Republic of Latvia

Cabinet
Regulation No. 353
Adopted 22 May 2012

Requirements for the Management of Waste Generated in Medical Treatment Institutions

Issued pursuant to
Section 6, Clause 6 of the Waste Management Law

I. General Provisions

1. This Regulation prescribes the requirements for the management of waste generated in medical treatment institutions (hereinafter — institutions).

2. When handling waste, the institution shall comply with this Regulation and other laws and regulations in the field of waste management, as well as the waste management requirements laid down in the plan of a hygienic and counter-epidemic regimen (hereinafter — the plan) of the institution developed in accordance with the laws and regulations regarding the basic requirements of a hygienic and counter-epidemic regimen in a medical treatment institution.

3. Waste generated as a result of the activity of the institution shall be divided into the following groups:

3.1. hazardous waste or waste that is handled as hazardous waste (hereinafter — hazardous waste):

3.1.1. sharp objects (e. g., needles, syringes, scalpels, broken medical equipment made of glass);

3.1.2. infectious waste (waste that contains or may contain microbes, viruses, parasites, fungi, e. g., microbiological waste, waste that contains blood or other bodily fluids, waste from a strict isolation regimen ward, waste from a ward of an infectious person that poses the risk of infection to the staff or other persons);

3.1.3. anatomical waste (e. g., human body parts, organs, or fluids, waste generated during labour or abortion — placenta, umbilical cord, foetus);

3.1.4. waste from cytotoxic and cytostatic medicinal products;

3.1.5. poor quality or expired medicinal products that are not returned to the suppliers;

3.1.6. waste containing hazardous chemical substances (e. g., laboratory agents, photographic industry waste, expired or unnecessary disinfection agents, waste containing heavy metals — broken thermometers, blood pressure measurement devices);

3.2. radioactive waste generated as a result of diagnostic radiology and radiation therapy (including unused radiopharmaceuticals, radioactively contaminated tools (e. g., syringes, needles), biological waste of patients who have undergone diagnostic radiology and radiation therapy procedures, radioactively contaminated objects and materials (e. g., tampons, dressings), other objects and materials having been in direct contact with patients);

3.3. municipal waste; and

3.4. waste from goods harmful to the environment in accordance the laws and regulations regarding natural resources tax (e. g., battery waste, electrical and electronic equipment waste).

4. Radioactive waste shall be handled in accordance with the requirements laid down in the laws and regulations for handling radioactive waste and related materials, as well as in accordance with the laws and regulations regarding mandatory requirements for medical treatment institutions and units thereof.

5. If municipal waste and hazardous waste is mixed together in the institution during its handling, all the mixed waste shall be regarded as hazardous waste. It is prohibited to separate mixed waste.

6. Accounting of the waste generated or managed in the institution shall be performed in accordance with the laws and regulations regarding the procedures for accounting, identification, storage, packing, labelling, and accounting of transportation of hazardous waste.

II. Requirements for the Packaging Used for the Collection, Storage, and Transportation of Hazardous Waste Generated in the Institution

7. Upon entering into a contract with a manager of hazardous waste, the institution shall agree on the packaging used for the collection, storage, and transportation of hazardous waste generated in the institution, including agree on the labelling of the abovementioned packaging, placing the label on the packaging, and filling in the label.

8. The institution shall ensure that the generated hazardous waste is collected and sorted in a packaging of a suitable size designated for the collection of hazardous waste (disposable bag, disposable or reusable bin, box, or container) that is waterproof, lightweight and securely closable, and labelled in accordance with the laws and regulations regarding the procedures for accounting, identification, storage, packing, labelling, and accounting of transportation of hazardous waste.

9. If a bag is used for the collection of hazardous waste, the institution shall ensure the following:

9.1. the volume of the bag corresponds to the volume of the waste collection container or the size of the bag holder;

9.2. bags manufactured for this particular purpose are used for the collection of infectious or anatomical waste; and

9.3. no metal wires or metallic clips are used for tying up or closing the bag designated for the collection of hazardous waste.

10. When collecting hazardous waste, the institution shall ensure that the bag designated for the collection of hazardous waste is filled up by two-thirds of the volume of the bag, then tied up or closed tightly and delivered to the central waste collection room referred to in Chapter V of this Regulation, the waste collection place referred to in Paragraph 35 of this Regulation, or the waste pre-processing facility in the institution (if there is such and it is intended to process the respective waste in the institution).

