

A REVIEW OF LEGAL FRAMEWORK FOR BIOMEDICAL WASTE MANAGEMENT

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ABSTRACT

Biomedical waste is generated as the result of diagnosis and treatment of patients at hospitals, labs and other healthcare institutions. Although hospital is a place known to serve the patients but at the same time it produces garbage which has potential to affect the human and environment. If hospital waste is not managed properly, it can cause potential hazards to human beings by infecting various diseases such as AIDs, Cancer, liver infection, leptospira, etc. In order to safeguard human and environment Apex court of India has been playing a significant role. The court has issued various directions time to time to concern department regarding establishment of legal frame work and conduct regulation. The present study is an attempt to analyze various legal frameworks and analyze.

Keywords: *Biomedical waste management, BMW regulations, BMW management plans*

1. INTRODUCTION

Biomedical waste management refers to procedures and methods used to handle waste generated through diagnosis and treatment of patients. The waste is an active source of various types of infections. If it is not disposed off in an efficient manner, the infected wastes may infect the human, animal and environment. Some part of biomedical waste is toxic in nature. In order to protect human life and environment, the governments of Indian, Ministry of Environment, Forest and Climate have published regulation called Bio-medical waste management, Rules, 2016. The regulation enforced all healthcare and associated institutions to handle the biomedical waste in accordance to the regulation and failure of which is punishable offence (Praveen Mathur et al.,2012). This is not the first time that government has framed law to protect environment, there are various separate legislations for environment protection such as The Water (Prevention and Control of Pollution) Act, 1974, The Air (Prevention and Control of Pollution) Act, 1981, The Environment Protection Act, 1986, The National and Green Tribunal Act, 2010. The current study attempts to explore and analyze various legal frameworks to protect human and environment. As present regulation for biomedical waste and management is derived from previously existing legislations, it will be a fruitful exercise to explore and find the relevance of present regulation.

2. ANALYSIS OF VARIOUS LEGAL FRAMEWORKS

In order to manage the biomedical waste generated through healthcare practices across the country, the Government of India in 1998 notified rules known as the Biomedical Waste (Management and Handling) Rules, 1998 which was published in Gazette of India, 1998). These biomedical waste management rules revised time to time to handle the emergence of different types of waste generated in the hospital. Latest amendments were carried on March 28, 2016; the Government of India published the Biomedical Waste Management Rules, 2016 in placed of the Biomedical Waste (Management and Handling) Rules, 1998. Various amendments and additions were made in the new rule book. The Biomedical Waste Management Rules, 2016 redefines the new definitions of biomedical waste, occupier, operator and prescribed authority (Anurag Sharma et al., 2015).

Table1: Salient feature of various legal frameworks

<i>Year</i>	<i>legal framework</i>	<i>Salient feature</i>
1974	The Waste Act (Prevention and Control of Pollution), 1974.	<i>Enacted to provide power to state and centre bodies to protect and control water pollution.</i>
1989	Hazardous Wastes (Management and Handling) Rules, 1989	<i>Framed to protect environment from various hazardous waste generated from 44 different procedures. It enclosed monitory collection, reception, treatment, storage, transportation and disposal of hazardous wastes.</i>
1981	<i>The Air (Prevention and Control of Pollution) Act, 1981</i>	<i>Enacted to provide power to state and centre bodies to protect and control air pollution.</i>
1998	<i>Biomedical Waste (Management and Handling) Rules, 1998</i>	<i>Specially designed to legally bind hospitals for better management of biomedical waste.</i>
2010	<i>The National Green Tribunal Act, 2010.</i>	<i>Enacted with the aim to provide the effective and expeditious disposal of cases relating to environment protection.</i>
2016	<i>Biomedical Waste (Management and Handling) Rules, 2016.</i>	<i>Framed for better regulation for conduct of biomedical waste management in all healthcare intuitions</i>

2018	<i>Bio-Medical Waste Management (Amendment) Rules, 2018.</i>	<i>Incorporated various amendment and ICT enabled services for better handing of biomedical waste at hospitals and common treatment plants.</i>
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There are various other regulations and acts such as The Water (Prevention and Control of Pollution) Act, 1974, The Air (Prevention and Control of Pollution) Act, 1981, The Environment Protection Act, 1986, The National and Green Tribunal Act, 2010.

- **The Air (Prevention and Control of Pollution) Act, 1981**

The Air (Prevention and Control of Pollution) Act, 1981 is an act to protect air pollution in India⁶. The act is called as “air act” and is incorporated various provisions for the prevention, control and abatement of air pollution. The act was established in coordination of state and central boards. To standardize the quality of air, various quality standards were established. The air act empowers state government to control over industrial sector and establish provision of certification in regard to prevent air pollution. Any other institutions, including hospitals, come under the provision of the act. Open burring of hospital waste was also prohibited under this act.

- **The National Green Tribunal Act, 2010:**

The National Green Tribunal Act, 2010 (2-june-2010) has been enacted with the aim to provide the effective and speedy proceedings and disposal of cases relating to environment protection⁸. It also covers cases related to conservation of forests and other natural resources. The act has provision impose fine or giving relief or compensation for damages to persons and property related to environment. As per section 2((e), the term environment includes air, land, water and inter-relationship which exists among and between these three(air , land , water). The act covers wider range of activities in definition of “handling of waste”, which includes manufacture, processing, treatment, package, storage, transportation, collection disposal, etc. The act provides provision to setup tribunal and nomination of members. Chapter-III defines power, proceedings of the tribunal. Various kinds of penalties were also enacted in chapter –IV. Failure to compliance of the NGT shall be punishable with imprisonment and fine or both.

