

Date: 21-JUN-21

To.

The Environmental Officer,
Karnataka State Pollution Control Board,
Regional Office: Anekal region
Nisarga Bhavan, Basaveshwaranagar
Bangalore – 560 010

Dear Sir,

Subject: Submission of Bio-Medical Waste Annual returns in form -4 from Apotex research pvt ltd plot No.2, 4th phase, Bommsandra industrial area, Jigani link road, Bangalore-560 099

Reference: Section 13(1) of Bio-Medical Waste Management Rules, 2016.

Find the enclosures herewith the Bio-medical waste annual returns for the year 2020 in Form- 4.

Kindly acknowledge the receipt of the same.

Thanking you

For Apotex Research pvt Ltd

rasanna kumar Signature

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Form - IV (See rule 13) ANNUAL REPORT

[To be submitted to the prescribed authority on or before 30th June every year for the period from January to December of the preceding year, by the occupier of health care facility (HCF) or common bio-medical

waste	treatment	facility	(CBWTF)]
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Sl. No.	Particulars	Details				
1	Particulars of the Occupier:	Dr. Yoganjaneya Reddy				
	(i) Name of the authorised person (occupier or operator of facility)	Managing Director				
	(ii) Name of HCF:	Apotex Research Private Limited				
	(iii) Address for Correspondence:	Plot-2, 4 th Phase, Bommasandra Industrial area, Jigani Link road, Anekal Taluk, Bangalore-560 099				
	(iv) Address of Facility	Plot-2, 4th Phase, Bommasandra Industrial area, Jigani Link road, Anekal Taluk, Bangalore-560 099				
	(v)Tel. No, Fax. No:	080-22891014; 080-22891099				
	(vi) E-mail ID:	yreddyl@apotex.co.in				
	(vii) URL of Website	http://apoweb.apotex.ca/Pages/default.aspx				
	(viii) GPS coordinates of HCF or CBMWTF	NA				
	(ix) Ownership of HCF: (State Government or Private or Semi Govt. or any other)	Private limited				
	(x). Status of Authorisation under the Bio- Medical Waste (Management and Handling) Rules	Authorisation No.: PCB/WMC/1253/BMW (2016)/2018-19/Reg. No.147702/H-958 dated 28-FEB-2019 valid up to 30-Jun-2021				
	(xi). Status of Consents under Water Act and Air Act	: valid up to:30-Jun-21				
	Type of Health Care Facility:	Bio equivalence & Bioavailability Study Centre.				
	Bedded Hospital: No. of Beds.	200				
i	Non-bedded hospital (Clinic or Blood Bank or Clinical Laboratory or Research Institute or Veterinary Hospital or any other)	NA .				
i	License number and its date of expiry	31-Dec-2025				
	Details of CBMWTF:	M/s Maridi Eco Industries Pvt Ltd				
	Number healthcare facilities covered by CBMWTF	NA				
	No of beds covered by CBMWTF:	NA				
i	Installed treatment and disposal capacity of CBM Kg per day	NA				
7	Quantity of biomedical waste treated or disposed by CBMWTF Kg/day	NA				
	Quantity of waste generated or disposed in Kg per annum (on monthly average basis)	Yellow Category: ATTACHED AS Red Category: ANNEXURE-1 White: Blue Category: General Solid waste:				

5.	Details of the Storage, treatment, transportation,	processing and Disposal Facility				
(i)	Details of the on-site storage facility	Size: 10x12x8 Capacity: 250 Kgs/day Provision of on-site storage: Dedicated storage facility.				
(ii)	Details of the treatment or: disposal facilities Type of treatment equipment No of units Capacity Kg/ day Quantity treated or disposed in kg per annum Incinerators, Plasma Pyrolysis, Autoclaves Microwave, Hydroclave, Shredder, Needle tip cutter or Destroyer, Sharps encapsulation or concrete pit, Deep burial pits: Chemical disinfection: Any other treatment equipment:	1				
(iii)	Quantity of recyclable wastes sold to authorized recyclers after treatment in kg per annum. Red Category (like plastic, glass etc.)					
(iv)	No of vehicles used for collection and transportation of biomedical waste	NA				
(v)	Details of incineration ash and ETP sludge generated and disposed during the treatment of wastes in Kg per annum Quantity generated Where disposed Incineration Ash, ETP Sludge					
(vi)	Name of the Common Bio-Medical Waste Treatment Facility Operator through which wastes are disposed of	M/s Maridi Eco Industries Pvt Ltd				
(vii)	List of member HCF not handed over bio- medical waste.	NA				
6	Do you have bio-medical waste management committee? If yes, attach minutes of the meetings held during the reporting period	Yes				
7	Details trainings conducted on BMW	Basic BMW management				
(i)	Number of trainings conducted on BMW Management.	10				
(ii)	Number of personnel trained	120				
(iii)	Number of personnel trained at the time of induction	10				
(iv)	Number of personnel not undergone any training so far	NIL				
(v)	Whether standard manual for training is available?	Yes				
(vi)	any other information)	NIL				
3	Details of the accident occurred during the year	NIL				
i)	Number of Accidents occurred	NIL				
ii)	Number of the persons affected	NIL				
(iii)	Remedial Action taken (Please attach details if any)	NIL OCH PRI				
(iv)	Any Fatality occurred, details.	NIL				

