

## CHAPTER VII

### CURRENT SCENARIO OF THE BIO-MEDICAL WASTE MANAGEMENT IN INDIA UNDER THE EXISTING LEGAL FRAMEWORK: A CRITICAL ANALYSIS OF BIO-MEDICAL WASTE MANAGEMENT RULES, 2016.

#### 7.1 The Existing Scenario of Bio-Medical Waste in India

In India, there are about 6,00,000 hospital beds, over 23,000 Primary Health Centers, thousands of registered nursing homes, countless unregistered nursing homes and dispensaries, and above all a very large number of quacks practicing at every nook and corner of urban and semi-urban locality. The hospitals are tertiary care hospitals usually associated with teaching colleges, district hospitals of more than 2000 and health care dispensaries. There are innumerable pathology laboratories, the data of which is hardly available<sup>1</sup>. According to health information statistics, 20% of total beds are in rural hospitals while 80% are in urban hospitals<sup>2</sup>. Extrapolating from past figures of number of beds and average quantity of waste generation at the rate of 1 kg per bed per day, it is estimated by Ministry of Environment and Forest (MoEF) that about 0.33 million tons of hospital waste is being generated per year<sup>3</sup>. But as per latest report, total bio-medical waste generation in the country is 484 tons per day from 1,68,869 healthcare facilities (HCF). Of this, 447 tons per day is treated.<sup>4</sup> The figure given below in the Table shows that 4,05,702 kg of Bio-Medical Waste (BMW) is generated in top five States in India with only 2,91,983 are being disposed of everyday. The figure confirms that every day, 1,13,719 kg of waste is left unattended which more often than not re-enters the system<sup>5</sup>.

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<sup>1</sup> Kamalakanta Muduli and Akhilesh Barve, "Challenges to Waste Management Practices in Indian Health Care Sector", International Conference on Environment Science and Engineering Vol. 32 IPCBEE pg. 63 (2012).

<sup>2</sup> A.D.P.Biharatil and A.V. Shekdar "Health-Care Waste Management in India" Vol. 63 Journal of Environmental Management pgs. 211–220 (2001).

<sup>3</sup> Kamalakanta Muduli and Akhilesh Barve, "Challenges to Waste Management Practices in Indian Health Care Sector," International Conference on Environment Science and Engineering Vol. 32 IPCBEE pg. 63 (2012).

<sup>4</sup> "New Rules Notified for Management of Bio-Medical Waste" *The Times of India*, March 27, 2016.

<sup>5</sup> Amitava Srivastava and Nirmala Ravindran, "Rich Trash Pickings, A flourishing repackaging industry brings disposed medical waste back into the nation's healthcare system" *India Today in*, November 5, 2011.

**Table 1****Top Five Bio-Medical Waste Generating States<sup>6</sup>**

<b>States</b>	<b>BMW generated (kg/day)</b>	<b>BMW disposal (kg/day)</b>
Karnataka	62,241	43,971
Uttar Pradesh	44,392	42,237
Maharashtra	40,197	40,197
Kerala	32,884	29,438
West Bengal	23,571	12,472
Total	4,05,702	2,91,983

The above data shows that how the countries healthcare waste problem has become a growing menace along with the municipal wastes turning the country into a dumping ground as it can be seen that everyday each part of the country is covered up with filth litters and waste garbage. What is most shocking is that despite the existence of the various laws on the subject and the adoption of different policies and guidelines by the government the situation remained unchanged and still there is a continuing tendency of not following of the laws as can be seen from the Table 2 below which is highly alarming. The government is also persistent in introducing new projects and the recent step being the launching of three mega urban schemes in India, i.e., Smart Cities Mission, Atal Mission for Rejuvenation and Urban Transformation (AMRUT), and Housing for all in urban areas, is an attempt to set in motion the process of urban transformation to enable better living. The missions are new, innovative and focused on pressing needs to improve the quality of life for citizens today, and in the future. Such steps is the outcome of countries Prime Minister Mr. Narendra Modi's vision to recast India's urban landscape includes among others sanitation including solid waste management, sustainable development and health and education.<sup>7</sup> In addition to it, the Prime Minister's dream vision towards a *Swachh Bharat* is with a view to complete eradication of the wastes to make a clean country habitable for all.

<sup>6</sup> S Manasi, K S Umamani, *et. al.*, "Biomedical Waste Management: Issues and Concerns - A Ward Level Study of Bangalore City" The Institute for Social and Economic Change, Bangalore pg. 5 (2014).

<sup>7</sup> Second Smart Cities India 2016 Expo held on 11, 12 and 13 May in Pragati Maidan, New Delhi highlighted the above core infrastructure elements.

**Table 2****States with Highest Number of Violators<sup>8</sup>**

<b>States</b>	<b>Number of facilities violating BMW Rules</b>
Maharashtra	4,667
Kerala	1,547
Bihar	1,221
West Bengal	632
Uttar Pradesh	532
Tamil Nadu	507
All India	13,037

From the table referred above it is clear that the most populated States of the country having growing number of health care facilities are the producer of the BMW and they at the same time are the violators of the existing laws. It is estimated that Indian health care industry is growing at a rate of 12% per annum<sup>9</sup>, which necessarily implies that the generation of such a huge quantity of BMW, if not properly controlled and managed would have a devastating effect having far reaching consequences not only to the environment but to the living and other beings that are part of it. In view of the above table, it is important to have a detail analysis of the existing State-wise scenario prevailing in the health care institutions and the steps already undertaken or to be undertaken by such institutions in the light of the existing laws. The selection of the State has been made in view of the top five generator of the Bio-Medical Waste in the country alongwith other States in order to get a clear picture about the existing scenario prevailing in the country.

**7.1.1 Maharashtra**

A detail analysis of the data on bio-medical waste during 2005-2010 shows that there was a significant increase in the number of health care facilities in

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<sup>8</sup> *Ibid.*

<sup>9</sup> Richa Prasad and Dr. Parul Sharma, *Bio-Medical Waste Management: An Emerging Issue*, cited in Dr. Ramesh Kumar Miryala and Dr. Ravi Aluvala (Eds.), *Trends, Challenges and Innovations in Management* pg. 104 (Zenon Academic Publishing, Hyderabad, 1<sup>st</sup> Edn., 2015).

Maharashtra from 2008-2009. The total volume of such waste generated in 2006 was higher than any other year<sup>10</sup>. Total bio-medical generated in the State is close to 43,380 kg/day<sup>11</sup>. This estimate includes wastes generated from both bedded and non bedded health care institutions. Region wise, as expected Mumbai contributes approximately 23.26% of the total BMW load. Pune contributes approximately 19.58% and Nagpur is close third with 17.33% contribution<sup>12</sup>.

There are thirty one common bio-medical waste treatment and disposal facilities operators and transporters operating for the proper treatment and disposal of the bio-medical waste in Maharashtra. All the operators have taken responsibility for transportation of such waste. Maximum number of operators and transporters are in Pune region. Some of the operators and transporters cover health care facilities in more than one region<sup>13</sup>.

The Mumbai Medical Waste Action Group and the All India Institute of Local Self Governance have studied the quantum of waste in Mumbai. According to its report<sup>14</sup> based on a questionnaire, the waste generation figure is given as in the table below:

**Table 3**

**Waste Generation in Mumbai's Hospitals**

<b>Hospital</b>	<b>Total waste per patient per day (kg)</b>
Private (upto 20 beds)	0.25
Private (21-50 beds)	0.19
Private (above 50 beds)	0.98
Municipal	1.08
Government	0.7

<sup>10</sup> Government of Maharashtra, "Status of Biomedical Waste Management in the State of Maharashtra, 2010" Maharashtra Pollution Control Board, Environment Management Centre pg. 10 (June, 2011). ,

<sup>11</sup> *Ibid* at pg. 19.

<sup>12</sup> *Ibid* at pg. 20.

<sup>13</sup> *Ibid* at pg. 28.

<sup>14</sup> Dr. Sushma Sahai, *Bio-Medical Waste Management* pg. 281 (A.P.H. Publishing Corporation, 1<sup>st</sup> Edn., 2009).

Out of the total waste generated in the health care institutions in the State whether owned privately or by the government, the following table gave a clear picture of different category of waste generated per bed per day in such institutions.

**Table 4**

**Category-Wise Waste Generated/Bed/Day<sup>15</sup>**

<b>Waste Type</b>	<b>Kg/Bed/Day</b>
Total Infectious	0.30
Non Infectious	0.41
Recyclable	0.05
Total Waste	0.76

The current waste management system is a two-bag system: yellow for infectious waste and black for non-infectious waste. Special jerry cans have been made for sharps that can be autoclaved. Tata Memorial Hospital, a cancer hospital in Mumbai has recently invested in alternative technology, in the form of hydroclave. The cytotoxic drugs and body parts are sent to the crematorium for burning while the rest are segregated and recycled<sup>16</sup>.

The Indian Express, dated August 22, 2013, reported that the Auditor General (AG) of Maharashtra had found the Maharashtra Pollution Control Board (MPCB) deficient in disposing the BMW generated at pet clinics in Pune region-Pimpri Chinchwad and Solapur. In Satara sub-region, none of the 162 institutions have obtained membership of the common BMW treatment facility and 87 of them have not even furnished the required undertaking. This issue poses a serious threat to the surrounding environment and people living there, the audit observed<sup>17</sup>.

State legislature's Public Accounts Committee (PAC) has also showed concern regarding the unscientific disposal of BMW unbridled in Mumbai and how it could pose serious threats to citizen's health. The PAC also sounded an alarm over

<sup>15</sup> The Bombay community Public Trusts, "Bio-Medical Waste Management: Understanding our Civic Issues," Available at: <http://www.bcpt.org.in/articles/biomedical.pdf> (Last visited on Sept. 15, 2016).

<sup>16</sup> *Ibid.*

<sup>17</sup> Partha Sarathi Biswas, "Audit: MPCB has failed to address veterinary bio-medical waste issue" *The Indian Express*, August 22, 2013.

rising urban pollution levels. The other worrying points it raised was that several hospitals and clinics in the city do not segregate the waste as also how the callous way of dumping waste has indeed caused a spurt in diseases such as malaria and even cancer. “Citizens in the big cities like Mumbai and Pune are exposed to the rising hazard of the epidemics and critical illnesses due to rising pollution and bad environmental conditions. The rise in critical illnesses like cancer is worrisome,” the report stated<sup>18</sup>.

### 7.1.2 Kerala

The number of health care facilities in the State is highest among all the States. With the increasing in number the complexities are also increasing in nature. The Environment Department (ED) is the administrative department at Government level for matters relating to environment. Kerala State Pollution Control Board (KSPCB) is the Prescribed Authority in the State to enforce the provisions of the Rules. The KSPCB has its head office at Thiruvananthapuram. There are three regional offices and fourteen district offices in the State. According to a report by Central Pollution Control Board (CPCB), Kerala has the highest number (about 27%) of health care institutions in India. The total bed strength of hospitals in Kerala is 1,13,530 of which 43,273 are in the Government sector, 2,740 in the cooperative sector and 67,517 in the private sector. The Board has so far identified nearly 4000 bio-medical waste generators in the State<sup>19</sup>. According to a research report<sup>20</sup> conducted over a period of one year during 2012-2014 with the aid of University Grant Commission (UGC) interviewing 200 health care workers and 100 residents living nearby, many of the hospitals in Kerala neither have a satisfactory waste disposal system nor a waste management and disposal policy. On an average the volume of total medical waste in hospitals in Kerala is estimated to range between 1 kg and 2 kg

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<sup>18</sup> *Hindustan Times*, August 10, 2013.

<sup>19</sup> Report of the Common Bio-Medical Waste Treatment Waste Treatment Facility, Malabar Enviro Vision Pvt. Ltd., Kerala “Pre-feasibility Project Report of centralized Bio-Medical Waste Treatment Facility in Kerala,” *Available at:* [http://www.nswai.com/nswaiadmin/Pdfs/insertPdf/i\\_2015/i\\_Dec15/Pre-feasibility%20Report%20Centralized%20Biomedical%20Waste%20Treatment%20Facility%20in%20Kerala.pdf](http://www.nswai.com/nswaiadmin/Pdfs/insertPdf/i_2015/i_Dec15/Pre-feasibility%20Report%20Centralized%20Biomedical%20Waste%20Treatment%20Facility%20in%20Kerala.pdf) (Last visited on Sept. 19, 2016).

<sup>20</sup> T.I. Andrews, “The Problem and Challenges of Medical Waste Management Study with Special Reference to Kerala State”, *Available at:* <http://www.catholiccollege.com/v1/projectCms3121.html?pid=11&mode=projectAction> (Last visited on Sept. 20, 2016).

per day on a per bed basis and most of the hospitals and clinics dispose of in the available open ground with no regard to hygiene considerations. Test check of the records maintained for the bio-medical waste in the forty health care facilities in the selected districts revealed that the segregation of waste as stipulated was not carried out in eighteen institutions till date. In three Medical Colleges and one General Hospital with bed strength ranging between 747 and 1,600 and generating substantial quantities of waste, segregation was started between February 2004 and November 2005 only against the prescribed date of June 2000<sup>21</sup>. In the absence of State level inventory of health care institutions and non-possession of authorisation by 83 per cent of the identified health care facilities, the Prescribed Authority/State Government has no mechanism to monitor the proper segregation of waste generated<sup>22</sup>.

It is surprising that bio-medical waste is not fully segregated at source in a State where there is 100% literacy. This, in turn, increases the risk factor of entire solid waste generated from health care facilities because the infectious bio-medical wastes when gets mixed with non-infectious waste turned the whole waste as infectious.

Regarding the treatment and disposal of the waste, though lately, the Government of Kerala has prepared a vision document<sup>23</sup> on biomedical waste management. This document is the first of its kind in India. As per the vision document, Government is proposing to install three Common Bio-Medical Waste Treatment Facility (CBMWTF) in the State. Already there is one common biomedical waste treatment and disposal plant in Kerala working at Palakkad district in the Indian Medical Association (IMA). Apart from this, the IMA is having proposal to start two more common facilities at other parts of the state, which are at different stages of its implementation. Once these common facilities become a reality the environmental problems due to such waste will be improved. Regarding authorisation, audit scrutiny

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<sup>21</sup>Government of India, Audit Report of the Environment Department (Civil), "Management and Handling of BMW" pg. 8 (March, 31 2007), Available at: <http://iced.cag.gov.in/wp-content/uploads/2014/02/3.-PA-on-Bio-Medical-WM-in-Kerala.pdf> (Last visited on Sept. 25, 2016).

