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DEPARTMENT OF FORESTRY, FISHERIES AND THE ENVIRONMENT

NO. 7085 **3 February 2026**

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

NATIONAL NORMS AND STANDARDS FOR THE TRANSPORTATION, STORAGE, AND TREATMENT OF HEALTH CARE RISK WASTE

I, Willem Abraham Stephanus Aucamp, Minister of Forestry, Fisheries and the Environment, hereby in terms of section 7(1)(c) read with sections 72 and 73 of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), give notice of my intention to make National Norms and Standards for the Transportation, Storage, and Treatment of Health Care Risk Waste, as set out in the Schedule hereto.

The proposed Norms and Standards aim to regulate the management of Health Care Risk Waste (HCRW) throughout its lifecycle in line with the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), and prescribe the responsibilities of transporters and waste managers when managing HCRW. They outline the requirements that aim to provide for mechanisms which could implement correct measures for storage, handling and transportation, proper treatment and correct disposal post treatment to ensure that the waste is well managed and ultimately safely disposed of after treatment, and to ensure third party protection. They further prescribe the frequency and quantity of testing that is required to confirm the level of disinfection obtained through efficacy testing by non-combustion treatment technologies.

Members of the public are invited to submit written comments, within 30 days from the date of publication of this notice in the Government *Gazette* or in the newspaper, whichever is the later date, to any of the following addresses:

By post to:	The Director General Attention: Mr Jeremia Sibande The Department of Forestry, Fisheries and the Environment Private Bag X447 **PRETORIA** 0001
By hand at:	Ground Floor (Reception), Environment House, 473 Steve Biko Road, Arcadia, Pretoria, 0001.
By email to:	jsibande@dffe.gov.za.

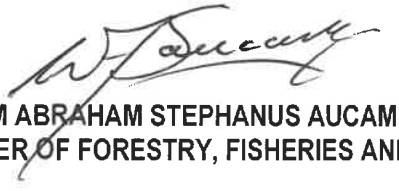
Should the 30-day written comment period overlap with the period from 15 December 2025 to 5 January 2026, this period will be excluded from the reckoning of days.

Any enquiries in connection with the Notice can be directed to Mr Jeremia Sibande jsibande@dffe.gov.za.at (012) 399 9832/067 417 3844.

The proposed National Norms and Standards can be accessed at http://sawic.environment.gov.za/ under "Draft documents for comment".

The Department of Forestry, Fisheries and the Environment complies with the Protection of Personal Information Act, 2013 (Act No. 4 of 2013). Comments received and responses thereto will be included in a comments and response report which may be made available to the public. If a commenting party has any objection to his or her name, or the name of the represented company/organization, being made publicly available in any comments and responses report, such objection should be highlighted as part of the comments submitted.

Comments received after the closing date may not be considered.



WILLEM ABRAHAM STEPHANUS AUCAMP
MINISTER OF FORESTRY, FISHERIES AND THE ENVIRONMENT

SCHEDULE

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CHAPTER 1

DEFINITIONS, PURPOSE AND APPLICATION

Definitions

1. In these Norms and Standards, any word or expression to which a meaning has been assigned in the Act has the meaning so assigned, and unless the context otherwise indicates —

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

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

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

"biological indicator" means a characterized preparation of a specific population of micro-organisms that are resistant to a set of measurable and controlled parameters;

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

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

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

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

"control trial" means a test to confirm the operational parameters and disinfection level of a treatment technology;

"d-value" means the time in minutes at a given temperature required to destroy 1 log cycle (90%) of the target microorganism;

"Department" means the Department responsible for environmental affairs;

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

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

(a) chemical waste;

(b) cytotoxic waste.
(c) genotoxic waste;
(d) infectious waste;
(e) isolation waste;
(f) laboratory waste;
(g) pathological waste;
(h) pharmaceutical waste;
(i) pressurized container waste;
(j) radioactive waste;
(k) sharps waste; and
(l) waste with heavy metals,

but excludes nappy and sanitary wastes unless such wastes are isolation wastes;

"Minister" means the national Minister responsible for environmental affairs;

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

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

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

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

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

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

"test trial" means testing to confirm disinfection of health care risk waste at the design specifications confirmed during the control trial;

"treatment technology" means any technology used to treat health care risk waste;

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

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

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

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

"waste residue" means material remaining after treatment of health care risk waste using a treatment technology; and

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

Purpose and Application

2. (1) The purpose of these National Norms and Standards is to—

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

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

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

(d) prescribe general duties for waste transporters and waste managers; and

(e) prescribe the minimum requirements for the efficacy testing and operation of a non-combustion treatment technology used to treat health care risk waste.

(2) These National Norms and Standards apply—

(a) uniformly throughout the Republic of South Africa;

(b) to all treatment technologies used to treat health care risk waste;

(c) alongside any applicable waste management licence.

