The World Bank

Environmental and Social System Assessment (ESSA)

PHSPP: Transforming India's Public Health Systems for Pandemic Preparedness (P175676)

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ABBREVIATIONS

AMR	Anti-Microbial Resistance
APHO	Airport Health Organization
ASHA	Accredited Social Health Activists
BSL	Bio-safety Level
CPCB	Central Pollution Control Board
CPGRMS	Centralized Public Grievance Redress and Monitoring System
CPWD	Central Public Works Department
CWAC	Capital Works Advisory Committee, ICMR
CWMC	Capital Works Monitoring Committee, ICMR
DALY	Disability-adjusted life year
DARPG	Department of Administrative Reforms and Public Grievances
DGHS	Director General of Health Services
DHR	Department of Health Research
DLI	Disbursement Linked Indicator
DMC	Disaster Management Cell
DPG	Directorate of Public Grievances
EIS	Epidemic Intelligence Service
ESSA	Environmental and Social System Assessment
GoI	Government of India
HEOC	Health Emergency Operation Center
HWC	Health and Wellness Centers
ICC	Internal Complaints Committee
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Program
IH Division	International Health Division
IHIP	Integrated Health Information Platform
IPC	Indian Penal Code
LBHU	Land Border Health Units
LCC	Local Complaints Committee
MOHFW	Ministry of Health and Family Welfare
MoU	Memorandum of Understanding
MRHRU	Model Rural Health Research Unit
MRU	Multi-disciplinary Research Unit

NBCC	National Buildings Construction Corporation
NCDC	National Center for Disease Control
NGO	Non-governmental Organization
NHM	National Health Mission
NIV	National Institutes of Virology
PAP	Program Action Plan
PDO	Program Development Objective
PFMS	Public Finance Management System
PforR	Program for Results
PH	Public Health
PHC	Primary Health Centers
PHO	Port Health Organization
PHSPP	Public Health Systems for Pandemic Preparedness
PM-ABHIM	Pradhan Mantri- Ayushman Bharat Health Infrastructure Mission
RTI	Right To Information
SC	Scheduled Caste
SDRF	State Disaster Response Fund
ST	Scheduled Tribe
VRDL	Virus Research and Diagnostic Laboratory
WB	World Bank
WWTP	Waste-water Treatment Plant

EXECUTIVE SUMMARY

Environmental and Social Systems Assessment (ESSA) for the PHSPP Program has been completed in line with the World Bank Guidance for conducting ESSAs for Program for Results (PforR) financing operations. The ESSA assesses the gaps in the existing institutional, operational and regulatory systems and capacities to manage Environmental and Social (E&S) risks and recommends measures for strengthening them. The ESSA process involved a desk review of relevant documents, technical studies/reports, and information related to working of the Ministry of Health and Family Welfare (MOHFW) and Indian Council of Medical Research (ICMR), National Center for Disease Control (NCDC), Disaster Management (DM) Cell, and International Health Division (IHD) of MOHFW. This was complemented with virtual and face-to-face consultations with relevant experts and officials from ICMR, NCDC, DM Cell, and IH Division to capture current practices, opinions, anecdotal evidence, functional knowledge, and concerns. The draft ESSA report has been shared with MOHFW and the implementing agencies for their comments and suggestions and was further presented in the multi-stakeholder consultation workshop on 28th April 2022 to a wide range of stakeholders for their feedback and suggestions. The revised ESSA report incorporates comments and suggestions received during the multi-stakeholder consultation workshop. The key findings of ESSA are summarized below.

Environment and Social Benefits, Risks and Impacts: The proposed program have range of environmental and social benefits. With expansion of disease surveillance systems supported by a network of public health laboratories, effective implementation of One Health, enhancing India's bio-security capacity by supporting bio-medical research capacity, it will lead to faster identification of any disease outbreaks, and ability to appropriately respond in addressing them. The program also aims towards strengthen the regional capacity and state capacity towards identifying and responding to any outbreaks locally, along with ensuring compliance with existing national environmental regulatory provisions and international environmental obligations. The program also needs to address the issues of silos and coordination.

The key environmental risks associated with (a) Construction-related occupational health and safety hazards and risks to the workforce and associated community safety and health aspects due to these activities; (b) Lack of incorporation of design safety in the construction plan of Biosafety laboratories poses occupational health risk to the laboratory workforce as well as to the community health and safety due to accidental escape/release of high-risk pathogens from such laboratories; and (c) Handling of high-risk pathogens and associated biomedical wastes pose a risk of biohazards exposure to the laboratory workforce, waste handlers and to the community in case of improper waste disposal. Besides working with specialized equipment e.g., autoclaves, centrifuges, and chemical reagents also pose occupational risk of exposure and/or chemical toxicity and injuries. Also, use of equipment having radiation risk and use of radioactive isotopes require specialized approaches, especially in storing and disposing radioactive wastes and decommissioning of such equipment. Some of the activities to be carried out by the IHD for implementation of International Health Regulations at Point of Entry such as airport, ports, and land border units may also pose occupational health and environmental risks and include: (i) screening of international passengers for diseases under surveillance; (ii) disinfection, and deratting of ships and aircraft; (iii) supervision of sanitation, drinking water supply, anti-mosquito and anti-rodent work; (iv) public health clearance of dead bodies; (v) administration of yellow fever vaccines etc. The key social risks emerge from (a) Identifying and transferring the land requested for construction of these centers and laboratories by the states in a transparent manner without any adverse social impacts; (b) Potential health and sanitation, safety, and labor management related concerns at construction sites; and (c) Community health and safety concerns.

Environmental and Social System Assessment: The provisions of the existing environmental legal and regulatory framework are adequate but require enabling institutional and technical capacity to comply with. While the provisions of the Biomedical Waste Management & Handling) Rules, 2016 – as amended up to 2019 are being implemented, provisions of other relevant environmental Acts, such

as, hazardous, solid, plastic and E-waste Rules 2016 require additional capacity building efforts. Efforts are required to improve the monitoring of the management of different kinds of wastes. The International Health Regulations (IHR), 2005 also mandates national governments to monitor and manage public health at the Points of Entry (PoE) that include airports, seaports and land border units where there is human travel and transfer of goods across the international borders. Though this was further incorporated in the Indian Aircrafts Public Health Rules, 2015 and Indian Ports Public Health Rules, 2015, the current national regulations is old and covers public health requirements not adequately congruent with the requirements of International Health Regulations, 2005.

The existing legislative framework is adequate to ensure social sustainability of the protection of interest of marginalized and vulnerable population including women, the elderly, the differently abled, ST, SC, women headed households, patients with chronic diseases informal sector workers (including domestic workers, laborers, and construction workers). It ensures (a) protection of the interest of all the vulnerable population as mentioned above, (b) non-discrimination based on religion, race, caste, and gender, and (c) transparency with right to information. Also, MOHFW have experience in protection of personal data through its various program such as the National AIDS Control Program (NACP) and during various surveillance programs. In addition, the Government of India is in an advance stage of enacting the law on personal data privacy which is soon expected to become the legislation. The building and other constructions workers related act, and the Occupational Safety, Health and Working Conditions Code, 2020 further strengthens the labor related framework and legislations. However, it requires enabling institutional, capacity, and regular monitoring to comply with.

The proposed infrastructure facilities such as NIVs, Regional NCDC Centre(s), NCDC branches, and BSL-3 laboratories are planned in such a manner that they are equitably distributed across states and region including backward states and states with higher tribal population, to address regional and state specific issues and concerns. For setting up various centers and laboratories, in most cases land is already made available by the states free from any encumbrances such as for establishing NIVs, One Health Centre, and some of the NCDC branches, and the BSL-3 laboratories. For the remaining infrastructure, the implementing agencies follow the process of requesting for land free from any encumbrances from states as part of their contribution towards the program. Both ICMR and NCDC will sign a Memorandum of Understanding (MoU) with the construction agency, which will build the infrastructure for ensuring inclusion of specific clauses and other environmental and social concerns. The construction agencies will follow all the legal provisions relating to such constructions. However, the issue of sub-contracting to local contractors often poses additional challenge, particularly with respect to occupational health and safety. Also, some of these constructions may amount to small labor camps at the construction sites, and hence, the emerging risk from health and sanitation, safety, and labor management related concerns at the construction sites for labor camps, apart from community health and safety concerns.

MOHFW and all the implementing agencies leverage existing country system to receive, resolve and manage grievances. The Centralized Public Grievance Redress and Monitoring System (CPGRMS) is an online web-enabled system (https://pgportal.gov.in/) in association with Directorate of Public Grievances (DPG) and Department of Administrative Reforms and Public Grievances (DARPG) to register and track grievance. Any grievances with respect to MOHFW, ICMR, NCDC, DM Cell, and IH Division as well as state specific grievances can also be lodged here which are further directed to respective agencies and state department for resolution and reported back through CPGRMS system.

Key Environmental and Social Gaps: The key environmental and social requiring further attention include (a) Improper screening of identified construction sites for any environmental and social risks and impacts; (b) need for designated organization for managing biosafety and biosecurity aspects arising out of current functioning as well as future expansion of laboratory system in NCDC; (c) there is no committee of NCDC which advises and/or monitors the works awarded for construction of various centres and laboratories; (d) need for increased training and capacity building on biosafety related to biomedical waste management and Occupational Health and Safety of the workforce in laboratories;

(e) the regulatory framework of current national regulations is old and covers public health requirements not adequately congruent with the requirements of International Health Regulations, 2005; and (f) the issue of sub-contracting to local contractors often poses additional challenge, particularly with respect to occupational health and safety of construction workers along with gaps in monitoring of labor health and safety, and community health and safety concerns.

Excluded Activities: The PHSPP program will not finance any activities that would cause high E&S risks and impacts including activities involving:

- Any land acquisition, physical relocation and/or involuntary resettlement impacts.
- Construction and establishment of BSL-4 laboratories
- Any work that would convert or encroach forest lands, notified wetlands or any eco-sensitive areas.
- Activities that are not in compliance with Central and State environmental legislation.
- Use of child or bonded or forced labor or labor involved in any hazardous activities.
- Destruction or damage to any physical and cultural resources.

Recommendations: The ESSA recommendations focus on strengthening the national systems and institutional arrangements for implementation, management, and reporting of E&S aspects, including:

1. Incorporation of environmental and social measures, for addressing potential negative impacts and risks, in the design, construction and operation of BSL3 laboratories. This would include provisions of undertaking an environmental impact assessment (EIA) for the proposed BSL3 laboratories. Annex 5 provides detailed step-by-step guidance for establishing BSL3 and a checklist for managing operations of a BSL3.
2. Setting up committee in NCDC to advise the Executing agency in design, and construction and help monitor the progress of BSL3 laboratories and other infrastructure facilities. In addition, NCDC to develop training program for building capacity on biosafety management focused on biomedical waste management and occupational health and safety for laboratory workers on a regular basis. NCDC is setting up a Biosafety and Biosecurity Division, which will play a critical role in strengthening these aspects.
3. NCDC/ ICMR to periodically assess the preparedness and response capacities of the organizations on biosafety management for which a Monitoring Committee be constituted and protocol developed for assessing such capacity.
4. All NCDC/ ICMR/ MOHFW healthcare facilities and diagnostic laboratories to report on biomedical waste generation and disposal through the CPCB mandated mobile application.
5. Inclusion of occupational health and safety as well as labor welfare provisions in the construction contracts and its periodic monitoring.
6. Managing E&S risks of potential substantial risk activities, through screening or site-specific Environment and Social management plans (ESMPs).
7. IHD to finalize the draft Indian Aircraft Public Health Rules, and Draft Port Health Rules, developed in 2015, so that these are adopted and published by the Government of India to bring national regulations in congruence with the specific requirements of International Health Regulations, 2005.
8. In case the need arises, any Government land undertaken is preferable, or else donation is done voluntarily without any coercion for doing so, and the process of donation shall be institutionalized through a transparent and through the process of gift deeds.

While most of the recommendations will be incorporated in the program operations manual, a higher-level action is recommended as part of the Program Action Plan (PAP) and includes:

Action Description	Responsibility	Due Date	Completion Measurement
Signing of an agreement and/or MoU with selected construction agency on ensuring key environmental and social clauses for addressing Occupational Health and Safety issues and compliances with the provisions of the national labor laws.	NCDC	Agreement / MoU signed before construction begins	MoU signed
Establishing mechanisms for technical advisory and monitoring of environmental and social activities by an experts group during implementation	MOHFW, ICMR, NCDC	Within 12 months of effectiveness	Guidelines prepared detailing mechanism for technical advisory and monitoring supervision of E&S activities, and expert group notified through a Government Order and/or Office Memorandum
Designing online training program on Biosafety, Biosecurity, Biomedical waste management, IPC and OHS for laboratory workforce	NCDC	Within 12 months of effectiveness	Online course available The course being developed under the COVID-19 Emergency Project will be used for this purpose.

1 PROGRAM DESCRIPTION

1.1 Background and Context

1. COVID-19 has underscored the urgency of revamping, reforming, and developing capacity for core public health functions at state and central levels. Infectious disease prevention and control requires a reliable system of health surveillance and public health intelligence that can generate data, disseminate guidance and respond to disease outbreaks in a timely manner. The system should be able to integrate environmental health data, national and international epidemic events, monitoring of risk factors associated with communicable diseases, surveillance of epizootics and diseases of animal origin, and monitoring of emergency and climate-related events, including natural disasters. enhanced Increasing global travel, and within country movement of people and goods also facilitates spread of infectious diseases, particularly for vulnerable communities who need to work every day for livelihoods. The high exposure between livestock, people, and wildlife combined with weak animal disease surveillance poses risks for disease outbreaks[1]. Most major epidemics in recent years (SARS, MERS, Nipah, Swine flu, Avian flu, Ebola, and COVID-19) were transmitted either through direct handling of live primates, bats, and other wildlife (or their meat), or indirect contact with farm animals such as chickens and pigs[2]. Currently, collaboration and coordination between human and animal health remains weak, with little sharing of information and data between relevant institutions.

2. COVID-19 Pandemic highlighted four important lessons for India. First, the importance of center and states working together to ensure effective local surveillance and containment. Community surveillance led by Accredited Social Health Activists (ASHAs) and Multipurpose Health Workers with backing from Health and Wellness Centers (HWCs) and Primary Health Centers (PHC) helps to identify local outbreaks. Prompt data triangulation by district surveillance units with support from panchayat bodies and local administration is essential for containing the spread. Second, the importance of test, trace, and isolate strategy. This requires rapid scaling of district level laboratories, involving the private sector, ensuring quality and access to reagents, as well as develop capacity for genomic surveillance to identify variants of concern and the need for network of virological laboratories capable of identifying novel and remerging virus, especially of zoonotic origin. While countries that did not have outreach workers struggled, India had the advantage of huge network of ASHAs to support contact tracing. Third, the need for dedicated facilities in public sector for effective management of infectious diseases offering different levels of care with efficient logistic systems for live saving supplies such as oxygen and competent human resources. Fourth, the role of vaccination in slowing down the pandemic.

3. With continuing vulnerability to future waves, India has four potential pathways to address the health systems challenges posed by the pandemic. First, ensuring high level of vigilance and effective response to future COVID waves building on investments made. Second, build a robust world class public health surveillance system that ensures prompt detection of disease outbreaks using real-time data and effective response systems, as envisaged under the Pradhan Mantri- Ayushman Bharat Health Infrastructure Mission (PM-ABHIM) and the white paper "Vision 2025 for Public Health Surveillance in India"[3]. Third, build stronger national institutes to provide effective direction and leadership including analytical underpinning for pandemic preparedness and enhanced biosecurity. Finally, India needs a 21st century people centric health system founded on a robust primary healthcare system capable

[1] Brucellosis, Toxoplasmosis, Cysticercosis, Echinococcosis, Japanese Encephalitis (JE), Leptospirosis, Scrub typhus, Zoonotic Tuberculosis, Kyasanur Forest Disease (KFD). Zoonotic disease outbreaks have been occurring in regular intervals in India including Leptospirosis (2005), Avian Flu (2006), NIPAH (2018); SARs (2003), Plague (1994), and the current COVID-19 (2020).

[2] Dobson, A. et al. 2020. Ecology and economics for pandemic prevention. https://science.sciencemag.org/content/369/6502/379

[3] Vision 2025, Public Health Surveillance in India: A white Paper; NITI Aayog, 2020 ISBN 978-81-949510-6-3

of handling its rapidly changing demographic, epidemiological, environmental, and social determinants of health, ensuring equity with a strong foundation in prevention and health promotion.

4. A complementary set of World Bank engagements is proposed to support this expansive and ambitious reform agenda. The proposed Program aims to build a resilient public health system by expanding disease surveillance systems supported by a network of public health laboratories, effective implementation of One Health, enhancing India's bio-security capacity by supporting bio-medical research on COVID-19 and other emerging and re-emerging infectious diseases and transforming core public health institutions and research agencies as global centers of excellence. A parallel complementary Program is being proposed to address reforms to achieve universal and effective health coverage, better public health spending and accountability for results. And a third program is focusing on strengthening the One Health approach through better integration of livestock and wildlife disease surveillance and diagnostic capacities.

5. The proposed Program leverages the Bank's engagement in strengthening disease surveillance and pandemic preparedness since 2004. The Program builds upon the Bank-supported Integrated Disease Surveillance Project (IDSP-2004-12) that established a common platform for India's surveillance, set up state and district surveillance units, introduced systematic outbreak investigation, with an IT-enabled backbone for data transmission and analysis. The proposed Program also builds on the ongoing India COVID-19 Emergency Response and Health Systems Preparedness Project (2020-24) that is contributing to enhancing the health system's capacity for laboratory diagnosis of viral infections, surveillance, isolation, and critical care.

1.2 Program Scope and Boundaries

1.2.1 Program Development Objective (PDO)

6. The program development objectives of the project is to "strengthen pandemic preparedness and response systems and institutions in India."

7. The PDO level results indicators include the following:

- Outbreak alerts generated by IHIP investigated within 48 hours by District/State Surveillance teams
- Metropolitan surveillance units meeting established performance benchmark
- NCDC publishes treatment guidelines on rational use of antibiotics for common infections based on AMR surveillance
- National risk-map with hot spots for Zoonotic diseases of human importance prepared and updated
- Researchers trained by Zonal NIVs with competency in genomic sequencing (disaggregated by gender)
- Advanced and frontline (disaggregated by gender) public health workforce received training to build core competencies in preventing, detecting, and responding to disease outbreaks

1.2.2 Key Result Areas

8. **Descriptions of the Program Result Areas:** The Program will support the three Result Areas that contribute to the overall outcomes of the Government Program. The key result areas of the program are as below.

