BIOMEDICAL WASTE (MANAGEMENT & HANDLING) RULES 1998 Amended on 2000

- The powers confirmed by section 6, 8, and 25 of the Environment (Protection) Act 1986, the Central Govt. has made the Biomedical Waste (Management & Handling) Rules to safeguard the public and health care workers from the risk arising due to Biomedical Waste. The penalties are same as specified in Environment (Protection) Act 1986.

Delhi hospitals alone produce more than 30 tonnes of biomedical waste every day. None of them has satisfactory biomedical waste management (CPCB 2001). There is a need to have centralised facility which will enable the authority to monitor and maintain in a better way.

1. Application

These rules apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle biomedical waste in any form

2. Definition: In these rules unless the context otherwise requires:

1.) "Act" means the Environment (Protection) Act, 1986 (29 of 1986);
2.) "Animal House" means a place where animals are reared/kept for experiments or testing purposes;
3.) "Authorisation" means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, disposal and/or any other form of handling of biomedical waste in accordance with these rules and any guidelines issued by the Central Government;
4.) "Authorised person" means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, dispose and/or handle biomedical waste in accordance with these rules and any guidelines issued by the Central Government;
5.) "Biomedical waste" means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or in research activities pertaining to in the production or testing of biologicals, and including categories mentioned in Schedule 1;
6.) "Biologicals" means any preparation made from organisms or micro organisms or product of metabolism and biochemical reaction intended for use in the diagnosis, immunisation or the treatment of disposal of human beings or animals or in research activities pertaining, hereto;
7.) "Biomedical waste treatment facility" means any facility wherein treatment, disposal of biomedical waste or processes incidental to such treatment or disposal is carried out;
8.) "Occupier" in relation to any institution generation biomedical waster, which includes a hospital, nursing home, clinic, dispensary, veterinary institutions, animal house, pathological laboratory, blood bank by whatever name called, means a person who has control over that institution and/or its premise.
9.) "Operator of a biomedical waste facility" means a person who owns or controls or operates a facility for the collection, reception, storage, transport, treatment, disposal or any other form of handling of biomedical waste;
10.) "Schedule" means schedule appended to these rules;

3. Duty of Occupier

It shall be the duty of every occupier of an institution generating biomedical waste, which includes a hospital nursing home, clinic, dispensary, veterinary institutions, and animal house, pathological laboratory, blood bank by whatever name called to take all steps to ensure that such waste is handled without any adverse effect to human health and the environment.

4. Treatment and Disposal

a.) Biomedical waste shall be treated and disposal of in accordance with Schedule 1, and in compliance with the standards prescribed in Schedule V.
b.) Every occupier, where required, shall set up requisite biomedical waste treatment facilities like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility.

5. Segregation, Packing, Transportation and Storage

a.) Biomedical waste shall not be mixed with other wastes.
b.) Biomedical waste shall be segregated into containers/bags at the point of generation in accordance with Schedule II prior to its storage, transportation, treatment and disposal. The containers shall be labeled according to Schedule III.
c.) If a container is transported from the premises where biomedical waste 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.
d.) Notwithstanding anything contained in the Motor Vehicle Act, 1988, or rules there under, untreated biomedical waste shall be transported only in such vehicles as may be authorised for the purpose by the competent authority as specified by the government.
e.) No untreated biomedical waste shall be kept/stored beyond a period of 48 hours:
Provided that if for any reason it becomes necessary to store the waste beyond such period, the authorised person must take permission of the prescribed authority and take measures to ensure that the waste does not adversely affect human health and the environment.

