CHAPTER-VII

LEGAL REGULATION OF BIO-MEDICAL WASTE MANAGEMENT IN INDIA
7.1 Introduction

Hospital is a place of almighty, a place to serve the patient. It is an institution, which is frequented by people from every walk of life in the society without any distinction between age, sex, race and religion. Although hospitals are known to serve the sick persons, at the same time they also produce filth and garbage, which has adverse effects on human body and environment.

If the waste generated by the hospital is not managed properly, it can cause potential health hazards to human beings by way of diseases like, AIDS, Hepatitis B, Cancer, laptospira, a brain infection and disorder in the liver. It has also far reaching ill-consequences on environment.

The issue of indiscriminate Bio-Medical Waste Management in India has attracted the attention of the Apex Court, which has from time to time issued various directives regarding management of Bio-Medical Waste. In this background of the directives of the Court, the Ministry of Environment and Forests, Government of India notified the Bio-Medical Waste (Management and


Handling) Rules on 27th July 1998 under the provisions of Environment (Protection) Act, 1986.³


The Bio-medical Waste (Management and Handling) Rules 1998 apply to all persons, who generate, collect, receive, transport, treat, dispose or handle biomedical waste in any form. Accordingly all the hospitals in the public and private sector are now bound to follow these Rules to evade legal action.⁴

'Bio-medical waste' under the Rules mean, any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biological,⁵ which includes:

(i) Human anatomical waste (human tissues, organs, body parts);

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

(iii) Microbiology and bio-technology waste (waste from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and industrial laboratories,

⁵ Rule 3(v) BMW (M & H) Rules 1998.
wastes from production of biological, toxins, dishes and devices used for transfer cultures;

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

(v) Discarded medicines and cytotoxic drugs (wastes comprising of the outdated, contaminated and discarded medicines);

(vi) Solid waste (items contaminated with blood, and body fluids including cotton, dressing, soiled plaster cases, lines, beddings, other material contaminated with blood);

(vii) Solid waste (waste generated from disposable items other than the waste sharps such as tubing, catheters, intravenous sets, etc.);

(viii) Liquid waste (waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities);

(ix) Incineration ash (ash from incineration of any biomedical waste);

(x) Chemical waste (chemical used in the production of biological, chemicals used in disinfections as insecticides, etc).6

Thus, as far as the definition of bio-medical waste is concerned, the Rules have defined it very extensively and comprehensively.

7.3 Duties and Responsibilities of the Occupier 7

(I) Effective handling of waste –

Every occupier of an institution generating biomedical waste is vested with a duty to take all reasonable steps to ensure that such waste is handled without any adverse effect to human health and the environment.9

In this connection, the Rules have laid down certain guidelines, which should be followed by the Occupier as well as the Operator of the facility,10 which are as under:-

The Occupier or the Operator of the facility shall ensure that bio-medical waste shall not be mixed with other wastes.11 In this connection an Occupier is vested with following duties.

(a) Segregation and collection of waste – Segregation is the essence of waste management and should be done at the source of generation of bio-medical waste like out-patient care activity areas, diagnostic services areas, operation theaters,

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7 Occupier in relation to any institution generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, pathological laboratory, blood banks or by whatever name called, means a person who has control over that institution and or its premises.

8 Institution includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called.


10 Operator of the bio-medical waste facility means a person who owns or controls or operators a facility for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste.

labour rooms, treatment rooms, etc. The most appropriate ways of identifying the categories of biomedical waste is by sorting the waste into colour coded plastic bags and containers. It is the duty of the Occupier or the Operator of the facility to see that the bio-medical waste is segregated into container/bags at the point of generation in accordance with schedule II of the Rules given here under.

Table -1
Schedule- II
Colour coding –Biomedical Waste Rules 1998

<table>
<thead>
<tr>
<th>Colour coding</th>
<th>Type of container</th>
<th>Waste categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
<td>Plastic bags</td>
<td>Cat 1 human anatomical waste</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cat 2 animal waste</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cat 3 micro biology waste</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cat 56 soiled waste</td>
</tr>
<tr>
<td>Red</td>
<td>Disinfected container</td>
<td>Cat 3 microbiological waste</td>
</tr>
<tr>
<td></td>
<td>plastic bags</td>
<td>Cat 6 solid waste</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cat 7 solid waste</td>
</tr>
<tr>
<td>Blue /White</td>
<td>Plastic bag/puncture proof containers</td>
<td>Cat 4 waste sharps</td>
</tr>
<tr>
<td></td>
<td>do-</td>
<td>Cart 7 plastic disposable tubings, etc</td>
</tr>
<tr>
<td>Black</td>
<td>do-</td>
<td>Cat 4 discarded medicines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cat 9 incineration ash</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cat 10 chemical waste</td>
</tr>
</tbody>
</table>

At ordinary room temperature, the collected waste should not be stored for more than 24 hours.