CHAPTER 2

GENERAL PROHIBITIONS

General Prohibitions

3. No person may—

(1) dispose of untreated infectious, laboratory, pathological or sharps waste to land;

(2) discharge health care risk waste to a municipal sewer without complying with the requirements of the National Water Act, 1998 (Act No. 36 of 1998), relating to wastewater, and without the approval of the municipality in whose area of jurisdiction the activity is conducted;

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

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

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

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

(7) recycle, recover or reuse any infectious health care risk waste without treating the waste first; and

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

CHAPTER 3

DUTIES OF WASTE TRANSPORTERS AND WASTE MANAGERS

General Duties

4. Every holder of health care risk waste must—

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

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

(b) to sort it; or

(c) for any other purpose; until that health care risk waste is received by a suitably authorised waste management facility.

(2) Comply with the waste manifest system as per the Waste Classification and Management Regulations.

(3) Have a spill response plan in place.

(4) Provide training to employees who are involved in the management of health care risk waste to ensure the following minimum principles and practices are understood and implemented –

(a) health care waste segregation;

(b) best infection control practices;

(c) waste minimisation; and

(d) improved environmental awareness.

(5) Waste transporters and waste managers must keep accurate and up to date records which must –

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

(b) be retained for a period of 5 (five) years; and

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

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

Duties of a Waste Transporter

5. (1) A waste transporter who stores health care risk waste is an operator of a waste transfer facility for the purposes of these Norms and Standards.

(2) A waste transporter must—

(a) not accept health care risk waste from a generator, unless that health care risk waste has been packaged and labelled in accordance with SANS10248-1 or SANS452 or the Waste Classification and Management Regulations,

(b) not accept health care risk waste from a major generator unless that waste has been weighed;

(c) transport health care risk waste in accordance with the National Road Traffic Act, 1996 (Act No. 93 of 1996);

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

(e) ensure that health care risk waste stored at a waste transfer facility before releasing the waste for treatment, is stored in accordance with the requirements set out in paragraph 5(2)(a);

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

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

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

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

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

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

(l) develop, document and implement procedures specific to the management of health care risk waste received at a waste transfer facility which must be made available to the competent authority on request and include as a minimum –

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

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

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

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

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

Duties of a Waste Manager

6. A waste manager must—

(1) Not accept health care risk waste from a waste transporter unless that waste is packaged and labelled in accordance with paragraph 5(2)(a).

(2) Weigh the quantity of health care risk waste received.

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

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

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

(6) Minimise manual handling of containers when loading the treatment technology.

(7) Ensure the integrity and functionality of any reusable containers handled on site are not damaged when opened and loaded into the treatment technology.

(8) Ensure that reusable sharps containers are only opened using methods which are mechanised.

(9) Treat human pathological waste such that it destroyed beyond recognition.

(10) Operate a non-combustion treatment technology in accordance with these Norms and Standards.

(11) Ensure the waste residue resulting from the treatment of health care risk waste is rendered unrecognisable.

(12) Deem the waste residue to be hazardous waste unless otherwise classified in terms of the Waste Classification and Management Regulations.

(13) Ensure waste residue is managed by an authorised waste treatment or disposal facility.

(14) Develop, document and implement procedures specific to the management of health care risk waste received on site which must be made available to the competent authority on request and include as a minimum,—

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

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

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

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

(e) a description of the storage areas;

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

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

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

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

(j) details of action taken during unplanned shutdowns.

CHAPTER 4

STORAGE

7. A storage area used for storing health care risk waste must as a minimum–

(1) Be inaccessible to unauthorised persons.

(2) Be secured by use of locks on entry doors, gates or container lids.

(3) Be sheltered from direct sunlight and rain.

(4) Be appropriately ventilated.

(5) Be vermin proof.

(6) Have access to:

(a) a spill containment and clean-up kit;

(b) water to facilitate cleaning;

(c) an appropriate wastewater management system; and

(d) adequate space for storing clean and dirty containers separately.

(7) Be clearly signposted with appropriate warning signs and emergency contact details on, or adjacent to, the exterior of the entry doors or gates, or on the containers.

CHAPTER 5

GENERAL EFFICACY REQUIREMENTS FOR NON-COMBUSTION TREATMENT TECHNOLOGY

General Efficacy Requirements

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

(a) *Geobacillus stearothermophilus* ATCC 7953; or

(b) *Bacillus atrophaeus* ATCC 9372.

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

(3) The Minister may, from time to time, by notice in the Government *Gazette,* amend the required level of viable spore concentration reduction and the list of biological indicators as contemplated in subparagraph (1).

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

(5) The application must be made by submitting the details of, and reason for, the use of alternative biological indicators in writing at least three (3) months prior to testing.

(6) The Minister must either approve or reject the application within three (3) months of receiving such an application, and provide written reasons in the event of rejecting the application.

