
A STUDY OF BIO MEDICAL WASTE MANAGEMENT RULES, 2016 AND ITS IMPLICATION

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INTRODUCTION

Bio medical waste are those waste which are generated from the hospital, clinics, dispensary etc. These bio medical wastes are infectious and cause disease to those who are exposed to these waste. Due to the extreme toxicity of bio medical waste, it is considered as hazardous. So, it is of great concern about the disposal of the bio medical waste. The concept of bio medical waste is not to be just restricted within a country but it is an international concept. Infact, the World Health Organization (WHO) has also even acknowledged the importance of bio medical waste management. In India, though there is no specific act but there are recognized rules for the treatment of bio medical waste. These rules are Bio Medical Waste Management Rules, 2016 and Amendment Rules, 2018. The rules hereby provide the detailed process and mechanism for the treatment of the bio medical waste. In addition to this, there are also some international conventions on bio medical waste. These conventions are equally important for the proper treatment of the bio medical waste. The issue for the proper treatment of bio medical is there quite a long back but after the outbreak of the pandemic in 2019 makes it a burning issue. The novel corona virus is an infectious disease where one got easily infected from the physical closeness of other infected person. So, in this it was recommended to wear mask, gloves and other protective kits. These kits, mask or gloves may contain viruses and so it is highly recommended to disposes of all the things properly which are directly or indirectly in contact with the contaminated persons. Thus, it is very much required to handle the bio medical waste rules properly because it affects the community, healthcare workers and the environment like air pollution, soil pollution or water pollution.

Further, bio medical waste is categorized into different types like animal anatomical waste, soiled waste, expired or discarded medicines, microbiology or other clinical laboratory waste, chemical waste, chemical liquid waste. The pertinent point is that these waste should be

segregated from each other as depending upon their category, types, recycle or reuse¹. Since, the bio medical waste is generated during the treatment of the patients, so there is very much that these waste products are contaminated and infected. So special importance should also be provided while collecting of the waste and later on storage and transportation of the wastes. In wake of the pandemic in 2019, the government has given high importance to the treatment of the bio medical waste. So, it is to be seen how the government and the private hospitals are treating to their bio medical waste and is the proper procedure and the laws are being followed in the management of the bio medical waste.

GENERATION OF BIO MEDICAL WASTE DURING COVID-19 AND POTENTIAL HAZARDS

The pandemic coronavirus is now a very common word and it has become a household name. The reason is that we all had suffered from this virus since last two years whether it is health issues, economic issues or any social issues. The treatment of this pandemic is different from the rest of the disease. It is a touchable disease and one needs to be very careful during its treatment. The protective kits, gloves, mask which are worn or used by the doctors, patients, attendant or any another person needs to be properly disposed because it might contain the virus. If any healthy person comes in contact with these used protective equipment than there is high chance of virus being transfer to the healthy persons and can easily infect them. Thus, it becomes very important to properly treat the bio medical waste.²

In India, we follow the Bio Medical Waste Rules, 2016. Along with this, the Central Pollution Control Board and State Pollution Control Board is there for their execution and providing guidelines time to time. Still it is being reported by the Central Pollution Control Board that in year 2018-2019, around 23,942 health care facilities had violated the rules and the guidelines. This data here is pre-existing of the pandemic, there we have seen such a large scale of violation. During the pandemic, the amount of bio medical waste is doubled than it is highly uncertain that how these health care facilities diligently managing the large amount waste. During the pandemic, the Central Board and the State Board asked the hospitals and health care facilities for strict adherence to the Bio Medical Waste Rules, 2016. In addition to these, the

¹Anupam Khajuria, *3R Approach towards Bio-Medical Waste Management System*, International Society of Waste Management, Air and Water, 2017.p 580-582.

