



## **LEGAL FRAMEWORK FOR HEALTH CARE WASTE MANAGEMENT : INDIAN EXPERIENCE**

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### **ABSTRACT :**

Health Care assumes prime place on the welfare and developmental agenda of all civilized nations as it is one of the fundamental requirement for the survival and development of the human race. As a consequence there has been continuous research in the area of health services which resulted in the tremendous advancements in the health care system over the years. The modern world witnesses establishment of a variety of health care institutions which includes hospitals, nursing homes, blood banks, pathological laboratories etc to address the health concerns of the world populace. These institutions are regarded as sacred and public beneficial as they offer solutions to the health problems of the people by providing immunization, diagnosis and treatment facilities. However, it is ironic that these health care settings, which restore and maintain community health are also threatening their well-being through creation of hazardous health care waste or hospital waste which poses risk for spreading certain infectious diseases and affecting human wealth and well being.

At present, management of hospital waste, has become a cause of concern at global and national levels. With advancement of medical science most of the hospitals/nursing homes are now equipped with latest instruments for diagnosis and treatment of various diseases. One of the most important aspect associated with hospitals is the safe management of the wastes; generated from these establishments, which contains human anatomical wastes, blood, body fluid, disposable syringe, used bandages, surgical gloves, Blood bags, intravenous tubes etc. It is a well established fact that there are many adverse and harmful effects to the environment including human beings which are caused by the "Hospital waste" generated during the patient care.

As Bio-medical waste may pose numerous health and safety hazards to patients, health care providers and to the community at large, the Central government had come out with a Bio-Medical Waste Management Rules as early as 1998 following a Supreme Court ruling in this regard. This paper, therefore, makes an attempt to critically





evaluate the Bio-Medical Waste (Management and Handlings) Rules notified by the Government of India on 27th July 98; under the provisions of Environment Act 1986.

**Key Notes:** Bio-Medical Waste, Environment, health hazards

## **INTRODUCTION:**

Hospital waste or health care waste is generated by the health care institutions which includes hospitals, nursing homes, blood banks, pathological laboratories etc during the diagnosis, treatment, or immunization of human beings or animals or in research activities in these fields or in the production or testing of biological matter. The development and innovations in the field of medi-services and research are no doubt boon to the mankind but it has dark side as well, which, inter alia, includes the generation of infectious and hazardous medical care wastei. With advancement of medical science most of the hospitals/nursing homes are now equipped with latest instruments for diagnosis and treatment of various diseases. The modern hospitals and health care institutions including research centers use a wide variety of drugs including antibiotics, cytotoxics, corrosive chemicals, radioactive substances, which ultimately become part of hospital wasteii.

At present, management of hospital waste, has become a cause of concern at global and national levels. One of the most important aspect associated with hospitals is the safe management of the wastes; generated from these establishments, which contains human anatomical wastes, blood, body fluid, disposable syringe, used bandages, surgical gloves, Blood bags, intravenous tubes etc. It is a well established fact that there are many adverse and harmful effects to the environment including human beings which are caused by the “Hospital waste” generated during the patient care.





The wastes generated from health care units are also classified as infectious and non-infectious. The infectious health care wastes are termed as 'bio-medical wastes' and are considered to be potentially hazardous in nature. Non-infectious waste is broadly classified as Kitchen waste and Office wastes. It is similar to household waste. In fact only 15% of hospital waste i.e. "Biomedical waste" is hazardous, not the complete. But when hazardous waste is not segregated at the source of generation and mixed with nonhazardous waste, then 100% waste becomes hazardous.

World Health Organisation (WHO, 2000) reported that from the total waste generated by healthcare activities, 80% is general waste and the balance is considered as hazardous, as it tends to be infectious, toxic or radioactive. On an average, hospital generates 1.5-2 kg waste per bed/ day. Out of this, 80% of the waste is general waste/ garbage which is just like the domestic waste and can be disposed off in municipal bins. 10-15% is the infectious waste which includes dressing material, sharps/ disposables etc. and it requires the attention of the health care professionals for its proper management<sup>iii</sup>.

### **Management of Health Care Waste:**

According to WHO (2000) the incorrect management of healthcare waste can have direct impacts on the community, individuals working in health care facilities and natural environment. The Hospitals and other health-care institutions dump their wastes, containing human tissues, blood soaked items, excreta, drugs, swabs, disposable syringes and needles, bandages, etc., in the municipal garbage dumps. These dumping sites are regularly visited by the 'Rag-pickers' who scan and sort out the plastics, disposable syringes, etc., so that they can be resold at various places for re-cycling. The problems of the waste disposal in the hospitals and other health-care institutions have become issues of





increasing concern<sup>iv</sup>. The centers of disease control of some of the developed countries and in particular, the United States of America have given estimates that the bio-medical waste may cause AIDS in 1 out of 250 persons and Hepatitis-B in between 6 and 30 percent of the total population.

