

## LEGAL REGULATION IN MEDICAL WASTE MANAGMENT

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**Abstract:** The management of medical waste is of great importance due to its potential environmental hazards and public health risks. Earlier, medical waste was often mixed with municipal solid waste and disposed of in residential waste landfills or improper treatment facilities. Due this issues Republic of Serbia has drafted legislation to improve their medical waste disposal- Law on Waste Management (2009, 2010) and Ordinance on Medical Waste Disposal (2010) . Nowadays, major effort have been made by Agency for Environmental Protection and waste generators to better manage the waste from healthcare facilities. Increasing amount of solid waste and as a parallel to this, increase in medical waste, have become a serious environmental problem due to growing population and industrialization. As a result of this, collecting medical waste separately from ham less household waste seems to be an effective solution worth considering. This paper presents an overview of the current management practices of medical waste and an overview of basic legal aspects of the medical waste management.

**Keywords:** medical waste, legal regulation, human health

### 1. INTRODUCTION

The link between waste management and public health is well known. Examples of poor waste management in different periods of human history led to the emergence and spread of numerous outbreaks of infectious diseases. On the bad examples from the past, we have learned that there are special hazards due to lack of proper waste treatment and awareness on waste management. The importance of waste management is great, and it is particularly significant medical waste management in the field of preserving public health or the health of the entire population. Approximately 25% of the total medical waste is a hazardous waste, which can cause serious public health consequences and environmental contamination. The main objectives of medical waste management is the introduction of health safe and environmentally acceptable ways of dealing with medical waste, appropriate national economic situation and the level of health care and protecting the population from infectious diseases, but also protection of the health and safety of all persons in health institutions and outside them (staff, patients, visitors and residents). (1)

Unfortunately, there is no one common specific definition of what constitutes medical waste.

The European Union (EU) in 1991, in response to some misunderstandings in relation to waste management, given the broad definition of waste, the so-called "waste by the directive": all waste generated in the delivery of health services in health institutions is medical waste.

World Health Organization (WHO) describes medical waste as a broad range of materials, from used needles and syringes to soiled dressings, body parts, diagnostic samples, blood, chemicals, pharmaceuticals, medical devices and radioactive materials.

In Serbia, medical waste is defined as: "all waste, hazardous or non-hazardous, which is generated in the provision of health services (diagnosis, prevention, treatment and research the field of human and veterinary medicine)." (3) In other words, under medical waste means all waste generated in medical institutions (governmental or private), medical research centers or laboratories.

### 2. LEGAL REGULATION OF MEDICAL WASTE

Serbia still has not passed a special Law on medical waste. The basic law in this area is the Law on Waste Management ("Official Gazette of RS", No. 36/09 and 88/10). More arranging medical waste and its management are achieved by a number of regulations, in the first place, with the Regulations for the Management Medical Waste. ("Official Gazette of RS", No. 78/2010).

Also, the number of EU regulations applicable in this field in the RS. Some of the most important are Council Directive 75/442 / EEC on waste (Framework Directive), Council Directive 99/31 / EC on the landfill of waste, Council Directive 94/62 / EC on packaging and packaging waste, Directive 96/61 / EEC on Integrated Pollution Prevention and Control, Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989), Directive 91/689 / EEC on hazardous waste, etc.

Waste Management Act provides a definition of hazardous waste ("Hazardous waste is waste that by its origin, composition or concentration of hazardous substances may cause danger to the environment and human health and has at least one of the hazardous characteristics defined by special regulations, including the packaging in which it is dangerous waste was or is packed") and prescribes measures for management of hazardous waste. During collection, classification, storage, transportation, reuse and disposal, hazardous waste is packaged and marked in a manner that ensures the protection of human health and the environment. The mixing of hazardous waste (with other hazardous waste or non-hazardous waste) is strictly prohibited. Hazardous waste must be treated before disposal, significantly reducing hazardous waste characteristics. However, should be borne in mind that previously treatment not eliminates all adverse effects of hazardous waste. According to the Law on Waste Management, the legal responsibility for the accurate identification, then a proper classification of medical waste lies with the waste producers. The law further states that the classification carried out in accordance with the Serbian version of the European Waste Catalogue (EWC), which is known as the Waste Catalogue of Serbia. EWC (and the derived Serbian version of the document) provides a universal system for the classification of waste that is used everywhere in the European Union. It is a simple numbering system that is based on the allocation of six-digit codes, which marks and classify waste.