² Ashish Dehal , Atul Narayan, Asirvatham Ramesh Kumar, Bio Medical Waste generation and management during Covid-19 Pandemic in India, Challenges and possible management strategies, Nature Public Health Emergency Collection, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8496889/>

All India Institute of Medical Science, New Delhi has also provided certain guideline for the safe handling and the disposal of the bio medical waste. If all the health care facilities take the proper steps than the bio medical wastes can easily be managed without causing much risk and infection to others.³

CLASSIFICATION OF BIO MEDICAL WASTE

It is to note that the bio medical waste is not of one single type. During the medical performance different types of waste is generated. Accordingly, World Health Organisation has divided bio medical waste into eight types which are as follow:-⁴

1. **Infectious waste-** Those waste material which possess the high chance of infecting the humans which includes blood soaked bandages, surgical gloves, swabs, bodily fluids, stocks of infectious agents from laboratory work etc. These discarded diagnostic waste and products are highly contaminated.
2. **Pathological waste-** During the operation and surgery in hospital and health care facilities, certain waste products are generated. These waste products contain the pathogens and are highly infectious and hence are termed as pathological waste. In other words, pathological waste is basically the by product from operations and other types of surgery which includes human tissues, body parts, bodily blood, fluids.
3. **Sharp waste-** It is a form of biomedical waste which comprises of syringes, needles, lancets, broken glass and other materials. These devices are highly infectious and need to be carefully handled.
4. **Genotoxic waste-** It is those biomedical waste containing genotoxic properties such as cytotoxic drugs used in the treatment of cancer and their metabolites.
5. **Pharmaceutical waste-** It includes unused, expired medicine, pills, creams, vaccines and other antibiotics. These are those medicines which cannot be used by any patients and hence it is considered as waste products.⁵

³ Sharad Chand, C.S.Shastry Shivakumar, Hiremath, Juno J.Joel, .H.Krishnabhat, Uday VenkatMateti , Updates on biomedical waste management during COVID-19: The Indian scenario, Clinical Epidemiology and Global Health, Vol-11 (2021) available at <https://www.sciencedirect.com/science/article/pii/S2213398421000191>

⁴Health care waste, World Health Organisation, available at <https://www.who.int/news-room/fact-sheets/detail/health-carewaste#:~:text=Infectious%20waste%3A%20waste%20contaminated%20with,e.g.%20swabs%2C%20bandages%20and%20disposable>

⁵ Malsparo, Type of medical Waste, available at <https://www.malsparo.com/types.htm>

6. **Radioactive waste-** It includes those waste which are generated from the nuclear medicine treatments, cancer therapies and other medical equipment that used radioactive isotopes. In other words, it includes the products infected by radionuclides including radioactive diagnostic material or radiotherapeutic materials.
7. **Chemical waste-** It includes the solvent or reagent used for laboratory preparation, disinfectants, heavy metals contained in medical devices or batteries. Furthermore, it also includes those liquid waste typically generated from machines, batteries.
8. **General/Other waste-** Those bio medical waste products which are non-infectious and are not contaminated. It does not pose any particular biological, chemical, radioactive or physical hazard. Still, it is required to be carefully handled.

As, it is observed that bio medical waste is classified into different categories and they have different method of treatment. So, for convenient it is drawn into chart.⁶

Category	Type of Waste	Waste Component	Method of treatment
Category I	Human Anatomical Waste	Human Tissues, Organs and body parts	Incineration/deep burial
Category II	Animal Waste	Animal tissues, organs, fluids, bleeding parts, waste generated from the veterinary hospitals, colleges.	Incineration/deep burial

⁶ Anurag Tiwari, Prashant Kadu, Bio Medical Waste Management Practices in India- A Review, Research Gate (2014), available at https://www.researchgate.net/figure/Category-and-components-of-Biomedical-waste_tbl2_262523529 , Also referred Bio Medical Waste and its segregation, Vikaspedia, available at <https://vikaspedia.in/energy/environment/waste-management/bio-medical-waste-management/biomedical-waste-and-its-segregation>

