Chapter- VIII

Adequacy and Effectiveness of the Regulatory Mechanisms

This chapter provides the status of observance of various regulations in the test-checked hospitals, such as, Bio-Medical Waste Management Rules, 2016, National Disaster Management Guidelines for Hospital safety, Uttar Pradesh Fire Prevention and Fire Safety Act, 2005, Clinical Establishments (Registration and Regulation) Act, 2010, Standards for Blood Banks & Blood Transfusion Services, 2007 of National Aids Control Organisation (NACO) and Atomic Energy (Radiation Protection) Rules, 2004.

Audit objective: ***Whether regulatory mechanisms in the Government hospitals were adequate?***

Brief snapshot of the Chapter

- Under the Bio-Medical Waste Management Rules, 2016, every occupier or operator handling bio-medical waste, irrespective of the quantity was required to obtain authorisation from the State Pollution Control Board. However, 72 *per cent* test-checked health care facilities were running without mandatory authorisation from the State Pollution Control Board.
- Health Care Facilities were required to establish a bar-code system by March 2019 for effective management of bio-medical waste to account and track the waste being sent out of the premises and disposed through Common Bio-medical Waste Treatment Facility. However, only two (13 *per cent*) out of 16 test-checked DHs were following the bar-code system. Further, it was not being followed in any of the 19 test-checked CHCs.
- National Disaster Management Guidelines for Hospital Safety, 2016 requires that hospitals shall acquire no objection certificate (NOC) from the Chief Fire officer. However, 88 *per cent* test checked DHs, all test checked CHCs and PHCs did not obtain NOC from Chief Fire Officer.
- None of the test checked health care facilities were registered under Clinical Establishments (Registration and Regulation) Act, 2010.
- Out of nine test checked DHs having blood bank, three DHs (33 *per cent*) were functioning without valid blood bank license.
- Out of 16 test-checked DHs, 10 District Hospitals were equipped with the X-ray machines, however, four hospitals (40 *per cent*) did not have Atomic Energy Regulatory Board (AERB) license for operation of X-ray machines.

8.1 Introduction

Regulation represents a key means by which a government gives effect to its health policy preferences, especially through the exercise of a government's law-making powers. The last three decades have seen major changes to the way that governments organize themselves, provide services and make and implement policy. A range of decisions that were once taken by Governments are now taken by regional and local governments, autonomous public sector agencies, private firms, non-governmental organizations and individuals. As a

result, regulation has grown in importance as a key lever for governments to affect the quantity, quality, safety and distribution of services in health systems.

Audit has covered various regularity issues which a hospital needs to comply with as discussed in the succeeding paragraphs.

8.1.1 Bio-medical Waste

According to the Bio-Medical Waste Management Rules, 2016, bio-medical waste means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps. Para 10 of the Rules stipulates that every occupier or operator handling bio-medical waste, irrespective of the quantity shall make an application in Form II to the prescribed authority, *i.e.*, State Pollution Control Board and Pollution Control Committee, as the case may be, for grant of authorisation and the prescribed authority shall grant the provisional authorisation in Form III and the validity of such authorisation for bedded health care facility and operator of a common facility shall be synchronised with the validity of the consents.

As per information provided (May 2022) by the Directorate of Medical Health Services, out of 31,474 Health Care Facilities (HCFs) in the State (Private 26234, Government 5240) as of December 2020, 26030 (Private 21,680, Government 4,350) HCFs (83 *per cent*) had the authorisation from Uttar Pradesh Pollution Control Board (UPPCB).

Further, seven[1] out of 16 test checked DHs, 11[2] out of 19 CHCs[3] and 35[4] out of 38 test checked PHCs were running without mandatory authorisation from UPPCB for management of generated Bio-medical waste. In GMC, Ambedkar Nagar, the college authority did not obtain the requisite authorisation from UPPCB till 15 November 2019 and was operating incinerator in the premises for the disposal of BMW whereas GMC, Meerut did not have Authorisation from UPPCB. As a result, these hospitals were not complying with the rules governing management of the waste generated during the diagnosis, treatment or immunization of human beings, though they were accountable to ensure management of bio-medical waste in accordance with the Rules.

The Government's reply was awaited (August 2024) despite reminders.

8.1.1.1 Disposal of the Bio-Medical Waste

As per Guidelines issued by the Central Pollution Control Board (CPCB) for Bar Code System for Effective Management of Bio-Medical Waste, the Bio-Medical Waste Management Rules, 2016 stipulated that it was the duty of

[1] Combined District Hospital, Kushinagar, DWH Ghazipur, DHM and DWH Jalaun, DHM Kanpur Nagar, DHM Lucknow and DHM Saharanpur.

