

# MAHARASHATRA POLLUTION CONTROL BOARD

Phone : 4010437/4020781  
/4037124/4035273  
Fax : 24044532/4024068  
/4023516  
Email : enquiry@mpcb.gov.in  
Visit At : <http://mpcb.gov.in>



Kalpataru Point, 3rd & 4th floor, Sion- Matunga  
Scheme Road No. 8, Opp. Cine Planet Cinema,  
Near Sion Circle, Sion (E),

Mumbai - 400 022

## LETTER OF BIO-MEDICAL WASTE AUTHORISATION

*[Authorisation for Collection, Reception, Storage, Transportation, Treatment, Disposal of Bio-Medical Wastes under Rule 7(4) of BMW (M & H) Rules, 1998]*

No. MPCB/PSO)/BMW/ Pune/2013 - 77

Dated : 18.07.2013

- I. File number of authorisation and date of issue
- II. **M/s. Bioclean Systems (India) Pvt. Ltd., Solapur**, is hereby granted an authorisation for generation of biomedical waste on the premises situated at **S.No. 44, Bhogaon, Municipal Solid Waste Dump, Old Barshi Road, Dist- Solapur.** (e-mail: \_\_\_\_\_)
- III. This authorisation is renewed w.e.f. 01.04.2013 and shall be valid for a period up to 31.03.2016. An application shall be made by the occupier/operator for renewal 3 Months before expiry of this authorisation.
- V. This authorisation is issued subject to compliance of the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Environment (Protection) Act, 1986.

### Terms and Conditions of authorisation

1. The "authorized Person" Director, M/s. Bioclean Systems (India) Pvt. Ltd., Solapur shall comply with the provisions of the Environment (Protection) Act, 1986, and the Rules made there under.
2. The authorisation shall be produced for inspection at the request of an officer authorized by the prescribed authority i.e. Member Secretary, MPCB.
3. Any unauthorized change in equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorisation.
4. It is the duty of the authorized person to take prior permission of the prescribed authority to close down the facility.

No. MPCB/PSO)/BMW/ Solapur/2013 - 77

Dated : 18.7.2013

Recd  
18/07/13



5. The authorisation is granted for collection, storage, transportation, treatment and disposal of Bio-Medical Waste (BMW) from the HCEs in their jurisdiction mentioned at clause No. 13. The waste categories and quantities listed here in below :

Sr. No.	Category	Description	Quantity not to exceed	UOM	Segregation Colour coding	Treatment & Disposal
1	Cat-1	Human Anatomical waste	13800	Kg/M	Yellow	Incineration
2	Cat- 2	Animal waste	150	Kg/M	Yellow	Incineration
3	Cat-3	Microbiology & Biotechnology Waste	2800	Kg/M	Yellow	Incineration
4	Cat-4	Waste Sharps	1200	Kg/M	Blue/ white translucent	Disinfection by chemical treatment, autoclaving, shredding and hand over to MPCB authorized metal recyclers.
5	Cat-5	Discarded Medicines and Cytotoxic drugs	1150	Kg/M	Yellow	Incineration
6	Cat-6	Soiled Waste	12800	Kg/M	Yellow	Incineration
7	Cat-7	Solid Waste	700	Kg/M	Red	Disinfection by chemical treatment, autoclaving, shredding and hand over to MPCB authorized plastic recyclers.
8	Cat-9	Incineration Ash	3500	Kg/M	Black	Sent to CHWTSDF

6. The liquid/solid waste generated from the treatment activity (from washing, cleaning, housekeeping and disinfecting activities) shall be treated suitably by providing effluent treatment facility to conform the standards prescribed in Schedule V of said Rules and the Environment (Protection) Act, 1986.
7. (i) BMW shall be treated and disposed of in accordance with Schedule I; and in compliance with the standards prescribed in Schedule V of said Rules.
- (ii) You shall setup requisite BMW treatment facilities like incinerator, autoclave, shredder, etc., in accordance with the BMW rules. You shall dispose of the duly treated Metal & Plastic waste to MPCB authorized recycler and incineration ash in secured land fill site at authorized Common Hazardous Waste treatment & disposal facility (CHWTSDF) at MEPL, Ranjangaon setup as per the Hazardous Waste (M & H) Rules, 1989 as amended.