- **Biomedical Waste (Management and Handling) Rules, 1998**

Biomedical Waste (Management and Handling) Rules-1998 came into existence on 20 July 1998. The act was established to overcome the objections of Environment (Protection) Act, 1986. These rules were applicable to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio-medical waste in any form. The occupier having 1000 beds has to take authorization from the concerned authority⁷.

- **Biomedical Waste (Management and Handling) Rules, 2016.**

The Biomedical waste management rules, 2016 redefines the new definitions of biomedical waste, occupier, operator and prescribed authority⁹.

Biomedical waste: “It is defined as waste generated during the diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps”(BMW, rules 2016).

Occupier: “A person having administrative control or occupies premises of the health institution which is generating biomedical waste is termed as occupier. The health institution refers hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment” (BMW, rules 2016).

Prescribed authority: “The State Pollution Control Board in respect of a State and Pollution Control Committee in respect of a Union territory”, (BMW, rules 2016).

The Biomedical Waste Management Rules, 2016 are divided into schedules, rules and forms as follows:

Schedules: There are four schedules that describe waste categories, labels schemes, standards of dispose, prescribe duties (BMW, rules 2016).

Table2: Various schedules in Biomedical waste regulation

Sr. No.	Schedule No	Description
1	Schedule 1	The schedule defines waste categories/ type of bag/ container used/ type of waste treatment /disposal options.
2	Schedule 2	The schedule defines standards for treatment and disposal of bio-medical wastes.
3	Schedule 3	The schedule provides list of prescribed authorities and the corresponding duties.
4	Schedule 4	The schedule provides label list for bio-medical waste containers or bags and label for transporting bio-medical waste bags or containers

Forms: It provides the performa of various forms that can be used for filling application, complaint, and annual report (BMW, rules 2016). Following is the list of various forms.

Table3: Various schedules in Biomedical waste regulation

Sr. No.	Form Name	Detail
1.	Form – I	Deals with accident reporting
2.	Form – II	Application for authorization or renewal of authorization
3.	Form –III	Deals with Authorization
4.	Form – IV	Provides format for Annual Report
5.	Form –V	Application for filing appeal against order passed by the prescribed authority

The various rules and recommendations related to collection, segregation, transport and disposal are defined in detail in booklet of Biomedical Waste Management Rules, 2016. Every health institution, hospital dispensary are bound to follow the biomedical practices as per the rules and recommendations cited in the Biomedical Waste Management Rules, 2016.

Bio-Medical Waste Management (Amendment) Rules, 2018:

Recent amendments in Biomedical waste management and handling rules 2016 is referred as Bio-Medical Waste Management (Amendment) Rules, 2018. Following are few amendments:

- **Phase out chlorinated plastic bags:** As per rules, 2018, all hospitals, nursing, animal houses, and other places use for treatment and care of human or animal will have to phase out chlorinated plastic carry bags, blood bags, gloves etc by 27-03-2019.

- **Web based annual reports:** It will be mandatory to publish annual reports on official website of the institution within 2 years of enactment of the regulation.
- **Bar-coding and GPS system:** There will be strict provision for tracking system based on bar coding and global positioning system.
- **District-wise bio-medical waste generation reporting:** The state Pollution Control Boards/Pollution Control Committees will compile district wise detail information about amount of waste generated, facilities for treatment of waste at common bio-medical waste treatment plant in new Form (Form IV A).
- **Follow guideline as per WHO Blue Book 2014:** Every hospital will also follow WHO guidelines for on-site pre-treat the laboratory waste, microbiological waste, blood samples, and blood bags through disinfection or sterilization. Guidelines for rest of the procedures are same as mentioned in regulation 2016.

Table 4: Compassion among BMW regulation

<i>BMW(Amendment) Rules-1998</i>	<i>BMW(Amendment) Rules-2016</i>	<i>BMW(Amendment) Rules-2018</i>
<i>There was restriction on number of beds for getting authorization from concern authority. The occupiers more than 1000 beds required to get permission.</i>	<i>There is no such restriction, rather every healthcare hospital, laboratory, have to obtain authorization.</i>	<i>Applicable to all healthcare institutions.</i>
<i>Duties of operators are not specified</i>	<i>Duties of operators are discussed in detail</i>	<i>Duties are also specified in detail</i>
<i>Not particular format of annual report.</i>	<i>There is particular report format. Online reports on web site are not mandatory.</i>	<i>There is particular format of annual report and it is mandatory to put reports on website.</i>
<i>Bar coding was not mandatory. GPS system was not covered.</i>	<i>Bar coding is mandatory on every bag for transportation. GPS system not discussed</i>	<i>Bar coding along with GPs are mandatory on every bag for transportation.</i>

Table4 clearly shows that recent amendments in the biomedical waste management rules make use of information technology tools for transparency in the procedure. It includes bar coding and GPs system which helps to track the biomedical, waste transportation.

CONCLUSION:

The Government has framed rules and regulation from time to time in order to protect the human and environment. It is the responsibility of the employees, staff and occupiers to follow these rules and protect the environment. Recent amendments in the regulation for handling of biomedical waste make use of information technology and ensure transparent procedures in handling of the waste. The study concluded that there is significant improvement in regulations and these regulations meet the current requirements for better handling of biomedical waste.

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