ISSN: 3048-9423(Online)
Naveen International Journal of Multidisciplinary Sciences (NIJMS)
© NIJMS | Vol. 2 | Issue 5 | April-May 2026
Available online at: https://nijms.com/
DOI: https://doi.org/10.71126/nijms.v2i5.132

# Legal and Regulatory Framework for Biomedical Waste Management in India: A Critical Review

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***ABSTRACT:***

*Biomedical waste management is a complex issue that combines public health, environmental sustainability, and regulatory effectiveness, and remains one of the most critical challenges for environmental governance in India. Healthcare infrastructure is being built at an accelerated pace across urban and rural areas, which has led to a corresponding rise in the amount of biomedical waste generated, and a high risk of environmental and occupational health hazards if these wastes are not managed properly. This doctrinal review discusses the legal and regulatory structure of biomedical waste management in India, highlighting its constitutional underpinnings, legislation, institutions, and barriers to enforcement. The study, through systematic analysis of legislation (specifically Biomedical Waste Management Rules, 2016), judicial pronouncements, government reports from the Central Pollution Control Board and the Ministry of Environment, Forest and Climate Change as well as peer reviewed scholarly literature, is able to highlight the substantive strengths, and continue to point out implementation gaps. Since 1998, the regulatory framework has developed comprehensively in India, but the challenges include non-uniformity in compliance, inadequate enforcement systems, lack of infrastructure in rural areas, and lack of coordination between institutions. Overall, the paper recommends that transformation of biomedical waste governance must go beyond mere attempts at incremental change in legislation, and must include adaptation of regulation, building capacities, and technological innovation.*

**NIJMS | Received: 30 April 26 | Revised: 24 May 26 | Accepted: 30 May 26 | Published: 31 May 26 (99)**

***Keywords:*** *Biomedical waste; Environmental law; Regulatory framework; Healthcare waste management; Institutional governance; Environmental protection.*

## 1. INTRODUCTION:

The healthcare sector in India has undergone rapid transformation over the last twenty years. In 2024, the country has just around 1.2 million registered medical practitioners alongside 450,000 allopathic hospitals and millions of diagnostic centres, nursing homes and clinics spread over by urban and rural territories. This proliferation is an indicator of progress the better management of diseases, greater access to treatment options, and the reinforcement of infection control measures. However, this expansion comes with a cost that is not well appreciated: exponential increase of biomedical waste.

Biomedical waste, i.e., any waste which emits during the activities of diagnosis, treatment, research and vaccination includes contaminated sharps (needles), pathological waste (body components), pharmaceutical waste such as drugs and materials that are rejected by clinics and hospitals due to shortages or expiration, chemical substances from laboratories or radioactive material. Once COVID-19 pandemic emerged, this issue became all the more pertinent as biomedical waste generation in some health care settings between 300 to 500%was estimated. In addition to pandemic contexts, the problem of routine biomedical waste streams persists as a significant ongoing danger. This not only pollutes our groundwater aquifers and kills a host of soil microbial systems essential to maintaining a healthy ecology, but also endangers the occupational clusters waste handlers or sanitation workers, who face already precarious working environments. Why does this matter legally? India's environmental governance is grounded in constitutional provisions. The right to a life (Article 21), A set of judicial pronouncements on the right to live/go to, over decades upon decades have expanded Article 21 into an eco-protection framework. Article 48A, State shall endeavour to protect and improve the environment; Article 51A(g): To protect and improve the natural environment including forests, lakes, rivers and wild life and to have compassion for living creatures. As it stands, even as constitutional ideals muddy the ground-level implementation. The issue is not just whether laws can be designed, it is an even more important challenge of institutional capacity, coherent enforcement and co-ordination within push-pull related but fragmented governance mechanisms.

The objective of this review is to do a critical analysis of India's biomedical waste regulatory regime not as an act to applaud the legislative detail, but rather engage with why extensive regulations often result in variable compliance. The evolution of regulation from 1998 onwards is shown in Table 1, and the contemporary baseline derived for the study is based on the 2016 Rules. It analyses institutional mechanisms, pinpoints the failure to implement apparent policy learning revealed in government reports and academic literature, and suggests legally grounded recommendations. The methodology employed here is doctrinal, involving systematic analysis of constitutional provisions, statutes, rules, judicial decisions, other government reports (especially CPCB assessments), and peer-reviewed scholarship published mostly between 2018–2026. Such an approach does not frame the governance of biomedical

waste through a comparative international lens. Instead, it locates that governance perpetually within India's specific constitutional, institutional and economic contexts. The paper covers a wide range of healthcare establishments, including hospitals, clinics, nursing homes, diagnostic laboratories and vaccination centres however it only addresses hazardous waste management in general terms while focusing on biomedical waste streams. The paper unfolds as follows: Section 2 outlines regulatory evolution; Section 3 provides a critical analysis of both substantive legal and institutional frameworks, assisted by Table 2, which summarizes key features of the 2016 Rules; Section 4 examines implementation gaps; recommendations are made in Section 5 (with reference to Table 3); and, finally, Section6 synthesizes findings around imperatives for good governance of institutions.

## 2. EVOLUTION OF THE LEGAL AND REGULATORY FRAMEWORK FOR BIOMEDICAL WASTE MANAGEMENT IN INDIA

Biomedical waste governance in India developed unevenly, often in reaction to crises and public protests rather than through thoughtful foresight. The constitutional foundations preceded decades of specific legislative focus.

### 2.1 Constitutional Anchoring

Environmental stewardship was not part of the Indian Constitution in 1950 (when it was adopted). Number 21, on the surface dealing with "right to life," has taken a revolutionary interpretive turn. The Supreme Court in *Subhash Kumar v. State of Bihar* (1991) ruled that right to life includes the right to enjoyment of pollution free water and air. Later judgments explicitly extended this framework to healthcare waste. In *Indian Council for Enviro-Legal Action v. Union of India* (1996) the Court highlighted that states are liable under environmental law due to industrial activity and waste disposal activities. Article 48A provides for protection and improvement of environment by the state; Article 51A(g) imposes corresponding citizen duties. Constitutional scaffolding was created by these provisions, on top of which statutory biomedical waste regulation rested subsequently.

