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Keeping in pace with the new Biomedical Waste Management Rules: What we need to know!

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ABSTRACT

Biomedical Waste Management Rules were first implemented in our country on 20th July 1998. Thereafter, the rules have undergone periodic updates and amendments in the years 2003 and 2011. Latest Biomedical Waste Management Rules, 2016, and (Amendment) Rules, 2018, were an update and simplification of BMW disposal as compared with the previous version, keeping in pace with the changes in the requirements of the health-care setup. Although exhaustive, numerous medical devices/products/kits did not find any mention even in the latest amendment of the rules. Thus, this article aims to bring out the key points to be known by all health-care workers and the gray areas which require clarification and inclusion in the rules for a completeness of the said rules.

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Introduction

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 It involves all persons and institutes which generate, collect, receive, store, transport, treat, dispose, or handle any form of BMW. 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.² Of the total BMW, about 75% and 90% of the waste is non-hazardous or general healthcare waste. The remaining 10%–25% of BMW is regarded as hazardous, and if not managed

properly, it can spread highly contagious diseases of which the most dangerous ones are hepatitis B, HIV-AIDS, and hepatitis C, thus a grave health hazard for current and future generations. It is also a threat to the environment, causing air, water, and soil pollution.^{3,4}

Past studies have reported that health-care workers in our nation are not entirely aware of proper BMW segregation and further disposal. There is an increasing awareness about BMW handling and disposal globally.⁵ In our nation, widespread publicity is required as evidenced from studies from various parts of our nation that suggest gaps in knowledge and lacunae in attitudes and practices are still prevalent to a worrying extent among the various categories of health-care workers.^{4,5} BMW management guidelines have been

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Table 1 – Salient differences between BMW Management Rules 1998 and 2016. (Amended and reproduced with permission).¹

Points	BMW management rules, 1998	BMW management rules, 2016
Duties of the occupier	Duties of the occupier not delineated better No pretreatment of waste on-site Chlorinated plastic bags, gloves, and blood bags were recommended ETP not mandatory The details of records not mandatory The annual report need not to be posted on website BMWM committee not compulsory Records not compulsory to maintain	Duties of the occupier are delineated better There is pretreatment by disinfection and sterilization on-site of infectious lab waste blood bags as per the WHO guidelines Occupier ensures non-chlorinated plastic bags, gloves, and blood bags within two years of notification Occupier ensures liquid waste is segregated at source by pretreatment, and ETP is mandatory Occupier ensures to maintain BMWM register daily and on website monthly Annual report should be made available on the website within two years The occupier (≥ 30 bedded) establishes BMWM committee Records of equipment, training, health checkup, and immunization are compulsory Duties are delineated better The occupier has to establish barcoding and GPS and ensure occupational safety of all its HCWs by TT and HBV vaccination Reporting of accidents and maintenance of records of equipment, training, and health checkup
Duties of the CBMWTF	Duties are not delineated better Barcoding and GPS not documented and vaccinations for HCWs not documented Records not documented	Major accidents are reported to authorities and in annual report Deep burial is an option for remote and rural areas Chemical treatment: 10% hypochlorite (rolled back to 1%–2% in 2018) Fetus younger than the age of viability is to be treated as human anatomical waste Antibiotics and other drugs and solid chemical waste suggested for incineration Cytotoxic drugs: return back to supplier and incineration up to 1200 °C Effluent treatment plant is mandatory, and effluent to conform to standards mentioned
Accident reporting	No specific reporting of accidents	
Deep burial	Deep burial allowed in villages and towns with less than 5 lakhs population	
Chemical treatment	Chemical treatment: 1% hypochlorite	
Fetus	No demarcation of fetus mentioned	
Drugs	All drugs to be discarded in the black bag For cytotoxic drugs, destruction and drugs disposal in secured landfills	
Liquid-infected waste	For liquid waste, chemical treatment and discharge into drains to conform to effluent standards mentioned	
Microbiology and biotechnology waste	Pretreatment not mandatory	Pretreatment of infectious waste is as per the WHO guidelines: 6 log reductions
Infected plastics, sharps, and glass	Infected plastics, metal sharps, and glass go in the blue container with disinfectant, and local autoclaving/microwaving/incineration is recommended	The infected plastics and sharps go in the red bag and the white container, respectively, and are sent to authorized recyclers. The glass articles are discarded in a cardboard box with blue marking (see Table 2 for update)
Recycling	Recycling of plastics and glass to authorized recyclers not mentioned	A focus on recycling of plastic, sharps, and glass to authorized recyclers
Form I	Application for authorization	Accident reporting
Form II	Annual report	Authorization or renewal of authorization
Form III	Accident reporting	Authorization for operating a facility for collection, reception, treatment, storage, transport, and disposal of BMW
Form IV	(Added in 2000 amendment) Authorization for operating a facility for collection, reception, treatment, storage, transport, and disposal of BMW	Annual report
Form V	(Added in 2000 amendment) Application for filing appeal against order passed by the prescribed authority	Application for filing appeal against order passed by the prescribed authority

