

[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 28th March, 2016

G.S.R. 343(E).-Whereas the Bio-Medical Waste (Management and Handling) Rules, 1998 was published *vide* notification number S.O. 630 (E) dated the 20th July, 1998, by the Government of India in the erstwhile Ministry of Environment and Forests, provided a regulatory frame work for management of bio-medical waste generated in the country;

And whereas, to implement these rules more effectively and to improve the collection, segregation, processing, treatment and disposal of these bio-medical wastes in an environmentally sound management thereby, reducing the bio- medical waste generation and its impact on the environment, the Central Government reviewed the existing rules;

And whereas, in exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government published the draft rules in the Gazette *vide* number G.S.R. 450 (E), dated the 3rd June, 2015 inviting objections or suggestions from the public within sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And whereas, the copies of the Gazette containing the said draft rules were made available to the public on the 3rd June, 2015;

And whereas, the objections or comments received within the specified period from the public in respect of the said draft rules have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998, except as respects things done or omitted to be done before such suppression, the Central Government hereby makes the following rules, namely:-

1.Short title and commencement.- (1) these rules may be called the Bio-Medical Waste Management Rules, 2016.

(2)They shall come into force on the date of their publication in the Official Gazette.

2. Application.-

(1) These rules shall apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories, blood banks, ayush

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

hospitals, clinical establishments, research or educational institutions, health camps, medical or surgical camps, vaccination camps, blood donation camps, first aid rooms of schools, forensic laboratories and research labs.

(2). These rules shall not apply to,-

- (ii) radioactive wastes as covered under the provisions of the Atomic Energy Act, 1962(33 of 1962) and the rules made there under;
- (iii) hazardous chemicals covered under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 made under the Act;
- (iv) solid wastes covered under the [Solid Waste Management Rules, 2016](#) [substituted by G.S.R. 234 (E) dt.16.03.2018] made under the Act;
- (v) the lead acid batteries covered under the Batteries (Management and Handling) Rules, 2001 made under the Act;
- (vi) hazardous wastes covered under the [Hazardous and Other Wastes \(Management and Transboundary Movement\) Rules, 2016](#) [substituted by G.S.R. 234 (E) dt. 16.03.2018] made under the Act;
- (vii) waste covered under the [E-Waste \(Management\) Rules, 2016](#) [substituted by G.S.R. 234 (E) dt. 16.03.2018] made under the Act; and
- (viii) hazardous micro organisms, genetically engineered micro organisms and cells covered under the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Micro organisms or Cells Rules, 1989 made under the Act.

3. Definitions.- In these rules, unless the context otherwise requires, -

- (a) "Act" means the Environment (Protection) Act, 1986 (29 of 1986);
- (b) "animal house" means a place where animals are reared or kept for the purpose of experiments or testing;
- (c) "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;
- (d) "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;

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

- (e) "biological" 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;
- (f) "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;
- (g) "bio-medical waste treatment and disposal facility" means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal is carried out, and includes common bio-medical waste treatment facilities;
- (h) "Form" means the Form appended to these rules;
- (i) "handling" in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste;
- (j) "health care facility" means a place where diagnosis, treatment or immunisation of human beings or animals is provided irrespective of type and size of health treatment system, and research activity pertaining thereto;
- (k) "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;
- (l) "management" includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste;
- (m) "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;
- (n) "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;
- (o) "prescribed authority" means the State Pollution Control Board in respect of a State and Pollution Control Committees in respect of an Union territory;
- (p) "Schedule" means the Schedule appended to these rules.