At present, management of hospital waste, has become a cause of concern at global and national levels. Most countries of the world, especially the developing nations, are facing the grim situation arising out of environmental pollution due to pathological waste arising from increasing populations and the consequent rapid growth in the number of health care centers. The World Health Organization has classified bio-medical waste into 9 categories and suggested means to regulate the generation, handling and disposal of this hazardous waste. Most of the countries enacted rules and regulations for the effective handling and management of the Health Care Waste.

### **Indian Scenario:**

As Bio-medical waste may pose numerous health and safety hazards to patients, health care providers and to the community at large, the Central government had come out with a Bio-Medical Waste Management Rules as early as 1998 following a Supreme Court ruling in this regard in *B.L. Wadhwa v. Union of India*<sup>v</sup>. The apex court in the above mentioned case while keeping in view the appalling conditions arising due to bio-medical waste disposal gave series of directions. The most important amongst them are:

- (a) All hospitals with 50 bed and above should install incinerators or Any other effective alternate method under their own administrative control.





- (b) The incinerator or alternative methods should be fitted with necessary pollution control mechanism, approved and confirming to the standards laid down by the Central Pollution Control Board.
- (c) The Central Pollution Control Board and the State Pollution Control Boards should regularly send its inspection teams in different areas to ascertain that the collection transportation and disposal of garbage/ wastes is carried out satisfactorily.

### **Bio-Medical Waste (Management and Handlings) Rules:**

Pursuant to the directives of the Supreme Court, the Government of India notified the Bio-Medical Waste (Management and Handlings) Rules on 27th July 98; under the provisions of Environment Act 1986. These rules have been framed to regulate the disposal of various categories of Bio-Medical Waste as envisaged therein; so as to ensure the safety of the staff, patients, public and the environment. The Bio-Medical Waste (Management & Handling) Rules 1998, hereinafter referred as BMW Rules, finally came into operation with effect from 20<sup>th</sup> July, 1998 vide S.O. 630 (E) II 3(ii), Gazette of India, Extra, Sl.No. 460 in exercise of the powers conferred by Sections 6, 8 and 25 of the Environment (Protection) Act, 1986. These Rules were further amended in 2000 and 2003. Bio-medical Rules is the first of its kind of national law in whole South- East Asian Region in relation to bio-medical waste management. The Rules, besides identifying the various waste categories, also recommend treatment and disposal methods and the standards to be laid down for the same. They specifically mention the duty of occupier, categories of bio-medical wastes and various standards for treatment and disposal of biomedical wastes.

The following are the main features of the rules:





### **Definition of Bio-Medical Waste:**

The Rules define bio-medical waste as “any waste which is generated during diagnosis, treatment or immunization of human beings or animals, or in research activities or in the production or testing of biological and including categories mentioned in schedule-I of the rules”<sup>vi</sup>. The Rules use the expression ‘Bio-medical waste’ rather than hospital waste or medical waste and intends to take care of the waste generated from medicare service/treatment centers/laboratories.

Schedule 1 of the Rules provides ten categories of bio-medical waste., which are listed below:

#### Category No. 1 **Human Anatomical Waste**

(human tissues, organs, body parts)

#### Category No. 2 **Animal Waste**

(animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals, colleges, discharge from hospitals, animal houses)

#### Category No 3 **Microbiology & Biotechnology Waste**

(wastes from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal culture used in research and infectious agents from research and industrial laboratories wastes from production of biological, toxins, dishes and devices used for transfer of cultures)





Category No 4 **Waste sharps**

(needles, syringes, scalpels, blades, glass, etc. that may cause disinfection, puncture and cuts. This includes both used and unused sharps)

Category No 5 **Discarded Medicines and Cytotoxic drugs**

(wastes comprising of outdated, contaminated and Discarded medicines)

Category No 6 **Solid Waste**

(Items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)

Category No. 7 **Solid Waste**

(wastes generated from disposable items other than the waste sharps such as tubings, catheters, intravenous sets etc).

