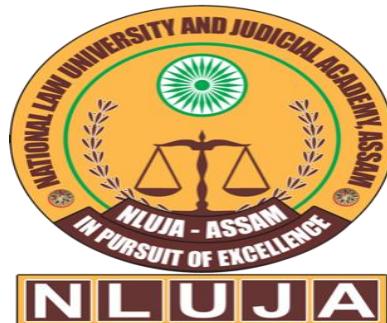


BIOMEDICAL WASTE MANAGEMENT: AN ANALYSIS OF REGULATORY FRAMEWORK IN INDIA



Dissertation submitted to National Law University and Judicial Academy, Assam
in partial fulfillment for award of the degree of
MASTER OF LAWS

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DECLARATION

I, **FARZIN NAZ**, pursuing Master of Laws (LL.M) from National Law University and Judicial Academy, Assam, do hereby declare that the present dissertation titled "**BIOMEDICAL WASTE MANAGEMENT: AN ANALYSIS OF REGULATORY FRAMEWORK IN INDIA**" is an original research work and has not been submitted, either in part or full anywhere else for any purpose, academic or otherwise.



Date: August 18, 2020.

Farzin Naz

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PREFACE

With rapid urbanization and ever increasing population growth there has been a substantial increase in the generation of solid waste with contamination of air, water and land resources. The solid wastes from different urban centers, when not managed properly, have been creating problems for human health and environment. Some of the solid wastes have been proved to be highly toxic and infectious. The uncontrolled dumping of such wastes have not only brought about increasing health hazards but also causing surface and ground water contamination and posing serious environmental threat to the human being. Bio-medical waste is as waste that is generated during diagnosis, treatment or immunization of human beings or animals or research activities. It includes sharps, solid waste, disposables, anatomical wastes, cultures, discarded material and is contaminated with body fluids (such as syringes, needles, ampoules, organs, body parts, placenta, dressings, disposable plastics and microbiological wastes). Bio-medical waste is generated from healthcare establishments and also some small sources as blood banks, laboratories and research institutes. Bio-medical waste contaminated by chemicals becomes hazardous. These chemicals include formaldehydes and phenols (used as disinfectants), mercury etc. Thus, taking account of the seriousness of the problem, the researcher through this paper has tried to explain the loopholes that our legal system is facing at present and also give some suggestions with respect to the same.

TABLE OF CASES

1. *Almitra H.Patel and Ors. v. Union of India.*
2. *Animal Welfare Board of India v A. Nagaraja and Others.*
3. *A.P Pollution Control Board v Prof. M.V Nayadu.*
4. *Applicants' v State of Kerela and Others.*
5. *Bangalore Medical Trust v B.S Mudappa.*
6. *Burrabazar Fireworks Association v The Commissioner of Police and Ors. Chidambaram v The Chief Secretary to the Government of Tamil Nadu, Chennai.*
7. *Cooverjee Bharucha v Excise Commissioner, Ajmer.*
8. *Dr. J. Umarani v State of Tamil Nadu.*
9. *Dr. B.L. Wadhera v Union of India.*
10. *D.S Nakara v Union of India.*
11. *Environment Protection Committee v Union of India.*
12. *Education Research Centre v Union of India.*
13. *Francis Carolie v Administrator, UT of Delhi.*
14. *Hamid Khan v Union of India.*
15. *Himachal Tiwari v Kamala Devi.*
16. *Haat Supreme Wastech Pvt. Ltd v State of Haryana.*
17. *Indira Nagar Jan Vikas Samiti v State of Uttarakhand and Others.*
18. *Krithika Gokulnath SN Raj Serenity Apartments v Registrar, Anna University and Others.*
19. *Keshavananda Bharti v State of Kerela.*
20. *Kalyaneshwari v Union of India.*
21. *Kinkri Devi and Another v State of Himachal Pradesh and Others.*
22. *Laishramcha Ji nine Meetei v State of Manipur and Others.*
23. *Mahesh Dubey v Chhattisgarh Environment Conservation Board and Others.*
24. *Maneka Gandhi v Union of India.*
25. *M.C Mehta v Union of India.*
26. *M.C Mehta v Union of India.*

27. *M.C Mehta v State of Orissa.*
28. *M.C Mehta v Union of India.*
29. *Meera Shukla v Municipal Corporation, Gorakhpur and Others.*
30. *Mandu Distilleries Pvt. Ltd v M.P Pradushan Niwaran Manadal.*
31. *Muarli S. Deora v Union of India.*
32. *Nirbhai Singh v State of Punjab.*
33. *Nuggehalli Jayasimha v Government NCT of Delhi.*
34. *Occupational Health & Safety Assn. v Union of India.*
35. *P.K Nayyar and Others v Union of India and Others. Mr. B.V Niren.*
36. *Praduman Tiwari v Union of India.*
37. *Paryavaran Mitra and Others v Gujarat Pollution Control Board and Others.*
38. *P.A Jacob v The Superintendent of Police, Kottayam.*
39. *Re: Scientific Disposal of Biomedical Waste arising out of Covid-19 and compliance of BMW Rules.*
40. *RWA Jain Colony v Govt. of NCT of Delhi.*
41. *Rural Litigation and Entitlement Kendra v State of Uttar Pradesh.*
42. *Rajnikant v State of Uttar Pradesh.*
43. *Ratanakar Satrusalya v State of Orissa.*
44. *Re- Berubari.*
45. *Rahul Vijay Chugh v State of Haryana and Others.*
46. *State of Himachal Pradesh v Ganesh Wood Products.*
47. *Subhash Kumar v State of Bihar.*
48. *Suo Motu v State of Rajasthan and Others.*
49. *Suo Muto proceedings in NGT v State of Kerela.*
50. *Shailesh Singh v Sheela Hospital & Trauma Centre, Shahjahanpur and Others: Kailash Hospital and Heart Institute and Others; Shri Ganga Charan Hospital (P) Ltd, Bareilly and Others.*
51. *The Cheerans Mayura Industries v Kerala Pollution Control Board.*
52. *Vellore Citizens Welfare Forum v Union of India.*

TABLE OF STATUTES

- 1988- Medical Waste Tracking Act.
- 1989- The Basel Convention on the control of Transboundary Movements of Hazardous Wastes and their Disposal.
- 1990- Clean Air Amendment Act.
- 1991- Bamako Convention on the Ban of the Import into Africa & the control of Transboundary Movement and Management of Hazardous Wastes within
- 1992- Africa.
- Clean Water Act.
- 1998- The Bio-Medical Wastes (Management and Handling) Rules.
- 2000- The Bio-Medical Wastes (Amendment) Rules.
- 2001- The Stockholm Convention on Persistent Organic Pollutants.
- 2002- The Bio-Medical Wastes (Amendment) Rules.
- 2013- Minamata Convention on Mercury.
- 2016- The Bio-Medical Wastes (Amendment) Rules.
- 2018- The Bio-Medical Wastes (Amendment) Rules.
- 2018- Regulation of Persistent Organic Pollutants.

TABLE OF ABBREVIATIONS

1.	AIR	All India Reporter
2.	BMW	Bio-Medical Wastes Management
3.	CPCB	Central Pollution Control Board
4.	CBWTF	Common Bio-Medical Waste Treatment and Disposal Facility
5.	DDT	Dichloro Diphenyl Trichloroethane
6.	EPA	Environmental Protection Agency
7.	HCF	Health Care Facilities
8.	IAEA	International Atomic Energy
9.	MOEF	Ministry of Environment and Forests
10.	NGT	National Green Tribunal
11.	NGO	Non Governmental Organization
12.	OSHA	Occupational Safety and Health Administration
13.	PIL	Public Interest Litigation
14.	POP	Persistent Organic Pollutants
15.	PCB	Polychlorinated Biphenyls
16.	PPE	Personal Protective Equipment
13.	SPCB	State Pollution Control Board
13.	UNGA	United Nation General Assembly
14.	UNEP	The United Nations Environment Programme
15.	WHO	World Health Organization

TABLE OF CONTENTS

	Page Number
Certificate	i
Declaration	ii
Acknowledgement	iii
Preface	iv
Table of Cases	vii
Table of Statutes	viii
Table of Abbreviations	viii
Ch-1 Introduction	1
1.1 Introductory	1
1.2 Statement of problem	7
1.3 Aims	7
1.4 Objectives	7
1.5 Scope and Limitations	8
1.6 Detailed Literature Review	8
1.7 Research Questions	13
1.8 Research Methodology	13
1.9 Research Design	14
Ch-2 International Agreements and Conventions relevant to management of Bio-Medical Waste	15
2.1 Conventions	15
2.1.1 The Basel Convention	15
2.1.1.1 Basel Convention and healthcare waste	16
2.1.1.2 Challenges in implementation of provisions of Basel	17
2.1.2 Convention	18
2.1.2.1 Bamako Convention	19
2.1.3 Bamako Convention and Bio-Medical Waste	19
2.1.3.1 The Stockholm Convention	21
2.1.4 The Stockholm Convention and Bio-Medical waste	22
2.1.4.2 Minamata Convention on Mercury	24
2.2 Challenges in implementation of the Minamata Convention	25
2.2.1 International Guidelines	25
2.2.2 WHO Guidelines on Safe Management of Wastes	26
WHO document on Overview of technologies for the treating	
2.2.4 infectious waste and Sharps	27

Compendium of Technologies for treating and destructing health-care waste	
2.2.5 Guidelines on the Environmentally Sound Management of Biomedical Waste, the Basel Convention	28
2.2.6 WHO Guidelines on Waste Management of COVID-19	29
Ch-3 Indian Legislations/Initiatives on Bio-Medical Waste Management	31
3.1 Legislations relevant to Bio-Medical Waste Management in India	31
3.1.1 Bio-Medical Waste (Management and Handling) Rules, 1998	31
3.1.2 Bio-Medical Waste Management (Amendment) Rules, 2000	38
3.1.3 Bio-Medical Waste Management (Amendment) Rules, 2003	39
3.1.4 Draft Bio-Medical Waste Management (Amendment) Rules, 2011	40
3.1.5 Bio-Medical Waste Management Rules, 2016	44
3.1.6 Bio-Medical Waste Management (Amendment) Rules, 2018	51
3.2 Guidelines on Bio-Medical Waste Management	54
3.2.1 CPCB's Guidelines on Management on Mercury Waste Generated from the Health Care Establishments	54
3.2.2 CPCB's Guidelines for Common Bio-Medical Waste Treatment and Disposal Facilities	54
3.2.3 CPCB's Guidelines for Bar Code System	55
3.2.4 CPCB's Guidelines for Handling Bio-Medical Waste for Utilization	56
3.2.5 Regulation of Persistent Organic Pollutants Rule of 2018	56
Ch-4 Constitutional Protection with respect to Bio-Medical Waste Management	58
4.1 Preamble	58
4.2 Fundamental Rights	59
4.2.1 Article 14/ Right to Equality	60
4.2.2 Article 19/ Freedom of Speech and Expression and of Trade and Business	60
4.2.3 Article 21/ Right to Life and Personal Liberty	62
4.3 Fundamental Duties	64
4.4 Directive Principles of State Policy	66
4.5 Legislative Powers	67
Ch-5 Judicial Decisions and Management of Bio-Medical Waste	70
5.1 The Cheerans Industries v Kerela Pollution Control Board	70
5.2 Rahul Vijay Singh Chugh v State of Haryana and Others	71
5.3 Nirbhai Singh v State of Punjab	72
5.4 Paryavaran Mitra v Gujarat Pollution Control Board	72
5.5 Haat Supreme Wastech Pvt. Ltd Case	74
5.6 P.K Nayyar v Union of India and Others	74
5.7 Mahesh Dubey v Chhattisgarh Environment Conservation Board	75
5.8 Chidambaram v CS to the Government of Tamil Nadu	76
5.9 Laishramcha Meetei v State of Manipur	76
5.10 Suo Motu Proceedings initiated in NGT	77
5.11 Shailesh Singh v Sheela Hospital Case	78

5.12	Indira Nagar Jan Vikas Samiti v State of Uttarakhand	79
5.13	Nuggehali Jayasimha v Government NCT of Delhi	79
5.14	Praduman Tiwari v Union of India	81
5.15	Dr. J. Umarani v State of Tamil Nadu	81
5.16	Krithika Gokulnath v Anna University	82
5.17	Scientific Disposal of Biomedical Waste arising out of COVID-19 treatment	82
Ch-6	Central Pollution Control Board's Guidelines on COVID-19 and Current Scenario in India	84
6.1	About Covid-19	84
6.2	Characteristics of Wastes generated during Covid-19	85
6.3	CPCB's Guidelines on Handling and Disposal of COVID-19 Wastes	85
6.4	Present Scenario of India at times of Covid-19	89
Ch-7	United States Regulation of Medical Waste and a comparison with Indian Biomedical Waste Regulation	92
7.1	United States Approach to Medical Waste Regulation	91
7.1.1	Historical Background	91
7.1.2	Medical Waste Tracking Act, 1988	92
7.1.3	Clean Air Amendment Act, 1990	96
7.1.4	Clean Water Act of 1992 and Marine Protection Research Act, 1992	98
7.1.5	Other Federal Authorities responsible for regulating Medical Waste	99
7.1.5.1	OSHA Acts and Regulations for Medical Waste Management	99
7.1.5.2	Department of Transportation and United States Regulations for Medical Waste	100
7.1.5.2.1	Department of Transportation Infectious Wastes Regulation, 2006	100
7.1.5.2.2	Provision for Special Permit for Shipping certain Infectious Wastes	101
7.1.6	State Regulations	101
7.1.6.1	Regulation in Texas	101
7.1.7	Guidelines	102
7.1.7.1	EPA's Model Guidelines developed by Council of State Government	102
7.1.7.2	Centre for Disease Control Guidelines for Environmental Infection Control in Healthcare Establishments	102
7.1.7.3	Interim Guidelines for Collecting, Handling and Testing Specimens from persons for Covid-19	103
7.2	United States Regulation vs. Indian Regulation- Lessons Learnt	104
Ch-8	Conclusion and Recommendation	106
	Bibliography	xi-xvi

CHAPTER 1

INTRODUCTION

“Let the wastes of the sick not contaminate the lives of the healthy”.

1.1 Introductory

The problem of environmental pollution has now become extremely acute. Some of the countries have laid down stringent standards to maintain balance in nature, particularly in an area of waste management. With respect to Bio-Medical Waste Management, developed countries have adopted stringent measures. But the Developing and Least Developed Countries have delayed such problems for very long, especially when it comes to Medical Waste. Bio-Medical Waste produced by the healthcare establishments are highly infectious and can cause deadly disease in both humans and animals.¹ Appropriate management of “Bio-Medical Waste” is necessary for protection of environment and all the health-care establishments must take this seriously. Therefore, anti-pollution strategy is to be adopted to stem the terrible implication of nature resulting from non-scientific disposal of Bio-Medical Waste.

For meeting the needs of growing population, the country witnessed a rapid growth of both private as well as public healthcare establishments. Medical care is crucial for wellbeing of a person and his health. However, the waste generated if not treated and disposed properly can pose a serious danger to mankind. The waste usually comprise of human organs, tissues, waste from animal house and Veterinary clinics, discarded/expired medicines, blood, used cotton, gloves, sharp materials, needles, knives, scalpels, etc.² The person who are at high risk of getting infection from discarded Bio-Medical waste are doctors, nurses, staffs, patients, rag pickers, waste workers, animals. Moreover, undisposed and untreated dumping of such wastes can cause environmental hazards like air pollution, water pollution and land pollution. Such wastes may also cause serious ailments in humans like AIDS, Diphteria, Hepatitis B, Hepatitis C, etc.³

¹ K. PARK, PREVENTIVE AND SOCIAL MEDICINE, 780-81(2015).

² *Id.* at 782.

³ *Id.* at 783.

1.1.1 Definition and Classification

Bio-Medical waste as per BMW Rules of 1988⁴ can be solid or liquid in nature, which also includes organs of humans, body tissues, tested blood, body fluids of human beings, veterinary wastes, human pathogens, cotton, bandage, plaster casts, etc. which may pose the risk of infection to humans. In simple sense, biomedical waste may be defined as waste that includes all wastes which are generated by healthcare establishments. The issue of Bio-Medical Waste has increased concern worldwide. The emergence and acceptance of the disposable hospital waste generation is an important factor in the current scenario. Bio-Medical Waste contains wastes which are discarded during the diagnosis or by treatment of people, animals, or in any research activities.⁵

1.1.2 Categories of Waste

Out of all the waste generated, major portion of such wastes are not hazardous. Only a small percentage is harmful waste which is required to be disposed properly so that it is rendered harmless. Annually, health-care establishments produces near about 70 to 90% of non-hazardous wastes, also referred to as general or domestic waste. The main sources of generation of such domestic or general waste are the kitchen, administrative departments (paper, used pens, wood, and plastic) and housekeeping Departments. Remaining 10 to 20% comprises of toxic and hazardous waste⁶.

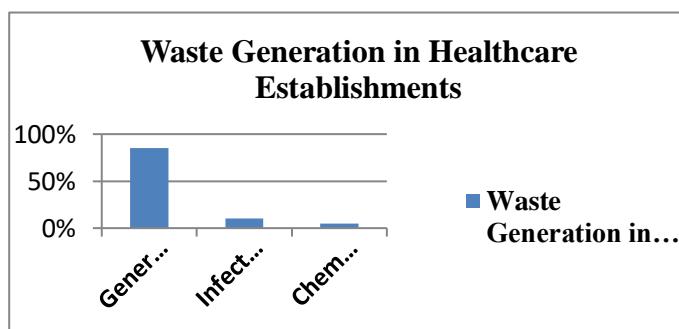


Fig: 1.1 Types of Waste

⁴ Biomedical Waste (Management and Handling) Rules, 1998, No.29 of 1986, Acts of Parliament (India)

⁵ *Id.*

⁶ *Safe Management of wastes from health-care activities*, Volume 1 (2014), (Mar 19, 2020, 10:04 AM),

https://apps.who.int/iris/bitstream/handle/10665/9789241548564_eng.pdf;jsessionid=0BDF7944CC3E30A25FB14A2A36213453?sequence=1

Classification of Medical waste as per BMW Rules⁷

CATEGORIES	DESCRIPTION AND EXAMPLES
Infectious Waste	Discarded Waste which consists of infectious disease causing pathogens. E.g. Cultures, waste generated from isolation ward, etc.
Pathological Waste	Tissues or Body fluids. E.g. parts of body, tested blood, etc.
Sharps	Sharp objects. E.g. Needles, infusion sets, scalpels, etc.
Pharmaceutical Waste	Waste containing discarded Bottles, boxes, etc.
Genotoxic Waste	Waste which are Genotoxic in nature. E.g. waste containing cytostatic drugs which is used in cancer therapy.
Chemical Waste	Discarded or used chemical substance. E.g. reagents used in Labs, film developer, disinfectants, etc.
Wastes containing metals	Used Batteries, used and broken thermometers, blood-pressure gauges, etc.
Pressurized Containers	Gas cylinders, gas cartridges, aerosol cans, etc.
Radioactive Waste	Waste having radioactive substances in them. E.g. unused liquids from radiotherapy or laboratory research, contaminated glassware, packages, urine, excreta, etc.

Fig 1.2: Classification as per BMW Rules, 1998.

⁷ Supra, 4, at Schedule 1.

1.1.3 Sources of Bio-Medical Waste

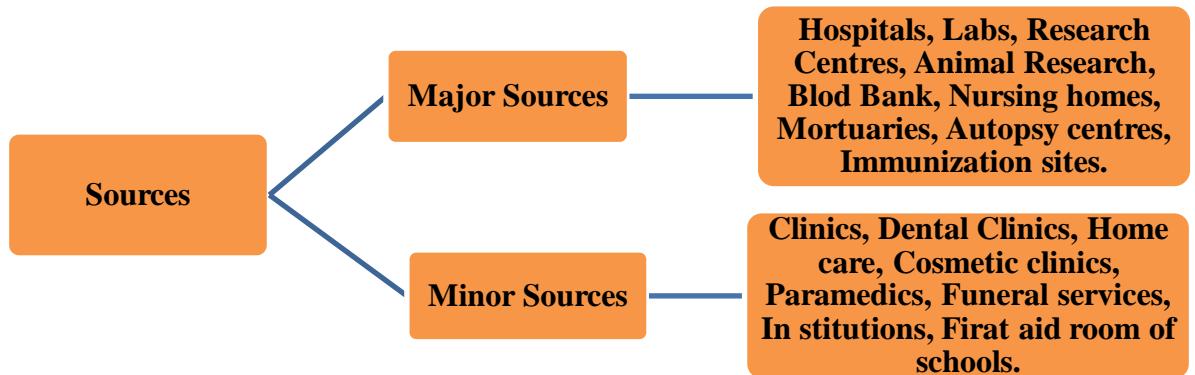


Fig: 1.3 Sources of health-care waste⁸

1.1.4 Risk associated Bio-medical Waste

Wastes discarded from healthcare establishments are infectious and also can cause serious injury to certain groups of people like doctors, nurses, workers, patients, visitors and rag pickers. It can pose threat to one's life and health due to one or more of the following characteristics⁹:

- ❖ It is highly infectious in nature;
- ❖ It also consists of certain highly toxic or hazardous chemicals or discarded pharmaceuticals products like medicines;
- ❖ Sharps like needles, discarded used glass items can be found in such wastes;
- ❖ Genotoxic elements are also present;
- ❖ Radio-active, mercury and its compounds are also present in it.

1.1.4.1 Environmental Hazards caused by improper disposal of Biomedical Waste

Improper disposal and poor handling of health-care waste can create environmental problems. Pathogens present in air can cause some serious diseases like AIDS, Hepatitis B and C, etc. or occupational hazards. In addition to this, burning of health-care waste

⁸ PARK, *supra* note 1, at 783.

⁹ *Id.* at 785.

like plastics and syringes can generate harmful greenhouse gases like carbon dioxide, etc. These gases are harmful for humans and can cause serious respiratory diseases like, emphysema, bronchial asthma, etc.

1.1.4.2 Infectious waste and sharps

Infectious waste consists of deadly viruses, which affect human being. Some of the disease that spread through infectious waste and sharps are Hepatitis B, Hepatitis C, HIV, etc.

1.1.4.3 Radioactive Waste's Hazards

Exposure to such wastes can result in headache, dizziness and vomiting and can sometimes cause other serious issues. Being Genotoxic in nature, it to a large extent affects genetic materials.

1.1.5 Need for Regulatory Measures

Due to the serious threat to health, air, water and land resources arising out of its improper management, people have started to realize the necessity of managing biomedical waste. With a judicious planning and management, however, the risk can be considerably reduced. On one hand, there is a need for developing law on scientific basis and on the other hand efficient enforcing agencies are the need of the hour. The need for specific law lies in the fact that it will help in proper management of bio-medical waste and will eventually reduce the risk associated with such waste.

The study will try to highlight loopholes and will analyze the existing laws in the present legislations. Further, the paper will focus exclusively on issue of biomedical waste management in India and will try to give some practical solutions to the problem.

The first chapter provides an introduction into the topic under study, definitions of biomedical wastes and analyzes the laws relating to biomedical waste management in India. The chapter also gives brief overview of the available literature, states the research questions and the research methodology chosen for the research.

The second chapter provides in brief the international measures taken up from time to time for protection of environment and analyses some of the important Conventions and treaties adopted at international level to fight against new problems like that of biomedical wastes. The chapter discusses in detail the provisions under Basel Convention 1989, Minamata Convention 2010, etc. which focuses on subject of biomedical waste.

The third chapter highlights the Indian Legal Framework on biomedical wastes management by analyzing the Biomedical Waste Management (BMW) Rules 1998, 1st Amendment to the BMW Rules 2000, 2nd Amendment to the BMW Rules 2003 and 3rd Amendment to BMW Rules 2016. Further, some important guidelines like Guidelines for Bar Code System for managing Bio-medical waste (2018), Guidelines for Disposal of Waste Generated through Diagnosis/Treatment/Quarantine of COVID-19 Patients (2020) has also been highlighted in this chapter.

The fourth chapter highlights some of the important constitutional provisions relating to environmental protection within framework of which biomedical waste could be managed.

Fifth chapter highlights the active role of judiciary on concern of environmental protection. This chapter further discusses the recent landmark decisions of NGT, High Courts and Apex Court with respect to biomedical waste management.

Sixth chapter highlights the Biomedical Waste Management Rules practiced USA and what India can learn from it.

Lastly, the seventh chapter provides for the conclusion arrived after completion of the study, with an attempt to answer the above framed research questions. In addition to this, the chapter further provides for possible suggestions for better mechanism.

1.2 Statement of problem

The problem of the research lies upon the fact that despite existence of BMW Rules and guidelines framed by Pollution Control Boards, the healthcare establishments are unsuccessful in management and proper disposal of the biomedical waste. The hazardous waste are posing a serious threat to human health and also causing environmental degradation. According to current status, unscientific dumping of Bio-Medical Waste continues. In spite of receiving strict order from NGT to curb the pollution caused by unscientific dumping of biomedical waste, the Government has hardly done anything so far. The question arises whether this Rules and Regulations at domestic level are sufficient to remove all issues relating to Bio-Medical Waste management or there is need for an effective legislation and scientific management of biomedical waste.

1.3 Aims

The aim of the dissertation is to study and evaluate problem of biomedical waste disposal in India and various legislations/Rules that have been formulated for proper management and disposal of biomedical waste. The dissertation also, seeks to suggest measures which must be adopted to fill the gap in the existing Biomedical Waste Management Rules.

1.4 Objectives

The paper will further attempt to achieve the following objectives in order to fulfill the aim:

- To study the harmful effects of biomedical waste and the challenges India is facing at present;
- To explore the international steps taken up for fighting the new problem of biomedical waste;
- To analyze the existing national framework governing biomedical waste management;
- To highlight the role of Pollution Control Boards in India in framing the guidelines for proper disposal of biomedical waste; and
- To study whether the administrative steps taken so far is sufficient enough to address the issue of biomedical waste.

1.5 Scope and Limitations

The scope of study is to focus on existing literature and to fill those gaps in those Literatures. The study will further focus on the role of Pollution Control Boards and Pollution Control Committees in implementing the provisions of Biomedical Waste Management Rules, 2016 and Bio-Medical Amendment Rules, 2018. The research paper limits its study to revisit and analyze the following policies and legislations adopted by the Government of India between 1998 and 2020.