Category III	Microbiology and Biotechnology	Waste generated from laboratory cultures, specimens of micro-organism, human and animal cell culture used in research.	Autoclaving, micro waving, incineration
Category IV	Waste Sharp	Used or unused needle, syringes, blades, glass or any other pointed object which helps in cutting or puncturing.	Disinfectant chemical treatments, autoclaving, microwaving
Category V	Expired or discarded medicines and cytotoxic drugs	It includes outdated, contaminated medicines, drugs	Destructions and drugs disposal in landfills.
Category VI	Solid Waste	It includes cotton, dressing, soiled plaster cuts or other material contaminated with blood.	Autoclaving or microwaving
Category VII	Liquid Waste	Waste generated from housekeeping, washing, cleaning and laboratory	Disinfections by chemical treatments and discharge into drains.
Category VII	Chemical Waste	Chemicals used in the insecticides, disinfectants or other activities.	Chemical treatments for removing the toxicity and discharge into drains.

Category VIII	Incineration Ash	Ash generated from incineration activity for treating bio medical waste	Disposals in municipal landfill
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LAWS ON THE TREATMENT OF BIO MEDICAL WASTE

I. BIOMEDICAL WASTE MANAGEMENT RULES, 2016

The Government of India in 2016, came up with the new rules for the treatment of bio medical waste named as **Biomedical Waste Management Rules, 2016**. The new rules are more advanced and come up with the changes which helps in the better treatment of waste generated by clinics and research facilities. The treatment advancements includes incorporate burning, microwaving, autoclaving, and synthetic treatment. This article incorporates the unbiased, notable elements, and ideas in regards to the new guidelines named as *Biomedical Waste Management Rules, 2016*.

Biomedical waste is characterized under the principles as any waste delivered during the conclusion of treatment, therapy, or inoculation of human or creature research exercises relating thereto or in the creation or testing of natural or in wellbeing camps.

In straightforward words, these squanders includes physical waste, human waste, clinical contraption like needles and different materials utilized in medical clinics and other laboratories (research focus, nursing homes, blood donation center, obsessive labs, and so forth) during the time spent in exploration and therapy.

NEED FOR THE STRINGENT LAWS

The treatment of bio medical waste rules are based on 3R's. The three 3R's stand for reduce, reuse and recycle. Efforts should be made to generate less of waste which can be done by reusing of the products which are possible to use and lastly to recycle of the waste. It has been said that as soon as the waste is generated, it should handle immediately or recycle in the beginning or at source. This will produce less of waste. One should not wait for the last for

treating of the waste. *The waste ought to be handled at the beginning or at source rather than the "finish of line approach".*⁷

However, the 2016 rules mainly focused on the application and execution of those rules, hence they are not being so effective. These rules does not take note of dangerous synthetic substances, metropolitan strong waste, radioactive waste, lead-corrosive batteries, e-waste, hereditarily designed creatures, and cells, and unsafe microorganisms which are administered under different standards.

According to the Indian government information, the absolute biomedical waste produced is 484 tons each day from 1,68,869 medical services offices in the nation, yet just 447 tons each day is managed and treated. There are just 198 normal biomedical waste therapy offices in activity. The quantity of medical care offices utilizing normal biomedical waste therapy offices is 1,31, 837 and around 21,870 medical services offices have their own therapy offices on location.⁸These data shows that we need to have proper laws and regulations so that bio medical waste can be easily and rapidly disposed off.

SOME MAIN PROVISIONS OF THE RULE:-

These rules have been drafted and arranged in such a way which will effectively managed the biomedical waste in the country. The term 'dealing with' is likewise being eliminated from the name which gives greater lucidity about the administration and ramifications of the standards. A portion of the refreshed and remarkable elements of the guidelines are as following:

1. These rules are applicable on immunization camps, blood gift camps, and careful camps.
2. Obligations of the two occupiers (one who has authoritative command over the medical services offices that is producing biomedical squanders) and administrators (one who controls the offices of assortment, gathering, transportation, therapy, and removal of biomedical squanders) are unambiguously determined and imposed under these principles.
3. Setting up of a scanner tag (barcode) framework for biomedical waste that will be sent for therapy or removal.

