AGREEMENT

Bio-Medical Waste Management Rules, 2016, the result of the review of the Bio-Medical Waste (Management and Handling) Rules, 1998 by the Ministry of Environment and Forests, Government of India provides a regulatory frame work for management of bio-medical waste generated in the country, for effective implementation of the rules 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 copies of the Gazette containing the said draft rules were made available to the public on the 3rd June, 2015 and 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;

day o	of the year	at		
	(hereinafter calle	ed as opera	itor with its	Registered
represented	by		Authorized	Signatory,
	-			
	represented	(hereinafter calle	(hereinafter called as opero	day of the year at (hereinafter called as operator with its _ represented by Authorized

Senior Medical Officer, I/c_____ hospital, (hereinafter referred to as the Occupier) represented by Dr._____

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

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

Whereas *operator* has setup a common facility at ______for collection, reception, storage, transportation, treatment and disposal of Bio-Medical Wastes (hereinafter called as BMW) generated by the Health Care Establishment (HCES- Hospitals, Nursing Homes, Clinics, Diagnostic Centres)

Whereas **operator** offers to provide services to the **Occupier** on a User Pay principle for collection, transportation, treatment and disposal of BMW at following rate.

 Functional Bed_____
 Average BOR _____

Total Accountable Bed ______ Rate per day per bed______

Whereas *operator* undertakes the liability of collection, transportation, treatment and disposal of BMW, the *Occupier* shall undertake to adhere to this contract of service by *operator* for a period of one year which can be extended upto 5 years on the mutual agreement basis for the period from June 2016 to May 2021. Admission of subsequent increase of 2.5% on rates as fixed in year 2013 for the years 2016-17 and 2017-18 are accepted by both the parties. Either of parties could terminate the agreement after giving a notice of minimum three months to other party. Further rates may be reviewed in May 2018 for the next following years

Whereas the *Occupier* is a Hospital and agrees to avail the services being provided by *operator* with terms and conditions as listed on succeeding paras.

Now, the parties agree on the following terms and conditions the process of which as under:

(A) Duties of the Occupier. - It shall be the duty of every occupier to-

i) 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;

ii) 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;

iii) 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;

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

v) 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;

vi) Not to give treated bio-medical waste with municipal solid waste;

vii) 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;

viii) 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;

ix) 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;

x) 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;

xi) Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);

xii) 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;

xiii) 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;

xiv) 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;

xv) 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;

xvi) 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;

xvii) 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;

xviii) 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;

xix) Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;

xx) 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.

xxi) All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.

xxii) 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.

xxiii) Mutilation or shredding must be to an extent to prevent unauthorized reuse.

xxiv) There will be no chemical pre-treatment before incineration, except for microbiological, lab and highly infectious waste.

xxv) 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.

xxvi) Dead Foetus 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.

xxvii) 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 0C.

xxviii) 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.

xxix) 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.

xxx) 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.

xxxi) 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.

xxxii) 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.

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 foetus 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. 	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial
	(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 Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired cytotoxic drugs and items 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 >1200ºC.
		All other discarded medicines shall be either sent back to manufacturer or disposed by incineration
(e) Chemical Waste: Chemicals used in production of biological and used of discarded disinfectants	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.
(f0 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.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre- treated before mixing with other waste water. The combined discharge shall conform to the discharge norms given in Schedule-III
(g) Discarded linen, mattresses , beddings contaminated with blood or body fluid	Non- chlorinated yellow plastic bags or suitable packing material	Non-chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery.
		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 Plasma Pyrolysis.
(h) Microbiology, Biotechnology and other clinical laboratory waste: Blood bags,	Autoclave safe plastic bags or	Pre-treat to sterilize with non-

	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.	containers	chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration
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.	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro- waving/hydroclavin g 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.
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	should not be sent to landfill sites. 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. (b) Metallic Body Implants 	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

Disposal by deep burial is permitted only in rural or remote areas where there is no access to common biomedical 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.