4. Duties of the Occupier.- It shall be the duty of every occupier to-

- (a) take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules;
- (b) make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in Schedule I, to 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 in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I;
- (c) 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) (c), [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;](#)
[substituted by G.S.R. 234 (E) dt.16.03.2018]
- (d) [phase out use of chlorinated plastic bags \(excluding blood bags\) and gloves by the 27th March, 2019;](#) [substituted by G.S.R. 234 (E) dt. 16.03.2018]
Explanation.- For removal of doubts, it is hereby clarified that the expression “Chlorinated plastic bags” shall not include urine bags, effluent bags, abdominal bags and chest drainage bags. [inserted by G.S.R. 360(E) dt.10.05.2019]
- (e) dispose of solid waste other than bio-medical waste in accordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time;
- (f) not to give treated bio-medical waste with municipal solid waste;
- (g) 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;
- (h) 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, in the manner as prescribed in the National Immunisation Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time;
- (i) establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or [for the further treatment and disposal in accordance with the guidelines issued by the Central Pollution Control Board by 27th March, 2019;](#) [substituted by G.S.R. 234 (E) dt.16.03.2018]
- (j) 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;
- (k) ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

Control of Pollution) Act, 1974 (6 of 1974);

- (l) ensure occupational safety of all its health care workers and others involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments;
- (m) 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;
- (n) ,in case of all bedded health care units, maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I; [substituted by G.S.R. 129 (E) dt.19.02.2019]
- (o) report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical 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;
- (p) ,in case of all bedded health care facilities (any number of beds), make available the annual report on its web-site within a period of two years from the date of publication of Bio-Medical Waste Management (Amendment) Rules, 2018; [substituted by G.S.R. 129 (E) dt.19.02.2019]
- (q) 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;
- (r) 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 and the healthcare establishments having less than thirty beds shall designate a qualified person to review and monitor the activities relating to bio-medical waste management within that establishment and submit the annual report;
- (s) maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;
- (t) existing incinerators to achieve the standards for treatment and disposal of bio-medical waste as specified in Schedule II for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

5.Duties of the operator of a common bio-medical waste treatment and disposal facility.-It shall be the duty of every operator to -

- (a) 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;
- (b) ensure timely collection of bio-medical waste from the occupier as prescribed under these rules;

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

- (c) establish bar coding and global positioning system for handling of bio- medical waste [in accordance with the guidelines issued by the Central Pollution Control Board by 27th March, 2019](#); [substituted by G.S.R. 234 (E) dt.16.03.2018]
- (d) inform the prescribed authority immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with these rules;
- (e) 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;
- (f) assist the occupier in training conducted by them for bio-medical waste management;
- (g) 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;
- (h) ensure occupational safety of all its workers involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipment;
- (i) report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical 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;
- (i) 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;
- (k) allow occupier , who are giving waste for treatment to the operator, to see whether the treatment is carried out as per the rules;
- (l) shall display details of authorisation, treatment, annual report etc on its web-site;
- (m)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;
- (n) supply non-chlorinated plastic coloured bags to the occupier on chargeable basis, if required;
- (o) common bio-medical waste treatment facility shall ensure collection of biomedical waste on holidays also;
- (p) maintain all record for operation of incineration, hydroor autoclaving for a period of five years; and
- (q) 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.

6. Duties of authorities.-The Authority specified in column (2) of Schedule-III shall perform the

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

duties as specified in column (3) thereof in accordance with the provisions of these rules.

7. Treatment and disposal.- (1) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards provided in Schedule-II by the health care facilities and common bio-medical waste treatment facility.

(2) Occupier shall hand over segregated waste as per the Schedule-I to common bio-medical waste treatment facility for treatment, processing and final disposal:

Provided that the lab and highly infectious bio-medical waste generated shall be pre-treated by equipment like autoclave or microwave.

(3) No occupier shall establish on-site treatment and disposal facility, if a service of `common bio-medical waste treatment facility is available at a distance of seventy-five kilometer.

(4) In cases where service of the common bio-medical waste treatment facility is not available, the Occupiers shall set up requisite biomedical waste treatment equipment like incinerator, autoclave or microwave, shredder prior to commencement of its operation, as per the authorisation given by the prescribed authority.

(5) Any person including an occupier or operator of a common bio medical waste treatment facility, intending to use new technologies for treatment of bio medical waste other than those listed in Schedule I shall request the Central Government for laying down the standards or operating parameters.

