CONTINUED MEDICAL EDUCATION

Salient Features of Bio-Medical Waste Management Rules, 2016

Jay K Sheth

Associate Professor, Department of Community Medicine, AMCMET Medical College, Maninagar, Ahmedabad - 380008, Gujarat

Corresponding Author

Address for Correspondence: Dr Jay K Sheth, Associate Professor, Department of Community Medicine, AMCMET Medical College, Maninagar, Ahmedabad - 380008, Gujarat.
E Mail ID: jayksheth@yahoo.com

Citation

Jay K Sheth. Salient Features of Bio-Medical Waste Management Rules, 2016. Indian J Comm Health. 2017; 29, 1: 5-9.

Source of Funding: Nil **Conflict of Interest:** None declared

Article Cycle

Received: 08/01/2017; **Revision:** 15/01/2017; **Accepted:** 15/02/2017; **Published:**31/03/2017

Abstract

Ministry of Environment, Forest & Climate Change, Government of India published the official notification no G.S.R. 343(E) in the government gazette, dated 28thMarch 2016. With this the new law on biomedical waste called as "Biomedical Waste Management Rules, 2016" came into force in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998.

Being an inevitable and inseparable part of our health care industry, it is obligatory for us that we discuss and understand the rule, legal provision as well as its implications. Being very recent, the provisions made in the new rules are not widely known. There are various changes in the new rule. An effort is made here to explain the technical aspects of the law in simpler way, comparing it with the old rule and highlighting on the key changes. Scientific basis for some changes in the rule are also highlighted appropriately. The article is particularly written to make health professionals more aware, well informed and better prepared. The larger interest however is to help & facilitate proper implementation of the rule at all levels.

Keywords

Biomedical Waste; Biomedical Waste Management; Biomedical Waste Management Rules 2016.

Introduction

As compared to the past, when the health care waste was considered under the Environment Protection Act 1986, the Biomedical Waste (Management & Handling) Rules 1998, greatly contributed in environmentally sound management of biomedical waste.(1) However, there were many issues with its scope, effective management and its implementation indicating an urgent need for greater commitments at policy and programme level.(2) A whole new industry has also grown on the basis of this rule. It was a long due felt-need to make necessary changes so as to improve the collection, storage, processing, treatment and disposal of these bio-medical waste in an environmentally sound manner thereby, reducing the biomedical waste generation as well as its impact on the environment.

The Central Government, Ministry of Environment, Forest & Climate Change published the draft rules in the Gazette, invited objections or suggestions and passed the rule called "Bio-Medical Waste Management Rules, 2016" (BMWM Rules 2016) which was published vide notification no. G.S.R.

343(E) dated 28thMarch 2016 and which came into force in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998.(3)

Being an inevitable and inseparable part of our health care industry, it is obligatory for us that we discuss and understand the rule, legal provision as well as its implications.

Salient Features: Starting with the name itself, the new rule is technically better named. Handling the waste is part of management itself.(4) So, the unnecessary phrase 'handling' is omitted and the rule is aptly named as "Bio-Medical Waste Management Rules, 2016."

Segregation of biomedical waste at the source of generation is the first and essential step in biomedical waste management & it continues to be the key message and central theme of the BMWR, 2016.(5) There was some confusion due to color option/choices available for some categories of biomedical waste. The failure to understand that more than one color option in some categories of biomedical waste is not simple choice or preference but dependent over the treatment & disposal option in the old rule, added to the confusion in the past. This issue has been promptly addressed now in the new rule. There is only one color choice for any category of biomedical waste and this adds to simplification of its understanding among health care workers.

The 10 categories of biomedical waste is now simplified and categorized in 4 different color categories only. A paradigm shift in schedule-I and change from 10 categories to 4 color categories reflects simplification. Reduction in categories does not mean that any particular type of biomedical waste is ignored or not being addressed to. What it means is that all types of wastes have been compiled in four categories for ease of segregation at a healthcare facility. Technically however, the categories of biomedical waste addressed through the rule are now increased as some categories are further split into sub categories (e.g. sharps including metals & glassware are now considered as separate category & color code).

