A REVIEW OF BIOMEDICAL WASTE (MANAGEMENT AND HANDING) RULES, 1998

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Citation: LW (2015) June 5

ABSTRACT

The Government of India has notified Biomedical Waste (Management and handing) Rules, 1998 under the Environment (Protection) Act, 1986 and is applicable to all persons who generate, collect, receive, store, transport, treat, dispose, or handle biomedical waste in any form. The World Health Organization estimated that around 20% of the total waste from health care activities are hazardous, i.e. toxic, radioactive or infectious, further as these wastes contain harmful microorganism it can infect patients, health care workers and the public in general. The Biomedical Waste (Management and handing) Rules, 1998 imposes a duty on occupier of an institution generating biomedical waste to take measures to prevent any adverse effect on human and the environment. The Schedule I of the BioMedical Waste (Management and Handling) Rules, 1998 provides for different methods of treatment and disposal of biomedical waste. The biomedical waste shall be segregated at the point of generation into container or bags and shall not be mixed with any other waste. The biomedical waste shall be segregated in accordance with Schedule II and the container shall be labeled in accordance with Schedule III. A Common biomedical waste treatment facility (CBWTF) plays an important role in the collection and treatment of biomedical waste, thereby, reduce threats to human health and the environment which may be caused untreated biomedical waste.

Introduction

The growth of hospitals and clinics are a good sign of access to health care facilities to the masses, however, this also increases the concern of collection and safe disposal of biomedical waste.[1] The Government of India notified Biomedical Waste (Management and handing) Rules, 1998 under the Environment (Protection) Act, 1986[2] and is applicable to all persons who generate, collect, receive, store, transport, treat, dispose, or handle biomedical waste in any form.[3] It is estimated that the hospitals in India, generates around 1 – 2 kg per bed per day of biomedical waste in a hospital and around 600 grams per day in a general practitioner's clinic.[4]

Meaning of the term 'Biomedical Waste'

The World Health Organization[5] defines biomedical waste as, "*Waste generated by health care activities and includes blood, used needles, pharmaceuticals, radioactive materials etc.*" The Biomedical waste is also known as infectious waste or medical waste[6] or health care waste.[7] The Biomedical Waste (Management and Handing) Rules, 1998 defines it as,

> "*Any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Schedule I"*

The Biomedical Waste (Management and Handing) Rules, 1998 gives a wider definition of biomedical waste, covers different sources generation of biomedical, and includes different types of biomedical waste. The Schedule 1 provides different waste categories like human anatomical waste, animal waste, microbiological and biotechnology waste, waste sharps, discarded medicine etc.

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[1] Rule 3 (5) of the Bio-Medical Waste (Management and Handling) Rules, 1998
[2] In exercise of the powers conferred by Sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986)
[3] Rule 1 , Application, of the Bio-Medical Waste (Management and Handling) Rules, 1998
[4] Indian Society of Hospital Waste Management, Frequently asked Questions Biomedical Waste Management, available at http://www.medwasteind.org/random.asp last accessed on May 15, 2015
[5] Available at http://www.who.int/topics/medical_waste/en/ last accessed on May 15, 2015
[6] Biomedical Waste Definition, available at http://www.ehow.com/about_5452204_biomedical-waste-definition.html last accessed on May 15, 2015
[7] *Ibid at 5*

The definition adopted in Indian law, i.e The Biomedical Waste (Management and handing) Rules, 1998 is similar to that of the definition adopted in the United States in the Medical Waste Tracking Act of 1988.[8]

Significance of biomedical waste management

Hospital waste management is a routine procedure of hospital administration as prescribed by law. Hospital waste, hospital acquired infection, transfusion transmitted diseases, rising incidence of Hepatitis B, HIV and other diseases, create potential threat of infection, contamination and serious health hazards to doctors, nurses, ward boys and other the health care workers, support staff, sanitation workers, rag pickers etc. who are regularly exposed to biomedical waste as an occupational hazard, as well as general public in the surrounding area.[9]

Even though, only 15% to 20% of hospital wastes i.e. "Biomedical waste" generated from biological sources or is used in the diagnosis, prevention, or treatment of diseases, is infectious and hazardous, but, if it is not segregated at the source of generation, and is mixed with other nonhazardous waste, then 100% waste becomes hazardous.[10] Segregation is the essence of Biomedical, hazardous waste management and should be done strictly at the source of its generation only. Sometimes, even the sharps used in the health care establishments create risk of injuries leading to infection to all categories of hospital personnel, patients and waste handlers and public living in the vicinity of hospital.