(6) On receipt of a request referred to in sub-rule (5), the Central Government may determine the standards and operating parameters for new technology which may be published in Gazette by the Central Government.

(7) Every operator of common bio-medical waste treatment facility shall set up requisite biomedical waste treatment equipments like incinerator, autoclave or microwave, shredder and effluent treatment plant as a part of treatment, prior to commencement of its operation.

(8) Every occupier shall [phase out use of chlorinated plastic bags](#) [substituted by G.S.R. 234 (E) dt. 16.03.2018] within two years from the date of publication of these rules and after two years from such publication of these rules, the chlorinated plastic bags shall not be used for storing and transporting of bio-medical waste and the occupier or operator of a common bio-medical waste treatment facility shall not dispose of such plastics by incineration and the bags used for storing and transporting biomedical waste shall be in compliance with the Bureau of Indian Standards. Till the Standards are published, the carry bags shall be as [per the Plastic Waste Management Rules, 2016](#). [substituted by G.S.R. 234 (E) dt. 16.03.2018]

(9) 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 such recyclers having valid authorisation or registration from the respective prescribed authority.

(10) The Occupier or Operator of a common bio-medical waste treatment facility shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.

- (11) The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.

8. Segregation, packaging, transportation and storage.-(1) No untreated bio-medical waste shall be mixed with other wastes.

- (2) The bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with Schedule I prior to its storage, transportation, treatment and disposal.
- (3) The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV.
- (4) Bar code and global positioning system shall be added by the Occupier and common bio-medical waste treatment facility in one year time.
- (5) The operator of common bio-medical waste treatment facility shall transport the bio-medical waste from the premises of an occupier to any off-site bio-medical waste treatment facility only in the vehicles having label as provided in part 'A' of the Schedule IV along with necessary information as specified in part 'B' of the Schedule IV.
- (6) The vehicles used for transportation of bio-medical waste shall comply with the conditions if any stipulated by the State Pollution Control Board or Pollution Control Committee in addition to the requirement contained in the Motor Vehicles Act, 1988 (59 of 1988), if any or the rules made there under for transportation of such infectious waste.
- (7) Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty –eight hours:

Provided that in case for any reason it becomes necessary to store such waste beyond such a period, the occupier shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and inform the prescribed authority along with the reasons for doing so.

- (8) Microbiology waste and all other clinical laboratory waste shall be pre-treated by sterilisation to Log 6 or disinfection to Log 4, as per the World Health Organisation guidelines before packing and sending to the common bio-medical waste treatment facility.

9. Prescribed authority.-(1) The prescribed authority for implementation of the provisions of these rules shall be the State Pollution Control Boards in respect of States and Pollution Control Committees in respect of Union territories.

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

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

function under the supervision and control of the Ministry of Defence.

- (3) The prescribed authorities shall comply with the responsibilities as stipulated in Schedule III of these rules.

10. 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.

11. 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 bio-medical 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.

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

- (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.

12. 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) of rule 11, 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 non-governmental 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.

13. 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 Form IVA before](#)^[substituted by G.S.R. 234 (E)]

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

dt.16.03.2018] the 31st July 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.

14. 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.

15. 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 in accordance with rule 13 by the occupier.

16. 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.

17. 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.

18. 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.

SCHEDULE I

[See rules 3 (e), 4(b), 7(1), 7(2), 7(5), 7 (6) and 8(2)]

Part-1

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

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	(a) Human Anatomical Waste: Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*
	(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.		
	(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.		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery
	(d) Expired or	Yellow coloured	Expired cytotoxic drugs and items

