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RESEARCH ARTICLE

IMPLEMENTATION AND CHALLENGE IN DEALING WITH THE BMW DISPOSAL GUIDELINES AND LEGISLATIONS

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Abstract

Biomedical Waste Management (BMWM) is a public health problem. Every hospital is generating BMW needs to set up requisite BMW treatment facilities on site or ensure requisite treatment of waste at common treatment facility. The Ministry of Environment & Forests notified the situation of pollution and framed out the Biomedical Waste (management & handling) Rules, 1998” to protect the Environment Protection Act, 1986 (29 of 1986); in our country on 20th July 1998 vide notification number S.O. 630 (E) dated the 20th July, 1998, by the Government of India in the erstwhile Ministry of Environment and Forests. Now, therefore, in exercise of the powers conferred by section 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998, except as respects things done or omitted to be done before such suppression, the Central Government hereby makes the following rules, namely Bio-Medical Waste Management Rules, 2016, and (Amendment) Rules, 2018, were an update and simplification of BMW not only human health and safety but also to the environment for the current and future generations. Effective BMWM is not only a legal necessity but also a social responsibility. This article reviews the current perspectives on BMWM and rules, conventions and the treatment technologies used worldwide. Furthermore, developing models for the monitoring of hospital health-care waste practices and research into non-burn eco-friendly sustainable technologies, recycling and polyvinyl chloride-free devices will go in long way for safe carbon environment. Globally, greater research in BMWM is warranted to understand its growing field of public health importance.

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Introduction:-

The very high percentage of BMW is regarded as hazardous, and if not managed properly, it can spread highly contagious and a grave health hazard for current and future generations. Biomedical waste is any kind of waste containing infectious or potentially infectious material and sometimes also called as Hospital waste. It may also include waste as located with the generation of BMW that visually appears to be of Medical or Laboratory origin e.g. packaging, unused bandages infectious PPE Kits etc as well as research laboratory waste containing Biomolecules or organisms that are mainly restricted from environmental release. They may be solid or liquid. Common Bio-medical Waste Treatment and Disposal Facility (CBWTF) is a set up where biomedical waste generated from member health care facilities is imparted necessary treatment to reduce adverse effects that this waste may pose on human health and environment. The treated recyclable waste may finally be sent for disposal in a secured landfill or for recycling.

India visualised the need of environmental protection through act (1986) before the United Kingdom & United state of America as explained in the legislation section.

Prevailing situation:

Despite having such stringent rules and regulation, situation in our country is not very satisfactory as we read in newspapers, see on TV and social media, regarding reuse of plastic syringes, needles PPE kits etc and the hospital waste PPE kits are being thrown nearby Hospital / Health care centre being disposed not properly endangering health of the nearby society. BMW generated in mass vaccinations (1.6 million) in and increases infectious injuries to scavengers which may be much higher after Covid vaccination in all countries, BMW in place or ones requiring major improvement.^{[1] [2]}

World Health Organization (WHO) study in 22 developing countries shows that they do not use proper waste disposal methods.^[3] In India, annually about 0.33 million tons of BMW is generated and rate ranges from 0.5 to 2.0 kg per bed per day.^[4] Study shows that poor BMW practices are attributed to lack of awareness and training as was concluded in a recent study.^[5]

Classification of BMWs:

In the US and other parts of the world there are four major types of medical waste.

1). General 2). Infectious 3). Hazardous 4). Radioactive

Some types of Medical waste have different name that can be used interchangeable depending on which country you are operating in to avoid controversies and to bring uniformity WHO classified BMW in following 10 categories (Annexure-I & II, CATEGORIES OF BIO-MEDICAL WASTE and COLOUR CODING AND TYPE OF CONTAINER FOR DISPOSAL OF BIO-MEDICAL WASTES, Rule 5, 6)

WHO has given clear cut guidelines and colour coding for segregation of BMWs / Hospital waste and these have to be followed up strictly.

With the 'motto' let the waste of 'sick' not contaminates the lives of 'the healthy'- It includes both human and animal infectious waste and the waste generated in any laboratory and veterinary practice. Any waste with a potential to pose a threat to human health and life is called Hazards waste.