1.6 Detailed Literature Review

For the study of the following topic the following literature has been reviewed:

Granite¹⁰ This article focused on the historical perspective of the hospital waste and its concern internationally throughout the world specially USA. The seriousness of improper Bio-Medical Waste management was brought to the limelight during the “beach wash-ups” during summer 1998; which was investigated by the Environment Protection Agency (EPA) of USA and it culminated in the passing of Medical Waste Tracking Act (MWTA) 1988 and made USA the pioneer as far as waste management is concerned.

Jariwala¹¹ the author in this article provides a detailed note on the how BMW Rules came into force in India, duties of various authorities under the Rules and standards provided for proper disposal of Bio-Medical Waste. With respect to historical background of BMW Rules 1998, it is provided that due to increase in number of infectious diseases, growing cases of AIDS and other deadly diseases, the Central Government realised the need for taking steps for managing biomedical waste. As a result, BMW rules, 1998 were notified by the Environment and Forest Ministry on 20th of July, 1998. The paper further highlights the role played by the apex court of India when the court was confronted with the problem of biomedical waste and a PIL was filed in 1994 by an advocate of Supreme Court of India. In the landmark case of *Wadhera v.*

¹⁰ Laurence D. Granite, *The Medical waste Tracking Act of 1988: An Analysis of its Provisions and its Effect on New York State*, 7 TLR, 259, 260-80 (1990).

¹¹ C.M Jariwala, *The Bio-Medical Waste- Direction of Law*, 41IL, 360, 368-82 (1999).

Union of India directions were issued to the concerned authority by the Supreme Court of India. The author has critically examined the BMW Rules of 1998 and held that attention must be paid by the Government to the suggestions put forth by the apex court. It was further suggested that a single authority must be established under the Rule by amending it and this authority must be vested with all powers as vested with the Pollution Control Boards. In this paper the author has rightly pointed out that more active lawyers and NGOs are required to throw light on the misactivities or inaction on the part of concerned authorities.

Khan¹² in his article writes about radioactive waste management in hospitals. The author further highlights the harmful effects of radioactive waste and how safe disposal of such waste are vital for entire mankind and environment. The paper also explains in detail the guidelines imposed by the International Atomic Energy (IAEA) for proper disposal of radioactive waste.

Mohankumar & Kottaiveeran¹³ the authors analyses the Bio-Medical Waste management system in India including the prevalent practice across the country. Further, it has been highlighted in the paper that the most ignored field which is causing enormous pollution is Bio-Medical Waste. Few suggestions are laid down for reducing the mismanagement of bio-medical waste disposal.

Muduli & Barve¹⁴ the author highlights the challenges of medical waste management in India. With increase number of healthcare establishments, amount of waste has also increased. Healthcare establishments are adopting methods with concern with reducing and managing of waste. However, these methods are not free from challenges like these methods have an adverse affect on environment. Healthcare establishments are not aware of other new techniques which will help in reducing health and environment hazards due to medical waste. For instance, the paper explains technique of Green Supply

¹² Shoukat Khan, *Radioactive Waste Management in a Hospital*, 4 IJHSC, 12, 39-46 (2010).

¹³ S. Mohankumar & Dr. K. Kottaiveeran, *Hospital Waste Management and Environmental Problems in India*, 2IJPBA, 1600, 1621-26 (2011).

¹⁴ Kamalakanta Muduli & Akhilesh Barve, *Challenges to Waste Management Practices in Indian Health Care Sector*, 32 IPCBEE, 50, 62-67 (2012).

Management, which has been widely adopted for disposing biomedical waste. GSM is concerned with improving quality of medical products and aims at producing sustainable products. The paper suggests certain important strategies that can be adopted by the Government for improving the existing management.

Singh, Kaur¹⁵ in their book provides the basic understanding of biomedical waste. The entire book is updated with current legislations and organized in different chapters. The authors have explained in details the categories of biomedical waste, ill effects of biomedical waste and the issues related to technicalities of biomedical waste management. One chapter is entirely devoted to waste minimization and advantages of waste minimization.

Tanksali¹⁶ in this paper the author has explained in details the systematic management of health-care waste including treatment of waste containing mercury. The author has highlighted the fact that in order to bring about proper management and reduction of health-care waste, more focus is to be put on bringing awareness among health-care professionals, Government and waste handlers. The author restricts the study to Bijapur district of Karnataka. It was found that wastes from OPDs are collected twice a week and is not properly disposed. Further, the paper highlighted the fact that waste handlers and other medical staffs are unaware of the existing Rules and there is a need to provide training to all medical staffs with respect to proper management of Bio-Medical waste.

Park¹⁷ The book contains factsheets on significant subjects identified with biomedical waste administration. The subjects covered are proper disposal of sharps, hospital waste management, disposal of plastics in healthcare, method of incineration, training related to handling of mercury, safety of healthcare worker, treatment processes etc. This book is relevant as it addresses primary issues of health care system like management of waste, disposal of sharps, plastic waste management and precautionary measures to be taken.

¹⁵ ANANTPREET SINGH & SUKHJIT KAUR, BIOMEDICAL WASTE DISPOSAL, (1st ed. 2012).

¹⁶ A.S Tanksali, *Management of Bio-Medical Waste*, 5 IJCRGG, 1000, 1214- 21 (2013).

¹⁷ K PARK, PREVENTIVE AND SOCIAL MEDICINE, 780-81(2015).

Patil¹⁸ this article gives a brief insight into the legal framework adopted at National Level. Some important legislation is discussed with respect to biomedical waste management like the Environment Protection Act 1986, BMW Rules 1998, Section 268 of IPC (Public Nuisance), Section 269 of IPC (Negligent act likely to spread infection of disease dangerous to life) and Section 270 of IPC.

Johnson¹⁹ in this particular paper a study was conducted in a two thousand bedded Hospital to understand the status of biomedical waste management after coming of Amendment of 2016. Interview method was adopted to collect data and to suggest changes necessary for implementation of BMW Rules, 2016.

Capoor²⁰In this study it was found that doctors, health workers and laboratory technicians have significantly less knowledge on legislative frameworks/Rules on Bio-Medical Waste Management. It was further suggested that weekly or monthly classes should be conducted for doctors, nurses and staffs on proper Bio-Medical Waste Management and its legal aspects.

Kumari²¹ the study mainly highlights on the health related issues of biomedical waste, source of biomedical waste, role played by private and government hospital in handling the biomedical waste, existing law in India and its limitation as well as socio-economic implementation of biomedical waste management Rules in India.

Changmai, Islam, Nongsiang, Deka, Saharia& Dey²² the authors in this article have tried to give a detailed explanation of the BMW Rules 1998 and the recent amendment to

¹⁸ Yuvraj Dilip Patil, *Disposal of Bio-Medical Waste in India*, 4 JKIMSU 100, 188-192 (2015).

¹⁹ Dr. Bijoy Johnson, *Implications of Bio-Medical Waste Management Rules 2016: A Case Study at a Tertiary Care Teaching Hospital*, 15 ISHWM 1, 15-21 (2016).

²⁰ Dr. Malini R Capoor, *Evaluating and comparing the Knowledge of Heath Care Workers about Legislation and Regulatory Mechanism on Bio-Medical Waste Management in a Tertiary Care Hospital in North India*, 16 ISHWM 1, 14-23 (2017).

²¹ Pavitra Kumari, *Limitations of Legal Enforcement in Bio-Medical Waste Management in India*, 2, IJERME 20, 33-36 (2017).

²² Arabinda Changmai, Tofiqul Islam, Dibarlan Nongsiang, Manoj Kumar Dey, Bhargab Jyoti Saharia, Ananata Choudhury & Biplab Kumar Dey, *Bio-Medical Waste Management in Different Hospitals of Guwahati and its Effect on environment*, 6 JOAPR, 1, 7-10 (2018).

the Rule of 1998. Further, the authors conducted a study and the article thus speaks about how the healthcare establishments in Guwahati are treating their hazardous bio-medical waste. Only hospitals with 200 beds were selected and study was carried out. Thus, other hospitals with more than 200 beds which generate a huge amount of waste were left out.

Manzoor, Sharma,²³ in this article the author reviews the harmful effect of biomedical waste on water, soil, air, the environment and human health due to disposal of Bio-Medical waste in an unscientific manner. The article has also featured the issue of proper identification, handing and disposal needs so that better management practices and laws can be established. The article is more focused towards highlighting the harmful impacts and no light has been thrown upon the need for change in BMW Rules or adoption of new practices.

Henam & Shrivastav ²⁴ in this newspaper article attention was drawn towards present scenario of Bio-Medical Waste management in India. The article also highlights that the Rules have only reduced to paper formality and there is lack of awareness among the healthcare establishments with respect to proper management.

Singh, Unnikrishnan, Dongre²⁵ in this article, the authors drew attention at the increasing amount of biomedical waste year after year and what is the risk associated with improper handling of biomedical waste. The article further explains the recent Amendment done in year 2018 to the BMW Rules and the present position of health-care waste management in our country.

The review of the existing literature on the subject matter although has been very helpful in understanding the issue of biomedical waste management and how International

²³ Javid Manzoor and Manoj Sharma, *Impact of Biomedical Waste on Environment and Human Health*, 31, ECJ 11, 311 (2019), <https://doi.org/10.1040/026.2019.1619265>

²⁴ Sonia Henam & Rashmi Shrivastav, *Biomedical Waste Management in India: Still a looming Concern*, Down to Earth (Apr. 08, 2019, 9 AM), <https://www.downtoearth.org.in/blog/health/biomedical-waste-management-in-india-still-a-looming-concern-63896>.

²⁵ Anju Singh, Seema Unnikrishnan and Samriddhi Dongre, *Biomedical Waste Management in India: Awareness and Novel Approaches*, 13, BJSTR, 1, 2 (2019), <https://biomedres.us/submit-manuscript.php>

Frameworks have made persistent effort to minimize the threat of biomedical waste, the literatures elucidates only the legislative measures without highlighting the defects. Moreover, in reference to United States laws on biomedical waste management, it can be seen that very little work has been done in Indian Legal structure. Moreover, none of the literature has examined the gaps in our Legal system and enforcement machinery.

1.7 Research Questions

- Whether the National Legal frameworks are in line with the International Regulatory framework on Bio-Medical Waste Management?
- Whether the legislative framework adopted by the Government of India is sufficient to deal with the problem of mismanagement of such waste in Guwahati?
- Whether management of Bio-Medical Waste is carried out according to those Rules?
- How is the issue of disposal of biomedical waste been handled by courts and tribunals?
- What India can learn from United States in management of Biomedical Waste?
- What are the laws adopted for managing COVID-19 biomedical waste in India?

1.8 Research Methodology

The research work is doctrinal in nature. Accordingly to suit the nature of research, various research methods such as analytical method, evaluative method and comparative method are employed. Analytical method is used to analyze various provisions of the Indian Constitution, all other legal provisions relating to environmental protection, hazardous, solid waste management and judicial decisions.

The researcher has applied the evaluative method, in order to find out the efficacy and adequacy of the existing laws in combating the environmental degradation. Comparative method is also applied mainly to compare the waste management laws in India with United States. In this research, for the purpose of exploring and identifying various statutory provisions and judicial decisions, web based legal data bases were relied. As a part of the doctrinal research the researcher has collected data from different sources (i.e.

primary and secondary). Under primary sources, substantial and relevant authority has been availed. Under the secondary sources, the researcher has collected published and unpublished⁶⁰ persuasive data from multiple sources.

1.9 Research Design

Considering the seriousness of the problem, an attempt has been made by the researcher to analyze the Bio-Medical waste Rules and to find out suggestive measures to fill up the gap. The researcher would collate to make this research paper as a socio legal research by following a descriptive data analysis strategy concluding with an inferential analysis testing the research questions in research proposal. Over the course a particular time frame would be followed, limiting the scope of research.

Chapter 2

International Agreements and Conventions relevant to management of Bio-medical waste

The below listed Agreements/Conventions are relevant in managing Bio-medical/Health-care Waste and protection of environment. The provisions of these important Agreement and Conventions are taken into consideration for framing national policies and legislative frameworks.

2.1 Conventions

2.1.1The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, 1989²⁶

In the late 1980s due to industrialization, generation of hazardous waste increased to maximum. Also, along with amount of wastes, disposal cost also rose up. As a result, the industries started exporting the hazardous wastes to least developed as well as developing countries as dumping was cheaper than treating the wastes. Worldwide concern and outrage led to adoption of the Basel Convention in the year 1992. The Convention was also ratified by India in 1992.²⁷ As per the preamble of the Basel Convention, the parties are required to take up necessary steps to ensure that the transboundary movement, management and disposal of hazardous waste are done in proper way, keeping in mind the protection of environment and human health. The preamble further recognizes sovereign right of State stating that the State can also put a ban on entry and disposal of foreign waste within its own territory. Further, the Convention imposes an obligation upon the parties to disposed wastes by following necessary provisions of the Convention.²⁸

The Convention regulates transboundary movement of hazardous and other wastes. Under the Convention parties are required to adopt a National Legislation for regulating

²⁶ *The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, 1989 : Text and Annexure*, UNEP, (Feb, 20, 2020, 11 A.M),

<https://www.basel./Portals/4/BaseL20Convention/docs/text/BaselConventionText-e.pdf>

²⁷ Shaza Quadri, *Analysis of the Effects and Reasons for Hazardous Waste in India and its implementation of the Basel Convention*, 22 Fla, Dec. 2010, at 467.

²⁸ Supra, 26, at 5.

hazardous wastes and thereby should define the term “hazardous waste” in that particular legislation.²⁹ Other important provisions include:

- Convention imposes certain general obligations upon the parties. As per the Convention, parties are required to notify other State parties if they are not willing to import hazardous waste from that particular State. Once notified, States/Parties who have been notified shall refrain from exporting hazardous wastes.³⁰
- The Convention imposes an obligation upon the parties to establish competent authority (one or more than one) having power to implement the Convention at National Level.³¹ In case of State of transit, one competent authority must receive notification with respect to same.
- The principle of “prior informed consent” is adopted. Before exporting, State exporting the wastes or the generator of wastes has to inform in writing to the authority of the State for import about their intention. On receiving the notification, State has to respond in writing within a period of 60 days.³²
- Where wastes are illegally trafficked without obtaining consent, the States or generators exporting such wastes are required to take back the waste into the State from where it was originated or the wastes are to be disposed of properly according to the provisions of the Convention.³³

2.1.1.1 Basel Convention and healthcare/Bio-Medical waste

Under the Basel Convention, Annexure I provides for classification of hazardous wastes which are required to be kept under control. Under the annexure, healthcare wastes are classified as;

- Clinical wastes generated from hospital and clinics are categorized as Y1.
- Wastes generated from pharmaceuticals production are categorized as Y2.
- Discarded pharmaceuticals, drugs and medicines are categorized as Y3.

²⁹ Supra, 26, at 13.

³⁰ Supra, 26, at 14.

³¹ Supra, 26, at 15

³² Supra, 26 at 16.

³³ Supra, 26, at 17.

Further, under Annexure III,³⁴ under Code H6, characteristics of hazardous wastes are provided. As per the Code, Infectious wastes are those that contain micro organisms and other toxics harmful for humans and animals.

As per the Convention, the wastes which are mentioned in Annexure I shall be regarded as hazardous waste and can be moved from one place to another for the purpose of disposal. Further, the wastes which although listed in Annexure I, but has the characteristics as mentioned in Annexure III, cannot be subject to transboundary movement.³⁵

The Secretariat further came up with a set of guidelines in 2003³⁶, focusing on segregation and treatment of bio-medical waste. The guidelines suggested for certain good practices that could be adopted for proper waste management.

2.1.1.2 Challenges in implementation of provisions of Basel Convention

Even after adoption of Basel Convention, problem of illegal dumping is prevalent internationally. Recently, India faced such a situation. About 38³⁷ containers filled with hazardous and plastic waste, sent by USA to be dumped in Indonesia, was actually illegally dumped in India. When containers were seized by Indonesian authorities, they were supposed to send back to the country from where it was exported. But instead, containers were diverted to India illegally. This shows that failure of Basel Convention to protect health as well as the environment. Few shortcomings of the Convention can be listed as:

- Prior Informed Consent Regime is not sufficient enough to deal with the problem of illegal dumping. Radioactive wastes and Persistent Organic Pollutants are not governed by the Basel Convention.

³⁴ Supra, 26, at 60.

³⁵ Supra, 2, at 5.

³⁶ *Technical Guidelines On The Environmentally Sound Management Of Biomedical Wastes, Secretariat Of The Basel Convention*, BASEL CONVENTION, (Feb, 27, 2020, 10 A.M), http://www.basel.int/Portals/4/Basel%20Convention/docs/meetings/ewg_2/otherDocs/INF-10%20Waste%20stream%20fact%20sheets.pdf

³⁷ Abhinandan Mishra, *Connivance between corrupt port and Government Officials*, SG Live, Dec 14, 2019.

- Further, the Convention does not put a complete ban of movement of such wastes from one region to another. Rather, it sets certain guidelines which are to be followed while trading of such hazardous wastes.
- The Convention failed to address the issue of minimization of wastes. Moreover, the definition of waste management is narrow as no preventive measures are listed. The Convention focuses more on management and trading, rather than minimizing of wastes.

2.1.2 Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa (1991)³⁸

In spite of having the Basel Convention in force, developing countries, especially African countries continued to receive hazardous wastes from other developed countries. One of the chief causes for such menace was that Africa offers a cheaper and less tedious option for disposal. Considering the failure of Basel Convention, the African countries themselves initiated a treaty in the year 1991. The treaty came to be known as the Bamako Convention. The Convention is in accordance with the objective of the Basel Convention which provides that States can enter into agreements with other States (Non-party also) as well as with non-parties for transboundary movement of wastes. Further, the scope of Bamako Convention is wider than Basel Convention as unlike Basel, Bamako addresses radioactive wastes too and puts a complete ban on import of wastes to African Countries.

Some of the important provisions of Bamako Convention include:

- The Convention imposes a complete ban on entry of hazardous wastes into Africa and such an act shall be termed as illegal and criminal in nature.³⁹
- The Convention, unlike Basel Convention bans dumping, incineration and disposing hazardous wastes into Sea and Internal Waters of African Countries.⁴⁰

³⁸ *Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa (1991)*, UNEP, (Feb, 23, 2020, 1 P.M), <https://www.jus.no/hazardous.waste.ban.african.import.bamako.convention.1991/portrait.pdf>.

³⁹ id., Art. 4 (1).

- The Convention further talks about adopting Precautionary principle as a means for preventing pollution. Further, States are prohibited from exporting hazardous wastes to such States which are not technologically sound and cannot treat the wastes in environmentally friendly manner.⁴¹
- The Convention provides for establishment of a competent authority to have all powers for implementing the provisions of the Convention.⁴²
- There is provision for proposing amendment to the Convention and any State Party can propose such amendment.⁴³

2.1.2.1 Bamako Convention and Bio-Medical Waste

Under the Bamako Convention, Annexure I⁴⁴provides for categories of hazardous wastes. Under the annexure, healthcare wastes are classified as;

- Clinical wastes generated from hospital and clinics are categorized as Y1.
- Wastes generated from pharmaceuticals production are categorized as Y2.
- Discarded pharmaceuticals, drugs and medicines are categorized as Y3.

2.1.3 The Stockholm Convention on Persistent Organic Pollutants⁴⁵

The Convention was adopted on 22nd May 2001 and it came into force in 2004. The Convention is based on Precautionary principle and aims to protect human health and environment from harmful effect of persistent organic pollutants.⁴⁶ As per the treaty, POPs are carbon-based organic chemicals. These are harmful in nature and once released they can remain intact for long period of time. Extensive contamination of environment by POPs has resulted in acute and chronic effects to health of both humans and wildlife.

POPs are absorbed in greatest concentration by birds, mammals and humans and when they travel, these POPs also travels with them. As a result, POPs can be found in people

⁴⁰ id., Art. 4 (2).

⁴¹ id., Art. 4 (3).

⁴² id., Art. 5.

⁴³ id., Art. 17

⁴⁴ id., Annex I

⁴⁵ *Stockholm Convention On Persistent Organic Pollutants (POP), 2001*, UNDP, (Feb 20, 2020, 10 A.M), https://www.wipo.int/edocs/lexdocs/treaties/en/unep-pop/trt_unep_pop_2.pdf

⁴⁶ id., Art. 1.

and animals living in regions, for instance those living in Arctic, which are thousands of kilometers from major POPs source. POPs are generally released from burning medical waste by process of incineration and combustion. POPs are released from medical wastes when they are not properly incinerated or when incinerated below 800 degrees Celsius. The Convention provides a framework that lays down guidelines for the parties to manage and control POPs and toxic substances. The Convention makes it mandatory for the parties to take legal steps to eliminate production and use of POPs.⁴⁷ Certain exceptions are also there. For instance, use of DDT (Dichloro Diphenyl Trichloroethane) is allowed in India for specific purposes. Persistent Organic Pollutants Review Committee in their fifteenth meeting⁴⁸ has added the following chemicals to the list of POPs:

- Perfluorohexane Sulfonic Acid and its salt
- Methoxychlor
- Dechlorane Plus

Some of the important provisions of Stockholm Convention are:

- Parties should adopt stringent measures to prohibit production; import and export of chemicals which are listed in Annexure A and B.⁴⁹ Chemicals listed in annexure A, B and C are referred to as subject to elimination, restriction and unintentional production accordingly.
- A Register is to be maintained by the Secretariat. The Register shall be accessible to public at all times and shall include details with respect to exemptions granted to State parties for chemicals.⁵⁰
- State parties to initiate action plans at regional or sub-regional level to reduce total release of POPs.⁵¹ The action plan should evaluate efficiency of laws, policies; promote education and training with respect to creating awareness among people.

⁴⁷ id., Art. 3.

⁴⁸ *Report of the Persistent Organic Pollutants Review Committee*, October 1, 2019. UNEP, (Mar, 20, 2020, 11 A.M), <http://www.pops.int/TheConvention/POPsReviewCommittee/ReportsandDecisions/tabcid/3309/Default>.

⁴⁹ Supra, 46, at Art. 3.

⁵⁰ Supra, 46, at Art. 4.

⁵¹ Supra, 46, at Art. 5(a).

- State parties are under a duty not to conceal information with respect to production of POPs. Further, the parties should always exchange information with respect to production, use, elimination and release of POPs with the Secretariat. Such information shall be shared via National focal point.⁵²
- Parties are required to undertake research activities for the purpose of developing alternatives for POPs. Further, parties are required to support the developing countries with exchange of data for enhancing research activities.⁵³
- The Convention has provision for peaceful settlement of dispute between the parties with respect to interpretation of the provision of the Convention. The parties when ratifying or approving the treaty has to identify and submit a written instrument with respect to mode of settlement of dispute. The dispute is to be taken up by the International Court of Justice.⁵⁴

2.1.3.1 Stockholm Convention and Bio-Medical Waste

As per Annexure C, certain POPs like Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF), Hexachlorobenzene (HCB) and Polychlorinated biphenyls (PCB) are accidentally produced. Further, dioxin and mercury are released in bulk from health sector on account of incomplete combustion, low technology incinerators, burning of blood bags, fluid bags; discarded and broken thermometers and blood-pressure meters. Such POPs are harmful and does not breakdown in environment. They actually accumulate in the food chain and enter human body via intake of food.⁵⁵

The parties have adopted certain practices with aim to avoid unintentional and formation of POPs from bio-medical wastes. For instance, some hospitals in India, Argentina and Lebanon have adopted the process of re-melting and recycling of plastic and glass materials like discarded injections, broken thermometers and blood-pressure devices,

⁵² Supra, 46, at Art. 9.

⁵³ Supra, 46, at Art. 11.

⁵⁴ Supra, 46, at Art. 18.

⁵⁵ *Chemicals and Waste Management for Sustainable Development*, UNDP, (Mar 23, 2020, 11 A.M), https://www.undp.org/content/dam/undp/library/Environment%20and%20Energy/Chemicals%20and%20Waste%20Management/UNDP-POPs%20publication%20April%202013/UNDP_StockholmConvention_April2.pdf.

test-tubes, etc. Certain modules have been developed and translated in different languages for proper training on healthcare waste management. The modules also highlight certain non-incineration techniques which are available worldwide that can help to reduce release of POPs. One such guideline on Healthcare management is Promoting Best Techniques for reducing biomedical wastes to avoid release of Dioxins, furans and Mercury.⁵⁶ The aim of the guideline/project is to establish best practices for managing health-care wastes, adoption of non-incineration technology, introduction of mercury-free devices and apparatus among health-care establishments; and enhancing training programs for capacity building.⁵⁷

2.1.4 Minamata Convention on Mercury⁵⁸

It is the first global Convention that aims for protection of human health and environment from harmful effect of release of mercury⁵⁹. The Convention is named after place Minamata in Japan, where near about thousands of people were poisoned and made crippled by mercury tainted wastewater discharged from factories during 20th Century.⁶⁰ Mercury is harmful for humans and can cause severe health issues like damage to nervous system, kidneys, lungs, can cause loss of memory and irreversible damage to brain cells. Mercury is naturally present in our environment and is used for wide variety of purposes. At present, mercury is used in production of Alkali paints, PVC production, extracting gold from gold mines, laboratories, chemicals, jewellery, light bulbs, batteries, etc. Mercury can be ingested by fishes and other marine creatures. Humans can come in contact with mercury either by ingestion of fishes or by inhaling accumulated mercury in air particles.⁶¹

⁵⁶ *Demonstrating and Promoting Best Techniques for reducing health-care wastes to avoid environmental release of Dioxins and Mercury*, STOCKHOLM CONVENTION, (Mar, 11, 2020, 12 A.M), https://noharm-uscanada.orgs/default/files/documents-files/2047/GEF_Summary.pdf

⁵⁷ ibid.

⁵⁸ *Minamata Convention on Mercury*, UNEP, (Mar, 22, 2020, 11 A.M), http://www.mercuryconvention.org/Portals/11/documents/Awareness%20raising/FACT%20SHEETS/Minamata%20Convention%20Mercury%20at%20a%20glance_04%2016.pdf

⁵⁹ id., Art. 1.

