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Review Article

Biomedical waste management rule and changes in the policy

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ABSTRACT

The amount of biomedical waste being generated in our country is increasing day by day. Biomedical waste if not handled properly can pollute the environment and can spread many harmful diseases. Health care workers in our country are still not fully aware about proper BMW handling and disposal, despite increasing global awareness on it. Biomedical waste management rules was first implemented in India on 20th July, 1998. Thereafter, the rules have undergone amendments in years 2003, 2011 and 2016. Latest biomedical waste management rules, 2016 and (amendment) rules, 2018, were simplification of BWM disposal as compared to 2018 rules. The objective of this study was to understand the difference and compare key points to be known by all health care workers and also clarification and inclusions in the rules.

Keywords: Biomedical waste management in hospitals, Biomedical waste, Universal precautions, Biohazard, Biomedical waste management rule 1998 and 2016, Hospital waste management

INTRODUCTION

The Healthcare industry in India is delivered mainly either by public or private providers. The healthcare industry in India comprises of Hospitals, medical centers, clinical trails, telemedicine, clinics, medical tourism, and health insurance.

The public healthcare focuses on delivering primary healthcare through community-level health programmes mainly focusing on reducing mortality and morbidity caused by various communicable and non-communicable diseases. Biomedical waste (BMW) is defined as any waste which is generated during the diagnosis, treatment, or vaccination of human beings or animals or in research or in the use of biological or in health camps.[1]

The healthcare industry is growing at a tremendous pace to reach $372 Billion by 2022 from $45.0 billion in 2008 owing to its strengthening coverage, services and increasing expenditure by public as well as private players.[2] In terms of employment and revenue, healthcare has been one of the largest sectors and is growing at a vigorous pace.

The basic principle of good BMW practice is based on the concept of Rs. 3, namely reduce, recycle and reuse. It follows the cradle to grave approach which is characterization, quantification, segregation, storage, transport, and treatment of BMW.

The best BMW management (BMWM) methods aim at avoiding generation of waste or recovering as much as waste as possible, rather than disposing. Therefore, the various methods of BMW disposal, according to their desirability, are prevent, reduce, reuse, recycle, recover, treat, and lastly dispose. Hence, the waste should be tackled at source rather than 'end of pipe approach'.[3]

Poor management of HCW exposes health-care workers, waste handlers and the community to infections, toxic effects and injuries. On an average, the hospital waste

generation rate ranges from 0.5 to 2.0 kg/bed/day which amounts to about 0.33 million tons annually.[4]

The most common problems associated with the healthcare workers with biomedical waste management handling is lack of awareness about segregation, health hazards, insufficient financial allocation and manpower for proper management. They need well updated information about rule and skill and practices in managing this waste besides reducing hospital acquired infections to protect their own health.

On 20th July 1998, first BMW (management and handling) rules were notified by Government of India, by the erstwhile Ministry of Environment and forest (MoEF), Government of India under Environment (Protection) Act, 1986 (29 of 1986). The BMW 1998 rules were modified and amendments in the following years- (a) 1st amendment dated 06/03/2000- BMW (management and handling) (amendment) rules, 2000; (b) 2nd amendment dated 17/09/2003; (c) 3rd BMW (management and handling) Rules, 2011; (d) 4th- BMWM Rules, 2016; (e) 5th- BMWM rules, 2016. The word 'management' includes handling; (f) 6th- BMWM rules, 2018. Amendment dated 16/03/2018

The MoE, F and CC has notified the new BMW (M) rules, 2016 on 28th March, under the Environment (Protection) Act, 1986 to replace the earlier rules (1998) and the amendments thereof Published in the Gazette of India, extraordinary, part II, section 3, sub-section (i) 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 (Gazetted on 28th March, 2016) and amended Rules, 2018 the BMWM rules.