<sup>22</sup> *Ibid.*

<sup>23</sup> Ministry of Environment, Forests & Climate Change, Govt. of India Sponsored, "Environment Information System, ENVIS, Kerala State Council for Science, Technology and Environment", Available at: [http://www.kerennis.nic.in/Database/Soil\\_836.aspx](http://www.kerennis.nic.in/Database/Soil_836.aspx) (Last visited on Sept. 26, 2016).

conducted in 2007<sup>24</sup> revealed that majority of the identified 5,200 health care institutions had not applied for authorisation. As a result 83 per cent of the identified institutions were functioning without authorisation in gross violation of the Rules.

### 7.1.3 Bihar

The prevalent bio-medical waste management practices in the State of Bihar are highly deficient. Storage of wastes at source is generally not attended to. The bio-medical waste has been grossly neglected in the State. Large number of hospitals, nursing homes, health care centers has been identified by the Bihar State Pollution Control Board (BSPCB) but do not take any measure for the safe disposal of the waste. As a result, the wastes get mixed up with the municipal solid waste and deposited at the common disposal site. Scrutiny conducted in July, 2014 by Comptroller and Auditor General (CAG)<sup>25</sup> revealed BSPCB neither prepared any comprehensive plan nor conducted any survey to identify the health care institutions to prevent, control and abate pollution. During scrutiny, it was observed that there was 2538 numbers of health care institutions identified in the State. Out of this, 1329 had applied for authorisation and granted authorisation to 1239 up to December 2013<sup>26</sup>. Thus, 1209 has failed to apply for authorisation which is an impediment in the management of the waste in the State. Further, out of 1329 health care institutions applied for authorisation, 90 have failed to receive any authorisation from the authority.

Regarding the treatment of waste scrutiny, the records revealed that effluent treatment plants were installed in only six out of 1239 authorised institutions. The existing position with regard to CBMWTF is also very poor. The CBMWTF operator at Patna covered 539 health care institutions having 11243 beds against norms of 10000 beds. The operator at Bhagalpur and Muzaffarpur reported that total 77 health care institutions are not sending the waste for treatment<sup>27</sup>.

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<sup>24</sup> Government of India, Audit Report of the Environment Department (Civil), "Management and Handling of BMW" pg. 85 (March, 31 2007).

<sup>25</sup> Government of Bihar, Performance Audit on the Working of the Bihar State Pollution Control Board, Environment and Forest Department pg. 10 (2014).

<sup>26</sup> *Ibid* at pg. 20.

<sup>27</sup> *Ibid* at pg. 22.



Further, according to guidelines issued by the CPCB (October 2013), the CBMWTFs operating bio-medical waste incinerator were required to get analysis report of the hazardous constituents of the incinerator ash generated through a recognised laboratory. This provision was being violated by three CBMWTFs in the State. The scenario of the capital city of Bihar is also the same. There are 31 public and private hospitals and more than 100 nursing homes in the city, according to Patna Municipal Corporation's Executive Engineer<sup>28</sup>. It is estimated that 3.6 tonnes of biomedical wastes is generated in the city per day<sup>29</sup>. The total quantity of waste generation estimated may go up further as there are large number of health clinics and similar health care institutions which do not have inpatient facilities and various types of clinical laboratories, dental clinics, etc. These health care institutions are not accounted for in this estimation of waste generation.

All types of wastes are mixed together and disposed of. Most of the health care institutions in the city are not having adequate facilities for the safe disposal of the biomedical waste. Wastes are either dumped in open space behind the hospital and occasionally burnt causing severe air pollution and land pollution. In certain hospitals, incinerators are provided, but the same is not meeting the statutory requirements of operation and emission standards and are a source of pollution. Presently, twelve captive incinerators/autoclaves are available in Patna, with variable efficiencies. It is observed that in reality, many of them are not in functional state<sup>30</sup>. The contaminated syringes and needles are dumped along with other wastes, which are being collected by scavengers and illegally returned to the hospitals. The body parts often dumped along with the wastes has been seen carried by birds and animals. The hospital authorities and staff are not fully aware of the seriousness of the problem created by the unscientific way of disposal of these wastes and hence give only very little attention to the disposal of these wastes.

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<sup>28</sup> S.K.Mandal, and J. Dutta "Integrated Bio-Medical Waste Management Plan for Patna City" Institute of Town Planners, India Journal pg. 9 (April - June 2009).

<sup>29</sup> *Ibid* at pg. 11.

<sup>30</sup> Final Environmental Impact Assessment, "Proposed Common Bio-Medical Waste Management and Recycling facility, Patna, Bihar" Ramky Enviro Engineers Limited, Hyderabad pg. 1.4 ( May 2015).

#### 7.1.4 West Bengal

The West Bengal Pollution Control Board (WBPCB) under the Environment Department (ED) is the Prescribed Authority for enforcement of bio-medical waste Rules in the State of West Bengal and the Health and Family Welfare Department (H&FWD) is responsible to provide funds and other infrastructural support to the occupiers under it to implement the Rules. The Deputy Director of Health Services and the Chief Medical Officers of Health (CMOH) were the licensing authorities for private health care units (HCU) in Kolkata and other districts respectively. Audit had test checked the records of ED, WBPCB and its four Regional/Sub Regional offices, H&FWD, one Common Bio-Medical Waste Treatment Facility operated by a private agency, for District Magistrates offices, eight Municipal Corporation/Municipalities, four CMOHs, twenty Government Colleges and Hospitals/District Hospitals/Subdivision Hospitals/General Hospitals/Rural Hospitals in seven sampled Districts. The following table will help in understanding the existing scenario of the generation, treatment and disposal of the BMW as per the findings of such Audit<sup>31</sup>.

**Table 5**

**The quantities of untreated BMW generated, treated and disposed of in the State during 2002-2008<sup>32</sup> were as follows:**

<b>Year</b>	<b>BMW generated (tonnes)</b>	<b>BMW treated (tonnes)</b>	<b>BMW disposed of untreated (tonnes)</b>	<b>Percentage of untreated waste</b>
2002-03	8595.39	487.52	8107.87	94
2003-04	7767.62	3239.38	4528.24	58
2004-05	8490.26	3309.82	5180.44	61
2005-06	8729.34	3899.29	4830.05	55
2006-07	8647.03	4147.13	4499.90	52
2007-08	8972.70	4936.00	4036.70	45

<sup>31</sup> Government of West Bengal, Audit Report (Civil), Environment and Health & Welfare Department, Government of West Bengal, 2008, pg. 93 (March 31, 2008).

<sup>32</sup> *Ibid.*

The figure shown above, although, is an estimate, however, it shows a healthy improvement in the reduction of untreated waste from 2002-03 to 2007-08 and if steps are taken for the strict compliance of the existing Rules considering its serious effect on the environment the situation will be changed in near future.

Regarding segregation, WBPCB had advised use of four colour coded bags i.e. red, yellow and blue for infectious, anatomical, sharps/needles/syringes respectively and black bags for Municipal Solid Waste (MSW). Bio-medical wastes were required to be segregated at the points of generation by using the said colour coded plastic bags/containers with 'bio-hazard' or 'toxic hazard' symbol. According to the report, inspection done by WBPCB disclosed that segregation at various government or private health care facilities was not done properly and the Central Pollution Control Board also reported mixing of bio-medical waste with MSW after random inspection of 17 private health care institutions in Kolkata<sup>33</sup>.

The scenario regarding transportation and disposal of the waste is also very poor. The report shows that the municipal authorities used to carry both treated and non-treated and sometimes even non-segregated bio-medical waste for disposal in dump site without considering the health hazards in violation of the Rules. H&FWD procured 16 waste treatment facilities for management of such wastes between September 2001 and March 2004 at a cost of Rs 3.76 crore under the West Bengal State Health System Development Project II (WBSHSDPII), a World Bank aided project. Out of eleven waste treatment facilities, five remained inoperative since installation due to absence/non cooperation of operator and non availability of consumables and two remained functional for only two to five months up to December 2006 due to theft/ damage of parts<sup>34</sup>.

In six districts of North Bengal, against 258 HCUs (8799 beds) under H&FWD there were only two autoclaves in working condition out of four installed. Thus, due to lackadaisical attitude of the department in operationalising the waste treatments facilities, the autoclaves though installed could not be used<sup>35</sup>.

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<sup>33</sup> *Ibid.*

<sup>34</sup> *Ibid.*

<sup>35</sup> *Ibid* at pg. 94.

North Bengal Medical College and Hospital with 589 beds, the only referral Government HCU in North Bengal (situated within Gram Panchayat near Siliguri town) had no facilities for the treatment of such wastes, not even a vat for storing of the same. The wastes are found dumped in different places inside the hospital premises and even within the vacant courtyard between wards and by the side of the walk away corridor (See the picture below) and burnt under the open sky. Thus, due to lack of infrastructure, awareness and initiatives on the part of the local authorities as well as the Department the situation is becoming worse.

**Figure 1:**

**Picture shown the present scenario of the Bio-Medical Waste in North Bengal Medical College & Hospital published in the Bengali Daily Anandabazar Patrika<sup>36</sup>**



<sup>36</sup> The daily Anandabazar Patrika, May 26, Thursday, 2016.

Figure 2:

## The North Bengal Medical College & Hospital is grinded by Bio-Medical Waste<sup>37</sup>



### 7.1.5 Tamil Nadu

The State of Tamil Nadu has been one of the few States in India to take active interest and initiative in addressing bio-medical waste management since early 2000. Through various government and non-government initiatives the Tamil Nadu Pollution Control Board (TNPCB) has been proactive in raising awareness and facilitating the setting up of CBMWTF across the State. Through partnership with Indian Medical Association (IMA) and Tamil Nadu Health Systems Project (TNHSP)

<sup>37</sup>*Ibid.* The news has been translated in English-The Bio-Medical Waste has been seen litters everywhere within the NBMC&H adjacent to the wards. The bad odour from the trashes is badly affecting the patients and the visitors who are using the corridor. This gives rises the question from all corner for the proper management of the waste. The patients and their relatives have alleged that the BMW and other wastes are being disposed of around the hospital whether it is the Medicine Ward, Emergency Ward or Labour Ward which resulted in the pollution to the surroundings. They also alleges that the patients whose bed is near the widow, they are the most sufferer. According to the correspondent, Rupees five lakhs had sanctioned five months back in the meeting of the Rogi Kalyan Samity, till date no work has been done to remove the same. On interviewing Dr. Nirmal Bera, Superintendent of the NBMC&H has said that there was some mistake in recording the name of the organisation with whom a contract had entered into. He further said that to remove the difficulties steps has been taken and very soon the problem will be sorted out. He failed to give any assurance as to when the work will begin after removing all difficulties.

the State has actively undertaken training and implementation activities in both private sector and government sector hospitals<sup>38</sup>. In 2008 waste awareness program had started through a “project for upgrading safety in health care” (PUSH). This programme is monitored by the Tamil Nadu Health System Project (TNHSP) in collaboration with National rural health mission, TNSPCB and Tamil Nadu AIDS prevention and control society<sup>39</sup>.

A large government hospital typically generates 10,015 kg of bio-medical wastes per month out of which 6,000 kg of needles and dressing material, 4,000 kg of ampoules, vials and other sharp implements and 15 kg of anatomical waste including placenta and amputated body parts<sup>40</sup>. According to Government statistics<sup>41</sup>, in Tamil Nadu the majority of beds are in six corporation areas and they are as follows:

**Table 6**

**Bed capacity in six corporation in Tamil Nadu**

<b>Corporation</b>	<b>No. of Beds</b>
Chennai	19,600
Coimbatore	6,500
Madurai	2,600
Salem	3,875
Trichy	2,800
Tirunelveli	2,000

Regarding segregation, which is the most important steps towards handling the BMW, study shows that the segregation is made as per the colour coding issued by the government of India and transported to the storage room available in the health care centers<sup>42</sup>. The nursing supervisors are fixed with the responsibility to supervise

<sup>38</sup>Government of Tamil Nadu, Final Technical Report, Global Health Care Waste Project, R. Rangarajan , “Indian Component of Global Project : Demonstrating and promoting Best Techniques and Practices for Reducing Health-Care Waste to avoid Environmental Releases of Dioxins and Mercury”,Tamil Nadu Pollution Control Board, pg. 22 (2013).

<sup>39</sup> *Ibid.*

<sup>40</sup> *Ibid* at pg. 23.

<sup>41</sup> *Ibid.*

<sup>42</sup> Deepali Deo, S. B. Tak, *et. al.*, “A Study of Knowledge Regarding Biomedical Waste Management among Employees of a Teaching Hospital in Rural Area” Journal of ISHWM, pg. 5 (April 2006).

biomedical waste registers regarding segregation maintained by the staff nurses available in all the work stations namely wards, outpatient services, casualty, labour room and operation theatres on day to day basis. The colour coding charts are provided in the regional language and pasted near the colour coded baskets in all work stations for immediate reference. With private public partnership the CBMWTF is taken care of by the private operators. Consent for operating CBMWTF facility was given by the government of Tamil Nadu to eight operators located at Chengalpattu, Sriperumpudur, Vellore, Salem, Tanjavur, Arupukottai, Tirunelveli and Coimbatore covering thirty districts of Tamil Nadu. It is the responsibility of these agencies to take away the biomedical wastes from the storage room of health care centers till safe disposal in the common treatment facility.

To monitor effective implementation of biomedical waste management, State level, district level and hospital level monitoring committees have been formulated. In the state and district level committees, NGO, IMA is included apart from government officials from TNPCB and municipal department. The outcome is that the Biomedical waste generated in Tamil Nadu for the year 2009-10 is 531896 kilograms, in 2010-11 it was 429395 Kilograms whereas in 2011-12 it was 282485 kilograms for the total bed strength of 55014. There was also a reduction of expenditure to CBMWTF operators from 2009 to 2011.

#### **7.1.6 Delhi**

In Delhi, there are 72 hospitals under government sector, 604 registered nursing homes and 936 dispensaries. In addition to this there are about 1550 unregistered establishments with different names like Nursing Homes, Medical centres, Dental Hospitals, MTP centres etc. About 40000 hospital beds are available in the public and private sector in Delhi.<sup>43</sup> Delhi is generating approximately 6500 metric tons of waste out of which 65 tons are expected to be Biomedical Waste<sup>44</sup>. The Government hospitals and major private hospitals have their own arrangement for treatment of biomedical waste. Biomedical waste generated in 30 Delhi govt.

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<sup>43</sup> Government of NCT of Delhi, "Bio-Medical Waste: Status in National Capital Territory of Delhi, Directorate of Health Services pg. 1 (2006).