⁷Center for science and environment, available at www.cseindia.org/bio-medical-waste-rules-made-stringent—3702

⁸<https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/centre-notifies-new-bio-medical-waste-management-rules/articleshow/51574715.cms>

4. A register is formed for the maintenance of biomedical waste. Everyday reporting is to be done either by the administrator or occupier. Furthermore, the multitude of records for activity of hydroclaving/cremation/autoclaving for a time of 5 years is to be preserved.
5. The strategy of isolation, bundling, transportation, and capacity of biomedical squanders has been improved. Furthermore for proper and effectual administration, the waste has been divided into four classes rather than ten classes.
6. The utilization of chlorinated synthetic gloves, packs, blood sacks, and so on ought to be step by step halted.
7. There is an obligation imposed on the occupier to pretreat or sterilize the waste produced from laboratory, research, clinics, hospitals which includes microbiologic waste, blood samples, blood bags before sending to waste treatment facility for final disposal. However, the technique for sanitization/sterilization should be as per the World Health Organization or the National AIDS Control Organization (NACO) standards.
8. There has been change in the guidelines for the use of the incinerators. Norms has been set for the use of the incinerators to make it more conducive to environment. Home time in the auxiliary office of the incinerator - two seconds; standard for dioxin and furans - 0.1 ng TEQ/Nm³ are as far as possible for SPM-50 mg/nm³.
9. The Ministry of Environment, Forest, and Climate change will screen the execution of rules yearly. The obligation of each state to check for consistence will be finished by setting up a region level advisory group under the chairpersonship of District Collector or District Magistrate or Additional District Magistrate. Furthermore, like clockwork, this advisory group will present its report to the State Pollution Control Board⁹.

CLASSIFICATION

Biomedical squanders are partitioned into four shading classification:

1. **Yellow:** In this class, eight kinds of waste are ordered which includes human physical waste, creature physical waste, ruined waste, lapsed or disposed of waste, substance squander, compound fluid waste(separate assortment framework prompting emanating

⁹Kharat, Dr. D.S. (2016). Biomedical Waste Management Rules, 2016: A review. International of advanced Research and Development. 1. 48-51.

treatment framework), disposed of material, sleeping pads, sheets tainted with blood or body liquid, and microbial science, biotechnology, and other clinical lab squander.

2. **Red:** It incorporates tainted waste that is recyclable like waste produced from dispensable things, for example, tubing, bottles, intravenous cylinders and sets, pee packs, needles, and gloves.
3. **White (Translucent):** It incorporates utilized, tainted and disposed of metal sharps.
4. **Blue:** It incorporates broken or defiled or disposed of glass and metallic body inserts.¹⁰

II. BIO MEDICAL WASTE AMENDMENT RULES 2018¹¹

With the need of the time, the Bio-medical waste Management Rules, 2016 is amended to match up with the present situation and better execution. Thus, the Government of India formed the Bio-Medical Waste Management (Amendment) Rules, 2018. A portion of the significant changes in 2018 standards are as follows:

1. Under this rule, duty is imposed on the occupier to manage and treat the bio medical waste which are generated from the laboratory waste, microbiological waste, blood samples and blood bags before sending to treatment facility or final disposal. These waste should be disinfected or sterilized on-site in the manner as provided by World Health Organisation.
2. Obligation is imposed on the occupier for the complete elimination of chlorinated plastic things, for example, sacks and gloves from the bio-clinical waste generators including emergency clinics, dispensaries, creature houses, centers, nursing homes, blood donation centers, and so forth within two years from the date of publication of the rules.
3. Establishment of bar code system for every bags and containers which are to be sent out for the treatment and disposal according to the guidelines issued by the Central Pollution Control Board.
4. All the hospital establishments should upload a yearly report on the site within two years of the issued guidelines.