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

	<p>Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.</p>	non-chlorinated plastic bags or containers	<p>contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 °C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200°C Or Encapsulation or Plasma Pyrolysis at >1200°C.</p> <p>All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.</p>
	<p>(e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.</p>	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	<p>(f) 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.</p>	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule- III.
	<p>(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid, routine mask and gown [inserted by G.S.R. 234 (E) dt.16.03.2018]</p>	Non-chlorinated yellow plastic bags or suitable packing material	<p>Non- chlorinated chemical disinfection followed by incineration or Plazma Pyrolysis or for energy recovery.</p> <p>In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plazma Pyrolysis.</p>
	<p>(h) 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</p>	<p>Autoclave or Microwave or Hydroclave safe plastic bags or containers</p> <p>[substituted by G.S.R. 234 (E) dt.16.03.2018]</p>	<p>Pre-treat to sterilize with non-chlorinated chemicals on-site as per World Health Organisation guidelines on Safe management of wastes from health care activities and WHO Blue Book, 2014 and thereafter sent for incineration.</p> <p>[substituted by G.S.R. 234 (E) dt.16.03.2018]</p>

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

	cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.		
Red	Contaminated Waste (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and <i>fixed needle syringes</i>) and vacutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	Waste sharps including Metals: 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	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control 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.	(a) Puncture proof and leak proof boxes or containers with blue colored marking [substituted by G.S.R. 234 (E) dt.16.03.2018]	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.
	(b) Metallic Body Implants	(b) Puncture proof and leak proof boxes or containers with blue colored marking [substituted by G.S.R. 234 (E) dt.16.03.2018]	

***Disposal by deep burial is permitted only in rural or remote areas where there is no access to common bio-medical waste treatment facility. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in [Schedule-II](#) [substituted by G.S.R. 234 (E) dt.16.03.2018]. The deep burial facility shall be located as per the provisions and guidelines issued by Central Pollution Control Board from time to time.**

Part -2

- (1) All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.
- (2) Chemical treatment using at least **1% to 2%** [substituted by G.S.R. 234 (E) dt.16.03.2018] Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log₁₀4 reduction efficiency for microorganisms as given in Schedule- III.
- (3) Mutilation or shredding must be to an extent to prevent unauthorized reuse.
- (4) There will be no chemical pretreatment before incineration, except for microbiological, lab and highly infectious waste.
- (5) Incineration ash (ash from incineration of any bio-medical waste) shall be disposed through hazardous waste treatment, storage and disposal facility, if toxic or hazardous constituents are present beyond the prescribed limits as given in the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008 or as revised from time to time.
- (6) Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.
- (7) Cytotoxic drug vials shall not be handed over to unauthorised person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature >1200 °C.
- (8) Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
- (9) On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organisation or National AIDS Control Organisation and then given to the common bio-medical waste treatment and disposal facility.
- (10) Installation of in-house incinerator is not allowed. However in case there is no common biomedical facility nearby, the same may be installed by the occupier after taking authorisation from the State Pollution Control Board.

- (11) Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage. Wherever the occupier is not linked to a disposal facility it shall be the responsibility of the occupier to sterilize and dispose in the manner prescribed.
- (12) Bio-medical waste generated in households during healthcare activities shall be segregated as per these rules and handed over in separate bags or containers to municipal waste collectors. Urban Local Bodies shall have tie up with the common bio-medical waste treatment and disposal facility to pickup this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal in the manner as prescribed in this Schedule.

SCHEDULE II

[See rule 4(t), 7(1) and 7(6)]

STANDARDS FOR TREATMENT AND DISPOSAL OF BIO-MEDICAL WASTES

1. STANDARDS FOR INCINERATION.-

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 a minimum of 800 °C and the secondary chamber shall be minimum of 1050°C + or - 50°C.

4). The secondary chamber gas residence time shall be at least two seconds.

B. Emission Standards

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

Sl. No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting concentration in mg/Nm^3 <small>[substituted by G.S.R. 234 (E) dt.16.03.2018]</small> unless stated	Sampling Duration in minutes, unless stated
1.	Particulate matter	50	30 or 1Nm^3 of sample volume, whichever is more
2.	Nitrogen Oxides NO and NO ₂ expressed as NO ₂	400	30 for online sampling or grab sample
3.	HCl	50	30 or 1Nm^3 of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1 ng TEQ/ Nm^3 (at 11% O ₂)	8 hours or 5Nm^3 of sample volume, whichever is more
5.	Hg and its compounds	0.05	2 hours or 1Nm^3 of sample volume, whichever is more

C.Stack Height: Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities as per requirement of monitoring of ‘general parameters’ as notified under the Environment (Protection) Act, 1986 and in accordance with the Central Pollution Control Board Guidelines of Emission Regulation Part-III.

