Note

Biomedical Waste Management Rules, 2016 (BMWM Rules, 2016) Notified by Ministry of Environment Forest & Climate Change in March, 2016, stipulates that every Healthcare Facility shall take all necessary steps to ensure that biomedical waste is handled without any adverse effect to human health and the environment. Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc are also generated by the Healthcare Facilities (HCFs) which are being utilized by pharmaceutical industry for production of drugs, reagent chemicals, markers, etc.

These guidelines provide guidance to Healthcare Facilities as well as the industry / vendors involved in utilization of biomedical wastes in collection, sending, transportation, utilization and disposal by ensuring adequate safeguards from risk of spread of infection during such handling. Wherein the responsibilities of the Healthcare Facilities given are;

- I. Inform the prescribed authority about the type of biomedical waste which is handed over to the vendor and accordingly shall amend the authorisation while applying afresh or seeking renewal of the same.
- II. Hospitals shall provide bio-medical waste only to those industries / vendors who are authorised by concerned SPCB/PCC under BMWM Rules, 2016 for collection and transportation of biomedical waste.
- III. Bio-medical waste intended for utilization shall be collected by the nursing staff directly into the leak proof, puncture proof, tamper proof containers/bottles provided by the authorised vendor/industry.
- IV. The containers/bottles containing bio-medical waste shall be stored in temporary biomedical waste storage area.
- V. Records should be maintained indicating the type of biomedical waste, quantity, date& time of generation and date of collection by the vendor/industry.

In view of above, we may facilitate the firm engaged in utilization of BMW for above purposes. Further healthcare facilities in the state may be advised to provide such waste to the authorised vendors / pharmaceutical/ Bio-technology industry with intimation to Board. Also, we may impose these conditions in the combined consent and BMW Authorizations of HCEs received in the Board. Healthcare Establishments shall handover such waste to the Drug Manufacturers as per CPCB Guidelines. In case, HCEs face any technical difficulty towards handing over the required BMW waste, they shall inform the Board accordingly. Conditions in this regard to be incorporated in the CCA to be issued and existing CCA shall be amended accordingly.

Submitted before CAC for discussion and decision in the matter.

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Speed Post

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18309-18343

March 25, 2019

To

Member Secretary
All SPCBs/PCCs

Sub: Guidelines for "Handling of Bio-Medical Waste for Utilization"-reg.

Sir,

This is to inform that CPCB has prepared guidelines for "Handling of Bio-Medical Waste for Utilization" outlining procedure for packaging and transportation of Bio-Medical Waste for the purpose of utilization by pharmaceuticals industries in production of drugs, reagent chemicals, markers etc. These guidelines are available at http://cpcb.nic.in/uploads/hwmd/Handling Biomedical Waste Utilization Feb 11.03.2019.pdf

It is therefore requested that your Board may kindly ensure authorization of industries involved in such utilization as per aforesaid guidelines.

Yours Faithfully,

(B.Vinod Babu) AD & DH WMD-I

Copy to:

(i) PS to 'MS'

: For kind information of 'MS', please

(B:Vinod Babu)

GUIDELINES FOR HANDLING OF BIOMEDICAL WASTE FOR UTILIZATION



CENTRAL POLLUTION CONTROL BOARD
(Ministry of Environment, Forest and Climate Change)
Parivesh Bhawan, East Arjun Nagar
DELHI-110 032

website: <u>www.cpcb.nic.in</u> February 2019

1. Introduction

Biomedical Waste Management Rules, 2016 (BMWM Rules, 2016) notified by Ministry of Environment Forest & Climate Change in March, 2016, stipulates that every Healthcare Facility shall take all necessary steps to ensure that biomedical waste is handled without any adverse effect to human health and the environment. Bio-medical wastes such as pleural fluid, ascetic fluid, HBsAG positive blood, placenta etc are also generated by the Healthcare Facilities (HCFs) which are being utilized by pharmaceutical industry for production of drugs, reagent chemicals, markers, etc.

