

New rules for handling medical waste

FAO employees of legal departments of medical organisations, pharmaceutical organisations, manufacturers of medicines and biomedical cellular products, as well as participants in the market of waste disposal

Pepeliaev Group advises that, on 2 August 2024, the Federation Council approved changes to the rules for handling medical waste¹.

Handling medical waste of Class A

Amendments are made to Federal Law No. 52-FZ "On the sanitary and epidemiological safety of the population" dated 30 March 1999, Federal Law No. 89-FZ "On production and consumption waste" dated 24 June 1998, and Federal Law No. 323-FZ "On the fundamentals of protecting the public's health in the Russian Federation" dated 21 November 2011.

We remind you that types of medical waste have been divided into five classes: A, B, C, D and E, depending on their toxicological, epidemiological and radioactive danger. Class A waste comprises waste that is not epidemiologically hazardous and that is, based on its composition, closer to solid domestic waste.

Class A medical waste will need to be handed over to regional operators that specialise in dealing with solid municipal waste.

We remind you that the current regulation already suggests that class A medical waste is subject to the rules for handling solid municipal waste².

Handling medical waste of classes B, C and D

Medical waste of classes B, C and D (similar to waste of hazard classes III, IV, and V) is to be detoxified pursuant to sanitary rules, which suggests they should be disinfected.

¹ Draft law No. 365183-8 "On amendments to individual items of the legislation of the Russian Federation" (the "Law") (<https://sozd.duma.gov.ru/bill/365183-8>)

² Clause 158 and clause 203(2) of SanPiN 2.1.3684-21 "Sanitary and epidemiological requirements for maintaining urban and rural areas, bodies of water, potable water and potable water supply, atmosphere, soils, residential premises, for operation of production and public spaces, and organising and conducting sanitary and anti-epidemiological (preventive) measures" approved by Resolution No. 3 of the Russian Chief State Sanitary Inspector dated 28 January 2021.

It is permitted to move non-detoxified medical waste of class B (epidemiologically hazardous waste) out of the area where the entity that has generated the waste operates.

Medical waste of class B (extremely epidemiologically hazardous waste) must be detoxified in the area where the entity that has generated the waste operates. It is prohibited to remove such waste unless it has been detoxified.

Medical waste of class D (similar to waste of hazard classes III, IV, and V) is to be detoxified if sanitary rules so provide.

Pepeliaev Group's comment

Under the current rules, regardless of to which of the five classes of consumption and production waste medical waste of class D is similar, it must be detoxified, transported and disposed of under the rules established for toxic industrial wastes,³ which is confirmed by the position of the Russian Ministry of Healthcare.⁴

Sanitary rules may provide that medical waste should be detoxified during the process of neutralising it.

The requirements for detoxifying medical waste will be established by sanitary rules. The Russian Government will also establish requirements for the procedure of transporting and detoxifying medical waste of classes B, C and D (which are similar to the composition of waste of hazard classes III, IV and V), including requirements for:

- transportation vehicles;
- equipment for detoxification;
- the availability of metering units for measuring the mass and volume of medical waste.

Once medical waste is detoxified, 'passports' will be issued with respect to it, and the waste itself will be handed over to persons that specialise in dealing with production and consumption waste to then be recycled or disposed of.

Medical waste of classes D (similar to waste of hazard classes I and II) and E

Medical waste of class D that is similar in composition to extremely hazardous and highly hazardous waste is circulated under the rules for hazard classes I and II, because they are morphologically similar. Such medical waste will need

³ Clause 205 of SanPiN 2.1.3684-21.

⁴ Letter No. 30-5/I/7-3018 of the Russian Ministry of Healthcare dated 28 February 2023.

to be handed over for recycling to the Federal State Unitary Enterprise 'Federal Environmental Operator'.

Radioactive medical waste falls within medical waste of class E. It must be delivered to the Federal State Unitary Enterprise 'National Operator for Dealing with Radioactive Waste'.

Waste generated from the production of medical devices

The law redefines medical waste⁵. From now on, medical waste will not include waste that is formed in the process of manufacturing medical devices.

The amendments suggest that waste from the production of medical items will be covered by the general requirements of legislation on handling waste of consumption and production. At the same time, as we understand, a considerable part of the waste generated during the production of medical items will be classified as solid municipal waste. We remind you that entities generating solid communal waste are subject, among other things, to the following requirements:

- entities generating solid municipal waste must enter into an agreement with the regional operator to supply services with respect to dealing with solid municipal waste⁶;
- solid municipal waste must be stored in areas defined in the agreement;
- the facilities for accumulating and storing solid municipal waste must be equipped with means for measuring solid municipal waste⁷;
- persons generating solid municipal waste must include in the register their own site for accumulating solid municipal waste⁸;
- The persons generating solid municipal waste must keep a record of and provide reports on how they meet the standards regarding recycling waste from the use of goods, etc.⁹.

The law provides that the new rules for handling medical waste will come into force on 1 September 2026.

What to think about and what to do

The reform of the handling of medical waste has been discussed over several years. The handling of waste has been regulated in bits and pieces. For the

⁵Article 49(1) of Federal Law No. 323-FZ "On the fundamentals of protecting public health in Russia" dated 21 November 2011.

⁶ The Russian Government's Resolution No. 1156 "On dealing with solid municipal waste and amending Resolution No. 641 of the Russian Government dated 25 August 2008" dated 12 November 2016.

⁷ Resolution No. 671 of the Russian Government dated 24 May 2024 "On commercial record keeping of the volume and/or mass of solid communal waste" (comes into force starting from 1 September 2024).

⁸ The Government's Resolution No. 1039 dated 31 August 2018 "On approving the Rules for equipping areas (sites) where solid municipal waste is accumulated and keeping a register of it".

⁹ The Government's Resolution No. 2010 dated 3 December 2020 "On approving the Rules for how manufacturers and importers of goods should report on compliance with standards for recycling waste from the use of goods".

most part the law did not govern the procedure for handling such waste after it was transferred to the transportation company to subsequently be neutralised, recycled and buried.

As a result, medical waste turned up at unauthorised dumps. It is assumed that the law will remove from the 'grey area' more than three million tons of waste and will be instrumental in creating a fully functional system for handling waste.

The reform will affect persons generating waste, as well as companies and individual entrepreneurs dealing with medical waste. Persons and individual entrepreneurs (that are not classed as persons generating medical waste) will not be entitled to transport and neutralise detoxified medical waste of classes B, C and D (that are similar in composition to waste under hazard classes III, IV and V), unless information about such persons is published on the website of a constituent entity of the Russian Federation. This, in turn, will result in such persons being required to comply with new requirements that the Government will draw up.

Help from your adviser

Pepeliaev Group's lawyers are ready to provide you with any necessary legal support on any matters connected with the handling of medical waste, as well as of production and consumption waste.

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