Article 56 provides a framework for managing medical waste (Management of waste from facilities that provide health care and pharmaceutical waste). Among other things, it requires that the waste from facilities that provide health care must be classified on hazardous and non-hazardous and that every institution of this type must have a waste management plan and the person responsible for implementing the plan. A person who manages the facility, which provides medical care is required to keep records of the quantities of hazardous waste and the data is delivered to the Agency for Environmental Protection (SEPA), because waste management plan in facilities in which annually produces more than 500 kilograms of hazardous waste must be approved by the ministry responsible for health. Also, this article gives an overview of pharmaceutical waste, which includes pharmaceutical products, drugs and chemicals that are scattered, prepared and unused or expired shelf life and must be rejected for any reason. Regulations for Management Medical Waste prescribes in detail the specific requirements relating to the management of medical waste (except radioactive waste).

Among other things, defines the different types of hazardous medical waste, regulate collection and sorting of medical waste to ensure protection of human health and the environment, highlighting that waste from sharp objects must be collected separately from other waste, defines packaging and labeling of medical waste, defines procedures approved for the treatment and (or) disposal of different flows of medical waste, etc. (2, 3)

### **3. MEDICAL WASTE MANAGEMENT AND PUBLIC HEALTH**

Medical waste management is a set of measures that include collecting, sorting, packaging, labeling, storage, transport, treatment and safe disposal of medical waste.

#### **3.1. Risks of medical waste**

Medical waste is made up of different materials which carry a variety of hazards that have the potential to seriously harm human health and the environment. All persons who may come into contact with medical waste are exposed to a potential health risk, namely: medical personnel (doctors, nurses, other medical and non-medical staff in health facilities), patients in and out of medical institutions and their visitors; employees of public utility companies that handle and transport the waste; employed in landfills, the population over the items that can be found in the trash outside health facilities. The main hazards that are associated with medical waste is divided into five categories: physical hazards, microbiological hazards, chemical hazards, environmental hazards, radiological hazards. Physical hazards are usually associated with sharp objects (needles, scalpels, etc.) that can cut or pierce the skin. Since the skin's natural protective barrier of the human body, its piercing opens a place for entry of pathogenic microorganisms. Other physical risks as heat, ionizing radiation, electricity, noise. Microbiological hazards are found in medical waste that is contaminated with pathogens. Pathogens are viruses, bacteria, parasites, protozoa, fungi.

All waste material contaminated with blood and other body fluids and facilities (urine, feces, vomit, saliva, semen, vaginal secretions, etc.) is considered a biological hazard.

The World Health Organization (WHO) has estimated that, globally, unsafe handling of medical waste led to approximately: twenty one million infections with hepatitis B virus (HBV) (32% of all new infections), two million hepatitis C virus (HCV) (40% of all new HIV infections), 260.000 HIV infection (5% of all new HIV infections). There are different types of medical waste that carry chemical hazards in themselves (substances that are used in laboratories, diagnostic X-ray services, other radiological services, like most drugs that are found in pharmacies). Type of hazard is directly related to the properties of the substances or chemicals (toxins, explosive and flammable substances, carcinogenic substances, mutagenic and teratogenic substances). And as regards environmental hazards, many types of medical waste pose a potential threat to the environment, such as wastes containing mercury ( e.g. thermometers), wastes containing other heavy metals- nickel, cadmium and lead (e.g. batteries) and many pharmaceutical products, such as drugs with expired shelf life, etc. (4, 5)

### **3.2. Classification and medical waste management**

Classification of waste is very important, because this ensures that all waste goes into properly identified and selected containers and bags, in order to reduce to a minimum potential negative impact on human health and the environment. Laws of the Republic of Serbia and EU laws prohibit the mixing of different types of hazardous waste, as well as the mixing of hazardous and non-hazardous waste.