### 2.2 Environment (Protection) Act, 1986: The Foundational Statute

The Environment (Protection) Act, 1986 (inspired from the terrible Bhopal disaster), gave us overarching power in every aspect of environment governance. Section 3 empowers the Central Government to prescribe standards for quality of environment; Section 6 empowers rules to prevent environmental pollution. Importantly, the Act also acts as enabling--rather than prescriptive legislation; it grants rule-making authority to government while setting up various enforcement mechanisms and penalty provisions. This conferring framework had now encompassed biomedical waste management. Early implementation remained minimal. Biomedical waste was nearly unchecked through the 1990s, managed haphazardly within health care organizations with little government oversight. Reports of unsafe disposal including scavengers picking infectious sharps from dumpsites led to understanding and regulation.

### 2.3 Biomedical Waste (Management and Handling) Rules, 1998

In 1998, the Rules were India's first comprehensive biomedical waste regulation. They set requirements for segregation (four colour-coded categories at first), collection and storage protocols, treatment standards, and developed approval processes for the disposal facilities that treat wastes. Hospitals were fined for non-compliance trivial by modern standards but codifying legal liability. In 1998, the framework reflected the contemporary understanding of waste streams. However, implementation was often uneven and particularly inconsistent in small hospitals and rural clinics. Segregation protocols were still not being understood well, treatment infrastructure remained weak and any co-ordination between health authorities and pollution control boards were non-existent. CPCB assessments indicated widespread non-compliance (especially with regard to segregation and treatment standards) by 2010.

### 2.4 Drivers for Regulatory Revision

There were three factors behind the shift to 2016 Rules. Firstly, the changing profile of waste streams such as more used medical equipment and much higher quantities of pharmaceutical products entering the waste stream by virtue of how treatment protocols evolved meant that better classification needed to take hold. Second the normative pressure for tougher standards was shaped by international frameworks (WHO guidelines on healthcare waste, Basel Convention principles on hazardous waste). Third, judicial pressure mounted. National Green Tribunal decisions in cases like *Almitra H. Patel v. Union of India* (2014) criticized inconsistent biomedical waste compliance and mandated regulatory strengthening.

### 2.5 Biomedical Waste Management Rules, 2016: Contemporary Framework

The 2016 Rules replaced 1998 provisions with broadened coverage, improved classification and made provisions for digital audit trails. The revised Rules extended colour-coding from four segregation categories to ten, treatment modalities for different waste types, Authorization by all healthcare establishments and quarterly reporting to the CPCB. For the first time, circular economy principles were incorporated in 2016 Rules that facilitate minimization and recovery of waste. This regulatory evolution is chronicled in Table 1.

**TABLE 1: EVOLUTION OF BIOMEDICAL WASTE MANAGEMENT LAWS IN INDIA**

| Year | Legislation/Regulation | Key Features | Limitations |
|---|---|---|---|
| **1950** | Indian Constitution (Articles 21, 48A, 51A(g)) | Constitutional foundation for environmental protection; right to life includes environmental rights | No specific biomedical waste provisions |
| **1986** | Environment (Protection) Act, 1986 | Umbrella legislation enabling rule-making; penalty provisions up to ₹1,00,000 | Generic framework; lacked biomedical-specific protocols |
| **1998** | Biomedical Waste (Management and Handling) Rules | First comprehensive regulation; four colour-coded categories; authorization mechanism; 48-hour storage limit | Weak enforcement; poor rural compliance; limited CBWTF infrastructure |

| | | | |
|---|---|---|---|
| **2010–2014** | CPCB Assessments & NGT Judgments | National assessments documented 40–60% non-compliance; regulatory strengthening mandated | Persistent gaps despite existing rules; infrastructure deficits identified |
| **2016** | Biomedical Waste Management Rules, 2016 | Expanded to 10 colour categories; mandatory Authorization for all generators; quarterly CPCB reporting; digital tracking protocols; circular economy principles | Implementation challenges persist; 2018/2019 amendments tightened plastic and pharmaceutical waste protocols |
| **2020–2024** | COVID-19 Emergency Guidelines & Post-Pandemic Adaptations | Emergency protocols for pandemic surge; temporary relaxations for healthcare facilities | Elevated waste volumes continue; infrastructure expansion required |

**Source:** Biomedical Waste Management Rules, 2016; CPCB Assessments (2022–2023); MoEFCC Notifications.

### 2.6 Post-2016 Amendments and Notifications

The two important amendments that altered 2016 rules. However, in light of single-use plastic issues, the 2018 Amendment established tougher provisions on plastic waste management. The 2019 Amendment tightened the specification on chemical waste treatment and improved pharmaceutical waste protocols. COVID-19 pandemic led to emergency protocols (2020), which aimed at relaxing some of the requirements in order to face the sharp rise of biowaste while guaranteeing safety standards.

### 2.7 Integration with Related Regulatory Frameworks

The governance of biomedical waste does not exist in isolation. Broad waste management principles are covered in the Solid Waste Management Rules, 2016; plastic components of biomedical waste within the Plastic Waste Management Rules, 2016; and Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 regulate hazardous chemical components. The regulatory plurality breeds both comprehensiveness and complexity as overlapping jurisdictions in multiple agencies risk coordination failures.

