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BMW RULES AND REGULATIONS

BIO-MEDICAL WASTE MANANGEMENT **RULES**

NOTE ;PLEASE FOCUS ON RED COLOURED LINES

**[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 THAT IS 28TH MARCH 2016.

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**

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,-

(a) radioactive wastes as covered under the provisions of the Atomic Energy Act, 1962(33 of 1962) and the rules made there under;

(b) hazardous chemicals covered under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 made under the Act;

(c) solid wastes covered under the Municipal Solid Waste (Management and Handling) Rules, 2000 made under the Act;

(d) the lead acid batteries covered under the Batteries (Management and Handling) Rules, 2001 made under the Act;

(e) hazardous wastes covered under the Hazardous Wastes (Management, Handling and

Transboundary Movement) Rules, 2008 made under the Act;

(f) waste covered under the e-Waste (Management and Handling) Rules, 2011 made under the Act; and

(g) 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;

(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) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;

(d) phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of these rules;

(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 place for any purpose within one year from the date of the notification of these rules;

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

(l) 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;

(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) 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;

(o) 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;

(p) make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of these rules;

(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;

(c) establish bar coding and global positioning system for handling of bio- medical waste within one year;

(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 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;

(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 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 biomedical 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

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(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

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(8) Every occupier shall phase out use of non-chlorinated plastic bags 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, 2011.

(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 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

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(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*

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(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 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 advise 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 organization.

(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.

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 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.

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 on or before 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 : **YELLOW**

Type of Waste

(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).

(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.

**(d) Expired or
Discarded Medicines:**

Pharmaceutical waste
like antibiotics,
cytotoxic drugs
including all items
contaminated with
cytotoxic drugs along
with glass or plastic
ampoules, vials etc.

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(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 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.

(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.

**(h) Microbiology,
Biotechnology and
other clinical
laboratory waste:**

Blood bags, Laboratory cultures, stocks or specimens of microorganisms, 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.

CATEGORY: **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 *fixed needle syringes*) and vaccutainers with their needles cut) and gloves.

CATEGORY: **WHITE**

**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

CATEGORY: **BLUE**

(a) Glassware:

Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.

(b) Metallic Body Implants

***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-III. 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 10% 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 IV

[See rule 8(3) and (5)]

Part A

**LABEL FOR BIO-MEDICAL WASTE
CONTAINERS or BAGS**

CYTOTOXIC HAZARD SYMBOL

HANDLE WITH CARE HANDLE WITH CARE

Part B

**LABEL FOR TRANSPORTING BIO-MEDICAL
WASTE BAGS OR CONTAINERS**

DayMonth

Year

Date of generation

Waste category Number

Waste quantity.....

Sender's Name and Address Receiver's Name and
Address:

Phone Number Phone Number

Fax Number..... Fax Number

Contact Person Contact Person

In case of emergency please contact :

Name and Address :

Phone No.

Note :Label shall be non-washable and prominently
visible.

FORM – I

[(See rule 4(o), 5(i) and 15 (2))]

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 you facility has an Emergency Control policy? If yes give details:

Date : Signature

Place: Designation.....

FORM - II
(See rule10)

**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:_____

(pl. attach map a map with GPS locations of CBMWTF
and area of coverage)

(viii) Quantity of Biomedical waste handled, treated or
disposed:

Category	Type of Waste	Quantity Generated or Collected, kg/day	Method of treatment and disposal
----------	---------------	---	--

(1)

(2)

(3)

(4)

Yellow

(a) Human Anatomical Waste:

(b)Animal Anatomical Waste :

(c) Soiled Waste:

(d) Expired or Discarded Medicines:

(e) Chemical Solid Waste:

(f) Chemical Liquid Waste :

(g) Discarded linen, mattresses, beddings
contaminated with blood or body fluid.

(h) Microbiology, Biotechnology and other
clinical laboratory waste:

Red Contaminated Waste (Recyclable)

White
(Translucent) Waste sharps including Metals:

Blue Glassware:
Metallic Body Implants

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)

No of units	Capacity of each unit
-------------	-----------------------

Incinerators :

Plasma Pyrolysis:

Autoclaves:

Microwave:

Hydroclave:

Shredder:

Needle tip cutter or
destroyer

Sharps encapsulation or

concrete pit:
Deep burial pits:
Chemical disinfection:
Any other treatment
equipment:

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 authorization

9. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in Relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date : Signature of the Applicant

Place : Designation of the Applicant

FORM –III

(See rule 10)

AUTHORISATION

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

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

2. M/s _____ an occupier or operator of the facility located at _____ is hereby granted an authorisation for;

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. M/s _____ is hereby
authorized for handling of biomedical waste
as per the capacity given below;

- (i) Number of beds of HCF:
- (ii) Number healthcare facilities covered by CBMWTF:

(iii) Installed treatment and disposal capacity: _____
Kg per day

(iv) Area or distance covered by
CBMWTF: _____

(v) Quantity of Biomedical waste handled, treated or
disposed:

Type of Waste Category	Quantity permitted for Handling
------------------------	------------------------------------

Yellow

Red

White (Translucent)

Blue

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

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

Date Signature.....

Place: Designation

Terms and conditions of authorisation *

1. The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.

2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.

3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.

4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.

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

facility and such other terms and conditions may be stipulated by the prescribed authority.

