MODULE 02

Regulatory Aspects

The presentation will focus on:

i) Legal mandate for managing bio-medical waste
ii) Salient features of BMW Management Rules, 2016
iii) Duties of different stakeholders
iv) Penal provisions and actions to be taken in the case of non-compliance with the rules

This session will unfold legal mandates, various conventions aligned to the BMWM, major penal provisions and the consequences arising due to the non-compliance. It will also discuss the application of the rules and duties of various stakeholders.

2.1 Legal Mandate

This session will also introduce the rules and regulations which cover BMW at the national and international level; the legal mandates and the global Convention and its applicability in India. Further, the session will introduce the participants to the various provisions of the BMW Management Rules, 2016, along with its salient features and the roles and responsibilities assigned to various stakeholders. The participants will also get to learn about the compliance and enforcement framework, penal provisions and the actions to be initiated in the case of non-compliance.

In India, the BMW Management Rules 2016 is the key legislation that provides guidelines on the management and reporting of all types of BMW generated in healthcare facilities. This legislation mandates segregation, transportation, treatment and safe disposal.

The BMW Management Rules, 2016, along with other waste management rules, have been notified under The Environmental (Protection) Act, 1986, which is also known as the Umbrella Act.

2.1.1 International Legal Framework On Biomedical Waste Management

India is a signatory to a number of global conventions mandating proper management of biomedical waste. This section will discuss some of the vital International agreements and Conventions that are relevant to bio-medical waste management.

Stockholm Convention

The Stockholm Convention is an international environmental treaty aiming to eliminate or restrict the production and use of persistent organic pollutants (POPs). Dioxin and furans are two such POPs that are generated when plastics and other materials containing chlorine are burned at high temperatures without proper control measures. They are listed in the very first list of the Convention's 'dirty dozen'. Dioxins and furans can be released when healthcare facilities or waste management facilities burn plastics components of the bio-medical waste in open-air or in incinerators without following proper temperature and emission standards.

Basel Convention

The Basel Convention is meant to control the transboundary movement of hazardous waste and the disposal of waste at a point nearest to its generation. It is always advisable to segregate infectious waste at the point of its generation and ensure its treatment and disposal at the nearest site possible.

Minamata Convention

The Minamata Convention is a treaty on mercury. Signed by more than 148 countries, the main objective of this treaty is to ensure the protection of human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. India has signed the treaty on October 2014, following which the country has to comply with the various obligations of this treaty. In order to comply with this treaty, India had to phase out mercury-based products, including thermometers and sphygmomanometers from healthcare facilities by 2020. Further provisions need to be made to phase down the usage of dental amalgam which contains mercury and ensure safe and environmentally sound disposal of mercury-bearing waste generated from hospitals.

2.1.2 Other applicable rules and regulations to the HCFs

Apart from BMW, HCFs generate other kinds of wastes as well, such as municipal solid waste, hazardous waste, lead acid batteries, outdated electrical and electronic waste, plastic waste, radioactive waste, liquid waste from laundry and labs, emission from boilers, DG sets, etc.

To deal with these wastes and chemicals, healthcare facilities are covered under the ambit of following acts, rules and notifications.

1. Water (Prevention and Control of Pollution) Act, 1974
2. Water (Prevention and Control of Pollution) Cess Act, 1977
3. Air (Prevention and Control of Pollution) Act, 1981

4. Environment (Protection) Act, 1986
5. The Public Liability Insurance Act, 1991
6. The National Environmental Tribunal Act, 1995
7. The National Environment Appellate Authority Act, 1997
8. The Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
9. Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016
10. The Coastal Regulation Zone Notification, 1991
11. The Chemical Accidents (Emergency, Planning, Preparedness, and Response) Rules, 1996
12. The Bio-medical Waste Management Rules, 2016
13. Recycled Plastics Manufacture and Usage Rules, 1999
14. Solid Waste Management Rules, 2016
15. The Noise Pollution (Regulation and Control) (Amendment) Rules, 2000
16. Batteries (Management and Handling) Rules, 2001.
17. EIA Notification, 2006
18. E-waste (Management) Rules, 2016
19. Radioactive wastes as covered under the provisions of the Atomic Energy Act, 1962
20. 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

2.2 Major provisions of BMWM Rules, 2016

Highlights of the presentation

a) Definitions: Healthcare facility, occupier, operator of a CBWTF and management
b) Application of the rules
c) Authorisation
d) Maintenance of records, annual reports and accident reporting

2.2.1 Definitions

a) **Healthcare facility** refers to a place where diagnosis, treatment or immunisation of human beings or animals is provided irrespective of the type and size of the health treatment system, and research activity pertaining thereto.

b) **Occupier** refers to a person having administrative control over the institution and the premises generating biomedical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, healthcare facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called.

c) **Operator of a common biomedical waste treatment facility** refers to a person who owns or controls a CBMWTF for the collection, reception, storage, transport, treatment, disposal or any other form of handling of biomedical waste.

d) **Management** includes all steps required to ensure that bio-medical waste is managed in such a manner as to protect health and the environment against any adverse effects due to handling of such waste.

e) **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 (CPCB).

f) **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

2.2.2 Application of the Rules

These rules shall apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio-medical waste in any form and shall not apply to:

- radioactive wastes,
- wastes covered under the SWM Rules, 2016,
- lead acid batteries,
- hazardous wastes,
- E-waste,
- hazardous microorganisms

2.2.3 Authorisation

Authorisation refers to permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of biomedical waste in accordance with rules and guidelines issued by the Central Government or the CPCB as the case may be.

