GAUTENG PROVINCE

DEPARTMENT OF AGRICULTURE, CONSERVATION AND ENVIRONMENT

ENVIRONMENT CONSERVATION ACT, 1989
(ACT NO. 73 OF 1989) –

GAUTENG HEALTH CARE WASTE MANAGEMENT REGULATIONS, 2004

The Member of the Executive Council responsible for Agriculture, Conservation and Environment has under section 24(c) of the Environment Conservation Act, 1989 (Act No. 73 of 1989), made the regulations in the Schedule.

SCHEDULE

ARRANGEMENT OF REGULATIONS

CHAPTER 1
DEFINITIONS

Definitions

1. In these Regulations unless the context indicates otherwise a word or expression that is defined in the Environment Conservation Act, 1989 (Act No. 73 of 1989) has the same meaning in these Regulations, and in addition–

'**animal**' means an animal kept at laboratory for the purposes of biological or scientific research and testing;
'**authorisation**' means the written authorisation issued by the Department in terms of these Regulations and '**authorised**' has a corresponding meaning;
'**CEO**' means-

(a) in the case of a natural person, that person or his or her duly authorised representative
(b) in the case of a partnership, a partner or duly authorised representative of the partnership;
(c) in the case of a juristic person,
  (i) the chief executive officer or equivalent officer of the juristic person or his or her duly authorised representative; or
  (ii) the person who is acting as such or his or her duly authorised representative;

'**challenge load**' means an amount of health care risk waste treated in one load that is a considerable challenge to the capacity and functioning constraints of a treatment facility;
'**chemical waste**' means waste which consists of discarded solid, liquid, and gaseous chemicals, including but not limited to-

(a) pharmaceutical waste;
(b) hazardous waste from diagnostic and experimental work; and
(c) hazardous waste from cleaning, housekeeping, and disinfecting procedures;

'**competent person**' means an independent analyst, scientist or professional consultant accredited by a relevant body or who has practical and documented experience that is recognised widely by relevant peers and who is fully capable of carrying out such independent analyses;
'**consignment**' means a load of health care risk waste, comprising of one or more health care risk waste containers, transported by a transporter;

'**controlled combustion treatment**' means any method, technique or process to convert health care risk waste to flue gasses and residues, by means of oxidation at temperatures as specified in Schedule 3, including but not limited to-

(a) oxidation;
(b) pyrolysis gasification; or
(c) plasma processes,

insofar as the substances resulting from the treatment are subsequently incinerated;

'**Department**' means the relevant Provincial Government Department responsible for environmental affairs in the Province;

'**disinfect**' means to render non-viable all recognised pathogenic micro organisms, but not necessarily all microbial forms and '**disinfection**' has the corresponding meaning;

'**domestic generator**' means-

(a) a household; or
(b) other generator;

which generates less than 1 (one) kilogram per day of health care risk waste calculated monthly as a daily average including but not limited to plasters, bandages, nappies or sanitary pads but excluding-

(i) households or facilities which generate health care risk waste such as sharps waste; or
(ii) households where there is one or more chronically ill persons requiring the use of equipment such as a dialysis machine;

'**EIA authorisation**' means a written authorisation granted by the Department in terms of section 22 of the Act;

'**final disposal**' means the ultimate disposal of health care risk waste once the waste has been treated in terms of these Regulations;

'**generator**' means a person, whose acts or processes produce health care waste and includes, but is not limited to-

(a) Household and home based care givers and organisations;
(b) Medical and dental practitioners, clinics, hospitals, surgery centres, laboratories, research laboratories, and General Practitioners;
(c) Veterinary practitioners, animal clinics, and animal hospitals;
(d) Traditional healers; and
(e) Tattoo artists; body piercers, undertakers, and embalmers,

but does not include a domestic generator;

'**genotoxic waste**' includes but is not limited to certain cytostatic drugs, vomit, urine, or faeces from patients treated with cytostatic drugs, genotoxic substances or chemicals which have mutagenic, tetratogenic or carcinogenic properties;

'**hazardous waste**' means waste that may, by circumstances of use, quantity, concentration or inherent physical, chemical or infectious characteristics, cause ill health or increase mortality in humans, fauna and flora, or adversely affect the environment when improperly treated, stored, transported or finally disposed of;

'**health care general waste**' means the non-hazardous component of waste generated by a generator and can include liquids, but excludes-

(a) health care risk waste; and
(b) health care waste generated from isolation wards;

'**health care risk waste**' means waste capable of producing any disease and includes but is not limited to the following:

(a) laboratory waste;
(b) pathological waste;
(c) isolation waste;
(d) genotoxic waste;
(e) infectious liquids and infectious waste;
(f) sharps waste;
(g) chemical waste; and
(h) pharmaceutical waste;

'**health care risk waste container**' means a rigid puncture resistant and leak resistant receptacle in which health care risk waste is placed;

'**health care risk waste inspector**' means a person duly appointed as such in terms of regulation 41(1);

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

'**health care waste officer**' means the person at a major generator appointed as such in terms of regulation 6(4);

'**HOD**' means the Head of the Department;

'**home based care**' means the provision of health services by formal and informal caregivers in the home in order to promote, restore and maintain a person's maximum level of comfort, function and health, including care for the duration that that person suffers from an illness or disease;

'**infectious agent**' means a type of micro organism including spores, bacteria, fungi, a parasite, or a virus which normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings;

'**infectious waste**' means waste which is-

(a) suspected to contain pathogens; and
(b) which normally causes, or significantly contributes to the cause of increased morbidity or mortality of human beings;

but excludes baby-nappies and sanitary pads which are not isolation waste;

'**internal transport**' means the movement of health care risk waste from one point within any premises or facility to another point within that premises or facility;

'**isolation waste**' means waste containing discarded materials contaminated with excretion, exudates, or secretions from humans or animals who or which are required to be isolated (by the infection control staff, the attending physician or surgeon, the attending veterinarian, or the local health practitioner,) in order to protect others from highly communicable or zoonotic diseases;

'**laboratory waste**' means-

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

'**leak resistant receptacle**' means a receptacle which is constructed of impermeable material, and which has no side or bottom openings, and which has a strength sufficient

to preclude ripping, tearing, or bursting under normal conditions of usage and handling when full;

'**MEC**' means the Member of the Executive Council responsible for the environmental affairs in the Province;

'**major generator**' means a generator that generates more than 20 kilograms per day of health care risk waste, including the container, calculated monthly as a daily average;

'**manage**' means to handle or deal in any way with health care risk waste, including but not limited to; plan for, collect, receive, segregate, containerise, transport, treat or finally dispose of such waste;

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

'**Minimum Requirements for the Handling, Classification and Disposal of Hazardous Waste**' means the Minimum Requirement's document which forms part of the Waste Management Series (second edition), produced by the Department of Water Affairs and Forestry in 1998, as amended from time to time;

'**non-combustion treatment**' means any method, technique or process for microbial inactivation or for otherwise altering the biological, chemical or physical characteristic of health care risk waste so as to sterilize such health care risk waste by any means of technology which does not constitute controlled combustion treatment;

'**non-hazardous waste**' means waste that does not cause an immediate or long term threat to human health or to the environment;

'**Occupational Health and Safety Act**' means the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993);

'**parametric monitoring**' means the monitoring of a treatment facility for compliance with these Regulations using operating parameters such as time, temperature, pressure, or size as an indicator of treatment efficiency;

'**pathological waste**' means-

(a) deceased animals or animal parts infected with zoonotic diseases;
(b) human and animal tissues, organs, body parts, blood, fluid blood products and body fluids;
(c) containers or equipment containing blood that is fluid or blood from animals known or suspected to be infected with any zoonotic disease; and
(d) human foetuses;

but excludes teeth, hair and nails;

'**performance testing**' means the testing required in terms of regulation 39 and Schedule 4 to be carried out by a non-combustion treatment facility;

'**permit**' means a permit issued to a person in terms of section 20(1) of the Act to establish, provide or operate a disposal site and '**permitted**' has the corresponding meaning;

'**person**' includes a natural person, juristic person, unincorporated body, trust, association, or organ of state;

'**pharmaceutical waste**' means-

(a) pharmaceutical products and medicinal chemicals that are no longer usable in human or animal treatment, and that have become outdated or contaminated or are no longer required; and
(b) items contaminated with cytotoxic pharmaceuticals;

'**Province**' means the Gauteng Province as contemplated in Section 103 of the Constitution;
'**puncture resistant receptacle**' means a rigid receptacle which is not easily penetrated under normal use;
'**reduced routine testing programme**' means the testing programme required in terms of regulation 39(18) and Schedule 4 to be carried out by a treatment facility;
'**sharps receptacle**' means a puncture resistant receptacle which when sealed cannot be opened without great difficulty, and which is spill resistant under normal handling conditions;
'**sharps waste**' means waste having acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to the following:

(a) hypodermic needles, syringes, blades, and needles with or without attached tubing; and
(b) broken glass items, such as Pasteur pipettes and blood vials contaminated with health care risk waste;

'**sterilize**' means, with respect to an object, the total destruction of all microbial forms to make the object free from all live bacteria or other micro-organisms;
'**storage**' means the keeping of health care risk waste in a manner that does not constitute treatment or disposal of such health care risk waste;
'**surrogate health care risk waste**' means selected general waste which has the approximate physical properties of health care risk waste;
'**temporary authorisation**' means the temporary authorisation issued by the Department in terms of regulations 26 or 33;
'**the Act**' means the Environment Conservation Act, 1989 (Act No. 73 of 1989);
'**these Regulations**' includes all Schedules to these Regulations;
'**tracking document**' means the tracking document specified in regulation 22 of these Regulations;
'**transfer facility**' means a place where health care risk waste is accumulated for bulk temporary storage prior to treatment;
'**transport**' means the movement of health care risk waste from the premises of the generator to any intermediate point and finally to the point of treatment or final disposal.
'**transporter**' means a person who transports health care risk waste, including health care risk waste generated by that person and health care risk waste generated by any other person, but does not include a person-

(a) who transports health care risk waste for the purposes of testing or research,
(b) who transports health care risk waste for the purposes of internal transport, or
(c) who transports less than 10 (ten) kilograms per day of health care risk waste calculated as a daily average on a monthly basis;

'**treatment**' means any method, technique, or process designed to change the biological character or composition of any health care risk waste so as to sterilize such health care risk waste, and '**treat**' and '**treated**' have a corresponding meaning;
'**treatment facility**' means a premises where health care risk waste is treated;
'**Waste Information Regulations**' means the Waste Information Regulations, 2004 promulgated under the Act;
'**WIS number**' means the Registration number issued in terms of the Waste Information Regulations;
'**zoonotic disease**' is a disease which can be spread from animals to humans.

CHAPTER 2
GENERAL REQUIREMENTS APPLICABLE TO HEALTH CARE RISK WASTE

General prohibitions and duty of care

2. (1) No person may manage health care risk waste other than in accordance with these Regulations.

(2) No person may manage health care risk waste in a manner that results in or creates an increased risk of harm to human health or the environment.

(3) A major generator must take all reasonable measures to prevent any other person from contravening sub-regulations (1) or (2) in relation to its health care risk waste which includes measures to ensure that a person involved with the management of health care risk waste generated by that major generator, is aware of and acts in compliance with these Regulations.

(4) No person may manually lift a container of health care risk waste which weighs in excess of 15 kilograms including the container.

(5) A generator, transporter, transfer facility and treatment facility must provide alternative means of handling, lifting and carrying health care risk waste so as to avoid, and where it cannot be avoided altogether, minimise, manual performance of these functions by employees.

Storage

3. (1) A person must store health care risk waste in accordance with the Minimum Requirements set out in Schedule 9.

(2) A major or minor generator may store health care risk waste for up to 30 days from the date the health care risk waste is generated or received by the relevant generator.

(3) The 30 day limit imposed in terms of sub-regulation (2) excludes any time the health care risk waste is stored at a temperature below –2 (minus two)°C.

(4) A generator must ensure that the time period between the collection of a consignment by a transporter from the relevant generator's premises and the treatment of that health care risk waste does not exceed 72 hours.