⁶⁰ *The Minamata Convention on Mercury by UNEP or the Interim Secretariat of the Minamata Convention.*, UNEP, (Mar, 22, 2020, 10 A.M), http://www.mercuryconvention.org/Portals/11/documents/%20raising/FACT%20SHEETS/Minamata%20Convention%20on%20Mercury%20at%20a%20glance_04%2016.pdf

⁶¹ ibid.

Some of the important provisions of Minamata Convention are:

- The parties should not allow primary mercury mining after ratifying the Convention if earlier such mining was not conducted within its territorial area. However, if such mining was already there before coming of the Convention, then the parties can allow such primary mercury mining up to the period of 15 years only. During that period parties have to make sure that the manufacturing and processing of mercury based products are done in accordance with Article 4 and Article 5 of the said Convention.⁶²
- The export of mercury is not allowed by the Convention. However, parties can export it only for use as listed and allowed as per the Convention.⁶³
- Further, the parties are to prohibit import or export of those mercury products which are listed in Annexure I of Annexure A, except for the exempted ones.⁶⁴
- The Convention further imposes an obligation upon parties to adopt environmentally sound measures with respect to storage of mercury and other mercury-added products. The parties while adopting measures and framing guidelines with respect to management and disposal of mercury products has to take into account the guidelines laid down by the Basel Convention.⁶⁵
- The Convention further provides for establishment of a Compliance Committee by the Conference of parties to look into implementation and compliance of the provisions of the Convention. The Committee shall review all the provisions of the Convention and make recommendations if needed.⁶⁶
- The Convention provides for establishment of financial mechanism to aid capacity building and to provide technical help to the developing countries by the developed countries.⁶⁷
- The Convention has certain information and awareness raising Articles within it. For instance,

⁶²Supra, 59, at Art. 3.

⁶³ Supra, 59, at Art. 3 (6).

⁶⁴ Supra, 59, at Art. 4 (1).

⁶⁵ Supra, 59, at Art. 10.

⁶⁶ Supra, 59, at Art. 15.

⁶⁷ Supra, 59, at Art. 13

- a) The parties are under an obligation to provide appropriate health-care facilities to people affected by the mercury exposure⁶⁸:
- b) The parties shall exchange information with respect to handling, reduction, elimination and alternatives, if so available for mercury; mercury-added products⁶⁹.

2.1.4.1 Minamata Convention and Bio-Medical Waste

With respect to health-sector, the Convention under Article 4(1) imposes an obligation upon the parties to stop manufacture, export or import of mercury-based instrument like the barometers, hygrometers, manometers, and sphygmomanometers after 2020.⁷⁰ Further, the Convention requires the parties to stop manufacture, export and import of liquid mercury used in Dentistry and to develop/adopt mercury free alternatives for dentistry. Further, to minimize use of mercury in dental restoration, parties are required to encourage dental professionals to educate the students of dental colleges to switch to alternative methods, develop best practices and adopt environmentally sound practices for proper disposal of mercury into land and water bodies.⁷¹

2.1.4.2 Challenges in Implementation of the Minamata Convention

Minamata Convention is not free from criticisms and critics have identified many loopholes in the Convention. The Convention lays down that only primary mining used for extracting mercury will be banned. However, the Convention provides that those mercury mines which are already in been used for extracting mercury shall be allowed up to a period of 15 years. Thus, it clearly shows that within a period of 15 years maximum mercury can be extracted by the miners and thereby pollution level will also go up. The Convention should have laid down a provision imposing total ban on existing mercury mining.

⁶⁸Supra, 59, at Art.16.

⁶⁹ Supra, 59, at Art. 17.

⁷⁰ Supra, 59, at Annex. A, Part I.

⁷¹ Supra, 59, at Annex A, Part II.

Further, the Convention provides that use of mercury will be allowed in extracting gold from mines by artisans and small scale miners. Thus, allowing use of mercury exposes the artisans and miners to high level of mercury. The Convention further directs the Contracting parties to find alternatives and phase out with use of mercury in dental fillings. This is a major drawback as use of mercury cannot be banned in dentistry unless and until alternatives are found and students are given training to minimize its use.

Further, the use of mercury in religious and traditional activities is not banned by this treaty. Thus, the treaty should have imposed a complete ban on using mercury in any such activities.

2.2 International Guidelines

2.2.1 WHO guidelines on Safe Management of wastes

In the year 2014, WHO came up with a practical guideline with an aim of improving public awareness with respect to proper handling and safe disposal of Bio-Medical wastes. The handbook is concise and detailed. The handbook precisely defines healthcare wastes, various types of bio-medical wastes, non-hazardous wastes, lists of discarded items which can be recycled, major sources of generation of bio-medical wastes, etc. The handbook further highlights the fact that wastes generation can be reduced to maximum by applying local measures⁷². The handbook is concerned with highlighting types of health hazards that are associated with improper disposal of health-care wastes and what is the environmental risk associated with disposal bio-medical wastes.

The handbook has rightly highlighted that wastes produced from hospitals are highly contagious in nature as it contains infected needles, radioactive wastes, cytotoxic wastes, which are hazardous in nature. The handbook further pointed out that inappropriate management of these wastes can cause serious diseases among people, animals and can also cause damage to our surroundings. This handbook addresses issues of climate change and how it is impacting health-care wastes management across the globe. One of

⁷² CHARTIER & JORGE EMMANUEL, SAFE MANAGEMENT OF WASTES FROM HEALTH-CARE ACTIVITIES, 100-180 (2d ed. 2014)

the advantages of this handbook is that it provides practical guidance on efficient and safe disposal of health-care wastes. Details of harms, how containers containing bio-medical wastes are to be kept and disposed of, how waste generation can be minimized and which wastes can be recycled and used again, is discussed in length. The guidelines are useful as its scope is wide enough to be suitable for both developed and developing countries.⁷³

2.2.2 WHO document on Overview of technologies for the treating infectious and sharps

In 2019⁷⁴, WHO came up with another set of practical guidelines suggesting techniques that can be employed for treating discarded infectious Sharps. Safe waste management supports the United Nations SDGs. It is globally evident that there is no safe management of Bio-Medical wastes and the situation is worse in LDCs⁷⁵. The handbook explains the technologies that can be employed in segregating, collecting and treating Bio-Medical wastes in an effective manner by developed, developing and Least Developing Countries. The handbook particularly focuses on LDCs and describes in length the environmentally sound techniques to meet the goals of major environmental treaties.

In this handbook, the guidance is provided keeping in mind the Stockholm Convention on POPs. As per the guidelines, States should give due consideration to use of those technologies which totally avoid release of harmful POPs into the environment. Further, States are directed to use non-incineration techniques for treatment of Bio-Medical Wastes. Governments are further recommended to allocate sufficient funds necessary for maintaining sound waste management in their respective countries. Health-care establishments are further directed to promote proper waste management by developing solutions which will aim at reducing volume of wastes generation and reducing toxicity associated with the wastes.

⁷³ *ibid.* at 201.

⁷⁴ Dr. UTE PIEPER, Ms. ARABLLA HAYTER & Dr. MAGGIE MONTGOMERY, OVERVIEW OF TECHNOLOGIES FOR THE TREATMENT OF INFECTIOUS AND SHARP WASTES, 1-12 (1st ed. 2019).

⁷⁵ *ibid.* at 3.

2.2.3 Compendium of Technologies for treating and destructing health-care waste

The document reviews in detail about health-care wastes, their impact on environment and health. The document discuss in detail about the constituent element of healthcare wastes like material contents, chemical contents and moisture contents. Further, the document provides for detail description about process by which wastes are treated, procedure for destructing pathogens, how emissions can be controlled, etc. The main purpose of this document is to assist the Government and all health organizations of the world, in adopting suitable technologies for treating biomedical wastes.⁷⁶

The main focus of the document is not on minimizing generation of biomedical wastes, but is only on destructing such wastes. With respect to incineration, it is provided that wastes treated by way of incineration are usually transformed into toxic ash, which is hazardous in nature. Thus, focus has been placed on some new technologies that can be adopted to transform wastes into disinfected one and can also help in recycling wastes and recovering materials. Some of those technologies include thermal process, chemical process which allows use of chemicals to destroy harmful pathogens, using radiation to destroy pathogens and biological process for naturally degrading the wastes.

2.2.4 Guidelines on Bio-Medical Wastes Management by Red Cross Society

International Committee of Red Cross (Herein after referred to as ICRC) in the year 2011 came up with certain guidelines on proper management of discarded hospital wastes. The guidelines were framed with an aim to assists both the LDCs as well as the Developed Countries. It is rightly highlighted in the manual that poor management of bio-medical wastes can jeopardize health of health workers, patients, their attendants and the nearby people. The focus of the manual is on routine management of wastes generated by medium sized hospitals i.e. hospitals having only 100 bed capacity.⁷⁷

The manual explain in details the legislations adopted at International level that must be taken into consideration before taking up steps for dealing with hazardous hospital waste.

⁷⁶ Dr. JORGE EMMANUEL, COMPENDIUM OF TECHNOLOGIES FOR TREATING AND DESTRUCTING HEALTH-CARE WASTE, 10-20 (1st ed. 2012).

⁷⁷ MEDICAL WASTE MANAGEMENT BY ICRC, 10-22 (1st ed. 2011).

Further, in framing rules at national level to deal with waste management, few other legislations should also be kept in mind. For instance, legislations on air, public health, Hazardous materials, safety regulations, etc.⁷⁸ The handbook provides for setting up of a waste management team at all hospitals whose main function would be to ensure that wastes are managed keeping in mind both the national as well as international legislation. Such team shall be responsible for framing a draft of rules and appointing a person who will help in supervising and coordinating wastes management. With respect to Recycling of wastes, it is not recommended by the handbook to use recycled plastic wastes of used needles.

2.2.5 Guidelines on the Environmentally Sound Management of Biomedical Wastes, the Basel Convention

The handbook fundamentally defines bio-medical waste and classifies them according to their characteristics. The handbook mainly focuses on reducing generation of bio-medical wastes by applying specialized techniques. Information is provided in details with respect to reducing wastes which can be applied by both public as well as private hospitals and clinics.⁷⁹ Further, the guidelines have addressed issues relating to disposal, occupational hazard, awareness of people, promotion of research activities for improving technologies. These guidelines are applicable to both large sourced as well as medium sourced health-care establishments. Specific precautions are laid down with respect to prevention of transmission of HIV, Hepatitis B and other deadly pathogens.⁸⁰

The primary aim of these guidelines is to assist the States in improving the waste management system in their respective countries. These guidelines are flexible in nature as once adopted by the parties can be amended and adjust as per their suitability. Further, the guidelines address the current need of Least Developed Countries. It has rightly recognized the difficulties faced by the Countries in managing wastes and thus special

⁷⁸ *ibid*, at 31.

⁷⁹ TECHNICAL GUIDELINES ON THE ENVIRONMENTALLY SOUND MANAGEMENT OF BIO-MEDICAL AND HEALTH-CARE WASTES (Y1;Y2), 10-27 (1st ed. 2003).

⁸⁰ *ibid* at 40.

attention has been given to identifying techniques keeping in mind the infrastructural capacity of the Countries.

2.2.6 WHO Guidelines on Waste Management for COVID-19⁸¹

The interim guidelines were laid down by WHO on April 2020, providing details on sanitation, protecting health of workers and safe disposal of waste generated from treating COVID 19 patients. The guideline has laid down certain measures that can be adopted for preventing spread of COVID-19 Virus. For instance, for maintaining hand hygiene it is recommended to use alcohol-based sanitizer or washing hands with soap and water. Proper PPE kits should be made available to all Sanitation workers and proper training should be given to them for handling waste generated at times of COVID-19. ⁸²Fragments of COVID-19 Virus have been found in excreta of patients. Thus, it is recommended that waste water should be properly treated in properly designed treatment plants. Moreover, it is recommended that Oxidation pond should be used for this purpose. This technology is suited for destroying pathogens by use of sunlight.⁸³

With respect to Bio-Medical wastes it is laid down that all wastes generated during treatment of COVID patient are highly infectious in nature and includes both sharps as well as pathological wastes. Thus, it is suggested that all such wastes should be properly collected in separate containers. Such wastes are to be pre-treated and disposed by Municipal Wastes Collectors. As the amount of discarded PPE will increase during the pandemic, thus it is suggested that additional treatment plants is to be set up and alternative techniques should be adopted for handling wastes. For water generated from washing PPE, Gloves and Reusable aprons, it is recommended that cleaning of PPE using soap and water and then should be decontaminated using sodium hypochlorite solution. All single-use gloves and gowns are not to be reuse as they are highly infectious in nature.

⁸¹ *Water, Sanitation and Waste Management of Waste for COVID-19*, WHO, (Jun 30, 2020, 11 A.M), <https://www.who.int/publications/i/item/water-sanitation-hygiene-and-waste-management--the-covid-19-virus-interim-guidance>

⁸² *ibid.*

⁸³ *id.*, at 3.

For handling dead bodies of COVID-19 patients, it is provided that all workers and cemetery staffs should wear scrub suits, disposable gowns, gloves, face shields, goggles and boots. Body of deceased person should be wrapped in a clean fabric and as soon as possible be cremated. Where there is discharge of excessive body fluids, then in such a case body bags can be used.⁸⁴

⁸⁴ id., at 14.

CHAPTER 3

Indian Legislations/Initiatives on Bio-medical Waste Management

The second chapter has examined in details various International Conventions and Guidelines relevant to management of Bio-Medical Wastes. Having done so, this chapter focuses on highlighting Indian Legislations and Guidelines governing Bio-Medical Waste Management in India. Prior to passing of specific legislations pertaining to Bio-Medical Waste Management, the Government of India came up with most important environment legislation i.e. the Environment Protection Act of 1986. The Environment Protection Act of 1986 is a comprehensive legislation enacted by Parliament which deals with all aspects of environmental pollution.

An entire chapter of the said Act is dedicated to Prevention and Abatement of Environmental Pollution. For handling and managing Hazardous Wastes, Section 8⁸⁵ of the Environment Protection Act of 1986 imposes a liability upon persons who are handling such wastes, to comply with the standard procedures and safeguards. Another important provision of the said Act was that, it also provides for imposing penalty in the form of imprisonment for violating the provisions of the Act.⁸⁶

3.1 Legislations relevant to Bio-Medical Waste Management in India

3.1.1 Bio-medical Waste (Management and Handling) Rules of 1998⁸⁷

The Indian Government came up with a specific legislation for managing Hazardous Wastes in the year 1989, by exercising power conferred by Section 6, 8 and 25 of the EP Act of 1986. The Legislation was named as Hazardous Wastes (Management and Handling) Rules of 1989. The said legislation did not cover Bio-Medical Wastes. It took six years to the Government of India to realize the harmful effect of Bio-Medical Wastes and then in year 1995, the Draft Rules on management of Bio-Medical Wastes was framed and objections from public were invited. Then after making necessary

⁸⁵ The Environment Protection Act, 1986, No. 29 of 1986, Acts of Parliament (India).

⁸⁶ id., at S. 18.

⁸⁷ Biomedical Waste (Management and Handling) Rules, 1998, Acts of Parliament (India).

corrections, the final Bio-Medical Waste (Management and Handling) Rules were published in year 1998 on 20th of July⁸⁸.

Some of the important highlights of the Bio-Medical Rules of 1998 are as follows:

I. Applicability:

With regard to applicability, the Rules of 1998 applies to persons who are indulged in generating, receiving, storing, transporting, treating and disposing of Bio-Medical Wastes.⁸⁹ Some of the important terms like Animal House, Bio-Medical Waste, Authorized Person, Bio-Medical Waste Treatment Facility, etc. have been defined precisely by the Rules. As per the Rules, the term Bio-Medical Wastes means and includes all such wastes which are generated after diagnosis, treatment or immunization of either humans or animals and also includes wastes generated from research activities.⁹⁰

II. Duties of Occupier:

- a) As per Rule 2(8)⁹¹ an occupier means the person who is the head of health-care establishment and has full control over the establishment. The Rules of 1998 imposes a duty upon the occupier of health-care establishment to take steps which ensure that wastes are handled in a way which has no adverse effect on human health.⁹²
- b) With respect to treatment, the Rule⁹³ imposes a duty upon the occupier to either set up treatment facilities within the healthcare/hospital campus like incinerators, autoclave machine or microwave system for treating and disposing bio-medical wastes or to ensure that bio-medical wastes are properly treated at Treatment Facility.
- c) Occupier of a health-care establishment providing services to more than 1000 patients per month is required to make a written application in prescribed manner to the Competent Authority under the Rules for getting

⁸⁸ Supra, at 11.

⁸⁹ Supra, 88, at R.2.

⁹⁰ Supra, 88, at R.3 (5).

⁹¹Supra, 88, at R.2 (8).

⁹² Supra, 88, at R.4.

⁹³ Supra, 88, at R.5.

authorization for handling Bio-Medical Wastes. Such application has to be accompanied by requisite fees.⁹⁴

- d) An annual report⁹⁵ stating amount of wastes collected and handled is to be prepared by the Occupier or the Operator and the same has to be submitted to the PCB/PCC by 31st January. All reports so received are required to be send in complied form by the Prescribed Authority to the CPCB by 31st March.

III. Rules for Segregation, Packing and Storage of Bio-Medical Wastes

- a) Rules explicitly states that generated waste should be kept in separate bags⁹⁶ or containers and should not be mixed with other kinds of wastes. Bio-medical wastes are to be segregated in accordance with Schedule II and must be labeled accordingly⁹⁷.
- b) Further, the Rules makes it clear that when Bio-medical wastes are transported somewhere outside the health-care premises then it is to be labeled properly and in accordance with Schedule IV⁹⁸. All untreated wastes are to be transported for treatment in such vehicles which are explicitly authorized for such transport by the Prescribed Authority⁹⁹. The prescribed Authority may be SPCB in case of States and in case of Union Territories; it shall be PCC.

IV. Authorities under the Rules and their Functions:

Some of the important authorities that are responsible for enforcing the provisions of the BMW Rules are:

- a) SPCB's are responsible for implementing and enforcing the provisions in States¹⁰⁰:
- b) Pollution Control Committees are responsible for implementing and enforcing the Rules in Union Territories:

⁹⁴ Supra, 88, at R8.

⁹⁵Supra, 88, at R10.

⁹⁶Supra, 88, at R.6 (1).

⁹⁷Supra, 88, at R.6 (2).

⁹⁸ Supra, 88, at R.6 (3).

⁹⁹ Supra, 88, at R. (4).

¹⁰⁰ Supra, 88, at R.7 (1).

- c) SPCB and PCC shall be appointed¹⁰¹ within period of one month and can be supervised and controlled by State Government or Government of Union Territories accordingly;
- d) The above listed authorities have power to grant, renew or cancel the authorization of handling bio-medical waste by the occupier. The Authorities shall also have the power to enquire after receiving requisite application in the form of Form I and if satisfied with the enquiry, can grant authorization to the applicant to handle Bio-Medical Waste¹⁰². Such authorization is granted for three years and can also be renewed by making a subsequent application by the applicant.¹⁰³
- e) In case the occupier fails to comply with any Rules, then the prescribe authority can cancel or suspend authorization so issued and may notify it in writing.¹⁰⁴
- f) An annual report is to be sent by the occupier or operator to the above mentioned authorities by 31st January of every year. On receiving the report, authority shall send all the reports in a complied form to the CPCB.
¹⁰⁵
- g) The Prescribed Authority shall also have the power to inspect and verify the records maintained by the Authorized persons¹⁰⁶.

V. Other important Rules:

Some other highlights of the said Rules are:

- a) The Rules further provides for appointing an Advisory Committee. The main function of such Committee would be to advise the State Government or Government of UT on matters relating to proper implementation of the BMW Rules

¹⁰¹Supra, 88, at R.7 (2).

¹⁰²Supra, 88, at R.7 (4).

¹⁰³ Supra, 88, at R.7 (5).

¹⁰⁴Supra, 88, at R.7 (8).

¹⁰⁵Supra, 88, at R.10.

¹⁰⁶Supra, 88, at R.11 (2).

- b) The persons authorized under the Rules are under an obligation to maintain records with respect to collection, storage, transportation and disposal of Bio-Medical Wastes¹⁰⁷.
- c) The Authorized person is under an obligation to report any accident which takes place while handling of Bio-Medical Wastes, to the Prescribed Authority¹⁰⁸.
- d) Rule 6 (3) of BMW Rules of 1998 provided for payment of fees by the Occupier along with application to the concerned authority for the purpose of authorization. However, this particular Rule was struck down by the Karnataka HC in the Case of Fr.Mueller's v. The Member Secretary and others¹⁰⁹.

VI. Labels prescribed by the BMW Rules, 1998

Rules prescribe for two labels that are to be used for labeling the containers and bags containing Bio-Medical Wastes. The labels should be non-washable and must be clearly visible on containers.



BIOHAZARD



CYTOTOXIC

VII. Categories of Wastes and their disposal guidelines as per Bio-Medical Waste Rules, 1998¹¹⁰

As per BMW Rules, wastes are classified into following ten categories and also their disposing options/methods are provided in the Schedule of the Rules.

¹⁰⁷ Supra, 88, at R.11.

¹⁰⁸ Supra, 88, at R.12.

¹⁰⁹ Supra, 23, at 30.

¹¹⁰ Supra, 88, Sch. I.

- a) Human Anatomical waste and it can be treated by incinerating or deeply burring it.
- b) Animal Waste and it can also be treated by incinerating or deeply burring it.
- c) Microbiology and Biotechnology Waste which includes waste from laboratories and it can be treated by process of local autoclaving, microwaving or by incineration.
- d) Sharps can be treated by disinfecting them with chemicals, autoclaving and microwaving.
- e) Discarded medicines and Cytotoxic drugs are to be incinerated, destructed and disposed in landfills.
- f) Solid Waste like bottles or items contaminated by blood are to be incinerated.
- g) Solid and liquid wastes are to be disinfected by using chemicals or by microwaving them.
- h) Ashes from incineration are to be disposed off in municipal landfills.

For proper disposal, Color Coding guidelines were also laid down in Schedule II of the said Rules:



All Human Anatomical wastes, animal wastes, Soiled and Biotechnology Wastes are to be discarded by packing in yellow plastic bags.



Microbiology, Btech. Wastes; Soiled Waste; Solid Waste are to be discarded by packing in Red Bags.



Ash generated from incinerators, other chemical wastes, discarded Medicines and Cytotoxic Waste.



Broken and discarded glass objects are to be dispossed of in blue bags.



All the sharps like needles, syringes, needle tip cutter, burner, blades, metal sharps and metallic implants.

However, in spite of some good provisions there are some shortcomings in the Rule too. The BMW Rules of 1998 contains no provisions with respect to segregation and labeling of containers containing wastes that are needed to be transported outside the health-care premises. But the Rules are silent and does not stress upon mode of transportation, which will be required for transporting Bio-Medical Wastes. Coming to the scope of BMW Rules, 1998, the Rules are narrower in scope as it does not cover within its ambit wastes generated from health-camps.

The ones in the forefront of catching deadly diseases are the health-workers and the one's handling and disposing Bio-Medical wastes. The Rules does not provide for any provisions with respect to protection of health workers or the ones handling, transporting or disposing hazardous bio-medical waste. There are no provisions with respect to immunization of health-workers or the handlers of Bio-Medical Wastes, against deadly diseases like Hepatitis B and Tetanus. Moreover, the Rules do not put any obligation upon the Occupiers to provide proper training to all the health-workers with respect to Bio-Medical Waste Management. In absence of such important obligations, the Occupiers /Authorized person may not provide adequate protecting devices or safety equipments to the handlers of Bio-Medical Wastes. Not all wastes generated from health-care establishments are non-recyclable in nature. Some of them can be recycled and reused again to prevent environmental degradation. But The Rules does not talk about recycling of Bio-Medical Wastes which includes discarded bottles, gloves, urine bags and syringes.

Further, the BMW Rules of 1998 have no provision or specific guidelines for cleaning storage devices, brooms and mops that are use for disinfecting and cleaning healthcare premises or Bio-Medical storage devices. Hand mops should be replaced with mechanical mops and handlers are to be made aware of necessity of cleanliness.

3.1.2 Bio-Medical Waste Management (Amendment) Rules, 2000¹¹¹

By Amendment of BMW Rules in 2000, certain changes were made in the BMW Rules of 1998. Some of them were:

- I.** The amendment added the definition of term Form into Rule 3. As per new Rule 3(7a)¹¹², the term form means the form appended to the BMW Rules, 1998. This particular definition was added by Rule 2(i) by way of amendment.
- II.** Amendment brought a change in Rule 6 of the 1998 Rules. New Rule was inserted i.e. Rule 6(6)¹¹³, which provides that the Municipal Bodies shall be entrusted with the duty of picking and transporting segregated non-biomedical solid waste from nursing homes and hospitals. Further, these Municipal Bodies shall also continue to collect treated bio-medical waste and dumped it in municipal sites.
- III.** Further changes were made in Rule 7. The amendment provided that the enforcing power of the Rules shall be in the hands of State Pollution Control Board in case of States and with respect to Union Territories, it shall be Pollution Control Committees¹¹⁴. Further, Rule 1A¹¹⁵ was inserted which provided that with respect to clinics, veterinary hospitals, animal houses, labs, blood banks and hospitals under the control of Armed Forces, are to be regulated by Director General of Armed Forces.
- IV.** Changes were both in Rule 8 by the Amendment. As per new Rule 8(4)¹¹⁶, the authorization to operate waste treatment facility is to be granted by the prescribed authority and the same is to be issued in Form IV.
- V.** Rule 13(1) was amended. As per new Rule, if anyone was aggrieved by the decision/order of SPCB or PCC, then the aggrieved person can prefer an

¹¹¹ Biomedical Waste Management (Amendment) Rules, 2000, No. 13, Acts of Parliament (India).

¹¹² id., R. 3 (7a).

¹¹³ id., R. 6 (6).

¹¹⁴ id., R. 7 (1).

¹¹⁵ id., R. 1A.

¹¹⁶ id., R. 8 (4).

appeal to higher authority as constituted by the Government of State/Union. Such an appeal is to be made in a manner prescribed in Form V.¹¹⁷

VI. Rule 14¹¹⁸ was inserted into BMW Rules. Rule 14 provides that Municipal Corporations, Municipal Boards and other Urban Bodies will be providing incineration sites for carrying out disposal of Bio-Medical Wastes, provided such wastes are generated within their jurisdiction of management. Where waste is generated outside the jurisdiction of Municipal Bodies, in such a situation the occupier generating wastes is to himself arrange suitable incineration sites for disposing Bio-medical wastes.