11. If the packaging designated for the collection of municipal waste is stained with blood or other biological fluids, the institution shall ensure that the respective packaging is inserted into a bag which is then tightly tied up before its transportation. In this case the waste together with the packaging shall be regarded as hazardous waste.

12. The persons referred to in Paragraph 7 of this Regulation shall ensure that the bag, bin, box, or container for the collection of hazardous waste that is intended for the transportation of hazardous waste is labelled in accordance with the laws and regulations regarding the transportation of dangerous goods.

13. If the institution collects the hazardous waste in a reusable bin, box, or container that comes into contact with hazardous waste, the institution shall ensure the disinfection of the abovementioned packaging to prevent any threats to human life and health, as well as the environment.

14. The institution shall ensure that sharp objects are collected in a solid crushproof, puncture-proof, waterproof container that is labelled in accordance with the laws and regulations regarding the procedures for accounting, identification, storage, packing, labelling, and accounting of transportation of hazardous waste. It is prohibited to collect sharp objects in an easily punctured or breakable bin (e. g., cardboard box, bag, glass container).

15. The institution shall ensure that, when collecting sharp objects, the container designated for the collection thereof is filled up by two-thirds of the volume of the container, then tightly closed and delivered to the central waste collection room, or to the waste pre-processing facility if pre-processing of waste is performed in the institution. If the container designated for the collection of sharp objects is punctured, it shall be inserted into another container that is labelled in accordance with the requirements referred to in Paragraph 8 of this Regulation. A container manufactured for the purpose of collecting sharp objects shall be filled up according to the instructions of the manufacturer.

16. The institution shall ensure that used up disposable sharp objects are collected immediately after the use thereof in a container that is labelled in accordance with the laws and regulations regarding the procedures for accounting, identification, storage, packing, labelling, and accounting of transportation of hazardous waste. The container for the collection of used up sharp objects shall be placed as close as possible to the place of performing the procedure without posing a threat to the patient.

17. The institution shall ensure that infectious waste materials that are not sharp objects or the waste of sharp objects are placed in a solid waterproof bag of a different colour (using a bag in a yellow, red, or orange colour as much as possible). Infectious sharp objects or liquid infectious waste shall be placed in a waterproof container or bin, ensuring that the waste cannot spill or fall out. The bag or container designated for the collection of infectious waste shall be labelled in accordance with the laws and regulations regarding the procedures for the accounting, identification, storage, packing, labelling, and accounting of transportation of hazardous waste.

18. The institution shall ensure that anatomical waste is collected in a solid waterproof packaging and delivered to the central waste collection room or the pathology division with a mortuary, or facilities for storing the deceased (if there is such in the institution).

19. The institution shall ensure that waste containing hazardous chemical substances is collected in a container or bin according to the state of matter of the waste in order to prevent the threat that the waste poses to human life and health, as well as the environment. A container or bin containing hazardous chemical substances shall be labelled in accordance with the laws and regulations regarding the procedures for the accounting, identification, storage, packing, labelling, and accounting of transportation of hazardous waste. The waste that does not contain any liquids (e. g., photographic films, photographic plates, and photographic paper) may be

collected in cardboard boxes, if it is provided for in the contract referred to in Paragraph 7 of this Regulation.

III. Requirements for the Management of Hazardous Waste

20. When managing sharp objects or the waste thereof, the institution shall ensure the conformity with the following requirements:

20.1. irrespective of whether the sharp objects or the waste thereof are infected, they shall be handled as hazardous waste;

20.2. it is prohibited to take off or break off a needle from a used up syringe, or to bend the needle. A needle of a used up syringe may be separated from the syringe only if the structure of the syringe permits or ensures the separation of the needle or if there is a special device in the institution designated for the separation of the needle. It is prohibited to place caps on the needles of used up syringes, except for cases where not placing the cap on the needle of a used up syringe can pose a threat to human life and health, as well as the environment; and

20.3. pre-processing of sharp objects shall be performed in accordance with the requirements referred to in Chapter VI of this Regulation.