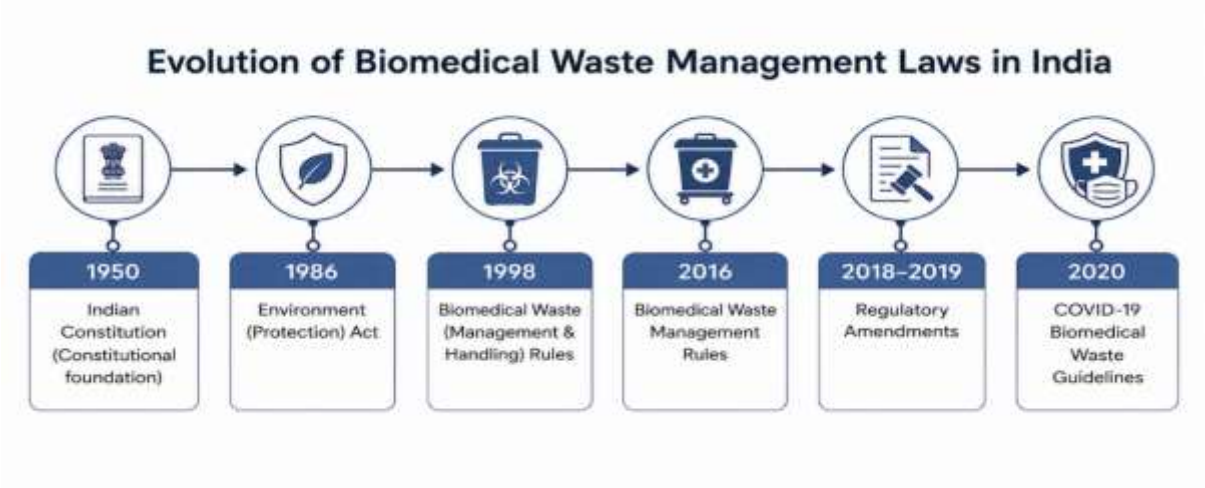


Figure 1. Evolution of the legal framework governing biomedical waste management in India.

### 2.8 International Influence

Indian regulatory thinking with respect to treatment technology standards has been shaped by WHO recommendations on health care waste, mainly the 2014 WHO Compendium of technologies for safe management of clinical waste. India imitated Basel Convention principles regarding the international transboundary movement of hazardous waste in formulating regulations and other governing devices pertaining to the export of biomedical waste. Introduction Sustainable Development Goal 3 (Good Health and Well-being) SDG-3 and SDG 12 (Responsible Consumption and Production) established normative frameworks for the health sector to minimize healthcare waste while ensuring environmental sustainability. However, the evolution of Indian regulation illustrated qualitative adaptation to local circumstances rather than blanket global imitation. Given the constraints of rural health facility infrastructure, the economic characteristics of smaller establishments and the required capacity deficits, standards needed to be nuanced according to birthsetting size and volume.

## 3. CRITICAL ANALYSIS OF THE EXISTING LEGAL AND INSTITUTIONAL FRAMEWORK

### A. SUBSTANTIVE LEGAL FRAMEWORK

### 3.1 Scope and Applicability

The 2016 Rules cover "every person" producing biomedical waste, specifically including hospitals, nursing homes, clinics as well as diagnostic laboratories, blood banks and vaccine centres and includes veterinary units along with research institutions. In practice, this broad definition potentially includes fragmented healthcare delivery a concern in India given its numerous unregistered informal practitioners who fall outside regulatory oversight. The Rules' definition of biomedical waste encompasses ten categories: (1) yellow anatomical waste; (2) red infectious waste; (3) white non-hazardous waste; (4) black general waste; (5) blue pharmaceutical waste; (6) green compostable waste; (7) radioactive waste; (8) chemical waste; (9) waste sharps; (10) pressurized containers. This categorisation theoretically enables differentiated treatment matching waste characteristics. The initial critical step remains the primary implementation failure point.

### 3.2 Segregation and Colour-Coding Requirements

Under the Rules, waste has to be segregated at the point of generation which means that healthcare workers will have to separate waste as soon as it is produced. The quality of segregation is a key determinant of treatment and occupational safety. Any contamination of recyclables at this point mixing infectious and non-infectious waste significantly complicates treatment and incurs high costs. Monitoring programmes by CPCB report that only a few (40–50%) of healthcare establishments exhibit either partial or inconsistent segregation. Why does this continue to happen despite clear regulatory guidance? One, the warning system is still poorly understood among healthcare workers with basic staff not even sufficiently trained to conduct segregation. Second, healthcare institutions hardly get any direct advantage of proper segregation (the benefits go primarily to waste handlers and environmental safety); costs are immediate

and visible. Third, enforcement is still inconsistent inspections conducted randomly rather than performed systematically suggest a low risk of non-compliance.

**TABLE 2: KEY FEATURES OF THE BIOMEDICAL WASTE MANAGEMENT RULES, 2016**

| Requirement | Specification | Compliance Rate (Evidence) |
|---|---|---|
| **Waste Segregation** | 10 colour-coded categories at point of generation | 40–50% adequate; rural clinics 35–40%; urban hospitals 70–75%[17] |
| **Collection Frequency** | Yellow/Red: daily or twice-daily; Blue: weekly; Green: daily/alternate day | 60–65% compliance; transport delays documented[18] |
| **Storage Duration** | Maximum 48 hours normal; 72 hours cold storage | 45–55% compliance; violations common in small facilities[19] |
| **Transportation** | Designated vehicles; sealed colour-coded containers; driver training | 50–60% compliance; inadequate vehicle maintenance common[20] |
| **Treatment Standards** | Yellow/Red: Incineration 800°C+; Blue: Chemical/Incineration; Green: Composting/Landfill | Infrastructure adequate urban areas; 40% CBWTFs lack advanced emission controls[21] |
| **Authorization** | All generators must obtain SPCB Authorization; valid 3 years | 15–20% small facilities operate without authorization[22] |
| **CBWTFs** | State-mandated regional facilities; serve 50–100 healthcare establishments | Metro cities 85–90% coverage; tier-2 cities 40–50%; rural 20–30%[23] |
| **Record Maintenance** | Waste generation logs; segregation records; staff training documentation | 70–75% maintain basic records; quality varies[24] |
| **Quarterly Reporting** | Facilities report volumes, treatment details, compliance status to CPCB | 80% submit reports; 20–30% data discrepancies documented[25] |
| **Penalties** | Warnings (first violations); ₹50,000–₹1,00,000 fines; facility closure; imprisonment up to 5 years | Penalty against ~5–8% violators; closures rare; prosecutions exceptional[26] |