VII. Sharps were inserted in the category of solid waste by Rule 9(v).

It is very difficult to say that the wastes collected by the Municipal Bodies is hundred percent non-biomedical or bio-medical. Thus, in such a case there are chances of both the wastes been mixed together and disposal of such waste can cause serious danger to health and environment. Further, as per Rule 8(1) healthcare establishments providing treatment to less than 1000 patients need not to apply for authorization. Thus, in such a situation these establishments may tend to violate the BMW Rules and may not handle wastes properly.

3.1.3 Bio-Medical Waste Management (Amendment) Rules, 2003¹¹⁹

By Amendment in 2003, certain changes were made in the BMW Rules of 1998. Some of them were:

I. Sub Rule 2 was inserted in Rule 9 by the BMW Amendment Rule of 2003. As per Rule 9 (2)¹²⁰, the Ministry of Defence is directed to constitute an Advisory Committee to advise head of the Armed Forces Medical Colleges with respect to implementation of the BMW Rules. Such Advisory Committee is to consist of Additional Director of AFMS, Representative of Defence Ministry to be

¹¹⁷ id., R. 13 (1).

¹¹⁸ id., R. 14.

¹¹⁹ Biomedical Waste Management (Amendment) Rules, 2003 (Mar. 22, 2020, 10:11 PM) [http://goaspb.gov.in/Media/Default/uploads/a\)%20Bio%20Medical%20Waste%20\(Management%20%20_%20Handling\)%20Rules,1998.pdf](http://goaspb.gov.in/Media/Default/uploads/a)%20Bio%20Medical%20Waste%20(Management%20%20_%20Handling)%20Rules,1998.pdf).

¹²⁰ ibid.

nominated by Ministry of Defence, Representative of MOEF and a Representative of Indian Society of Hospitals Waste Management.

- II.** Amendment further inserted Rule 9A into BMW Rules. As per new Rule 9A, CPCB shall have the power to monitor and inspect whether the BMW Rules are properly implemented in all Armed Forces Health-care establishments¹²¹.
- III.** Rule 13¹²² was amended and Rule (13) 2 was inserted by Rule 5 (b) of the BMW Amendment Act of 2003. As per Rule 13 (2), a person has a right to appeal before the Central Government in the MOEF, provided he is aggrieved by the decision of the Director General of Armed Forces Medical College. Such an appeal is to be made within time of thirty days from the date of order.

3.1.4 Draft Bio-Medical Waste Management (Amendment) Rules, 2011¹²³

The BMW Rules of 1998 had been in force for years. It also suffered from various challenges. Some of them were like improper management of Bio-Medical Wastes, lack of workers, lack of finance and insufficient infrastructure. Thus, MOEF suggested certain amendments and under the EP Act of 1986, issued a draft BMW Rules, 2011 on 21st September. These Rules with further amendments came into force in the year 2016.

The silent features of the draft Rules are as follows:

I. Application¹²⁴

As per the draft Rules, the BMW Rules of 2011 is applicable to persons who are involved in collecting, receiving, storing, transporting, treating, disposing and handling of discarded healthcare wastes. With regard to non-applicability, it is provided in the amended Rules that these Rules will not apply to the following:

- a) Radioactive wastes and such wastes are to be managed in accordance with Atomic Energy Act of 1962,
- b) All the hazardous chemicals covered by the Hazardous Chemical Rules of 1989,
- c) Solid Wastes,

¹²¹ id., at R. 9A.

¹²² id., at R. 13 (2).

¹²³ Himanshu Joshi, *Biomedical Waste (Management & Handling) Rules, 2011: An Overview*, 1 IJAPMBS, 1, 20-22 (2015).

¹²⁴ ibid.

- d) E-Wastes,
- e) Microbes,
- f) Genetically Modified Microorganisms.

II. Duties of Occupier: ¹²⁵

In the draft Rules, certain new Rules were assigned to the Occupier. As per the draft Rules, Occupier means and includes the health-care establishments. For instance, hospitals, labs, animal houses, etc. can be regarded as Occupier. Some of their duties were:

- a) As per the draft BMW Rules of 211, the occupier is under a duty to ensure that bio-medical wastes is handled properly and it does not have an harmful affect on both human health and the environment.
- b) Further, the draft Rules provided that Occupier should be concern for Occupational Safety of the workers at workplace and provide adequate training to them on safe handling of waste;
- c) It shall be his duty to ensure that wastes are properly segregated;
- d) It shall be the duty of the Occupier to immunized all the health-care workers ;
- e) It shall be his duty to conduct regular health checkup of all the workers and same has to be recorded in a register maintained for this purpose;
- f) It shall be his duty to report accidents caused during handling of health-care wastes like injuries from handling Sharps, outbreak of fire, spilling of mercury, etc. ;
- g) He shall provide adequate PPE to all the health- workers including the ones handling and disposing hazardous wastes generated from the hospital;
- h) Further, as per the draft Rules, the Occupier is to set up a Waste Management Cell for monitoring proper disposal.

¹²⁵ id., at R.4.

III. Duties of Operator of CBWTF:¹²⁶

Draft Rules for the first time assigned certain duties to the Operator of CBWTF. As per draft Rules, Operator¹²⁷ means the person who is either owns or controls the CBWTF and is involved in collecting, segregating and disposing Bio-Medical Wastes. The Operator of CBWTF is under following obligation:

- a) The Operator is under a duty to ensure that wastes are timely collected from health-care premises;
- b) He is under an obligation to conduct training programs to educate workers on safely handling and disposing of bio-medical wastes;
- c) Further, he is to ensure that after collecting wastes from the Occupier/health-care establishments , it is properly transported for treating and disposing it in CBWTF;
- d) Like Occupier, Operator also has to ensure that workers are timely immunized and records are maintained for the same;
- e) The Operator has to maintain a book and record details of equipment used for treating bio-medical wastes. The book shall also have details about categories of wastes and which process was adopted in treating a particular category of wastes;
- f) The Operator further is under an obligation to complain the concerned authority about any health-care establishments, which are not properly disposing their wastes or not handling over segregated wastes to the Operator.

IV. Categories of Wastes:

In the first ever Bio-Medical Rules of 1998, the bio-medical wastes were classified under ten categories and were listed in Schedule I.¹²⁸ However, in the draft Rules of 2011, the categories were reduced to eight. As per the draft Rules, bio-medical wastes were classified into following:

¹²⁶ id.; at R. 5.

¹²⁷ id.; at R. 3.

¹²⁸ Supra, at 122.

- a) Human Anatomical Waste, which includes parts of body, tissues and organs of human body and according to draft Rules, it can be treated by the process of incineration;
- b) Animal wastes, which includes organs, tissues, carcasses of animals, animals used in research and the same waste can be treated by incineration;
- c) Discarded outdated Medicines and other drugs and are to be discarded by land filing or by incinerating;
- d) Solid wastes like blood, fluids, used cotton, plaster casts, etc. and it can be treated by incinerating;
- e) Microbiology wastes and other Biotech wastes are to be treated by disinfecting them with chemicals or by adopting other process like autoclaving, microwaving, shredding, etc.;
- f) Sharps Wastes like needles, syringes, blades, etc. and these wastes are to be recycled, disinfected by using chemicals and non-recyclable parts like needle tips are to be disposed of by land filing;
- g) Infectious Wastes like used gloves, used saline bottles, etc. are to be treated by autoclaving and finally should be mutilated;
- h) Lastly, Chemical Wastes like disinfectants or insecticides are to pre-treated before discharging it into drains.

The draft Rules of 2011 created confusion among people with regard to its applicability. It provided that the Rules will be applicable to only those persons who were indulged in generating, collecting, transferring and disposing waste. These Rules were confusing as to who those persons are upon whom the Rules will apply.

With respect to categories of wastes, the number was reduced from Original ten Categories to Eight. The Draft Rules of 2011 did away with two categories containing liquid waste and ashes from incineration namely. Laboratory and Biotechnology wastes were removed from forming a separate category and same was included in Category 1 i.e., Human Anatomical Wastes. This step was taken to minimize use of containers and also to reduce confusion.

1.1.4 3.15 Bio-Medical Waste Management Rules, 2016¹²⁹

BMW Rules were notified in year 1998 and was modified for several times. A major development to the BMW Rules took place in year 2016 with passing of an amendment to the BMW Rules of 1998. Biomedical Waste Management Rules of 2016 came into force in suppression of original BMW Rules of 1998. The new BMW Rules of 2016 was published through gazette notification on March 2016. With the aim to implement the BMW Rules more effectively and to improve the collection, segregation process, treatment, disposal procedures of Bio-Medical Wastes and to reduce waste generation, the Central Government reviewed and came up with new BMW Rules of 2016.

Some of the important features of the BMW Rules of 2016 are discussed below:

I. Applicability:¹³⁰

The scope and applicability of BMW Rules 2016 were expanded in year 2016 by way of amendment. As per new Rules, 2016 the rule now applies to all dispensaries, pathological labs, veterinary institutions, blood donation camps, First Aid Rooms of Schools, Research Labs and Forensic Labs. The amendment further provided that the Rules will not apply to-

- a) Radioactive wastes that are governed by the provisions of the Atomic Energy Act of 1962.
- b) All hazardous Chemicals coming under the purview of Hazardous Rules of 1989.
- c) Wastes covered by the Municipal Solid Waste Rules, 2000.
- d) Lead and Acid Batteries
- e) Other Hazardous Wastes
- f) E-Waste
- g) Genetically Engineered Micro-Organisms.

II. Duties of Occupier:

Certain important changes were bought in the duties of Occupier. As per new amended Rules of 2016;

¹²⁹ Biomedical Waste Management Rules, 2016, G.S.R. 343 (E), Acts of Parliament (India) (Mar. 29, 2020, 10.04 AM) http://www.cpcbenvis.nic.in/pdf/BMW_Rules_2016.pdf

¹³⁰ id., at R.2.

- a) The occupier must ensure that clean, safe and ventilated room is available for storing segregated bio-medical wastes. Further, it is to be ensured that all such segregated wastes are to be stored in to proper colored bags and labeled containers. The segregated wastes are to be directly transported to CBWTF for disposal purpose. Such direct transfer ensures that wastes are not scattered by animals and there is no secondary handling of wastes.¹³¹
- b) Further, the wastes are to be pre-treated before transferring it to CBWTF, in accordance with the guidelines laid down by WHO on Safe Disposal of Bio-Medical Waste or the guidelines issued by NACO.¹³²
- c) Within period of two years from coming of the Rules into force, all the hospitals, nursing homes, blood banks and other health-care establishments are directed to discontinue use of chlorinated plastic bags, gloves and blood bags for disposing bio-medical wastes.¹³³ Such provision was inserted with the aim of eliminating emission of dioxin and furans, which are emitted from burning of chlorinated bags and blood bags.
- d) All other types of solid waste are to be dispose of in accordance with relevant laws and not as per the BMW Rules.
- e) Occupiers are under an obligation to provide training to the healthcare workers and all other staffs, who are indulged in handling of Bio-Medical Wastes. Such training is to be provided at least once in a year and details of such training are to be reflected in their Annual Report¹³⁴.
- f) All the health workers and others who are involved in handling of bio-medical, must be immunized in a manner as prescribe by National Immunization Policy or as provided by the Ministry of Health and Family Welfare. Such Immunization ensures protection against Hepatitis B and Tetanus.¹³⁵
- g) BMW Rules, 2016 further provided for establishment of bar code system. As per new Rules, all the bags and containers containing bio-medical

¹³¹ id., at R. 4(b).

¹³² id., at R. 4(c).

¹³³ id., at R. 4(d).

¹³⁴ id., at R. 4(g).

¹³⁵ id., at R. 4(h).

wastes are to be bar-coded when such bags/containers are required to be sent out for disposal or for any other purpose.¹³⁶ Bar coding will help in keeping a track of quantity of wastes collected, treated and disposed and at times when wastes are not properly disposed, bar code system will help in identifying the actual source of generation of wastes.

- h) With respect to liquid chemical wastes, some important Rules were laid down. Occupier has to ensure that discharged liquid chemical wastes are to be pre-treated and neutralized before mixing it with other discharged effluents. Treatment and disposal liquid wastes are to be done in accordance with the provisions of the Water Act of 1974.¹³⁷
- i) The Amended Rules further imposes an obligation upon health-care establishments to conduct health-check up of all health-workers. Such check-up is to be conducted in at least once in a year and record is to be maintained for the same.¹³⁸

III. Duties of Operator of CBWTF: ¹³⁹

For Operators, 2016 provided for a separate set of Rules. Some of which includes:

- a) The Operators are under an obligation to ensure that bio-medical wastes after collection is properly transported, handled and disposed of.
- b) Bar Coding system¹⁴⁰ is to be adopted within time period of one year and wastes should be collected timely from the Occupiers and in accordance with the Rules made by the Union Government or CPCB.
- c) It shall be their duty to give information to the concerned authorities about those healthcare establishments, who are not properly segregating wastes.

¹⁴¹

¹³⁶id., at R. 4 (i).

¹³⁷ id., at R. 4 (k).

¹³⁸id., at R. 4 (m).

¹³⁹ id., at R. 5.

¹⁴⁰ id., at R. 5(c).

¹⁴¹ id., at R. 5(d).

- d) It shall be the duty of the Operators is to provide requisite training to all the workers who are indulged in handling bio-medical wastes and they should also assist the Occupiers by giving them training for bio-medical waste management.¹⁴²
- e) Further, the Operator is to conduct proper medical examination of all the healthcare workers, once in a year. They should also be immunized for protecting them against Hepatitis B and Tetanus.¹⁴³
- f) Adequate PPE kits are to provide to all the workers by the Operator and he is to ensure for their occupational safety.¹⁴⁴
- g) The Operator is under a duty to give details to the concerned authority about an accident that may have happen during handling of wastes. Further, along with this report, annual report on Biomedical Waste is also to be submitted to the concerned authority.¹⁴⁵
- h) A log Register or Book is to be maintained by the Operators highlighting the information relating to amount of wastes treated, name of the category of wastes which was treated, time taken for such treatment, etc.¹⁴⁶
- i) Only non-chlorinated bags are to be given to the Occupier and fees can be charged by the Operator for providing such bags and same should be processed by CBWTF on regular basis.¹⁴⁷
- j) There should be regular collection of Bio-Medical wastes including holidays.¹⁴⁸

IV. Process of Segregation:

After identification of different categories of Bio-Medical Wastes, segregation is done. Rule 8 of the Bio-Medical Wastes Rules of 2016 lays down provision with respect to Segregation of wastes:

- a) It is laid down that biomedical wastes must not be mixed with other kinds of wastes;¹⁴⁹

¹⁴²id., at R. 5(e), (f).

¹⁴³id., at R.. 5 (g).

¹⁴⁴ id., at R.5 (h).

¹⁴⁵ id., at R. 5(i).

¹⁴⁶ id., at R. 5(j).

¹⁴⁷id., at R. 5(n).

¹⁴⁸ id., at R. 5(o).

- b) Prior to treatment, storage and disposal of wastes, it is to be kept in separate bags and containers and in accordance with Rules laid down in Schedule I.¹⁵⁰ the labeling is to be done in accordance with Schedule IV.¹⁵¹
- c) Segregated waste is to be collected and transported in vehicles, which are authorized for collecting wastes. Such vehicles must also adhere to the Rules laid down by SPCB or Pollution Control Committee and must also adhere to Rules under MV Act of 1988.¹⁵²
- d) Wastes consisting of Human Anatomical and other Animal Wastes which are not treated must not be kept or stored more than 48 hours. In situations, where such wastes has to be kept beyond a period of 48 hours, then the Occupier is required to inform the concerned authority about the same and must take necessary steps to prevent such wastes from adversely affecting human life and environment.¹⁵³

V. Categories of Bio-Medical Wastes:

Unlike the Draft Rules of 2011, the New Amended Rules of 2016 , made drastic progress by reducing the number of wastes from eight categories to only four. This step was taken to clear all ambiguities which existed prior to passing of this Rules. Different types of discarded Bio-Medical Wastes are inserted under only four categories, which are as follows:

- a) Category I consists of Anatomical Wastes of both human and animals; Soiled Waste; Discarded Medicines; Discarded Chemicals and Disinfectants; Liquid Chemicals discarded from production and use of disinfectants; Discarded used beddings, mattresses, blood, body fluids and Microbiology and Laboratory Wastes.
- b) Category II consists of Recyclable wastes which includes used urine bags, syringes, bottles, gloves. Such wastes however will not include discarded needle tip and fixed needle syringes.

¹⁴⁹ id., at R.8(1).

¹⁵⁰ id., at R. 8(2).

¹⁵¹ id., at R. 8 (3).

¹⁵²id., at R. 8(6).

¹⁵³id., at R. 8 (7).

- c) Category III consists of Sharps and includes needles, fixed needle syringes, used blades, other contaminated sharp objects and metals.
- d) Lastly, Category IV shall consist of broken glassware, used metallic implants and other cytotoxic wastes.

For proper disposal, Color Coding guidelines were also laid down in Schedule II of the said Rules:



VI. Concerned Authorities under the Rules:

Like other previous Rules, the concerned authorities under the New BMW Rules of 2016 are SPCB or Pollution Control Committees. Healthcare establishments working under the control of Ministry of Defence shall be monitored by Dg of Armed Forces Medical Services.¹⁵⁴

VII. Complying with Standards:

2016 Rules also talked about following Standards for properly disposing plastic bags, As per Rule 7(8), plastics bags used for storing and transporting Bio-Medical Wastes must comply with BIS standards and should be non-chlorinated. Such used

¹⁵⁴ id., at R. 9.

plastic bags should not be disposed of by incinerating and should be treated as per Plastic Waste Rules of 2011.¹⁵⁵

VIII. Treatment Rules:

New Rules of 2016 made an attempt to make treatment process more effective. Accordingly, certain changes were made, like;

- a) Bio-Medical Waste is to be treated following the Rules laid down in Schedule I and II. Wastes are to be handed over after proper segregation to CBWTF for final disposal.¹⁵⁶
- b) In situation where CBWTF are not available, then Occupiers are required to set up other treatment equipments like incinerators, autoclaving machines, Microwave, etc. However, such treatment facilities should not be set up provided CBWTF is available within a distance of 75 km.¹⁵⁷
- c) All the Occupiers are required to stop use of non-chlorinated bags within period of 2 years.

IX. Implementation of Rules:

MOEF is entrusted with the power to review and implement the BMW Rules of 2016. CPCB shall be responsible for monitoring implementation of Rules in Armed Forces Hospitals. At District Level, monitoring Committees are to be constituted

The New Bio-Medical Rules of 2016 remove the confusion with respect to application of the Rules. The New Rule made it clear that the Rules shall apply to specific class of persons and it also listed about the ones upon whom the Rules will not apply. The Rules was an improvement upon Draft Rules of 2011 as it specified that batteries, e-waste, hazardous chemicals, radioactive wastes, etc. will not be covered within the ambit of BMW Rules of 2016.

With respect to categories of Bio-Medical wastes, the New Rule of 2016 has reduced the categories from eight to four. This was a major step towards reducing use of number of

¹⁵⁵id., at R. 7(8).

¹⁵⁶ id., at R. 7(2).

¹⁵⁷id., at R..7(4).

containers for storing and disposing Bio-Medical Waste. Moreover, reducing categories also reduced the risk which was associated with mishandling of Bio-Medical Wastes.

1.1.5 Bio-Medical Waste Management (Amendment) Rules, 2018¹⁵⁸

With an aim to protect both the human life as well as the environment, BMW Rules of 2016 were amended by the MOEF.¹⁵⁹ In exercise of power conferred under the EP Act of 1986, the Biomedical Waste Rules of 2016 was amended in year 2018. 2016 Rules were amended after having discussion with all the stakeholders and important Ministries like Health and Family Welfare Ministry, CPCB, SPCB and healthcare establishments. These Rules were referred to as Bio-Medical Waste Management (Amendment) Rules of 2018. Certain important changes were made and the Rules came into force on 16th of March 2018. Some of the important changes bought by this amendment were as follows:

- I. Changes were made in Rule 2(2) of the Biomedical Waste Management Rules of 2016. In Rule 2 (2) (c), the term ‘Municipal Solid Waste (Management) Rules of 2000, was substituted by the term “Solid Waste Management Rules of 2016.”¹⁶⁰
- II. Further, the term “Hazardous Wastes” in the Hazardous Wastes Management Rules of 2008¹⁶¹, was substituted by the word “Hazardous and Other Wastes Management Rules of 2016”.¹⁶²
- III. In clause f, the term E-Waste Rules of 2011 was substituted by E-Waste Rules of 2016.¹⁶³
- IV. Important changes were made in Rule 4 of Biomedical Waste Management Rules of 2016. Some of them were:

¹⁵⁸ Biomedical Waste Management (Amendment) Rules, 2018, G.S.R. 234 (E), Acts of Parliament (India) (Mar. 29, 2020, 10.04 AM) http://www.cpcbenvis.nic.in/pdf/BMW_Rules_2018.pdf

¹⁵⁹ Dr. Harsh Vardhan, *Biomedical Waste Management Rules Amended to Protect Human Health*, PRESS INFORMATION BUREAU, GOVERNMENT OF INDIA, MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE (Mar. 12, 2020, 10 AM), <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1526326>.

¹⁶⁰ Supra, 141, at R. 2(2)(c).

¹⁶¹ Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008, S.O 2265 (E), Acts of Parliament (India) (Mar. 29, 2020 11 AM) <http://npcb.nagaland.gov.in/wp-content/uploads/2016/03/HWM-2008.pdf>

¹⁶² Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016, G.S.R No. 395 (E), Acts of Parliament (India) (Mar. 29, 2020, 12 AM) [https://upload.indiacode.nic.in/showfile?actid=AC_RJ_83_1096_00001_00001_1563872109827&type=rul e&filename=hazardous_and_other_wastes_\(management_and_transboundary_movement\)_rules,_2016.pdf](https://upload.indiacode.nic.in/showfile?actid=AC_RJ_83_1096_00001_00001_1563872109827&type=rule&filename=hazardous_and_other_wastes_(management_and_transboundary_movement)_rules,_2016.pdf)

¹⁶³ Supra, 141, at R. 2 (2)(f).

- Occupiers shall be under an obligation to pre-treat all the discarded bio-medical wastes of their premises, as per the guidelines laid down by the World Health Organization. They should follow the WHO Bluebook on Management of Healthcare Wastes or can follow Guidelines on Safe Management of Wastes.¹⁶⁴
 - All the healthcare establishments have to discontinue use of Chlorinated Plastic bags and gloves by March 27, 2019. However, blood bags are exempted from this particular Rule.¹⁶⁵ Further, it is laid down that the Operators have to ensure that discarded wastes are treated and disposed of in accordance with the Rules or Guidelines issued by CPCB by March 27, 2019.
 - With respect to publication of Annual Report, it was laid down that all the Healthcare establishments irrespective of the number of bedding facility they have, have to ensure that their reports are available on the websites of the respective healthcare establishments within period of two years from the date of coming of this Rule into force¹⁶⁶.
- V. Further, certain changes were made in Rule 5 of the BMW Rules of 2016. 2018 Amendment provided that Operator has to ensure that the discarded bio-medical waste is to be treated in accordance with the Rules establish by CPCB by 27th March 2019. The words “within one year “in Rule 5(c) was substituted by the word “in accordance with Rules establish by CPCB.¹⁶⁷
- VI. Rule 7(8) was amended. The amendment in place of non-chlorinated bags, substituted chlorinated bags. Further, it was provided that bags used for storing biomedical waste and other plastics generated from incinerating wastes are to be managed as per the Plastic Waste Management Rules of 2016. ¹⁶⁸
- VII. With respect to Schedule I, certain changes were made. In category of Chemical Waste, two new items were included namely routine mask and gown. Further, in

¹⁶⁴ Supra, 141, at R. 4(c).

¹⁶⁵ Supra, 141, at R. 4(d).

¹⁶⁶ Supra, 141, at R. 4(p).

¹⁶⁷ Supra, 141, at R. 5(c).

¹⁶⁸ Supra. 141, at R. 7(8)

treatment of Microbiology and Laboratory waste, one more method was provided i.e., Hydroclaving for treating plastic bags and containers.¹⁶⁹

VIII. With respect to Form IV, certain other changes were made. After Form IV, a new Form, Form IV A was inserted. Form IV A provides for format for submitting Annual Report on BMW Wastes by hospitals to SPCB and Pollution Control Committees. Such Report is to be submitted to the concerned Authority by 31st July of every year. The Form shall consists of details of the following¹⁷⁰:

- a) Name of the establishment
- b) Email Id of concerned Nodal Officer
- c) Details about Occupiers
- d) Bedding Details
- e) Details about Blood banks
- f) Research Institutions
- g) AYUSH
- h) Total Number of Beds in the establishment
- i) Details of Authorization
- j) Amount of Wastes generated per day
- k) Details about treatment and disposal of Bio-Medical Wastes
- l) Total Number of CBWTF, etc.

Bio-medical Wastes Rules of 2018 added important Rules. It was an improvement over BMW Rules of 2016. The amended Rules provided for introduction of Global Positioning System (GPS) in all vehicles carrying Bio-Medical Wastes and to ensure that all discarded wastes are pre-treated properly before transferring it for disposal. These new Rule is yet to be monitored. In spite of advantages, there are few disadvantages also. For instance, the defaulters of the Rules are only suspended by DM of the District and are never levied heavy fine.

¹⁶⁹ Supra, 141, at Sch. I.

¹⁷⁰ Supra, 141, at Form IV A.

3.2 Guidelines on Bio-Medical Waste Management

3.2.1 Central Pollution Control Board's Guidelines on Management of Mercury Waste Generated from the Health Care Establishments (2012)¹⁷¹

Mercury is used in medical devices like thermometers, sphygmomanometers, thirmerosal, barometer, etc. Thus, mercury is an integral part of healthcare establishment. Mercury has an adverse impact on the environment as well as on human health. Considering the harmful effects of mercury, CPCB in year 2012, came up with guidelines to ensure that discarded mercury wastes from healthcare establishments are properly disposed of. The guidelines provides for strategies that can be adopted to manage the mercury waste. Some of them include segregating reusable and non-reusable products in separated containers; recycling those products which can no longer be used; developing proper clean up protocols; switching to alternatives, etc. This guideline also lays down certain precautions which can be taken by all the healthcare establishments in case there is an accidental mercury spillage. Further, stress is given upon imparting training among all the health workers and other housekeeping staffs, for proper and safe management of mercury waste. The guidelines also highlight the issue that immediate policy decision has to be taken up for switching over to non-mercury based products.