<sup>44</sup> According to official figures 70 tons of BMW is generated in the city every day. Unofficial sources put it even higher at about 100 tons daily, *Main online India*, ( July 25, 2013).

hospitals vary from 780 grams/bed/day (Shushruta Trauma Centre) to 30 gram /bed/day (Guru Nanak Eye Centre) with an average of 260 gram /bed /day. Similarly Bio-medical waste generated in 31 hospitals other than Delhi government vary from 580 grams/bed/day (Infectious Disease Hospital) to 30 gram /bed/day (Venu Eye Institute and Research Centre) with an average of 200 gram /bed /day<sup>45</sup>. An examination of the records covering the period 2010-11 to 2012-13 of eight government hospitals (four in Delhi and four outside Delhi) under the administrative control of the Ministry of Health & Family Welfare, was undertaken to assess the compliance of the Rules by these hospitals with respect to generation, collection, treatment, handling and disposal of bio-medical wastes. The findings are as follows:

In Lady Hardinge Medical College and its associated hospitals, intermittent shortage of coloured bags was noticed. Delhi Pollution Control Committee (DPCC) stated that no intimation regarding shortage of bags for disposal of waste was given by the hospitals to the DPCC officials during inspections. In the absence of proper garbage bags possibility of improper segregation and disposal of BMW in this hospital could not be ruled out<sup>46</sup>.

Regarding storage and transportation the existing Rule stipulates that untreated bio-medical waste shall not be kept stored beyond a period of 48 hours provided that if for any reason it becomes necessary to store the waste beyond such period, the occupier must take permission of the prescribed authority and take measures to ensure that the waste does not adversely affect human health and the environment. In Shri Vinoba Bhave Civil Hospital, according to the report such waste was stored for more than 48 hours on many occasions during 2010 to 2013<sup>47</sup>.

The treatment and disposal of the bio-medical waste as per the Rule is in compliance with the standards prescribed in Schedule I and V. This standard further stipulates that liquid waste generated from the hospitals shall conform to specified parameters and permissible limits and shall be disinfected by chemical treatment before being discharged into drains.

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<sup>45</sup> *Ibid* at pg. 6.

<sup>46</sup> Government of India, Report on Management of Bio-Medical Waste in Government Hospitals, Ministry of Health and Family Welfare, (2014).

<sup>47</sup> *Ibid* at pg.51.



In May 2008, DPCC decided that hospitals having 50 beds or more shall install Effluent Treatment Plant/ Sewage Treatment Plant to treat the effluent generated from the hospital. All the four hospitals located in Delhi, covered in audit, however, showed that three hospitals had not installed the Plant and in one hospital the installed Sewage Treatment Plant was non-functional. Thus the situation in at least two hospitals was highly unsatisfactory and carried high risk to the environment.

At present as per records in Delhi 18 incinerators, 18 autoclaves and 3 microwaves are in operation. Besides this, a Government facilitated operator (Synergy Waste Management Private Limited) has established facility at Okhla that has become operational in November 2006<sup>48</sup>.

### **7.1.7 Karnataka**

Rapid growth in population has resulted in the establishment of large number of Hospitals and Nursing Homes in all places. These health care institutions are undoubtedly necessary for keeping up the well-being of our community, but there waste which is the neglected part needs to be handled carefully. Karnataka has identified 26,927 health care institutions as on March 2014<sup>49</sup> out of which bedded units are 5170 and non-bedded units are 21757. Approximately 62 tons of health care waste generates from such health care institutions per day. In order to treat such waste 27 CBMWTF had established and out of which 19 are operational. Most of the health care systems follow indiscriminate disposal, which leads to adverse effect both on life and environment<sup>50</sup>.

The scenario of other States of the country is no different. Looking into the above perspective and showing highly concerned, the Environment Ministry has issued show cause notices to 3,585 defaulting health care institutions and common bio-medical waste treatment facilities (CBMWTFs) across the country. Maharashtra state topped the list with 640 show cause notices, Rajasthan, is in second place with health care facilities, while in Uttar Pradesh, Delhi and Karnataka respectively 382,

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<sup>48</sup> Government of NCT of Delhi, "Bio-Medical Waste: Status in National Capital Territory of Delhi" Directorate of Health Services, pg. 7 (2006).

<sup>49</sup> Status of Bio-Medical Waste Management in Karnataka State, *Available at:* <http://kspcb.kar.nic.in/Status%20of%20BMW%20in%20Karnataka%20state.pdf>

<sup>50</sup> A.S.Tanksali, "Management of Bio-Medical Waste" International Journal of ChemTech Research, pg. 1214 (April-June 2013).

380 and 374 health care facilities were served show cause notices. As per an order of the Principle Bench of National Green Tribunal (NGT), 33 hospitals in New Delhi were inspected and 17 hospitals were found to be violating the Bio-Medical Waste (Management & Handling) Rules 1998 which the hospitals attributed to financial crunch<sup>51</sup>.

Therefore, the need of the hour is to have an overview of the whole system in the control and management of the bio-medical waste to find out the answer of different question that are floating on the air. The most important question among others is what are the reasons that are making hindrances in the path of management of bio-medical waste despite having the effective laws on the subject? Whether the existing laws are insufficient? Or whether there is any need to change the existing laws or the problem can be handled under it? Or why the number of waste generated every day in the country remained un-disposed or disposed of in violation of the existing laws? Looking into the above perspective of failure to manage the waste and to find out the root cause for such lacking behind, the researcher has undertaken under this Chapter to make a review of the present Bio-Medical Waste Management Rules<sup>52</sup>, 2016, earlier Rules on the subject and its various amendments considering the hazardous elements present in such waste. Further, a brief analysis has also made on the National Guidelines on Hospital Waste Management, 2002 and the Five-year plan of the Government to review such problem. The aim of this Chapter is to find out the lacunae of the existing Rules, to highlight on the actual problem in the direction for the proper implementation of the Rules and also to suggest appropriate measures in combating the present situation.

## **7.2 The National Regulatory Framework for the Management of Bio-Medical Waste**

It has already been discussed in the previous chapter that the need of national legislation is the basis for improving the overall conditions of all living in an environment which should be conducive and when such environment gets polluted due to the human activities it adversely affects not only the wholesome environment

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<sup>51</sup> “Goa State Pollution Control Board finds Aldona PHC ‘Polluting’”, *The Times of India City*, August 22, 2013.

<sup>52</sup> Hereinabove termed as the BMW Rules.

but the very existence of all living beings in such an atmosphere becomes impossible. To get rid of the situation and to make the environment habitable there is a need to pass stringent laws the strict compliance of which would help in combating the situation and in turn it would help in the establishment of healthy environment. The deteriorate conditions of the environment, as it believe, is due to the human activities who undertook manifold steps to make faster development and in this journey they made unscientific use of all those which come on the way including the natural resources and this resulted in the imbalance to the ecology which gives rise the concept of pollution. Such is the situation all over the world and India being one of them among others is presently facing an enormous increase of pollution in the environment which made the life of human being and other beings miserable. Such situation that exists in India is not new. A country, when freed from the British rules, it undertook several developmental policies by stepping into the field of industry, adopted various technology to make development faster, uses chemicals to increase productivity etc. forgetting the ill-effect of such technology and chemicals in the environment which turned the atmosphere more worsen to live a healthy life. Similarly, due to industrialisation need was felt towards the urbanisation providing civic amenities to the people and the development of hospital industry is one of such amenities among others which requires special mention here. The consequence of the establishment of various hospital industries on the one hand helped in increasing the health of the people, at the same time it started threatening the environment with the new menace on the other, the hospital borne wastes which is popularly known as bio-medical waste in India. This is inevitable. In fact, development and pollution has been considered as the *sine qua non* to each other. Therefore, the necessity of passing respective law to control, manage and reduce such wastes was felt and the outcome was the passing of the Bio-Medical Wastes (Handling & Management) Rules, 1998.

Prior to 1998 there was no such laws on the subject although the Apex Court showing concern on such wastes, for the first time brought to the day light the duty of the government for the safe disposal of such waste in the year 1996 in *Dr. B. L Wadhera's*<sup>53</sup> case. While delivering the judgement in this case the Hon'ble Supreme

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<sup>53</sup> *Dr. B. L. Wadhera v. Union of India*, AIR 1996 SC 2969.

Court directed the Delhi Municipal Corporation to take appropriate measures to deal with the same. In fact, the Bio-Medical Wastes (Handling & Management) Rules, 1998 has been considered as the outcome of the Apex Court's concern on the subject. Since then and till date various research work have been undertaken on the subject criticising its provisions and the outcome of which is the amendments of the Rules (2000 and 2003) for twice and the framing of draft Rules in the year 2011 to overcome the difficulties. Despite such an attempts, it was found that the Rules still suffered from further lacunaes and there is an urgent need to re-draft and to have a new rule on the subjects to cope up with the existing bio-medical waste related problem and this culminated in the passing of the new Bio-Medical Wastes Management Rules, 2016. With the passing of the new Rules the question remains whether the existing Rules is comprehensive and the problem of the bio-medical waste in the country could be resolve within the ambit of the new Rule or whether some more steps required to be taken to solve such problem within the ambit of the present Rules.

In search of the answer to the above questions, where on the one hand, there is an urgent need to control and manage such waste at the earliest possible without any delay under the existing regulatory framework to reduce the menace arising from such wastes, it is also important to have an overview of the Rules, 2016 on the other, to find out the drawbacks in the existing Rules, which is putting hindrances on the way for the proper and effective management of it. It is important to note here that not all wastes that comes under the term bio-medical waste is harmful. It is the hazardous substances involved in such wastes are highly infectious in nature and are the responsible for various infectious borne diseases and also are the cause of concern which need to be carefully segregated, treated and is to be disposed of properly. Although the quantity of hazardous waste is very meager out of the total generation of bio-medical wastes, it is considered as most harmful due to the infectious elements present in it. Therefore, in the quest to find out an immediate healthy relief to cope up with such menace, an elaborate analysis of the Rules have been made under this chapter concentrating mainly on the hazardous nature of such waste, so that it would be possible to reach to identify the root cause and thereby suggest and recommend certain measures highlighting on the actual problem the country is facing before making concluding remarks. Here, it is pertinent to mention that in the subsequent

chapter an analysis of the provisions of other relevant laws having relations with the bio-medical wastes as a whole have been made to understand whether an action may be properly undertaken under such laws against the generators who comes within its fore violating such provisions. In the same chapter an analytical study has also made of those specific Acts/Rules that are connected with the various types of bio-medical wastes. Bio-medical waste Rules, being the research topic, the researcher thought it fit to make an extensive analysis separately under this chapter which would help in finding the possible solution of the problem along with suggestive measure to mitigate the same.

Before starting with an extensive discussion on the topic it is relevant to focus on the Government's approach towards the effective management of bio-medical wastes in the light of national guideline and the measures adopted under the long term five-year policies. This would help in taking appropriate steps on the part of the generator of the bio-medical waste with a view to curve the menace involve in it.

### **7.2.1. National Guidelines on Hospital Waste Management, 2002**

It was issued by the Ministry of Health & Family Welfare (MoHFW), Government of India in March 2002. These guidelines include safety measures, waste management, training and related administrative functions in hospitals and its environment. As per the Guidelines, the head of the hospital shall form a Waste Management Committee (WMC) under his Chairmanship. The Committee shall meet regularly to review the performance of the waste disposal. The Committee is responsible for making hospital specific action plan for hospital waste management and for its supervision, monitoring implementation and looking after the safety of the bio-medical waste handlers<sup>54</sup>. The important aspects of these guidelines are the aim, definition and categories of Bio-Medical Wastes. The policy statement aims to provide for a system for management of all potentially infectious and hazardous waste in accordance with the Rules.

Besides these, the national guidelines have been clearly laid down as to transportation, treatment of different types of wastes, safety measures and training of

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<sup>54</sup>Government of India, "Guidelines for Bio-Medical Waste Disposal", Press Information Bureau, Ministry of Health & Family Welfare, (August 28, 2012).

medical and paramedical personnel. The constitution of the waste management committee with the head of the hospital as its chairman has been strongly advocated. Besides, co-ordination between the hospital agencies has been recommended. Finally the educative and co-operative angle of these guidelines is seen when the NGOs involvement in dissemination of information is solicited while laying down that healthcare units with treatment facilities should extend the same to others in the vicinity.

### **7.2.2 Infection Management and Environment Plan (IMEP), 2007**

In addition to the above, a National Policy Framework document and Operational Guidelines for Community Health Centres, Primary Health Centres and Sub-centres have also been developed by MoHFW in 2007, for implementation of Infection Management and Environment Plan under Reproductive and Child Health Programme to address the issues relating to infection control and waste management. The purpose of the IMEP is to ensure that all parties/stakeholders recognise that the maintenance of sanitary conditions, use of appropriate disinfection and sterilisation techniques, provision of potable water and clean air in the health care facilities and nosocomial infection control are the basic infrastructural requirements for delivery of Reproductive and Child Health (RCH) services.

Through a structured and systematic approach, the IMEP aims to bring in state-of-the-art, best practices in managing these health and environmental risks effectively. It comprises two volumes –

**Policy Framework:** A summary version that gives a broad overview and generic guidance to central and state level institutions on the establishment of a system for sound infection control and bio-medical waste management.

**Operational Guidelines:** Designed as an instruction manual for healthcare workers at PHC, CHCs and SCs and provides details of the procedures, plans and guidelines of infection control and waste management procedures.

While the Policy Framework is targeted to senior management, the Operational Guidelines are mainly for doctors, nurses and various levels of healthcare

workers. Hence, the range of the IMEP covers the entire chain of stakeholders in the healthcare system.

For infection control, it has come up with various steps to be followed while handling infectious bio-medical waste by insisting on the hand washing among others. Apart from hand washing, it also insisted on the personal protective equipments which include personal protective gears while handling waste, wearing head gears, eye covers (glasses), mask, apron, gloves and boots. These constitute the barrier for transmission of infections. Taking immunisation against Hepatitis B and Tetanus are the important universal precautions suggested by the IMEP. The plan also emphasises on the use of disinfectants such as bleaching powder and the procedure to follow in this regard<sup>55</sup>.

### **7.2.3 Guidelines of the Central Pollution Control Board (CPCB)<sup>56</sup>**

CPCB has brought out Guidelines that are relevant for the health sector as given below. Under the National Rural Health Mission these guidelines should be used wherever applicable.

#### **7.2.3.1 CPCB Manual on Hospital Waste Management, 2000**

CPCB brought out this technical guidance in the areas of bio-medical waste segregation, storage, transport and treatment. The CPCB manual gave special emphasis to incineration, covering incinerator emissions, maintenance requirements, operational problems & solutions, and pollution control systems.

#### **7.2.3.2 Guidelines for Universal Immunisation Programme**

Universal Immunisation Programme (UIP) in India is one of the largest health programmes in the world for giving vaccinations to children and women. The vaccination practice of the UIP so far involved the use of either glass or disposable syringes. Such waste generated in rural areas, particularly at outreach points, is a matter of concern. CPCB has prepared guidelines for disposal of biomedical wastes

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<sup>55</sup>Government of India, “Infection Management and Environment Plan” Guidelines for Healthcare Workers for Waste Management and Infection Control in Community Health Centres, Ministry of Health & Family Welfare, pg. 7 (March, 2007).