8. (i) BMW shall not be mixed with other wastes or reused or sold in any form.
- (ii) BMW shall be segregated into containers / bags at the point of generation in accordance with Schedule-II prior to storage, treatment and disposal. The containers shall be labeled according to Schedule III of BMW Rules 1998..
- (iii) If a container containing BMW is to be transported from the premises where BMW is generated to any waste treatment facility outside the premises, the container shall, apart from the Label prescribed in Schedule III, also carry information prescribed in Schedule IV and shall be transported by authorized Transporter only.
- (iv) Notwithstanding anything contained in the Motor Vehicles Act, 1988 or Rules there under, BMW shall be transported only in such vehicle as may be authorized for the purpose by the competent authority as specified by the Government.
- (v) No untreated BMW shall be kept stored beyond a period of 48 hours.
- (vi) Necessary protective gear for the waste handlers shall be provided by the hospital authority.
- (vii) You shall ensure proper collection of mercury spillage arising mainly due to breakage of thermometers pressure gauges (Sphygmomanometers) other equipments used in health care facilities (HCFs) as well as its storage in accordance with the Hazardous waste (Management & Handling) Rules (presently these Rules has to be read as 'Hazardous Waste (Management & Handling and Transboundary Movement) Rules, 2008) and returning it to the instrument manufacturers apart from necessary taking steps to ensure that the spilled mercury does not become a part of bio-medical or other solid wastes generated from the HCFs.

9. Standards for waste autoclaving:

The autoclave should be dedicated for the purposes of disinfecting and treating bio- medical waste,

- (I) When operating a gravity flow autoclave, medical waste shall be Subjected to:
  - (i) a temperature of not less than 121<sup>0</sup> C and pressure of 15 pounds per Square inch (psi) for an autoclave residence time of not less than 60 minutes; or
  - (ii) a temperature of not less than 135<sup>0</sup>C and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or
  - (iii) a temperature of not less than 149<sup>0</sup>C and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.
- (II) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air. The waste shall be subjected to the following.
  - (i) a temperature of not less than 121<sup>0</sup>C and a pressure of 15 psi for an autoclave residence time of not less than 45 minutes; or
  - (ii) a temperature of not less than 135<sup>0</sup>C and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes; or
- (III) Medical waste shall not be considered properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure were reached during the autoclave process. If for any reasons, time temperature or pressure indicates that the required temperature, pressure or residence time was not reached, the



entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved.

- (IV) *Recording of operational parameters*, - Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.
- (V) *Validation test: Spore testing*. - The autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be *Bacillus stearothermophilus* spores using vials or spore strips, with at least  $1 \times 10^4$  spores per milliliter. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than  $121^\circ \text{C}$  or a pressure, less than 15 psi.
- (VI) *Routine Test*.—A chemical indicator strip/tape that changes color when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste package at different location to ensure that the inner content of the package has been adequately autoclaved.

10. The liquid / solid waste generated from the treatment activity (from laboratory and washing, cleaning, housekeeping and disinfecting activities) shall be treated suitably to conform to the standards prescribed in Schedule V of said Rules and the Environment (Protection) Act, 1986.

#### 10.1 Standards for LIQUID waste :

The effluent generated should conform to the following limits

PARAMETERS	PERMISSIBLE LIMITED
PH	6.5- 9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l.
BOD	30 mg/l
COD	250 mg/l
Bio-assay test	90% survival of fish after 96 hours in 100% effluent

These limits are applicable to those hospitals which are either connected with sewers without terminal sewage treatment plant or not connected to public sewers. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

#### 10.2 CONDITIONS UNDER AIR ACT:-

The incinerator should meet the following operating and emission standards:  
Standards for emissions of air Pollutants

##### Operating Standards

1. Combustion efficiency (CE) shall be at least 99.00%.



2. The Combustion efficiency is computed as follows;

$$\text{C.E.} = \frac{\% \text{CO}_2}{\% \text{CO}_2 + \% \text{CO}} \times 100$$

3. The temperature of the primary chamber shall be  $800 + 50^\circ \text{C}$ ,

4. The secondary chamber gas residence time shall be at least 1 (one) second at  $1050 \pm 50^\circ \text{C}$  with minimum 3% Oxygen in the stack gas.

S.No	Parameters	Conc.Mg/Nm <sup>3</sup> at (12%CO <sub>2</sub> correction)
1	Particulate matter	150
2	Nitrogen Oxides	450
3	HCL	50

5. Minimum stack height shall be 30 meters above the ground

6. Volatile organic compounds in the ash shall not be more than 0.01%

7. The Applicant shall provide ports in the chimney and facilities such as ladder, platform etc for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's staff. The chimneys shall be numbered as S-1, S-2 etc and these shall be painted / displayed to facilitate identification.

8. The applicant shall carry out monitoring of above mentioned parameters atleast quarterly from the approved laboratory and submit rept of the same to the Board.

Note :

- Suitably designed pollution control devices should be installed / retrofitted with the incinerator to achieve the above emission limits, if necessary.
- Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- Chlorinated plastics shall not be incinerated.
- Toxic metals in incineration ash shall be limited within the regulatory quantities as defined under the Hazardous Waste (Management and Handling Rules,) 1989.
- Only low sulphur fuel like L.D.O./L.S.H.S./Diesel shall be used as fuel in the incinerator.
- The occupier shall comply with above operating and emission standards during the validity period of this Authorization. In case of failure your authorization may be cancelled.