The new rule adds to the clarity with certain more additions in the examples to which it applies. The additional establishments e.g. AYUSH Hospitals, Research/educational institutes, Health camps, Medical or surgical camps, Vaccination camps, Blood donation camps, First aid rooms of schools, Forensic laboratories etc adds to the clarity and widens the scope of its applicability. Contrary to general belief that a widened scope and more HCEs under the legal framework will further clog the authorization process, Actually the new rule have simplified the process of authorisation by addressing some important hurdles in the process of getting authorisation. The occasional undue long wait for the authorisation is now over. All the applications of authorisation shall be disposed within a period of 90 days from the date of receipt of completed application. A clear permission of authorisation or details of objections will now be available from the prescribed authority. In case of a 'pending' application beyond the time frame of 90 days, the authorisation shall be deemed to have been granted. With the widened scope of authorisation and adding many more Health Care Establishments (HCEs) under the Act-net, the small non-bedded HCEs (e.g. dispensaries, clinics) are taken care of as well with "one time authorisation", bringing them in the legal purview, under the law, but at the same time avoiding unnecessary formality and paperwork-renewal etc.

The old rule clearly mentioned that it shall be the duty of every occupier / Common Biomedical Waste Treatment Facility (CBWTF) operator generating/handling the biomedical waste to "take all steps to ensure" that such waste is handled without any adverse effect to human health and the environment. However, it was lacking in the clarity and detailed guidelines. Throwing light on this grey area, the new rule specifically enlists 20 points for the duty of the occupier and 17 points for the duty of the CBWTF operator. Adding further on the clarity, the list of prescribed authorities and their corresponding duties are also clearly mentioned in the new rule. This clause is going to facilitate better understanding & implementation of the act as it addresses the key component of any legal framework, namely the 'duties' and the 'responsibilities'.

Considering the environmental hazard due to the emission of toxic gases like dioxin & furan due to inadvertent burning of chlorinated plastics, the new

rule has made the provision to phase out use of chlorinated plastic bags, gloves and blood bags within 2 years.(6) These bags shall be in compliance with Bureau of Indian Standards (BIS) and till then it should be as per plastic waste management rules, 2011. While use of colored biomedical waste bag with biohazard symbol helped in identifying the biomedical waste, it was difficult to identify the health care institution from which the waste has been collected. This has given rise to the problem of untreated biomedical waste which was handed over to the CBWTF by the HCEs. The provision of Bar-Code System for Biomedical waste bags or containers has been given one year time frame. Moreover, with GPS enabled system, the biomedical waste bags can be tracked as well. So now it will be possible to track the biomedical waste bag and the original health care institution can be made accountable for untreated-improperly treated or improperly segregated biomedical waste.

The methods of treatment and disposal are not hard and fast. The flexibility is still kept as a unique feature of the Indian law. Any new technology that is environmentally sound and achieves the operating standards may be adopted after approval and authorisation. However, the central government may be requested for standards of operating parameters before adopting the new technology and revised authorization. There was need to skip to newer, widely accepted, economical, and environment-friendly technologies.(7) The use of hydroclave and plasma pyrolysis for the incineration of biomedical wastes leads to lesser environmental degradation, negligible health impacts, safe handling of treated wastes, lesser running and maintenance costs, more effective reduction of microorganisms, and safer disposal.(7,8) Both these newer technologies are now incorporated in the new rule. Waste incineration process poses a significant threat to public health and the environment.(7) So, the inclusion of Plasma Pyrolysis as an additional method of choice as an alternative to incineration, is appreciated aloud by environmental agencies and activists who are against the growing number of incinerators in the country. The alternative of deep burial earlier available for remote rural area during the phased implementation of the old rule is still mentioned but applicable only in remote rural areas where no CBWTF is available.

The standard for treatment and disposal of biomedical waste has been revised e.g. the acceptable SPM emission of 150 mg/Nm^3 has been reduced to 50 mg/Nm^3 in the new rules. Similarly, the standard retention time in the secondary chamber has been increased from 1 second to 2 seconds. This is done to reduce the levels of hazardous gases like dioxins and furans. Since the operating standard of the incinerator is revised, the existing incinerators are given 2 years time period to achieve the standards for treatment and disposal. Considering the environmental risk, research has documented that outsourcing should be explored as a viable method of Biomedical disposal rather than establishing an entirely new unit.9 Consequently, the establishment of new treatment and disposal facility in a health care institution is not allowed if the nearest CBWTF is within 75 kms of the health care institution. However, those health care institutions which already have such facility may continue to operate the same but shall comply to the operating standards within a maximum time frame of 2 years.(6)

Putting the scenario as a naked fact, generally the treatment of biomedical waste implies either incineration or autoclaving only. Chemical treatment has been either not used or used infrequently and improperly. Even when chemical treatment is done with hypochlorite solution, the negligence on part of the health care workers/system resulted into sending the chemically treated biomedical waste for incineration, further adding the environmental risk of toxic gases through burning of biomedical waste treated with (and thus containing) chlorine. This issue has been addressed with use of non-chlorinated chemical disinfection whenever the chemical disinfection is applied onsite at the source of generation. Being a major shift from the existing practices, this will be a major change related to the practice of chemical disinfection, but from the environmental point of view, definitely this is a welcome step.