<sup>56</sup> *Ibid.*

that will be generated. The salient features of these Guidelines are captured in the Operational Framework included in this document.

### **7.2.3.3 Guidelines on Auto Disable (AD) Syringes**

Studies on injection safety has revealed that a significant number of injections are used in immunisation are unsafe. The Government of India decided to introduce Auto Disable (AD) syringes instead of glass or disposable syringes to minimise the risk of infections through reuse of inadequately sterilised and/or infected syringes. However the use of AD syringes will generate relatively large quantities of plastic bio-medical waste, which need to be disposed in an environmentally sound manner. This guidance is provided by CPCB in its Guidelines on AD syringes. This is similar (not contrasting) in content with the Guidelines on Universal Immunisation Programme.

### **7.2.3.4 Guidelines on Mercury-Contaminated Wastes**

CPCB has recognized that there is a possibility of waste containing mercury and its compounds to be above the permissible limit in terms of the concentration, and hence has to be regarded as hazardous. In November 2005, CPCB has written to all State Pollution Control Boards to make the segregation of mercury-contaminated waste materials a condition for granting authorisation to the healthcare facilities. CPCB also notes that new healthcare establishments will have to ensure the mercury-laden waste is properly segregated, treated and disposed

### **7.2.3.5 CPCB Guidelines for Bio-Medical Waste Incinerators**

CPCB Guidelines for bio-medical waste incinerators include requirements for the incinerator design and its air pollution control device, physical structures (incineration and waste storage rooms), operator qualifications, personal protection equipment, and emergency procedures.

## **7.2.4 National Health Mission<sup>57</sup>**

Under the National Health Mission (NHM), financial assistance is provided to State/Union Territory Governments within their resource envelope for Bio-medical

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<sup>57</sup> Government of India, “Disposal and Recycling of Bio-medical Waste” Press Information Bureau , Ministry of Health and Family Welfare, (March 3, 2015).



waste management and infection control activities in public health facilities based on their proposals in Programme Implementation Plan (PIP) of NHM. This includes support for Civil Works for Operationalising Infection Management & Environment Plan at health facilities, Human Resource for Biomedical waste management activities such as Incinerator Operators, procurement of equipment such as trolleys, autoclaves, incinerators, colour coded bins, and buckets etc., IMEP training of medical officers, district and state programme managers, health staffs etc., in Biomedical Waste Management Practices, IMEP protocols and activities.

### **7.2.5 Infection Control and Waste Management under National AIDS Control Project (NACP) III<sup>58</sup>**

The Programme Implementation Plan of NACP III has provided a detailed plan on infection control and waste management and recommended that good practices may be further tailored to suit the facility's needs. The Plan has been developed on the following framework:

1. **Waste Segregation and On-site Storage:** This Component includes segregation at source, availability of designated segregation points as close as possible to the generation points, good quality and adequately sized containers, use of non-chlorinated plastic bags, needle cutters and safety boxes, strict adherence to colour-coding provided in the Bio Medical Rules and compliance to the above to be ensured by programme implementers of NACP III.
2. **Collection and Transportation of Biomedical Wastes:** This section encompasses transport of waste to a central location, specially designated waste routes to avoid patient care areas within the facility, Special timing for transportation of biomedical waste to the central point, use of dedicated wheeled-containers, trolleys or carts to transport the waste to the collection/treatment site and training and provision of barriers for waste handlers.
3. **Treatment and Disposal of Biomedical Wastes:** It delineates, disinfection of used blood bags, syringes and other infectious plastic and liquid wastes in accordance with the existing Bio-medical Waste Rules, proper handling and

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<sup>58</sup> Government of India, Infection Control and Waste Management Plan for National AIDS Control Support Project (NACSP)" National AIDS Control Organisation, Ministry of Health & Family Welfare, pg.36 (2012-17), (December, 2012).

disinfection of infected linen and maintenance of a log book for quantity of waste generated by type, name of waste handler, time of emptying waste container, time of cleaning the containers and pouring disinfectant.

4. Sharps Management: This section prescribes use of barrier protection; segregation and storage in puncture-proof containers at the point of generation; mutilation of sharps before treatment and disposal; disinfection and appropriate disposal of mutilated sharps; final disposal in a secured landfill or sharp pits and mandatory immunisation against Hepatitis B for all the health care workers.
5. Infection Control: The four key areas of infection control recommended are immunisation against, nosocomial infections, availability and use of barrier protection, timely management of PEP, and creating awareness about infection control at all levels.

#### **7.2.6 National Long-term Policy on Bio-medical Waste under the Five-Year Plans**

It was for the first time under the 9th Five Year Plan 1997-2002<sup>59</sup> the concern for the bio-medical waste had seriously undertaken considering it a part of long-term policy matter for managing it. This was due to the reason that the framing of the Rule on the subject had only thought for and given effect to during these period. After the preparation of the draft Rule and getting final assent in the year 1997 finally it was notified in the month of July 1998. The plan made it mandatory that every hospital located in and around Delhi must have their own disposal system and shall not dump into Municipal bins. The effect of such plan made it possible to follow the direction and implement the same throughout the country.

Under 10th Five Year Plan<sup>60</sup> it was suggested for the strict rules for proper collection, storage, transportation, treatment and disposal of bio-medical waste and in order to give effect of such rules, the hospitals are supposed to install treatment facilities like incinerators, autoclaves etc. and the plan required that these treatment facilities should operate at designed efficiency level. The use of autoclaves and check

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<sup>59</sup>Government of India, Planning Commission, Ninth Five Year Plan, 1997-2002.

<sup>60</sup>Government of India, The Bio-Medical Waste, Tenth Five Year Plan, 2002-07, Forest and Environment.

by efficiency test of autoclaves by spore testing methodology was made compulsory to be followed by the health care authority as part of the hospital waste management system.

In the meeting of the Steering Committee held during the 11th five year plan<sup>61</sup> for the management of bio-medical wastes it was decided that the Guidelines for Management and Handling of Bio-medical Wastes shall be finalised after incorporating the comments of the members of the Steering Committee. It was also suggested certain amendments to the Bio-medical Rules required to be made in order to avoid confusion created by the existing Rules. Along with this, the Plan also envisaged a clear commitment to pursue a development agenda which is environmentally sustainable, based on a strategy that translates the vision of environmental sustainability which require that environmental concerns are given a high priority in development planning at all levels.

The 11th five year plan has also proposed for the implementations of “action plans” formulated by Ministry of Health and Family Welfare to take infrastructural development of bio-medical waste. The Central Pollution Control Board (CPCB) suggested for an Environmental Monitoring and Governance because CPCB serves as a technical wing of the Ministry and coordinates with the State Pollution Control Boards (SPCBs)/Pollution Control Committees (PCCs) for implementation of plans and programmes relating to abatement of pollution. The Board had also suggested for the proper and effective implementation of various Rules including the bio-medical waste rule.

In order to monitor hazardous substance management under the 11th Plan, a roadmap has been evolved for proper management of wastes in the country, including issues such as Municipal solid waste, plastic waste, e-waste, Bio-Medical wastes etc. It was suggested for a co-ordinated programme for analysis of trends, for monitoring and work on strategies and support for development of suitable technologies and implementation thereof in an effective manner. Assistance for projects for treatment and disposal of hazardous and biomedical waste was also a part under this plan. The Plan also encourages to have more Common Bio-Medical Waste Treatment Facilities

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<sup>61</sup> 2007-2012.

(CBMWTF) from 126 CBMWTF, including 13 under installation, in the country as on March, 2005<sup>62</sup>.

In the 11<sup>th</sup> five year plan it was also recommended<sup>63</sup> that some measures are required to be adopted for the minimisation of waste which also includes hazardous and bio-medical waste among others. They are:

Hazardous Waste:

1. To strengthen the SPCB's, facilitating them in development of technical skills.
2. To identify organisations and agencies for carrying out the field level activities;
3. To identify institutions for carrying out activities that could be applied in the field directly;
4. Strengthening of laboratories for carrying out analytical work;
5. Develop and implement viable models of public-private partnerships for setting up and operating common treatment storage disposal facilities for toxic and hazardous waste, industrial and Bio-Medical Waste, on payment by users;
6. Develop and implement strategies for clean up of pre-existing toxic and hazardous waste dumps, in particular, in industrial areas, and reclamation of such land for future, sustainable use;
7. Give legal recognition to, and strengthen the informal sector systems for collection and recycling of various materials; in particular enhance their capacity and provide access to appropriate technologies and institutional finance;
8. Provide subsidy or tax exemption to waste management activities;
9. Sales and service tax exemption for recyclable waste that is recycled in an environmentally sound manner;

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<sup>62</sup> Government of India, Report of the Steering Committee on the Environment and Forests Sectors for the Eleventh Five Year Plan, 2007-2012 pg. 21 Planning Commission, New Delhi, (2007).

<sup>63</sup> *Ibid* at pgs. 54-55.

10. Facilitate demonstration projects and provide subsidies for application of new technologies such as plasma technology for more efficient and environment friendly disposal hazardous wastes.

**Bio-Medical Waste:**

1. To facilitate in establishing more common and shared facilities;
2. Specific training programmes to be funded and organised for the medical professionals, paramedical professionals and other staff working in the health care institutions;
3. Special training programmes for safai karamcharis;
4. Awareness programmes to be organized through media and other sources for general public; and
5. To involve local communities and NGO's.

Under the 12th five year plan<sup>64</sup>, the main emphasis is on “Managing the Environment and Ecology”. The Planning Commission has identified twelve Strategy Challenges for the approach paper with the five components and the Waste management and Pollution Abatement being one of the important components has find places in it. This includes bio-medical waste management. The management of waste being an important part of the general expectations of the citizens covering healthy surroundings must be given utmost priority so the citizens can live in a pollution free environment. The 12th Plan has suggested for the institutional mechanisms, infrastructure and science and technology in the management of environment and ecology and it has also specifically suggested the following measures<sup>65</sup>:

1. Encourage 4 R's (Recycle, Reuse, Reduce and Remanufacture) and co-processing of Hazardous Waste for recovery of energy.
2. Incentivise public-private partnership for creating the required infrastructure for Setting up of Treatment Storage and Disposal Facilities (TSDF) for hazardous waste management across the country.

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<sup>64</sup> 2012-2017.

<sup>65</sup> Government of India, Managing the Environment and Ecology, Twelveth Five Year Plan 2012-2017 pg. 4, Planning Commission.

3. Ensure Segregation of Bio-medical wastes as per existing rules and the infectious and hazardous wastes treated in dedicated facilities. Common facilities are to be setup.
4. Enhance recycling facilities for E-wastes in the country.
5. Ensure Municipal solid waste segregation, collection and setting up of facilities for complete disposal. Where ever possible recycling and processing has to be ensured during the 12th Plan to protect our people and the environment.
6. Green belt for dust and noise abatement and odour mitigation is considered essential.

Therefore, according to the approach paper of 12<sup>th</sup> five year plan the problem relating to bio-medical waste management has given emphasis considering it as an important aspect of environmental concern and if it can be successfully implemented it would be a great achievement the fruit of which can be seen in near future.

#### **7.2.7 The Bio-Medical Waste Management<sup>66</sup> Rules, 2016**

“New Bio-Medical Waste Management Rules will change the way Country used to manage waste earlier; make a big difference to Clean Indian Mission”: Shri Prakash Javadekar, Union Minister of State (IC) Environment, Forest & Climate Change<sup>67</sup>.

Notified on March, 28, 2016 in the Gazette of India, the Centre published new Rules for the management of bio-medical wastes in the country and prescribes more stringent standards for incinerators to reduce emissions and envisage the creation of a bar-code system for bags containing such refuse. The Rules is applicable to all providing “health care facility” and according to Rule 3(j) of the new Rules it 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. The Rules also bring vaccination, blood donation and

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<sup>66</sup> As per the Bio-Medical Waste Management Rules, 2016 the word ‘Management’ includes ‘Handling’.

<sup>67</sup> New Rules Notified for Management of Bio-Medical Waste, *The Times of India*, March 27, 2016.

surgical camps under its ambit while providing for pre-treatment of laboratory and microbiological waste and blood samples and bags on-site as prescribed by the World Health Organisation (WHO) and National Aids Control Organisation (NACO)<sup>68</sup>. Apart from the above mentioned features the Bio-Medical Wastes Management Rules, 2016 laid down the following feature:

- a) The ambit of the rules has been expanded to include vaccination camps, blood donation camps, surgical camps or any other healthcare activity.
- b) Phase-out the use of chlorinated plastic bags, gloves and blood bags within two years.
- c) Pre-treatment of the laboratory waste, microbiological waste, blood samples and blood bags through disinfection or sterilisation on-site in the manner as prescribed by WHO or NACO.
- d) Provide training to all its health care workers and immunise all health workers regularly.
- e) Establish a Bar-Code System for bags or containers containing bio-medical waste for disposal.
- f) Report major accidents.
- g) Existing incinerators to achieve the standards for retention time in secondary chamber and Dioxin and Furans within two years.
- h) Bio-medical waste has been classified in to 4 categories instead 10 to improve the segregation of waste at source.
- i) Procedure to get authorisation simplified. Automatic authorisation for bedded hospitals. The validity of authorization synchronised with validity of consent orders for Bedded HCFs. One time authorisation for Non-bedded HCFs.
- j) The new rules prescribe more stringent standards for incinerator to reduce the emission of pollutants in environment.
- k) Inclusion of emissions limits for Dioxin and furans.
- l) State Government to provide land for setting up common bio-medical waste treatment and disposal facility.

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<sup>68</sup> *Ibid.*

- m) No occupier shall establish on-site treatment and disposal facility, if a service of `common bio-medical waste treatment facility is available at a distance of seventy-five kilometer.
- n) Operator of a common bio-medical waste treatment and disposal facility to ensure the timely collection of bio-medical waste from the HCFs and assist the HCFs in conduct of training

Although we have new Bio-Medical Waste Management Rules, 2016, but any discussion on this Rule without an extensive analysis of the Bio-medical Waste (Management & Handling) Rules, 1998 including its amendments<sup>69</sup> would be futile because if the researcher confines its analytical research only on the new Rules, 2016 it would not be possible to extract and identify the actual problems and a fair doctrinal research would be far from the truth. Therefore, in order to get a detailed overview of the existing Rules it is important to make an extensive analysis of the Bio-medical Waste (Management & Handling) Rules, 1998 including its amendments to understand the subject properly.

### **7.3 An Overview of the Bio-Medical Waste (Management & Handling) Rules, 1998 and its amendments including the draft Bio-Medical Waste (Management & Handling) Rules, 2011**

The Environment (Protection) Act, 1986 makes possible the issuance of many rules and notifications. Incidentally, in 1989 the Government of India, in exercise of powers conferred under sections 6<sup>70</sup>, 8<sup>71</sup> and 25<sup>72</sup> of the Environmental (Protection) Act, 1986 formulated the Hazardous Waste (Management & Handling) Rules, 1989.