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9	Are you meeting the standards of air Pollution from the incinerator? How many times in last year could not met the standards? Details of Continuous online emission monitoring systems installed	NA
10	Liquid waste generated and treatment methods in place. How many times you have not met the standards in a year?	NA
11	Is the disinfection method or sterilization meeting the log 4 standards? How many times you have not met the standards in a year?	NA
	Any other relevant information	NA
	(Air Pollution Control Devices attached with the Incinerator)	NA

Certified that the above report is for the period from January 2020 to December-2020

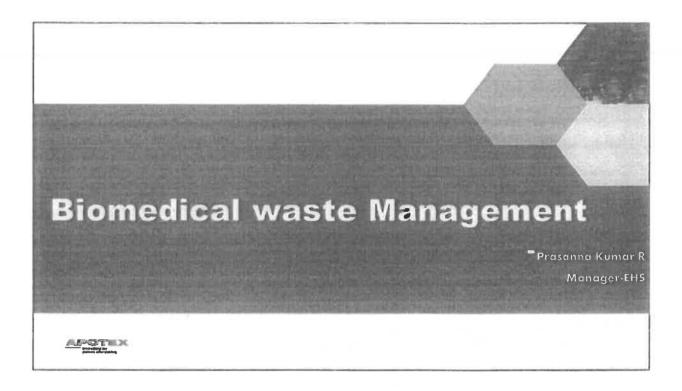
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Name and Signature of the Head of the Institution

Date: 23-Jun-21 Place: Bengaluru







Definition

"Any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to BMW rules 2016" - World Health Organization



Sources of waste

☐ Hospital waste: refers to all waste, biological or non biological that is discarded and is not intended for future use

Medical waste: refers to material generated as a result of patient diagnosis, treatment, immunization of human being or animals.

Infectious waste; are the portion of medical waste that could transmit an infectious disease.

Pathological waste: waste removed during surgery, autopsy or other medical procedures including human tissues, organs, body parts, body fluids and specimen along their container.

Major sources Minor sources •Hospitals •Clinics •Labs •Dental clinics •Research centers •Home care •Animal research
•Cosmetic clinics •Blood banks •Paramedics •Nursing homes •Funereal services •Mortuaries •Institutions
80% 15% 3% 1% 1% Non infectious waste Pathological and infectious waste Chemical and pharmaceutical waste
Sharps Radioactive, cytotoxic and heavy metals

APOTEX

WASTE CATEGORIES TYPES OF WASTE

Category no. 1 Human anatomical waste(Human tissues, organs, body parts)

Category no. 2 Animal Waste(Animal tissues, organs, body parts, carcasses, bleeding parts, fluid, blood)

Category no. 3 Microbiological and biotechnological waste(Wastes from laboratory cultures, stocks or specimen of organism)

Category no. 4 Waste sharps(Needles, syringes, scalpels, blades, glass, etc. that may cause puncture and cuts)

Category no. 5 Discarded medicine, cytotoxic waste(Wastes comprising of outdated, contaminated, discarded medicines)

Category no. 6 Soiled waste(Items contaminated with body fluids including cotton, dressings, soiled plaster casts)

Category no. 7 Solid waste(Waste generated from disposable items as tubing, catheters, intravenous set)

Category no. 8 Liquid waste(Waste generated from the laboratory and washing, cleaning)

Category no. 9 Incineration waste(Ash from Incineration of any biomedical waste)

Category no. 10 Chemical waste(Chemicals used in production of biological, chemicals used in disinfecting)

Signature

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Occupier shall ta	ke all necessary st	eps to ensure tha	at bio-medical was	te is handled.	Secretary State Confession Confes
☐ Make a provision	to follow the stand	lard color coding	system.		
☐ Phase out use o	f chlorinated plastic	c bags, gloves an	nd blood bags with	in 2 year	
□ Pre-treatment of	the laboratory was	te ,microbiologica	al waste, blood sa	mples and blood bag	s through
disinfection or steri	lization.				
☐ Conduct check	up and immunizatio	n of the workers	every year.		
☐ Report major ac	cidents.				

