Bio-Medical Waste Management Rules, 2018

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GOVERNMENT OF INDIA MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION (New Delhi, the 16TH March, 2018)

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7. MUNICIPALITIES OR CORPORATIONS, URBAN LOCAL BODIES AND GRAM PANCHAYATS

OPERATOR OF A COMMON BIO-MEDICAL WASTE TREATMENT FACILITY (CBMWTF): PASSCO ENVIRONMENTAL SOLUTIONS LTD PUNE

(Occupier)

SMT. KASHIBAI NAVALE MEDICAL COLLEGE AND GENERAL HOSPITAL
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<th>DOCUMENT NAME</th>
<th>BIOMEDICAL WASTE MANAGEMENT MANUAL</th>
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<td>(Professor And Head Microbiology )</td>
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<td>DESIGNATION: Chair Person Of Biomedical Waste Management Committee</td>
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<td>NAME: Dr. (COL) Parvinder Singh Chawla</td>
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<td>(M.D. Community Medicine)</td>
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<td>RESPONSIBILITY OF UPDATING</td>
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FOREWORD

Medical care is vital for our life and health, but biomedical waste management is crucial health issue for community. Improper segregation and disposal of hospital waste poses a serious threat to our environment and healthcare.

Biomedical waste management is an essential component of quality healthcare assurance in hospitals. Meticulous biomedical waste disposal management has been documented to reduce the hospital acquired infections to a great extent.

Most health professionals are not aware about the risk involved when they handle biomedical waste. The sole purpose of this biomedical waste management manual is to develop awareness to all health professionals about the recent biomedical waste management rules, 2018 by Government of India and it is mandatory to implement.

I hope this manual will give an overview of guidelines of biomedical waste management which in turn will help to reduce biomedical waste hazards and ultimately have an impact on hospital acquired infections and quality health care can be achieved.

Dr. Arvind. V. Bhore  
MBBS MD (Microbiology)  
Director  
Smt. Kashibai Navale Medical College and General Hospital
Safe handling of the biomedical waste has revealed a significant impact on preserving and sustaining optimum level of human health and is mitigating environmental degradation.

Appropriate management of biomedical waste is a continuous process. Hence its requirement and significance should be inculcated in health service providers.

This Biomedical waste Management manual will certainly help in increasing appropriate awareness about biomedical waste segregation and disposal. Biomedical waste management is a team task and responsibility of each personnel. In view of the latest guidelines and amendment biomedical waste management rules, 2018 issued by Government of India, we are providing this biomedical waste management manual to all stakeholders to use as and when required. We hope it will help in reducing incidence of hospital acquired infections and hence improve wellness of patients and improvement of environment.

Dr. (COL) Parvinder Singh Chawla
(M.D. Community Medicine)
DEAN
Smt. Kashibai Navale Medical College and General Hospital
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</table>
I) BIOMEDICAL WASTE MANAGEMENT GUIDELINES, SKNMC & GH

INTRODUCTION

BIO MEDICAL WASTE - means any waste which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps.

Health Hazards of Biomedical Waste-

One of the causes for increase in infectious diseases is improper waste management. Blood, body fluids & body secretions which are constituents of bio-medical waste, harbor most of the viruses, bacteria and parasites that cause infection. Human immunodeficiency virus (HIV) and hepatitis viruses are leading in the list of infections and diseases documented to have spread through biomedical waste. Tuberculosis, pneumonia, diarrheal diseases, tetanus, whooping cough etc. are other common diseases spread due to improper waste management.

Occupational Health hazard:

The health hazards due to improper waste management can not only affect the occupants in institutions, but can also spread in the vicinity of the institutions. Occupational health hazard is more likely for sanitary workers, laundry workers, nurses, emergency medical personnel and workers in the waste disposal. Injuries from sharps and exposure to harmful chemical waste and radioactive waste are health hazards to employees. Proper management of waste can solve the problem of occupational hazards to a large extent.

Hazards to the general public:

Improper practices such as dumping of biomedical waste in municipal dustbins, open spaces, water bodies’ etc, lead to the spread of diseases. Recycling of disposables without sterilization also can occur due to improper disposal.

Health hazards to animals and birds:

Bio-medical waste can cause health hazards to animals and birds. Plastic waste can choke animals, which scavenge on openly dumped waste. Injuries from sharp are common affecting the animals.
Quantum of Waste:

- 1-2 kg of waste is generated per bed per day in a hospital
- An average of 2500 – 3000 Kgs of biomedical waste is generated per month at SKNMC&GH
- Non-infectious general waste 80-85%
- Infectious / hazardous waste 10%
- If mixed, entire waste could be potentially dangerous.
- Hence segregation is the key to healthcare waste management.

Waste characterisation-

A) Non-hazardous waste-

It consists of general and office waste and kitchen waste.

- General& office waste - wrapping paper, office paper, cartons, packaging material including plastic sheets, newspapers and bouquets etc.
- Kitchen waste - leftover food, peels of fruits and vegetable skin and dirty water

B) Hazardous waste-

- Infectious waste-
  a) Dressings and swabs contaminated with blood, pus and body fluid
  b) Laboratory samples, cultures, stocks of infectious agents, laboratory glassware
  c) Instruments used in patient care like endoscopes, syringes and needles, sharps and other instruments.
  d) Potentially infected materials, placenta, tissues, tumours, organs removed during surgery.
  e) Potentially infected animals used in diagnostic or research studies
  f) Liquid waste - waste generated from washing, cleaning and disinfecting activities

- Toxic waste-
  a) Chemical waste
  b) Pharmaceutical waste
  c) Radioactive waste
Segregation -

Waste should be segregated into different streams at the point of generation. Segregation at source helps in –

a) Reducing the total cost of disposal
b) Preventing general waste from becoming infectious
c) Reducing chances of infection in health care workers
<table>
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<tr>
<th>Sr.No.</th>
<th>Category</th>
<th>Type of waste</th>
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<tr>
<td>1.</td>
<td>Yellow coloured non-chlorinated plastic bags-</td>
<td>a) <strong>Human anatomical waste</strong>: Human tissues, organs, body parts and foetus below the viability period</td>
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<td></td>
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<td>b) <strong>Animal Anatomical Waste</strong>: Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.</td>
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<td>c) <strong>Soiled Waste</strong>: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components.</td>
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<td>d) <strong>Expired or Discarded Medicines</strong>: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.</td>
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<td></td>
<td>e) <strong>Chemical Waste</strong>: Chemicals used in production of biological and used or discarded disinfectants.</td>
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<td>f) Discarded linen, mattresses, beddings contaminated with blood or body fluid routine mask and gown.</td>
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<td>g) <strong>Microbiology, Biotechnology and other clinical laboratory waste</strong>: Blood bags, Laboratory cultures, stocks or specimens of micro-organisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.</td>
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<td><strong>Note</strong>: Autoclaving of Microbiology, Biotechnology and other clinical laboratory waste before disposal into yellow bags.</td>
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<tr>
<td>2.</td>
<td>Red coloured non-chlorinated plastic bags-</td>
<td><strong>Contaminated Waste (Reyclable)</strong>-Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vaccutainers with their needles cut) and gloves.</td>
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</table>
For segregation following **four categories**/colored bags/ containers should be used as follows.