(5) The 72 hour limit imposed in terms of sub-regulation (4) excludes any time that the health care risk waste is stored at a temperature below –2 (minus two)°C at a transfer facility for not more than 90 days.

(6) Notwithstanding anything contained elsewhere in these Regulations-

(a) a person may store sharps waste and pharmaceutical waste for up to 90 days;

(b) if the odour from stored health care risk waste cannot be controlled and the odour poses a nuisance to any person, the person responsible for storing the health care risk waste must effect more frequent removal; and

(c) pathological waste not treated within 24 hours of generation must be stored at a temperature below –2 (minus two)°C.

Final disposal

4. (1) No person may finally dispose of treated health care risk waste except-

(a) by a method approved in writing by the Department; and

(b) in the manner set out in item 3 of Schedule 9.

(2) In exceptional circumstances, and upon application, the MEC may grant an exemption in writing from the operation of sub-regulation (1), for a specified amount of health care risk waste and for a limited period only.

General

5. (1) Within 30 days of any material change to the information specified in any application form submitted to the Department in terms of these Regulations, the applicant must submit an updated application form.

(2) All records required in terms of these Regulations must be kept for a period of 3 (three) years.

(3) The MEC may impose a reasonable fee for the administration of these Regulations, by notice in the *Provincial Gazette*.

(4) Within 1 (one) year of the promulgation of these Regulations and thereafter once annually, the Department must publish in the *Provincial Gazette* and on the Department's official website, a list of all persons authorised in terms of these Regulations.

(5) The MEC may by notice in the *Provincial Gazette* amend the Schedules to these Regulations.

CHAPTER 3
REQUIREMENTS APPLICABLE TO GENERATORS

General requirements

6. (1) A major generator must take all reasonable measures to ensure that health care risk waste generated at its facility is stored, transported, treated and disposed of in strict compliance with these Regulations.

(2) A major generator may not release health care risk waste to a transporter until it has first-

(a) made reasonably certain, once this information is available on the Department's official website, that the transporter is authorised by the Department to operate as transporter;

(b) made reasonably certain that a transporter whose services are engaged, transports any consignments from that major generator only to a permitted treatment facility; and

(c) obtained a tracking document from the transporter for the consignment.

(3) A major generator must conduct an ongoing training and education programme attended by all employees involved in managing health care waste including

reduction planning and implementation at the major generator to ensure that the following principles are understood and implemented at the major generator:

(a) health care waste segregation;
(b) best infection control practices;
(c) waste minimisation; and
(d) improved environmental awareness

(4) A major generator must appoint a suitably qualified person to act as the health care waste officer for the major generator.

(5) The health care waste officer is responsible for the day-to-day monitoring, management and problem solving in relation to the management of health care risk waste including liasing with the health care risk waste service providers.

Segregation

7. (1) A generator must segregate health care risk waste from health care general waste at the point of generation, and take all reasonable measures to maintain such segregation at all times thereafter.

(2) A generator may not cause health care risk waste to be treated together with health care general waste.

Waste minimisation

8. (1) A generator must where reasonably practicable, minimise the volume of health care risk waste in its operations by minimising the generation of health care risk waste at source.

(2) The Department may set targets for waste minimisation, in general or for a specific sector or institution, by publication of a notice in the *Provincial Gazette*.

Packaging

9. (1) For the purposes of transport and storage a generator must pack health care risk waste in health care risk waste containers which clearly indicate the contents and which are colour coded and marked in accordance with SANS Code of Practice 10248: Management of Health Care Waste, or the international ISO Biohazard symbol, or other internationally recognised symbol.

(2) A generator may only pack health care risk waste in containers which comply with the Minimum Requirements for packaging of health care risk waste, as set out in Schedule 1.

(3) A major generator must clearly indicate the name or registration number of that generator on all containers containing its health care risk waste by using marking or a digital identification.

(4) A minor generator must clearly indicate on all containers containing its health care risk waste that the contents were generated at a minor generator by using marking or a digital identification.

(5) A generator must seal a container when necessary, to prevent leakage or expulsion of contents.

(6) For the purposes of internal transport a generator must place health care risk waste in one or more leak resistant receptacles.

(7) A generator must place a leak resistant container containing health care risk waste in a health care risk waste container in accordance with items 1 and 2 of Schedule 9.

(8) A generator must place liquid health care risk waste in a capped or tightly secured leak resistant and spill resistant container.

(9) A generator must place sharps waste in a sharps container at the point of generation and keep such waste in a sharps container at all times thereafter.

(10) A generator must seal a sharps container when it is full with a non reversible sealing design, to prevent the release of sharps waste from the container.

Internal transport

10. (1) A major generator must ensure that all internal transport takes place in accordance with the Minimum Requirements set out in item 1 of Schedule 9.

(2) A major generator must implement an internal transportation system in accordance with the minimum requirements set out in item 1 of Schedule 9, within 1 (one) year from the date of commencement of these Regulations.

Health and safety

11. (1) A generator must take all reasonable measures to ensure that once health care risk waste is placed in a health care risk waste container, the health care risk waste is not removed from that container for the purposes of-

(a) decanting it into another container;

(b) sorting it; or

(c) any other purpose;

until such health care risk waste is received by the relevant treatment facility.

(2) To avoid injuries to or infection of people, a generator must-

(a) take all necessary measures to ensure that reusable containers are effectively disinfected before re-use, according to the standards specified in Schedule 2; and

(b) provide and require all persons who manually handle containers of untreated health care risk waste to wear clean, protective gloves and overalls, changeable lab coats or other appropriate personal protective equipment.

Health care waste management plans

12. (1) A major generator which commences operations after the date of commencement of these Regulations must have an approved health care waste management plan before it commences operations.

(2) A major generator in operation at the date of commencement of these Regulations must prepare a health care waste management plan, and submit the plan to the Department within 180 days after the date of commencement of these Regulations.

(3) As a minimum, a health care waste management plan must include the matters set out in item 3 of Schedule 7.

(4) The Department must review the health care waste management plan within 60 days of receipt thereof, and either approve or reject the plan.

(5) The Department must-

(a) notify the major generator in writing of its decision; and

(b) provide reasons for any decision to reject the plan.

(6) If the Department rejects the plan, the relevant major generator may amend the plan and resubmit it within 30 days from the date of receipt of the notice referred to in sub-regulation (5)(a).

(7) The Department must review the plan resubmitted within 30 days of receipt thereof, and either approve or reject the amended plan.

(8) The Department must notify the major generator in writing of its decision and must provide reasons for any decision to reject the amended plan.

Audit report

13. (1) At least 180 days but no more than 260 days prior to the expiration of a period of 2 (two) years from the date of the Department's approval of a health care waste management plan and prior to the end of every subsequent period of 2 (two) years thereafter, a major generator must submit a written audit report to the Department.

(2) The audit report may be compiled by either an internal or external auditor, and must include as a minimum the matters set out in item 4 of Schedule 7.

(3) The Department must review the audit report within 60 days of receipt thereof, and either approve or reject the audit report.

(4) The Department must-

(a) notify the major generator in writing of its decision; and

(b) provide reasons for any decision to reject an audit report.

(5) If the Department rejects the audit report, the relevant major generator may amend the audit report and resubmit it within 30 days from the date of receipt of the notice referred to in sub-regulation (4)(a).

(6) The Department must review the audit report resubmitted within 30 of receipt thereof, and either approve or reject the amended audit report.

(7) The Department must notify the major generator in writing of its decision and must provide reasons for any decision to reject the amended audit report.

Minor generators

14. (1) A Municipality must ensure that a service is provided for the safe collection and treatment of health care risk waste generated by minor generators.

(2) A Municipality must before 1 October 2006 prepare and submit to the Department its Municipal health care risk waste management plan prepared in accordance with Schedule 6.

(3) The Department must support Municipalities to comply with sub-regulation (1) and (2), including but not limited to assisting in the development of the plans.

(4) The MEC must provide a Guideline for the development of Municipal health care risk waste management plans to assist Municipalities to meet their obligations.

CHAPTER 4
REQUIREMENTS APPLICABLE TO TRANSPORTERS

Authorisation

15. (1) Without affecting the application of the duty-of-care principle to the generator, a transporter must ensure that all health care risk waste is treated and finally disposed of in accordance with these Regulations.

(2) A transporter which commences operations after the date of commencement of these Regulations, must apply to the Department for an authorisation before commencing operations.

(3) The application must comply with form 2 set out in Schedule 5 .

(4) The application form must either state the applicant's WIS number or must be accompanied by an application in terms of the Waste Information Regulations for such a number.

(5) The Department must review an application submitted in terms of sub-regulations (2) and (9) within 60 days of receipt thereof, and either approve or reject the application.

(6) The Department must-

(a) notify the applicant in writing of its decision;

(b) provide reasons for any decision to reject the application; and

(c) if the application is rejected, provide the applicant with an opportunity to make representations.

(7) Within 30 days of receipt of the representations the Department must consider the representations, and must either-

(a) confirm its previous decision; or

(b) issue the applicant with an authorisation.

(8) In deciding on whether to issue an authorisation, the Department must consider, amongst others, the following factors:

(a) whether granting the authorisation would result in an unreasonable risk of harm to public health or the environment;

(b) the ability of the applicant to safely operate as a transporter in compliance with these Regulations; and

(c) any other factor which may be relevant.

(9) A transporter in operation at the date of commencement of these Regulations must apply for an authorisation from the Department within 90 days after the date of commencement of these Regulations.

(10) The application must comply with form 2 set out in Schedule 5.

(11) An authorisation is valid for 2 (two) years and is not transferable.

Authorisation conditions

16. (1) The Department may impose any conditions on the authorisation of a transporter it considers necessary.

(2) The Department may amend, add to or vary the authorisation conditions at any time and must provide the transporter with an opportunity to make representations on the proposed amendment, addition or variation.

(3) If the holder fails to comply with any authorisation condition, the Department may withdraw the authorisation: Provided that the Department gives the holder-

(a) written notice of such non-compliance;
(b) at least 30 days within which to remedy the non-compliance; and
(c) an opportunity to make representations to the Department.

Renewal of authorisation

17. (1) A transporter must apply to the Department for renewal of its authorisation not less than 60 days prior to the expiry date of its existing authorisation.

(2) The application must comply with form 2 set out in Schedule 5.

(3) The Department may only renew an authorisation if-

(a) the Department has approved the audit report required in terms of regulation 21; and
(b) the Department has reviewed the compliance history of the applicant with the Waste Information Regulations.

(4) The Department may not renew an authorisation or must specify additional authorisation conditions if-

(a) within the 2 (two) year period preceding the date of application, the applicant has breached any laws or regulations governing health care risk waste; and
(b) such breaches or offences demonstrate a recurring pattern of non-compliance or pose, or have posed, a significant risk to the environment or public health.

Termination of authorisation

18. An authorisation will terminate prior to its expiry date if the holder-

(a) sells or otherwise transfers the business or facility; or
(b) surrenders the authorisation to the Department because the holder ceases operations.

Health and safety

19. A transporter must provide and require all persons manually handling containers of untreated health care risk waste to wear clean protective gloves and overalls, changeable lab coats, or other protective clothing.

General transportation requirements

20. (1) A transporter must transport untreated health care risk waste in a health care risk waste container.

(2) A transporter may not transport untreated health care risk waste in the same vehicle with other waste unless the untreated health care risk waste is-

(a) contained separately; and

(b) kept separate from other waste by suitable barriers.

(3) A transporter must transport untreated health care risk waste in strict compliance with the Minimum Requirements set out in item 2 of Schedule 9.

(4) A transporter may only transport health care risk waste to-

(a) a minor or major generator, to consolidate such waste prior to the further transport or treatment of such waste;

(b) a transfer facility which is permitted, and which is authorised to consolidate such waste prior to its transport to a permitted treatment facility; or

(c) a treatment facility which is permitted and authorised.

(5) A transporter must obtain prior written approval of the Department for the transport of any health care risk waste outside of the Province.

