On behalf of:

Federal Ministry
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of the Federal Republic of Germany

Umwelt Bundesamt

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Improvement of Handling Medical Waste in Healthcare Facilities in two Pilot Regions of the Russian Federation

Recommendations for the extension of the segregation and classification guideline on healthcare waste inside health facilities

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ON BEHALF OF THE
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List of Abbreviations

CJD	Creutzfeldt-Jakob Disease
EU	European Union
ELW	European List of Waste
HIV	Humane Immundefizienz-Virus
HUS	haemolytic-uraemic syndrome
SanPin	Sanitary and epidemiologic rules and regulation
TSE	Transmissible Spongiform Encephalopathy
UNEP	United Nation Environmental Program

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1 Introduction

1.1 Objective

This interpretive guideline shall provide practical advice on the correct classification, handling and disposal of waste generated by all health-care establishments within the framework of human and veterinary health care and research. This interpretive guideline aims at providing for a safe and proper waste disposal which is economically reasonable and avoids disease transmission and environmental pollution. In addition to these goals, the de facto situation of the different, individual establishments and the state of the technology shall be considered.

This document is considering the relevant legal international, Russian and European laws, conventions, standards and guidelines:

1) Basel Convention: Technical Guidelines on environmentally sound management of biomedical and healthcare waste (UNEP 2003)
    a. This Technical Guidelines are based on the “Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal” and deal with all biomedical and health-care waste, but focus on the segregation and treatment of hazardous biomedical and health-care waste.
2) SanPin 2.1.7.2790-10: Sanitary requirements for the management of medical waste (Russian Federation)
    a. These SanPin (health rules or regulations) are the main guidelines for the management of healthcare waste and try to establish mandatory sanitary and epidemiological requirements for the management (collection, temporary storage, decontamination, disposal, transportation) of healthcare waste generated during medical and/or pharmaceutical activities.
3) European Waste Framework Directive (Directive 2008/98/EC on waste) and the European List of Waste (Commission Decision 2000/532/EC)
    a. Directive 2008/98/EC sets the basic concepts and definitions related to waste management, such as definitions of waste, recycling, recovery. The Directive lays down some basic waste management principles.
    b. The European List of Waste and hazardous waste list (Annex III to Directive 2008/98/EC) is used for the classification of all wastes and hazardous wastes and are designed to form a consistent waste classification system across the EU.

1.2 European List of Waste

In the European Union the “List of Waste” was introduced to harmonize the waste management system among the member countries. Healthcare waste is included in the chapter 18 of the “List of Waste”: “Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care).” The waste stream is further divided in wastes from natal care, diagnosis, treatment or prevention of disease in humans (18 01) and wastes from research, diagnosis, treatment or prevention of disease involving animals (18 02).

Following the six-digit code of the List of Waste, the following waste codes for 18 01 can be found:

18 01 01 sharps (except 18 01 03)

18 01 02 body parts and organs including blood bags and blood preserves (except 18 01 03)

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

18 01 04 wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)

18 01 06* chemicals consisting of or containing dangerous substances

18 01 07 chemicals other than those mentioned in 18 01 06

18 01 08* cytotoxic and cytostatic medicines

18 01 09 medicines other than those mentioned in 18 01 08

18 01 10* amalgam waste from dental care

The List of Waste was established by the Decision 2000/532/EC and is closely linked to the list of the main characteristics which render waste hazardous contained in Annex III to the Waste Framework Directive (Directive 2008/98/EC).

1.3 Comparison of relevant classification systems

In the table below the waste classification system of the Russian Federation is compared with the international and European classification system of healthcare waste. The table indicates the common character and the differences. This comparison is based on the:

- „Interpretive Guideline for the disposal of waste generated by health-care establishments“ developed by the Joint Working Group of the German Federation/Federal States on Waste (LAGA M18).

