

# Pollution Control Board:: Assam Bamunimaidam; Guwahati-21

(Department of Environment & Forests :: Government of Assam)
Phone: 0361-2652774 & 2550258; Fax: 0361-2550259

Website: www.pcbassam.org

No. WB/Z-V/T-383/01-02/339

Dated Guwahati, the 30th September, 2022

# FORM – III [See Rule 10] AUTHORISATION

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

- 1. File number of Authorization & date of issue
- : No. WB/Z-V/T-383/01-02/338 dtd. 30/09/2022
- 2. M/s Sri Sankaradeva Nethralaya, an occupier or operator of the facility, located at 96 Basitha Road, Guwahati, Kamrup (M), Assam-781028 with Bed capacity of fifty (50), is hereby granted an authorization for-

Activity:				
Generation	- 🗸	Recycling	- []	X
Segregation	- 🗸	Disposal		/
Collection	- 🗸	Destruction	- ,	/
Storage	- 🗸	Use	- 3	X
Packaging	- 🗸	Offering for sale, Transfer	- 5	X
Reception	- X	Treatment or Processing or	- ,	/
Transportation	- X	Conversion  Any other form of handling	- ]	X

3. M/s. Sri Sankaradeva Nethralaya is hereby authorized for handling of biomedical waste as per the capacity given below:

Quantity permitted for Handling
2.13 kg/Day
5.11 kg/Day
0.49 kg/Day
6.72 kg/Day

- 4. This Authorization shall be in force for the period up to 31st March, 2027.
- 5. 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 in force under the Environment (Protection) Act, 1986

## Terms & Conditions of Authorization:

 As per the provisions of the Water (Prevention and Control of Pollution) Act, 1974 as amended and the Air (Prevention and Control of Pollution) Act, 1981 as amended, any Officer empowered by the Board on its behalf shall have without interruption, the right at any reasonable time to enter the unit for inspection, collection of sample for analysis and may call for any information as deemed necessary. Denial of this right will cause withdrawal of this Order.

Contd....P/2





- 2. The unit should strictly follow the relevant norms and standard as laid down in Bio Medical Waste Management Rules, 2016 which has been notified by the Ministry of Environment, Forest & Climate Change (MoEF&CC), Govt. of India vide GSR.343(E) dtd. 28.03.2016, especially with the conditions mentioned in Appendix-A
- 3. The HCF shall submit Annual Report in Form-4 on or before 30th June every year.
- The Authorization or its renewal shall be produced for inspection at the request of an officer authorized by the prescribed authority.
- 5. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
- 6. The unit shall have a valid 'Consent to Operate' from the Board.
- 7. The unit shall not burn any waste inside the premises.
- 8. The unit shall implement Bar Code system for transportation of Bio Medical Waste.
- 9. The unit shall develop its own website and display details of Bio Medical Waste.

## A. Solid Waste Aspect-

- 1. Adequate facility should be created for collection, storage, transportation, treatment & disposal of solid waste generated from the unit.
- 2. Adequate system should be adopted on reduction of waste generation and enhancement of re-utilization & recycling of waste materials.
- 3. Solid waste generated in the unit shall be disposed of as per the provisions of Solid Waste Management Rules, 2016.

## **B. Plastic Waste Aspect:**

- Plastic Waste generated in the unit shall be disposed of in accordance of the provisions under Plastic Waste Management Rules, 2016.
- 2.The unit shall submit the report annually regarding generation and disposal of Plastic Waste (excluding the items covered under Bio Medical Waste Management Rules, 2016)

# C. E-Waste Aspects:

- Electronic wastes generated in the unit shall be disposed of as per the provisions of E-Waste Management Rules, 2016.
- 2. The unit shall submit the Annual Report in the Form-III within 30<sup>th</sup> June every year.

