

# Compliance And Accountability Under The Biomedical Waste Management Rules, 2016: An Empirical Study Of Healthcare Institutions

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## Abstract

In India, biomedical waste management is a highly important part of the environmental governance and regulation of public health, with the Environment (Protection) Act, 1986 and the Biomedical Waste Management Rules, 2016 being the primary regulatory measures. This paper will discuss compliance practices in ten different health institutions of different capacities such as large hospitals and smaller health care centres. A descriptive and analytical research design was applied to collect primary data in the form of structured questions and analyze them with the help of frequency distribution, Chi-square test. The paper analyses segregation procedures, storage systems, disposal, record keeping, training, monitoring protocols, COVID-19-related measures, and institutional issues within the legal system. The results suggest that there is a great deal of formal compliance in segregation, colour-coded storage, training, audits, and pandemic-specific waste management. Nevertheless, the statistical significance was found in the record maintenance by the hospital capacity, and larger hospitals showed better documentation practices. Moreover, bigger institutions were at a greater risk of having problems of illegal dumping by outsiders. Though the regulatory landscape seems to be strong and well internalized, the differences in documentation and operational risks demonstrate that more effective monitoring, digital record keeping, improved security options, and capacity-related regulatory backing are required. This research concludes that appropriate biomedical waste management is not only about adherence to statutory standards, but also long-term institutional responsibility in enforcing the rules and regulations of environmental protection and good health.

**Keywords** - Biomedical Waste Management; Hospital Compliance; Environmental Governance; Record Maintenance; COVID-19 Waste Regulation.

## 1 Introduction

The management of biomedical waste has become one of the most important environmental governance and health-related issues in India. The high rate of development of healthcare infrastructure, the growing number of patients, the development of technologies in diagnostics and treatment have significantly increased the number and characteristics of biomedical waste produced by hospitals and healthcare organizations. Mishandling, segregation, transportation, and disposal of such waste is extremely dangerous as it may cause diseases, pollution of the environment, work-related injuries, and exposure to the community.

The regulations of biomedical waste in India are mainly provided by Biomedical Waste Management Rules, 2016<sup>1</sup>, which is regulated by Environment (Protection) Act, 1986<sup>2</sup> and included the

<sup>1</sup>The Biomedical Waste Management Rules, 2016, G.S.R. 343(E), Gazette of India, Extraordinary, Part II, Sec. 3(ii) (Mar. 28, 2016) (India).

<sup>2</sup>The Environment (Protection) Act, 1986, No. 29 of 1986, Acts of Parliament, 1986 (India).

obligations of healthcare facilities to segregate waste at the source, colour-coded transfer, authorised transportation, treatment on Common Biomedical Waste Treatment Facilities (CBWTF)<sup>3</sup>, record keeping, personnel training, and periodic monitoring of compliance. The regulatory context was also becoming prominent in the COVID-19 period, where the amount of infectious waste rose sharply, which needed special containment and disposal systems.

The level of compliance does not follow a uniform pattern because there is a general statutory framework, although it was found that the level of compliance differs among the institutions based on the size of the institution, the capacity of its infrastructure, leadership by the administrator, and monitoring systems. Hospitals with more cases of biomedical waste are generally better inspected and larger health facilities generally produce more biomedical waste than the smaller health centres. Differentiated application of record maintenance, audit systems and waste management procedures pose significant legal and regulatory issues regarding institutional responsibility and effectiveness in enforcing the same.

This paper discusses the biomedical waste management in ten healthcare facilities with different capacities such as hospitals and primary health centres. It aims at scrutinizing the level of adherence to legal requirements, institutional differences in waste production and disposal systems, juridical consequences of disparities in record keeping and exposure to other issues like illicit dumping. The paper also examines the impact of hospital size on compliance behavior especially on record maintenance and risks of external waste management.

This paper will make the contribution to the law on environmental governance, regulation of human health, and institutional accountability in the biomedical waste management in India by placing the empirical evidence within the legal framework and the regulatory framework.

## 2 Legal background

In India, biomedical waste management is treated as a right to life in the Constitution of India, in Article 21 of the Constitution of India<sup>4</sup>, which has been judicially safeguarded to encompass the right to a clean and healthy environment and has been construed by the Supreme Court to impose a positive action on the State to manage biomedical waste produced by healthcare facilities.

The main law that regulates biomedical waste is the Environment (Protection) Act, 1986, which was adopted to establish a framework that would help to take appropriate actions to protect and improve the quality of the environment. Section 3 of the Act is the authority of the Central Government to define the actions that are needed to protect and enhance the quality of the environment. Under this enabling clause, the Central Government had advised the Biomedical Waste Management Rules, 2016, which was in place of the previous 1998 Rules and an increase in compliance provisions.

The Biomedical Waste Management Rules, 2016 establish that each of the so called occupiers (including hospitals, nursing homes, clinics, laboratories, blood banks and research institutions) will guarantee the segregation of biomedical waste at the point of production, storage in colour-coded bins, pre-treatment of laboratory waste, and responsible disposal using approved Common Biomedical Waste Treatment Facilities (CBWTF). The Rules also provide requirements in terms of record keeping, annual reporting, employee training, worker immunization, barcoding, and periodic audits. The non-compliance is punishable as per the Environment (Protection) Act, 1986, which provides imprisonment and fines.