**Source:** Biomedical Waste Management Rules, 2016; CPCB Compliance Assessments (2023).

### 3.3 Collection, Storage, Transportation, and Treatment

The Rules regulate the frequency of collection (yellow and red waste are to be collected on a daily or twice-daily basis according to volume), storage times (maximum 48 hours at normal temperatures; 72 hours in cold conditions) and transportation, including containerization standards and vehicle types. This separation occurs based on the types of waste: incinerated (infectious and anatomical), chemotherapeutic or autoclave (certain pharmaceutical wastes), burial in landfills (non-hazardous, following specification). Transportation represents particular vulnerability. Waste must be transported in properly labelled, sealed containers by permitted transporters from healthcare facilities to the treatment site. But it appears that documenting a number of vehicle maintenance failures, driver training shortcomings and cases where biomedical is loaded with general municipal waste while in transit. Within transport, the segment functions almost as a "black box" with far less oversight than most non-coal power generation segments. Treatment standards themselves proved adequate when implemented. Incineration at temperatures exceeding 800°C effectively renders infectious material non-hazardous. Yet infrastructure constraints mean many facilities lack access to quality treatment infrastructure. A 2022 CPCB survey identified

substantial gaps in CBWTF coverage, particularly in smaller cities and rural areas where 2–5 healthcare facilities depend on single treatment facility, often located 30–50 kilometres distant.

### 3.4 Authorization and Compliance Requirements

All the healthcare facilities involved in the generation of biomedical waste were to be registered with State Pollution Control Boards as per 2016 Rules. Authorization is predicated upon adequate segregation infrastructure (eg, storage capacity, sufficient staffing to deploy necessary training protocols and access to authorized treatment facility). Program Facilities must keep at least one copy of the authorization certificates and display them prominently. In theory, authorization ties accountability to enforcement facilities could be executed if they do not meet standards. However, even the processes for authorizations are worn down in an administrative capacity. CPCB reports reveal authorisation backlogs in many states; smaller units function for years without formal authorisation with virtually no action being taken. [35]In many cases, the state pollution control board lacks the capacity to administer such programs northeastern and low-income states may not have the resources of more affluent areas and even though it may take time to process applications expeditiously or conduct inspections that mean something.

### 3.5 Monitoring, Reporting, and Record Maintenance

Healthcare facilities would have to keep detailed records of waste generation volumes, segregation practices, details of treatment facilities, staff training logs and incident reports (such as spillages or unauthorised disposal). Quarterly reports to State Pollution Control Boards record the compliance. The Rules nevertheless require CPCB to report at the state-level on an annual basis, clustering data from individual facilities. Record maintenance functions as compliance proxy facilities maintaining detailed documentation demonstrate commitment to regulatory adherence. But documentation so often becomes ritualized (for regulatory purposes rather than reflecting actual change). There are countless problems with data quality in aggregated reporting; there was a particularly notable discrepancy between volumes of waste reported by facilities compared to the CPCB assessment, suggesting widespread under-reporting of these volumes.

### 3.6 Penalties and Enforcement Mechanisms

The Rules establish penalty provisions under the Environment (Protection) Act, 1986. Violations can result in: (1) warnings for first minor violations; (2) closure of non-compliant facilities; (3) financial penalties ranging from ₹50,000 to ₹1,00,000 for individual violations; (4) criminal liability for severe breaches including unauthorized waste disposal. Penalty provisions are substantive, but enforcement is patchy. CPCB data has shown that formal closure is very rare and reserved for extreme cases of pollution. Financial penalties, if and when imposed, often end up being subsumed within facility budgets as operational costs rather than driving changes to behaviour. Criminal Enforcement: Prosecutions for criminal violations are still extremely rare, mostly brought to light after the media steps in or following an environmental disaster.

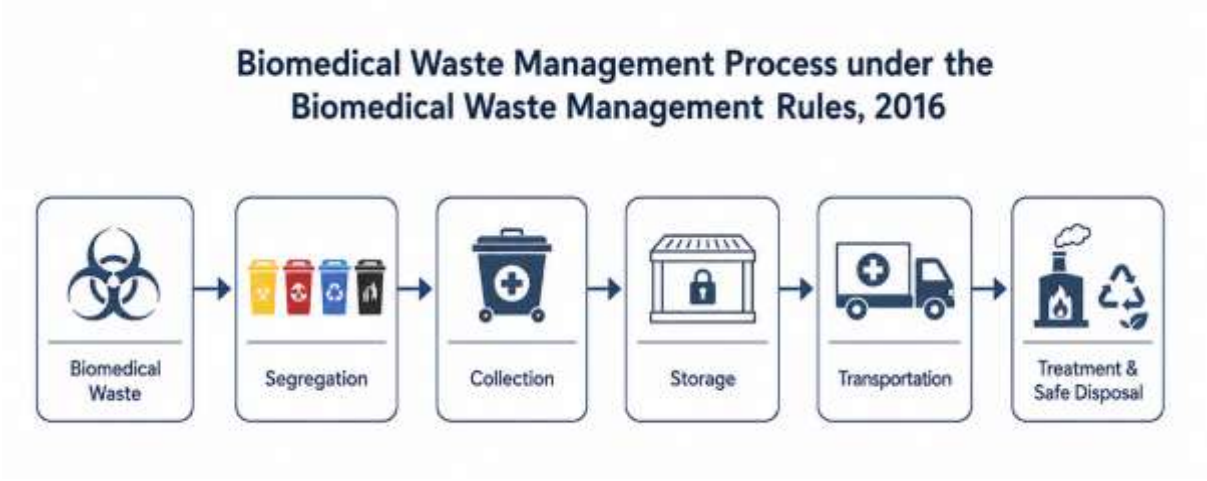


Figure 2. Operational workflow for biomedical waste management under the Biomedical Waste Management Rules, 2016.

## B. INSTITUTIONAL FRAMEWORK

### 3.1 Ministry of Environment, Forest and Climate Change (MoEFCC)

The MoEFCC serve as an apex policy body that formulates rules, guidelines and monitoring mechanism. It works with the Ministry of Health and Family Welfare on aspects relevant to healthcare; however, coordinated efforts have been somewhat limited. MoEFCC delegates significant functional powers to the CPCB and State Pollution Control Boards, with most of its central role remaining in policy making and oversight. It is this quasi-delegation which breeds organisational efficiency, but also seeps accountability.

