
GOVERNMENT NOTICES

GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH DEPARTEMENT VAN GESONDHEID

No. R. 375

23 May 2014

THE NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)

REGULATIONS RELATING TO HEALTH CARE WASTE MANAGEMENT IN HEALTH ESTABLISHMENTS

The Minister of Health intends, in terms of section 90 (1) (n) of the National Health Act, 2003 (Act No. 61 of 2003) as amended after consultation with the National Health Council to make regulations contained in the Schedule hereto.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Department of Health (For attention of Director: Environmental Health, Ms APR Cele Private Bag X828, Pretoria, 0001), within a period of three months from the date of publication of this notice.

SCHEDULE

CHAPTER 1

1 DEFINITIONS

In these Regulations unless the context indicates otherwise a word or expression that is defined in the Act bears the same meaning in these Regulations, and in addition:

'**chemical waste**' means solid, liquid and gaseous products that are to be discarded and that contain dangerous or polluting chemicals that pose a threat to humans, animals or the environment, when improperly disposed of;

'container' means disposable or reusable vessels in which waste is placed for the purpose of storing, accumulating, handling, transporting, treating or disposing of that waste, and includes bins, bin-liners and skips;

'collection' means accumulation of wastes from intermediate storage sites for movement to a primary waste holding area or from several primary waste holding areas to the treatment or final disposal site or both;

'cytotoxic waste' means waste that is toxic to cells and that can lead to cell death;

'disposal' means the burial, deposit, discharge, abandoning, dumping, placing or release of any waste into, or onto land;

'domestic generator' means a householder or 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 households or facilities which generate health care risk waste such as sharps waste or households where there is one or more chronically ill persons requiring the use of equipment such as a dialysis machine;

'environmental health practitioner' means, subject to the provisions of the Health Professions Act, 1974 (Act No. 56 of 1974) as amended, any person registered as such with the Health Professions Council of South Africa and, includes an Environmental Health Practitioner doing compulsory community service and a health officer appointed in terms of the Act;

'genotoxic waste' means waste capable of interacting with living cells and causing genetic damage;

'green procurement' means selection for purchase of products and services that minimizes the impact of the products and services on the environment;

'handling' means functions associated with the movement of health care waste, including storage, treatment and ultimate disposal, by the use of both the manual systems and automated systems;

'health care general waste' means the non-hazardous components 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 professional' means an individual that provides preventive, curative, promotional or rehabilitative healthcare services in a systematic way to any individual, family or community in need thereof;

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

- (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) Radioactive waste; and
- (j) Sharps waste.

'health care waste' means waste generated at a health establishment and includes both health care general waste and health care risk waste;

'health care waste officer' means the person that shall be designated and / or may be appointed by the owner or person in charge of a health establishment as such in terms of regulation 10;

'health establishment' means a health establishment as defined in section 1 of the Act;

'hazard' means a source of or exposure to danger or harm;

'infectious waste' means material suspected to contain pathogens (bacteria, viruses, parasites or fungi) in sufficient concentrations or quantity to cause disease in susceptible hosts;

'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 in order to protect others from highly communicable or zoonotic diseases;

'laboratory waste' means human or animal specimen cultures from health care and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; 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 waste containing any microbiological specimens sent to a laboratory for analysis;

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

'minor generator' means a generator that generates up to 20 kilograms per day of health care risk waste, including the container, calculated monthly as daily average, but excludes a domestic generator;

'non-health care professional' means a person engaged in an occupation that requires working on the human body, but does not require training in the medical profession;

'pathological waste' means tissues, organs, body parts, blood, body fluids, human fetuses, infected animal carcasses and other waste from surgery and autopsies on patients with infectious diseases;

'pharmaceutical waste' means unused medicines, medications and residues of medicines that are no longer usable as medication;

'private health establishment' means a private health establishment as defined in section 1 of the Act;

'public health establishment' means a public health establishment as defined in section 1 of the Act;

'radioactive waste' means liquid, solid or gaseous materials that contain, or are contaminated with, radionuclides at concentrations or activities greater than the clearance levels and for which no use is foreseen;

'registered' means registered with a recognized professional body;

'risk' means the probability that injury or damage will occur;

'sharps waste' means items that could cause cuts or puncture wounds, including needles, hypodermic needles, scalpels and other blades, knives, infusion sets, saws, broken glass and pipettes;

'rural and remote setting' means the formal or informal healthcare facilities in areas that are permanently or periodically difficult to access by road or rail, and where there are limited private or public services, for example, waste removal, electricity, water and telecommunication;

'segregation' means systematic separation of health care waste into designated categories;

'the Act' means the National Health Act, 2003 (Act No. 61 of 2003) as amended.