### Chemical liquid waste:

Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.

**Disposal method**- Separate collection system leading to **effluent treatment system**

**Treatment**- After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater.

Chemical treatment using at least **1 to 2 % Sodium Hypochlorite having 30% residual chlorine for twenty minutes** or any other equivalent chemical reagent that should demonstrate Log$10^4$ reduction efficiency for microorganisms.

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<tr>
<th>3. White (Translucent) Puncture proof, Leak proof, tamper proof containers-</th>
<th>Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes used, discarded and contaminated metal sharps.</th>
</tr>
</thead>
</table>
| 4. Puncture proof and leak proof boxes or container with blue colored marking | **a) Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.  
**b) Metallic Body Implants** |
LABEL FOR BIOMEDICAL WASTE CONTAINERS/BAGS

Biohazard  Radiation Hazard

All bins must be lined with bags and must also have the biohazard symbol

Handling sharps-

• Most injuries occur between the point of use and disposal
• Always wear gloves
• Segregate sharps from rest of the waste at the point of generation
• Clipping, bending, recapping or breaking of needles must not be practiced
Handling of waste bags-

- Bags must be replaced when three fourth full
- It should be effectively sealed
- Pick up sealed bag by its neck
- Minimize manual handling
- Do not clasp bag against body
- Avoid bag hitting body
- Carry sharp containers with handle
- Do not support from bottom

Transportation-

a) Inside the hospital to central storage area- This should follow designated routes and should utilize:
   - Dedicated wheeled containers/trolleys should be used
   - Use separate trolleys for clinical & general waste
   - Trolleys should be cleaned & disinfected thoroughly after each use
b) Transport off-site:

- Biomedical Waste from storage area is transferred to the common regional facility for BMW final disposal - Passco Environmental Solutions Pvt.Ltd, MPCB, Pune.

Bar code reading and weighing of bags by Passco
Storage-

A safe, ventilated and secured location for storage of segregated biomedical waste in coloured bags or containers should be available

- Secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals should not occur.
- Biomedical Waste shall not be stored beyond a period of forty-eight hours from its generation.
- Establish a bar-code and global positioning system for bags or containers containing biomedical waste to be sent out of the premises or place.

Record keeping-

- Maintain and update on day to day basis the biomedical waste management register.
- Maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for a period of five years.

Occupational safety:

Proper training should be given to all the staff involved with segregation and storage of waste. They should also receive training regarding universal safety precautions.

Personal safety devices:

The use of protective equipment should be mandatory for all the personnel handling waste.

Gloves: Heavy duty rubber gloves should be used for waste handling by the waste handlers. After handling the waste, the gloves should be washed twice, once while wearing (to avoid the dirt contaminating the skin) and then after it is removed. The gloves should be washed after every use with soap and a disinfectant. The size should fit the operator. It should be replaced as and when it undergoes wear and tear or every month, whichever is earlier. The gloves should be hung separately when not in use.

Masks: Waste handlers should also wear a mask while handling the waste, especially while sweeping.

Gumboots: Gumboots provide greater protection to the skin when splashes or large quantities of infected waste have to be handled.

Health check-up and immunization: Health check-up should be conducted at the time of induction and at least once in a year for all health care workers and others involved in handling of bio-medical waste and maintain the record of the same. All health care workers should be immunised with hepatitis B and Tetanus toxoid vaccination.
II) BIOMEDICAL WASTE MANAGEMENT COMMITTEE

Every hospital should have biomedical waste management committee.

Objectives of Biomedical Waste Management committee

- To ensure that bio-medical waste of SKNMC & GH is handled in accordance with Biomedical waste Management Rules, 2018 & Environment Protection Act without any adverse effect to human health & environment of the hospital
- To ensure occupational safety of all health care workers involved in handling of bio-medical waste.

The committee should comprise following members.

THE COMMITTEE MEMBERS

1. Dean
2. The medical superintendent.
3. The HOD of Microbiology.
4. The HOD of Medicine.
5. The HOD of PSM.
6. The HOD of surgery.
7. Professor of Anaesthesia.
8. The officer in charge of central store.
9. The nursing superintendent.
10. The accounts officer.
11. The administrative officer.
12. The house keeping in charge.
13. The sanitary inspector.
14. The officer in charge BMW (Microbiologist).

Responsibilities of each committee member

Dean-

Administration, careful planning, monitoring, periodic review, co-ordinate and control disposal operations, revision or updating if necessary.

- The medical superintendant- Circulation of enough copies of BMW rules & guidelines for implementation of the same in clinical departments. Responsibilities of individual professionals will be highlighted in these guidelines.
- Organize “Awareness Programme”
- Organize training programmes for medical professionals, nursing professionals and sanitation professionals.
• Allocate sufficient financial & manpower resources to ensure efficient and effective implementation of the BMW.

The HOD of Microbiology-
• Formulation and implementation of guidelines for BMW
• Renewal of authorization of BMW
• To hold meetings of the BMW committee and formulate detailed plan of action in regard to segregation, collection, storage and transport of waste from all patient care areas.
• To guide the officer in charge BMW.

The HOD of PSM-
• Monitoring of work of sanitary inspector & guidance regarding ETP & liquid waste management.

The Professor of Surgery & Medicine-
• To ensure that all doctors, nurses, clinical and non-clinical staff in their respective departments are aware of & trained in waste management procedures as prescribed under BMW Guidelines.
• Liaise with the officer in charge BMW for effective monitoring and reporting errors in implementation of BMW management.

The Professor of Anaesthesia-
• Coordination of biomedical waste management work as per guidelines of NABH-safei.
• Organize & monitor the training programme of biomedical waste management for all hospital staff to implement the norms & regulations as per NABH-safei programme.

The officer in charge of central store-
• To procure colour coded bags, containers & any other material required for BMW work as per requisite & make them available in all patient care areas.
The nursing superintendent-
- Designate one sister in charge of biomedical waste management.
- Conduct surprise rounds and review and evaluate the BMW management at all levels from generation and segregation to final disposal.
- Co-ordinate the training of nurses on BMW management.

The accounts officer-
- Provision of funds for renewal of certificate, funds for supply of colour coded bags & containers.

The administrative officer-
- Circulation of enough copies of BMW rules & guidelines for implementation of the same in clinical departments
- Co-ordination of housekeeping & assistance in renewal of BMW certificate.

The house keeping in charge-
- Administration of people in biomedical waste management & their duty arrangement.

The sanitary inspector-
- Implementation, monitoring and evaluation of BMW management from collection & storage of hospital waste to its final disposal.
- To ensure the training of the staff posted under him.

The officer in charge BMW (Microbiologist) –
- In charge of BMW and liaise with other members of the committee.
- Monitoring the BMW management from time to time at various levels i.e. generation, segregation, collection, storage, transportation and treatment including disposal.
- Responsible for circulation of all policy decisions and the hospital waste management manual.
III) ECONOMICS

- An estimated Rs.25 lakhs as capital cost for 1200 bedded SKNMC & GH, which includes final disposal of BMW

- Passco Environmental Solutions Pvt. Ltd, MPCB is charging **Rs.5.77 per bed per day** of infectious waste.

