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Biomedical waste management rules, 2016: A review

Dal Singh Kharat

Central Pollution Control Board, Delhi, India

Abstract
Hospitals generate substantial quantity of wastes that has potential to cause health and environmental hazards. In order to streamline the waste collection, processing and disposal practices, the Government of India in 1998 notified rules known as the Biomedical Waste (Management and Handling) Rules, 1998. These Rules were revised from time to time. On March 28, 2016, the Government of India published the Biomedical Waste Management Rules, 2016 in superstation of the Biomedical Waste (Management and Handling) Rules, 1998. In the new Biomedical Waste Management Rules, 2016, several changes and additions have been made to further improve the collection, segregation, processing, treatment and disposal of the biomedical wastes in an environmentally sound manner. The existing biomedical waste treatment facilities need to meet the revised standards of emissions and effluent also to install the continuous monitoring equipments. This review highlights the main changes and additions included in the Biomedical Waste Management Rules, 2016.

Keywords: Hospital; Biomedical waste; Autoclaving; Incineration

1. Introduction
The hospitals generate wide range of wastes including infectious or biomedical waste during diagnosis, treatment or immunization (Radha *et al.*, 2009) [5]. The biomedical wastes need to be properly segregated at source of its generation and colour coded for transportation, storage, appropriate treatment and disposal. The treatment technologies identified for the biomedical wastes include chemical treatment, autoclaving, microwaving and the incineration (UNEP, 2012; European Commission, 2006) [6]. Shredding, deep burial and mutilation are also related methods for the waste disposal (CPCB, 2014) [1]. In order to streamline the waste collection, processing and disposal practices in the country, the Government of India in 1998 notified rules known as the Biomedical Waste (Management and Handling) Rules, 1998 (Gazette of India, 1998). These Rules were revised from time to time. On March 28, 2016, the Government of India published the Biomedical Waste Management Rules, 2016 (Gazette of India, 2016) in supersession of the Biomedical Waste (Management and Handling) Rules, 1998. In the new BMW Rules, 2016, several changes and additions have been made to further improve the collection, segregation, processing, treatment and disposal of the biomedical wastes in an environmentally sound manner. These Rules come into force from the date of the publication. The existing waste treatment and disposal facilities are required to meet the new standards and stipulations in 1 to 2 years. This review highlights the main changes and additions included in the BMW Rules, 2016.

2. Definitions and Abbreviations
Biomedical waste: waste generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps.
BMW Rules, 1998: the Biomedical Waste (Management and Handling) Rules, 1998.
BMW Rules, 2016: the Biomedical Waste Management Rules, 2016.
Occupier: a person having administrative control over the institution and the premises generating biomedical waste including hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment.
Operator: a person who owns or controls a common biomedical waste treatment facility for the collection, reception, storage, transport, treatment, disposal or any other form of handling of biomedical waste.
Prescribed authority: the State Pollution Control Board in respect of a State and Pollution
Control Committee in respect of a Union territory.
Treatment and disposal facility: facility wherein treatment, disposal of biomedical waste or processes incidental to such treatment and disposal is carried out, and includes common bio-medical waste treatment facilities.

3. Review
It is notices that the word 'Handling' is omitted from the title of the Rules. The BMW Rules, 2016 bring more clarity in the application. The Rules apply to hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories, blood banks, ayush hospitals, clinical establishments, research or educational institutions, health camps, medical or surgical camps, vaccination camps, blood donation camps, first aid rooms of schools, forensic laboratories and research labs. It has been clarified that the BMW Rules, 2016 do not apply to radioactive wastes, hazardous chemicals, hazardous wastes, municipal solid wastes, lead acid batteries, e-wastes, hazardous microorganisms, genetically engineered microorganisms and cells, which are governed by the other respective Rules.
The prescribed authorities for implementation of the provisions of the BMW Rules, 2016 are the State Pollution Control Boards in respect of States and the Pollution Control

Committees in the Union territories. Other prescribed authorities included in the BMW Rules, 2016 with specific duties are:

- Ministry of Environment, Forest and Climate Change, Government of India;
- Central or State Ministry of Health and Family Welfare, Central Ministry for Animal Husbandry and Veterinary or State Department of Animal Husbandry and Veterinary;
- Ministry of Defence;
- Central Pollution Control Board;
- State Government of Health or Union Territory Government or Administration; and
- Municipalities or Corporations, Urban Local Bodies and Gram Panchayats.

It is mandatory that every State Government or Union territory Administration will constitute an Advisory Committee for the respective State or Union territory under the chairmanship of the respective health secretary to oversee the implementation of the rules in the respective state. Similarly, the Ministry of Defence is to constitute the Advisory Committee (Defence) under the chairmanship of Director General of Health Services of Armed Forces.

Further, every State Government or Union Territory Administration will constitute district level monitoring committee under the chairmanship of District Collector or District Magistrate or Deputy Commissioner or Additional District Magistrate to monitor the compliance of the provisions of these rules in the health care centres and in the common biomedical waste treatment and disposal facilities. The Monitoring Committee to submit its report once in 6 months to the State Advisory Committee with copy endorsed to the State Pollution Control Board or Pollution Control Committee concerned for taking further necessary action.