CHAPTER 2

GENERAL REQUIREMENTS APPLICABLE TO HEALTH CARE WASTE MANAGEMENT

2. General prohibitions

- (1) No health establishment may manage health care waste:
 - (a) other than in accordance with these regulations and the national norms and standards relating to environmental health; or
 - (b) in a manner that may pose a risk or hazard to human health and the environment.

3. Environmental Principles

- (1) All health establishments that generate health care waste:
 - (a) have a duty to dispose of the waste safely;
 - (b) are legally and financially responsible for the safe handling and environment sound disposal of the waste they produce;
 - (c) must always assume that the waste is hazardous until shown to be safe; and
 - (d) have a responsibility of the waste from the point of generation until its final treatment and disposal.

4. Scope of regulations

- (1) The provisions of these regulations shall be applicable to all private and public health establishments.
- (2) The regulations shall regulate the handling, storage, collection, transportation, treatment and disposal of health care waste.

- (3) This regulation shall not apply to radioactive, electronic and animal wastes.

5. Health and safety

- (1) A minor and major generator shall take all reasonable measures to ensure that:
- a. 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 decanting it into another container; sorting it or; any other purpose; until such health care risk waste is received by the licensed treatment facility;
 - b. reusable containers are effectively disinfected before reuse;
 - c. provide and require all persons who manually handle containers of untreated health care risk waste to wear clean, protective gloves and overalls, changeable laboratory coats or other appropriate personal protective equipment; and
- (2) A minor and a major generator shall ensure that it has a health and safety policy and an emergency response policy and strategy in place.

CHAPTER 3

HEALTH CARE WASTE MANAGEMENT PLANS

6. Minimum requirements for a health care waste management plan

- (1) Each health care waste major generator shall have a health care waste management plan in place.
- (2) The contents of the health care waste management plan referred to in sub-regulation (1) shall include the following:
- (a) The types of health care services provided;
 - (b) The number of beds available;

- (c) The categories of health care waste streams generated;
- (d) Monthly generation rate of health care risk waste and health care general waste recorded in the form of tables and graphs;
- (e) The name and registration number of the transporter/s utilized;
- (f) The name and license number of the treatment facility/ies utilized;
- (g) The name and contact details of the person in charge (chief executive officer / facility manager);
- (h) The name and contact details of the health care waste officer (if applicable);
- (i) The scope of the health care waste officer's duties;
- (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;
- (l) A diagram indicating the routes for internal transport of health care risk waste and 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;
- (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 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;
- (p) An on-going education and training programme on health care waste management to be developed for employees;
- (q) A description of internal transportation system to be used;
- (r) Each management plan must be signed by the person in charge;
- (s) The quality 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;
- (t) Measures to implement an effective management of spills during handling, collection and removal of health care waste;

- (u) List, contact details and duties of the waste management team; and
- (v) A waste management service rendering contract between the health establishment and the appointed waste management contractor.

CHAPTER 4

REQUIREMENTS APPLICABLE TO HEALTH ESTABLISHMENTS

- 7. (1) The owner or person in charge of a health establishment shall ensure that health care waste generated is handled, collected, transported, removed, treated and disposed off in a manner as not to pose a risk, hazard or danger to human health and the environment;
- (2) The owner or person in charge shall ensure that monthly records are kept for each category of health care risk waste generated, transported, treated or disposed.
- (3) The records referred to sub-regulation (2) shall be kept for a period of at least 5 years before being destroyed.

Establishment of a health care waste management team or committee

- 8. (1) The owner or person in charge shall establish a health care waste management team or committee;
- (2) The health care waste management team or committee referred to in sub-regulation (1) shall comprise, but not limited to, of the following staff members:
 - (a) The Chief Executive Officer / Facility Manager;
 - (b) The designated and / or appointed Health Care Waste Officer;
 - (c) A representative of the section responsible for Procurement;
 - (d) A representative of the section responsible for Cleaning and Hygiene Services;

- (d) An Infection and Prevention Control Officer;
- (e) An Occupational Health and Safety Officer;
- (f) A Quality Control Officer;
- (g) Environmental Health Practitioner of the area; and
- (h) A nominated health and safety representative.

