Bio-Medical Waste (Management & Handling) Rules, 1998

(AS AMENDED TO DATE)
MINISTRY OF ENVIRONMENT & FORESTS

NOTIFICATION

New Delhi, 20th July, 1998

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) 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 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 (and includes common treatment facilities). Added by Rule 2(1) of the Bio-Medical waste (M&H) (Second Amendment) Rules, 2000 notified vide notification No.S.O.545 (E), dated 2-06-2000 and came into force w.e.f 2-6-2000. (7 (a) Form means Form appended to these Rules)

(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 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 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 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.

(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 biomedical wastes for disposal at municipal dump site. Inserted by Rules 3 of the Bio-Medical Waste (Management & Handling ) (Second Amendment) Rules, 2000 vide notification S.O.545 (E), dated 2-6-2000.

7. PRESCRIBED AUTHORITY
1[1) 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).

2) Substituted by Rule2 (a) of the Bio-Medical Waste (M&H) (Amendment) Rules,2003 vide notification S.O.1069 (E) dated 17-09-2003

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

(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 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 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 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 1 to the prescribed authority for grant of authorisation.

(2) Every operator of a bio-medical waste facility shall make an application in Form 1 to the prescribed authority for grant of authorisation.

(3) Every application in Form 1 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 authorization 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

(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 organization including non-governmental organizations. 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.

(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 institution, 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.

1) Inserted by Rules 5 of the Bio-Medical Waste (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 17-09-2003

1) Additional Director General of Armed Forces Medical Services
2) A representative of the Ministry of Defence not below the rank of Deputy Secretary, to be nominated by that Ministry
3) A representative of the Ministry of Environment and Forests not below the rank of Deputy Secretary to be nominated by that Ministry
4) A representative of the Indian Society of Hospitals Waste Management, Pune

1 "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
Every occupier/operator shall submit an annual report to the prescribed authority in Form 11 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.

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 III to the prescribed authority forthwith.

13. APPEAL

(1) 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 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.

(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 on which the order is communicated to him, prefer an appeal to the Central Government in the Ministry of Environment and Forests:

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].
## CATEGORIES OF BIO-MEDICAL WASTE

<table>
<thead>
<tr>
<th>Option</th>
<th>Waste Category</th>
<th>Treatment &amp; Disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. 1</td>
<td>Human Anatomical Waste (human tissues, organs, body parts)</td>
<td>Incineration @/deep burial*</td>
</tr>
<tr>
<td>No. 2</td>
<td>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)</td>
<td>Incineration @ / deep burial*</td>
</tr>
<tr>
<td>No. 3</td>
<td>Microbiology &amp; 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)</td>
<td>local autoclaving / micro-waving / incineration@</td>
</tr>
<tr>
<td>No. 4</td>
<td>Waste sharps (needles, syringes, scalpels, blades, glass, etc. that may cause puncture and cuts. This includes both used and unused sharps)</td>
<td>disinfection (chemical treatment @ 01/auto claving / micro- waving and mutilation/ shredding&quot;)</td>
</tr>
<tr>
<td>No. 5</td>
<td>Discarded Medicines and Cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)</td>
<td>Incineration @@/destruction and drugs disposal in secured landfills drugs disposal in secured</td>
</tr>
<tr>
<td>No. 6</td>
<td>Solid Waste (Items contaminated with blood, and body fluids including cotton dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)</td>
<td>Incineration @ autoclaving / micro-waving</td>
</tr>
<tr>
<td>No. 7</td>
<td>Solid Waste (wastes generated from disposable items other than the waste sharps such as tubings, catheters, intravenous sets etc.)</td>
<td>disinfection by chemical treatment @ @ autoclaving/micro-waving and mutilation/ shredding##</td>
</tr>
<tr>
<td>No. 8</td>
<td>Liquid Waste (waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities)</td>
<td>disinfection by chemical treatment@ @ and discharge into drains.</td>
</tr>
<tr>
<td>No. 9</td>
<td>Incineration Ash (ash from incineration of any bio-medical waste)</td>
<td>disposal in municipal landfill</td>
</tr>
</tbody>
</table>
Category: Chemical Waste

No. 10 (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.

