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# GENERAL NOTICE

## NOTICE 453 OF 2012

## DEPARTMENT OF ENVIRONMENTAL AFFAIRS

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

## DRAFT NATIONAL STANDARDS FOR VALIDATION OF THE TREATMENT EFFICACY AND OPERATION OF A NON-COMBUSTION TECHNOLOGY FOR THE TREATMENT OF HEALTH CARE RISK WASTE

I, Bomo Edith Edna Molewa, Minister of Water and Environmental Affairs, hereby give notice of my intention, under section 7(1)(c) and (2)(c) read with section 73 of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), to set national standards regarding the management of the healthcare risk waste in the Schedule hereto.

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

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

By fax to: (012) 320 0024;

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

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

The draft standards can also be accessed at www.sawic.org.za.

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

Comments received after the closing date may not be considered.

**BOMO EDITH EDNA MOLEWA**

**MINISTER OF WATER AND ENVIRONMENTAL AFFAIRS**

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## PART 1

## DEFINITIONS, PURPOSE AND APPLICATION

### 1. Definitions

(1) In these Standards a word or expression that is defined in the Act bears the same meaning, unless the context requires otherwise-

**'biological indicator'** means an inoculated carrier container ready for use and providing a defined resistance to the specified treatment process;

**'challenge load'** means a typical waste load that reflects the maximum waste quantity that is intended to be processed and includes all the waste streams that the treatment device is authorised to treat;

**'competent person'** means a person that is generally recognised within the scientific community as having the capability of conducting in conformance with generally recognised scientific principles, microbiological examination, independent analysis or assessment;

**'control indicator'** means a biological indicator drawn from the same batch of indicators used for validation testing which does not undergo treatment but is incubated with the validation indicators to confirm the viability of the biological indicators prior to treatment;

**'control trial'** means a test to confirm the operational parameters of the treatment device;

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

**'disinfect'** means to render non-viable potential human and animal pathogens, but not necessarily all microbial forms to the level set out in Part 2 of these standards;

**'dry heat treatment'** means processors that utilise hot air without the addition of water or steam to treat healthcare risk waste;

**'D value'** means the exposure time required to secure inactivation of 90% of a population of test organisms under stated conditions;

**'efficacy'** means the capacity to produce an effect;

**'efficacy testing'** means testing of a non-combustion health care risk waste treatment system conducted by a competent person, independent of the system manufacturer, to establish operating parameters for the systems effective treatment of health care risk waste;

**'moist heat treatment'** means processors that utilise steam as part of a treatment process for healthcare risk waste;

**'spore strip'** means a sealed strip containing bacterial spores at a specified concentration;

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

**'test trial'** means a test to confirm the efficacy of the treatment device.

## 2. Purpose and Application

(1) This Standard prescribes the minimum requirements for the efficacy testing and operation of a non-combustion treatment technology treating health care risk waste in terms of the Health Care Risk Waste Management Regulations, 2012.

(2) This standard does not apply to facilities utilising chemicals for the treatment of health care risk waste.

## PART 2

## EFFICACY REQUIREMENT

## 3. General Efficacy Requirements

(1) A non-combustion device for the treatment of health care risk waste must, as a minimum, achieve a 4 Log 10 or greater reduction of bacterial spores of-

(a) *Geobacillus stearothermophilus* ATCC 7953 for moist heat treatment; or

(b) *Bacillus atrophaeus* ATCC 9372 for dry heat treatment.

(2) The spores must have a certified thermal D-value of-

(a) 121$^{o}$C moist heat (*Geobacillus stearothermophilus*) $\geq$ 1.5 minutes; and

(b) 160$^{o}$C dry heat (*Bacillus atrophaeus*) > 2.0 minutes.

## PART 3

## EFFICACY VALIDATION TESTING

## 4. General Validation Requirements

(1) Biological indicators used in validation testing must-

(a) conform to the requirements in section 3 of this standard;

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

(c) be placed in the parts of the load that have been identified as being the most difficult to treat.

(2) The control indicator must be processed through the treatment device before disposal.