Guidelines for disposal of BMWs:

Health is a state subject as per the constitution of India as well as health is also a fundamental right of each and every citizen. WHO is responsible for safeguarding the health of all the individuals of the world may be rich / poor of any cast or creed living in developed, undeveloped and even developing countries. so its guidelines have to followed strictly and should be made compulsory to each member country (which are 192 in Numbers). These countries are signatories to follow the constitution of WHO, for the safety of global health.

According to the Bio-medical Waste Management Rules, 2016, "bio-medical waste treatment and disposal facility" means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal is carried out and includes common bio-medical waste treatment facilities. This subject should be taken up at a top priority in view of modern times pandemic e.g. Covid 19, which has almost shut down the whole world jeopardizing health including social, economic and all most every sector of human life.

It is not liability of WHO only to contain the present pandemic and to prevent any occurrence of such incidence in future, which can affect global health again. It is the combined responsibility of all the countries and communities to be vigilant against such recurrence of pandemic or epidemics.

Thus there is an urgent need to formulate strict international regulation by WHO for their implementation by all the member country and they to be follow these guidelines.

Methodology:-

All the countries have to decide effective and practical guidelines for the implementation of BMWs suited of their condition.

National issues or Indian scenario:

India is also facing lot of challenges in implementation of guidelines BMWs disposal. We have broadly divided the country in to states, Union Territories and Army establishments. We need strict uniform guideline for their implementation.

BMW includes certain point which has been explained as below;

Occupier:

a person (i.e., HCF) shall hand over segregated waste as per the Schedule-I to common bio-medical waste treatment facility for treatment, processing and final disposal and ensuring treatment and disposal of generated bio-medical waste through a CBWTF, located within a distance of 75 KM, who has control over that institution and/ or its premises; in relation to any institution generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called to take all steps to ensure that such waste is handled without any adverse effect to human health and the environment.

Operator:-

means a person who owns or controls or operates a facility for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste. In addition, it requires separate dedicated and trained skilled manpower and infrastructure development for proper operation and maintenance of treatment systems with disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines for final disposal.

Bio-medical waste treatment facility:-

Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and Schedule-II by the health care facilities and common bio-medical waste treatment facility wherein treatment, disposal of bio-medical waste or process incidental to such treatment or disposal is carried out and includes common treatment facilities within a distance of seventy-five kilometer.

The CBWTFs are also required to set up based on the need for ensuring environmentally sound management of bio-medical waste keeping in view the techno-economic feasibility and viable operation of the facility with minimal impact on human health and environment. In turn, it reduces the monitoring pressure on regulatory agencies. By running the treatment equipment at CBWTF to its full capacity, the cost of treatment of per kilogram bio-medical waste gets significantly reduced. Its considerable advantages have made CBWTF popular and proven concept in most part of the world.

Follow up Schedule:-

Schedule appended to these rules. All Schedules should be follow up for categorization, labeled containers, proper storage, transportation, treatment and disposal according to Schedule (Rules 6 & 7. See. Annexure/Schedule)

Segregation, packaging, transportation and storage (Rules 6 & 7. See. Annexure/Schedule):-

- (1) Bio-medical waste shall not be mixed with other wastes.
- (2) Bio-medical waste shall be segregated into containers/bags at the point of generation in accordance with Schedule II prior to its storage, transportation, treatment and disposal. The containers shall be labeled according to Schedule III.

(3) If a container is transported from the premises where bio-medical waste is generated to any waste treatment facility outside the premises, the container shall, apart from the label prescribed in Schedule III, also carry information prescribed in Schedule IV.

(4) Notwithstanding anything contained in the Motor Vehicles Act, 1988 (59 of 1988), or rules thereunder, untreated bio-medical waste shall be transported only in such vehicle as may be authorised for the purpose by the competent authority as specified by the Government.

(5) No untreated bio-medical waste shall be kept stored beyond a period of 48 hours:

Provided that if for any reason it becomes necessary to store the waste beyond such period, the authorised person must take permission of the prescribed authority and take measures to ensure that the waste does not adversely affect human health and the environment.

(6) The Municipal body of the area shall continue to pick up and transport segregated non bio-medical solid waste generated in hospitals and nursing homes, as well as duly treated bio-medical wastes for disposal at municipal dump site.

Treatment and disposal.-

(1) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards prescribed in Schedule V.

(2) Every occupier, where required, shall set up in accordance with the time-schedule in Schedule VI, requisite bio-medical waste treatment facilities like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment or any other waste treatment facility.

