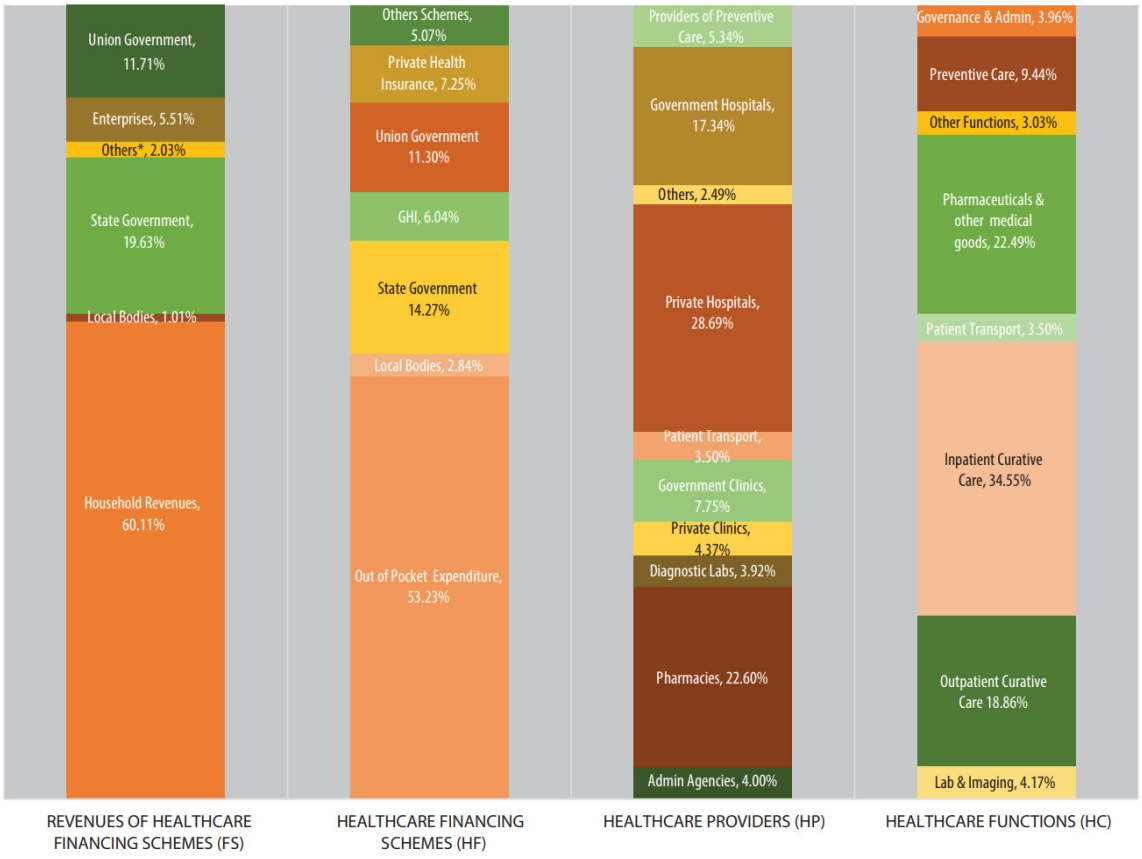
# Chapter-8
# Adequacy and effectiveness of the regulatory mechanisms

# Chapter-8: Adequacy and effectiveness of the regulatory mechanisms

## *8.1 Introduction*

Regulation is an important function in the healthcare sector. Regulations are necessary to standardize and supervise healthcare, ensuring that healthcare bodies and facilities comply with public health policies and that they provide safe care to all patients and visitors to the healthcare system. 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 programs. 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 attempt to improve healthcare quality and follow local, state, and national guidelines.

National Health Accounts (NHA) estimates for India for the Financial Year 2018-19 released in year 2022 describe health expenditures and the flow of funds in both Government and private sectors in the country. As per NHA 2018-19, the distribution of Current Health Expenditure (2018-19) according to Healthcare Financing Schemes, Revenues of Healthcare Financing Schemes, Healthcare Providers and Healthcare Functions *(per cent)* is given below:



As can be seen from above, Government Hospitals account for only 17.34 *per cent* of the Current Health Expenditure. However, role of Government is not limited to Government Hospitals, it is also responsible for regulation of private sector hospitals, clinics, pharmacies, etc. in healthcare sector. To assess whether higher safety standards are being adhered to the implementation of following Acts have been covered in this audit:

Clinical Establishment Act 2010, Fire Protection and Fire Safety rules, Atomic Energy (Radiation Protection) Rules, 2004, Standards prescribed under National Medical Commission Act 2019, Uttarakhand Nurse and Nurse Midwives Act 2004, Drugs and Cosmetics Act 1940 and Rules 1945, Pre-Conception & Pre-Natal Diagnostic Techniques Act (PC-PNDT Act) and Bio-Medical Waste Management Rules, 2016.

## *8.2 The Laws governing the Commissioning of the hospital*

These laws make sure that the hospital facilities are created after due process of registration and are safe for the public.

### *8.2.1 Clinical Establishments Act*

'**Clinical Establishments Act**[1]**'** aims to provide for registration and regulation of all clinical establishments in the country with a view to prescribing minimum standards of facilities and services which may be provided by them, so that mandate of article 47 of the Constitution of India[2] for improvement in public health may be achieved. For implementation of Act *ibid*, State Government had notified (2015) the Uttarakhand Clinical Establishments (Registration and Regulation) Rules, 2015. The Act is applicable to all kinds of clinical establishments from public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception is establishments run by the Armed forces, which will not be regulated under this Act. In the implementation of Act and rules, it was observed as under:

#### *i. Implementation of rules*

Health being a State subject, and the respective state Governments are empowered to make their own rules regarding the subject. Accordingly, the Government of Uttarakhand adopted and notified the Uttarakhand Clinical Establishments (Registration and Regulations) Rules, Act 2015, under clinical establishment Act for standardization of health care facilities in the state. On review, audit observed as under

The State Council, being decision making body for Clinical Establishment, was formed after a lapse of 4 years of notification of rules i.e., on 01 August 2019. After expiry of its tenure (July 2020), no notification thereafter was issued by the State Government for the extension or for formation of the State Council.

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1 Adopted by Uttarakhand in March 2011.

2 Article 47 of The Constitution of India is one of the Directive Principles which directs the State to raise the level of nutrition and the standard of living and to improve public health as among its primary duties and, in particular, the State shall endeavor to bring about prohibition of intoxicating drinks and drugs which are injurious to health.