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<sup>69</sup> 1<sup>st</sup> Amendment was made on 06/03/2000, 2<sup>nd</sup> on 17/09/2003 and on 24/08/2011 a draft Bio-medical Wastes Rules, 2011, the 3<sup>rd</sup> Rules was notified.

<sup>70</sup> Section 6 (1) of the Environmental (Protection) Act, 1986 says-The Central Government may, by notification in the Official Gazette, make rules in respect of all or any of the matters referred to in Section 3. (2) In particular, and without prejudice to the generality of the forgoing power, such rules may provide for all or any of the following matters, namely: (a) The standards of quality of air, water or soil for various areas and purposes. (b) The maximum allowable limits of concentration of various environmental pollutants (including noise) for different areas. (c) The procedures and safeguards for the handling of hazardous substances. (d) The prohibition and restrictions on the handling of hazardous substances in different areas. (e) The prohibition and restrictions on the location of industries and the carrying on of processes and operations in different areas. (f) The procedures and safeguards for the prevention of accidents which may cause environmental pollution and for providing for remedial measures for such accidents.

<sup>71</sup> The Section states that “No person shall handle or cause to be handled any hazardous substance except in accordance with such safeguards as may be prescribed”.

<sup>72</sup> The Section deals with “power to make rules”. The Section reads as, “the procedure in accordance with and the safeguards in compliance with hazardous substances shall be handled or caused to be handled under Section 8”.



At the time of formulation of the hazardous waste Rules there was no such intention to include the bio-medical wastes which involved within its ambit, some elements of hazardous wastes also, although in a very small quantity. Later on, a draft notification on Bio-Medical Wastes (Management and Handling) Rules, 1995 was issued on 24th April, 1995 vide S.O. 378(E) II 3(ii) Gazette of India Extra., Sl. No.19 and objections were invited from public. After duly considering necessary amendment in the Draft Rules, the Bio-Medical Waste (Management & Handling) Rules, 1998 finally came into operation with effect from 20th July, 1998 vide S.O. 630 (E) II 3(ii), Gazette of India, Extra Serial No. 460. These Rules are applicable to all persons who generate, collect, receive, store, transplant, dispose or handle Bio-Medical Waste in any form.

The Rules contain 14 Sections, 6 Schedules and 5 Forms. Primarily the Rules focus on management and handling of bio-medical waste by prescribing standards as to treatment and disposal. As a corollary, these Rules mandate compliance of different procedures as to segregation, packaging, transportation and storage. These Rules also create duties on every occupier of an institution generating bio-medical waste, which includes hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank etc. These Rules also envisages a prescribed authority for the purpose of enforcement.

### **7.3.1 Meaning of Bio-Medical Waste**

The analysis of the various provisions of the bio-medical waste Rules is not possible and would remain incomplete without understanding the meaning of various terms that have been defined under it. The exact interpretation of those provisions would be possible only if they are interpreted in the light of those terms whenever confusion arises and this would help in understanding properly the scope and ambit within the framework of which the justification of those provisions can fairly be made.

According to Sub-rule (5) of Rule 3 of the Bio-Medical Waste (Management & Handling) Rules, 1998, Bio-Medical Waste means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or in research activities pertaining thereto or in the production or testing of biological and including categories mentioned in Schedule I.

According to Rule 3(6) “biologicals” means any preparation made from organisms or micro-organisms or product of metabolism and biochemical reactions intended for use in the diagnosis, immunisation or for the treatment of human beings or animals or in research activities pertaining thereto.

In this connection it is important to highlight on some important points that has brought changes in the definition of the term ‘bio-medical waste’. Originally, the term ‘bio-medical waste’ did not include ‘health camps’. But under the new Rules, 2016 the scope of the definition has given a wide range with regard to its applicability including health camp also. While in 2011, the bio-medical waste Rules 1998 were amended to include all persons who generate, collect, receive, store and transport such waste, the new Rules 2016 bring more clarity by specifying that vaccination camps, blood donation camps, surgical camps and all other health care facilities have been included.

### **7.3.2 Applicability of the Rules**

The scope of the applicability of the new Rules has been broadened under Rules 2 to include within its domain 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. It is also applicable to those providing health care facilities at home. Earlier, as per the bio-medical waste Rules, 1998 read with the draft bio-medical waste Rules 2011, it was confined only to all who generate, collect, receive, store, transport, treat, dispose, or handle such waste and thereby created confusions as to who are those specific persons to be brought within the purview of this Rules. The new Rules, 2016 has cast away all the doubts with regard to its applicability making it specific and the controversy which existed has been set off so far. The new Rules also made it clear by providing detail specification as to whom this Rules are not applicable. Thus, according to the new Rules, it shall not apply to radioactive wastes, hazardous chemicals, solid wastes, lead batteries, hazardous wastes, e-waste and hazardous micro organisms as these wastes comes under the

respective Acts/Rules<sup>73</sup> enacted so far to tackle the same. This is because the persons who are handling all the above types of wastes are already covered by the respective Acts/Rules and in case of violation of either of the Acts or Rules, an action would successfully be made for not following the strict regulations in this connection.

### **7.3.3 Categories/Types<sup>74</sup> of Bio-Medical Waste**

As per the Bio-Medical Waste (Management & Handling) Rules 1998, the bio-medical waste has been grouped into the following ten categories/types under Schedule I:

1. Human Anatomical Waste: Pathological waste consists of human tissues, organs, body parts, human fetuses, blood, body fluids.
2. Animal Waste: This category contains 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.
3. Microbiology & Biotechnology Waste: Wastes from laboratory cultures stocks or specimens of micro-organisms, live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biologicals, toxins, dishes and devices used for transfer of cultures.
4. Waste Sharps: Sharps are items that could cause cuts or puncture wounds. This category includes needles, hypodermic needles, syringes, scalpels, blades, knives, infusion sets, saws, broken glass and nails. This includes both used and unused sharps. Owing to their property of invading the primary defence barrier of the body i.e. the skin they are the most potent way of transmission of blood borne pathogens.
5. Discarded Medicines and Cyto-toxic Drugs: Such waste comprised of outdated contaminated and discarded pharmaceutical products, drugs, vaccines and sera. Cytotoxic or antineoplastic drugs, the principal substances in this

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<sup>73</sup> For example, The Atomic Energy Act, 1962, The Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989, The Municipal Solid Waste (Management and Handling) Rules, 2000, The Batteries (Management and Handling) Rules, 2001, The Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008, etc.

<sup>74</sup> 2<sup>nd</sup> Amendment, 2000 of the Rule: In the sub-heading, after the words, “waste category” the word “Type” shall be added.

category, have the ability to kill or stop the growth of certain living cells and are used in chemotherapy of cancer.

6. Solid Waste<sup>75</sup>: Items contaminated with blood and body fluids including cotton, dressings, soiled plaster casts, linens, beddings, other materials contaminated with blood.

7. Solid Waste: Wastes generated from disposable items other than the waste sharps<sup>76</sup> such as tubings, catheters, intravenous sets etc. Basically these include plastics used in patient care.

8. Liquid Waste: Waste generated from laboratory and washing, cleaning, housekeeping and disinfecting activities.

9. Incineration Ash: Incineration ash of any biomedical waste is categorized as hazardous waste under the Hazardous Waste Rules. The ash can have heavy metals and can be contaminated with toxins such as dioxins and furans.

10. Chemical Waste: Chemicals used in production of biological and chemicals used in disinfection, as insecticides etc.

It is interesting to note that the Bio-Medical Waste (Management and Handling) Rules 1998 which was originally contained ten categories of wastes have been reduced to eight under the draft Bio-Medical Waste (Management & Handling) Rules, 2011. The 2011 Rules have discarded Category No. 8 (containing liquid waste generated from laboratory, cleaning and washing and disinfection activities) and Category No. 9 (containing incineration ashes). However, laboratory wastes listed in Category 8 has been included in the present Category 1 under the head of type of waste<sup>77</sup>. The reduction of number of various categories/types to minimum is with a view to avoid confusions and overlapping regarding the use of various colour coded containers/bags. It has been seen that so long there exist as many containers/bags of different colours, there is every possibility of mixing up of a particular type of waste with the others and the very purpose of management of the bio-medical wastes gets be affected. This is due to the fact that for the proper management of such wastes the very first step is to segregate the same by identifying of specific colour coded containers/bags where specific categories/types of the wastes are to be kept for the

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<sup>75</sup> By the 2<sup>nd</sup> amendment made in 2003 the word “soiled” is substituted by “solid”.

<sup>76</sup> “Sharps” has been substituted in place of “Shapr”.

<sup>77</sup> Category 1(f), Schedule I of the Bio-Medical Waste Management Rules, 2016.

time being not beyond a period of forty eight hours<sup>78</sup> and thereafter the same is to be send for proper treatment as per the existing Rules. This would not only help in reducing the cost of keeping many containers/bags, the risk factor involved in handling the hazardous nature of the bio-medical wastes would also reduced. This would also foster the proper treatment and disposal of the wastes as per the provisions of the Rules to overcome the difficulties. If situation exist and it would not be possible to follow the next step beyond the prescribed 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.

Unlike the draft Rules, 2011, the Bio-Medical Waste Management Rules, 2016 also has made a drastic step by further reducing the categories of bio-medical waste to four only and thereby made an effort to clear all the ambiguities that had existed earlier under the previous draft Rules and its amendments. The different types of bio-medical wastes that have been placed under four categories of the Bio-Medical Wastes Management Rules, 2016<sup>79</sup>, are as follows:

#### **7.3.3.1 Category I**

- a. Human and Animal Anatomical Waste- Consisted of Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).
- b. Animal Anatomical Waste- Such waste includes experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.
- c. Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components.

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<sup>78</sup> As per Rule 8(7) of the Bio-Medical Waste Management Rules, 2016, maximum period prescribed is 48 hours.

<sup>79</sup> SCHEDULE I [See rules 3 (e), 4(b), 7(1), 7(2), 7(5), 7(6) and 8(2)] Part-1 of the Bio-Medical Wastes Management Rules, 2016.

- d. Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.
- e. Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.
- f. Chemical Liquid Waste : Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.
- g. Discarded linen, mattresses, beddings contaminated with blood or body fluid.
- h. Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.

#### **7.3.3.2 Category II**

Contaminated Waste (Recyclable) is divided into (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and (b) vaccutainers with their needles cut and gloves.

#### **7.3.3.3 Category III**

Termed as Waste Sharps such category consists of metals, needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes used, discarded and contaminated metal sharps.

#### **7.3.3.4 Category IV**

- a. Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.
- b. Metallic Body Implants

An interesting development in the waste category is that contaminated waste which is recyclable, waste sharps including metals and glassware and metallic body implants are the three categories of bio-medical wastes that has find places under the Rules, 2016. It is to be noted that the reduction of the number of category does not mean the removal of particular type of waste from the purview of the new Rules, it has, in fact, by way of including new types of wastes extended the ambit of the Rules. The purpose behind such reduction in four categories is to avoid the confusion that was subsisted earlier with regard to the use of particular type of colour coded containers/bags at the time of segregation of different types of wastes. Now considering the nature of the wastes and to remove such confusions, Category I included eight numbers of categories of wastes that is to be stored only in one colour coded container i.e. yellow container or bag with a view to follow the appropriate treatment and disposal methods.

#### **7.4 The Process of Segregation of Bio-Medical Waste**

After identifying different categories of wastes mentioned above, the next important step to be followed is the segregation. This would help in the effective management<sup>80</sup> of the bio-medical waste because if the different types of such waste are not segregated properly, the whole process of management would be in vein. For the purpose of segregation, such wastes can be broadly classified into the following categories:

- General or non-hazardous/non-infectious medical waste.
- Infectious or hazardous medical waste.

In the process of minimising the risk factor present in the bio-medical waste, segregation is considered as the most important steps that needs careful attention

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<sup>80</sup> Rule 3 (1) of the Bio-Medical Waste Management Rules, 2016 defines management as “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.

because if the non-hazardous bio-medical waste involving zero risk factor is not segregated from hazardous bio-medical waste of highly infectious in nature, the whole wastes would become infectious and the whole process of bio-medical waste would be jeopardised.

Under the Rule 6<sup>81</sup> of the Bio-Medical Waste (Management & Handling) Rules, 1998 provision have prescribed for segregation of the bio-medical wastes. According to Sub-rule 2 of Rule 6, the waste shall be segregated into containers/bags at the point of generation in accordance with Schedule II prior to its storage, transportation, treatment and disposal. Schedule II prescribed different coloured disinfected and puncture proof plastic bags/containers in which specific categories of bio-medical wastes are to be packed after identifying its nature except liquid and chemical wastes. Such wastes being liquid is to be disinfected at the first instance and then to discharge into the drain.

On the other hand under Rule 8(2) of the Bio-Medical Waste Management Rules, 2016 such waste categorised four in number 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. While segregating the particular bio-medical waste the first step would be to identify it and then segregate the same in accordance with the Rules. The identification of the particular type of wastes is very important in the sense that if properly identified, it would help in reducing the risk factor involved in such waste and thereby would foster towards the management and eradicating the problem of the bio-medical wastes. The present Rule prescribed with same rule as it was present under the draft Bio-Medical Waste (Management & Handling) Rules, 2011. In addition, the second part of Schedule I i.e. Part 2 of the Bio-Medical Waste Management Rules, 2016 lay down that all plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable. Such additional protection is with a view to insisting on the use of punctured proof plastic bags so that the risk factor involved in the use of ordinary plastic bags could be avoided. If any accident takes place due to the use of such plastic bags, unlike the draft Rule, 2011, the new Rule, 2016 has strictly requested for

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<sup>81</sup> Rule 6(2) of the Bio-Medical Waste Management Rules, 2016: “Bio-Medical Waste shall be segregated into containers or bags at the point of generation in accordance with Schedule II prior to its storage, transportation, treatment and disposal. The containers shall be labeled according to Schedule III.



reporting accidents that might take place at the time of handling<sup>82</sup> the same right from segregation till its disposal. Under Rule 15, in case of any major accident<sup>83</sup> at any institution or facility or any other site while handling bio-medical waste, the authorised person shall intimate immediately to the prescribed authority about such accident and forward a report within twenty-four hours in writing regarding the remedial steps taken in Form I. Information regarding all other accidents and remedial steps taken shall be provided in the annual report in accordance with rule 13 by the occupier.

### **7.5 Duty of the Occupier<sup>84</sup> in segregating of Bio-Medical Waste**

The new Rules 2016 has, as part of segregation, imposes certain duties on the occupier under Rule 4 which are as follows:

- Duty to 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. Such duty also include that there shall be no secondary handling, pilferage of recyclables or inadvertent scattering or spillage by animals<sup>85</sup>.
- Duty to 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<sup>86</sup>.