### 3.2 Central Pollution Control Board (CPCB)

Role of CPCB as the National Technical Authority, (i) technical standards definition, (ii) assessment of compliance at the state level, (iii) providing technical assistance for SPCBs and (iv) collating national-level data on biomedical waste management. CPCB has a regular national survey to estimate waste generation, treatment infrastructure and compliance behaviour. These surveys fill important data gaps associated with the implementation shortfalls described in this paper, but they cannot provide real-time accountability since their frequency is infrequent (generally including every 3–5 years). The CPCB has a modest technical capacity, but it’s limited. National-level monitoring, with not-without-all field staff available to them, relies heavily upon reporting at the state level along with asymmetries in information. Though CPCB serves a role in advisory towards SPCBs, it does not have direct enforcement authority which caps its corrective capacities.

### 3.3 State Pollution Control Boards (SPCBs)

The primary implementer of SPCBs is composed of: (1) authorizing facilities; (2) inspections, monitoring; (3) penalties kinds studied in the field together with (4) documenting data on hazardous waste management at the state-level. The capacity of SPCBs differ greatly from state to state. States with greater resources (Delhi, Maharashtra, Karnataka) have strong inspection regimes and adequate technical capacity. Small, under-resourced states (especially in the Northeast) have major capacity limitations, little technical expertise and almost zero training budgets. This leads to regulatory fragmentation in fact pattern. In states with higher general capacity, its health-care facilities are monitored in a systematic manner while

in states with lower general capacity, the reverse is true. An identical healthcare facility in a tier-2 city might experience an annual audit; whereas, in a rural setting they might only receive scrutiny once every 3–5 years.

### 3.4 Healthcare Establishments

Healthcare facilities have overall culpability with respect to segregation, pre-treatment and waste management protocols. However, it is still unclear how burden-sharing should take place among smaller entities. Another requirement for achieving compliance is lack of propriety staff members within nursing homes or smaller clinics who are fully dedicated to waste management. For larger hospitals, professional waste managers are more common; for smaller facilities, waste processing falls instead upon general staff with limited training. The regulatory incentives for healthcare facilities are still wrong. Biomedical waste management also raises the operational costs for facilities as it does not generate revenue. On the other hand, non-compliance usually has low monetary financial-related impact in terms of operational costs. And this cost-benefit calculus is precisely what incentivizes corners-cutting.

### 3.5 Common Biomedical Waste Treatment Facilities (CBWTFs)

CBWTFs theoretically address infrastructure constraints by providing regional treatment capacity for multiple smaller facilities unable to individually afford treatment infrastructure. Although CBWTFs have been established through the 2016 Rules in India allowing for planning at the state level for facility coverage. Still, CBWTF expansion has not taken a linear path. Urban areas continue to have a reasonable coverage of CBWTFs, but rural areas are still far from the point of saturation. CBWTFs face doubts regarding sustainability as well. The treatment makes little revenue, with facilities relying heavily on municipal subsidies financing or cross-subsidisation from alternate waste streams. Insufficient subsidies lead to many CBWTFs operating below capacity, making their cost per unit of treatment higher and creating a perverse incentive to under-report waste volumes.

### 3.6 Local Authorities

Municipal corps/rural local bodies have only a policy role and are even at the borderline of managing general municipal waste streams in biomedical waste governance. Their role in biomedical waste management is still restricted, and they primarily identify site for CBWTFs while coordinating solid waste collection systems of municipalities. Potentially Better local authority engagement could build stronger compliance ensuring proper segregation and transport especially but the present remains in its infancy.

## C. ASSESSMENT OF EFFECTIVENESS

Has the legal framework achieved intended protective outcomes?

### 3.1 Compliance Improvement

Also, compliance after 2016 Rules improved greatly compared to the period of1998–2015. Segregation practices enforced; facility approval granted; validity of CBWTF coverage increased. Yet "improvement" requires qualification. A recent 2023 assessment by the CPCB provided the evidence that about 60–65% of surveyed facilities were effectively practising segregation an improvement but far from full

compliance. Compliance rates were lower at rural (45–50%) than urban establishments (70–75%). The variation of compliance is closely related to the scale and location of the facility. In large urban hospitals (500+ beds), compliance is > 85%, but in smaller rural clinics often ranges from 30–40%. This bifurcation indicates that regulatory framework can function well for an institutional actor endowed with necessary resources, a reasonable infrastructure and satisfactory technical capacity but fails in case of establishments constrained by sheer resource scarcity.

### 3.2 Environmental Risk Reduction

Biomedical waste continues to contaminate the environment despite regulations. A study from 2021 in *Environmental Research* showed heavy metal pollution of groundwater around disposal sites across several Indian cities, pointing to incomplete incineration or landfill confinement. Likewise, studies from medical colleges in Delhi and Bangalore confirmed that they could find antimicrobial-resistant bacteria in hospital waste streams, showing continued infection risks. However, identifying the causal role of regulatory frameworks is still a challenging normative effort. Because the uncontaminated medium is relatively rare (as we are all too aware), it should not be accepted that any single causal factor, and certainly not gross failure of approach by private interests or local authorities can be allowed to pass, so founding agents mask culpability in that contamination comes about from a death by a thousand cuts: treatment technology, segregation failures; ineffective containment in landfills.

### 3.3Accountability Enhancement

This is what gives the regulatory framework its nominal strength in terms of accountability: (1) authorization mechanisms that put responsibility in traceable places; (2) reporting requirements that create documentation and (3) penalty provisions that enable enforcement. Yet documented enforcement remains inconsistent. CPCB annual Report data reveals only 5–8% of non-compliant facilities identified in inspection subjected to penalty. Closures are even rarer still, happening usually only as a result of court order or press coverage. This enforcement inconsistency undermines accountability. Facilities can anticipate that non-compliance carries manageable consequences perhaps a warning or modest financial penalty. Conversely, full compliance requires sustained investment in segregation infrastructure, staff training, and treatment arrangements. The cost-benefit calculus favours non-compliance or partial compliance.

## 4. EMERGING CHALLENGES AND IMPLEMENTATION GAPS

However, regulatory comprehensiveness has not resulted in effective governance. This results in a persistent failure of implementation that can be understood as the intersection of multiple factors. Table 3 (in below) summarizes key implementation barriers and relevant legal reform proposals.

