

CHAPTER 8

Adequacy and Effectiveness of the Regulatory Mechanism

Bio-medical waste management in the healthcare facilities was inadequate. Many of the healthcare facilities (HCFs) functioning in the State had no authorisation from the SPCB. There were shortfalls in the submission of annual reports. The District Level Monitoring Committees did not meet regularly, to monitor bio-medical waste management in the HCFs. Bio-medical equipment were lying idle, as they had been procured without provisioning ancillary infrastructure.

Administration of the Odisha Clinical Establishment (Control and Regulation) Act and Rules made thereunder, was deficient and the Rules and provisions of the Act, were not being complied with, allowing Clinical Establishments to function unauthorisedly, escaping the mandatory conditions and prescribed standards of the Act/ Rules.

8.1 Implementation of Bio-Medical Waste Management Rules

Bio-Medical Waste (BMW), being hazardous, toxic, infectious and even lethal, should not be allowed to get mixed with other municipal waste and needs proper handling. As per the BMW Management Rules, 2016, issued by Government of India, hospitals should ensure that BMW is handled without any adverse effect to human health and the environment. 'Handling' includes collection, segregation, treatment, storage, packaging, transportation, disposal, etc. The State Pollution Control Board (SPCB) is the authority for enforcement of the provisions of the BMW Management Rules. IPHS guidelines and the BMW Management Rules, 2016, stipulate standards for the management of BMW.

Audit observed the following deficiencies, in adherence to the BMW Management Rules, by the healthcare facilities:

8.1.1 Authorisation for generating bio-medical waste and annual reporting

The BMW Management Rules, 2016, require hospitals generating bio-medical waste, to obtain authorisation from the SPCB. Every occupier or operator of a common BMW treatment facility is required to submit an annual report to the SPCB, in the prescribed format, by 30 June every year.

The details of health care facilities (HCFs) functioning in the State and their authorisation, by the SPCB, for generating BMW, along with the status of submission of annual reports, during the period from FYs 2016-17 to 2021-22, are given in **Table 8.1**.

Table 8.1: HCFs functioning in the State

Financial Year	Number of HCFs			
	Functioning in the State	Having authorisation from SPCB	Functioning without authorisation	Submitted annual reports
2016-17	1,766	878	888	716
2017-18	1,775	1,026	749	751
2018-19	1,801	1,228	573	902
2019-20	1,808	1,616	192	1,044
2020-21	1,812	1,669	143	1,069
2021-22	1,819	1,636	183	855

(Source: Data obtained from the Director of Public Health, Odisha)

Audit observed that about 8 to 50 per cent of the HCFs, running in the State, had no authorisation from the SPCB, during the period from FYs 2016-17 to 2021-22. Also, many of the authorised HCFs had not submitted their annual reports to the SPCB regularly. During FY 2021-22, 53 per cent of the HCFs functioning in the State, had defaulted in submission of annual reports.

In the test-checked hospitals, Audit found that four HCFs

¹⁵² had no valid authorisation from the SPCB, as of March 2022, to generate and handle BMW. Authorisation of the SPCB for DHH, Dhenkanal, had expired in March 2022 and had not been renewed further. The application for renewal was pending with the SPCB, Odisha.

Functioning of HCFs without authorisation and non-submission of annual reports to the competent authority, was not in compliance with the provisions of the BMW Management Rules, 2016, which were intended to assure proper treatment and disposal of hazardous/ toxic/ lethal waste, generated from the hospitals.

The H&FW Department stated (February 2023) that the DPH(O) had requested all the districts for doing the needful to get the authorisation in time and to submit the annual reports timely.

8.1.2 Segregation, collection and disposal of BMW

The BMW Management Rules, 2016, require hospitals to segregate different categories of BMW in separate coloured bins, at the source of generation. The waste is to be stored in appropriate colour coded bags, at the point of generation and collected by the Common Bio-Medical Waste Treatment Facilitator (CBWTF), for treatment and disposal, without any adverse effect to the human health and the environment, in accordance with the BMW Rules, 2016, and guidelines issued by Government. The Ministry of H&FW, GoI had also issued Guidelines for management of healthcare wastes, as per the BMW Management Rules, 2016.

