Bio Medical Waste Management in India

Introduction

Biomedical waste (BMW) is any waste produced during the diagnosis, treatment, or immunization of human or animal research activities pertaining thereto or in the production or testing of biological or in health camps. It follows the cradle to grave approach which is characterization, quantification, segregation, storage, transport, and treatment of BMW.

The basic principle of good BMW practice is based on the concept of 3Rs, namely, reduce, recycle, and reuse. The best BMW management (BMWM) methods aim at avoiding generation of waste or recovering as much as waste as possible, rather than disposing.

> Only about 10%–25% of BMW is hazardous, and the remaining 75%–95% is nonhazardous. The hazardous part of the waste presents physical, chemical, and/or microbiological risk to the general population and health-care workers associated with handling, treatment, and disposal of waste

In a World Health Organization (WHO) meeting in Geneva, in June 2007, core principles for achieving safe and sustainable management of health-care waste were developed. The first edition of WHO handbook on safe management of wastes from health-care activities known as "The Blue Book" came out in 1999. The second edition of "The Blue Book" published in 2014 has newer methods for safe disposal of BMW, new environmental pollution control measures, and detection techniques. In addition, new topics such as health-care waste management in emergencies, emerging pandemics, drug-resistant bacteria, and climate changes were covered in the second edition.

Biomedical Waste Situation in India

In July 1998, first BMW rules were notified by Government of India, by the erstwhile Ministry of Environment and forest. In India, BMW problem was further compounded by the presence of scavengers who sort out open, unprotected health-care waste with no gloves, masks, or shoes for recycling, and second, reuse of syringe without appropriate sterilization.

During 2002–2004, International Clinical Epidemiology Network explored the existing BMW practices, setup, and framework in primary, secondary, and tertiary health care facility (HCF) in India across 20 states. They found that around 82% of primary, 60% of secondary, and 54% of tertiary HCFs in India had no credible BMWM system. In 2009, around 240 people in Gujarat, India contracted hepatitis B following reuse of unsterilized syringes. This and many more studies shows that despite India being among the first country to initiate measures for safe disposal of BMW, there is an urgent need to take action for strengthening the existing system capacity, increase the funding and commitment toward safe disposal of BMW.

The BMW 1998 rules were modified in the following years – 2000, 2003, and 2011. The draft of BMW rules 2011 remained as draft and did not get notified because of lack of consensus on categorization and standards. Now Ministry of Environment, Forest and Climate change in March 2016 have amended the BMWM rules [Table 1]. These new rules have increased the coverage, simplified the categorization and authorization while improving the segregation, transportation and disposal methods to decrease environmental pollution [Table 2]. It has four schedules, five forms and eighteen rules.

Table 1

Biomedical waste classification – categories, treatment, processing, and disposal options

Category	Type of waste	Color and type of bag to be used	Treatment and disposal options
Yellow	Human anatomical waste Animal anatomical waste	Yellow-colored nonchlorinated plastic bags	Incineration or plasma pyrolysis or deep burial
	Soiled waste	Yellow-colored nonchlorinated plastic bags	Incineration or plasma pyrolysis or deep burial. In the absence of above facilities, autoclaving or microwave/hydroclaving followed by shredding/mutilation/combination of sterilization and shredding. Treated waste to be sent for energy recovery
	Expired or discarded medicines	Yellow-colored nonchlorinated plastic bags	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 CBMWTF or hazardous waste treatment, storage, and disposal facility for incineration at >1200° C or encapsulation or plasma pyrolysis at 1200° C
	Chemical waste	Yellow-colored nonchlorinated plastic bags	Disposed of by incineration or plasma pyrolysis or encapsulation in hazardous waste treatment, storage, and disposal facility
	Chemical liquid waste	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pretreated before mixing with other waste forms
	Discarded linen, mattresses beddings contaminated with blood or body fluids	Nonchlorinated yellow plastic bags or suitable packing material	Nonchlorinated chemical disinfection followed by incineration or plasma pyrolysis or for energy recovery
	Microbiology, biotechnology, and other clinical laboratory waste	Autoclave safe plastic bags or containers	Pretreat to sterilize with nonchlorinated chemicals on-site as NACO or WHO guidelines, thereafter for incineration
Red	Contaminated waste (recyclable)	Red-colored nonchlorinated plastic bags or containers	Autoclaving or microwaving/hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered recyclers or for energy recovery or plastics to diesel or fuel oil or for road making
White (translucent)	Waste sharps including metals	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
Blue	Glassware Metallic body implants	Cardboard boxes with blue-colored marking	Disinfection or through autoclaving or microwaving or hydroclaving and then sent for recycling