Table 1: Comparison of local and international waste classification systems

SanPin	Basel Convention	ELW / LAGA M18
Class A Healthcare Waste with a composition similar to municipal solid waste	Group A Health-care wastes with the same composition as household and municipal waste A1 Normal household and municipal waste	Municipal waste: 20 03 01 mixed municipal waste
Class B Epidemiologically hazardous waste	Group B Biomedical and health-care waste requiring special attention B1 Human anatomical waste (tissues, organs, body parts, blood and blood bags) B2 Waste sharps (needles, syringes, scalpels, slides, ampoules, etc.) B5 Blood and body fluid waste (materials contaminated with blood or other body fluids, soiled cotton from non-infected patients) Wastes which only require special measures to prevent the risk of infection during their management.	 18 01 01 sharps (except 18 01 03) 18 01 02 body parts and organs including blood bags and blood preserves 18 01 04 non-infectious HCW waste
Class C Epidemiologically extremely hazardous waste	Group C Infectious wastes	18 01 03* infectious waste
Class D Toxicologically hazardous waste - divided in the hazard classes 1 – 4 1. Highest danger, very high risk for human and the environment 2. High risk for humans and the environment, recovering of ecosystem may take up to 30 years 3. Moderate risk for human and environment, recovering of ecosystem takes about 10 years 4. Low risk and low hazard for human health and the	Group D Other hazardous wastes Not exclusive to the medical health-care sector, e.g. solvents, chemicals, batteries, fixer solutions, etc. .	 18 01 06* chemicals consisting of or containing dangerous substances 18 01 07 chemicals other than those mentioned in 18 01 06 18 01 10* amalgam waste from dental care Acids and Bases: 06 01 06* other acids,

environment		06 02 05* other bases Solvents: 07 01 03* organic halogenated solvents, washing liquids and mother liquors, 07 01 04* other organic solvents, washing liquids and mother liquors Photographic wastes: 09 01 01* water-based developer and activator solutions, 09 01 03* solvent-based developer solutions, 09 01 04*, fixed solutions,
	B3 Pharmaceutical waste (e.g. expired medicines)	18 01 09 medicines other than those mentioned in 18 01 08
	B4 Cytotoxic pharmaceutical wastes	18 01 08* cytotoxic and cytostatic medicines
Class E - Radioactive waste	E Radioactive waste from health care.	-

2 Class A - Healthcare Waste with a composition similar to municipal solid waste

Mixed wastes whose type and composition correspond to mixed waste from human settlements shall be assigned to this waste class. These wastes shall be disposed of as waste from human settlements and must be collected separately from wastes of the waste Class B, C, D or E. Only if Class B or C waste is decontaminated in a safe matter, a disposal together with the wastes pursuant to the waste Class A is possible. Food waste from large-scale catering establishments and canteens shall be collected separately from other waste in accordance with the relevant federal and regional regulations and must be made available to a disposal by registered companies.

3 Class B: Epidemiologically hazardous waste

3.1 Infectious and Sharp Waste

Wastes whose collection and off-site disposal is not subject to special requirements in order to prevent infection include wastes contaminated with blood, secretions or excretions, such as dressings, plaster casts, disposable linen, stool diapers, disposable items and others arising directly from the immediate patient care to the extent that they are not covered by waste Class C.

Wastes separately collected at the source of their generation and not contaminated with blood, secretions or excretions (such as paper, magazines, packages etc.) and wastes not arising directly from the immediate patient treatment do not fall within this waste code and can be assigned to more specific waste codes.

The wastes in question require special attention (items contaminated with pathogens which are not listed as Class C waste and that are subject to registration).

According to the current knowledge, wastes of this Class can occur in connection with the following human diseases (in parentheses: relevant excretion/body liquid containing pathogens):

Transmission through direct contact with injured or not intact skin or mucous membrane (e.g. through inoculation):

- AIDS / HIV Infection (blood)
- Virus Hepatitis (blood)

Wastes of this type are usually generated:

- In diagnostic and treatment wards,
- in the operating theatre,
- in maternities,
- In outpatient areas,
- in dialysis units and centres,
- in pathological departments,

but also:

- in physician offices with the focus on the treatment of patients,
- in prisons,
- in retirement homes,
- Etc.