- For the smooth implementation of CEA, only one meeting (July 2020) against the required quarterly meetings was held by the State council. The District Registering Authorities (DRAs) were also not holding meetings as per norms.
- Provision of posts of coordinators and data entry operators at State and district level for implementation of the Act was required to be done. No dedicated staff was provided for data compilation and implementation of the Act either at state level or at DRA level. It was found that proposal[3] for providing staff for State Council was only submitted in September 2021 to Government for approval. As no dedicated staff was provided for the compilation of Clinical Establishment data it adversely affected the preparation, submission of reports & returns and other activities as detailed below:

***Functions of State Council***

***Rule 4***

(*e*) *Publication of a report on annual basis on the State of implementation of standards within Uttarakhand.*

(*f*) *Monitor the implementation of the provisions of the Act and rules in the Uttarakhand.*

(g) *Recommend to the Government for any modifications required in the rules in accordance with changes in technology or social conditions.*

***Functions of District Registering Authority***

***Rule 10***

(b) *To enforce compliance of the provisions and rules of the Clinical Establishments (Registration and Regulation) Act, 2010.*

(*e*) *To report the State Council on a quarterly basis of action taken against non-registered clinical establishments operation in violation' of the Act.*

***Rule 11***

*(2) The meetings of the District Registering Authority (DRA) shall be held at least once in a month at a stipulated date and time.*

  - Monthly returns were forwarded by State council to National Council only from January 2020. As a result, details/data with respect to yearly increase of clinical establishment, especially private ones prior to that, was not compiled/available with the State Council. Thus, the incremental growth of private clinical establishments over the years could not be ascertained either by Government or in audit.
  - The State Council as well as DRA was unaware about the actual number of HCFs running in the districts. It was noticed that DRA was restricted to issuance of provisional registrations that too those who approached to the DRA. The mechanism to identify that no clinic is operational in the district without permission or against rules was not in place [Refer para 8.2.1 (vi)]. The DRAs were passive recipients and acting only on the complaints received. The facts were admitted by the authorities. The below Case study also proves the facts regarding working of DRAs.

[3] One state coordinator and one administrative assistant cum data entry operator for state level office and 13 district coordinators and 13 administrative assistants cum data entry operators.

**Case Study**

Writ Petition (PIL) No. 120 of 2016

The Petitioner has filed a complaint to the effect that two hospitals namely B.D. Hospital Doraha Bazpur and Public Hospital Sarkari Road Kela Khera, District Udham Singh Nagar were being run by persons without having any medical degree and without any registration under the Clinical Establishments (Registration and Regulations) Act, 2010 (hereinafter referred to as the Act, 2010). The operations were being conducted by the persons having no medical degree in surgery.

***The writ petition was disposed of by Honourable High Court of Uttarakhand after issuing following mandatory directions:-***

a. The State of Uttarakhand is directed to seal all the clinical establishments which are not registered under the Clinical Establishments (Registration and Regulation) Act, 2010 forthwith.
b. The State Government is directed to ensure that all the clinical establishments registered under the Act, 2010 follow the Operational Guidelines for Clinical Establishments Act as well as Clinical Establishment Act Standard for Hospitals (Level 1A & 1B).
c. All the Clinical Establishments throughout the State of Uttarakhand are directed that the patients are not unnecessarily put to diagnostic tests. Only necessary diagnostic tests are ordered to be undertaken to access the clinical condition of the patient.
d. All the doctors throughout the State of Uttarakhand including government doctors and doctors serving in Clinical Establishments are ordered to prescribe only generic medicines which are readily available. No patient shall be forced to buy branded medicines.
e. The State Government is directed to prescribe the rates for various diagnostic tests or procedures or surgeries or treatments extended by clinical establishments, within one month from today.
f. The outer wall of the Intensive Care Unit (one of its sides) shall be fitted with transparent glass, closed with cloth curtains to enable the attendants of the patient to see the patient. The attendants of the patient shall be informed about the health/condition of the patient after every 12 hours and the same is ordered to be video graphed.

- State Council for Clinical Establishments (SCE) as well as the District Registering Authorities (DRA) were to compile a State/ District Register for Clinical Establishments in the prescribed format. It was however, observed that neither SCE nor test checked DRAs[4] had compiled/ maintained the information regarding doctors, nurses, paramedical staff available and types of services actually provided by the private HCFs in the State.

[4] Dehradun & Nainital.

The fact that information about non-registered clinics operating in the state and unavailability of data in regard to doctors, nurses and other staff in the HCF registered under CEA was not available either at State council level or at DRA level was accepted by the state council. The authorities further stated that the matter relating to preparation of district and State level register will be discussed in the State Council meeting. The reply is self-explanatory about the partial implementation of the provisions of the Rules.

In Exit Conference, the Secretary-In-Charge stated that notification for the establishment of Clinical Establishment (CE) Council will be issued soon.

### *ii. Revision of rules and Patient Rights*

Chapter 2 rule 4 of the Uttarakhand Clinical Establishment Rules provides following functions of the State Council:

- Monitor the implementation of the provisions of the Act and rules in the Uttarakhand.
- Recommend to the Government for any modifications required in the rules in accordance with changes in technology or social conditions.
- Perform any other function as may be outlined by the National council.

It was noticed that in 8th meeting held in 2016 by National Council a commitment was given to revise the Clinical Establishment Rules (CER) of the State. However, no action or initiative was taken by the State Council after its formation. Further, National Council[5] for Clinical Establishments approved for inclusion of the additional patient rights (August 2021) but directions for its implementation were also not issued due to the defunct Council.

The State Council asserted that the revision of rules had not been initiated yet. The non-fulfillment of the quorum prevented the finalization of additional patients' rights adoption. However, the fact remains that the State Council had not taken any action or provided recommendations to the Government for rule revision, despite its formation in August 2019. Moreover, the Council was convened only once, which deviates from the prescribed meeting frequency according to the rules.

Thus, the State Council's reluctance to initiate the revision of rules following its formation and the Government's decision not to extend the tenure of the State Council beyond July 2020 indicate a concerning lack of commitment on the part of both the State Council and the Government to effectively implement the act and regulations.

### *iii. Registration of HCFs*

The Clinical Establishments Act was enacted to provide for registration and regulation of all clinical organizations with a view to prescribe the minimum standards of facilities and services[6] provided by them.

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5 Recommended by National Advisory for Human Rights.

6 Under the Act, standard treatment guidelines are specified for certain diseases, including dengue, chikungunya and malaria. The hospitals are supposed to abide by minimum standards in terms of infrastructure, services, staff, equipment and lighting arrangements.

Audit noticed that the online registration facility for clinical establishments is available through the dedicated website[7] of the Government of India. However, registration was also done in offline mode as well as by the respective DRAs. On cross verification of HCFs registered under the Clinical Establishment Act with those under Bio Medical Waste Management Rules by Uttarakhand Pollution Control Board revealed discrepancy in the number of registered HCFs operational and registered in the State. It was found that 3,868 HCFs were registered under CEA as against 4,282 HCFs registered with the Uttarakhand Pollution Control Board in the year 2021. This indicates monitoring and registration process by the DRAs needs attention.