(B). Duties of the operator of a common bio-medical waste treatment and disposal facility. -

It shall be the duty of every operator to-

- 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;
- 2. Ensure timely collection of bio-medical waste from the occupier as prescribed under these rules;
- 3. Establish bar coding and global positioning system for handling of bio- medical waste within one year;
- 4. Inform the prescribed authority immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with these rules;
- 5. 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;
- 6. Assist the occupier in training conducted by them for bio-medical waste management;
- 7. Undertake appropriate medical examination at the time of induction and at least once in a year and immunize 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;
- 8. Ensure occupational safety of all its workers involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipment;

- 9. 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;
- 10.Maintain a log book for each of its treatment equipment according to weight of the batch; categories of waste treated; time, date and duration of the treatment cycle and total hours of operation;
- 11.Allow occupier, who is giving waste for treatment to the operator, to see whether the treatment is carried out as per the rules;
- 12. Shall display details of authorization, treatment, annual report etc on its website;
- 13.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 authorization or registration from the respective State Pollution Control Board or Pollution Control Committee;
- 14.Further, it is informed that cost of plastic bags will be Rs.6.00 per bag to be paid by the concerned health institutions extra till the tender for the same is issued to a dedicated firm for PHSC institutions;
- 15.Common bio-medical waste treatment facility shall ensure collection of biomedical waste on holidays also;
- 16. Maintain all record for operation of incineration, hydro or autoclaving for a period of five years; and
- 17.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.

(III). Treatment and disposal.-

(1) Biomedical 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 kilometre.

(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 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.

(IV). 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 labelled 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.

(V).Terms and conditions

(a) 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.

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

(b) 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.

(c) 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

(d) STANDARDS FOR TREATMENT AND DISPOSAL OF BIO-MEDICAL WASTES

1. STANDARDS FOR INCINERATION.-

- A. Operating Standards
- 1). Combustion efficiency (CE) shall be at least 99.00%.

2). The temperature of the primary chamber shall be a minimum of 800 0C and the secondary chamber shall be minimum of 1050 0C + or - 50 0C.

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

B. Emission Standards

S.No.	Parameter	Standards	
(1)	(2)	(3)	(4)
		Limiting	Sampling Duration in
		concentration in mg	minutes, unless stated
		Nm ³ unless stated	
1	Particulate matter	50	30 or INM ³ of sample
			volume, whichever is
			more
2	Nitrogen Oxides NO and	400	30 for online sampling
	NO2 expressed as NO		or grab sample
3	HCI	50	30 or INM ³ of sample
			volume, whichever is
			more
4	Total Dioxins and Furans	0.IngTEQ/ Nm ³ (at	8 hours or 5NM ³ of
		11%O2)	sample volume,
			whichever is more
5	Hg and its compounds	0.05	2 hours or INM 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.

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 prevacuum pulses 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 Geobacillus stearothermophilus spores using vials or spore Strips; with at least 1X106 spores. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30

minutes, a temperature less than 1210 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 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
рН	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l

Bio-assay tests 90% survival of fish after 96 hours in 100% effluent.

(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

Other STANDARDS OF MICROWAVING, STANDARDS FOR DEEP BURIAL, STANDARDS FOR EFFICACY OF CHEMICAL DISINFECTION, STANDARDS FOR DRY HEAT STERILIZATION to be followed as per the STANDARDS FOR TREATMENT AND DISPOSAL OF BIO-MEDICALWASTES under schedule II of the BWM rules 2016

5. **Operator** shall meet all the rules and regulations stipulated by the Punjab Pollution control Board, Patiala and the **occupier** shall not be liable for improper handling and management of BMW.

- 6. The rates approved upon by PHSC and **occupier** are subject to respective hospital's previous year's BOR.
- 7. The concerned Deputy Medical Commissioner shall make all efforts to pay the monthly bill of service provider within 15 days and this payment will be made through RTGS after getting required certificate of satisfaction from the concerned SMOs.
- 8. At no point of time **Operator** shall stop collecting Bio-medical waste from **occupier** in case of delay of payment but would report the matter to the Deputy Medical commissioner and to the Managing Director, PHSC.
- 9. The mandatory provisions of Income Tax for deducting tax at source shall apply.
- 10. **Operator** shall indemnify all costs, expenses, damages etc. in relation to handling /mishandling /omission to handle the bio-medical waste