9. **Results Area 1 (RA1): Expanding an Information Technology (IT) enabled surveillance system and One Health coordination**. This RA aims to prepare India's surveillance system to be 21st century ready to "detect and report" epidemics of potential international concern through real-time surveillance and reporting, enhanced accessibility and use of surveillance data; ensure "rapid response"

by expanding surveillance capacity and developing and exercising emergency preparedness and response plans; and "prevent" emergence or release of pathogens including those constituting public health risk by enhancing surveillance of AMR and zoonotic diseases. Specific thematic areas under this results area include:

- Development and strengthening of surveillance reporting through Integrated Health Information Platform (IHIP) to generate real time surveillance data to provide early alerts of infectious disease outbreaks.
- Strengthening of Points of Entry to meet international health regulation standards for enhanced cross border surveillance.
- Strengthening of capacities of metropolitan cities to identify and contain disease hotspots and populations vulnerable to emerging and remerging diseases.
- Strengthening of disaster and epidemic preparedness by creating healthy emergency operation centers.
- Strengthening of all divisions of NCDC focused on applied public health capacity building and establishment of regional centers.
- Enhancement of ability to detect novel pathogens by expanding biosafety laboratory network to enhance advanced outbreak investigations and response.
- Expansion of network of sentinel sites for One Health surveillance and network of One Health coordinators to monitor trends of zoonotic diseases.
- Implementation of an enhanced national program for anti-microbial resistance.
- Support for measures to ensure pandemic preparedness and response plans cater to the needs of women and other vulnerable populations, including through gender disaggregated data reporting.
- Preparation of state level action plans on climate change and health to strengthen climate resilience.

10. While a large body information exists on prevalence of reproductive tract and sexually transmitted infections in women, gender disaggregated data on women impacted by communicable diseases and outbreaks is scanty. It is therefore important to obtain gender segregated surveillance information from the IHIP platform to better understand vulnerabilities of women. Under the PHSPP, the NCDC will prepare a report on number of women affected by reported outbreaks and ensure pandemic preparedness and response plans are grounded in sound gender analyses and needs of other vulnerable populations. PHSPP will also strengthen climate resilience by ensuring that all states prepare action plans on climate change and health. Specific activities supported under this results area will include civil works, goods, consultancies, training, workshops and incremental costs.

11. **Results Area # 2: Enhancing Bio-security Capacity**. This RA is implemented by the ICMR, India's premier bio-medical research agency with a focus on enhancing capacity to detect emerging and remerging pathogens with a focus on zoonotic disease risk mapping to inform India's bio-security response including commercialization of new technologies to prevent, detect or treat diseases of national importance and collaborative research with other countries in southeast Asia region to identify novel pathogens. Key thematic areas under this results area include:

- Identification of hotspots for zoonotic diseases and creation of national risk maps through establishment of a new center for One Health research to build One Health research capacity.
- Capacity building of medical colleges and state research institutes in viral diagnostics including genome sequencing, including through establishment of zonal national institutes of virology.

- Expansion of network of viral disease research laboratories for expanded surveillance of pan-respiratory viruses and improved diagnosis of fevers of unknown etiology.
- Promotion of commercialization of technologies to prevent, diagnose and treat infectious diseases through strengthening of ICMR's Medical Devise and Diagnostic Mission Secretariat to create relevant policies and establish public-private platform to engage with the industry.
- Building of Southeast Asia regional capacity to undertake collaborative research on disease dynamics of identified regionally important pathogens by creating a regional platform.
- Development of tools and playbooks for early warning signals and community engagement and risk communication during health emergencies
- Capacity building in disease elimination science through establishment and operation of a new division for research in disease elimination at ICMR's National AIDS Research Institute.
- Capacity building in applied research for diseases of national importance, including through expansion of partnerships with medical colleges and state research institutions through multi-disciplinary research units and model rural health research units.

12. Under the PHSSP, the ICMR will be supporting capacity building of young scientists in advanced diagnostic technique, disease elimination, mathematical modeling and also undertaking multi-disciplinary research. To encourage career advancement of women professionals, ICMR will be reporting gender disaggregated data of trainees attending these programs. Specific activities supported under this results area will include civil works, goods, consultancies, training, workshops and incremental costs.

13. **Results Area #3: Transforming core Public Health Institutions and Research Agencies.** This RA specifically focuses on building institutional capacity to implement the program to deliver high quality results as envisaged. This area also has focus on initiating actions to transform NCDC and ICMR as world class institutions over medium term. Specific activities include:

- Creation of a national Pandemic Preparedness Coordination Structure to enhance collaboration and complementarity between NCDC and ICMR and to regularly update India's pandemic preparedness plans.
- Strengthening of Epidemic Intelligence Service (EIS) cell at the NCDC for promoting training and career pathways in EIS, getting EIS program affiliated to universities, and expanding field epidemiology training program.
- Capacity building of NCDC for Program implementation, including through relevant leadership enhancement, divisions and support agencies to ensure timely implementation and operationalization through planned infrastructure, equipment and human resources.
- Review of NCDC capacity and best global practices to develop an action plan to transform NCDC to a world class institute for prevention and control of diseases, and implementation of such action plan.
- Strengthening of procurement and internal audit functions at the ICMR.
- Training of public health workers to develop competencies in prevention, detection and response to disease outbreaks.

14. Further, under the PHSSP, the NCDC will be training over 1000 public health work force to develop competencies in prevention, detection and response to disease outbreaks. Additionally, NCDC will review its existing HR policies and organizational culture to promote gender equality at the workplace in consonance with Government of India guidelines. Specific interventions will include the following: (i) establishing safety cells; (ii) promoting flexibility in working hours, including

transport/mobility support for women professionals who choose to work in night shifts, (iii) childcare pilots at workplaces to reduce women's care burden and (iv) develop women's networks to provide young women professionals with a support system and link them to women mentors. Specific activities supported under this results area will include civil works, goods, consultancies, training, workshops and incremental costs.

1.3 Government Program and Bank Financed Program (P Vs p)

15. The overall government program is broadly defined in the National Health Policy of 2017 and the policy documents for PM-ABHIM. To drive a holistic and broader reform agenda, the Government's program (p) will include: (a) Relevant institutions of the Ministry of Health and Family Welfare (MOHFW) that includes the Department of Health Research leading biomedical research through the ICMR and NCDC, Disaster Management Cell under Public Health (PH) Division and the International Health (IH) Division under the Directorate General of Health Services; and (b) prioritized activities under the PM-ABHIM program relevant for pandemic preparedness and response. The Transforming India's Public Health Systems for Pandemic Preparedness PforR ("P") is focused on strengthening pandemic preparedness and response in MOHFW agencies. The scope will include: (i) key public health agencies, i.e., the ICMR, the NCDC and divisions within MOHFW (PH and IH); (ii) three select results areas from activities being implemented by the three key agencies.

16. Considering the results areas and attributable program results, the overall expenditure framework of the government program ("p") for FY2022-23 to FY2026-27 is estimated at US$1.66 billion. The proposed PforR Program ("P") is a subset of the government program ("p"). The fiscal boundary of this Program will be the expenditure lines related to strengthened surveillance and pandemic response, including research, and will be based on two major components: 1) regular budget allocated to the PH and IH divisions of MOHFW, the NCDC and relevant institutions of the ICMR for the abovementioned areas, and 2) incremental cost for improving effectiveness and scaling up these interventions under PM-ABHIM. The total Program expenditure framework for five years is estimated at US$1.26 billion, to which the World Bank contribution will be US$500 million (equivalent to 40 percent of the total Program financing). The Bank Program boundary will exclude costs for BSL-IV labs at NCDC and ICMR and will include projected recurring expenditures for ICMR Headquarters and relevant institutions (National Institute of Virology & National AIDS Research Institute Pune). During the Program boundary analysis due care has been taken to include only the expenditure trends/projections for the above-mentioned agencies (under the Central Sector components of the PM-ABHIM scheme), and there is no overlap with the Program Expenditure Framework (PEF) for the Enhanced Health Service Delivery Program, the other PforR operation focused on the Centrally Sponsored Scheme (CSS) components of the PM-ABHIM scheme, being prepared in parallel.

17. The Program has no overlap with the ongoing India COVID 19 Emergency Response and Health System Preparedness (ER&HSP) project. Considering the scale of the COVID pandemic in India, the COVID 19 ER & HSP project had invested almost all of its resources on emergency COVID-19 response. Other components such as health system strengthening at national and state level to support preparedness, strengthening of pandemic research and multisector institutions and platforms for One Health and training on core competencies for disease surveillance are moved to the PM-ABHIM. The project was restructured twice to reflect this change. Further, the project is now over 91% expended and MOHFW has requested early closure of the project.

18. The boundaries of the PforR Program have been defined as per the table below:

	Government program ("p")	Program supported by the PforR ("P")	Reasons for non-alignment
Objective	To build a resilient and adaptable health system and ensure preparedness for future pandemics and other emergencies.	To strengthen pandemic preparedness and response systems and institutions in India	To build a resilient and adaptable health system and ensure preparedness for future pandemics and other emergencies.
Duration	2021-2026	2022-2027	Supporting first phase and expected extension
Geographic coverage	Nationwide	Central Sector components implemented through IH and PH divisions of MOHFW, NCDC and ICMR	Priority engagement for pandemic response in the country is being dealt with under this operation
Results areas	Ongoing central and State health initiatives under MOHFW, NHM and PM-ABHIM	Three results areas with focus on reform and innovations	The Bank program will support a sub-set of Government program
Overall Financing	US$1.66 billion	US$1.26 billion	The expenditures of identified subset are lower than the Government program

1.4 Geographic Scope of the Program

19. The proposed program is across all states of the country. The PM Ayushman Bharat Health Infrastructure Mission (PM-ABHIM) is one of the largest pan-India health schemes for strengthening healthcare infrastructure that was launched on 25 October 2021 to accomplish the vision of comprehensive healthcare across the country, and to fill the critical gaps in public health infrastructure, especially in surveillance and response mechanism including laboratories, critical care facilities, and primary care in both the urban and rural areas.

1.5 Key Program Implementing Agencies and Partners

20. The MOHFW will provide overall stewardship for the proposed Program. The program will be implemented by relevant institutions of MOHFW namely (a) Department of Health Research (DHR) through the Indian Council of Medical Research (ICMR) and its select institutions (b) the National Center for Disease Control (NCDC) (c) Disaster Management Cell (DMC) and (d) Points of Entry of International Health (IH) Division.

21. The **ICMR** is an autonomous society under the Department of Health Research (DHR). It is the apex body for formulation, coordination, and promotion of biomedical research and is headed by the Director General. The Secretary DHR is the administrative head of the Department of Health Research. At present, ICMR has 26 Institutes/ Regional Research Centers spread across different parts of the country and each of these are headed by a Director (Scientist 'G'). Administratively, within the Department of Health Research, ICMR comes under the purview of the JS (ICMR & VRDL). All project activities coming under ICMR will be implemented through Divisions/Cells of ICMR. Decentralized operations are only expected to be undertaken by ICMR, through its two branches - National Institute of Virology (NIV), Pune and National AIDS Research Institute (NARI), Pune.

22. The **NCDC** is a subordinate office of the Directorate General of Health Services (DGHS) under the MOHFW and plays a lead role in investigation and management of disease outbreaks across the country. Presently, it has 8 branch offices and plans to expand to more sites in the future. NCDC is headed by a technical officer of the rank of DDG and comes under the purview of the DGHS. Administratively, it comes under the Public Health Division of MOHFW headed by the Joint Secretary

(Public Health). All project activities coming under NCDC will be implemented by the concerned technical wings and branch offices of NCDC and the Public Health Division of the MOHFW in coordination with other divisions of MOHFW.

23. The **Disaster Management (DM) Cell** was established in December 2020 as a technical unit of the MOHFW. The cell is tasked to (i) plan for prevention, mitigation and ensure preparedness to manage public health emergencies (of international and national concern), major epidemics and pandemics (ii) respond to public health emergencies (iii) address health consequences of natural and man-made disasters (iv) implement International Health Regulations, 2005 (v) implement ongoing Central Sector Schemes. The DM Cell is headed by a DDG rank officer assisted by two Central Health Service Medical Officers. Administratively, the DDG reports to Joint Secretary (Public Health).

24. All the Point of Entries (POEs) Organizations are part of the **International Health (IH) Division** of the DGHS. It is tasked to prevent, protect against, control and provide a public health response to the global spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade in keeping with International Health Regulations, 2005. The nodal In-charge for all POEs is the Deputy Director General - International Health (DDG-IH) who reports to the Director General of Health Services. Administratively, POEs comes under the Public Health Division of MOHFW headed by the Joint Secretary (Public Health).

25. The **Directorate General of Health Services (DGHS)** is an attached organization of the MOHFW. It is headed by the Director General of Health Services, an officer of Central Health Services, who renders technical advice on medical and public health matters to MOHFW. The Secretary - Health and Family Welfare is the administrative head of the Department of Health and Family Welfare.

1.6 Borrower's Previous Experience

26. The proposed PHSPP program leverages the Bank's earlier engagement with MOHFW in strengthening disease surveillance and pandemic preparedness since 2004 through the Bank-supported Integrated Disease Surveillance Project (IDSP-2004-12) that established a common platform for India's surveillance, set up state and district surveillance units, introduced systematic outbreak investigation, with an IT-enabled backbone for data transmission and analysis. Over the last two decades, World Bank has had multiple engagements with Health sector programs at national level in India that includes Malaria Control Project (1997-2005), Immunization strengthening Project (2003-13), Reproductive & Child Health program (2006-12), Second National Tuberculosis Control Program Project (2007-12), Accelerating Universal Access to Early and Effective Tuberculosis (TB) Care Project (2014-18), various phases of National AIDS Control Project (1999-2017), and ongoing programs such as Program Towards Elimination of Tuberculosis Project (2019-24). The proposed Program also builds on the ongoing India COVID-19 Emergency Response and Health Systems Preparedness Project (2020-24) that is contributing to enhance the health system's capacity for laboratory diagnosis of viral infections, surveillance, isolation, and critical care.

27. India has seen several outbreaks, epidemics and infectious disease spread since last three decades leading to several lessons learnt and measures taken to boost national capacity. However, it is the COVID-19 pandemic that mounted a national response, which is unparalleled in history. India reported over 42 million COVID-19 cases and about 511,000 deaths due to COVID as of February 24, 2022. India led an impressive COVID-19 vaccination program that administered 1.77 billion shots by February 2022 and nearly 70% of India's 1.3 billion population received at least one dose with a majority among them fully vaccinated. Testing capacity was expanded with the network of nearly 3,300 labs offering RT PCR tests. Genomic surveillance has been scaled up with 58 laboratories participating in India SARS Cov-2 Genomic Consortium (INSACOG) and so far over 150,000 sequences were undertaken. Besides this, over 23,000 dedicated COVID-19 healthcare facilities were established and about 800,000 healthcare personnel received some kind of COVID-19 waste handling training.

Table (1.1): Details of Few Epidemics and Infections in India

S. No.	Epidemic/ Disease outbreak	Year	Infection types	Infected Regions/States	Additional Remarks
1	Plague outbreak	1994	Bubonic and pneumonic	south-central and western India	About 700 suspected cases
2	Cholera	2001		Odisha	About 34,111 people affected
3	Plague outbreak	2002	pneumonic plague	Himachal Pradesh	16 cases and 4 deaths reported
4	Plague outbreak	2004	Bubonic plague	Uttarakhand	8 cases and 3 deaths reported
5	Meningococcal meningitis	2005	meningitis and septicemia	Delhi, UP and Maharashtra	408 cases and 48 deaths reported
6	Japanese Encephalitis	2005	Mosquito-borne flavivirus disease	Uttar Pradesh and Bihar	1235 cases and 296 deaths reported
7	Chikungunya outbreak	2006	Aedes mosquitoes born disease	Andaman and Nicobar Islands, Madhya Pradesh, Maharashtra, and Gujarat	About 1.5 Million cases recorded
8	Dengue	2006	Dengue fever	Several states including Delhi, Chandigarh, UP, Punjab, AP, West Bengal	Over 10,300 cases reported and 162 deaths recorded
9	Swine flu	2009 to 2010 and 2015	H1N1 influenza virus	Multiple states	In 2009-10 over 36,000 cases recorded In 2015 about 33,000 cases recorded
10	Hepatitis B	2015-2016	Jaundice	Himachal Pradesh	1600 people were infected
11	Acute Encephalitis Syndroms (AES)	2017	Gorakhpur Japanese Encephalitis	Uttar Pradesh	Over 1000 deaths reported
12	Nipah virus	2018	Nipah virus /By fruit bats	Kerala	19 Infected and 17 deaths
13	Acute Encephalitis Syndroms (AES)	2019	Hypoglycemia/ Chamki Bukhar in Bihar	Bihar	161 deaths
14	Zika Virus	2021	mosquito-borne flavivirus	Keral and Uttar Pradesh	123 cases
15	Nipah virus	September 2021	By fruit bats	Kerala	1 confirmed and 1 death
16	Black fungus	2021	Mucormycosis	Multiple states	45374 cases and 4300 deaths

28. India is now reforming and rebuilding its national systems for responding to and managing epidemics and pandemics in a much more optimal, timely and efficient manner. As seen from the table above, several of the disease incidences could be prevented with better hygiene, waste management and timely diagnostics. National programs like the Swatch Bharat have come a long way in improving the hygiene and sanitation across the country. One Health approach has been developed, and key committees have been constituted. However, there are areas where further work is needed, including improved diagnostics and reporting and the proposed program will strengthen these areas.