In General hospital in Leskovac medical waste is separated into the following categories:

municipal waste, infectious waste, pathoanatomic waste, pharmaceutical waste (drugs with expired shelf life). Municipal waste/non-hazardous waste makes up the largest part of the waste generated in. It consists of food waste, paper, cardboard, glass, plastic and metal (typically the remains of packaging), therefore it is comparable with household waste. As the healthcare facilities can't be considered a household, this part of the waste is referred to as "municipal waste" and classified as non-hazardous waste. Municipal waste is included in regular municipal waste collection. Infectious waste is waste that, due to the presence of pathogens, poses a risk to human health: culture from the laboratory; equipment, materials and instruments that have come into contact with blood, blood derivatives, other body fluids, excretions of patients who were clinically confirmed infection; waste of dialysis, infusion and similar procedures, including all materials and devices disposable; sharp objects (objects or materials that could cause cuts or puncture wounds, regardless of whether they come into contact with the patient or other infectious material. (needles, scalpels, etc.). Waste from health facilities contaminated with blood, secretions and other secretions, which, due to the potential presence of pathogenic microorganisms, may represent a potentially infectious waste e.g., bandages, plaster, linen, etc.

Treatment of infectious waste and sharps shall be methods of incineration and co-incineration plants dedicated to the thermal treatment in accordance with the best available techniques and methods of disinfection / sterilization in an autoclave or sterilizer, grinding or crushing in crushers, as well as other recognized methods which is achieved by removing the hazardous properties of medical waste. Pathoanatomic waste is waste containing recognizable tissue, body parts, human fetuses and blood bags. This type of waste is managed in special way, primarily for ethical reasons. It must be packaged in a durable brown bags and clearly marked before temporary storing in the fridge or freezer, designed exclusively for it. Thereafter, pathoanatomic waste is disposed of burial or cremation in a designated crematorium.

Pharmaceutical waste- all drugs, including their primary packaging, and all accessories used for the application of such products, drugs that have become unusable due to expiry or because they do not meet the required quality standards. Method of treatment of pharmaceutical waste (especially cytotoxic substances) and organic chemical waste is burning at high temperatures (up to 1100 ° C) in specialized facilities with equipment for purification of exhaust gases produced in the operation of the plant. Due to the lack of adequate treatment plants described hazardous waste streams in Leskovac, and Serbia also, many kinds of chemical and pharmaceutical waste is exported and treated abroad.

After sorting medical waste, comes to the conclusion that the largest fraction of risky medical waste belongs to the course of infectious medical waste. In defining models of infectious waste management system in the Republic of Serbia, it is applied the principle of proximity, which has led to the development and implementation of a system based on administrative districts- each of the 26 administrative districts in Serbia equipped the autoclave for the treatment of infectious waste( EU donations). The principle of operation of the autoclave is based on the effect of moist heat or steam under pressure at a temperature between 121 ° C and 134 ° C, depending on the types of vehicles and of the selected cycle.

#### **4. CONCLUSION**

Adequate procedures are known and predicted all ordinances, regulations and safeguards.

However, in real conditions in Leskovac , and Serbia also, proper medical waste management is possible only if there is a significant managerial involvement, adequate training of staff and constant monitoring. Otherwise, there is a risk that the infectious and hazardous materials can be disposed of in the normal municipal waste stream.

It is said that infectious waste makes up the largest part of hazardous medical waste, and because of the risk that bears upon the human health requires special attention.

Although it is said that after treatment in autoclaves infectious waste became non hazardous waste, contamination of groundwater and soil can cause, first of all, inadequately disposed of infectious waste. Namely, after sterilization in autoclaves, waste is going to shredding and grinding to the finest particles. Thus obtained powder is collected in special bags and disposed of with household waste. Such waste disposal may cause mechanical damage to the packaging bag containing milled infectious waste, which contains a significant amount of metal particles. These metal particles may indirectly, through groundwater and soil, come into contact with people and harm their health.

Authors of this paper wish to point to this omission and emphasize the need of finding a better solution for disposal this type of waste.

#### **LITERATURE**

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