Advisory committee.-

(1) The Government of every State/Union Territory shall constitute an Advisory Committee. The Committee will include experts in the field of medical and health, animal husbandry and veterinary sciences, environmental management, municipal administration, and any other related department or organisation including non-governmental organisations. [* * *] As and when required, the Committee shall advise the Government of the State/Union Territory and the prescribed authority on matters related to the implementation of these rules.

(2) Notwithstanding anything contained in sub-rule (1), the Ministry of Defence shall constitute in the Ministry, an Advisory Committee consisting of the following in respect of all health care establishments including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories and blood banks of the Armed Forces under the Ministry of Defence, to advise the Director General, Armed Forces Medical Services and the Ministry of Defence in matters relating to implementation of these rules, namely:-

(1)	Additional Director General of Armed Forces Medical Services	Chairman
(2)	A representative of the Ministry of Defence not below the rank of Deputy Secretary, to be nominated by that Ministry	Member
(3)	A representative of the Ministry of Environment and Forests not below the rank of Deputy Secretary, to be nominated by that Ministry	Member
(4)	A representative of the Indian Society of Hospitals Waste Management, Pune	Member.]

Monitoring of implementation of the rules in Armed Forces health care establishments.-

(1) The Central Pollution Control Board shall monitor the implementation of these rules in respect of all the Armed Forces health care establishments under the Ministry of Defence.

(2) After giving prior notice to the Director General Armed Forces Medical Services, the Central Pollution Control Board alongwith one or more representatives of the Advisory Committee constituted under sub-rule (2) of rule 9, may, if it considers it necessary, inspect any Armed Forces health care establishments.

Annual report:-

Every occupier/operator shall submit an annual report to the prescribed authority in Form II by 31st January every year, to include information about the categories and quantities of bio-medical wastes handled during the preceding year. The prescribed authority shall send this information in a compiled form to the Central Pollution Control Board by 31st March every year.

Maintenance of records.-

(1) Every authorised person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of bio-medical waste in accordance with these rules

and any guidelines issued, referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report.

(2) All records shall be subject to inspection and verification by the prescribed authority at any time.

Accident reporting .-

When any accident occurs at any institution or facility or any other site where bio-medical waste is handled or during transportation of such waste, the authorised person shall report the accident in Form III to the prescribed authority forthwith.

Appeal .-

(1)[Save as otherwise provided in sub-rule (2), any person] aggrieved by an order made by the prescribed authority under these rules may, within thirty days from the date on which the order is communicated to him, prefer an appeal [in Form V] to such authority as the Government of State/Union Territory may think fit to constitute:

Provided that the authority may entertain the appeal after the expiry of the said period of thirty days if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.

[(2) Any person aggrieved by an order of the Director General, Armed Forces Medical Services under these rules may, within thirty days from the date on which the order is communicated to him, prefer an appeal to the Central Government in the Ministry of Environment and Forests.]

Common disposal/incineration sites .-

Without prejudice to rule 5 of these rules, the Municipal Corporations, Municipal Boards or Urban Local Bodies, as the case may be, shall be responsible for providing suitable common disposal/incineration sites for the bio-medical wastes generated in the area under their jurisdiction and in areas outside the jurisdiction of any municipal body, it shall be the responsibility of the occupier generating bio-medical waste/operator of a bio-medical waste treatment facility to arrange for suitable sites individual or in association, so as to comply with the provisions of these rules.]

Legislation:

History:- Need to have rules and regulations regarding proper management were felt by most of the countries of the world. India visualised its need by framing EPA in 1986 which is earlier than developed countries like UK & USA.

India seems to be a pioneer in legislation procedures regarding BMW management i.e. environmental protection ACT 1986 in comparison to developed countries like **United Kingdom**, Applicable Legislation include the EPA in 1990 along with the Waste Management & licensing regulation 1994 and Hazardous waste management regulation (England & Wales)2005, Biomedical Waste is usually regulated as Medical waste in USA.

The United States Federal government passed the Medical waste Tracking ACT in 1988 which allowed the EPA to establish rules for management of medical waste in some parts of the country. The act expired in 1991 then responsibility to regulate and pass laws concerning the disposal of medical waste returned to the individual state regulation in these states vary from none to very strict.