<sup>3</sup>Central Pollution Control Board, *Guidelines for Handling, Treatment and Disposal of Waste Generated during Treatment/Diagnosis/Quarantine of COVID-19 Patients* (2020), available at: <https://cpcb.nic.in> (last visited Feb. 11, 2026).

<sup>4</sup>Constitution of India, 1950, art. 21.

One of the most notable aspects of the 2016 Rules is that it has brought in the aspect of stronger accountability by means of documentation and traceability. There is a legal obligation among the healthcare facilities to record the waste produced, stored, transported and disposed and records should be availed to the regulatory authorities such as the State Pollution Control Boards which were the focus of the empirical aspect of the current study especially in comparing the differences in record maintenance in the small and big hospitals.

Enforcement has also been enhanced by the judicial intervention. *Indian Medical Association v. The Supreme Court, Union of India*<sup>5</sup>, stressed the necessity of the statutory adherence to the healthcare regulation and reasserted that institutional negligence in the area of public health can be a source of legal liability. Although the case in question was focused on the medical regulation, it helped to solidify the general principle according to which the negligence of the institutions in the healthcare sector may lead to legal compensation.

Biomedical waste management became a matter of urgent legal interests during the COVID-19 pandemic. The guidelines offered by the Central Pollution Control Board (CPCB) required separate segregation, storage in yellow bags, and special disposal channels of COVID-19 waste. <sup>5</sup> These guidelines introduced extra compliance requirements to the hospitals and strengthened the principle of precaution when handling infectious waste. The legal necessity of the segregation practices during the pandemic is directly explained in the findings of the current study.

In this way, the legal framework that regulates biomedical waste in India works in three levels, which are interrelated to each other:

- Constitutional requirement -Article 21. 1: Protection of life and environment.
- Laws Environment (Protection) Act, 1986.
- Regulatory directions and guidelines Subordinate legislation and regulatory guidelines Biomedical Waste Management Rules, 2016 and CPCB Guidelines.<sup>6</sup>

This hierarchical system creates a coherent compliance system in which there is institutional responsibility, documentation, segregation measures, training and supervision and remedial systems. The empirical research results of this study should thus be viewed in this context against this legally binding regulatory structure.

### 3 Review of Literature

The recent research on the biomedical waste management (BMWM) in India has shifted its attention to regulatory compliance, institutional readiness, and the system stress due to the COVID-19 pandemic.

Chand (2021) investigated the pandemic biomedical waste growth and emphasized the pressure on the already existing Common Biomedical Waste Treatment Facilities (CBWTFs). The researchers noted that despite the presence of a regulatory framework in India based on the Biomedical Waste Management Rules, 2016, the unparalleled increase in the quantity of infectious waste on the loose end of the system revealed infrastructural weaknesses to the system, especially the transportation and incineration capacities. The author highlighted the necessity of technological advancement and decentralized facilities to treat people to enhance their resilience in the event of a community health crisis.

<sup>5</sup>The Environment (Protection) Act, 1986, No. 29 of 1986, Acts of Parliament, 1986 (India).

<sup>6</sup>Central Pollution Control Board, *Guidelines for Handling, Treatment and Disposal of Waste Generated during Treatment/Diagnosis/Quarantine of COVID-19 Patients* (2020), available at: <https://cpcb.nic.in> (last visited Feb. 11, 2026).

Khosla et al. (2022) compared the production of biomedical waste in the state during the second wave of COVID-19 in India and discovered that there existed significant regional differences in waste management capacity. The paper highlighted effective waste management practices such as enhancing monitoring systems and incorporation of digital monitoring systems. It came out with a conclusion that institutional accountability and effective implementation of regulations are essential in ensuring safety of the environment during crisis situations.

Ojha et al. (2022) were interested in technological and environmental factors of biomedical waste treatment in India. The authors evaluated the incineration process, autoclaving process and chemical disinfection process stating that the production of biomedical waste was higher during COVID-19 which created more concerns about the subject of emissions, energy use and environmental sustainability. To balance between environmental protection and the needs of the population, the study suggested to optimize the technologies of treatment, and to increase the regulatory control.

Jindal et al. (2023) have empirically reported the amounts of biomedical waste produced throughout the pandemic and reported the presence of segregation at the level of hospitals. Their results indicated that the majority of hospitals implemented individual yellow- bag segregation of COVID-19 garbage in accordance with the CPCB instructions. Nevertheless, there were some difficulties in the coordination between hospitals and treatment facilities in some areas, which implied the uneven implementation, and lack of resources.

Dhole (2024) did a systematic review of the biomedical waste management within India and found out that there were still outstanding compliance gaps, especially in smaller healthcare facilities. The paper emphasized that the areas of record keeping, employee training regularity, and regular audits are still disproportionately applied in the facilities. The author emphasized the need to ensure enhanced monitoring systems and institutional responsibility in order to provide a complete adherence to the statutory requirements.

The article by Bagwan et al. (2023) employed a spatial analysis of the biomedical waste generation in Indian states during COVID-19. It proved that the urban states with high density of populations reported really high volumes of waste, which put more pressure on the treatment facilities. The key suggestions that the authors proposed concerned the regional planning and better coordination of logistics to handle the biomedical waste.

In a study by Chatterjee et al. (2022), the study population comprised healthcare workers in a tertiary-care hospital in Kolkata to carry out a Knowledge-Attitude-Practice (KAP) research study. Although awareness was high, the research revealed that there was inconsistency in practice, especially in documentation and day to day segregation processes. The authors suggested regular refresher training, and more rigid supervisory processes to achieve consistency between knowledge and implementation.