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

+ 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 authorization.
Form-IV
[see Rule 8 (4)]

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

1. File number of authorization and date of issue ………………………………
2. ……………………………of………………….. is hereby granted an authorization to operate a facility for collection, reception, storage, transport and disposal of biomedical waste on the premises situated at ………………………………………
3. This authorization shall be in force for a period of …………………. Years from the date of issue.
4. This authorization 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 authorization *

1. The authorization 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 authorized 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 unauthorized change in personnel, equipment or working conditions as mentioned in the application by the person authorized shall constitute a breach of his authorization.
5. It is the duty of the authorized person to take prior permission of the prescribed authority to close down the facility.
FORM IV
[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.

Date: ________________ Signature: ________________

Name & Address: ________________

F.No.23 (2/96-HSMD
V. RAJAGOPLAN, Jt. Secretary
# SCHEDULE II

(see Rule 6)

**COLOUR CODING AND TYPE OF CONTAINER FOR DISPOSAL OF BIO-MEDICAL WASTES**

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

**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

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 ........ Receiver's Name & Address ........

Phone No ........ Phone No ........
Telex No .... Telex No ....
Fax No ........ Fax No ........
Contact Person .... 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 1)

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:

\[
\text{C.E.} = \frac{\% \text{CO}_2}{\% \text{CO}_2 + \% \text{CO}} \times 100
\]

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

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

B. Emission Standards

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Concentration mg/Nm³ at (12% CO₂ correction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Particulate matter</td>
<td>150</td>
</tr>
<tr>
<td>(2) Nitrogen Oxides</td>
<td>450</td>
</tr>
<tr>
<td>(3) HCI</td>
<td>50</td>
</tr>
<tr>
<td>(4) Minimum stack height shall be 30 metres above ground</td>
<td></td>
</tr>
<tr>
<td>(5) Volatile organic compounds in ash shall not be more than 0.01%</td>
<td></td>
</tr>
</tbody>
</table>

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.0dLS.H.S.1Diesel 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 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 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 °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 °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 °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 the 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 $1 \times 10^4$ 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 or a pressure less than 15 psi.

(VI) Routine Test

A chemical indicator strip/tape the 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.

STANDARD FOR LIQUID WASTE:

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

<table>
<thead>
<tr>
<th>PARAMETERS</th>
<th>PERMISSIBLE LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH</td>
<td>63-9.0</td>
</tr>
<tr>
<td>Suspended solids</td>
<td>100 mg/l</td>
</tr>
<tr>
<td>Oil and grease</td>
<td>10 mg/l</td>
</tr>
<tr>
<td>BOD</td>
<td>30 mg/l</td>
</tr>
<tr>
<td>COD</td>
<td>250 mg/l</td>
</tr>
<tr>
<td>Bioassay test</td>
<td>90% survival of fish after 96 hours in 100% effluent.</td>
</tr>
</tbody>
</table>

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 car cases, 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 limit.

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 x 10^1 spores per milliliter.

STANDARDS FOR DEEP BURIAL

1. A pit or trench should be dug about 2 meters 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 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 population of 30 lakhs by 31st December, 1999 or earlier and above

B. Hospitals 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
FORM I
(see rule 8)

[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:
   (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: 

Place: 

Signature of the Applicant

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 .................................

[F.No.23-2/96-HSMD]
VIJAY SHARMA, Jt. Secy.
GUIDELINES FOR DESIGN AND CONSTRUCTION OF BIO-MEDICAL WASTE INCINERATOR

1. General

1. These guidelines shall be applicable only to the new installation of incinerators. However, the existing incinerator shall be retrofitted with Air Pollution Control Device as mentioned in these guidelines.

2. Incinerator shall be allowed only at Common Bio-medical Waste Treatment Facility (CBWTF).

3. Installation of individual incineration facility by a healthcare unit shall be discouraged as far as possible but approval may be granted only in certain inevitable situations where no other option is available.

2. Incinerator

Following design criteria may be adopted for better performance:

I. The incinerator shall be designed for capacity more than 50 kg/hr. For 50 kg/hr capacity, the minimum hearth area shall be 0.75 sq. m (8 sq. feet) and the minimum flow of the flue gas in the secondary chamber shall be 0.6 m³/sec at 1050°C. Each incinerator must be installed with an air pollution control system (as specified in the section 3).

II. The size of the opening through which the waste is charged shall be larger than the size of the waste bag to be fed. The volume of the primary chamber shall be atleast five times the volume of one batch.

