have adequate space for storing clean and dirty containers separately; and

(j) be clearly signposted with appropriate warning signs on, or adjacent to, the exterior of the entry doors or gates, or on the containers.

CHAPTER 4

DUTIES OF A GENERATOR, A WASTE TRANSPORTER AND A WASTE MANAGER

General Duties

9. (1) Every holder of health care risk waste must—

(a) take reasonable measures to ensure that once health care risk waste is placed in a container, it is not removed from that container–

(i) in order to decant it into another container;

(ii) to sort it; or

(iii) for any other purpose,

until that health care risk waste is received by a suitably licensed waste management facility.

(b) comply with the waste manifest system as contemplated in the Waste Classification and Management Regulations;

(c) have a spill response plan in place; and

(d) provide training to employees who are involved in the management of health care risk waste to ensure the following principles and practices are understood and implemented, namely–

(i) health care waste segregation;

(ii) best infection control practices;

(iii) waste minimisation; and

(iv) improved environmental awareness.

(2) Major generators, waste transporters and waste managers must keep accurate and up to date records which must:

(a) reflect the quantities of health care risk waste generated, transported, treated or disposed;

(b) be retained for a period of five years; and

(c) be made available to the competent authority upon request.

(3) Notwithstanding the storage timeframes provided in these Regulations if health care risk waste poses a nuisance the holder of the waste must ensure it is removed, transported and/or treated immediately.

Duties of a Generator

10. A generator must—

(a) ensure health care risk waste is segregated, packaged, labelled and stored in accordance with regulations 5, 6, 7 and 8 before releasing the waste to a waste transporter;

(b) in the case of major generators, not release health care risk waste unless that health care risk waste is weighed on site by the generator or the waste transporter;

(c) only release health care risk waste to a transporter with a vehicle acceptable for such use;

(d) ensure that liners and interim storage containers used at the source of generation are packaged in rigid containers prior to release to a waste transporter;

(e) store infectious waste for no longer than 14 days from the date the container is sealed to the date of collection by a waste transporter unless stored at a maximum temperature of -2°C, in which case the waste must be collected within 30 days from the date the container is sealed;

(f) store pathological waste prior to collection by a waste transporter for no longer than 72 hours from the date the container is sealed if stored unrefrigerated, for no longer than seven days from the date the container is sealed if stored at a temperature between 4°C and -1°C, or for no longer than 30 days from the date the container is sealed if stored at a maximum temperature of -2°C;

(g) store sharps waste, chemical waste or pharmaceutical waste for no longer than 30 days from the date the container is sealed to the date of collection by a waste transporter;

(h) in the case of all other health care risk waste, storage must not exceed 14 days from the date the container is sealed;

(i) ensure that isolation waste is stored in an access controlled area prior to collection by a waste transporter; and

(j) ensure that health care risk waste is treated and/or disposed of by an authorised waste treatment and/or disposal facility.

Duties of a Waste transporter

11. (1) A waste transporter who stores health care risk waste is an operator of a waste transfer facility for the purposes of these Regulations.

(2) A waste transporter must—

(a) not accept health care risk waste from a generator, unless that health care risk waste has been packaged and labelled in accordance with regulations 6 and 7;

(b) not accept health care risk waste from a major generator unless that waste has been weighed in accordance with regulation 10(b);

(c) transport health care risk waste to a waste transfer, waste treatment or waste disposal facility authorised to accept such waste;

(d) ensure that health care risk waste stored at a waste transfer facility before releasing the waste for treatment, is stored in accordance with the requirements set out in regulation 8;

(e) store infectious waste, at a waste transfer facility, for no longer than 48 hours from the date of collection from the generator to the date of delivery at a waste treatment facility unless stored at a maximum temperature of -2°C, in which case the waste must be delivered at a waste treatment facility within 30 days from the date of collection from the generator;

(f) store pathological waste, at a waste transfer facility, for no longer than 24 hours from the date of collection from the generator to the date of delivery at a waste treatment facility unless stored at a maximum temperature of -2°C, in which case the waste must be delivered at a waste treatment facility within 30 days from the date of collection from the generator;

(g) store sharps waste, chemical waste or pharmaceutical waste, at a waste transfer facility, for no longer than 30 days from the date of collection from the generator to the date of delivery at a waste treatment or waste disposal facility;

(h) store health care risk waste in a vehicle suitable to transport such waste only if such vehicle is parked at a secure location;