(6) The Department may grant approval if the transporter demonstrates to the reasonable satisfaction of Department that-

(a) the health care risk waste will ultimately be transported to a treatment facility which is permitted; and

(b) the conditions at the treatment facility comply with the Minimum Requirements as set out in item 3 of Schedule 9.

(7) Waste approved in terms of sub-regulation (5) and (6) may be temporarily stored at a transfer facility outside the Province: Provided that the transporter demonstrates to the reasonable satisfaction of the Department that the transfer facility is permitted and that the storage conditions at the transfer facility comply with the Minimum Requirements as set out in Schedule 9.

Audit report

21. (1) At least 180 days but no more than 240 days prior to an application for renewal of an authorisation in terms of regulation 17(1), a transporter must submit a written audit report to Department.

(2) The audit report may be compiled by either an internal or external auditor, and must include as a minimum the requirements set out in item 4 of Schedule 7.

(3) The Department must review the audit report within 60 days of receipt thereof, and either approve or reject the audit report.

(4) The Department must-

(a) notify the transporter in writing of its decision; and

(b) provide reasons for any decision to reject an audit report.

(5) If the Department rejects an audit report, the relevant transporter may amend the audit report and resubmit it to the Department within 30 days of receipt of the notice referred to in sub-regulation 4(a).

(6) The Department must review the audit report resubmitted within 30 days of receipt thereof and either approve or reject the amended audit report.

(7) The Department must notify the transporter in writing of its decision and must provide reasons for any decision to reject the amended audit report.

Tracking documents

22. (1) A transporter must maintain completed tracking documents for all health care risk waste it transports.

(2) Upon receiving or collecting health care risk waste from a generator, a transporter must provide that generator with a copy of the tracking document for the generator's records.

(3) Upon release of health care risk waste to a transfer facility or treatment facility, a transporter must provide the relevant person with a copy of the tracking document for that person's records.

(4) A transporter must return a copy of the tracking document duly signed by the treatment facility or the operator of a transfer facility, to the generator within reasonable time.

(5) A transporter must maintain a copy of all tracking documents for a minimum of 3 (three) years.

(6) A transporter must submit to the Department, upon request, copies of any tracking documents which the transporter is required to maintain.

(7) The tracking document must include at least the information set out in Schedule 8.

(8) A transporter transporting health care risk waste in a motor vehicle must have the relevant tracking document in his or her possession in the relevant motor vehicle.

(9) A tracking document must be shown upon demand to a health care risk waste inspector or to any law enforcement officer.

(10) If the health care risk waste is transported by rail, vessel, or air, the railway operator, vessel operator, or airline operator must enter on the shipping or other transport documentation any information concerning the health care risk waste, which the Department may require.

CHAPTER 5
REQUIREMENTS APPLICABLE TO TRANSFER FACILITIES

General

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

(2) A generator which receives an amount of health care risk waste which is more than 20 percent of the gross health care risk waste generated at that generator, from another generator, is an operator of a transfer facility for the purposes of these Regulations.

Authorisation of transfer facility not in operation at date of commencement

24. (1) If a transfer facility is not operating at the date of commencement of these Regulations the operator of the transfer facility must apply to the Department for an authorisation for the transfer facility before commencing operations.

(2) The application must comply with form 2 set out in Schedule 5.

(3) The application form must either state the applicant's WIS number or must be accompanied by an application in terms of the Waste Information Regulations for such a number.

(4) The Department must review the application for authorisation within 60 days of receipt thereof, and must either approve or reject the application.

(5) The Department must-

(a) notify the applicant in writing of its decision;

(b) provide reasons for any decision to reject the application; and

(c) if the application is rejected, provide the applicant with an opportunity to make representations to the Department.

(6) Within 30 days of receipt of the representations the Department must consider the representations, and must either-

(a) confirm its previous decision; or

(b) issue the applicant with an authorisation.

(7) The Department may only issue an authorisation if the applicant has been issued with an EIA authorisation for the relevant transfer facility.

(8) In deciding whether to issue an authorisation, the Department must consider, amongst others, the following factors:

(a) the applicant's EIA authorisation;

(b) whether granting the authorisation would result in an unreasonable risk of harm to public health or the environment;

(c) the ability of the applicant to safely operate the transfer facility in compliance with the provisions of these Regulations; and

(d) any other factor which may be relevant.

(9) An authorisation is valid for 2 (two) years and is not transferable.

Authorisation of transfer facility with EIA in operation at date of commencement

25. (1) If a transfer facility is in operation at the date of commencement of these Regulations, and the operator of the transfer facility has been issued with an EIA authorisation, the operator must apply to the Department for an authorisation for the transfer facility within 90 days from the date of commencement of these Regulations.

(2) The application must comply with form 2 set out in Schedule 5.

(3) The application form must either state the applicant's WIS number or must be accompanied by an application in terms of the Waste Information Regulations for such a number.

(4) The Department must review the application within 60 days of receipt thereof, and either approve or reject the application.

(5) The Department must-

(a) notify the applicant in writing of its decision;

(b) provide reasons for any decision to reject the application; and

(c) if the application is rejected, provide the applicant with an opportunity to make representations to the Department.

(6) Within 30 days of receipt of the representations the Department must consider the representations, and must either-

(a) confirm its previous decision; or

(b) issue the applicant with an authorisation.

(7) The Department may only issue an authorisation if the applicant has been issued with an EIA authorisation for the relevant transfer facility.

(8) In deciding whether to issue an authorisation, the Department must consider, amongst others, the following factors:

(a) the applicant's EIA authorisation;

(b) whether granting the authorisation would result in an unreasonable risk of harm to public health or the environment;

(c) the ability of the applicant to safely operate the transfer facility in compliance with the provisions of these Regulations; and

(d) any other factor which may be relevant.

(9) An authorisation is valid for 2 (two) years and is not transferable.

Authorisation of transfer facility without EIA authorisation in operation at date of commencement

26. (1) If a transfer facility is in operation at the date of commencement of these Regulations, but the operator of the transfer facility has not been issued with an EIA authorisation, the operator must apply to the Department for a temporary authorisation for the transfer facility within 60 days of the date of commencement of these Regulations.

(2) The application must comply with form 1 set out in Schedule 5.

(3) The application form must either state the applicant's WIS number or must be accompanied by an application in terms of the Waste Information Regulations for such a number.

(4) The Department must grant the applicant a temporary authorisation within 30 days of receipt of the application.

(5) A temporary authorisation not transferable and is valid for a maximum of 2 (two) years but the Department may in writing extend the validity of a temporary authorisation for a maximum additional period of 1 (one) year.

(6) Within 180 days of being issued with a temporary authorisation an operator of a transfer facility must submit to the Department a report which must include at least the information set out in item 2 of Schedule 7.

(7) An operator issued with a temporary authorisation for a transfer facility must apply to the Department for an authorisation not less than 90 days prior to the expiry of its temporary authorisation.

(8) The application must comply with form 2 set out in Schedule 5.

(9) The Department must review the application for authorisation within 60 days of receipt thereof, and either approve or reject the application.

(10) The Department must-

(a) notify the applicant in writing of its decision;

(b) provide reasons for any decision to reject the application; and

(c) if the application is rejected, provide the applicant with an opportunity to make representations to the Department.

(11) Within 30 days of receipt of the representations the Department must consider the representations, and must either-

(a) confirm its previous decision; or

(b) issue the applicant with an authorisation.

(12) In deciding whether to issue an authorisation, the Department must consider, amongst others, the following factors:

(a) the audit report submitted in terms of regulation 30(1);
(b) the compliance of the applicant with these Regulations; and
(c) whether granting the authorisation would result in an unreasonable risk of harm to public health or the environment.

(13) An authorisation is valid for 2 (two) years and is not transferable.

Renewal of authorisation

27. (1) An operator of a transfer facility must apply to the Department for renewal of authorisation of the transfer facility not less than 30 days prior to the expiry date of its existing authorisation.

(2) The application must comply with form 2 set out in Schedule 5.

(3) The Department may only renew an authorisation if-

(a) the Department has approved the audit report required in terms of regulation 30(1);
(b) the Department has reviewed the compliance history of the applicant under any local, provincial or national laws relating to health care risk waste; and
(c) the Department has reviewed the compliance history of the applicant with the conditions in the applicant's EIA authorisation, where applicable.

(4) The Department may not renew an authorisation or must specify additional authorisation conditions, if-

(a) within the 2 (two) year period preceding the date of application, the applicant has breached any condition contained in the applicant's EIA authorisation, where applicable; or
(b) within the 2 (two) year period preceding the date of application, the applicant has breached any laws or regulations governing health care risk waste at a facility owned or operated by the applicant; and
(c) the breaches or offences demonstrate a recurring pattern of non-compliance or pose, or have posed, a significant risk to the environment or public health.

Authorisation conditions

28 (1) The Department may impose any conditions in respect of an authorisation or temporary authorisation of a transfer facility it considers necessary.

(2) The Department may amend, add to or vary the authorisation or temporary authorisation conditions at any time: Provided that-

(a) the Department gives the holder an opportunity to make representations regarding the amendment, addition or variation to the authorisation or temporary authorisation conditions; and
(b) The Department considers the representations.

(3) If the holder fails to comply with any authorisation or temporary authorisation condition, the Department may withdraw the authorisation or temporary authorisation: Provided that the Department gives the holder-

(a) written notice of such non-compliance;
(b) at least 30 days within which to remedy the non-compliance; and
(c) the opportunity to make representations to the Department.

Termination of authorisation

29. An authorisation or temporary authorisation will terminate prior to its expiry date if the holder-

(a) sells or otherwise transfers the facility; or
(b) surrenders the authorisation or temporary authorisation to the Department because the holder ceases operations.

Audit report

30. (1) At least 180 but no more than 240 days prior to the application for renewal of an authorisation the operator of transfer facility must submit a written audit report to the Department.

(2) The audit report may be compiled by either an internal or external auditor, and must as a minimum contain the requirements set out in item 4 of Schedule 7.

(3) The Department must review an audit report within 60 days of receipt thereof, and must either approve or reject the audit report.

(4) The Department must-

(a) notify the operator of the transfer facility in writing of its decision; and
(b) provide reasons for any decision to reject the audit report.

(5) If the Department rejects the audit report, the relevant operator of the transfer facility may amend the audit report and resubmit it to the Department within 30 days from the date of receipt of the notice referred to in sub-regulation (4) (a).

(6) The Department must review the audit report re-submitted within 30 days of receipt thereof and must either approve or reject the amended audit report.

(7) The Department must notify the transfer facility of its decision and must provide reasons for any decision to reject the amended audit report.

(8) All records must be kept by a transfer facility for a minimum of 3 (three) years and must be made available, upon request, to the Department for inspection.

CHAPTER 6
REQUIREMENTS APPLICABLE TO TREATMENT FACILITIES

Authorisation of treatment facility not in operation at date of commencement

31. (1) A treatment facility which commences operations after the date of commencement of these Regulations must apply to the Department for an authorisation before commencing operations.

(2) The application must comply with form 2 set out in Schedule 5.

(3) The application form must either state the applicant's WIS number or must be accompanied by an application in terms of the Waste Information Regulations for such a number.

(4) The Department must review the application for authorisation within 60 days of receipt thereof, and either approve or reject the application.

(5) The Department must-

(a) notify the applicant in writing of its decision;

(b) provide reasons for any decision to reject the application; and

(c) if the application is rejected, provide the applicant with an opportunity to make representations to the Department.

(6) Within 30 days of receipt of the representations the Department must consider the representations, and must either-

(a) confirm its previous decision; or

(b) issue the applicant with an authorisation.

(7) The Department may only issue an authorisation if the applicant has been issued with an EIA authorisation.

(8) In deciding whether to issue an authorisation, the Department must consider, amongst others, the following factors:

(a) the applicant's EIA authorisation;

(b) the results of the performance testing requirements set out in Schedules 3 and 4, as applicable;

(c) whether granting the authorisation would result in an unreasonable risk of harm to public health or the environment; and

(d) the ability of the applicant to safely operate the treatment facility in compliance with these Regulations.