III. The double chamber incinerator shall preferably be designed on "controlled-air" incineration principle, as particulate matter emission is low in such incinerator. Minimum 100% excess air shall be used for overall design. Air supply in the primary and secondary chamber shall be regulated between 30%-80% and 170%-120% of stoichiometric amount respectively. Primary air shall be admitted near / at the hearth for better contact. Flow meter / suitable flow measurement device shall be provided on the primary & secondary air ducting. The combustion air shall be supplied through a separate forced draft fan after accounting for the air supplied through burners.

Optional: For higher capacity incinerators, typically above 250 kg/hr, other design e.g. Rotary Kiln shall be preferred.

IV. A minimum negative draft of 1.27 to 2.54 mm of WC (Water Column) shall be maintained in the primary chamber to avoid leakage of gaseous emissions from the chamber and for safety reasons. Provision shall be made in the primary chamber to measure the Water Column pressure.

V. The waste shall be fed into the incinerator in small batches after the fixed interval of time in case of fixed hearth incinerator and continuous charging using appropriate feeding mechanism incase of rotary kiln incinerator or as recommended by the manufacturer. The size of the hearth i.e. primary chamber shall be designed properly.

VI. The sides and the top portion of the primary and secondary chambers shall preferably have rounded corner from inside to avoid possibility of formation of black pockets/dead zones.

VII. The size of the secondary chamber shall be properly designed so as to facilitate a minimum of one second of residence time to gas flow. For the estimation of residence time in the secondary chamber its volume shall be calculated starting from the secondary burner tip to the thermocouple.

VIII. The refractory lining of the chamber shall be strong enough to sustain minimum temperature of 1000°C in the primary chamber and 1200°C in the secondary chamber. The refractory & insulation bricks shall have minimum 115 mm thickness each & conform to IS:8-1983 & IS:2042-1972 respectively.

IX. The Incinerator shell shall be made of mild steel plate of adequate thickness (minimum 5 mm thick) & painted externally with heat resistant aluminum paint suitable to withstand temperature of 250°C with proper surface preparation. Refractory lining of the hot duct shall be done with refractory castable (minimum 45 mm thick) & insulating castable (minimum 80 mm thick). Ceramic wool shall be used at hot duct flanges & expansion joints.

X. The thermocouple location shall be as follows:

In Primary chamber - Before admission of secondary air
In Secondary chamber - At the end of secondary chamber or before admission of dilution medium to cool the gas

XI. There shall be a separate burner each for the Primary & Secondary chamber. The heat input capacity of each burner shall be sufficient to raise the temperature in the primary and secondary chambers as
800±50°C and 1050±50°C respectively within maximum of 60 minutes prior to waste charging. The burners shall have automatic switching "off/on" control to avoid the fluctuations of temperatures beyond the required temperature range.

a) Each burner shall be equipped with spark igniter and main burner.
b) Proper flame safeguard of the burner shall be installed.
c) Provide view ports to observe flame of the burner.
d) Flame of the primary burner
e) shall be pointing towards the centre of the hearth.
f) shall be having a length such that it touches the waste but does not impinge directly on the refractory floor or wall.
g) The secondary burner shall be positioned in such a way that the flue gas passes through the flame.

XII. There shall not be any manual handling during charging of waste in to the primary chamber of the incinerator. The waste shall be charged in bags through automatic feeding device at the manufacturer's recommended intervals ensuring no direct exposure of furnace atmosphere to the operator. The device shall prevent leakage of the hot flue gas & any backfire. The waste shall be introduced on the hearth in such a way so as to prevent the heap formation. Suitable raking arrangement shall be provided for uniform spreading of waste on the hearth.

XIII. A tamper-proof PLC (Programmable Logic Control) based control system shall be installed to prevent:

- Waste charging until the required temperature in the chambers are attained during beginning of the operation of the incinerator.
- Waste charging unless primary & secondary chambers are maintained at the specified temperature range.
- Waste charging in case of any unsafe conditions such as - very high temperature in the primary & secondary chambers; failure of the combustion air fan, ID fan, recirculation pump; low water pressure & high temperature of the flue gas at the outlet of air pollution control device.

XIV. The incineration system must have an emergency vent. The emergency vent shall remain closed i.e it shall not emit flue gases during normal operation of the incinerator.

XV. Each incineration system shall have graphic or computer recording devices, which shall automatically and continuously monitor and record dates, time of day, batch sequential number and operating parameters such as temperatures in both the chambers. CO, CO2 , and O2 in gaseous emission shall also be measured daily (atleast ½ hour at one minute interval).

XVI. The possibility of providing heat recovery system/heat exchanger with the incinerator shall also be considered wherever possible.