(i) store health care risk waste in a vehicle suitable to transport such waste for no longer than 72 hours;

(j) thoroughly clean and decontaminate any vehicle used to transport health care risk waste to an aesthetically acceptable level; and

(k) develop, document and implement procedures specific to the management of health care risk waste received at a waste transfer facility which shall be made available to the competent authority on request and shall include, but not be limited to –

(i) a description of the types and volumes of health care risk waste stored on site;

(ii) the length of time health care risk waste is stored on site prior to transport to a treatment and/or disposal facility;

(iii) details of the treatment or disposal facility to which the health care risk waste is transported;

(iv) a description of the storage areas on site; and

(v) details of a cold room or refrigeration unit used to store infectious and pathological waste.

Duties of a Waste Manager

12. A waste manager must—

(a) not accept health care risk waste from a waste transporter unless that waste is packaged and labelled in accordance with regulations 5, 6 and 7;

(b) not accept health care risk waste unless a waste manifest document accompanies the waste in accordance with regulation 9(1)(a);

(c) weigh the quantity of health care risk waste received;

(d) comply with the waste manifest document requirements in accordance with regulation 9(1)(a);

(e) store infectious waste for no longer than 72 hours from the date of arrival at the waste treatment facility unless the waste is stored at a maximum temperature of -2°C, in which case the waste must be treated within 30 days from the date of arrival on site;

(f) store pathological waste for no longer than 24 hours from the date of arrival at the waste treatment facility unless the pathological waste is stored at a maximum temperature of -2°C, in which case the waste must be treated on site or sent to a suitably authorised waste treatment facility within 30 days from the date of arrival on site;

(g) store sharps, chemical or pharmaceutical waste for no longer than 30 days from the date of arrival at the waste treatment facility to the date of treatment on-site or to the date of transport to a suitably authorised waste treatment and/or waste disposal facility;

(h) minimise manual handling of containers when loading the treatment technology;

(i) ensure the integrity and functionality of any reusable containers handled on site are not damaged when opened and loaded into the treatment technology;

(j) ensure that reusable sharps containers are only opened using methods which are mechanised;

(k) treat human pathological waste by incineration;

(l) operate a non-combustion treatment technology in accordance with the Norms and Standards for the Validation of the Treatment Efficacy and Operation of a Non-combustion Treatment Technology Used to Treat Health Care Risk Waste;

(m) operate an incinerator in accordance with the National Environmental Management: Air Quality Act;

(n) ensure the waste residue resulting from the treatment of health care risk waste is rendered unrecognisable;

(o) deem the waste residue to be hazardous waste unless otherwise classified in terms of the Waste Classification and Management Regulations;

(p) ensure waste residue is managed by an authorised waste treatment or disposal facility; and

(q) develop, document and implement procedures specific to the management of health care risk waste received on site which shall be made available to the competent authority on request and shall include, but not be limited to—

(i) a description of the types and volumes of health care risk waste received and treated on site;

(ii) a description of the types and volumes of health care risk waste sent off-site for treatment;

(iii) details of the off-site waste treatment and/or waste disposal facility;

(iv) a description of the radiation detection system in place and the contingency plan in the event that radiation levels above background level are detected in waste loads delivered for treatment;

(v) a description of the storage areas;

(vi) the length of time health care risk waste is stored prior to treatment or transport off-site;

(vii) volume and composition of the waste residue emanating from the treatment system;

(viii) details of the waste management facility where waste residue is sent;

(ix) details of the routine maintenance conducted on site; and

(x) details of action taken during unplanned shutdowns.

CHAPTER 5

GENERAL MATTERS

Offences and Penalties

13. (1) A person commits an offence if that person—

(a) contravenes or fails to comply with a provision of regulations 4, 5, 6, 7, 8, 9, 10, 11 and 12; or

(b) supplies false 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 subregulation (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 subregulation (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

14. (1) With the exception of regulations 6, 7, 8 and 10(e), (f) and (g), these Regulations take effect on the date of publication in the Gazette.

(2) Regulations 6, 7, 8 and 10(e), (f) and (g) take effect six months after the date of commencement of these Regulations.

(3) These Regulations are called the National Health Care Risk Waste Management Regulations, 2018.

