



STATE POLLUTION CONTROL BOARD, ODISHA

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FORM-III (See Rule 10)

AUTHORISATION ORDER

No. 5214 / SPCB/Authorization (Biomedical Waste) Date 31.03.2022
IND-IV-BW-448 BY SPEED POST

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: 3916734

Mahesh Kumar Agrawalla, Managing Director of M/s. Sani Clean Private Ltd., Khordha (herein after is known as the "Authorized Operator") is hereby granted authorization for operating the facility for collection, reception, storage, transportation, treatment and disposal of bio-medical waste at Tangiapada, Dist: Khordha. The unit shall have Incinerator of 3200 kg/d capacity with a primary chamber and a secondary chamber, an autoclave of 400 kg/d capacity.

This authorization shall be valid up to 31.03.2024.

An application shall be made by the operator for renewal of authorization in Form-II before four months from the date of expiry of this authorization.

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

(A) **GENERAL CONDITIONS:**

1. The occupier 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. Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty-eight hours.

7. The biomedical waste disposal site shall be properly fenced and suitable notice with warning shall be displayed.
8. 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.
9. The authorized operator shall maintain records related to 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.
10. The State Pollution Control Board, Odisha reserves the right to modify, revoke or review the authorization granted.
11. The occupier shall ensure collection, transportation, treatment and disposal of wastes as stated in Part-1 and Part-2 stated below;

Part-1

Category	Type of Waste	Type of Bag or Container to be Collected from the HCEs	Treatment and Disposal options at the facility
y(1)	(2)	(3)	(4)
Yellow	a) Human Anatomical Waste: Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*
	(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	
	(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.	Yellow coloured non-chlorinated plastic bags	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,	Yellow coloured non-chlorinated plastic bags or	Expired cytotoxic drugs and items contaminated with

	cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	containers	cytotoxic drugs to be returned back to the manufacturer or supplier or shall be incinerated 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 Formalin, infected secretions, aspirated body fluids , liquid from laboratories and floor washings, cleaning, housekeeping and disinfecting activities etc.	Not applicable	Onsite treatment and it shall meet the standards prescribed for liquid effluent
	(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid, routine mask and gown.	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, 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 hydroclave 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	Red coloured non-chlorinated plastic bags or containers	Autoclaving or microwaving followed by shredding or mutilation

	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.		and then to be sent to the authorized recyclers for recycling.
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	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
	(b) Metallic Body Implants	Puncture proof and leak proof boxes or containers with blue coloured marking.	microwaving or hydroclaving and then sent for recycling.

*** Disposal by deep burial is permitted only in rural or remote areas. Deep burial shall be carried out as specified in this order. The deep burial facility shall be located as per the guidelines issued by Central Pollution Control Board from time to time.**

Part -2

- (1) 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 as stipulated in this order.
- (2) Mutilation or shredding must be to an extent to prevent unauthorized reuse.
- (3) There will be no chemical pretreatment before incineration, except for microbiological, lab and highly infectious waste.
- (4) Incineration ash (ash from incineration process) 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 and Other Wastes (Management and Transboundary Movement) Rules, 2016 or as revised from time to time.
- (5) Cytotoxic drug vials collected if any shall be sent back to the manufactures for necessary disposal or these shall be incinerated.

(8) Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge collected if any shall be disposed at hazardous waste treatment, storage and disposal facility.

(B) STANDARDS FOR TREATMENT AND DISPOSAL OF BIOMEDICAL WASTES

Standards for treatment and disposal of biomedical wastes shall be as follows;

1. INCINERATOR:

(i) Operating Standards and Emission standards

Operating standard	
Parameters	Operating Standards
Combustion efficiency	99%
Temperature of primary chamber	800
Temperature of secondary chamber	1050 ± 50°C
Gas residence time in secondary chamber	At least 2 seconds

(ii) Emission standards

Sl. No.	Parameters	Standards	
		Limiting concentration in mg/ Nm ³ unless stated	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) Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- (b) 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.
- (c) The operator shall install continuous emission monitoring system for the parameters as stipulated and transmit the real time data to the servers at State Pollution Control Board and Central Pollution Control Board.

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 atrophaeus* spores using vials or spore strips with at least 1×10^4 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. AUTOCLAVE:

Standards for Autoclaving

The autoclave should 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 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 are achieved.

4. STANDARDS FOR LIQUID WASTE

- (i) The effluent generated or treated from the premises of occupier shall conform to the following limits

PARAMETERS

pH
Suspended solids
Oil and grease
BOD
COD
Bio-assay test

PERMISSIBLE LIMITS

6.5-9.0
100 mg/l
10 mg/l
30 mg/l
250 mg/l
90% survival of fish after 96 hours
in 100% effluent.

Note:

- Above limits are applicable which are either connected with sewerage network without terminal STP or non-connected to public sewers
- 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 incinerated or handed over to the authorized hazardous waste treatment, storage and disposal facility.

5. DEEP BURIAL:

Standards for Deep Burial

- (a) A pit or trench should be dug about 2 meters deep. It should be half filled with waste, 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 should 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 location of the deep burial site will be authorized by State Pollution control Board, Odisha, Bhubaneswar.
- (h) The facilitator (authorized person) shall maintain a record of all pits for deep burial.
- (i) The ground water table level should be a minimum of six meters below the lower level of deep burial pit.

