

THE MINISTRY OF ENVIRONMENTAL PROTECTION AND PHYSICAL PLANNING

2247

Pursuant to Article 104, paragraph 1, subparagraph 8, of the Waste Act (Official Gazette 178/04 and 111/06), the Minister competent for Environmental Protection, subject to the approval of the Minister competent for Health, hereby issues the

ORDINANCE

ON MEDICAL WASTE MANAGEMENT

I GENERAL PROVISIONS

Article 1

- (1) This Ordinance establishes the methods and procedures for the management of medical waste that is generated in healthcare provided to people and animals, and in the research pertaining thereto (hereinafter: medical waste).
- (2) Within the meaning of this Ordinance, medical waste management is separate collection and temporary storage of medical waste at the point of generation, as carried out within the activity of medical waste management: collection, transport and temporary storage, treatment, recovery and/or disposal of medical waste, as well as recovery and/or disposal of the waste generated by treatment, recovery and/or disposal of medical waste.
- (3) The provisions of this Ordinance do not apply to the management of radioactive medical waste or other types of waste from healthcare, which are governed by special regulations.
- (4) The provisions of this Ordinance do not apply to the procedures for sterilization of cultivated micro-organisms, tissues and equipment that are a part of regular work processes of microbiological and similar laboratories, and of surgical and similar wards and doctor's offices, which are not considered as waste management operations and which are carried out in line with the rules of the medical profession.

Article 2

- (1) For the purposes of this Ordinance the following definitions are used:

Medical waste is any waste from the waste catalogue in accordance with the Regulation on categories, types and classification of waste with a waste catalogue and list of hazardous waste (Official Gazette 50/05).

A generator of medical waste is any legal or natural person involved in the provision of healthcare to people and animals and/or the research pertaining thereto, or involved in the performance of scientific activities, provision of services or similar activities generating waste similar to that generated during the provision of healthcare to people and animals and/or the related research.

A major source is a generator of medical waste which annually generates more than 200 kilograms of hazardous medical waste and which, as a waste generator, is obliged to draft a waste management plan in line with the Waste Act.

A minor source is a generator of medical waste which annually generates 200 kilograms and less of hazardous medical waste and which, as a waste generator, is not obliged to draft the waste management plan in line with the Waste Act.

Medical waste management is a set of all activities and measures stipulated by the Waste Act.

An authorized person is any legal or natural person who has a licence for medical waste management in accordance with the Waste Act.

Infectious waste is hazardous medical waste containing pathogen micro-organisms, which due to their type and/or concentration can cause diseases in human beings and animals; culture media and equipment from microbiological laboratories; equipment, materials and accessories that were in contact with blood and other patient excretions, including surgical interventions and autopsies; waste from the isolation ward for infectious patients; waste from dialysis, infusions and similar interventions, including sharps, gloves and other disposable equipment; inoculated infectious waste that was in contact with trial animals, and the related potentially infectious waste.

Chemical waste is hazardous medical waste that contains toxic or dangerous chemicals, including cytotoxic, cytostatic and similar substances; it is non-hazardous when it does not contain anything of the aforementioned.

Pathological waste are body parts, amputated parts, tissues and organs removed during surgical interventions, tissues taken for diagnostic purposes, placenta and other anatomic waste that is defined by the healthcare personnel or by the public and that as the waste emanating from human medicine requires special disposal conditions due to ethical reasons, while such waste emanating from veterinary medicine shall be disposed of in line with special regulations.

Sharps are all medical waste with sharp or pointed ends and include used infectious and potentially infectious needles, lancets, syringes, scalpels and similar sharp objects that were in contact with patients or potentially infectious materials.

Cytotoxic waste is hazardous medical waste generated by the use, production and preparation of pharmaceutical substances with cytotoxic effects, including primary packaging materials and all equipment used for the preparation and use of such substances.

Endangered persons are all persons exposed to hazardous medical waste either through an accidental contact in healthcare or through any other source of medical waste, as well as persons who manage or are exposed to negligent waste management.

Pharmaceutical waste refers to all medicinal products and medicated substances, including their primary packaging and similar excipients which have become useless due to the expiry of shelf life, leakage, and dissipation, as well as those which were not used although prepared, or those that cannot be used due to any other reasons.

Physical procedures for treatment of medical waste are steam disinfection/sterilization, dry heat sterilization or any other similar procedure resulting in the elimination of the hazard characteristics of the infectious medical waste.