¹⁰Bio-Medical Waste Management Rules-2016, Department of Health and Research, available at <<https://dhr.gov.in/document/guidelines/bio-medical-waste-management-rules-2016>>

¹¹ Bio Medical Waste Management (Amendment) Rules, 2018, TeamLeaseReg tech, available at <https://www.teamleaseregtech.com/legalupdates/article/3241/bio-medical-waste-management-amendment-rules-2018/>, Also referred <<https://dhr.gov.in/hi/document/guidelines/bio-medical-waste-management-rules-2016>>

5. As per the rules given by the Central Pollution Control Board, every operator of the bio-medical waste treatment and disposal facility need to develop global positioning system and barcoding framework for treatment of bio-clinical waste.
6. The State Pollution Control Board needs to assemble, audit and examine the data got by the administrators and furthermore need to send these reports to the Central Pollution Control Board before 31st July of every year.

III. SOME MAJOR CONSTITUTIONAL MANDATE RELATING TO BIO MEDICAL WASTE

ARTICLE 21

No person shall be deprived of his life and personal liberty except according to the procedure established by the law¹²

Our Apex Court has widely expand the ambit of Article 21 where the said article also include right to clean and healthy environment. So, for the healthy environment it is necessary to properly treat the bio medical waste so that any kind of infection will not spread.

ARTICLE 47

Duty of the state to raise the level of nutrition and the standard of living and to improve public health.¹³

The said Article comes under Directive Principle of State Policy which is in Part IV of the Constitution of India. The article imposes an obligation upon the state to improve the public health and wellbeing of the citizen of India. Maintenance and cleaning of hospital is also the part in improving of the public health.

ARTICLE 48 A

Protection and improvement of environment and safeguarding of forests and wildlife.¹⁴

The Article 48A was added in the constitution by the 42nd amendment in the year 1976. This article put obligation on the state for providing clean and healthy environment. The Bio medical

¹² Indian Constitution Article 21

¹³ Indian Constitution Article 47

¹⁴ Indian Constitution Article 48A

waste severely impact the environment by polluting them if not treated properly.

IV. INTERNATIONAL LAWS ON BIO-MEDICAL WASTE

I. THE BASAL CONVENTION ON HAZARDOUS WASTE¹⁵

The objective of the convention was to protect the human from any kind of hazardous waste. Further, it provide the guidelines to dispose of the hazardous waste in an environmentally sound principle. Since bio medical waste are also infectious waste, hence it can be guided by this convention.¹⁶

II. STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS¹⁷

This convention came about into a global arrangement to shield human and climate from Persistent Organic Pollutants (POPs). POPs are polychlorinated dibenzo-p-dioxins and dibenzofurans which are risky to both human and natural life. This convention discusses diminishing and disposing of these substances through Best Accessible Technologies (BAT) inside four years and set up a rules to manage them. The BAT rules for BMW incinerators and waste water to accomplish emanation levels of dioxins and furans not over the degree of 0.1 ng.

III. MINAMATA CONVENTION ON MERCURY¹⁸

The convention was on mercury and its utilization, which came into force on august 16, 2017. It was a multilateral climate arrangement intends to shield human and climate from anthropogenic substances delivered structure mercury and its compound. It can be considered as one of the best convention climate in term of bio clinical waste.

¹⁵Chartier Y, Emmanuel J, Pieper U, Press A, Rushbrook P, Stringer R, et al., editors. Safe Management of Wastes from Health-Care Activities. 2nd ed. Geneva, Switzerland: WHO Blue Book; 2014

¹⁶ Basel Convention on the control of Transboundary Movements of Hazardous wastes, United Nation Environment Programme, available at <https://www.unep.org/resources/report/basel-convention-control-transboundary-movements-hazardous-wastes#:~:text=The%20Basel%20Convention%20regulates%20the,flammable%2C%20ecotoxic%20and%20infectious%20wastes.>

¹⁷ WHO. WHO core principles for achieving safe and sustainable management of health-care waste WHO (2007a). Geneva: World Health Organization; 2007. Available from: http://www.who.int/water_sanitation_health/medicalwaste/hcwprinciples/en/index.html. [Last accessed on 2020 May 14].