These are wastes that are generated during the process of diagnosing, treating and caring for patients. These wastes are contaminated with blood / serum, excretion or secretion containing pathogens or they contain blood / serum in liquid form, or they consist of body parts and organs of patients with the respective diseases.

Collection and transport

The wastes under waste Class B shall be collected directly at the source of their generation and put in tear-resistant, moisture-proof and tight containers. They must not be poured into another container or sorted in any way and shall be transported in securely closed containers (if necessary, in combination with returnable containers) to the central collection point. To ensure safe handling, the containers should not be too large. The prohibition to pour the wastes into another container or sort it in any way shall also apply to the collection point.

When dealing with larger amounts of body liquids in containers, the use of suitable absorbing materials shall ensure that no liquid waste contents are spilled during the storage and transport of these wastes. If a waste water plant is connected to the health facilities, containers with body liquids can be discharged while taking into account those aspects of occupational safety and health that are related to hygiene and infection prevention; then its contents can be discharged into the waste water while observing water management requirements. Otherwise this waste needs to be disinfected by the listed and approved chemicals before disposal.

Storage

The waste must be stored in such manner that a gas formation in the collection containers is avoided (e.g. a storage temperature of less than +15°C when the waste is stored for a maximum period of one week). If the storage temperature is less than +8°C, the storage time can be extended in consultation with a person responsible for hygiene (e.g. hospital sanitarian or hygiene specialist).

Treatment

Without prior compacting or shredding them, these wastes must be treated and decontaminated de-central or central.

Class B waste can be disinfected through processes approved by the relevant authority. A spillage of wastes that are not disinfected must be avoided in either case. Disinfected wastes can be disposed of together with waste pursuant to Class A waste; the still existing physical risk of injuries that might be caused by sharps must be taken into account.

The disinfection units must be operated in accordance with the operating parameters specified for waste disinfection. The operational mode must be documented. The operation is only permissible if the operator can provide proof that the construction and functions of the unit meet the federal requirements - and that it is being tested and operated in accordance with these provisions.

Additional requirements for sharp waste

Waste such as canulaes, scalpels and items with a similar risk to cause cuts or puncture wounds must be collected in puncture- and shatter-proof single-use containers that have to be closed tightly and stored, transported and disposed of safely - with no access for unauthorised persons. Safe containment must be ensured until the drop-off into the collecting container for wastes to be disposed of occurs (e.g. press container).

A compaction is only permissible if the occupational safety and health requirements are met until the final disposal.

A recycling after disinfection is only permitted if the occupational safety and health requirements are met and approved by the relevant authority. In any case, the process technology must ensure that all health risks associated with the contamination with blood are addressed when handling this type of waste.

3.2 Pathological Waste

Body parts and organ waste, including containers filled with blood or blood products (e.g. banked blood that was not used) must be separately collected at the source of the waste generation and brought to a special disposal facility (crematory or cemetery) without having been commingled with waste from human settlements.

The waste must be transported in suitable, securely closed containers to the central on-site storage and drop-off point and made available for collection. Pouring the waste into another container or sorting it is not permitted.

The waste must be stored in such manner that a gas formation is avoided (e.g. a storage temperature of less than +15°C when the waste is stored for a maximum period of one week). If the storage temperature is less than +8°C, the storage time can be extended in consultation with the person responsible for hygiene. Deep-frozen waste can be stored up to 6 months in health-care facilities.

Note: extracted teeth are not considered to be body parts within this meaning.

4 Class C: Epidemiologically extremely hazardous waste

4.1 Highly Infectious Waste

In accordance to the relevant SanPin highly infectious waste is waste which collection and disposal is subject to special requirements in order to prevent infections and is classified as microbiological Group 1-2 of pathogen microorganisms.

The special requirements for the collection and disposal of this type of waste result from the known or (based on medical experience) expected contamination with pathogens of the following diseases if these pathogens can cause a spread of the disease. Therefore, the list includes diseases which - with due regard to

- the danger of infection (contagiousness, infection dosage, epidemic potential),
- the survival capability of the pathogen (duration of the infection capability),
- the transmission route,
- the extent and type of the potential contamination,
- the amount of the contaminated waste and
- the severity of the disease that has been caused (as the case may be) and the possibility of a respective treatment

The wastes in question require special attention (items contaminated with pathogens that are subject to registration).

