



E-mail: rospcb.kalinganagar@ospcbboard.org
Website: www.ospcbboard.org

**REGIONAL OFFICE OF THE
STATE POLLUTION CONTROL BOARD, ODISHA**
[DEPARTMENT OF FOREST & ENVIRONMENT, GOVERNMENT OF ODISHA]
**Common Facility Center, JCD, Kalinganagar,
Dist- Jajpur-755026, Odisha, India**

FORM-IV [(See Rule 7 (5) & 8 (4))]
PROVISIONAL AUTHORISATION ORDER

Letter No. 536 /

Date. 29/02/17 By Registered post

(Provisional authorization 27/RO-SPCB-KNG/BMW)

Sub: Authorization under Biomedical Waste (Management & Handling) Rules, for operating a facility for collection, transportation, reception, storage, treatment and disposal.

Shri. Bachhan Kumar, Sr. Vice President of the facility Kaliapani Chromite Mine of M/s Balasore Alloys Ltd, located at At/PO Kaliapani of Jajpur District hereby granted an authorization, to operate a facility for generation, segregation, collection, storage, packing and use offering for sale of biomedical waste on the premises situated at
The authorization shall be valid till further order.

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.
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 authorized person to take prior permission of the State Pollution Control Board, Odisha to close down the facility.
6. 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.
7. The biomedical waste container shall be labeled as specified schedule-IV.

8. The vehicles used for transportation of bio-medical waste shall comply with the conditions if any stipulated by the State Pollution Control Board in addition to the requirement contained in the Motor Vehicles Act, 1988 (59 of 1988), if any or the rules made there under for transportation of such infectious waste.
9. Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty-eight hours.
10. The biomedical waste disposal site shall be properly fenced and suitable notice with warning shall be displayed.
11. 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.
12. Every authorised person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for a period of five years, in accordance with these rules and all records shall be subject to inspection and verification of the officials of State Pollution Control Board, Odisha at any time.
13. The State Pollution Control Board, Odisha reserves the right to modify, revoke or review the authorization granted.

(B) STANDARDS FOR TREATMENT AND DISPOSAL OF BIOMEDICAL WASTES

Standards for treatment and disposal of Bio medical wastes shall be followed as per Schedule – II of the Rules.

1. (i) Operating Standards and Emission standards (Incinerator)

Operating standard	
Parameters	Operating Standards
Combustion efficiency	99%
Temperature of primary chamber	800
Temperature of secondary chamber	1050 + 500C

(ii) Emission standards

Sl. No.	Parameters	Standards	
		(3)	(4)
		Limiting concentration in mg Nm³ unless stated	Sampling Duration in minutes, unless stated
	Particulate matter	50	30 or 1Nm ³ of sample volume, whichever is more
	Nitrogen Oxides NO and NO ₂ expressed as NO ₂	400	30 for online sampling or grab sample
	HCl	50	30 or 1Nm ³ of sample volume, whichever is more
	Total Dioxins and Furans	0.1ngTEQ/Nm ³ (at 11% O ₂)	8 hours or 5Nm ³ of sample volume, whichever is more
	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 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.

Note:

- The existing incinerators shall comply with the above by March 27, 2018.
- The existing incinerators shall comply with the standards for Dioxins and Furans of 0.1ngTEQ/Nm³, as given by March 27, 2018.
- All upcoming common bio-medical waste treatment facilities having incineration facility or captive incinerator shall comply with standards for Dioxins and Furans.
- The existing secondary combustion chambers of the incinerator and the pollution control devices shall be suitably retrofitted, if necessary, to achieve the emission limits.
- Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- 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 Transboundary Movement) Rules, 2016 as amended from time to time.

(g) 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.

(h) The occupier or operator of a common bio-medical waste treatment facility shall monitor the stack gaseous emissions (under optimum capacity of the incinerator) once in three months through a laboratory approved under the Environment (Protection) Act, 1986 and record of such analysis results shall be maintained and submitted to the prescribed authority. In case of dioxins and furans, monitoring should be done once in a year.

(i) The occupier or operator of the common bio-medical waste treatment facility shall install continuous emission monitoring system for the parameters as stipulated by State Pollution Control Board or Pollution Control Committees in authorisation and transmit the data real time to the servers at State Pollution Control Board or Pollution Control Committees and Central Pollution Control Board.

(j) All monitored values shall be corrected to 11% Oxygen on dry basis.

(k) Incinerators (combustion chambers) shall be operated with such temperature, retention time and turbulence, as to achieve Total Organic Carbon content in the slag and bottom ashes less than 3% or their loss on ignition shall be less than 5% of the dry weight.

The occupier or operator of a common bio-medical waste incinerator shall use combustion gas analyzer to measure CO₂, CO and O₂.

2. Standards for Microwaving.

1. Microwave treatment shall not be used for cytotoxic, hazardous or radioactive wastes, contaminated animal carcasses, body parts and large metal items.
2. 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.
3. 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.

TEMPERATURE (In degree centigrade)	PRESSURE (pounds per square inch)	RESIDENCE TIME (in minutes)
Not less than 121 °C	15	Not less than 60
Not less than 135 °C	31	Not less than 45
Not less than 149 °C	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 °C	15	Not less than 45
Not less than 135 °C	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.

Standards for Liquid Waste

- (1) The effluent generated or treated from the premises of occupier or operator of a common biomedical waste treatment and disposal facility, before discharge to sewer should confirm the following limits:-

SL. NO	PARAMETERS	PERMISSIBLE LIMIT
(i)	pH	6.5 – 9.0
(ii)	Suspended Solids	100 mg/l
(iii)	Oil & Grease	10 mg/l
(iv)	BOD	30 mg/l
(v)	COD	250 mg/l
(vi)	Bio-assay test	90% survival of fish after 96 hours in 100% effluent.