These new rules have increased the coverage, simplified the categorization and authorization while improving the segregation, transportation and disposal methods to decrease environmental pollution. It has four schedule, five forms and eighteen rules.

The BMW 1998 rules were modified in the following years- 2000, 2003, 2011 and 2016.

The draft of BMW rules 2011 remained as draft and did not notifies because of lack of consensus on categories and standards. Now Ministry of Environment, Forest and Climate change in March 2016 have amended the BMWM rules (999).[5]

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.

REVIEW

The Biomedical Waste Management Rules, 2016 brings more clarity in the application, duties of occupier and operator, reduce use of number of colour code bins and categories of waste. 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.

Comparison and differences of Biomedical Waste (Management and Handling) Rules, 1998 and Bio-Medical Waste Management Rules, 2016 is given in Table 1.

Table 1: Major difference between BMW rules 1998 and 2016.

Title	Bio-Medical Waste (Management and Handling) Rules, 1998	Bio-Medical Waste Management Rules, 2016
Date	20th July, 1998	28th Mach, 2016
Act	Environment (Protection) Act, 1986 (29 of 1986)	Environment (Protection) Act, 1986 (29 of 1986)
Appli-cation	Apply to all persons who generate, collect, receive, store, transport, treat, dispose or handle bio-medical waste in any form.	Apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form including 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.
	Rules Shall not apply was not defined	Rules shall not apply to a) Radioactive wastes as covered under the provisions of the Atomic Energy Act, 1962 (33 of 1962) and rules made there under; b) Hazardous chemicals covered under the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 made under the Act; c) Solid wastes covered under the Municipal Solid Waste (Management and Handling) Rules, 2000 made under Act; d) The lead acid batteries covered under the Batteries (Management and Handling) Rules, 2001 made under Act; e) Hazardous wastes covered under the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 made under act; f) Waste covered under the e-waste (Management and Handling) Rules, 2011 made under the Act; g) Hazardous microorganisms, genetically engineered microorganisms and cells covered under the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Microorganisms or Cells Rules, 1989 made under the Act.
Definition	Limited to 10 definitions	Extended to 16 definitions included form, handling, health care facility, major accident, management and prescribed authority.
Duties of occupiers	Every occupier of an institution generating bio-medical waste which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house pathologic, 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. Pretreatment, chlorinated bags, separate liquid waste, bar-code, training and immunization was not included.	Included: a) Pre-treat the laboratory waste, microbiological waste, blood samples and blood bags. b) Phase out use of chlorinated plastic bags, gloves and blood bags within two (2) years from the date of notification c) Dispose of solid waste other than bio-medical waste accordance with respective waste management rules. d) Not to give treated bio-medical waste with municipal solid waste. e) 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 f) Immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including hepatitis B and tetanus g) Establish a Bar-Code System for bags or containers containing bio-medical waste to be sent out of the premises h) Ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974) i) Conduct health check up at the time of induction and at least once in a year for all its health care workers j) Maintain and update on day-to-day basis the bio-medical waste management register and display the monthly record on its website k) Report major accidents including accidents caused by fire hazards, blasts during handling of biomedical waste and the remedial action taken and the records in Form-1

Continued.