(Shantanu Kr. Dutta)

<u>Member Secretary</u>

Dated Guwahati, the 30<sup>th</sup> September, 2022

Memo No. WB/Z-V/T-383/01-02/339-A,

Copy to:

M/s. Sri Sankaradeva Nethralaya, 96 Basitha Road, Guwahati, Kamrup (M), Assam-781028 for information and compliance of conditions. This has reference to online application vide No.486774.

(Shantanu Kr. Dutta) Member Secretary

# Appendix- A GENERAL STIPULATIONS 1. The issuance of this Consent does not carry any property right in either real or personal property or any exclusive privileges nor does it authorize any injury to private property nor any invasion rights nor any infringement of Central, State or Local Laws or Regulations. 2. The Consent has been given by the Board basing on the information furnished in the Consent application and the Consent will become automatically invalid if any changes or alternations or deviations except mentioned in this Consent are made in actual practice from the particulars furnished in the application form. 3. The Board reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the reserves the right to review from time to time any of the conditions imposed in this Consent and make any reasonable and the review from time to time any of the conditions imposed in this Consent and make any reasonable and the review from time to time any of the conditions imposed in this Consent and the review from time to time any of the conditions in the review from time to time any of the conditions in the review from time to time any of the conditions in the review from time to time any of the conditions in the revi

- variation thereof or revoke any of the conditions as it thinks fit in accordance with provisions of Air (Prevention & Control of Pollution) Act, 1981 as amended in 1987 &
- The Consent does not authorize or approve the construction of any physical structures of facilities or undertaking or any works except to the extent of works specially instructed herein.
- The Consent is granted subject to payment of necessary 'FEES' as per the Rule framed under Water (Prevention & Control of Pollution) Act, 1974 as amended.
- 6. Be it mentioned that, if any of the above conditions are not fulfilled, this consent shall be treated as cancelled.
- 7. The Board has the right to add, delete or modify any of the above conditions in future to protect and safeguard the environment.

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

- Take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and environment and in accordance with these rules;
- 2. Make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in coloured bags or containers in the manner as specified in Schedule-I, to ensure segregated bio-medical waste in coloured 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 Schedule-I.
- 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;
- 4. Phase out use of chlorinated plastic bags (excluding blood bags)and gloves within two years from the date of notification of these rules;
- 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
- Not to give treated bio-medical waste with municipal solid waste;
- Provide training to all its health care workers and others, involved in handling of bio medical waste at the time of induction and
  thereafter at least once every year and the details of training programmes conducted, number of personnel trained and number of
  personnel not undergone any training shall be provided in the Annual Report;
- 8. 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 biomedical waste, in the manner as prescribed in the National Immunization Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time;
- 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;
- 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;
- Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);
- Ensure occupational safety of all its health care workers and others involved in handling of biomedical waste by providing appropriate and adequate personal protective equipment.
- 13. 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;
- 14. 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;
- 15. 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;
- 16. 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;
- 17. 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;
- 18. 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 qualified person to review and monitor the activities relating to bio-medical waste management within that establishment and submit the annual report;
- 19. Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;
- 20. 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.

## C. Treatment and disposal:

- 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.
- 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 biomedical waste generated shall be pre-treated by equipment like autoclave or microwave.

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.

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 authorization given by the prescribed authority

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.

- 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.
- Every operator of common bio-medical waste treatment facility shall set up requisite biomedical waste treatment equipment 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, 2016.
- 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 authorization 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.