According to the current knowledge, wastes of this group can occur in connection with the following human diseases (in parentheses: relevant excretion/body liquid containing pathogens):

Transmission through direct contact with injured or not intact skin or mucous membrane (e.g. through inoculation):

- TSE (Transmissible Spongiform Encephalopathy) (body tissue, liquor)
- CJD, vCJD (Creutzfeldt-Jakob disease)1

Faecal-oral transmission (smear infection):

- Cholera (faeces, vomited matter)
- Dysentery, HUS (haemolytic-uraemic syndrome) (faeces)
- Typhus/Paratyphus (faeces, urine, bile, blood)

Aerogen transmission / droplet infection; smear infection:

- Active Tuberculosis (sputum, urine, faeces)
- Meningitis / Encephalitis (including, but not limited to, meningococcal meningitis) (sputum / pharyngeal secretion)
- Brucellosis (blood)
- Diphtheria (sputum / pharyngeal secretion, ichor)

[1] Wastes contaminated with TSE pathogens must always be incinerated.

- Leprosy (nasal discharge, ichor)
- Anthrax (sputum / pharyngeal secretion, ichor)
- Pest (sputum / pharyngeal secretion, ichor)
- Pox (pharyngeal secretion, pustule discharge)
- Poliomyelitis (sputum, pharyngeal secretion, faeces)
- Psittacosis (see Vet. Med. no transmission by humans)
- Q Fever (see Vet. Med. not transmission by humans)
- Maliasmus (sputum / pharyngeal secretion, ichor)
- Rabies (sputum / pharyngeal secretion)
- Tularaemia (ichor, pus)
- Virus-induced Haemorrhagic Fever (incl. Hantavirus (with renal syndrome / HFRS; with pulmonary syndrome / HPS)) (blood, sputum / pharyngeal secretion, ichor, urine)

Wastes of this type are usually generated:

- in clinical chemistry laboratories and serology laboratories for infection testing,
- in microbiological laboratories
- in isolation units of hospitals
- in dialysis units and centres in known virus carriers,
- in pathological departments,

but also:

- in the operating theatre or
- in physician offices with the focus on the treatment of patients with the listed diseases (i.e. not only treatment of sporadic individual cases).

These are wastes that are generated during the process of diagnosing, treating and caring for patients who are infected with the above listed diseases. These wastes are contaminated with blood / serum, excretion or secretion containing pathogens or they contain blood / serum in liquid form, or they consist of body parts and organs of patients with the respective diseases.

In order to assess the infection risk, detailed knowledge is required. Therefore measures, which are required in individual cases in the health-care establishments, shall be determined in consultation with the physician or person responsible for hygiene (e.g. the hospital sanitarian or the hygiene specialist), the company physician and the specialist for occupational safety and health. Local conditions must be considered.

In any event, these wastes include all not inactivated / disinfected microbiological cultures that are generated in institutions for hygiene, microbiology and virology, in laboratory medicine, physician offices and similar facilities with respective activities and where a replication of the pathogens of any kind has occurred. The compliance with the provisions of the Biological Agents Regulation and the Technical Rules for Biological Working Substances shall have priority.

For infectious diseases usually transmissible by inoculation, requirements for safety and health at work shall have priority. Therefore these wastes include sharps, blood-filled containers and blood-soaked waste from operations of respective patients, respective specialised medical

practices and laboratories and discarded dialysis systems from the treatment of known virus carriers. They do not include contaminated dry (non-dripping) wastes of respectively diseased patients from the treatment of individual patients, such as contaminated swaps from taking blood samples, non-dripping dressings or operation drapes and covers, cotton rolls from the dentist offices.

In case of infections that are transmitted faecally/orally, urine and faeces can discharged into the waste water while observing the respective rules of personal hygiene and occupational safety and health (a waste water treatment plant must be connected to the facility).