Note:

- (a) The existing incinerators shall comply with the above within a period of two years from the date of the notification.
- (b) The existing incinerators shall comply with the standards for Dioxins and Furans of 0.1 ng TEQ/ Nm^3 , as given below within two years from the date of commencement of these rules.
- (c) All upcoming common bio-medical waste treatment facilities having incineration facility or captive incinerator shall comply with standards for Dioxins and Furans.
- (d) The existing secondary combustion chambers of the incinerator and the pollution control devices shall be suitably retrofitted, if necessary, to achieve the emission limits.
- (e) Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- (f) Ash from incineration of biomedical waste shall be disposed of at common hazardous waste treatment and disposal facility. However, it may be disposed of in municipal landfill, if the toxic metals in incineration ash are within the regulatory quantities as defined under the Hazardous Waste (Management and Handling and Transboundary Movement) Rules, 2008 as amended from time to time.
- (g) Only low Sulphur fuel like Light Diesel Oil or Low Sulphur Heavy Stock or Diesel, Compressed Natural Gas, Liquefied Natural Gas or Liquefied Petroleum Gas shall be used as fuel in the incinerator.

- (h) The occupier or operator of a common bio-medical waste treatment facility shall monitor the stack gaseous emissions (under optimum capacity of the incinerator) once in three months through a laboratory approved under the Environment (Protection) Act, 1986 and record of such analysis results shall be maintained and submitted to the prescribed authority. In case of dioxins and furans, monitoring should be done once in a year.
- (i) The occupier or operator of the common bio-medical waste treatment facility shall install continuous emission monitoring system for the parameters as stipulated by State Pollution Control Board or Pollution Control Committees in authorisation and transmit the data real time to the servers at State Pollution Control Board or Pollution Control Committees and Central Pollution Control Board.
- (j) All monitored values shall be corrected to 11% Oxygen on dry basis.
- (k) Incinerators (combustion chambers) shall be operated with such temperature, retention time and turbulence, as to achieve Total Organic Carbon content in the slag and bottom ashes less than 3% or their loss on ignition shall be less than 5% of the dry weight.
- (l) The occupier or operator of a common bio-medical waste incinerator shall use combustion gas analyzer to measure CO₂, CO and O₂.

2. **Operating and Emission Standards for Disposal by Plasma Pyrolysis or Gasification:**

A. **Operating Standards:**

All the operators of the Plasma Pyrolysis or Gasification shall meet the following operating and emission standards:

- 1) Combustion Efficiency (CE) shall be at least 99.99%.
- 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 combustion chamber after plasma gasification shall be 1050 ± 50 °C with gas residence time of at least 2(two) second, with minimum 3 % Oxygen in the stack gas.
- 4) The Stack height should be minimum of 30 m above ground level and shall be attached with the necessary monitoring facilities as per requirement of monitoring of 'general parameters' as notified under the Environment (Protection) Act, 1986 and in accordance with the CPCB Guidelines of Emission Regulation Part-III.

B. **Air Emission Standards and Air Pollution Control Measures**

- (i) Emission standards for incinerator, notified at SI No.1 above in this Schedule, and revised from time to time, shall be applicable for the Plasma Pyrolysis or Gasification also.

- (ii) Suitably designed air pollution control devices shall be installed or retrofitted with the 'Plasma Pyrolysis or Gasification to achieve the above emission limits, if necessary.
- (iii) Wastes to be treated using Plasma Pyrolysis or Gasification shall not be chemically treated with any chlorinated disinfectants and chlorinated plastics shall not be treated in the system.