Audit observed that:

- Guidelines (Paragraphs 2.3.4 and 2.5) for management of healthcare wastes provided that BMW units were to be established away from the public/ visitors' access, and wastes should not be stored in patient care areas and procedures areas. Contrary to this, the BMW Management unit at DHH, Bhadrak, was located near the Surgery ward and residential

¹⁵² PHC, Ertal; PHC, Indragarh; PHC, Ranjabrodi; PRM MCH

quarters. At CHC, Khariar Road, it was situated near the residential quarters.

There was no dedicated space for BMW management at CHC, Khariar Road and no autoclave¹⁵³ had been provided to the waste handler¹⁵⁴. Bio-medical wastes were treated manually and the treated wastes were dumped in an open nearby space in a residential area. Treated wastes at DHHs of Kandhamal and Nuapada were found dumped without being disposed of.

- Waste generated from disposable items, such as plastic vials, plasters/rods, glass material, urine containers, sputum containers, testing kits, *etc.*, was being dropped into a deep burial pit, meant for human anatomical wastes, at CHC, Tikabali, in departure from the provisions of Schedule-I of BMW Management Rules. This was due to refusal by the outsourcing agency for collecting these solid wastes, for further recycling.
- The BMW workers involved in the handling of BMW at DHH, Sundargarh, had no adequate personal protective equipment, like heavy duty gloves, gum boots/ safety shoes, head caps and splash proof gowns/aprons, for ensuring occupational safety, as required under the Guidelines (Paragraph 5.4).
- BMW management registers, as required under BMW Management Rules, 2016 (Rule 4), were not being maintained in two (Dhenkanal and Nuapada) out of the seven test-checked DHHs.
- In the test-checked MCHs, segregation of BMW, at the point of generation, was not being done properly. Black and red polythene bags, for black and red coloured bins/ containers, were not available at different unit¹⁵⁵, in the test-checked MCHs, as envisaged in the Guidelines (Paragraph 2.2) for BMW management.

All the test checked hospitals had coloured bins for segregation and collection of bio-medical wastes.

¹⁵³ An equipment to treat bio-medical wastes

¹⁵⁴ Persons handling Bio-medical wastes at hospitals

¹⁵⁵ Cytology; Central Laboratory; Emergency (Casualty); Labour room in PRM MCH 23 May 2022 and Maternity Wards III, VI and IV in MKCG MCH, on 13 July 2022



Treated waste dumped in open air inside treatment plant premises at DHH, Nuapada, without being disposed off (1 July 2022)



Treated waste dumped in open air inside treatment plant premises at DHH, Kandhamal, without being disposed off (20 May 2022)



Treated waste stored at CHC, Khariar Road, in open space (23 June 2022)



Recyclable plastic/ solid wastes put into the deep burial pit meant for human anatomical wastes at CHC, Tikabali (6 May 2022)

Thus, BMW management in the test-checked hospitals, was not in conformity with the provisions of BMW Management Rules, 2016.

The H&FW Department stated (February 2023) that video conference had been done to review the status and involve all the health-related staff, involved in waste management, and funds had been provisioned for outsourcing BMW services up to PHC level.

8.1.3 Bio-medical equipment procured and supplied without creating infrastructure

As per the decision of the State Advisory Committee and requisition placed (April 2019) by the Director of Public Health, Odisha, OSMCL had procured (FY 2019-20) 1,753 autoclaves and 1,487 shredder machines, at a cost of ₹52.64 crore, for bio-medical waste management. These equipment were supplied to

healthcare facilities, for treatment of biomedical wastes, generated from the hospitals.

Audit observed that BMW management equipment was supplied to healthcare facilities like DHHs, SDHs, CHCs and PHCs, without provisioning for civil structures and three-phase electricity connections, which were required to make these items of machinery operational. Consequently, these items of equipment were lying idle in the health facilities. During Joint Physical Inspection of the test-checked hospitals, Audit found these autoclaves and shredders lying without installation, due to want of civil structures and three-phase connectivity, even though they had been reported as having been installed by the OSMCL. In MCH, Baripada, also, the shredder and autoclave were lying idle, for want of three-phase connectivity.