Steam disinfection/sterilization is the exposure of waste to saturated steam under pressure in a pressure vessel or an autoclave.

Dry heat sterilization is the exposure of waste, over the requisite time, to the temperature necessary to achieve sterilization of the entire quantity of the medical waste.

Chemical disinfection/sterilization is the exposure of medical waste to chemically active substances that deactivate pathogen micro-organisms.

Fumigation is the use of chemical substances in the isolated space that, as highly toxic gaseous fumigators, disinfect/sterilize medical waste, equipment, objects and similar infectious and potentially infectious materials.

Other methods for treatment of medical waste are those that have not been yet widely accepted and are limited in use, such as radiation (e.g. microwave, gamma and ultraviolet radiation), and other treatment methods (encapsulation, filtration, etc.).

Incineration of medical waste is the recovery and/or disposal of waste by oxidation at high temperatures whereby organic substances are transformed into gaseous oxides (mainly carbon dioxide) and water.

Article 3

(1) According to its physical state, medical waste can be classified into:

- solid,
- liquid, and
- collected gaseous waste.

(2) According to properties, medical waste is either:

- hazardous process waste or
- non-hazardous process waste.

Article 4

(1) With regard to hazard characteristics defined by special regulations, hazardous medical waste is classified into:

1. infectious;
2. chemical waste containing hazardous substances;
3. sharps;
4. cytotoxics and cytostatics;
5. amalgam waste from dental care, and
6. other hazardous waste – any waste presumed to have any hazard properties.

(2) Non-hazardous medical waste is any waste that does not have any hazard properties as described in paragraph 1 of this Article or in the waste catalogue stipulated by a special regulation.

II THE OBLIGATIONS OF GENERATORS OF MEDICAL WASTE AT THE POINT OF GENERATION

Article 5

Legal or natural persons involved in any activity generating medical waste are generators of medical waste, and depending on size, they are classified into:

- major sources, and
- minor sources, such as general practitioner offices; convalescent homes; clinics; old people's and nursing homes; contract physician's offices; dentist's offices; animal feeding sites and hunting dog kennels; tattoo and piercing salons; acupuncture offices and salons; veterinarian's offices; pharmacies and other drugstores; beauty, pedicure and similar salons; zoos, safari parks, and similar activities in which medical waste is generated.

Article 6

(1) The generator of medical waste shall ensure the management of such waste at the point of generation in accordance with the Waste Act, this Ordinance and special regulations, in particular with regard to its separate collection, record keeping, storage in appropriate containers and temporary storage in specially separated areas until treatment or delivery to the authorized person having the relevant permit for medical waste management.

(2) The generator of medical waste shall take over medical waste generated by home care and similar activities generating medical waste, and ensure its treatment, recovery and/or disposal at its own cost.

(3) The employees of home care institutions, home health agencies and institutions engaged in similar activities shall take over medical waste generated by their activities for its treatment, recovery and/or disposal.

(4) Pharmacies shall take over expired medicinal products and similar pharmaceutical waste irrespective of its origin.

Article 7

(1) The head of a major source of medical waste shall appoint the person responsible for the separate collection and temporary storage of medical waste at the point of generation, drafting

of the medical waste management plan at the point of generation in accordance with a special regulation, and for training of ancillary personnel involved in the segregation, segregate collection, labelling of containers, temporary storage, recovery and/or disposal of medical waste at the point of generation, keeping of requisite records, and delivery of data pursuant to the Waste Act.

(2) The head of a minor source of medical waste shall be responsible for activities referred to in paragraph 1 of this Article in the case of a minor source of medical waste.

Segregate collection of infectious medical waste at the point of generation

Article 8

(1) Infectious medical waste shall be collected separately at the point of generation into air-tight and leak-proof containers resistant to breakage and leakage, and transported to a temporary warehouse, without sorting or transfer to other containers.

(2) Containers with infectious waste shall be labelled with a symbol in accordance with regulations on transport of hazardous substances.

(3) Infectious waste shall be collected and transported in the way preventing direct contact with endangered persons, and it shall not be transferred to other containers during storage and delivery.

Storage of medical waste at the point of generation

Article 9

(1) Medical waste shall be locked at the point of generation and kept in a fenced and separate temporary warehouse until treatment, recovery and/or disposal or its delivery to the authorized person.