AIDS = Acquired immunodeficiency syndrome, NACO = National AIDS Control Organization, WHO = World Health Organization, CBMWTF = Common bio-medical waste treatment and disposal facility

Table 2

Difference between biomedical waste rules 1998 and 2016

BMW 1998	BMWM rules, 2016
Application	
These camps and such healthcare-related activities not covered under BMW 1998 rules	The realm of the rules have been expanded to include vaccination camps, blood donation camps, surgical camps, or any other health care activity
Duties of occupier	
Pretreatment of the laboratory waste, blood bags, etc. was not required	Pretreatment of the laboratory waste, microbiological waste, blood samples, and blood bags
Use of chlorinated plastic bags, gloves, and blood bags was mentioned	Phase-out the use of chlorinated plastic bags, gloves, and blood bags within 2 years
Liquid waste not to be separated at source and ETP is not mandatory	Liquid waste to be separated at source by pretreatment and ETP is required
Training and immunization not compulsory	Provide training to all HCWs in BMW rules and handling and immunize all HCWs against hepatitis B and tetanus
No barcoding system was in place	Establish a bar code system for bags or containers containing BMW for disposal
Reporting of accidents not specified and mentioned	Report all major accidents
Duties of the operator of a CBMWTF	
No such recommendation were in place	To establish barcoding and GPS of BMW waste carrying vehicle within 1 year
No such records were maintained	Maintain all records of incinerator/hydroclaving/autoclaving for a period of 5 years
No such records were maintained	Maintain a log book of each cycle of treatment with all details such as time, date, weight, duration, and hours of treatment
CBMWTF	
Every HCFs shall set up a requisite BMW treatment facility or ensure requisite treatment at a CBMWT	No occupier shall establish on their site a BMW treatment and disposal plant, if, a CBMWTF is available within 75 km of the HCF If no CBMWTF not available, the occupier should establish a BMW treatment and disposal plant after taking prior permission from authority
Segregation, packaging, transportation, and storage of BMW	
BMW classified into 10 categories based on treatment options	BMW classified into 4 categories based on treatment options
If untreated BMW should be stored beyond 48 h, authorization needed	IF untreated human anatomical waste, animal anatomical waste, soiled waste, and biotechnology waste should be stored beyond 48 h, no authorization needed
Treatment and disposal of waste	
Chemical treatment with 1% hypochlorite	Chemical treatment with at least 10% hypochlorite having 30% residual chlorine for 20 min or any other equivalent chemical reagent that should demonstrate $\log_{10}$ 4 reduction efficiency for microorganisms
Deep burial to be allowed in towns with population>5 lakhs	Deep burial is only an option in remote rural or remote areas, where there is other disposal option. The groundwater table level should be a minimum of 6 m below the lower level of deep burial pit
Cytotoxic drugs disposal in secured landfills	Cytotoxic waste and items contaminated with cytotoxic waste should be returned to manufacturer or CBMWTF for incinerator at 1200° C or encapsulation or plasma pyrolysis at 1200° C
All drugs discarded in black bags	All drugs including expired antibiotics should be sent back to manufacturer or to incinerator
All infected metal, plastic, and glass waste to be put in blue bag and then sent for autoclaving, microwaving, and incinerator	The BMW waste to be segregated – plastics in red bag, sharps in white container (after mutilation), and glass articles in cardboard box with blue marking; then sent to authorized recycler
This was not included	After proper treatment of plastics and glassware, these recyclables should be given to recyclers having valid registration
Authorization	
All HCFs treating 1000 or more patients/month need to obtain authorization from SPCB	One time authorization for nonbedded HCFs and for bedded HCFs, the validity of authorization should be coordinated with consent order
Standards for emission from incinerators	
Permissible limit for SPM-150 mg/Nm³	Permissible limit for SPM-50 mg/Nm³
Residence time in secondary chamber of incinerator at least 1s	Residence time in secondary chamber of incinerator 2 s
Standards for dioxin and furans – not defined	Standards for dioxin and furans- 0.1 ngTEQ/Nm³
Monitoring of implementation	
Not defined	Ministry of environment, forest and climate change should review the implementation of the rules in the country once a year
Not defined	SPCB of each state shall constitute district level monitoring committee under the chairpersonship of district collector or district magistrate or additional district magistrate to monitor the compliance of the above BMW rules
Not defined	The district level monitoring committee shall submit its report once every 6 months to the SPCB

SPCB = State pollution control board, HCFs = Health care facilities, ETP = Effluent treatment plant, CBMWTF = Common bio-medical waste treatment and disposal facility, BMW = Biomedical waste, BMWM = Biomedical waste management, SPM = Suspended particulates matter, HCWs = Healthcare workers

