THE WORLD BANK

ENVIRONMENTAL AND SOCIAL SYSTEMS ASSESSMENT (ESSA)

FOR THE

India: Program Towards Elimination of Tuberculosis (P167523)

-draft-

DECEMBER 2018

This document is being made publicly available so that views of interested members of the broader public may also be considered before all Program decisions are made final.

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List of Acronyms

ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immuno- Deficiency Syndrome
BMGF	Bill and Melinda Gates Foundation
BMW	Bio Medical Waste
BMWM	Bio medical Waste Management
C&DST	Culture and Drug Susceptibility Testing
CAAA	Controller of Aid, Accounts, and Audit.
CAG	Comptroller and Auditor General
CBMWTF	Central Biomedical Waste Treatment Facility
CIEs	Central Level Internal Evaluations
CMSS	Central Medical Services Society
CPF	Country Partnership Framework
CPCB	Central Pollution Control Board
CPP	Central Procurement Portal
CTD	Central TB Division
CTF	Common Treatment Facility
CVC	Central Vigilance Commission
DALY	Disability-Adjusted Life Year
DBT	Direct Benefit Transfer
DDG	Deputy Director-General
DLI	Disbursement-Linked Indicator
DMC	Designated Microscopy Centres
DLR	Disbursement-Linked Result
DOHFW	Departments of Health and Family Welfare
DOTS	Directly Observed Treatment Therapy
DR-TB	Drug-Resistant TB
EMP	Environment Management Plan
ESSA	Environmental and Social Systems Assessment
FM	Financial Management
FMR	Financial Monitoring Report
FPIC	Free and Prior Informed Consultation
FSA	Fiduciary System Assessment
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GFR	General Financial Rules
GoI	Government of India
GOI	Government of India
GPS	Global Positioning System
GST	Goods and Services Tax
HDI	Human Development Index
HIV	Human Immune- Deficiency Virus
IBRD	International Bank of Reconstruction and Development

IC	Infection Control
ICT	Information and Communications Technology
IDA	International Development Association
IEC	Information, Education, and Communication
IFSA	Integrated Fiduciary System Assessment
IMEP	Infection Management and Environmental Plan Framework
IPHS	Indian Public Health Standards
INR	Indian National Rupee
INT	Institutional Integrity
IRL	Intermediate Reference Laboratory
IRR	Internal Rate of Return
ISM	Implementation Support Mission
IT	Information Technology
IVA	Independent Verification Agency
JEET	Journey of Enhancing Targeted Interventions
JICA	Japan International Cooperation Agency
JMM	Joint Monitoring Mission
MDR-TB	Multidrug Resistant Tb
MoHFW	Ministry of Health and Family Welfare
MoEFCC	Ministry of Environment and Climate Change
NCD	Noncommunicable Diseases
NGO	Non-Governmental Organization
NHM	National Health Mission
NPV	Net Present Value
NPY	Nikshay Poshan Yojana
NRL	National Reference Laboratory
NSP	National Strategic Plan
OPRC	Operational Procurement Review Committee
PAD	Project Appraisal Document
PAP	Program Action Plan
PDO	Program Development Objective
PFMS	Public Financial Management System
PforR	Program for Results
PIP	Program Implementation Plan
PP	Public Private
PPE	Private Provider Engagement
PPM	Public-Private Mix
PTETB	Program Towards Elimination of TB
PWD	Public Works Department
RNTCP	Revised National TB Control Program
RoP	Record of Proceedings
SC	Scheduled Castes
SPCB	State Pollution Control Boards
ST	Scheduled Tribes
TA	Technical Assistance

TB	Tuberculosis
TSU	Technical Support Unit
WHO	World Health Organization
XDR-TB	Extensively drug-resistant TB

EXECUTIVE SUMMARY

Environmental and Social Systems Assessment (ESSA)

1.   As per World Bank policy and the directive on Program for Results (PforR) financing, an ESSA was carried out to assess the adequacy of environmental and social systems at the national and focused state level in the context of the Program boundary; promote environmental and social sustainability in the Program design; avoid, minimize, or mitigate adverse impacts; and promote informed decision-making related to the PforR's environmental and social impacts. The specific objectives of the ESSA included the following: (a) identify potential environmental and social benefits, risks, and impacts applicable to the Program interventions; (b) review the policy and legal framework related to management of environmental and social impacts of the Program interventions; (c) assess institutional capacity for environmental and social management systems within the Program system; (d) assess Program system performance with respect to the core principles of the PforR instrument and identify gaps, if any; and (e) describe actions to be taken to fill the gaps that will be used as inputs to the Program Action Plan (PAP).