- Allowed weight 0.075 kg per day per bed.

- Excess is charged Rs.36.06 per kg.

- Monthly allowed weight for 1200 bed is 2790 Kg

- At SKNMC&GH average monthly weight is 2900 Kg
IV) IMPORTANT PRECAUTIONS

- Needle recapping must be strictly prohibited.
- Segregation of infectious waste should be done early.
- Heavy duty gloves should be worn while handling infectious waste.
- Colour coding should be strictly adhered to.
- Infectious and non-infectious waste should never be allowed to mix.
- Bags should be tied when they are to be removed for transportation.
V) HANDLING BLOOD SPILLS

Steps:

- Cover contaminated surface with absorbent material i.e. tissue paper or ordinary newspaper.
- Pour disinfectant fluid i.e. 1% sodium hypochlorite solution around and over the contaminated areas.
- Keep it for 10 minutes.
- Remove the paper with gloved hands and put it in the yellow bag.
- Clean the area with the mop. Put the mop in a bucket of 1% sodium hypochlorite solution to disinfect.
- Wash the mop in running tap water and then dry it.
- Always wear gloves during the above-mentioned cleaning and decontaminating procedures.
VI) TRAINING PROGRAMMES

I) Training of doctors:

Doctors should understand the general protocol for hospital waste management. They should be aware of the general rules and guidelines decided by hospital infection control committee and should follow the special instructions as per their working places e.g. OPD, OT, Labour Rooms, ICCU etc. This information should be given in workshops which should be conducted every time when new residents join the institute.

II) Training of nurses:

Nurses form the most important part of hospital staff and are the main persons who have to observe segregation and proper management of waste at source. They should ensure proper segregation of waste, proper storage and handling by the mamas, maushis, sweepers etc. They should realize the importance of the protocol for patients’, waste handlers’, rag pickers’ and their own well being and also well being of the society in general. They should also be well aware of the ill effects if any short cuts are taken.

III) Training mamas and maushis:

Mamas and maushis actually involved in the manual work of segregating waste material and transporting waste bags & bins. They have to seal the bag, lift and do an internal transport to the storage site. They should know that the protocol is important for their own protection and also they must be aware of the ill effects or the hazards if any failure occurs. They must know the different colour coded bags and their use. They should be able to identify type of disposal and segregation as per the scheme followed in the hospital. They should understand that action will be initiated by their superiors if the protocol is not followed.
VII) BIO-MEDICAL WASTE MANAGEMENT RULES, 2018

[Published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i)]

GOVERNMENT OF INDIA MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

NOTIFICATION

New Delhi, the 16th March, 2018

Important features of the notification are summarised as follows:

Application-

These rules shall apply to-

- Hospitals, nursing homes, clinics, dispensaries
- Veterinary institutions, animal houses
- Pathological laboratories, blood banks
- Ayush hospitals
- Clinical establishments
- Research or educational institutions
- Health camps, medical or surgical camps, vaccination camps
- First aid rooms of schools
- Forensic laboratories and research laboratories

These rules shall not apply to-

- Radioactive wastes
- Hazardous chemicals
- Solid wastes covered under municipal solid waste “Solid waste management, 2016
- Lead acid batteries
- Hazardous waste covered under hazardous waste rules (Management and Transboundary movement) Rules, 2016 made under the Act;
- Waste covered under E-Waste (Management) Rules, 2016 made under the Act: and
- Hazardous microorganisms, genetically engineered microorganisms and cells covered under rules 1989
Important definitions

"Bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules.

“Major accident” means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills.

"Authorisation" means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be.

"Authorised person" means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be;

“Occupier” means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

"Operator of a common bio-medical waste treatment facility" means a person who owns or controls a Common Bio-medical Waste Treatment Facility (CBMWTF) for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste;

“Prescribed authority” mean the State Pollution Control Board in respect of a State and Pollution Control Committees in respect of a Union territory;
Biomedical waste management is implemented all over India through a sequential authority hierarchy as follows:

**Authority**

1. Ministry of Environment, Forest and Climate change, Government of India

2. Central or State Ministry of Health and Family Welfare, Central Ministry for Animal Husbandry and Veterinary or State Department of Animal Husbandry and Veterinary

3. Ministry of Defence

4. Central Pollution Control Board

5. State Government of Health or Union Territory Government or Administration

6. State Pollution Control Boards or Pollution Control Committees

7. Municipalities or Corporations, Urban Local Bodies and Gram Panchayats

Operator of a common bio-medical waste treatment facility (CBMWTF)

Occupier

List of Prescribed Authorities and the Corresponding Duties

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<th>Corresponding Duties</th>
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<td>(ii) Providing financial assistance for training and awareness programmes on bio-medical waste management related activities to for the State Pollution Control Boards or Pollution Control Committees.</td>
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<td>(iii) Facilitating financial assistance for setting up or upgradation of common bio-medical waste treatment facilities.</td>
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<td>2.</td>
<td>Central or State Ministry of Health and Family Welfare, Central Ministry for Animal Husbandry and Veterinary or State Department of Animal Husbandry and Veterinary.</td>
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<td>(iv) Undertake or support operational research and assessment with reference to risks to environment and health due to bio-medical waste and previously unknown disposables and wastes from new types of equipment.</td>
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<td>(v) Constitution of Monitoring Committee for implementation of the rules.</td>
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<td>(vi) Hearing Appeals and give decision made in Form- V against order passed by the prescribed authorities.</td>
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<td>(viii) Notify the standards or operating parameters for new technologies for treatment of bio medical waste other than those listed in Schedule- I.</td>
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<tr>
<td>i) Grant of license to health care facilities or nursing homes or veterinary establishments with a condition to obtain authorisation from the prescribed authority for bio-medical waste management.</td>
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<tr>
<td>(ii) Monitoring, Refusal or Cancellation of license for health care facilities or nursing homes or veterinary establishments for violations of conditions of authorisation or provisions under these Rules.</td>
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<td>(iii) Publication of list of registered health care facilities with regard to bio-medical waste generation, treatment and disposal.</td>
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<tr>
<td>(iv) Undertake or support operational research and assessment with reference to risks to environment and health due to bio-medical waste and previously unknown disposables and wastes from new types of equipment.</td>
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<td>(v) Coordinate with State Pollution Control Boards for organizing training programmes to staff of health care facilities and municipal workers on bio-medical waste.</td>
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<td>(vi) Constitution of Expert Committees at National or State level for overall review and promotion of clean or new technologies for bio-medical waste management.</td>
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<td>(vii) Organizing or Sponsoring of trainings for the regulatory authorities and health care facilities on bio-medical waste management related activities.</td>
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<td>(viii) Sponsoring of mass awareness campaigns in electronic media and print media.</td>
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|   | Ministry of Defence | i) Grant and renewal of authorisation to Armed Forces health care facilities or common bio-medical waste treatment facilities.  
(ii) Conduct training courses for authorities dealing with management of bio-medical wastes in Armed Forces health care facilities or treatment facilities in association with State Pollution Control Boards or Pollution Control Committees or Central Pollution Control Board or Ministry of Environment, Forest and Climate Change.  
(iii) Publication of inventory of occupiers and biomedical waste generation from Armed Forces health care facilities or occupiers  
(iv) Constitution of Advisory Committee for implementation of the rules.  
(v) Review of management of bio-medical waste generation in the Armed Forces health care facilities through its Advisory Committee.  
(vi) Submission of annual report to Central Pollution Control Board within the stipulated time period. |
|---|---|---|
| 4 | Central Pollution Control Board | i) Prepare Guidelines on bio-medical waste Management and submit to the Ministry of Environment, Forest and Climate Change.  
(ii) Co-ordination of activities of State Pollution Control Boards or Pollution Control Committees on biomedical waste.  
(iii) Conduct training courses for authorities dealing with management of bio-medical waste.  
(iv) Lay down standards for new technologies for treatment and disposal of bio-medical waste and prescribe specifications for treatment and disposal of bio-medical wastes.  
(v) Lay down Criteria for establishing common biomedical waste treatment facilities in the Country.  
(vi) Random inspection or monitoring of health care facilities and common bio-medical waste treatment facilities. |
(vii) Review and analysis of data submitted by the State Pollution Control Boards on bio-medical waste and submission of compiled information in the form of annual report along with its observations to Ministry of Environment, Forest and Climate Change.