Table 3

Difference in schedule for biomedical waste of 1998 and 2016

Schedule	1998	2016
Schedule I	Categories of waste	Color code and type of waste with treatment and disposal
Schedule II	Color/code type of waste, waste category, treatment option	Standard for treatment of disposal of BMW (Autoclaving/ Microwaving/deep burial/dry heat sterilization/chemical disinfection)
Schedule III	Label of BMW category/bags	List of prescribed authorities and their duties
Schedule IV	Label for transport of BMW	Part A - label for container/bag Part B - label for transport of BMW bag/container
Schedule V	Standard for treatment and disposal of BMW	Added to schedule II
Schedule VI	List of prescribed authorities and their duties	Added to schedule III

BMW = Biomedical waste

Table 4

Different forms with biomedical waste 2016

Forms	Use of the Form
F1	Accident reporting
F2	Application for authorization or renewal of authorization (submitted by occupier of HCWs of CBMWTFs)
F3	Authorization (for operating, facility) for generation, collection, reception, treatment, storage, transport, disposal
F4	Annual report
F5	Application for filling "appeal" against order pass by the prescribed authority

HCWs = Healthcare workers, CBMWTFs = Common bio-medical waste treatment and disposal facilities

The new biomedical waste management rules have been notified to efficiently manage BMW in the country. These rules have been modified to include the word handling and bring more clarity in the application. In addition, strict rules have been made to ensure no pilferage of recyclables item, no secondary handling or in advent scattering or spillage by animals during transport from the HCFs to the common BMW treatment facility (CBMWTF). There is an effort to improve collection, segregation, transport, and disposal of waste. Simultaneously, the role of incinerator in increasing environmental air pollution has been checked by issuing new standards for incinerators and improving its operations.

Data from Government of India site indicates the total BMW generated in the country is 484 TPD (tones per day) from 1, 68,869 HCFs. Unfortunately, only 447 TPD is treated, and 37 TPD is left untreated. There are 198 CBMWTF in operation and 28 under construction. The numbers of HCFs using CBMWTFs are 1, 31,837, and approximately 21,870 HCFs have their own treatment facilities on-site.

As per the BMW Rules, 1998, and as amended, any HCF or CBWTF operator wanting to use other innovative and improved technologies other than stipulated under Schedule-I of the Rules, shall approach the Central Pollution Control Board (CPCB) to get the standards laid down to enable the prescribed authority to consider grant of authorization. During

the year 2010–2013, CPCB have granted conditional or provisional approval to new technologies (other than notified under BMW Rules) for treatment of BMW. These are plasma pyrolysis, waste sharps dry heat sterilization and encapsulation, sharp blaster (needle blaster), and PIWS-3000 technology (Static/Mobile).

Salient Features of Biomedical Waste Rules 2016

1. The scope of the rules has been expanded to include various health camps such as vaccination camps, blood donation camps, and surgical camps.
2. Duties of the occupier of a HCFs have been revised. Occupier is the person having administrative control over the HCF that is generating BMW.
    a. Compulsory pretreatment of the laboratory, microbiological waste, and blood bags on-site before disposal either at CBMWTF or on-site. The method of sterilization/disinfection should be in accordance with National AIDS Control Organization (NACO) or WHO
    b. The use of chlorinated plastic bags, gloves, blood bags, etc. should be gradually stopped and this phasing out should be within 2 years from the date of notification of these rules
    c. To provide training to all its HCWs and protect them against diseases such as hepatitis B and tetanus by immunization
    d. Liquid waste to be separated at source by pretreatment before mixing with other liquid waste
    e. To set up a barcode system for BMW containing that is to be sent out of the premises for treatment and disposal
    f. All major accidents including accidents caused by fire hazards, blasts, during handling of BMW, and remedial action taken by the prescribed authority should be reported
    g. The existing incinerator should be upgraded/modified to achieve the new standard within 2 years from the date of this notification
    h. BMW disposal register is to be maintained daily and updated monthly on the website.
3. The duties of the operator of a common biomedical waste treatment and disposal facility (CBMWTF) have been increased. They should assist in training of HCW from where the waste is being collected. Furthermore, there should be barcoding and global positioning system established for handling of BMW within 1 year. Maintain all records for operation of incineration/hydroclaving/autoclaving for a period of 5 years
4. The segregation, packaging, transportation, and storage of BMW have been improved. Biomedical waste has been classified into four categories based on color code-type of waste and treatment options. In addition, untreated human anatomical waste, animal anatomical waste, soiled waste, and biotechnology waste should not be stored beyond a period of 48 h. In case, there is a need to store beyond 48 h, the occupier should take all appropriate measures to ensure that the waste does not adversely affect human health and the environment (no permission to be obtained)
5. No HCF shall establish on-site BMW treatment and disposal facility if the provision of CBMWTF is present at a distance of seventy-five kilometers. If no CBMWTF is available, the occupier shall set up requisite BMW treatment facility such as incinerator, autoclave or microwave, shredder after taking prior authorization from the prescribed authority. After confirming treatment of plastics and glassware by autoclaving or microwaving followed by mutilation/shredding, these recyclables should be given to authorized recyclers
6. Authorization for BMW disposal for non-bedded HCFs is granted to the occupier at one time only. The validity of authorization shall be synchronized with validity of consent orders for bedded HCFs
7. Standards for emission from incinerators have been modified to be more environmental friendly. These are permissible limit for SPM-50 mg/nm^3; residence time in secondary chamber of incinerator – two seconds; standard for dioxin and furans – 0.1 ng TEQ/Nm^3
8. Ministry of Environment, Forest, and Climate change will monitor the implementation of rules yearly. The responsibility of each state to check for compliance will be done by setting up district-level committee under the chairpersonship of District Collector or District Magistrate or Additional District Magistrate. In addition, every 6 months, this committee shall submit its report to the State Pollution Control Board.