3.2.2 Central Pollution Control Board's Guidelines for Common Bio-Medical Waste Treatment and Disposal Facilities (2016)¹⁷²

In 2016, CPVB came up with guidelines to ensure uniformity in site selection and proper establishment of CBWTF. These guidelines were issued in accordance with the Biomedical Wastes Management Rules of 2016, where it is enshrined that the Operator of every CBWTF shall have the duty to ensure that wastes collected from healthcare establishments are properly transported and disposed of. The guidelines also covered other aspects and are mandatory in nature. It lays down in details the criteria for setting up of a new CBWTF in any area. With respect to applicability it is provided that these

¹⁷¹ *Environmentally Sound Management of Mercury Waste Generated from the Health Care Facilities*, CENTRAL POLLUTION CONTROL BOARD (MINISTRY OF ENVIRONMENT AND FORESTS), (Mar 29, 2020 11 AM), <https://jspcb.nic.in/upload/uploadfiles/files/Guidelines%20for%20CBWTF.pdf>

¹⁷² *Guidelines for Common Bio-Medical Waste Treatment and Disposal Facilities*, CENTRAL POLLUTION CONTROL BOARD (MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE), (Mar 30, 2020 10 AM), <https://jspcb.nic.in/upload/uploadfiles/files/Guidelines%20for%20CBWTF.pdf>

guidelines shall apply to all newly constructed CBWTF. It is further provided that in order to establish or operate a CBWTF; consent is to be taken from concerned authorities under Rule 25 of the Water Act¹⁷³ and Rule 21 of the Air Act.¹⁷⁴ As per the guidelines, CBWTF should treat Biomedical Wastes as per incineration or plasma pyrolysis, autoclave, microwaving, chemical disinfection, shredding, deep burial, etc.

3.2.3 Central Pollution Control Board's Guidelines for Bar Code System (2018)¹⁷⁵

BMW Rules of 2016 inserted a new Rule and provided for establishment of bar code system which would help in monitoring and tracking the biomedical wastes. Bar Code System helps in keeping track of amount of wastes generated, collected, treated, transported and disposed. These guidelines were developed in year 2018 by CPCB to facilitate both the Occupier as well as the Operators of CBWTFs to help them in establishing and adopting Bar Code System. These guidelines also aim in bringing out uniformity throughout the country with respect to adoption of Bar Code. The guidelines have made it clear that SPCB (in States), PCC (in UTs) and DGAFMS (in Armed Forced Medical Services) are the ones who are responsible for overall implementation of these guidelines. Details with respect to labeling of bar code were also specified in the guidelines. As per the guidelines, label can be printed directly on containers and bags and the charges for labeling bags and containers are to be levied by the Operators. With regard to implementation of bar code system, it is further provided that both the Operators of CBWTF as well as the Occupiers of HCFs are equally responsible for implementing it. These guidelines further provide information with respect to bar code scanner, bar-coding software, mobile bar code system, etc.

¹⁷³ The Water (Prevention and Control of Pollution) Act, 1974, No. 6, Acts of Parliament, 1974 (India).

¹⁷⁴ The Air (Prevention and Control of Pollution) Act, 1981, No. 14, Acts of Parliament, 1981 (India).

¹⁷⁵ *Guidelines for Bar Code System for Effective Management of Bio-Medical Waste*, CENTRAL POLLUTION CONTROL BOARD (MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE), (Mar 30, 2020 10 AM),https://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/Guidelines_for_Bar_Code_System_for_HCFs_and_CBWTFs.pdf.

3.2.4 Central Pollution Control Board's Guidelines for Handling Bio-Medical Waste for Utilization (2019)¹⁷⁶

These guidelines were developed in year 2019 by CPCB and these guidelines are in conformity with the BMW Rules of 2016. Guidelines are basically framed with the aim of providing guidance to all healthcare establishments as well as handlers of biomedical waste, with respect to proper utilization of wastes. Further, these guidelines ensure that adequate safety is provided to all health workers who are involved in handling of Bio-Medical Wastes. The guidelines provide further information with respect to responsibilities of Healthcare establishments and vendors who are responsible for collecting Bio-Medical Wastes.

3.2.5 Regulation of Persistent Organic Pollutants Rule of 2018¹⁷⁷

India ratified the Stockholm Convention on POP in year 2006. The Central Government of India prepared a draft Rules on POP and the same was published and made available to public on 29th August, 2017. These Rules were adopted in year 2018. Some of the important key features of the Regulation are:

- I. Rule 2 of the said Regulation provides for list of seven chemicals, whose manufacture, trade, use, importing or exporting is prohibited under this Regulation. The chemicals include Chlordcone, Pentachlorobenzene, Hexabromocyclododecane, etc.¹⁷⁸
- II. Under the Regulation, the Occupiers of Industries shall disclose the quantity of chemicals (as mentioned in Rule 2) which is stored in the stockpiles. Such declaration has to be made to the concerned Ministry (Environment and Forest Ministry) within a period of six years and in appropriate manner.¹⁷⁹

¹⁷⁶ *Guidelines for Handling Bio-Medical Waste for Utilization*, CENTRAL POLLUTION CONTROL BOARD (MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE), (Mar 30, 2020 10 AM), https://www.mpcb.gov.in/sites/default/files/biomedicalwaste/Guidelines_for_Handling_of_Biomedical_Waste_for_Utilization03032020.pdf

¹⁷⁷ Regulation of Persistent Organic Pollutants, 2018, Acts of Parliament, (India)

¹⁷⁸ id., R. 2.

¹⁷⁹ id., R. 3.

- III. Further, the Occupier is under an obligation to not discharge the aforesaid chemicals directly into the drains, treatment plants, land, inland surface water bodies or in any marine coastal areas.¹⁸⁰
- IV. The wastes which consist of these prohibited chemicals are to be properly disposed of and in accordance with the Hazardous Rules of 2016.¹⁸¹
- V. However, the prohibited chemicals can be allowed to use for research activities in Government Labs, Research Institutes, CSIRL or Central Universities, with prior approval of Environment and Forests Ministry.¹⁸²

¹⁸⁰ id., R. 4.

¹⁸¹ id., R. 5.

¹⁸² id., R. 6.

Chapter 4

Constitutional Provision with respect to Biomedical Waste Management

Constitution is the law of the land and it is a complete document to maintain its wholesomeness. When our Constitution was drafted, even the word “environment” did not find place in the Constitution. Though there was no specific constitutional provision to protect the environment in general, but the new Part IV-A, which was incorporated by the 42nd Amendment to the Constitution of India, imposes a duty upon all the citizens of India to protect as well as improve the environment.¹⁸³ However, prior to coming of Article 51-A (g), there were certain other provisions in the Constitution of India which had direct bearing on the environment. Some of which includes improving the public health,¹⁸⁴ duty of the state to organize agricultural activities including animal husbandry on scientific lines,¹⁸⁵ duty of the state to protect our monuments,¹⁸⁶ etc. Thus, it is clearly seen that protection of environment is inherently included in the Constitution of India.

Some of the important provisions concerned with the protection of environment are as follows:

4.1 Preamble

The preamble of our Constitution of India has been given a place of pride by the makers of the Constitution of India. The importance of Preamble has been highlighted in various occasion by the Apex Court of our country. For instance, in the famous re-Berubari¹⁸⁷ case, it was laid down by the Supreme Court of India that the preamble shows the general purposes behind the provisions of our Constitution. It is a key to open the mind of our Constitution Makers. In Keshavananda Bharti's case¹⁸⁸, the Supreme Court further held that the Preamble is a part of the Constitution of India and it is of extreme importance. It was further laid down that the Constitution should be read and interpreted in the light of vision expressed in the Preamble.

¹⁸³ INDIA CONST. art. 51A, cl. g.

¹⁸⁴ id., at art. 47.

¹⁸⁵ id., at art. 48.

¹⁸⁶ id., at art. 49.

¹⁸⁷ Re-Berubari, AIR 1960 SC 845(India)

¹⁸⁸ Keshavananda Bharti v State of Kerela, AIR 1973 SC 1461 (India)

The Preamble opens with the words, “We, the people of India”, which indicates that the source of authority of our Constitution is the people of India. . Thus, people are solely responsible for constituting India into a Sovereign, Socialistic, Secular and Democratic Society. Further, the Preamble talks about creation of welfare state and this proofs that the State has a responsibility towards the people and environmental. At present time, environmental pollution has become a biggest threat to our society and thus, State is obliged to protect the environment. Further, State is under obligation to provide decent standard of living to the people of all strata of society.¹⁸⁹

In the case of D.S Nakara¹⁹⁰, Supreme Court laid down that the main aim of a Socialist state should be to minimize the inequality among people with respect to income, status and standard of living.

Further, as per K.S Dakshinamurty, environment as a subject matter has entered into our life and it can be ignored while discussing the socio-economic or socio-political issues of our country. Thus, it has become an integral part of socio, economic or political justice. It is a responsibility of the State to take up all necessary steps to protect environment¹⁹¹.

4.2 Fundamental Rights

Fundamental rights are considered to be a superior class of Rights and these are some of the most important human rights that an individual can posses. These Rights are necessary to protect the rights and liberties of every individual. The object behind dedicating an entire chapter, i.e.; Part III, is to establish a government of law and not of man. There are no explicit provisions on environmental protection under Part III of the Constitution of India. However, the judiciary from time to time has widened the scope of the fundamental rights and gave decisions in favor of environmental pollution. The following provisions have a bearing with respect to environmental protection:

¹⁸⁹ Dr. SUKANTA K. NANDA, ENVIRONMENTAL LAW 82-83 (4th ed. 2015).

¹⁹⁰ D.S Nakara v Union of India, AIR 1983 C 130 (India)

¹⁹¹ Supra, 193, at 84.

4.2.1 Right to Equality¹⁹²

Article 14 embodies the general principles of equality before law and also prohibits unreasonable discrimination. Article 14 can be used as a potential weapon against decisions of government intended to environmental degradation. At many a times, the Apex Court has widened the scope of Article 14 and given decisions on environmental matters. For instance, Supreme Court in case of Mandu Distilleries Pvt. Ltd v M.P Pradushan Niwaran Manadal¹⁹³, it was held by the Supreme Court that there was error in decision making process of the Pollution Control Board. The Board issued the order which directed closure of the industry on ground that the industry was causing water pollution. The Apex court quashed the order and held it to be violative of Article 14.

Similarly, in the case of Bangalore Medical Trust v B.S Mudappa¹⁹⁴, the Apex Court prevented construction of a nursing home by converting a public park. In the said case, the Apex Court highlighted the importance of open spaces like public parks for recreation and fresh air and held that conversion of such public places for private use would amount to violation of constitutional mandate. Further, in the Ganesh Woods Products case¹⁹⁵, it was held that ecological factors and sustainable use of natural resources should be kept in mind while framing any environmental policy.

Further, in another case¹⁹⁶, Article 14 was invoked and it was laid down that grant of license for mining activities in hilly tracks of Himalaya would have an adverse impact on the resources of our country and at the same time violates the provision of Article 14.

4.2.2 Freedom of Speech and Expression and of Trade and Business

The Rights guaranteed by Article 19¹⁹⁷ are available to citizens and not to any alien or foreigner.

¹⁹² INDIA CONST. art.14

¹⁹³ Mandu Distilleries Pvt. Ltd v M.P Pradushan Niwaran Manadal AIR 1995 MP 57 (India)

¹⁹⁴ Bangalore Medical Trust v B.S Mudappa AIR 1991 4 SCC 54 (India)

¹⁹⁵ State of Himachal Pradesh v Ganesh Wood Products, AIR 1996 SC 149 (India)

¹⁹⁶ Kinkri Devi and another v State of Himachal Pradesh and Ors. AIR 1987 HP 4 (India)

¹⁹⁷ INDIA CONST. art.19

Environmental problems that form a part and parcel of DPSP under the Constitution of India may also be enlightened under Article 19(1) (a). Article 19 (1) (a) says that all citizens shall have the right to freedom of speech and expression. However, this right is subject to certain restrictions which are imposed under Article 19 (2). Attention of Government towards the environmental problems was attracted through judicial activism, under the purview of this particular Article. Of late, the judiciary has entered into new era and its new creative period it has come down heavily against the Government and Administrative mechanism. After a hard struggle the courts started deviating from the conservative stand to protect social interests by innovating new ideas and principles. In the process, the court accepted the concept of locus standi of an individual to bring a case before the Court on a very broad basis. Any public spirited person has right to inform the Courts about the environmental problems and this right to inform is possible under Article 19(1) (a)¹⁹⁸.

Article 19 deals with protection of certain rights in clause I and this freedom means the right to express one's opinions freely. Thus, in present day we find frequent use of loudspeakers to express one's ideas, although use of loudspeakers is not specifically mentioned in Article 19. But it has assumed the status of fundamental right. Allahabad High Court while dealing a case¹⁹⁹, in which the petitioner challenged the laws made by State Government which involves taking permission from Municipal Board before using a loudspeaker held that such a provision of law does not violate the right guaranteed under Article 19 (1) (a).

Further, in another case of P.A Jacob v The Superintendent of Police, Kottayam²⁰⁰, the Kerala High Court laid down that the Article 19 (1) (a) does not guarantee the right to cause noise pollution by using loudspeakers and amplifiers. Further, it is to be noted that pollution is the mainly from trade activities and industrial establishments. There is a growing problem in front of our Government to maintain a balance between freedom of trade and protection of environment. It is evident that some of the business activities are

¹⁹⁸ Supra, 193, at 80.

¹⁹⁹ Rajnikant v State of Uttar Pradesh, ALL L.J 56 (India)

²⁰⁰ P.A Jacob v The Superintendent of Police, Kottayam AIR 1993 Ker. 1 (India)

carried out in such a manner that it results in environmental pollution and disrupts the ecological balance. Taking note of the issue, the Supreme Court has played a crucial role through a spate of cases. For instance, in Himachal Tiwari v Kamala Devi's Case²⁰¹, the Supreme Court held that forests, ponds, mountains, etc. and other material resources are nature's bounty. These material resources maintain ecological balance and must be protected for a proper healthy environment.

In a matter²⁰² relating to pollution of Chilika Lake on account of use of mechanized diesel motor boats, it was observed by the apex court that if there is a clash between environmental protection and freedom of trade, then it is upon the courts to maintain a balance between environmental interests and fundamental rights. Further, in M.C Mehta v Union of India²⁰³, the attention of the apex court was drawn towards stone crushing operations around Delhi. The dust particles polluted the air. In this particular case, the Supreme Court observed that environmental changes at times of industrial development are inevitable but, at the same time industrial development cannot be allowed to an extent that it becomes a threat to health of the citizens. The Court thus ordered closure of quarries and concerned authorities were asked to allot alternative sites to quarry owners.

4.2.3 Right to Life and Personal Liberty²⁰⁴

Most important fundamental right is the right to life and personal liberty enshrined in Article 21. The right to life under Article 21 is a basic human right and the concept has been transformed by the courts through active judicial interpretations. New dimensions have been added to Article 21 in the Maneka Gandhi Case²⁰⁵. For the first time after this case, Supreme Court has transformed the concept of fundamental rights into positive rights and has imposed significant duties upon the State from time to time²⁰⁶. The Supreme Court reflected its view on the famous Francis Carolie's Case²⁰⁷ and held that Article 21 cannot be restricted only to mere animal existence but it includes more than

²⁰¹ Himachal Tiwari v Kamala Devi (2001) 6 SCC 496 (India)

²⁰² Ratanakar Satrusalya v State of Orissa, 2015 (5) FLT 117 (India)

²⁰³ M.C Mehta v Union of India (1992) Supp 2 SCC 85 (India)

²⁰⁴ INDIA CONST. art.21

²⁰⁵ Maneka Gandhi v Union of India, A.I.R 1978 SC 597 (India)

²⁰⁶ DR. J.N. PANDEY, CONSTITUTIONAL LAW OF INDIA 253-54 (53rd ed. 2016)

²⁰⁷ Francis Carolie v Administrator, UT of Delhi A.I.R 1981 SC 746 (India)

mere physical survival. Further, it was laid down that the Right to live with human dignity, which also includes accessibility to nutrition, clothing and shelter, is a part of Article 21.

The apex Court in M.C Mehta v Union of India²⁰⁸ held that Article 21 does not permit causing pollution of most vital necessities of life like water, soil and air. It was further laid down that the Court has to take up liberal approach towards protection of human rights and give due regard to right of community at large. Considering a writ petition to protect the health non-smokers in public area, the apex Court in Muarli S. Deora v Union of India²⁰⁹ held that in view of the adverse effect of smoking, it is necessary to prohibit smoking in public places. Court was further of the view that non-smokers cannot be compelled to become victim of pollution caused by cigarette smokers. In this case, while relying on right to health under Article 21, apex Court held that non-smokers being compelled to suffer from various diseases like lung cancer, due to activities of smokers, are indirectly depriving the non-smokers of his life under Article 21.

In an important judgment in Subhash Kumar v State of Bihar²¹⁰, the Supreme Court in the same breath held that Right to Life includes the right to live properly and have the benefit of all natural resources, i.e, unpolluted air and water. The Court further held that Right to live is a fundamental right under Article 21 and every citizen has the right to approach Court under Article 32 for removing pollution of water and air. In this same case, the Apex Court further went on saying that citizens have right to have access to pure and pollution free water. Subsequently, in several other cases like Vellore Citizens Case²¹¹ and A.P pollution Board Case²¹², the Supreme Court in clear words held that citizens have the right to live in a clean and healthy environment. Right to clean environment is a guaranteed fundamental right under purview of Article 21.

²⁰⁸ M.C Mehta v Union of India (2004) 12 SCC 118 (India).

²⁰⁹ Muarli S. Deora v Union of India (2001) 8 SCC 764 (India).

²¹⁰ Subhash Kumar v State of Bihar A.I.R 1991 SC 420 (India).

²¹¹ Vellore Citizens Welfare Forum v Union of India A.I.R 1996 SC 2669 (India).

²¹² A.P Pollution Control Board v Prof. M.V. Nayadu A.I.R 1999 SC 812 (India).

Yet in another case of Kalyaneshwari v Union of India²¹³, where a writ petition was filed for banning use of white asbestos as these asbestos were alleged to contain carcinogenic properties and its use can cause serious health disorders. Taking note of the consequence and its effects as highlighted in the case of Consumer Centre v Union of India²¹⁴, the court gave certain directions to the State. It was laid down by the Supreme Court that it is necessary to maintain a balance between health hazards caused by use of white asbestos in one hand and the fact that a large number of populations are dependent upon production of asbestos, on other hand. Thus, it can be seen that in order to give effect to Article 21 and keeping in mind health of people, apex court has expanded the scope of Article 21 from time to time.

4.3 Fundamental Duties

42nd Amendment added a separate chapter on fundamental. Part IV A directly deals with environment. It imposes a duty upon all the citizens to protect and improve our forests, rivers, wildlife, etc. and also to have compassion towards other living things.²¹⁵ Article 51 A (g) uses the expression “Natural Environment”, which implies that every citizen have a duty to protect and improve our forests, lakes, rivers and wildlife. Further, Article 48 A on the other hand uses the term “Environment”, which implies that it shall be the duty of the State or Government to take steps to safeguard our forests and environment. These provisions clearly show that there should be national consensus on environmental problems and protection.²¹⁶

While deciding a matter on discharge of untreated effluents into river named Nambu, the Gauhati High Court in Environment Protection Committee v Union of India²¹⁷, held that Article 51 A imposes an obligation towards protection and improvement of our environment. The encroachers were held responsible for violating Article 51 A and the Court further went on saying that the encroachers should be severely punished under

²¹³ Kalyaneshwari v Union of India (2011) 3 SCC 287 (India).

²¹⁴ Education Research Centre v Union of India (1995) 3 SCC 42 (India).

²¹⁵ INDIA CONST. art.51 A (g)

²¹⁶ M.C Mehta v State of Orissa A.I.R 1992 Ori 225 (India)

²¹⁷ Environment Protection Committee v Union of India 2011 (1) FLT 326

relevant provisions of law. The Court directed that all the encroachers should be evicted and no mercy should be shown to them.

In another case, Justice Mishra while hearing the matter²¹⁸ held that Constitution imposes an obligation upon the citizens as well as upon State to look into preservation of environment. He further went on saying that it is our duty to maintain an ecological balance. It is our fundamental duty and social obligation as per Article 51 A (g) to protect our environment. In another case of Kinkari Devi v State,²¹⁹ it was laid down that the Constitution of India has laid down joint responsibility on both the Government as well as on the citizens of our country to work towards betterment of our natural environment and wildlife. It was further laid down that the failure to perform the duty as provided by Article 51 A (g), will amount to betrayal of one's duty towards the Country and thus, every individual is bound to fulfill the aforesaid duty.

A case came for consideration before the High Court of Rajasthan in year 1988²²⁰. In this case, a PIL was filed asking the Court to direct the Municipality Board to fulfill their obligation to clean the public streets, places, sewers and other public area. In this particular case, it was held that Article 51 A gives right to every citizen to move to the Court and enforce the duties of State Agencies/Authorities towards the environment. It was further laid down that the citizens have right to check that whether the State Authorities are discharging their primary functions in accordance with law or not. The High Court directed the State Authorities/Municipality to discharge their duties and remove the dirt from the public sewers, places and streets within a specified time.

The Rajasthan High Court again took *Suo Motu*²²¹ recognition of a case through facts stated in a public newspaper. It was highlighted in one of the news article that due to immersion of idols of god/goddess in one of the river of the city of Jaipur, the water got polluted and its quality was deteriorating day by day. Thus, Rajasthan High Court directed

²¹⁸ Rural Litigation and Entitlement Kendra v State of Uttar Pradesh A.I.R 1987 SC 359

²¹⁹ Kinkari Devi v State A.I.R 1988 H.P. 4

²²⁰ L.K Koolwal v State A.I.R 1988 Raj 2

²²¹ *Suo Motu* v State of Rajasthan and Others 2015 (5) F.L.T.55 (India)

a notice calling the Chairman of Improvement Trust, the Collector and the Municipal Corporation Body of Udaipur to explain as to what prevented them from taking due cognizance of the matter. Further, the Court enquired as to why no necessary steps were taken up by these bodies to curb the problem of idol immersion into water bodies.

In another recent case of A. Nagaraj and Ors²²², the Apex Court of India delivered a landmark judgment. In this case, the Supreme Court banned the exercises like Jallikattu and other Bullock Cart Racing held at different parts of India. Supreme Court laid down that such an activity torments the animals both physically and mentally. Jallikattu was declared to be a cruel festival towards the animals and at it was further declare that such an activity poses serious threat to public safety. In the same case the Court also considered the Rights of Animals as a Constitutional Rights and also bought the aspect of Article 51 A into consideration to support the statement.

4.4 Directive Principles of State Policy

DPSP or Directive Principles of State Policy embodies certain responsibilities of the State towards the citizen of the country. DPSP imposes Constitutional duty upon State for attaining socio-political goals and work for the welfare of the people. All the Articles are not directly related or talks about environmental protection. However, Article 48 A talks about environmental protection which was inserted by the 42nd Amendment to the Constitution of India.

The basic principle embodied in Article 47 of the Constitution of India clearly calls upon the State to perform some basic duty to look after the health of citizens and take necessary steps to improve their standard of living. In the case of *Talcher Swasthya Surakshya Paraishad v Chairman cum MD Mohandi Coal Fields Ltd*, it was held by the Orissa High Court that it is the function of the Pollution Control Board to ensure that the guidelines are been followed in matters of air and water pollution. It was further laid down by the Court that for industrial development no person should become ill on account of water pollution and surface erosion.

²²² Animal Welfare Board of India v A. Nagaraja and Others Civil Appeal No. 5287 of 2014
<https://www.lawctopus.com/academike/jallikattu-verdict-supreme-court/>

Further, in the case of *Hamid Khan v State of MP*²²³, the attention of the Court was drawn towards negligence of the State Government in not taking proper measures before supplying water from hand-pumps. Such supply resulted in colossal damage to the people. In this case the Court held that State Government was responsible as it has failed to discharge primarily responsibility.

The improvement of standard of living is possible only when there is a raise in public health and people are ensured pollution free environment. In the case of *Vincent v Union of India*²²⁴, it was held by the Supreme Court that Right to Health is a fundamental right and the State is under a legal obligation to prohibit sale of banned drugs.

4.5 Legislative Powers

India is a Federal Country and the relation between the Legislative and Administrative Organs are governed by specific provisions under the Constitution. Part XI²²⁵ contains those provisions. For instance, Articles 245²²⁶ to 255²²⁷ deals with distribution of Legislative Powers between the Union and the State. Further, Article 256 to 261 highlights the provisions relating to Administration Relations. By virtue of Article 245, our Parliament is empowered to make laws for the whole of India and the State Legislatures are empowered under same Article to legislate for States. As per Article 246, the Parliament has exclusive power to make laws with respect to nay matters mentioned in the Union List i.e, List I and the State Legislatures can make laws on any subjects which are mentioned in the State List i.e, List II.

Our Constitution provides instances where Parliament can directly legislate on any matters falling within the List II. In this case, reference can be made to Articles 252 and Article 253. Article 252 provides that before legislating on any matter mention in the State List, the Parliament has to take consent from the concerned States at first. In such a

²²³ Hamid Khan v State of MP AIR 1997 M.P. 191 (India).

²²⁴ Vincent v Union of India AIR 1987 SC 990 (India).

²²⁵ INDIA CONST. Part XI.

²²⁶ INDIA CONST. art.245.

²²⁷ INDIA CONST. art.255.

situation, the Centre has to approach the concerned State Legislature to pass an enabling Legislation requesting the Parliament to enact Legislation on matter on behalf of the State Legislatures. This process was followed by the Central Government while passing a national Legislation/Act on controlling water pollution i.e, Water (Prevention and Control of Pollution) Act of 1974.

