

Biomedical 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. 746 (E) dated 16th October 1997 inviting objections from the public within 60 days from the date of publication of the said notification on the Biomedical Waste (Management and Handling) Rules, 1998 and whereas all objections received were duly considered;

Now therefore, in exercise of the powers conferred by section 6,8 and 25 of the Environment (Protection) Act, 1986 the Central Government hereby notifies the Rules for the management and handling of the biomedical waste.

1. SHORT TITLE AND COMMENCEMENT

- (1) These rules may be called the Biomedical 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 biomedical waste in any form.

3. DEFINITIONS

- In these rules unless the context otherwise requires:
- (1) "Act" means the Environment (Protection) Act, 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 generated during the diagnosis, treatment or immunisation of human being 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 biomedical reactions intended for use in the diagnosis, treatment or immunisation of human being or animals or in research activities pertaining thereto;
 - (7) "Biomedical waste treatment facility" means any facility wherein treatment or disposal of biomedical waste or processes incidental to such treatment or disposal is carried out and includes common treatment facilities;
 - (7a) "Form" means Form appended to these rules;
 - (8) "Occupier" in relation to any institution generating biomedical 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 biomedical waste facility" means a person who owns or controls or operates a facility for the collection, reception, storage, transport, treatment or any other form of handling of biomedical 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 biomedical 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) Biomedical waste shall be treated and disposal 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 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.

6. SEGREGATION, PACKAGING, TRANSPORTATION & STORAGE

- (1) Biomedical waste shall not be mixed with other waste.
- (2) 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.
- (3) If a container is transported from the premises where 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 any thing contained in the Motor Vehicles Act, 1988, or rules there under, untreated biomedical 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 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) The Municipal body of the area shall continue to pick up and transport segregated non bio-medical waste generated in hospitals and nursing homes, as well as duly treated bio-medical wastes for disposal at municipal dump sites.

7. PRESCRIBED AUTHORITY

- (1) The Prescribed authority for enforcement of the provisions of these rules shall be the State Pollution Control Boards in respect of States and Pollution Control Committees in respect of the Union Territories and all pending cases with a prescribed authority appointed earlier shall stand transferred to the concerned State Pollution Control Board, or as the case may be, the Pollution Control Committees.
- (2) The prescribed authority for the 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 biomedical 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 period of one year from the date of issue. There after, 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 in Form I for grant of authorisation shall be cancelled or suspended without giving 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 biomedical waste in any other manner, except such occupier of clinics, dispensaries, pathological laboratories, blood banks providing treatment/services to less than 1000 (one thousand) patients per month, shall make an application in form I to the prescribed authority for the authorisation.
2. Every operator of a biomedical 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.
4. The authorisation to operate a facility shall be issued in Form IV, subject to conditions laid therein and such other condition, as the prescribed authority, may consider it necessary.

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, environment management, municipal administration and any other related department or organisation including nongovernmental organisations. 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 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.

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 biomedical waste in accordance with these rules and any guidelines issued.
2. All records shall be subject to inspection and verification by the prescribed authority.

12. ACCIDENT

REPORTING

When any accident occurs at any institution or facility or any other site where biomedical waste is handled or for the transportation of such waste, the authorised person shall report the accident in Form III 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 in Form V to such authority as the Government of State or Union territory may think fit to constitute. Provided that the authority may entertain the appeals 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.

14. COMMON DISPOSAL/INCINERATION SITES

Without prejudice to Rule 5 of these rules, the Municipal Corporations, Municipal Boards or Urban Local Bodies, as the case may be, shall be responsible for providing suitable common disposal/incineration sites for the bio-medical wastes generated in the area under their jurisdiction and in areas outside the jurisdiction of any municipal body, it shall be the responsibility of the occupier generating bio-medical waste/operator of a bio-medical waste treatment facility to arrange for suitable sites individually or in association, so as to comply with the provisions of these rules.