Category No. 8 **Liquid Waste**

(waste generated from laboratory and washing, cleaning, housekeeping and disinfecting activities)

Category No. 9 **Incineration Ash**

(ash from incineration of any bio-medical waste)

Category No. 10 **Chemical Waste**





(chemicals used in production of biological, chemicals used in disinfection, as insecticides,

### ***Application of the Rules:***

These Rules are applicable to all persons who “generate, collect, receive, store, transplant, dispose or handle bio-medical waste in any form”<sup>vii</sup>. All persons will include any individual, industry, institution caring medical aid and also imparting medical education, training and conducting research. The rules also enumerate institutions generating bio-medical waste, which include hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories and blood banks<sup>viii</sup>.

### ***Occupier & his Responsibilities:***

The waste generator under the BMW Rules includes any person (Occupier) who has control over the Medicare institution and/or its premises. It shall be the duty of every occupier of an institution generating biomedical waste which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, 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<sup>ix</sup>.

The occupier is also imposed with three more responsibilities. First, he shall maintain all records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of biomedical waste in accordance with these rules and any guidelines issued. These records shall be subject to inspection and verification by the prescribed authority at any time.





Secondly, the occupier/authorized person is required to report on the prescribed format about any accident which occurs while handling or transportation of any bio-medical waste.

Thirdly, the occupier and operator is require to submit every year an annual report to the prescribed authority in the prescribed format about the information relating to the categories and quantities of bio-medical wastes handled during the preceding year. The prescribed authority in turn is required to send the information to the Central Pollution Control Board<sup>x</sup>.

### ***Segregation, Packaging, Transportation & Storage :***

Rule 6 deals with segregation, packaging, transportation and storage of bio-medical waste. For proper treatment of these biomedical wastes, it is necessary that these wastes first be isolated from other wastes for their special treatment and disposal. The segregation process requires the bio-medical wastes be put in separate container/bags. Schedule II to the BMW Rules provides colour coding for the container/bags—yellow, red, blue or while and black for different categories of the bio-medical wastes. This technique is provided to identify the categories of wastes for their special treatment and disposal. Schedule III demonstrates the way in which the labels have to be marked on the container/bag. The BMW Rules also mandates that Biomedical waste shall not be mixed with other waste.

As regards transportation of the bio-medical waste is concerned, Rule 6 (3) and 6 (4) impose two conditions: One, the container, over and above the colour coding, must also provide certain basic information provided in Schedule IV. Two, the waste shall be transported only in





such vehicle as may be authorized by the competent authority prescribed by the government.

Rule 6 (5) takes care of storing of the medical waste. It prohibits storages of the waste beyond a period of 48 hours unless the prescribed authority had given permission and the authorized person takes care that such overtime storage does not affect human health and environment.

### ***Treatment and Disposal:***

Schedule I read with Rules provides large number of modes through which a particular bio-medical waste shall be treated or disposed of. These include incineration, autoclaving, microwaving, mutilation or shredding, chemical treatment or disinfection, landfill or deep burial<sup>xi</sup>, and discharge in drains.

Moreover, the BMW Rules make it mandatory to comply with the standards prescribed in Schedule V for treatment and disposal. This schedule provides in great detail standards for each method of disposals prescribed under Schedule I. All types of incinerators have to follow two types of standards: one, the operating standards; and two, the emission standards. In case of autoclaving different temperatures, pressures, residence and times are prescribed for both a gravity flow and a vacuum autoclaves. It also prescribed certain permissible limits for effluents generated from hospitals. The standards of microwaving and deep burial simply provide for do's and dont's.

### ***Common Biomedical Waste Treatment Facilities:***





Without prejudice to Rule 5 of these rules, the Municipal Corporations, Municipal Boards or Urban Local Bodies, as the case may be, shall be responsible for providing suitable common disposal/incineration sites for the bio-medical wastes generated in the area under their jurisdiction and in areas outside the jurisdiction of any municipal body, it shall be the responsibility of the occupier generating bio-medical waste/operator of a bio-medical waste treatment facility to arrange for suitable sites individually or in association, so as to comply with the provisions of these rules<sup>xii</sup>.

### **Authorities:**

The BMW Rules provide for two types of authorities i.e., a) **Prescribed Authority** and b) **Advisory Committee**. The Prescribed authority for enforcement of the provisions of these rules shall be the State Pollution Control Boards in respect of States and Pollution Control Committees in respect of the Union Territories and all pending cases with a prescribed authority appointed earlier shall stand transferred to the concerned State Pollution Control Board, or as the case may be, the Pollution Control Committees<sup>xiii</sup>. The prescribed authority shall function under the supervision and control of the respective Government of the State or Union Territory. It has the power to grant or renew authorization for handling biomedical waste on an application made to it by an occupier/operator.

