

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

The powers conferred 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 centralized 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 bio-medical 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. "Authorization" 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. "Authorized person" means an occupier or operator authorized 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 immunization 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, immunization or the treatment or disposal of human beings or animals or in research activities pertaining, hereto;
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 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 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;

3. 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 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. Bio-medical 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 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.

5. Segregation, Packing, Transportation and Storage

- a. Bio-medical waste shall not be mixed with other wastes.
- b. 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.
- c. 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.
- 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 authorized for the purpose by the competent authority as specified by the government.
- e. 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 authorized 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 authorization 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 bio-medical waste in accordance with these rules, grant or renew an authorization as the case may be.
- e. **An authorization 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 authorization shall be for a period of three years. A provisional authorization 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 authorization.
- g. Every application for authorization 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 authorization, 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 authorization shall be cancelled or suspended without giving a reasonable opportunity to the occupier/operator of being heard.

7. Authorization

a. 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 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 authorization.

b. Every operator of a bio-medical waste facility shall make an application in Form 1 to the prescribed authority for grant of authorization.

c. Every application in Form 1 for grant of authorization 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 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 organization including non-governmental organizations. 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 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 31 March every year.

10. Maintenance of Records

a. Every authorized 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.

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

11. Accident Reporting

When any accidents occur at any institution or facility or any other site where bio-medical waste is handled or during transportation of such waste, the authorized 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 is prevented by sufficient cause from filing the appeal in time.

Schedule-I

CATEGORIES OF BIO-MEDICAL WASTE

Option	Waste Category	Treatment & 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 & Biotechnology Waste (Wastes from laboratory cultures, stocks or micro-organisms live or 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 autoclaving/micro-waving/incineration@
Category No. 4	Waste Sharps (needles, syringes, scalpels, blade, glass, etc. that may cause puncture and cuts. This includes both used and unused sharps)	disinfection (chemical treatment @@@/auto claving/microwaving and mutilation/shredding##
Category No. 5	Discarded Medicines and Cytotoxic drugs (Waste comprising of outdated, contaminated and discarded medicines)	incineration@/destruction and drugs disposal in secured landfills
Category No. 6	Soiled Waste (items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines, bedding, other material contaminated with blood)	incineration@autoclaving/microwaving
Category No. 7	Solid Waste (Waste generated from disposal items other than the sharps such a 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, housekeeping and disinfecting activities)	disinfection by chemical treatment@@ and discharge into drains
Category No. 9	Incineration Ash Ash from incineration of any bio-medical waste)	disposal in municipal landfill
Category No. 10	Chemical Waste (Chemicals used in production of biologicals, 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

Note :

- @ There will be no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated.
- * Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.
- @@ Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfection.
- ## Mutilation/shredding must be such so as to prevent unauthorised reuse.

Category	Type of Waste	Container	Colour
Cat. 1	Human Anatomical Waste, blood and body fluids, bandages, animal and slaughter house waste, microbiology and biotechnology waste, extremely soiled linen	Tubs, buckets with lids	YELLOW
Cat. 2	Sharps - Two types <i>Reusable sharps</i> such as some needles, scalpels, surgical instruments separated by needle/sharp separator	Veterinary institutions, dispensaries and animal houses	WHITE or TRANSLUCENT
	<i>Waste sharps</i> such as broken glass, disposable needles, blades etc.	Cardboard carton	BLUE
Cat. 3	Disposable plastics, rubber/latex gloves	Bags or buckets, stainless steel drums	RED
Cat. 4	Chemical wastes, all hazardous wastes	Bucket with lid, cardboard container	BLACK
Cat. 5	Compost able waste	Buckets/drums/trolley	GREEN
Cat. 6	Office paper	Cardboard boxes	

Schedule-II

COLOUR CODING AND THE TYPE OF CONTAINER FOR DISPOSAL OF BIO MEDICAL WASTES


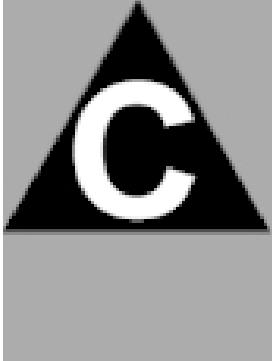
Color Coding	Type of Container	Waste Category	Treatment options as per Schedule-I
Yellow	Plastic bag	Category 1, 2 and Category 3, 6	Incineration/deep burial
Red	Disinfected container/Plastic bag	Category 3, 6, 7	Autoclaving/Microwaving/Chemical Treatment
Blue/White translucent	Plastic bag/puncture proof container	Category 4, 7	Autoclaving/Microwaving Chemical Treatment and destruction/shredding
Black	Plastic bag	Category 5, 9 and Category 10 (solid)	Disposal in secured landfill