29. India has gathered significant experience during COVID19 and taken several proactive measures to deal with a fast-emerging situation. Since the outbreak of COVID19, India has proactively

taken several measures for containing the disease which are in line with guidance form WHO, CDC and other international best practices guidance and learning. While many of these policies are evolving based on the COVID19 pandemic situation in India, some of the guidance relevant to environmental and social measures are as below:

i. Advisory on Social Distancing – March 2020 – MOHFW
ii. Advisory on Mass Gatherings – March 2020 – MOHFW
iii. Guidelines for home quarantine – March 2020 – MOHFW
iv. Guidelines for handling, treatment and disposal of waste generated during treatment, diagnostics and quarantine of COVID19 patients – March 2020 and April 2020 – Central Pollution Control Board
v. Strategy of COVID19 Testing in India – March 17, 2020, from Indian Council of Medical Research
vi. Standard Operating Procedures for Passenger Movement Post Disembarkation (including SOP for Quarantine) – March 2020 – MOHFW
vii. Guidelines for Notifying COVID19 Affected Persons by Private Institutions – March 2020 – MOHFW
viii. Gazette Notification – Essential Commodities Order 2020 – with regards to masks and hand sanitizers
ix. National Pharmaceutical Pricing Authority (NPPA) Order regarding Masks, Hand Sanitizers and Gloves
x. COVID19 Guidelines on Dead Body Management – March 15, 2020 – Director General of Health Services (DGHS), MOHFW (EMR Divisions)
xi. Office Memorandum on Preventive Measures to be taken to contain the spread of Novel Coronavirus (COVID19) – March 16, 2020 – Department of Personnel and Training), Ministry of Personnel, Public Grievances and Pensions
xii. Guidance document on appropriate management of suspect/confirmed cases of COVID-19 - Types of Covid-19 dedicated facilities
xiii. Guidelines for Quarantine facilities COVID-19
xiv. Guidance for COVID-19 & Pregnancy & Labour Management
xv. Guidance document on appropriate management of suspect/confirmed cases of COVID19 - Types of Covid-19 dedicated facilities
xvi. Advisory issued by Ministry of Rural Development to the State Rural Livelihoods Missions on actions to be taken to address the COVID 19 outbreak
xvii. Norms of assistance from State Disaster Response Fund (SDRF) in wake of COVID19 outbreak
xviii. Containment Plan for Large Outbreaks of COVID-19
xix. Model Micro plan for containment of local transmission of COVID19
xx. Advisory for quarantine of migrant workers
xxi. Various mass awareness generation activities and guidance
xxii. Various audiovisuals and print material on Psycho-Social support along with setting up toll free helpline-08046110007
xxiii. Ordinance to protect healthcare workers form abuse and assault
xxiv. Guidelines on preventive measures to contain spread of COVID-19 in workplace settings
xxv. Advisory for managing Health care workers working in COVID and Non-COVID areas of the Hospital
xxvi. Guidance note for Immunization services during and post COVID outbreak

2 ENVIRONMENT AND SOCIAL SYSTEM ASSESSMENT (ESSA) – METHODOLOGY ADOPTED

2.1 Overview of ESSA

30. For each proposed PforR operation, the World Bank assesses at the Program level potential environmental and Social (E&S) effects, including direct, indirect, induced, and cumulative effects as relevant; the applicable legal /regulatory framework and the borrower's organizational capacity and performance to manage those effects.

31. This ESSA has been prepared by a World Bank ESSA Team for the proposed Transforming India's Public Health Systems for Pandemic Preparedness (PHSPP), which will be supported by the World Bank's Program for Results (PforR) financing instrument. In accordance with the requirements of the World Bank Policy Program-for-Results Financing (PforR Policy), PforRs rely on country-level systems for the management of environmental and social effects.

32. The PforR Policy requires that the Bank conducts a comprehensive ESSA to assess the degree to which the relevant PforR Program's systems promote environmental and social sustainability and to ensure that effective measures are in place to identify, avoid, minimize, or mitigate environmental, health, safety, and social impacts. Through the ESSA process, recommendations to enhance environmental and social management outcomes within the program are developed, which subsequently become a part of the overall Program Action Plan.

2.2 Purpose and Objectives of ESSA

33. The main purposes of this ESSA is to: (i) identify the Program's environmental, health, safety, and social effects; (ii) assess the legal and policy framework for environmental and social management, including a review of relevant legislation, rules, procedures, and institutional responsibilities that are being used by the Program; (iii) assess the implementing institutional capacity and performance to date, to manage potential adverse environmental and social issues and (iv) recommend specific actions to address gaps in the Program's environmental and social management system, including with regard to the policy and legal framework and implementation capacity.

34. The ESSA describes the extent to which the applicable government environmental and social policies, legislations, program procedures and institutional systems are consistent with the six 'core principles' of OP/BP 9.00 and recommends actions to address the gaps and to enhance performance during Program implementation. These six core principles are listed below and further defined through corresponding Key Planning Elements in this report:

(a) Core Principle 1: Environmental and Social Management: Environmental and social management procedures and processes are designed to: (a) promote environmental and social sustainability in Program design; (b) avoid, minimize, or mitigate against adverse impacts; and (c) promote informed decision making related to a Program's environmental and social effects

(b) Core Principle 2: Natural Habitats and Physical Cultural Resources: Environmental and social management procedures and processes are designed to avoid, minimize, and mitigate any adverse effects (on natural habitats and physical and cultural resources) resulting from the Program.

(c) Core Principle 3: Public and Worker Safety: Program procedures ensure adequate measures to protect public and worker safety against the potential risks associated with: (a) construction and/or operations of facilities or other operational practices developed or promoted under the Program; and (b) exposure to toxic chemicals, hazardous wastes, and otherwise dangerous materials.

(d) Core Principle 4: Land Acquisition: Land acquisition and loss of access to natural resources are managed in a way that avoids or minimizes displacement, and affected people are assisted in improving, or at least restoring, their livelihoods and living standards.

(e) Core Principle 5: Indigenous Peoples and Vulnerable Groups: Due consideration is given to cultural appropriateness of, and equitable access to, Program benefits, giving special attention to the rights and interests of indigenous peoples and to the needs or concerns of vulnerable groups.

(f) Core Principle 6: Social Conflict: Avoid exacerbating social conflict, especially in fragile states, post-conflict areas, or areas subject to territorial disputes.

35. An additional purpose of this ESSA is to account for the decisions made by the relevant authorities in the borrower country and to aid the Bank's internal review and decision process associated with the proposed PHSPP program. The findings, conclusions and opinions expressed in this document are those of the World Bank and the recommended actions that flow from this analysis will be discussed and agreed with Ministry of Health and Family Welfare (MOHFW), Government of India as the counterpart and will become legally binding agreements under the conditions of the new loan.

36. Environmental and Social Systems Assessment (ESSA) for Transforming India's Public Health Systems for Pandemic Preparedness (PHSPP) has been carried out following the Bank's Guidance Document on "Environmental and Social Systems Assessment for Program-for-Results Financing". In the context of ESSA requirements mentioned in the said document, the specific objectives of this exercise for PHSPP (this operation) included:

a. to identify the potential environmental and social impacts/ risks applicable to the Program interventions,
b. to review the policy and legal framework related to management of environmental and social impacts of the Program interventions,
c. to assess the institutional capacity for environmental and social impact management within the Program system,
d. to assess the Program system performance with respect to the core principles of the PforR instrument and identify gaps in the Program's performance,
e. to include assessment of M&E systems for environment and social issues, and
   to describe actions to fill the gaps that will input into the Program Action Plan in order to strengthen the Program's performance with respect to the core principles of the PforR instrument.

2.3 Methodology Adopted for ESSA

37. ESSA refers both to the process for evaluating the acceptability of a borrower's system for managing the Program's E&S risks in the operational context, and to the final report that is an output of that process. The ESSA process is a multistep methodology in which the World Bank team analyses the E&S effects, including indirect and cumulative effects, of activities associated with the defined Program; analyses the borrower's systems for managing the identified E&S effects, including reviewing practices and the performance track record; compares the borrower's systems - laws, regulations, standards, procedures, and implementation performance against the core principles and key planning elements to identify any significant differences between them that could affect Program performance; and recommends measures to address capacity and performance on policy issues and specific operational aspects relevant to managing the Program risks such as staff training, implementing institutional capacity building programs, developing and adopting internal operational guidelines.

38. The ESSA primarily relied on desk review of existing information and data sources, complemented by consultations, interviews/ discussions with key stakeholders in the program implementing agencies (ICMR, NCDC, DM Cell, and IH Division) to capture current practices, opinions, anecdotal evidence, functional knowledge, and concerns. It involved (a) a comprehensive

review of government policies, legal frameworks, Program documents, national guidelines relevant for the proposed program's environmental and social management systems; (b) interviews and consultations were conducted with relevant experts and officials from ICMR, NCDC, DM cell, and IH Division, and other key institutional stakeholders among others. In addition, multi-stakeholder consultations was conducted with key stakeholders including the non-governmental organizations (NGOs) at the national level.

39. The World Bank ESSA team and the borrower (MOHFW - along with ICMR, NCDC, DM Cell, and IH Division) worked closely to identify and consider the range of E&S impacts that may be relevant to the Program. The PforR approach distinguishes specific roles and responsibilities regarding major steps and tasks at the various phases of the program cycle. The World Bank team prepared this ESSA report that provides an overview and analysis of the GoI's as well as state government's policies and regulatory frameworks for the environmental and social aspects for the PHSPP operation. The ESSA discusses relevant environmental and social legislations for the PHSPP program. Findings of the assessment have been used in the formulation of an overall Program Action Plan (PAP) with key measures to improve environmental and social management outcomes of the Program. The findings, conclusions, and opinions expressed in the ESSA document are those of the World Bank. Recommendations contained in the analysis will be discussed and agreed with MOHFW, GoI.

40. The World Bank ESSA team extensively consulted the key officials from the ICMR, NCDC, DM Cell and IH Division. Interviews and consultations were done both physical and virtually with relevant experts and officials. The Bank team assessed organization's monitoring arrangements/provisions on E & S aspects, including construction contract for EHS compliance, workplace hazards and risk assessment, safe work procedures, employee medical surveillance, emergency response plan and personal protective devices in the unit. The assessment also touched up on how climate resilience provisions, for example, availability of WASH, energy conservation, green construction structures, sustainable procurement of chemicals, foods, machinery and services etc. are considered?

41. The draft ESSA was further shared with MOHFW along with ICMR, NCDC, DM Cell and IH Division for their comments and suggestions and was revised based on feedback from stakeholders. This revised ESSA will be made publicly available in accordance with the Bank's policy on Access to Information. The final ESSA will be re-disclosed prior to World Bank Board consideration of the Program.

2.4 Structure of the ESSA Report

42. The ESSA report for Transforming India's Public Health Systems for Pandemic Preparedness (PHSPP) has been structured as follows:

Section 1: Program Description

Section 2: Environment and Social Systems Assessment – Methodology Adopted

Section 3: Environment and Social Over-view

Section 4: Potential Environmental and Social Effects, Risks and Benefits

Section 5: Assessment of Environmental and Social Management Systems relevant to the Program (including description of the applicable systems against core principles and planning elements/practices; performance and track record)

Section 6: Consultations with Key Stakeholders and Disclosure

Section 7: Recommendations

Annexures

3 ENVIRONMENTAL AND SOCIAL CONTEXT

3.1 Environmental Context

43. The proposed Program will support strengthening national capacity in disease surveillance and diagnostics and will be complimented by other parallel Bank-financed Programs particularly the one focusing on One Health, which integrates wildlife disease surveillance with the livestock disease surveillance. At some point, it is envisaged that the human-related disease surveillance will also be reported on a single digital platform. Infectious diseases of wildlife origin, construction of new and upgrading of existing laboratory network, including biosecurity level 3 (BSL3) laboratories, biomedical waste management, energy efficiency and occupational health risks frames the system level environmental context for the proposed program.

44. Expansion of the current network of Public Health Laboratories through construction of new BSL-3 laboratories and strengthening of the capacity of existing public health laboratories is a key thrust area under the program. The laboratories construction and their operationalization are planned by both the key program beneficiaries i.e., NCDC and ICMR to enhance their surveillance capacity and research capabilities respectively. The construction activity as well as functioning of such laboratories may pose occupational health and safety risks to the construction workers as well as laboratory workers during routine functioning. In addition, generation and management of biomedical wastes in such laboratories also poses occupational health and safety as well as community health risks, if not managed properly. Additionally, activities by International Health Division carried out for implementation of International Health Regulations at Point of Entry such as Airport, ports and land border units may also pose occupational health, safety and environmental risks. ESSA has attempted to assess the capacity of the existing national system in managing these potential program level risks.

45. With the objectives of providing quality care and better service delivery, the biomedical waste generation is projected to grow exponentially over the next few years. The current waste management infrastructure will require substantial investments to handle, store, manage and dispose the wastes of the health sector. As reported by State Pollution Control Boards (SPCB), about 619 tons/day of biomedical waste was generated during the year 2018-2019 by 3,22,425 numbers of Healthcare Facilities. Out of 619 tons/day of biomedical waste only 544 tons/day of biomedical waste is treated and disposed off by 202 CBWTFs and 18,015 nos. of captive treatment facilities installed by Healthcare Facilities. Biomedical waste of about 74 tons/day might get disposed off through deep burials located at isolated places.

Table (3.1): Biomedical wastes generation and treatment

Type of infrastructure	Number
No. of HCFs	322425
No. of bedded HCFs	1,06,796
No. of non-bedded HCFs	215780
No of beds	2486327
No of CBWTF-Operational	202
No of CBWTF-Under Installation	35
No of HCFs granted authorization	153885
No. of HCFs having Captive Treatment Facilities	18015
No. of Captive Incinerators Operated by HCFs	136
Quantity of bio-medical waste generated in Tonnes/day	619 MT
Quantity of bio-medical waste treated in Tonnes/day	544

Type of infrastructure	Number
No. of HCFs violated BMW Rules	29062
Source: Annual Report on Biomedical Waste Management as per BMW, Rules, 2016 for the year 2019 – Central Pollution Control Board	

46. At the national level, installed capacity of 1200 MT/day to treat biomedical waste appears adequate as against the 814 MT/day biomedical waste generated, in terms of installed capacity utilization, there are variations across different states.

Table (3.2): Capacity Utilization by States to Treat Biomedical Waste

Capacity utilization by CBWRFs	Name of the states
No CBWTF, disposal through captive treatment facilities	Andaman & Nicobar Island, Arunachal Pradesh, Dadar Nagar Haveli, Goa, Lakshadweep, Mizoram, Nagaland, Sikkim
Inadequate capacity	Meghalaya, Odisha, Puducherry, Tripura
Capacity utilization less than 25%	Bihar, Chhattisgarh, Haryana, Telangana
Capacity utilization 25-50%	Andhra Pradesh, Delhi, Gujarat, Himachal Pradesh, Karnataka, Madhya Pradesh, Maharashtra, Manipur,
Capacity utilization 51-75%	Chandigarh, Punjab, Rajasthan, Uttarakhand, Uttar Pradesh, West Bengal
Capacity utilization more than 75%	Jammu Kashmir, Kerala, Tamil Nadu

47. COVID-19 placed extra strain on the national capacity for treating biomedical wastes. An analysis of COVID-19 biomedical wastes data from CPCB across 10 states responsible for generating maximum wastes revealed that substantial quantities of biomedical waste was generated, due to single use gloves, coveralls, masks, swabs, diagnostic kits etc. The total wastes across the ten states ranged from 2451.5 to 4633.6 Tons/day during early pandemic (June to December 2020). These ten states contributed to 74.14 % to 89.22 % of the total Covid-19 BMW generated during this period.

Table (3.3): BMW Management during Covid-19 pandemic (Early pandemic June-Dec 2020)

Name of state / UT	June 20 TPD	July 20 TPD	August 20 TPD	Sept 20 TPD	Oct 20 TPD	Nov 20 TPD	Dec 20 TPD	No. of CBWTFs engaged
Maharashtra	524.82	1180	1359	524.82	542.31	609	629.3	29
Gujarat	350.8	306.1	360.0	622.9	545.9	423.5	479.6	20
Delhi	333.4	389.6	296.1	382.5	365.9	385.5	321.3	2
Tamil Nadu	312.3	401.3	481.1	543.8	524.2	300.8	251.2	8
Madhya Pradesh	224.6	56.1	106.6	339	308.4	208.7	249.5	13
Uttar Pradesh	210	307.5	408.9	507.2	478.1	316.7	276.5	18
West Bengal	195	136.4	235.1	434.8	486.8	330.8	279.1	6
Kerala	141.3	291.3	588.1	494.1	642	600.3`	542.5	1
Karnataka	84	540.3	588	168	218	211	218	26
Haryana	75.3	184.2	210.7	278.3	238.5	239.4	209.9	11
Covid-19 BMW generated by 10 states	2451.5	3795.1	4633.6	4295.3	4350	3625.7	3456.8	134
Source: Data from monthly report on state-wise generation of Covid-19 related BNW in states / UTs on CPCB website								

48. According to the Intergovernmental Panel on Climate Change (IPCC), the climate effects of higher temperatures, humidity, variable precipitation, can lead to Increased risks of waterborne and vector borne diseases. These changes affect accelerated microbial growth, survival, persistence, transmission, shifting geographic and seasonal distribution of diseases. In addition, high temperature and humidity also affect the health and wellbeing of healthcare workforce working in the field and reduce their work capacity as well as increase health risks due to heat-stress on their physical and mental health. The Climate Change and health department of NCDC has initiated studies on heat stress and air pollution impacts on health sector workforce. It participates and contributes to the National Program on Climate Change and Human Health. The unit plans for further actions on the greening of the health infrastructure and air pollution impacts on health workforce. In ICMR, the department of non-communicable diseases identifies epidemiological studies on occupational and environmental health including children's environmental health, intentional and non-intentional injuries etc.as thrust areas for research.

49. Based upon the findings of the ESSA, some program actions are proposed to augment national capacities and systems, primarily of the implementing organizations, NCDC and ICMR, for managing potential environmental risks. While details are provided in other sections, key system strengthening provisions include incorporation of design safety elements in BSL laboratories plan for construction, inclusion of occupational safety and health as well as labour welfare provisions in the construction contracts, establishing mechanisms for technical advisory and monitoring supervision by experts' groups during program activities implementation etc. In addition, at PoEs include implementation of occupational health and safety, chemical safety, safe work practices and training and supervisory enhancements etc.

3.2 Social Context

50. India being one of the most diverse societies in the world with its plurality in its geographical, demographic, historical, political, economic and socio-cultural base. Its social diversity has been expressed in various forms such as languages, religions, tribes and castes. Among them, the Scheduled Castes (SCs) and Scheduled Tribes (STs) are the most disadvantaged socio-economic groups in India. According to Census 2011, SC and ST population account for 18.5% and 11.3% of India's rural population.

51. India accounts for a relatively large share of the world's disease burden and is undergoing an epidemiological transition that the non-communicable diseases dominate over communicable in the total disease burden of the country. The health status and the drivers of health loss are expected to vary between different parts of the country and between the states. The India State-Level Disease Burden Initiative (2017), observes that the disease burden due to communicable, maternal, neonatal, and nutritional diseases, as measured using Disability-adjusted life years (DALYs), dropped from 61% to 33% between 1990 and 2016. In the same period, disease burden from non-communicable diseases increased from 30% to 55%. The epidemiological transition, however, varies widely among Indian states: 48% to 75% for non-communicable diseases, 14% to 43% for infectious and associated diseases, and 9% to 14% for injuries.

52. India is increasingly facing a high burden of emerging infectious diseases along with substantially enhanced prevalence of non-communicable diseases. Mortality and disability caused by communicable diseases and other emerging infections (e.g., COVID-19) is significantly impacting human life and economic growth of the country. The country needs to devise effective healthcare solutions that not only boost control of existing diseases like HIV, TB, and Malaria, but also prepared to effectively detect, prevent, control, and manage emerging infectious diseases and threats to human health. This calls for identifying cost-effective and efficient healthcare diagnosis and delivery mechanisms.