Title	Bio-Medical Waste (Management and Handling) Rules, 1998	Bio-Medical Waste Management Rules, 2016
		l) Make available the annual report on its web-site and all the health care facilities shall make own website within two years from the date of notification of these rules m) Establish a system to review and monitor the activities related to bio-medical waste management, either through an existing committee or by forming a new committee and the Committee shall meet once in every six months and the record of the minutes of the meetings of this committee shall be submitted along with the annual report n) Maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years
Duties of the operator	No such Recommendation	Included: a) To establish barcoding and global positioning system (GPS) for handling of bio- medical waste within one year. b) Maintain all record for operation of incineration, hydroclaving/ autoclaving for a period of five (5) years. c) Maintain a log book for each cycle of its treatment equipment according to weight of batch; categories of waste treated; time, date and duration of treatment cycle and total hours of operation
Authoriz-ation	Every Occupier with more than 1000 beds required to obtain authorization	Expanded to include vaccination camps, blood donation camps, surgical camps or any other healthcare activity. The authorization shall be one time for non-bedded occupiers and the authorization in such cases shall be deemed to have been granted
Treatment and disposal facility	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 facility or any other waste treatment facility.	Treated and disposed of in accordance with Schedule-I and in compliance with the standards provided in Schedule -II Occupier shall hand over segregated waste as per the Schedule-I to common bio-medical waste treatment facility for treatment, processing and final disposal. No occupier shall establish on-site treatment and disposal facility if central biomedical waste treatment facility is available within 75 Km. Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards provided in Schedule-II by the health care facilities and common bio-medical waste treatment facility. Provided that the lab and highly infectious bio-medical waste generated shall be pre-treated by equipment like autoclave or microwave.
Segregati-on, package-ing, transport-ation and storage	BMW classified into 10 categories based on treatment options. Schedule I for Categories of Bio-Medical waste. Segregated into containers/bags at the point of generation. Schedule II for Segregation Schedule III for Labeled No untreated bio-medical waste shall be kept stored beyond a period of 48 hours.	BMW classified into 4 categories based on treatment options. Schedule I for Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options. The containers or bags referred to in sub-rule (2) shall be labeled as specified in Schedule IV. Bar code and global positioning system shall be added by the Occupier and common bio-medical waste treatment facility. Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty-eight 48 hours
Treatment and disposal of waste	a) Chemical treatment with 1% hypochlorite b) Deep burial to be allowed in towns	a) Chemical treatment with at least 10% hypochlorite having 30% residual chlorine for 20 minute or any other equivalent chemical reagent that should demonstrate $\log_{10}$ 4 reduction efficiency for microorganisms. b) Deep burial is only an option in remote rural or remote areas.

Continued.

<table>
<tr><th>Title</th><th>Bio-Medical Waste (Management and Handling) Rules, 1998</th><th colspan="4">Bio-Medical Waste Management Rules, 2016</th></tr>
<tr><td></td><td>with population >5 lacks.
c) Cytotoxic drugs disposal in secured landfills.
d) All drugs discarded in black bags
e) All infected metal, plastic and glass waste to be put in blue bag and then for autoclaving, microwaving or incinerator.</td><td colspan="4">c) 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.
d) All drugs including expired antibiotics should be sent back to manufacturer or to incinerator.
e) BMW plastics in red bag, sharps in white container and glass articles in blue marking box; then sent to authorized recycler. After proper treatment of plastics and glassware, these recyclables should be given to recyclers having valid registration.</td></tr>
<tr><td>Advisory Committee</td><td>The Government of every State/Union Territory shall constitute an advisory committee.</td><td colspan="4">Advisory Committee constituted shall meet at least once in six months and review all matters</td></tr>
<tr><td>Annual report</td><td>Every occupier/operator shall submit an annual report to the prescribed authority in Form II by 31 January every year.</td><td colspan="4">Every occupier or operator shall submit an annual report to the prescribed authority in Form-IV, on or before the 30th June of every year.</td></tr>
<tr><td>Mainte-nance of records</td><td>Shall maintain records.</td><td colspan="4">Every authorised person shall maintain records for a period of five (5) years.</td></tr>
<tr><td>Accident reporting</td><td>Shall report the accident in Form III</td><td colspan="4">About such accident and forward a report within twenty-four hours in writing in Form -I</td></tr>
<tr><td>Schedule I</td><td>Categories of Bio-Medical waste
Biomedical waste divided in ten (10) categories
Category 1- Human Anatomical Waste
Category 2- Animal Waste
Category 3- Microbiology and Biotechnology Waste
Category 4- Waste Sharps
Category 5- Discarded Medicine and Cytotoxic Drugs
Category 6- Solid Waste (Item contain blood)
Category 7- Solid Waste (Disposable Item)
Category 8- Liquid Waste
Category 9- Incineration ash
Category 10- Chemical waste</td><td colspan="4">Colour code category (yellow, red, white and blue) and types of waste, type of waste and treatment and disposal options and divided into 4 categories- biomedical wastes categories and their segregation, collection, treatment, processing and disposal options. Divided into 4 categories- biomedical wastes categories and their segregation, collection, treatment, processing and disposal options:
<table>
<tr><th>Category</th><th>Type of waste</th><th>Type of bag</th><th>Treatment and disposal options</th></tr>
<tr><td>Yellow</td><td>Human anatomical waste, animal anatomical waste, soiled waste, expired or discarded medicines, chemical waste</td><td>Yellow coloured non-chlorinated plastic bags</td><td>Yellow coloured non-chlorinated plastic bags</td></tr>
<tr><td></td><td>Discarded linen, mattresses, beddings contamina-ted with blood or body fluid</td><td>Non-chlorinated yellow plastic bags or suitable packing material</td><td>Non- chlorinated chemical disinfection</td></tr>
<tr><td></td><td>Microbiol-ogy, Biotechnol-ogy and other clinical laboratory waste</td><td>Autoclave safe plastic bags or containers</td><td>Pre-treat</td></tr>
<tr><td>Red</td><td>Contaminat-ed waste (recyclable)</td><td>Red coloured non-</td><td>Autoclaving or micro-waving/ hydroclaving</td></tr>
</table></td></tr>
</table>