Collection and Transport

All wastes of this waste code shall be collected directly at the source of their generation and put in tear-resistant, moisture-proof and tight containers (e.g. type-approved packages for hazardous materials). They must not be poured into another container or sorted in any way and shall be transported in suitable, securely closed containers (if necessary, using bags in combination with returnable containers) to the central collection point. (Labelling of the containers with the biohazard symbol). A contamination of the collection containers at their outside must be avoided in any case. To ensure safe handling, the containers should not be too large.

For certain wastes, such as wastes with a high percentage of liquids, synthetic or paper bags - if used as the only containment during transport in the hospital and other health-care establishments - will not be considered to be meeting the safety standard. These bags may only be transported in a solid container that can also be used as a returnable container. Returnable containers must be easy to clean and allow for disinfection with approved procedures.

Storage

The waste must be stored in such manner that a gas formation in the collection containers is avoided (e.g. a storage temperature of less than +15°C when the waste is stored for a maximum period of one week). If the storage temperature is less than +8°C, the storage time can be extended in consultation with a person responsible for hygiene (e.g. hospital sanitarian or hygiene specialist).

Treatment

Without prior compacting or shredding them, these wastes must be treated and decontaminated at the facility where it is generated without transport on public roads. If no body parts and organ wastes or TSE pathogens are contained, they can be disinfected through processes approved by the relevant authority. A spillage of wastes that are not disinfected must be avoided in either case. Disinfected wastes can be disposed of together with waste pursuant to Class B waste; the still existing risk of injuries that might be caused by sharps must be taken into account.

The disinfection units must be operated in accordance with the operating parameters specified for waste disinfection. The operational mode must be documented. The operation is only permissible if the operator can provide proof that the construction and functions of the unit meet the federal requirements - and that it is being tested and operated in accordance with these provisions.

5 General requirements for a proper waste management

In order to fulfil the basic environmental duties, the health-care establishments are obliged to use all possibilities of avoiding and recycling waste to the maximum extent possible.

5.1 In-house requirements

In-house measures include:

- the separate collection of wastes at the source of their generation,
- the collection and transportation to central on-site collection points (storage and drop-off points),
- if necessary and available, any treatment and preparation measures for their disposal.

While doing so, dust and aerosol formation and the contamination of the environment must be avoided.

Collection

The wastes must be collected in suitable containers (puncture-proof, tear-resistant, liquid-tight) and transported and stored safely - with no access for unauthorised persons.

A proper disposal system can only be based on a comprehensive collection of all wastes. As a principle, the wastes must be collected and disposed of separately - in accordance with the categorization in this document. This requires an organisation that is oriented on such separation taking into account the respective premises. For a multi-material collection system, a respective conception of space is needed.

Collection containers must be chosen in accordance with the requirements for the disposal (transport-proof, moisture-resistant and tightly closable) and conspicuously labelled pursuant to the waste and hazardous substances law. It is advisable to not only prominently mark the containers whose contents require special treatment, but to use containers in special colours.

Transport

Wastes shall be collected at the source of their generation in containers that are designated for such use; they must be in a proper condition in terms of hygiene (i.e. avoiding outer contamination). Then they shall be made available for transport. As a rule, organic wastes shall be transported from the source of their generation to the central collection points on a daily basis.

While establishing an on-site collection and transport system, the existing off-site disposal routes must be considered. The requirements of the public-law parties responsible for waste management or a third party assigned by it or the waste disposal company must be taken into account, in particular in case of hazardous waste. The different types of waste must be subjected to the respective different recycling and disposal processes.

The on-site transport of wastes to the central storage and drop-off points and their provision must be executed in such manner that helps avoid any spillage of waste. Opening of bags and pouring or placing their contents in other bags or containers is not allowed for hazardous waste for wastes of the waste codes and sorting them is not permissible.

Disturbances that might occur during the waste transport such as the rupture of waste bags must be taken into account while determining the disposal routes (e.g. avoiding areas that are

sensitive in terms of hygiene). The use of returnable containers that are returned to the source of the waste generation requires their cleaning and, if necessary, decontamination, before transporting them back.