53. India's current epidemiological and demographic status, with the rapid rise in non-communicable diseases, a double burden of chronic and infectious diseases, and unfinished agenda of reproductive, maternal new-born and child health services has created an increasing demand on health care and public health services. At the same time, high costs of care, persistent health inequalities, and reduced access to essential public health services particularly for those living in remote areas and in slum and slum like areas, challenge our health system. COVID 19 and predecessor infectious diseases such as SARS, H1N1, NIPAH and Zika outbreaks have highlighted that the health systems need to fully prepare and gear up to respond to public health emergencies.

54. The disease burden in the country also demonstrates the need for provision of high-quality laboratory services. The complexity of COVID-19 pandemic, which has spread across the World, has highlighted the need of having competent core capacities for surveillance and response, diagnostic labs, logistics (including PPEs, Masks, Sanitizers and Disinfectants) and appropriate quarantine and isolation facilities at various levels. Also, the public health surveillance for abnormal morbidity/mortality, reporting of human or animal disease patterns and testing of samples etc. for public health needs remains a weak area.

55. The emerging infections continue to disrupt the health care system and are becoming increasingly complicated to detect and treat successfully. The public health system is continually reminded of the challenges posed by the unexpected, whether it is the pandemic or a bioterrorist act. Thus, there is increasing need to strengthen the infrastructure for creating favorable environment for epidemiological studies on virus outbreak and other pathogens related to public health importance. Also, there is need for setting up institutions which can serve to advance an evolving science of disease elimination to design and develop theoretical, quantitative, qualitative, behavioral and applied research practice in order to better translate evidence to policy in partnership with other research institutes, national programs and international organizations towards making time bound promise of communicable disease elimination a reality.

56. Emergence of highly infectious and pathogenic viral infections cause significant burden on public health system. It becomes difficult controlling such diseases, which are highly infectious and pathogenic in nature and have zoonotic origin or spread by aerosols or vectors. Recently, our country has witnessed recent emergence of infections like Ebola, H5N1, CCHF, KFD, Nipah, H7N9, and MARS CoV, SARS CoV 1 & 2. This has shown countrywide need of enhancing laboratory capacity, networking of institutions dealing with emerging viral diseases of zoonotic importance for by sharing the expertise, reagents and various trainings including biosafety and biosecurity to laboratory management to deal with these.

57. There is also a need for an integrated surveillance program at all levels (Regional/Zonal and State levels) and also its expansion to various metro cities.

4 POTENTIAL ENVIRONMENTAL AND SOCIAL BENEFITS, ADVERSE EFFECTS AND RISKS

4.1 Environmental and Social Benefits of the Program

4.1.1 Environmental Benefits of the Proposed Program

58. The range of environmental benefits of the proposed program are many. While these would be led by national agencies, the positive impacts would percolate down to the healthcare and laboratory facility level, besides ensuring compliance with existing national environmental regulatory provisions and international environmental obligations. Some of the notable environmental benefits are:

- Inclusion of environmental concerns in planning, construction and operationalization of laboratory systems, including BSL3.
- An efficient biomedical waste management system in the laboratories leading to prevention of pollution of the land, water and air and thus protect health of the laboratory workforce as well as nearby communities by preventing spread of risky infections though such wastes
- Safe and healthy laboratory workforce is likely to contribute to effective emergency response due to timely detection and diagnosis of infections under disease surveillance activities in medical emergencies and shall prevent national and state health systems to collapse due to high level of health workforce infections, illness and morbidity
- Establishment and implementation of an effective occupational health and safety management system in the laboratories being planned under the program would protect the laboratory workforce from biohazards and other workplace hazards and keep them healthy and functioning
- Training and capacity building opportunities for healthcare workers at various levels

4.1.2 Social Benefits of the Proposed Program

59. The proposed PHSPP program aims to strengthen resilient public health system by expanding disease surveillance systems supported by a network of public health laboratories, effective implementation of One Health, enhancing India's bio-security capacity by supporting bio-medical research capacity, and will lead to timely identification of any disease outbreaks, and ability to appropriately respond in addressing them. The program also aims to strengthen the regional capacity and state capacity towards identifying and responding to any outbreaks locally. The project aims to support development of laboratory network from district to state and national level with the specific aim to strengthen timely referral of samples for quality high-end diagnostics. The IPHL networks, BSL-3 mobile laboratories and mobile hospitals further enhance outreach of the services to remote and geographically challenging areas such as the case with North-Eastern states. These activities in turn will benefit in saving citizen's life and asset, and potential social and economic shocks, by reducing chances of morbidity and mortality with early identification and response mechanism.

4.2 Environmental and Social Risks and Adverse Effects

4.2.1 Environmental Risks and Adverse Effects of the Proposed Program

60. While the program aims to strengthen national capacity on various technical and operational issues relating to pandemic preparedness , including, for example, improved diagnostics, upgraded

laboratory infrastructure etc., some program level risks are envisaged, particularly in areas where gaps are observed during the course of undertaking this ESSA. Some of these potential risks include: One of the key risks centers on management of additional biomedical waste generated during pandemic and/or epidemic, particularly due to non-availability of common treatment facilities in some geographies. Highly infectious biomedical wastes also have additional requirements, for example, double/triple plastic covering for COVID-19 wastes leading to excessive use of plastics that pose risk of environmental degradation.

61. Environmental hazards and risks associated with expansion of laboratory networks through construction and operationalization of BSL3 Laboratories. More specifically:

- Construction related occupational health and safety hazards and risks to the construction workforce and associated community safety and health aspects due to these activities.
- Lack of incorporation of design safety in the construction plan of biosafety laboratories pose serious occupational health risk to the laboratory workforce as well as serious risk to the community health and safety due to accidental release of high-risk pathogens from such laboratories into air, water and land.
- Handling of high-risk pathogens and biomedical wastes generated pose risk of biohazards exposure to the laboratory workforce during routine working and may pose risk to the community in case of accidental release.
- Usage of specialized equipment, for example, autoclaves, centrifuges and chemical reagents during work performance pose occupational risk of exposure to chemical toxicity and injuries.
- Use of equipment having radiation risk and use of radioactive isotopes require specialized approaches, especially in storing and disposing radioactive wastes and decommissioning of such equipment.

62. Environmental hazards and risks at Points of Entry (PoE) under International Health Division due to activities carried out for implementation of International Health Regulations:

- Occupational exposure to biological pathogens during screening of international passengers for diseases under surveillance.
- Occupational exposure to toxic chemicals during disinfection, disinfection and deratting of ships and aircrafts and supervision of sanitation, drinking water supply, anti-mosquito and anti-rodent work.
- Occupational exposure to infections during public health clearance of dead bodies.
- Occupational exposure to biological pathogens during administration of yellow fever vaccine and generation of biomedical and plastic wastes at identified yellow-fever vaccination centers.

4.2.2 Social Risks and Adverse Effects of the Proposed Program

63. The proposed PHSPP program along with strengthening capacities and systems and process for disease surveillance, and mechanism for identifying and responding to any disease outbreaks, supports the complimentary much needed enabling infrastructure through the implanting agencies i.e., ICMR, NCDC, DM Cell, and the IH Division. This includes support towards establishing 4 National Institute of Virology, a One Health Centre, Five Regional NCDCs, 22 NCDC branches at State level, 17 BSL-3 laboratories, 4 Mobile BSL-3 laboratories, 20 Metropolitan Public Health Surveillance units, two container based mobile hospitals; 15 Health Emergency Operation Centers (HEOCs); 17 new Field Health Units at point of entry and strengthening existing 33 Field Health Units. The BSL-4 laboratories planned under the PM-ABHIM is excluded from the PHSPP program given its high risk.

64. While in many cases for land is made available by the states free from any encumbrances for establishing NIVs, One Health Centre, some of the NCDC branches, and most of the BSL-3

laboratories. And, for the remaining infrastructure, the implementing agencies follow the process of requesting for land free from any encumbrances from states as part of their contribution towards the program such as the case with NCDC Regional centers and some NCDC Branches, BSL-3 Laboratories, Metropolitan Public Health surveillance units, HEOCs, and Field Health Units. While states will identify land required for above facilities, in majority of the cases it has been part of existing Government institution land or other government land, however, it requires close monitoring and screening to identify and mitigate any social risks.

65. Both ICMR and NCDC will sign a MoU with the selected agency for constructing the infrastructure. The construction agencies are expected to be reputed with good national experience. The issue of sub-contracting to local contractors often pose additional challenge, particularly with respect to occupational health and safety and would be closely monitored. Also, some of these constructions may amount to small labor camps at the construction sites, and hence, the emerging risk from health and sanitation, safety, and labor management related concerns at the construction sites for the labor camps, apart from community health and safety issues.

4.2.3 Environmental and Social Benefits and Risk Matrix

66. The key infrastructure activities that are planned under the proposed PM-ABHIM program is as below and potential environmental and social risks associated with it.

Key Institutions and Activities	Particulars	Potential Environmental and Social Risks and Impacts
A. Indian Council of Medical Research (ICMR)		
Four new research laboratories as Regional National Institute of Virology (NIV) A center for One Health center is proposed to be setup at Nagpur with BSL-4 facility. Five BSL-3 laboratories - these BSL-3 laboratories are proposed to be setup in the existing Virus Research & Diagnostic Laboratories (VRDLs) for laboratory upgradation	• Of the four NIVs, of which two would be setup at Chandigarh and Bangalore with BSL-3 facility and remaining two will be setup at Nagpur and Dibrugarh. • Land for all the NIVs, One health center, and BSL laboratories are already made available free from any encumbrances. In most cases they well defined and part of existing Government institution campuses. • Memorandum of Understanding (MoU) to be signed between ICMR and the selected construction agency for construction of all these centers and laboratories.	Key environmental and social risks emerge from: • The construction related occupational health and safety hazards. • Risks to the workforce and associated community safety and health aspects. • Potential health and sanitation, safety, and labor management related concerns at the construction sites. • Occupational health and safety risks to laboratory workforce due to poor design of laboratories leading to increased risk of exposure to biological and chemical hazards during operational phase. • Occupational health and safety risks due to potential exposure to pathogens, laboratory chemicals, biomedical wastes and usage of equipment during routine work in laboratories. • Community exposure to high-risk pathogens due to accidental release of pathogens during transportation od laboratory samples or poor management of biomedical wastes from laboratories.

Key Institutions and Activities	Particulars	Potential Environmental and Social Risks and Impacts
		• Given, BSL-4 being high risk activity, it is excluded from the program support.
Four Mobile BSL-3 Laboratories are proposed to be procured/ hired by ICMR under PM-ABHIM	• Mobile BSL-3 to laboratory housed in a vanity bus/ container truck. • These laboratories will be established on similar lines that has been designed and built by ICMR in collaboration with Mumbai based bio-safety equipment maker Klenzaids and launched in February 2022.	• No specific social risk. In fact, this will enhance the reach of such facilities in remote areas such as in North-Eastern states, and other such areas. • Environmental risks of exposure, as discussed above, are valid for mobile BSL3 laboratories.
B. National Centre for Disease Control (NCDC)		
Strengthening of Regional Centre for Disease Control	• Five Regional NCDCs to be established - One each in West, North, South, Central and North-East.	• Environmental risks same as discussed above, particularly relating to BSL3 laboratories. • Potential social risk emerges from need for land to establish BSL-3 laboratories and NCDC branches. • The construction related occupational health and safety hazards. • Risks to the workforce and associated community safety and health aspects. • Potential health and sanitation, safety, and labor management related concerns at the construction sites. • Given, BSL-4 being high risk activity, it is excluded from the program support. • Similarly, any land acquisition is also excluded from the program support.
Strengthening Laboratory Network under NCDC	• 10 BSL-III at select locations and one BSL-IV at selected location. • Some of these BSL-III laboratories will be housed in the NCDC branches and some will be as an independent laboratory across different states (as decided by the higher authorities for equitable distribution of BSL-III laboratories across states including those by ICMR).	
Strengthening of Surveillance	• Support the setting of 22 new NCDC branches in different states and upgrading the existing 8 NCDC branches to ensure its distribution across different states. • NCDC will sign an Agreement and/or MoU with the selected construction agency for construction	

Key Institutions and Activities	Particulars	Potential Environmental and Social Risks and Impacts
	of BSL laboratories, and NCDC branches/ Regional NCDCs. • While for some NCDC branches and BSL laboratories, land is already made available by the states. However, for other BSL labs, and NCDC centers/ branches, the process involves requesting selected state to provide land free from any encumbrances as part of their contribution.	
NCDC upgradation and strengthening	• Strengthening of Divisions under NCDC Delhi, namely i. Epidemiological Intelligence Services ii. Biosecurity and Biological Threat Reduction iii. Centre of International Health iv. NCDC Centre of Excellence for Occupational Health & Climate Change v. National AMR Containment Program vi. Division for One Health and Inter-sectoral coordination vii. Division for Fungal Infection Diseases viii. Diseases for Zoonotic Infectious Diseases ix. Expansion of IHIP (CSU at NCDC)	• NCDC upgradation may also involve some renovation and will have social risks as mentioned above. • Environmental risks are similar to the ones discussed above.
Establishing 20 Metropolitan Public Health Surveillance at selected metropolitans	• 20 Metropolitan Public Health Surveillance units – a tentative list includes Tier-1 cities like Ahmedabad, Chennai, Pune, Delhi, Thane, Hyderabad, Kolkata, Mumbai, and Lucknow; and Tier-II cities like Agra, Jaipur, Bhopal, Nagpur, Bhubaneshwar, Shimla, Chandigarh, Gurgaon, Guwahati, and Patna.	• No specific social risk. In fact, this will help enhance the disease surveillance mechanism in large urban cities.

Key Institutions and Activities	Particulars	Potential Environmental and Social Risks and Impacts
	• Metropolitan Centre(s) will be a separate unit where the space will be provided by the Municipal corporations in consultation with State Health Directorate and with basic amenities. Once the space is provided, the Metropolitan centre for surveillance will be setup by NCDC.	
Expansion of IHIP-pan India	• Expansion of integrated health information platform (IHIP) does not involve any construction/ civil work by NCDC. NCDC will help strengthen the capacity building and quality of services and information sharing by the District Public health laboratories.	• No specific social risk. In fact, this will help enhance the disease surveillance mechanism across all districts in the country.
Disaster Management Cell (under MOHFW)		
Two state-of-the-art Self-contained container based mobile hospitals	• Two container based mobile hospitals will be setup to serve in any health emergency	• Occupational health and safety risks due to potential exposure to pathogens released in air, blood and skin contact with cases during clinical examination and sample collection. • No specific social risk. In fact, this will help provide the much-needed health care services during any emergency situation.
15 Health Emergency Operation Centres (HEOCs) towards Strengthening Disaster and Epidemic Preparedness and response	• The 15 Health Emergency Operation Centers (HEOCs) has been proposed in disaster vulnerable States/UTs depending on the concurrence for the same by the States/UTs • The Health Emergency Operation Centre (HEOC) is the hub of data collection, collation and analysis. It provides technical inputs to MoHFW/ State Health Department for initiating various	Establishing these HEOC will have civil works and hence the key social risk is from: • Potential social risk emerges from need for any land to establish HEOCs • The construction related occupational health and safety hazards.

Key Institutions and Activities	Particulars	Potential Environmental and Social Risks and Impacts
	response measures during and after any epidemic, pandemic, disaster and public health emergency of national/ international importance. This will also include activities: i. Maintaining continuous situational awareness for all public health emergencies and coordinating timely response as and when needed. ii. Collection, collation, analysis, presentation, dissemination and utilization of event data and information. iii. Enabling response-related decision-making, planning, operations, and logistics functions. iv. Ensure preparedness and updation of plans, procedures and ICT equipment upkeep. v. Facilitate acquisition and deployment of resources, including surge capacity, services and material to support all EOC functions. vi. Preparation of public communications and coordination with response partners to support public awareness.	• Risks to the workforce and associated community safety and health aspects.
International Health (IH) Division of the Directorate General of Health Services (DGHS)		
Strengthening Points of Entry (airports, seaports and land crossings) by	• Establishing 17 New Field Health Units (13 Airport Health Organization (APHOs) + 4 Land Border Health Units (LBHUs))	▪ Occupational health and safety risks due to potential exposure to pathogens released in air, blood and skin contact with cases during clinical examination and sample collection.

Key Institutions and Activities	Particulars	Potential Environmental and Social Risks and Impacts
		▪ Occupational health risks due to exposure to insecticides and rodenticide chemicals used for vector control and deratting activities at PoEs. ▪ Community health risks due to poor waste management practices for chemical and biomedical wastes at PoEs. Establishing these Field Health Units will have civil works and hence the key social risk is from: • Potential social risk emerges from need for any land to establish APHOs and LBHUs • The construction related occupational health and safety hazards. Risks to the workforce and associated community safety and health aspects.
Strengthening of 33 Existing Field Health Units	• Strengthening 19 APHOs + 11 Port Health Organizations (PHOs) + 3 LBHUs	• Strengthening existing Field Units may not pose any social risks. • Depending on the nature of support for strengthening of FHUs, some of the environmental risks discussed above may be relevant.

4.3 Indirect and Cumulative Impacts

67. PM-ABHIM being the largest pan-India schemes for strengthening healthcare infrastructure across the country that aims to provide a much-needed impetus to India's capacity to address emergent Public Health issues, and a shift towards making the healthcare system and infrastructure more resilient in addressing any future disease outbreaks and/or pandemic like situations, and which was felt as major gap during the COVID19 pandemic. Thus, the PM-ABHIM program brings immense benefits in providing a more accessible and affordable quality health care services to citizens. With enhanced ability towards identification of diseases including zoonotic diseases will also help in timely responses and containing any disease outbreaks will also save losses in production and in turn contributing towards economic development of the state and the country.

68. Cumulative environmental impacts relate primarily to generation of additional biomedical wastes across the country. On an individual healthcare facility and laboratory level, biomedical waste generated might not be significant, but on an aggregate basis, this could overwhelm the existing capacity, particularly for facility level storage and transport to final disposal site.

69. Some positive cumulative impacts are also anticipated. Efficient and functional laboratory services during acute health emergencies is likely to have a positive impact on improving the emergency response and thus shortening the duration and severity as well as spread of disease outbreaks.

70. By helping in keeping the health workforce healthy and functional during disease outbreaks, the indirect adverse impacts on non-emergency and routine essential healthcare services, such as, planned surgeries, deliveries, cancer, non-communicable diseases management and immunizations etc., would be minimized.

