
BIO-MEDICAL WASTE (MANAGEMENT AND HANDLING) RULES, 1998

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BIO-MEDICAL WASTE (MANAGEMENT AND HANDLING) RULES, 1998

Whereas, a notification in exercise of the powers conferred by Sections 6,8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), was published in the Gazette, vide S.O. No.746(E), dated October 16,1997, inviting objections from the public within 60 days from the date of the publication of the said notification on the Bio-Medical Waste (Management and Handling) Rules, 1998,

and whereas all objections received were duly considered; Now, therefore, in exercise of the powers conferred by Sections 6,8 and 25 of the Environment (Protection) Act, 1986, the Central Government hereby notifies the rules for the management and handling of bio-medical waste:-

1. Short title and commencement :-

(1) These rules may be called the Bio-Medical Waste (Management and Handling) Rules, 1998.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Application :-

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

3. Definitions :-

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 bio-medical 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 bio-medical waste in accordance with these rules and any guidelines issued by the Central Government;

(5) "Bio-Medical Waste" means 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;

(6) "Biologicals" means any preparation made from organisms or

micro-organisms or product of metabolism and bio-chemical reactions intended for use in the diagnosis, immunisation or the treatment of human beings or animals or in research activities pertaining thereto;

(7) "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;

(8) "Occupier" in relation to any institution generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called, means a person who has control over that institution and/or its premises;

(9) "Operator of a bio-medical 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 bio-medical waste;

(10) "Schedule" means schedule appended to these rules.

4. Duty of occupier :-

It shall be the duty of every occupier of an institution generating bio-medical waste which includes a hospital, nursing home, clinic, dispensary, veterinary institution, 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.

5. Treatment and disposal :-

(1) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards prescribed in Schedule V.

(2) Every occupier, where required, shall set up in accordance with the time-schedule in Schedule VI, requisite bio-medical 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.

6. Segregation, packaging, transportation and storage :-

(1) Bio-medical waste shall not be mixed with other wastes.

(2) Bio-medical 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 labelled according to Schedule III.

(3) If a container is transported from the premises where bio-medical 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.

(4) Notwithstanding anything contained in the Motor Vehicles Act, 1988, or rules thereunder, untreated bio-medical waste shall be transported only in such vehicle as may be authorised for the purpose by the competent authority as specified by the Government.

(5) No untreated bio-medical 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.

7. Prescribed authority :-

(1) The Government of every State and Union Territory shall establish a prescribed authority with such members as may be 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.

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

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

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

(5) 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.

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

(7) Every application for authorisation shall be disposed of by the prescribed authority within ninety days from the date of receipt of the application.

(8) The prescribed authority may cancel or suspend an authorisation, if for reasons, to be recorded in writing, the occupier/operator has failed to comply with any provisions 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.

8. Authorisation :-

(1) Every occupier of an institution generating, collecting, receiving, storing, transporting, treating, disposing and/or handling bio-medical waste in any other manner, except such occupier of clinics, dispensaries, pathological laboratories, blood banks providing treatment/service to less than 1,000 (one thousand) patients per month, shall make an application in Form I to the prescribed authority for grant of authorisation.

(2) Every operator of a bio-medical waste facility shall make an application in Form I to the prescribed authority for grant of authorisation.

(3) Every application in Form I for grant of authorisation shall be accompanied by a fee as may be prescribed by the Government of the State or Union Territory.

9. Advisory committee :-

The Government of every State/Union Territory shall constitute an 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 Control Board/Pollution Control Committee shall be represented. As and when required, the committee shall advise the Government of the State/Union Territory and the prescribed authority about matters related to the implementation of these rules.

10. Annual report :-

Every occupier/operator shall submit an annual report to the prescribed authority in Form II by January 31, every year, to include information about the categories and quantities of bio-medical wastes handled during the preceding year. The prescribed authority shall send this information in a compiled form to the Central Pollution Control Board by March 31, every year.

11. Maintenance of records :-

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

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

12. Accident reporting :-

When any accident occurs at any institution or facility or any other site where bio-medical waste is handled or during transportation of such waste, the authorised person shall report the accident in Form in to the prescribed authority forthwith.

13. Appeal :-

Any person aggrieved by an order made by the prescribed authority under these rules may, within thirty days from the date on which the order is communicated to him, prefer 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 was prevented by sufficient cause from filing the appeal in time.