6. Prescribed Authority

a.) The Government of every State and Union Territory shall establish a prescribed authority with such members as may specified for granting authorisation and implementing these rules. If the prescribed authority comprises of more than one member, a chairperson for the authority shall be designated.

b.) The prescribed authority for the State or Union Territory shall be appointed within one month of the coming into force of these rules.

c.) The prescribed authority shall function under the supervision and control of the respective Government of the State or Union Territory.

d.) The prescribed authority shall on receipt of Form 1 make such enquiry as it deems fit and if it is satisfied that the applicant possesses the necessary capacity to handle biomedical waste in accordance with these rules, grant or renew an authorisation as the case may be.

e.) An authorisation shall be granted for a period of three years, including an initial trial period of one year from the date of issue. Thereafter, an application shall be made by the occupier/operator for renewal. All such subsequent authorisation shall be for a period of three years. A provisional authorisation will be granted for the trial period, to enable the occupier/ operator to demonstrate the capacity of the facility.

f.) The prescribed authority may after giving reasonable opportunity of being heard to the application and for reasons thereof to be recorded in writing, refuse to grant or renew authorisation.

g.) Every application for authorisation shall be disposal of by the prescribed authority within ninety days from the date of receipt of the application.

h.) The prescribed authority may cancel or suspend an authorisation, if for reason, to be recorded in writing, the occupier/operator has failed to comply with any provision of the Act or these rules.

Provided that no authorisation shall be cancelled or suspended without giving a reasonable opportunity to the occupier/operator of being heard.

7. Authorisation

a.) Every occupier of an institution generating, collecting, receiving, storing, transporting, treating, disposing and/or handling biomedical waste in any other manner, except such occupier of clinic, dispensaries, pathological laboratories, blood banks providing treatment/service to less than 1000 (one thousand) patients per month, shall make an application in Form 1 to the prescribed authority for grant of authorisation.

b.) Every operator of a biomedical waste facility shall make an application in Form 1 to the prescribed authority for grant of authorisation.

c.) Every application in Form 1 for grant of authorisation shall be accompanied by a fee as may be prescribed by the Government of the State of Union territory.

8. Advisory Committee

The Government of every State/Union Territory shall constitute and advisory committee. The Committee will include experts in the field of medical and health, animal husbandry and veterinary sciences, environmental management, municipal administration, and any other related department or organisation including non-governmental organisations. The State Pollution Board/ Pollution Control Committee shall be represented. As and when required, the committee shall advise the Union Territory /State Government about matters related to the implementation of these rules.

9. Annual Report

Every occupier/operator submit an annual report to the prescribed authority in Form II by 31 January every year, to include information about the categories and quantities of biomedical wastes handled during the preceding year. The prescribed authority shall send this

information in a compiled form to the Central Pollution Control Board by 31 March every year.

10. Maintenance of Records

a.) Every authorised person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of biomedical waste in accordance with these rules and any guidelines issued.

b. All records shall be subjected to inspection and verification by the prescribed authority at any time. M

11. Accident Reporting

When any accidents occur at any institution or facility or any other site where biomedical waste is handled or during transportation of such waste, the authorised person shall report the accident in Form III to the prescribed authority forth with.

12. Appeal

Any person aggrieved by an order by the prescribed authority under these rules may, within thirty days from date on which the order is communicated to them, refer an appeal to such authority as the Government of State/Union Territory may think fit to constitute: Provided that the authority may entertain the appeal after the expiry of the said period of thirty days if it is satisfied that the appellant of prevent by sufficient cause from filing the appeal in time.

SCHEDULE 1 (See Rule 5) CATEGORIES OF BIOMEDICAL WASTE, TREATMENT & DISPOSAL

CategoryBiomedical waste	**Treatment & Disposal**
Human Anatomical Waste (Human tissues, organs, body parts)	Incineration/deep burial *
Animal Waste (Animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals colleges, discharge from hospitals, animals houses).	Incineration/deep burial *
Microbiology & Biotechnology Waste (Wastes from lab. Cultures, stocks of specimens of micro-organisms live or	Autoclaving/ micro-waving.