(2) In addition to requirements arising from special regulations, the space for the storage of hazardous medical waste at the point of generation shall:

- have leak-proof and resistant floor surfaces easy to clean and disinfect;
- be connected to water supply and sewer;
- be easily accessible to the personnel in charge of internal waste management;
- be locked to prevent unauthorized access;
- be easily accessible to collection vehicles (trolleys, etc.);
- be inaccessible to animals, insects and birds;
- have good lighting and ventilation;
- be situated sufficiently far from the storage of fresh food and places for food preparation;
- be situated close to cleaning equipment, protective clothing and waste containers.

(3) A minor source of medical waste shall not be obliged to have a warehouse for storage of waste at the point of generation, but it shall collect hazardous waste separately into appropriate containers and treat it or deliver it to the authorized person within a maximum of eight days.

Article 10

(1) Hazardous medical waste shall be packed into appropriate packaging material, labelled in accordance with regulations on transport of hazardous substances and valid international agreements, if exported for treatment.

(2) The container shall be resistant to its contents, cracks and breakage in the event of sharps, aggressive chemicals and similar materials, and it shall be resistant to normal handling and transport conditions, such as vibrations and changes in temperature, humidity and pressure. The container shall be tailor made and if necessary, certified for this purpose.

(3) Every container shall carry the inscription stating the basic information about the generator of waste, including the name of the institution and department, and the key waste number and name in line with a special regulation. In the case of infectious waste, it shall be labelled in accordance with a special regulation.

(4) The inscription with the data referred to in paragraph 3 above shall be affixed to the container or written on the label which must not be smaller than fifty times seventy-five millimetres.

(5) The packaging material for non-hazardous medical waste does not have to meet the requirements of this Article.

Article 11

(1) The storage of infectious waste at the point of generation shall not exceed fifteen days if the temperature is up to +8°C, or eight days at the temperature from +8°C to +15°C.

(2) Infectious waste shall not be stored at temperatures exceeding + 15 °C.

(3) Pathological medical waste shall be kept in a cold storage until its delivery to the authorized person.

III MEDICAL WASTE MANAGEMENT

Article 12

(1) The generator shall deliver the generated medical waste to the authorized person only.

(2) The generator of medical waste shall have the right to treat, recover and/or dispose of its own medical waste independently, provided that it has the relevant equipment and procures the licence for medical waste management.

(3) The person responsible for the collection and transport of medical waste shall sign the agreement on the acceptance of medical waste with the person authorized for treatment, recovery and/or disposal of medical waste.

(4) The generator of hazardous medical waste shall appropriately package the waste it generated, and deliver it to the authorized person along with the appropriate delivery note.

Treatment of infectious medical waste

Article 13

(1) The treatment of infectious medical waste shall comprise the physical procedures for disinfection/sterilization. If the relevant instruments are unavailable, chemical procedures for disinfection/sterilization, such as fumigation or other approved procedures for the elimination of the hazard characteristics of the infectious medical waste, can be applied.

(2) Thermal procedures for physical treatment are more acceptable than chemical treatment procedures or fumigation due to a higher level of safety and a lower level of environmental emissions.

(3) Only when thermal treatment procedures are not feasible, chemical treatment procedures or treatment with gaseous fumigants, such as formaldehyde, or other treatment methods that are approved and covered by the relevant certificates, shall be employed.

(4) The treatment procedures referred to in paragraph 1 of this Article can be employed either alone or in combination, depending on risk assessment and/or defined emission limit values.

(5) The effects of treatment procedures from paragraph 1 of this Article shall be tested by appropriate indicators or measurement instruments. Once a year, the authorised person shall have the treated medical waste checked for presence of micro-organisms by authorized laboratories in accordance with the rules of the medical profession and in line with the adopted standards, thereby proving that the treated hazardous medical waste has become non-hazardous.

Recovery and/or disposal of medical waste

Article 14

(1) The infectious waste untreated by procedures referred to in Article 13 of this Act shall be delivered to the person authorized for material or energy recovery of hazardous medical waste by incineration and/or co-incineration.

(2) The disposal of medical waste by incineration shall be permitted only in the case when there is no authorized person with the plant for energy recovery of medical waste in the county or in neighbouring counties.

(3) Recovery and/or disposal of medical waste by incineration or co-incineration shall be carried out exclusively in the authorized plant with continuous monitoring of hazardous gas emissions pursuant to a special regulation, whereby dioxin and furan emissions shall not exceed the limit value stipulated by a special regulation.