**TABLE 3: MAJOR IMPLEMENTATION CHALLENGES & RECOMMENDED REFORMS**

| Challenge | Evidence | Root Cause | Recommended Reform | Timeline |
|---|---|---|---|---|
| **Weak Enforcement** | 1–2 inspections/year in resource-constrained | Limited SPCB capacity; reactive inspection model | Increase field staff; random inspections targeting 30% | 12–24 months |

| | | | | |
|---|---|---|---|---|
| | states; <5% detection for minor violations | | facilities annually; third-party audits for facilities >100 beds | |
| **Inconsistent Compliance** | Large hospitals 85%+ compliance; small clinics 30–40%; 15–20% lack Authorization | Resource disparities; informal sector (65% of practitioners) unregulated | Differentiated standards by facility size; financial incentives (tax breaks, fee waivers) for compliant facilities | 18–24 months |
| **Rural Infrastructure Gaps** | 40% of facilities in rural areas; 20–30% lack CBWTF access; transport 50–100 km+ | Geographical dispersion; inadequate CBWTF network; rigid urban-designed standards | Government-subsidized CBWTFs in rural clusters; mobile treatment units; permit 72-hour storage with cold storage | 36 months |
| **Inadequate Treatment Infrastructure** | Metro 85–90% CBWTF coverage; tier-2 cities 40–50%; rural 20–30%; 40% CBWTFs lack emission controls | Uneven investment; municipal budget constraints; financial viability issues | National CBWTF Master Plan; mandate advanced incineration technology; viability gap funding (government subsidies) | 24–36 months |
| **Training Deficiencies** | 60% nursing staff, 75% support staff received no formal training; <2% medical curricula time allocated | Education system gaps; training low-priority; no certification standards | Mandatory biomedical waste curriculum (20 hours) in medical/nursing programmes; facility annual training requirement; central certification institute | 18–24 months |
| **Financial Constraints** | Treatment costs ₹50–200/kg; small facilities cannot absorb; 2–4% margin reduction from compliance | Framework imposes obligations without compensation; no revenue from waste management | Government cost-sharing (40–60%) for facilities <100 beds; graduated authorization fees; 50% tax deduction on waste management expenses | 18–24 months |
| **Pandemic Surge** | COVID-19: 300–500% waste surge; CBWTF capacity overwhelmed; inadequate disaster preparedness | Single-event infrastructure design; emergency protocols not integrated permanently | Pandemic preparedness protocols in permanent regulations; require CBWTFs maintain 30–40% excess capacity; pre-established emergency authorization procedures | 12–18 months |
| **Unregulated Sources** | 15–20% biomedical waste from home healthcare, private diagnostic labs, informal clinics | Framework focuses on institutional settings; rapid growth of informal delivery | Extend regulation to home healthcare providers; formalize standalone diagnostic labs; incentivize informal clinic registration | 18–36 months |
| **Poor Digital Tracking** | Large hospitals 85% adoption; small clinics <20%; no standardized platforms; state-level system fragmentation | Technology adoption costs; IT infrastructure gaps; no mandatory requirement | Expedite National Digital System (government-funded); mandate digital reporting for facilities >50 beds within 18 months; phased rollout for smaller facilities | 18–24 months |

| | | | | |
|---|---|---|---|---|
| **Inter-Agency Coordination Failures** | Health-environment ministries minimally coordinated; state health-SPCB coordination weak; facility planning silos | No formal coordination mechanism; conflicting ministry incentives | Establish National Biomedical Waste Governance Authority (CPCB-based, Health Ministry representation); state-level coordination committees; integrated facility planning | 12–18 months |

**Source:** CPCB Compliance Gap Analysis (2023); MoEFCC Implementation Reviews; NGT Decisions (2018–2024).

### 4.1 Weak Enforcement and Monitoring

Enforcement tends to be reactive rather than proactive. Under-resourced SPCBs typically conduct 1–2 facility visits per inspector every year, and limited inspections are only conducted when resources allow. This corresponds to well-nigh certainty of undetected detection in very minor offenses. It could take months for a healthcare facility to fail on segregation without coming up on the inspection radar. Detection probabilities end up so low that a rational facility manager could compute virtually zero meaningfully expected penalty costs from non-compliance to such regulations. Data quality issue with monitoring data itself. Facilities report the volumes of waste self-reported; CPCB has little independent verification ability. Periodic surveys conducted by the CPCB have shown systematic differences between waste volumes reported and what is estimated based on facilities surveyed indicating under-reporting in the range of 20–30%.This results in blind spots actual waste generation and disposal practices are still insufficiently documented, restricting evidence-based policymaking.

### 4.2 Inconsistent Compliance Among Healthcare Establishments

Institutions, their capacity and access to resources reflect in compliance patterns. In fact, large hospitals in metropolitan cities have dedicated biomedical waste managers and sophisticated segregation protocols along with good quality treatment facility. In contrast, small rural clinics run by individual physicians or small partnerships often lack even minimal waste management infrastructure. This divide shows the trends of Indian healthcare fragmentation at a larger scale. Around 65% of India's healthcare delivery takes place through private practitioners, a lot of them operating informally as unregistered establishments. The nature of regulation also differs, with a predominant reach to registered facilities and informal health care delivery existing entirely outside regulatory oversight.

### 4.3 Rural and Small Healthcare Facilities

Around 40% of India's healthcare infrastructure is situated in rural areas; however, compliance rates are largely lower than expected. Rural PHCs, private clinics, and rural nursing homes often do not have: (1) segregation infrastructure; (2) storage facilities; and (3) access to appropriate treatment infrastructure. The closest CBWTF may be 50–100 km away, resulting in transport logistical issues. Coarse regulatory standards made for urban facility profiles turn out not to be operationally viable in a rural context. Explanatory scope: A regulation stating that waste must be treated within 48 hours presumes the existence of a nearby treatment facility; e.g. a rural clinic without transport may need 3–5 days in order to transfer

their waste to a facility more than an hour away. Rather than sparking compliance, inflexible regulatory requirements become nearly impossible to meet.

