

MAHARASHTRA POLLUTION CONTROL BOARD

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LETTER OF BIO-MEDICAL WASTE AUTHORISATION [Authorisation for of Bio-Medical Wastes under See Rule 10]

(Authorisation for operating a facility for generation, collection, reception, treatment, storage, transport and disposal of biomedical waste)

I. File number of authorisation and date of issue
MPC/SRN-I/BMW/2103000135

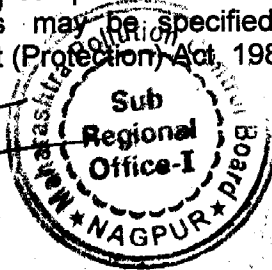
Dtd: 04/03/2021

II. **M/s. Dr. Kale's Multispeciality Hospital** is hereby granted an authorisation for generation of biomedical waste on the premises situated at Plot No. 59, Deendayal Nagar, Nagpur, DIST-NAGPUR.

III. This authorisation shall be in force for a period up to 31/05/2023. an application shall be made by the occupier/operator for renewal 3 Months before expiry of earlier authorisation.

IV. 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.

V. No of Beds: 5 beds.



Terms and Conditions of authorisation

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorized by the prescribed authority.
3. The personal authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
4. Any unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of this authorization.
5. It is the duty of the authorized person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.

6. The authorisation is granted for generation of Bio-Medical Waste (BMW) in waste categories and quantities listed here in below :

Sr. No.	Category	Type of Waste	Quantity Generated or Collected, Kg/Day	Method of Treatment and Disposal (Refer Schedule-I)
1	Yellow	a) Human Anatomical Waste	-	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
		b) Animal Anatomical Waste	-	
		c) Soiled Waste	-	
		d) Expired or Discarded Medicines	-	
		e) Chemical Solid Waste	5	
		f) Chemical Liquid Waste	3	
		g) Discarded Linen, Mattresses, beddings contaminated with blood or body fluid.	1	
		h) Microbiology, Biotechnology and other clinical laboratory waste		
2	Red	Contaminated Waste (Recyclable)	--	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
3	White (Translucent)	Waste Sharps including Metals	2	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
4	Blue	Glassware	---	Bio-medical Waste shall be sent to CBMWTSDF authorised by MPCB
		Metallic Body Implants		

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

8. (i) BMW shall be treated and disposed of in accordance with Schedule I; and in compliance with the standards prescribed in Schedule II of said Rules.

(ii) You shall setup requisite BMW, treatment facilities like incinerator, autoclave / Microwave, shredder etc., at the disposal side in accordance with the BMW rules 2016. You shall disposed of the duly treated BMW and incineration ash in secured land fill site at your own premises / at MSW secured land fill site of Municipal Council authorized by MPCB and duly earmarked for disposal of treated BMW / at common H.W. treatment & disposal facility setup as per the Hazardous Waste (M & TM) Rules, 2016 as amended and authorized by MPCB.



[Handwritten signature]

9. (i) BMW shall not be mixed with other wastes or reused, recycled 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.
- (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 & till then it shall be stored in cold container.
- (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 (HCF's) 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 Trans boundary 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 HCF's.
- (viii) Authorized person shall obtain prior permission from MPCB for generation & disposal, if Bio-Medical waste quantity of category specified exceed the limits authorized at condition No 6 above.

10. **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 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 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 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 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 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.

Signature: *[Handwritten Signature]*

Regional Office-I

Sub-Regional Office-I

Board

*MPCB/3

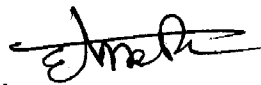
Biological indicator for autoclave shall be Bacillus stearothermophilus spores using vials or spore strips, with at least 1×10^4 spores per milliliter. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 121°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.

11. Standards for deep burial:

1. A pit or trench should be dug about 2 meters deep. It should be half filled with waste, and then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil.
 2. It must be ensured that animals do not have any access to burial sites. Covers of galvanized iron/wore meshes may be used.
 3. On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.
 4. Burial must be performed under close and dedicated supervision.
 5. The deep burial site should be relatively impermeable and no shallow well should be close to the site.
 6. The pits should be distant from habitation, and sited so as to ensure that no contamination occurs of any surface water or ground water. The area should not be prone to flooding or erosion.
 7. The location of the deep burial site will be authorized by the prescribed authority.
 8. The institution shall maintain a record of all pits for deep burial.
12. Every 'Authorized Person' shall submit an Annual Report to the prescribed authority in Form-II by 31st January every year including information about the categories and quantities of BMW handled during the preceding year.
13. (i) Every 'Authorized Person' shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of BMW in accordance with these Rules and any guidelines issued.
- (ii) All records shall be subject to inspection and verification by the prescribed authority at any time.
14. 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.
15. The Occupier will obey all the lawful instructions issued by the Board Officers from time to time.

For and on behalf of the
Maharashtra Pollution Control Board


(Hema Deshpande)
Sub-Regional Officer,
M.P.C. Board, Nagpur-I.

To
The applicant,
Dr. Kale's Multispeciality Hospital,
Plot No.59, Deendayal Nagar, Nagpur,
DIST-NAGPUR.

Copy to: Regional Officer, MPCB, for information.