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<sup>82</sup> Rule 3(i) of the Bio-Medical Waste Management Rules, 2016 defines ‘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.

<sup>83</sup> Under Rule 3(k) of the Bio-Medical Waste Management Rules, 2016 ‘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.

<sup>84</sup> As per Rule 3(m) of the Bio-Medical Waste Management Rules, 2016 ‘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;

<sup>85</sup> Rule 4 (b) of the Bio-Medical Waste Management Rules, 2016.

<sup>86</sup> Rule 4 (h) of the Bio-Medical Waste Management Rules, 2016.

- To 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<sup>87</sup>.
- For ensuring occupational safety of all its health care workers and others involved in handling of biomedical waste the occupier should provide with appropriate and adequate personal protective equipments<sup>88</sup>.
- To 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<sup>89</sup>.

Similar duties have been conferred on the operator of the common bio-medical waste treatment and disposal facilities which is discussed separately in this chapter.

It is interesting to note that in the Bio-Medical Waste (Management & Handling) Rules, 1998 there was no specific mention of the duty to be discharged by the occupier at the time of handling or segregating such waste. Rule 4<sup>90</sup> prescribed the duty in general without mentioning it specifically. It created confusions as to what are those specific duties the non-fulfillment of which would make the occupier responsible. To remove such difficulties the draft Bio-Medical Waste (Management & Handling) Rules, 2011 lay down certain additional duties relating to the segregation which is to be read along with the general duty formulated under the Rules of 1998. Under the new Rules, 2016, there are altogether twenty duties that are required to be discharged by the occupier in the process for the management of bio-medical waste to ensure that while handling of such waste it should not have any adverse effect to human health and the environment<sup>91</sup>.

In order to ensure whether the health care institutions are acting in accordance with the Rule, Rule 14 prescribed the duty on the authorised person<sup>92</sup> for the

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<sup>87</sup> Rule 4 (j) of the Bio-Medical Waste Management Rules, 2016.

<sup>88</sup> Rule 4 (l) of the Bio-Medical Waste Management Rules, 2016.

<sup>89</sup> Rule 4 (m) of the Bio-Medical Waste Management Rules, 2016.

<sup>90</sup> Under Rule 4 of the Bio-Medical Waste Management Rules, 2016, It shall be the duty of every occupier of an institution generating bio-medical 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>91</sup> Rule 4 (a) of the Bio-Medical Waste Management Rules, 2016.

<sup>92</sup>Rule 3 (d) of the Bio-Medical Waste Management Rules, 2016 defines authorized person as “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

maintenance of records in connection with the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for a period of five years as per the rules and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be which will be verified and inspect by the prescribed authority or the Ministry of Environment, Forest and Climate Change at any time.

## **7.6 The Process of Packaging into the Colour Coded Containers/Bags**

After segregation of the bio-medical wastes the same is to be packed or stored into the containers/bags of specific colours. According to Rule 6 of the Bio-Medical Waste (Management & Handling) Rules, 1998, after segregation of wastes into infectious and non-infectious category it should be packed properly. The infectious waste which has packed into specific colour coded containers/bags shall be treated and disposed of in accordance with Schedule I. The non-infectious or non-hazardous waste shall be picked up and transported by the Municipal authority at municipal dump site. Schedule II of the Rules, 1998 provides for colour coding for the containers/bags in order to segregate the biomedical waste appropriately which are:

- Yellow plastic bag that needs to incinerate or deep buried may contain human anatomical waste, animal waste, microbiological waste and soiled waste.
- Red disinfected container or plastic bag that need to be autoclave, disinfected with chemical, or microwaved used for plastic waste and chemical treatment for microbiological waste, soiled waste and solid waste.
- Blue or white plastic bag or puncture proof container need to autoclave, microwave, chemical treatment and destruction or shredding which includes wastes like waste sharps, solid waste etc.
- Black plastic bag that used to be sent for secured landfill or burial incineration, used for discarded medicines and cytotoxic drugs, and chemical solid waste.

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these rules and the guidelines issued by the Central Government or the Central Pollution Control Board, as the case may be.

Although, Schedule II of the Rule provides for a number of options or alternatives in establishing a colour coded waste management and segregation systems but it has introduced too many colour coded bags. It is very difficult to accommodate all colour coded bags in valuable space of the hospital. This raises the complexities for which an effective system should be adopted which will provide a simple method. As per the draft Bio-Medical Waste (Management & Handling) Rules, 2011 untreated bio-medical wastes shall not be mixed with other wastes and shall be segregated into four types of colour coded containers/bags at the point of generation in accordance with Schedule II. There was overlapping with regard to colour coding and segregation of waste. For instance, wastes under category 3 and 6 can be collected either in yellow or red bags. Similarly, wastes under category 7 may be collected either in red or blue bags. This caused confusion in segregation. In the Rules, 2011 colour coding for containers for collection of various categories of bio-medical wastes has been clearly specified to avoid overlapping and confusion by way of allotting one colour code to each category of waste.

Under the new Bio-Medical Waste Management Rules, 2016 also the number of colour coded containers has reduced to four in number (yellow, red, white and blue) and included the same in Schedule I along with the different categories of wastes and thereby tried to remove all the difficulties existed earlier while handling the particular type of wastes using appropriate containers/bags. The minimisation of the colour coded containers/bags does not mean that a particular kind of biomedical waste is not being adhered to. What it means is that all types of wastes have been compiled in four categories for ease of segregation at a healthcare facility. For example, for category I waste (eight in number) yellow coloured non-chlorinated bags have been prescribed. Red coloured non-chlorinated plastic bags or containers has been prescribed for category II type of waste. White translucent puncture proof, leak proof and tamper proof containers are for category III type of waste and lastly, for category IV wastes, i.e. glassware, metallic body etc. cardboard boxes with blue coloured marking have been prescribed.

The Rules, 2016 also talked about phasing out of the chlorinated plastic bags, gloves and blood bags within two years to eliminate emission of dioxins and furans from burning of such wastes. According to Part 2 of Schedule I all plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste

Management Rules shall be applicable. A bar code system has also provided for by imposing a duty on the occupiers and the operators of common waste treatment facility under Rule 4 (i) and Rule 5(c) respectively to establish the same for bags/containers containing bio-medical waste and immunisation of health workers upon their induction and after every one year interval.

The following are the criteria recommended by the International Committee of Red Cross for choosing plastic bags: appropriate size for the container and the quantity of waste produced, sufficiently thick (70 µm – ISO 7765 2004) and of suitable quality (tear-resistant), non-halogenated plastic (no PVC). Anatomical waste cannot always be collected in yellow plastic bags for cultural or religious reasons. It must be treated in accordance with local customs (often buried). Chemical and pharmaceutical wastes must be sorted and treated separately. The sub-categories include mercury wastes, light bulbs, batteries, photographic developers, laboratory chemicals, pesticides and medicines. Bags and containers must be closed whenever they are two-third full<sup>93</sup>.

## **7.7 Labelling**

Another important step in the process of the management of bio-medical wastes after segregating and storing the same in different containers/bags is the labelling of the containers/bags. Strict rules have been prescribed by taking special care of the wastes which is infectious in nature. Under Schedule III of the Bio-Medical Waste (Management & Handling) Rules 1998 read with Rule 6 it is prescribed that such containers/bags should be non-washable and there should prominently visible the tag 'handle with care'. According to sub-Rule 2 of Rule 6 the containers/bags shall be labelled according to Schedule III. Provision has also been laid down for the label of the vehicle transporting the bio-medical wastes under Schedule IV read with Rule 6. In addition to the label prescribed in Schedule III, the label on the vehicle should consist of the detailing as to the waste category number, classes of waste alongwith the sender's and receiver's name and address on it including phone number, telex number etc. Under sub-Rule 3 of Rule 6 if a container

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<sup>93</sup> International Committee of the Red Cross, "Medical Waste Management" pgs. 72-73, (November, 2013), Available at: <https://www.icrc.org/eng/assets/files/publications/icrc-002-4032.pdf> (Last visited on Nov. 3, 2016).

is transported from the premises where bio-medical waste is generated to any waste treatment facility outside the premises, the container shall, also carry information as per Schedule IV.

Rule 8(3) and 8(5) of the Bio-Medical Waste Management Rules, 2016 have provided with the same criteria to be complied, with minor changes. Under the earlier Rules, 1998 although mention was made of labelling of the containers/bag as well as of vehicle carrying the waste but it did not make anyone responsible if the same is not followed. The new Rule by way of casting duty on the operator of the common bio-medical waste treatment facilities prescribed that for the purpose of off-site bio-medical waste treatment and disposal the vehicle carrying the same should be labeled as provided in the Schedule IV Part A. The criteria are the same as it was provided under the old Rule. Whereas Part B lays down for the label of vehicle carrying such wastes along with necessary information as required which is also same as it was in the earlier Rule.

### **7.8 Treatment and Disposal**

The purpose of treatment is to reduce the potential hazard present in the bio-medical waste so that it would be possible to protect the environment from its harmful effect. Rule 5 read with Schedule I of the Bio-Medical Waste (Management & Handling) Rules, 1998 provides large number of modes through which a particular bio-medical waste shall be treated and disposed of. These include incineration, autoclaving, microwaving, mutilation or shredding, chemical treatment or disinfection, land fill and deep buried and discharge in drains. Syringes, needles and gloves after use should always be disinfected with freshly prepared bleaching powder solution, i.e. 1% hypochlorite solution or autoclaved before mutilation or shredding. Such treatment and disposal was to be made in accordance with the standards prescribed in Schedule V. Different treatment and disposal methodology have been prescribed under the Bio-Medical Waste (Management & Handling) Rules, 1998, for example, for categories 1, 2, 3 only incineration treatment method have been provided. For categories 4 autoclaving, microwaving, mutilation or shredding, for categories 5 and 6 alongwith incineration, destruction and disposal in secured landfills and autoclaving or microwaving treatment methods have been prescribed. For solid (category 7), liquid (category 8) and chemical (category 10) wastes, disinfection by

chemical treatment with autoclaving or microwaving and thereafter discharge into drains are required to be followed and finally for category 6 waste disposal in municipal landfill is to be adopted.

Schedule II read with Rule 6 of the same Rules, 1998 also prescribed treatment and disposal of colour coded containers/bags. Incineration/deep burial is for yellow plastic bags (categories 1, 2, 3 and 6). Red disinfected containers/plastic bags consisting of wastes of categories 3, 6 and 7 are to be autoclaved or microwaved including chemical treatment. For category 4 and 9, where blue or white translucent plastic puncture proof bag has been prescribed, the treatment and disposal methods that have been prescribed for Categories 3, 6, and 7 was to be adopted. Lastly, the black plastic bags had to be disposed of in secured landfill containing wastes of categories 5, 9 and 10. It is also prescribed under the note of the Schedule that the waste collection bags for collection of different types of wastes which shall be incinerated should not be of chlorinated plastic because the toxin and furans that will be formed during incineration are harmful to the environment. Categories 8 and 10 do not required any containers/bags being liquid waste and for the same different treatment methods have been prescribed.

Under the draft Bio-Medical Waste (Management & Handling) Rules, 2011 also the above said options have been prescribed despite the fact that some of such treatment and disposal methods are not environment friendly and constantly posing threat forgetting its ill-effect in the environment. The Rules also had not stated where an on-site treatment facility is necessary and where dependence on a common bio-medical waste treatment is justified. It also did not mention who will provide land for setting up of the same.

To overcome such problem the Bio-Medical Waste Management Rules, 2016 make necessary changes which are a welcome attempt in this regard to make the whole treatment and disposal methods more effective. As for instance, in the definition of the phrase 'bio-medical waste treatment and disposal facility' which is relevant in connection with treatment and disposal certain changes have been made and the inclusion of the phrase 'common bio-medical waste treatment facilities' is such a step in this regard. Accordingly, under the new Rules, 2016 it 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.<sup>94</sup>

Changes has also made in connection with the treatment and disposal options. Under the new Rules, 2016 options like ‘plasma pyrolysis’, ‘waste sharps dry heat sterilisation followed by shredding or mutilation or encapsulation in metal container or cement concrete’, ‘pre-treatment to sterilise with non-chlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for incineration’ etc. have been included with a view to make the treatment and disposal options more environment friendly. The inclusion of new technological treatment and disposal is with a view to reduce the harmful effect in the environment that may arise if a specific treatment methodology is followed regarding the treatment of a particular category of waste without strictly fulfilling such criteria. It is to be noted here that during the last five years, the Central Pollution Control Board has also granted conditional or provisional approval to new technologies of the above types other than notified under earlier bio-medical waste Rules for treatment of bio-medical waste<sup>95</sup>.

The expression plasma pyrolysis is a method of treatment of the plastic items. Plasma pyrolysis uses extremely high temperatures of plasma-arc in an oxygen starved environment to completely decompose waste material into simple molecules. Hot plasmas are particularly appropriate for treatment of solid waste and can also be employed for destruction of toxic molecules by thermal decomposition. Unlike incinerators, segregation of chlorinated waste is not essential in this process. Another advantage of plasma pyrolysis is the reduction in volume of organic matter, which is more than 99%. Based on numerous advantages of plasma technology it is speculated that in the near future, plasma pyrolysis reactors will be widely accepted for toxic waste treatment<sup>96</sup>. Unlike their smoke-belching, conventional counterparts, plasma pyrolysis facilities burn the waste without producing any harmful residuals. In plasma pyrolysis the quantity of toxic residuals (dioxins and furans) is much below the accepted emission standards and it does not require segregation of hazardous waste.

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<sup>94</sup> Rule 3(g) of the Bio-Medical Waste Management Rules, 2016.

<sup>95</sup> Government of India, Ministry of Environment & Forest, “Bio-Medical Waste Management: An Overview” Environmental Information system (ENVIS), Newsletter, Central Pollution Control Board pg. 16 (2014).

<sup>96</sup> S. K. Nema and K. S. Ganeshprasad, “Plasma Pyrolysis of Medical Waste” Vol. 83 Current Science pg. 273 (2002).



In addition, the pathogens are completely killed and there is a possibility to recover energy<sup>97</sup>.