The risk of contamination and infection is also associated with improper disposal of hazardous chemicals, drugs and "disposables" in the open, which may be picked up by rag pickers or other unscrupulous people, who may repack and sell them.

All biomedical waste generated in the health care establishments, poses great danger not only to human life, but also, to the environment. Air pollution due to emission of hazardous gases by

[8] "Any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals." This definition includes, but is not limited to :blood-soaked bandages, culture dishes and other glassware,discarded surgical gloves, discarded surgical instruments, discarded needles used to give shots or draw blood (e.g., medical sharps), cultures, stocks, swabs used to inoculate cultures, removed body organs (e.g., tonsils, appendices, limbs), discarded lancets. Available at http://www.epa.gov/osw/nonhaz/industrial/medical/tracking.htm last accessed on May 15, 2015

[9] Available at http://www.who.int/topics/medical_waste/en/ last accessed on May 15, 2015

[10] Hem Chandra, Hospital Waste An Environmental Hazard and Its Management, International Society of environmental Botanists, Vol. 5 No. 3 - July 1999

incinerators such as Furan, Dioxin, Hydrochloric acid etc. and, contaminating water with dispersing biomedical waste including incineration emissions and ash in it leads to dangerous water and soil pollution as well. This has compelled the authorities to think seriously about proper disposal of biomedical waste, failing which, it will lead to pollution, infection and will involve huge money, manpower and resources on treatment and rectification measures.[11]

Biosafety[12] is essentially an internationally accepted, preventive concept inclusive of all kinds of safety precautions to be undertaken. Biomedical waste management is a multidimensional and multidisciplinary area touching every field of medicine, scientific research, management techniques, law, and environment as well as social and political issues.

Magnitude of the Problem

The World Health Organization estimated that around 20% of the total waste from health care activities are hazardous, i.e. toxic, radioactive or infectious, further as these wastes contain harmful microorganism it can infect patients, health care workers and the public in general.[13]

According to Medindia[14] news *'Over Half of Biomedical Waste is Disposed with Municipal Waste'*,[15] India generates 4.2 lakh Kg of biomedical waste on a daily basis with only 157 facilities to treat the biomedical waste, there is a huge shortage of between biomedical waste generation capacity of the country and the capacity to treat and dispose it.

Duty of the Occupier

The Biomedical Waste (Management and Handing) Rules, 1998 imposes a duty on the occupier of an institution generating biomedical waste, to take measures to prevent any adverse effect on human and the environment.[16] The occupier includes a hospital, nursing home, clinic, dispensary,

[11] *ibid*
[12] Available at http://www.thefreedictionary.com/biosafety last accessed on May 15, 2015
[13] Waste from health-care activities, available at http://www.who.int/mediacentre/factsheets/fs253/en/ last accessed on May 15, 2015
[14] Available at http://www.medindia.net/aboutus.asp last accessed on May 15, 2015
[15] Available at http://www.medindia.net/news/over-half-of-bio-medical-waste-disposed-with-municipal-garbage-67655-1.htm last accessed on May 15, 2015
[16] Rule 4 of the Bio-Medical Waste (Management and Handling) Rules, 1998

veterinary institution, animal house, pathological laboratory, blood bank and means a person who has control over that institution and or its premises.[17]

Treatment and disposal of biomedical waste

The Schedule I of the Bio Medical Waste (Management and Handling) Rules, 1998 provides for different methods of treatment and disposal of biomedical waste. For instance, category no.1 provides for human anatomical waste, which shall be incinerated and deep buried. These methods of treatment and disposal shall comply with Schedule V. The Schedule V of the rules provides for standard of treatment and disposal of biomedical waste like standards for incineration, standards for autoclaving, standard for liquid waste etc. The occupier of an institution shall install biomedical treatment facility within the period provided under the Schedule[18] and ensure that the biomedical waste is sent to the common waste treatment facility.[19] The Biomedical Waste (Management and handing) Rules, 1998 under Schedule 1 provides different categories of biomedical waste. The categorization of biomedical is important for proper treatment and disposal.[20] There are total ten categories of biomedical waste and as per their categorization, they treated and disposed.

