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

MINISTRY OF ENVIRONMENT & FORESTS

NOTIFICATION

New Delhi, 20th July , 1998

[1]S.O. 630(E). - 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 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 Section 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. 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:

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[1] Inserted Rule 9A by Rule 4 of the Bio Medical Waste (M&H) (Amendment) Rules, 2003 notified vide Notification No.S.O.1069(E), dated 17.9.2003.

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 biochemical 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 [1][and includes common treatment facilities.]

[1][(7a) 'Form' means Form appended to these rules;]

[1]Added by rule 2((i) of the Bio-Medical Waste (M & H)(Second Amendment) Rules, 2000 notified vide notification No. S.O.545(E), dated 2.6.2000 and came into force w.e.f.2.6.2000.

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] Inserted by Rule 2(ii) of the Bio-Medical Waste (M&H) (Second Amendment) rules, 2000 notified vide Notification No.S.O.545(E), dated 2.6.2000 and came into force w.e.f. 2.6.2000.

(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 labeled 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.

[1][(6)The Municipal body of the area shall continue to pick up and transport segregated non bio-medical solid waste generated in hospitals and nursing homes, as well as duly treated bio-medical wastes for disposal at municipal dump site].

7. PRESCRIBED AUTHORITY

[1]Inserted by Rule 3 of the Bio-Medical Waste (M & H) (Second Amendment) Rules, 2000 vide notification S.O.545(E), dated 2.6.2000.

[1][(1) [2][Save as otherwise provide, the prescribed authority for enforcement] of the provisions of these rules shall be the State Pollution Control Boards in respect of States and the 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].

[3][(1A)The prescribed authority for enforcement of the provisions of these rules in respect of all health care establishments including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, Animal houses, pathological laboratories and blood banks of the Armed Forces under the Ministry of Defence shall be the Director General, Armed Forces Medical Services].

(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.

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

1Substituted by Rule 4 of the Bio-Medical Waste (M & H) (Second Amendment) Rules, 2000 vide notification S.O.545(E), dated 2.6.2000.

2Substituted by Rule 2 (a) of the Bio-Medical Waste (M&H) (Amendment) Rules, 2003 vide notification S.O.1069 (E), dated 17.9.2003.

3Inserted sub-rule (1A) by Rule 2(b), ibid.

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 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

(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 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 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.

Form IV, subject to conditions laid therein and such other condition, as the prescribed authority, may consider it necessary.]

9. ADVISORY COMMITTEE

[2][(1)]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 [3][***] . 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.

[4][(2) Notwithstanding anything contained in sub-rule (1), the Ministry of Defence shall constitute in that Ministry, an Advisory Committee consisting of the following in respect of all health care establishments including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories and blood banks of the Armed Forces under the Ministry of Defence, to advise the Director General, Armed Forces Medical Services and the Ministry of Defence in matters relating to implementation of these rules, namely:-

[1]Inserted by Rule 5 of the Bio-Medical Waste (M&H) (Second Amendment) Rules, 2000 vide notification S.O.545(E), dated 2.6.2000.

[2]Re-numbered as Sub Rule (1) by Rule 3 of the Bio Medical Waste (M&H) (Amendment) Rules, 2003 notified vide Notification No.S.O.1069(E), dated 17.9.2003.

[3]Omitted by Rule 6 of the Bio-Medical Waste (M & H)(Second Amendment) Rules, 2000 vide notification S.O.545(E), dated 2.6.2000.

[4]Inserted sub Rule (2) by Rule 3 of the Bio Medical Waste (M&H) (Amendment) Rules, 2003 notified vide Notification No.S.O.1069(E), dated 17.9.2003.

(1) Additional Director General of Armed Forces Medical Services …….. Chairman

(2) A representative of the Ministry of Defence not below the rank of Deputy Secretary, to be nominated by that Ministry …….. Member

(3) A representative of the Ministry of Environment and Forests not below the rank of Deputy Secretary To be nominated by that Ministry. …….. Member

(4) A representative of the Indian Society of Hospitals Waste Management, Pune …….. Member]

[1][9A. MONITORING OF IMPLEMENTATION OF THE RULES IN ARMED FORCES HEALTH CARE ESTABLISHMENTS

(1)The Central Pollution Control Board shall monitor the implementation of these rules in respect of all the Armed Forces health care establishments under the Ministry of Defence.