6. CHEMICAL DISINFECTION:

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 CBWTF shall abide by all the provisions/conditions/stipulations made in the Biomedical Waste Management Rules, 2016 and amendments made thereafter.
2. The CBWTF shall strictly follow the updated guidelines of CPCB for Handling, Treatment and disposal of waste generated during treatment/ diagnosis / quarantine of COVID-19 patients (Latest one dtd 21.07.2020) while handling and managing the COVID-19 waste.
3. The CBWTF shall comply with all the conditions, stipulations and provisions contained in the "Revised guidelines for Common Biomedical Waste Treatment & Disposal Facilities dtd. 21.12.2016 prepared by CPCB.
4. It shall use COVID19BMW App of CPCB immediately for tracking of COVID-19 Biomedical Waste and feed daily data pertaining to collection, transportation and disposal of Biomedical Waste.
5. The CBWTF shall enter into MoU with nearest CBWTF located within the State as an alternate arrangement in conformity to the item (3) of Guidelines of CPCB for CBWTFs dt. 21.12.2016.

6. It shall install online continuous emission monitoring system (OCEMS) in the Incinerators for Particulate Matter (PM), Nitrogen Oxides (NO & NO₂) expressed as NO₂, HCL, CO, CO₂, O₂ and flue gas temperature of primary and secondary chambers immediately with facility of real time data transfer to the servers of CPCB and SPCB. Installation of online monitoring system for temperature at Primary and Secondary Chambers shall be made immediately so that the real time data can be made available publicly on Website.
7. The CBMTF shall cater Health Care Establishments as per the CPCB guidelines specified for the coverage area of CBMTF. The segregated biomedical waste shall be collected from the Health Care Establishments within the coverage area for treatment and disposal. The treatment of waste shall be made within the time limit specified in the principal rule.
8. An identification board displaying the name of the facility, owner name, address, telephone no, name of the prescribed authority and validity period of the authorization shall be installed at the entrance of the facility.
9. The treatment and disposal of biomedical waste shall be carried out in compliance to the standards specified in B (1, 2, 3, 4, 5 & 6) of this authorization order.
10. The waste containing equal to or more than 50 ppm of mercury is treated as hazardous waste and it shall be disposed of as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 or as revised from time to time.
11. The occupier shall maintain a log book for each of its treatment equipment according to weight of batch; categories of treated; time, date and duration of treatment cycle and total hours of operation. The occupier shall also display details of authorization, treatment and annual report etc on its website.
12. The occupier shall submit the statement regarding spillage and collection of mercury during the period January to December along with the annual report in Form-IV by 30th of June of every year. The Annual report shall be available online on its website.
13. In case of any major accident while handling bio-medical waste, the authorized person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty four hours in writing regarding remedial steps taken in Form-I.
14. The waste containing equal to or more than 5 gm/kg of silver is treated as hazardous waste and it shall be disposed of as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 or as revised from time to time.
15. The pre-treated 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) guidelines on Safe Management of Waste from health care activities and WHO Blue Book, 2014) shall be collected by the occupier of the Common Biomedical Waste Treatment and Disposal Facility for final treatment and disposal.
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 immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus and other epidemics 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.
18. The occupier shall establish a Bar- Code System and GPS system for handling bio-medical waste in accordance with the guidelines issued by the Central Pollution Control Board within 3 months from the date of issue of this order. This Bar coding facility shall be implemented strictly in accordance with the guidelines of CPCB April 2018.
19. The occupier shall install continuous online monitoring system for the emission parameters prescribed in the Rules and for the parameters specified in the item No.- 10(f) of CPCB guidelines for CBWTFs dt. 21.12. 2016. The real time continuous stack emission monitoring data is to be transmitted to the servers of CPCB and State Pollution Control Board with immediate effect.
20. The occupier shall provide port hole and platform at appropriate height in the stack attached to incinerator to facilitate manual monitoring of stack emission.
21. Wastewater generated from all sources including the scrubbed effluent of incinerator and wastewater from vehicle washing facility shall be adequately treated so as to meet the prescribed standard as mentioned at **4(i)** of this order. It shall comply to all the provisions specified at item No. 9(k) (for Effluent Treatment Plant) of CPCB guidelines for CBWTFs dt. 21.12. 2016.
22. 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.
23. The occupier shall ensure timely collection of biomedical waste even on holidays from the occupiers. The vehicles used for transportation of waste shall comply with the requirement contained in the Motor Vehicle Act, 1988(59 of 1988), if any or the rules made thereunder for transportation of such infectious waste.
24. The occupier shall inform the State Pollution Control Board immediately the name of the health care facility which is not handling over the biomedical waste in accordance with the rule.
25. The occupier shall assist the health care facility (HCF from where the waste is collected for treatment) in training conducted by them for biomedical waste management.
26. The occupier shall ensure occupational safety of all its workers involved in handling of biomedical waste by providing appropriate and adequate personal protective equipment.

27. After ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from treated biomedical wastes such as plastic & glass shall be given to recyclers having valid consent or authorization or registration from State Pollution Control Board.
28. The occupier shall supply non-chlorinated plastic colored bags and containers to the health care facilities on chargeable basis, if required.

To

**Mahesh Kumar Agrawalla, Managing Director,
M/s. Sani Clean Private Ltd.,
At: Plot No. 401, N-4, 42/FM IRC VILLAGE,
Bhubaneswar-751 015**





Member Secretary

State Pollution Control Board,
Odisha, Bhubaneswar

Memo No. _____ / Dated _____ /

Copy forwarded to the Regional Officer, SPC Board, Bhubaneswar file (Head Office) for information and necessary action.


Addl. Chief Env. Engineer