As far as waste categories are concerned, there are 11 categories as given in Table 1 with addition of two categories (Glassware and Metallic body parts) and omission of one category (Incineration ash) (Gazette of India, 2016). The waste categories are coded as yellow, red, white and blue. The black colour code is no more in practice. In the MBW Rules, 2016, the duties of occupier and operator are clearly specified. Training to workers, immunisation, health check-up and occupation safety of workers are the important elements. Operator is also required to assist the occupier in training programme. The occupier and operator are required to phase out chlorinated plastic bags/gloves and establish a bar-coding for the outgoing bags containing the biomedical wastes within 1 year. It is mandatory for operator and occupier to post the annual report on web-site etc. In addition, the operator is required to establish a global positioning system for the handling of the biomedical waste within 1 year.

Table 1: Biomedical wastes, colour coding and the treatment options

Waste category	Type of wastes	Treatment and disposal options
Yellow	**(a) Human Anatomical Waste:** Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).	Incineration or plasma pyrolysis or deep burial
	(b)Animal Anatomical Waste: Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses	
	(c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components	Incineration or plasma pyrolysis or deep burial. In absence of above facilities, autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.
	(d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Expired `cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200 ℃ Or Encapsulation or Plasma Pyrolysis at >1200 ℃. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.
	(e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.	Disposed of by incineration or Plasma Pyrolysis or encapsulation in hazardous waste treatment, storage and disposal facility.
	(f) Chemical Liquid Waste (Separate collection system leading to effluent treatment system): Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms.
	(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid	Non-chlorinated chemical disinfection followed by incineration or plazma pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or plazma pyrolysis.
	(h) Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial	Pre-treat to sterilize with nonchlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration.

	laboratories, production of biological, residual toxins, dishes and devices used for cultures.	
Red	**Contaminated Waste (Recyclable):** (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and *fixed needle syringes*) and vaccutainers with their needles cut) and gloves.	Autoclaving or micro-waving/hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	**Waste sharps including Metals:** Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps.	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
Blue	**(a) Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Disinfection (by soaking the washed glass waste after cleaning with detergent and sodium hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.
	(b) Metallic Body Implants	

There is provision that no occupier shall establish on-site treatment and disposal facility, if the service of common biomedical waste treatment facility is available within 75 km distance. The existing incinerators should be upgraded to achieve prescribed limit for retention time in secondary combustion chamber, and dioxin and furans shown in Table 2 (Gazette of India, 1998; Gazette of India, 2016).

Table 2: Emission standards for incinerator

Parameter	BMW Rules, 2016		BMW Rules, 1998
	Limit (mg/Nm^3) unless stated	Sampling duration (min) unless stated	Limit (mg/Nm^3) (at 12% CO_2 correction)
Particulate matter	50	30 or 1 Nm^3 of sample volume, whichever is more	150
Nitrogen oxides NO and NO_2 expressed as NO_2	400	30 for online sampling or grab sample	450
HCl	50	30 or 1 Nm^3 of sample volume whichever is more	50
Total dioxins and furans	0.1ngTEQ/Nm^3 (at 11% O_2)	8 h or 5 Nm^3 of sample volume whichever is more	--
Hg and its compounds	0.05	2 h or 1 Nm^3 of sample volume whichever is more	--

All the monitored values should be corrected to 11% oxygen on dry basis. The secondary chamber gas residence time shall be at least 2 seconds as per the BMW Rules, 2016. The occupier or operator of a common biomedical waste incinerator should install continuous emission monitoring system. The incinerator is to be operated with such temperature/retention time/turbulence, as to achieve total organic carbon content in the slag and bottom ashes < 3% or their loss on ignition should be < 5% of the dry weight. Standards for calculation of efficiency for plasma pyrolysis or gasification are included in BMW Rules 2016 with limit of gas residence time of at least 2 seconds in secondary chamber and minimum 3% oxygen in the stack. Emission standards framed for the incinerator will also apply to the plasma pyrolysis or gasification.

The chemical treatment revised to use at least 10% sodium hypochlorite having 30% residual chlorine for 20 minutes or any other equivalent chemical reagent that should demonstrate $Log_{10}4$ reduction efficiency for microorganisms. It is seen that there is no changes in operating conditions of autoclaving. However, various tests (validation test, routine test, spore test) have been discussed at length. No changes are seen with regards to microwaving. Dry heat sterilisation standards are added in BMW Rules 2016 that specifies dry heat sterilization at a temperature of not less than 185 ^oC, at least for a residence period of 150 minutes in each cycle, with sterilization period of 90 minutes. There are no changes in operational parameters of effluent treatment and deep burial. The deep burial is permitted only in rural or remote areas where there is no access to a common biomedical waste treatment facility. This will be carried out with prior approval from the prescribed authority

4. Conclusion

It can be seen that the BMW Rules, 2016 clearly define mandate of occupier and the operator. This would serve as check list to accomplish the task of the biomedical waste management for the occupier, operator and the prescribed authority or regulatory authority. Various concerned Miniseries/departments at Central and State level and the Municipal Corporation/municipalities are involved as the prescribed authorities. In addition, there is provision to form advisory committee for the State or Union Territory and the monitoring committee at district level under the chairmanship of District Collector/District Magistrate or Deputy Commissioner/Additional District Magistrate to monitor the compliance of the provisions of these rules. This entire framework would improve the implementation of the MBW Rules, 2016. Attempts have been made to minimise possible variations in emission monitoring by specifying the sampling duration (or volume) along with the parameters to be monitored. The occupier and operator are required to upgrade the existing facility to meet the standards of total dioxins and furans in stack emissions, maintaining 2 minutes residence time in secondary incineration chamber, installing continuous emission monitoring equipment, chemical treatment and other new measures that necessitates resources.

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