***iv. Registration of Medical Diagnostic Laboratories or Pathological Laboratories***

Minimum standards in respect of Medical Diagnostic Laboratories (or Pathological Laboratories) were notified in May 2018. The main amendment in the said notification was the definition for minimum standards of facilities and services for the diagnostic labs and a schedule detailing the basic requirements for the various types of laboratories along with requirement of infrastructure, human resources etc. Further, Rule 18(1) of Uttarakhand Clinical (Registration and Renewal) Rules, 2015, implies that the clinical establishments shall apply for permanent registration before 30 days of the expiry of the validity of the provisional registration, which is 12 months from the date of issue of a provisional certificate with fees. In case the renewal application is not submitted within the stipulated period the authority shall allow for renewal on payment of double the amount of the renewal fee with a penalty of ₹ 100 per day till the date of renewal application is accepted.

It was noticed that checked DRAs were not taking the initiative to ensure compliance as per the notification issued by GoI. Consequently, 166 out of 189 laboratories and diagnostic facilities failed to secure permanent registration[8], even though more than four years have elapsed since the prescribed minimum standards for labs were notified. Additionally, it was observed that DRAs did not adhere to the instructions issued by the Director General of Medical Health & Family Welfare in December 2019, as provisional registrations for clinical establishments were not renewed within the stipulated timeframe. Due to this non-compliance, a recoverable amount of ₹ 2.71 crore for the renewal of expired registrations from 430 Healthcare Facilities (HCFs) could not be ensured by the DRA, Dehradun.

The department stated that gazette notification for minimum standards was not notified by the Government of India as a result it was not mandatory for the clinical establishment viz. hospitals/clinics/day care centers to apply for permanent registration. The response is inadequate, especially given that provisional registrations for clinical establishments were

[7] www.clinicalestablishments.gov.in.

[8] Against provisionally registered 87 pathology labs and 44 diagnosis centers only 6 & 2 respectively have applied and received permanent registration from DRA Dehradun. In Nainital, against provisionally registered 58 pathology and diagnosis centers only 15 were permanently registered.

not renewed within the specified timeframe by DRAs, despite explicit instructions issued by the Director General of Medical Health & Family Welfare in December 2019. In addition, despite the notification of minimum standards for labs and diagnostic centers, compliance continued to be lacking.

***v. Reporting standards not followed***

As per para 21 of the Clinical Establishment Rules, it is obligatory for Health Care facilities registered under CEA to provide health information and statistics[9] in respect of national programs and furnish it in the prescribed format to District Authority in three monthly reports.

It was found that none of the test checked DRAs were collecting the information/statistics as required under the rules. No initiative was taken at State Level or by District level authorities to enforce the Act and make the Health Care facilities bound to submit returns and reports according to Act. As a result, Government could not get statistics/ information for public health interventions including outbreak and disaster management. Facts were accepted by the test checked DRAs and state level authorities.

Thus, the objective of planning improvement in public health quality by eliminating quacks could not materialize due to unavailability of data relating to the Health Care Infrastructure, Manpower, Clinical Diagnosis.

In Exit Conference, the Secretary-In-Charge stated that the DRAs will be directed to ensure that all Health Care facilities submit reports and returns as per rule and get all the Pathological and Diagnostic Labs permanently registered as early as possible.

***vi. Fraudulent and frivolous Clinical Establishment***

The aim of the Act was to discourage and disallow the fraudulent and frivolous clinical establishment operating in the State.

One pathologist can only work in not more than two labs in the state of Uttarakhand. It was found that Uttarakhand Medical Council had pointed out that technician run labs have got their labs registered under Clinical Establishment Act by using the names of erring Registered Medical Practitioners involving each of them in several labs. The council had requested the competent authorities to take necessary action based on following observations:

a) No pathologist can represent for more than two labs
b) Digital signatures of the pathologist under the report are not allowed
c) Technician run labs are an act of contempt of apex court.
d) The Registered Medical Practitioner representing these labs are violating the professional conduct, Etiquettes and Ethics Regulations, 2002, of the IMC Act, 1956 which have been in to adopted by the NMC Act, 2019.

[9] Information of Government programs such as Mother and child health, Immunisation, Family Planning, RNTCP, IDSP, NRHM initiative- Asha and JSY etc.

In respect of above, no action as on date was taken by the regulatory authority (DRA). In the meantime, Uttarakhand Medical Council had summoned laboratory owners and Pathologists that were operating labs against the medical code of ethics. It was noticed that doctors had accepted the concerns in front of the Ethics & Disciplinary Committee of UKMC and agreed to change the name of pathology lab into collection centre.

In Exit Conference, the Secretary-In-Charge stated that the DRAs will be instructed to act against the fraudulent and frivolous Clinical Establishment communicated by Indian Medical Association.

### *8.2.2 Regulatory issues of AYUSH*

The Board of Indian Medicine (for Registration of Ayurvedic and Unani practitioners), Uttarakhand was established in the year 2004 and registration of practitioners was started in February 2005. As per Schedule II of Central Council of Indian Medicine (CCIM) Act 1970, practitioners of Indian Medicine have to get registration with the State Register of Indian Medicine. CCIM norms also stipulated that, registrations should be renewed every five years by Board of Indian Medicine in every State.

#### *8.2.2.1 Registrations of medical practitioners (Ayurveda and Unani) not renewed*

Scrutiny of records revealed that renewal of registration of 1,320 out of 4,715 registered practitioners was pending as detailed in **Table-8.1** below. This also resulted in loss of revenue of ₹ 49.60 lakh to the said Board.

**Table-8.1: Pendency of Renewals**

| Particulars | Pendency < 5 years | Pendency >5 <10 years | Pendency >10 <15 years | Pendency >15 years | Total |
|---|---|---|---|---|---|
| ***Bachelor of Ayurvedic, Medicine and Surgery*** | 664 | 214 | 248 | 142 | 1,268 |
| ***Bachelor of Unani Medicine and Surgery*** | 36 | 10 | 4 | 02 | 52 |
| **Total** | **700** | **224** | **252** | **144** | **1,320** |
| **Amount due if charged timely (in the interval of Five years)** | ₹ 2,000/- per | ₹ 4,000/- per | ₹ 6,000/- per | ₹ 8,000/- per | |
| **Loss of amount as not charged timely** | ₹14,00,000/- | ₹ 8,96,000/- | ₹ 15,12,000/- | ₹ 11,52,000/- | ₹ 49,60,000/- |

***Source: Information provided by the department.***

The Government replied (November 2022) that registrations of these practitioners were cancelled after issuing notices. Now, these practitioners are applying afresh for registration.

In contravention to the CCIM directions (March 2007), the Board of Indian Medicine, Uttarakhand (March 2021) decided that the re-registration/renewal will be done in 15 years instead of five years. The decision on the one hand dented self-generating financial resources of the State board but also allowed patients being put in danger though unregistered medical practitioners practicing illegally.

The Government replied (November 2022) that constitution of new board is under way and after constitution the proposal will be put up for ensuring earlier procedure to be followed.