(3) Each validation test must include a control indicator in accordance with Tables 1, 2 and 3 in this standard.

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

(5) Each validation test must include the use of an integrator strip, a thermal data logger or a data tracer that indicates the treatment temperature and the length of time at the treatment temperature.

(6) An auditable process must be in place to ensure consecutive biological indicators are used and that all indicators from a particular batch can be accounted for.

(7) Instruments monitoring operating parameters and scales must be calibrated according to the manufacturer's specifications and reported on in accordance with section 9 of this standard.

**5. Site Commissioning Validation Requirements**

(1) Site commissioning validation must be undertaken on each unit, after the waste management licence has been issued in accordance with the Act and the device has been installed.

(2) The site commissioning validation test must-

(a) be undertaken by an independent competent person;

(b) commence with control trials followed by the test trials;

(c) use surrogate waste for the control trials;

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

(e) consider the waste used in the test trials as untreated and which must be disposed of at a hazardous landfill site;

(f) use the number of biological indicator per validation trial listed in Table 1 in this standard;

(g) include a minimum of three separate control tests and three separate test trials;

(h) ensure that the biological indicators are protected from coming into contact with the health care risk waste;

(i) ensure that the biological indicators are cultured at an accredited laboratory to confirm a microbial reduction in accordance with section 3 of this standard;

(j) ensure that the positioning of the biological indictors is varied to assess where treatment may be challenged;

(k) demonstrate that the device does not create bio-aerosols during and after treatment;

(l) include ambient monitoring for microbial emissions on the operating floor and at exhausts, vents or similar outlets; and

(m) include volatile organic compound emission monitoring on the operating floor and at exhausts, vents or similar outlets.

(3) On completion of the validation procedure the operator must submit to the Department a validation report compiled by an independent competent person for approval.

(4) The validation report must:

(a) document the validation procedure;

(b) provide details of the independent competent person who conducted the validation procedures;

(c) provide details of the challenge load used;

(d) confirm the treatment efficacy of the treatment device;

(e) document the operating parameters (e.g. residence time, temperature and pressure);

(f) identify positions within the process where treatment may be challenged;

(g) provide details of the accredited laboratory used; and

(h) document the lot number, expiry date; organism used, d-value and concentration of the biological indicator used.

(5) Once the commissioning validation testing has been completed the facility must not commence operation until the validation report has been approved by the Department.

(6) Sub-sections (1), (2), (3) and (4) of this standard must be repeated-

(a) if any process parameters are altered from those assessed during the site commissioning and validation testing;

(b) if mechanical or engineering changes are made to the treatment device;

(c) if the waste stream changes such that the challenge load considered during the validation is no longer the waste case scenario;

(d) for new treatment devices, every 48 months during the operational life of the treatment device; or

(e) for existing treatment devices, within 48 months of coming into operation of this standard and repeated every 48 months thereafter.

Table 1: Minimum number of biological indicators required for site commissioning validation

| | Minimum number of spore strips | | Minimum number of ampoules or self-contained vials | |
|---|---|---|---|---|
| Single load capacity (kg) Continuous throughput (kg per hour) | Recovered per validation test | Retained as controls per validation test | Recovered per validation test | Recovered per control runs |
| 0 – 10 kg | 3 | 2 | 3 | 2 |
| 11 – 50 kg | 4 | 2 | 4 | 2 |
| 51 – 250 kg | 6 | 2 | 6 | 2 |
| 251 – 500 kg | 8 | 2 | 8 | 2 |
| 501 – 750 kg | 10 | 2 | 10 | 2 |
| > 750 kg | 12 | 2 | 10 | 2 |

## 6. Routine Validation Requirements

(1) The treatment device must be operated using the operational parameters confirmed in the approved site commissioning validation report.

(2) Real time monitoring of the operational parameters of the treatment device must be recorded and reported according to the requirements of section 9 of this standard.

(3) Daily efficacy validations test must be undertaken as follows:

(a) in accordance with section 4 of this standard;

(b) under normal operating conditions; and

(c) using the number of biological indicators listed in Table 2 in this standard.