Category	Type of Waste	Treatment and Disposal Options
Category 1	Human Anatomical Waste (Human tissues, organs, body parts)	Incineration/Deep Burial
Category 2	Animal waste (Animal tissues, organs, body parts, carcasses, bleeding parts,blood and experimental animals used in research)	Incineration/Deep Burial
Category 3	Microbiology and biotechnology waste (waste from lab culture, specimens from microorganisms, vaccines, cell cultures, toxins, dishes, devices used to transfer cultures)	Local Autoclaving/ Microwaving/ Incineration
Category 4	Waste Sharps (Needles, Syringes, scalpels, blades, glass)	Chemical Disinfection Autoclaving/ Microwaving, Mutilation and

[17] Rule 3(8) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998
[18] Schedule VI of the Bio-Medical Waste (Management and Handling) Rules, 1998
[19] Bio-medical waste treatment facility means any facility wherein treatment. disposal of bio-medical waste or processes incidental to such treatment or disposal is carried out. Sec. 3(7) of the Bio-Medical Waste (Management and Handling) Rules, 1998
[20] Rule 5, treatment and disposal, of the Bio-Medical Waste (Management and Handling) Rules, 1998

		Shredding
Category 5	Discarded medicines and cytotoxic drugs (outdated, contaminated, discarded drugs)	Incineration/Destruction and disposal in land fills
Category 6	Soiled waste (contaminated with blood and body fluids including cotton, dressings, soiled plasters, linen)	Autoclaving/ Microwaving/ Incineration
Category 7	Solid waste (tubes, catheters, IV sets)	Chemical Disinfecion/Autoclaving/ Microwaving, Mutilation and Shredding
Category 8	Liquid waste (Waste generated from laboratory and washing, cleaning, disinfection)	Disinfection by chemical treatment and discharge into the drains
Category 9	Incineration ash	Land fills
Category 10	Chemical waste	Chemical disinfection and discharge into the drains

Segregation, packaging, transportation and storage

The guidelines emphasizes that, biomedical waste shall be segregated at the point of generation into container or bags[21] and shall not be mixed with any other waste.[22] The biomedical waste is required to be segregated in accordance with Schedule II and the container must be labeled in accordance with Schedule III. The Schedule II provides color codes and types of container for disposal of biomedical waste. For instance, yellow color-coding is used for storage of waste categories[23] in a plastic type container or bag. The Schedule III provides for the label, which shall have a non-washable and noticeably visible Biohazard and Cytotoxic symbols. If biomedical waste is transported outside the premises[24] where the waste is generated for the purpose of disposal, it shall also contain information, such as sender's name and address, receiver's name and address etc.[25] The untreated biomedical waste shall be transported only in a specially designed and approved vehicle[26] and shall

[21] Rule 6(2) of the Bio-Medical Waste (Management and Handling) Rules, 1998
[22] Rule 6(1) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998
[23] category 1, category 2, category 3, category 6
[24] Rule 6(3) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998
[25] As per Schedule IV
[26] Rule 6(4) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998

not be stored beyond a period of 48 hours[27] without permission from approved authority and care should be taken that it does not adversely affect human health and the environment.[28]

Colour Coding	Type of Container -I Waste Category	Treatment options as per Schedule I
Yellow	Plastic bag Cat. 1, Cat. 2, and Cat. 3, Cat. 6.	Incineration/deep burial
Red	Disinfected container/plastic bag Cat. 3, Cat. 6, Cat.7.	Autoclaving/Microwaving/ Chemical Treatment
Blue/White translucent	Plastic bag/puncture proof Cat. 4, Cat. 7. Container	Autoclaving/Microwaving/Chemical Treatment and destruction/shredding
Black	Plastic bag Cat. 5 and Cat. 9 and Cat. 10. (solid)	Disposal in secured landfill

Authority

The State Government[29] is empowered to appoint a prescribed authority for granting authorization and for the implementation of rules under the Biomedical Waste (Management and handing) Rules, 1998.[30] The authority is empowered to make enquiry, which it may deem fit and grant permission, or renew authorization, cancel[31] or suspend authorization[32] to handle biomedical waste.[33] The State Government shall establish a advisory committee consisting of experts from medical and health, animal husbandry and veterinary, environment management and other related department, to give advice to the Government in the matter of connected implementation of Biomedical rules.