(viii) Inspection and monitoring of health care facilities operated by the Director General, Armed Forces Medical Services.

(ix) Undertake or support research or operational research regarding bio-medical waste.

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5</strong></td>
<td>State Government of Health or Union Territory Government or Administration</td>
</tr>
<tr>
<td>i)</td>
<td>To ensure implementation of the rule in all health care facilities or occupiers.</td>
</tr>
<tr>
<td>ii)</td>
<td>Allocation of adequate funds to Government health care facilities for bio-medical waste management.</td>
</tr>
<tr>
<td>iii)</td>
<td>Procurement and allocation of treatment equipments and make provision for consumables for bio-medical waste management in Government health care facilities.</td>
</tr>
<tr>
<td>iv)</td>
<td>Constitute State or District Level Advisory Committees under the District Magistrate or Additional District Magistrate to oversee the biomedical waste management in the Districts.</td>
</tr>
<tr>
<td>v)</td>
<td>Advise State Pollution Control Boards or Pollution Control Committees on implementation of these Rules.</td>
</tr>
<tr>
<td>vi)</td>
<td>Implementation of recommendations of the Advisory Committee in all the health care facilities.</td>
</tr>
</tbody>
</table>

| **6** | State Pollution Control Boards or Pollution Control Committees |
| i) | Inventorisation of Occupiers and data on bio-medical waste generation, treatment & disposal. |
| ii) | Compilation of data and submission of the same in annual report to Central Pollution Control Board within the stipulated time period. |
| iii) | Grant and renewal, suspension or refusal cancellation or of authorisation. |
| iv) | Monitoring of compliance of various provisions and conditions of authorisation. |
| v) | Action against health care facilities or common biomedical waste treatment facilities for violation of these rules. |
| vi) | Organizing training programmes to staff of health care facilities and common bio-medical waste treatment facilities and State Pollution Control Boards or Pollution Control Committees Staff on segregation, collection, storage,
transportation, treatment and disposal of bio-medical wastes.

(vii) Undertake or support research or operational research regarding bio-medical waste management.

(viii) Any other function under these rules assigned by Ministry of Environment, Forest and Climate Change or Central Pollution Control Board from time to time.

(ix) Implementation of recommendations of the Advisory Committee.

(x) Publish the list of Registered or Authorised (or give consent) Recyclers.

(xi) Undertake and support third party audits of the common bio-medical waste treatment facilities in their State.

<table>
<thead>
<tr>
<th>7</th>
<th>Municipalities or Corporations, Urban Local Bodies and Gram Panchayats</th>
</tr>
</thead>
<tbody>
<tr>
<td>i)</td>
<td>Provide or allocate suitable land for development of common bio-medical waste treatment facilities in their respective jurisdictions as per the guidelines of Central Pollution Control Board.</td>
</tr>
<tr>
<td>ii)</td>
<td>Collect other solid waste (other than the biomedical waste) from the health care facilities as per the Municipal Solid Waste Management Rules, 2016 or as amended time to time.</td>
</tr>
<tr>
<td>iii)</td>
<td>Any other function stipulated under these Rules.</td>
</tr>
</tbody>
</table>

**Duties of the operator of a common bio-medical waste treatment and disposal facility.** -

- Take all necessary steps to ensure that the bio-medical waste collected from the occupier is transported, handled, stored, treated and disposed of, without any adverse effect to the human health and the environment, in accordance with these rules and guidelines issued by the Central Government or, as the case may be, the central pollution control board from time to time.
- Ensure timely collection of bio-medical waste from the occupier as prescribed under these rules;
- Establish bar coding and global positioning system for handling of bio-medical waste within one year
- Inform the prescribed authority immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with these rules
- Provide training for all its workers involved in handling of bio-medical waste at the time of induction and at least once a year thereafter
- Assist the occupier in training conducted by them for bio-medical waste management
- Undertake appropriate medical examination at the time of induction and at least once in a year and immunise all its workers involved in handling of bio-medical waste for protection against diseases, including Hepatitis B and Tetanus, that are likely to be transmitted while handling bio-medical waste and maintain the records for the same.
- Ensure occupational safety of all its workers involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipment.
- Report major accidents including accidents caused by fire hazards, blasts during handling of biomedical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report.
- Maintain a log book for each of its treatment equipment according to weight of batch; categories of waste treated; time, date and duration of treatment cycle and total hours of operation.
- After ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from the treated bio-medical wastes such as plastics and glass, shall be given to recyclers having valid consent or authorisation or registration from the respective State Pollution Control Board or Pollution Control Committee.
- Supply non-chlorinated plastic coloured bags to the occupier on chargeable basis, if required.
- Common bio-medical waste treatment facility shall ensure collection of biomedical waste on holidays also.
- Maintain all record for operation of incineration, hydro or autoclaving for a period of five years.
- Upgrade existing incinerators to achieve the standards for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

**Duties of the occupier**

- Make a provision within the premises for a **safe, ventilated and secured location for storage** of segregated biomedical waste in coloured bags or containers.
- Ensure that there shall be **no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals** and the bio-medical waste from such place or premises shall be directly transported to the common bio-medical waste treatment facility.
- **Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or guidelines on safe management of wastes from health care activities and WHO Blue Book, 2014 and then sent to the Common bio-medical waste treatment facility for final disposal**
- **Phase out use of chlorinated plastic bags, (excluding blood bags) and gloves by 27th March, 2019**
• Not to give treated bio-medical waste with municipal solid waste.
• Provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report.
• Immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste.
• Establish a Bar-Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose.
• Ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities.
• Ensure treatment and disposal of liquid waste
• Report major accidents including accidents caused by fire hazards, blasts during handling of biomedical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report
• Ensure occupational safety of all its health care workers and others involved in handling of biomedical waste by providing appropriate and adequate personal protective equipments
• Conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio-medical waste and maintain the records for the same.
• Inform the prescribed authority immediately in case the operator of a facility does not collect the bio-medical waste within the intended time or as per the agreed time
• Establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months and the record of the minutes of the meetings of this committee shall be submitted along with the annual report to the prescribed authority.
• No occupier shall establish on-site treatment and disposal facility, if a service of common biomedical waste treatment facility is available at a distance of seventy-five kilometre.
• Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty –eight hours.
• The occupier or an operator of a common bio-medical waste treatment facility shall be liable for all the damages caused to the environment or the public due to improper handling of bio-medical wastes.
Procedure for authorisation

Every occupier or operator handling bio-medical waste, irrespective of the quantity shall make an application in Form II to the prescribed authority i.e. State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III and the validity of such authorisation for bedded health care facility and operator of a common facility shall be synchronised with the validity of the consents.