India

In India Ministry of Environment & Forests notified the situation of pollution and ruled out the Biomedical Waste (management & handling) Rules, 1998” to protect the Environment Protection (Umbrella) Act, 1986 (29 of 1986); in our country on 20th July 1998 vide notification number S.O. 630 (E) dated the 20th July, 1998, by the Government of India in the erstwhile Ministry of Environment and Forests.

Now, therefore, in exercise of the powers conferred by section 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998, except as respects things done or omitted to be done before such suppression, the Ministry of Environment Forests and Climate Change, Central Government hereby makes the following rules, namely Bio-Medical Waste Management (BMWM) rules, 2016 on 28th March 2016, under the provisions of EPA, 1986 and (Amendment) Rules, 2018, were also notified by Central Govt. Each state's Pollution Control Board or Pollution control Committee will be responsible for implementing the new legislation.

After that India became the first country to implement BMW rules in 1998 (amended as draft in 2003, 2011) under Environment Protection Act (EPA), 1986. These rules fill up the gaps in the old rules to regulate the disposal of various categories of BMW.^{[6],[7]} India was signatory to an international legally binding and environmental treaty, Stockholm Convention, 2004, on persistent organic pollutants (POPs) that aims to eliminate or restrict production of POPs.^[8]

Due to the competition to improve quality and so as to get accreditation from agencies like ISO, NABH, JCI, many private organizations have initiated proper bio-medical waste disposal but still the gap is huge and a large number of healthcare facilities were found to be sorting the waste incorrectly. Updating this article around 26 March 2020. The National Green Tribunal (NGT) has been very stringent on the application of the BMW 2016 over the past 12 months. There are now over 200 licensed Common Bio Medical Waste Treatment and Disposal Facilities (CBWTF) or Common Treatment Facility (CTF) in the country. The rules have been updated over the years. You can find the BMW 2016 act and the subsequent amendments at this site "<https://earthron.com/bmw-act-and-process>". These rules fill up the gaps in the old rules to regulate the disposal of various categories of BMW.

Different courts (high courts & Supreme Court) have shown its concern for implementing the guidelines to be followed strictly in the disposal of BMWs and fixed penalties and punishments to those not following the correct procedure which can influence the health of citizens of India. e.g. as per new guideline issued by government BMWs management rule 2016, all health care units handling medical waste in any form must pretreated it on site through disinfection or sterilization process, failure to which can lead to imprisonments of five years or fine of 1 lac or more.

Bio-Medical Waste Management: States to pay Fine of Rs 1 crore per month if Hospitals found violating rules, says NGT Farhat Nasim By Farhat Nasim Published On 20 July 2019 9:54 AM | Updated On 20 July 2019 9:54 AM Advertisement Bio-Medical Waste Management: States to pay Fine of Rs 1 crore per month if Hospitals found violating rules, says NGT New Delhi: In a stringent view of unscientific disposal of bio-medical waste and its impact on public health, the National Green Tribunal (NGT) has directed all States and Union Territories to observe the bio-medical waste management or pay a fat sum of Rs 1 crore every month till the non-compliance lingers in their region. This comes following a report submitted by the Central Pollution Control Board (CPCB) that proposed the formula for calculation of Environmental Compensation for HCFs-

Environmental Compensation for HCFs = HR x T x S x R x N

Where; HR –Health Risk factor

T- Type of Healthcare Facility

S – Size of Health Care Facility

R – Environmental Compensation factor

N – Number of days of Violation

HR Health Risk (HR) is a number from 0 to 100 and increasing HR value denotes the increasing degree of health risk due to improper handling of BMW in a healthcare facility.

CPCB report further added, "In any case minimum Environmental Compensation in respect to Healthcare Facility shall not be less than Rs.1200/- per day."

Prior to this, small clinics were under scanner and one such clinic in the capital had to pay a fine of Rs 14 lakh for violating the said rules. Medical Dialogues had earlier reported that in a major penalty, the Delhi Pollution Control Committee (DPCC) had directed a small dental clinic situated in the south Delhi area to pay a penalty of Rs 14.30 Lakh on account of operating without obtaining/ applying for mandatory Authorization under Bio-Medical Waste Management Rules, 2016. In recent row, a petition was filed by Shailesh Singh against Sheela Hospital & Trauma Centre, Shahjahanpur &Ors.; Kailash Hospital and Heart Institute&Ors; Shri Ganga Charan Hospital (P) Ltd., Bareilly &Ors. ; Katiyar Nursing Home, Hardoi&Ors, seeking shut down o thesef healthcare establishments involved in the improper disposal of bio-medical waste in violation of Bio-Medical Waste Management Rules, 2016.