2) After giving prior notice to the Director General Armed Forces Medical Services, the Central Pollution Control Board along with one or more representatives of the Advisory Committee constituted under sub-rule (2) of rule 9 may, if it considers it necessary, inspect any Armed Forces health care establishments.]

10. ANNUAL REPORT

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.

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[1] Inserted Rule 9A by Rule 4 of the Bio Medical Waste (M&H) (Amendment) Rules, 2003 notified vide Notification No.S.O.1069(E), dated 17.9.2003.

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

13. APPEAL

[1][(1)] [2][Save as otherwise provided in sub-rule (2), 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 [3][in

form V] 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.

4[(2) Any person aggrieved by an order of the Director General, Armed Forces Medical Services under these rules may, within thirty days from the date

1Re-numbered as sub-rule (1) by Rule 5 (a) of the Bio Medical Wastes (M&H) (Amendment) Rules, 2003 notified vide Notification No.S.O. 1069(E), dated 17.9.2003.

2Substituted by Rule 5(a), ibid.

3Inserted by Rule 7 of the Bio-Medical Waste (M & H) (Second Amendment) Rules, 2000 vide notification S.O.545 (E), dated 2.6.2000. 4Inserted sub-rule (2) by Rule 5(b) of the Bio Medical Waste (M&H) (Amendment) Rules, 2003 notified vide Notification No.S.O.1069(E), dated 17.9.2003.

on which the order is communicated to him prefer an appeal to the Central Government in the Ministry of Environment and Forests.]

1[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 biomedical 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].

1Inserted by Rule 8 of the Bio-Medical Waste (M&H) (Second Amendment) Rules, 2000 notified vide S.O.545(E), dated 2.6.2000.

SCHEDULE I

(See Rule 5)

CATEGORIES OF BIO-MEDICAL WASTE

[1][Waste Category No.]	Waste Category [2][Type]	Treatment and Disposal [3][Option +]
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 Wastes (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, waste from production of bio-logicals, toxins, dishses and devices used for transfer of cultures)	local autoclaving/micro-waving/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@@/aut claving/ 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	[4][Soiled] Waste (Items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines beddings, other material contaminated with blood)	incineration @ autoclaving/microwaving

[1]Substituted by Rule 9 (i) of the Bio-Medical Waste (M & H) (Second Amendment) Rules, 2000 notified vide S.O.545(E), dated 2.6.2000.

[2]Added by Rule 9(ii), ibid.

[3]Substituted by Rule 9 (iii), ibid.

[4]Substituted by rule 9(iv), ibid.

Category No.7	Solid Waste (wastes generated from disposable items other than the waste [1][sharps] such as tubing's, 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 bio-medical 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

@@ 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 unauthorized reuse.

@ 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.

[2][+ Options given above are based on available technologies. Occupier/operator wishing to use other State-of-the-art technologies shall approach the Central Pollution Control Board to get the standards laid down to enable the prescribed authority to consider grant of authorisation].

1Substituted by Rule 9 (v) of the Bio-Medical Waste (M & H) (Second Amendment) Rules, 2000 notified vide S.O.545(E), dated 2.6.2000.

2Substituted by Rule 9 (iii) of the Bio-Medical Waste (M& H) (Second Amendment) Rules, 2000 notified vide S.O.545 (E), dated 2.6.2000.

SCHEDULE II

(see Rule 6)

COLOUR CODING AND 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	Cat.1, Cat. 2, 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

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…….

Year ……..

Date of generation…….

Waste category No……

Waste Class

Waste description

Sender's Name & Address

Phone No…… Telex No…….. Fax No…… Contact Person……..

Receiver's Name & Address

Phone No…….. Telex No…… Fax No…….. Contact Person……..