Further, Article 253²²⁸ empowers the Parliament of India to enact specific legislations to implement India's obligation and decisions made by our country in some of the International Conference/Association/Body or through signing any Convention. In respect of this provision, along with Entry 13 of Union List empowers the Parliament of our country to enact laws and pass legislations to implement any of the International Obligation. Thus, in past few years the Parliament has enacted Air Act of 1981²²⁹ and EP Act, 1986²³⁰. Preamble of the Water Act as well as of Air Act provides that the Act was enacted for implementing the obligations which India took to implement at the Stockholm Convention of 1972.

There are certain subjects in which the Parliament alone is entitled to legislate. For instance, the Parliament can make laws with respect to industries, oilfields, mines, minerals, railways, river valleys, fishing, inter-state rivers, etc.²³¹ In this connection reference can be made to Entry 13 (Union List). It provides that in order to implement the obligations of the International Conferences, Entry 13 provides that Parliament has been empowered to enact legislations on any subjects mentioned in the State List. There are few subjects upon which both the Union and the State shall have the power to make laws. Such subjects includes making laws on cruelty on animals, protection of birds and animals, family planning matters, factories, agriculture, water, fisheries, etc. With respect to inconsistency which may arise between the laws made by the Union and the State on any of the subject mention in the Concurrent List, it is provided in the constitution that only the laws made by the Parliament will prevail. However, when the law made by the

²²⁸ INDIA CONST. art.253.

²²⁹ Air (Prevention and Control of Pollution) Act, 1981, No. 14, Acts of Parliament, 1981 (India).

²³⁰ Water (Prevention and Control of Pollution) Act, 1974, No.6 Acts of Parliament, 1974 (India).

²³¹ Supra, 193, at 107.

State Legislature has also received the assent of the President, in such a situation the law shall prevail.

Certain changes were made in the Seventh Schedule²³² by the 42nd Amendment. It added and transferred certain entries from one list to another. In List III, Entry 17A, 17B and 20A were added which provides for forest, wildlife protection, protection of birds, family planning and control. Thus, this particular Amendment enabled the Parliament to legislate on these subjects, keeping in view the national and international environmental perspectives. Further, 73rd Amendment added a new schedule i.e, Eleventh Schedule, The schedule has 8 entries. These entries are linked with protection and conservation of environment. The entries includes conservation of soil, management of water resources, social forestry, arid forestry, managing drinking water, maintenance of assets of communities, to manage non-conventional sources of energy, etc²³³. Further, 74th Amendment²³⁴ added a new Schedule i.e, Twelfth Schedule. The subjects include regulation of land use, urban forestry, environmental protection, promotion of ecological aspects. By virtue of this Amendment, Panchayats and Municipalities were empowered to exercise administrative control over subjects mentioned above and thus carry out environmental protection. The Twelfth Schedule mentioned 18 subjects upon which Municipality will be empowered by the State Legislature by law to exercise its administrative control.

Thus, giving powers to the local bodies on these matters relating to environment means to make the people actively participate in the procedure and make laws and act accordingly for the betterment of their lives and take necessary steps for protection of the environment and water resources.

²³² INDIA CONST. Sch. VII.

²³³ Supra, 193, at 109.

²³⁴ DR. JN PANDEY, CONSTITUTIONAL LAW OF INDIA 646-49 (53rd ed. 2016).

Chapter 5

Judicial decisions and Management of Bio-medical Waste

The cases discussed in the previous chapter did not specifically dealt with the issues of bio-medical waste management. This issue is of recent origin and thus before that issue of bio-medical waste was not given any serious concern as compared to other types of wastes. In recent times, the Courts have laid emphasis on bio-medical waste management and have given some landmark decisions with respect to same. From time to time, the Courts have issued directives to various concerned authorities highlighting the importance of managing these wastes. With the phenomenal growth in environmental awareness and development of environmental legislation's, the judiciary came to play a major role in giving effect to various litigations concerning environment. To lessen the burden, demand for finding an alternative redressal mechanism also grew. As a result, the Government of India came constituted the NGT in the year 2010²³⁵. The National Green Tribunal along with the Supreme Court and High Court, have played an active role in providing speedy environmental justice and has looked into the matter of bio-medical waste management since 2010. The following chapter deals with the cases decided between years 2010 to June 2020.

5.1 The Cheerans Industries v KPCB²³⁶

The following appeal was filed by KPCB and M/s. Cheeran's (Industry making incinerators) against the order passed by the Appellate Authority established under the Air Act. The Cheeran's industry manufactures incinerators and operates it using coconut shell as its fuel. The industry filed an application before the KPCB for getting certificate of authorization for manufacturing and operating the incinerators. The said certificate was issued with a condition that the incinerators must comply with the guidelines issued by the Environment Ministry. The Government of Kerala directed all the Urban Local Bodies as well as the Gram Panchayats to use the incinerators manufactured by the Cheeran's. Later on an order was passed by the KPCB cancelling the certificate. M/s

²³⁵ Supra, 193, at 442

²³⁶ The Cheerans Mayura Industries v Kerala Pollution Control Board, W.P (C) No. 16336 of 2010 (N), ker (India) <https://indiankanoon.org/doc/768901>

Cheeran's filed a writ petition challenging the said order before the Appellate Authority under the Air Act. Upon hearing, the application was dismissed and the order was upheld. Again, an appeal was filed before the Kerala High Court. The question which was to be considered was whether the appellant can be allowed to use coconut shell as fuel to run incinerators.

In this appeal, the Court held that as per 1988 Rules, biomedical waste cannot be chemically treated with any chlorinated disinfectants before incinerating it. Further, with respect to controversy relating to use of coconut as fuel, it was laid down by the Court that as per the Schedule 5 of the BMW Rules of 1998 and as per MSW Rules, 2000, only those fuels which are low in sulphur emissions can be used like LDO/LSHS/Diesel. The particular appeal was allowed by the Court and the matter was disposed of by allowing the appellant to use coconut shell as a fuel to operate incinerators. According to the Court, the Rules do not provide for a restricted interpretation that only low LDO/LSHS and Diesel can be used. Thus, the Court made it clear that the Rules of BMW, 1998 AND MSW, 2000 do permit use of coconut shell as fuel. The Court further directed the KPCB that no such application asking for authorization in near future shall be rejected on the ground that fuel used by those incinerators was coconut shell.

5.2 Rahul Vijay Singh Chugh v State of Haryana and Others²³⁷

The petition drew the court's attention towards the issue that a number of hospitals and nursing homes were not complying with the BMW Rules of 1998. Petitioner further alleged that the equipments for treating the biomedical waste were also not installed in many hospitals and nursing homes. On hearing day, the Court directed the respondents to file an affidavit. The Court was of the view that the State of Punjab has to satisfy the Court as to whether or not the Disposal Sites were located within a distance of 150 kms from the nearest hospitals and nursing homes. Secondly, the Court directed the PCBs of both Punjab and Haryana to carry out inspection of the disposal site and to check whether the sites are functioning properly or not. It was further brought into notice of the Court

²³⁷ Rahul Vijay Chugh v State of Haryana and Others, 2012 SCC OnLine P&H 1521 (India).

that the previous order of the Court directing the authorities to set up a common incinerator on the outskirts of the city was not yet executed.

The court contended that in spite of giving number of orders, PPCB has failed to implement the Court orders as well as the violated the provisions of the BMW Rules, 1998. In the matter, affidavit were asked to be filed by the PPCB. The affidavit stated that two hospitals of the region were found violating the provisions of the BMW Rules and show cause notices were served on those hospitals by the PPCB. Disposing the petition, the Court directed the Pollution Control Board of Punjab and Haryana to constantly keep a constant vigil upon the hospitals and nursing homes. It was further held by the Court that the petitioner can bring into the notice of the Court any act of non-compliance by the respondents in near future.

5.3 Nirbhai Singh v State of Punjab²³⁸

The case highlighted the issue of contamination of Budha Nullah stream due to illegal dumping of biomedical waste. The court in this matter held that although the city has four treatment facilities for treating biomedical waste, they were not sufficient to treat the huge amount of daily generated wastes. The Court directed the Government to file an affidavit on this matter. The affidavit stated that total discharge of effluents into the Budha Nullah stream was near about 500 million liters per day and many of such discarded effluents were untreated. The Court directed the PPCB, Municipal Corporation and to take up corrective measures to ensure that the effluents do not cause air, soil and water pollution.

5.4 ParyavaranMitra v Gujarat PCB²³⁹

The following application was filed by the applicants alleging air and water pollution of Which was caused by Rajkot MSW Disposal site at a village named Nakravadi. The Municipal Corporation was given authorization by the GPCB to set up disposal facility for treating MSW. On receiving authorization the Municipal Corporation entered into a

²³⁸ Nirbhai Singh v State of Punjab, 2011 SCC OnLine P & H 15414: ILR (2012) 2P& H 916 (India).

²³⁹ ParyavaranMitra and others v Gujarat Pollution Control Board and others 2013 SCC OnLine NGT 53 (India).

contract with a company, and erected a waste disposal plant for treating the wastes. Under the terms of the said contract, the company was bound to provide proper service and maintain hygiene as required. In this application it was contended that the Municipal Corporation and the State Government later on granted permission to the company to use a part of village land for treating MSW. As a result of such use, the land got affected by dispersion of wastes. On assessment it was found that the waste has caused damage to crops, to livestock, affected health of villagers, polluted sources of water, etc. On assessment it was further found that in spite of receiving repeated orders, it failed to comply with the provisions of the MSW Rules of 2000.

CPCB contended that it had no role to play in this matter as it has no authority to control the municipal affairs as per MSW Rules. CPCB further contended that as per Rule of MSW Rules of 2000, it is the duty of GPCB to monitor the quality of groundwater, air quality and also has the responsibility to look after the incinerator quality. The Municipal Corporation resisted the application on the ground that the MSW was disposed upon ground allotted by the State Government. They further contended that the application was filed after a period of five years of the commencement of the activity at the facility. The aggrieved parties contended that the facility should be closed and compensation should be provided. Hearing this, Municipal Corporation replied that on an average of 400 to 500 MT of MSW wastes are processed everyday and shutting down of facility would cause serious damage to environment as there will be no other alternative to process such wastes. The Tribunal thus, dismissed the application asking for closure and ordered the authorities to comply with the Rules and prevent any further mishandling of wastes. The Tribunal further held that the location where facility is located is not illegal but “Polluter pay principle” is to be applied to pay the compensation and imposed penalty. On CPCB’s contention that it has no obligation towards MSW, it was held by the Tribunal that as per Ministry of Environment and Forests notification CPCB has the power under Sec. 5 of the Environment Protection Act of 1986 to give directions to any authority for violating any Rules relating to hazardous wastes, biomedical wastes or MSW. The Tribunal directed the respondents to pay one lakh to the applicants.

5.5 Haat Supreme Wastech Pvt. Ltd Case²⁴⁰

The question that came for consideration before the NGT was whether biomedical disposal plants were required to get Environmental Clearance as per the Environmental Clearance Regulation of 2006. The appellants who were running two biomedical facilities filed an application before SPCBs for renewal of authorization. On receiving the application, the premises were being inspected by the SPCBs and certain shortcomings were highlighted after the inspection. The appellants were asked to deposit a sum of rupees five lakh each as a bank guarantee that they will comply with the provisions of the BMW Rules. Later on, a new notice was served by CPCB upon the appellants, asking them to again deposit a sum of ten lakh each as bank guarantee. This particular notice of CPCB was challenged in this petition to be declared arbitrary and illegal.

The Tribunal stated that obtaining an environmental clearance for establishment of any biomedical facility is necessary. The biomedical facility has to be operated in compliance with both the BMW Rules of 1998 as well as the Notification of 2006. Notification issued in 2000 has been issued by Environment Ministry with reference to the provisions of the BMW Rules of 1998. The appellants were thus directed by the Tribunal to get environmental clearance in terms of site location, proposed environmental safeguards and potential environmental impacts.

5.6 P.K Nayyar v UOI & Others²⁴¹

A petition was filed asking for shifting of CBWTF from Okhla to a suitable site. The petitioners claim that the CBWTF was situated in a residential area of Delhi and people of that area were concerned about the health effects which the biomedical waste may pose to them. As a result, the residents seek remedial measures from the Court. Upon receiving directions from the Court, Government of NCT of Delhi constituted a committee to monitor the matter. The Committee was entrusted with the duty of assessing the complaints received, to examine whether the CBWTF was operating inappropriately and if found so, must suggest an alternative for removing the plant into new site. The

²⁴⁰ Haat Supreme Wastech Pvt. Ltd v State of Haryana, 2013 SCC OnLine NGT 279 (India).

²⁴¹ P.K Nayyar & Ors v Union of India & Ors, Mr. B.V. Niren, CGSC , W.P (C) No. 5683/2010 2013 SCC OnLine Del 201 (India).

Committee suggested for moving the plant to another site as complete shutting it down will lead to mismanagement of biomedical waste. In a meeting, new site was allotted by Govt. of NCT of Delhi for setting up of CBWTF. But another writ petition was filed by the residents of Sukhdev Vihar seeking complete closure of the plant as it was not closed as decided. Three sites were allotted for setting up of CBWTF in nearby area.

It was held by the High Court that biomedical waste can cause severe deadly disease among people. The facility which was operated within a distance of 30 meters is not safe enough and is likely to effect the environment and health of residents. It was further held by the Court that the Government should have shifted the Plant to an area where setting up such Plant will not pose any harm to nearby population. The Court also upheld the decision laid down in the case of Subhash Kumar v State of Bihar that, right to live under Article 21 also includes right to enjoy pollution free water and air. The Court went on saying that it has right to direct shifting of such facility under Article 226.

5.7 Mahesh Dubey v Chhattisgarh Environment Conservation Board²⁴²

The applicant raised the issue of mismanagement of biomedical waste in Chhattisgarh. The applicant prayed for issuing direction to the State Government and other authorities to ensure proper and effective compliance of the BMW Rules of 1998. The applicant alleges that he has approached the authorities in several occasions but none took his complaint seriously. He alleges that there is lack of implementation of BMW Rules as SPCB has given notices to near about 18 hospitals (both public and private) who were not complying with the BMW Rules. The notices were given out as neither these healthcare institutions were not segregating biomedical wastes, nor they were sending the biomedical wastes to the treatment facility. The discarded biomedical wastes were allegedly mixed with other waste and were scattered in public places. The applicant alleged that the authorities although aware of the matter, are negligent and casual in handling the issue.

²⁴² Mahesh Dubey v Chhattisgarh Environment Conservation Board and Others, MANU/GT/0140/2016.

The Tribunal was of the view that issue of non-compliance of laws in the State of Chhattisgarh is large. According to Tribunal it is dire necessary that immediate steps are taken up for implementation of BMW Rules of 2016. The Tribunal directed for setting up of a Committee at State level to monitor the issue and prepare a report and send it to the Tribunal within the period of three months.

5.8 S. Chidambaram v CS to the Govt. of Tamil Nadu²⁴³

The matter came before the Madras High Court in year 2018. In this petition, the petitioner alleged the failure on the part of the administrative authorities in preventing pollution of the district of Tirunelveli. It was contended by the petitioner that large quantity of biomedical wastes were transported in wooden boxes to Tirunelveli from Kerala. When the same was intercepted by the District authorities, it was sent back to the place of origin. But the Lorries carrying the wastes did not go back but instead dumped the biomedical wastes in Puliankudi area. The Court held that BMW Rules clearly states that manner in which the biomedical wastes are to be treated and disposed off. The wastes were transported to the area of Tirunelveli from Kerala without any checking. When situation became worse, the issue was addressed by the District officials and they formed a District Level Bio-Medical Waste Management Committee to look into the issue of illegal dumping of wastes. The Court directed the Committee so formed, to meet frequently and to issue directions for ensuring that biomedical wastes are not transported to the area of Tirunelveli in near future. Further, the Committee should also adhere to the Rules and Guidelines issued by AIIMS Delhi for disposing biomedical wastes in a scientific manner.

5.9 Laishramcha Meetei v. State of Manipur²⁴⁴

This particular PIL was filed focusing on important aspect of bio-medical waste management and to direct the authorities for implementing the provisions of BMW Rules of 2000. The Respondents including the State and Pollution Control Board of Manipur

²⁴³S. Chidambaram v The Chief Secretary to the Government of Tamil Nadu, Chennai, W.P No.24286/2018, <https://indiankanoon.org/doc/58040628>

²⁴⁴Laishramcha Ji-nine Meetei v State of Manipur represented by the Chief Secretary to the Government of Manipur and Others, P.I.L No. 8 of 2005, 2019 SCC OnLine Mani 48 (India)

were asked to file their responses. The response stated that they do have complied with the provisions stated in BMW Rules of 2000. The High Court observed that only few district hospitals have complied with the Rules and rest all had violated the Rules, despite serving notices. The Court directed the concerned authorities to take immediate action against those hospitals who were not complying with the Rules. In the meantime, the Central Government amended the BMW Rules of 1998 and came up with the BMW Rules of 2016. In view of the new BMW Rules of 2016, in order to aid the Courts in discharging their duties, it is necessary for the PCBs to strictly implement the provisions of the BMW Rules, 2016.

Thus, Court was of the view that in view of the new BMW Rules of 2016 and for its proper implementation, hospitals violating the Rules are to be properly identified and Advocate Commissioners are to be appointed by the Court to monitor those hospitals. It was further held by the Court that despite repeated orders, no action was taken up by the authorities towards the violators of the Rules. Thus, total of five Advocate Commissioners were appointed by the Court and were directed to give requisite report to the Court from time to time. Manipur PCB was directed to take proper steps for inspecting all healthcare establishments which has not been inspected so far, to install treatment plant for disposing liquid waste and to give requisite training to all handlers of biomedical waste collectors.

5.10 Suo Motu Proceedings initiated in NGT²⁴⁵

This particular case was with respect to pollution which was caused to river Periyar in Kerela by illegal dumping of biomedical waste and slaughter house waste. A Suo Motu petition was initiated by the NGT on the basis of a letter which was sent to NGT by the former Judge of Kerela High Court. NGT while disposing the application came to a conclusion that authorities were not taking any steps towards stopping hospitals that were illegally dumping biomedical waste into the river. The Tribunal further was of the view that SPCB was aware of the situation, yet no steps were taken up by them. The Tribunal

²⁴⁵ Suo Motu proceedings initiated based on the representation received from Justice R. Bhaskaran v State of Kerela, O.A No. 585/2018 2019 SCC OnLine NGT 873 (India).

constituted joint committee. The Committee was responsible for furnishing an action plan to enable compliance with the BMW. The Committee further was directed to assess the amount of damages which was required to be recovered.

On the basis of the report of the joint Committee, the Tribunal directed both the hospitals to pay a hefty amount of thirty three lakh eighty one thousand. The Tribunal further directed that the compensation should be recovered as soon as possible. Further, similar notices to comply with the BMW Rules were also issued to other two hospitals of Kerela, who were found to be violating the Rules. The Joint Committee also identified near about 64 new HCFs who were also not complying with the BMW Rules. The Tribunal took strict action towards them.

5.11 Shailesh Singh v Sheela Hospital Case (NGT Order)²⁴⁶

The application before NGT raised the issue that the HCFs and SPCBs of various States and UTs are violating the BMW Rules of 2016. The application also highlighted the issues that unscientific disposal of biomedical waste may cause serious infectious diseases among human beings. The said matter was reviewed by NGT and an order was delivered on 12 March 2019. After taking note of the issue, the Tribunal noted that biomedical wastes if not properly disposed may cause gastrointestinal, respiratory, eye and other genital infection. It was further held by the tribunal that the steps taken up by the UP Government was inadequate and there has been wide violation of BMW Rules. All the States were asked to furnish the report to the tribunal by 30st April 2109 and the defaulting States would be required to pay an amount one crore. The Tribunal also directed CPCB to prepare an action plan to recover compensation from the ones violating the BMW Rules.

On the basis of report made by CPCB, the Tribunal directed all the States and UTs to take steps as suggested by CPCB in its report. Tribunal further, directed that the States which do not have a CBWTF shall construct one within period of two months. States and UTs were also ordered to furnish information as to establishment of barcode system, as laid down in the BMW Rules of 2106. The Tribunal further directed all the States SPCBs and

²⁴⁶ Shailesh Singh v Sheela Hospital & Trauma Centre, Shahjahanpur & Others; Kailash Hospital and Heart Institute & Others; Shri Ganga Charan Hospital (P) Ltd., Bareilly & Others, O.A No. 710/2017 SCC OnLine NGT 879 (India).

PCCs to file report as per BMW Rules of 2016 i.e; before 30 April every year, failure to which they will be liable to pay a compensation of around one crore per month till the date of delaying.

5.12 Indira Nagar Jan Vikas Samiti v State of Uttarakhand²⁴⁷

The present petition raised a question of public importance. According to the petitioner, the respondents were allowing dumping of biomedical waste near river named Gola. The petition also highlighted the fact that dumping zone was barely 200 meters away from residing area. The biomedical wastes can get into the river and pollute the entire water bodies. After enquiry, the Court came to a conclusion that dumping biomedical wastes near river bank is in serious violation of the BMW Rules of 2016. Certain directions were laid down. The Court directed the respondent No.5 to set up a Solid Waste Management plant or a dumping ground within six months from the date of order. Till the Waste Management plant is set up, the respondent was directed by the Court to stop dumping of biomedical waste near river Gola to prevent pollution of the river. The State Government was directed to allot lands for setting up recycle facilities and to properly fence the said site. Allotted site should not be near to any national parks, wetlands, water bodies or nay historical sites. Occupiers were directed to segregate biomedical waste into separate colored bags and they were also directed to pre-treat the biomedical waste in a manner prescribed by WHO. All the Operators of the biomedical facility were directed to treat and disposed of biomedical waste as per Rule 7 of the BMW Rules of 2016. Uttarakhand Pollution Control Board were also directed to register criminal cases against those officials who are not complying with the Solid Waste Management Rules of 2016.

5.13 Nuggehali Jayasimha v. Govt. NCT of Delhi Case²⁴⁸

The application before the NGT raised the issue of air, water and soil pollution caused by certain dairy industries of Delhi. It was alleged that the dairy industries were dumping solid, liquid and gaseous wastes into river Yamuna, which resulted in heavy pollution of

²⁴⁷ Indira Nagar Jan Vikas Samiti v State of Uttarakhand and Others, W.P No. 40/2017, 2018 SCC OnLine Utt 654.

²⁴⁸ Nuggehali Jayasimha v. Government NCT of Delhi, O.A No. 46/2018 SCC OnLine NGT 890 (India).

the river water. Further, it was highlighted that wastes from such dairies were clogging the drainage system of the city and was becoming the breeding ground for mosquitoes and other deadly insects. The rotten wastes were also releasing huge amount of ammonia and nitrogen oxide into air and thus was negatively impacting the air quality. Along with the above stated problems, the foul smell release from the dairy industries were causing severe headache and migraine issues among the residents.

On receiving the application, inspection was conducted by the Animal Welfare Board of India on order of the Tribunal. In the inspection report it was laid down by the Board that the diaries were responsible for dumping untreated and used oxytocin injections, drugs, syringes, plastic bottles into the river Yamuna. The report also highlighted that the diaries were violating the provisions of the BMW Rules of 2016 and Food Safety and Standards Regulations of 2011. It was not noted by the Tribunal that although Delhi Pollution Control Committee (DPCC) was a party to the suit, yet it did not come forward to make any suggestion for enforcing the provisions of the Rules nor did it take the responsibility of the issue. It was also noted by the Tribunal that DPCC failed to fulfill its responsibilities as stated under the provisions of the Water Act of 1974 and the Air Act of 1981. The Tribunal imposed a sum of Rupees Ten Lakh as an interim compensation upon DPCC and Municipal Corporation. The Authorities were further directed to guarantee a sum of Rupees Ten Lakh each to CPCB and enable CPCB to take necessary steps for restoring the environment within three months. On receiving the order from the Tribunal, DPCC in order to cover up their fault started imposing penalties on other authorities like Municipal Corporations and other Local Bodies. On hearing this, the Tribunal held that DPCC has no authority to collect such amount as compensation and held that it is DPCC's responsibility to enforce the provisions of the Water and Air Act. Further, DPCC was directed to apply Polluter Pay Principle to impose penalties and recover compensation from polluting bodies.

5.14 Praduman Tiwari v UOI²⁴⁹

In this particular matter, the applicant approached the Tribunal alleging that the respondents were discharging untreated biomedical waste into one of the river of Allahabad and were also disposing some of the waste by burning. For inspecting into the matter, a committee was formed by the Tribunal. The committee furnished a report which highlighted that there were certain shortcomings in the functioning of biomedical plant. It was found that the plant was discarding unsegregated biomedical waste, autoclave machine was not operating and the emissions from the incinerators were not meeting the required norms of air quality.

Upon recommendation of the committee, the Tribunal directed the respondent (Ferro Build Hards Pvt. Ltd) to pay a sum of eight lakh rupees as compensation towards restoration of environment. Further, certain recommendations were given to the biomedical facility plant. Some of them were: to properly maintain the Air Pollution Control Device, to regularly monitor, maintain and repair the automatic feeding system of the incinerator, to provide a list to UPPCB of HCFs which are not sending segregated biomedical waste to the facility and thus enable UPPCB to imposed penalties upon those HCFs. Further, facility was ordered to supply adequate PPE kits to all health care workers and to adopt bar coding system as mentioned by BMW Rules of 2016.

5.15 Dr. J. Umarani v State of Tamil Nadu²⁵⁰

The petition was filed by a practicing doctor highlighting the issue of that the Tamil Nadu Pollution Control Board, has not issued required license to any concerned body for treating biomedical wastes. The petitioner further contended that the discarded untreated wastes were posing serious threat to environment as well as to health of public. As there is no authorize person to handle the biomedical waste, the discarded biomedical wastes are not transported .The used linens and clothing are washed openly in public water bodies. As a result of which the water bodies' gets contaminated and such contamination

²⁴⁹ Praduman Tiwari v Union of India and Others, O.A No. 420/2016 (M.A. No. 918/2016) 2019 SCC OnLine NGT 206 (India).

²⁵⁰ Dr. J. Umarani v State of Tamil Nadu, W.P. No. 43370/2016 and W.M.P No. 377228/2016, 2019 SCC OnLine Mad 2769 (India).

attracts the provisions of the Water Act. The petitioner contended that the healthcare establishments are aware of the provisions of BMW Rules but still these Rules are not properly followed and implemented by them.