(4) Biological indicators used during routine validation must be kept and made available to the independent auditor when the site is audited and then must be retreated by the device prior to disposal.

| Table 2: Daily monitoring | | | |
|---|---|---|---|
| Single load capacity (kg) Continuous throughput (kg per hour) | Minimum number of ampoules or self-contained vials per validation test | Number of controls per validation test | Number of test runs per day |
| 0 – 500 kg | 8 | 2 | 2 |
| 500 – 1000 kg | 10 | 2 | 3 |

(5) A quarterly efficacy validation test must be undertaken as follows:

(a) testing must be undertaken by an independent competent person;

(b) testing must be undertaken within an 8 (eight) hour period;

(c) using the number and type of biological indicators listed in Table 3 in this standard;

(d) spore strips are to be cultured and plated at an accredited laboratory to confirm microbial reduction in accordance with section 3 of this standard.

| Table 3: Quarterly validation requirements | | | | |
|---|---|---|---|---|
| Single load capacity (kg) Continuous throughput (kg per hour) | Minimum of spore strips | Minimum number of ampoules or self-contained vials | Number of control strips | Number of validation tests |
| 0 – 500 kg | 3 | 3 | 3 | 3 |
| 501 – 1000 kg | 4 | 4 | 3 | 3 |

## 7. System failure

(1) If parametric indicators fail, the process must be stopped immediately and the Department notified of the interruption.

(2) The process may not be restarted until the parametric monitoring is reinstated and is fully operational.

(3) If one or more of the microbial indicators used in the validation test indicates a failure of the treatment device to achieve the efficacy standards in accordance with section 3 of this standard the test must immediately be repeated.

(4) If one or more of the microbial indicators in the second test indicates a failure in accordance with section 3 of this standard, the process must be stopped immediately and the Department informed of the interruption.

(5) Through the period of interruption the treatment device may only be operated to undertake validation testing.

(6) In order for treatment operations to resume-

(a) efficacy testing in accordance with section 6(4) of this standard must be undertaken;

(b) the treatment device must achieve the general efficacy requirements in accordance with section 3 of this standard; and

(c) the Department must be informed of details of the successful validation test.

(7) If the validation test in accordance with subsection (6) of this standard fails, validation in accordance with section 5 of this standard must be undertaken.

(8) Waste is regarded as untreated and must be retreated-

(a) if parametric failure occurred;

(b) if efficacy requirements were not obtained; and

(c) during validation testing undertaken in accordance with section 7 of this standard.

**8. Emissions to the environment**

(1) Shredders operated prior to treatment of health care risk waste must be operated under negative pressure.

(2) Shredders operated after the treatment of health care risk waste must be fitted with an air extraction system.

(3) All emissions from exhausts, vents or similar outlets must be filtered through a high efficiency particulate air filter which achieves a minimum particle removal efficiency of 99.97% of all particles of 0.3 µm diameter.

(4) Quarterly emission monitoring of volatile organic compounds must be undertaken by an independent competent person at exhausts, vents or similar outlets in accordance with the Occupational Health and Safety Act, Act No 85 of 1993 and the relevant regulations.

(5) Quarterly ambient monitoring for hazardous biological agents must be undertaken by an independent competent person at exhausts, vents or similar outlets in accordance with the Occupational Health and Safety Act, Act No 85 of 1993 and the relevant regulations.

## PART 4

## AUDITING AND REPORTING

### 9. Auditing and Reporting

(1) An annual audit must be undertaken by an independent competent person.

(2) An annual audit report must be submitted to the Department within 30 days of the audit being undertaken.

(3) The first annual audit is required to be undertaken within the 13th month of operation.

(4) The annual audit must-

(a) confirm that the parametric and validation testing met the requirements of this standard;

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

(c) confirm that the monitoring results of emissions to the environment demonstrated no pathogenic growth; and

(d) confirm that instruments monitoring operating parameters and scales were calibrated in accordance with the manufactures specifications.

(5) Records of all validation testing and monitoring must be maintained by the facility for a period of at least 5 years.

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