Occupier responsibility

- ☐ Annual report of training program should be maintained.
- ☐ Occupational safety of all health care workers.
- ☐ Untreated human anatomical waste, animal anatomical waste, solled waste and, biotechnology waste shall not be stored beyond a period of 48 hours:
- ☐ Maintain and update on day to day basis the bio-medical waste management register.
- ☐ Establish a system to review and monitor the activities related to BMW by forming a committee.
- Survey of waste generated
- Segregation of hospital waste
- Collection and categorization of waste
- Storage of waste
- •Transportation of waste
- Treatment of waste



WHAT GENERATORS CAN DO?

- (Hospitals) In house segregation (collection, segregation, packing in color coded bags) Common storage point al hospitals Transportation (Approved special vehicles) Unloading the waste collected Treatment (Incineration , autoclaving, shredding) Disposal (Recycling and landfill) Waste water to TP Reuse
- Differentiate the types of waste
- · Quantity the waste generated
- Determine the points of generation and types of waste generated at each point
- Determine the level of generation and disinfection within the hospital



Segregation

- 11 It refers to the basic separation of different category of waste generated at source and thereby reducing the risks as well as cost of handling and disposal.
- ☐ Segregation is the most crucial step in BMW. Effective segregation alone can ensure effective BMW management.
- The bins and bags should carry the biohazard symbol indicating the nature of waste to the patient and public.
- ☐ Labels shall be non washable and prominently visible.
- ☐ The collection of BMW involves of different types of containers.
- $\hfill\square$ The containers should be placed in such a way that 100% collection is achieved.
- Sharps must always be kept in puncture proof containers to avoid injuries and infection to the waste handlers.
- BMW should be handled properly by using universal precautions to prevent from any kind of infection.



Storage, segregation & disposal of BMW

- -
- ☐ Once collection occurs then biomedical waste is stored in proper place. Segregated waste of different categories need to be collected in identifiable containers.
- ☐ The duration of storage should not exceed 8-10 hours in big hospitals and 24 hours in nursing homes.
- $\hfill\square$ Each container should be clearly labeled to show the ward where it is kept.

Transportation devices-

- Trolleys
- Wheelbarrows
- Manual loading should be avoided as far as possible.
- · The containers should be tied before transportation.
- Container should be accompanied with a signed document by nurse/doctors mentioning date, shift, quantity and destination.

APOTE

Our Responsibilities

- ☐ Avoid needle stick injuries.
- □ Avoid spilling and clean them with disinfectant.
- ☐ Proper labeling should be done of the bags.
- □ Make the provision of safe segregation, handling and transport of BMW.
- ☐ Use universal precautions to avoid infection.
- ☐ Immunize self and others time to time and maintain the records.
- ☐ Report major accidents.
- Regular visits of all the wards and high risk units.

ADVANCING GENERICE Signature

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BIOMEDICAL WASTE COLLECTION RECORD (JAN-20 to DEC-20)

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Prepared By:	<i>~</i>		December	November	October	September	Auguest	August	June	iviay	30	A STATE OF THE STA	Marsh	January	Month
16. KO 1. 8.) \ ()		105.00	97.00	93.00	73.00	77.00	65,00	61.00	59.00	50.00	22.00	65.00	90.00	Yellow (Kgs)
8- KA1-0-1	الار بدولا	Grand Total	0.35	0.20	0.35	0.30	0.45	0.40	0.25	0.26	0.45	0.55	0.25	0.30	Blue (Kgs)
			387.00	356.00	270.00	263.00	293,00	190.00	193.00	186.00	173.00	190.00	193.00	219.00	Red (Kgs)
			32.00	29.00	31.00	34.00	29.00	27.00	22.00	24.00	25.00	33.00	13.00	18.00	White Can (Kgs)
		4156.11	524.35	482.20	394.35	370.30	399.45	282.40	276.25	269.26	258,45	300.55	271.25	327.30	Total (Kgs)

By:-----





INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.

Certificate Issued Date

Account Reference

Unique Doc. Reference

Purchased by

Description of Document

Description

Consideration Price (Rs.)

First Party

Second Party

Stamp Duty Paid By

Stamp Duty Amount(Rs.)