[27] Rule 6(5) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998
[28] *Ibid*
[29] Including Government of Union Territory
[30] Rule 7(1) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998
[31] Rule 7(8) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998
[32] No authorization shall cancelled or suspended without giving a reasonable opportunity
[33] Rule 7(4) of the of the Bio-Medical Waste (Management and Handling) Rules, 1998

Common biomedical waste treatment facility

A Common biomedical waste treatment facility (CBWTF) plays an important role in the collection and treatment of biomedical waste, thereby; reduce threats to human health and the environment, which may be caused due to untreated biomedical waste. The Central Pollution Control Board has issued guidelines for setting up Common biomedical waste treatment facility for treatment and disposal of biomedical waste.[34] The guideline provides the requirement of land, covered area, treatment equipment, infrastructure setup etc.[35]

The CBWTF concept is a viable concept for safe treatment of biomedical waste as it is professionally managed and significantly reduces cost of biomedical waste treatment,[36] moreover, it can be set up only in compliance with environmental law[37] in a prescribed area.[38]

Conclusion

The waste generated by the health care establishment includes a wide range of waste materials like used needles and syringes, soiled dressings, body parts, diagnostic samples, blood, chemicals, pharmaceuticals, medical devices and radioactive materials etc. which is legally termed as biomedical waste. The greatest risk of biomedical waste is from the infectious and sharp components of the waste because the health care workers handling waste may contact with HIV or AIDS, Hepatitis B and C. These biomedical wastes pose tremendous risk to uninfected population if it comes in contact with it. Thus, it is essential that, the biomedical waste is properly handled, segregated and properly and safely disposed off.[39]

[34] February 26, 2014

[35] Available at http://www.cpcb.nic.in/wast/bioimedicalwast/Rev_Draft_Gdlines_CBWTFs_26022014.pdf last accessed on May 15, 2015

[36] Introduction, Guidelines for Common Bio-medical Waste Treatment Facilities, Februrary 26, 2014

[37] 'Consent to Establishment' under Rule 25 of the Water (Prevention and Control of Pollution) Act, 1974 and under Rule 21 of the Air (Prevention and Control of Pollution) Act, 1981, authorization under Rule 8 of the BMW Rules, 1998, 'Environmental Clearance (EC)' from the Ministry of Environment & Forests (MoEF) in compliance to the Honourable National Green Tribunals order dated 28.11.2013.

[38] It shall be located in non residential area or shall be developed in industrial area or as a part of existing treatment storage and disposal facility.

[39] Sujata Pawar, "Implementation Of The Biomedical Waste (Management And Handling) Rules 1998 by Hospitals In Satara City" Minor Research Project, UGC, 2015

The Government of India took a major step by enacting The Biomedical Waste (Management and Handling) Rules, 1998, under Section 6 and 25 of the Environmental Protection Act 1986, the rules deal with the generation/storage/handling/treatment and disposal of Biomedical Waste. India is among very few countries, which have comprehensive biomedical waste laws in practice.

The State Government plays an important role in the implementation of biomedical rules as, health is a subject matter under the State list,[40] and similarly, the health care establishment too plays an important role, as they are generator of biomedical waste and are responsible in collecting, segregating, storing and disposing it.

The need for proper biomedical waste management has gained importance in recent years with the growth private health care sector in India and technology is playing a major role in bringing quality in healthcare, be it better nursing, better health care communication systems, patient monitoring devices, better diagnostic techniques or tele-medicine to provide a low cost diagnosis to remote patients etc.

Due to availability of experienced and renounced medical experts, substantially cheaper fees and expenses for medical services in comparison with foreign countries and strong network of private Health care institutions present in India, make it a favorite choice for medical tourism, for people from all over the world. In this scenario, a separate and autonomous department of the Government with strict penal powers is the need of the hour to effectively deal with biomedical waste management in India.

[40] Seventh Schedule, List – II, Constitution of India, Public health and sanitation; hospitals and dispensaries