### 4.4 Infrastructure and Capacity Constraints

Treatment infrastructure remains geographically uneven. Usually, 3–5 CBWTFs would be present in metro areas; while many cities with population of 100,000–500,000 have no or only one facility with limited capacity. These bottlenecks; these health care facilities become holding stations of waste awaiting treatment, exceeding storage duration, and increasing the risk to safety. CBWTFs use low-technology incineration technology many furnaces do not have contamination control systems. The post-treatment residue incineration ash must go to a landfill, but suitable hazardous-waste landfills are still in short supply. Others are simply a disposal intermediary you create and pass the problem instead of solving it.

### 4.5 Capacity Building and Training Deficiencies

Understanding of segregation protocols, treatment procedures and safety measures by staff is the basis for regulatory compliance. However, healthcare professional training is still insufficient. In 2022, Indian Nursing Association performed a survey and reported that around 60% nursing staff were not given any biomedical waste management training; and more than 75% of general support staff had received none. This reflects systematic training gaps. Very little emphasis is put on biomedical waste management in both under graduate and post graduate medical curricula. This domain is similarly poorly addressed in nursing education. Management of waste is rarely covered in continuing medical education. Healthcare facilities are said to bear the burden of purposefully training workers, yet many lack resources or experience in meaningful training.

### 4.6 Financial and Administrative Limitations

Effective and efficient biomedical waste management is a financial concern, especially for small health care establishments. Infrastructure for segregation, as well as storage and treatment solutions and personnel training, require capital must be invested regularly. In the case of less-resourced facilities that run on narrow margins, financial resource allocation to the management of biomedical waste competes with core service delivery providing medical services. Needless to say, the regulatory framework imposes obligations without compensatory financial support. The larger establishments cover their costs via service charges; the smaller facilities simply cannot shift costs to patients this way. This creates the worst incentive structure ever, this means that there is no obligation to invest in compliance.

### 4.7 Pandemic-Related Surge and Management

COVID-19 pandemic exposed systemic vulnerabilities. In some facilities, the generation of biomedical waste reached 300–500%, as there was an exponential increase in PPE usage and increasingly accumulating test samples leading to so much medical waste being generated. The vast majority of CBWTFs operate for baseline load but were inundated with volume surges. Temporary garbage accumulation emergencies occurred in several cities medical waste piled up due to the overload of recycling mechanism. Pandemic netted the waiving of some emergency protocols-such as the use of

single-use plastic, incineration when normally an alternative treatment were required. Following pandemic decline, volumes of waste are still above 2020 pre-pandemic baseline, which continuously puts pressure on treatment capacity.

**4.8 Unregulated Biomedical Waste Sources**

Regulatory framework focuses on institutional healthcare delivery. Yet biomedical waste generation occurs increasingly outside formal healthcare settings. Home healthcare nursing care, dialysis, insulin administration conducted in residential settings generates biomedical waste remaining entirely unregulated. Diagnostic laboratories increasingly operate as standalone entities; many remain insufficiently supervised. Private diagnostic clinics frequently generate pathological waste managed informally. A 2021 study estimated that approximately 15–20% of total biomedical waste originates from non-institutional sources, remaining largely outside regulatory control. This represents substantial governance blind spot.

**4.9 Digital Tracking and Monitoring Challenges**

The 2016 Rules provide for digital tracking facilities must use barcoding or go digital to monitor waste from generation until treatment. Implementation has proven inconsistent. While many of the larger urban facilities keep adopting digital systems, the smaller ones still write them down by hand. We still do not have standardized digital platforms that allow for real-time monitoring. States use different reporting systems, preventing seamless tracking at the national level. National Digital Biomedical Waste Management System- Proposed by CPCB but only partially implemented (as of 2024). The full operationalisation would allow real time monitoring, itself reducing information asymmetries between facilities and regulators. But it is technically difficult, often expensive and has institutional coordination challenges.

**4.10 Inter-Agency Coordination Deficiencies**

The agencies involved in the governance of biomedical waste include multiple ministries (Ministry of Health, Ministry of Environment), State Pollution Control Boards (SPCBs), healthcare authorities and city municipal corporations. Coordination mechanisms remain underdeveloped. Inter-ministerial coordination between Ministry of Health (MoH) and MoEFCC are scanty, state health departments having very limited coordination with SPCBs in terms of these waste management protocols. That leads to silos health authorities are much more concerned with delivering treatment than in the final outcome of disposal. Occasional conflicts emerge. Health departments may recommend the expansion of facilities, but then do not provide the necessary infrastructure for waste management; environmental authorities mandate regulations without considering the constraints in healthcare service delivery. Systematic inter-agency cooperation would find synergies; its absence creates friction.

# 5. RECOMMENDATIONS FOR STRENGTHENING BIOMEDICAL WASTE GOVERNANCE

Provide an integrated framework to address the institutional, technical and behavioural dimensions of biomedical waste management. Legislative amendments alone are ineffective, it requires new governance structures to drive meaningful change. The recommendations discussed here (see Table 3) tackle implementation obstacles with tangible solutions.

### 5.1 Strengthening Enforcement Mechanisms Through Probabilistic Accountability

Based on inspection, non-detection of minor violations is near-certain at present. There are a few approaches worth considering: (1) random unannounced inspections increase detections; (2) periodic third-party audits by accredited auditors lessen the burden on SPCB resources; (3) financial incentives for compliance in the form of tax breaks or certification benefits create positive assumptions into risk mitigation not solely based on avoidance of penalties and finally, (4) mandatory reporting of incidents requires facilities to report their failure to manage bad waste independently from detection by regulators, thus shifting the accountabilities from detection by regulators to disclosure at the facility.

### 5.2 Expanding and Strengthening Common Biomedical Waste Treatment Facility Network

Indicate geographic gaps in availability of facility at national and subnational level; to ensure that all healthcare facilities are within 30km of a CBWTF, targeted investment in infrastructure should be made. Potential investment mechanisms are as follows: (1) government capital subsidy for construction of facilities in under-resourced areas; (2) viability gap funding to ensure financial sustainability; or (3) mandatory shared facility arrangements, where clusters of health care facilities located in geography with limited waste volume would be required to develop and share new facilities. Modernize CBWTF technology, Incineration systems should integrate high-end emission control technologies satisfying international benchmarks Post-treatment residual management (ash disposal) must be planned systematically, with large size of hazardous waste land-filling capacity.