A bench headed by NGT Chairperson Justice A K Goel noted that unscientific disposal of bio-medical waste had a potential of serious diseases including Genital infection, Skin infection, Anthrax, Meningitis, AIDS, Haemorrhagic fevers, Septicaemia, Viral Hepatitis type A, Viral Hepatitis type B and C, etc. The Tribunal further noted that NGT

had required the State of Uttar Pradesh to furnish performance guarantee in the sum of Rs. 10 Crores. However, the tribunal was informed that the said direction was stayed by the Supreme Court. The Tribunal noted that the steps taken in the State of Uttar Pradesh for compliance of the BMW Rules were inadequate and not a single person was shown to have been convicted in spite of large violation, nor any compensation was shown to have been recovered. No scale of compensation had been laid down, nor an action plan had been prepared. The unsatisfactory state of affairs was not confined to the State of Uttar Pradesh, Punjab, Haryana and Uttarakhand who were before the Tribunal but also to the other States. The BMW Rules provide for the furnishing of annual reports by the States to the CPCB and by the CPCB to the Ministry of Environment, Forest and Climate Change and also being made available on the website of the concerned State. The Tribunal directed all the States and UTs to furnish such reports, failing which the defaulting States will be required to pay compensation at the rate of Rs. 1 Crore per month after 01.05.2019. The States were also required to prepare their respective action plans within one month. The Tribunal also directed the CPCB to furnish its comments on the action plans and to undertake study and prepare a scale of compensation to be recovered from the violators of BMW Rules without prejudice to the State PCBs taking steps for recovery of compensation from the polluters or laying down their own scales which should not be less than the scale of the CPCB. Accordingly, a report has been filed by the CPCB wherein it recommended Environmental Compensation for Healthcare Facilities. With no meaningful objection being raised by any of the parties, the report of the CPCB has been accepted by the tribunal. Subsequently, the tribunal in its order stated, "We place on record our disapproval of the inaction of States in furnishing the inventory studies as well as for incomplete inventories. It is regretful to note that 25% of identified HCFs have not even taken authorization from the concerned State PCBs in absence of which, monitoring of waste management is not taking place. The States which have not set up common treatment and disposal facilities must do so within two months as per Rules." "It is made clear that if even after two months the States/UTs are found to be non-compliant, the compensation will be liable to be recovered from the said States/UTs at the rate of Rs. 1 Crore per month till the non-compliance continues," t <https://medicialdialogues.in/bio-medical-waste-management-govt-to-pay-fine-of-rs-1-crore-per-month-if-hospitals-found-violating-rules-says-ngt>

Suggestions:-

1. Increase the Political Will of each country of the world for the cause of proper disposal of BMW as the health is now a global issue and unequal development in the health sector is dangerous to the whole world.
2. Strict awareness of international and national rules and regulations
3. Increased need of awareness in the country so as to follow sanitary practices (At individual level also).
4. Impart Training to the health professional & other Health care workers and increase the number of advanced training centers at state level according to need.
5. Medical colleges, government or private, should become training centers at secondary level and district hospital at the primary level in an organized way with emphasis on training of trainers.
6. District administration should be utilized for implementation of guidelines in this concern with proper legislative power for enforcement with DM (District level) as incharge.
7. NMC erstwhile MCI should have checklist for inspection of medical colleges and should be as strict in their approach to close them if they are not following the guidelines.
8. There can be a compulsory foundation course for this aspect for each faculty engaged in medical college.
9. CM and PM should directly monitor the activities of various pollution boards of state and National

Conclusion/ Vision:-

Swachh Bharat Abhiyan, Swachh Bharat Mission is country wide campaign initiated by government of India in 2014 with symbol of Mahatma Gandhi Goggle which was his dream of swachh Bharat, Whose Dream with the slogan "Swachh Bharat Abhiyan" the programme was launched by our respected Prime Minister Mr. Narendra Modi. On 2nd October 2014 at Raj Ghat to gift Rashtra Pita Babu a CLEAN INDIA on his 125 Anniversary. This dream can never come true if we do not successfully implement the correct methodology dealing with BMWs. This aspect is of paramount importance as it safeguards the health of every citizen of India and will help in attainment of the highest level of health.