The Court directed the State Government and the Pollution Control Board that they should ensure that sewerage treatment plants are functional. Further, the Court went on saying that the TNPCB should carry out inspection of all public and private healthcare establishments, once in every two months. The respondents were also directed to implement the orders given by the honorable SC for setting up of Biomedical Management Committee. The Committee is to conduct inspection and prepare a report reflecting the defects at managing biomedical waste at both public and private hospitals. The respondents were directed by the Court to take action on the basis of that report.

5.16 Krithika Gokulnath v Anna University²⁵¹

The grievance which was highlighted in this application was of non-compliance of BMW Rules by the Laboratories and Research Institutes who are dealing with analysis of DNA. The petitioner argued that DNA analysis is a by-product of biomedical waste and thus such laboratories must adhere to BMW Rules of 2016. The principal bench of NGT thus, directed all the States and UT's to inspect all such Laboratories and Research institutes running without taking proper authorization and to identify the one's not adhering to the BMW Rules.

5.17 Scientific Disposal of Biomedical Waste arising out of COVID-19 treatment²⁵²

In this particular matter, NGT raised the concern over biomedical waste which is discarded after handling and treatment of COVID-19 patients. NGT considered the issue to address the gaps in compliance with the BMW Rules of 2016 at times of COVID-19. The Tribunal mentioned that although it is dealing with the issue of addressing gaps in the BMW Rules of 2016, waste generated due to ongoing pandemic has called for this

²⁵¹ Krithika Gokulnath SNN Raj Serenity Apartments v Registrar, Anna University and Others, MANU/GT/0157/2020.

²⁵² Re: Scientific Disposal of Biomedical Waste arising out of COVID-19 treatment and Compliance of BMW Rules of 2016, O.A No. 72/2020, NGT (India).

immediate order. The Tribunal further went on saying that guidelines framed by CPCB for dealing with biomedical waste generated at times of COVID-19, has to be revised so as meet all the broad concerns relating to proper and scientific disposal of biomedical waste. Guidelines according to the Tribunal should take care of waste management both at institution level as well at individual level. At times of pandemic, when not much incinerators are available, color guidelines are to be followed for bins used for collecting biomedical waste. SPCBs and PCCs were directed to develop necessary software that can be used for creating awareness among people about COVID-19, providing training to Local Bodies, Health Departments of the States, etc. The Tribunal further directed SPCBs and PCCs to take steps in mitigating the risk of unscientific disposal of COVID-19 waste.

Chapter 6

CPCB Guidelines on Covid-19 and Current Scenario in India

What we are currently facing is a totally unexpected and turbulent change. This pandemic has locked crores of people in their homes, closed service organizations and bought everything to a halt. Covid 19 is of recent origin. During this time, safe disposal of waste generated from examination and treatment of COVID-19 patients, in an effective manner is must to protect the health of the people. As the cases continue to rise in India, the amount of waste generated from Generated during Treatment/Diagnosis/Quarantine of COVID-19 Patients is increasing day by day. Besides controlling the pandemic, the Government is facing another issue i.e., safe and scientific disposal of biomedical waste. At present, India is producing near about 2, 00,000 tonnes of waste p.a. Increase in biomedical waste in city of Pune has resulted in breakdown of the city's only incinerator for treating bio-medical wastes²⁵³. This shows that the Government has to take up necessary steps and follow proper disposal methods to prevent spread of infection.

6.1 About Covid-19

Coronavirus generally belongs to the family of Viruses commonly known as “*Coronaviridae*” and it derives its name from the Latin word “*Corona*” which means Crown. They are found in both animals as well as in human beings and can cause severe respiratory diseases in humans like “*Severe Acute Respiratory Syndrome*” also known as SARS. A new strain was identified recently and was named as “*nCov*”. As it was identified in year 2019, hence it has been referred to as “*COVID-19*”²⁵⁴. The first case of COVID-19 was detected in the city of Wuhan in China in the month of December 2019. It was further declared as a Public Health Emergency by the World Health Organization on January 2020 and later was termed as pandemic.

²⁵³ Umesh Ishalkar, *Covid-19 waste surge breakdown incinerator*, T.O.I, June, 15, 2020, at 6.

²⁵⁴ Anurag Bortahkur, *Coronavirus and India*, A.T, March, 19, 2020, at 6.

6.2 Characteristics of Wastes generated during Covid-19²⁵⁵

Wastes generated during Treatment of COVID-19 Patients includes Human Anatomical, Disinfectants, Discarded bed sheets, mattresses, blood, body fluids, Sharps, gloves, masks, gowns as well as other Recyclable wastes. As per WHO Guideline²⁵⁶, the wastes generated are highly infectious in nature and must be properly disposed. Such wastes are to be pre-treated and disposed by Wastes Collectors. As the amount of discarded PPE will increase during the pandemic, thus it is suggested that additional treatment plants is to be set up and alternative techniques should be adopted for handling wastes. For water generated from washing PPE, Gloves and Reusable aprons, it is recommended that it should be cleaned by using soap and water and then should be decontaminated using sodium hypochlorite solution. All single-use gloves and gowns are not to be reuse as they are highly infectious in nature. As per the recent study on the surface stability of the virus, shows that the deadly virus can survive up to 72 hours on materials like plastic and stainless steel and with respect to copper surfaces, it can last only up to 4 hours. Thus, immediate environment surrounding an infected person can be good source for spread of infection. Currently, the studies have not proved the spread of virus from faeces of infected person.

6.3 CPCB's Guidelines on Handling COVID-19 Wastes²⁵⁷

With the aim of dealing the pandemic situation, specific guidelines was laid down by CPCB on April 2020. For dealing with COVID-19 and treating the one's suffering from it, State Government as well as the Central Government took up various steps. Such steps included setting up of Quarantine Camps, forming isolation wards, collecting samples of blood and saliva in laboratories, etc. Thus, in order to manage the biomedical waste generated through treatment of COVID -19 patients; CPCB came up with certain

²⁵⁵ id., at 7.

²⁵⁶ *Water, Sanitation and Waste Management for COVID-19 virus*, WORLD HEALTH ORGANIZATION (Jun 28, 2020, 10 10665/331846/WHO-2019-nCoV AM), https://apps.who.int/iris/bitstream/handle/-IPC_WASH-2020.3-eng.pdf

²⁵⁷ *Guidelines for Handling, Treatment and Disposal of Waste Generated during Treatment/Diagnosis/Quarantine of COVID-19 Patients*, CENTRAL POLLUTION CONTROL BOARD (MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE), (Apr 30, 2020 10 AM), https://tnpcb.gov.in/pdf_2020/BMW-GUIDELINES-COVID_Revised_April2020.pdf

guidelines which need to be followed by all the healthcare establishments. As per the guidelines, along with the BMW Rules of 2016, these Rules are to be followed. Some important key features of the guidelines are:

I. Isolation Ward:

As per the guidelines, Isolation Ward means the wards that are used for keeping and treating patients suffering from Covid-19. As per the new guideline, healthcare establishments and quarantine centers need to follow certain steps for ensuring proper management and handling of biomedical waste, generated from treatment of Covid-19 patients²⁵⁸. Some of the important steps include:

- Using separate color coded containers and bags for segregating Covid-19 wastes as per the BMW Rules of 2016;
- For collecting wastes from Covid-19 Wards, double layered color coded bags are to be used for ensuring that there is no leakage whatsoever;
- Such wastes should be properly separated from other biomedical wastes. All such bags and containers used for collecting and keeping Covid-19 Wastes are to be properly labeled as “COVID-19 Waste” so as to easily distinguish it from other wastes;
- General Wastes discarded from Covid wards are to be disposed of as per Solid Waste Management Rules of 2016;
- Separate trolleys for collecting wastes from Covid wards are to be used and such trolleys should be labeled as “Covid 19 waste”. Used trolleys and Bins should be disinfectant by using 1% Sodium Hypochlorite;
- Faeces discharged by Covid patients should be discarded in yellow color coded bags as prescribed by the BMW Rules of 2016;
- Used Goggles, PPE Kits, masks, face shields, apron, Hazmet Suit, Gloves are to be collected and disposed of in Red Color Coded bags or containers;

II. Quarantine Camps/ Homes:

As per CPCB Guidelines, Quarantine Camps and Homes are those places where people who are suspected of suffering from Covid-19 or the ones who are

²⁵⁸ id., at 2.

suffering from Covid-19 are kept under observation. Such persons are kept under observation for a period of 14 days or more if symptoms persist²⁵⁹.

III. Duties of persons who are operating Quarantine Camps and Homes:

The persons who are operating the quarantine camps and Homes are under an obligation to undertake following below listed steps for proper disposal of biomedical waste:

- Solid Waste discarded from such centers/camps/Homes are to be handed over to the Waste collectors as identified by SPCB's at Local Level;
- If any Biomedical Waste is generated from such centers/camps/homes, then such wastes are to be kept in yellow color coded bags and containers as prescribed by the BMW Rules of 2016; Such bags are to be handed over to those authorized waste collectors as identified by Local Bodies or SPCBs;
- They are under⁴ an obligation to call up CBWTFs in case of any difficulty faced by them for disposing the wastes.²⁶⁰

IV. Duties of CBWTF:²⁶¹

Operators are under duty to provide adequate PPE to all the workers and report about amount of collection of wastes to the concerned PCB's from time to time. Properly sanitize the vehicle used for collecting Covid wastes.

V. Duties of SPCBs and PCCs:

The SPCBs and PCCs of Uts are under an obligation to take up following steps:

- SPCBs and PCCs as per the guidelines, are under an obligation to maintain records of all Covid 19 Centers/Camps/Homes being operated under their respective State and UT respectively;
- They should ensure that wastes are collected from such centers/ Camps/Homes by following the provisions of the BMW Rules of 201 and steps as mentioned under these guideline;

²⁵⁹ id., at 4.

²⁶⁰ id., at 5.

²⁶¹ id., at 6.

- SPCBs and PCCs can direct the CBWTFs to operate for little extra hours than normal, with the aim of disposing huge amount of discarded wastes from Covid wards and Centers;
- SPCBs and PCCs can allow the workers of CBWTF s to collect wastes as and when required;
- Where there are no CBWTFs at local level and in remote areas, then in such a situation SPCB or PCC can identify any existing facility available at nearby hospital to be used for disposing and treating Covid 19 Wastes. Only Deep burial method is to be allowed for disposing wastes that fall under yellow category of the BMW Rules of 2016:

VI. Duties of Local Bodies:

CPCB also laid down certain steps to be taken up by the Local and Urban Bodies to be followed at times of Covid. Some of which includes²⁶²:

- All Local and Urban Bodies have to collect information on Quarantine Centers/ camps/Homes and must provide updated list to SPCBs;
- They must give contact details of CBWTF to all Quarantine Centers/Camps/Homes,;
- It is upon them to make arrangements with respect to pick up and disposal of waste and for that they can enter into agreement with CBWTFs;
- Proper color coded bags and containers through CBWTF are to be provided to all quarantine centers/camps/homes;
- Door to Door waste collectors are to be employed for collecting quarantine center's waste;
- Proper training is to be provided to all health care workers with respect to sanitizing and other methods of collecting and disposing Covid 19 waste; They should be directed to wear PPE Kit at all times while handling such waste;
- Alls staffs involved in handling such wastes must be provided with proper PPE Kits, N95 Masks, Gloves, Gowns, Gumboots and Goggles.

²⁶² id., at 6.

VII. Managing Wastewater:

Although it is not yet proved that Covid 19 can be transmitted from sewerage systems and waste water, yet CPCB laid down few important steps which is to be followed by HCFs and STPs in States and all UTs. Some of the steps are;

- All HCFs and STPs are directed to continue disinfecting the wastewater to prevent spread of Coronavirus;
- They are required to practice best possible hygienic practices while handling and disposing biomedical waste. They must ensure that workers wears PPE at all times;

6.4 Present Scenario of India at times of Covid-19

Managing biomedical waste in environmentally sound manner is the key challenge at present. During pandemic, the amount of waste generated from Quarantine Centers/Camps/Homes has increased. The task of managing the discarded waste has become more difficult as there are many such States which do not have strict monitoring policy. In a field work, Delhi based Organization named Think Tank published a report highlighting that in many remote areas nothing has been done, nor have any contractors been appointed to manage the collection of wastes. Further, the report also highlighted that many incinerators were also not properly upgraded as per the CPCB guidelines. No facility was added in those incinerators for burning highly infectious wastes in high temperature that would be discarded from quarantine centers. With respect to bar code system, it was reported that in many States the system has not been strictly implemented till date. This means in many such States not having any proper bar code system, the movement of wastes cannot be tracked. Looking on the current pandemic situation, States not having bar code system can pose a threat to proper management of Covid-19 waste²⁶³. In spite of these detailed guidelines on dealing with COVID-19 Wastes, it is seen that these guidelines are not been properly followed. In a recent report²⁶⁴, State of

²⁶³ Vishwa Mohan, *Dealing with biomedical waste in time of covid-19*, TIMES OF INDIA (May, 23, 2020) <https://timesofindia.indiatimes.com/dealing-with-biomedical-waste-in-the-time-of-covid-19-presents-huge-challenge/articleshow/75905790.cms>

²⁶⁴ S Thakur, *Assam Struggles with biomedical waste at times of Covid 19*, TIMES OF INDIA (Jul, 15, 2020) <https://timesofindia.indiatimes.com/city/guwahati/assam-struggles-with-biomed-waste-with-1-treatment-facility/articleshow/76976984.cms>

Assam is facing tough situation as there is only one CBWTF in the city of Guwahati. As per the reports, the amount of wastes generated in the city of Guwahati is near about 3 tonnes on a daily basis. At times when the city has only one CBWF, not all waste ends up in the facility. Huge amount of used PPE kits and other Covid 19 biomedical wastes are treated using chemicals, followed by deep burial in barren lands of the city. This act can pose a serious threat to groundwater contamination. In another instance, on May 15, 2020²⁶⁵, a video of a man with mental illness, wearing PPE and walking on roads became viral on internet. It was reported that the PPE Kit was collected by the person from a dustbin nearby quarantine center.

India is fighting with another bigger problem, along with COVID-19 pandemic, i.e it is facing waste crisis. Masks, gloves, PPE Kits, gowns, headgears, quarantine wastes including bed sheets and used quilt, laboratory wastes, etc. after use, ends up creating huge amount of wastes. The discarded wastes contain almost all types of wastes like human anatomical waste, plastic wastes and sharps. Over growing amount of wastes has resulted in overflowing of landfills, breaking up incinerators, etc. These wastes pose a serious threat to sanitation workers and rag pickers. Although guidelines have been laid down for providing proper PPE Kits, boots and masks to all the sanitation workers, who are at the high risk of getting infected, but it is evident that they are handling these wastes by only wearing masks.²⁶⁶ In a recent report from Mumbai's Common Biomedical Waste Treatment Facility, near about 600kg of wastes in form of discarded masks and gloves ends up in landfills instead of proper incinerating sites as people are not segregating domestic wastes properly. Till date, near about 80 sanitation workers have tested positive, out of which 25 workers have died. Moreover, there is a suspicion amongst the scientists that Covid-19 can even effect animals since a tiger named Nadia in New York was alleged to have contracted with Coronavirus from humans and similarly several other cases where both wild and domestic animals were alleged to have contracted with the virus²⁶⁷.

²⁶⁵ Anurag Bortahkur, *Coronavirus and India*, A.T, March, 19, 2020, at 6.

²⁶⁶ Jayashree Nandi, *India stares at biomedical crisis*, H.T, June, 23, 2020.

²⁶⁷ ibid.

As such if Covid-19 wastes are not disposed properly and are left open then it might even affect the animals in the concerned environment. India in total only has 198 Common Bio-Medical Waste Treatment Facilities (CBMWTS) and 225 captive incinerators which were reported to have been able to recycle only 78% of Bio-medical wastes in 2017. It can therefore be easily estimated that the present scenario of waste management infrastructure might not be able to handle the huge amount of Covid-19 wastes that are generated on daily basis which are highly infectious are very dangerous for the survival of the ecosystem²⁶⁸. During this time, if biomedical waste generated during treatment and testing of Covid-19 patients are not disposed properly, than there will be situation of community spreading of virus. It is therefore required that people should be made aware of such possibility of spread of virus and NGOs should also come forward and assists the Government.

Thus, besides criticizing our administration, it is also the responsibility of the people to make the ignorant citizens aware about taking proper measures while disposing used masks and gloves. Arrangements shall be made by every citizen for disposing their household wastes within their campus or locality itself through safe measures so that transportation of such wastes can be reduced. Those wastes that cannot be disposed within one's campus shall be segregated and properly isolated in a safe place so that the virus could die. These measures will reduce the burden on the municipal corporations which will allow them to focus more on disposing those wastes that are generated during treatment of Covid-19 wastes. Separate chambers shall be constructed at alternative places where bio-medical wastes from quarantine centers, Covid-19 laboratory clinics as well as hospitals can be kept in isolation for seven days alternatively in different chambers in isolation for allowing the virus to die before disposal. However, the areas where such chambers will be constructed must be isolated from all kinds of humans, animals or even birds.

²⁶⁸ Helen Davidson, *Hong Kong warns residents not to kiss pets after dog contracts Coronavirus*, The Guardian (Mar 5, 2020, 03:54 AM), <https://www.theguardian.com/world/2020/mar/05/hong-kong-warns-residents-not-to-kiss-pets-after-dog-contracts-coronavirus>.

Chapter 7

United States Regulation of Medical Waste and a comparison with Indian Biomedical Waste Regulation

Stockholm Conference is the milestone towards combating various problems relating to environment. Many Countries have adopted Rules and Regulations to address the issue of biomedical waste management. In the past years, no specific legislations were passed on the key issue of biomedical waste. It was only in the year 1989, when the Basel Convention was adopted and it highlighted the importance of managing waste properly and also highlighted the importance of managing wastes discarded from hospitals, the issue of Biomedical waste came into limelight. A comparative analysis gives us a better understanding and knowledge our own legal system. In order to reach to a conclusion that whether the laws adopted by Indian Legal System with respect to biomedical waste management is sufficient or not, it is important to focus on different laws adopted by various countries relating to the biomedical waste management. Thus, the following chapter examines and analyses the laws relating to biomedical waste management of U.S. Analyzing will not only help in to find out the major defects in our existing legal system, but at the same time will also help to find out the measures which can be adopted in sorting out the problems or loopholes in our existing legal system. Laws adopted by the United States of America with respect to biomedical waste management are discussed below:

4.1 United States Approach to Medical Waste Regulation

6.1.1 Historical Background

In 1978, when Environmental Protection Agency (EPA) classified infectious wastes as hazardous wastes under Resource Conservation Act, biomedical waste was recognized as a separate kind of waste. Resource Recovery Conservation Act (RCRA)²⁶⁹ is a primary legislation of US which governs the disposal of Solid waste as well as hazardous waste. In 1979, EPA notified that the infectious wastes including biomedical waste did not pose any threat to health of people. Further, when EPA promulgated the RCRA Act in year

²⁶⁹ *EPA; Resource Conservation and Recovery Act*, ENVIRONMENTAL PROTECTION AGENCY, U.S, (Apr 30, 2020 10 AM), <https://www.epa.gov/epa-history-resource-conservation-and-recovery-act>

1980, it did not notify infectious wastes as hazardous as according to EPA, infectious wastes did not pose any serious threat to human health. EPA treated medical waste as solid wastes and thus never issued any separate regulations to regulate it. The concern over hazards arising from healthcare wastes grew in late 1980s. The concern arose when tonnes of healthcare wastes were washing the east coast beaches in year 1980. Further, another incident came into light where 12 children were reported playing with discarded blood bags outside a medical office. After taking sample of the blood bags it was found that bags were infected with AIDS virus and it was illegal to dump such hazardous waste in an open area at that point of time. Environmental Protection Agency (EPA) was given the responsibility to draft legislations on healthcare waste. EPA took up reference guide to manage medical waste effectively. However, EPA failed to take up immediate steps as were required to be taken up for ensuring proper transportation, handling of solid waste. EPA was of the view that legislations could be taken up at local and State levels for regulating medical waste but it did not take up such action. In 1987, Senators of 25 States demanded that quick action must be taken up EPA. However, EPA did not take up any steps. Taking note of the serious issue, the Congress enacted the Medical Waste Tracking Act of 1988 to curb the menace of biomedical waste in USA.²⁷⁰ It was a two year demonstration programme which was designed temporarily to effectively manage the medical waste in US and also to compel EPA to take up some permanent steps towards regulating of medical waste. EPA was required to play an active role and was supposed to work closely with States and healthcare facilities.

6.1.2 Medical waste Tracking Act, 1988 (Herein after referred to as MWTA)

The Act is also referred to as Subchapter X-Demonstration Medical Waste Tracking Program. This was a demonstration program which was launched to enable the Congress to take up empirical data and research surrounding the issue of medical waste. MWTA was not a final legislation. It was only first step towards controlling the situation. MWTA amended the Solid Waste Disposal Act by adding a new subtitle “Demonstration Medical waste Tracking Program”. The main aim of the demonstration program was to ensure

²⁷⁰ Christina Louise Martini, *Medical Waste Regulation in the United States: A Dire Need for Recognition and Reform*, 14 NJILB, 206, 207-10 (1993).

that the waste generated gets transferred properly from point of generation to treatment facility centre. Further, the aim of the program was to reduce the generation of medical wastes in USA²⁷¹. Some important provisions of MWTA are:

I. Definition of Medical Waste:²⁷²

The term medical waste was not defined anywhere in the Solid Waste Disposal Act of 1988. MWTA thus, filed the void and properly defined the term “medical waste”. As per MWTA, Medical wastes include the wastes generated from diagnosis, treatment and carrying out immunization of humans and animals. As per MWTA, the term Medical Wastes includes:

- cultures of infectious agents, pathological labs, discarded vaccines, used dishes and devices used for keeping cultures;
- Discarded tissues, organs, plasma, serum and blood components;
- Sharps including syringes, used needles, other used laboratory equipments;
- Body parts and carcasses of animals ;
- Wastes generated during autopsy, dialysis, surgery;
- Biological Wastes.

II. Tracking of Biomedical Waste:²⁷³

The MWTA further focused on tracking of biomedical waste by following the famous cradle to grave method. The method involved tracking of transportation of wastes from generation site to final disposal of such wastes. As per MWTA, within period of six months the Authorities were to promulgate certain rules and regulations for tracking biomedical waste. The wastes which are to be disposed of in incinerators are to be tracked only after it is incinerated. MWTA further provided that wastes generated are to be segregated in separate containers so as to protect the health of waste handlers as well as that of the public. As per the Act, the containers storing the waste have to adhere to the criteria s laid down

²⁷¹ Laurence D. Granite, *The Medical waste Tracking Act of 1988: An Analysis of its Provisions and its Effect on New York State*, 7 TLR, 259, 260-80 (1990).

²⁷² Medical Waste Tracking Act, 3515 U.S. S.11001-3063 (1998).

²⁷³ id., at S. 11003.

under MWTA. All containers should be rigid, leaked proof, must be strong enough to carry and hold wastes.

The Regulations with respect to tracking of medical waste are detailed and the generators of the wastes are required to take up extensive steps with respect to handling of wastes, transporting and final disposal. MWTA also recognizes small quantity waste generators like doctor's offices/clinics, laboratories and hospitals. The Act provides that any generator who is producing 50 pounds or more amounts of wastes should comply with the provisions of the Act. On the other hand, the generators who use onsite-incinerators for treating and disposing their wastes are also covered by MWTA. As per MWTA, such generators are also required to maintain a record of type and amount of wastes incinerated during the period of six months from the date of coming of the Act into force.

III. Inspection and Enforcement Machinery²⁷⁴

The Act provides for a simple enforcement machinery and inspection system. The generators, handlers or the ones who transports wastes are required to provide access to premises by any officer or employee of EPA, willing to conduct inspection. Officers and Employees of EPA can enter the premises use for generating, storing or treating wastes, and at all reasonable times. Such officers and employees are required to monitor and conduct inspection from time to time.

With respect to enforcement machinery²⁷⁵, the provisions under MWTA were actually modeled on the Solid Waste Disposal Act. After inspection, if the Officers and Employees of EPA discovered nay violation of the provisions, then a fine of \$25000 per day can be imposed upon the generator of waste. The officers of EPA can also bring a civil suit in US District Courts against the generator. On receiving the suit, the Court can issue either a temporary or permanent injunction. If after receiving the orders from the Court, the generator further fails to comply with it and violates the provisions of the Act, then the

²⁷⁴ id., at S. 11004.

²⁷⁵ id., at S. 11005.

authorities under EPA can impose a fine of \$25000 for each passing day of non-compliance. Further, where a person knowingly violates the provisions of MWTA and knowingly omits important material information can be convicted for period of not less than two years. The convicted person can also be liable to pay an amount of \$50000 for each day. Further, any person who knowingly violates the provisions, knowing that such violation would place any person in imminent danger, then in such a situation, fine of \$25000 can be imposed upon the violator and he can also be imprisoned for a period of 15 years. Any organization or establishment convicted under MWTA for violating the provisions can be subjected to pay a fine of \$1000, 000.

IV. States included under MWTA:

The States which were included under MWTA were New York, Connecticut, New Jersey and other States contagious to Great Lakes. As per MWTA, the Governor can notify that a particular State will not be covered by MWTA. The aforesaid States also have the option to opt out of the program by requesting the authorities of EPA. The Act also provided that States could apply for getting under the purview of this program by requesting EPA. EPA at its own discretion could allow the States to be covered under the program. Thus, by applying through a petition, States like Rhode Island, Puerto Rico and District of Columbia, also got the opportunity to get included under the program and get rid of their wastes problem²⁷⁶.

6.1.3 Clean Air Amendment Act (CAAA), 1990²⁷⁷

In year 1970, the Congress enacted a much stronger law to control air pollution and it was the Clean Air Act of 1970. In the same year EPA was created and was entrusted with the primary function to regulate the laws relating to Air. Clean Air Act is a law governing the whole of U.S. In year 1990, the responsibilities of EPA were expanded by Congress by way of Amendment. The Amendment authorizes EPA to enforce the regulations

²⁷⁶ Supra, 257, at 275.