Form - IV

(See rule 13)

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)]

Particulars:

1 . Particulars of the Occupier :

(i) Name of the authorised person (occupier or operator of facility):

(ii) Name of HCF or CBMWTF :

(iii) Address for Correspondence :

(iv) Address of Facility:

(v) Tel. No, Fax. No :

(vi) E-mail ID :

(vii) URL of Website

(viii) GPS coordinates of HCF or CBMWTF

(ix) Ownership of HCF or CBMWTF : (State Government or Private or Semi Govt. or any other)

(x). Status of Authorisation under the Bio-Medical Waste (Management and Handling) Rules;

: Authorisation No.:

.....
.....valid up to

(xi). Status of Consents under Water Act and Air Act:

Valid up to:

2. Type of Health Care Facility :

(i) Bedded Hospital : No. of Beds:.....

(ii) Non-bedded hospital

(Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other):

(iii) License number and its date of expiry:

3. Details of CBMWTF :

(i) Number healthcare facilities covered by CBMWTF:

(ii) No of beds covered by CBMWTF :

(iii) Installed treatment and disposal capacity of
CBMWTF:

_____ Kg per day

(iv) Quantity of biomedical waste treated or disposed
by CBMWTF

_____ Kg/day

4. Quantity of waste generated or disposed in Kg per
annum (on monthly average basis):

Yellow Category :

Red Category :

White:

Blue Category :

General Solid waste:

5 Details of the Storage, treatment, transportation,
processing and Disposal Facility:

(i) Details of the on-site storage facility:

Size :

Capacity :

Provision of on-site storage : (cold storage or any other provision)

(ii) Details of the treatment or :

disposal facilities	no,of units	capa city kg/d	quantity treated or disposed kg/anum
Incenarators			
Plasma Pyrolysis			
Autoclaves			
Microwave			
Hydroclave			
Shredder			
Needle tip cutter or destroyer			
Sharps encapsulation or concrete pit			
Deep burial pits:			
Chemical disinfection:			
Any other treatment equipment:			

(iii) Quantity of recyclable wastes sold to authorized 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 Bio-Medical 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

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

.....

Name and Signature of the Head of the Institution

Date:

Place

FORM –V
APPEAL

(See rule 16)

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.....

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

(Bishwanath Sinha)

Joint secretary to the Government of India

Health Care Waste Management

Introduction

Wastes generated from health care facilities are varied in nature, ranging from ordinary organic waste to highly hazardous liquid and solid waste. The waste thus generated is a potential health and environmental hazard, and if not properly managed can pose a serious health risk to health care providers, patients, and the general public. Therefore, institutionalizing effective waste management systems is introduced.

The details of the Bio Medical Waste (Management & Handling) Rules are available on the website of Ministry of Environment & Forest, Government of India www.envfor.nic.in at following web link <http://www.envfor.nic.in/legis/hsm/biomed.html> **Authorization (Legal Aspect)**

In compliance with Bio-medical waste (Management & Handling) Rules 1998, the health care facilities are required to obtain authorization / renewal of authorization certificate from state pollution control board. Obtaining authorization from RPCB is necessary for all health care facilities with registered patient (OPD & IPD) in excess of 1000 per calendar month. However, implementation of HCWM system is recommended at all health care establishments. The formats of authorization application and affidavit are as following:

- [Formats of Authorization Application for 50 and more than 50 bedded hospitals](#)
- [Formats of Authorization Application for 30 to 49 bedded hospitals](#)
- [Formats of Authorization Application for PHCs and Dispensaries](#)

FORM - I

APPLICATION FOR AUTHORISATION / RENEWAL OF AUTHORISATION

(To be submitted in duplicate)

To,

The Regional Officer

Rajasthan Pollution Control Board

1. Particulars of Applicant

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

(ii) Name of the Institution -----
Address: -----

Telephone & Fax No. -----

2. Activity of which Authorisation is sought :

(i) Generation

(ii) Collection

(iii) Reception

(iv) Storage

(v) Transportation

(vi) Treatment

(vii) Disposal

(viii) Any other form of handling

3. Please State whether applying for fresh authorisation or for renewal
(In case of renewal previous authorisation number and date)

4. (i) Address of the institution handling bio-medical wastes:

(ii) Address of the place of the treatment facility:

(iii) Address of the place of disposal of the waste:

5. (i) Mode of transportation (in any) of bio-medical waste:

(ii) Mode (S) of treatment:

6. Brief description of method of treatment and disposal

(i) Yellow Bag : -----

(ii) Red Bag : -----

(iii) Black Bag : -----

(iv) Blue Bag / PPTC : -----

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

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

8. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date:

Place:

Signature of Hospital In-charge

Name in Capital Letters

(Hospital Seal)

Fee for authorization under BMW Rules

(Demand Draft is to be made in favor of "Member Secretary, RPCB")

S. No.	Applicant	Amount in Rs.
1.	Clinics, pathological laboratories and blood banks	1000.00 Per Year
2.	Veterinary institutions, dispensaries and animal houses	1000.00 Per Year
3.	Hospitals, Nursing Homes and Health Care establishments	1000.00 Per Year up to 4 beds. Additional Rs. 100 per bed per year from fifth bed onwards
4.	Operator of the facility of Bio-Medical Waste (excluding transportation)	10000.00 Per Year
5.	Transporter of Bio-Medical Waste	7500.00 Per Year

Note: The Authorization Fee is likely to be revised from time to time

THANK YOU

DR MANJU RATHI

MBBS.MD.LL.B LL.M