ESSA Methodology

2.   The ESSA primarily relied on desk reviews of existing information and data sources, complemented by primary data collection, assessment through consultations, interviews, discussions with key stakeholders and select field visits to high risk settings such as drug resistant TB (DR-TB); anti-retroviral centres (ART centres), central bio medical waste treatment facilities (CBMWTFs), and TB containment laboratories including private laboratories currently engaged under the RNTCP. Additionally, the ESSA included consultations with experts, government officials and community groups (including tribal population) to observe and capture opinions, anecdotal evidences, functional knowledge, and concerns. The discussions and visits that were conducted by staff who were managing and working within these facilities created the basis for the development of this ESSA. The desk review included all available guidance documents provided by CTD, and past reports from bank funded engagements. The primary data collection and assessment involves consultations, discussions and interviews with CTD officials in charge of environment and social aspects and consultations with various sector experts, State TB officers, and development partners during the Program preparation workshop in Delhi, Lucknow, Mumbai, Pune, Hyderabad, and Udaipur, and NGOs/academia currently engaged in the RNTCP Program. A free and prior informed consultation (FPIC) with tribal communities was also conducted in tribal blocks of Pune and Udaipur districts belonging to Schedule-V areas under the constitution of India.

Applicability of the ESSA Core Principles

Core Principle 1: Applicable
Environmental and social management procedures and processes are designed to: (a) promote environmental and social sustainability in the Program design; (b) avoid, minimize, or mitigate against adverse impacts; and (c) promote informed decision-making relating to a Program's environmental and social effects
Summary Findings:
This is determined as relevant and applicable. India has an adequate legal framework for

environmental, health and safety, and waste management (including hospital, general, plastics and liquid wastes) backed by a set of comprehensive laws, regulations, technical guidelines and standards, which apply nationwide. Over the decades, it has gradually evolved into a comprehensive system that is generally consistent with the PforR. However, capacity is required to be strengthened in order to implement these guidelines/ regulations effectively.

Certain interventions under the Program would require mitigation actions and sustainable approaches to better manage Program's environmental effects. These include, among others (i) Strengthen environment health and safety monitoring capacity in CTD and States on BMW, IC, and AIC (ii) Support accreditation criteria for C&DST labs to include enhanced EHS and biosafety criteria (iii) Update BMW trainings to include management of all wastes including e-waste and hazardous wastes, to all staff engaged under RNTCP (iv) Ensure emergency response mechanisms such as fire detection, and accident reporting and response mechanisms are functional at all HCFs and Labs (v) AIC and IC capacity is strengthened at facility level through the public health system (vi) develop guidance for State and District TB officers to understand and implement EHS aspects as part of national guidelines/ regulations. Adverse impacts associated limited physical works/renovations supported under the PforR include dust, noise, and solid waste generation, but these are expected to be minor in nature and limited to the healthcare facility, and easily mitigated.

The PforR will ensure the environmental and social sustainability under the context of government's investment in the NSP, which is aligned with the global End TB Strategy and Sustainable Development Goal targets.

Core Principle 2: Not Applicable   *Environmental and social management procedures and processes are designed to avoid, minimize, or mitigate adverse impacts on natural habitats and physical cultural resources resulting from the Program.*
Summary Findings: This is determined as not applicable. Interventions proposed under the Program would largely take place within existing facilities and not impact natural habitats and physical cultural resources.
Core Principle 3: Applicable   *Environmental and social management procedures and processes are designed to protect public and worker safety against the potential risks associated with: (i) construction and/or operations of facilities or other operational practices under the Program; (ii) exposure to toxic chemicals, hazardous wastes, and other dangerous materials under the Program; and, (iii) reconstruction or rehabilitation of infrastructure located in areas prone to natural hazard.*
Summary Findings: TB diagnosis and treatment exposes healthcare and lab workers to risks associated with exposure to TB, hazardous materials, infections, as well biosafety, and would require mitigations These include, among others: (i) Improving occupational health and safety practices at healthcare facilities through infrastructure design, AIC, infection control, protocols for addressing accidental spills; (ii) Providing protective clothing and personal safety equipment, as required; (iii) Ensuring safe storage, segregation, transport and disposal of biomedical and hazardous wastes; (iv) good practices with regards to cleanliness, hygiene and general waste management; (v) worker and public health and safety focusing on emergency response; fire safety (vi) maintenance of critical lab safety equipment (vii) training for workers in sputum collection transport on biosafety and use of spill kits and (viii)