The final disposal of the treated biomedical waste should be environmentally sound. Reduce, Recycle & Reuse should be promoted so far as possible.(10) Plastic waste should not be sent to landfill sites. The new rule has clearly mentioned that treated biomedical waste should not be given and mixed with other municipal solid waste. All recyclable

waste should be sent to the registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Disinfected sharp waste may be sent to iron foundries having consent to operate from the State Pollution Control Boards or Pollution Control Committees. These recyclers should have valid authorisation or registration. CBWTF has to keep a record of recyclable waste and be submitted to prescribed authority as part of their annual report.

One of the welcome provisions in the new rule is regarding the training & health check-up of all the health care workers, which has been documented time and again to be of utmost important in improving the situation regarding biomedical waste.(4,11,12) While this is unarguably considered to be important, without a clear mention of the time frame or a compulsory requirement, there was wide variation in the practices regarding the same between different health care institutions. It is now clearly mentioned that training and health checkup is to be conducted at the time of induction and yearly thereafter. These details are also required to be mentioned in the annual report as well. Owing to the absence of clear written guideline in the past, the supply of adequate personal protective equipments and effective immunization of the health care workers remained more of moral – ethical concern rather than legal. The new BMWM Rules 2016 mentions that occupier has to ensure occupational safety of all its health care workers and others involved in handling of biomedical waste by providing appropriate & adequate personal protective equipments and effective immunization against diseases likely to be transmitted. This addition of written guideline is a welcome step and will be helpful to the health care workers in protecting themselves from the occupational risk of hazardous health care waste.

Healthy HCE-CBWTF operator relationship was a necessity and need of time but it was on a fragile platform in a hostile environment where both the parties shun away from their own responsibility and continue to play the blame game on one another for any lacunae within the system. This attitude of shunning away from the responsibility created an unhealthy environment between them which existed only & only because of a law and which grew more on commercial basis than on a professional basis.(13) This required an urgent legal intervention and the new rule has carefully addressed this felt-need in terms of some provisions. As per the new rule, the CBWTF operator has to collect the biomedical waste even on holidays and in no case the time limit should cross the prescribed limit. The untreated biomedical waste shall not be stored beyond a period of 48 hours. The occupier of the HCE has to inform the prescribed authority immediately in case the CBWTF operator does not collect the bio-medical waste within the intended time or as per the agreed time and take appropriate steps to safeguard human health and environment. The occupier can also visit the CBWTF operator and check “whether the treatment is carried out as per the rules?” On the other hand the CBWTF operator needs to inform the prescribed authority immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with these rules. These provisions add soul to this relationship with “equal independence” and “reciprocal obligations” to the already mutually dependent relationship between the HCEs & the CBWTF operators. Most importantly, these provisions will help and facilitate the ultimate aim of environmentally sound management of the biomedical waste.

The biomedical waste records remained more of paper work and formality. With the provision of maintenance of records of the biomedical waste on daily basis in the register and display the monthly record on its website, the rule is expected to bring transparency, public scrutiny and uncover various issues underneath these data. It is a welcome step that a time-frame of 2 years is given to the HCEs to create their own website.

Another improvement in the new rules is in the monitoring sector. While the old rule had no clear provision for a monitoring authority, the 2016 rules state that the MoEFCC will review health care facilities once a year through state health secretaries, the SPCB and the CPCB. The SPCB, in its turn, will oversee implementation through district level monitoring committees that will report to the State advisory Committee or the SPCB. Moreover, according to the new rules, the advisory committee on biomedical waste management is now mandated to meet every six months. Assigning the responsibility to a person or having a monitoring system in place has shown to be very useful in effective management of the biomedical waste.2

Guidelines as per the new BMWM Rules, 2016 also describe monitoring at the level of HCEs. Small HCEs with <30 beds have to designate a qualified person to review and monitor the activities related to bio-medical waste management. In the larger HCEs, the same needs to be monitored through a system of previously established or newly formed committee which should meet at least once in 6 months. The minutes of the meetings of this committee should be recorded and submitted in the annual report as well. The legal provision for the violation of the act is usually framed quite strictly in many of the act. However, in view of the biomedical waste, these are seldom applied and perceived to be enforced quite lightly. It is clear, without any doubt, that the regulatory authority should monitor and supervise all HCEs, but in the absence of a clear guideline regarding implementing agency, the enforcement of the act and punitive actions in case of a breach in law had been seldom enforced. The BMWM Rules has made it clear with strict as well as legal provisions including fixing the liability. The occupier of a HCE or an operator of a CBWTF shall be liable for all the damages caused to the environment or to the public due to improper handling of bio- medical wastes and they shall be liable for action under section 5 and section 15 of the Act (EPA, 1986), in case of any violation.