Function(s) of the health care waste management team or committee

9. (1) The function(s) of the health care waste management team or committee shall include, but not limited to the following:

- (a) The team or committee shall meet on a quarterly basis or when a need arises;
- (b) Facilitate and coordinate health care waste management issues within the health establishment;
- (c) Provide advice, guidance and technical support on health care waste management issues within the health establishment;
- (d) Develop strategies, policies, guidelines, protocols, schedules, plans, procedures, instructions etc on health care waste management, training, personal and workplace hygiene, inspection and quality control, health and safety, emergency response, infection control and disinfection within the health establishment;
- (e) Development, approval and dissemination of information, education and communication materials on health care waste management within the health establishment;
- (f) Ensuring training to all medical and non medical staff on proper health care waste management systems and record keeping thereof is conducted;
- (g) Ensuring routine inspections and record keeping of inspections concerning health care waste management compliance is conducted;
- (h) Monitoring the implementation of strategies, policies, guidelines, protocols, schedules, plans, procedures, and instructions;
- (i) Monitor health care waste management systems in all and/or relevant wards, areas of the health establishment;
- (j) Taking corrective action to remedy non compliance;

- (k) Reporting on the outcome of inspection, non-compliance, accidents and recommended actions to the health care waste management team, relevant heads of department, person in charge of the health establishment and relevant Environmental Health Practitioner of the municipal area/district; where necessary;
- (l) Managing and monitoring of the health care waste management contractor;
- (m) Financial management and budgeting for health care waste service;
- (n) Responsible for tender and the appointment of the compliant health care waste service provider;
- (o) Appointment of a chairperson and a secretariat for the team or committee;
- (p) Prescribing terms of reference for the team or committee;
- (q) Prescribing the roles and responsibilities of each team member with regards to the functions of the health care waste management team and other functions relating to health care waste management; and
- (r) Perform any other function related to health care waste management within the health establishment.

Designation and / or appointment of Health Care Waste Officers

10. (1) The owner or person in charge of a health establishment shall designate and / or may appoint health care waste officers to manage the health care waste;
- (2) The designation and / or appointment of health care waste officers shall be done in writing by the owner or person in charge of the health establishment.
- (3) The designated health care waste officer shall meet the following qualities:
- (a) Any full or part time employee who is:
 - i. A registered and qualified professional nurse, or;
 - ii. A registered and qualified infection prevention control nurse, or;
 - iii. A registered and qualified quality control nurse, or;
 - iv. A registered and qualified occupational health nurse, or;
 - v. A registered and qualified occupational health officer, or;
 - vi. A registered and qualified environmental health community service practitioner, or;

- vii. A registered and qualified environmental health assistant, or;
 - viii. A registered and qualified environmental health practitioner, appointed in terms of the Act; and
- (b) Have attended a continuous professional development accredited training on health care waste management;
 - (c) Able to communicate well at all levels;
 - (d) Able to facilitate team work;
 - (e) Have excellent problem solving skills;
 - (f) Have initiative and self motivation; and
 - (g) Has report writing skills.
- (4) The appointed health care waste officer shall meet the following qualities:
- (a) Any full or part time employee who is:
 - i. A qualified environmental management officer, or;
 - ii. A registered and qualified environmental health practitioner, appointed in terms of the Act.
 - (b) Have attended a continuous professional development accredited training on health care waste management;
 - (c) Able to meet the qualities outlined in sub-regulation (3)(c)-(g).

Duties of persons designated and / or appointed as Health Care Waste Officers

11. (1) The duties of the designated and / or appointed Health Care Waste Officers within the health establishment shall include but not limited to the following:
- (a) Ensure the minimization of health care general waste in terms of recycling, reuse and reduce;
 - (b) Monitor proper segregation, containerization, recycling, intermediate storage, internal transport and collection, centralized storage and removal of health care waste;
 - (c) Liaising with the health care waste management team and the appointed waste management contractor;

- (d) Day to day monitoring, management and problem solving in relation to the management of health care waste;
- (e) Provide information on health care waste policies and other legislative matters;
- (f) Ensure ongoing training programmes, including awareness activities;
- (g) Promote continuous improvement in proper health care waste management and encourage waste minimization and recycling;
- (h) Development of a written health care waste management plan;
- (i) Provide technical advice in the development of health and safety policy, infection control policy, cleaning and disinfection procedures and instructions, emergency response strategies and health care waste training plans; health care waste service contract specifications and other relevant matters in the capacity of the health care waste officer to provide technical advice;
- (j) Compile inspection reports; and
- (k) Report non-compliance and recommended actions to the health care waste management team, relevant heads of department, person in charge of the health establishment and relevant Environmental Health Practitioner of the municipal area/district, where necessary.

