CHAPTER VIII

ADEQUACY AND EFFECTIVENESS OF REGULATORY MECHANISMS

A robust regulatory mechanism is essential for assurance that the healthcare system is complying with its statutory obligations and the interest of various stakeholders are protected. In several instances, the regulatory mechanism in the health sector was found to be inadequate. The implementation of Clinical Establishments Act and Rules which, *inter alia*, had the objective of prescribing standards of facilities and services had not progressed much and the objectives remain unachieved. Some blood banks in the State were found to be functioning without licences. The existing bio-medical waste treatment and disposal facilities in the State were under stress and there was an immediate requirement for establishing more such facilities. Radiographic equipment was being utilised in some hospitals without AERB licence.

Regulation is an important function in healthcare sector. The role of regulatory bodies is to protect healthcare consumers from health risks, provide a safe working environment for healthcare professionals and ensure that public health and welfare are served by health programmes.

Regulatory agencies thus monitor individual and corporate healthcare practitioners and facilities, inform the Government about changes in the way the healthcare industry operates, ensure higher safety standards, and endeavour to improve healthcare quality.

8.1. Implementation of the Clinical Establishments Act and Rules in the State

The Clinical Establishments Act was passed (August 2010) by GoI, to provide for registration and regulation of all clinical establishments in the country with a view to prescribe minimum standards of facilities and services.

In line with GoI Act, GoK framed the Kerala Clinical Establishments (Registration and Regulation) Act, 2018 and Rules, 2018 thereunder. The following observations are made with regard to enactment of the State Act and discharge of functions under the provisions of the Act:

8.1.1. Delay in effecting registration

GoK formed (December 2018) a State Council for Clinical Establishments for implementation of the Act and Rules. As per the Act, no person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of the Act and Rules. A total of 6,856 institutions which included 3,748 public and 3,108 private institutions had registered with the Council (March 2022). Audit noticed that 17,122 and 16,922 healthcare facilities functioned in the State as per records of Kerala State Pollution Control Board

(KSPCB) (December 2020) and IMAGE[95] (March 2021) respectively. Thus, the coverage by the State Authority is only approximately 40 *per cent.*

Thus, 60 *per cent* of institutions were not covered even after three years of commencement of registration.

8.1.2. Delay in preparation of minimum standards and not granting permanent registration to clinical establishments

Section 13 of the Act stipulates that different standards shall be prescribed by the Government for clinical establishments of different categories[96] and the Council shall determine within a period of two years from the date of commencement of the Act, the first set of standards for ensuring proper healthcare. The State Authority stated (March 2022) that committees for standardisation of different categories were constituted (September 2019) and the minimum standards reports of four[97] categories of establishments were at notification stage.

Audit noticed that as against the provisions in the Act, GoK has not finalised the standards for any category of establishments even after a period of four years from the date of commencement of the Act. Audit observed that the Authority could grant only provisional registration to all units under its registry till date (March 2022) due to non-finalisation of standards for each category of establishments.

8.2. Drugs Controller of the State

The Drugs Control Department was formed in the year 1961 for the enforcement of the Drugs and Cosmetics Act, 1940 and Rules, 1945 framed thereunder. The Department is responsible for the enforcement of the said Act and Rules through licensing and inspection, drawal and testing of drug samples, and initiating prosecution against offenders. The Drugs Controller of Kerala (DC) has under his control 39 blood banks and 54 blood storage centres in Government sector alone (July 2022).

Scrutiny of records of the office of the DC revealed the following deficiencies in discharge of functions as per provisions of the Act and Rules:

8.2.1. Absence of centralized licensing system

There was no centralized database for monitoring the blood bank licensing process. The applications for grant/ renewal of licence were processed manually. Even though the Central Drugs Standard Control Organization (CDSCO) had launched (August 2021) an Online National Drug Licensing System (ONDLS) portal for the grant/ renewal of licence, it has not become operational due to technical issues (April 2022). In the absence of a centralised

[95] IMAGE (Indian Medical Association Goes Eco-friendly) – One of the two agencies for collecting biomedical waste from healthcare facilities in the State.
[96] Modern Medicine, Dental, etc.
[97] Modern Medicine, Dental, Laboratories and Diagnostic centres

online system, monitoring of blood banks including the validity of licence, etc., was not effective as seen in the subsequent paragraph:

8.2.2. Functioning of blood banks without valid licence

The blood banks have to function with the prescribed requirements of infrastructure, technical staff, equipment, etc., as detailed[98] in the Drugs and Cosmetics Rules, 1945 and obtain valid licence[99] and licence once obtained is valid for five years. Blood banks are to be licenced and renewed jointly by the State Licensing Authority and Central Licence Approving Authority.