21. When managing infectious waste (except sharp objects or the waste thereof), the following requirements shall be observed:

21.1. after the collection and packing, infectious waste shall be delivered to the central waste collection room in accordance with the requirements referred to in Chapter VI of this Regulation, or to the waste pre-processing facility in accordance with the requirements referred to in Chapter VI of this Regulation, or inserted into containers designated for transportation which conform to the requirements of the laws and regulations regarding the transportation of dangerous goods;

21.2. if the institution performs pre-processing of infectious waste in accordance with the requirements referred to in Chapter VI of this Regulation, the waste generated in the pre-processing of waste, if it conforms to the requirements referred to in Paragraph 55 of this Regulation, shall be classified as municipal waste in accordance with the laws and regulations regarding waste classification and managed as municipal waste; and

21.3. if the institution does no perform pre-processing of infectious waste, it shall be transferred to the manager of hazardous waste with whom the institution has concluded a contract on the management of such waste and who has received a permit for the performance of Category A or B polluting activities in accordance with the laws and regulations regarding pollution.

22. When managing anatomical waste, the following requirements shall be conformed to:

22.1. irrespective of whether the anatomical waste is infectious, it shall be handled as hazardous waste; and

22.2. anatomical waste shall be handed over for cremation or pre-processed with chemical methods (e. g., tissue decomposition device), or transferred to the manager of hazardous waste with whom the institution has concluded a contract on the management of such waste and who has a permit for the management of such waste.

23. Waste containing cytotoxic and cytostatic medicine shall be regarded as hazardous waste in accordance with the laws and regulations regarding waste classification and the properties making waste hazardous. Such waste shall be handed over to the manager of hazardous waste with whom the institution has concluded a contract on the management of such waste and who has a permit for the management of such waste.

24. Poor quality or expired medicinal products (except the medicinal products referred to in Paragraph 26 of this Regulation) shall be handled in accordance with the laws and regulations regarding the procedures for acquisition, storage, use, registration, and disposal of medicinal products in medical treatment institutions.

25. Amalgam waste shall be managed in accordance with the laws and regulations regarding mandatory requirements for medical treatment institutions and their units.

26. The waste of biopsy tissue, teeth, and small tissue materials in dental offices shall be stored before its delivery to the waste manager in tightly closed plastic containers with a waterproof sealing in a disinfection solution (e. g., 10% formalin solution or 2.5% sodium hypochlorite solution).

IV. Requirements for Handling Municipal Waste and its Packaging

27. If a bag is used for the collection of municipal waste, the institution shall ensure that its volume corresponds to the volume of the waste collection container or the size of the bag holder. It is prohibited to use metal wires or metallic clips to tie up or close the bag designated for the collection of municipal waste.

28. The bag for the collection of municipal waste shall be filled up so that it is possible to tie it up.

29. The collected municipal waste shall be delivered to the central waste collection room or to the municipal waste containers in accordance with the contract signed between the institution and the waste manager on the management of municipal waste.

30. Food waste from the institutions shall be:

30.1. collected, transported, and processed in accordance with the requirements laid down in:

30.1.1. Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002;

30.1.2. Commission Regulation No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive; and

30.2. collected and handled as infectious waste if it is generated during the admission, placement, and care of an infectious patient or by applying an isolation regimen in accordance with the laws and regulations regarding the basic requirements of a hygienic and counter-epidemic regimen in a medical treatment institution.

31. The waste that does not contain hazardous chemical substances in accordance with the laws and regulations regarding the classification, labelling, and packaging of chemical substances and chemical products shall be managed as municipal waste.

V. Collection and Storage of Waste in the Territory of the Institution

32. The staff that is involved in the collection and movement (transportation) of waste shall use gloves during such activities in accordance with the laws and regulations regarding the basic requirements of a hygienic and counter-epidemic regimen in a medical treatment institution. When moving hazardous waste in the territory of the institution, personal protection equipment shall be used in accordance with the laws and regulations regarding labour protection.

33. The equipment designated for the movement of hazardous waste shall not be used for moving any other substances or objects. The equipment designated for the movement of hazardous waste shall be washed and disinfected to ensure the collection and movement of waste in a way that does not pose any threat to human life and health, as well as the environment.

34. Waste receptacles of the institution shall be placed in easily cleaned places or rooms intended for such purpose. The institution shall ensure regular emptying, as well as washing and disinfection of waste receptacles in order to secure the collection and movement of waste in such a way that it does not pose any threat to human life and health, as well as the environment.

35. Outpatient medical treatment institutions with no more than five treatment and diagnostics rooms may establish a place for the collection of waste instead of a waste collection room, ensuring that the notice referred to in Paragraph 36 of this Regulation is placed.

36. Waste collection rooms of the institution shall have a notice at the entrance with the name of the room, as well as a warning about hazardous waste in the room.