DEPARTMENT OF ENVIRONMENTAL AFFAIRS

NO. 464 30 APRIL 2018

NATIONAL ENVIRONMENTAL MANAGEMENT: WASTE ACT, 2008 (ACT NO. 59 OF 2008)

NATIONAL NORMS AND STANDARDS FOR VALIDATION OF THE TREATMENT EFFICACY AND OPERATION OF A NON-COMBUSTION TREATMENT TECHNOLOGY USED TO TREAT HEALTH CARE RISK WASTE

I, Bomo Edna Edith Molewa, Minister of Environmental Affairs, hereby give notice of my intention to make the national norms and standards for the validation of the treatment efficacy and operation of a non-combustion treatment technology used to treat health care risk waste, in terms of section 7(1)(c) read with sections 72 and 73 of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), hereby set out in the Schedule hereto.

Members of the public are invite to submit to the Minister, within 30 days of publication of this notice in the *Gazette*, written representations or inputs to the following addresses:

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

By hand at: Reception, Environment House, 473 Steve Biko Road, Arcadia, Pretoria, 0083
By e-mail:
The draft Regulations on Health Care Risk Waste can also be accessed at http://sawic.environment.gov.za under "Draft documents for comment".

Any inquiries in connection with the notice can be directed to Dr Shauna Costley at 012 399 9775.

Comments received after the closing date may not be considered.

BOMO EDNA EDITH MOLEWA
MINISTER OF ENVIRONMENTAL AFFAIRS

SCHEDULE

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CHAPTER 1

DEFINITIONS, PURPOSE AND APPLICATION

Definitions

1. In these Norms and Standards, unless the context indicates otherwise, a word or expression that is defined in the Act has the same meaning in these Norms and Standards, and in addition—

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

'**bioaerosol emissions**' means a suspension of airborne particles that contain living organisms;

'**biological agent**' means any micro-organism, cell culture or human endoparasite, including any which have been genetically modified, which may cause any infection, allergy or toxicity, or otherwise create a hazard to human health;

'**biological indicator**' means a characterized preparation of a specific population of microorganisms that are resistant to a set of measurable and controlled parameters;

'**challenge load**' means a mixture and quantity of health care risk waste treated in one load that is a considerable challenge to the capacity and functioning constraints of a treatment technology;

'**control indicator**' means a biological indicator which does not undergo treatment but is incubated with the test indicators to confirm the viability of the test indicators prior to treatment;

'**control trial**' means a test using surrogate waste to confirm the operational parameters and disinfection level of a treatment technology;

'**disinfection**' means to render non-viable potential human and animal pathogens, but not necessarily all microbial forms;

'**existing non-combustion treatment facility**' means any non-combustion waste treatment facility that was legally authorized to operate before the date on which these Norms and Standards take effect;

'**competent microbiologist**' means a person qualified and working in the field of microbiology, independent of the system manufacturer and the waste treatment facility;

'**competent person**' means a person qualified and working in the field of waste management, independent of the system manufacturer and the waste treatment facility;

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

'**operating parameters**' means the specific conditions of pressure, temperature, residence time, chemical concentration and any other physical or engineering conditions that a treatment technology must operate at to ensure effective disinfection of health care risk waste;

'**Regulations**' means the National Health Care Risk Waste Management Regulations;

'routine validation testing' means testing conducted during daily operation of a treatment technology, the purpose of which is to demonstrate the effective disinfection of health care risk waste;

'site commissioning validation testing' means testing conducted on installation of a treatment technology, the purpose of which is to demonstrate the effective disinfection of health care risk waste at the design specifications of the treatment technology;

'surrogate waste' means selected general waste which has the approximate properties of health care risk waste;

'test indicators' means biological indicators which are used to confirm the effective disinfection of health care risk waste by the treatment technology;

'test trial' means testing using a challenge load to confirm disinfection of health care risk waste at the design specifications confirmed during the control trial;

'treatment technology' means a non-combustion treatment technology used to treat health care risk waste;

'validation testing' means testing conducted during site commissioning and routine operation of a treatment technology, the purpose of which is to confirm the effective disinfection of health care risk waste;

'Waste Classification and Management Regulations' means the Waste Classification and Management Regulations, 2013;

'waste manager' means the person who supervises the overall operation of the waste treatment facility; and

'waste residue' means material remaining after treatment of health care risk waste using a non-combustion treatment technology.

Purpose

2. The purpose of these National Norms and Standards is to prescribe the minimum requirements for the efficacy testing and operation of a non-combustion treatment technology used to treat health care risk waste.