#### *8.2.2.2 Registrations of medical practitioners (Homoeopathic Medicine Board) not renewed*

In case of Homoeopathic Medicine Board, Uttarakhand which was established in the year 2005 and registration of the practitioners were started in 2009. It was noticed that registration of 161 Homoeopathic practitioners out of 1,168 was due for renewal (November 2021).

The Government replied (November 2022) that 70 registrations were renewed, 28 registrations were cancelled and remaining 63 process of renewal was under way.

### *8.2.3 Directorate of Medical Education*

The Department of Medical Education was bifurcated in the year January 2013 from the Department of Medical Health Services. The separate directorate of Medical Education was established in 2013. It controls Medical Colleges and attached teaching hospitals as well as Nursing and Paramedical colleges in the state of Uttarakhand.

#### *8.2.3.1 Establishment and infrastructure of Medical Education Institutes*

The National Medical Commission Act (NMC), 2019 provides for a medical education system that improves access to quality and affordable medical education, ensures the availability of adequate and high-quality medical professionals and enforces high-quality and ethical standards in all aspects of medical services. In the exercise of the power conferred by section 57 of the NMC Act 2019 (30 of 2019), the "Minimum requirements for annual M.B.B.S Admissions Regulations, 2020" were notified on 28th October 2020.

It was noted that four medical colleges were operational in the state. Further, three new medical colleges[10] under the Centrally Sponsored Scheme of "Establishment of New Medical Colleges attached with District/Referral hospitals' were approved by GoI and are still under construction.

#### *8.2.3.2 Establishment of medical colleges under Uttarakhand Ayurveda University*

Uttarakhand Ayurveda University was established by the Government of Uttarakhand vide Uttarakhand Ayurveda University Act, 2009 for the purpose of ensuring, effective and systematic instructions, teaching, training, research and development in Ayurveda. Review of documents provided by the Ayurveda University revealed as under:

#### *8.2.3.2 a Affiliation fee from Private AYUSH Medical Colleges*

Affiliation fee for the courses conducted under Uttarakhand Ayurveda University Dehradun is to be deposited by both Government and Private educational institutions at applicable rates/fee[11].

[10] MC Rudrapur, Udham Singh Nagar; MC Pithoragarh and MC Haridwar.

[11] Processing fee was to be deposited each year, Affiliation fee and Security Deposit was to be deposited one time by these Medical Colleges.

Scrutiny of records revealed that Private AYUSH Medical Colleges had neither paid processing fee nor security deposits. Audit calculated that an amount of ₹ 8.10 crore[12] was due to be collected from these Private AYUSH Medical Colleges since 2014.

The Government replied (November 2022) that instructions were issued to Private Medical Colleges to deposit the aforesaid amount.

#### *8.2.3.2 b Extension of affiliation granted to the Private AYUSH Medical Colleges*

Uttarakhand Ayurvedic University grants extension of affiliation to the Private AYUSH Medical Colleges before commencement of the academic year. Inspection teams were constituted by the University to inspect these AYUSH Medical Colleges in the given format prepared by the University. The extension of the affiliation of the Private AYUSH Medical Colleges is granted after the inspection team provides a certificate that all formalities have been completed.

It was noticed that while inspecting the entity, an undertaking/certificate was given by each member of the team that they will be fully responsible in case any deficiency is found. However, scrutiny of inspection reports (2021-22) revealed that essential documents as required in the format were not attached/not found correct as per the **Table-8.2** given below-

**Table-8.2: Details of Essential Documents**

| Number of Private Medical College | Required Essential Documents | | | |
|---|---|---|---|---|
| | Valid Society Registration | Ownership of Land | Certificate/ NOC of Fire Department | Certificate of Earthquake structure |
| 16 | Yes-10<br>No- 06 | Yes-05<br>No- 09<br>Partial-02[13] | Yes-03<br>No- 09<br>Partial-04[14] | Yes-01<br>No- 15 |

***Source: Information extracted from the records of the department.***

The Government replied (November 2022) that a letter had been issued to the institutes to fulfil the shortcomings. The reply is self-explanatory that the certificates were issued without ensuring the required formalities.

## *8.3 Fire Protection and Fire Safety Requirements*

As per Uttarakhand Fire & Emergency Service, Fire Prevention and Fire Safety Act, 2016, it is mandatory for all hospitals to obtain "**No Objection Certificate"** from the concerned Fire Department to ensure a minimum requirement for a reasonable degree of safety from fire emergencies in hospitals.

***Procedure to be adopted for obtaining NOC from fire Department***

- The Chief Fire Officer issue the "**No Objection Certificate"** from fire safety and means of escape point of view after satisfying himself that the entire fire protection measures are implemented and functional as per approved plans.
- Any deficiencies observed during inspection is communicated to the Authority for rectification.
- Based on undertaking given by the Fire Consultant / Architect, the Chief Fire Officer shall renew the fire clearance in respect of the hospital buildings on annual basis.

[12] ₹ 2.94 crore of affiliation fees, ₹ 1.20 crore of processing fees and ₹ 3.96 crore of security deposit.
[13] The ownership papers were on the name of the Management or on the name of the owner.
[14] Fee deposit but certificate not available, Conditional certificate issued, conditions fulfilled or not, not verified.

It was found that majority of HCFs that have applied for NOC were operating without valid NOC from fire department as can be seen in the **Table-8.3** given below:

**Table-8.3: Status of NOC**

| District | Registered as per CEA | HCFs as per Fire Department. | |
|---|---|---|---|
| | | Total applied | Running With valid NOC |
| **Almora** | 155 | 23 | 8 |
| **Bageshwar** | 44 | 35 | 5 |
| **Chamoli** | 150 | 8 | 2 |
| **Champawat** | 38 | 23 | 2 |
| **Dehradun** | 1,407 | 132 | 83 |
| **Haridwar** | 570 | 117 | 62 |
| **Nainital** | 425 | 59 | 37 |
| **Pauri** | 331 | 12 | 9 |
| **Pithoragarh** | 53 | 16 | 11 |
| **Rudraprayag** | 68 | 8 | 4 |
| **Tehri** | 76 | 19 | 6 |
| **Udham Singh Nagar** | 508 | 120 | 23 |
| **Uttarkashi** | 43 | 14 | 5 |
| **Total** | **3,868** | **586** | **249** |

***Source: Fire Department & DG, MH&FW Department.***

If compared with HCFs registered under CEA and that who are running with valid[15] fire NOC, the percentage was negligible (6.44 ***per cent).***

It was further noticed that the test checked hospitals were flouting fire safety norms. Most of them were functioning without obtaining NOC (***Refer Chapter-3 para-3.7.13.2)*** from Chief Fire Officer thus putting occupants of the health care facility at risk. Occupiers did not also bother to conduct regular maintenance of the fire prevention systems installed in their buildings and were having inadequate equipment installed (***Refer Chapter-3 para 3.7.13.2)***.