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Annexure-I**SCHEDULE I**

(See Rule 5)

CATEGORIES OF BIO-MEDICAL WASTE

[Waste Category No.]	Waste Category [Type]	[Treatment and Disposal Option]
Category No. 1	Human Anatomical Waste (human tissues, organs, body parts)	Incineration/deep burial
Category No. 2	Animal Waste (animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals colleges, discharge from hospitals, animal houses)	Incineration/deep burial
Category No 3	Microbiology & Biotechnology Waste (wastes from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biological, toxins, dishes and devices used for transfer of cultures)	Local autoclaving/micro-waving/incineration
Category No 4	Waste sharps (needles, syringes, scalpels, blades, glass, etc. that may cause puncture and cuts. This includes both used and unused sharps)	disinfection (chemical treatment)/autoclaving/micro-waving and mutilation/shredding
Category No 5	Discarded Medicines and Cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)	Incineration/destruction and drugs disposal in secured landfills
Category No. 6	[Solid] Waste (Items contaminated with blood, and body fluids including cotton dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)	Incineration autoclaving/micro-waving
Category No. 7	Solid Waste (wastes generated from disposable items other than the waste [sharps] such as tubings, catheters, intravenous sets etc).	disinfection by chemical treatment autoclaving/micro-waving and mutilation/shredding
Category No. 8	Liquid Waste (waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities).	Disinfection by chemical treatment and discharge into drains.

Category No. 9	Incineration Ash	
	(ash from incineration of any bio-medical waste)	disposal in municipal landfill
Category No. 10	Chemical Waste	
	(chemicals used in production of biological, chemicals used in disinfection, as insecticides, etc.)	[chemical treatment] and discharge into drains for liquids and secured landfill for solid.

Annexure –II**SCHEDULE II**

(See Rule 6)

COLOUR CODING AND TYPE OF CONTAINER FOR DISPOSAL OF BIO-MEDICAL WASTES

Colour Coding	Type of Container	Waste Category	Treatment options as per Schedule I
Yellow	Plastic bag	Cat. 1, Cat. 2, Cat. 3 and Cat. 6.	Incineration/deep burial
Red	Disinfected container/plastic bag	Cat. 3, Cat. 6, Cat.7	Autoclaving/Microwaving/Chemical Treatment
Blue/White translucent	Plastic bag/puncture proof Container	Cat. 4, Cat. 7	Autoclaving/Microwaving/Chemical Treatment and destruction/shredding
Black	Plastic bag	Cat. 5, Cat. 9 and Cat. 10. (solid)	Disposal in secured landfill

Notes. -

1. Colour coding of waste categories with multiple treatment options as defined in Schedule I, shall be selected depending on treatment option chosen, which shall be as specified in Schedule I.
2. Waste collection bags for waste types needing incineration shall not be made of chlorinated plastics.
3. Categories 8 and 10 (liquid) do not require containers/bags.
4. Category 3 if disinfected locally need not be put in containers/bags.

SCHEDULE III

(See Rule 6)

LABEL FOR BIO-MEDICAL WASTE CONTAINERS/BAGS

BIOHAZARD SYMBOL	CYTOTOXIC HAZARD SYMBOL
BIOHAZARD	CYTOTOXIC
HANDLE WITH CARE	

SCHEDULE IV

(See Rule 6)

LABEL FOR TRANSPORT OF BIO-MEDICAL WASTE CONTAINERS/BAGS

Waste category No.....	Day Month
Waste class	Year
Waste description	Date of generation
Sender's Name & Address	Receiver's Name & Address
Phone No.....	Phone No.....
Telex No.....	Telex No.....
Fax No.....	Fax No
Contact Person.....	Contact Person.....
In case of emergency please contact:	
Name & Address :	
Phone No.	

