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#### OFFICE OF THE REGIONAL OFFICER STATE POLLUTION CONTROL BOARD, ODISHA

[DEPARTMENT OF FOREST, ENVIRONMENT & CC, GOVT. OF ODISHA] Plot No 287/A, 1st Lane, Kasturi Nagar, Rayagada, 765001

## FORM-III (See Rule 10) <u>AUTHORISATION ORDER</u>

Letter No. 1555

SPCB/Authorization (Biomedical Waste)

Date: 19.04.2022

BY REGD.POST

RGD/BMW/AUTH/107

Sub: Authorization under Biomedical Waste Management Rules, 2016 and Amendment thereof for operating a facility for collection, transportation, reception, treatment, storage and disposal.

Your online application no **3672058**.

Dr N V Jagannadha Rao, Registrar, of M/s GIET University, Gunupur an Occupier of the facilities i.e. University Dispensary, Microbiology Lab of Biotechnology Department & Pathological Lab of Nursing Institution located in the Premises of GIET University, At/PO-**Gunupur, District- Rayagada, Odisha** is hereby granted an authorization for operating a facility for.

| SI NO | Activity    | Please<br>tick | SI NO | Activity                              | Please tick |
|-------|-------------|----------------|-------|---------------------------------------|-------------|
| 1     | Generation, | ✓              | 7     | Transportation                        |             |
| 2     | Segregation | <b>✓</b>       | 8     | Treatment or processing or conversion | <b>✓</b>    |
| 3     | Collection, | ✓              | 9     | Recycling                             |             |
| 4     | Storage     | ✓              | 10    | Disposal or destruction               | ✓           |
| 5     | Packaging   |                | 11    | Use offering for sale, transfer       |             |
| 6     | Reception   |                | 12    | Any other form of handling            |             |

#### The Authorization shall be in force from the date of issue of this order until further orders.

This authorization is subject to the conditions, standards & special conditions stated below.

#### (A) **GENERAL CONDITIONS:**

- 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, i.e., State Pollution Control Board, Odisha.
- 3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the State Pollution Control Board, Odisha.
- Any unauthorized change in personnel, equipment or working conditions as mentioned in the 4. application by the person authorized shall constitute a breach of his authorization.
- 5. It is the duty of the occupier to report major accidents including accidents caused by fire hazards, blasts during handling of bio-medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form-I to the prescribed authority and also along with the annual report.

- 6. The biomedical waste container shall be labeled as specified schedule-IV of the rules.
- 7. Untreated Bio-medical waste shall not be stored beyond a period of forty-eight hours.
- 8. The biomedical waste disposal site shall be properly fenced and suitable notice with warning shall be displayed.
- 9. The biomedical waste disposal site shall be selected and developed in a manner so that ground, water surface water or ambient air shall not be adversely affected.
- 10. 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 and all records shall be subject to inspection and verification of the officials of State Pollution Control Board, Odisha at any time
- 11. The State Pollution Control Board, Odisha reserves the right to modify, revoke or review the authorization granted.
- 12. The occupier shall ensure segregation, treatment and disposal of wastes as stated in Part-1 and Part-2 below or ensure requisite treatment and disposal of segregated waste at the common facility/centrally located facility authorized by State Pollution Control Board, Odisha.

#### (B) STANDARDS FOR TREATMENT AND DISPOSAL OF BIOMEDICAL WASTES.

Standards for treatment and disposal of biomedical wastes shall be followed as per Schedule-II of the Rules (Annexure-I).