The second authority is the Advisory Committee. It shall be constituted by every State Government /Union Territory to advise the government and prescribed authority about matters related to the implementation of the BMW Rules. The committee will include experts in the field of medical and health, animal husbandry and veterinary





sciences, environment management, municipal administration and any other related department or organization including nongovernmental organizations<sup>xiv</sup>.

**Authorization:**

Every occupier of an institution generating, collecting, receiving, storing, transporting, treating, disposing and/or handling biomedical waste in any other manner shall make an application in form I to the prescribed authority for the authorization. However, the such occupier of clinics, dispensaries, pathological laboratories, blood banks providing treatment/services to less than 1000 (one thousand) patients per month have been exempted from obtaining such authorization<sup>xv</sup>.

At the initial stage, a provisional authorization for one year will be granted and thereafter, on satisfactory facility performance, authorization for a period of 3 years, including the trial period of one year, shall be granted. Thereafter, an application shall be made by the occupier/operator for renewal. All such subsequent authorization shall be for a period of three years. Every application for authorization shall be disposed of by the prescribed authority within ninety days from the date of receipt of the application. The prescribed authority is given power to cancel or suspend authorization of the occupier who fails to comply with the provisions of Environmental Protection Act and the BMW Rules. This power is subject to two conditions: one, the occupier shall be given a reasonable opportunity of hearing, two, reasons for such action shall be recorded in writing. This will satisfy the principles of natural justice.

**Appeal:**

Any person aggrieved by an order made by the prescribed authority under these rules may, within thirty days from the date on which the order is communicated to him, prefer an appeal in Form V to such





authority as the Government of State or Union territory may think fit to constitute. Provided that the authority may entertain the appeals after the expiry of the said period of thirty days, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time<sup>xvi</sup>.

### **CONCLUSION:**

The health care waste in general and bio-medical waste in particular generated today are many times more than what was it three decades ago posing increased danger to human life and environment. Further, its quality has also become more hazardous and infectious because of large number of pathogens of virulence significance which increases a chance of epidemic of infectious diseases. All India Institute of Medical Sciences expressed alarm over the multi dimensional ramifications of BMW including health hazard to patients, hospital staff as well as to the general public, causing death and even posing threat to the environment and ecological balance.

However, the enforcement and implementation of the Bio-medical Waste (Management & Handling) Rules, 1998 are not satisfactory to the extent it has been expected and contemplated. At present, most of the health care institutions in our country except for some associated hospitals of Medical Colleges and some District hospitals are not able to do the proper/ scientific disposal of the hospital waste. The main reason for this is not the financial crunch or lack of resource but, is the lack of awareness/ knowledge of scientific waste management practices. Proper awareness, orientation and commitment found to be lacking in understanding of issues involved in the management of biomedical waste and the waste management practices to be adopted to tackle the issues. Instead of serious and committed approach, many health care institutions and health personnel adopts a casual and nonchalant





approach towards tackling grave issue of safe management of health care waste. Most of the personnel associated with health care institute, particularly the auxiliary and household staff who are mainly connected with collection and segregation of bio-medical waste adopts a casual attitude and approach towards the management of bio medical waste due to lack of proper scientific training and lack of awareness about drastic effects of BMW on human health and environment.

It is the primary responsibility of the government to look after the implementation of the rules, regulations as well as the recommendations and directions given by the Supreme Court in this regard. Equally there is a duty upon all hospitals, nursing homes and Medicare centers to follow the legal norms on BMW. The implementation of BMW rules, therefore, assumes great significance and has become a prime concern for the concerned governmental authorities, healthcare institutions, environmentalists, human rights activists, NGOs and general public. If we want to protect our environment and health of the community we must sensitize ourselves to this important issue in the interest of community and take adequate steps to secure the effective enforcement of BMW rules.

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<sup>1</sup> AIR 1996 SC 2969

<sup>1</sup> Rule 3 (5) of BMW Rules, 1998.

<sup>1</sup> Rule 2 of BMW Rules, 1998.

<sup>1</sup> See Rule 3 (8).

<sup>1</sup> Rule 4 of the BMW Rules, 1998

<sup>1</sup> Vide Rules 10, 11 & 12

<sup>1</sup> This method of disposal through deep burial is permissible in towns with population of less than 5 lakhs and in rural areas.

<sup>1</sup> See Rule 14.

<sup>1</sup> See Rule 7

<sup>1</sup> See Rule 9

<sup>1</sup> Vide Rule 8

<sup>1</sup> Rule 13