71. Continuous training and learning opportunities are expected to build cumulative capacity across the country in management of biomedical wastes and lead to strengthened biosecurity and biosafety provisions.

5 ASSESSMENT OF ENVIRONMENTAL AND SOCIAL MANAGEMENT SYSTEM, CAPACITY AND PERFORMANCE

5.1 Legal and Regulatory System

72. India has specific policy, legal and regulatory provisions directly relevant to the activities being carried out in the project. Annex-3 lists legal instruments that manage the biomedical and other wastes, pollution prevention, labor related aspects relevant to the project. It also lists other relevant international and regional conventions to which India is a signatory.

73. The provisions of the existing environmental legal and regulatory framework are adequate but require enabling institutional and technical capacity to comply with. While the provisions of the Biomedical Waste Management & Handling) Rules, 2016 – as amended up to 2019 are being implemented, provisions of other relevant environmental Acts, such as, hazardous, solid, plastic and E-waste Rules 2016 require additional capacity building efforts. Efforts are required to improve the monitoring of the management of different kinds of wastes.

74. International Health Regulations (IHR), 2005 as developed by World Health Organization provide a regulatory framework for managing international public health through effective detection and management of public health emergencies of international concerns (PHEIC). The regulations are implemented by WHO member countries including India. The IHR mandates national governments to monitor and manage public health at the Points of Entry (PoE) that include airports, seaports and land border units where there is human travel and transfer of goods across the international borders.

75. India being signatory to International Health Regulations (IHR) 2005, the PoEs have elaborate procedures and protocols for disease screening, immunization, disinfection and vector control activities as required by IHR. The national regulations, for example, Indian Aircrafts Public Health Rules, 1954 and Indian Ports Public Health Rules, 1955 regulate public health functions related to screening, disinfection, vector control and quarantine aspects at PoEs. However, since International Health Regulations were implemented by the WHO member states from 2008 onwards only, the specific provisions of IHR, 2005 are not reflected in the current national regulations. Keeping these lacunae in the regulatory framework, the Government of India has drafted Indian Aircrafts Public Health Rules, 2015 and Indian Ports Public Health Rules, 2015, incorporating the IHR, 2005 provisions into national regulations. The draft rules need to be adopted at the earliest to bring national regulations in congruence with the International Health Regulations, 2005.

76. The existing legislative framework is adequate to ensure social sustainability of the protection of interest of marginalized and vulnerable population including women, the elderly, the differently abled, ST, SC, women headed households, patients with chronic diseases informal sector workers (including domestic workers, laborers, and construction workers). It ensures (a) protection of the interest of all the vulnerable population as mentioned above, (b) non-discrimination based on religion, race, caste, and gender, and (c) transparency with right to information. The Building and Other Constructions Workers (Regulation of Employment and Conditions of Service) Act 1996, the other labor related acts on minimum wages and payment of wages, workmen's compensation, prohibition of child labor, along with the Occupational Safety, Health and Working Conditions Code, 2020 further strengthens the labor related framework and legislations. However, while they are adequate, it requires enabling institutional, capacity, and regular monitoring to comply with.

5.2 Institutional Arrangement for Program Implementation

77. The MOHFW will provide support to the overall stewardship for the proposed Program. The program will be implemented by relevant institutions of MOHFW namely (a) Department of Health Research (DHR) through the Indian Council of Medical Research (ICMR) and its select institutions (b)

the National Center for Disease Control (NCDC), (c) Disaster Management Cell (DMC), and (d) Points of Entry of International Health (IH) Division.

78. **ICMR**: The ICMR is an autonomous society under the Department of Health Research (DHR). It is the apex body for formulation, coordination, and promotion of biomedical research and is headed by the Director General. The Secretary DHR is the administrative head of the Department of Health Research. At present, ICMR has 26 Institutes/ Regional Research Centers spread across different parts of the country and each of these are headed by a Director (Scientist 'G'). Administratively, within the Department of Health Research, ICMR comes under the purview of the JS (ICMR & VRDL). All project activities coming under ICMR will be implemented through Divisions/Cells of ICMR. Decentralized operations are only expected to be undertaken by ICMR, through its two branches - National Institute of Virology (NIV), Pune and National AIDS Research Institute (NARI), Pune.

79. **NCDC**: The NCDC is a subordinate office of Directorate General of Health Services (DGHS) under the MOHFW that plays a lead role in investigation and management of disease outbreaks across the country. It has 8 branch offices and plans to expand to more sites as proposed under the program. NCDC is headed by a technical officer of the rank of DDG and comes under the purview of the DGHS. Administratively, it comes under the Public Health Division of MOHFW headed by the Joint Secretary (Public Health). All project activities coming under NCDC will be implemented by the concerned technical wings and branch offices of NCDC and the Public Health Division of the MOHFW in coordination with other divisions of MOHFW.

80. **Disaster Management (DM) Cell**: The Disaster Management (DM) Cell was established in December 2020 as a technical unit of the MOHFW. The cell is tasked to (i) plan for prevention, mitigation and ensure preparedness to manage public health emergencies (of international and national concern), major epidemics and pandemics (ii) respond to public health emergencies (iii) address health consequences of natural and man-made disasters (iv) implement International Health Regulations, 2005 (v) implement ongoing Central Sector Schemes. The DM Cell is headed by a DDG rank officer assisted by two Central Health Service Medical Officers. Administratively, the DDG reports to Joint Secretary (Public Health).

81. **International Health (IH) Division**: All the Point of Entries (POEs) Organizations are part of the International Health (IH) Division of the DGHS, . It is tasked to prevent, protect against, control and provide a public health response to the global spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade in keeping with International Health Regulations, 2005. The nodal In-charge for all POEs is the Deputy Director General - International Health (DDG-IH) who reports to the Director General of Health Services. Administratively, POEs comes under the Public Health Division of MOHFW headed by the Joint Secretary (Public Health).

82. The Directorate General of Health Services (DeGHS) is an attached organization of the MOHFW. It is headed by the Director General of Health Services, an officer of Central Health Services, who renders technical advice on medical and public health matters to MOHFW. The Secretary - Health and Family Welfare is the administrative head of the Department of Health and Family Welfare.

5.2.1 Institutional Capacity and Gaps

83. **ICMR**: ICMR has already signed MoU with CPWD for construction of NIVs, One Health Centre, and BSL Laboratories. The sites for construction are already identified and allotted to them. ICMR has also ensured that an official from their side is deputed for each of the construction site to coordinate with CPWD and help provide necessary guidance and technical support where required. ICMR also have two committees i.e., Capital Works Advisory Committee (CWAC) and Capital Works Monitoring Committee (CWMC) to advise on planning and designing of the capital works at each stage and monitor them. CWAC includes both internal and external members. The external members are

Senior Engineers mainly from Civil, Mechanical, Electrical, Architect, subject experts from Animal house/ BSL/ Repository etc. either in service or retired from Central/ State Government/ Public Sector Units (PSUs). The internal members include Director, Senior Scientists, Administrative officers, representative from Accounts section, and other technical officers. The CWMC also have both external and internal members and includes Senior Scientist of the Institute, any two among the external experts from CWAC, Administrative officers, representative from Accounts section, and other technical officers, and invitee from the Executing Agency. CWMC reviews both physical and financial progress in a periodic manner and submit report. The ICMR has recently published "General guidelines for establishment of Biosafety Level 3 Laboratory" in 2019 that comprehensively covers technical and managerial aspects for planning, construction, managing and monitoring such laboratories. The organization also possess mechanisms for training and capacity building on environmental, health and social aspects.

84. **NCDC**: While the human resources and institutional capacity of NCDC is also being strengthen and the details of which is reflected in the technical assessment under the PM-ABHIM program, for infrastructure creation, NCDC also plans to sign an Agreement and/or MoU with the selected construction agency for all the constructions under the program on their behalf. There is a larger committee to advise on BSL laboratories, and which also has members from MOHFW and ICMR. While there is a committee in NCDC on biomedical waste management, there is none that advises and monitors the works awarded for construction of various centres and laboratories. Given the large set of infrastructure being created for NCDC, there is a need for having a committee to advise the Executing agency at different stages and also help monitor the progress, so that the infrastructure being created are done in timely manner and as per the NCDC's need taking into account any specific and specialized requirements for constructing the BSL3 laboratories that require engineering interventions for both biosecurity and biosafety. The provisions for managing biomedical wastes include a BMWM Core Committee with defined roles and responsibilities specified in its Terms of References and a checklist for Annual Internal Audit for BMWM.

85. **Disaster Management (DM) Cell**: As mentioned above, the DM Cell has been established in December 2020 as a technical unit of the MOHFW and will follow the practices as per MOHFW for establishment of HEOCs in different states in a phased manner. With increasing frequency of natural and man-made disasters, including complex emergencies, a pressing need has been felt for disaster preparedness based on all-hazard approach, enhanced coordination and multi-sectoral coordination. This also gives an opportunity to develop these capacities through the Health Emergency Operation Centres (HEOCs) and the self-contained container based mobile hospitals.

86. **International Health (IH) Division:** All the POE Organizations at Airport, Port and Land Borders are well equipped for any construction related activities and have their own dedicated engineering wings.

5.3 Performance ESSA Against Core Principles

(Covering System and Capacity assessment; Key Gaps Identified; and Recommendations against each of the Core principles)

5.3.1 Core Principle -1: Program E&S Management System

Program E&S management systems are designed to: (a) avoid, minimize, or mitigate adverse impacts; (a) promote E&S sustainability in the Program design; (b) avoid, minimize, or mitigate adverse impacts; and (c) promote informed decision-making relating to a Program's E&S effects.

System and Capacity Assessment

87. The proposed program builds on the health sector experience of handling COVID-19 emergency operation which not only developed and streamlined many policies and procedures but also helped in understanding the strength and weaknesses of the system and institutions to further strengthen them for any future outbreaks and shocks. And all the four implementing agencies were central to streamlining and operationalizing the COVID19 response program of the Government of India including ICMR being involved in research and development of vaccines. The proposed program aims to strengthen health infrastructure to detect, investigate, prevent, and combat public health emergencies and disease outbreaks efficiently and effectively.

88. The COVID 19 pandemic has highlighted the fact that essential public health functions necessary to respond to such an outbreak need to be further strengthened. Limited laboratory capacity at all levels meant that functions of testing, case detection, surveillance and outbreak management were challenging.

89. The COVID19 pandemic has brought to forefront the challenges and limitations of the existing health facilities as well as common biomedical waste treatment facilities in managing the COVID19 associated biomedical wastes. Large amounts of such waste were generated from the regular health facilities as well as additional facilities that were converted into COVID19 treatment and quarantine facilities across the nation. In this regard, the existing mechanisms at NCDC cover environment management limited to biomedical wastes management and infection prevention and control in general through a core committee on BMW management and annual BMW audit using a basic checklist.

90. NCDC has published a "Biosafety manual for Public Health Laboratories" in 2016. However, a training and capacity building program in this area is not present.

91. The existing mechanisms at ICMR seem adequate as there exist supervision mechanisms for construction design advisory and construction monitoring, Memorandum of Understanding with Central Public Works Department (CPWD) for major construction works and technical guidelines on safe laboratory practices, Infection prevention and control and establishment of BSL3 laboratories along with training and capacity building program.

92. The activities at PoEs are governed by International Health Regulations, 2005 and specific national regulations that are implemented through procedures and protocols, along with training and capacity building mechanisms on International Health Regulations (IHR) in place. The monitoring of IHR activities is conducted by PoE Health organizations internally as well as in some cases e.g. vector control, periodic surveys by NCDC also.

93. For many of the infrastructure work, State Governments have contributed or expected to contribute by providing the land free of any charges and from any encumbrances. However, it might be useful to do a screening of the site provided for any adverse environmental and social risks and impacts at the time of planning and before any construction activities starts.

94. The Government of India is in an advance stage of enacting the law on personal data privacy which started in 2017 and where the Supreme Court of India (the apex judicial body in India) declared the right to privacy as a fundamental right protected under the Indian Constitution. In 2018 the court asked the government to create more robust data protection rules, and the Personal Data Protection (PDP) bill was first passed by India's Parliament in 2019. And was further sent to Joint Parliamentary Committee (JPC) for suggestions. On 16 December 2021, the JPC gave its suggestion on finalizing the Data Protection Bill, 2021, which is expected to soon become a legislation guiding the protection of personal data. The updated draft law seeks to protect the digital privacy of citizens and create a relationship of trust between individuals and entities processing their data and goes several steps beyond in ensuring protection of personnel data. While the MoHFW through various surveillance mechanism and through National AIDS Control program ((NACP) already has the experience of data privacy and protection of personal data, the current law in making will further strengthen this process.

Key Gaps Identified

95. At present, the mechanism adopted for identifying any potential environmental and social issues of the given infrastructure sites are bit informal even in cases where it is claimed to be practiced and requires a proper E&S screening to identify any adverse risks and impacts and plan to mitigate accordingly.

96. The organizational arrangements and provisions, such as, designated biosafety officers and necessary training and capacity for managing specific OHS and environmental risks of working in biosafety laboratories are at present lacking.

97. National regulations applicable for managing International Public Health at PoEs lack congruence with the provisions as specified under WHO International Health Regulations, 2005 and need updating with respect to the current international public health context.

5.3.2 Core Principle -2: Natural Habitat and Physical and Cultural Resources

Program E&S management systems are designed to avoid, minimize, or mitigate adverse impacts on natural habitats and physical cultural resources resulting from the Program. Program activities that involve the significant conversion or degradation of critical natural habitats or critical physical cultural heritage are not eligible for PforR financing.

System and Capacity Assessment

98. While the state Government once identify and hand over the site to the respective agencies, it is expected that they are not violating any regulations especially to with eco-sensitive areas or conservation areas and meet the necessary provisions as per legal and regulatory framework even though some necessary permissions may be required prior to any construction. However, the screening process can further strengthen this to ensure compliance.

99. Most medium to large healthcare facilities and laboratory infrastructure are generally planned and built in urban and peri-urban areas and do not pose any risk to natural habitats and physical and cultural resources. PHCs in rural areas are established in villages and towns and, again, do not pose any risk to natural habitats.

Key Gaps Identified

100. No major gaps are identified with respect to this Core Principle.

5.3.3 Core Principle -3: Public and Workers Safety

Program E&S management systems are designed to protect public and worker safety against the potential risks associated with (a) the construction and/or operation of facilities or other

operational practices under the Program; (b) exposure to toxic chemicals, hazardous wastes, and otherwise dangerous materials under the Program; and (c) reconstruction or rehabilitation of infrastructure located in areas prone to natural hazards.

System and Capacity Assessment

101. The legal framework that addresses and promotes workplace safety is already in place but requires monitoring and technical support. Large construction companies have the resources to deploy trained and competent safety officers. However, the issue of sub-contracting to local contractors often poses additional challenge, particularly with respect to occupational health and safety. Also, some of these constructions may amount to small labor camps at the construction sites, and hence, the emerging risk from health and sanitation, safety, and labor management related concerns at the construction sites for labor camps, apart from community health and safety concerns.

Key Gaps Identified

102. For NCDC, in the absence of an oversight mechanism for design safety during construction of infrastructure, including BSL3 laboratories, there is potential occupational health and safety risks from biohazards and toxic chemicals to the laboratory workers due to poor design of laboratories during operational stage. Several of the safe laboratory practices and accident prevention approaches involve engineering solutions, and therefore, this is seen as a gap.

103. Lack of biosafety training and capacity building provisions, for instance, designated biosafety officers and defined awareness and training program posing occupational health and safety risks to laboratory workforce as well as risk of spread of infections from laboratory to the community.

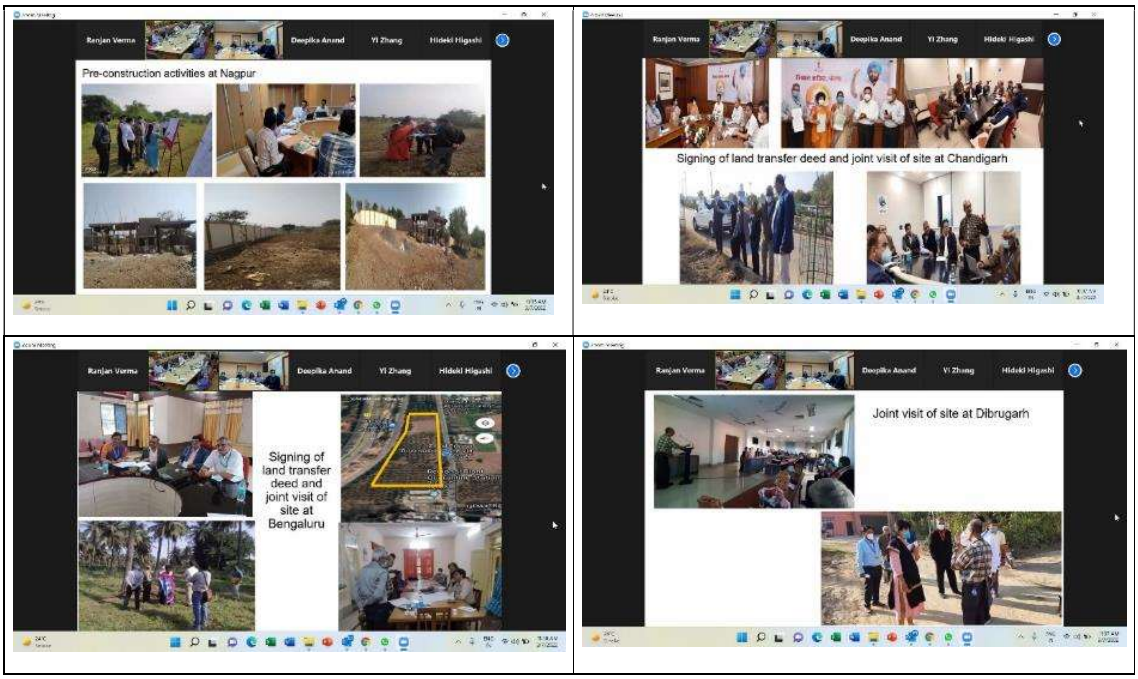
5.3.4 Core Principle -4: Land Acquisition and Resettlement

Program E&S systems manage land acquisition and loss of access to natural resources in a way that avoids or minimizes displacement and assists affected people in improving, or at the minimum restoring, their livelihoods and living standards.