Central conveying systems are problematic; at the current state of technology they are often a source of disturbance. Chutes are not permissible for hygiene reasons.

Central collection / Storage

Central collection or storage points must be ventilated to avoid dust formation and bad smells and keep the place clear of vermin. The rooms' design must allow disinfection of all surfaces.

The central collection point must also house facilities for hand disinfection and cleaning and the change of protective clothing. The location of rooms or roofed places for the central waste collection must preclude any impairment of adjacent areas (kitchen, nursing areas etc.).

On-site treatment

Shredding and/or compacting waste is only permissible if the safety and health at work is ensured.

Wastes pursuant to the waste Class B and C may only be shredded in disinfection equipment approved by the relevant federal authority and, if necessary, only after that process be compacted. Waste treatment equipment (e.g. for disinfecting, shredding or compacting the waste) may only be operated at an area that is separated from patient care and medical service areas. The waste delivery and the feeding of the units may only be carried out by personnel that have been respectively instructed. The waste drop-off systems and their operation must be designed to preclude any spill or loss of liquids or solids.

The shredding equipment must be designed to allow for any necessary saturated steam vapour disinfection (e.g. in case of repair works due to disturbances). The physician or person responsible for hygiene (e.g. the hospital sanitarian or the hygiene specialist), the company appointee for waste management, the safety specialist and the company physician are to be involved in the planning of the on-site waste treatment technology (e.g. shredding or compacting technology). Before starting its operation, the waste treatment equipment is subject to an acceptance procedure to be performed by the person responsible for hygiene. He or she shall be obliged to supervise the operation in terms of hygiene and determine the scope and frequency of the cleaning and disinfection processes.

5.2 External requirements

Any off-site handling of the wastes requires special care in relation to the requirements of environmental protection, occupational safety and health, hygienic control of epidemics and public safety.

The proper disposal requires a practical and manageable handling of the waste and a transparency of the waste flows.

Therefore the collection, storage and treatment of waste generated by health-care establishments require a well thought out and controllable in-house/on-site system that is coordinated with the terms and conditions of the external disposal procedures and routes, as

- due to the composition of certain wastes (e.g. material associated with risks of injury, pathogens etc.) safety measures must be taken, in particular, for the staff entrusted with the disposal, and

- in terms of waste management and environmental hygiene, it must be ensured that recyclable materials can be collected and treated separately.

Depending on the environmental relevance and the toxicity of the wastes, different requirements apply to the disposal. A distinction is to be made between hazardous waste and non-hazardous waste.

The hazardous wastes include the types of waste of Class B, C, D and E. They are always subject to a proof-based procedure (proof of proper disposal and accompanying document / proof of proper collective disposal and acceptance certificate). In addition, producers of hazardous waste are obliged to keep registers pursuant to the specified provisions.

5.3 Information based on the Legislation relating to Hazardous Material

Wastes can have different hazardous properties and thus require transportation as hazardous material. This may result in the need to use separate collection containers and packages or the prohibition of a joint transport that must be observed even if it is waste of one waste code. The provisions of the hazardous material legislation must be observed.

6 References

(1) ADR (2013), European Agreement Concerning the International Carriage of Dangerous Goods by Road, Volume 1, United Nations
(2) Basel Convention (2003): Technical Guidelines on environmentally sound management of biomedical and healthcare waste (UNEP)
(3) Council Directive 91/689/EEC on hazardous waste (1991), European Union
(4) Directive 2008/98/EC on waste (2008), European Waste Framework Directive; European Parliament and the council of the European Union
(5) The European List of Waste (Commission Decision 2000/532/EC)
(6) Law on infection prevention (IfG) (2000); Law on Preventing and Combating of infectious diseases in humans, Germany
(7) LAGA M18 (2009); Interpretive Guideline for the disposal of waste generated by health-care establishments; Joint Working Group of the German Federation/Federal States on Waste; Germany.
(8) SanPin 2.1.7.2790-10 (2011): Sanitary requirements for the management of medical waste; Registration N 19871; (Russian Federation)