(9) An authorisation is valid for 2 (two) years and is not transferable.

Authorisation of treatment facility with EIA authorisation in operation at date of commencement

32. (1) A treatment facility which is in operation at the date of commencement of these Regulations, and which has been issued with an EIA authorisation must apply to the Department for an authorisation within 90 days from the date of commencement of these Regulations.

(2) The application must comply with form 2 set out in Schedule 5 .

(3) The application form must either state the applicant's WIS number or must be accompanied by an application in terms of the Waste Information Regulations for such a number.

(4) The Department must review the application for authorisation within 60 days of receipt thereof, and either approve or reject the application.

(5) The Department must-

(a) notify the applicant in writing of its decision;

(b) provide reasons for any decision to reject the application; and

(c) if the application is rejected, provide the applicant with an opportunity to make representations to the Department.

(6) Within 30 days of receipt of the representations the Department must consider the representations, and either-

(a) confirm its previous decision; or

(b) issue the applicant with an authorisation.

(7) The Department may only issue an authorisation if the applicant has been issued with an EIA authorisation.

(8) In deciding whether to issue an authorisation, the Department must consider, amongst others, the following factors:

(a) the applicant's EIA authorisation;

(b) the results of the performance testing requirements set out in Schedules 3 and 4, as applicable;

(c) whether granting the authorisation would result in an unreasonable risk of harm to public health or the environment; and

(d) the ability of the applicant to safely operate the treatment facility in compliance with these Regulations.

(9) An authorisation is valid for 2 (two) years and is not transferable.

Authorisation of treatment facility without EIA authorisation in operation at date of commencement

33. (1) A treatment facility which is in operation at the date of commencement of these Regulations, but which has not been issued with an EIA authorisation, must apply to the Department for a temporary authorisation within 60 days of the date of commencement of these Regulations.

(2) The application must comply with form 1 set out in Schedule 5.

(3) The application form must either state the applicant's WIS number or must be accompanied by an application in terms of the Waste Information Regulations for such a number.

(4) The Department must grant the applicant a temporary authorisation within 30 days of receipt of the application.

(5) A temporary authorisation not transferable and is valid for a maximum of 2 (two) years but the Department may in writing extend the validity of a temporary authorisation for a maximum additional period of 1 (one) year.

(6) Within 180 days of being issued with a temporary authorisation a treatment facility must submit to the Department the report referred to in sub-regulation (7).

(7) The report must include at least the results of the minimum environmental performance requirements tests and all other information set out in item 1 of Schedule 7.

(8) If the report indicates that the applicant does not comply with the minimum environmental performance requirements for a controlled combustion or non-combustion treatment facility set out in Schedules 3 and 4, the applicant may elect either-

(a) to permanently cease to operate as a treatment facility and to properly decommission the treatment facility; or

(b) to submit to the Department a plan detailing the steps which the applicant will take and the time frames within which these steps will be taken, to achieve compliance with the relevant performance requirements, within 12 months from the date of submission of the report.

(9) The Department must review the plan submitted in terms of sub-regulation (8)(b) within 60 days of receipt thereof and either approve or reject the plan.

(10) The Department must-

(a) notify the applicant in writing of its decision; and

(b) provide reasons for any decision to reject the plan.

(11) If the Department rejects the plan submitted, the applicant may amend the plan and resubmit it to the Department within 30 days from receipt of the notice referred to in sub-regulation (10)(a).

(12) In deciding whether to approve a plan, the Department must consider, amongst others, the following factors:

(a) whether authorising the applicant to operate in terms of the plan would result in an unreasonable risk of harm to public health or the environment; and

(b) the ability of the applicant to safely operate the treatment facility in compliance with these Regulations.

(13) A temporary authorisation is valid for a maximum of 2 (two) years and is not transferable.

(14) The Department may in writing extend the validity of a temporary authorisation for a maximum additional period of 1 (one) year.

(15) A treatment facility issued with a temporary authorisation must apply to the Department for an authorisation not less than 90 days prior to the expiry of its temporary authorisation.

(16) The application must comply with form 2 set out in Schedule 5.

(17) The Department must review an application for authorisation submitted in terms of sub-regulation (15) within 60 days of receipt thereof, and either approve or reject the application.

(18) The Department must-

(a) notify the applicant in writing of its decision;

(b) provide reasons for any decision to reject the application; and

(c) if the application is rejected, provide the applicant with an opportunity to make representations to the Department.

(19) Within 30 days of receipt of the representations the Department must consider the representations, and must either-

(a) confirm its previous decision; or

(b) issue the applicant with an authorisation.

(20) In deciding whether to issue an authorisation, the Department must consider, amongst others, the following factors:

(a) the applicant's report submitted in terms of sub regulation (6);

(b) the applicant's compliance with the plan approved in terms of sub-regulation (9) or sub-regulation (12);

(c) whether granting the authorisation would result in an unreasonable risk of harm to public health or the environment; and

(d) the ability of the applicant to safely operate the treatment facility in compliance with these Regulations.

(21) An authorisation is valid for 2 (two) years and is not transferable.

Renewal of authorisation

34. (1) A treatment facility must apply to the Department for renewal of its current authorisation not less than 60 days prior to the expiry date of its authorisation.

(2) The application must comply with form 2 set out in Schedule 5.

(3) The Department may only renew an authorisation if-

(a) the Department has approved the audit report required in terms of regulation 40(1);

(b) the Department has reviewed the applicant's compliance history under any local, provincial or national laws relating to health care risk waste or; and

(c) the Department has reviewed the applicant's compliance history under the applicant's EIA authorisation, where applicable.

(4) The Department may not renew an authorisation or must specify additional authorisation conditions, if-

(a) within the 2 (two) year period preceding the date of application, the applicant has breached any condition contained in the applicant's EIA authorisation, where applicable; or

(b) within the 2 (two) year period preceding the date of application, the applicant has breached any laws or regulations governing health care risk waste at a facility owned or operated by the applicant; and

(c) the breaches or offences demonstrate a recurring pattern of non-compliance or pose, or have posed, a significant risk to the environment and public health.

Authorisation conditions

35. (1) The Department may impose any conditions on an authorisation or temporary authorisation of a treatment facility it considers necessary including, but not limited to, conditions relating to the performance and other tests, and minimum requirements set out in Schedules 3 and 4.

(2) The Department may amend, add to or vary the authorisation or temporary authorisation conditions at any time: Provided that the Department-

(a) gives the holder a reasonable opportunity to make representations regarding the amendment, addition or variation; and

(b) considers the representations.

(3) If a treatment facility fails to comply with any authorisation or temporary authorisation condition, the Department may withdraw the authorisation or temporary authorisation: Provided that the Department-

(a) gives the relevant treatment facility written notice of such non-compliance and at least 30 days in which to remedy the non-compliance; and

(b) provides the treatment facility with an opportunity to make representations to the Department regarding the proposed withdrawal.

Termination of authorisation

36. An authorisation or temporary authorisation will terminate prior to its expiry date if-

(a) the Department rejects the plan submitted in terms of regulation 33 (8) (b) or 33(11) and no representation is made in terms of sub-regulation 33 (18) (c) or such representation is unsuccessful; or

(b) the holder of the authorisation or temporary authorisation sells or otherwise transfers the facility; or

(c) the holder surrenders the authorisation or temporary authorisation to the Department because the holder ceases operations.

Treatment

37. (1) A treatment facility must comply with all of the performance testing requirements and minimum requirements and standards set out in Schedules 3 and 4.

(2) The Department may approve any treatment technology that renders health care risk waste reasonably unrecognisable and which-

(a) results in the necessary level of destruction of pathogenic micro-organisms, without posing a risk to human health or the environment; and

(b) which meets with all of the requirements for the treatment of health care risk waste as prescribed in these Regulations.

(3) Such approval must be reflected in the EIA authorisation, or in the authorisation or temporary authorisation conditions.

(4) Any form of microbial inactivation or other treatment of health care risk waste must take place at a treatment facility which is permitted and authorised.

(5) Any form of microbial inactivation or other treatment of health care risk waste must take place in accordance with-

(a) the treatment facility's EIA authorisation, where applicable; and

(b) all conditions attached to an authorisation or temporary authorisation issued to the facility.

(6) The Department may, by publication of a notice in the *Provincial Gazette*, set or amend standards including, but not limited to standards for-

(a) ash residues from controlled combustion treatment including standards for maximum allowable percentage of combustible matter;

(b) maximum contents of heavy metals, with a view to forcing optimisation of the combustion efficiency and segregation of heavy metal containing components from the waste stream, or

(c) any other testing method, emission or residue level.

(7) Residues from non-combustion treatment must meet the same requirements with respect to the heavy metal content as any such requirements for controlled combustion treatment as set out in Schedule 3.

Minimum environmental performance requirements for a controlled combustion treatment facility

38. A controlled combustion treatment facility must comply with the minimum performance requirements set out Schedule 3.

Minimum environmental performance requirements and testing programmes for a non-combustion treatment facility

39. (1) A non-combustion treatment facility must comply with the minimum environmental performance requirements set out in item 1 of Schedule 4.

(2) The Department may from time to time amend the list of approved representative biological indicators set out in item 1 of Schedule 4, by notice in the *Provincial Gazette*.

(3) A non-combustion treatment facility must apply to the Department for approval of any organisms, including but not limited to species and cultures, which are not listed in item 1 of Schedule 4, which the non-combustion treatment facility intends to use for testing in terms of Schedule 4.

(4) The application must be made by submitting the details of the relevant organisms in writing to the Department at least 3 (three) months prior to testing.

(5) The Department must either approve or reject an application within 3 (three) months of receiving such application, and provide written reasons for rejecting any such application.

(6) A non-combustion treatment facility must comply with the performance testing requirements set out in item 2 of Schedule 4, prior to submitting an application for authorisation.

(7) The results of the performance tests required in terms of item 2 of Schedule 4 must demonstrate that the non-combustion treatment facility can satisfy the microbial inactivation standards as set out in item 1(2) of Schedule 4 on a challenge load.

(8) The CEO of the non-combustion treatment facility, in consultation with a competent person, must determine what constitutes a challenge load for the relevant non-combustion treatment facility.

(9) The non-combustion treatment facility must apply to Department for approval of the challenge load determined in terms of sub regulation (8).

(10) The application must be made by submitting the details of the challenge load in writing to the Department at least 1 (one) month prior to the challenge load being tested.

(11) Health care risk waste treated during any performance test undertaken in terms of these Regulations, must be retained until satisfactory levels of microbial inactivation have been demonstrated.

(12) In the event that any performance test fails, all health care risk waste which was utilised for the purposes of the failed test must be successfully re-treated prior to its final disposal.

(13) A non-combustion treatment facility must submit the results of performance testing undertaken in terms of these Regulations to the Department as a report, and must at a minimum-

(a) provide details of the batch and tube numbers for the vial used;
(b) record the date and time of the test run;
(c) provide the results of the tests on the microbial species;
(d) provide details of the sampling, storage and testing procedures used; and
(e) provide an evaluation of the results obtained, together with a comparison of results obtained in any previous report.

(14) A non-combustion treatment facility must comply with the minimum regular testing programme as set out in item 3 of Schedule 4 for a period of 12 months after the date of issue of an authorisation to the non-combustion treatment facility.

(15) If the results of the second test required in terms of item 3(c) of Schedule 4 indicate that a non-combustion treatment facility is unable to achieve the microbial inactivation standards specified in item 1(2) of Schedule 4, the non-combustion treatment facility must immediately suspend operations and notify the Department in writing.

(16) On receipt of such notification, the Department may require the non-combustion treatment facility to commence with a further testing programme, in accordance with the performance testing requirements, as set out in item 2 of Schedule 4.

(17) The non-combustion treatment facility must submit the results of the regular testing programme to the Department in writing as a report every 3 (three) months for the period for which the programme is undertaken.

(18) A non-combustion treatment facility may apply to the Department for approval as set out in item 4 of Schedule 4, to follow a reduced frequency of testing.