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13 Ibid.
Though the Rules specify the colour-code, type of containers; waste category etc, for segregation and collection of waste, how far the hospitals adhere to these norms is the issue. To take an example, Delhi, India’s capital city has innumerable hospitals and clinics, which treat lakhs of patients every day. It is estimated that there are around 27 big hospitals and about 2,500 nursing homes and dispensaries. It has 40,000 hospital beds of which 20,000 beds are in the government sector. The waste generation is about 1.5 k.g. per bed which comes about 60 tonnes of waste per day. Surprisingly, these hospitals do not have trained staff and segregation systems. Wrong bags for segregation of wastes are used in these hospitals. For instance, Palika Hospital run by NDMC and Kasturba Hospital use red bags for syringes, yellow for infectious waste and black for non-infectious waste, violating the specifications laid down in the Schedule. A survey conducted by Srishti, Delhi Pollution Control Committee (DPCC) and Delhi Health Ministry of Medical Waste Management shows that only 20 percent of the hospitals are achieving good segregation but 60 percent are not following basic segregation.\footnote{Satpal Singh, \textit{Mismanaging Hospital Waste, Economic and Political Weekly}, April 21, 2001, p.1297.}

It is fair to imagine such a type of situation in many hospitals in other parts of the country. Since segregation of waste is the first step in handling the waste, if it is not done properly, there are chances of it being mixed with other wastes.
(b) Transportation of waste-

When the waste is transported, the container has to bear the label as prescribed in Schedule III. If the container is transported from the premises where biomedical waste is generated to any waste treatment facility outside the premises, the containers, apart from label prescribed in Schedule III, shall also carry information prescribed in Schedule-IV. This provision has been made to indicate the nature of waste to the patients and public. Further, the label shall be non-washable and prominently visible.

However, the Rules are silent about the mode of transportation, which is also equally important in handling the bio-medical waste.

Following points may be taken into consideration by the Occupier or the Operator of the facility with regard to transportation.

(i) Within the hospital, waste routes may be designated to avoid the passage of waste through patient care areas.

(ii) Separate time should be earmarked for transportation of bio-medical waste to reduce chances of its mixing with general waste.

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15 Schedule-III gives Label for bio-medical waste containers bags.

Biohazard Symbol  

Cytotoxic Hazard Symbol  

Biohazard  

Cytotoxic

16 Hema chandra, supra note 12, p.3.
(iii) Desiccated, wheeled containers, trolleys or carts should be used to transport the waste/plastic bags to the site of storage/treatment.

(iv) Trolleys or carts should be thoroughly cleaned and disinfected in the event of any spillage.17

(v) Manual loading should be avoided as far as possible.

(vi) The bags and containers should be properly tied/lidded before transportation, accompanied with signed document by Nurse/Doctor mentioning date, shift, quantity and destination.

(vii) The driver’s compartment should be separated from the load compartment with a bulkhead. The load compartment should be provided with roof vents for ventilation.

(viii) The driver must be trained in the procedures he must follow in case of an accidental spillage.18

If the above guidelines are taken into consideration by the Occupier or an Operator of the facility, then no doubt transportation of the biomedical waste can be done effectively. Apart from this there is also a need to protect the health of those persons who carry the biomedical waste. For this purpose, an Occupier or Operator of the facility should make the following arrangements for the persons who carry the biomedical waste.

(i) **Gloves:** Heavy-duty rubber gloves should be used for waste handling by the waste retrievers. After handling the waste, the gloves should be washed twice. The gloves should be washed after every use with carbolic soap and disinfectant. The size should fit the operator.

(ii) **Aprons, gowns, suits or other apparels:** Apparel is worn to prevent contamination of clothing and protect skin. It could be made of cloth or impermeable material such as plastic. People working in incinerator chambers should have gown or suits made of non-inflammable material.