XVII. Structural design of the chimney / stack shall be as per IS:6533-1989. The chimney/stack shall be lined from inside with minimum of 3 mm thick natural hard rubber suitable for the duty conditions and shall also conform to IS:4682 Part I-1968 to avoid corrosion due to oxygen and acids in the flue gas.

XVIII. The location and specification of porthole, platform ladder etc. shall be as per the Emission Regulations, Part-3 (COINDS/20/1984-85), published by CPCB.

3. Air Pollution Control Device:

It is not possible to comply with the emission limit of 150 mg/Nm³ (corrected to 12% CO2) for Particulate Matter, without Air Pollution Control Device (APCD). Therefore, a bio-medical waste incinerator shall always be equipped with APCD.

i) No incinerator shall be allowed to operate unless equipped with APCD.

ii) The incinerator shall be equipped with High Pressure Venturi Scrubber System as ordinary APCD such as wet scrubber or cyclonic separator cannot achieve the prescribed emission limit. For the facilities operating for 24 hrs a day, APCD in terms of dry lime injection followed by bag filter can be considered. The details of High Pressure Venturi Scrubber System are given in ANNEXURE-I.

4. Incinerator room and waste storage room:

i) The incinerator structure shall be built in a room with proper roofing and cross ventilation. There shall be minimum of 1.5 m clear distance in all the directions from the incinerator structure to the wall of the incinerator room.
ii) Adjacent to the incinerator room, there shall be a waste storage area. It shall be properly ventilated and so designed that waste can be stored in racks and washing can be done very easily. The waste storage room shall be washed and chemically disinfected daily.

iii) The floor and inner wall of the incinerator and storage rooms shall have outer covering of impervious and glazed material so as to avoid retention of moisture and for easy cleaning.

iv) The incineration ash shall be stored in a closed sturdy container in a masonry room to avoid any pilferage. Finally, the ash shall be disposed in a secured landfill.

5. Operator of the incinerator:

i) A skilled person shall be designated to operate and maintain the incinerator. The operator shall have adequate qualification in relevant subject and shall be trained and certified by the incinerator supplier in operation & maintenance of the incinerator.

ii) There shall be at least one assistant designated at the incinerator plant to keep track of the wastes, records of incinerator operation, cleanliness of the surrounding area and incinerator & waste storage room. They shall also take care of waste charging and incineration ash disposal.

iii) All the staff at the incinerator plant shall put on protective gears such as gumboots, gloves, eye glasses, etc. for safety reasons.

iv) Any accident occurred shall immediately be reported to the facility operator. The facility operator shall have well defined strategies to deal with such accident/emergency.

[The guidelines will help in selection/installation of better incinerator system. However, it shall be ensured that the incinerator shall comply with the standards stipulated in the Bio-medical Waste (Management & Handling) Rules, 1998.]
ANNEXURE-I

Details of High Pressure Venturi Scrubber System

1. The venturi scrubber shall have minimum pressure drop of 350 mm WC to achieve the prescribed emission limit. The temperature of the flue gas at the outlet of the venturi scrubber shall be approx 70-80° C to ensure the saturation of the flue gas.

2. The venturi scrubber shall preferably be made of stainless steel - 316L grade or better material or mild steel lined with acid resistant bricks to avoid corrosion.

3. The water to be used in venturi scrubber shall be added with caustic soda solution to maintain the pH of the scrubbing liquid above 6.5.

4. The scrubbing medium shall be circulated @ 2-2.5 ltrs/m3 of saturated flue gas at venturi outlet. This shall be done using a pump & piping made of stainless steel - 316 grades or better material. The scrubbing medium shall be recirculated as far as possible.

5. Venturi scrubber shall be followed by centrifugal type droplet separator to remove water droplets from flue gas.

6. The material of construction of the droplet separator and interconnecting ducting from venturi scrubber to droplet separator, droplet separator to ID fan & ID fan to stack, shall be mild steel lined from inside with minimum 3 mm thick natural hard rubber suitable for the duty conditions and shall also conform to IS: 4682 Part I-1968 to avoid corrosion due to oxygen and acids in the wet flue gas.

7. The wastewater generated from the air pollution control device shall be properly handled so as to avoid any non-compliance of the regulatory requirements.

8. Stack emission monitoring and ash analysis as per the requirement of the Bio-medical Waste (Management & Handling) Rules, 1998, shall be done quarterly i.e. once in every three months and record shall be maintained by the facility operator.