These items of equipment were also found lying in the open space, in the premises of some hospitals.



This indicated lack of planning and non-assessment of the operational capability of the healthcare facilities, at the level of Government/ Directorate/ OSMCL, before procurement of the equipment. Non-provisioning of the ancillary infrastructure, required for functioning of the procured autoclaves and

shredders, had led to idling of these items of equipment, acquired at a cost of ₹52.64 crore, for the last two years, at the cost of the State exchequer, as of July 2022, rendering the entire expenditure, unfruitful.

To the Audit query, regarding status of the bio-medical equipment, the Director of Public Health stated (July 2022) that the installation process of the equipment had got delayed due to Covid-19 restrictions, and, to expedite the process of installation, the H&FW Department had transferred ₹103.76 crore, to the Panchayati Raj and Drinking Water Department, for construction of buildings, at PHCs and provisioning of three-phase electricity supply.

The H&FW Department stated (February 2023) that due steps were being taken to instal and functionalise the equipment, along with construction of storage-cum-equipment room. The reply was not tenable, as provisioning of ancillary infrastructure had not been considered before procurement. The Department should fix responsibility on the officials, responsible for such lapses, which had led to unfruitful expenditure, due to idling of equipment.

8.1.4 Disposal of liquid waste

As per the instructions (September 2014) of SPCB, all healthcare establishments, having 100 beds or more, should install an Effluent Treatment Plant (ETP). The ETP was to treat waste water generated from the hospitals.

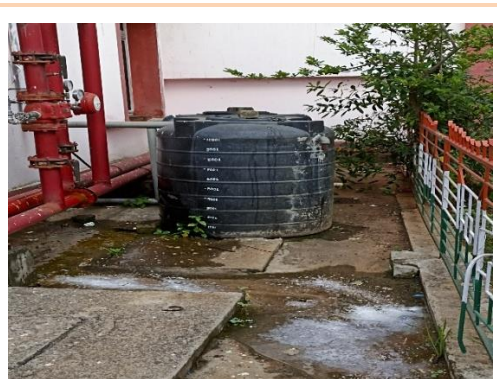
Audit observed that an ETP/ sewage treatment plant, for treatment of waste water generated from the hospitals, had been established only in the DHH, Sundargarh.

ETPs had not been established in the other six test-checked DHHs and MCH, Baripada. These hospitals had to depend on low cost treatment of liquid bio-medical waste, through chlorination in small tanks, to release the effluent to the common sewerage system/ drains. Thus, the effluents were being released into the drains/ sewerage system, after low cost treatment, which was fraught with the risk of contamination of air/ water and spread of diseases to patients and general public.

The H&FW Department stated (February 2023) that establishment of ETPs would be set up in the HCFs during the period from FYs 2022-23 to 2027-28, in phased manner.

8.1.5 Working of District Level Monitoring Committees

The Bio-Medical Waste Management Rules, 2016, provide that the State Government should constitute District Level Monitoring Committees (DLMC), to monitor the compliance of the provisions of these Rules, in the HCFs. The committees were to meet on a six monthly basis and submit their reports to the State Advisory Committee, with copies to the SPCB, for taking further necessary action.



Liquid waste deposit/ treatment tank, using bleaching powder at DHH, Dhenkanal (9 May 2022)

Audit observed that the DLMCs, though constituted at the district level, were not meeting regularly, to oversee the bio-medical waste management in HCFs. The DLMC meetings were held intermittently. It was noticed that no DLMC meetings had been held in four¹⁵⁶ districts, whereas only one DLMC meeting had been conducted in eight¹⁵⁷ districts, during the period from FYs 2016-17 to 2021-22.

Thus, compliance of the provisions of BMW Rules, 2016, was not monitored in the HCFs, leading to deficient bio-medical waste management, as discussed in the preceding paragraphs.