(iii) **Masks:** Various types of masks, goggles, and face shields are worn alone or in combination, to provide a protective barrier. Operator must wear appropriate mask covering both with filters.

(iv) **Boots:** Leg covering boots or shoe-covers provide greater protection to the skin when splashes or large quantities of infected waste have to be handled. The boots should be rubber soled and anti-skid type. They should cover the leg up to the ankle.\(^{19}\)

However, the Rules have not provided any kind of provisions to protect the health of the persons carrying the biomedical waste. Under such circumstances, there are many chances of the Occupier not taking adequate steps in providing protective devices to the Operator of the waste. The Rules also have not laid down any specifications for cleaning devices and storage devices. For example, when the worker is using the broom to clean any device of bio-medical waste, it should

\(^{19}\) Id., p.14.
be of such diameter and length that, it should be convenient for the worker to handle, so that he need not stoop to sweep. While mopping, mops with long handles must be used for swabbing the floor and it has to be replaced after wear and tear. The mechanical screw type mop is convenient for squeezing out the water.20

It is also very important to assess the quantity of waste generated at each point. Dustbins should be of such capacity that they do not over flow between each cycle of waste collection. Dustbins should be cleaned after every cycle of clearance of waste with disinfectants. Further, rooms or sheds to house the collected waste from the institution should be located away from functional areas. It should also be located away from chimneys, diesel generator sets, oil storage, gas storage chambers and other potential sources of fire, to prevent fire hazards.

However, any kind of above guidelines are not found under the Rules. If the biomedical waste is untreated, it shall be transported in such vehicle as may be authorized for the purpose by the competent authority as specified by the Government.21

(II) An Occupier is not supposed to keep the untreated biomedical waste or store it beyond the period of 48 hours.22

However if it becomes necessary to store the waste beyond such period, the authorized person must take permission of the prescribed authority and take

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20 Id., p.15.
measures to ensure that the waste does not adversely affect human health and the environment.  

However, the Rules do not prescribe any measures on part of the authorized person to ensure that the waste does not adversely affect human health and environment. For example, the Rules ought to have prescribed the following:

(i) The chamber in which the untreated waste is stored should be far away from drinking water tanks.

(ii) The area should be cordoned off with barbed wire fencing and netting to prevent access to animals and birds.

(iii) Security should be provided to strictly prohibit unauthorized access of human beings.

(III) Transportation of the segregated non-biomedical wastes and duly treated bio-medical waste

It is the responsibility of the municipal body of the concerned area to pick up and transport segregated non-biomedical solid waste generated in hospitals and nursing homes, as well as duly treated bio-medical wastes for disposal at municipal dump sites.

However, it is very difficult to assess or say that waste is 100% non-biomedical or solid waste. A small carelessness in throwing a syringe or a needle or infectious waste will cause serious danger. Utmost care is required while segregation and the Rules do not provide any measures for standard of care

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23 Supra note 17.

required during segregation. In this matter, the Rules are not at all being properly implemented.25

Further, in areas other than municipalities, the individual Occupier/Operator of treatment facilities is made responsible for arranging suitable sites individually or in association.26 This does no good to the environment beyond dividing it into urban, sub-urban and rural environment. There is a lot of difference between observance of a Rule by a state action or private action. The Rules adopt the age-old approach of cleaning the Kings Street only. This encourages the problem of illegal dumping of bio-medical waste in sub-urban and rural areas for lack of proper infrastructure, treatment and disposal facilities thereby leading to inefficient outcomes for the environment because generators in such areas can dump waste anywhere. Even vigorous tracking and monitoring by the enforcement agencies can hardly detect and the generators can dump the waste illegally.27

(IV) Treatment and Disposal of Bio-medical waste:

The Occupier is vested with a duty to treat and dispose off the biomedical waste in accordance with schedule-I. The treatments methods prescribed under Schedule-I are:

(a) Incinerators;

27 M.Ayub Dar, supra note 2, p.138.
(ii) Autoclaving

(iii) Microwaving and

(v) Deep Burial

Schedule –V sets out the standards to be observed by the Occupier/Operator while treating the waste in any one of the above methods. However, there are many problems associated with above types of treatment. There are many better options and alternatives available for the treatment of bio-medical waste, which can be prescribed under the Rules. If the occupier does not have the above facilities for the disposal of waste, he can also avail the common waste treatment facility or any other treatment facility set up by the municipal authority.