#### (C) **SPECIAL CONDITIONS:**

- 1. This authorization is issued under the category of Research or Educational Institutions for **NIL** no. of beds. For any increase in no of beds, the applicant shall obtain prior permission of the prescribed authority.
- 2. The unit shall deposit the balance authorization fees (if any) within 30 days from the date of issue of authorization to keep this order in force.
- 3. Biomedical wastes shall not be mixed with general wastes. Under no circumstances untreated biomedical waste shall be handed over to the Municipality/ NAC for disposal in landfill site.
- 4. The occupier shall treat the segregated biomedical wastes in the manner described or **shall ensure** requisite treatment of segregated wastes at the common facility, authorized by State Pollution Control Board. Odisha.
- 5. The occupier shall pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilization on-site in the manner as prescribed by the World Health Organization (WHO) or National AIDs Control Organization (NACO) guidelines and then sent to the common bio medical waste treatment facility for final disposal.
- 6. Unit has to provide adequately designed deep burial pits (2 nos.) & safe pit for sharps (1 No.) in its contaminant area within 15 days from date of issue of this authorisation order to keep this order in force.
- 7. Unit has to provide adequate capacity of Autoclave within three months from the date of issue of this authorisation order for better treatment of Bio Medical Wastes being generated from the unit.
- 8. The occupier shall ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with the rules.
- 9. The disposal of Solid Waste other than bio-medical waste shall be made in accordance with the provisions of Solid Waste (Management) Rules, 2016 and amended from time to time.
- 10. The handling and disposal of all mercury and lead waste shall be in accordance the respective rules and regulations.
- 11. The occupiers shall ensure proper segregation of waste at the source of generation before treatment and disposal as stipulated. In case of handing it over to the common facility/centrally located facility, the segregated waste in coloured bags or containers shall be stored safely at a place within the premises from where the common facilitator/operator of centrally located facility can collect the segregated waste.
- 12. The occupier of all bedded health care facility shall maintain and update on day to day basis the biomedical waste management register in terms of category and colour coding as stipulated in this order and display the monthly record on its website. Annual report (in form-IV) also shall be displayed on its website.
- 13. The occupier shall establish a bar-code system for bags or containers containing bio-medical waste to be sent out if any to the common facility or centrally located facility.
- 14. The occupier of the facility shall submit the annual report for the period from January to December of the preceding year in Form-IV specified in principal rule by 30<sup>th</sup> of June of every year.
- 15. The occupier shall phase out use of chlorinated plastic bags used for storing and transportation of wastes with immediate effect.

16. The occupier shall 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.

17. The occupier shall 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.

18. The occupier shall 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.

19. The unit shall comply to the duties of Occupier specified in Rule 4 (Annexure-II).

20. The Unit shall furnish copy of the license of the Health Department, Govt. of Odisha, within 30 Days from the date of issue of this order to keep this authorization in force.

21. The occupier shall designate a qualified person/constitute a committee to review and monitor the activities relating to bio-medical waste management within that establishment.

To

Dr N V Jagannadha Rao, Registrar M/s GIET University, Gunupur, At/PO- Gunupur Dist- Rayagada, Odisha.

**REGIONAL OFFICER** 

Memo No: 1556(4) Dt: 19-04-2022

Copy forwarded to

- 1. The Member Secretary, State Pollution Control Board, Odisha, Bhubaneswar.
- 2. The Collector & District Magistrate, Rayagada.
- 3. The C.D.M.O, Rayagada.

4. Guard File.

**REGIONAL OFFICER** 

# SCHEDULE II [See rule 4 (1), 7(1) and 7 (6)] STANDARDS FOR TREATMENT AND DISPOSAL OF BIO-MEDICALWASTES

#### 1. INCINERATOR.

### (i) **Operating Standards**

| Operating standard                           |                           |  |  |
|--|---------------------------|--|--|
| Parameters                                   | Operating Standards       |  |  |
| Combustion efficiency (CE) shall be at least | 99%                       |  |  |
| Temperature of primary chamber               | 800                       |  |  |
| i) Temperature of secondary chamber          | i) 1050° C <u>+ 5</u> 0°C |  |  |
| ii) Gas residence time in secondary chamber  | ii) At least 2 seconds    |  |  |

#### (ii) Emission standards

| Sl. No. | Parameters                                  |  | Standards  |
|---------|---|--|--|
| (1)     | (2)   | (3)  | (4)  |
|         |   | Limiting<br>concentration in mg<br>Nm3 unless stated | Sampling Duration in minutes, unless stated                |
| 1.      | Particulate matter                          | 50   | 30 or 1NM <sup>3</sup> of sample volume, whichever is more |
| 2.      | Nitrogen Oxides NO and NO2 expressed as NO2 | 400  | 30 for online sampling or grab sample                      |
| 3.      | HCl   | 50   | 30 or 1NM <sup>3</sup> of sample volume, whichever is more |
| 4.      | Total Dioxins and Furans                    | 0.1ngTEQ/Nm3 (at 11% 0 <sub>2</sub> )                | 8 hours or 5NM³ of sample volume, whichever is more        |
| 5.      | Hg and its compounds                        | 0.05   | 2 hours or 1NM³ of sample volume, whichever is more        |

(iii) **Stack Height**: Minimum stack height shall be 30 meters above the ground and shall be attached with the necessary monitoring facilities.