While framing any rule, it is very important that the provisions made therein should not violate other legal guidelines or acts. Various other standard and related guidelines are now incorporated integrally with the new BMWM Rules, 2016. Quality of non-chlorinated plastic bags in compliance with Bureau of Indian Standards (BIS) & plastic waste management rules, 2011, Vehicles transporting the BMW as per the state PCB/MVA, laboratory waste sterilization to log 6 or disinfection to log 4 as per WHO guidelines, on-site disinfection/sterilisation of infectious biomedical waste in the manner prescribed by the World Health Organization (WHO) or National Aids Control Organisation (NACO) guidelines etc are some of the linkages of the BMWM Rules with the other rules/standard guidelines. This adds to clarity and helps in avoiding any confusion or conflict with other laws regarding its implementation.

References

1. Biomedical Waste (Management and Handling) Rules 1998, Ministry of Environment and Forest, Government of India. http://envfor.nic.in/legis/hsm/biomed.html
2. INCLEN Program Evaluation Network (IPEN) study group, New Delhi, India Bio--medical waste management: situational analysis & predictors of performances in 25 districts across 20 Indian States. Indian J Med Res 2014, 139:141–153
3. Bio-Medical Waste Management Rules 2016, Ministry of environment, forest and climate Change, Government of India.http://envfor.nic.in/sites/default/files/BMW%20Rules,%202016_1.pdf
4. Kumar A, Duggal S, Gur R, Rongpharpi SR, Sagar S, Rani M, Dhayal D, Khanijo CM. Safe transportation of biomedical waste in a health care institution. Indian J Med Microbiol. 2015 Jul-Sep;33(3):383-6. doi: 10.4103/0255-0857.158559. PubMed PMID: 26068340.[PubMed].
5. Sengodan VC. Segregation of biomedical waste in an South Indian tertiary care hospital. J Nat Sci Biol Med. 2014 Jul;5(2):378-82. doi: 10.4103/0976-9668.136194. PubMed PMID: 25097419; PubMed Central PMCID: PMC4121919.[PubMed]
6. Clarification regarding the biomedical waste management rules, 2016. No. 18-15/2016 by Ministry of Environment, Forest & Climate change, Government of India dated 30th May 2016 available at http://envfor.nic.in/sites/default/files/OM%20on%20Clarificaiton%20on%20BMW.pdf
7. Sharma R, Sharma M, Sharma R, Sharma V. The impact of incinerators on human health and environment. Rev Environ Health. 2013;28(1):67-72. doi: 10.1515/reveh-2012-0035. Review. PubMed PMID: 23612530.[PubMed].
8. Hamer G. Solid waste treatment and disposal: effects on public health and environmental safety. Biotechnol Adv. 2003 Dec;22(1-2):71-9. Review. PubMed PMID: 14623044.[PubMed]
9. Jindal AK, Gupta A, Grewal VS, Mahen A. Biomedical waste disposal: A systems analysis. Med J Armed Forces India. 2013 Oct;69(4):351-6. doi: 10.1016/j.mjafi.2012.09.007. Epub 2012 Nov 30. PubMed PMID: 24600142; PubMed Central PMCID: PMC3862903.[PubMed]
10. Hossain MS, Santhanam A, Nik Norulaini NA, Omar AK. Clinical solid waste management practices and its impact on human health and environment--A review. Waste Manag. 2011 Apr;31(4):754-66. doi: 10.1016/j.wasman.2010.11.008. Epub 2010 Dec 24. Review. PubMed PMID: 21186116.[PubMed]
11. Manar MK, Sahu KK, Singh SK. Hospital waste management in nonteaching hospitals of lucknow city, India. J Family Med Prim Care. 2014 Oct-Dec;3(4):393-5. doi: 10.4103/2249-4863.148122. PubMed PMID: 25657950; PubMed Central PMCID: PMC4311349.[PubMed]
12. Pandit NB, Mehta HK, Kartha GP, Choudhary SK. Management of bio-medical waste: awareness and practices in a district of Gujarat. Indian J Public Health. 2005 Oct-Dec;49(4):245-7. PubMed PMID: 16479910.[PubMed].
13. Sheth JK, Jhala VN. Biomedical Waste Management: Some food for Thought. NHL Journal of Medical Sciences, 2014;3(1):5-7.