(1) The authorisation shall be one time for non-bedded occupiers and the authorisation in such cases shall be deemed to have been granted, if not objected by the prescribed authority within a period of ninety days from the date of receipt of duly completed application along with such necessary documents.

(2) In case of refusal of renewal, cancellation or suspension of the authorisation by the prescribed authority, the reasons shall be recorded in writing: Provided that the prescribed authority shall give an opportunity of being heard to the applicant before such refusal of the authorisation.

(3) Every application for authorisation shall be disposed of by the prescribed authority within a period of ninety days from the date of receipt of duly completed application along with such necessary documents, failing which it shall be deemed that the authorisation is granted under these rules.

(4) In case of any change in the bio-medical waste generation, handling, treatment and disposal for which authorisation was earlier granted, the occupier or operator shall intimate to the prescribed authority about the change or variation in the activity and shall submit a fresh application in Form II for modification of the conditions of authorisation.

Advisory Committee

(1) Every State Government or Union territory Administration shall constitute an Advisory Committee for the respective State or Union territory under the chairmanship of the respective health secretary to oversee the implementation of the rules in the respective state and to advice any improvements and the Advisory Committee shall include representatives from the Departments of Health, Environment, Urban Development, Animal Husbandry and Veterinary Sciences of that State Government or Union territory Administration, State Pollution Control Board or Pollution Control Committee, urban local bodies or local bodies or Municipal Corporation, representatives from Indian Medical Association, common biomedical waste treatment facility and non-governmental organisation.

(2) Notwithstanding anything contained in sub-rule (1), the Ministry of Defence shall constitute the Advisory Committee (Defence) under the chairmanship of Director General of Health Services of Armed Forces consisting of representatives from the Ministry of Defence,
Ministry of Environment, Forest and Climate Change, Central Pollution Control Board, Ministry of Health and Family Welfare, Armed Forces Medical College or Command Hospital.

(3) The Advisory Committee constituted under sub-rule (1) and (2) shall meet at least once in six months and review all matters related to implementation of the provisions of these rules in the State and Armed Forces Health Care Facilities, as the case may be.

(4) The Ministry of Health and Defence may co-opt representatives from the other Governmental and non-governmental organisations having expertise in the field of bio-medical waste management.

**Monitoring of implementation of the rules in health care facilities**

(1) The Ministry of Environment, Forest and Climate Change shall review the implementation of the rules in the country once in a year through the State Health Secretaries and Chairmen or Member Secretary of State Pollution Control Boards and Central Pollution Control Board and the Ministry may also invite experts in the field of bio-medical waste management, if required.

(2) 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.

(3) The Central Pollution Control Board along with one or more representatives of the Advisory Committee constituted under sub-rule (2) may inspect any Armed Forces health care establishments after prior intimation to the Director General Armed Forces Medical Services.

(4) Every State Government or Union territory Administration shall constitute District Level Monitoring Committee in the districts under the chairmanship of District Collector or District Magistrate or Deputy Commissioner or Additional District Magistrate to monitor the compliance of the provisions of these rules in the health care facilities generating bio-medical waste and in the common bio-medical waste treatment and disposal facilities, where the bio-medical waste is treated and disposed of.

(5) The District Level Monitoring Committee constituted under sub-rule (4) shall submit its report once in six months to the State Advisory Committee and a copy thereof shall also be forwarded to State Pollution Control Board or Pollution Control Committee concerned for taking further necessary action.

(6) The District Level Monitoring Committee shall comprise of District Medical Officer or District Health Officer, representatives from State Pollution Control Board or Pollution Control Committee, Public Health Engineering Department, local bodies or municipal corporation, Indian Medical Association, common bio-medical waste treatment facility and registered nongovernmental organisations working in the field of bio-medical waste
management and the Committee may co-opt other members and experts, if necessary and the District Medical Officer shall be the Member Secretary of this Committee.

**Annual report**

(1) Every occupier or operator of common bio-medical waste treatment facility shall submit an annual report to the prescribed authority in Form-IV, on or before the 30th June of every year.

(2) The prescribed authority shall compile, review and analyse the information received and send this information to the Central Pollution Control Board in IVA before the 30th June of every year.

(3) The Central Pollution Control Board shall compile, review and analyse the information received and send this information, along with its comments or suggestions or observations to the Ministry of Environment, Forest and Climate Change on or before 31st August every year.

(4) The Annual Reports shall also be available online on the websites of Occupiers, State Pollution Control Boards and Central Pollution Control Board.

**Maintenance of records**

(1) Every authorised person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for a period of five years, in accordance with these rules and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.

(2) All records shall be subject to inspection and verification by the prescribed authority or the Ministry of Environment, Forest and Climate Change at any time.

**Accident reporting**

(1) In case of any major accident at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I.

(2) Information regarding all other accidents and remedial steps taken shall be provided in the annual report by the occupier.
Liability of the occupier, operator of a facility

(1) The occupier or an operator of a common bio-medical waste treatment facility shall be liable for all the damages caused to the environment or the public due to improper handling of bio-medical wastes.

(2) The occupier or operator of common bio-medical waste treatment facility shall be liable for action under section 5 and section 15 of the Act, in case of any violation.

Appeal

(1) Any person aggrieved by an order made by the prescribed authority under these rules may, within a period of thirty days from the date on which the order is communicated to him, prefer an appeal in Form V to the Secretary (Environment) of the State Government or Union territory administration.

(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 in Form V to the Secretary, Ministry of Environment, Forest and Climate Change.

(3) The authority referred to in sub-para (1) and (2) as the case may be, 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) The appeal shall be disposed of within a period of ninety days from the date of its filing.

Site for common bio-medical waste treatment and disposal facility

(1) Without prejudice to rule 5 of these rules, the department in the business allocation of land assignment shall be responsible for providing suitable site for setting up of common biomedical waste treatment and disposal facility in the State Government or Union territory Administration.