**Case Study: Fire incident due to inaction towards ensuring fire safety**

It came to the notice of audit through news/media that fire had broken in the trauma centre of Laxman Datt Bhatt Government Hospital (February 2021) which resulted in the complete destruction of equipment worth ₹ 12 lakh and threat to patient's life. Information obtained from the hospital further revealed that prior to the fire incident, the hospital was inspected (January 2021) by the fire department and it was instructed to the PMS to equip the hospital with firefighting equipment such as Hose reel, terrace tank (10 thousand litres), Static tank 50 thousand litres, fire hydrants and install fire alarms within a week for obtaining NOC. But no action had been taken by the occupant of the HCF.

In Exit Conference, the Secretary-In-Charge stated that all CMOs will be directed to ensure that all Government HCFs get installed fire equipment and obtain NOC from the Fire Department as early as possible.

[15] Issued by Fire Department.

## *8.4 Compliance of Atomic Energy Act*

Atomic Energy Regulatory Board (AERB) enforces regulatory requirements to ensure safe operation of X-ray equipment such as Cath Lab equipment, Computed Tomography machines, C-Arm, Mammography machines, General purpose medical radiography machines etc. Hence, a regulatory consent[16] from AERB is essential to ensure radiation safety in operating the X-ray equipment.

- ***Consent for operating of X-ray equipment***

In the State 148 number[17] of X-Ray Machines, Computed Tomography machines, C-Arm, Mammography machines, General purpose medical radiography machines etc. are installed in Government HCFs (DHs, SDHs, CHCs and PHCs) as per survey conducted by the Department. Analysis of the survey report revealed that 81 machines were commissioned and operationalized without obtaining prior approval of competent authority as per AERB Rules 2004. It was noticed that the process of Compliance, Infrastructure Development for Safety Regulations and Issuance of License for operation was taken up only after Government of India organized workshop (October 2017) wherein directions[18] were issued to place demand in PIP 2018-19 for meeting the expenses on such activity. Despite funds released[19] under NHM, the intervention was yet to be implemented. Thus, the process of Compliance, infrastructure development for Safety Regulations and Issuance of License for operation was delayed. The department stated that the AERB implementation program is under process. After hiring the AERB Authorised Service Agency, the said Agency will provide the necessary license to operational X-ray facilities.

***Thermoluminescent dosimeters (TLD) for Radiation Protection***

As per Atomic Energy (Radiation Protection) Rules, 2004 and AERB Safety Codes, monitoring equipment such as TLD badges[20] shall be provided to radiation workers and dose records shall be maintained. In case of any institution violating the prescribed

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16 The operational safety of X-ray equipment is ensured by issuance of License/Registration to the utility after review of all aspects related to radiation safety and after ensuring that patient, staff, and public are adequately protected.

17 In DHs (43 numbers of machines), SDHs (46 numbers of machines), CHCs (58 numbers of machines) and PHCs (one numbers of machines).

18 Neither budgetary provisions nor any directions were issued to HCFs by the Directorate/CMOs to obtain license from the regulatory body (AERB) during the period 2004-2016.

19 A demand of ₹ 2.55 crore was raised under NHM and approved in 2019- 20 instead of 2018-19. Nothing out of the released funds were utilised for meeting the requisite compliance. No funds were planned in 2020-21 for executing the said activity while ₹ Three crore for such activity was planned in the PIP of 2021-22 out of which ₹ 1.50 crore was released and an expenditure of ₹ 46 thousand were done (till October 2021) for advertisement /tendering process.

20. Thermoluminescent dosimeters or TLDs are made from materials that measure cumulative exposure to ionizing radiation. They are worn for periods of approximately three months and are then processed to determine the dosage of radiation detected. TLD badges are logged to maintain cumulative records of an individual's exposure to radiation over an extended period. TLD badges include several types of Thermoluminescent dosimeters, devices that can measure doses as low as millirem.

regulatory requirements, AERB is empowered to suspend/ modify/ withdraw the licence/ registration issued to the X-ray installation or seal the X-ray installation(s) in accordance with Rules 10 and 31 of the Atomic Energy (Radiation Protection) Rules, 2004 respectively.

Survey report made available by the department revealed that TLD badges were not provided to all radiation workers in the government HCFs of the State. However, the number of workers who did not receive TLD badges was not available in the survey report. Further, to determine the dosage of radiation for occupational workers, it was found in DH Nainital that TLD badges were not got processed from Bhabha Atomic Research Centre (BARC), since 2019. Thus, the safety aspects were compromised at the hospitals[21] where X-ray services were available.

In Exit Conference, the Secretary-In-Charge stated that compliance of AERB rules will be ensured, and all radiation workers will be provided with TLD badges.

## *8.5 Implementation of PC-PNDT Act*

The PC-PNDT Act was enacted with the intent to prohibit prenatal diagnostic techniques for the determination of the sex of the foetus leading to female feticide. The Act is legislated in a manner that it should be a deterrent for those indulging in sex determination. There is a suspension of registration, filing of criminal cases and sealing of machines. Besides, criminal prosecution brings suspension and cancellation of registration granted by the State Medical Council.

It was noticed as under:

- Silent observers/ trackers are very important surveillance tool and for cross examination of records. In the State, 524 (Government 75 + Private 449) Ultrasound Clinics/image centers were registered up to March 2021 wherein 899 number of machines were installed. However, silent observers were not installed in all machines.
- Under the PC-PNDT Act, it is mandatory to maintain records and submit a quarterly progress report to the concerned State authority. During COVID-19, some provisions of the Act were deferred/suspended till June 2020 thereafter all reports were to be submitted. Joint Director, PC-PNDT Uttarakhand had made it clear (April 2020) that on completion of lockdown, all concerned ultrasound operators will submit their report to CHOs in hard Copy. However, it was noticed that the directions were not followed, and no quarterly report was submitted (September 2021) to the authority concerned.
- The number of premises inspected by the appropriate authorities during the period July 2019 to November 2021 was not available with the Department.

[21] CHCs- Chakrata, Doiwala, Sahaspur, Betalghat, Bhimtal, Kotabagh and Ramgarh had not been provided TLD Badges and no pocket dosimeters were provided SDH Prem Nagar and Haldwani.

- In test check hospitals it was noticed that the ultrasound machines including new ones that were installed and used were operated either with expired NOC or without obtaining authorization from the competent authority.

The Government replied (November 2022) that trackers are being installed in all USG machines in the state. Further, new machines will not be registered without tracker.

### *8.6 Laws governing the qualifications/practice and conduct of professionals*

These laws make sure that the employees employed in the hospital are qualified and authorised to perform their jobs.