CHAPTER 5

IDENTIFICATION, CLASSIFICATION, SEGREGATION AND MINIMIZATION OF HEALTH CARE WASTE

12. Identification and classification

- (1) All health care risk waste generated shall be identified and classified in accordance with the provisions in the South African National Standards 10234: *Globally Harmonized System of classification and labeling of chemicals*.

- (2) All health care risk waste transported shall be identified and classified in accordance with the provisions in the South African National Standards 10228: *The identification and classification of dangerous goods for transport by road and rail modes*.
- (3) Employees shall be trained on an ongoing basis in the correct identification and classification of health care waste; and
- (4) Records of all training referred to in sub-regulation (3) shall be kept.

13. Segregation and Minimization

- (1) All health care waste shall be segregated at the point of generation and shall be containerized to minimize the risk of contamination or pollution to human health and the environment;
- (2) Employees shall be trained on an ongoing basis in the correct segregation and minimization of health care waste.
- (3) Records of all training referred to in sub-regulation (3) shall be kept.

CHAPTER 6

PACKAGING AND LABELLING OF HEALTH CARE WASTE

14. (1) All health care risk waste to be transported shall be packaged and labeled in accordance with the provisions in the South African National Standard 10229-1: *Transport of dangerous goods-Packaging and large packaging for road and rail transport, Part 1: Packaging* and the South African National Standards 452: *Non-reusable and reusable sharps containers* and any amendments thereof; and
- (2) All health care risk and general waste shall be packaged and labelled in accordance with the provisions in the South African National Standard 10248-1: *Management of healthcare waste, Part 1: Management of healthcare risk*

waste from a healthcare facility; South African National Standard 10248-2: *Management of healthcare waste, Part 2: Management of healthcare risk waste for healthcare facilities and healthcare providers in rural and remote settings*; South African National Standard 10248-3: *Management of healthcare waste, Part 3: Management of healthcare risk waste from minor generators, registered healthcare professionals and non-healthcare professionals*.

CHAPTER 7

HEALTH CARE WASTE STORAGE

15. (1) All health care risk waste shall be stored in accordance with the provisions in the South African National Standard 10248-1: *Management of healthcare waste, Part 1: Management of healthcare risk waste from a healthcare facility*; South African National Standard 10248-2: *Management of healthcare waste, Part 2: Management of healthcare risk waste for healthcare facilities and healthcare providers in rural and remote settings*; South African National Standard 10248-3: *Management of healthcare waste, Part 3: Management of healthcare risk waste from minor generators, registered healthcare professionals and non-healthcare professionals*;
- (2) The owner or person in charge of a health establishment shall establish intermediate and central storage areas for health care risk waste storage;
- (3) The health care risk waste intermediate storage area must, at a minimum, include the following:
- (a) Easy access to the area;
 - (b) Well ventilated, illuminated and easy to clear;
 - (c) Regular collection to prevent accumulation and nuisance free;
 - (d) Space for storage of empty containers;
 - (e) Lockable door, where applicable, to ensure controlled access or under close supervision;
 - (f) Size of the area shall be determined by the rate of waste generated;

- (g) Easy to clean with smooth surfaces.
 - (h) Equipped with a spill kit; and
 - (i) Clear posting of the international biohazardous signage.
- (4) The health care risk waste central storage area must, at a minimum, include the following:
- (a) Sufficient space to contain the required accumulation of waste between collections as well as over weekends and public holidays;
 - (b) Easy access with ramps, if necessary;
 - (c) Security from authorized entry;
 - (d) Clear posting of the international biohazardous sign;
 - (e) Good ventilation and lighting in terms of National Building Regulations and Standards Act, 1977 (Act No. 103 of 1977);
 - (f) Smooth, impervious floor for easy cleaning with gulleys;
 - (g) Running water and washing facilities with water to be disposed off in a closed system;
 - (h) Rodent proof;
 - (i) Lockable with a permanent power supply;
 - (j) Protected from direct sunlight;
 - (k) Adequate refrigeration and freezers to store health care risk waste at the appropriate temperatures and time limits as stipulated in the provisions of the South African National Standard 10248-1: *Management of healthcare waste, Part 1: Management of healthcare risk waste from a healthcare facility*; South African National Standard 10248-2: *Management of healthcare waste, Part 2: Management of healthcare risk waste for healthcare facilities and healthcare providers in rural and remote settings*; South African National Standard 10248-3: *Management of healthcare waste, Part 3: Management of healthcare risk waste from minor generators, registered healthcare professionals and non-healthcare professionals* shall be adhered to; and
 - (l) The name of the person in charge of the storage area and contact details displayed on or adjacent to the exterior doors or gates.