IN-KA71148984869136S

29-Jun-2020 11:44 AM

NONACC (FI)/ kacrsfi08/ GANDHINAGAR/ KA-BA

SUBIN-KAKACRSFL0846514823577716S

MARIDI BIO INDUSTRIES PVT LTD

Article 12 Bond

AGREEMENT

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(Zero)

MARIDI BIO INDUSTRIES PVT LTD

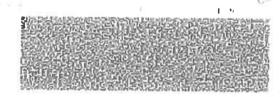
APOTEX RESEARCH PVT LTD

MARIDI BIO INDUSTRIES PVT LTD

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(Twenty only)





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Please write or type below this line

MEMORANDUM OF UNDERSTANDING

Reg.No: 493

M/s. Maridi Bio Industries Pvt Ltd., having its registered office at No. 8, SUNAGA ARCADE, 4th Floor, 1st Main, 8th Cross, S.R.nagar, Bangalore-560027, Phone No: 080-41512958/22103270, Email id: maridibmwargmail.com and having Its Plant at Sy.No. 1/37 & 1/38, 35th Milestone, Gabbadi Kaval, Kanakapura Road, Ramanagar District, here in after referred to as, M/s. Maridi Bio Industries Pvt Ltd. representation of the Authorized Signatory and M/s. APOTEX REASERCH PV. Center # Plot No. 2, Site No. 1, 4th Phase, Bomma and Tra Industrial Area.

Statutory

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be verified at "www.shcilestam .com" Any discrepancy in the detail

2. The onus of checkl and the certificate.
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4th Phase, Jigani Link Road, Bangalore-560099. Mob: 9538601717. Tel No: 080-71501433/ 080-22891099/ 080-22891014. Email: vnkumar@apotex.co.in .Here in after referred to as M/s. APOTEX REASERCH PVT LTD is hereby agreed and come to the Memorandum of Understanding on this 2nd Day of July month year 2020 as detailed below:

- a. M/s. Maridi Bio Industries Pvt Ltd. with consent from Karnataka State Pollution Control Board is having a common treatment facility for Managing Bio-Medical Waste in Ramanagaram district at 36th Mile Stone, Kanakapura Road. The facility is having a state of art Auto clave system along with the shredder and Incinerator.
- b. M/s. APOTEX REASERCH PVT LTD having gives its bio-medical waste properly packed in color-coded bags as per pollution control Board regulations for treatment and final disposal to M/s. Maridi Bio Industries Pvt Ltd. The waste should be given at one single point by the M/s. APOTEX REASERCH PVT LTD at given time of M/s. Maridi Bio Industries Pvt Ltd. Vehicle.
- c. M/s. Maridi Bio Industries Pvt Ltd. will charge a price as per below table (Excluding Poly bags) transportation, treatment and final disposal of biomedical waste. This Price will be fixed for a period of one (1) year from date of this agreement and thereafter there will be 5% (Five Percent) escalations in the price for every one-year on existing rate. As per Below Table.

PARTICULARS	AMOUNT			
01-04-2020 to 31-03-2021	17945/-			
01-04-2021 to 31-03-2022	18842/-			
01-04-2022 to 31-03-2023	19784/-			

- d. M/s. APOTEX REASERCH PVT LTD will not enter into any agreement with any other party or organization for the waste treatment and disposal unless cancel of this agreement.
- e. M/s APOTEX REASERCH PVT LTD is assuring that payment should be made through Account Payee cheque In favour of M/s. Maridi Bio Industries Pvt Ltd. on or before 5th of every month.
- f. M/s. Maridi Bio Industries Pvt Ltd. is not responsible for any cash payments and also we will collect cheque bounce charges.
- g. In case of non-receipt of payment on the agreed date from M/s. APOTEX REASERCH PVT LTD M/s. Maridi Bio Industries Pvt Ltd., will stop the collection of waste immediately with intifaction to Karnataka State Pollution Control Board. The delayed payments will be collected with an interest of 18% per annum.