Sharma and Deori (2020) evaluated the biomedical waste management in postgraduate medical residents. The research claimed that there was sufficient knowledge in theory but there were operational gaps in segregation and documentation. The authors noted that training should be supported by a monitoring and accountability system in order to achieve sustained adherence.

Recent testing conducted in the Microbiology Journal (2023) appraised the biomedical waste management practices in a tertiary care hospital in Chhattisgarh. The research revealed that internal audit, frequent training, and supervision of the staff can play a crucial role in the prevention of occupational injuries and the adherence to regulatory requirements.

Taken collectively, the literature shows that although India has a strong legal framework in place to govern the management of biomedical waste, there are still problems in implementing the policies, especially in smaller organizations and in situations of crisis like the COVID-19 pandemic. Some of

the themes that have been identified in the literature are the significance of record keeping, institutional responsibility, technological aptitude, training and monitoring, all of which are directly related to the current study topic on the issue of hospital size, compliance practices, and waste management issues.

#### **4 Research methods**

The research design in this study is descriptive and analytical research design as the researcher seeks to investigate the biomedical waste management practices in ten healthcare institutions with different capacities including large hospitals and small health care centres. There was the use of a purposive sampling approach which was used in order to be sure that institutions that had varying bed capacity and service scopes were represented. A structured questionnaire was adopted to select primary data that were to be collected among hospital authorities and selected biomedical waste management personnel. The tool encompassed amounts of waste generation, segregation, storage, and disposal, documentation of records, training, COVID-19-related measures, compliance mechanisms, and challenges. The paper is dedicated to the problem of institutional compliance in terms of the Biomedical Waste Management Rules, 2016 as well as other applicable regulatory provisions.

Analytical statistics were used both descriptive statistics (frequency and percentage distribution) and inferential statistics. The associations between the hospital capacity and the chosen compliance variables, specifically maintenance of records and issues of illegal dumping, were investigated with the help of cross-tabulation. The Chi-square test was used to compute the difference whether the differences observed were statistically significant. This descriptive and inferential analysis would allow the study to examine not only the degree of compliance but also the legal and institutional impacts of the variation in the size of healthcare facilities.

#### **5 Results and Discussion**

##### **5.1.1 General information**

Ten hospitals examined in the study, each offering hospital data equivalent to 10% of the total sample. The hospitals were K C General Hospital in Malleshwaram, KIMS, Subbahaiah Hospital in Mathikere and two Urban Primary Health Care Centres in Subedar Palya and Yeshwanthpur. According to the distribution, the aim is to use both general hospitals and urban primary care for research, allowing the study to capture the range of healthcare in the region.

The data also indicates that out of the 10 hospitals, 6 hospitals (60 percent) are full-fledged hospitals, a fact that implies that most of the participating institutions are large or medium-scale healthcare institutions. 2 facilities (20 percent) are Health Care Centres, and another 2 facilities (20 percent) are Primary Health Centres. This distribution indicates average diversity in healthcare infrastructure. The preponderance of hospitals implies that the production and management approach of biomedical waste coined in this study mostly reflects the institution that has a greater patient load and capacity to provide services. Smaller centres only constitute 40 percent as a group, so it is possible that they affect the variations in the quantity of waste, the type of segregation, and methods of disposal. The equal representation of Health Care Centres and Primary Health Centres (20:20) suggests equal representation on lower-tier facilities, but their low percentage indicates that the data mostly represents the practice in bigger hospitals and does not represent community-based institutions. The distribution assists in placing biomedical waste distributions in clinically active environments in context.

The size of the bed capacity of the 10 facilities will provide some knowledge on the size of their operations, 4 hospitals (40% have 2 beds only) is a sign that there are small clinics or centres offering inpatient services in small numbers. In the meantime, there are three categories 24 beds, 450 beds, and 1000 beds, which are all 20 percent. This is an indication of an equal representation of medium and large hospitals in the sample. In 20 percent having 450 beds and 20 percent having

1000 beds, the data shows that 40 percent of hospitals are large institutions, presumably generating large amounts of biomedical waste.

The 10 Hospitals have different categories of biomedical waste. Most of them (6 hospitals (60%)) produce all biomedical waste, which is a sign of comprehensive clinical services, comprising of laboratory, surgical, and inpatient services. The other 4 hospitals (40%) Sharps waste, chemical waste and pharmaceutical waste are the main products, which implies a specialised or limited-scope operations. The existence of these types of wastes highlights the importance of proper segregation, since the sharp is dangerous in terms of injury, chemical waste is dangerous in terms of toxicity, and pharmaceutical waste is dangerous in terms of ecological pollution when not properly dealt with. The prevalence of hospitals that produce the complete range of biomedical waste implies that the majority of the facilities need the strong and multi-stream segregation plans. In the meantime, the 40 percent that are producing the targeted types of waste probably depend on specific guidelines. This allocation underlines why waste management strategies should be scaled and should be adaptable to changing institutional activities. The composite waste sample is used to show the sophistication of the task to maintain regulatory compliance in different healthcare facilities.