[2] CHCs Fazilnagar, Hata (Kushinagar), Muskara, Sarila (Hamirpur), Talgram, Chhibramau (Kannauj), Puwarka (Saharanpur), Kadaura (valid upto 04/2021), Jalaun (valid upto 04/2021) (Jalaun), Sarsaul (Kanpur Nagar) and Aishbagh (Lucknow).

[3] Records of BMW not made available to Audit of CHC Bhadaura, Saidpur (Ghazipur).

[4] PHC Katehru, Pansariya, Sikadarpur Karn (Unnao), Jaura bazar, Koilaswa, Sakrauli, Mahuadih (Kushinagar), Anauni, Gorkha, Bara, Deval (Ghazipur), Biwar, Bihuni, Jalalpur, Puraini (Hamirpur), Ata, Parasan, Urgaon (Jalaun), Meharban Singh Ka Purwa, Dyodhighat, Pali, Gujaini (Kanpur Nagar), Baisapur, Amolar, Prempur, Sikandarpur (Kannaunj), Rahimabad, Kasmandi Kalan, Poorab Gaon, Juggaour, Naka (Lucknow), Devla, Halalpur, Pilkhani, Qutubpur (Saharanpur).

every HCF to establish a Bar-code System by 27 March 2019 to account and track the waste being sent out of the premises and disposed through Common Bio-medical Waste Treatment Facility (CBMWTF). The Bar Code System is required to be established by operator of a CBMWTF with mandatory participation of HCFs. The Bar Code System serves as an important tool for regulatory authorities especially for tracking of Bio-medical Waste from source of its generation to its ultimate disposal. Bar Code System would also help in controlling the pilferage of recyclable Bio-medical waste.

Out of two test checked GMCs, GMC Meerut commenced Bar-code system for disposal of BMW in April 2021. GMC, Ambedkar Nagar was not required to implement Bar-code system as incineration of BMW was being done by in-house facility.

Out of 16 test checked DHs, only DHM and DWH Lucknow were following the Bar-code system leaving a large number of test-checked hospitals without having necessary system of bar coding. Further, it was not being followed in all 19 test checked CHCs. In absence of bar-code system, possibility of pilferage/ mis-management of recyclable Bio-medical waste could not be ruled out.

Disposal of BMW was being carried out through burial pit in 31 PHCs out of 38 test-checked PHCs. In Saharanpur, two[5] PHCs used to send BMW in CHCs concerned for disposal and in five[6] PHCs, disposal was being done through outsourced operators.

The Government's reply was awaited (August 2024) despite reminders.

Case study: Improper disposal of Bio-Medical Waste

Scrutiny of records of DGMH and further information collected from districts revealed that a firm (M/s Biomedical Waste Disposal Agency, Mathura) was engaged for collection and disposal of BMW from 30 March 2019. The plant site for disposal of BMW was located at Mathura. However, due to breach of BMW conditions, UPPCB sealed the plant site vide its order dated 22 August 2019, which was reopened by the UPPCB in January 2020 after getting the penalty deposited by the firm. Audit observed that though the site had been sealed, the firm collected BMW from various hospitals in district Mathura, Kasganj and Aligarh during the intervening period of August 2019 and January 2020, disposal of which was not possible due to sealing of plant site. As such, unhygienic and unsafe dumping of BMW at a place(s) without having a disposal plant could not be ruled out.

The Government's reply was awaited (August 2024) despite reminders.

8.2 Presence of stray animals in hospital premises

As per 'Guidelines for Management of Healthcare Waste as per Biomedical Waste Management Rules, 2016', health care facilities will ensure that there is no stray animal in the health care facility premises. Audit, however, noticed

[5] PHC Pilkhani and Kutubpur.
[6] PHC Halalpur (Saharanpur), Meharban Singh Ka Purwa and Gujaini (Kanpur Nagar), Naka and Gadhi Kanaura (Lucknow).

several instances of presence of stray animals in the premises of the test-checked hospitals as depicted in following photographs:

<table>
<tr><td>  </td><td>  </td></tr>
<tr><td>Stray animals in the compound of DHM Unnao</td><td>Stray dog in OPD registration area of CDH Kushinagar</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Stray dog in IPD area of DHM Saharanpur</td><td>Stray animals in the compound of PHC Dewal, Ghazipur</td></tr>
</table>

Thus, the measures to prevent entering of stray animals in the hospital premises was not sufficient enough. Resultantly patients, their attendants and the hospital staff were not only exposed to risk of infection but also injury.