10.3 The Applicant shall install , operate and maintain of Power generating sets (Diesel) as per provisions of Environment (Protection) Act, 1986.

11. (i) You shall submit an Annual Report to MPCB(HQ), MUMBAI in Form-II by 31st January every year including information about the categories and quantities of BMW handled during the preceding year.

(ii) You shall maintain records related to the collection, reception, storage, transportation, treatment, disposal and / or any form of handling of BMW in accordance with these Rules and any guidelines issued.

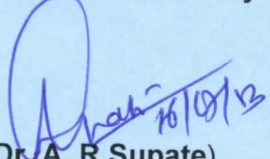
(iii) All records shall be subject to inspection and verification by the prescribed authority at any time.

12. When any accident occurs at any institution or facility or any other site where BMW is handled or during transportation of such waste, the authorized person shall report the accident in Form III to the prescribed authority forthwith.



13. M/s. Bioclean Systems (India) Pvt. Ltd., at S.No. 44, Bhogaon, Municipal Solid Waste Dump, Old Barshi Road, Dist- Solapur shall collect and transport BMW from Solapur, District covering all Tahsils for treatment and disposal at your facility situated at above address. The area allocated vide letter dated 15.01.2013 is subject to revision by the Board. You shall also obtain NOC of concerned local bodies for collection and transportation of waste from jurisdiction of concerned local body. Also, you shall obtain NOC of Solapur Municipal Corporation (SMC) for treatment and disposal of BMW collected from area outside SMC at above site of common facility.
14. This authorization is issued subject to condition as mentioned below,
- To submit B.G. of Rs. 6.50 lakhs towards compliance of condition mentioned at Annexure - A valid for three years. B.G. conditions will be reviewed every six months.
  - You shall also carry out self monitoring of ETP- Inlet and Outlet, Stack, Hazardous waste, Spore test
  - You shall obtain Consent to operate from Board under Water (P & CP) Act, 1974 and Air (P & CP) Act, 1981.
15. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.

Sd/-  
(V.M.Motghare)  
Member Secretary  
and  
Prescribed Authority

  
(Dr. A. R. Supate)  
Principal Scientific Officer

To  
M/s. Bioclean Systems (India) Pvt. Ltd.,  
S.No. 44, Bhogaon, Municipal Solid Waste Dump,  
Old Barshi Road, Dist- Solapur

Authorization Fees Received:-

Sr. No.	Amount	DD. No.	Date	Drawn On
1	52500	816803	01.03.2013	Axis Bank Ltd.

Copy to:

1. Chief Accounts Officer, MPCB Board Mumbai – for information.
2. Regional Officer, MPCB, Pune – for information and necessary compliance of the condition mentioned in the authorization. He is also directed to ensure the timely compliance of condition No. 14, regarding Bank Guarantee, compliance and obtaining consent application and report to PSO.
3. Sub Regional Officer, Solapur, MPCB, for information and necessary action.

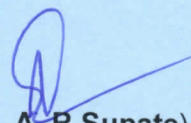


**Annexure -A**

Statement of conditions to be complied and Bank Guarantee imposed to ensure timely compliance to be observed by M/s. Bioclean Systems (India) Pvt. Ltd., Solapur.

Sr. No.	Activity / Condition to be Complied	Compliance Timeline (Months)	Bank Guarantee Amount
<b>I (A)</b>	<b>Operation and Maintenance</b>		
1	To achieve temperature of Primary and Secondary chamber of Incinerator	Continuous	1,00,000
2	To conduct and meet sterilization validation test and temperature test for Autoclave	Continuous	50,000
3	To Operate and maintain Air Pollution Control Device(s) to achieve prescribed Stack emissions (e.g. Particulate Matter, HCL, NOx, VOC)	Continuous	1,00,000
<b>I (B)</b>	<b>Records</b>		
1	To Maintain records of BMW and submission of Annual Report in Form -II before 31 <sup>st</sup> January	Continuous	25,000
2	To maintain records of BMW material delivered to CBMWTSDF (Transporters only)	Continuous	25,000
<b>II</b>	<b>Performance</b>		
1	To provide Separate BMW storage facility	Six	75,000
2	To provide Automatic BMW feeding system	Six	75,000
3	To provide PLC based online temperature monitoring system	Six	1,00,000
4	To provide Emergency vent to Secondary chamber	Six	50,000
5	To provide Graphical Temperature, Pressure & Time recording system	Six	50,000
		<b>Total,</b>	<b>6,50,000/-</b>
<b>Rupees Six Lakh Fifty thousand only</b>			

Sd/-  
(V.M.Motghare)  
Member Secretary  
and  
Prescribed Authority

  
(Dr. A. R. Supate)  
Principal Scientific Officer