In case of emergency please contact :

Name & 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 :

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

3. The temperature of the primary chamber shall be 800 ± 50c$_o$.

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

B. Emission Standards

Parameters	Concentration mg/Nm$_3$ 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 limits, 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 bio-medical waste,

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

(i) a temperature of not less than 121$_o$C 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$_o$C 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$_o$C 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$_o$C 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$_o$C 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 approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be Bacillus stearothermophilus spores using vials or spore strips, with at least 1x10$_4$ 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$_o$C 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 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	10 mg/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 into public

sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

STANDARDS OF MICROWAVING :

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 bio-logical 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 $1x10_4$ spores per milliliter.

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 within 50 cm of the surface, before filling the rest of the pit with soil.

2. It must be ensured that animals do not have any access to burial sites. Covers of galvanized 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 groundwater. The area should not be prone to flooding or erosion.

7. The location of the deep burial site will be authorized by the prescribed authority. 8. The institution shall maintain a record of all pits for deep burial.

[1][SCHEDULE VI]

(see rule 5)

SCHEDULE FOR WASTE MANAGEMENT FACILITIES LIKE INCINERATOR/AUTOCLAVE / MICROWAVE SYSTEM

A. Hospitals and nursing homes in towns with population of 30 lakhs and above	By 30th June, 2000 or earlier
B. Hospitals 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. (c)With 50 beds and above but less than 200 beds (d)With less than 50 beds	By 30th June, 2000 or earlier By 31st December, 2000 or earlier By 31st December, 2001 or earlier 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

1Substituted 'Schedule VI' by Rule 2 of the Bio-Medical Waste (M&H) (Amendment) Rules, 2000 notified vide notification S.O.201(E), dated 6.3.2000 and came into force w.e.f. 6.3.2000.

FORM I

(See rule 8)

[1][APPLICATION FOR AUTHORISATION/RENEWAL OF 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:
5. (ii) Address of the place of the treatment facility:
6. (iii) Address of the place of disposal of the waste :

(i) Mode of transportation (in any) of bio-medical waste :
(ii) Mode(s) of treatment :

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

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[1]Substituted by Rule 10 of the Bio-Medical Waste (M &H) (Second Amendment) Rules, 2000 notified vide S.O.545(E), dated 2.6.2000.

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 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

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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 : ……

Place: ……

Signature …….

Designation ……..

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[1][FORM IV

[see Rule 8(4)]

(Authorisation for operating a facility for collection, reception, treatment, storage, transport and disposal of biomedical wastes.)

1. File number of authorisation and date of issue…….

2. …….of …… is hereby granted an authorisation to operate a facility for collection, reception, storage, transport and disposal of biomedical waste on the premises situated at ……

3. This authorisation shall be in force for a period of ……. Years from the date of issue.

4. This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Date ……. ……

Signature……..

Designation ……..

Terms and conditions of authorisation *

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made thereunder.
2. The authorization or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority. 4. Any unauthorised change in personnel, equipment or working conditions as

mentioned in the application by the person authorised shall constitute a breach of his authorisation.

5. It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility.

_____ *

Additional terms and conditions may be stipulated by the prescribed authority.

1Added by Rule 11 of the Bio-Medical Waste (M &H) (Second Amendment) Rules, 2000 notified vide S.O.545(E), dated 2.6.2000.

1[FORM V]

(see rule 13)

Application for filing appeal against order passed by the prescribed authority at district level or regional office of the Pollution Control Board acting as prescribed authority or the State/Union Territory level authority.

1. Name and address of the person applying for appeal :

2. Number, date of order and address of the authority which passed the order, against which appeal is being made (certified copy of order to be attached)

3. Ground on which the appeal is being made.

4. List of enclosures other than the order referred in para 2 against which appeal is being filed.

Signature ……..

Date : Name & Address……..

F.No.23(2)/96-HSMD

V.RAJAGOPALAN, Jt. Secretary

Note : The Principal rules were published in the Gazette of India vide number S.O.630(E), dated 20.7.98 and subsequently amended vide (1) S.O.201(E), dated 6.3.2000; (2) S.O.545(E), dated 2.6.2000; and (iii) S.O.1069(E), dated 17.9.2003.

1Added by Rule 11 of the Bio-Medical Waste (M &H) (Second Amendment) Rules, 2000 notified vide S.O. 545(E), dated 2.6.2000.