attenuated vaccines, human and animal incineration* cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biologicals, toxins, dishes and devices used for transfer of cultures)	
Waste Sharps Needles, syringes, scalpels, blades, glass etc. that may cause puncture and cuts. This includes both used and unused sharps)	Chemical/ disinfection autoclave/ micro-waving and mutilation/shredding
Discarded Medicines & Cytotoxic drugs (Wastes comprising of outdated contaminated and discarded medicines)	incineration/destruct & drugs disposal in secured landfills
Solid Waste (Items contaminated with blood, and body fluids including cotton, dressing, soiled plaster casts, lines, beddings, other material contaminated with blood)	incineration/ autoclave micro-waving
Solid Waste (Waste generated from disposable items other than sharps such as tubings catheters, intravenous sets, etc.)	Chemical disinfection autoclave/micro-waving and mutilation/shredding
Liquid Waste (Waste generated from laboratory and washing, cleaning house-keeping and disinfecting activities)	Disinfect-chemically & discharge into drains
Incineration Ash (Ash from incineration of any biomedical waste)	disposal in municipal landfill
Chemical Waste (Chemical used in production of biologicals, chemicals used in insecticides etc.)	Chemically treatment disinfection and discharge of drains for liquid and secured landfill for solids.

Note:

1.) Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent should ensure disinfection.
2.) Mutilation/shredding must be such so as to prevent unauthorised reuse.
3.) There will be no chemical pretreatment before incineration. PVC shall not be incinerated.

The Central Pollution Control Board has recommended two types of incinerators:

- Incinerators or individual hospitals/nursing homes/medical establishments.
- Common incinerator to handle waste from a number of hospitals/nursing homes/ pathological laboratories etc.

Site for Incinerator

Incinerators should be installed at appropriate location to avoid nuisance to patients and neighbourhood.

COLOUR CODING AND TYPE OF CONTAINER FOR DISPOSAL OF BIO-MEDICAL WASTE

Colour Coding	**Type of Container**	**Waste Category**	**Treatment options**
Yellow	Plastic Bag	Categories 1, 2, 3 & 6.	Incineration deep burial Red.
	Plastic Bag	Categories 3, 6, 7	Autoclaving/Micro-waving Chemical Treatment
Blue/White Translucent	Plastic Bag /puncture proof containers	Cat. 4, Cat. 7	Autoclaving/Micro-waving/ Chemical Treatment & Destruction / shredding
Black	Plastic Bag	Categories 5, 9, 10	Disposal in secured landfill.

Notes:

1.) Colour coding of waste categories with multiple treatment options as defined in schedule 1, shall be selected depending on treatment option chosen, which shall be as specified in Schedule I.
2.) Waste collection bags for waste types needing incineration shall not be made of chlorinated plastics.
3.) Categories 8 and 10 (liquid) do not require containers/bags.
4.) Category 3, if disinfected locally need not be put in containers/bags.

STANDARDS FOR INCINERATORS

All incinerators shall meet the following operating and emission standards.

A. **Operating Standards**

Combustion efficiency (CE) shall be at least 99.0%
The combustion efficiency is computed as follows:

$$C.E. = \frac{\%CO_2 \times 100}{\%\ COS + \%\ CO}$$

1.) The temperature of the primary chamber shall be 800+_ 50 deg C
2.) The secondary chamber gas resistance time shall be at least 1 (one) second at 1050 deg + - 50 deg C, with a minimum of 3% Oxygen in the stack gas.

B. Emission Standards

Parameters Concentration mg/Nm3
at (12% CO2 correction)
1.) Particulate matter 150
2.) Nitrogen Oxide 450
3.) HCl 50
4.) Minimum stack height shall be 30 meters above ground.
5.) Volatile organic compounds in ash shall not be more than 0.01 %.

References

Jugal Kishore. Joshi TK. Biomedical Waste Management. Employment News 2000. Govt of India. Feb 19-25.
The Gazette of India. Biomedical Waste (Management & Handling) Rule 1998. No 460 July 27th 1998 and Amended No. 375, June 2nd 2000