C. Disposal of Ash Vitrified Material: The ash or vitrified material generated from the 'Plasma Pyrolysis or Gasification shall be disposed off in accordance with the Hazardous Waste (Management, Handling and Transboundary Movement) Rules 2008 and revisions made thereafter in case the constituents exceed the limits prescribed under Schedule II of the said Rules or else in accordance with the provisions of the Environment (Protection) Act, 1986, whichever is applicable.

3. STANDARDS FOR AUTOCLAVING OF BIO-MEDICAL WASTE.-

The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste.

- (1) 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.
- (2) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of three pre-vacuum pulse to purge the autoclave of all air. The air removed during the pre-vacuum, cycle should be decontaminated by means of HEPA and activated carbon filtration, steam treatment, or any other method to prevent release of pathogen. 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;
- (3) Medical waste shall not be considered as 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.

(4)**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.

(5)**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 center of three containers with the waste. Personal protective equipment (gloves, face mask and coveralls) shall be used when opening containers for the purpose of placing the biological indicators. At least one of the containers with a biological indicator should be placed in the most difficult location for steam to penetrate, generally the bottom center of the waste pile. The occupier or operator shall conduct this test three consecutive times to define the minimum operating conditions. The temperature, pressure and residence time at which all biological indicator vials or strips for three consecutive tests show complete inactivation of the spores shall define the minimum operating conditions for the autoclave. After determining the minimum temperature, pressure and residence time, the 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.

(6)**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. It may be necessary to use more than one strip over the waste package at different locations to ensure that the inner content of the package has been adequately autoclaved. The occupier or operator of a common bio medical waste treatment facility shall conduct this test during autoclaving of each batch and records in this regard shall be maintained.

(7)**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 *Geobacillusstearothermophilus* spores using vials or spore Strips; with at least 1×10^6 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 bio medical waste treatment and disposal facility shall conduct this test at least once in every week and records in this regard shall be maintained.

4. **STANDARDS OF MICROWAVING.-**

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

(2) The microwave system shall comply with the efficacy test or 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 are ensured by approved biological indicator at the maximum design capacity of each microwave unit. Biological indicators for microwave shall be *Bacillus atrophaeus* spores using vials or spore strips with at least 1×10^4 spores per detachable strip. The biological indicator shall be placed with waste and exposed to same conditions as the waste during a normal treatment cycle.

5. **STANDARDS FOR DEEP BURIAL.-** (1) A pit or trench should be dug about two 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 or 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 located so as to ensure that no contamination occurs to surface water or ground water. The area should not be prone to flooding or erosion.

(7) The location of the deep burial site shall be authorised by the prescribed authority.

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

(9) The ground water table level should be a minimum of six meters below the lower level of deep burial pit.

6. 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.

7. STANDARDS FOR DRY HEAT STERILIZATION

Waste sharps can be treated by dry heat sterilization at a temperature not less than 185°C, at least for a residence period of 150 minutes in each cycle, which sterilization period of 90 minutes. There should be automatic recording system to monitor operating parameters.

(i) Validation test for Sharps sterilization unit

Waste sharps sterilization unit should completely and consistently kill the biological indicator *Geobacillus Stearothermophilus* or *Bacillus Atropheauspoers* using vials with at least log₁₀ 6 spores per ml. The test shall be carried out once in three months

(ii) Routine test

BIO-MEDICAL WASTE MANAGEMENT RULES, 2016 as amended till 2019

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. It may be necessary to use more than one strip over the waste to ensure that the inner content of the sharps has been adequately disinfected. This test shall be performed once in week and records in this regard shall be maintained.

8.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-

PARAMETERS	PERMISSIBLE LIMITS
pH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l

Note— Bio-assay test 90% survival of fish after 96 hours in 100% effluent.

- 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 comply with the output discharge standard for liquid waste by 31st December, 2019. [substituted by G.S.R. 129(E) dt.19.02.2019]
- 4.Non-bedded occupiers shall dispose infectious liquid wastes only after treatment by disinfection as per Schedule – II (6) of the principal rules. [inserted by G.S.R. 234 (E) dt. 16.03.2018]

(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.