- 11. **Operator's** failure to collect & transport the bio-medical waste as per provisions of Bio-Medical Waste Management Rules, 2016, within 48 hours, then the **occupier** will inform the **Operator** and entail liquidated damages of Rs.5000/- per incident after giving the opportunity to the **Operator** for failure to collect Bio-Medical Waste. If DMC is not satisfied with the explanation given by the **Operator** only then the liquidated damages will be imposed in addition to the payment for days of absence should be deducted provided the Service provider will have to collect and transport the Bio-Medical Waste within next 24 hours otherwise this will be informed to the State Pollution Control Board.
- 12. All disputes, differences, claim etc. relating to / arising from or out of the agreement shall be subject to the exclusive arbitration of the Managing Director of the Punjab Health Systems Corporation or his nominee, whose decision shall be final and binding on the parties. Such proceedings will be held under the provisions of Indian Arbitration and Conciliation Act, 1996 and for the purpose only Chandigarh/Ajitgarh Courts would have the jurisdiction.
- 13. The courts except at Chandigarh/Ajitgarh will have no jurisdiction to entertain any matter relating to / arising from and out of the agreement.
- 14. In the event of persistent default (exceeding three times in a month) the corporation will have the option to terminate the contract, in addition to and without prejudice to the imposition of liquidated damages. The decision to terminate the contract will be within the sole discretion of the Managing Director of the Corporation and the same will be arrived at after hearing the view point of SP. The said decision will be final and shall not be called in question in any court on any ground whatsoever.

SERVICE PROVIDER	GENERATOR
Witnesses:-	
1. Name:	2. Name:
Address:	Address:
Signature:	Signature:

ANNEXURE

SCHEDULE IV

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

Part A LABEL FOR BIO-MEDICAL WASTE CONTAINERS or BAGS

BIOHAZARD SYMBOL CYTOTOXIC HAZARD SYMBOL

Part B LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

Day.....Month..... Year.... Date of generation.....

Waste category Number...... Waste quantity.... Sender's Name and Address Phone Number..... Fax Number.... Contact Person....

Receiver's Name and Address: Phone Number..... Fax Number..... Contact person.....

In case of emergency please contact: Name and Address: Phone No. Note: Label shall be non-washable and prominently visible.

FORM – 1 [(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 of 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 -11

(See rule 10)

APPLICATION FOR AUTHORIZATION OR RENEWAL OF AUTHORIZATION

(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:
 - ii. (In block letters & in full)
 - iii. Name of the health care facility (HCF) or common bio-medical waste treatment facility(CBWTF)
 - iv. Address for correspondence:
 - v. Tele No., Fax No.:
 - vi. Email:
- vii. Website Address:
- 2. Activity for which authorization is sought

ActivityPlease tickGeneration, segregationCollectionCollectionStoragePackingPackingReceptionTransportationTreatment or processing or conversionRecyclingDisposal of destructionUseOffering for sale, transferAny other form of handling

- 3. Application for fresh or renewal of authorization (please tick whatever is applicable)
- (i) Applied for CTO/CTE Yes/No
- (ii) In case of renewal previous authorization 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 (CBWTFF)

(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 location of CBMWTF and area of coverage)

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

Category	Type of waste	Quantity Generated or Collected, Kg/day	Method of Treatment and Disposal (Refer Schedule-1)
(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	Waste sharps including Metals:		
(Translucent)			
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 fulfil any conditions stipulated by the prescribed authority.

Date	Signature of the Applicant
Place	Designation of the Applicant

FORM -- III (See rule 10) AUTHORISATION

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

- i. File number of authorization and date of issue.....
- ii. M/s.....an occupier or operator of the facility located at.....is hereby granted an authorization for ;

Activity

Please tick

Generation, segregation

Collection

Storage

Packing

Reception

Transportation

Treatment or processing or conversion

Recycling

Disposal of destruction

Use

Offering for sale, transfer

Any other form of handling

- 1. M/sis 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 CBWTF:-----
 - iii. Installed treatment and disposal capacity:-----Kg per day
 - iv. Area or distance covered by CBWTF:-----
 - v. Quantity of Biomedical waste handled, treated or disposed

Type of Waste CategoryQuantity permitted by HandlingYellowRedWhite (Translucent)Blue

- 2. This authorization shall be in force for a period ofYears from the date of issue.
- 3. This authorization is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being under the Environment(Protection) Act, 1986

Date	Signature
Place	Designation

Terms and conditions of authorization*

- 1. The authorization shall comply with the provisions of the Environment(Protection) Act, 1986 and the rules made there under
- 2. The authorization or its renewal shall be produced for inspection at the request of an officer authorized by the prescribed authority.
- 3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
- 4. Any unauthorized change in personnel equipment or working conditions as mentioned in the application by the person authorized a breach of his authorization.
- 5. It is the duty of the authorized person to take prior permission of the prescribed authority to close down the facility 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)}