(19) The application must be made by submitting to the Department the details in writing of the non-combustion treatment facility's ability to meet the criteria required by the regular testing programme set out in item 3 of Schedule 4.

(20) If a non-combustion treatment facility at any stage does not comply with the standards of microbial inactivation, the non-combustion treatment facility must immediately notify the Department in writing.

(21) On receipt of such notification, the Department may require the non-combustion treatment facility to commence a further testing programme in accordance with the performance testing requirements, as set out in item 2 of Schedule 4.

(22) The non-combustion treatment facility must submit the results of the reduced frequency testing programme to the Department in writing as a report every 6 (six) months for the period for which the programme is undertaken.

Audit report

40. (1) At least 180 but no more than 240 days prior to the application for renewal of an authorisation in terms of regulation 34(1), a treatment facility must submit a written audit report to the Department.

(2) The audit report may be compiled by either an internal or external auditor, and must include as a minimum the information set out in item 4 of Schedule 7.

(3) The Department must review the audit report within 90 days of receipt thereof, and must either approve or reject the audit report.

(4) The Department must-

(a) notify the treatment facility in writing; and

(b) provide written reasons for any decision to reject an audit report.

(5) If the Department rejects an audit report, a treatment facility may amend the audit report and resubmit it to the Department within 30 days from the date receipt of the notice referred to in sub-regulation (4)(a).

(6) The Department must review the audit report resubmitted within 30 days of receipt thereof and must either approve or reject the amended audit report.

(7) The Department must notify the treatment facility of its decision and must provide reasons for any decision to reject the amended audit report.

(8) A treatment facility must keep records of the environmental performance test results required by Schedules 3 and 4 for a period of at least 3 (three) years and must be make the records available to the Department on request.

(9) The Department may in writing request a treatment facility to carry out independent tests to verify compliance with the requirements for emissions, effluents and residues as set out in Schedule 3.

CHAPTER 7
ENFORCEMENT

Appointment of health care risk waste inspector

41. (1) The HOD may in writing appoint a suitably qualified person as a health care risk waste inspector.

(2) For the purposes of these Regulations a "suitably qualified person" may include but is not limited to-

(a) an authorised representative, director or employee of the Department;
(b) an environmental health specialist;
(c) a local health practitioner;
(d) an environmental health practitioner; or
(e) a person appointed as a health officer or similar position in terms of any other legislation.

(3) For the purposes of these Regulations, a person who is currently registered as an environmental health practitioner in terms of the Health Act, 1977 (Act No. 63 of 1977) is deemed to be a health care risk waste inspector.

(4) The HOD must provide a health care risk waste inspector with a certificate of appointment signed by the HOD.

(5) Sub-regulation (4) does not apply to the appointment of an environmental health practitioner referred to in sub-regulation (3) as a health care risk waste inspector.

Powers and duties of health care risk waste inspector

42. (1) A health care risk waste inspector may with the consent of the owner or occupier, at any reasonable time, enter or cross a property with the necessary persons, vehicles, equipment and material to carry out a routine audit or inspection of any transporter, transfer facility, treatment facility or disposal facility.

(2) A health care risk waste inspector may, at any reasonable time and without prior notice, on the authority of a warrant, enter a property with the necessary persons, vehicles, equipment and material, and perform any action necessary to-

(a) investigate whether these Regulations or anything issued in terms of these Regulations are being contravened; or
(b) investigate whether any information supplied in connection with these Regulations is accurate.

(3) A warrant must be issued by a judge or a magistrate who has jurisdiction in the area where the property in question is situated, and must only be issued if it appears from information obtained on oath that there are reasonable grounds for believing that-

(a) these Regulations, or anything issued in terms of these Regulations are being contravened; or

(b) any information supplied in connection with these Regulations is inaccurate.

(4) If a warrant is likely to be issued if applied for but the delay involved in obtaining a warrant is likely to defeat the object of an inspection in terms of sub-regulation (2)(a) or (b), a health care risk waste inspector may enter a property without a warrant.

(5) A health care risk waste inspector entering property must, at the request of any person on that property, identify him or herself and present the certificate of appointment referred to in regulation 41(4) or documentation confirming that he or she is registered as an environmental health practitioner in terms of the Health Act, 1977 (Act No. 63 of 1977).

(6) Notwithstanding any provision in these Regulations a health care risk waste inspector may not, under any circumstances, enter a dwelling without the consent of the occupier or without a warrant authorising entry.

Duty to assist health care risk waste inspector

43. (1) When a health care risk waste inspector enters any property or site referred to in regulation 42, the operator, owner or manager and the employee performing any work there must assist the health care risk waste inspector, furnish answers to questions and provide any facility that the inspector reasonably requires.

(2) A person questioned by a health care risk waste inspector in terms of sub-regulation (1) must answer the question to the best of his or her ability, but no person is required to answer any question if the answer may reasonably be self-incriminating.

Duty to produce documents

44. A person who holds or should hold an authorisation or any other document, including an electronic document, issued or required in accordance with these Regulations, must produce it at the request of a health care risk waste inspector and must-

(a) allow the health care risk waste inspector, for the purpose of the inspection, to remove any articles or objects pointed out by the health care risk waste inspector;

(b) allow the inspection of documents specified by the health care risk waste inspector including the making of copies thereof; and

(c) furnish the health care risk waste inspector, at the health care risk waste inspector's reasonable request, with any information under that person's control.

Powers of health care risk waste inspector to deal with unsafe conditions

45. (1) Subject to sub-regulation(2), if a health care risk waste inspector reasonably believes that a condition or activity present on the site of, or connected with any activity conducted by a generator, transporter, transfer facility, treatment facility, or disposal facility is a threat or may present a reasonable risk to human health or the environment, the health care risk waste inspector may issue a written directive to a person responsible for that condition or activity directing that-

(a) the activity be restricted, suspended, or made subject to any conditions; and

(b) action be undertaken within a reasonable time by the person concerned to remove the threat.

(2) The health care risk waste inspector must provide the relevant person with the opportunity to make representations to the Department.

(3) A person issued with a directive under sub-regulation (1) must take the steps set out in the directive, within the specified period, to rectify the activity or condition referred to in the directive.

(4) If a person fails to comply, or inadequately complies with a directive the Department may take reasonable measures to remedy the situation.

(5) The Department may recover all costs incurred as a result of it acting under sub-regulation (4) from the person to whom the directive was issued.

CHAPTER 8
OFFENCES AND PENALTIES

Offences and penalties

46. (1) A person who-

(a) fails to comply with regulations 2(5) or 3(2) or 3(6)(c) or 6(3) or 7(2), 11(1) or 11(2) or 12(1) or 12(2), 19 or 22(1) or 22(2) or 22(3) or 22(4) or 22(5) or 22(8) or 22(9) or 30(8) or 40(8);

(b) fails to comply with regulations 2(1) or 2(2) or 2(3) or 3(1) or 3(6)(d) or 7(1) or 9(1) or 9(2) or 9(3) or 10(1) or 10(2) or 20(1) or 20(2) or 20(3);

(c) fails to comply with regulations 4(1) or 6(1) or 6(2) or 12(3) or 13(1) or 15(2) or 15(9) or 20(4) or 20(5) or 20(7) or 21(1) or 24(1) or 25(1) or 26(1) or 26(6) or 30(1) or 31(1) or 32(1) or 33(1) or 33(5) or 37(1) or 37(4) or 37(5) or 38 or 39(1) or 40(1);

(d) fails to comply with a directive, notice, order, instruction or condition issued, given or determined in terms of these Regulations;

(e) submits inaccurate, false or misleading information in connection with any matter required to be submitted in terms of these Regulations; or

(f) contravenes any other provision of these Regulations;

commits an offence.

(2) A person convicted of an offence in terms of-

(a) sub-regulation (1)(a) is liable to a fine not exceeding R20 000 (twenty thousand Rand) or to a term of imprisonment exceeding two years or to both such fine and such imprisonment;

(b) sub-regulation(1)(b) is liable to a fine not exceeding R40 000 (forty thousand Rand) or to a term of imprisonment not exceeding six years or to both such fine and such imprisonment;

(c) sub-regulation (1)(c) is liable-

(i) to a fine not exceeding R100 000 (one hundred thousand Rand) or to a term of imprisonment not exceeding 10 (ten) years or to both such fine and such imprisonment; and

(ii) to a fine not exceeding three times the commercial value of anything in respect of which the offence was committed; and

(d) sub-regulations 1(d) or 1(e) or 1(f) is liable to a fine or to imprisonment for a period not exceeding six months or to both a fine and such imprisonment.

Enquiry in respect of compensation for harm, loss or damage suffered

47. Where a person is convicted of an offence under these Regulations and-

(a) another person has suffered harm or loss as a result of the act or omission constituting the offence; or

(b) damage has been caused to property or to the environment, the Court may, in the same proceedings-

(i) at the written request of the person who suffered the harm or loss; or

(ii) at the written request of the MEC; and

(iii) in the presence of the convicted person,

enquire without pleadings into the harm, loss or damage and determine the extent thereof.

Award of damages

48. After making a determination in terms of regulation 47, the Court may order the convicted person to-

(a) pay damages for the loss or harm suffered by the person referred to in regulation 47 (a);

(b) pay for the cost of any remedial measures implemented or to be implemented; or

(c) implement the remedial measures.

Director's liability

49. A person who is or was a director of a juristic person at the time of the commission by that juristic person of an offence under these Regulations is himself or herself guilty of the said offence and is liable on conviction to the penalty specified if the offence in question resulted from the failure of the director to take all reasonable steps that were necessary under the circumstances to prevent the commission of the offence.

Offences in relation to employer and employee relationships

50. Whenever an act or omission by an employee or agent –

(a) constitutes an offence in terms of these Regulations, and takes place with the express or implied permission of the employer or principal, the employer or principal is, in addition to the employee or agent, liable to conviction for that offence; or

(b) would constitute an offence by the employer or principal, in terms of these Regulations, that employee or agent will, in addition to that employer or principal, be liable to conviction for that offence, provided that proof of the said offence by the employer, principal or agent, must constitute *prima facie* evidence that the said person is guilty under this sub-regulation.

Interdict or other order by High Court

51. A High Court may, on application by the MEC, grant an interdict or any other appropriate order against a person who has contravened any provision of these Regulations, including an order to discontinue any activity constituting the contravention and to remedy the adverse effects of the contravention.

Directive to cease activities

52. (1) If a person contravenes a condition attached to an authorisation or temporary authorisation, or if in the opinion of the HOD, a person conducts an activity in relation to health care risk waste management or fails to conduct an activity, as a result of which human health or the environment is or may be damaged, endangered or detrimentally affected, the HOD may, subject to sub-regulation (2), in writing direct such person–

(a) to cease such activity; or

(b) to take such steps as the HOD may deem fit to prevent any further harm or damage.

(2) The HOD must-

(a) provide the relevant person with written notice of his or her intention to issue such a directive;

(b) provide the relevant person with an opportunity to make representations to the HOD; and

(c) consider the representations.

(3) If a person fails to comply, or inadequately complies with a directive the HOD may take reasonable measures to remedy the situation.

(4) The Department may recover all costs incurred as a result of the HOD acting under sub-regulation (3).

Manner of appeal

53 (1) An affected person may appeal to the MEC against–

(a) a decision to issue, renew or reject an application for the issue or renewal of an authorisation or temporary authorisation;

(b) a provision or condition of an authorisation or temporary authorisation issued or renewed; or

(c) any directive issued in terms of these Regulations.

(2) An appeal must set out all the facts as well as the grounds of appeal, and must be accompanied by all relevant documents or copies thereof which are certified as true by a commissioner of oaths and must be accompanied by the appeal fee determined by the MEC from time-to-time, and published in a notice in the *Provincial Gazette*.

(3) The Department must in writing acknowledge an appeal made in terms of subsection (1) and the appeal must be dealt with in an expeditious, fair and reasonable manner or in the manner prescribed in terms of section 35(3) of the Act.