### 5.3 Institutional Coordination Through Integrated Governance Structure

But that fragmentation of governance should not go unaddressed; it can only reduce coordination between the various venues formally. Such a task could be undertaken by national biomedical waste management authority (possibly within CPCB but with representation from Ministry of Health) to coordinate across health and environment sectors. Inter-department committees would specify accountability and define areas of responsibility for each department, formalising state-level coordination. Sustaining coordination is critical for health authorities to factor waste management into facility planning and operation.

### 5.4 Capacity Building and Training Integration

Regulatory compliance presupposes staff comprehension as a paramount requirement. Redesigning training architecture : (1) biomedical waste management should be a compulsory chapter in the undergraduate medical and nursing curricula; (2) intentional credits for attending workshops or trainings on biomedical waste management; (3) facilities level training programs with government facilitation

where every staff (medical, nursing, support.) is trained uniformly once a year; and (4) certification programs for biomedical waste managers to form credential-based full-fledged professional identity. Focus on practical implementation considerations, not on abstract regulatory requirements, so that training ultimately results in operational change.

## 5.5 Differentiated Regulatory Standards by Facility Type

The heterogeneity of the healthcare landscape renders uniform regulatory standards operationally infeasible. Differentiated standards should be: (1) major urban hospitals (500+ beds): strict requirements, mandatory monitoring of results on an ongoing basis with annual audits; (2) mid-sized establishments (100–500 beds): moderate requirements, monitoring biennially; and finally,(3) smaller-sized facilities and clinics (< 100 beds): easier tailored or adapted novel requirements for compliance to include pragmatic triennial monitoring by certifying agents also financially resourced to better facilitate compliance. It recognises the inequity of resources yet prevents devastating safety outcomes. The low bar requirements for small facilities could be permission to accumulate waste for 72 hours (instead of accepted 48) if the conditions in which it is stored are adequate, reimbursement for transportation through informal arrangements, and proceed with using government-associated subsidized treatment slots at CBWTFs.

### 5.6 Digital Monitoring and Real-Time Accountability

Implementation of the National Digital Biomedical Waste Management System to be fast-tracked. Platform must support: capacity of facility to self-report on generation, volumes and treatment arrangements; (2) timely data aggregation for SPCB monitoring; (3) auto-alerts to noted violations (e.g., exceeding storage duration); and (4) public transparency dashboard comparing performance across facilities. Digital systems reduce monitoring burden on SPCB field staff, enabling risk-based inspection targeting high-risk facilities rather than routine inspections.

### 5.7 Incorporating Circular Economy and Waste Minimization Principles

Shift regulatory framework from "treating waste generation" to prevention Possible measures include (1) incentives to minimize waste or authorization fee reductions for the facilities demonstrating reduced waste generation, (2) mandatory waste audits to identify opportunities for decreasing waste generation through the establishment of research priorities in decentralized technologies, (3) promoting house-to-house services and consultations on source segregation of wastes helpful to decrease the cross-contamination reducing landfill use by sharing technological guidelines, and (4) specific strategies for managing pharmaceutical wastes due to poor inventory management that generates disposal of expired medicines. International evidence suggests that effective waste minimisation can reduce biomedical waste generation by 15–25%, while still ensuring a safe level of infection control.

### 5.8 Addressing Unregulated Sources

Biomedical waste is generated more from health care services that are not institutional. The regulatory framework must be expanded to: (1) require registration and basic compliance requirements for home healthcare providers;(2) target regulation and monitoring of private diagnostic laboratories; and (3)

incentivize the formalization of informal diagnostic clinics with simplified compliance pathways. This does not mean that regulation has to be one-size-fits-all simplified requirements could apply to small informal providers, while substantive obligations could apply to institutional actors.

### 5.9 Alignment with Sustainable Development Goals and Circular Economy

Biomedical waste governance, with vaccine-pollution and heath-impacts linkage to SDG 3 (Good Health), SDG 12 (Responsible Consumption) and SDG 13 (Climate Action). This means: (1) quantifying health (occupational health protection, disease prevention) as an outcome of proper biomedical waste management; (2) assessing circular economy outcomes (waste recovery, material reuse); (3) tracking greenhouse gas emissions from treatment technologies; and, finally, (4) integrating climate resilience into facility planning purposefully to address the impact of extreme weather events and pandemics on operationalization of waste management. This integration positions biomedical waste governance within broader sustainability framework, generating political support and resource allocation.

## 6. CONCLUSION

The India biomedical waste management regime has undergone a significant transformation from Biomedical Waste (Management and Handling) Rules, 1998 to the new Biomedical Waste Management Rules, 2016, which provide a comprehensive legal regime and clear guidelines on waste classification, treatment, standards, and institutional responsibilities. But regulation sophistication does not necessarily equate to regulation effectiveness. Difficulties persist in the health system, especially for small and rural health care facilities, such as weak enforcement, insufficient infrastructure, financial difficulties, limited institutional capacity and non-uniform compliance. The differences reflect that the greatest issue is not lacking in legislation, but ensuring governance mechanisms and capacities are enhanced. Institutional strengthening is essential for sustainable biomedical waste management, which can be done by strengthening regulations, raising the amount of funding, improving inter-agency coordination, providing universal staff training, and providing access to treatment infrastructure in an equitable manner. At the same time compliance incentives should be created for resource constrained healthcare establishments along with proportionate regulatory support. India should focus on effective implementation of existing provisions by revamping institutional structures, instead of introducing new laws. This will have a positive impact on environmental sustainability, occupational health and safety, public health and lead to a consistent and equitable protection of the country's comprehensive legal instruments in all healthcare settings.

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## *Cite this Article:*

***Paramita Das and Dr. Manindra Singh Hanspal*," *Legal and Regulatory Framework for Biomedical Waste Management in India: A Critical Review*", *Naveen International Journal of Multidisciplinary Sciences (NIJMS), ISSN: 3048-9423 (Online), Volume 2, Issue 5, pp. 99-120, April-May 2026.***

*Journal URL: https://nijms.com/*

***DOI:** https://doi.org/10.71126/nijms.v2i5.132*