37. All waste collection rooms in the institution must be lockable.

38. The following features shall be ensured in the central waste collection room of the institution:

38.1. easy-to-clean surfaces;
38.2. lighting;
38.3. ventilation;
38.4. waterproof covering to prevent damage from weather effects; and
38.5. measures to prevent unauthorised access to human beings and access to animals.

39. If both municipal and hazardous waste materials are stored in the room or place for the collection of waste, the storage of the abovementioned waste shall be ensured in such a way that the waste is not mixed.

40. The room or place for the collection of waste shall be disinfected after each removal of waste in order to ensure the placement of waste in the room or place for the collection of waste or the removal of waste from the room or place for the collection of waste without posing any threat to human life and health, as well as the environment.

41. The waste shall be stored in accordance with the laws and regulations regarding the requirements for waste collection and sorting sites.

42. It is prohibited to sort infectious waste. If infectious waste is mixed together with other types of waste, all waste shall be considered infectious waste.

VI. Pre-processing of Waste

43. Pre-processing of medical waste is the change of waste properties in order to perform any other processing or recovery operations (waste recovery type R12 in accordance with the laws and regulations regarding waste recovery and disposal types) or a physico-chemical treatment of waste that results in compounds or mixtures which are discarded (waste recovery type D9 in accordance with the laws and regulations regarding waste recovery and disposal types).

44. If the institution has a suitable equipment for the pre-processing of waste and it has received a permit for the performance of Category A or B polluting activities in accordance with the laws and regulations regarding pollution, the institution shall perform the pre-treatment in order to decrease the hazardousness of waste (e. g., by disinfection) or to change the look of waste (to make the waste unrecognisable, e. g., by cutting).

45. If the institution does not perform the pre-processing of waste, it shall deliver the waste to the waste manager with whom the contract referred to in Paragraph 7 of this Regulation has been concluded, and who has received a permit for the management of the respective waste in accordance with the laws and regulations regarding pollution or waste management.

46. Transportation of hazardous waste to the pre-processing facilities outside the institution shall be performed in accordance with the laws and regulations regarding the transportation of dangerous goods.

47. Only waste referred to in the permit referred to in Paragraph 44 or 45 of this Regulation may be accepted for pre-processing.

48. Pre-processing of infectious waste shall be performed in such a way to ensure that the waste generated during the pre-processing conforms to the requirements referred to in Paragraph 55 of this Regulation.

49. Anatomical waste shall be processed in the pre-processing stage until it is unrecognisable.

50. Pre-processing of waste shall be performed in rooms that are equipped with drainage installation and waterproof floor covering.

51. If necessary, the waste shall be stored in the pre-processing area before its treatment in such a way to prevent the mixing of waste. The waste (including the waste placed in bags) shall be stored in solid waterproof containers before its pre-processing.

52. The institution or waste manager that performs the pre-processing of infectious waste shall comply with the operating instructions of the facility and ensure the pre-processing of waste according to the requirements of the permit issued for the performance of Category A or B polluting activities.

53. The institution or waste manager that performs the pre-processing of infectious waste shall ensure the inspection of the waste pre-processing facility once a month. In order to inspect the operation of the facility, samples of the waste generated during the pre-processing shall be taken to verify its compliance with the requirements referred to in Paragraph 55 of this Regulation. Sample sterility (infectivity) tests shall be performed in an accredited laboratory in order to verify whether the operation of the facility ensures the prevention of hazardousness of waste.

54. Sample taking and compliance verification of waste referred to in Paragraph 53 of this Regulation shall be performed by laboratories which are accredited by the limited liability company "Standardization, Accreditation and Metrology Centre" in accordance with the standard LVS EN ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories" and regarding which information has been published by the Ministry of Economics in the newspaper *Latvijas Vēstnesis* [the Official Gazette of the Government of Latvia] (hereinafter — the laboratory), or laboratories or authorities to which the competent authorities of a Member State of the European Union, the European Economic Area, the European Free Trade Association, or the Organisation for Economic Co-operation and Development have issued a confirmation or attestation that the relevant studies have been performed and supervised in accordance with the principle of good laboratory practice.

55. The waste shall not be considered hazardous if the bacteria, fungi, viruses, parasites, and microbacteria in it are inactivated to 6 $\log_{10}$ or a higher level, or *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores are inactivated to 4 $\log_{10}$ or a higher level.

Informative Reference to the European Union Directive

This Regulation contains legal norms arising from Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU.

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