System and Capacity Assessment

104. The program excludes any land acquisition. In most cases for land is already made available by the states free from any encumbrances for establishing NIVs, One Health Centre, some of the NCDC branches, and most of the BSL-3 laboratories. And, for the remaining infrastructure, the implementing agencies follow the process of requesting for land free from any encumbrances from states as part of their contribution towards the program and this may include land requirements for NCDC Regional centers, Branches, BSL-3 Laboratories, and Metropolitan Public Health surveillance units. The process for HEOCs, and Field Health Units is also expected to follow the same mechanism for any land requirement. While the process for allotting land may remain the same as request by implementing state to provide land free of any cost and free from any encumbrances, this process requires close monitoring to ensure no adverse social impacts arising due to this.

105. Below are the photographs of some of the land transfer and pre activities undertaken by ICMR.



Key Gaps Identified

106. While there are no major gaps, the process of land allotment for the infrastructure facilities does require proper monitoring and screening to ensure no adverse environmental and/or social risks and impacts.

5.3.5 Core Principle- 5: Rights and Interests of Indigenous People

Program E&S systems give due consideration to the cultural appropriateness of, and equitable access to, Program benefits, giving special attention to the rights and interests of Scheduled Tribe people (Indigenous Peoples) and scheduled caste people, and to the needs or concerns of vulnerable groups

System and Capacity Assessment

107. The proposed infrastructure facilities such as NIVs, Regional NCDC Centre(s), NCDC branches, and BSL-3 laboratories are planned in such a manner that they are equitably distributed across states and region including backward states and states with higher tribal population, to address regional and state specific issues and concerns.

108. MOHFW including ICMR and NCDC also have Institutional Complaints Committee Mechanism (ICC) as per sexual harassment at workplace. Apart from above. ICMR also have a Liaison Officer system for the marginalized group of employees (SC, ST, OBC). Such employees are free to approach different National Commissions like SC, ST, OBC, Women, Differently Abled persons and Human Rights.

109. MOHFW and all the implementing agencies have engaged in communicating to public at large and to specific risk groups on various diseases over a long period and more specifically during the COVID19 pandemic to keep the community and other stakeholders aware of any risks and impacts and safety precautions that they need to follow to safeguard themselves.

Key Gaps Identified

110. No major gaps are identified for this Core Principle.

5.3.6 Core Principle- 6: Social Conflict

Program E&S systems avoid exacerbating social conflict, especially in fragile states, post-conflict areas, or areas subject to territorial disputes.

111. The program activities do not exacerbate any social conflict in fact it benefits by enhancing disease surveillance for early identification and responses of any disease outbreaks.

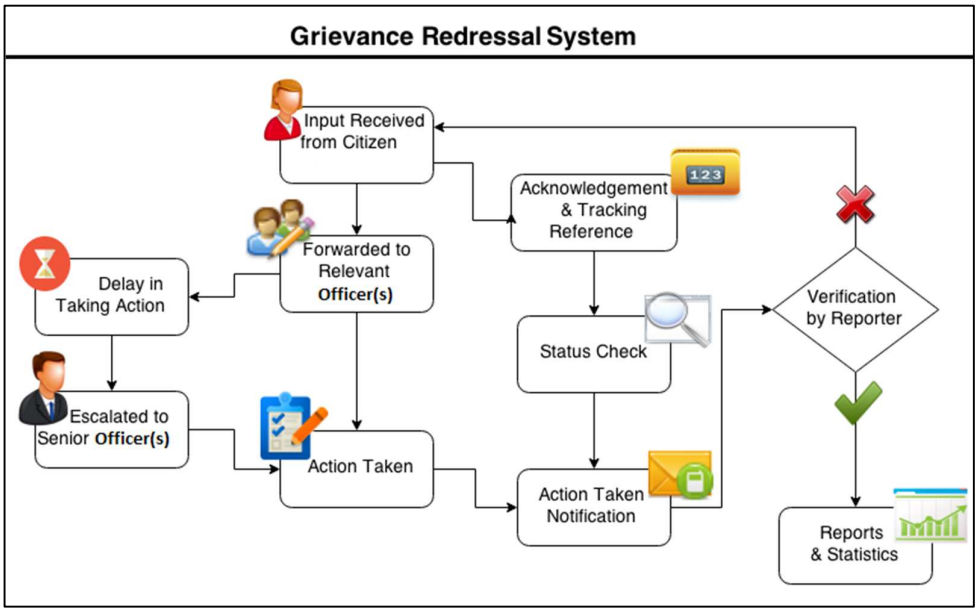
112. The physical infrastructure creation activities are mainly restricted to select metropolitan cities and bigger towns even though the services will cover the whole state/ region. Experience from other health programs as well as COVID19 emergency project operations, no conflicts are reported to have been faced.

5.4 Grievance Redressal Mechanism

113. The current grievance redress mechanism in the participating states has multiple ways to register grievances and get redressal. This includes:

a. Using Right to Information (RTI) Act to get information and resolution of grievances as mandated under the Act. All states and departments follow RTI and have deputed officials looking after the RTI within their department.

b. At the national level for all the implementing agencies and MOHFW leverage existing country system to receive, resolve and manage grievances. The Centralized Public Grievance Redress and Monitoring System (CPGRAMS) is an online web-enabled system (https://pgportal.gov.in/) in association with Directorate of Public Grievances (DPG) and Department of Administrative Reforms and Public Grievances (DARPG) to register and track grievance. And is being used in all Central Ministries and Departments including for MOHFW. Any Central Government Institution specific such as ICMR, NCDC, DM Cell, and IH Division specific grievances, and State specific grievances can also be lodged here which are further directed to respective agencies and state department for resolution and reported back through CPGRAMS system. In addition, in each of the implementing



agency, there is an officer deputed for addressing any grievances. The schematic description of grievance flow in CPGRAMS is as below.

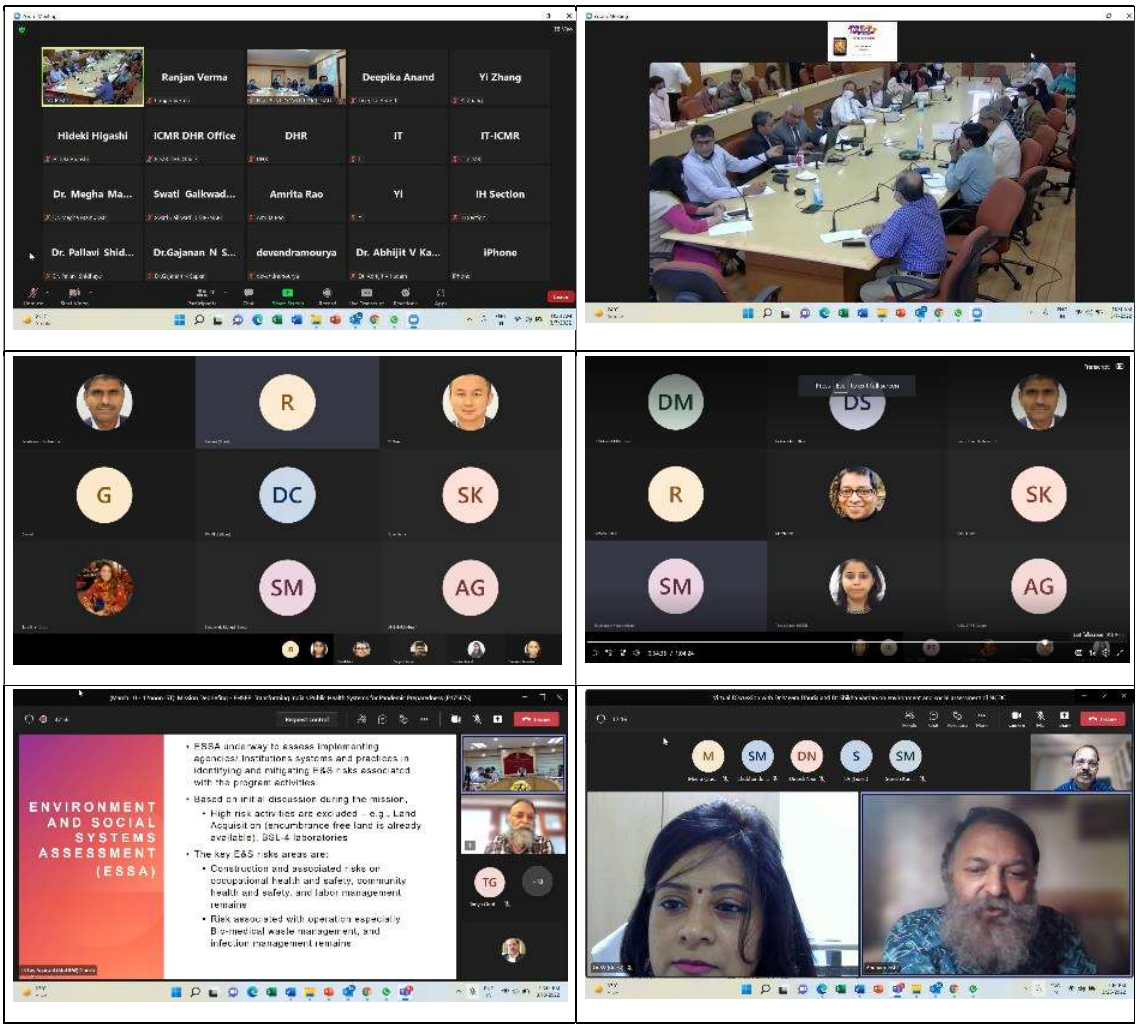
c. In addition, at the state level, registering grievances are generally done online through Chief Minister's (CM's) grievance cell, or through Health Department's call center were functional. On receipt of the grievances, and initial screening, it is directed to specific department and institutions for resolution.

6 CONSULTATIONS WITH KEY STAKEHOLDERS AND DISCLOSURE

6.1 Stakeholder consultations

114. As part of preparation, consultations were undertaken with key officials from the ICMR, NCDC, DM Cell, and IH Division in both physical and virtual manner over the February and March 2022 period. In addition, a detailed checklist was prepared specific to each implementing agency and was shared for their written feedback. The draft ESSA incorporates the summary of desk review, discussions and consultations with each of implementing agencies, and written information received from implementing agencies as per the ESSA checklist.

115. Below are some of the photographs of the virtual/ hybrid consultations.



116. The consultation with all the implementing agencies and the seeking information through checklist was largely concentrated in the areas of (a) key activities that the implementing agency is planning under the PM-ABHIP and proposed PHSPP program; (b) the institutional mechanism including environmental and social capacity within each of these institutions; (c) key infrastructure including BSL laboratories planned and its geographic spread; (d) mechanism for ensuring biosafety and biosecurity including handling of bio-medical wastes, and other hazardous wastes; (e) occupational health and safety related issues and concerns for staffs/ workers, laborers and community; (f) land requirement for infrastructure and mechanism for identifying and procuring land; (g) institutional

mechanism for construction of the laboratories and centers proposed; (h) grievance redress mechanisms and stakeholder engagement process; and (i) concerns related to training and capacity building of staffs on identifying and managing environmental and social risks and impacts.

117. The preparation was also informed by the progress and achievements of the India COVID-19 Emergency Response and Health Systems Preparedness Project as the ICMR and NCDC are also actively engaged in that program and there has been as ongoing dialogue with them on implementation of Environmental and Social Management Framework of the said project.

6.2 Multi-stakeholder consultation workshop

118. A multi-stakeholder workshop was conducted on 28th April 2022 at national level covering participants from all stakeholders' groups to seek their feedback and suggestions. The revised Draft ESSA report will be prepared considering the suggestions and feedback during multi-stakeholder workshop. Among the participants officials from all the implementing agencies i.e. NCDC, ICMR, DM Cell and IH Division of MOHFW; other government Ministries/ departments/ agencies such as Ministry of Environment, Forests and Climate Change (MoEFCC), National Disaster Management Agency (NDMA), Niti Aagyog, and National AIDS Control Organization (NACO); civil society organization such as Public Health Foundation of India (PHFI) and Voluntary Health Association of India (VHAI); and representatives from WHO joined the stakeholder workshop and provided their feedback and suggestions. The detail list of participants is presented in Annex-4.

119. While all the participants appreciated the findings from ESSA, the feedback and suggestions from the multi-stakeholder consultation workshop is broadly grouped in a manner to inform program design and ESSA and presented below.

a. Dr Lata Kapoor from NCDC explained the limited capacity of NCDC in managing environmental and social safeguards and sought World Bank's support during program implementation for building capacity towards undertaking EIA and preparation of ESMP.

b. The Bio-medical waste reporting through App developed by CPCB has been recommended, currently it is mainly covering the COVID19 related waste information. However, CPCB in association with MoEFCC is in the process of developing a bar coding system for tracking biomedical waste from generation to disposal. It was agreed to explore enlarging the scope of the current App for covering all biomedical wastes

c. CPCB further informed that the data for BMWM mentioned in the ESSA report is currently taken from CPCB website, and now there are more updates available, and the ESSA report can update it accordingly.

d. CPCB further mentioned that there is a lot of infrastructure work envisaged under the project, there is a need to setup common bio-medical waste treatment facilities, as these are missing in many parts of the states and districts across the country. Also, management of domestic BMW is another area that is not covered by the project and the project may consider including that. It was clarified by the World Bank team that this is an important area, however, it is beyond the scope of this program to address the same.

e. CPCB further informed that with support from UNIDO, capacity building manuals on BMWM have been developed, but not aware about any portal that provides any online courses on BMWM.

f. The DM cell informed that the HEOC to come up within the state land and use their own auxiliary service. Also, for e-waste Ministry of Environments guidance on e-waste management will be complied with.

g. Niti Aayog highlighted that there is coordination issue especially on the surveillance aspects among different agencies as they are currently working in silos, therefore, there is need to bring them together such as the case in AMR surveillance. The World Bank task team mentioned that the interorganizational coordination is a key aspect of the program and the challenge as well, to which the program plans to first explore coordination between key implementation organizations e.g., NCDC, ICMR, IHD and Ministry of Health and gradually expand to other stakeholders.

h. Dr. Manjeet from WHO mentioned that the inclusion of environmental concerns in the planning and operationalization of laboratories as planned under the program is a good initiative. He emphasized the need for adaptation of making the new constructions climate resilient, and the use of renewable source of energy should also be part of the strategy. Also, BMW is an ongoing process and additional capacity is very much required along with emphasis on other wastes such as e-waste etc. and the provision of adequately skilled personnel in the laboratory is paramount. And hence, the self-paced course on BMW is very useful.

i. The strengthening of surveillance systems should talk about potential reductions in GHG emissions due to paper less data collection and monitoring and can be considered. The World Bank team also agreed that this is a good suggestion and will try to initiate a study during implementation to identify potential opportunities for reducing GHG emission.

j. Dr. Anup from PHFI raised the issues related to equity issues in BMWM process especially the workers handling BMWM and the community living closer to waste dumping generally being from low-income categories and requires specific measures addressing their equity concerns. Also, although the ESSA report mentioned about labor laws being adequate there is increasing trend on migrant labors who generally come for very short time or part time and gets missed out. The World bank team clarified that though equity concerns among waste handlers and around the waste dumping sites are important, however, they are beyond the scope of the program to be addressed under this project, but the labor management related concerns are very much valid, and the gaps observed are mainly in monitoring construction sites for adherence. The team further informed that planning of BSL-3 laboratories and other infrastructure planned in an equitable manner and will be emphasized in the assessment report.

k. Dr. Dharmesh from ICMR emphasized the need for capacity building of private sector personnel in handling BMW and how the program can address the same shall be further clarified in the assessment. Dr. Avinash from the IH Division further mentioned that BMWM course is being offered by IGNOU and there are trainings already happening on BMW by the private sector agencies. Mr Dinesh Runiwal from MoEFCC shared that UNIDO has already developed a portal on BMWM and details are available at https://bmwm-e-learning.org/.

l. The representative from MoEFCC mentioned that the report currently mentions about BMWM rules 1998 (amended up to 2018) which requires correcting as it superseded by the BMWM rule 2016 and are amended thrice thereafter, first in 2018 and then twice in 2019; the assessment report should use the updated versions.

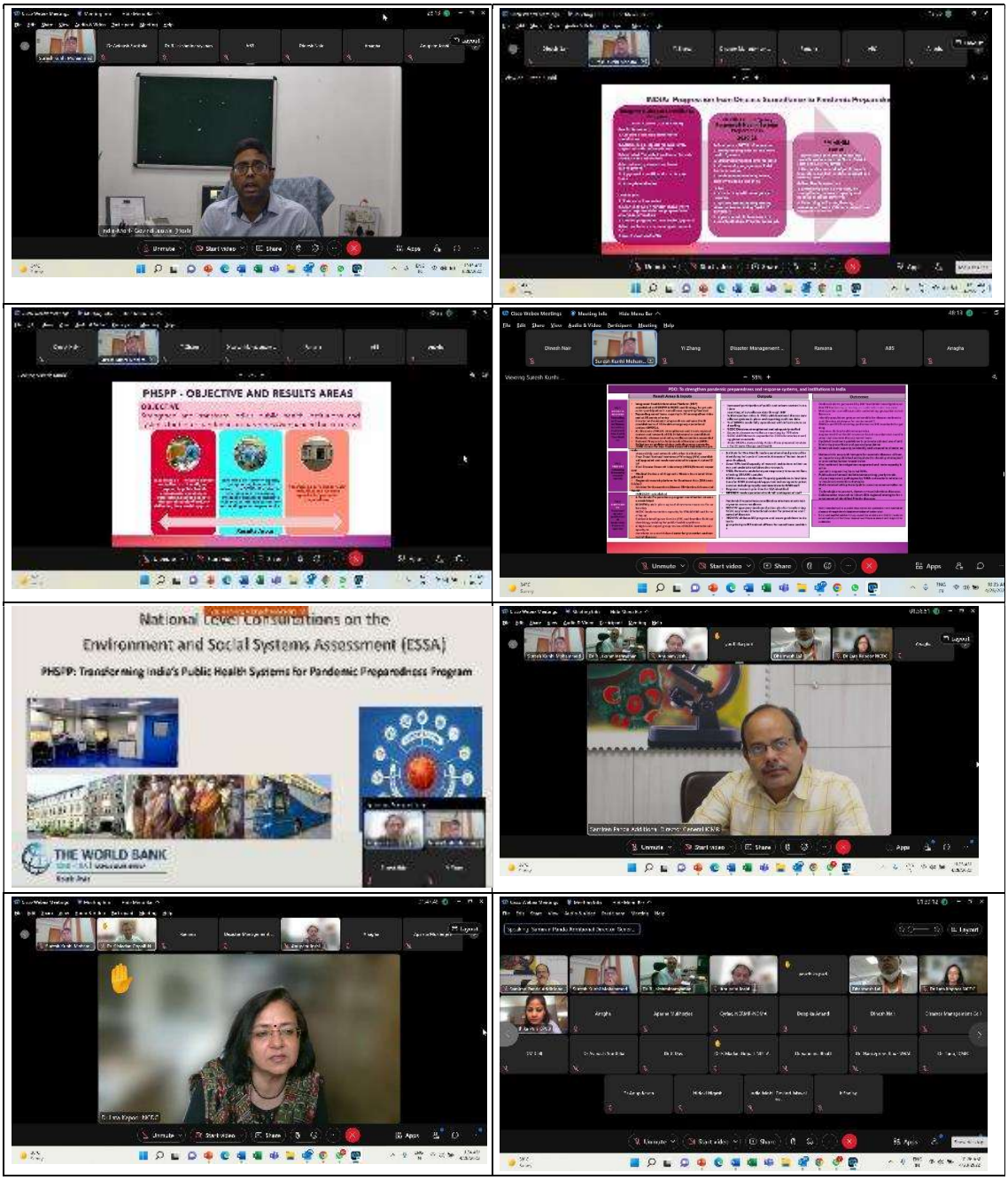
m. Dr. Nancepreet from VHAI mentioned that the program may consider involving CBOs, CSOs for environmental assessments and identify areas for collaborations.