(2) The selection of site for setting up of such facility shall be made in consultation with the prescribed authority, other stakeholders and in accordance with guidelines published by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board.
## Schedule-I

**Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options**

<table>
<thead>
<tr>
<th>Category</th>
<th>Type of waste</th>
<th>Type of bag or container to be used</th>
<th>Treatment &amp; disposal options</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yellow</strong></td>
<td>(a) Human anatomical waste: Human tissues, organs, body parts and foetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).</td>
<td>Yellow coloured non-chlorinated plastic bags</td>
<td>Incineration or plasma pyrolysis or deep burial</td>
</tr>
<tr>
<td></td>
<td>(b) Animal Anatomical Waste: Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components.</td>
<td></td>
<td>Incineration or Plasma Pyrolysis or deep burial</td>
</tr>
<tr>
<td></td>
<td>(d) Expired or Discarded Medicines: Pharmaceutical waste like</td>
<td>Yellow coloured non-chlorinated plastic bags or containers</td>
<td>Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>(a) Antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.</th>
<th>for incineration at temperature &gt;1200 °C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at &gt;1200° C or Encapsulation or Plasma Pyrolysis at &gt;1200° C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.</td>
<td>Yellow coloured non-chlorinated plastic bags or containers</td>
</tr>
<tr>
<td>(f) Discarded linen, mattresses, beddings contaminated with blood or body fluid routine mask and gown.</td>
<td>Non-chlorinated yellow plastic bags or suitable packing material</td>
</tr>
<tr>
<td>(g) Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of micro-organisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories,</td>
<td>Autoclave safe plastic bags or containers</td>
</tr>
<tr>
<td>Category</td>
<td>Type of waste</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Red</strong></td>
<td><strong>Contaminated Waste (Recyclable)</strong> (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vaccutainers with their needles cut) and gloves.</td>
</tr>
<tr>
<td><strong>White (Translucent)</strong></td>
<td><strong>Waste sharps including Metals:</strong> Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps</td>
</tr>
</tbody>
</table>
Committees) or sanitary landfill or designated concrete waste sharp pit.

Blue

(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes 

(b) Metallic Body Implants

Puncture proof and leak proof boxes or container with blue colored marking.

Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

<table>
<thead>
<tr>
<th>Type of waste</th>
<th>Type of bag or container to be used</th>
<th>Treatment &amp; disposal options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical liquid waste:</td>
<td>Separate collection system leading to effluent treatment system</td>
<td>After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater.</td>
</tr>
<tr>
<td>Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Chemical treatment using at least 1 to 2% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate $\log_{10}^{4}$ reduction efficiency for microorganisms.

**STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION**

- Microbial inactivation efficacy is equated to “Log10 kill” which is defined as the difference between the logarithms of number of test microorganisms before and after chemical treatment. Chemical disinfection methods shall demonstrate a 4 Log10 reduction or greater for Bacillus subtilis (ATCC 19659) in chemical treatment systems.
STANDARDS FOR LIQUID WASTE-

(1) The effluent generated or treated from the premises of occupier or operator of a common bio medical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits-

<table>
<thead>
<tr>
<th>PARAMETERS</th>
<th>PERMISSIBLE LIMITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6.5-9.0</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>Bio-assay test</td>
<td>90% survival of fish after 96 hours in 100% effluent.</td>
</tr>
</tbody>
</table>

Note:

1. Above limits are applicable to the occupiers of Health Care Facilities (bedded) which are either connected with sewerage network without terminal sewage treatment plant or not connected to public sewers.

2. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 (29 of 1986) shall be applicable.

3 Health Care Facilities having less than ten beds shall have to install Sewage Treatment Plant by the 31st December, 2019.

4 Non-bedded occupiers shall dispose infectious liquid wastes only after treatment by disinfection as per Schedule – II (6) of the principal rules.”.

(2) Sludge from Effluent Treatment Plant shall be given to common bio-medical waste treatment facility for incineration or to hazardous waste treatment, storage and disposal facility for disposal.

STANDARDS FOR AUTOCLAVING OF BIO-MEDICAL WASTE-

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

- The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste.
- (I ) 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) 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) Temperature of not less than 149° C and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.
Validation test for autoclave:

- The validation test shall use four biological indicator strips, one shall be used as a control and left at room temperature, and three shall be placed in the approximate centre of three containers with the waste.
- Occupier or operator of a common biomedical waste treatment facility shall conduct this test once in three months and records in this regard shall be maintained.
- **Routine Test:** A chemical indicator strip or tape that changes colour when a certain temperature is reached can be used to verify that a specific temperature has been achieved. The occupier or operator of a common biomedical waste treatment facility shall conduct this test during autoclaving of each batch and records in this regard shall be maintained.
- **Spore testing:** Biological indicator for autoclave shall be Geobacillus stearothermophilus spores using vials or spore Strips; with at least 1X10⁶ spores. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, a temperature less than 121°C or a pressure less than 15 psi. The occupier or operator of a common biomedical waste treatment and disposal facility shall conduct this test at least once in every week and records in this regard shall be maintained.
FORM – I
ACCIDENT REPORTING

1. Date and time of accident:
2. Type of Accident:
3. Sequence of events leading to accident:
4. Has the Authority been informed immediately?
5. The type of waste involved in accident:
6. Assessment of the effects of the accidents on human health and the environment:
7. Emergency measures taken:
8. Steps taken to alleviate the effects of accidents:
9. Steps taken to prevent the recurrence of such an accident:
10. Does your facility have an Emergency Control policy? If yes give details:
Date: ......................... Signature ............................ Place:
  ...........................  Designation ........................
FORM - II

APPLICATION FOR AUTHORISATION OR RENEWAL OF AUTHORISATION
(To be submitted by occupier of health care facility or common bio-medical waste treatment facility)

To
The Prescribed Authority
(Name of the State or UT Administration)
Address.

1. Particulars of Applicant:

(i) Name of the Applicant:
(In block letters & in full)

(ii) Name of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

(iii) Address for correspondence:

(iv) Tele No., Fax No.:

(v) Email:

(vi) Website Address:

2. Activity for which authorisation is sought:

Activity Please tick
Generation, segregation
Collection,
Storage
packaging
Reception
Transportation
Treatment or processing or conversion
Recycling
Disposal or destruction
use
offering for sale, transfer
Any other form of handling

3. Application for fresh or renewal of authorisation (please tick whatever is applicable):

(i) Applied for CTO/CTE Yes/No

(ii) In case of renewal previous authorisation number and date:
(iii) Status of Consents:

(a) under the Water (Prevention and Control of Pollution) Act, 1974

(b) Under the Air (Prevention and Control of Pollution) Act, 1981:

4. (i) Address of the health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

(ii) GPS coordinates of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

5. Details of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF):

(i) Number of beds of HCF:
(ii) Number of patients treated per month by HCF:
(iii) Number healthcare facilities covered by CBMWTF: _______
(iv) No of beds covered by CBMWTF: _______
(v) Installed treatment and disposal capacity of CBMWTF: ______ Kg per day
(vi) Quantity of biomedical waste treated or disposed by CBMWTF: _____ Kg/day
(vii) Area or distance covered by CBMWTF: ______________
(viii) Quantity of Biomedical waste handled, treated or disposed