Continued.

Title	Bio-Medical Waste (Management and Handling) Rules, 1998	Bio-Medical Waste Management Rules, 2016			
				chlorinated plastic bag	followed by shredding
		White (transluc-ent)	Waste sharps including metals	Puncture proof, leak proof, tamper proof containers	Autoclaving or dry heat sterilization followed by shredding
		Blue	Glassware	Cardboard boxes with blue colored, instead of cardboard boxes, now these will be disposed in puncture proof and leak proof boxes or containers with blue marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and sodium hypochlorite treatment)
Schedule II	Colour coding (yellow, red, blue/white and black) and type of container for disposal of bio-medical wastes.	Standards for treatment and disposal of bio-medical wastes (incineration, autoclaving, microwaving, deep burial, chemical disinfection, heat sterilization and liquid waste)			
Schedule III	Label for BMW containers/bags-biohazard symbol and cytotoxic hazard symbol	List of prescribed authorities and the corresponding duties			
Schedule IV	Label for transport of bio-medical waste containers/bags	Part A- label for bio-medical waste containers or bags Part B- label for transporting bio-medical waste bags or containers			
Schedule V	Standards for treatment and disposal of bio-medical wastes	Added to schedule -II			
Schedule VI	Schedule for waste treatment facilities like incinerator/autoclave/microwave system	Added to schedule -III			
Form-I	Application for authorization	Accident reporting			
Form-II	Annual report No format of annual report Reporting period 30th January for the calendar year.	Application for authorization or renewal of authorization. Format provided. On or before 30th June every year for the period from January to December of the preceding year			
Form- III	Accident reporting	Authorization			
Form- IV	Not Implemented	Annual report- prescribed format is given and to be submitted on or before 30th June every year All the health care facilities (any number of beds) shall make own website and shall make available the annual report on its web-site within a period of two years			
Form-V	Not implemented	Application for filing appeal against order passed by the prescribed authority in prescribed format.			

CONCLUSION

Biomedical Waste Management Rules, 2016 clarify various responsibilities of occupier, operator and regulatory authorities. The number of forms and reduced and categories of waste to 4 only. Continuous awareness, training programs and regular monitoring and audits must be done by the healthcare facilities for implementation of the rule. The rules, 2016 would improve the implementation in healthcare facilities of the MBW rules.

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