The Government's reply was awaited (August 2024) despite reminders.

8.3 Fire safety

As per National Disaster Management Guidelines for Hospital Safety (February 2016), all healthcare facilities shall be so designed, constructed, maintained and operated so as to minimize the possibility of a fire emergency requiring the evacuation of occupants, as safety of hospital occupants cannot be assured adequately by depending on evacuation alone. Hence measures shall be taken to limit the development and spread of a fire by providing appropriate arrangements within the hospital through adequate staffing and careful development of operative and maintenance procedures. Hospitals shall acquire No Objection Certificate (NOC) from the Chief Fire officer.

Further, Uttar Pradesh Fire Prevention and Fire Safety Act, 2005 provides that every building likely to be used for a purpose such as medical or other treatment or care of persons suffering from physical or mental illness, diseases or infirmity shall submit plan and obtain a permission from entity authorized by the GoUP that safety from fire is reasonably attainable in practical and can be achieved.

Audit observed that, 14[7] out of 16 test checked DHs, all 19 test checked CHCs and 38 PHCs did not obtain NOC from the Chief Fire Officer. Further, in GMC, Meerut installation of firefighting system was initiated in December 2015 to be completed by March 2018. However, the installation work was abandoned midway and therefore could not be installed as of May 2022. In GMC, Ambedkar Nagar, NOC was not obtained from the fire department. Thus, not only the provisions of the guidelines were not followed but this was also fraught with the risk of fire hazard in the hospitals.

The Government (MET) stated (November 2022) that the contractor for installation of fire safety in GMC Meerut had been blacklisted by the executing agency (UPSIDCO). The Government has now nominated a new executing agency (UPPCL) for the work and the estimates for the work has been sent to the Government for approval. However, reply of the MHFW Department was awaited (August 2024) despite reminders.

8.4 Clinical Establishments Act

The Clinical Establishments (Registration and Regulation) Act, 2010[8] has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them. The Act is applicable to all types (both therapeutic and diagnostic types) of Clinical Establishments from the public and private sectors, belonging to all recognized systems of medicine, including single doctor clinics[9]. As per the Act, no person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act. The Clinical Establishment Act, 2010 stipulates that the existing establishment shall prefer an application for its registration within one year from the date of commencement of the Act and a clinical establishment which comes into existence after commencement of this Act, shall apply for permanent registration within a period of six months from the date of its establishment.

Uttar Pradesh has notified the Uttar Pradesh Clinical Establishments (Registration and Regulation) Rule, 2016 under this Act in July 2016. The State Government further issued (November 2021) orders for registration of hospitals having more than 30 beds under this Act which was revised in January 2022 by relaxing the norm for registration of hospitals having more than 50 beds.

As per data available on the website of the Ministry of Health and Family Welfare, Government of India as on 6 December 2022, 617 clinical establishments (including 611 allopathic clinical establishments) were registered under the Clinical Establishment Act, 2010 in Uttar Pradesh.

Audit observed that test checked hospitals, viz., two GMCs, 16 District hospitals, 19 CHCs and 38 PHCs were not registered under Clinical

[7] District Male Hospital, District Female Hospital (Unnao), Combined District Hospital (Kushinagar), District Male Hospital, District Female Hospital (Ghazipur), District Male Hospital, District Female Hospital (Hamirpur), District Male Hospital, District Female Hospital (Jalaun), District Male Hospital, District Female Hospital (Kanpur Nagar), District Male Hospital, District Female Hospital (Saharanpur), Veerangana Avanti Bai (DWH), Lucknow.

[8] GoI has notified the National Council for Clinical Establishments and the Clinical Establishments (Central Government) Rules, 2012 under this Act vide Gazette notifications dated 19th March, 2012 and 23rd May, 2012 respectively.

[9] Not applicable on the hospitals run by the Armed forces.

Establishments (Registration and Regulation) Act, 2010[10]. This shows that concerned authorities had not got these government hospitals registered under the Act even after a lapse of six years since notifying the Uttar Pradesh Clinical Establishments (Registration and Regulation) Rule, 2016.

The Government's reply was awaited (August 2024) despite reminders.