(4) The MEC may, after considering an appeal, confirm set aside, vary or add to the decision, provision, condition or directive or any part thereof or make any other appropriate order.

(5) An appeal under this section does not suspend an authorisation, or any provisions or conditions attached thereto, or any directive, unless the MEC directs otherwise.

Short title and commencement

54. These Regulations are called the Gauteng Health Care Waste Management Regulations, 2004 and come into effect on a date fixed by the MEC in the *Provincial Gazette*.

SCHEDULE 1

1. Minimum requirements for packaging of health care risk waste in terms of regulation 9(2)

(1) A plastic bag with a capacity of 60 litres or more must be at least 80 microns in thickness.

(2) A plastic bag with a capacity of less than 60 litres must be at least 60 microns in thickness.

(3) A plastic bag used as a barrier in a container and which is at no time removed from the container, other than for the treatment of the contents, must be at least 40 microns in thickness.

(4) A plastic bag which is used as a smaller intermediate barrier within a single ward or similar, and that is subsequently placed in a container or a further plastic bag must be at least 40 microns in thickness.

(5) A plastic bag and a disposable container must be manufactured from polypropylene or polyethylene polymers; or polymers that cause, at a maximum, equivalent environmental impacts to those caused by polypropylene or polyethylene polymers when finally disposed of by incineration, or treated by means of any available alternative technology.

(6) A health care risk waste container must have a fitted cover, and be kept clean and in good repair.

(7) A container used for the storage of pathological waste must be manufactured from suitable materials able to withstand the low temperatures at which such pathological waste is stored.

(8) A lid used for a disposable sharps container must be secured in such a way that it cannot be reopened once closed, without major structural damage to the container.

(9) A lid used for a pathological waste container must provide an airtight seal to prevent the emission of odours.

(10) For the purpose of ensuring sufficient tensile strength, the maximum allowable percentage of recycled materials in a liner is 10 (ten) percent; provided that for outer packaging the maximum allowable percentage of recycled materials is 15 percent.

SCHEDULE 2

Standards for disinfection of reusable health care risk waste containers in terms of regulation 11(2)(a)

(1) There must be suitable written operating procedures for disinfecting a reusable health care risk waste container, which must include-
  (a) approved testing methodologies for relevant biological and other indicators relating to the adequate disinfection of a health care risk waste reusable container for each unit; and
  (b) all pertinent operating parameters.

(2) The minimum frequency of testing to be conducted in terms of item 1, must be in accordance with the following:
  (a) initial testing prior to commencement of operations: daily swab tests of a sample of disinfected reusable health care risk waste containers for 5 (five) working days;
  (b) testing during usual operation: weekly swab tests of a sample of disinfected reusable health care risk waste containers before dispatch and monthly swab tests of a sample of reusable health care risk waste containers after delivery to a generator;
  (c) after 4 (four) consecutive months of achieving reasonably adequate levels of disinfection, the test frequency as required by (a) and (b) above, may be reduced to 50 percent: Provided that should any one sample fail to indicate a reasonably adequate level of disinfection, the frequency levels required by (a) and (b) above must be adhered to.

(3) Adequate disinfection of reusable health care risk waste containers must be tested and documented based on swab tests or similar sampling procedures for relevant biological indicators, which tests or sampling must be conducted by a competent person.

(4) Such samples must be processed by an accredited laboratory for the following biological indicators:
  (a) Bacterial cultures; and
  (b) Fungal cultures.

(5) A report must compiled quarterly by a competent person regarding the level of disinfection achieved by the facility, based on:
  (a) a reasonable number of representative samples; and
  (b) the results of the tests conducted in terms of item 1.

(7) A report required in terms of sub-item (5) must include details of all procedures used and must be retained for a period of 3 (three) years and must be made available to a generator on request.

(8) The number of swab samples taken for the purpose of monitoring in terms of this Schedule must be reasonable in relation to the number of reusable health care risk waste containers disinfected per day at the disinfecting facility and must be determined and signed off by a competent person.

(9) The specific area of a reusable health care risk waste container to be used for sampling, as well as the location at which a reusable health care risk waste

container is intercepted and diverted for sampling must be determined by a competent person.

SCHEDULE 3

Minimum environmental performance requirements for a controlled combustion treatment facility in terms of regulation 38

(1) Emissions to the atmosphere:

Table 1

Type	Maximum allowable emission to the air from a controlled combustion treatment facility (Daily average values)	Monitoring frequency samples per year Standard (may be reduced after period of documented compliance)
Units	mg/Nm^3	
PM/dust	25	Continuous
CO	50	Continuous
Dioxin/furan (nanogram) TEQ	0.2	1
HCl	30	Continuous
HF	-	-
SO_2	25	Continuous
NO_x	-	-
NH_3	-	-
Pb, (same for Cr, Be, Ar, As, Sb, Ba, Ag, Co, Cu, Mn, Sn, V, Ni)	0.5	4 (1)
Cd (same for Tl)	0.05	4 (1)
Hg	0.05	4 (1)
Reference Conditions and definitions	11percent O_2, 273 Kelvin, 101.3 kPa. All parameters to be defined and measured as in the Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on Incineration of Waste	

(2) **Operating requirements**

(a) A controlled combustion treatment facility must be designed, equipped, built and operated in such a way that the gas resulting from the process is raised, after the last injection of combustion air, in a controlled and homogeneous fashion and even under the most unfavourable conditions, to a temperature of 1 100 °C.

(b) The temperature must be measured for two seconds near the inner wall, or at another representative point of the combustion chamber, as authorised by the Department,

(c) Each line of the controlled combustion treatment facility must be equipped with at least one auxiliary burner.

(d) The burner must-

(i) be switched on automatically when the temperature of the combustion gases after the last injection of combustion air falls below 1 100 °C; and

(ii) also be used during start-up and shut-down operations at the controlled combustion treatment facility in order to ensure that the temperature of 1 100°C is maintained at all times during these operations, and at least for as long as unburned waste is contained in the combustion chamber.

(e) During start-up and shut-down or when the temperature of the combustion gas falls below 1 100°C the auxiliary burner must not be fed with fuels which can cause higher emissions than those resulting from the burning of gas oil or diesel, liquefied gas or natural gas.

(f) Temperatures must be monitored and recording achieved on-line.

(g) Controlled combustion treatment must be conducted in an enclosed combustion chamber, such as a furnace.

(h) No open burning is permitted.

(3) **Safeguard of human health and the environment, and stack height.**

(a) A controlled combustion treatment facility must be designed, equipped, built and operated in such a way as to prevent emissions into the air giving rise to significant ground-level air pollution.

(b) Exhaust gases must be discharged in a controlled fashion by means of a stack.

(c) The height of the stack must be sufficient so as to safeguard human health and the environment.

(4) **Discharges to sewer system**

(a) Any discharge of effluent must be approved by the relevant Municipality.

(b) No effluent from the treatment process may be discharged unless it complies with the standards set by the Department of Water Affairs and Forestry or any relevant Municipality.

(5) **Quality of residues from a controlled combustion treatment facility**

(a) Residues must be rendered reasonably unrecognisable as consisting of health care risk waste.

(b) All sharps waste and any other single object in the health care risk waste must be broken and rendered unusable.

(c) The loss of ignition for the residues after treatment must be a maximum of 5 (five) percent by weight.

SCHEDULE 4

1. Minimum environmental performance and testing requirements for a non-combustion treatment facility in terms of regulation 39 (1)

(1) **Emissions to the atmosphere.**

(a) A non-combustion treatment facility must take adequate measures to avoid emissions of any pathogens or odours via exhausts, vents or similar outlets.

(b) Information relating to the use of all filter materials and the maintenance and replacement of such filters at a treatment facility must be recorded in writing by the treatment facility.

(2) **Microbial inactivation standards** which must be achieved at all times are as follows:

(a) Vegetative bacteria, fungi, lipophillic/hydrophilic viruses, parasites and mycobacteria: $\geq 6\ Log_{10}$ *reduction;*

(b) *G. stearothermophilus* spores or *B.* atrophaeus spores: $\geq 4\ Log_{10}$ *reduction.*

(3) **Representative biological indicators.**

(a) Representative biological indicators must be used to indicate microbial inactivation standards.

(b) One or more of the following organisms from each group must be used for test purposes:

Vegetative Bacteria:

Staphylococcus aureus (ATCC 6538)

Pseudomonas aeruginosa (ATCC 15442)

Fungi:

Candida albicans (ATCC 18804)

Penicillum chrysogenum (ATCC 24791)

Aspergillus niger

Viruses:

MS-2 *Bacteriophage* (ATCC 15597 – B1)

Mycobacteria:

Mycobacterium terrae

Mycobacterium bovis (BCG) (ATCC 35743)

Spores:

Geobacillus stearothermophilus (ATCC 7953) [1]

Bacillus atrophaeus (ATCC 9372)

2 Performance testing requirements for non-combustion treatment facility in terms of regulation 39(6)

(1) For the purposes of this Schedule 4, a competent person must be an independent analyst from an accredited testing laboratory or a health practitioner licensed in terms of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

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[1] Strain derived from ATCC #7953 has been reclassified and is now called Geobacillus stearothermophilus (formerly Bacillus stearothermophilus). The reclassification is a name change only. The strain and its use remain the same.

(2) The following performance tests must be complied with:

(a) An accredited testing laboratory or a health practitioner licensed in terms of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) must conduct a performance test at the treatment facility to:

(i) demonstrate, using surrogate health care risk waste, together with indicator organisms, that the treatment facility is able to achieve the microbial inactivation standards specified in item 1(2)(a); and

(ii) determined the parameters for parametric monitoring for effective performance, including but not limited to:

(aa) temperature;

(bb) maximum throughput; and

(cc) time.

(b) The treatment facility must, thereafter, operate within these parameters, unless it is demonstrated during the performance test that these parameters need to be adjusted.

(c) Once the treatment facility is able to meet the microbial inactivation standards as set out in item 1(2)(a) using surrogate waste, the treatment facility must use health care risk waste to conduct a further performance test to demonstrate that the treatment facility is able to meet the microbial inactivation standards specified in item 1(2).

(d) The performance test must thereafter be carried out daily for 4 (four) consecutive days using health care risk waste, as determined by the competent person.

(e) For the duration of this performance test a reference sample must be included with each run, that is, a sample that has undergone the same preparation, transportation and storage, but not treatment, as the entire batch in order to determine the microbial inactivation standards achieved during treatment.

(3) During the performance testing phase for batch processes, each load must be tested against the bacterial spores *B.* atrophaeus or *G. stearothermophilus.*

(4) For continuous processes, the process must be tested every 2 (two) hours against the bacterial spores *B.* atrophaeus–or *G. stearothermophilus*, in terms of the microbial inactivation standards specified in item 1(2).

(5) A minimum of 2 (two) samples of treated residues produced as a result of performance tests based on surrogate health care risk waste must be submitted for relevant leaching tests as determined by a competent person.

3. Regular testing programme requirements for non-combustion treatment facility in terms of regulation 39(14)

(a) The system must be tested daily against bacterial spores *B.* atrophaeus or *G. stearothermophilus,* in terms of the microbial inactivation standards specified in item 1(2).

(b) The system must be tested at least once a month, by a competent person, as listed in item 1(3), against mycobacteria, and *B.* atrophaeus or G.

stearothermophilus, in terms of the microbial inactivation standards specified in item 1(2), using vials prepared by an accredited laboratory.

(c) Should the results of any test conducted as part of the regular testing programme specified in this item 3, indicate that the treatment facility is unable to achieve the microbial inactivation standards specified in item 1(2), the treatment facility must immediately conduct a second test.

(d) A minimum of 4 (four) samples of the treated residues produced as a result of regular operation of the treatment facility must be submitted annually for relevant leaching tests as determined by a competent person.

(e) The samples submitted must be representative of the treated residues produced for the whole of the preceding 12 month period.

4. Application requirements for reduced routine testing programme in terms of regulation 39 (18)

(1) The motivation for a reduced frequency of testing must be prepared or certified by the competent person and submitted to the Department.