As per records in the office of the DC of the State, 27 out of 93 Government blood banks/ blood storage centres (29 *per cent*) were functioning without valid licence (March 2022) due to non-submission of documents for renewal of licence, delay in rectification of defects pointed out by DC, delay in conducting inspection by DC, etc. Scrutiny of files revealed that in TH Kottarakkara and DH Perinthalmanna, the delay in conducting joint inspection by the authorities was 10 months and 36 months respectively.

Drugs Controller stated (February 2022) that the blood centres in Government hospitals and Government Medical Colleges are functioning under DHS and DME. The ministerial staff in these offices were normally not aware of the importance of blood centre licensing system and hence the reporting of rectification did not reach the office of the DC in time. Further, shortage of staff in Department, delay in obtaining convenient dates of the Central Authority for joint inspection, travel restrictions due to COVID-19 pandemic, etc., caused delay in finalising renewal applications.

The reply is not tenable as both the HFWD and DC were responsible to enforce the provisions of Acts and Rules governing their activities. The fact that 27 blood banks/ blood storage centres were functioning without licence does not inspire confidence and there is no assurance that standards set under the Acts and Rules were attained/ maintained.

8.3. Bio-Medical Waste Management

Bio-Medical Waste Management Rules, 2016, (BMWM Rules, 2016) applies to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio-medical waste in any form. State Pollution Control Board **(**SPCB**)** is the prescribed Authority in the State to implement the BMWM Rules. The entrusted duties include inventorisation of Occupiers[100] and generation of data on bio-medical waste, treatment and disposal, submission of data to the Central Pollution Control Board (CPCB), grant and renewal, cancellation of

[98] Schedule F Part XII B of Drugs and Cosmetics Rules,1945
[99] As per Rule 122-F of Drugs and Cosmetics Rules,1945
[100] Occupier is a person having administrative control over the institution and the premises generating Bio-Medical waste which include a hospital, clinic, blood bank, etc.

authorisation[101], monitoring compliance of various provisions of authorisation, etc. Audit noticed monitoring lapses/ deficiencies in implementing the Rules and guidelines and ensuring its compliance as discussed below:

Every Occupier or Operator[102] handling bio-medical waste, irrespective of the quantity shall receive authorisation from SPCB[103]. Since the overall efficiency of authorisations in the country was far from satisfactory at 48 *per cent*, CPCB advised SPCBs[104] (2019) to expedite the process of authorising of healthcare facilities (HCFs) so that waste generated from facilities can be verified for proper collection and disposal.

The BMWM Rules, 2016 and guidelines issued by CPCB envisage display on the website, of Annual Reports with monthly records by HCFs and display of relevant information by the Common Bio-Medical Waste Treatment Facility (CBWTF) like environmental clearance obtained, list of all member healthcare facilities, charges levied on the member HCFs, copy of the annual report, list of HCFs which have not taken membership etc.

8.3.1. Healthcare facilities generating bio-medical waste without obtaining authorisation from KSPCB

The number of HCFs operating without authorisation and without submission of annual reports to KSPCB is shown in **Table 8.1**.

Table 8.1: Operation of unauthorised HCFs during calendar years 2017 to 2021

Year	Total number of HCFs in operation	Number of HCFs operating without authorization	Percentage of HCFs operating without authorization	Number of Occupiers who did not submit annual reports	Percentage of non-submission of annual reports
2017	9628	4865	50.53	7754	80.53
2018	12668	5916	46.70	9554	75.42
2019	13869	7134	51.44	10592	76.37
2020	17122	3774	22.04	14635	85.47
2021	17875	1083	6.06	13859	77.53

(Source: Data obtained from KSPCB)

- In Kerala, percentage of authorisation had increased from 49.47 in 2017 to 93.94 *per cent* in 2021. However, Audit noticed that 16[105] out of 20 major hospitals test-checked had not obtained authorization from SPCB (April and May 2022).

[101] Authorisation means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, processing, disposal or any other form of handling of bio-medical waste in accordance with Rules and guidelines issued by GoI or Pollution Control Board.
[102] Operator of a common bio-medical waste treatment facility is a person who owns or controls a CBWTF
[103] Rule 10 of BMWM Rules, 2016
[104] In the Annual Report on BMWM for the year 2019 of CPCB
[105] THQH Kayamkulam, SAT Thiruvananthapuram, DH Nedumangad, GH Neyyattinkara, TH Fort, MCH Alappuzha, MC Thiruvananthapuram, Dental College Thiruvananthapuram, THQH Malayinkeezhu, DH Tirur, TH Wandoor, THQH Tirurangadi, WCH Ponnani, GH Kalpetta, THQH Vythiri, MC Manjeri.