Benefits of the new biomedical waste rules

The new rules are stringent and elaborate and should bring about a change in the way, the BMW is being managed in India. Under the new rules, coverage has increased to include various health-care related camps such as vaccination camps, blood donation camps, and surgical camps.

Another distinction is in the segregation, packaging, transport, and storage of BMW waste. The categories have been reduced to four to bring about ease of segregation. One of the main principle of disposal of BMW is that segregation has to be done at the source of generation of the waste. To overcome confusion created by large number of categories, this has been simplified to make it convenient and manageable for all HCWs. Now, the color coding (i.e., yellow, red, white, and blue) of the bags/containers is linked to a particular type of waste and its specific treatment option. For example, the disposal of chemical solid waste and cytotoxic waste to be done in yellow bag which goes for incineration/plasma pyrolysis/deep burial.

In addition, the HCF has to do pretreatment of various laboratory waste and blood bags according to guidelines of WHO and NACO, to decrease chances of infections being transmitted to HCWs handling waste at treatment stage. Within 2 years, plastic bags, gloves, and blood bags have to be phased out to eliminate emissions of dioxins and furans during their burning into the environment. The new rule also calls for a bar code system for all bags/containers used for BMW treatment and disposal. This step will help in tracking and identifying bags during inspection for quality control and also quality assurance.

The BMW in red/blue bag or container which is for recycling will be sent only to an authorized recycler. This will keep the recycler in realm and in control of various government agencies. Greater emphasis has been given to recycling of waste to conserve resources as well as decrease pollution.

The 2016 guidelines are more specific regarding the dependence of HCFs on CBMWTF and who will provide land for setting up CBMWTF. State government or UT government will provide land for setting up CBMWTF and no occupier of an HCF shall establish an on-site treatment and disposal facility if a CBMWTF is available within 75 kms. This has several advantages as installation and functioning of individual BMW treatment facility as well as recruiting separate, dedicate, and skilled workforce require high capital investment. CBMWTF is a popular concept in developed countries because by operating it at its full potential, the cost of treatment/kg BMW gets significantly reduced. Further, this makes control and checking of various waste disposal plants less tedious. Furthermore, maintaining records and log book will streamline the documentation.

The emission standards for incinerator have been made more stringent (acceptable SPM reduced to 50 mg/nm^3, retention time in secondary camber lowered to 2 s). This will reduce dioxins and furans release (which are produced at temperature greater than 600°C) and lead to production of carbon dioxide and water.

The new rules lays down new criteria for authorization of an HCF and have made the procedure for getting authorization very simple. Bedded hospitals will get automatic authorization and non-bedded HCFs will get a one-time authorization.

Another improvement in the new rules is in the monitoring sector. The MoEF (Ministry of Environment, Forest, and Climate change) will review HCFs once a year through state health secretaries and the SPCB (State Pollution Control Board). Moreover, according to the new rules, the advisory committee on BMWM is now mandated to meet every 6 months.

Challenges in the Implementation of New Biomedical Waste 2016 Rules

One of the biggest challenges the government hospitals and small HCFs will face, during the implementation of BMW 2016 rules will be due to the lack of funds. To phase out chlorinated plastic bags, gloves, blood bags and to establish a bar code system for bags/containers the cost will be high and time span for doing this i.e. two years is too short.

Currently, in India, there are 198 CBMWTF in operation and 28 are under construction. There is a great need for rapid development of many more CBMWTF to fulfill the need of treatment and disposal of all BMW generated in India. Incinerator emits toxic air pollutants, and incinerator ash is potentially hazardous.

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5784295/