(2) If such permission is granted by the Department, the facility must nevertheless continue to demonstrate that it is able to meet the standards of microbial inactivation specified in item 1(2).

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17/8/21 .....
DATE SIGNATURE

SCHEDULE 5

Application forms for temporary authorisation in terms of regulations 26(2) and 33(2); and authorisation in terms of regulations 15(3), 15(10), 17(2), 24(2), 25(2), 26(8), 27(2) , 31(2), 32(2), 33(16) and 34(2)

Form 1
Application for Temporary authorisation for: transfer facilities and treatment facilities.

Section A: Details			
Name of entity:		**WIS number:**	
Commercial registration number:			
Name of contact person:		**Name of alternative contact person:**	
Physical Address:		**Postal address:**	
Telephone No.		**Facsimile (Fax) No.**	
Section B: treatment facilities only			
Describe the treatment principle (material flow, use of containers, degree of mechanisation, use of manual handling, treatment technology, types of emissions and effluents and pollution abatement measures)			
Does the treatment facility presently comply with the performance requirements set out in Schedules 3 and 4 of these Regulations? (Attach all supporting documentation)			

Section C: transfer facilities only

Describe the storage area and layout of the transfer facility, quantities of health care risk waste storage space for the various storage methods and all other relevant capacity details of the facility

Does the transfer facility comply with the storage requirements set out in regulation 3 of these Regulations?

I, _____ (name), with my signature declare that all information submitted above is correct and accurate and that I am authorized to submit the above information in my capacity as _____ for the above-named entity.

Date: _____ Place: _____

Signature: _____

For Official Use only:

Type of entity	Temporary authorisation No.	Temporary authorisation commence-ment date	Temporary authorisation expiry date	Application for authorisation to be submitted on or before
Transfer facility ☐				
Treatment facility ☐				

Responsible Official:		**Date:**		**Signature:**	
Other notes:					

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17/8/04 ....
DATE SIGNATURE

Form 2
Application for authorisation for:
transporters, transfer facilities and treatment facilities.

Section A: All parties							
Type of Activity (Tick as appropriate)		Transporter		Transfer facility		Treatment facility	
Name of Entity:				**WIS number:**			
Commercial registration number:							
Name of Contact person:			**Name of alternative contact person:**				
Physical Address:			**Postal Address:**				
Name of Municipality			**Facsimile (Fax) No.**				
Telephone No.			**Email address:**				
Section B: Transporters only							
Transporter	Type and number of vehicles operated for this service						
	Name and authorisation number of treatment facility/ies used within Gauteng						
	Name and province of treatment facility/ies used outside of Gauteng						
	Are all vehicles operated for this service equipped with spill kits						
Section C: Transfer facilities only							
Transfer facility	Type of transfer						
	Is the facility permitted			YES		NO	
	Date authorised in terms of these Regulations (if applicable)						
	Permit / EIA authorisation number (as applicable)						
	HCRW transfer capacity (tonnes/months)						

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Form 2 Application for authorisation for transporters, transfer facilities and treatment facilities (continued)

Describe the transfer principle or material flow, use of containers, degree of mechanisation, use of manual handling, transfer technology, types of emissions and effluents and pollution abatement measures

Section D: Treatment facilities only onsite and offsite

Treatment Facility	Type of treatment technology used		
	Authorised or permitted	YES	NO
	Date authorised in terms of these Regulations		
	Permit / EIA authorisation number (as applicable)		
	Treatment capacity (tonnes/months)		

Describe the treatment principle including material flow, use of containers, degree of mechanisation, use of manual handling, treatment technology, types of emissions and effluents and pollution abatement measures.

Does the treatment facility comply with the performance requirements set out in Schedules 3 and 4 of these Regulations? (Attach documentation)	

I, _____(name), with my signature declare that all information submitted above is correct and accurate and that I am authorized to submit the above information in my capacity as _____ for the above-named entity.

Date: _____ Place: _____

Signature: _____

Form 2 Application for authorisation for transporters, transfer facilities and treatment facilities (continued)					
For Official Use only:					
Type of Entity		**Authorisation No.**	**Registration Application: Date Received**	**Temporary Waste Information System password**	**Permanent Waste Information System password**
Transporter ☐					
Transfer facility ☐					
Treatment facility ☐					
			Authorisation commence-ment date	**Authorisation expiry date**	**Application for renewal of authorisation to be submitted on or before**
Transfer facility ☐					
Treatment facility ☐					
Responsible Official:		**Date:**		**Signature:**	
Other notes:					

SCHEDULE 6

Content of Municipal health care risk waste management plan in terms of regulation 14(2)

(1) A Municipal health care risk waste management plan must, at a minimum, include the following information:

(a) Objectives of the health care risk waste management plan.

(b) A status quo report including:

(i) An assessment of the type and number of generators in the relevant area including, but not limited to:

- General Practitioners,
- Traditional Healers,
- tattoo artists and body pierces,
- research and educational institutions,
- laboratories,
- pharmaceutical industries,
- medical clinics,
- hospitals,
- veterinary clinics, and
- undertakers;

(ii) an assessment of the total monthly quantities of health care risk waste generated by minor generators;

(iii) a mapping of all current treatment and disposal facilities; and

(iv) the current status of by-laws regarding health care risk waste.

(c) An investigation of the needs and options for health care risk waste management, including:

(i) an assessment of the need for, and shortcomings of, current health care risk waste service delivery and options for providing or improving on such service;

(ii) an assessment of current collection systems in terms of logistics, affordability, required level and control over service delivery;

(iii) an assessment of possible systems in terms of logistics, affordability, required level and control over service delivery; and

(iv) an overall assessment detailing the time frame, financing and cost recovery and other operational requirements of the required service delivery system.

(d) Details relating to:

(i) target setting;

(ii) the role of generators, Municipalities and the private sector respectively;

(iii) the development or amendment of by-laws or other decision-making tools;

(iv) details of an action plan; and

(v) a consultation plan for the initial implementation of the Municipal health care risk waste management plan.

SCHEDULE 7

1. Content of report to be submitted by a treatment facility in terms of regulation 33(7)

(1) **Company information, including:**
- (a) the name and location of the treatment facility;
- (b) the name of the Municipality in whose area of jurisdiction the treatment facility is located;
- (c) contact person at the treatment facility, including contact details such as telephone number, fax number and e-mail address;
- (d) the WIS number allocated to the treatment facility, if applicable; and
- (e) data as available of quantities of health care risk waste treated over a maximum of the preceding 12 months, including graphs of the monthly tonnage of health care risk waste for that period.

(2) **Detailed site plan indicating:**
- (a) the treatment facility's regional setting;
- (b) the position and scale of current and proposed buildings and infrastructure within the treatment facility;
- (c) temporary storage areas of incoming health care waste;
- (d) liquid effluent and solid waste storage and disposal areas;
- (e) storm-water management system;
- (f) access control and traffic flow;
- (g) staff ablution and washing facilities;
- (h) vehicle cleaning areas;
- (i) surrounding land-use, including the location of schools, hospitals, old age homes (etc.,) and similar public places; and
- (j) climate and topographical features, including elevation of buildings and stack height (where applicable), which may influence dispersion of emissions.

(3) **Technical design drawings and dimensions of the following systems and equipment used at the treatment facility:**
- (a) treatment equipment;
- (b) feed mechanism;
- (c) primary and secondary chambers or other key components of the treatment facility as applicable;
- (d) stack height and location (if applicable);
- (e) cleaning and de-ashing ports (if applicable);
- (f) system for collection and dispatch of residues after treatment;
- (g) stack and effluent outlet (if applicable);
- (h) pollution control equipment, including its position and the retrofitting thereof; and
- (i) fuel storage infrastructure (if applicable).

(4) **Technology description, including:**
- (a) the type, quantity and source of fuel or energy used in treatment;
- (b) operating hours;
- (c) treatment capacity;

(d) nominal and typical throughput or treatment rate;
(e) mass balances;
(f) temperatures in the primary and secondary chambers, and the monitoring and continuous maintaining of required temperatures (as applicable);
(g) calculation of the residence time in the secondary chamber (if applicable);
(h) start-up and shutdown management including any related pollution control equipment system;
(i) retrofitting of the new pollution control technology;
(j) maintenance requirements and program;
(k) early detection of technology malfunction, prediction and prevention of failures, correction of problems etc.; and
(l) decommissioning of any infrastructure (e.g.)including but not limited to redundant stacks or treatment equipment.

(5) **Environmental impact assessment:**
(a) description of all solid, liquid and gaseous emissions (quality and quantity); and
(b) evaluation of environmental impacts, including cumulative impacts, on air, water, soil, noise, odours, natural habitats or features e.g. wetlands, worker health and safety, and public health.

(6) **Impact management and pollution control:**
(a) details of all mitigation measures undertaken and proposed to minimise adverse impacts;
(b) description of pollution systems, the associated technology, how it functions, etc.,
(c) alternatives considered and comparative technology assessment;
(d) current and projected emissions;
(e) expected reduction of emissions and clean-up efficiency;
(f) comparison with international best practice, and performance of similar/same systems elsewhere;
(g) details of how the system deals with and/or reduces specific emissions;
(h) details of the use of raw materials in the treatment system;
(i) details of the quantity, quality (hazard classification in terms of the Minimum Requirements for the Handling, Classification and Disposal of Hazardous Waste), management and disposal of any waste/ by-products from the system;
(j) monitoring of clean-up efficiency;
(k) on-line temperature monitoring;
(l) for combustion technology only: on-line emission monitoring, including but not limited to details on the presence of inspection ports which allow for isokinetic sampling of flue gases, the ability to retrofit to allow for stack monitoring etc.
(m) For non-combustion technology only: measures in place for compliance monitoring for achieving of microbial inactivation levels;
(n) impact of construction activities on current operations on site, and the monitoring and management thereof;
(o) environmental management plan for the construction of the system;

(p) operational and emergency procedures related to inefficient operation and shutdown of the system;
(q) maintenance requirements and program; and
(r) reporting of pertinent operational issues including incident reporting, how these incidents were managed, and the recurrence thereof prevented.

(7) **Waste management:**
(a) procedure for receiving of waste, including but not limited to recording of weight, and source;
(b) management procedure to deal with waste not acceptable for treatment, including the early detection thereof;
(c) rotation of waste in the storage areas;
(d) ash/residue removal and disposal procedures, including the final disposal site where ash/residue is finally disposed of, and the quality and quantity;
(e) spill management;
(f) effluent quantity, quality and disposal;
(g) use of disinfectants and the disposal thereof;
(h) pest control measures;
(i) back-up plan should the technology fail to function for more than 72 consecutive hours; and
(j) procedures in case of needle stick injuries or other occupational injuries.

(8) **Performance test results:**
Detailed report of results of tests done in order to determine compliance with the requirements in Schedule 3 or 4 as applicable (including air emissions, operations, ash and residues, sewer discharge, microbial inactivation, biological indicators, testing programs).

(9) **Compliance plan:**
In the event that the performance tests required in terms of item 1(8) indicate non-compliance with the requirements in Schedule 3 or 4, as the case may be, the treatment facility must submit a detailed plan as required by regulation 33 (7)(b).

(10) **Public participation:**
(a) the intention of the treatment facility to apply for authorisation in terms of these Regulations must be advertised in a local newspaper and at the treatment facility's site;
(b) adjacent landowners must be informed in writing of the application for authorisation for the treatment facility in terms of these Regulations;
(c) interested and affected parties must be given a 30 day period within which to lodge any comments, queries or objections;
(d) after the 30 day period has expired, the Department must be informed of any comments, queries or objections raised by interested and affected parties ("I&APs")together with an indication as to how these will be addressed, if at all;
(e) relevant comments, queries or objections must be addressed; and
(f) a description of the public participation followed, including proof of notification, and a list of interested and affected parties (I&APs) and their comments included in the report, together with information regarding any public information or participation programme which has occurred at any time in the past with respect to the treatment facility.