#### *8.6.1 Functioning of State Medical Council*

The State Medical Council was established (December 2002) under the Uttaranchal Medical Council Act, 2002 for fulfilment of the aims and the objectives as laid down in the Act. The main functions of the Council were to register the qualified medical persons who are possessing the qualifications recognized by the Medical Council of India. It keeps a register of bio-data of the qualified doctors. The council keeps a strict watch on the conduct and ethics practiced by medical professionals. The Council conducts enquiry on receipt of complaints against the registered medical practitioners and if found guilty, may award such punishment, as per applicable Rules. Records of the council revealed that:

- Prescribed[22] number of meetings as required were not held by the Governing Body and Executive Body. This would negatively impact on: timely[23] decisions on misconduct by medical practitioners resulting in reprimand/suspension/removal from list of registered practitioners; lack of timely action on complaints from the public (including patients and their relatives) against misconduct or negligence by a medical practitioners; Delay in finalising amendments and to prescribe a code of ethics for regulating the professional Conduct of practitioners.
- The medical council had intimated the Government to act against 34 Path Laboratory operating against the medical ethics in the state. However, action at the DRA level was still pending.
- Lack of coordination between the Medical College, DG, MH&FW and State Medical Council allowed 248 bonded doctors to obtain NOC from the State Medical Council without fulfilling the conditions of the bond.

The fact was accepted by the State Council who stated further that the issuance of NOC to the bonded candidates cannot be restricted by the State Medical Council without the coordination of all departments.

The Government replied (November 2022) that no information regarding bonded doctors was received earlier in Uttarakhand Medical Council.

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[22] Four & Six in a year by Governing body and Executive Body respectively.

[23] 86 out of 145 complaints were pending for action. The delay ranged from 1 to 6 years.

### *8.6.2 Nursing Council Act*

Uttarakhand Nursing Council was established under notification no 1016/M-2-2004-220/2002 dated 17th April 2004 for the fulfilment of the aims and the objectives as laid down in the Nursing, Midwives, Health Visitors and Auxiliary Nurse Midwives Registration Act 1934. In the implementation of rules, it was noticed as under:

***The functions of council included***

- *Granting recognition to the nursing institutions and its periodical inspection.*
- *Registration and granting certificate to qualified persons to practice their profession.*
- *Local supervision over nurses, Midwives, Health Visitors and Auxiliary Nurse Midwives.*

- ***Defunct Nursing Council***

Records revealed that Nursing Council was defunct since 2017, the reason being Government not extending tenure or issuing fresh notification for its establishment. It was stated that proposal for issuing fresh notification was submitted several times but was pending with Government.

- ***Registers of registered nurses, midwives, registered health visitors and auxiliary nurse midwives in accordance with the Act not maintained.***

As per section 18(1) of the Uttarakhand Nursing Council Act 2002, the Registrar of the State Nursing Council is responsible for the maintenance of registers[24] in the State. He shall from time to time make all necessary alterations in the registered addresses of appointments of such Nurses, Midwives, Assistant Midwives and erase the names of any registered Nurses, Midwives, Assistant Midwives who may have died or ceased to live and practice in India. To enable the registrar to fulfil the duties imposed upon him by sub-section (1) he may send through the post a letter to any person registered as Nurses, Midwives, Assistant Midwives, addressed according to the registered address or appointment of such person to inquire whether he has ceased to practice or whether his appointment has been changed; and, if no answer to any such letter within a period of six months from the dispatch, the Registrar may erase the name of such person from the register in which it is entered.

Records of the state council revealed as under:

- No records were maintained by council in relation to Nurses/Midwives that have already registered in the State but not renewed their registration after expiry of five years.
- The State council had never sent any letter/reminder for knowing status and details of Nurses/ANM whether they are still practicing or not. The council was also unaware about how many had died or ceased to practice.

[24] Register of Nurses, Midwives, Assistant Midwives (Auxiliary Nurse-Midwives).

- The register was required to print and publish correct list of the names for every year on or before a date fixed by the Council as per clause 23 of the Act, which was also not done.
- Unregistered nurses, midwives, health visitors and auxiliary nurse midwives were not prohibited from practicing.

Based on available records, it was noticed that a total of 8,685 Nurses were registered since 2006 to 2015 against which only 6,910 Nurses got their registrations renewed during the period 2015 to 2021. The council was, therefore, unaware about how many out of 1,775 have died or ceased to live or practice after expiry of five years of original registration. In the test checked hospitals Nurses were performing their duties without renewing the registration. It was stated that due to shortage of staff the activities required to be carried out under the Act could not be performed in totality. The council was, therefore, unaware of nurses practicing unauthorizedly and could not also collect due fee from renewal of registrations[25]. Thus, in the absence of an apex body and shortage of staff the monitoring mechanism was not in place.

In Exit Conference, the Secretary-In-Charge stated that the notification for the establishment of Nursing Council will be issued soon.

### *8.6.3 State Pharmacy Council*

Uttarakhand State Pharmacy Council is a statutory body constituted under the Pharmacy Act 1948 (Central Act). It regulates the profession and practice of pharmacy in the state. The State Pharmacy Council was constituted in the year 2006. However, the following was observed:

i. The honourable Government, by notification (January 2014) cancelled the election of the Council for not complying with the provisions of Clause 23[26] and 24[27] of the Act. It was further noticed that the new council has not been constituted since July 2014 due to non-holding of elections. The DG, MH&FW is discharging the duty as an interim measure.

***Duties of Inspector***

***(a) inspect any premises where drugs are compounded or dispensed and submit a written report to the Registrar;***

***(b) enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist;***

***(c) investigate any complaint made in writing in respect of any contravention of this Act and report to the Registrar;***

***(d) institute prosecution under the order of the Executive Committee of the State Council;***

***(e) exercise such other powers as may be necessary for carrying out the purposes of Chapters III, IV and V of this Act or any rules made thereunder.***

***(f) every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860).***

[25] To be utilised or applied for the purposes of this Act in such manner as prescribed in section 27 of the Act.

[26] **President and Vice-President of State Council**.—(*1*) The President and Vice-President of the State Council shall be elected by the members from amongst themselves.

[27] **Mode of elections**.—Elections under this Chapter shall be conducted in the prescribed manner, and where any dispute arises regarding any such election, it shall be referred to the State Government whose decision shall be final.

ii. Section 26A of the Pharmacy Act 1948, State Council may appoint Inspectors having the prescribed qualifications for the purposes of Chapters[28] III, IV and V of this Act. However, it was noticed that no appointment of Inspector was made by the Pharmacy Council in the State. The facts were accepted by the department.

In the absence of State Council and Inspectors, the inspection of premises where drugs are compounded and dispensed, investigation of complaints, etc. were not being carried out and reported to the Registrar.

In Exit Conference, the Secretary-In-Charge stated that the notification for the establishment of Pharmacy Council will be issued soon.

## *8.7 Law governing storage/sale of drugs and safe medication*

The Drug and Cosmetic Act control the usage of medication, chemicals, prevent their misuse and regulate their sale.

### *8.7.1 Implementation of Drug and Cosmetic regulations*

The Drugs and Cosmetics Act, 1940 regulates the import, manufacture, and distribution of drugs in India through licensing. The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective[29] and conform to state quality standards. Following are the salient features of the Act.