SCHEDULE 1

Categories of bio-medical waste

SCHEDULE 1		
(See Rule 5)		
Categories of bio-medical waste		
Option	Waste category	Treatment and disposal
Category No. 1	Human anatomical waste (human tissues, organs, body parts)	incineration@/deep burial
Category No. 2	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, animal houses)	incineration@/deep burial
Category No. 3	Microbiology and bio-technology waste (waste from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal 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)	local autodaving/ microwaving/ incineration@
Category No. 4	Waste sharps (needles, syringes, scalpels, blades, glass, etc., that may cause puncture and cuts. This includes both used and unused sharps)	disinfection (chemical treatment@@/ autoclaving /microwaving and multilation/shredding##)
Category No. 5	Discarded medicines and cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)	incineration@/destruction and drugs disposal in secured landfills
Category No. 6	Solid waste (items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)	incineration@ Autoclaving/micro waving
Category No. 7	Solid waste (wastes generated from disposable items other than the waste sharps such as tubings, catheters, intravenous sets, etc.)	disinfection by chemical treatment@@ autoclaving/microwaving and mutilation/shredding ##
Category No. 8	Liquid waste (waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities)	disinfection by chemical treatment@@ and discharge into drains.
Category No. 9	Incineration ash (ash from incineration of any biomedical waste)	disposal in municipal landfill
Category No. 10	Chemical waste (chemicals used in production of biologicals, chemicals used in disinfection, as insecticides, etc.)	chemical treatment@@ and discharge into drains for liquids and secured landfill for solids.

SCHEDULE 2

Colour coding and type of container for disposal of bio-medical wastes

SCHEDULE 2

(See Rule 6)

Colour coding and type of container for disposal of bio-medical wastes

Colour coding	Type of container	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 container	Cat. 4, Cat. 7	Autoclaving/ microwaving/chemical treatment and destruction/shredding
Black	Plastic bag	Cat. 5 and Cat. 9 and Cat. 10 (solid)	Disposal in secured landfill.

SCHEDULE 3

Label for bio-medical waste containers/bags

SCHEDULE 4

Label for transport of bio-medical waste containers/bags

SCHEDULE 4

(See Rule 6)

Label for transport of bio-medical waste containers/bags

Day.....Month.....

Year.....

Waste category No.....
generation.....

Date of

Waste class

Waste description

Sender's name and address

Receiver's name and address

Phone No.....
No.....

Phone

Telex No.....
No.....

Telex

Fax No.....
No.....

Fax

Contact person.....
person.....

Contact

In case of emergency please contact:

Name and address:

Phone No.....

SCHEDULE 5

Standards for treatment and disposal of bio-medical wastes

SCHEDULE 5

(See Rule 5 and Schedule I)

Standards for treatment and disposal of bio-medical wastes

STANDARDS FOR INCINERATORS:

All incinerators shall meet the following operating and emission standards:

A. Operating standards:

1. Combustion efficiency (CE) shall be at least 99.00 per cent.
2. The combustion efficiency is computed as follows:

$$C.E = \%CO_2 / \%CO_2 + \%CO_2 \times 100$$

3. The temperature of the primary chamber shall be 800 50C
4. The secondary chamber gas residence time shall be at least 1 (one) second at 1050 50C, with minimum 3 per cent oxygen in the stack gas.

B. Emission standards:

Sl. No.	Prameters	Concentration mg/Nms at (12% COz correction)
(1)	Particulate matter	150
(2)	Nitrogen oxides	450
(3)	Ha	50
(4)	Minimum stack height shall be 30 metres above ground	
(5)	Volatile organic compounds in ash shall not be more than 0.01%	

SCHEDULE 6

Schedule for waste treatment facilities like incinerator/ autoclave/microwave system

SCHEDULE 6

(See Rule 5)

Schedule for waste treatment facilities like incinerator/ autoclave/microwave system

A.	Hospitals and nursing homes in towns with	by 31st December, 1999,
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	population of 30 lakhs and above	or earlier
B.	Hospital and nursing homes in towns with population of below 30 lakhs	
	(a) with 500 beds and above	by 31st December, 1999, or earlier
	(b) with 200 beds and above but less than 500 beds	by 31st December, 2000, or earlier
	(c) with 50 beds and above but less than 200 beds	by 31st December, 2001, or earlier
	(d) with less than 50 beds	by 31st December, 2002, or earlier
C.	All other institutions generating bio-medical waste not included in A and B above	by 31st December, 2002, or earlier