In the new Rules, 2016 along with the earlier treatment and disposal options it has included new technological options in order to remove the difficulties that was in existence in the previous treatment technologies. Reference may be made of the treatment technologies like autoclaving, microwaving or hydroclaving with regard to the treatment of particular type of waste e.g. soiled waste. After adopting any of these treatment options and successful completion of the same, the further steps to be followed is shredding or mutilation or combination of sterilisation and shredding for the same category and lastly the treated waste is to be sent for energy recovery. Such additional steps are required to be followed with a view to root out the risk factor absolutely as it was found present following the treatment method as per the Rule, 1998. It means that the earlier treatment methods were not out of risk. Likewise, the method which was earlier prescribed for the treatment of chemical waste under the previous Rule, 1998 is different from and a new method for the disposal of the same either by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility has been provided under the new Rules, 2016. It seems that for the treatment of such waste the method provided under the previous Rule was not enough and a new technology was needed for the same and accordingly the new Rules by the inclusion of new treatment method made an attempt to remove the difficulties existed earlier. Further, for the treatment of the waste sharps consisting of needles, syringes, scalpels, blades etc. also the option prescribed is new compare to the previous options. Along with autoclaving, dry heat sterilisation followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving and finally the residue shall be sent for final disposal to iron foundries or sanitary landfill or designated concrete waste sharp pit have been prescribed. Previously it was limited only to autoclaving or microwaving including shredding and mutilation.

The new Rules, 2016 also added new provision for three 'R's' i.e. reduce, recycle and reuse relating to contaminated waste prescribed in the Schedule I under the treatment and disposal options. For recyclable contaminated wastes which were earlier included under the category of solid waste, autoclaving or micro-waving/

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<sup>97</sup> *Ibid.*

hydroclaving followed by shredding or mutilation or combination of sterilisation and shredding have been prescribed. The treated waste is to be sent to registered or authorised recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible.

Regarding deep burial, an old option for the treatment and disposal of the bio-medical waste, the new Rules, 2016 brought some changes. According to the Schedule I disposal by deep burial is permitted only in rural or remote areas where there is no access to common bio-medical waste treatment facility and the same is to be carried out with prior approval from the prescribed authority and as per the Standards specified in Schedule-III. The site of the deep burial shall be as per the provisions and guidelines that has been issued or to be issuable from time to time by the Central Pollution Control Board.

In addition to the above, Part 2 of the Schedule I of the new Rules, 2016 prescribed for the adoption of various other treatment options which is significant from the point of view that it would help in reducing the pollution in the environment if followed properly in according with the Rules. They are as under:

1. Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log<sub>10</sub>4 reduction efficiency for microorganisms as given in Schedule- III.
2. Mutilation or shredding must be to an extent to prevent unauthorised reuse.
3. There will be no chemical pre-treatment before incineration, except for microbiological, lab and highly infectious waste.
4. Incineration ash (ash from incineration of any bio-medical waste) shall be disposed through hazardous waste treatment, storage and disposal facility, if toxic or hazardous constituents are present beyond the prescribed limits as given in the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008 or as revised from time to time.
5. Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the

operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.

6. Cytotoxic drug vials shall not be handed over to unauthorised person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature  $>1200$  0C.
7. Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
8. On-site pre-treatment of laboratory waste, microbiological waste, blood samples and blood bags should be disinfected or sterilised as per the Guidelines of World Health Organisation or National AIDS Control Organisation and then given to the common bio-medical waste treatment and disposal facility.
9. Installation of in-house incinerator is not allowed. However in case there is no common biomedical facility nearby, the same may be installed by the occupier after taking authorisation from the State Pollution Control Board.
10. Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage. Wherever the occupier is not linked to a disposal facility it shall be the responsibility of the occupier to sterilize and dispose in the manner prescribed.
11. Bio-medical waste generated in households during healthcare activities shall be segregated as per these rules and handed over in separate bags or containers to municipal waste collectors. Urban Local Bodies shall

have tie up with the common bio-medical waste treatment and disposal facility to pickup this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal in the manner as prescribed in this Schedule.

### **7.9 Duty of Occupier in the Treatment and Disposal of Bio-Medical Waste**

In addition to the above duties discussed under the segregation part, the occupier has the following duties relating to the treatment and disposal of bio-medical waste under Rule 7 of the Bio-Medical Waste Management Rules, 2016.

- Occupier shall hand over segregated waste as per the Schedule-I to common bio-medical waste treatment facility for treatment, processing and final disposal. Provided that the lab and highly infectious bio-medical waste generated shall be pre-treated by equipment like autoclave or microwave<sup>98</sup>.
- No occupier shall establish on-site treatment and disposal facility, if a service of `common biomedical waste treatment facility is available at a distance of seventy-five kilometer<sup>99</sup>.
- In cases where service of the common bio-medical waste treatment facility is not available, the Occupiers shall set up requisite biomedical waste treatment equipment like incinerator, autoclave or microwave, shredder prior to commencement of its operation, as per the authorisation given by the prescribed authority<sup>100</sup>.
- Any person including an occupier or operator of a common bio medical waste treatment facility, intending to use new technologies for treatment of bio medical waste other than those listed in Schedule I shall request the Central Government for laying down the standards or operating parameters<sup>101</sup>.
- After ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from the treated bio-medical wastes such as plastics and glass shall be given to such

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<sup>98</sup> Rule 7 (2) of the Bio-Medical Waste Management Rules, 2016.

<sup>99</sup> Rule 7(3) of the Bio-Medical Waste Management Rules, 2016.

<sup>100</sup> Rule 7(4) of the Bio-Medical Waste Management Rules, 2016.

<sup>101</sup> Rule 7(5) of the Bio-Medical Waste Management Rules, 2016.

recyclers having valid authorisation or registration from the respective prescribed authority<sup>102</sup>.

- 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<sup>103</sup>.
- The handling and disposal of all the mercury waste and lead waste shall be in accordance with the respective rules and regulations<sup>104</sup>.
- Every authorised person<sup>105</sup> shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal or any other form of handling of bio-medical waste, for a period of five years, in accordance with these rules and guidelines issued by the Central Government or the Central Pollution Control Board or the prescribed authority as the case may be.

## 7.10 Standards for Treatment and Disposal

To achieve the goal of proper treatment and disposal the Bio-Medical Waste (Management & Handling) Rules, 1998 under Schedule V prescribed certain standards to be followed by the operator of such technologies. Different standard have been enumerated under this Schedule for different treatment processes which are as under:

- **Incineration** - It is divided into operating standards and emission standards. A well designed pollution control devices should be installed with the standards provided for treatment and disposal incinerator to achieve the emission standards systems. To follow the operating standards, the Schedule prescribed for the combustion efficiency of at least 99.00%

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<sup>102</sup> Rule 7(9) of the Bio-Medical Waste Management Rules, 2016.

<sup>103</sup> Rule 7(10) of the Bio-Medical Waste Management Rules, 2016.

<sup>104</sup> Rule 7(11) of the Bio-Medical Waste Management Rules, 2016.

<sup>105</sup> Under Rule 3 (d) of the Bio-Medical Waste Management Rules, 2016 “athorised 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.

and the temperature of the primary chamber shall be a minimum of 800° C and secondary chamber shall be minimum of 1050° C + or – 50° C. The Schedule also prescribed the emission standards under part B. For different parameters like particulate matter, nitrogen oxide, HCL etc. different concentration (150, 451, 50 etc.) of mg/Nm<sup>3</sup> at 12% CO<sub>2</sub> was prescribed. In order to follow the same certain instruction have been provided under the note such as suitably designed pollution control devices should be installed with the incinerator to achieve the above emission limits, chlorinated plastics shall not be incinerated, toxic metals in incineration ash shall be limited within the regulatory quantities etc.

- **Autoclave-** Different temperature, pressure and time limit has been prescribed. Bio-medical waste shall not be considered as properly treated through autoclaving unless the time, temperature and pressure indicators indicate that the required time, temperature pressures were reached during the autoclave process. If for any reasons, time temperature or pressure indicator indicates that the required temperature, pressure or residence time was not reached, the entire medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved. The Schedule also prescribed certain permissible limits for effluents generated from hospital. The autoclave machine must satisfy the validation test which is of two types: spore test and routine test. Under the spore testing, the autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit which shall be bacillus stearothermophilus spores using vials or spore strips. For the routine test, the chemical indicator strip/tape help in viewing the changes of colour when a certain temperature is reached which helped in verifying that a specific temperature has been achieved.
- **Liquid Waste** – The effluent generated from the hospital should conform to the limits as provided in the Schedule. For different parameters different permissible limits have been prescribed. These limits are applicable to those hospitals which are either connected with sewers without terminal sewage treatment plant or not connected to public sewers. For discharge

into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

- **Microwaving** – The standards of microwaving simply provides for dos and don'ts. It has to comply with the efficacy test and routine test. Along with this a performance guarantee may be provided by the suppliers before the operation of the unit. It should completely and consistently kill the bacteria and other pathogenic organisms that are ensured by approved biological indicator at the maximum design capacity of each microwave unit.
- **Deep Burial**- It also provide for dos and don'ts. A pit or trench should be dug about 2 meters deep. It must be ensured that animals do not have any access to burial sites for that covers with meshes may be used. The pit should be distant from habitation and sited so as to ensure that no contamination occurs of any surface water or ground water. The deep burial must be performed under close and dedicated supervision.

Unlike the Bio-Medical Waste (Management & Handling) Rules, 1998, the Bio-Medical Waste (Management & Handling) Rules, 2011 also prescribed similar acceptable emission standards for incinerator. But the Bio-Medical Waste Management Rules, 2016 lay down stricter standards of emission from incinerators which has been reduced to 50mg/Nm<sup>3</sup>. Similarly, the standard retention time in the secondary chamber has been increased from one second to two seconds. The secondary chamber in incineration is where the temperature is lowered to 100 or 200 degree Celsius. This is done to reduce dioxins and furans as, at low temperature, incineration of biomedical waste leads to the production of carbon dioxide and water. Regarding the existing incinerators and all upcoming incinerators, the new Rules, 2016 by imposing a duty on the occupier lay down that such incinerators shall comply with the standard for dioxins and furans within a period of two years from the date of commencement of these rules<sup>106</sup>. The fuel to be used in the incineration are low sulphur fuel like light diesel oil or low sulphur heavy stock or diesel, compressed natural gas, liquefied petroleum gas etc<sup>107</sup>. The similar operating standard has been provided under the new Rules, 2016 for plasma pyrolysis or gasification. The emission standard to be followed for the same is as provided in the emission standard

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<sup>106</sup> Rule 4(t) of the Bio-Medical Waste Management Rules, 2016.

<sup>107</sup> Part B, Note (g) in Schedule II of the Bio-Medical Waste Management Rules, 2016.

for incinerator although under the new head 'air emission standard and air pollution control measures'. Accordingly it lay emphasis and prescribed the air emission standard for incinerator, notified at Serial No.1 above in this Schedule, and revised from time to time. It has also prescribed for the installation or retrofitted suitably designed air pollution control devices. Such waste should not be chemically treated with any chlorinated disinfectants and chlorinated plastics shall not be treated in the same system<sup>108</sup>. Lastly, the ash or vitrified material generated from the Plasma Pyrolysis or Gasification shall be disposed off in accordance with the Hazardous Waste (Management, Handling and Transboundary Movement) Rules 2008.

The standards for autoclaving of bio-medical waste are divided into three parts. The first part under serial no. 1 prescribed the standard for operating a gravity flow autoclave either in a temperature of not less than 121 degree Celsius and pressure of 15 pounds per square inch for an autoclave residence time of not less than 60 minutes or a temperature of not less than 135 degree Celsius and a pressure of 31 pounds square inch for an autoclave residence time of not less than 45 minutes etc. For operating a vacuum autoclave medical waste shall be subjected to a minimum of three pre-vacuum pulse to purge the autoclave of all air. It is also subject to the temperature standard as referred in serial no. 2 of the same and serial no. 3 lay down the same option as it was there under the Bio-Medical Waste (Management & Handling) Rules, 1998 which is relating to the pressure indicators as mentioned above. The new Rules, 2016 also lay down the provisions relating to validation test, spore test and routine test. It has added a new technology to be installed in the autoclave machine for recording of operational parameters which will automatically and continuously monitor and record dates, time etc. along with load identification number the operating parameters throughout the entire length of the autoclave cycle.

For microwave and deep burial the new Rules, 2016 alongwith the same standard prescribed in the earlier Rules, 1998 some additional standard has also been prescribed. For example, Biological indicators for microwave shall be *Bacillus atrophaeus* spores using vials or spore strips with at least  $1 \times 10^4$  spores per detachable strip. The biological indicator shall be placed with waste and exposed to same conditions as the waste during a normal treatment cycle. Likewise, for deep burial, an additional and important point find place in the Rule which says that the ground water

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<sup>108</sup> Part B, Serial No. 2 clause (iii), Schedule II of the Bio-Medical Waste Management Rules, 2016.



table level should be a minimum of six meters below the lower level of deep burial pit. The inclusion of the clause is for the purpose of avoiding all types of risk involved in the deep burial which has a tendency of percolating the underground water.

In addition to the above said standards the new Rules, 2016 also provided with two new standards namely the standard for efficacy of chemical disinfection and for dry heat sterilisation. The use of technical terms for chemical disinfection made it difficult to follow the same standard unless trained properly. Compare to this, the standard for dry heat sterilisation is somehow easy which lay that waste sharps can be treated by dry heat sterilisation consisting of automatic recording system to monitor operating parameters at a temperature not less than 1850 C, at least for a residence period of 150 minutes in each cycle, which sterilisation period of 90 minutes<sup>109</sup>.

### 7.11 Comparison of Treatment Technologies for Bio-Medical Wastes<sup>110</sup>

The following are the comparison made of various treatment technologies in order to find out the viability of such treatment technology:

**Table 7**

#### **Different treatment technologies and its characteristics**

<b>Treatment Systems</b>	<b>Autoclave</b>	<b>Hydroclave</b>	<b>Microwave</b>	<b>Incinerator</b>	<b>Chemical</b>
Description	Steam sterilisation (Direct heating)	Steam sterilisation, (indirect heating) simultaneous shredding and dehydration	Microwave heating of pre-shredded waste	High temperature waste incineration	Mixing pre-ground waste with chemical, such as chlorine
Sterilisation efficacy	Medium	Medium	Medium	High (total destruction of micro-organism)	Dependent on chlorine strength and dispersment through the waste
Capital Cost	Low	Low	High	High	Moderate
Operating cost	Low	Low	High	High	Low

<sup>109</sup> Standard 7, Schedule II of the Bio-Medical Waste Management Rules, 2016.

<sup>110</sup> B. Ramesh Babu, A.K. Parande, *et. al.*, "Management of Biomedical Waste in India and Other Countries: A Review" Vol. 4(1) Journal of International Environmental Application & Science pg. 68 (2009).