These guidelines provide guidance to Healthcare Facilities as well as the industry/vendors involved in utilization of biomedical wastes in collection, sending, transportation, utilization and disposal by ensuring adequate safeguards from risk of spread of infection during such handling. Following guidelines would be applicable for such utilization of bio-medical waste;

2. Applicability of Authorization

- a) The industries/vendors involved in collection and transportation of biomedical waste for the purpose of utilization shall obtain authorization from the concerned Pollution Control Board/Pollution Control Committee of the State/UT where they are engaged in collection and transportation of biomedical waste. They shall also obtain authorization for collection, use and disposal of biomedical waste from State / Union Territory where their facility exists.
- b) The Health Care Facility involved in providing biomedical waste to an industry or vendor for the purpose of their utilization shall inform concerned SPCB and they shall provide such details while seeking renewal of authorization.
- c) The industry/vendor engaged in utilization of biomedical waste shall be liable for any environmental and health risk that may arise during transport and handling of biomedical waste from the point of collection till utilization and disposal as per the provisions laid down under E(P) Act, 1986, including payment of environmental compensation charges as may be applicable.

3. Responsibilities of the Healthcare Facilities

- a) Inform the prescribed authority about the type of biomedical waste which is handed over to the vendor and accordingly shall amend the authorisation while applying afresh or seeking renewal of the same.
- b) Hospitals shall provide bio-medical waste only to those industries / vendors who are authorised by concerned SPCB/PCC under BMWM Rules, 2016 for collection and transportation of biomedical waste.
- c) Bio-medical waste intended for utilization shall be collected by the nursing staff directly into the leak proof, puncture proof, tamper proof containers/bottles provided by the authorised vendor/industry.

- d) The containers / bottles containing bio-medical waste shall be stored in temporary bio-medical waste storage area.
- e) Records should be maintained indicating the type of biomedical waste, quantity, date & time of generation and date of collection by the vendor/industry.

4. Responsibilities of Vendor/Industry

- a) Shall obtain authorization from concerned SPCB/PCC where they are engaged in collection and transportation of BMW for utilization.
- b) Ensure use of appropriate bottles/containers and safe packaging as specified in section 5 of this document.
- c) The containers/bottles used for collection of bio-medical waste shall be labelled with bio-hazard symbol in accordance with BMWM Rules, 2016.



d) The containers/bottles used for collection of bio-medical waste shall be labelled with the following information with indelible ink:

Name of the Sender (Healthcare Facility):
Address & Contact Number:

Name of the ward :
Type of biomedical waste :
Date of collection :

Name of the receiver (Industry/vendor):
Address & Contact number:

- e) Shall ensure safe transportation of biomedical waste either by own vehicles or by any transport agency.
- f) Industry or vendor shall be liable for any leakages and environmental consequences thereof.
- g) Ensure disposal of used or residual BMW as well as the containers used in collection and transportation of BMW through an authorised CBWTF located close to the facility where the BMW is intended to be utilized.
- h) Ensure disposal of un-used or spent biomedical waste, as per BMWM Rules, 2016.
- i) Shall maintain records / log book for the waste being collected by industry/vendor.
- j) The industry / vendor shall possess valid consent and authorisation from the State, where their unit is installed.

5. Procedure for packaging:

The substances in bio-medical waste intended for utilization might contain viable microorganism such as bacterium, virus, parasite or fungus that may cause disease in humans or animals. Therefore, packaging of such bio-medical waste shall be done in triple packaging system comprising of three layers of packaging as specified below:

- <u>Primary receptacle</u>: Bottle/container for bio-medical waste shall be leak proof, puncture proof and tamper proof. Each bottle containing biomedical waste shall be sealed in self sealing plastic bags provided with absorbent so as to absorb the liquid in case of any leakages. In case of liquid bio-medical waste, size of each bottle shall not exceed 500ml.
- <u>Secondary receptacle</u>: This is a second layer of packing which will be water tight, leak proof receptacle such as big plastic bag to enclose and to protect primary receptacle.
 Several primary receptacles wrapped along with absorbent may be placed in one secondary receptacle.
- <u>Third receptacle</u>: After secondary layer packaging, the secondary receptacle shall be placed in hard / rigid box for protection. This box shall also contain absorbent material such as foam cushioning to absorb the leakages, if any.
- The packaging material should be labelled with symbol of biohazard along with warning text as below;