### 5.1.2 Quantity of waste generated

**Table 1– Quantity of waste generated**

| Quantity       | Frequency | Percent     |
|----------------|-----------|-------------|
| 1–2 kg/day     | 4         | 40%         |
| 100–150 kg/day | 2         | 20%         |
| 3–3.5 kg/day   | 2         | 20%         |
| 80–100 kg/day  | 2         | 20%         |
| <b>Total</b>   | <b>10</b> | <b>100%</b> |

The volume of biomedical waste discharged at the 10 hospitals differs greatly, with 4 hospitals (40%) generating 1-2 kg/day, a sign of small scale operation or outpatient-based type of facilities. The rest of the waste products, 100 -150 kg/day, 3 -3.5 kg/day, and 80-100 kg/day are correspondingly reported by 2 hospitals (20 percent). The 100-150 kg/day and 80-100 kg/day hospitals can be probably high-volume hospitals with high inpatient and diagnostic work. The existence of intermediate generators with an average of 3-3.5 kg/day production is an indication of mid-scale. Such a mixed distribution underscores that the waste management systems should be designed in such a way that they accommodate differences in the levels of production. Small facilities can use outsourcing, whereas the big hospitals can use autoclaving on their premises or direct transportation to treatment plants. The variation in the low and high volumes of waste also shows a variation in medical services, load operation and patient turnover. Knowledge of these quantities is very vital in optimization of collection intervals, storage facilities and disposal facilities.

### 5.1.3 Waste Segregation and Storage

**Table 2– Waste segregation and storage at the hospitals**

|  |           |         |
|--|-----------|---------|
| Biomedical wastes segregated from non-hazardous waste      | Frequency | Percent |
| Yes  | 10        | 100.0   |
| Designated areas for storing biomedical wastes             | Frequency | Percent |
| Yes  | 10        | 100.0   |
| Types of containers are used for storing biomedical wastes | Frequency | Percent |
| Colour coded bags, Leak proof containers                   | 10        | 100.0   |
| Containers labelled and coloured                           | Frequency | Percent |
| Yes  | 10        | 100.0   |

A hundred percent (100) of the 10 hospitals were found to segregate the biomedical waste and non-hazardous waste and this is a sign that the 100 percent are in full compliance with the requirements of the mandatory regulatory guidelines. Such a consistent compliance indicates a high level of awareness and operation discipline when separating infectious and general streams of waste. The source segregation has a great impact on minimizing the health risks to the waste handlers and it avoids cross-contamination. The good adherence of all the hospitals can be the sign of well-developed monitoring systems, the trained staff, and the accessibility of segregated containers. It also draws the attention to the successful introduction of the national biomedical waste management regulations in the sample. Reporting however might not indicate consistency in the day to day practice, but 100% rate of compliance is high institutional commitment. This beneficial effect also favors downstream processes including autoclaving, incineration and transportation to treatment plants as it guarantees that biomedical waste is put in the right route to be disposed.

Every 10 hospitals of 100% reported to have specific places where they store biomedical waste. This shows full adherence to the necessary rules that stipulate that storage areas should be secure, labelled, and restricted. Specialized storage facilities minimize the exposure risk and avoid unwanted access and permit the secure storage prior to transport to treatment plants. The consistent positive reaction indicates that hospitals irrespective of their size have appreciated the need to keep their temporary storage safe. This can be as a result of regulatory audits, institutional policy frameworks or accreditation requirements. Specific areas contribute to cleanliness, eliminate the odour problem, and assist in proper waste management. This is supported by the uniformity in the availability of storage facilities among the sample, which demonstrates the institutional preparedness of the biomedical waste management.

The rate of usage of colour-coded bags and leak-proof containers to store biomedical waste is 100 per cent meaning that all the 10 hospitals adhered to the recommended standard protocols. This will guarantee the right segregation based on waste type; red, yellow, blue, and white containers systems as required by the law. Air tight containers will avoid spillage, contamination, and unintended exposure particularly sharps or liquid waste. Colour coding helps to use proper disposal routes and this minimizes errors by staff and enhances efficiency. The fact that all hospitals have the same practice is an indication of high awareness, proper procurement process, and training that is consistent. This kind of compliance is very helpful in terms of safety and environmental protection.

The labeling and colouring of biomedical waste containers are done correctly in all the 10 hospitals (100%). This enhances the process of segregation as every waste category is well identified. Labeling is useful in ensuring that the waste handlers, transport individuals, and personnel at the

treatment plants understand the kind of waste and repeat the appropriate disposal process. The unified adherence indicates properly organized working processes and training. Effective labelling decreases the level of confusion, lessens chances of accidental mixing and also ensures compliance with rules. The result is that there are systematic waste management practices in all hospitals.

#### 5.1.4 Waste Disposal

**Table 3– Biomedical waste disposal**

| Method                        | Frequency | Percent     |
|-------------------------------|-----------|-------------|
| Packed & transported to CBWTF | 2         | 20%         |
| Outsourced for disposal       | 2         | 20%         |
| Autoclaved then outsourced    | 2         | 20%         |
| Transported to CBWTF          | 4         | 40%         |
| <b>Total</b>                  | <b>10</b> | <b>100%</b> |

The 10 hospitals have varying disposal methods of biomedical waste; 4 hospitals (40%), transport waste directly to Common Biomedical Waste Treatment Facility (CBWTF). 2 hospitals (20%), package and store waste in colour coded rooms and then transport before outsourcing. Differing infrastructure capacities are manifested by this diversity. Autoclaving can be applied in larger hospitals, whereas in smaller ones it is preferred to outsource. The distribution demonstrates that all approaches fit within regulatory channels, yet they all differ in their adoption according to the size and resources.