- Manufacture, distribution and sale of drugs and cosmetics by qualified persons only.
- To prevent substandard in drugs, presumably for maintaining high standards of medical treatment.

Under the Act, the Drug controllers are responsible for regulating the manufacturing, distribution, sale, and use of pharmaceutical products within their jurisdiction. Evaluate applications for the approval or licensing of new drugs, as well as for changes to existing drug products. Conduct inspections of pharmaceutical manufacturing facilities to ensure compliance with good manufacturing practices (GMP) and other regulatory requirements. It also ensures that only safe, effective, and high-quality drugs are available to patients.

#### *8.7.1.1 Testing of drugs*

Scrutiny of records of the Drug Controller revealed that a total of 270 tests were conducted during 2019-21. It was further noticed that test reports were being provided late, due to which the process of stopping or recalling the sale of substandard drugs in the open market was not being ensured in time. The details of submission of their test reports are given in **Table-8.4** given below.

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[28] Chapter-III-Education Regulations, Chapter IV- Registration & preparation of register; Chapter-V Penalty for falsely claiming to be registered etc.

[29] Maximum penalty life imprisonment and fine of ₹ 10 lakhs or 3 times the value of the confiscated goods, whichever is more. Besides officers from the Drug Controller's Office, other gazetted officers also authorized to launch prosecution under the Act.

**Table-8.4: Testing of drugs**

| Days taken for submission of reports | | | | | | |
|---|---|---|---|---|---|---|
| **Days** | 01-15 | 16-30 | 31-60 | 61-120 | 120 days to above | No records |
| **Total Test 270** | **07** | **40** | **79** | **99** | **21** | **24** |

### *8.7.1.2 Registration and renewal of license*

The Drugs and Cosmetics Act, 1940 regulates the manufacture, sale and distribution of drugs and cosmetics. According to this, no person or firm can stock, sell or distribute drugs without a suitable license issued by the State Government. Further, as per the provision of the Act, the drug dealers must be inspected once in three years.

It was found that no manual record/register[30] were being maintained by the department of the registered licensed businessmen. However, information related to the drug business operating in the state was made available by the department on the Government of India portal https://xlnindia.gov.in. Scrutiny of the information available on the portal revealed that the licenses of 155 drug dealers have expired as per the detail given in ***Appendix-8.1***. There was no record/information available either in the office or on the portal whether dealers had applied for renewal and action taken to those dealers to whom license had expired and are still doing business in the state. Apart from this, the drug dealers are to be inspected once in every three years but it was found that only 11 out of 155 drug dealers, whose license had expired, were inspected.

The department stated that the licenses of the firms are considered valid till 6 months after the expiry of their validity with late fee, as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules 1945 and after the expiry of this period, the license of the firm is automatically deemed to be canceled. The response lacks justification due to the inadequate adherence to the inspection mechanism, which is essential for ensuring that no unregistered or unlicensed drug dealers can engage in drug-related activities within the state.

### *8.7.1.3 Strengthening of State Drug Regulatory System*

Under the Strengthening of State Drug Regulatory System Scheme (DRSS), a new drug testing laboratory was to be established/constructed. The state Government submitted a revised (January 2019) proposal of ₹ 29.35 crore for the said purpose was subsequently approved by the GoI. The following works were to be done.

- Construction of a new drug testing laboratory in the Dehradun district with an annual testing capacity of 3,000 samples and the existing laboratory to be upgraded.
- Strengthening of drug control organization for effective implementation of prescribed standards with the development of information technology infrastructure at the district level.

[30] Which could provide information about how many businessmen were registered, when license was issued to them and what was its validity date?

- Construction of two zonal headquarters offices at Nainital and Pauri and a new building of the State Drug Controller's office in Dehradun.

For taking up of above works[31], ₹ 8.75 crore in the year 2018-19 and ₹ 5.25 crore (total ₹ 14 crore) in the year 2019-20 was released by the Government of India to the state. It was found that only 84 *per cent* physical progress of construction work[32] was done with ₹ 2.97 crore (December 2020). The building was finally handed over but could not be utilised for the purpose due to the unavailability of manpower (July 2022). Further, the Gap Analysis report of the existing laboratory at Rudrapur had recommended that:

- Most of the machines available in the laboratory were non-functional, which required repairs for which about ₹ 10 lakh was required.
- Some equipment in the laboratory like Dissolution apparatus, Disintegration test apparatus, Auto titrator, Water purification system etc. were not available for which about ₹ 70 lakh was required.
- Against the sanctioned 14 technical posts in the laboratory, only five posts of human resources were deployed, which urgently needed to be filled.

Audit scrutiny revealed that neither any amount was spent for the strengthening of State Food and Drug Analysis School, Uttarakhand, Rudrapur nor appointments were made on vacant posts despite the availability of Central funds of ₹ 10 crore under the scheme. It was stated by the department that the purchase of new machines and repair of old machines for the State Food and Drug Analysis Centre, Rudrapur is under process. The requisition for filling up the technical posts has been submitted for the approval of the Government.

In Exit Conference, the Secretary-In-Charge stated that all construction activities of strengthening of State Drug Regulatory System had been completed except construction of the Zonal Headquarters at Pauri and Nainital. Similarly, manpower for operating the lab at Dehradun was yet to be provided. However, action on pending items is underway.

#### *8.7.1.4 Achievement of Targets fixed for inspection*

Department of Food and Drug Administration was carved out as an independent department from the Health Department in the Uttarakhand in 23rd September 2019 for regulations of Food Standard and Safety Act 2006 and Drugs & Cosmetics Act 1940 and Rules 1945 more effectively. These statutes are aimed at ensuring supply of quality medicines, cosmetics & food stuffs to the public at large at affordable prices and also safeguarding the unwary public from misleading advertisement of drug/food articles & drug abuse. Prior to this, food and drugs control programme in the state was functioning under Director General of Health Services.

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[31] The Memorandum of Understanding was signed between the Government of India and the State Government in the month of January 2019 for the construction of new drug testing laboratory, State Drug Controller's office and for the construction of divisional offices.

[32] Drug control office building and drug testing laboratory

As per provisions contained in Drugs and Cosmetics Act 1940, District Drug Control Officer (DCO) must conduct inspection of retail and wholesale firms for further quality analysis. The achievement against total number of firms in the state is shown in the **Table-8.5** below.

**Table-8.5: Shortfall in achievement of inspection against total number of firms**

| Year | Total number of firms | Annual target | Achievement | Pending inspection |
|---|---|---|---|---|
| **2016-17** | 1,011 | No annual targets were set | 864 | 147 |
| **2017-18** | 1,961 | | 1,619 | 342 |
| **2018-19** | 4,582 | | 3,473 | 1,109 |
| **2019-20** | 7,694 | | 5,468 | 2,226 |
| **2020-21** | 11,717 | | 6,789 | 4,928 |
| **2021-22** | 16,310 | | 5,649 | 10,661 |

***Source: Departmental information.***

It is evident from the table that there has been shortfall in achievement for inspection conducted by DCO's. As per D&C Act, 1940 it is provisioned that every license premises shall be inspected once in three years. No annual targets were set for inspection but regular and complaint based/surprise inspections/raids are carried out. In regard to pending inspections it was stated due to lack of manpower all the firms are not inspected as per scheduled timeline.