#### Note:

- a) Pollution control device shall be installed in the incinerator to achieve the emission limits.
- b) Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- c) Ash from incineration of biomedical waste shall be disposed of at Common Hazardous Waste Treatment and Disposal Facility. However, it may be disposed of in municipal landfill, if the toxic metals in incineration ash are within the regulatory quantities as defined under the Hazardous and Other Wastes (Management and Tran boundary Movement) Rules, 2016 as amended from time to time.
- d) Only low Sulphur fuel like Light Diesel Oil or Low Sulphur Heavy Stock or Diesel, Compressed Natural Gas, Liquefied Natural Gas or Liquefied Petroleum Gas shall be used as fuel in the incinerator.
- e) The occupier or operator of the incinerator shall install continuous emission monitoring system for the parameters as stipulated in authorization and transmit the data real time to the servers at State Pollution Control Board and Central Pollution Control Board.
- f) All monitored values shall be corrected to 11% Oxygen on dry basis.

#### 2. MICROWAVE

#### **Standards for Microwaving**

- **I.** Microwave treatment shall not be used for Cytotoxic, hazardous or radioactive wastes, contaminated animal carcasses, body parts and large metal items.
- **II.** The microwave system shall comply with the efficacy test/routine tests and a performance guarantee may be provided by the supplier before operation of the unit.

III. The microwave should completely and consistently kill the bacteria and other pathogenic organisms that are ensured by approved biological indicator at the maximum design capacity of each microwave unit. Biological indicators for microwave shall be Bacillus atrophaeusspores using vials or spore strips with at least  $1 \times 10^4$  spores per detachable strip. The biological indicator shall be placed with waste and exposed to same conditions as the waste during a normal treatment cycle.

#### 3. AUTOCLVE

#### Standards for Autoclaving

The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste. When operating a gravity flow autoclave, medical waste shall be subjected to the following standards.

#### Following standards.

| TEMPERATURE            | PRESSURE                 | RESIDENCE TIME   |
|------------------------|--------------------------|------------------|
| (in degree centigrade) | (pounds per square inch) | (in minutes)     |
| Not less than 121      | 15                       | Not less than 60 |
| Not less than 135      | 31                       | Not less than 45 |
| Not less than 149      | 52                       | Not less than 30 |

When operating a vacuum autoclave, medical waste shall be subjected to a minimum of three pre-vacuum 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.

| TEMPERATURE            | PRESSURE                 | RESIDENCE TIME   |
|------------------------|--------------------------|------------------|
| (in degree centigrade) | (pounds per square inch) | (in minutes)     |
| Not less than 121      | 15                       | Not less than 60 |
| Not less than 135      | 31                       | Not less than 45 |

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. LIQUID WASTE.

#### 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 test   | 90% survival of fish after 96 hours in 100% effluent |

#### Note:

- a. The above limits applicable to the occupiers of health care units (bedded) which are either connected with sewerage network without terminal STP or Not-connected to public sewers.
- b. Non bedded occupiers shall dispose of liquid wastes after treatment by disinfection as specified in this order.
- c. For discharge into public sewers with terminal facilities, the general standards as notified under the E (P) Act, 1986 (29 of 1986) shall be applicable.

(ii) 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.