- Audit also noticed that the compliance to the Rules by the HCFs and CBWTF was not ensured by the KSPCB as only two[106] out of 20 (10 *per cent*) taluk/ district level hospitals test-checked had submitted Annual Reports to KSPCB and uploaded Annual Reports in their websites. The CBWTF uploaded only the number of HCFs in each district and the charges levied on them.

  GoK stated (September 2023) that directions were given to bring all HCFs under the purview of the Board. The matter was also being taken up in the District Level Monitoring Committees constituted. GoK also attributed the deficiencies in monitoring to shortage of staff.

  Audit is of the opinion that critical requirements like display of environmental clearance of CBWTF, annual reports, healthcare facilities not covered by CBWTFs etc. are to be insisted upon by the Board.

8.3.2. Lack of adequate infrastructural facility and capacity for waste disposal

As per Annual Report on BMWM of CPCB for 2019, Kerala is one among the six States/ Union Territories where the capacity utilization of existing common infrastructure had exceeded 75 *per cent*. Therefore, CPCB had recommended that the State may examine the need for establishing additional facilities by conducting gap analysis.

As per the statistics of 35 States/ UTs (2019) published in the Annual Report of CPCB, 30 States/UTs were generating BMW in the range 0.10 to 41.60 tonnes/ day and 16 of them were operating two to 20 CBWTFs for its disposal. However, Kerala generated 42.90 tonnes per day and had only one CBWTF for its disposal till May 2021. CPCB also had observed that in Kerala, against 42.90 tonnes of BMW generated per day, the quantity treated and disposed was 40,270 kg/day[107]. Besides, the Chairman, KSPCB in State Level Advisory Committee meeting (September 2019) emphasized the need for establishment of at least four CBWTFs since the existing CBWTF was overloaded and inadequate. Audit noticed that though gap analysis revealed need for minimum four CBWTFs as early as in September 2019, only one CBWTF functioned till May 2021. Two CBWTFs were functioning in the State as of April 2022.

GoK replied (September 2023) that integrated Consent To Establish has been issued by the Board to another CBWTF at Adoor and hence the capacity of CBWTFs was adequate to treat biomedical waste generated in the State. Further, the Board entrusted National Institute for Interdisciplinary Science and Technology (NIIST CSIR) to conduct a gap analysis and based on the detailed study, all gaps noticed by Audit can be addressed.

However, Audit observes that since the third plant was not made operational, the issues of inadequacy of CBWTFs and saturation of capacity persist.

[106] DH Mavelikkara, MCH Alappuzha
[107] 3,417 kg/day through captive treatment facility and 36,853 kg through CBWTF

8.3.3. Non-conducting of third-party inspection of the existing Common Bio-Medical Waste Treatment Facilities

Bio-medical Waste Management Rules, 2016 stipulates the SPCBs to undertake and support third party audits of the CBWTFs in their States.

Audit noticed that third party audit as prescribed in the BMWM Rules has not been conducted during the audit period. One agency (NIIST CSIR) was entrusted with the gap analysis study and inventory on Biomedical Waste Management in Kerala as per third party audit and MoU was entered into with the agency only on 29 September 2023.

8.4. Unauthorised operation of radiographic equipment

As per Rule 3 of Atomic Energy (Radiation Protection) Rules, 2004 issued by Department of Atomic Energy, GoI, no person shall, without a licence establish a radiation installation for siting, design, construction, commissioning and operation and decommission a radiation installation and handle any radioactive material or operate any radiation generating equipment, except in accordance with the terms and conditions of a licence.

Audit noticed that five radiographic equipment[108] were being operated in five hospitals without obtaining licence of Atomic Energy Regulatory Board which is in violation of the relevant norms thereby raising concern over the safety of the public as well as hospital staff operating the machines.

No remarks were furnished by GoK (November 2023).

8.5. Recommendations

- Government should ensure that the Clinical Establishments Act is implemented in the State in a time bound manner so that permanent registration is provided to those establishments which maintain prescribed minimum standards.
- Government should ensure that the Drugs Controller establishes a mechanism to monitor the validity of licences of blood banks and also ensures that the same are renewed without delay. Further, programmes may be conducted for Departmental staff to create awareness about the importance of adhering to relevant Acts and Rules.
- Government should ensure that urgent and time bound action is taken for establishment of new Bio-Medical Waste (BMW) Treatment Facility in the State and a mechanism established for assessing the BMW generated in the State, so as to ensure that all BMW is properly disposed of.

[108] X–ray unit in the Mental Health Centre, Thiruvananthapuram, X-ray units at GAMC and GHMC Thiruvananthapuram, Dental X-ray in TH Thuravoor and X-ray unit 60 mA in DH Tirur