2. Content of report to be submitted by a transfer facility in terms of regulation 26(6)

(1) **Company information, including:**
- (a) the name and location of the transfer facility;
- (b) the name of the Municipality in whose area of jurisdiction the transfer facility is located;
- (c) contact person at the transfer facility, including contact details such as telephone number, fax number and e-mail address;
- (d) the WIS number allocated to the transfer facility, if applicable;
- (e) data, as available, of quantities of health care risk waste received over a maximum of the preceding 12 months, including graphs of the monthly tonnage of health care risk waste for that period.

(2) **Detailed site plan indicating**:
- (a) the transfer facility's regional setting;
- (b) the position and scale of current and proposed buildings and infrastructure within the transfer facility;
- (c) temporary storage areas of incoming health care risk waste;
- (d) liquid effluent and solid waste storage and disposal areas;
- (e) storm-water management system;
- (f) access control and traffic flow;
- (g) staff ablution and washing facilities;
- (h) vehicle cleaning areas; and
- (i) surrounding land-use, including but not limited to the location of schools, hospitals, old age homes and other public places.

(3) **Environmental impact assessment:**
Description of all solid, liquid and gaseous emissions (quality and quantity), where applicable.

(4) **Impact management and pollution control:**
- (a) details of all mitigation measures undertaken and proposed to minimise adverse impacts; and
- (b) reporting of pertinent operational issues including but not limited to incident reporting, how these incidents were managed, and the recurrence thereof prevented.

(5) **Waste management:**
- (a) procedure for receiving of waste, including but not limited to the recording of weight, and source;
- (b) rotation of waste in the storage areas;
- (c) spill management;
- (d) effluent quantity, quality and disposal;
- (e) pest control measures;
- (f) back-up plan should the technology fail to function for more than 72 consecutive hours; and
- (g) procedures in case of needle stick injuries or other occupational injuries.

(6) **Public participation:**

(a) the intention of the transfer facility to apply for authorisation in terms of these Regulations must be advertised in a local newspaper and at the transfer facility site;
(b) adjacent landowners must be informed in writing of the application for authorisation for the transfer facility;
(c) interested and affected parties must be given a 30 (thirty) day period within which to lodge any comments, queries or objections;
(d) after the 30 (thirty) day period has expired, the Department must be informed of any comments, queries or objections raised by interested and affected parties together with an indication as to how these will be addressed, if at all;
(e) relevant comments, queries or objections must be addressed;
(f) a description of the public participation followed, including proof of notification, and a list of (I&APs)interested and affected parties and their comments must be included in the report, together with information regarding any public information or participation programme which has occurred at any time in the past with respect to the transfer facility.

3. Content of health care waste management plan for a major generator in terms of regulation 12(3)

The health care waste management plan must, as a minimum, include the following:
(a) the types of health care services provided by the major generator;
(b) the number of beds available at the major generator;
(c) the number of out-patients treated at the major generator;
(d) monthly generation rate of health care risk waste and health care general waste at the major generator, recorded in the form of tables and graphs;
(e) the name and authorisation number of the transporter/s utilised by the major generator;
(f) the name and authorisation number of the treatment facility/ies utilised by the generator;
(g) the name and contact details of the CEO of the major generator;
(h) the name and contact details of the health care waste officer of the major generator;
(i) the scope of the health care waste officer's duties in terms of regulation 6(5);
(j) the scope and objectives of the health care waste management plan including evaluation of technologies, procedures and personnel;
(k) the health care waste management system employed including systems used by any third parties operating from the major generator;
(l) a plan drawing of the major generator's facility indicating the routes for internal transport of health care risk waste and the location of the central waste store room(s);
(m) measures to implement health care waste reduction options into management practices and procedures, including analysis of health care waste streams and individual processes, and opportunities to reduce or eliminate health care waste generation.

(n) an evaluation of data on the types, amount, and hazardous constituents of health care waste generated, the source and reason for the generation, potential health care waste reduction and the recycling techniques applicable to those health care wastes;

(o) an evaluation of objective means to reduce the volume of health care risk waste and the management of all health care waste that is generated by the major generator;

(p) details of employee awareness and training programmes implemented in terms of regulation 6(3); (Such programmes must involve employees in health care waste reduction planning and implementation at the generator;)

(q) a description of the internal transportation system to be used at the major generator, in terms item 1 of Schedule 9.

(r) each management plan must be signed by the CEO of the relevant major generator;

(s) the major generator must consider the quantity of waste, the hazardous properties of the waste, the safety of its patients and employees, economic costs and savings, and other appropriate factors in developing a plan.

4. Content of health care waste management audit reports in terms of regulations 13(2), 21(2), 30(2) and 40(2)

(1) Each health care waste management audit report must as a minimum include the following:

(a) the name and location of the person submitting the audit report;

(b) name of the Municipality in whose area of jurisdiction the person is located;

(c) contact person for the relevant person including contact details such as telephone number, fax number and e-mail address;

(d) the authorisation number allocated to the person submitting the audit report;

(e) an estimate of the quantity of health care risk waste generated, stored, transported or treated as the case may be and an estimate of the quantity of health care waste treated, both on site and off site, during the current reporting year including graphs of the monthly tonnage of health care risk waste for that year;

(f) reporting of pertinent operational issues involving:

(i) incidents which have occurred involving health care risk waste;

(ii) material changes to the waste management system;

(iii) replacement of infrastructure related to health care risk waste management;

(iv) changes to services and/or capacity which may impact on the tonnage of waste generated, transported, stored or treated;

(v) use and status of waste tracking documents;

(vi) change of CEO or health care risk waste officer during the audit period, if applicable;

(vii) training undertaken specific to health care risk waste; and

(viii) changes to external service providers;

(g) a description of factors which have, during the current audit period affected health care waste generation and on site or off site treatment of such waste;

(h) *for major generators only:* an assessment of the effect, during the current audit period, of each health care waste reduction measure implemented, on the generation and the on-site and off-site management of health care waste; and an indication of the major generator's compliance with the health care waste management plan submitted in terms of regulations 12(1) or 12(2) for the audit period; and

(i) results of performance tests conducted in terms of Schedules 3 and 4, where applicable.

(2) The audit report must be signed and approved by the CEO or the competent person.

CERTIFIED BY STATE LAW ADVISERS
GAUTENG
17/8/04 ..... AR .....
DATE SIGNATURE

SCHEDULE 8

Form 1

Minimum information requirements for a tracking document in terms of regulation 22(7)

GAUTENG PROVINCIAL GOVERNMENT	**HEALTH CARE RISK WASTE TRACKING AND COLLECTION DOCUMENT**				
	Generator Name, Address			**Date:** / /	
				Requisition No:	
				Contact details	
				Tel:	
				Fax:	
	WIS Number:			Email:	
Waste details	**Disposable containers** (Qty)	**Total mass** (kg)		**Reusable containers** (Qty)	**Total mass** (kgs)
Infectious					
Sharps					
Pathological					
Pharmaceutical					
Other (specify)					
	Design Volume/Size *(Litres)*	***Type of Container*** *(Box (B), Wheeled bin (W), Drum (D), Other (O))*	***Reusable/Disposal*** *(R or D)*	***Content*** *(General infectious (G), sharps (S), anatomical (A), pharmaceutical/chemical (P), Other (O))*	***Quantity*** *(kgs)*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Note: *Disposable containers placed inside reusable containers are not to be recorded separately.*					
Special Instructions					

GENERATOR'S CERTIFICATION:	**TRANSPORTER'S ACKNOWLEDGEMENT OF RECEIPT OF MATERIALS**
I hereby declare that the contents are properly described, packaged, marked and labelled prior to transportation according to all relevant legislation	I hereby declare that the contents as described, are packaged, marked and labelled according to all relevant legislation and is collected for transportation
Generator Name	Transporter Name
WIS Number	WIS Number
Name:	Name:
Signature:	Signature:
Date: / /	Date: / /

TREATMENT VERIFICATION	
Treatment Facility Name:	***Facility WIS No.***
Confirmation of Waste Received	**Confirmation of Waste Treated**
Name:	Name:
Signature:	Signature:
Date: / /	Date: / /

SCHEDULE 9

Minimum requirements for transport, storage, collection and disposal of health care risk waste in terms of regulations 3(1), 4(1), 10(1) and (2), 20(3) and 20(6) and (7)

1. Minimum requirements for the internal transport and storage of health care risk waste in terms of regulations 10(1) and (2).

Minimum requirements for internal transport and storage

(a) **Collection from point of generation:**

(i) a major generator must collect and remove health care risk waste from all wards, departments and similar on a daily basis, and store such waste in a safe area;

(ii) where reasonably practicable no health care risk waste may be handled by health care risk waste management staff unless contained in a container, bottle or HCRW container; and

(iii) the required personal protective equipment must be used when handling health care risk waste containers.

(b) **Internal transport:**

(i) internal transport of health care risk waste must occur in such a manner so as not to cause a risk of harm to any person;

(ii) where it is reasonably practicable, given the number of containers to be transported, health care risk waste must be transported on trolleys suitable for that purpose, with sufficient storage space and designed to avoid spillage, breakage and other damage;

(iii) containers must not be loaded onto transportation trolleys higher than the design level, and unsecured containers may not be loaded onto the trolleys;

(iv) unless the contents of the trolley are reasonably inaccessible, the trolleys must be locked and must not constitute a risk of contact with infectious agents to others;

(v) trolleys must not be left unattended when full, unless under secure lock; and

(vi) health care risk waste must during any internal transportation over distances exceeding 100 metres, be protected by a HCRW container.

(c) **Storage on site:**

(i) all storage facilities at a major generator must have sufficient capacity to store up to 8 (eight) days of waste generated at the facility;

(ii) any and all areas used for the storage of health care risk waste containers must be secured so as to prevent access to these areas to unauthorised persons;

(iii) a storage area at a generator must be clearly marked with warning signs on, or adjacent to, the exterior of entry doors, gates, or lids;

(iv) a storage area may be secured by use of locks on entry doors, gates, or receptacle lids;

(v) a storage area must be maintained so as to prevent the entry of animals and natural elements, and to prevent the storage area from becoming breeding sites or food sources for insect vectors or rodents;

(vi) for the purpose of item 1(c) 'animals' includes those animals not kept at laboratories for the purposes of biological or scientific research and testing.

2. Minimum requirements for external collection and transport in terms of regulation 20(3)

(1) **Collection from on-site storage area**:

(a) health care risk waste must not be handled by health care risk waste management staff unless containerised;

(b) health care risk waste storage areas must be closed and secured on completion of the collection round; and

(c) no health care risk waste container may be left unattended.

(2) **Loading of health care risk waste containers**:

(a) manual handling of health care risk waste containers must be minimised;

(b) access to health care risk waste vehicles must be safe and unobstructed;

(c) containers must be secured when loaded; and

(d) where containers are to be stacked, the maximum allowable stacking height for the particular types of containers must be adhered to.

(3) **Vehicle design**:

(a) health care risk waste collection vehicles must be equipped with spill kits; and

(b) health care risk waste collection vehicles must be clearly marked as transporting health care risk waste.

3. Minimum requirements for final disposal of treated health care risk waste in terms of regulations 4(1) and 20(6)

(1) General

(a) Disposal of treated health care risk waste may not occur in a manner which causes harm to the public health or the environment.

(b) Health care risk waste which has been effectively treated, may be mixed with general waste, provided this is in accordance with the Minimum Requirements for the Handling, Classification and Disposal of Hazardous Waste.

(2) Disposal of residues:

Treated health care risk waste must be classified according to the Minimum Requirements for the Handling, Classification and Disposal of Hazardous Waste, and residues must be finally disposed of or landfilled accordingly.

(3) All health care risk waste, subject to the exception provided for in regulation 4(2), must be finally disposed of in the following manner:

(a) For treated health care risk waste that is solid or semi-solid after treatment – final disposal at a waste disposal site permitted to receive such waste, and where duly authorised staff are available to complete any manifest or

tracking document which may be required in terms of these Regulations or any other law.

(b) For treated health care risk waste that remains liquid after treatment - discharge to a public sewage system in a manner that complies with all applicable wastewater discharge requirements of the relevant Municipality and the relevant National Government department.