7.4 Duties and responsibilities of Enforcement Authorities under the Rules

(I) Implementation of the Rules:

The implementation of the Rules has been entrusted to the State Pollution Control Boards (SPCBs) in States and Pollution Control Committees (SPCCs) in Union Territories. Before taking the task of implementation into their hands

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28 Rule 5, BMW (M & H) Rules 1988, See Appendix, Schedule- V.
29 The problems associated with incinerations has been discussed in chapter II.
30 The alternative methods for treatment and disposal of waste have been discussed in chapter II.
PCBSs/PCCs must be appointed as Prescribed Authorities within one month of the coming into force of the Rules.33

(II) Grant of Authorization:

One of the most important responsibilities of the SPCBs and PCCs is to grant authorization to the applicant upon being satisfied that, he possesses the necessary capacity to handle the bio-medical waste in accordance with the Rules.34

However, even institutions generating bio-medical waste have been grouped into two categories viz, those which require an authorization under Rule 8 and those pathological laboratories, and blood banks, dispensaries, clinics, which provide treatment to less than 1000 patients in a month.35 Only those institutions, which provide treatment to more than 1000 patients in a month, require authorization. This demarcation between medical institutions narrows down the scope of Rules. The institutions providing services to less than 1000 patients per month are treated as insignificant for the purposes of the Rules and do not require an authorization. This can encourage mushroom growth of such institutions so as to be away from the net of Rules by merely making paper promises to handle the waste properly.36

The Rules prescribe the following mandates on part of SPCBs and PCCs when the authorization is granted.

36 M. Ayub Dar, supra note 2, p.133.
(i) An authorization shall be granted for a period of three years including an initial trial period of one year from the date of issue. Thereafter an application shall be made by the Occupier/Operator for renewal. All such subsequent authorization shall be for a period of three years. A provisional authorization will be granted for the trial period to enable the Occupier/Operator to demonstrate the capacity of the facility.37

(ii) The Prescribed Authority may after giving reasonable opportunity of being heard to the applicant and for reasons thereof to be recorded in writing refuse to grant or renew authorization.38

(iii) Every application for authorization shall be disposed of by the Prescribed Authority within ninety days from the date of receipt of the application.39

(iv) The Prescribed Authority may cancel or suspend an authorization, if for reason, to be recorded in writing, the occupier/operator has failed to comply with any provisions of the Act or these Rules. Provided that no authorization shall be cancelled or suspended without giving a reasonable opportunity to the Occupier/Operator of being heard.40

The SPCBS and PCCs have not been given the absolute authority in the implementation of the Rules. They shall function under the supervision and

38 Rule 7 (6), BMW (M & H) Rules 2000.
40 Rule 7 (8), BMW (M & H) Rules 2000.
control of respective Government of the State or Union Territory.\textsuperscript{41} To advise the Government of every State or Union Territory and the Prescribed Authority on matters related to implementation of the Rules, the Government of every State /Union Territory is to constitute an Advisory Committee consisting of experts in the field of medical and health, animal husbandry and veterinary sciences, environmental management, municipal administration and any other related department or organisation including NGOs.\textsuperscript{42} The Committee should give its advice as and when required by the Government and the Prescribed Authority. Other than that, it has no responsibility to ensure proper implementation of the Rule. Instead of vesting only the responsibility of advising; the Committee could have been vested with monitoring duty above SPCBs and PCCs. This could have made the SPCBs /PCCs to work more efficiently.

(III) Annual Report

It is the duty of the Prescribed Authority to send the information on annual report\textsuperscript{43} submitted by the Occupier /Operator to the Central Pollution Control Board by 31\textsuperscript{st} of March every year.\textsuperscript{44}

\textsuperscript{41} Rule 7 (3), BMW (M & H) Rules 2000.
\textsuperscript{42} Rule 9 BMW (M & H) Rules 2000.
\textsuperscript{43} Every Occupier/Operator has to submit an annual report to the Prescribed Authority in Form II by Jan 31, every year, to include information about the categories and quantities of bio-medical waste handled during the preceding year.
\textsuperscript{44} Rule 10 BMW (M & H) Rules 2000.
(IV) Verification of records:

The enforcement authorities can verify and inspect the records maintained by the Occupier/Operator.45

(V) Accident Reporting

When any accident occurs at any institution or facility or any other site where the bio-medical waste is handled or during transportation of such waste, the authorized person shall report the accident in Form III to the Prescribed Authority.46 Many authorized persons are involved in handling the biomedical waste from the state of generation to disposal. The Rule embrace all of them. This vagueness complicates most important and integral issues pertaining to the liability of authorized peons in respect of harm, caused due to accidents, on human health and the environment, the emergency measures taken and the steps to be taken to alleviate the ill-effects and recurrence of such an accident.47

Mismanagement of biomedical waste in Karnataka Institute of Medical Science (KIMs)

Karnatak Institute of Medical Sciences (KIMs) at Hubli is one of the very well-known medical institutions in Karnataka. Inspite of being considered as a prestigious institution the hospital does not have a proper biomedical waste handling facility though produced in large quantity.

45 Acc to Rule 11(1), every Occupier/Operator shall maintain records related to generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of bio-medical waste in accordance with these Rules and any guidelines issued.
47 M. Ayub Dar, supra note 2, p. 136.
All sorts of biomedical waste including hand gloves, syringe covers, bandage, dressing pad, saline bottles, the bisected parts of human organs etc are just thrown in the waste bin near the incinerator behind the mortuary. The overflowing waste in the bin is not at all cleaned and is always found with dogs and pigs causing of foul smell in and around the hospital. The situation worsens during the rainy season.

Besides this waste dump, there is a canteen and many wards are situated. Although the hospital has incinerator, it is not put to proper use. Some waste from Dharwad Civil Hospital and K.L.E. Hospital Hubli are also brought here for disposal. However, the concerned persons just throw it at their backyard and the incinerator is put to use only for two hours.

Although boxes of different colour are kept in the wards for segregation of waste as per Rules it is reported that the waste is not at all segregated. It is reported by the incinerator staff that infected hand gloves, dressing pads and even the dissected organs of the gangrene affected persons are just put into the "dry boxes" which then directly go to the dumping bins instead of the incinerator. Incinerator itself is under repairs since many months. It is a pity that the concerned hospital authorities are not at all bothered about proper disposal of biomedical waste.\textsuperscript{48}

\textsuperscript{48} As reported in Kannada Local Newspaper, Prajavani, on 11 December 2006, at p.3.
Inspite of mismanagement of biomedical waste in such a well-known hospital, the concerned authorities have not taken any steps to enforce the Rules and take action against the concerned hospital authorities.

This situation is found not only in KIMS, but also in many other prestigious institutions also. For example, Bahampur Hospital is a premier health care establishment in Lucknow, in North India. It has been reported in a survey conducted in this hospital that, infectious and non-infectious wastes are dumped together within the hospital premises, resulting in a mixing of the two, which are then disposed of with municipal waste at the dumping sites in the city. All types of wastes are collected in common bins placed outside the patient wards. The hospital does not have any treatment facility for infectious waste. The laboratory waste materials, which are disposed of directly into the municipal sewer without proper disinfections of pathogens, ultimately reach the Gomti River. All disposable plastic items are segregated by the rag-pickers from the hospital as well as municipal bins and dumps. The waste deposited either in side the hospital grounds, or outside in the community bin for further transportation and disposal along with municipal solid waste. The open dumping of the waste makes it freely accessible to rag pickers who become exposed to serious health hazards due to injuries from sharp needless and other types of materials used when giving injections.49

This shows that, there is a need for the strict enforcement of the legal provisions for the proper disposal of biomedical waste.

7.5 Conclusion

Hospital waste or the biomedical waste if not disposed properly can lead to the spread of many diseases. It not only affects the human life, but also leads to degradation of environment. The Ministry of Environment and Forests considering the problem of biomedical waste enacted the Biomedical Waste (Management and Handling) Rules in the year 1998 which were further amended in the year 2000 and 2003. However lack of proper enforcement of the legal provisions and lack of awareness and technical guidance in the management of biomedical waste has led to the hospitals becoming centers in spreading diseases, rather than working towards eradicating them. To protect the environment and health of community, there is a need for scientific management of biomedical waste. This can be achieved by overcoming the loopholes present in the Rules by proper enforcement of the Rules and increased awareness about proper disposal of waste, among medical and paramedical staff.