²⁷⁷ *The Plain English Guide to the Clean Air Act*, ENVIRONMENTAL PROTECTION AGENCY, U.S, (Aug 2, 2020, 11 A.M), <https://www.epa.gov/sites/production/files/2015-08/documents/peg.pdf>

throughout the Nation with respect to air pollution. Some important features of this Act are:

I. Role of EPA:

EPA is entrusted with the responsibility to set certain limits of emissions. They are also empowered to set limits of certain specific pollutants which are released from Chemical Plants, Small industries and Mills in United States. Further, EPA has the power to give approval to plans of State, Local and Tribal Agencies with respect to reducing pollution. In places where Plans as suggested by the States, Local or Tribal Agencies, do not meet the required necessary limits of the Air Act, then in such a situation EPA can impose sanctions upon these agencies. EPA also undertakes research activities and gives financial aid to aforesaid agencies with respect to reducing air pollution²⁷⁸.

II. Aims and Objectives of the Act:

Certain programs are undertaken by EPA to fulfill the following objectives of the Act:

- To reduce the amount of pollutants which are responsible for causing smog, haze and acid rain;
- To reduce emissions of carcinogenic pollutants;
- To phase out with use of such chemicals which are responsible for degrading stratosphere,²⁷⁹

III. Role of State, Local and Tribal Agencies:

Under the Act, State, Local and Tribal Agencies are equally obliged to take active part in reduction of air pollution. They can develop and undertake certain steps at local level for better understanding of local industries, air emission pattern, housing and other travel patterns. Under the EPA's Tribal Authority Rules, Indian Tribes are empowered to develop certain programs and implement those parts of the Air Act which they think are appropriate for their lands.

²⁷⁸ id., at 3

²⁷⁹ id., at 4.

IV. Incineration Standards for Medical Waste:

The Act further addresses the important aspect of biomedical waste, which is waste disposed using incineration. Method of incineration was widely followed in disposing infectious biomedical waste in USA as the only benefit of incinerating is that it totally destroys the waste. The only disadvantage of incinerating waste is that it releases huge amount of dioxin and furans. Along with this, ashes are released after the entire process is over. Ashes contain toxic pollutants, which were disposed on lands can lead to environmental degradation. The Amendment of 1990 in the Clean Air Act clearly addresses the issue of setting limit of air emissions for biomedical waste.

Under the Clean Air Act, Section 129 specifically deals with the issue of combustion. The Section provides that EPA to develop Standards and prepare new set of guidelines for incinerating units, incinerating units treating biomedical waste and other municipal combustors. Further, under the aforesaid provision, EPA is also empowered to set numerical limits for acidic gases (Sulfur Dioxide and Hydrogen Chloride) emissions²⁸⁰.

6.1.4 Clean Water Act (CWA) of 1992 & Marine Protection Research Act (MPRSA), 1992

Clean Water Act as well as Marine Protection Act, was enacted for the purpose of regulating medical waste in U.S. The main aim of both these Acts is to prevent water pollution caused by unscientific disposal of medical waste. Apart from this, the Acts also aims at protecting beaches from pollution caused by improper disposal of medical waste. Section 1311 of the Clean Water Act provides that a person discharging wastes or pollutants into navigable waters can be punished under the provisions of the Act. For instance, in the case of U.S v Villegas, a practicing doctor was convicted and penalized for unlawfully disposing blood bags into the bulkhead river²⁸¹.

²⁸⁰ Laura Carlan Battle, *Regulation Medical Waste in the United States*, 14 PELR, 500, 559-60 (1994).

²⁸¹ Supra 266, at 558.

Coming to Marine Protection Act, this Act is also popularly referred to as Ocean Dumping Act in U.S. The main aim of the Act is to protect the Oceans from illegal dumping of Medical Waste. The Act prevents illegal dumping of all kinds of wastes, both hazardous and Non-hazardous, which would have an adverse effect on marine life and health of individuals. The term medical waste is defined under the provisions of Marine Act. As per the Act, medical waste means and includes discarded blood products, sharps, anatomical wastes, dialysis wastes and other discarded medical wastes. The Act also prohibits dumping of radiological, pathological, chemical and other warfare wastes into the ocean. The Act also impose civil liability upon the violators of amount take may go up to \$50,000. Further, any person who is guilty of engaging in any activity which amounts to dumping of wastes into ocean can be made liable to pay a amount of \$125000²⁸².

6.1.5 Other Federal Authorities responsible for regulating Medical Waste

Other than EPA, there are other Federal Authorities which are responsible for regulating Medical Waste in U.S. Some of them are the Occupational Safety and Health Administration; Dept. of Transportation of U.S; for controlling pharmaceutical wastes, there is Drug Enforcement Agency and other U.S Portal Service also plays an important Role in regulating Medical Waste.

6.1.5.1 OSHA Acts and Regulations for Medical Waste Management

OSHA, was created by the Congress with the aim of ensuring safety and healthful working conditions of all working persons of U.S. OSHA provides technical assistance, training and enforce standards. It is a part of Department of Labor of U.S Government. OSHA Act was passed in the year 1970 and was recently amended in year 2004²⁸³. OSHA aims to regulate and has put its effort on eradicating two deadliest viruses, Hepatitis B and HIV. The Secretary of OSHA has said that it has got the power to regulate disposal of medical waste and also have the power to set certain standards for attaining safety and protection of working people. At present, there are 4 standards been

²⁸² Supra 266, at 570.

²⁸³ *OSHA Laws and Regulations*, UNITED STATES DEPARTMENT OF LABOR, (Aug 2, 2020, 11 A.M), <https://www.osha.gov/laws-regulations/oshact/toc>

set by OSHA which directly addresses the problems faced by working men and women due to infectious wastes. The Organization further predicted that the standards laid down by them would prevent near about 300 deaths and 9000 infections every year. Thus, most hospitals and other healthcare institutes have adhered to such Standards²⁸⁴.

One such standard of OSHA is on Hazard Communication, which imposes an obligation upon all the employers of healthcare establishments to prepare a list of hazardous chemicals been used in such establishments, risks associated with it, how it is to be used and emergency contact. Further, another standard which is on Chemical Hygiene, it requires the employers to make policies with respect to procedures to be followed while handling a chemical, equipments required to be used, protection of all workers from infectious pathogens. OSHA Acts and Regulations deals with handling of biomedical waste but till date, OSHA didn't mandate any procedures, highlighting treatment of such wastes. The only aim of these OSHA Standards is to take steps to reduce the risks of contracting infectious disease by the working class. OSHA recognizes the rights of workers to work in a clean environment.

6.1.5.2 Dept of Transportation (DOT) and U.S and Regulations for Medical Waste

Since 1972, DOT has regulated hazardous materials. DOT regulations require the hospital shipping wastes to properly pack the waste materials that are required to be transported. The Regulations further requires the Shipping hospital to properly train those workers who are involved in such shipment. With respect to healthcare establishments, it is provided that healthcare establishments can ship all kinds of wastes including compressed gases, chemicals, etc.

6.1.5.2.1 DOT Infectious Wastes Regulation of 2006²⁸⁵

In this new regulation the Dept. classified Infectious wastes into two categories, A and B. The classification was done on the basis of guideline developed by UN Committee of Experts, WHO. Along with infectious waste, regulated medical waste is regarded as

²⁸⁴ Ibid.

²⁸⁵ *Transporting Infectious Substance Safely*, U.S DEPARTMENT OF TRANSPORTATION, (Aug 3, 10 A.M.), <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/Transporting-Infectious-Substances-Safely.pdf>

hazardous wastes for the purpose of this regulation. The Regulation ensures safe transfer and disposal of hazmat suits and other infectious wastes by railcar, vessel, airways and by road. The Regulation contained detail procedure with respect to classification, packing and transportation of infectious wastes. The Regulation makes it mandatory to meet the standards prescribed before packing and shipping. With respect to packing, in order to make it leak proof, triple layer packing is made mandatory by the DOT.

6.1.5.22 Provision for Special Permit for shipping certain infectious wastes

DOT also gives special permit to any shipper or carrier carrying hazardous/infectious wastes, which due to some reason, fails to comply with DOT Regulations. For instance, when huge amount of wastes was generated during Ebola outbreak in U.S, DOT issued special permit for its transportation. This special permit was allowed on the basis that the waste has to be packed differently to accommodate large quantity disposal. So, the permit gave flexibility to the shippers to packed wastes as per requirements but they were also directed not to compromise with the health of public²⁸⁶.

6.1.6 State Regulations

Near about 90% of the States have their own regulation with respect to medical waste. After MWTA Act came to end in year 1991, States themselves started regulating medical waste.

6.1.6.1 Regulation in Texas²⁸⁷

For instance, in Texas, the Texas Health and Safety Code was amended so as to define the term medical waste and regulate it. Apart from the THSC, the Texas Water Code also has some provisions with respect to handling of medical waste. At the beginning, the initial stage, the regulations relating to medical wastes was codified in TCEQ in chapter 330. New Guidelines has also been issued in year 2016. With respect to treated medical waste, as per the regulation treated medical waste has to be managed like municipal solid waste and disposed off in MSW landfill. Medical waste has been described as treated and

²⁸⁶ *Infectious Substance Special Permit*, U.S. DEPARTMENT OF TRANSPORTATION, (Aug 3, 12P.M), <https://www.phmsa.dot.gov/transporting-infectious-substances/infectious-substance-special-permits>

²⁸⁷ *The Regulation of Medical Waste in Texas*, PILLSBURY, U.S., (Aug 2, 2020, 1 A.M), <https://www.pillsburylaw.com/en/news-and-insights/medical-waste-covid-19-regulation.html>

untreated medical waste. Further, TCEQ has also notified that wastes which are a mixture of both medical as well as other hazardous waste will be considered as hazardous under the Texas Rules, for the purpose of disposal.

On March 2020, the Texas Commission on Environmental Quality (TCEQ) released new guideline for regulating Covid-19 waste²⁸⁸. As per the guideline, Covid 19 waste is to be treated in the same way as the waste from seasonal flu. Further, it is to be disposed like municipal waste.

6.1.7 Guidelines

6.1.7.1 EPA's Model Guidelines developed by Council of State Government (1992)²⁸⁹

The regulations of MWTA expired in year 1991. After expiration EPA concluded that medical waste have high potential of spreading disease at the point of generation. Thus, EPA concluded that in order to reduce the risk of spread of deadly diseases, it's better to hand over the regulations to the States. Thus, Council of State Government came up with Model Guidelines in year 1992 as a reference tool for managing medical waste. The Guidelines was a detailed document that helped many States in framing their own respective Statutes for managing medical waste. These guidelines were not made mandatory and only intended to serve as a reference. The guideline also serves the purpose of fulfilling the aim of RCRA's objective, i.e; to provide information of management and disposal of medical waste.

6.1.7.2 Centre for Disease Control Guidelines for Environmental Infection Control in Healthcare establishments²⁹⁰

CDC just like EPA has issued certain guidelines with respect to infectious waste. CDC has been equipped with the power of surveillance and investigation in field of infectious

²⁸⁸ *TCEQ Regulatory Guidance: Covid 19 Waste and Disposal*, TEXAS COMMISSION ON ENVIRONMENTAL QUALITY (TCEQ), (Aug 3, 2020, 2 A.M), <https://www.tceq.texas.gov/response/covid-19/waste-disposal-guidance>

²⁸⁹ *Model Guidelines for State Medical Waste Management*, THE COUNCIL OF STATE GOVERNMENTS, U.S, (Jun 20, 2020, 12 A.M) https://www.epa.gov/production/files/2016-02/documents/model_guidelines_for_state_medical_waste_management.pdf

²⁹⁰ *Guidelines for Environmental Infection Control in Healthcare Establishment*, CENTRE FOR DISEASE CONTROL, U.S, (Aug 3, 2020, 11 A.M), <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>

waste. It is a federal public health agency like EPA. CDC conducts researches, collects data, conducts surveys and also makes recommendations deemed necessary for controlling certain diseases. CDC published series of guidelines addressing the issue of medical waste. Some of them includes Recommendation on HIV Transmission (1987) and Guidelines for Hand washing and disease Control (1987). Recently, CDC came up with guidelines on infection control in year 2003, which was updated in year 2019.

The guideline classifies medical waste on the basis of quantity and presence of infectious pathogens. Further, the guidelines directs all healthcare establishments to take additional precautions so as to avoid generation of aerosols during handling of items contaminated with blood of patients suffering from diseases like Ebola and Lassa Fever. Further, as per the guideline healthcare establishments should switch to other methods developed in recent years, which includes shredding, radio wave treatments, disinfecting and grinding. The guideline emphasizes the need of proper labeling of bags and containers used for storing medical waste. It further highlights the need for regulating infectious waste as human health and safety of environment depends on it.

6.1.7.3 Interim Guidelines for Collecting, Handling and Testing Specimens from persons for COVID-19 (2020)²⁹¹

These guidelines were updated on 15th July 2020. The guidelines provide recommendations on infection prevention and control routine healthcare practices at times of pandemic. The guidelines is applicable to all healthcare establishments in U.S. CDC recommends use of additional infection preventive measures along with available standard practices. These practices are to be applied upon all patients irrespective of whether he or she is infected with COVID 19 or not. As per the guidelines, high quality strategies are to be followed up for regular patients so that they do not come in contact with Coronavirus. Screening of all persons is made mandatory. Covid 19 waste is not regarded as Category A waste by CDC. Thus, in order to dispose of the waste generated

²⁹¹ *Interim Guidelines for Collecting, Handling and Testing Specimens from persons for COVID-19 (2020)*, CENTRE FOR DISEASE CONTROL AND PREVENTION, (Aug 3, 2020, 10 A.M.), <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

from treating Covid patients, 2003 Additional guidelines of CDC on Environmental Infection Control is to be followed.

6.2 U.S Regulation vs. Indian Regulation- Lessons Learnt

As seen in recent days, Indian Government has failed to regulate medical waste on a national level. This is largely due to lack of strict legislative framework. As noted above, United States has provided a uniform standard regulation for infectious waste management. To make effective management of medical waste certain steps have been taken up by various Federal Agencies of U.S. For instance, by virtue of Clean Air Act, Government has set emissions limit of certain pollutants. The Act further addresses the important aspect of biomedical waste, which is waste disposed using incineration. Those units found violating the provisions can be penalized under the Act. U.S. has specifically addressed the issue of marine pollution caused due to dumping of medical waste under the Marine Protection Act. The Act criminalizes dumping of medical waste on beaches and into navigable waters of ocean. However, as noted above, United States has authorized the States to take up steps and provide practical solutions to the medical waste problem. If the States so desire, they can promulgate a much stricken regulation in accordance with its own individual needs.

Other Federal Authorities like OSHA set Standards in order to reduce the risks of contracting infectious disease by the working class. OSHA recognizes the rights of workers to work in a clean environment. Other, authorities like Department of Transportation has developed certain guidelines which are required to be followed while shipping and transporting medical waste in and outside U.S. There is a separate regulation that grants special permit with respect to treatment of specific infectious waste. In addition to these, The Department of Health has undertaken a separate programme on improperly disposition of hypodermic needles and syringes which involve the risks of injury due to accidental needle sticks which results in the transmission of blood borne infections, including hepatitis B and C, and human immune deficiency virus. In the USA at present an estimated three billion syringes are used annually for self administration of medications and illicit drugs. Under the programme the Department has offered technical

assistance, distributed educational materials, and created Web-based resources to foster development of community-based collection sites.

As noted above, U.S. has provided a uniform standard for infectious waste by treating it as hazardous goods. It appears that India has somewhat missed to properly regulate the waste. In the light of above, it can be laid down that both India and U.S. has taken up radically different approaches with respect to medical waste management. U.S has a historical approach towards medical waste regulation. U.S. realized that medical waste, particularly infectious wastes must be clearly address and regulated, so that those involved in production, transport and disposal would be fully aware of the delegation of responsibility. Unfortunately, the Government body with the requisite authority to enact legislation is Ministry of Forests and Climate Change. Because of which it is extremely overworked and overburdened. At times, due to huge workload, MOEF fails to meet the regulatory guidelines and address waste problems. Clearly, U.S waste regulation should provide incentive to India to revise its biomedical waste regulation.

This change must take place as soon as possible. Clearly, the implementation of reforms will be costly. Additional research costs will be incurred with regard to the threats associated with the various types of medical waste, in addition to deciding upon the best way to regulate their treatment, transport, and disposal. Moreover, legislative costs will increase, because Parliament of India must essentially start a new national program for medical waste regulation. India fortunately has other legislation to draw from and does not have to start completely from scratch. In light of the benefits to be obtained from such a system, and the burdens to be endured without it, it is clear that India should bear these costs of reform and should see them as an investment.

Chapter 8

Conclusion and Suggestion

Bio-Medical Wastes poses hazards to both health and the environment. But it is ignored due to lack of knowledge and awareness about its harmful effects. As a result, most of the hospitals, animal shelters, nursing homes, etc. does not take utmost care in properly disposing the harmful Bio-Medical Wastes. Most of the time, Bio-Medical Waste are dumped in water bodies or disposed of openly on land. A lot has been said but a little has been done towards the problem of mismanagement of Bio-Medical Wastes. On one hand, the health-care institutions are playing vital role in saving the valuable lives of the people and on other hand, it has the potential to infect the people with some deadly infectious diseases if Bio-Medical Wastes are not properly disposed. A recent incident of such mismanagement was witnessed in Guwahati, where a mentally-ill person was seen wearing discarded PPE and roaming around the city.²⁹²

Therefore, taking into consideration the necessity of addressing the issue of biomedical waste throughout the country and also to examine the efficiency of existing Rules and Guidelines, the researcher took up this topic and had tried to reach to the findings. The researcher had taken up certain objectives, did an in depth study of the legislative measures adopted at National and International Level, highlighted the constitutional provisions relating to environmental protection, the role played by Courts & Tribunals , analysis of current guidelines on COVID-19 in India and also highlighted the good regulatory framework adopted by U.S with respect to Medical Waste management. The Chapterization of the dissertation is based on hypothesis that whether efficient implementation of Biomedical Waste Management Rules can be sufficient enough to address the issue of biomedical waste disposal or whether the Role of PCB and PCC in the management, control and proper disposal of biomedical waste is insufficient.

After detail analysis and looking into current scenario of waste management in India, it has been concluded by the researcher that despite having Rules, is not adhering to proper

²⁹² <https://www.indiatoday.in/india/story/assam-mentally-ill-man-roams-roads-wearing-used-ppe-video-goes-viral-1678181-2020-05-15>, May 15, 2020.

management of wastes. On the basis of the secondary data, certain conclusions were drawn. At first, it can be concluded that in spite of Bio-Medical Rules of 2016 and 2018, many states are still facing the issue of mismanagement and unscientific disposal of Bio-Medical Wastes. Legal obligation to comply with the provisions of BMW Rules has been reduced to paper and there is lack of awareness among people with respect to proper management of Bio-Medical Waste. Secondly, there is lack of adequate facilities for storage, collection, treatment and segregation of Bio-Medical Wastes in most of the cities. Thirdly, there is lack of awareness among health-care workers as they are not given adequate training programmes on management of Bio-Medical Wastes. Although, BMW Rules 2016 provides that training programmes is necessary, yet it has not been strictly followed till date. Lastly, although numbers of advanced technical equipments are available for management of Bio-Medical wastes, yet health-care establishments are not willing to adapt those advanced equipments. For instance, although Autoclaves are readily available in India, still health-care institutions are using incinerators and not switching to other equipments. A lot has been said but in reality, a very little has been done with respect to medical waste management. Although, BMW Rules, 1998 got amended in year 2016 and 2018, the healthcare establishments are yet to react and adjust to the new Rules. Major challenges that India is facing are:

- Lack of proper segregation practices. There is inadequate practice of segregating biomedical wastes as in reports and news article. Wastes from hospitals are transported without following biomedical waste practices.
- CPCB and SPCB are the authorities responsible for enforcing the Rules. These authorities are found to lack adequate powers in one hand, and also there is lack of commitment. For instance, even after receiving order from NGT to shift the dumping ground from Boragaon to some other place, as the site was posing threat to Ramsar Site Deepor Beel, SPCB has fail to comply with the order²⁹³. Most of the hospitals are not adhering to the Rules and are indulged in open dumping of untreated medical wastes. Moreover, Rules are

²⁹³ No Relocation of Dumping Ground in Guwahati, GUWAHATI PLUS, (Jun 12, 2020, 11 A.M), <https://timesofindia.indiatimes.com/city/guwahati/assam-struggles-with-biomed-waste-with-1-treatment-facility/articleshow/76976984.cms>

not been publicized widely as required. Hence, a very few people and HCFs are aware of these Rules.

- There is lack of adequate facilities for collection, treatment and disposal of healthcare wastes in India. Also, India is lacking behind in terms of technological development. Available technologies are not been able to cope up with the complexity of waste problems in present days.
- Although the new amended BMW Rules of 2016 and 2018 provides for use of alternative techniques, but the healthcare establishments till date are using incinerators although other alternatives are available. They are reluctant to change and there is hardly any change seen in Indian hospitals.
- There is inadequate pressure from various pressure groups. No doubt the persons who are educated and enlightened are aware of the issue of biomedical waste management, but when it comes to taking stand there is lack of will to come forward and raise the issue.

Recommendations:

The following recommendations arrived after the study:

1) Waste Reduction and treating waste before disposal:

Waste reduction technique can be applied in India by reducing wastes initially generated and also recycling possible waste products. By this way issue of huge amount of biomedical waste can be lessened in India. This method will ensure that if all other methods fail with respect to treatment of wastes, at least the amount of wastes will be diminished.

2) Adopting new Biomedical Waste Treatment technologies:

With respect to treatment methods, CPCB, SPCB and PCC can switched to and promote other alternative techniques. Prior evaluations can be conducted before adopting new techniques and health-based considerations must also be kept in mind.

3) Conducting Research and Scientific analysis:

Legislations are passed and guidelines are given without conducting any prior research. Thus, proper scientific research should be conducted before announcing any new legislative framework.

4) Setting up of Biomedical Waste Management Unit in every healthcare establishment:

Government can set up separate BMW Cell/Unit in each and every hospital which would be entrusted with the function of maintain record of amount of waste generated ward wise and also would record the quantum of wastes actually sent for treatment. Such a unit or Cell should consist of members from all departments like nursing, housekeeping, doctors, etc. The Cell should be entrusted with the responsibility of framing a waste management strategy for ensuring that all legislative guidelines are properly followed.

5) Proper training and Education:

Adequate training to all staffs should be given by all healthcare establishments to minimize the risk of injury which is associated with biomedical waste. Imparting education should not be left in the hands of operators of CBWTFs; rather it should be imposed upon the occupiers of HCFs. Training of healthcare personnel's is an important aspect as it focuses on all principles relating to waste management. Training manual should be made available in local language and should be readily available to all personnel's. The manual should give brief introduction to biomedical waste, its sources, health risks associated with it, policy, guidelines, planning at HCF level and development of strategic approach.

6) Strict Attitude of Pollution Control Board:

Due to lethargic attitude of employees of PCB's, proper disposal of biomedical waste is still at sea. Therefore, the concern officers should show a rigorous approach and this can be done if they make surprise visits to the

healthcare establishments or treatment facilities. On such visits, if any discrepancy is found by officers, then in such a situation they may also cancel their authorization.

7) Introducing provision of penalty:

No specific provisions have been made on punishment for violating the BMW Rules of 2016. As per 2016 Rules, the violator is subject to punishment under Section 15 of the Environment Protection Act, 1986 and which can be extended to a period of seven years only. Thus, by way of amendment further changes can be made to this Rules and more power to be conferred upon concerned authorities. PCB's can be conferred with the power to impose criminal penalties and having power to sent defaulters to jail.

8) Installing technologies for reprocessing:

In order to encourage the healthcare establishments to go for reuse and recycling of certain biomedical waste, reprocessing technologies can be installed within the compound of hospitals and other research laboratories. This will reduce the tendency of disposing biomedical waste which is also an expensive process. Moreover, at the beginning the healthcare establishments would find it affecting their budget, but in the long run, the same installation will prove in cost reduction and will also create new jobs as more people will be engaged in recycling process.

9) Personal Protective Equipments:

Workers who handle biomedical waste are at greater risk of contracting with infectious diseases. The municipal workers who collect the wastes from treatment plants and the rag pickers, who represent the informal waste management sector, they play an important role in reducing amount of waste. Thus, rag pickers play a significant role in waste management and so their personnel needs and safety should be considered. Steps should be taken up to

educate rag pickers and teach them about health hazards associated with biomedical waste.

10) Focusing on Segregation first:

The current practice which is prevalent in many hospitals is that all categories of wastes are mixed together. As a failure to follow segregation protocol, wastes leaving healthcare establishments can pose a threat to environment as well as human health. No matter what procedure is followed up at treatment facilities, it is critical that biomedical wastes are properly segregated at first. Stringent laws should be developed and strict penalties should be imposed upon those hospitals which fail to comply with segregation protocols.

11) Incentives and awards:

Awards should be instituted at National, State and Local level to best healthcare establishments for best management of biomedical waste. Further, incentives and gifts should be provided by hospitals to healthcare workers who are involved in handling waste. Giving awards and recognizing their work will inspire the workers to work with full dedication and follow the rules.

12) Loans and Subsidies:

Entrepreneurs should be encouraged by the Government to set up waste treatment plants by providing loans, subsidies and adequate training. This will on one hand create job opportunities, and in other hand will make availability of more biomedical treatment facilities.

13) Focus Legislative efforts on Small Generators of Biomedical Waste:

As per BMW Rules, only those HCF's are required to get themselves registered who are treating 1000 or more patients in a month. But in reality, small generators of medical waste accounts for a considerable amount of waste. Thus, legislative measures should be adopted and should be directed at small generators too.

There is no denying the fact that some of the recommendations mentioned above have been already following by the health care institutions because they are the basis which are universally applicable in every health care institutions throughout the world for the management and disposal of the Bio-Medical Waste. This includes framing of policy, establishment of management cell, training and educating of the health care personnel engaged in the whole management aspect etc. With a positive vigor and attitude it should be successfully implemented and to make it successful the steps which have been recommended under each head of recommendation is strictly to be followed. It has been seen that due to careless and lethargic attitude among most of the health care personnel the basic framework for the management of the Bio-Medical Waste failed in its root level. This attitude could be change if the concern authority i.e. the pollution control board changes its perception towards the same.

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