"Sealed Bio-Medical Waste – Handle with Care"		
	CAUTION BIOHAZARD	
	X	
As per Authorization:		
datedissued by		
Date of collection:		

6. Transportation of Biomedical Waste:

Following guidelines shall be applicable for transportation of bottles/containers containing BMW packaged for utilisation purpose as per the procedure given under section 5;

- a) Can be transported by road or by railways, and by ensuring compliance to relevant provisions under Motor Vehicles Act and Indian Railways Act.
- b) For transportation by air, WHO guidelines vide WHO/HSE/GCR/2015.2 entitled "Guidance on regulations for the transport of infectious substance 2015-2016" shall be followed.

- c) Industry/vendor may make own arrangement for transportation of BMW or may engage professional transportation agency.
- d) A spill kit containing absorbent material, a disinfectant, a leak proof waste disposal container and heavy duty reusable glove should be kept in the transport vehicle.
- e) All the vehicles used for collection of bio-medical waste from the health care facilities should have symbol of BMW.
- f) The industry/vendor utilizing biomedical waste shall be responsible for transportation and the risks and liabilities associated with transportation.
- g) Only covered vehicles should be used for transportation of bio-medical waste

7. Management of plastic containers:

- a) After emptying the plastic containers (used for the collection of biomedical fluids), packaging material (zip lock bag, plastic jumbo bag, gloves, masks etc.) should also be disposed as per the provisions under BMWM Rules, 2016.
- b) The plastic containers used for collection of biomedical fluids should be emptied and Pretreated by autoclaving or by non-chlorinated chemicals. The pre-treated containers should be collected in red colour coded bags/containers and handed over to Common Biomedical Waste Treatment Facility (CBMWTF) authorized by the State Pollution Control Board/Pollution Control Committee for further treatment and disposal.
- c) Residual/discarded biomedical fluids shall be collected separately and pre-treated for disinfection (by non-chemical methods) prior to mixing with other effluent in industry for further treatment. Treatment Methods specified for Yellow (f) category waste as specified in CPCB guidelines for management of Healthcare waste asper BMW Rules, 2016.
- d) Red coloured bags/containers should be provided with bio hazard symbol and should be labeled as per Schedule IV of the BMWM Rules, 2016.
- e) Separate temporary storage area shall be provided inside the premises of industry for temporary storage of colour coded biomedical waste bags/containers.
- f) Daily records should be maintained with respect to waste generation in yellow and red coloured bag/container.
- g) In case plastic crates in which the bottles are placed are to be re-used , then the same shall be disinfect with sodium hypochlorite and shall be washed with detergent prior to re-use the same.
- h) Other solid waste like gloves, mask, cotton, gauze piece, syringe, gels, plastic columns, etc. used or generated during the process of utilization shall be stored in yellow colour plastic bag/container and handover the same to CBWTF operator.

8. Management of liquid waste from utilization process

- a) Industry shall provide Effluent Treatment plant (ETP) for the treatment of effluent generated during the process of utilization, washing of containers, floors etc.
- b) Effluent generated from the process of utilization shall be disinfected followed by further treatment in ETP.

- c) Treated effluent should comply with the liquid discharge standards stipulated under the BMWM Rules, 2016 and other standards as may be stipulated by SPCBs/PCCs.
- d) ETP sludge shall be analyzed to check the hazardous constituents and in case the hazardous constituents are present beyond the prescribed limit as given in Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2016 then the ETP sludge should be disposed through Hazardous Waste Treatment, storage and Disposal Facility.
- e) Records should be maintained w.r.to the waste water generation, its treatment and disposal.

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