Note :

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

Schedule-III

LABEL FOR BIO-MEDICAL WASTE CONTAINERS/BAGS

BIOHAZARD SYMBOL	CYTOTOXIC HAZARD SYMBOL
 <p>BIOHAZARD</p>	 <p>CYTOTOXIC</p>

HANDLE WITH CARE

Note : Label shall be non-washable and prominently visible.

Important Precautions

Never transfer sharps directly from person to person



Never recap the needles



Never overload bins used for storing Bio Medical Waste

Do not inhale chemicals directly. Use always mask.

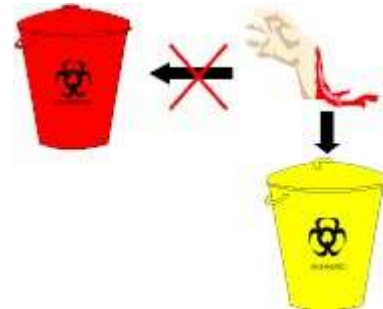


Keep away sharps medicines from children

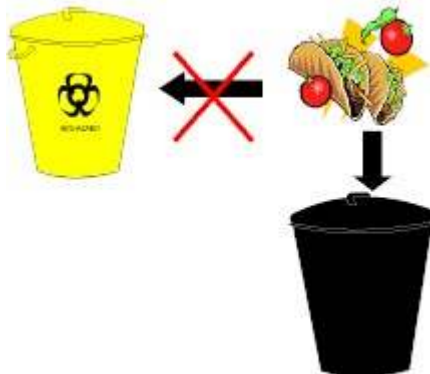


Never transfer sharp directly

Always incinerate human anatomical waste.



General waste to be put in black container.



Display the Bio-Hazardous Symbol and the types of waste to be put in each container as per Schedule-II



FORM I (see rule 8)

APPLICATION FOR AUTHORISATION

(To be submitted in duplicate.)

To

The Prescribed Authority
(Name of the State Govt/UT Administration) Address.

1. Particulars of Applicant

- (i) Name of the Applicant
(In block letters & in full)
- (ii) Name of the Institution:
Address:
Tele No., Fax No. Telex No.

2. Activity for which authorisation is sought:

- (i) Generation
- (ii) Collection
- (iii) Reception
- (iv) Storage
- (v) Transportation
- (vi) Treatment
- (vii) Disposal
- (viii) Any other form of handling

3. Please state whether applying for fresh authorisation or for renewal:
(In case of renewal previous authorisation-number and date)

4. (i) Address of the institution handling bio-medical wastes:

(ii) Address of the place of the treatment facility:

(iii) Address of the place of disposal of the waste:

5. (i) Mode of transportation (in any) of bio-medical waste:

(ii) Mode(s) of treatment:

6. Brief description of method of treatment and disposal (attach details):

7. (i) Category (see Schedule 1) of waste to be handled

(ii) Quantity of waste (category-wise) to be handled per month

8. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date :

Signature of the Applicant

Place :

Designation of the Applicant

FORM II

(see rule 10)

ANNUAL REPORT

(To be submitted to the prescribed authority by 31 January every year).

1 . Particulars of the applicant:

(i) Name of the authorised person (occupier/operator):

(ii) Name of the institution:

Address

Tel. No

Telex No.

Fax No.

2. Categories of waste generated and quantity on a monthly average basis:

3. Brief details of the treatment facility:

In case of off-site facility:

(i) Name of the operator

(ii) Name and address of the facility:

Tel. No., Telex No., Fax No.

4. Category-wise quantity of waste treated:

5. Mode of treatment with details:

6. Any other information:

7. Certified that the above report is for the period from

Date.....

Signature.....

Place.....

Designation.....

FORM III

(see Rule 12)

ACCIDENT REPORTING

1. Date and time of accident:
2. Sequence of events leading to accident
3. The waste involved in accident :
4. Assessment of the effects of the accidents on human health and the environment,.
5. Emergency measures taken
6. Steps taken to alleviate the effects of accidents
7. Steps taken to prevent the recurrence of such an accident

Date

Signature

Place.....

Designation.....