SI.No.	Particulars		
1	Particulars of the Occupier	:	
	(i) Name of the authorized	:	
	person(occupier or operator of		
	facility)		
	(ii) Name of HCF or CBMWTF	:	
	(iii) Address for Correspondence	:	
	(iv) Address of Facility	:	
	(v) Tele No.Fax.No.	:	
	(vi) E-mail ID	:	
	(vii) URL of Website	:	
	(viii) GPS conditions of HCF or	:	
	CBWTF		
	(ix) Ownership of HCF or CBMWTF	:	(State Government or Private or
			Semi Govt. or any other)
	(x) Status of Authorisation under the	:	Authorisation
	Bio-medical Waste (Management		Novalid up
	and Handling) Rules		to
	(xi) Status of Consents under Water	:	Valid up to
	Act and Air Act		
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	:	Kg per day
	capacity of CBMWTF:		
	(iv) Quantity of biomedical waste	:	Kg/day
	treated or disposed by CBMWTF		Vallary Catalysis
4	Quantity of waste generated or	:	Yellow Category :

	disposed in Kg per annum (on		
	monthly average basis)		
			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		Size :
	facility	•	Capacity:
			Provision of on-site storage :
			(cold storage or any other
			provision)
	(ii) disposal facilities		Type of No Capacity Quantity
			treatment of Kg/day
			treatment
			equipment units
			disposal
			In Kg
			per annum
			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:
	(iii) Quantity of recyclable wastes	:	Red Category (like plastic, glass etc.)
	sold to authorized recyclers after		
	treatment in Kg per annum		
	(iv) No. of vehicles used for	:	
	collection and transportation of		
	biomedical waste		
	(v) Details of incineration ash and	:	Quantity Where
		•	
	ETP sludge generated and disposed		Generated disposed

	during the treatment of wastes in Kg		Ash
	per annum		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		
Ũ	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		
5	Pollution from the incinerator? How		
	many times in last year could not		
	met the standards?		
	Details of Continuous online		
	emission monitoring systems		
	installed		
10			
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
			attac	hed with the	e Incinerato	or)

Certified that the above report is for the period from

Name and Signature of the Head of the Institution

Date:

Place

FORM – V (See rule 16)

Application for filing appeal against order passed by the prescribed authority

- 1. Name and address of person applying for appeal.
- 2. Number, date of order and address of the authority which passed the order, against which appeals 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.....

Major changes proposed in the Bio-Medical Waste Management Rules, 2016 and its likely implication

Bio-medical waste (Management and Handling) Rules, 2011	Bio-medical waste Management Rules, 2016	Reasons and likely implications
Title Bio-medical waste (Management and Handling) Rules, 2011	Bio-medical waste Management Rules, 2016	The word "Management" includes Handling
	Application	
These rules apply to all persons who generate , collect, receive, store, transport, treat disposal or handle bio medical waste in any form	 These rules apply to all persons who generate , collect, receive, store, transport, treat disposal or handle bio medical waste in any form and shall not apply to Radioactive wastes, Wastes covered under the MSW Rules, 2000, Lead acid batteries, Hazardous wastes,, E-waste, Hazardous microorganisms 	Modified to bring more clarity in the application Clarified that vaccination camps, blood donation camp, surgical camps or any other healthcare activity undertaken outside the healthcare facility, will be covered
	Duties of the Health care facilities	5
Every occupier of an institution generating bio- medical waste which includes a hospital nursing home, clinic , dispensay veterinary institution, animal house, pathological laboratory, blood bank to take all steps to ensure that such waste is handled without any adverse effect to human health and the environment	Additions: Health care facilities (HCF) shall make a provision within the premises for a safe, ventilated and secured location for storage of segregation bio medical waste. Pre-treat the laboratory waste, microbiological waste, blood sample and blood bags through disinfection or sterilization on site in the manner as prescribed by the World Health Organisation (WHO) or National Aids Control Organisation (NACO) guidelines and sent to the common bio medical waste treatment facility for final disposal.	To ensure that there shall be no secondary handling, pilferage of recyclable or inadvertent scattering or spillage by animals and the bio medical waste from such place or premises can be directly transported in to the common bio medical waste treatment facility. This Is to prevent the possible microbial contamination.
	Phase out use of chlorinated	