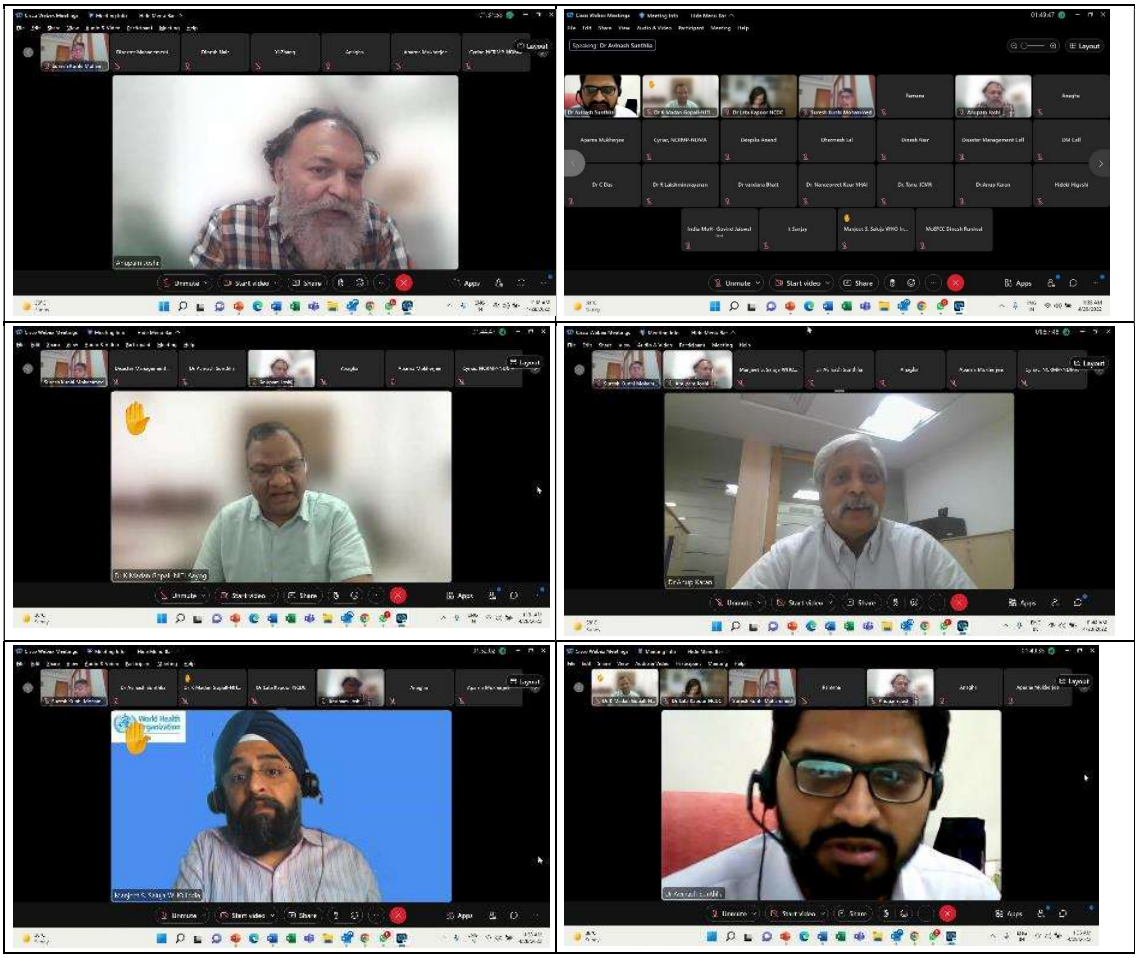
n. Lastly, Dr. Das from NACO informed the participants about the Surveillance activities under NACO that utilizes digitalization in a big way. She stressed on the need for digitalized information about BMW too. She raised concerns about data confidentiality issues with HIV-AIDS that can affect disease early warning system. emphasized that data confidentiality should also be taken care of as part of the program mainly for surveillance.

o. Dr Govind Jaiswal further stressed in his closing remark that BMW has legal requirement for healthcare facilities that must be complied. In addition, biosafety and biosecurity are emerging concepts that are gaining importance and would need to be developed as part of the program. He stressed on the need for implementation organizations to adhere to the action plan timelines of the program and seek World Bank guidance where required.

120. While some of the suggestions are already addressed in the ESSA for the program, the others will also be considered within the program scope to feed into operationalizing the design and further implementation.

121. Some of the snapshots of the multi-stakeholder consultations workshop are as below.





6.3 Disclosure of ESSA

122. The draft ESSA was disclosed in country at the MOHFW website on XXDATEXX and on the World Bank's external website XXDATEXX, prior to appraisal of the program, to serve as the basis for discussion and receipt of further feedback and comments. The Final ESSA report will be redisclosed on the World Bank's external website before negotiation.

7 RECOMMENDATIONS AND ACTIONS

7.1 Exclusion of High-Risk Activities

123. PHSPP program will not finance any activities that would cause high E&S risks and impacts including activities involving:

a. Any land acquisition, physical relocation and/or involuntary resettlement impacts.

b. Construction and establishment of BSL-4 laboratories

c. Any work that would convert or encroach forest lands, notified wetlands or any eco-sensitive areas.

d. Activities that are not in compliance with Central and State environmental legislation.

e. Use of child or bonded or forced labor or labor involved in any hazardous activities.

f. Destruction or damage to any physical and cultural resources.

7.2 Summary of Identified Gaps

124. The key gaps emerge from:

a. Improper screening of identified construction sites for any environmental and social risks and impacts.

b. Lack of designated organization for managing biosafety and biosecurity aspects arising out of current functioning as well as future expansion of laboratory system in NCDC. Further, there is no committee of NCDC which either advises and/or monitors the works awarded for construction of various centres and laboratories. Given the large set of infrastructure being created for NCDC, there is a need for having a committee to advise the Executing agency at different stages and help monitor the progress, to ensure that the infrastructure being created are as per the NCDC's requirements.

c. Lack of defined strategy and structured program for training and capacity building on biosafety related to biomedical waste management and Occupational Health and Safety of the workforce in laboratories.

d. Regarding IHD-PoE, the regulatory framework of current national regulations is old and covers public health requirements not adequately congruent with the requirements of International Health Regulations, 2005.

e. The issue of sub-contracting to local contractors often poses additional challenge, particularly with respect to occupational health and safety of construction workers. Also, some of these constructions may amount to small labor camps at the construction sites, and hence, the emerging risk from health and sanitation, safety, and labor management related concerns at the construction sites and the labor camps, apart from community health and safety concerns.

7.3 Key Recommendations

125. The ESSA recommendations focuses on strengthening the national systems and institutional arrangements for implementation, management, and reporting of E&S aspects, including:

a. Incorporation of environmental and social measures, for addressing potential negative impacts and risks, in the design, construction and operation of BSL3 laboratories. This

would include provisions of undertaking an environmental impact assessment (EIA) for the proposed BSL3 laboratories. Annex 5 provides detailed step-by-step guidance for establishing BSL3 and a checklist for managing operations of a BSL3.

b. Setting up committee in NCDC to advise the Executing agency in design, and construction and help monitor the progress of BSL3 laboratories and other infrastructure facilities. In addition, NCDC to develop training program for building capacity on biosafety management focused on biomedical waste management and occupational health and safety for laboratory workers on a regular basis.

c. NCDC/ ICMR to periodically assess the preparedness and response capacities of the organizations on biosafety management for which a Monitoring Committee be constituted and protocol developed for assessing such capacity.

d. All NCDC/ ICMR/ MOHFW healthcare facilities and diagnostic laboratories to report on biomedical waste generation and disposal through the CPCB mandated mobile application.

e. Inclusion of occupational health and safety as well as labor welfare provisions in the construction contracts and its periodic monitoring.

f. Managing E&S risks of potential substantial risk activities, through screening or site-specific Environment and Social management plans (ESMPs).

g. IHD to finalize the draft Indian Aircraft Public Health Rules, and Draft Port Health Rules, developed in 2015, so that these are adopted and published by the Government of India to bring national regulations in congruence with the specific requirements of International Health Regulations, 2005.

126. In case the need arises, any Government land undertaken is preferable, or else donation is done voluntarily without any coercion for doing so, and the process of donation shall be institutionalized through a transparent and through the process of gift deeds.

7.4 Measures for Inclusion in the Program Action Plan

127. The following table outlines the Program Action Plans, the responsible party or parties that are responsible to take the necessary actions and the timelines for completion. It also outlines how these actions will be measured.

Action Description	DLI#	Responsibility	Recurrent	Frequency	Due Date	Completion Measurement
Signing of an Agreement/MoU with the selected construction agency on ensuring key environmental and social clauses for addressing Occupational Health and Safety issues and compliances with the provisions of the national labour laws.		NCDC	No	One time	Agreement/MoU signed before construction begins	MoU signed
Establishing mechanisms for technical advisory and monitoring of environmental and social activities by anxperts group during implementation		MOHFW, ICMR, NCDC	No	One time	Within 12 months of effectiveness	Guidelines prepared detailing mechanism for technical advisory and monitoring supervision of E&S activities, and expert group notified through a Government Order and/or Office Memorandum
Designing online training program on Biosafety, Biosecurity, Biomedical waste management, IPC and OHS for laboratory workforce		NCDC	No	One time	Within 12 months of effectiveness	Online course available

ANNEXURES

ANNEXURE – 1: LIST OF DOCUMENTS REVIEWED

Aircraft Public Health Rules, 1954

Annual Report 2020-21. Department of Health & Family Welfare, Ministry of Health & Family Welfare (MOHFW), Government of India. 2021. Available at https://main.mohfw.gov.in/sites/default/files/Annual%20Report%202020-21%20English.pdf.

Annual Report on Biomedical Waste Management as per Biomedical Waste Management Rules, 2016 For the year 2019, Central Pollution Control Board

Biosafety manual for Public Health Laboratories, NCDC, 2016

Detailed Proposal for EFC- Public Health- Strengthening of National Centre for Disease Control for surveillance of infectious diseases and outbreak response (Concept Note)

General Guidelines Establishment of Biosafety Level-3 Laboratory. Indian Council of Medical Research. Government of India. 2019. Available at https://main.icmr.nic.in/sites/default/files/upload_documents/Revised_ICMR_Guidelines_2_December.pdf.

General guidelines: Establishment of Biosafety Level 3 Laboratory: Indian Council of Medical Research 2021

Generation of COVID19 related Biomedical Waste in States/UTs: Central Pollution Control Board, Delhi

Good Clinical Laboratory Practices Guidelines, Indian Council of Medical Research 2021

Guideline on Integrated Public Health Laboratories. National Health System Resource Centre (NHRC). 2022. Available at https://nhsrcindia.org/pradhan-mantri-aatmanirbhar-swasthya-bharat-pm-asby.

Hospital Infection Control Guidelines, Indian Council of Medical Research

India Epidemic Intelligence Service (EIS) Training Programme, National Communicable Diseases Centre (NCDC) and Centre for Disease Control and Prevention, Atlanta, USA

Indian Port Health Rules, 1955,

Information checklists-NCDC, IH and EMR divisions of NCDC

Memorandum of Understanding between Indian Council of Medical Research (ICMR) and Central Public Works Department (CPWD) dated 10th March, 2022, on Planning and Construction of Building(s) of Indian Council of Medical Research (ICMR) including Maintenance & Up-gradation, renovation of buildings constructed by CPWD at various locations in the country assigned to CPWD for the purpose.

MOHFW. Activities of the International Health Division, MOHFW. Available at IHR POE (mohfw.gov.in).

Office Memorandum on establishment of Capital Works Advisory Committee, and Capital Works Monitoring Committee. Indian Council of Medical Research. Government of India. 2020.

Operational Framework for building climate resilient health systems. Geneva: World Health Organization; 2015

Operational Guideline for Pradhan Mantri - Ayushman Bharat Health Infrastructure Mission. National Health System Resource Centre (NHSRC). Government of India. 2021. Available at https://nhsrcindia.org/pradhan-mantri-aatmanirbhar-swasthya-bharat-pm-asby.

Vision 2035: Public Health Surveillance in India - A White Paper. Niti Aayog. Government of India. 2020. Government of India. Available at https://www.niti.gov.in/sites/default/files/2020-12/PHS_13_dec_web.pdf.

Water, sanitation and hygiene in health care facilities: practical steps to achieve universal access, World Health Organization; 2019

WHO guidance for climate-resilient and environmentally sustainable health care facilities, World Health Organization, 2020

Websites:

Central Pollution Control Board: https://cpcb.nic.in/

Indian Council of Medical Research: https://www.icmr.gov.in/

Ministry of Environment, Forests and Climate Change (MoEFCC): https://moef.gov.in/en/

National Centre for Communicable Diseases:
https://ncdc.gov.in/index4.php?lang=1&level=0&linkid=28&lid=33

World Health Organization SEARO https://www.who.int/india/health-topics/international-health-regulations

ANNEXURE – 2: APPLICABLE LEGAL AND REGULATORY FRAMEWORK

The Government of India and the state government have enacted a range of laws, regulations, and procedures relevant to managing the environmental and social effects of the proposed Program. The following criteria were used to select the relevant legislation that best describes the country's system for managing the Program's effects:

i. environmental and social policies,
ii. environmental and social protection laws, and
iii. laws, regulations, or guidelines in the relevant sectors and subsectors that provide relevant rules or norms for environmental and social management

Table A3.1: Environmental and Social Laws, Regulations and Policies that are relevant to the proposed program

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
National Acts and Regulations			
1.	The Constitution of India Part IVA (Art.51A-Fundamental Duties)	under Part IVA (Art. 51A-Fundamental Duties) casts a duty on every citizen of India to protect and improve the natural environment	Relevant to the overall system
2.	Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010) (Central Government) Amendment Rules, 2020	In the Clinical Establishments (Central Government) Rules, 2012, in the Schedule for heading at Sl. No. III relating to „ HUMAN RESOURCE	All the health care facilities have to register under this Act.
3.	Bio-medical Waste Management Rules, 2016 (Amended up to 2019)	Schedule 1: Categorization and Management Schedule 2: Standards for treatment and disposal of BMW Schedule 3: Prescribed Authority and duties	Highly relevant

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
		Schedule 4: Label of containers, bags and transportation of Bio-Medical waste The provisions under the rules provide for both solid and liquid medical wastes. Liquid waste should be treated with 1% hypochlorite solution before discharge into sewers. Hospitals not connected to municipal Waste-water Treatment Plants (WWTPs) should install compact on-site sewage treatments (i.e. primary and secondary treatment, disinfection) to ensure that wastewater discharges meet applicable thresholds	
4.	Construction and Demolition Waste Management Rules, 2016	Waste comprising of building materials, debris and rubble resulting from construction, re-modeling, repair and demolition of any civil structure	Relevant as there will be construction waste generated. CPCB guidelines on Environmental Management of C&D Waste Management in India (2017) will be applicable.
5.	Solid Wastes Management Rules, 2016	These rules govern solid waste from domestic, institutional, commercial and any other non-residential solid waste generator situated in the areas except industrial waste, hazardous waste, hazardous chemicals, bio medical wastes, e-waste, lead acid batteries and radio-active waste, that are covered under separate rules framed under the Environment (Protection) Act, 1986.	Relevant. Majority of wastes generated from healthcare facilities, laboratories and PoE health organizations is general solid waste e.g. paper, packaging, dry leaves, food wastes etc. and needs to be collected, stored, handled and treated separately from hazardous wastes.
6.	The Hazardous and Other Waste Management Rules, 2016	The H&OW Management Rules, 2016 provide for generation, collection, treatment, transport, import, storage and disposal of hazardous wastes. Improper storage, handling, transportation,	Relevant to all health programmes

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
		treatment and disposal of hazardous waste results in adverse impact on ecosystems including the human environment.	
7.	E-Waste (Management and Handling) Rules 2011as Amendment up to 2018	To address leakage of e-waste to informal sector at all the stages of channelization. The 2016 Amendment brought health care facilities (with turnover over INR 20 crores or more than 20 employees).	Relevant as it is applicable for consumers or bulk consumer. The disposal of E-wastes to be done at the specified collection centers and reported annually.
8.	Plastic Waste Management Rules 2016	All institutional generators of plastic waste, shall segregate and store the waste generated by them in accordance with the Solid Waste Management Rules, and handover segregated wastes to authorized waste processing or disposal facilities or deposition centers, either on its own or through the authorized waste collection agency	Relevant as hospitals/ Laboratories are generators of large quantity of plastics, including non-reusable types. The APHO, PHO and LBUHOs under International Health also generate plastic wastes dueing Yellow Fever vaccinations.
9.	Water (Prevention and Control of Pollution) Act 1974 Air (Prevention and Control of Pollution) Act 1981 Environment Protection Act (and Rules), 1986 & 1996	Provisions are largely to prevent air and water pollution by not releasing untreated effluents and harmful emissions. Most provisions are already discussed under the Bio-Medical Waste Rules	Relevant and largely complied with; gaps exist in disposal of liquid wastes from healthcare facilities
10.	Environment Impact Assessment 2006	The schedule of the Act lists investment activities under two categories 'A' and 'B', including expansion of existing ones and sets up State EIA Authority. All investment activities listed under 'A' require approval from the Expert Appraisal Committee of the Ministry of Environment, Forests and Climate Change.	Applicable if project finances: a) Common Hazardous Waste Treatment facility having landfill with incineration or incineration alone; b) Common Effluent Treatment

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
			Plant; and c) building with built up area ≥ 20,000 sq.m. and < 1,50,000 sq.m.
11.	The Epidemic Diseases Act 1897 The Epidemic Diseases (Amendment) Ordinance, 2020	The Epidemic Diseases Act 1897 provides for better prevention of the spread of dangerous diseases. The Epidemic Diseases (Amendment) Ordinance, 2020 was promulgated on April 22, 2020. The Ordinance amends the Epidemic Diseases Act, 1897. The Act provides for the prevention of the spread of dangerous epidemic diseases. The Ordinance amends the Act to include protections for healthcare personnel combating epidemic diseases and expands the powers of the central government to prevent the spread of such diseases.	To ensure safety of communities, workers and project staff especially during this period of COVID pandemic. The ordinance includes provisions for protection of health and safety of health workers from the acts of violence and aggression during management of Covid-19 response in the health facilities and communities.
12.	The Water (Prevention & Control of Pollution) Act 1974. The Air (Prevention & Control of Pollution) Act 1981. Environment Protection Act (and Rules), 1986 and 1996 Environment (Protection) Second Amendment Rules 2002	Provisions are largely to prevent air and water pollution by not releasing untreated effluents and harmful emissions from Generator sets and incinerators. Most provisions are already discussed under the Bio-Medical Waste Rules. The Act mandates to control and abate water pollution. The Diesel Generator sets installed during construction should comply with maximum permissible noise levels and noise control measures for diesel generators up to 1000 KVA capacity as specified in the Act.	Relevant
13.	National Disaster Management Act 2005	Provides for the timely and effective response to disaster. The Act provides effective management of disasters and for matters connected there with or incidental thereto. The main focus of this act is to provide the people who are affected with disasters, their	Applicable when project implementation is during or encounters natural disaster or is relevant under current circumstances of COVID pandemic.