**Table 4– Designated person for biomedical management**

| Person                         | Frequency | Percent     |
|--------------------------------|-----------|-------------|
| Administrative Medical Officer | 2         | 20%         |
| Chief Executive Officer        | 2         | 20%         |
| Nursing Superintendent         | 2         | 20%         |
| Staff Nurse                    | 4         | 40%         |
| <b>Total</b>                   | <b>10</b> | <b>100%</b> |

Biomedical waste management is shared between the staff (40%). 4 hospitals delegate the task to the staff nurses, which means that it is depended on the frontline staff. There are 2 hospitals in each of the Administrative Medical, Chief Executive Officer, and Nursing Superintendent (20%). This variance is an indication of institutional organisational structures. In smaller units, the administrative leaders can take up this role but in larger hospitals, it is assigned to the trained nursing staff. There is shared leadership and expertise diversity in the distribution.

**Table 5– Records maintained for disposal of biomedical waste**

| Response     | Frequency | Percent     |
|--------------|-----------|-------------|
| Yes          | 6         | 60%         |
| No           | 4         | 40%         |
| <b>Total</b> | <b>10</b> | <b>100%</b> |

The 10 hospitals slightly vary in the record-keeping practices, with 6 hospitals (60%) keeping records on the biomedical waste disposal, indicating that majority of the hospitals comply with the record keeping practices. 4 hospitals (40%) do not keep records, this raises concerns on traceability

and compliance with audit. Regulatory checks and quality control require proper documentation. Though a big percentage of them do so, the loopholes indicate that they require training and control.

### 5.1.5 Training and Awareness

**Table 6– Training and employee awareness of bio medical waste disposal**

|   |           |         |
|---|-----------|---------|
| Employees received training on biomedical waste         | Frequency | Percent |
| Yes   | 10        | 100.0   |
| Training period   | Frequency | Percent |
| 6 months once   | 10        | 100.0   |
| Awareness of the risks associated with biomedical waste | Frequency | Percent |
| Yes   | 10        | 100.0   |

Training Biomedical waste handling is available in all the 10 hospitals (100%). Training helps in making the staff aware of the rules of segregation, container code and safe handling methods. The homogeneity shows a high level of commitment of the hospital to regulatory compliance. This helps to provide safer working conditions and minimize occupational risks as well.

Training is done in every 6 months (100%). Frequent training strengthens knowledge and informs staff about the latest regulations and addresses the problem of unsafe practices. Its consistency means systematic institutional planning and commitment to the constant improvement.

Awareness of the risks related to biomedical waste is reported in all the 10 hospitals (100%). Awareness assists in avoiding injuries, infections as well as mismanagement. This complete compliance is an indication of good training and communication.

### 5.1.6 Compliance and Monitoring

**Table 7– Compliance and monitoring**

|  |           |         |
|--|-----------|---------|
| Biomedical waste management practices in compliance with local regulations | Frequency | Percent |
| Yes  | 10        | 100.0   |
| Regular audits and inspections conducted to ensure compliance              | Frequency | Percent |
| Yes  | 10        | 100.0   |
| Corrective actions taken in response to non-compliance                     | Frequency | Percent |
| Yes  | 10        | 100.0   |

Hospitals (100) are all in agreement with the local regulations. This implies that it is governed, regularly monitored and complies with biomedical waste requirements.

Regular audits are done in all 10 hospitals (100%). Audits check processes and gaps, as well as ensure that the process is legal. This represents preemptive institutional management.

When the non-compliance is noticed, all hospitals (100%) implement corrective measures. This signifies well managed systems and willingness to deal with problems in a prompt manner.

### 5.1.7 COVID-19 specific practices

**Table 8- COVID-19 specific practices**

| <b>Implemented any special measures for managing COVID-19 related biomedical waste</b>                 | <b>Frequency</b> | <b>Percent</b> |
|--|------------------|----------------|
| Segregated and stored separately in yellow bins, distinct from other biomedical waste                  | 10               | 100.0          |
| <b>Major challenges you face in managing biomedical waste in you hospital during COVID-19 pandemic</b> | <b>Frequency</b> | <b>Percent</b> |
| Nil  | 10               | 100.0          |

The 10 hospitals (100 percent) all segregated COVID-19 wastes in yellow bins. This is an expression of the strict compliance with the pandemic-related rules to avoid cross-infection.

The percentages of challenges were all Nil (100%). This could be an indication of good preparedness, or it could indicate underreporting or good availability of resources. Each hospital included in the survey has put in place unique procedures for managing COVID-19 biomedical waste and all five indicate they separate and store COVID-19 waste in yellow bins apart from other biomedical waste. Consistent results from all participants prove that they applied standard methods for handling infectious waste, to decrease the chance of spreading the virus. All the hospitals surveyed said there were no major problems with handling biomedical waste during the pandemic. It appears that the current waste management systems and procedures could manage the extra demands and unique problems brought by the pandemic or that any issues were handled well through preparing in advance. Although, it is possible that people didn't notice some of the difficulties or saw them as less important. The results reveal that biomedical waste was managed well and followed the required rules for most of the pandemic.