<table>
<thead>
<tr>
<th>Category</th>
<th>Type of waste</th>
<th>Quantity generated or collected, kg/day</th>
<th>Method of treatment and disposal (refer Schedule-I)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>(2)</td>
<td>(3)</td>
<td>(4)</td>
</tr>
<tr>
<td>Yellow</td>
<td>a) Human Anatomical Waste:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>b) Animal Anatomical Waste:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>c) Soiled Waste:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>d) Expired or Discarded Medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>e) Chemical Solid Waste:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>f) Chemical Liquid Waste:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>h) Microbiology, Biotechnology and other clinical laboratory waste:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red</td>
<td>Contaminated Waste</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6. Brief description of arrangements for handling of biomedical waste (attach details):

(i) Mode of transportation (if any) of bio-medical waste:

(ii) Details of treatment equipment (please give details such as the number, type & capacity of each unit)

<table>
<thead>
<tr>
<th>No of units</th>
<th>Capacity of each unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incinerators:</td>
<td></td>
</tr>
<tr>
<td>Plasma Pyrolysis:</td>
<td></td>
</tr>
<tr>
<td>Autoclaves:</td>
<td></td>
</tr>
<tr>
<td>Microwave:</td>
<td></td>
</tr>
<tr>
<td>Hydroclave:</td>
<td></td>
</tr>
<tr>
<td>Shredder:</td>
<td></td>
</tr>
<tr>
<td>Needle tip cutter or destroyer</td>
<td></td>
</tr>
<tr>
<td>Sharps encapsulation or Concrete pit:</td>
<td></td>
</tr>
<tr>
<td>Deep burial pits:</td>
<td></td>
</tr>
<tr>
<td>Chemical disinfection:</td>
<td></td>
</tr>
<tr>
<td>Any other treatment equipment:</td>
<td></td>
</tr>
</tbody>
</table>

7. Contingency plan of common bio-medical waste treatment facility (CBWTF)(attach documents):

8. Details of directions or notices or legal actions if any during the period of earlier authorisation

9. Declaration

I do hereby declare that the statements made and information given above is 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 fulfil any conditions stipulated by the prescribed authority.

Date: Signature of the Applicant

Place: 

Designation of the Applicant
Form - IV
ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical waste treatment facility (CBWTF)]

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Particulars</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Particulars of the Occupier:</td>
</tr>
<tr>
<td></td>
<td>(i) Name of the authorised person (occupier or operator of facility):</td>
</tr>
<tr>
<td></td>
<td>(ii) Name of HCF or CBMWT:</td>
</tr>
<tr>
<td></td>
<td>(iii) Address for Correspondence:</td>
</tr>
<tr>
<td></td>
<td>(iv) Address of Facility:</td>
</tr>
<tr>
<td></td>
<td>(v) Tel. No, Fax. No:</td>
</tr>
<tr>
<td></td>
<td>(vi) E-mail ID:</td>
</tr>
<tr>
<td></td>
<td>(vii) URL of Website:</td>
</tr>
<tr>
<td></td>
<td>(viii) GPS coordinates of HCF or CBMWTF:</td>
</tr>
<tr>
<td></td>
<td>(ix) Ownership of HCF or CBMWTF: (State Government or Private or Semi Govt. or any other)</td>
</tr>
<tr>
<td></td>
<td>(x) Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules: Authorisation No.: ……………………………… Valid up to …………..</td>
</tr>
<tr>
<td></td>
<td>(xi) Status of Consents under Water Act and Air Act: Valid up to:</td>
</tr>
<tr>
<td>2.</td>
<td>Type of Health Care Facility:</td>
</tr>
<tr>
<td></td>
<td>(i) Bedded Hospital: No. of Beds…</td>
</tr>
<tr>
<td></td>
<td>(ii) Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other):</td>
</tr>
<tr>
<td></td>
<td>(iii) License number and its date of expiry:</td>
</tr>
<tr>
<td>3.</td>
<td>Details of CBMWTF:</td>
</tr>
<tr>
<td></td>
<td>(i) Number healthcare facilities covered by CBMWTF:</td>
</tr>
<tr>
<td></td>
<td>(ii) No of beds covered by CBMWTF:</td>
</tr>
<tr>
<td></td>
<td>(iii) Installed treatment and disposal capacity of CBMWTF: _______ Kg per day</td>
</tr>
<tr>
<td></td>
<td>(iv) Quantity of biomedical waste treated or disposed by CBMWTF: _____ Kg/day</td>
</tr>
<tr>
<td>4.</td>
<td>Quantity of waste generated or disposed in Kg per annum (on monthly average basis): Yellow category:</td>
</tr>
<tr>
<td></td>
<td>Red category:</td>
</tr>
<tr>
<td></td>
<td>White:</td>
</tr>
<tr>
<td>Blue category:</td>
<td>General solid waste:</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>5. Details of the Storage, treatment, transportation, processing and Disposal Facility</td>
<td></td>
</tr>
</tbody>
</table>

(i) Details of the on-site storage facility : Size: Capacity: Provision of on-site storage : (cold storage or any other provision)

<table>
<thead>
<tr>
<th>disposal facilities</th>
<th>Type of treatment equipment</th>
<th>No of units</th>
<th>Capacity Kg/ day</th>
<th>Quantity treated or disposed in kg per annum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incinerators</td>
<td>Plasma Pyrolysis</td>
<td>Autoclaves</td>
<td>Microwave</td>
<td>Hydroclavve</td>
</tr>
</tbody>
</table>

(iii) Quantity of recyclable wastes sold to authorize recyclers after treatment in kg per annum. : Red Category (like plastic, glass etc.)

(iv) No of vehicles used for collection and transportation of biomedical waste : |

(v) Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum : Quantity generated Where disposed Incineration Ash ETP Sludge |

(vi) Name of the Common Biomedical Waste Treatment Facility Operator through which wastes are disposed of : |

(vii) List of member HCF not handed over bio-medical waste. : |

6. Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period |

7. Details trainings conducted on BMW |

(i) Number of trainings conducted on BMW Management |
(ii) number of personnel trained
(iii) number of personnel trained at the time of induction
(iv) number of personnel not undergone any training so far
(v) Whether standard manual for training is available?
(vi) any other information)

8. Details of the accident occurred during the year
(i) Number of Accidents occurred
(ii) Number of the persons affected
(iii) Remedial Action taken (Please attach details if any)
(iv) Any Fatality occurred, details.

9. Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards?

Details of Continuous online emission monitoring systems installed

10. Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?

11. Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?