While attributing the reasons for non-conduct of DLMC meetings to the Covid-19 situation, the Director of Public Health, Odisha, stated (March 2022) that all the districts had been sensitised to conduct DLMC meeting regularly.

The H&FW Department stated (February 2023) that all the districts had been sensitised to conduct DLMCs at their level in time.

Recommendation 8.1:

State Government may ensure strict adherence to the BMW Management Rules, in order to provide an infection-free environment in the hospitals.

Recommendation 8.2:

State Government may ensure construction of effluent treatment plants in all DHHs.

Recommendation 8.3:

State Government may ensure creation of the required infrastructure, before procurement of biomedical equipment, so that the procured equipment is made functional, for treatment of bio-waste.

8.2 Clinical Establishment Act

Government of Odisha enacted The Odisha Clinical Establishment (Control and Regulation) Act, 1991 (OCE Act), and framed The Odisha Clinical Establishment (Control and Regulation) Rules, 2018 (OCE Rules), in April 2018, for regulating the establishment and functioning of clinical establishments (CEs) in the State. CEs include nursing homes, physical therapy establishments, clinical laboratories, maternity homes, blood banks, private hospitals, dispensaries, X-Ray institutions or establishments and such other institutions or establishments, as the Director of Health Services may, with the approval of the State Government, specify.

Audit, however, observed the following deficiencies, in the regulation of clinical establishments, by the State:

8.2.1 Grant of registration and renewal of certificate

Section 3(1) of the OCE Act and Rules framed thereunder, requires that persons desirous of establishing a CE are to apply for registration to the supervising authority (DMET), who, after making enquiry and being satisfied about

¹⁵⁶ Cuttack; Deogarh; Ganjam; Malkangiri

¹⁵⁷ Boudh; Dhenkanal; Gajapati; Jharsuguda; Khurda; Koraput; Rayagada; Subarnapur

availability of required facilities, may issue a certificate of registration, valid for two years. Application for renewal of registration is to be submitted before one month of the due expiry date, along with the required fees and such renewal of registration is to be granted after adopting procedure, similar to that of registration.

As per Notification (November 2020) of H&FW department, the DMET, Odisha is the State Level Supervising Authority/ Registering Authority, in regard to clinical establishments, having more than 30 beds, whereas the CDM&PHOs of each district are the supervising/ registering authorities of the concerned districts, for CEs with 30 beds or less.

The OCE Act, 1990 and the OCE Amendment Act, 2016 stipulates that any person who establishes or maintains a clinical establishment in contravention to the provisions of the Act, shall be punishable with fine or imprisonment, or both.

On scrutiny of records and data made available to Audit, it was noticed that, out of 313 CEs, functioning in the test-checked districts, 289 had valid registration, as of March 2022. The remaining 24 CEs were running without valid registration, as shown in **Table 8.2**.

Table 8.2: CEs functioning with valid registration in the test-checked districts

District	Number of CEs registered	Number of CEs having valid registration	Number of CEs without valid registration
Bhadrak	35	32	3
Dhenkanal	48	40	8
Kandhamal	14	14	0
Nabarangpur	17	15	2
Nuapada	8	7	1
Puri	50	40	10
Sundargarh	141	141	0
Total	313	289	24

(Source: Records of the test-checked DHHs)

Audit observed the following in this regard:

- The registration validity of two¹⁵⁸ CEs in the Nabarangpur district had lapsed since March 2021 and October 2021, reminders had been issued to these CEs, by the CDM&PHO, Nabarangpur, for renewal.
- In Nabarangpur district, 21 CEs were functional, without being registered under the Act. Only one CE (Urban Care Home Clinic, Nabarangpur) had applied for registration, which was cancelled by the CDM&PHO, due to deficient manpower. The CDM&PHO, Nabarangpur, had issued show-cause notices to other 20 CEs, repeatedly, during February 2017 to March 2022, for not registering the establishments, under the Act. The action of the authority was, thus, limited to issue of show cause notice only, without taking any stringent action as provided in the Act. Resultantly, these CEs had continued to operate without registration, for years together.
- The Bhadrak Municipality had issued trade licenses to 17 CEs, for running pathology clinics, ultrasound clinics, X-ray clinics, Nursing

¹⁵⁸ Modern Pathological Clinic: Nabarangpur and General Clinic: Panija street, Nabarangpur

homes, etc., without their having been registered under the OCE Act, as per the list, furnished by the DHH. Thus, these CEs had remained outside the purview of the Act.