#### 5. Standards for Deep Burial

- (a) A pit or trench should be dug about 2 meters deep. It should be half filled with waste, and then covered with lime within 50 cm of the surface before filling the rest of the pit with soil.
- (b) It must be ensured that animals do not have any access to burial sites.
- (c) On each occasion when wastes are added to the pit a layer of 10 cm of soil shall be added to cover the wastes.
- (d) Burial must be performed under close and dedicated supervision
- (e) The deep burial site should be relatively impermeable and no shallow well should be close to the site.
- (f) The pit shall be distant from the habitation, and sited so as to ensure that no contamination occurs of any surface water or ground water. The area should not be prone to flooding or erosion.
- (g) The facilitator (authorized person) shall maintain a record of all pits for deep burial.
- (h) The ground water table level should be a minimum of six meters below the lower level of deep burial pit.

#### 6. Standards for efficacy of chemical disinfection

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

Part-1
Biomedical wastes categories and their segregation, collection, treatment, processing and disposal of waste

| waste    |  |   |   |  |
|----------|--|---|---|--|
| Category | Type of Waste  | Type of Bag or<br>Container to be<br>used                                 | Treatment and Disposal options  |  |
| (1)      | (2)  | (3)   | (4)   |  |
| Yellow   | a) Human<br>Anatomical Waste:  | Yellow coloured non-<br>chlorinated plastic<br>bags                       | Incineration or Plasma Pyrolysis or deep burial*  |  |
|          | (b)Animal<br>Anatomical Waste :  |   |   |  |
|          | (c) Soiled Waste:  | Yellow coloured non-<br>chlorinated plastic<br>bags                       | Incineration or deep burial* In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation. Treated waste to be sent for energy recovery.   |  |
|          | (d) Expired or<br>Discarded<br>Medicines:  | Yellow coloured non-<br>chlorinated plastic<br>bags or<br>containers      | Expired `cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier or disposed by Incineration at authorizers Common Bio-medical Waste Treatment facility or hazardous waste treatment and Disposal Facility or Hazardous Waste treatment, Storage and Disposal Facility. |  |
|          | (e) Chemical Waste:  | Yellow coloured<br>containers or non-<br>chlorinated plastic<br>bags      | Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.   |  |
|          | (f) Chemical Liquid<br>Waste:  | Separate collection<br>system leading to<br>effluent treatment<br>system  | After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms.   |  |
|          | (g) Discarded linen, mattresses, beddings Contaminated with blood or body fluid. | Non-chlorinated<br>yellow plastic bags or<br>suitable packing<br>material | Non- chlorinated chemical disinfection followed by incineration or Plazma 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.   |  |

|                        | (h) Microbiology,<br>Biotechnology and<br>other<br>clinical laboratory<br>waste:   | Autoclave or microwave safe plastic bags or containers                       | Pre-treat to sterilize with non-chlorinated chemicals on-site as per WHO guidelines on Safe Management of Waste from health care activities and WHO Blue Book, 2014 and thereafter sent 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-<br>chlorinated plastic<br>bags or containers               | Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible.  Plastic waste should not be sent to landfill sites. |
| White<br>(Translucent) | Waste sharps including Metals: Needles, syringes with fixed needles, Scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts.  | Puncture proof, Leak<br>proof, tamper proof<br>containers                    | Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete.   |
| Blue                   | (a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.  (b) Metallic Body  | Puncture and Leak proof boxes with blue coloured marking.  Puncture and Leak | Sodium Hypochlorite treatment or through autoclaving or microwaving or hydroclaving and then sent for recycling.  |
|                        | Implants   | proof boxes with blue coloured marking.                                      |   |

\* 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 as per the Standards specified.

#### Part -2

- 1. All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.
- 2. Chemical treatment using at least 1% to 2% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log104 reduction efficiency for microorganisms or greater for *Bacillus subtilis* (ATCC19659) in chemical treatment system.
- 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 (Management and Transboundary Movement) Rules, 2016 or as revised from time to time.
- 6. Cytotoxic drug vials shall not be handed over to unauthorized 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/centrally located bio-medical waste treatment and disposal facility or hazardous waste, treatment, storage & disposal facility.
- 7. 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.

#### Rule 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 I 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 sterilization on-site in the manner as prescribed by the World Health Organization (WHO) or National AIDs Control Organization (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 neutralization 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 bio medical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report;
- p) 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 biomedical 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.