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
		life back and helping them. It also lays down guidelines to be followed by the State Authorities in drawing up the State Plans.	
14.	The Constitution of India (especially, Articles 15,16 and 46)	The Indian Constitution (Article 15) prohibits any discrimination based on religion, race, caste, sex, and place of birth. Article 16 refers to the equality of opportunity in matters of public employment. Article 46 directs the state to promote with special care the educational and economic interests of the weaker sections of the people, particularly of the Scheduled Castes and the Scheduled Tribes and also directs the state to protect them from social injustice and all forms of exploitation.	Relevant to the overall Program
15.	Indian Penal Code (IPC)	Section 278 (making atmosphere noxious to health) and Section 269 (negligent act likely to spread infection or disease dangerous to life, unlawfully or negligently.	Relevant Although individuals would require providing evidence
16.	Right to Information Act, 2005	Provides a practical regime of right to information for citizens to secure access to information under the control of Public Authorities. The act sets out (a) obligations of public authorities with respect to provision of information; (b) requires designating of a Public Information Officer; (c) process for any citizen to obtain information/disposal of request, etc. (d) provides for institutions such as Central Information Commission/ State Information Commission.	Relevant as all documents pertaining to the Program requires be disclosed to public.
17.	The Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013	An act that aims at providing a sense of security at the workplace that improves women's participation in work and results in their economic empowerment. It requires an employer to set up an "Internal Complaints Committee" (ICC) and the Government to	Relevant and applicable to all health directorates and most of the health care facilities

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
		set up a 'Local Complaints Committee' (LCC) at the district level to investigate complaints regarding sexual harassment at workplace and for inquiring into the complaint in a time bound manner. The ICC need to set up by ever organization and its branches with more than 10 employees.	
18.	Criminal Law (Amendment) Act, 2013: Sexual Offences	The Act recognizes the broad range of sexual crimes to which women may fall victim, and a number of ways in which gender-based discrimination manifests itself. It also acknowledges that lesser crimes of bodily integrity often escalate to graver ones and offences such as acid attack, sexual harassment, voyeurism, stalking has been incorporated into the Indian Penal Code (IPC). It seeks to treat cases as "rarest of the rare" for which courts can award capital punishment if they decide so. The Act clarifies and extends the offense of sexual assaults or rape as a result of abuse of position of trust. As per the Act, the police will also be penalized for failing to register FIRs – this will make it easier for rape victims to report their cases.	Relevant and applicable to deal with GBV including SEA/ SH issues.
19.	The Building and Other Constructions Workers (Regulation of Employment and Conditions of Service) Act, 1996 and the associated Central Rules, 1998	This is a social welfare legislation that aims to benefit workers engaged in building and construction activities across the country and regulates the employment and conditions of service of building and other construction workers and to provide for their safety, health and welfare measures and for other matters connected therewith or incidental thereto.	Relevant to the program and applicable for sub-projects involving construction.
20.	Workmen's Compensation Act, 1923 & Rules 1924	The Act provides for compensation in case of injury by accident arising out of and during employment.	Relevant to the program and applicable for sub-projects involving construction.

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
21.	Minimum Wages Act, 1948	This Act provide for fixing minimum rates of wages in certain employments and requires the employer to provide to every worker engaged in a scheduled employment to be paid wages at a rate not less than the minimum rate of wages fixed by such notification for that class of employees in that employment without any deductions except as may be authorized within such time and subject to such conditions as may be prescribed.	The Minimum Wages Act is applicable, and the contractor is mandated to provide compliance as per the act.
22.	Payment of Wages Act 1936; and Equal Remuneration Act 1976	The payment of wages act lays down as to by what date the wages are to be paid, when it will be paid and what deductions can be made from the wages of the workers.	Relevant. The contractor will be mandated to provide compliance as per agreed terms of payment of Wages.
23.	The Child Labour (Prohibition and Regulation) Act, 1986; and Amendment Act, 2016	This Act prohibits the engagement of children in all occupations and prohibits the engagement of adolescents (under 18 years of age) in hazardous occupations and processes and the matters connected therewith or incidental thereto.	Relevant, especially on hiring contract labor for construction activities.
24.	Indian Port Health Rules, 1955	The rules lay down the requirements for sanitation and hygiene, medical examination of ship workers and passangers, deratting, vector control etc. at the sea ports.	Relevant. The Port Health Organization has to implement the provisions under the regulation
25.	Indian Aircrafts Public Health Rules, 1954	To protect public health by prevention of entry or exit of infections of public health importance through air travel and cargo with airports as PoE. The provisions cover quarantine, medical examination of seamen and passengers, provisions for detecting and preventing PHEIC on arrival and departure etc.	Relevant. The airport health organization has to implement such provisions.
26.	Food Safety and Standards Act, 2006	The act specifies the provisions relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to	Relevant. The airport and Port Health Organizations are mandated by the act to manage food safety at the establishments

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
		ensure availability of safe and wholesome food for human consumption	and for the food items for import / export to / from the country.
27.	National Building Codes of India 2016	The Code provides regulations for building construction by departments, and public bodies. It lays down a set of minimum provisions to protect the safety of the public about structural sufficiency, fire hazards and health aspects. The Code mainly contains administrative regulations, development control rules and general building requirements; fire safety requirements; stipulations regarding materials, structural design and construction (including safety); building and plumbing services; signs and outdoor display structures; guidelines for sustainability, asset and facility management, etc.	Relevant for any building being constructed or upgraded.
28.	The Occupational Safety, Health and Working Conditions Code, 2020	This code on occupational safety, health and working conditions applies to all establishments with 10 or more workers and includes building and construction workers. It is applicable to all infrastructure works supported under the program. The Occupational Safety, Health, and Working Conditions Code ("Code") is enacted to consolidate and amend the laws regulating the occupational safety, health, and working conditions of the persons employed in an establishment, and for the connected and incidental matters. The Code also lists benefits to the inter-state migrant workman such as the benefits of the insurance and provident fund benefits either in the native state or the state of employment, portability of benefits of the inter-state migrant worker working for building or other construction work out of the building and other construction cess fund in the destination State where such inter-state migrant worker is employed. It also mandates free health check-ups for	Relevant for all workers and construction activities.

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
		who attained the age of forty-five years for prescribed industries such as factories, mines, plantations, workers employed in hazardous process.	
International Regulations			
29.	International Health Regulations (IHR) 2005	The International Health Regulations (IHR) is an international legal instrument that is binding on 196 countries across the globe, including all the Member States of WHO. The aim of the IHR (2005) is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide.	Highly relevant. India is a signatory as WHO member state. Director National Centre of Disease Control is the National Focal Point of IHR (2005). Airport, Port and Land Border Health Units under Directorate International Health are mandated to implement the IHR provisions.
30.	Basel and Stockholm Convention	As a signatory, India is committed to meet its obligations related to the transportation of clinical wastes and emissions of dioxins and furans which result from incineration of hospital waste, as well as that of ensuring safe use and disposal of pesticides in vector control activities.	Relevant to all health programs
31.	Minamata Convention	As a signatory, India is committed to meet its obligations related to ensuring safe handling and storage of Mercury wastes in health facilities and common biomedical waste treatment facilities, replacing Mercury based products and technologies with non-Mercury based ones and ultimately phasing out of Mercury usage in health sector through effective time bound phase out plans.	Relevant to laboratories and health facilities under the program.

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
National/International Guidelines			
32.	CPCB Guidelines for CBWTFs (2003). CPCB Guidelines for BMW Incinerators (2003). Draft Guidelines for Bio-medical Waste Incinerator, 2017 Guidelines for Management of Healthcare Waste in Health Care Facilities as per Bio Medical Waste Management Rules, 2016 Guidelines for Bar Code System for Effective Management of Bio-Medical Waste Standards for treatment and disposal of Biomedical waste by Incineration Environmentally Sound Management of Mercury Waste Generated from Health Care Facilities.	Any activities from BMW temporary storage, transportation, and Disposal/treatment requires valid license. CPCB has also notified Revised Guidelines for Common Bio-medical Waste Treatment and Disposal Facilities which covers the location setting of the incinerator, operational and maintenance performance standards and monitoring. The State Pollution Control Board plays an important role in granting consent to establish and operate licence to the CTF operators, which are largely private sector players.	Relevant to all health care programs
33.	Guidelines for Handling, Treatment, and Disposal of Waste Generated during	To manage waste generated during diagnostics and treatment of COVID-19 suspected / confirmed patients	Relevant for ongoing and future pandemics and/or epidemics

S. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Project and key Findings
	Treatment/Diagnosis/ Quarantine of COVID-19 Patients (25 March 2020)		
34.	Mental Health in the times of COVID-19 Pandemic Guidance for General Medical and Specialized Mental Health Care Settings (April 2020)	For addressing concerns regarding 'normal' people being exposed to 'extraordinary situations' like anxiety, depression, effects on sleep, appetite disturbances as well as severe mental illness and substance misuse	Relevant particularly during disease outbreaks
35.	Novel Coronavirus Disease 2019 (COVID-19): Additional guidelines on rational use of Personal Protective Equipment (15 May 2020)	Guidelines for health care workers and others working in non-COVID hospitals and non-COVID treatment areas of a hospital which has a COVID block	Relevant during epidemics and/or pandemics

ANNEXURE – 3: LIST OF PARTICIPANTS IN MULTI-STAKEHOLDER CONSULTATION WORKSHOP

A multi-stakeholder workshop was conducted on 28th April 2022 at national level covering participants from all stakeholders' groups to seek their feedback and suggestions. The detailed list of participants is mentioned below.

MOHFW

- Mr. Govind Jaiswal, Director (Coordination, PH, IH, IC)

Implementing Agencies

- Dr. Samiran Panda, Additional Director General ICMR
- Dr. Lata Kapoor, Joint Director, NCDC
- Dr. R. Lakshminarayan, Deputy Director General (Administration), ICMR
- Dr. Dharmesh Kumar Lal, Scientist E, ICMR
- Mr. Rajiv Roy, Senior Financial Advisor, ICMR
- Dr. Tanu Anand, Scientist D, ICMR
- Dr. Aparna Mukherjee. Scientist E, ICMR
- Dr. Yogesh Kumar, CMO, DM Cell, MoHFW
- Dr. Avinash Sunthlia, MO, IH Division, MoHFW

Other Government Departments and Institutions

- Dr. K. Madan Gopal, Niti Aayog
- Dr. Dinesh Runiwal, Ministry of Environment, Forest and Climate Change (MoEFCC)
- Shri Cyriac K.J., National Disaster Management Agency (NDMA)
- Dr K.Sanjay, National Disaster Management Agency (NDMA)
- Dr Chinmoyee Das, National AIDS Control Organization (NACO)
- Ms. Roselyn, National AIDS Control Organization (NACO)
- Dr. Yogesh, Integrated Disease Surveillance Project, Madhya Pradesh
- Dr. Nyan Kikon, Integrated Disease Surveillance Project, Nagaland

UN Agencies and NGOs

- Dr Manjeet Singh Saluja, WHO
- Dr Nancepreet Kaur, Voluntary Health Association of India (VHAI)
- Dr. Anup Karan, Public Health Foundation of India (PHFI)
- Dr Vandana Bhatt

World Bank

- Dr. Suresh Kunhi Mohammed, Senior Health Specialist
- Dr. Dinesh M. Nair, Senior Health Specialist
- Dr. Gandham N.V. Ramana, Technical Advisor
- Dr. Hideki Higashi, Senior Health Economist
- Dr. Anupam Joshi, Senior Environmental Specialist
- Mr. Ranjan B Verma, Social Development Consultant
- Dr. Shubhendu Mudgal, Environmental Consultant
- Ms. Deepika Anand, Public Health Consultant
- Ms. Anagha Khot, Public Health Consultant

ANNEXURE – 5: DESIGNING, CONSTRUCTING, COMMISSIONING AND OPERATING A BSL3 LABORATORY

Stage-wise Guidance on Process and Best Practice

1.		**Pre-Planning**
1A.		Proposal for Establishing a BSL3 Lab
1B.		Constitute a National Committee for the BSL3 Project
1C.		Appoint a Biosafety Officer for the BSL3 Project
1D.		Framing TORs for EIA and Biosafety/Biosecurity Assessments
1E.		Contracting a Qualified Agency for conducting the EIA and preparing the EMP
2.		**Planning and Design Stage**
2A.		Construction Site Selection and Risk Assessment of the Area
2B.		Preparing workplan schedule and timeline
2C.		Outlining Site Security Arrangements
2D.		Finalizing Equipment List
2E.		Hiring Design Consultants and Preparing Final Drawings
2F.		Developing Bidding Documents with integrated EMP and LMP
2G.		Finalizing the choice of construction material and technology as per best practices
2H.		Finalize General and Specific Training(s) for Staff/Personnel and Prepare Training Manuals
3.		**Construction**
3A.		Appointing Quality Assurance Engineers
3B.		Appointing Environmental Officer for implementing the EMP/LMP requirements
3C.		Construction (Waste) Management as per Best Practice and EMP
3D.		Testing of all Building Systems (electrical, plumbing, airflow, drainage, waste management, biomedical waste segregation, storage, disinfection/treatment and disposal etc.) and Building Completion Certification
3E.		Building Energy Audit and Green Building Certification (optional but recommended)
4.		**Commissioning**
4A.		Installation and Validation of Equipment
4B.		Developing and Testing Emergency Protocols and Contingency Plans
4C.		Installing and Checking Primary/Secondary Barriers and Biosafety/Biosecurity Measures
4D.		Printing and Displaying Emergency Measures, Workflow Protocols, SOPs

4E.		Inspection of Each Safety/Security System and Process by an Expert Committee and Certification
4F.		Awarding Maintenance Contracts
4G.		Handing over the Facility
5.		**Operation**
5A.		Prior to Commencing Actual Operations, Drills for Each Aspect of Normal and Emergency Operation (including Pilot Testing of SOPs)
5B.		Monitoring of Health of Staff/Personnel
5C.		Documentation and Logbooks for Daily Operations/Research
5D.		SOPs and Protocols for safe disposal of biomedical wastes as per national/state/local regulatory requirements and International Best Practices
5E.		Application of biosecurity and biosafety measures (including disinfection protocols) for use of PPE/pathogens/consumables and other requirements

ADDITIONAL POINTS AND CHECKLIST (should be periodically updated)

S. No.	Criteria/Question	Yes	No	Remarks
1.	Specifying the need for engineering controls			
2.	Testing laboratory SOPs to find out where biosafety and biosecurity breach can happen			
3.	unidirectional air flow using room pressure gradients of negative pressure			
4.	exhaust air being HEPA (high efficiency particulate air) filtered			
5.	procedures for disposal of biomedical waste			
6.	Measures of waste disposal and effluent decontamination should be followed as per the guidelines of biosafety of containment laboratories.			
7.	protective clothing (outer scrubs/apron removal)			
8.	Disinfection Soap and Shower Room			
9.	Solid biomedical waste generated from laboratories which includes gloves, soiled gauze pads, cotton, *etc*. should be soaked in 2.5 per cent solution of sodium hypochlorite and 0.25N NaOH for 16 h or more			
10.	Also if the laboratory has an autoclave facility, the biohazardous laboratory waste should be autoclaved at 121°C at 15 psi pressure for 20 min for complete decontamination; it can then be disposed off in accordance with the State/local pollution control bodies requirements.			
11.	Toxic liquid effluents generated from the BSL-3 laboratories should be decontaminated with a 1:1 (v/v) mixture of 2.5 per cent sodium hypochlorite and 0.25N NaOH, mixed well and kept for 8 h.			
12.	Equipment and Work Surface disinfection			
13.	All the contaminated glasswares should be soaked in a mixture of 2.5 per cent sodium hypochlorite and 0.25N NaOH solution for 8 h. Alternatively, glasswares can also be soaked in 5 per cent sodium hypochlorite solution for 8 h.			
14.	*BSL-3 laboratory with anteroom or workroom as an access zone*			

S. No.	Criteria/Question	Yes	No	Remarks
15.	biohazard plastic bags for waste packing when waste cannot be disinfected before transportation			
16.	Isolation room with medical facilities, oxygen cylinders and ventilators			
17.	HEPA filtration of exhaust air,			
18.	effluent decontamination or chemical kill tank			
19.	entry and exit protocols for the laboratory personnel			
20.	positive air pressure respirators			
21.	Biosafety cabinets (BSC) and decontamination autoclaves are essential part of such a containment facility			
22.	Exhaust ventilation should be provided above the exterior door of the autoclave to remove the heat and steam when the door is opened			
23.	rodent proofing of laboratory and installing air curtains particularly in the laboratories which would be dealing with arthropod-borne diseases, are essential features			
24.	Will there be Animal holding space ?			
25.	individual ventilated cages (IVCs) for animals to prevent aerosols generated by animal care from entering the general room environment			
26.	Maintaining sound, vibrations, temperature and humidity, and air ventilation rates			
27.	the outlets or exit air ducts have to be provided with double washable pre-filter to block skin flaxes, feather and hair which quickly block the HEPA filters			
28.	specific training in handling pathogenic and potentially lethal agents			

Imp. As per the guidelines of the Ministry of Environment & Forests, India, various animal pathogens and plant pests are classified and defined in G.S.R. 1037(E) conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986)