EHS

- h. M/s. Maridi Bio Industries Pvt Ltd. will collect bio medical Waste Regularly as per Mentioned in Registration Form (Except Sunday) and treat the waste as per the regulations. M/s. Maridi Bio Industries Pvt Ltd. will not collect any General waste that is not segregated or not properly packed M/s. Maridi Bio Industries Pvt Ltd. will not collect general garbage.
- i. M/s. Maridi Bio Industries Pvt Ltd. will issue a proof of waste collection from M/s. APOTEX REASERCH PVT LTD as per your declarations in the application form. This will help the individual Clinic for getting compliance with the State Pollution Board. The individual Clinic/Nursing home can take their Authorization from the pollution control board by informing the board that M/s Maridi Bio Industries Pvt Ltd. treats their waste (The same has to be mentioned in the Authorization Form.
- j. In case APOTEX REASERCH PVT LTD find any irregularities in collection of waste, they can send a notice in writing to M/s. Maridi Bio Industries Pvt Ltd. for immediate action.
- k. M/s Maridi Bio Industries Pvt Ltd. will maintain their plant in good running condition all the time and ensure continuity of service as per agreement with your APOTEX REASERCH PVT LTD.
- l. This Memorandum of understanding is entered into on the express understanding that M/s Maridi Bio Industries Pvt Ltd. will maintain and run the facilities and collect transport and treat the waste at their plant strictly in accordance with the consent of the Karnataka State Pollution Control Board and it shall be the responsibility to obtain the consent and keep the same always current.
- m. In case of violation of any of the agreed condition of the MOU by either Issue of notice may terminate this MOU three months in advance by either party for terminating their respective obligations.
- n. All disputes to this understanding are subject to the Jurisdiction of the court in Bangalore only.
- o. MOU Renewal Charges of Rs.200 Extra for next Year.
- p. This Agreement is effective from 01.04.2020 to 31.03.2023.



ಫ್ಯಾಡ್ಸ್ / Fax : 080-25586321

ಆಮೇಲ್ / E-mail : ho@kspcb.gov.in ವೆಟ್ಡ್ ಸ್ಟ್ರೇಟ್ / Website : http://kspcb.gov.in



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ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿ Karnataka State Pollution Control Board

"ಪರಿಸರಭವನ", 1 ರಿಂದ 5ನೇ ಮಹಡಿಗಳು, ನಂ.49, ಚರ್ಚ್ಸ್ಟ್ರೀಟ್, ಬೆಂಗಳೂರು – 560 001, ಕರ್ನಾಟಕ, ಭಾರತ "Parisara Bhavana", 1st to 5th Floor, # 49, Church Street, Bengaluru - 560 001, Karnataka, INDIA FORM—III (See rule 10)

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

AUTHORISATION

2. M/s. Apotex Research Private Limited, an occupier or operator of the hospital located at Plot No. 2, 4th Phase, Bommasandra Industrial Area, Jigani Link Road, Bengaluru-560099, is hereby granted an authorisation for;

Activity Please tick:
Generation, segregation
Collection,
Storage
Packaging
Reception
Transportation
Treatment or processing or conversion
Recycling
Disposal or destruction use offering for sale, transfer
Any other form of handling

3. <u>M/s.Apotex Research Private Limited</u>. Hospital is hereby authorized for handling of biomedical waste as per the capacity given below;

(i) Number of beds of HCF: 200 beds

Type of Waste Category

Quantity permitted for Handling:

Yellow

Red

White (Translucent)

Blue

4. This authorisation shall be in force for a period of <u>01.07.2018</u> to <u>30.06.2021</u> Years from the date of issue.

5. This authorisation is subject to the conditions stated below and to such other conditions as

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AVOID USE OF PLASTICS- BE 'ECO' FRIENDLY

may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Place: Bangalore

ENIOR ENVIRONMENTAL OFFICER

To,
The Occupier,
M/s. Apotex Research Private Limited,
Plot No. 2, 4th Phase, Bommasandra Industrial Area,.
Jigani Link Road, Bengaluru-560099.

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TERMS AND CONDITIONS OF AUTHORISATION *

- 1. The applicant shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made there under.
- 2. The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
- 3. The person authorized shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
- 4. Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
- 5. It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility and such other terms and conditions may be stipulated by the prescribed authority.
- 6. Applicant shall take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules.
- 7. Applicant shall make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in Schedule I of the Bio-Medical Waste Management Rules, 2016.
- 8. Applicant shall ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the biomedical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I the Bio-Medical Waste Management Rules, 2016.
- 9. Applicant shall pre-treat the 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) or National AIDs Control Organisation (NACO) guidelines and then sent to the common

bio-medical waste treatment facility for final disposal;

SENIOR ENVIRONMENTAL OFFICER

- 10. Applicant shall phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of these rules;
- 11. Applicant shall dispose 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;
- 12. Applicant shall not to give treated bio-medical waste with municipal solid waste;
- 13. Applicant 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;
- 14. Applicant 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 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;
- 15. Applicant 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 within one year from the date of the notification of these rules;
- 16.Applicant shall ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;
- 17. Applicant shall ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974);
- 18. Applicant shall ensure occupational safety of all its health care workers and others involved in handling of biomedical waste by providing appropriate and adequate personal protective equipments;
- 19. Applicant 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;

SENIOR ENVIRONMENTAL OFFICER