	plastic bags, gloves and blood bags within two years from the date of notification of these rules.	
	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.	dioxin and furans from burning of such wastes.
	Immunize 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.	Will improve the management of BMW including collection, segregation
	Establish a Bar-Code System for bags or containers containing bio- medical waste to be sent out of the premises	To protect the health of workers.
	Report major accidents including accidents caused by fire hazards, blasts during handling of bio- medical waste and the remedial action taken to SPCB. Existing incinerators shall achieve the standards for retention time in secondary chamber and Dioxin	Will improve the segregation, transportation and disposal system. Also will eliminate pilferage on the way of BMW to disposal facility.
	and Furans within two years from the date of this notification	Help to monitor and improve the management.
		Will improve the environment in the vicinity treatment facility
Duties of the ope	rator of a common bio-medical wa disposal facility	aste treatment and
Nil	Same as the duties of HCFs and additionally they shall ensure timely collection of bio-medical waste from the HCFs, assist the HCFs in the conduct of training.	Specific responsibility on the operator of a common bio- medical waste treatment and disposal facility will be make them clear of their duties

	Treatment and disposal	
Every HCFs, where required, shall set requisite bio- medical waste treatment facilities like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility.	site treatment and disposal facility; if a service of common bio-medical waste treatment facility is available at a distance of seventy-five kilometer. In cases where service of the common bio-medical waste treatment facility is no more	This is to make the installation and operation of common treatment facility a viable one
Segrega	tion, packaging, transportation ar	nd storage
Bio-medical waste classified into 10 categories based on treatment options. No untreated bio-medical waste shall be kept stored beyond a period of 48 hours. Provided that if for any reason it becomes necessary to store the waste beyond such period, the authorised person must take permission of the prescribed authority and take measures to ensure that the waste does not adversely affect human	Bio-medical waste classified in to 4 categories based on treatment options. Untreated human anatomical waste, animal anatomical waste, soiled waste and biotechnology waste shall not stored beyond a period of forty-eight hours. 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 enviroment and inform the SPCB along with	Will improve the segregation of waste at source channelize proper treatment and disposal. Will eliminate obtaining permission within 48 hours which is not practically feasible.
health and the environment.	he reasons. Authorisation	
Hospital treating 1000 or more patients per month to obtain authorization from SPCBS/PCCs	One time Authorisation for Non- bedded HCFs. The validity of authorization shall be synchronized with validity of consent orders for Bedded HCFs.	HCFs can make application along with consent and hence getting authorization will not be getting authorization will not be additional burden for HCFs, and operator of treatment facility.

		It will also help to SPCB in making single inspection / monitoring to consider both the consent and authorization.
	Advisory Committee	
The Government of every State/Union Territory shall constitute an advisory committee with the experts in the field of medical and health, animal husbandry and veterinary sciences, environmental management, municipal administration, and any other related department or organization including non- governmental organization. Ministry of Defence shall constitute an Advisory Committee under Additional Director General of Armed Forces Medical Services with representative of Ministry of Defence, MoEFCC, for HCFs under Armed forces under the Ministry of Defence.	No change in the concept except additional members. Shall meet once in Six months.	Advisory Committee has strengthened suitably with additional members.
Sta	indards for emission from incinera	ators
SPM in the Incinerator's Emission 150 mg/nm3 Residence Time in Secondary chamber of incinerators is 1 second	50 mg/nm3 2 second	The proposed stringent standards for emissions from Incinerators (reduction of permissible limit for particulate matter, introduction of standards for Dioxin and Furans and
Nil	Standards for Dioxin and furans prescribed.	increasing the residence time in the Incinerator Chambers) will improve the operation of incinerator and reduce the emission of pollutants in the environment.
Site for commo	n bio-medical waste treatment and	d disposal facility
NIL	The department dealing the allocation of land shall be responsible for providing suitable site for setting up of common	Getting suitable land is the problem in many states for establishment of waste management facility . Making

	biomedical waste treatment and disposal facility in the State Government	the responsibility to provide land by the department dealing the allotment of land would eliminate the issue of getting land for the waste management facility.
	Monitoring of implementation	
NIL	 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 CPCB, SPCBs State Government shall constitute District level Monitoring Committee under the chairmanship of District collector or District Magistrate to monitor the compliance of the provisions of these rules in the health care facilities. The District Level Monitoring Committee shall submit its report once in six months to the State Advisory Committee , State Pollution Control Board for taking further necessary action. The District Level Monitoring Committee shall comprise of District Medical Officer or District Health Officer, representatives from SPCB Public Health Engineering Department Local bodies or Mincipal Corporation Indian Medical Association Common Bio Medical Waste treatment facility Registered NGO working in the field of bio-medical waste management District Medical Officer shall be the Member Secretary of this committee 	The monitoring of the implementation was earlier only with SPCBs and review of implementation through the District Committee is likely to improve the implementation.