- Five¹⁵⁹ CEs in the Bhadrak district had no valid registration certificates, due to expiry of the validity period of their existing registrations during October 2016 to November 2021. These hospitals were, however, empaneled under the BSKY, *i.e.* the flagship programme of the State Government to provide cashless treatment to patients. Even after empanelment, the MoUs of these hospitals had been renewed from time to time, even though the CEs had no valid certificate of registration. This indicates the indifference of the concerned registering authorities, in taking action in this regard.
- Applications for renewal of 10 CEs in Puri district, had been returned, as they had not been submitted in the online mode. These CEs were operating, without possessing valid registrations.

Thus, the unregistered CEs had escaped the mandatory conditions/ minimum standards applicable under the OCE Act and Rules.

The H&FW Department stated (February 2023) that the matter would be enquired for checking further irregularities.

8.2.2 Inspection of Clinical Establishments

Rule 6 of the Clinical Establishment Rules, 2018, provides that the Supervising Authority or the Inspecting Authority, shall inspect the CEs, by entering into the premises, as and when required, in the presence of the In-charge of a CE or, in his absence, any other person looking after the affairs and management of the establishment, so as to satisfy himself that the provisions of the Act and the rules, have been duly complied.

Audit observed that the Supervising or Inspecting Officers did not conduct regular inspections, of the CEs, in six out of the seven test-checked districts. Inspection of CEs, was only made at the time of registration/ renewal/ shifting of CEs, or at the time, complaints were received.

In Puri district, 22 inspections were conducted, in addition to the inspections conducted at the time of registration/ renewal.

Further, the State Level Inspection Team, constituted (January 2019) by the department, to inspect CEs once in every three months, had not conducted any inspections, during the period from FY 2019-20 to 2021-22. Details of inspections conducted by the district authorities, were also not available with the DMET.

Thus, inspection of CEs, for ensuring running of CEs, as per the provisions of the OCE Act, was either absent or inadequate, both at the district and State levels. Consequently, compliance to the provisions of the Act/ Rules, by the CEs functioning in the State, could not be assured. Many CEs continued to

¹⁵⁹ Subham hospital (valid up to 31 May 2016); Umashankar Healthcare (valid up to 7 November 2021); Panigrahi Healthcare (valid up to 27 August 2016); Padhi Healthcare (valid up to 15 November 2015); Binayak Nursing Home Private Limited (valid up to 7 October 2015)

function without registration, for years together, as discussed in *Paragraph 8.2.1* above.

The OCE Rules, 2018 provide that the CEs should maintain registers and records¹⁶⁰ and display certificates of registration and renewal thereof, including fire safety certificate, rate charts, *etc.* at conspicuous place for public information.

During JPI conducted by Audit with the staff of the test-checked hospitals, shortcomings, such as non-maintenance of prescribed registers (Medico-legal case register, staff register, *etc.*), non-display of registration certificates/PCPNDT, rate charts, *etc.*, were noticed in 15 out of the 35 CEs, as detailed in *Appendix 8.1*.

The H&FW Department assured (February 2023) that the concerned authorities would be instructed to inspect the running CEs, as per the provisions of the OCE Act.

Recommendation 8.4:

The Health and Family Welfare Department may strengthen the enforcement mechanism and ensure regular inspections, so that all the clinical establishments, functioning in the State, comply with the provisions of the Odisha Clinical Establishment (Control and Regulation) Act and Rules.

Recommendation 8.5:

The Department may initiate disciplinary action against the officials responsible for the laxity, whereby the clinical establishments, which were not registered under the Odisha Clinical Establishment (Control and Regulation) Act, were issued trade licenses.

¹⁶⁰ OPD/IPD patient register; Medico legal register; Register of staff engaged, acquaintance ledgers, *etc.*