Application

3. These National Norms and Standards—

(a) apply uniformly throughout the Republic of South Africa;

(b) apply to all non-combustion treatment technologies used to treat health care risk waste;

(c) do not apply to incineration of health care risk waste; and

(d) will apply alongside any applicable waste management licence..

CHAPTER 2

GENERAL EFFICACY REQUIREMENTS

General Efficacy Requirements

4. (1) A treatment technology must as a minimum, achieve a 6 Log10 reduction in viable spore concentration during site commissioning and a 4 Log10 or greater reduction in viable spore concentration during routine operation of, depending on the system manufacturer's specifications, either—

(a) *Geobacillus stearothermophilus* ATCC 7953; or

(b) *Bacillus atrophaeus* ATCC 9372.

(2) The Department may require additional biological indicators as necessary to demonstrate effectiveness of treatment.

(3) The Department may from time to time amend the required level of viable spore concentration reduction and the list of biological indicators set out in subparagraph (1) above, by notice in the *Gazette*.

(4) A non-combustion treatment facility must apply to the Department for approval of any biological indicators which are not listed in subparagraph (1) above, which the non-combustion treatment facility intends to use for testing in terms of subparagraph (1).

(5) The application must be made by submitting details of and reason for use of alternative biological indicators in writing to the Department at least three months prior to testing.

(6) The Department must either approve or reject an application within three months of receiving such as application, and provide written reasons for rejecting any such applications.

CHAPTER 3

VALIDATION TESTING

General Validation Testing

5. (1) Biological indicators used in validation testing must—

(a) conform to the requirements in Chapter 2, paragraph 4;

(b) be located in a full load of health care risk waste;

(c) be placed in the parts of the load that are the most difficult to treat; and

(d) be protected from mechanical damage during testing.

(2) Incubation of the biological and control indicators must be undertaken in accordance with the manufacturer's specifications.

(3) The control indicators used during validation testing must be treated through the treatment technology before disposal.

(4) An auditable process must be in place to ensure all biological indicators used during testing are accounted for.

(5) Operating parameters must be recorded on-line, automatically or electronically.

(6) Instruments monitoring the operation of the treatment technology must be calibrated as per the manufacturer's specifications.

Site Commissioning Validation Testing

6. (1) Prior to routine operation of a treatment technology the waste manager must conduct site commissioning validation testing.

(2) The site commissioning validation testing must, as a minimum—

(a) be undertaken by a competent microbiologist;

(b) employ the relevant spore in accordance with Chapter 2, paragraph 4(1);

(c) confirm the disinfection levels as in Chapter 2, paragraph 4(1) have been reached;

(d) confirm the design specifications of the treatment technology;

(e) commence with a control trial followed by a minimum of three test trials;

(f) use surrogate waste for the control trial;

(g) use a challenge load for the test trials;

(h) use the control trial to determine the most difficult areas of the load of waste to treat;

(i) consider the treated surrogate waste as general waste and dispose of the waste in accordance with the Waste Classification and Management Regulations;

(j) ensure that challenge loads used in the test trials are retreated prior to disposal of the waste in accordance with the Waste Classification and Management Regulations;

(k) for each trial undertaken, use a minimum of eight biological indicators, two of which must be used as control indicators;

(l) recover a minimum of six undamaged test indicators after each trial for the results to be valid otherwise the trial must be repeated; and

(m) demonstrate that bioaerosol emissions from the treatment technology are controlled during operation.

(3) A waste manager must submit an operational plan within 60 days after completion of the site commissioning validation testing to the Department.

(4) The operational plan must as a minimum—

(a) be signed by a waste manager;

(b) be compiled by a competent person who may be the microbiologist who conducted the site commissioning validation testing;

(c) provide details of the microbiologist who conducted the site commissioning validation testing;

(d) document the site commissioning validation testing procedure undertaken;

(e) document the site commissioning validation testing results;

(f) confirm the treatment efficacy of the treatment technology at the design specifications provided;

(g) document the operating parameters of the treatment technology to be followed during routine operation;

(h) provide details of how the challenge load was determined;

(i) provide details on how the most difficult areas of a load to treat were identified;

(j) provide details of the waste used during the site commissioning validation testing process;

(k) document the spore, lot number, expiry date; d-value and concentration of the biological indicators used;

(l) document the auditable process developed to ensure all biological indicators used during testing are accounted for;

(m) provide details of bio-aerosol emissions from the treatment technology and proposals for routine monitoring of the emissions;

(n) document the system that will be used to record the operating parameters during routine operation;

(o) provide details of where the waste residue generated during site commissioning was disposed of and where waste residue generated during routine operation will be disposed of;

(p) document the types of health care risk waste that will be treated by the treatment technology;

(q) document the procedures for and frequency of routine validation testing;

(r) document the procedures for and frequency of calibration of parametric controls; and

(s) document the procedures to be followed during system failure.