#### *8.7.1.5 Licenses and Good Manufacturing Practices (GMPs) Certificates not renewed*

As per Drugs & Cosmetics Rules 1945, the license of a Pharmacy shall be deemed to have expired if the application for its renewal was not made within three months of its expiry.

Scrutiny of records of Directorate, Ayurveda revealed that 45 licenses and 16 Good Manufacturing Practice (GMP) certificates out of 323 pharmacy licenses issued were due for renewal. This indicated lax enforcement of the statutory provisions by licencing authority[33].

The Government replied (November 2022) that delay in renewal was mainly due to time taken by pharmacies in the removal of objections raised during inspections. The Government's reply, however, is silent on strict enforcement through awareness and punitive actions.

### *8.8 Law governing environmental protection*

These laws are for the protection of the environment through the prevention of air, water and surface pollution.

#### *8.8.1 Implementation of Bio-Medical Waste Management Rules, 2016*

Bio-Medical Waste Management Rules, 2016 stipulates that all person shall apply for authorisation who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form. It includes hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories, blood banks, AYUSH hospitals and clinical establishments.

[33] Licensing officer of Directorate, Ayurveda.

### *8.8.2 Health Care Facilities generating Bio Medical Wastes without obtaining authorisation*

Bio-Medical Waste Management Rules, 2016 provide that every occupier or operator of common bio-medical waste treatment facility shall submit an annual report to the prescribed authority on or before the 30th of June of every year, giving the details of the respective treatment facility including location, waste quantities generated etc. This information is to be compiled, reviewed and analysed for the whole State and sent to the Central Pollution Control Board.

During scrutiny of records, it was noted that there were many HCFs which were in operation without applying for the authorisation from Uttarakhand Pollution Control Board (UPCB). It was further noted that all the authorized HCFs were not submitting the annual reports. As per annual reports available on the site of UPCB, year-wise detail of such HCFs are shown in the **Table-8.6** given below:

**Table-8.6: 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 report | Percentage of non-submission of annual report |
|---|---|---|---|---|---|
| **2017** | 849 | 533 | *63%* | 317 | *37%* |
| **2018** | 2,312 | 1,730 | *75%* | 1,539 | *67%* |
| **2019** | 3,185 | 933 | *29%* | 404 | *13%* |
| **2020** | 4,442 | 521 | *12%* | 1,012 | *23%* |
| **2021** | 5,355 | 749 | *14%* | 1,540 | *29%* |

***Source: Information taken from annual reports uploaded on portal of board, UPCB.***

As can be seen from above table, between 2017 and 2021, unauthorized operation of Healthcare Facilities (HCFs) ranged from 12 *per cent* to 75 *per cent* while non-compliance with annual report submissions ranged from 13 *per cent* to 67 *per cent*. Thus, indicating the insufficient regulatory oversight of Bio-Medical Waste Management in the State.

Records of Uttarakhand Pollution Control Board (UPCB) further revealed as under:

- Bar code facilities were not installed in 48 out of applicable 82 HCFs[34]. This includes government hospitals of two sampled districts (B D Pandey Male and Female Hospital, Coronation Hospital and Doon Women Hospital etc.) to whom notices were also issued by the Uttarakhand Pollution Control Board.
- 2,582 HCFs had captive treatment[35].

[34] Having more than or equal to 50 beds across all districts.

[35] Means a facility developed within the premises of an occupier for treatment, storage, and disposal and disposal facilities storage and disposal facility.

- Only 118 HCFs had installed liquid waste treatment plants in the state.
- UPCB had no information as to how many occupiers have constituted Bio Medical Waste Committees as per bio medical rules.
- No report was submitted by the CMOs of the respective districts to the DG, Medical Health and Family Welfare indicating the status of number of HCFs (both Government and Private) that have not received authorisation for disposal of BMW or yet not applied for the same to UPCB. On audit observation, the DG, Medical Health and Family Welfare issued several reminders to the district authorities, but no response was received. It was stated by the Directorate that information of total HCFs authorized by the UPCB is being sought from the CMO's and utmost thrust is given to meet all the requirements under BMW rules.
- Centralised records of authorisation, types and methods used for disposal of BMW and of defaulters were not maintained at the directorate despite a separate wing established in the directorate office for the said purpose.
- ETP/STPs in Government Facilities were not installed yet. While admitting the facts the DG, MH&FW stated that efforts to get ETP/STPs installed in Government HCFs are underway.
- Other deficiencies in the implementation of BMW rules, such as unavailability of a proper storage/collection system, not collecting of generated waste on daily basis, etc. were also noticed in the test checked hospital (***Refer Chapter 3 para 3.7.6 & 3.7.7***). For non-compliance of Bio Medical rules notices and penalty of fifty thousand were also imposed on various HCFs including test-checked hospitals[36] by the Uttarakhand Pollution Control Board.

In Exit Conference, the Secretary-In-Charge stated that most of the HCFs had received authorisation from the Uttarakhand Pollution Control Board and those who have applied or are running without authorisation will be instructed to obtain authorisation as early as possible. Further, the department is working on providing barcode facilities to HCFs.

## *8.9 Conclusion*

The DRAs were primarily focused on managing provisional registration/renewals for nursing homes, private and Government hospitals. Most of the Health care facilities were running without obtaining authorisations from Uttarakhand Pollution Control Board, indicating inadequate oversight of Bio-Medical Waste Management. Laxity in the enforcement of the statutory provisions by drug licencing authority were found. The Nursing council was unaware of Nurses practicing unauthorizedly and could also not collect due fee from renewal of registrations. Test checked hospitals were found disregarding fire safety norms, operating without obtaining necessary NOCs as well.

[36] Medical Superintendent BD Pandey, Male & Female Hospital, Nainital, Coronation hospital, Doon Women Hospital.

## *8.10 Recommendations*

1. ***The Government may ensure that the targeted number of inspections of firms engaged in retail and wholesale selling/supplying of drugs are carried out to ensure the quality of the drugs sold;***
2. ***The Government may ensure that all utilities generating bio-medical waste comply with the provisions with regard to authorisation, bar coding, annual returns along with third party inspection to regulate the generation and disposal of bio-medical waste;***
3. ***The Government may ensure that all requisite regulatory bodies are constituted as per the respective statutory norms;***
4. ***The Government may ensure that the various regulatory bodies may adopt an adequate and effective monitoring mechanism to guarantee conformity with the necessary minimum standards;***
5. ***The Government may ensure to get all the hospital buildings independently assessed for fire safety and ensures that these are fully equipped with firefighting equipment.***