12. Any other relevant information

: (Air Pollution Control Devices attached with the Incinerator)

Certified that the above report is for the period from

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Name and Signature of the Head of the Institution

Date:

Place
“Form IVA

[See rule 13(2)]

Format for Submission of the Annual Report Information on Bio-medical Waste Management (to be submitted

by the State Pollution Control Boards or Pollution Control Committees and Director General Armed Forces Medical

Services to Central Pollution Control Board on or before 31st July of every year for the period from January to December

of the preceding calendar year)

Part-1 (Summary of Information)

(1) Name of the Organization :

(2) Name of the Nodal Officer with contact telephone number and e-mail :

(3) Total no. of Health Care Facilities / Occupiers :

(i) Bedded Hospitals and Nursing Homes (bedded) :

(ii) Clinics, dispensaries :

(iii) Veterinary institutions :

(iv) Animal houses :

(v) Pathological laboratories :

(vi) Blood banks :

(vii) Clinical establishment :

(viii) Research Institutions :

(ix) AYUSH

(4) Total no. of beds :

(5) Status of authorisation :

(i) Total number of Occupiers applied for authorisation :

(ii) Total number of Occupiers granted authorisation :

(iii) Total number of application under consideration :

(iv) Total number of applications rejected :

(v) Total number of Occupiers in operation without applying for authorisation :
(6) Quantity of Bio-medical Waste Generation (in kg/day):

(please enclose District Wise Bio-medical Waste Generation as per Part-2)

(i) Bio-medical waste generation by bedded hospitals (in kg/day):

(ii) Bio-medical waste generation by non-bedded hospitals (in kg/day):

(iii) Any other:

Total: ______ Kg/day

(7) Bio-medical waste treatment and disposal

(a) By Captive bio-medical waste treatment and disposal by Health Care Facilities (please enclose details as per Part-3)

(i) Number of Health Care Facilities having captive treatment and Disposal facilities:

(ii) Total bio-medical waste treated and disposed by captive treatment facilities in kg/day:

(b) Bio-medical waste treatment and disposal by Common Bio Medical Waste Treatment Facilities (please enclose details as per Part 4)

(i) Number of Common Bio Medical Waste Treatment Facilities in Operation:

(ii) Number of Common Bio Medical Waste Treatment Facilities under construction:

(iii) Total bio-medical waste treated in kg/day:

(iv) Total treated bio-medical waste disposed through authorised recyclers (in Kg/day):

(8) Total no. of violation by:

(i) Health Care Facilities (bedded and non-bedded):

(ii) Common Bio Medical Waste Treatment Facilities:

(iii) Others (please specify):

(9) Show cause notices/directions issued to defaulters:

(i) Health Care Facilities (bedded and non-bedded):

(ii) Common Bio Medical Waste Treatment Facilities:

(iii) Others:

(10) Any other relevant information:

(i) Number of workshops / trainings conducted during the year:

(ii) Number of occupiers installed liquid waste treatment facility:
(iii) Number of captive incinerators complying to the norms:

(iv) Number of occupiers organised trainings:

(v) Number of occupiers constituted Bio-medical Waste Management Committees:

(vi) Number of occupiers submitted Annual Report for the previous calendar year:

(vii) Number of occupiers practising pre-treatment of lab microbiology and Bio-technology waste:

(viii) Number of Common Bio Medical Waste Treatment Facilities that have installed Continuous Online Emission Monitoring Systems

Part 2: District-wise Bio-medical Waste Generation (for the previous calendar year .......)

Part 4: Information on Common Bio-Medical Waste Treatment and Disposal Facilities (for the previous calendar year .......)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name of the State / Union Territory</th>
<th>Name of the District</th>
<th>Bio-medical Waste Generation (in Kg/day)</th>
<th>Existing Total bio-medical waste treatment capacity (both captive and CBMWTFL in kg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Equipment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Incinerator:</td>
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<td></td>
<td>Autoclave:</td>
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<td>Deep:</td>
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<td>Burial:</td>
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<td></td>
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<td>Any other:</td>
</tr>
</tbody>
</table>

Part 3: Information on Health Care Facilities having captive treatment facilities (for the previous calendar Year .......)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Name and address of the Health Care Facility</th>
<th>Quantity of Bio-medical Waste Generation (in kg/day)</th>
<th>Total Installed Treatment Capacity in kg/day</th>
<th>Total bio-medical waste treated and disposed by Health Care Facilities in kg/day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yellow</td>
<td>Red</td>
<td>Blue</td>
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</tbody>
</table>

previous calendar year .......
(a) Total Number of transportation vehicles used for collection of Bio-medical Waste on daily basis by the Common Bio-Medical Waste Treatment Facilities:

(b) List of Health Care Facilities not having membership with the Common Bio-Medical Waste Treatment Facilities and neither having captive treatment facilities:

(c) Number of trainings organised by the Common Bio-Medical Waste Treatment Facility operators:

(d) Number of Accidents reported by the Common Bio Medical Waste Treatment Facilities:".

[F. No. 3-1/2000-HSMD]

RITEESH KUMAR SINGH, Jt. Secy. Note: The principal rules were published in the Gazette of India, Extraordinary, PART II–Section 3–Sub-section (i), vide G.S.R. 343(E), dated the 28th March, 2016. Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064 and Published
FORM – V

Application for filing appeal against order passed by the prescribed 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 and Address..........................
References:

2. Biomedical waste (management and handling) Rules, 2018 published in Gazette of India, by Ministry of Environment, Forest and Climate change.

Biomedical Waste Management Manual

Published On 2018
A) Human Anatomical Waste: Human Tissue, Organ, Body Parts and Foetus below the Viability Period.

B) Animal Anatomical Waste: Experimental Animal Carcasses, Body Parts, Organs, Tissues, Including the Waste Generated From Animals Used In Experiments or Testing In Veterinary Hospitals or Colleges or Animal Houses.


E) Chemical Waste: Chemicals Used in Production Of Biological And Used Or Discarded Disinfectants.

F) Chemical Liquid Waste: Liquid Waste Generated Due To Use Of Chemicals In Production Of Biological And Used Or Discarded Disinfectant, Silver X-Ray Film Developing Liquid, Discarded Formularies, Infected Secretions, Aspirated Body Fluids, Liquid From Laboratories And Floor Washing Cleaning, House Keeping And Disinfecting Activities Etc. (SEPARATE COLLECTION SYSTEM LEADING TO EFFLUENT TREATMENT SYSTEM).

G) Discarded Linen, Mattresses, Beddings Contaminated With Blood Or Body Fluid, Routine mask and gown.

H) Microbiology, Biotechnology And Other Clinical Laboratory Waste: Blood Bags, Laboratory Cultures, Stocks Or Specimens of Micro-Organisms, Live Or Attenuated Vaccines, Human & Animal Cell Cultures Used In Research Industrial Laboratories, Production Of Biological, Residual Toxins, Dishes And Devices Used For Cultures. AFTER STERILISATION AS PER WHO GUIDELINES

RED BAG: Wastes Generated From Disposable Items Such As Tubing, Bottles, Intravenous Tubes And Sets, Catheters, Urine Bags, Syringes (Without Needles) And Vaccinators With Their Needles & Needle Gloves.

WHITE TRANSLUCENT CONTAINER: WHITE (TRANSLUCENT) (PUNCTURE, Leak Proof Container) Waste Sharps Including Metals: Needles, Syringes With Fixed Needles, Needles From Needles Tip, Cutter Or Burner, Scalpels, Blades, Or Any Other Contaminated Sharp Object That May Cause Puncture and Cuts. This Includes Used, Discarded And Contaminated Metal Sharps.

PUNCTURE PROOF & LEAK PROOF BOXES OR CONTAINER WITH BLUE COLORED MARKING: A) GLASSWARE: Broken Or Discarded And Contaminated Glass Including Medicine Vials and Ampoules Except Those Contaminated With Cytotoxic Wastes. B) METALLIC BODY IMPLANTS:

II YEAR MBBS STUDENTS - SKIT PLAY FOR AWARENESS ON BIOMEDICAL WASTE MANAGEMENT