CHAPTER 6

VALIDATION TESTING FOR NON-COMBUTION TREATMENT TECHNOLOGY

Validation Testing

9. (1) A non-combustion treatment facility may apply to the Minister for an alternative validation methodology in cases where validation using biological indicators is not possible.

(2) Biological indicators used in validation testing must conform to the requirements in paragraph 8(1) and be—

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

(b) placed in the parts of the load that are the most difficult to treat.

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

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

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

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

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

Site Commissioning Validation Testing for non-combustion treatment technology

10. (1) Prior to routine operation of a non-combustion treatment technology, a waste manager must conduct site commissioning validation testing.

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

(a) be undertaken by a competent microbiologist;

(b) employ the relevant spore in accordance with paragraph 8(1);

(c) confirm the disinfection levels as in paragraph 8(1) have been reached;

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

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

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

(g) use surrogate waste for the control trial;

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

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

(j) dispose of the waste generated during site commissioning in accordance with the *Waste Classification and Management Regulations*;

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

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

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

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

(4) The operational plan must as a minimum—

(a) be signed by a waste manager;

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

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

(5) The operational plan must as a minimum provide details of—

(a) the microbiologist who conducted the site commissioning validation testing;

(b) how the challenge load was determined;

(c) how the most difficult areas in a load to treat were identified;

(d) the waste used during the site commissioning validation testing process;

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

(f) where the waste residue generated during site commissioning was disposed of and where waste residue generated during routine operation will be disposed of.

(6) The operational plan must as minimum document the—

(a) site commissioning validation testing procedure undertaken;

(b) site commissioning validation testing results;

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

(d) routine maintenance schedule;

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

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

(g) the system to be used to record the operating parameters during routine operation;

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

(i) procedures for and frequency of routine validation testing;

(j) procedures for and frequency of calibration of parametric controls; and

(k) procedures to be followed during system failure.

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

(8) The operational plan must, as a minimum, be reviewed after the re-validation testing as set out in paragraph 8.

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

Routine Validation Testing for Non-combustion Treatment Technology

11. (1) Routine validation testing must be undertaken as a minimum—

(a) once a day; and

(b) using three test indicators and one control indicator per test.

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

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

(4) Biological indicators used during routine validation testing must be made available to the competent microbiologist during the independent validation testing as set out in paragraph 12.

Independent Validation Testing

12. (1) Independent validation testing must—

(a) be conducted every three months;

(b) be conducted by a competent microbiologist;

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

(d) recover a minimum of three undamaged test indicators after a routine validation test for the results to be valid, failing which the routine validation test must be repeated;

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

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

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

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

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

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

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

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

Re-validation Testing

13. (1) The procedure as contemplated in paragraphs12 (1) and (2) must be repeated—

(a) if any—

(i) of the operating parameters are altered;

(ii) changes are made to the treatment technology; or

(iii) changes are made to the waste stream being treated.

(b) every five years on request from the Department; or

(c) whichever occurs first.

(2) A validation testing report outlining the re-validation testing conducted and demonstrating that the general efficacy requirements as in paragraph 12 are being met, must be submitted within 30 days after completion to the Department.

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

CHAPTER 7

GENERAL MATTERS

Waste Residue

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

(a) shredded; and

(b) be deemed unrecognisable.

System failure

15. (1) If a parameter fails during operations, a waste manager must—

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

(b) handle all health care risk waste processed by the treatment technology during the failure as untreated and retreat it to the prescribed minimum requirements as in paragraph 9; and

(c) repeat routine validation testing for non-combustion treatment technology until three consecutive validation tests show no growth of test indicators.

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

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

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

(c) handle all health care risk waste processed by the system during the failure as untreated and retreat it to the acceptable standards.

(3) A waste manager must—

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

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

(c) inform the Department in writing within 24 hours of

(i) a system failure; and

(ii) resumption of operations detailing the corrective actions taken.

Record-keeping

16. (1) Records of all validation testing and system failure contemplated in paragraphs, 9, 10, 11, 12, and 13 must be—

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

(b) made available to the Department upon request.

Implementation and Transitional Arrangements

17. (1) A person who lawfully operated a treatment facility to treat health care risk waste prior to and on the date of coming into effect of these Norms and Standards must—

(a) continue with the activity as per the conditions stipulated in their waste management licence; and

(b) after renewal or review of the waste management licence, comply with these Norms and Standards and the waste management licence.

(2) A person who operated a treatment facility that did not require a waste management licence on the date of coming into effect of these Norms and Standards, must comply with these Norms and Standards within six (6) months of their coming into effect.

Short tittle and commencement

18. These Norms and Standards are called the National Norms and Standards for Health Care Risk Waste**,** 2025, and will come into operation on the date of their publication for implementation in the Government *Gazette*.