STATE POLLUTION CONTROL BOARD, ODISHA

A/118, Nilakanthanagar, Unit-VIII, Bhubaneswar 751012
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FORM-III (See Rule 10)

AUTHORISATION ORDER

No. 648 **/ SPCB/Authorization (Biomedical Waste) Date** 11.01.2022 **/**
IND-IV-BW-600 **BY SPEED SPOST**

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

APPLICATION NO: 3856922

Dr. Sarangadhar Samal, Director of **M/s Kalinga Eye Hospital, Dhenkanal** an occupier of the facility located at/**PO: Dakhinakali Road, Dist: Dhenkanal sharing the treatment and disposal facility at M/s Sani Clean Pvt. Ltd., Tangiapada, Dist: Khurda** is hereby granted an authorization for;

Activity

Generation and Segregation √, Collection√, Storage √, Packaging √, Reception√, Transportation√, Treatment √ and Recycling√

The authorization is valid up to 31.03.2025 for handling wastes generated from 20 no. of beds. For any increase in number of beds, the applicant shall obtain prior permission of the prescribed authority.
An application shall be made by the Occupier for renewal of authorization in Form-II before four months from the date of expiry of this authorization.
This authorization order supersedes the earlier authorization order issued vide No. 15896, dtd. 16.10.2021.

This authorization is subject to the general 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.
4. Any unauthorized change in personnel, equipment or working conditions as mentioned in the 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 authorized 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. In case of all bedded health care units, the authorized person shall 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.
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.

Part-1

Practice of segregation, collection, treatment and disposal of waste

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	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*
	(b)Animal Anatomical Waste		
	(c) Soiled Waste	Yellow coloured non-chlorinated plastic 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 cytotoxic drugs or Discarded Medicines	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 or disposed by incineration at authorizes Common Bio- medical Waste Treatment and Disposal Facility or Hazardous Waste Treatment, Storage and Disposal Facility.
	(e) Chemical Waste	Yellow coloured containers or nonchlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	(f) Chemical Liquid Waste	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms.
	(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 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

	other clinical laboratory waste	containers	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-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	**Waste sharps including Metals:** Needles, syringes with fixed needles, scalpels, blades or any other contaminated sharp object that may may cause puncture or cuts.	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.
Blue	**(a) Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Puncture and leak proof boxes with blue coloured marking.	Sodium Hypochlorite treatment or through autoclaving or microwaving or hydroclaving and then sent for recycling.
	(b) Metallic Body Implants	Puncture and leak 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 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 a 4 Log10 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 Wastes (Management and Trans boundary 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 shall 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 authorization from the State Pollution Control Board.

(B) STANDARDS FOR TREATMENT AND DISPOSAL OF BIOMEDICAL WASTES

1. INCINERATOR

(I) Operating Standards

Operating standard	
Parameters	**Operating Standards**
Combustion efficiency	99%
Temperature of primary chamber	800
I)Temperature of secondary chamber Ii) Gas residence time in secondary chamber	i)1050 ^{0}C ± 50^{0}C ii)At least 2 seconds

(II) Emission standards

Sl. No.	Parameters	Standards	
		Limiting concentration in mg/ Nm^3	Sampling Duration in minutes, unless stated
1.	Particulate matter	50	30 or 1NM^3 of sample volume,whichever is more
2.	Nitrogen Oxides NO and NO_2 expressed as NO_2	400	30 for online sampling or grab sample
3.	HCl	50	30 or 1NM^3 of sample volume, whichever is more
4.	Total Dioxins and Furans	0.1ngTEQ/Nm^3 (at 11% O_2)	8 hours or 5NM^3 of sample volume, whichever is more
5.	Hg and its compounds	0.05	2 hours or 1NM^3 of sample volume, whichever is more

(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 in 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 Transboundary 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 x 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 shall be dedicated for the purpose of disinfecting and treating biomedical waste. When operating a gravity flow autoclave, medical waste shall be subjected to the following standards.

TEMPERATURE (In degree centigrade)	PRESSURE (pounds per square inch)	RESIDENCE TIME (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 pulse to purge the autoclave of all air. The air removed during the pre-vacuum, cycle should be decontaminated by means of HEPA and activated carbon filtration, steam treatment, or any other method to prevent release of pathogen. The waste shall be subjected to the following:

TEMPERATURE (In degree centigrade)	PRESSURE (pounds per square inch)	RESIDENCE TIME (in minutes)
Not less than 121	15	Not less than 45
Not less than 135	31	Not less than 30

Medical waste shall not be considered properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure are reached during the autoclave process. If for any reasons, time, temperature or pressure indicator indicates that the required temperature, pressure or residence time is not reached, the entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time are achieved.

4. LIQUID WASTE

Standards for liquid waste

(i) *The effluent discharged from the premises of occupier shall 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.

Note:

a. The above limits are 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 common hazardous waste treatment, storage and disposal facility for its necessary treatment and disposal.*

5. Standards for Deep Burial

a. A pit or trench shall be dug about 2 meters deep. It shall 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 shall be relatively impermeable and no shallow well should be close to the site.

f. The pits 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 shall 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.

(C) SPECIAL CONDITIONS:

1. 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.
2. Biomedical wastes shall not be mixed with general wastes under any circumstances.
3. 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.
4. The handling and disposal of all mercury and lead waste shall be in accordance the respective rules and regulations.
5. The occupier 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

2. Biomedical wastes shall not be mixed with general wastes under any circumstances.
3. 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.
4. The handling and disposal of all mercury and lead waste shall be in accordance the respective rules and regulations.
5. The occupier 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.
6. The occupier all bedded health care facility shall maintain and update on day today basis the bio-medical 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.
7. 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.
8. 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 30th of June of every year.
9. The occupier shall phase out use of chlorinated plastic bags used for storing and transportation of wastes with immediate effect.
10. 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;
11. 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
12. 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.
13. The occupier shall designate a qualified person to review and monitor the activities relating to bio-medical waste management within that establishment.

To

Dr. Sarangadhar Samal, Director,
M/s Kalinga Eye Hospital,
At/PO: Dakhinakali Road,
Dist: Dhenkanal

11/1/2022

Addl. Chief Env. Engineer
State Pollution Control Board,
Odisha, Bhubaneswar

Memo No._____/Dated _____/

Copy forwarded to the Director, Public Health, Heads of Department building, Unit-V, Bhubaneswar / Regional Officer, SPC Board, Angul /Guard file (Head Office) for information.

Addl. Chief Env. Engineer
State Pollution Control Board,
Odisha, Bhubaneswar