BIO-MEDICAL WASTE (MANAGEMENT

AND HANDLING) RULES, 1998

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

S.O. 630 (E), dated 20th July, 1998.[1]-Whereas a notification in exercise of the powers conferred by Secs. 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) was published in the Gazette vide S.O. 746 (E), dated 16 October, 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 Secs. 6, 8 and 25 of the Environment (Protection) Act, 1986 the Central Government hereby notifies the rules for the management and handling of biomedical waste.

1. Published in the Gazette of lndia, Extraordinary, Pt.II, Sec. (ii), dated 27th July, 1998.

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 biomedical 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 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 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 microorganisms or product of metabolism and biochemical reactions intended for rise 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 biomedical waste or processes incidental to such treatment or disposal is carried out;

(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, disposal 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 batik 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. -

(l) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliant 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 waste, or, ensure requisite treatment 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 in accordance to Schedule III.

(3) 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.

(4) Notwithstanding anything contained in the Motor Vehicles Act, 1988, or rules thereunder, 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.

7. Prescribed Authority. -

(l) 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 designed.

(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 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 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's 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.

8. Authorisation. -

(l) 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 service to less than 1000 (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 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.

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 31 January every year, to include information about the categories and quantities of biomedical waste 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. -

(l) 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 at any time.

12. Accident Reporting. -When any accident occurs 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 an 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 I

(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[1]/deep burial[2]
Category No. 2	Animal Waste (Animal tissue, 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[1]/deep burial[2]
No. 3 Category	Microbiology and Biotechnology Waste (Wastes 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 autoclaving/micro- waving/incineration[3]

No. 4 Category	Waste Sharps (Needles, syringes, scalpels, blades, glass, etc., that may cause puncture and cuts. This includes both used and unused sharps)	Disinfections / chemical Treatment[3]/auto craving/ Micro-waving and Mutilation/shredding[4]
No. 5 Category	Discarded Medicines and Cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)	Incineration[5]/destruction and drugs disposal in secured landfills
No. 6 Category	Solid Waste (Items contaminated with blood, and body fluids including cotton, dressing, soiled plaster casts, lines, beddings, other material contaminated with blood)	Incineration[5] autoclaving/ micro waving
No. 7 Category	Solid Waste (Wastes generated from disposable items other than the waste sharps such as tubings, catheters, intravenous sets etc.).	Disinfections by chemical treatment[3]/ autoclaving/ micro waving and Mutilation/shredding[4]
No. 8 Category	Liquid Waste (Waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities)	Disinfection by chemical Treatment[3] and discharge into drains.

No. 9 Category	Incineration Ash (Ash from incineration of any biomedical waste)	Disposal in municipal landfill
No. 10 Category	Chemical Waste (Chemicals used in production of biologicals, chemicals used in disinfection, as insecticides, etc.)	Chemical treatment[3] and Discharge into drains for Liquids and secured landfill for solids

1. There will be no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated.

2. Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.

3. Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfection.

4. Multilation/shredding must be such so as to prevent unauthorised reuse.

5. There will be no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated.

SCHEDULE II

(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,	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

Notes:

1. Colour 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.

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.

SCHEDULE III

(see rule 6)

Label for Bio-Medical Waste Containers/Bags

BIOHAZARD SYMBOL **CYTOTOXIC HAZARD SYMBOL**

BIOHAZARD **CYTOTOXIC**

HANDLE WITH CARE

Note:

Label shall be non-washable and prominently visible.

SCHEDULE IV

(see rule 6)

Label for Transport of Bio-Medical Waste Containers/Bags

Day Month

Day…….Month……..

Year……..

Date of generation……..

Waste category No……..

Waste class

Waste description

Sender's Name and Address

Phone No…….

Telex No……

Fax No

Contact Person

In case of emergency please contact

Name and Address:-

Phone No.

Note:

Label shall be non-washable and prominently visible.

SCHEDULE V

(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%.

2. The Combustion efficiency is computed as follows

$$C.E.= \frac{\%CO2}{\% C02 + \% CO} \times 100$$

3. The temperature of the primary chamber shall be 800 ± 50 deg. C^0.

4. The secondary chamber gas residence time shall be at least 1 (one) second at 1050 50 C^0, with minimum 3% Oxygen in the stack gas.

B. Emission Standards

Parameters	Concentration mg/Nm3 at (12% CO_2 correction)
(1) Particulate matter	150
(2) Nitrogen Oxides	450
(3) HCL	50

(4) Minimum stack height shall be 30 metres above ground

(5) Volatile organic compounds in ash shall not be more than 0.01%

Note:

* Suitably designed pollution control devices should be installed/retrofitted with the incinerator to achieve the above emission limit, if necessary.

* Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.

* Chlorinated plastics shall not be incinerated.

* Toxic metals in incineration ash shall be limited within the regulatory quantities as defined under the Hazardous Waste (Management and Handling Rules,) 1989.

* Only low sulphur fuel like L.D.O./L.S.H.S./Diesel shall be used as fuel in the incinerator.

STANDARDS FOR WASTE AUTOCLAVING:

The autoclave should be dedicated for the purposes of disinfecting and treating biomedical waste.

(1) When operating a gravity flow autoclave, medical waste shall be subjected to

(i) A temperature of not less than 121 C^0 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^0 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^0 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^0 and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or

(ii) A temperature of not less than 135 C^0 and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes;

(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 indicator 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. Biological indicator for autoclave shall be a Bacillus

stearothermophilus spore using vials or spore strips, with at least I x 10^4 spores per millilitre. 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^0 or a pressure less than 15 psi.

(VI) Routine Test

A chemical indicator strip/tape that changes colour 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.

STANDARDS FOR LIQUID WASTE:

The effluent generated from the hospital should conform to the following limits:

PARAMETERS	PERMISSIBLE LIMITS
Ph	6.5-9.0
Suspended solids	100 mg/1
Oil and grease	10mg/1
BOD	30 mg/1
COD	250 mg/1
Bio-assay test	90% survival of fish after 96 hours in 100% effluent.

These limits are applicable to those hospitals, which are either connected with sewers without terminal sewage treatment plant or not connected to public sewers. For discharge not public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

STANDARDS OF MICROWAVNG:

1. Microwave treatment shall not be used for cytotoxic, hazardous or radioactive wastes, contaminated animal carcasses, body parts and large metal items.

2. The microwave system shall comply with the efficacy test/routine tests and a performance guarantee may be provided by the supplier before operation of the unit.

3. The microwave should completely and consistently kill the bacteria and other pathogenic organisms that is ensured by approved biological indicator at the maximum design capacity of each microwave unit. Biological indicators for microwave shall be Bacillus Subtilis spores using vials or spore strips with at least 1×10^4 spores per millilitre.

STANDARDS FOR DEEP BURIAL:

1. A pit or trench should be dug about 2 metres deep. It should be half filled with waste, then covered with lime with 50 cm of the surface, before filling the rest the pit with soil.

2. It must ensured that animals do not have any access to burial sites. Covers of galvanised iron/wire 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 authorised by the prescribed authority.

8. The institution shall maintain a record of all pits for deep burial.

SCHEDULE VI

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

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 and 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 resh authorisation or for renewal (In case of renewal previous

authorisation-number and date)

4. (i) Address of the institution handling biomedical 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 biomedical waste

(ii) Mode(s) of treatment

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

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

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

8. Declaration

I do hereby declare that the statement 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 alleviate the effects of accidents

Date …….. Signature:…….

Place ……. Designation:…….