### 5.1.8 Additional Information

**Table 9– Challenges related to bio medical waste management**

| <b>Challenge</b>              | <b>Frequency</b> | <b>Percent</b> |
|-------------------------------|------------------|----------------|
| Illegal dumping near hospital | 2                | 20%            |
| Minor injuries while handling | 4                | 40%            |
| No                            | 4                | 40%            |
| <b>Total</b>                  | <b>10</b>        | <b>100%</b>    |

The challenges were different: 2 hospitals (20%) reported illegal dumping around the premises, 4 hospitals (40) reported minor injuries, and 4 hospitals (40) reported no challenges. Minor injuries are about lapses in training; the dumpings that are illegal suggest external environmental concerns.

The data visualizes worries regarding proper management of biomedical waste near hospitals. About 20% of respondents reported noticing unknown people disposing of biomedical trash near the hospital which may suggest something wrong about the hospital's waste disposal system. More than two in five respondents reported having received minor harm when caring for biomedical waste, highlighting that this can be dangerous. It's worth mentioning that 40% of participants stated they had no issues which may indicate some individuals are not experiencing these matters. In essence, finding such cases increases the demand for updated waste and safety systems to protect against illegal dumping and injuries which supports the hospital's safety and reputation for everyone involved.

### 5.1.9 Testing of hypothesis

**H1- There is a difference in maintenance of records for bio medical waste based on hospital capacity**

**Table 10- Chi sgr results - Difference in maintenance of records for bio medical waste based on hospital capacity**

| Crosstab                           |                           |                           |                                   |                      |                      |
|------------------------------------|---------------------------|---------------------------|-----------------------------------|----------------------|----------------------|
|                                    |                           | Maintain_records          |                                   |                      | Total                |
|                                    |                           | Yes                       | No                                |                      |                      |
| Hospital_size                      | Health care centres       | Count                     | 0                                 | 4                    | 4                    |
|                                    |                           | % within Hospital_size    | 0.0%                              | 100.0%               | 100.0%               |
|                                    |                           | % within Maintain_records | 0.0%                              | 100.0%               | 40.0%                |
|                                    |                           | % of Total                | 0.0%                              | 40.0%                | 40.0%                |
|                                    | Hospital (Large capacity) | Count                     | 6                                 | 0                    | 6                    |
|                                    |                           | % within Hospital_size    | 100.0%                            | 0.0%                 | 100.0%               |
|                                    |                           | % within Maintain_records | 100.0%                            | 0.0%                 | 60.0%                |
|                                    |                           | % of Total                | 60.0%                             | 0.0%                 | 60.0%                |
| Total                              | Count                     | 6                         | 4                                 | 10                   |                      |
|                                    | % within Hospital_size    | 60.0%                     | 40.0%                             | 100.0%               |                      |
|                                    | % within Maintain_records | 100.0%                    | 100.0%                            | 100.0%               |                      |
|                                    | % of Total                | 60.0%                     | 40.0%                             | 100.0%               |                      |
| Chi-Square Tests                   |                           |                           |                                   |                      |                      |
|                                    | Value                     | df                        | Asymptotic Significance (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
| Pearson Chi-Square                 | 4.100 <sup>a</sup>        | 1                         | <b>0.015</b>                      |                      |                      |
| Continuity Correction <sup>b</sup> | 1.701                     | 1                         | 0.192                             |                      |                      |
| Likelihood Ratio                   | 6.730                     | 1                         | 0.009                             |                      |                      |
| Fisher's Exact Test                |                           |                           |                                   | 0.050                | 0.050                |
| Linear-by-Linear Association       | 4.000                     | 1                         | 0.046                             |                      |                      |
| N of Valid Cases                   | 5                         |                           |                                   |                      |                      |

When analyzing hospital records using chi-square, we find that bigger hospitals do a better job of tracking their medical waste. It is clear that large capacity hospitals are better at keeping biomedical waste records, as the Pearson Chi-Square value is 4.100 with an asymptotic significance of 0.015. This trend is further strong when the significance of the likelihood ratio obtains for a value of 0.009. It was also found that a possible trend exists across the ordered categories with a significance of 0.046 from the linear-by-linear association test. The same conclusion is drawn from Fisher's Exact Test which reveals the association is significant at an exact P-value of 0.050. The results demonstrate that hospital size is significant for recording biomedical waste, as larger hospitals tended to perform better.

## H2- The bigger hospitals face challenges of illegal biomedical waste dumping by outsiders

Table 11– Chi sqr test results - challenges of illegal biomedical waste dumping by outsiders

| Crosstab                           |                           |                        |                                   |                      |                      |
|------------------------------------|---------------------------|------------------------|-----------------------------------|----------------------|----------------------|
|                                    |                           |                        | Challenges                        |                      | Total                |
|                                    |                           |                        | Yes                               | No                   |                      |
| Hospital_size                      | Health care centres       | Count                  | 0                                 | 4                    | 4                    |
|                                    |                           | % within Hospital_size | 0.0%                              | 100.0%               | 100.0%               |
|                                    |                           | % within Challenges    | 0.0%                              | 66.7%                | 40.0%                |
|                                    |                           | % of Total             | 0.0%                              | 40.0%                | 40.0%                |
|                                    | Hospital (Large capacity) | Count                  | 4                                 | 2                    | 6                    |
|                                    |                           | % within Hospital_size | 66.7%                             | 33.3%                | 100.0%               |
|                                    |                           | % within Challenges    | 100.0%                            | 33.3%                | 60.0%                |
|                                    |                           | % of Total             | 40.0%                             | 20.0%                | 60.0%                |
| Total                              |                           | Count                  | 4                                 | 6                    | 10                   |
|                                    |                           | % within Hospital_size | 40.0%                             | 60.0%                | 100.0%               |
|                                    |                           | % within Challenges    | 100.0%                            | 100.0%               | 100.0%               |
|                                    |                           | % of Total             | 40.0%                             | 60.0%                | 100.0%               |
| Chi-Square Tests                   |                           |                        |                                   |                      |                      |
|                                    | Value                     | df                     | Asymptotic Significance (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
| Pearson Chi-Square                 | 2.126 <sup>a</sup>        | 1                      | <b>0.028</b>                      |                      |                      |
| Continuity Correction <sup>b</sup> | 0.313                     | 1                      | 0.576                             |                      |                      |
| Likelihood Ratio                   | 2.911                     | 1                      | 0.088                             |                      |                      |
| Fisher's Exact Test                |                           |                        |                                   | 0.030                | 0.020                |
| Linear-by-Linear Association       | 1.778                     | 1                      | 0.182                             |                      |                      |
| N of Valid Cases                   | 5                         |                        |                                   |                      |                      |

