

THE BIO-MEDICAL WASTE RULES, 2016**◆ LEARNING OBJECTIVES ◆**

After completing this chapter, reader should be able to:

- ❖ Learn about the Biomedical Waste Rule, 2016.
- ❖ Learn about the Disposal System of Biomedical Waste.

17.1 INTRODUCTION

G.S.R. 343(E): (Whereas the Bio-Medical Waste (Management and Handling) Rules, 1998 was published vide notification number S.O. 630 (E) dated the 20th July, 1998, by the Government of India in the erstwhile Ministry of Environment and Forests, provided a regulatory framework for management of bio-medical waste generated in the country;

(And whereas, to implement these rules more effectively and to improve the collection, segregation, processing, treatment and disposal of these bio-medical wastes in an environmentally sound management thereby, reducing the bio- medical waste generation and its impact on the environment, the Central Government reviewed the existing rules;)

And whereas, in exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government published the draft rules in the Gazette vide number G.S.R. 450 (E), dated the 3rd June, 2015 inviting objections or suggestions from the public within sixty days from the date on which copies of the Gazette containing the said notification were made available to the public;

And whereas, the copies of the Gazette containing the said draft rules were made available to the public on the 3rd June, 2015; And whereas, the objections or comments received within the specified period from the public in respect of the said draft rules have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998, except as respects things done or omitted to be done before such suppression, the Central Government hereby makes the following rules, namely:

Short Title and Commencement:

- (1) These rules may be called the Bio-Medical Waste Management Rules, 2016.
- (2) They shall come into force on the date of their publication in the Official Gazette.

Applications:

- (1) These rules shall 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.
- (2) These rules shall not apply to.
 - (a) Radioactive wastes as covered under the provisions of the Atomic Energy Act, 1962 (33 of 1962) and the 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 the Act;
 - (d) The lead acid batteries covered under the Batteries (Management and Handling) Rules, 2001 made under the Act;
 - (e) Hazardous wastes covered under the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 made under the Act;
 - (f) Waste covered under the e-Waste (Management and Handling) Rules, 2011 made under the Act; and
 - (g) Hazardous micro organisms, genetically engineered micro organisms and cells covered under the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Micro organisms or Cells Rules, 1989 made under the Act.

Definitions:

In these rules, unless the context otherwise requires,

- (a) "**Act**" means the Environment (Protection) Act, 1986 (29 of 1986);
- (b) "**animal house**" means a place where animals are reared or kept for the purpose of experiments or testing;
- (c) "**authorisation**" means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with these rules and guidelines issued by the Central Government or Central Pollution Control Board as the case may be;
- (d) "**authorised person**" means an occupier or operator authorised by the prescribed authority to generate, collect, receive, store, transport, treat, process, dispose or handle bio-medical waste in accordance with these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be;

- (e) "**biological**" means any preparation made from organisms or micro-organisms or product of metabolism and biochemical reactions intended for use in the diagnosis, immunisation or the treatment of human beings or animals or in research activities pertaining thereto;
- (f) "**bio-medical waste**" means any waste, which is 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, including the categories mentioned in Schedule I appended to these rules;
- (g) "**bio-medical waste treatment and disposal facility**" means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal is carried out, and includes common bio-medical waste treatment facilities;
- (h) "**Form**" means the Form appended to these rules;
- (i) "**handling**" in relation to bio-medical waste includes the generation, sorting, segregation, collection, use, storage, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale, transfer, disposal of such waste;
- (j) "**health care facility**" means a place where diagnosis, treatment or immunisation of human beings or animals is provided irrespective of type and size of health treatment system) and research activity pertaining thereto;
- (k) "**major accident**" means accident occurring while handling of bio-medical waste having potential to affect large masses of public and includes toppling of the truck carrying bio-medical waste, accidental release of bio-medical waste in any water body but exclude accidents like needle prick injuries, mercury spills;
- (l) "**management**" includes all steps required to ensure that bio- medical waste is managed in such a manner as to protect health and environment against any adverse effects due to handling of such waste; (m) "occupier" means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called;
- (n) "**operator of a common bio-medical waste treatment facility**" means a person who owns or controls a Common Bio-medical Waste Treatment Facility (CBMWTF) for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste;
- (o) "**prescribed authority**" means the State Pollution Control Board in respect of a State and Pollution Control Committees in respect of an Union territory;
- (p) "**schedule**" means the schedule appended to these rules.