- (2) Sludge from effluent treatment plant shall be given to common biomedical waste treatment facility for incineration or to hazardous waste treatment, storage and disposal facility for disposal.

(IV) STANDARDS FOR DEEP BURIAL

- 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.
- It must be ensured that animals do not have any access to burial sites.
- On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.
- Burial must be performed under close and dedicated supervision.
- The deep burial site should be relatively impermeable and no shallow well should be close to the site.
- The pits 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.
- The location of the deep burial site will be authorized by State Pollution Control Board, Odisha, Bhubaneswar.
- The facilitator (authorized person) shall maintain a record of all pits for deep burial.
- The ground water table should be a minimum of six meters below the lower level of deep burial pit.

(V) **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. This authorization is issued for Nil nos. of beds. For any increase in number of beds, the applicant shall obtain prior permission of the prescribed authority.
2. Treated 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.
3. Biomedical wastes shall be segregated in to coloured containers/ bags at the point of generation as per Schedule-II of the rules and shall be followed by proper quantification of different categories of waste. The containers shall be labelled with biohazard and cytotoxic symbol.
4. The occupier shall treat the segregated biomedical wastes in the manner described below or **shall ensure requisite treatment of segregated wastes at the common facility, authorized by State Pollution Control Board, Odisha.**

Part-1

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
(1)	(2)	(3)	(4)
Yellow	a) Human Anatomical Waste: Human tissues, organs, body parts and 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*

	<p>(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.</p>		
	<p>(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.</p>		<p>Incineration or Plasma Pyrolysis or deep burial*</p> <p>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.</p>
	<p>(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.</p>	<p>Yellow coloured non-chlorinated plastic bags or containers,</p>	<p>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.</p> <p>All other discarded medicines shall be either sent back to manufacturer or disposed by incineration</p>

	<p>(e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.</p>	Yellow coloured containers or nonchlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	<p>(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.</p>	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 given in Schedule- III.
	<p>(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.</p>	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.
	<p>(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,</p>	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration.

	dishes and devices used for cultures.		
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 <i>fixed needle syringes</i>) and vacutainers with their needles cut) and gloves		
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.	Cardboard boxes with blue colored marking -9-	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or

	(b) Metallic Body Implants	Cardboard boxes with blue colored marking	microwaving or hydroclaving and then sent for recycling.
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* 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 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.

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 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log104 reduction efficiency for microorganisms as given in Schedule- III.
- (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 and Other Wastes (Management and Transboundary Movement) Rules, 2016 or as revised from time to time.
- (6) Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.
- (7) Cytotoxic drug vials shall not be handed over to unauthorised person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature $>1200^{\circ}\text{C}$.
- (8) 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.
- (9) On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organisation or National AIDS Control Organisation and then given to the common bio-medical waste treatment and disposal facility.

(10) 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.

(11) 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.

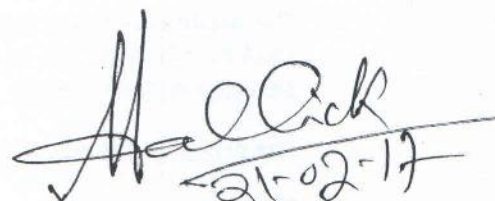
(12) Bio-medical waste generated in households during healthcare activities shall be segregated as per these rules and handed over in separate bags or containers to municipal waste collectors. Urban Local Bodies shall have tie up with the common bio-medical waste treatment and disposal facility to pickup this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal in the manner as prescribed in this Schedule.

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5. The treatment and disposal of biomedical waste shall be carried out in compliance to the standards specified in B (1, 2, 3, 4 & 5) of this authorization order.
 6. The waste containing equal to or more than 50 ppm of mercury is treated as hazardous waste and it shall be disposed off as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.
 7. The authorized person of the unit 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 as specified in Schedule I;
 8. The health care unit shall submit the statement regarding spillage and collection of mercury during the period January to December alongwith the annual report in Form-IV by 30th of June of every year.
 9. The waste containing equal to or more than 5 gm/kg of silver is treated as hazardous waste and it shall be disposed off as per the Hazardous and Other Wastes (Management and Tran boundary Movement) Rules, 2016.
 10. The occupier will obey all the lawful instructions issued by the Board officers from time to time.
 11. 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;
 12. The occupier shall phase out use of chlorinated plastic bags, gloves and blood by March 27, 2018;
 13. 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 programs conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report.

14. 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
15. transmitted by handling of bio-medical waste, in the manner as prescribed National Immunization Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time;
15. The occupier shall 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 by March 27, 2017;
16. The occupier shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);
17. 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;
18. The occupier shall make available the annual report on its web-site and all the health care facilities shall make own website by March 27, 2018;
19. The occupier shall 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;
20. The unit shall apply for renewal of authorization in Form-II as per Biomedical Waste Management Rules, 2016 before four months from the date of expiry of this authorization order enclosing all necessary documents and compliance to the conditions stipulated in this order.

To

Shri. Bachhan Kumar, Sr. Vice President
Kaliapani Chromite Mine of M/s Balasore Alloys Ltd
At/PO-Kaliapani, Dist.- Jajpur, Odisha


21-02-17

REGIONAL OFFICER
STATE POLLUTION CONTROL BOARD, ODISHA
KALINGANAGAR, JAJPUR

Memo No. _____

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Copy forwarded to Member Secretary, SPC Board, and Bhubaneswar for your kind information.

REGIONAL OFFICER

Memo No. _____

dt. _____

Copy forwarded to ADMO (Medical), District Headquarter Hospital, Jajpur for your kind information.

REGIONAL OFFICER