At present, for healthcare facilities;

- One-time authorisation for non-bedded HCFs is required
- For bedded HCFs, the authorisation is synchronised with the validity of consent

2.2.4 Maintenance of records

According to Section 14 of the 2016 Rules, it is mandatory for every authorised unit to maintain records on the generation, collection, reception, storage, transportation, treatment, disposal and any other form of handling of bio-medical waste for a period of five years.

- Records must be maintained in a waste-disposal register, under the heads of 'category of waste' and 'the amount of waste generated per day' in each category
- Record keeping has to be done ward-wise and the gross daily total tallied
- The record register must be checked and signed by the officer in charge
- The record must be made available to Pollution Control Board (PCB) officials as and when needed

2.2.5 Annual report

Every occupier and operator must submit an annual report to the prescribed authority in Form IV under Section 13 of the 2016 Rules on or before June 30 of every year. This report must include information about the categories and quantities of bio-medical wastes handled during the preceding year.

The Annual Reports shall also be available online on the websites of Occupiers, State Pollution Control Boards (SPCB) and CPCB.

2.2.6 Accident reporting

When an accident occurs at any institution or facility or any other site during handling or transportation of bio-medical waste, the authorised person shall immediately intimate the prescribed authority and forward a report within twenty-four hours in writing about the remedial steps taken in Form I. Accident reports for both major and minor accidents should be submitted to respective SPCBs/ Pollution Control Committees (PCCs), along with the number of persons affected, remedial actions taken and the number of fatalities, annual report (for the preceding calendar year).

As per the Bio-medical Waste Management Rules, 2016, the accidents are classified into two categories; major and minor:

As per the guidelines on bio-medical management rules, 2016 by the CPCB[3]:

Major accidents include but not limited to following

- Toppling of the truck carrying bio-medical waste
- Accidental release of bio-medical waste in any water body
- Fire hazards
- Blasts
- Flooding or erosion of the deep burial pit etc

Minor accidents include but not limited to the following

- Needle stick injuries (NSI)
- Splash exposure or
- Spillage of mercury/chemicals etc

All healthcare facilities must report every NSI taking place within their premises. A problem well defined is half resolved. The reporting of NSI will help in identifying the problems, viz., the source and frequency of occurrence of such incidents. Accordingly, preventive measures and post exposure prophylaxis (PEP) can be administered as and when the demand arises. Also, more focused training on the NSI can be planned to prevent the occurrence of such mishaps.

2.3 Salient features

Some of the salient features of these amended BMWM rules are as follows;

a) Bio-medical waste generators, including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories, blood banks, healthcare, and clinical establishments had to phase out chlorinated plastic bags (excluding blood bags) and gloves by March 27, 2019.

b) All healthcare facilities shall make available the annual report on its website within a period of two years from the date of publication of the Bio-Medical Waste Management (Amendment) Rules, 2018.

c) Operators of common bio-medical waste treatment and disposal facilities had to establish bar coding and global positioning system for handling of bio-medical waste in accordance with guidelines issued by the Central Pollution Control Board by March 27, 2019.

d) The SPCBs/PCCs have to compile, review and analyse the information received and send this information to the CPCB in a new Form (Form IV A), which seeks detailed information regarding district-wise bio-medical waste generation, information on healthcare facilities having captive treatment facilities, information on common bio-medical waste treatment and disposal facilities.

e) Every occupier, i.e. a person having administrative control over the institution and the premises generating biomedical waste shall 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 Organization (WHO) or guidelines on safe management of wastes from healthcare activities and the WHO Blue Book 2014 and then sent to the CBWTF for final disposal.

2.4 Duties of HCFs

- HCF shall make a provision within the premises for a safe, ventilated and secured location for the storage of segregated biomedical wastes
- 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 WHO or National AIDs Control Organisation (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal.

3 Guidelines for Management of Healthcare Waste as per Biomedical Waste Management Rules, 2016 prepared by CPCB and Ministry of health and family welfare

- Phase-out use of chlorinated plastic bags and gloves within two years from the date of notification of these rules
- Provide training to all its healthcare workers and others involved in the handling of bio-medical waste at the time of induction and thereafter at least once every year
- Immunise all its healthcare 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,
- Establish a Bar-Code System for bags or containers containing bio-medical waste to be sent out of the premises
- Report major accidents, including accidents caused by fire hazards and blasts during handling of bio-medical waste and the remedial action taken to SPCB
- Existing incinerators shall achieve the standards for retention time in the secondary chamber and Dioxin and Furans within two years from the date of this notification
- To ensure that the committee formed for monitoring and review of BMW management is functioning properly.

2.5 Duties of CBWTF operators

- All the duties of HCFs
- They should ensure timely collection of BMW from the HCF and assist them in conducting training programmes

2.6 Penal provisions

Any HCFs or CBWTF failing to comply with or contravening any of the provisions of the Environment Protection Act, 1986, or the rules made or orders or directions issued thereunder, shall, in respect of each such failure or contravention, be punishable as stated under Section 15 of the Act with:

- Imprisonment for a term of up to five years
- A fine that may extend to Rs 1 lakh
- Both, the imprisonment, and fine
- In case the failure or contravention continues, an additional fine may extend to Rs 5,000 per day during which such failure or contravention continues after the conviction for the first such failure or contravention
- If the failure or contravention continues beyond a period of one year after the date of conviction, the offender shall be punishable with imprisonment for a term that may extend to seven years