WHO: World Health Organization, CBMWTF: common biomedical waste treatment facility, BMW: biomedical waste, ETP: effluent treatment plant, BMWM: Biomedical Waste Management, HCW: Healthcare Workers, TT: Tetanus Toxoid, HBV: Hepatitis B Virus.

frequently amended,^{1,6} in addition, with lack of self-update has contributed to the increase in knowledge gap.

Biomedical waste management rules

BMW Management Rules were implemented in our country on 20th July 1998 under the Environment Protection Act, 1986. These were followed by amendments in 2000 and draft amendments in 2003 and 2011. As per these rules, BMW was divided into ten categories (later reduced to eight). Multiple categories of waste were clubbed to be disposed into the four color coded bags. This was very confusing and difficult to remember, especially by the housekeeping staff, which formed the weakest link in the BMW management.⁵ The occupiers had their own treatment facilities (such as incinerator, burial pits, etc.) for the final disposal of BMW. It was found that up to 82% of the health-care facilities had no credible BMW management or required significant improvement,⁷ thereby posing a threat to public and environment.

To address these issues, new BMW Management Rules were notified by the Ministry of Environment, Forest and Climate Change on 28th March 2016 under the Environment Protection Act, 1986.⁸ The ambit of these rules includes all facilities generating BMW such as vaccination camps, surgical camps, first aid rooms, and so on. All health-care establishments in Armed Forces come under the purview of these rules.

The major changes are as follows: (1) the removal of multiple categories and to continue with only four color-codes (2)

that no occupier was permitted to establish an on-site treatment and disposal facility if service of a common biomedical waste treatment facility (CBMWTF) is available within a distance of 75 km, and (3) changes in the form numbers of accident reporting, authorization, annual reporting, and appeal. The salient differences between the BMW Management Rules published in 1998 and 2016 are mentioned in [Table 1](#).

Further to this, Biomedical Waste Management (Amendment) Rules, 2018, were published by the Ministry of Environment, Forest and Climate Change on 16th March, 2018.⁹ In these amendments, typographical errors were corrected, rules regarding non-infectious wastes were updated, and the advised concentration of 10% sodium hypochlorite was rolled back to 1%–2% as described in the existing literature.⁶ These amendments have been covered in [Table 2](#).

However, numerous medical devices/products/kits did not find a mention in Schedule-I of the BMW Management Rules, 2016. These missing/ambiguous items comprised the gray areas. A workshop titled ‘Workshop on Gray Areas in Schedule-I, BMW Management Rules, 2016’ was organized by the Government of India, Office of the Medical Superintendent and Safdarjung Hospital, and Vardhman Mahavir Medical College, New Delhi, on 25th September, 2017.¹⁰ Participants from various health-care setups including the Armed Forces Medical Services discussed in detail about these gray areas, and the final output regarding their segregation and disposal is compiled in [Table 3](#). It is to be noted from [Table 3](#) that although various types of solid and soiled waste are discarded in yellow bags, the final disposal is different for each. Lab waste, especially live cultures and vaccines, should be pre-treated before discarding. All recyclable plastic wastes should

Table 2 – Amendments as per the Biomedical Waste Management (Amendment) Rules, 2018.⁹