## D. Segregation, packaging, transportation and storage:

- 1. No untreated bio-medical waste shall be mixed with other wastes.
- 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.
- 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 thereunder 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.
- Microbiology waste and all other clinical laboratory waste shall be pre-treated by sterilization to Log 6 or disinfection to Log 4, as per the World Health Organization guidelines before packing and sending to the common bio-medical waste treatment facility.
- All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.
- Chemical treatment using at least 1-2% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log<sub>10</sub>4 reduction efficiency for microorganisms.
- Mutilation or shredding must be to an extent to prevent unauthorized reuse.
- 12. There will be no chemical pre-treatment before incineration, except for microbiological, lab and highly infectious waste.
- 13. 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.
- 14. Dead Futes 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 behanded 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.
- 15. 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 bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis is at temperature >1200°C.
- 16. 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.
- 17. On-site pre-treatment of laboratory waste, microbiological waste, blood samples, and blood bags should be disinfected or sterilized as per the Guidelines of World Health Organization or National AIDS Control Organization and then given to the common bio-medical waste treatment and disposal facility.
- 18. 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 authorization from the State Pollution Control Board.

- 19. 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.
- 20. Bio-medical waste generated in households during healthcare activities shall be segregated as perthese 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 pick up this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal.

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

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.

- E. Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options
  - The applicant shall adhere to all procedures in handling the bio-medical wastes during incineration, segregation, packaging, transportation, storage, treatment and disposal for safe management of bio-medical wastes as per Bio-Medical Waste (Management & Handling) Rule, 2016.
  - 2. The incinerator should be installed at appropriate location away from the neighbourhood.
  - 3. The Health Care Facilities shall treat their wastes as per following guidelines: -

Catego ry	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
(1)	(2)	(3)	(4)
(,)	(a) Human Anatomical Waste: Human tissues, organs, body parts and fet us below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time)	Yellow coloured non- chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial
	(b)Animal Anatomical Waste: Experimental animal car cases, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.	ij.	
Yellow	(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/ hydroplaning 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>1200°C.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 or 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.
	(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 Formal in, 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 wasteshall be pre-treated before mixing with othe wastewater. The combined discharge shall conform to the discharge norms given in Schedule-III.
	g) Discarded linen, mattresses, beddings contaminated with blood or body fluid, routine mask, gown.	Non-chlorinated yellow plastic bags or suitable packing 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 or Plazma Pyrolysis.
	(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.	Autoclave or Microwave or Hydro clave safe plastic bags or containers.	

		-4-	
Red	Contaminated Waste(Recyclable)  (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes handsets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vacutainers with their needles cut) and gloves.	Red coloured no chlorinated plastic bags or containers.	Autoclaving or micro-Waving/hydroplaning followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Transluc ent)	Waste sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers.	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
Blue	(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Puncture proof and Leak proof boxes or containers with blue coloured marking.	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite Treatment) or through autoclaving or microwaving or hydro claving and then sent for
	(b) Metallic Body Implants	Puncture proof and Leak proof boxes or containers with blue coloured marking.	recycling.

## INCINERATION:

All incinerators shall meet the following operating and emission standards-

- a) Operating Standards:
  - 1. Combustion efficiency (CE) shall be at least 99.00%.
  - The temperature of the primary chamber shall be a minimum of 800 °C and the secondary chamber shall be minimum of 1050°C + or 50°C.
  - 3. The secondary chamber gas residence time shall be at least two seconds.
- b) Emission Standards:

S1.		Standards	
Sl. No.	Parameter	Limiting concentration in mg per Nm³ unless stated	Sampling Duration in minutes, unless stated
1.	Particulate matter	50	30 or 1NM3 of sample volume, whichever is more
	Nitrogen Oxides NO and NO <sub>2</sub> expressed as NO <sub>2</sub>	400	30 for online sampling or grab sample
3.	HCI	50	30 or 1NM3 of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1ngTEQ/Nm3(at 11%O2)	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

c) 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

## F. STANDARDS FOR LIQUID WASTE:

 The effluent generated or treated from the premises of occupier or operator of a common biomedical waste treatment and disposal facility, before discharge into the sewer should conform to the following limits.

PARAMETERS	PERMISSIBLE LIMITS
PH	6.5-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l
Bio-assay test	90% survival of fish after 96 hours in 100% effluent.

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.

> (Shantanu Kr. Dutta) Member Secretary Pollution Control Board, Assam