Note. Label shall be non-washable and prominently visible.**SCHEDULE V**

(See rule 5 and Schedule I)

STANDARDS FOR TREATMENT AND DISPOSAL OF BIO-MEDICAL WASTES STANDARDS FOR INCINERATORS

All incinerators shall meet the following operating and emission standards:-

A. Operating Standards

1. Combustion efficiency (CE) shall be at least 99.00%.
2. The Combustion Efficiency is computed as follows:-

$$\text{C.E.} = \frac{\% \text{CO}_2}{\% \text{CO}_2 + \% \text{CO}} \times 100$$

3. The temperature of the primary chamber shall be $800 \pm 50^\circ\text{C}$.
4. The secondary chamber gas residence time shall be at least 1 (one) second at $1050 \pm 50^\circ\text{C}$, with minimum 3% Oxygen in the stack gas.

B. Emission Standards	
Parameters	Concentration mg/Nm ³ at (12% CO ₂ correction)
(1) Particulate matter	150
(2) Nitrogen Oxides	450
(3) HCl	50
(4) Minimum stack height shall be 30 metres above ground	
(5) Volatile organic compounds in ash shall not be more than 0.01%	

Note.

- *Suitably designed pollution control devices should be installed/retrofitted with the incinerator to achieve the above emission limits, if necessary.
- *Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- *Chlorinated plastics shall not be incinerated.
- *Toxic metals in incineration ash shall be limited within the regulatory quantities as defined under the Hazardous Waste (Management and Handling) Rules, 1989.
- *Only low sulphur fuel like L.D.O/L.S.H.S./Diesel shall be used as fuel in the incinerator.

STANDARDS FOR WASTE AUTOCLAVING

The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste.

- (I) When operating a gravity flow autoclave, medical waste shall be subjected to :-
 - (i) a temperature of not less than 121°C and pressure of 15 pounds per square inch (psi) for an autoclave residence time of not less than 60 minutes; or
 - (ii) a temperature of not less than 135°C and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or
 - (iii) a temperature of not less than 149°C and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.
- (II) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air. The waste shall be subjected to the following:-
 - (i) a temperature of not less than 121°C and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or
 - (ii) a temperature of not less than 135°C and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes;
- (III) 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 were achieved.
- (IV) **Recording of operational parameters**

Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.

(V) Validation test

Spore testing:

The autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be *Bacillus stearothermophilus* spores using vials or spore Strips; with at least 1×10^4 spores per millilitre. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 121°C or a pressure less than 15 psi.

(VI) Routine Test

A chemical indicator strip/tape the changes colour when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste package at different location to ensure that the inner content of the package has been adequately autoclaved.

STANDARD FOR LIQUID WASTE:

The effluent generated from the hospital should conform to the following limits :-

PARAMETERS	PERMISSIBLE LIMITS
PH	6.3-9.0
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.

These limits are applicable to those hospitals which are either connected with sewers without terminal sewage treatment plant or not connected to public sewers. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

STANDARDS OF MICROWAVING

- 1 Microwave treatment shall not be used for cytotoxic, hazardous or radioactive wastes, contaminated animal car casses, 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 is ensured by approved biological indicator at the maximum design capacity of each microwave unit. Biological indicators for microwave shall be *Bacillus Subtilis* spores using vials or spore strips with at least 1×10^4 spores per milliliter.

STANDARDS FOR DEEP BURIAL

1. 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.
2. It must be ensured that animals do not have any access to burial sites. Covers of galvanised iron/wire meshes may be used.
3. On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.
4. Burial must be performed under close and dedicated supervision.
5. The deep burial site should be relatively impermeable and no shallow well should be close to the site.
6. The pits should be distant from 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.
7. The location of the deep burial site will be authorised by the prescribed authority.
8. The institution shall maintain a record of all pits for deep burial.

[SCHEDULE VI]

(See Rule 5)

**SCHEDULE FOR WASTE TREATMENT FACILITIES LIKE
INCINERATOR/AUTOCLAVE/MICROWAVE SYSTEM**

A. Hospitals and nursing homes in towns with population of 30 lakhs and above	by 31st December, 1999 or earlier
B. Hospitals and nursing homes in towns with population of below 30 lakhs,	
(a) with 500 beds and above	by 31st December, 1999 or earlier
(b) with 200 beds and above but less than 500 beds	by 31st December, 2000 or earlier
(c) with 50 beds and above but less than 200 beds	by 31st December, 2001 or earlier
(d) with less than 50 beds	by 31st December, 2002 or earlier
C. All other institutions generating bio-medical waste not included in A and B above	by 31st December, 2002 or earlier

FORM I

(See rule 8)

[APPLICATION FOR AUTHORISATION/RENEWAL OF AUTHORISATION]

(To be submitted in duplicate.)