Point	Amendment
Solid wastes	Covered under the Municipal Solid Waste (Management and Handling) Rules, 2016
Hazardous wastes	Covered under the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2016
Electronic waste	Covered under the e-Waste (Management and Handling) Rules, 2016
Pretreatment of laboratory waste, microbiological waste, blood samples, and blood bags through disinfection	As per the guidelines on Safe management of wastes from health-care activities and the WHO Blue Book, 2014, and then sent to the CBMWTF for final disposal
Use of chlorinated plastic bags (excluding blood bags) and gloves	To be phased out by 27th March, 2019
Global positioning system and barcode on bags and containers	To be established in accordance with the guidelines issued by the Central Pollution Control Board by 27th March, 2019
Website and annual report	All the health-care facilities (any number of beds) shall make available the annual report on its website by 15th March, 2020
Bags used for disposal	Shall be as per the Plastic Waste Management Rules, 2016
For hospitals under Armed Forces Medical Services	1. The Central Pollution Control Board shall monitor the implementation of BMW Management Rules 2. The Central Pollution Control Board along with one or more representatives of the Advisory Committee constituted under the subrule (2) of rule 11 may inspect any Armed Forces health-care establishments after prior intimation to the Director General Armed Forces Medical Services.
Disposal of glassware and metallic body implants	Instead of cardboard boxes, now these will be disposed in puncture proof and leak proof boxes or containers with blue marking
Chemical treatment/pretreatment using sodium hypochlorite	Recommended concentration rolled back from 10% to 1%–2%

WHO: World Health Organization, CBMWTF: common biomedical waste treatment facility, BMW: biomedical waste.

Table 3 – Gray areas/ambiguous^d/missing articles in Schedule-I of the BMW Management Rules, 2016. (Amended and reproduced with permission).⁶

Color	Type of waste	Gray areas	Type of bag/container	Disposal
Yellow	Human/animal anatomical waste Soiled waste: items contaminated with blood and body fluids such as dressings, plaster casts, cotton swabs, caps, gowns, and masks.	– Shoe cover, blotting paper with infectious material, wooden swab stick, paraffin blocks, and indicator tapes Expired or discarded medicines: antibiotics, drugs Chemical waste: solid discarded chemicals	Yellow-colored non-chlorinated plastic bags ($\geq 50 \mu\text{m}$) or containers	Incineration
	Cytotoxic drugs ^a , cytotoxic vials broken/intact, cytotoxic container/bag	Cytotoxic drugs dispensed in dextrose/saline bottles, cytotoxic container/bag	Yellow-colored non-chlorinated plastic bags ($\geq 50 \mu\text{m}$)/yellow-colored non-chlorinated plastic containers with cytotoxic labels	Sent back to manufacturer or disposed of by incineration by the CBMWTF for incineration Expired cytotoxic drugs to be returned back to the manufacturer or supplier or CBMWTF for incineration at temperature $>1200^\circ\text{C}$
	Chemical liquid waste: liquid waste generated because of use of chemicals and used or discarded disinfectants	All samples from patients need to be pretreated and neutralized and then discharged in ETP	Separate collection system leading to ETP system	The infected secretions/samples to be pretreated before mixing with waste water. The combined discharge shall conform to the discharge norms given in Schedule-II
	Discarded linen: contaminated with blood or body fluid	–	Non-chlorinated yellow plastic bags	Non-chlorinated chemical disinfection (5% phenol, 5% cresol, 5% lysol, 70% ethyl alcohol, lime milk, 3% hydrogen peroxide, quaternary ammonium compounds) on-site followed by incineration by the CBMWTF
	Microbiology, biotechnology, and other clinical laboratory waste ^b	Plastic culture plates (autoclave and then respective category of plastic as red), live or attenuated vaccines, cell cultures, biologicals, toxins vials (autoclave and then respective category of plastic as red and glass as blue)	Autoclave-safe plastic bags or containers	Autoclave/microwave/hydroclave or pretreat to disinfection site in HCF and then disposed in their respective category

(continued on next page)

Table 3 – (continued)