8.5 Blood bank licenses

As per Standards for Blood Banks & Blood Transfusion Services, 2007 of National Aids Control Organisation (NACO), all blood banks should be licensed by State Drug Controller and approved by Drugs Controller General (India) and should be regulated by Drugs and Cosmetics Act, 1940 and rules thereunder. Drugs and Cosmetics Rules, 1945 also provides rules regarding licencing of blood banks/processing of whole human blood for components/manufacture of blood products for sale or distribution.

Audit observed that licence of blood bank of GMC Ambedkar Nagar[11] expired in January 2022. Further, two District Hospitals[12] and one Combined District Hospital[13] (33 *per cent*) out of nine test checked district hospitals were functioning without valid license. Applications for renewal of the license were given by the CDH Kushinagar, DHM Saharanpur and DHM Unnao to the competent authority but licence were not renewed (March 2022). Thus, operation of blood banks without having valid licences was against the provisions of NACO and Drugs and Cosmetics Act.

The Government's reply was awaited (August 2024) despite reminders.

8.6 Compliance with Radiation Protection Rules

Atomic Energy (Radiation Protection) Rules, 2004 provides that no person shall, without a licence, establish a radiation installation for siting, design, construction, commissioning and operation; and decommission a radiation installation. Further, an authorisation shall be necessary for sources and practices associated with the operation of medical diagnostic X-ray equipment.

Scrutiny of records revealed that out of 16 test-checked DHs, 10 and eight District Hospitals were respectively equipped with the X-ray machines and CT scan machines. However, four hospitals[14] did not have AERB license for operation of X-ray machines. CT scan facility was being provided through PPP mode and license was obtained from AERB.

Further, both test-checked GMCs were operating X-ray machines and CT scanner for patient diagnosis without having license for operation from AERB. In GMC, Meerut, NOCs[15] from AERB for operation of Cobalt 60 machine were

[10] As per the information provided by the CMO, Kanpur Nagar 37 Private Hospitals were registered under this Act in 2021-22.
[11] License of blood bank available in GMC Meerut.
[12] District male hospital, Unnao and District male hospital, Saharanpur
[13] Combined district hospital, Kushinagar.
[14] DHM (Unnao), DHM (Jalaun), CDH (Kushinagar) and DHM Saharanpur.
[15] 1- Authorisation certificate for new Cobalt 60 source. 2. Procurement certificate for new Cobalt 60 source. 3. NOC for safe disposal of old Cobalt 60 source. 4. Registration of Radiation Oncologist. 5. Updation of newly appointed professionals.6.Registration of all newly appointed professionals. 7. Site map approval of new linear accelerator which is to be procured under PMSY.8. Procurement and license for all new radiation emitting equipment including Cath lab.9. NOC for safe disposal of unused Cs-137 sources. 10. Updation of new licensee etc.

required while changing the Teletherapy Source Product. However, out of ten issues, NOCs from AERB for only seven issues were obtained by the GMC. Further, the Cobalt machine[16] could not be made functional till March 2022 due to non-replacement of old radioactive material.

Catheterisation lab, commonly known as a Cath lab, is used for several tests, procedures and pacemaker implant which requires AERB license for its operation. Audit observed that in GMC, Meerut, a Cath Lab was functional under Cardiology department since 2020-21 without having license from AERB. It was further observed that 969 angiographies were performed in the Cath Lab during March 2021 to March 2022.

Thus, operation of radiological equipment/ machines without valid licenses was not only against the rules but was also fraught with the risk of radiation exposure to the patients, doctors and technicians.

The Government (MET) stated (November 2022) that in GMC, Meerut, Cobalt-60 machine was operationalised in May 2022. However, it was not functioning for past few months due to unavailability of radio safety officer. Government had attached one radio safety officer from JK Cancer Institute, for operationalisation of Cobalt-60 machine. All the formalities would be completed as per the standards of the AERB by removing difficulties. MHFW Department's reply was awaited (August 2024) despite reminders.

To sum up, compliances to various regulations, viz., Bio-Medical Waste Management Rules, Clinical Establishment Act, Atomic Energy (Radiation Protection) Rules, etc., were not complied with in majority of hospitals.

Recommendations:

State Government should:

27. ***ensure availability of adequate fire safety measures in case of short circuits and fire hazards especially in ICUs;***
28. ***ensure that all utilities generating bio-medical waste comply with the provisions under Bio-Medical Waste Management Rules, 2016 and take strict action against healthcare facilities violating these Rules;***
29. ***ensure hygiene and prevent access of stray animals in the hospitals premises;***
30. ***ensure adherence of various regulations, viz., Clinical Establishment Act, radiation safety, etc., by the State Government hospitals.***

[16] Non-functional since May-2015.