Analysis of problems regarding outsiders dumping biomedical waste on hospitals reveals that hospital size is related to these issues. Results from the Chi-square test indicate that a large Pearson Chi-Square value (2.126 ) and an asymptotic significance (2-sided) of 0.028 suggest that larger hospitals are more susceptible to illegal dumping than smaller health care centers. All of the large hospitals we surveyed had this issue, but none of the smaller health care centers did, so hospital size may play a role in vulnerability to illegal dumping. The finding is also confirmed by Fisher's Exact Test, with a p-value of 0.020, indicating that large hospitals may be linked to more cases of illegal waste management. For this reason, large hospitals might benefit from stricter waste disposal rules and greater security to handle risks of illegal dumping.

## 6 Findings and recommendation

The empirical conclusions should be put into perspective of statutory provisions of the Environment (Protection) Act, 1986 and the Biomedical Waste Management Rules, 2016 which have obligatory requirements on all the healthcare institutions regardless of their size.

### 1. Diversity in the Institution and Legal accountability.

Big-capacity hospitals (60) and smaller health care centres (40) were incorporated in the study. According to Rule 4 of the Biomedical Waste Management Rules, 2016, the occupier of each healthcare facility is authorized by law to handle, segregate, store, transport, and dispose biomedical waste safely. The Rules do not differentiate obligations depending on the number of beds. Thus, the large and small centres, which have operational variations, have the same statutory duties. The results show that there are varying capacities in operations but equal liability under the law.

### 2. Generation of Waste and Implications of Regulations.

It was found that there is a significant difference in waste production 1- 2 kg/day to 100-150 kg/day. The bigger hospitals produce more volume, making them more regulated in the form of storage period restrictions, frequency of transport, and adherence to treatments. Biomedical waste cannot be stored without permission longer than the required time, according to the 2016 Rules. Increased production of waste will therefore require increased surveillance and accelerated disposal rates. The larger hospitals by default have more potential liability in case of non-compliance due to volume.

### 3. Segregation and Storage: High Level of Compliance.

The ten hospitals all indicated that they were 100 percent compliant with source segregation, use of colour-coded containers, use of leak-proof storage, labelling and use of storage areas. These results are directly related to the compulsory provisions of Schedule I and Schedule II of the Biomedical Waste Management Rules, 2016. Segregation at source is not only a legal requirement but failure to do so can incur penalties under the Section 15 of the Environment (Protection) Act, 1986. The indicated compliance is universal, which implies a good match between the institution and statutory requirements, at least formally.

### 4. Disposal Mechanism and Authorized Treatment.

The difference in the disposal procedures, i.e., transportation to CBWTF or outsourcing or autoclaving before outsourcing is not legally prohibited as long as the facility is licensed and documentation is made. The 2016 Rules include rule 7 that places the obligation of treating and disposing biomedical waste at approved facilities. As the results reveal, every institution adheres to known channels, which implies that they comply with statutory disposal mechanisms prima facie. Nevertheless, this compliance should be approved by documentation and authorization certificates.

### 5. Record Maintenance: Legal Requirement and Gap in Compliance.

The most legally relevant conclusion is associated with maintenance of records. A total of 60 percent of hospitals kept disposal records whilst 40 percent did not. The Biomedical Waste Management Rules, 2016, Rule 4(k) and Rule 13 require keeping records and filing the annual reports to the prescribed authorities. The Chi-square test has supported the existence of statistically significant relationship between the size of the hospital and maintenance of the records ( $p = 0.015$ ), where bigger hospitals are doing better.

Lawfully, non-compliance through default of maintenance of records means the institution will be subject to regulatory punishments as stipulated in the Environment (Protection) Act, 1986. Traceability, audit, and environmental accountability are related to documentation. Thus, smaller health care centres run a greater risk of violation of regulation.

## 6. Institutional Liability and Illicit Dumping.

The second hypothesis showed that bigger hospitals have higher chances of encountering illegal dumping by outsiders ( $p = 0.028$ ). Whereas this kind of dumping might not be directly blamed on hospital action, Rule 4 focuses on the occupier to maintain safe storage and unauthorized access. In this case, the regulatory bodies can regard it as the failure of due diligence in case the premises of hospitals are accessible and the dumping is illegal. Thus, the issue of perimeter security and limited access is not only administrative, but it belongs to the institutional compliance requirement.