Article 15

(1) In accordance with the Waste Act and special regulations governing waste management and international waste transport, the generator of medical waste shall export and thus ensure recovery and/or disposal of even those types and categories of medical waste that cannot be treated, recovered and/or disposed of in the Republic of Croatia.

(2) Disposal of hazardous medical waste in landfills shall not be permitted.

Article 16

Pathological waste, such as body parts or similar wastes, shall be managed under special conditions by incineration in crematories or burial at cemeteries, while pathological waste of animal origin shall be managed in accordance with special regulations.

Article 17

(1) Management of used sharps shall require the undertaking of measures for prevention of injuries and infections during handling.

(2) The waste referred to in paragraph 1 of this Article shall be collected and disposed of separately from other wastes.

(3) The containers for the collection of sharps shall be resistant to breakage or leakage.

(4) Sharps shall be temporarily stored only under the supervision of trained and authorized personnel.

(5) Sharps originating from healthcare shall be managed in the same way as infectious waste.

Article 18

Recovery and/or disposal of pharmaceutical, cytotoxic and chemical or similar hazardous medical waste shall be carried out in the facility authorized for recovery and/or disposal of hazardous waste by incineration.

Article 19

The use of mobile facilities for the treatment, recovery and/or disposal of medical waste shall be permitted subject to the procurement of a permit pursuant to the Waste Act.

Article 20

(1) The person authorized for treatment, recovery and/or disposal of hazardous medical waste shall assign a new key number to the newly generated waste in line with a special regulation, and ensure the material or energy recovery of useful properties of waste generated by the treatment of medical waste.

(2) The person authorized for treatment shall ensure the energy recovery of waste generated by the treatment of medical waste by its delivery to the authorized incinerator or any other power plant authorized for incineration or co-incineration of non-hazardous waste.

(3) If there is no incinerator or no authorized person managing the plant for the recovery of waste in the county or counties bordering with the county where the medical waste was generated, this waste can be disposed of in landfills in accordance with a special regulation.

IV TRANSITIONAL AND FINAL PROVISIONS

Article 21

(1) Within six months from the entry into force of this Ordinance, the Ministry competent for Environmental Protection shall invite public tenders for the award of concession agreements to persons authorized for collection, treatment, recovery and/or disposal of medical waste.

(2) By virtue of the signed agreement referred to in paragraph 1 of this Article, the authorized person shall become the concession holder for collection and temporary storage and/or treatment, recovery and/or disposal of medical waste.

(3) Within three months from the entry into force of this Ordinance, the Ministry competent for Health shall prepare and deliver to the Ministry competent for Environmental Protection a proposal of the network of generators of medical waste, divided by territory, as the basis for a public tender for the award of concessions.

(4) The validity of the concession agreement, along with the possibility of its renewal, shall be determined pursuant to Article 55 of the Waste Act, upon analysis of the previously procured proposal from paragraph 3 of this Article, while the fee and the duration of concession shall depend on:

- technology of treatment, recovery and/or disposal,
- location of the facility with respect to the generator of medical waste, and
- special conditions from the public tender referred to in paragraph 1 of this Article.

(5) A representative of the Ministry competent for Health shall be a member of the commission for the award of concessions.

Article 22

Within one year from the entry into force of this Ordinance, the generator of medical waste must harmonise his medical waste management activities with the provisions of this Ordinance and conclude the agreement with the concession holder pursuant to Article 21, paragraph 1, of this Ordinance.

Article 23

(1) Pursuant to Article 21, paragraph 1, of this Ordinance, the concession holder shall twice a year submit a report on the types and quantities of treated, recovered and/or disposed of medical waste, along with the list of all generators of medical waste with whom he had concluded the agreement referred to in Article 22, paragraph 1, of this Ordinance, to the Croatian Environment Agency.

(2) In addition to the data referred to in paragraph 1 of this Article, the concession holder shall also deliver the data about the quantity, key number in line with a special regulation, and the method for the management of waste generated by treatment, recovery and/or disposal of medical waste, as well as the name of the authorized person who received the newly generated waste for recovery and/or disposal, to the Croatian Environment Agency.

Article 24

This Ordinance shall enter into force on the eighth day after the day of its publication in the Official Gazette.

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Minister

Marina Matulović Dropulić, m.p.