(5) The Department may request further validation testing to be conducted.

(6) The operational plan must, as a minimum, be reviewed after the re-validation testing set out in paragraph 9.

(7) Any modification of the operational plan must be submitted to the Department.

Routine Validation Testing

7. (1) Routine validation testing must be undertaken at least twice a day using, as a minimum, three test indicators and one control indicator per routine validation test.

(2) A minimum of three undamaged test indicators must be recovered after a routine validation test for the results to be valid otherwise the test must be repeated.

(3) A monthly report of the results of the routine validation testing must be submitted to the Department.

(4) Biological indicators used during routine validation testing must be made available to the competent microbiologist during the independent validation testing as in paragraph 8.

Independent Validation Testing

8. (1) Independent validation testing must—

(a) be conducted every three months;

(b) be conducted by a competent microbiologist;

(c) use a minimum of three test indicators and one control indicator per routine validation test;

(d) recover a minimum of three undamaged test indicators after a routine validation test for the results to be valid otherwise the routine validation test must be repeated.

(e) be repeated in three separate cycles in a batch system or every two hours until three routine validation tests have been conducted for a semi-continuous or continuous system; and

(f) be conducted within a consecutive eight hour period.

(2) The results of the independent validation testing contemplated in subparagraph (1) above must be submitted within 30 days after completion to the Department.

(3) The independent validation testing contemplated in subparagraph (1) above must—

(a) indicate whether the required disinfection levels are obtained;

(b) indicate whether the operating parameters are being met;

(c) identify any non-conformances and indicate corrective measures taken; and

(d) indicate whether the instruments monitoring operating parameters and scales have been calibrated in accordance with the manufacturer's specifications.

Re-validation Testing

9. (1) Paragraphs 6 (1) and (2) above must be repeated—

(a) if any of the operating parameters are altered;

(b) if any changes are made to the treatment technology; or

(c) if any changes are made to the waste stream being treated; otherwise

(d) every five years during the operational life of the treatment technology.

(2) A validation testing report outlining the re-validation testing conducted and demonstrating that the general efficacy requirements as in Chapter 2, paragraph 4 are being met, must be submitted within 30 days after completion to the Department.

(3) The Department may require further validation testing to be conducted or may request further information.

CHAPTER 4

GENERAL MATTERS

Waste Residue

10. (1) Any waste residue from a treatment technology must—

(a) be shredded; and

(b) be unrecognisable.

System failure

11. (1) If one or more of the biological indicators indicate growth the waste manager must—

(a) conduct troubleshooting to determine the source of the problem;

(b) handle all health care risk waste processed by the treatment technology during the failure as untreated and retreat it to the prescribed minimum requirements as in Chapter 2, paragraph 4; and

(c) repeat routine validation testing until three consecutive validation tests show no growth of test indicators.

(2) A waste manager, should a parameter fail during operations, must—

(a) cease operation of the treatment technology, using emergency shutdown procedures if appropriate, until corrective action is taken and operating parameters are verified through validation testing;

(b) conduct an analytical investigation with regard to the cause of the parameter failure before resuming treatment operations; and

(c) handle all health care risk waste processed by the system during the failure as untreated and retreat it to the prescribed minimum requirements specified in chapter 2, paragraph 4.

(3) A waste manager must—

(a) have a backup plan in place outlining the process to be followed when there is system failure;

(b) have a process in place to document system failure and action taken;

(c) inform the Department in writing within 24 hours of system failure; and

(d) inform the Department in writing within 24 hours of resumption of operations detailing the corrective actions taken.

Record Keeping

12. Records of all validation testing and system failure contemplated in paragraphs 6, 7, 8, 9, 10 and 11 must be—

(a) retained for a period of at least five years; and

(b) made available to the Department on request.

Implementation and Transitional Arrangements

13. A person who lawfully operated a non-combustion treatment facility to treat health care risk waste prior to and on the date of coming into operation of these Norms and Standards may continue with the activity as per the conditions stipulated in the waste management licence, and after renewal or review of the waste management licence must comply with these Norms and Standards and the waste management licence.