DEPARTMENT OF ENVIRONMENTAL AFFAIRS

NO. 464 **30 APRIL 2018**

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

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

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

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

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

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

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

Comments received after the closing date may not be considered.

BOMO EDNA EDITH MOLEWA
MINISTER OF ENVIRONMENTAL AFFAIRS

SCHEDULE

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CHAPTER 1

DEFINITIONS, PURPOSE AND APPLICATION

Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Purpose

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

Application

3. These National Norms and Standards—

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

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

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

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

CHAPTER 2

GENERAL EFFICACY REQUIREMENTS

General Efficacy Requirements

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

(a) *Geobacillus stearothermophilus* ATCC 7953; or

(b) *Bacillus atrophaeus* ATCC 9372.

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

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

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

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

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

CHAPTER 3

VALIDATION TESTING

General Validation Testing

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

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

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

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

(d) be protected from mechanical damage during testing.

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

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

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

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

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

Site Commissioning Validation Testing

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

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

(a) be undertaken by a competent microbiologist;

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

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

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

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

(f) use surrogate waste for the control trial;

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

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

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

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

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

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

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

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

(4) The operational plan must as a minimum—

(a) be signed by a waste manager;

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

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

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

(e) document the site commissioning validation testing results;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Routine Validation Testing

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

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

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

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

Independent Validation Testing

8. (1) Independent validation testing must—

(a) be conducted every three months;

(b) be conducted by a competent microbiologist;

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

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

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

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

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

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

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

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

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

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

Re-validation Testing

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

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

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

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

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

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

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

CHAPTER 4

GENERAL MATTERS

Waste Residue

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

(a) be shredded; and

(b) be unrecognisable.

System failure

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

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

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

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

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

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

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

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

(3) A waste manager must—

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

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

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

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

Record Keeping

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

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

(b) made available to the Department on request.

Implementation and Transitional Arrangements

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