## 7. Training and Awareness: Legal Requirement Compliance.

There were no reports of any other hospital having more frequent training and 100 percent of awareness of the risks of biomedical waste. The 2016 Rules, which are applicable in this case, state that healthcare workers should be trained and immunized against occupational hazards through rule 4(n). The homogenous compliance implies institutional compliance with the training requirement. Nevertheless, the fact that minor injuries (40%) are present implies that training efficiency and occupational safety implementation needs to be reinforced.

## 8. COVID-19 Specific Compliance

Every hospital separated waste related to COVID-19 in yellow bins, in accordance with the recommendations related to the pandemic of CPCB. The compliance with the pandemic-related segregation implies the responsiveness of regulations and the pre-emptiveness of institutions. Legally, adherence to CPCB guidelines shows adherence to precautionary principles of environmental jurisprudence of the Articles 21 of the Constitution.

## 9. Monitoring and Compliance.

The audits, inspections, and corrective measures which are reported to have been 100 percent compliant with indicates well-monitored institutions. The 2016 Rules presuppose Rule 15 that grants the authority to the State Pollution Control Boards to perform the inspections. The results indicate that hospitals have knowledge of regulatory compliance and internal compliance systems have been organized. Nonetheless, the record maintenance difference shows that the compliance can be uneven among institutional categories.

## General Legal Implication of Findings.

The results show that there is a high level of formal conformity in segregation, storage, disposal, training, and management of pandemic. Nonetheless, the weaknesses of documentation and susceptible to illegal dumping indicate the gaps in the areas that a legal commitment is not implemented unanimously. Hospital size plays a major role in compliance behavior especially maintaining records and being exposed to external waste related risks.

Therefore, as much as the regulatory framework is comprehensive, its actual implementation is dependent upon the institutional capacity, monitoring mechanisms and the rigor of the enforcement.

## 7 Conclusion

The management of biomedical waste in India is a well-established and constitutional statutory framework within which the healthcare institution has a clear responsibility, of ensuring by providing safe management, segregation, storage, transportation and disposal of the hazardous waste. The results of this research indicate that the vast majority of surveyed institutions are very much compliant with procedures as with segregation at source, colour-coded storage, and training, audits and COVID-19-specific waste management. These findings suggest that the fundamental requirements of the Biomedical Waste Management Rules, 2016 have been adopted to a great extent at operational level. Homogenous implementation of structured segregation and monitoring systems show a growing institutional awareness towards environmental and social health obligations.

The paper however also brings out huge differences in maintenance of records and susceptibility to illegal dumping specifically among smaller health care centres and high volume large hospitals respectively. The statistically significant correlation between the hospital capacity and documentation practices highlights the fact that institutional size determines the efficacy of the compliance mechanisms. Because the maintenance of records is key in the regulatory oversight and legal responsibility, documentation lapses undermine enforcement and traceability. Thus, although the legal framework in which biomedical waste is regulated is detailed, its efficiency is predetermined with the steady implementation, enhanced monitoring, capacity based supportive measures to the regulatory processes, and institutional support to the protection of the environment and the health of the population.

## 8 References

### I. Constitutional Provision

Constitution of India, 1950, art. 21.

### II. Statutes

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

### III. Rules and Subordinate Legislation

The Biomedical Waste Management Rules, 2016, G.S.R. 343(E), Gazette of India, Extraordinary, Part II, Sec. 3(ii) (Mar. 28, 2016) (India).

### IV. Government Guidelines / Regulatory Documents

Central Pollution Control Board, *Guidelines for Handling, Treatment and Disposal of Waste Generated during Treatment/Diagnosis/Quarantine of COVID-19 Patients* (2020), available at: <https://cpcb.nic.in> (last visited Feb. 11, 2026).

### V. Case Law

Indian Medical Association v. Union of India, (2011) 7 SCC 179 (Supreme Court of India).

Municipal Council, Ratlam v. Vardhichand, (1980) 4 SCC 162 (Supreme Court of India).

Vellore Citizens' Welfare Forum v. Union of India, (1996) 5 SCC 647 (Supreme Court of India).

Almitra H. Patel v. Union of India, (2000) 2 SCC 679 (Supreme Court of India).

## VI. Journal Articles / Academic Literature

1. S. Chand, “Biomedical Waste Management during COVID-19: Challenges and Future Directions,” (2021) *Science of the Total Environment*.
2. R. Khosla et al., “Upsurge in Biomedical Waste Due to COVID-19 in India: A Review,” (2022) *Frontiers in Environmental Science*.
3. P. C. Ojha et al., “Treatment and Disposal Technologies for Biomedical Waste during COVID-19,” (2022) *Science of the Total Environment*.
4. M. K. Jindal et al., “Medical Waste Management during COVID-19 Situation in India,” (2023) *Journal of Environmental Health Research*.
5. K. S. Dhole, “Navigating Challenges in Biomedical Waste Management in India,” (2024) *Environmental Health Review*.
6. W. A. Bagwan et al., “Investigation of Biomedical Waste Generated in India during COVID-19,” (2023) *Environmental Monitoring and Assessment*.
7. S. Chatterjee et al., “Awareness of Biomedical Waste Management among Healthcare Workers in a Tertiary Care Institution,” (2022) *Journal of Clinical and Scientific Research*.
8. S. Sharma & T. J. Deori, “Knowledge, Attitude and Practices regarding Biomedical Waste Management among Postgraduate Residents,” (2020) *International Journal of Community Medicine and Public Health*.