17.2 DUTIES OF THE OCCUPIER

It shall be the duty of every occupier to:

- (a) take all necessary steps to ensure that bio-medical waste is handled without any adverse effect to human health and the environment and in accordance with these rules;
- (b) make a provision within the premises for a safe, ventilated and secured location for storage of segregated biomedical waste in colored bags or containers in the manner as specified in Schedule I, to ensure that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals and the bio-medical waste from such place or premises shall be directly transported in the manner as prescribed in these rules to the common bio-medical waste treatment facility or for the appropriate treatment and disposal, as the case may be, in the manner as prescribed in Schedule I;
- (c) pre-treat the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal;
- (d) phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of these rules;
- (e) dispose of solid waste other than bio-medical waste in accordance with the provisions of respective waste management rules made under the relevant laws and amended from time to time;
- (f) not to give treated bio-medical waste with municipal solid waste;
- (g) 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 and the details of training programmes conducted, number of personnel trained and number of personnel not undergone any training shall be provided in the Annual Report;
- (h) immunise all its health care workers and others, involved in handling of bio-medical waste for protection against diseases including Hepatitis B and Tetanus that are likely to be transmitted by handling of bio-medical waste, in the manner as prescribed in the National Immunisation Policy or the guidelines of the Ministry of Health and Family Welfare issued from time to time;
- (i) establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place for any purpose within one year from the date of the notification of these rules;
- (j) ensure segregation of liquid chemical waste at source and ensure pre-treatment or neutralisation prior to mixing with other effluent generated from health care facilities;
- (k) ensure treatment and disposal of liquid waste in accordance with the Water (Prevention and Control of Pollution) Act, 1974 (6 of 1974); 5

- (l) ensure occupational safety of all its health care workers and others involved in handling of biomedical waste by providing appropriate and adequate personal protective equipments;
- (m) conduct health check up at the time of induction and at least once in a year for all its health care workers and others involved in handling of bio- medical waste and maintain the records for the same;
- (n) maintain and update on day to day basis the bio-medical waste management register and display the monthly record on its website according to the bio-medical waste generated in terms of category and colour coding as specified in Schedule I;
- (o) report major accidents including accidents caused by fire hazards, blasts during handling of biomedical waste and the remedial action taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report;
- (p) 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;
- (q) inform the prescribed authority immediately in case the operator of a facility does not collect the bio-medical waste within the intended time or as per the agreed time;
- (r) 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 to the prescribed authority and the healthcare establishments having less than thirty beds shall designate a qualified person to review and monitor the activities relating to bio-medical waste management within that establishment and submit the annual report;
- (s) maintain all record for operation of incineration, hydro or autoclaving etc., for a period of five years;
- (t) existing incinerators to achieve the standards for treatment and disposal of bio-medical waste as specified in Schedule II for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

Duties of the operator of a common bio-medical waste treatment and disposal facility:

It shall be the duty of every operator to:

- (a) take all necessary steps to ensure that the bio-medical waste collected from the occupier is transported, handled, stored, treated and disposed of, without any adverse effect to the human health and the environment, in accordance with these rules and guidelines issued by the Central Government or, as the case may be, the central pollution control board from time to time;
- (b) ensure timely collection of bio-medical waste from the occupier as prescribed under these rules;

wastes such as plastics and glass shall be given to such recyclers having valid authorisation or registration from the respective prescribed authority.

- (10) The Occupier or Operator of a common bio-medical waste treatment facility shall maintain a record of recyclable wastes referred to in sub-rule (9) which are auctioned or sold and the same shall be submitted to the prescribed authority as part of its annual report. The record shall be open for inspection by the prescribed authorities.
- (11) The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations.

Segregation, Packaging, Transportation and Storage:

- (1) No untreated bio-medical waste shall be mixed with other wastes.
- (2) The bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with Schedule I prior to its storage, transportation, treatment and disposal.
- (3) The containers or bags referred to in sub-rule (2) shall be labelled as specified in Schedule IV.
- (4) Bar code and global positioning system shall be added by the Occupier and common bio-medical waste treatment facility in one year time.
- (5) The operator of common bio-medical waste treatment facility shall transport the bio-medical waste from the premises of an occupier to any off-site bio-medical waste treatment facility only in the vehicles having label as provided in part 'A' of the Schedule IV along with necessary information as specified in part 'B' of the Schedule IV.
- (6) The vehicles used for transportation of bio-medical waste shall comply with the conditions if any stipulated by the State Pollution Control Board or Pollution Control Committee in addition to the requirement contained in the Motor Vehicles Act, 1988 (59 of 1988), if any or the rules made there under for transportation of such infectious waste.
- (7) Untreated human anatomical waste, animal anatomical waste, soiled waste and, biotechnology waste shall not be stored beyond a period of forty –eight hours: Provided that in case for any reason it becomes necessary to store such waste beyond such a period, the occupier shall take appropriate measures to ensure that the waste does not adversely affect human health and the environment and inform the prescribed authority along with the reasons for doing so.
- (8) Microbiology waste and all other clinical laboratory waste shall be pre-treated by sterilisation to Log 6 or disinfection to Log 4, as per the World Health Organisation guidelines before packing and sending to the common bio-medical waste treatment facility.