Color	Type of waste	Gray areas	Type of bag/container	Disposal
Red	Contaminated waste (recyclable), plastics tubing, bottles, intravenous tube sets, catheters, urine bags, syringes (without needles), and vacutainers with their needles cut and gloves	Vacutainers (PVC): red PVC gloves: red Pipette tips, plastic pipette, eppendorf, rubber teats, antispash plastic gown, rubber apron Plastic cards LAT, ICT kit device, ELISA plate, BMD plate: Autoclave/ disinfect: red, Micropore filters, eppendorf tubes: red Positive controls of kits ^b plastic/ glass vials: Autoclave preferably/ disinfection: red/blue, respectively, depending on plastic/glass Vaccines plastic/glass (live/ attenuated) ^b : Autoclave: red/blue, respectively.	Red-colored non-chlorinated plastic bags or containers	Autoclave/microwave/hydroclave at the CBMWTF followed by shredding or mutilation and sent to authorized recyclers or waste to energy recovery
White ^c (translucent)	Waste sharps: fixed needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpel blades	Not all sharps can be mutilated (lumbar puncture needle, laryngoscope blade, trocar cannula, IABP cannula, scissors, clipper blade/oscillator blade/ arthroscopy blade, pins, all wires, metal, insulin pen needle, lancet needle, removal needle, eye needle, cardioplegia needle, stab knife)	Puncture-proof, leak-proof, tamper-proof containers	Autoclave or disinfection by the CBMWTF and sent for final disposal to authorized iron foundries (SPCB)
Blue	Glass vials or broken or discarded including medicine vial and infected glass Metallic implants	Glass slides, coverslips (disinfection), glass pipettes, glass chamber (glass) Sternal wire: metal, gigli saw wire, orthopedic splint	Cardboard boxes with blue-colored marking (changed to puncture-/ leak-proof containers in 2018 amendments)	Autoclaving/chemical disinfection CBMWTF to send such waste to registered or authorized recyclers The infected glass is pretreated on-site with autoclaving/disinfection and sent to the CBMWTF to be sent to government authorized recyclers. The non-infected glass is not pretreated on-site

HCF: health-care facility, ETP: effluent treatment plant, CBMWTF: common BMW treatment facility, PVC: polyvinyl chloride, LAT: latex-agglutination test, ICMR: Indian Council of Medical Research, ICT: immuno-chromatographic tests, BMD: broth microdilution, IABP: intra-aortic balloon pump, SPCB: State Pollution Control Board.

^a Cytotoxic drugs: ICMR is formulating cytotoxic guidelines.

^b The articles which require pretreatment of autoclaving/microwaving at HCF include culture media with growth of microorganisms, broth with live cultures, live and attenuated vaccines, positive control of kits, pipette tips/articles used in processing of culture of organisms, and blood bags. The specimens received from patients need to be autoclaved or disinfected.

^c Not all sharps can be mutilated (blades and thick needles, knife, suture needles, lumbar puncture needles, etc.), therefore, they go directly in white containers to prevent injury or health hazard to the health-care workers. Needle cutters are preferred over needle destroyers.

^d The articles such as robotic instruments, large combination articles with plastic and/or glass and or metal are gray areas as rules do not specify their disposal.

be segregated in red bags as the final disposal after sterilization is energy recovery. Needles are to be discarded in white containers, and syringes, in red. However, syringes with fixed needles are to be discarded in white container. Except for blood bags, only non-chlorinated plastic material and bags should be used.

Relevance for Armed Forces healthcare facilities

Before the BMW Management Rules, 2016, came into force, all hospitals under Armed Forces Medical Services (AFMS) were carrying out the final disposal in their own campuses. Now, the same needs to be outsourced to a CBMWTF nominated by the Central or State Pollution Control Board/Committee in the respective area. Under the new guidelines, all bedded as well as non-bedded facilities such as Medical Inspection (MI) rooms, polyclinics, and so on too need to apply for authorization for generation of BMW. For non-bedded facility, authorization would be one-time, and for a bedded facility, it would be valid for a period of five years.

In places where CBMWTF are non-existent and there is need to continue in-house BMW treatment, they would continue to do so as per earlier guidelines; with the operating and emission standards as per Schedule - II of BMW Management Rules, 2016.

Conclusion

By means of BMW Management Rules, 2016, the Government of India has tried to simplify the BMW management in our nation. Final disposal of BMW requiring high-maintenance infrastructure was a vexation for health-care facilities, which has been done away with by the provision of CBMWTF. With simpler color-coded categories, updating the knowledge on the same, and on-ground implementation of BMW, segregation at source by the health-care workers still remains the biggest challenge.¹ Widespread publicity, continuous training programs, and audits must be encouraged to increase the awareness regarding the threats posed by the

mismanagement of BMW and to bring uniformity in practices through all echelons of health-care facilities.

Conflicts of interest

The authors have none to declare.

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