- (5) All health care general waste shall be stored in refuse receptacles as stipulated in the provisions of the *National Domestic Waste Collection Standards, 2011* under the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008) and any amendments thereof.
- (6) All health care risk waste shall be weighed prior to collection by the appointed waste management contractor.
- (7) A calibrated scale shall be installed at all major generators with a built in back up power supply by the appointed waste management contractor;
- (8) All scales installed must be checked regularly and calibrated annually;
- (9) Calibration certificates shall be made available by the appointed waste management contractor on an annual basis; and
- (10) Verification and authorization of the weighing of the health care risk waste shall be done by the designated and / or appointed health care waste officer.

CHAPTER 8

COLLECTION AND TRANSPORTATION

16. (1) The collection and transportation of health care waste within and off site shall be in accordance with the provisions in the South African National Standards 10248-1: *Management of healthcare waste, Part 1: Management of healthcare risk waste from a healthcare facility*; South African National Standard 10248-2: *Management of healthcare waste, Part 2: Management of healthcare risk waste for healthcare facilities and healthcare providers in rural and remote settings*; South African National Standard 10248-3: *Management of healthcare waste, Part 3: Management of healthcare risk waste from minor generators, registered healthcare professionals and non-healthcare professionals*; *National Domestic Waste Collection Standards, 2011* under the National Environmental

Management: Waste Act, 2008 (Act No. 59 of 2008) and any amendments thereof.

CHAPTER 9

TREATMENT AND DISPOSAL OF RESIDUES

17. (1) The facilities used for the treatment and disposal of residues from health care risk waste shall conform to the provisions as stipulated in the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), National Waste Information Regulations, 2012, relevant norms and standards and the National Environmental Management: Air Quality Act, 2004 (Act No. 39 of 2004) and any amendments thereof.

CHAPTER 10

GREEN PROCUREMENT

18. (1) All health establishments shall conform to the provisions as stipulated in the 10248-1: *Management of healthcare waste, Part 1: Management of healthcare risk waste from a healthcare facility* on green procurement.

CHAPTER 11

ENFORCEMENT, COMPLIANCE AND MONITORING

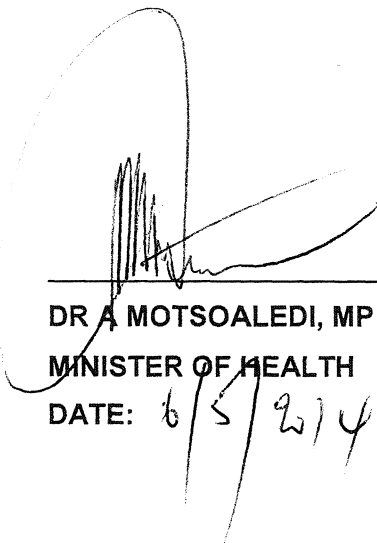
19. (1) The Environmental Health Practitioners of the municipal area/district must ensure compliance, enforcement and monitoring of these regulations at the health establishments; and
- (2) The Environmental Health Practitioner of the municipal area/district must conduct routine inspections and environmental health investigations at the health establishments under the Act.

CHAPTER 12**GENERAL PROVISIONS****20. Offences and Penalties**

- (1) Any person in charge of a health establishment:
- (a) who fails to comply with a provision of these regulations; and or
 - (b) submit inaccurate, false or misleading information in connection with any matter required to be submitted in terms of the provisions of these regulations shall be guilty of an offence .
- (2) Any person in charge of a health establishment convicted of an offence in terms of sub-regulation (1) shall be liable to a fine or to a term of imprisonment not exceeding two years or to both such fine and imprisonment.

21. Short title and commencement

These regulations shall be called the Regulations Relating to Health Care Waste Management in Health Establishments, 2014 and come into effect on a date of publication in the Government Gazette.



DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 6/5/2014