¹⁸https://www.researchcollection.ethz.ch/bitstream/handle/20.500.11850/387293/Sharma2019_Article_implemmentationOfTheMinimataCon.pdf?sequence=3

METHODS FOR THE TREATMENT OF BIO MEDICAL WASTE¹⁹

As we are talking about the treatment of bio medical waste and the guidelines to be followed while treating the waste, it is also necessary to know some of the major methods or techniques for the treatment of these waste.

Some major techniques are as follows

1. Autoclaving: the process includes a low hotness warm cycle where a steam is utilized on squander for certain time period to sanitize the waste.
2. Microwaving: the warm electromagnetic radiation is utilized between explicit frequencies between 300-300000 MHz for microorganisms to become inactive.
3. Shredder: in this process, the waste are unformed or cut into more modest pieces, this work in two ways first it makes it difficult to be reuse and recognizable that the waste has been disinfect.
4. Profound burial: Any waste which are ordered under classification of 1 and 2 of Biomedical Waste Rule of 1998 can be discarded through by covering it exceptionally profound yet with specific preconditioned which must be followed.
 - The population of the town should be under five lakh.
 - The prior permission must be taken from the concerned authority of the site.
 - It should not be near residential area
 - Region ought not be inclined to flood and disintegration

DIFFICULTIES WHILE EXECUTING GUIDELINES²⁰

1. One of the significant difficulty that will be looked by the medical care offices and emergency clinics in carrying out these standards and rules is lack of assets and funds for eliminating chlorinated plastic bags. Further, an immense expense will occurred in building up a worldwide situating and a scanner tag framework for biomedical waste. Added to this, all these have to be completed within a very short period of time that is within two years.

¹⁹Ashok Kashyap, Bio Medical Waste, available at <https://www.legalserviceindia.com/legal/article-3209-bio-medical-waste.html>

²⁰Bio Medical Waste Management Rules, 2016 , IPleader, available at <https://blog.ipleaders.in/biomedical-waste-management-rules-2016/> , last updated on 15th June 2020

2. Another significant test is the utilization of incinerators and the dangers it causes. Though the incinerators are useful in killing the pathogens while using high temperature but while using, it produces number of toxins during the process which includes incomplete combustion or toxins. These toxins are not destroyed rather dispersed in the environment which causes serious health problem affecting the immune and endocrine system of humans.
3. The significant innovation utilized for removal of biomedical waste is burning, microwaving, autoclaving, and compound therapy, however aside from these a few new advancements have likewise been created or are as yet under examination like warm cycles, organic cycles, irradiative cycles, and synthetic cycles.
4. In the process of management of waste, different innovative technologies are used like microwaving, incineration, autoclaving and chemical treatment but for their effective use still more research is required. In organic cycles, bio converter and biodegradable plastic frameworks are utilized for the removal of biomedical waste. Hence, here also another substitute is required for plastic so that no reaction take place.

CONCLUSION

It is to conclude that for the healthy environment, not only government but people should also put their efforts in cleaning and maintaining the hygiene. The Rules of 2016 has effectively pointed the various aspect for the management of the bio medical waste. Further, it was more enhanced and developed by the Rules of 2018. To keeping pace with the modern time, bar code system has been developed for packages, efforts to be made to remove chlorinated bags. For the effective application of the rule, accountability is placed on the occupier also. The paper pin pointed the issues which will be faced while implementing the rules. Lastly, the provisions of the law of both the Indian and International is also been dealt in the paper.