Operator maintenance skill	Low skill level required	Low skill level required	Automated, but highly complex and high level maintenance skill required	High level operator and maintenance skills required	High level required for chemical control and grinder
Air emissions	Odorous but not-toxic	Somewhat odorous but non-toxic	Somewhat odorous but non-toxic	Can be highly toxic	Some chlorine emissions
Water emissions	Odorous, may contain live micro-organisms	Odorous but sterile	Negligible	None	None
Treated waste characteristics	Wet waste, all material recognizable	Dehydrated, shredded waste, unrecognisable material	Shredded but wet waste	Mostly ash, may contain toxic substances	Shredded wet waste, containing chemicals used as disinfectants

From the above table it is clear that the treatment and disposal technologies prescribed by the Rules have some defects. It can be said that not every treatment technologies is said to be perfect and can dispose of the bio-medical waste without leaving any harmful effect in the environment. In some technology the capital cost is high and in some other although it is low but it has some consequential effect which has effect in the degrading condition of the environment. What is required is to adopt much more advance technologies for the treatment and disposal of such waste so that the risk factor involved in such technologies could possibly be removed. Although, the new Rules, 2016 has made an attempt to overcome such difficulties by way of including further treatment options to be followed after adopting a particular treatment technology for the treatment of the bio-medical waste, it is important that the authority should keep a vigilant eyes to ensure that the provisions of the Rules are being strictly followed. For instance the operator should keep in mind that while operating the incinerator it is maintaining its optimum level and if the operator follow careless attitude the treatment of particular type of waste through incinerator would remain far away from the target and the main purpose of rooting out the problem of bio-medical waste would be at stake. In most of the surveys carried out, incinerators run at temperatures lower than those specified in the rules and due to this poor operation and maintenance, these incinerators do not destroy the waste, need a lot of

fuel to run, and are often out of order. When every hospital uses an incinerator, it is under utilised since the amount of infectious waste of a single hospital is not sufficient for the optimum use of the machine and this would lead to the improper treatment of the same. Therefore on the whole, it is not feasible for every hospital to use an incinerator and it is preferable to have centralised incinerators instead. By improving the condition of existing treatment technologies system and following of the new treatment technology under the new Rules, it would be possible to cope up with the problem of bio-medical waste in an extensive manner and if the Rule as a whole is strictly implemented than in the future there will be no bio-medical waste problem. To achieve such target the new Rules prescribed that the existing incinerators shall achieve the standards for retention time in secondary chamber and dioxin and furans within two years from the date of this notification with a view to improve the environment in the vicinity treatment facility.

#### **7.12 Need for Common Bio-Medical Waste Treatment Facilities**

The Common Bio-Medical Waste Treatment Facility (CBMWTF) is a set up that can be used to treat biomedical waste generated in a number of health care facilities to reduce the adverse effects that may arise out of this waste<sup>111</sup>. It may have more than one treatment option, to take care of various categories of waste from different health care units. The treated waste may finally be sent for disposal in a landfill or for recycling purposes. Installation of individual treatment facilities by small healthcare facilities requires comparatively high capital investment. In addition, it requires separate manpower and infrastructure development for proper operation and maintenance of treatment systems. The concept of CBMWTF not only addresses such problems but also prevents proliferation of treatment equipment in a city. In turn it reduces the monitoring pressure on regulatory agencies. By running the treatment equipment at CBMWTF to its full capacity, the cost of treatment of per kilogram gets significantly reduced. Its considerable advantages have made CBMWTF popular and proven concept in many developed countries<sup>112</sup>. Advantages of a centralised facility

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<sup>111</sup> Government of India, Revised Draft Guidelines for Common Bio-medical Waste Treatment Facilities, Central Pollution Control Board, pg. 1 (July, 2016).

<sup>112</sup> *Ibid.*

are reduction in pollution and energy consumption, streamlined collection, and treatment of waste. This facility has been widely accepted in the developed countries.

In India, the Bio-Medical Waste (Management & Handling) Rules, 1998, gives an option to the bio-medical waste generator that such waste can also be treated at the common bio-medical waste treatment facility<sup>113</sup>. The Second Amendment of the Rules in June, 2000, further eased the bottleneck in upbringing the CBMWTF by making Local Authority responsible for providing suitable site within its jurisdiction. But no further detail had prescribed relating to the setting up of such technologies.

Owing to the growing number of pollution cases and the high cost consumption in an individual set up for the treatment and disposal of various categories of bio-medical waste, the Bio-medical Waste Management Rules, 2016 under Sub-rule 4 of Rule 7 read with Rule 3(g) has laid down rule for the setting up of CBMWTF with a view to remove such difficulties. The Rule restricts occupier for establishment of an on-site treatment and disposal facility, if a service of common bio- medical waste treatment facility is available at a distance of seventy-five kilometer<sup>114</sup>. In cases where service of the common bio-medical waste treatment facility is not available, the occupiers shall set up requisite biomedical waste treatment equipment as per the authorisation given by the prescribed authority<sup>115</sup>.

Rule 17 of the Bio-Medical Waste Management Rules, 2016 lay down the rule relating to the site for CBMWTF which says that without prejudice to rule 5 of these rules, the department in the business allocation of land assignment shall be responsible for providing suitable site for setting up of common biomedical waste treatment and disposal facility in the State Government or Union territory Administration. The selection of the site for setting up of such facility shall be made in consultation with the prescribed authority, other stakeholders and in accordance with guidelines published by the Ministry of Environment, Forest and Climate Change or Central Pollution Control Board. Based on the information published by the Central Pollution Control Board<sup>116</sup> the detailed of the present bio-medical waste management scenario in the country is given below:

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<sup>113</sup> Rule 5 (2) of the Bio-Medical Waste (Management & Handling) Rules, 1998.

<sup>114</sup> Rule 7(3) of the Bio-Medical Waste Management Rules, 2016.

<sup>115</sup> Rule 7(4) of the Bio-Medical Waste Management Rules, 2016..

<sup>116</sup> Government of India, Annual Report on Status and Issues on implementation of Bio-medical Waste (Management & Handling) Rules, 1998 and as amended, Central Pollution Control Board, Hazardous Waste Management Division, March 26, 2015.

**Table 8****Annual Report of Bio-Medical Waste management scenario in India**

<b>Particulars</b>	<b>As per Annual Report Information for the year 2013</b>
No. of healthcare facilities	1,68,869
No. of beds	17,13,742
No. of Common Bio-medical Waste Treatment Facilities (CBWTFs)	198 (in operation)+28 (under installation)
No. of healthcare facilities (HCFs) using CBWTFs	1,31,837
No. of HCFs having treatment & disposal facilities	22,245
No. of healthcare facilities applied for authorization	1,06,805
No. of healthcare facilities granted authorization	1,05,270
Total no. of on-site/captive treatment equipment installed (excluding CBWTFs) by the HCFs: 1. No. of incinerators i) With Air Pollution Control Device (ii) Without Air Pollution Control Device 2. No. of autoclaves 3. No. of microwaves 4. No. of Hydroclave 5. No. of Shredders	331 217 3,112 250 15 5,179
Total no. of treatment equipment installed by the CBWTFs: 1. No. of incinerators 2. No. of autoclaves 3. No. of microwaves 4. No. of Hydroclave 5. No. of Shredders	198 189 06 03 202
Quantity of bio-medical waste generated in Tons/day	484
Quantity of bio-medical waste treated in Tons /day	447
No. of HCFs/CBWTFs violated BMW Rules	7,894
No. of Show-cause notices/Directions issued to defaulter HCFs/CBWTFs	4,391

### **7.12.1 Duties of the Operator of a Common Bio-Medical Waste Treatment Facility<sup>117</sup>**

Apart from the duties of the occupier the present rules have also listed some duties liabilities on the operators of common bio-medical waste treatment facility.

They are:

1. To 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.

2. To ensure timely collection of bio-medical waste from the occupier as prescribed under these rules.

3. To establish bar coding and global positioning system for handling of bio-medical waste within one year.

4. To inform the prescribed authority immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with these Rules.

5. To provide training for all its workers involved in handling of bio-medical waste at the time of induction and at least once a year thereafter.

6. To assist the occupier in training conducted by them for Bio-Medical Waste management.

7. To undertake appropriate medical examination at the time of induction and at least once in a year and immunise all its workers involved in handling of bio-medical waste for protection against diseases, including Hepatitis B and Tetanus, that are likely to be transmitted while handling bio-medical waste and maintain the records for the same.

8. To ensure occupational safety of all its workers involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipments.

9. To report major accidents including accidents caused by fire hazards, blasts during handling of biomedical waste and the remedial action

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<sup>117</sup> Rule 5of the Bio-Medical Waste Management Rules, 2016.

taken and the records relevant thereto, (including nil report) in Form I to the prescribed authority and also along with the annual report.

10. To maintain a log book for each of its treatment equipment according to weight of batch; categories of waste treated; time, date and duration of treatment cycle and total hours of operation.

11. To allow occupier, who are giving waste for treatment to the operator, to see whether the treatment is carried out as per the rules.

12. Shall display details of authorisation, treatment, and annual report etc. on its web-site.

13. After ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from the treated bio-medical wastes such as plastics and glass shall be given to recyclers having valid consent or authorisation or registration from the respective State Pollution Control Board or Pollution Control Committee.

14. Supply non-chlorinated plastic coloured bags to the occupier on chargeable basis, if required.

15. Common bio-medical waste treatment facility shall ensure collection of biomedical waste on holidays also.

16. Maintain all record for operation of incineration, hydro or autoclaving for a period of five years, and

17. Upgrade existing incinerators to achieve the standards for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

Besides the above duties, every occupier or operator of common bio-medical waste treatment facility shall submit an annual report to the prescribed authority in Form-IV, on or before the 30th June of every year as per Rule 13 (1) of the Bio-Medical Waste Management Rules, 2016. The Annual Reports shall also be made available online on the websites of Occupiers under Rule 13 (4).

#### **7.12.2 Liability of the Occupier & Operator of Common Bio-Medical Waste Treatment Facility (CBMWTF)**

As per Rule 18 of the Bio-Medical Waste Management Rules, 2016 the occupier or an operator of a common bio-medical waste treatment facility shall be

liable for all the damages caused to the environment or the public due to improper handling of such waste. The Rule also prescribed that the occupier or operator of CBMWTF shall be liable if they do not follow any of the direction given by the Central Government such as closure, prohibition or regulation of any industry, operation or process or stoppage or regulation of the supply of electricity or water or any other service under section 5 of the Environment Protection Act, 1986. For non-compliance of the rules, orders or directions the Act under Section 15 prescribed punishment with imprisonment for a term which may extend to five years with fine which may extend to one lakh rupees or with both. In case if violation continues, with additional fine up to five thousand rupees for every day failure or contravention after the conviction for the first such failure or contravention. A further punishment up to seven years is also prescribed if the contravention continues beyond a period of one year after such conviction. The inclusion of this Rule is to ensure that lack of carelessness on the part of occupier and operator in dealing with CBMWTF would subject them to the stringent liability. The imposition of punishment in terms of fine in case there is failure to comply with the rule and of conviction for continuous violation is an important step towards reducing the ill effect of the bio-medical waste because without strict penalty the persons responsible for the management of the waste would have a casual attitude which will make the Rule ineffective.

### **7.13 The Process of Authorisation and the Duties of the Prescribed Authority**

Rule 10 of the new rules, 2016 lay new criteria for authorisation of the health care facility. The Rule says that every occupier generating of bio-medical waste irrespective of its quantity shall apply under Form II to the State Pollution Control Board or Pollution Control Committee as the case may be for authorisation. In the 1998 Rule, it was prescribed that hospitals with more than one thousand beds must obtain authorisation from the State Pollution Control Boards while the 2011 draft expanded the ambit of institutions that require authorisation to include all the health care facilities. The new Rules, 2016 make the procedure of getting an authorisation very simple i.e. bedded hospital will get automatic authorisation and non-bedded hospitals will get a one-time authorisation. The grant of authorisation by the prescribed authority shall at first be provisional in Form III subject to some changes in the treatment technologies if directed and after making necessary changes the



occupier shall submit a fresh application in Form II for modification of the conditions of authorization to make it final<sup>118</sup>.

The new Rule, 2016 further prescribed some duties on the prescribed authorities relating to the grant of authorisation. Apart from grant and renewal of licence the authorities have the duty to suspend or refuse to grant and also to cancel the authorisation if there is any violation on the part of the occupier.

#### **7.14 Monitoring Committee**

Another improvement in the new Rules is in the monitoring sector. While the 2011 rules have no provision for a monitoring authority, the 2016 rules state that the Ministry of Environment and Forest will review health care facilities once a year through State Health Secretaries, the State Pollution Control Board (SPCB) and the Central Pollution Control Board (CPCB)<sup>119</sup>. Whereas the CPCB shall monitor the implementation of these rules in respect of all the Armed Forces health care establishments and may also inspect such establishments along with one or more representatives of the Advisory Committee constituted under sub-rule (2) of Rule 11, the SPCB shall after constituting District Level Monitoring Committee in the districts under the chairmanship of District Collector or District Magistrate or Deputy Commissioner or Additional District Magistrate monitor the compliance of all the Rules in the health care facilities. Rule 12 (6) states the composition of the District Level Monitoring Committee and this consisted of the District Medical Officer or District Health Officer, representatives from State Pollution Control Board or Pollution Control Committee, Public Health Engineering Department, local bodies or municipal corporation, Indian Medical Association, common bio-medical waste treatment facility and registered non-governmental organisations working in the field of bio-medical waste management and the District Medical Officer shall be the Member Secretary of this Committee.

The establishment of District Level Monitoring Committee is an important step in the effective implementation of the existing bio-medical waste rule that comprises of almost all sectors those are directly or indirectly responsible or has some connection in the proper management of such wastes. The involvement of different

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<sup>118</sup> Rule 19 (4) of the Bio-Medical Waste Management Rules, 2016.

<sup>119</sup> Rule 12 (1) of the Bio-Medical Waste Management Rules, 2016.

pollution control bodies along with the NGO's who are working on the subject is a welcome step towards eradicating the menace of bio-medical waste completely in near future. In the absence of monitoring committee earlier it was not possible to oversee whether the whole process of management of the bio-medical waste are being performed by those persons specially the occupier and operator in accordance with the existing Rules and due to the carelessness on the part of these persons responsible in handling such waste, the whole mechanisms of bio-medical waste management would be in vein. What is necessary is that the Committee should discharge the duties in compliance of the Rules in order to root out the problem relating to such waste.

### **7.15 An Overview**

On the basis of above discussions it can be summarise that although the Rules on the Bio-Medical Waste is not new and the same has been subject to amendment thrice between 1998-2011, still it suffered with lacunaes which necessitated the passing of new Rules in the year 2016 to overcome the problems for proper and effective management of it. A throwback to the existing scenario showed the tremendous rise of the problem in the country which could not be handled under the previous Rules and the outcome is the passing of the new Rules in this connection. What is to be seen is that despite few drawbacks in the present Rules whether the Bio-Medical Waste problem could possibly be properly controlled and managed or more stringent Rules is required for the same or the problem lies somewhere which could not be properly identified. This gives rise to the need of empirical research on the subject to find out the exact problem relating to the Bio-Medical Waste so that appropriate and effective measures could be adopted to fight with it.