To,

The Prescribed Authority
(Name of the State Government/Union Territory Administration)
Address.

1. Particulars of the Applicant:

- (i) Name of the Applicant
(In block letters & in full)
- (ii) Name of the Institution
Address
Tele No.
Fax No.
Telex No.

2. Activity for which authorisation is sought:

- (i) Generation
- (ii) Collection
- (iii) Reception
- (iv) Storage
- (v) Transportation
- (vi) Treatment
- (vii) Disposal
- (viii) Any other form of handling

3. Please state whether applying for fresh authorisation or for renewal:

(In case of renewal previous authorisation number and date)

4. (i) Address of the institution handling bio-medical wastes:

- (ii) Address of the place of the treatment facility:
- (iii) Address of the place of disposal of the waste:

5. (i) Mode of transportation (in any) of bio-medical waste:

- (ii) Mode(s) of treatment:

6. Brief description of method of treatment and disposal (attach details):

7. (i) Category (see Schedule 1) of waste to be handled

- (ii) Quantity of waste (category wise) to be handled per month:

8. Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information.

I do also hereby undertake to provide any further information sought by the prescribed authority in relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date.....

Place.....

Signature of the Applicant.....
Designation of the Applicant.....

FORM II
(See rule 10)
ANNUAL REPORT

(To be submitted to the prescribed authority by 31 January every year)

1. Particulars of the applicant:
 - (i) Name of the authorised person (occupier/operator):
 - (ii) Name of the institution:
- Address
- Tel. No
- Telex No.
- Fax No.
2. Categories of waste generated and quantity on a monthly average basis:
3. Brief details of the treatment facility:
In case of off-site facility:
 - (i) Name of the operator
 - (ii) Name and address of the facility:
- Tel. No.
- Telex No.
- Fax No.
4. Category-wise quantity of waste treated:
5. Mode of treatment with details:
6. Any other information:
7. Certified that the above report is for the period
from.....
.....
.....
Date.....
Place.....
Signature.....
Designation.....

FORM III
(See Rule 12)
ACCIDENT REPORTING

1. Date and time of accident:
2. Sequence of events leading to accident:
3. The waste involved in accident:
4. Assessment of the effects of the accidents on human health and the environment
5. Emergency measures taken:
6. Steps taken to alleviate the effects of accidents :
7. Steps taken to prevent the recurrence of such an accident :
- Date.....
- Place.....
- Signature.....
- Designation.....

[FORM-IV]
[See Rule 8 (4)]
**AUTHORISATION FOR OPERATING A FACILITY FOR COLLECTION, RECEPTION, TREATMENT,
STORAGE, TRANSPORT AND DISPOSAL OF BIO-MEDICAL WASTES**

1. File number of authorization and date of issue.....

2.of.....is hereby granted an authorization to operate a facility for collection, reception, storage, transport and disposal of bio-medical waste on the premises situated at

3. This authorization shall be in force for a period of..... Years from the date of issue.

4. This authorization is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Environment (Protection) Act, 1986.

Date.....

Signature.....

Designation.....

TERMS AND CONDITIONS OF AUTHORISATION*

1. The authorization shall comply with the provisions of the Environment (Protection) Act, 1986 and the rules made thereunder.

2. The authorization or its renewal shall be produced for inspection at the request of an officer authorized 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 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 prescribed authority to close down the facility.

Additional terms and conditions may be stipulated by the prescribed authority.

FORM V

(See rule 13)

APPLICATION FOR FILING APPEAL AGAINST ORDER PASSED BY THE PRESCRIBED AUTHORITY AT DISTRICT LEVEL OR REGIONAL OFFICE OF THE POLLUTION CONTROL BOARD ACTING AS PRESCRIBD AUTHORITY OR THE STATE/UNION TERRITORY LEVEL AUTHORITY

1. Name and address of the person applying for appeal:

2. Number, date of order and address of the authority which passed the order against which appeal is being made (certified copy of order to be attached)

3. Ground on which the appeal is being made.

4. List of enclosures other than the order referred in para 2 against which appeal is being filed.

Date.....

Signature.....

Name of Address.....