having qualified biomedical engineers and technical staff available to service, maintain and conduct safety testing on critical lab equipment in the IRLs.
Core Principle 4: Not Applicable   *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.*
Summary Findings: The Program does not intend to do any land acquisition or resettlement, as it does not support any major construction and is limited to minor renovation and repairs within the existing footprint of the health facilities and laboratories. However, in order to rule out any adverse social effects and exclude activities/ sub-activities leading to land acquisition and/ or resettlement, screening will be conducted in facilities where any repair, renovation and/or expansion is proposed under the Program by the healthcare facility in charge, under the guidance from DTO. The resettlement which is to be avoided includes involuntary displacement of people who are illegally occupying areas within the grounds of the health facilities.
Core Principle 5: Applicable   *Due consideration is given to cultural appropriateness of, and equitable access to, Program benefits giving special attention to rights and interests of Indigenous Peoples and to the needs or concerns of vulnerable groups.*
Summary Findings: The program provides for special incentives in the tribal and difficult to reach areas for transportation to patients and sputum sample transportation to enhance access. However, in recent years some of these areas have been reporting a high incidence of not only drug sensitive but also drug resistant TB cases. The NSP 2017-25 also recognizes that there has been limited progress in the form of a special action plan for tribal populations and requires enhancing access and coverage not only through screening and treatment mechanisms, but also by adopting culturally appropriate ACSM and communication activities. The RNTCP tribal action plan requires to be updated to address NSP concerns and the changing context.
Core Principle 6: Not Applicable   Avoid exacerbating social conflict, especially in fragile states, post-conflict areas, or areas subject to territorial disputes.
Summary Findings: While there are some conflict-affected areas including the presence of left wing extremist (LWE) areas in the nine Program focus states, it is important to note that Program interventions do not exacerbate any social conflicts as it is trying to improve upon the overall health of the residents and attempting to reach out to all vulnerable pockets for TB case finding and linking them to treatment. Exclusion of any groups in terms of caste, religion, and/ or geography by the program activities is not expected.

Key Findings of Institutional Assessment on Environment and Social Aspects

3.   CTD has already implemented three Bank funded projects for Tuberculosis control and management. While these projects are now closed, the institutional setup is still functional and active, and the environment management framework for bio medical waste management and capacity building remains relevant. Over the years, BMW has seen considerable improvement at all levels of healthcare

facilities. This is indicative of good borrower capacity to deal with the environmental and social aspects of the proposed Program. The RNTCP has guidelines for most of its activities including: (i) engagement of the private sector, (ii) SOP for labs and biosafety guidelines (iii) Treatment of DR-TB, and (iv) AIC guidelines, (v) reaching out to tribal and difficult areas, (vi) Advocacy communication and social mobilization (ACSM), and (vii) social and behavior change communication (SBCC). However, they should be updated with the current context and the agenda set forth in the NSP 2017-25. This includes institutional reorganizing, building capacity at all levels, and updating 'Partnership guidelines' and 'Technical and Operational Guidelines for TB Control in India'. It also includes monitoring mechanisms and tools such as Central Level Internal Evaluation (CIE) and State Level Internal Evaluation (SIE) specific to the areas mentioned above to address the issues raised in the NSP 2017-25 and the guidance suggested therein. In addition, the key institutional gaps in CTD, and the State TB Cell, is the lack of dedicated and skilled manpower to plan and implement partnerships, advocacy, communication and social mobilization (ACSM) and psycho social support (PSS) activities in a coherent manner. There is also a lack of biomedical engineers which is critical to sustaining C/DST laboratory services, and uninterrupted service. According to national guidelines, Airborne Infection Control (AIC) Committees are proposed to be formed at State, District and Health care facility level, committees to plan and manage this aspect were not always fully operational, and capacity needs to be institutionalized in the RNTCP structure. This will need strengthening through the PforR Program. Biomedical waste management is being addressed through collection transport and disposal with a private agency and is adequately managed. There are however, opportunities for continuous training of staff on management of BMW and all other types of wastes.

Legal and Regulatory Framework

4.   The existing legislative framework is adequate to ensure social sustainability and the interest of marginalized and vulnerable populations including the SC and ST population, but require strengthening institutional capacity to comply. It ensures: (a) protection of the interest of SC and ST population, (b) non-discrimination based on religion, race, caste, and gender (c) transparency with right to information, and (d) the right to fair compensation in case of land acquisition.

5.   The provisions of the existing environmental legal and regulatory framework are adequate but require enabling institutional and technical capacity for compliance. While the provisions of the Biomedical Waste Management & Handling) Rules, (as amended on March 2018), are being implemented, provisions of other relevant environmental acts such as, hazardous, solid, plastic and e-waste Rules applicable to RNTCP require additional capacity building efforts. Efforts are also required to improve the monitoring of the management of different kinds of wastes, including liquid waste and effluents. The existing National and RNTCP Program guidelines are adequate for addressing the following: (i) patient and worker safety, (ii) ensuring biosafety, (iii) air borne infection control, (iv) packaging and transport of infectious samples for DST and (v) Screening of TB workers.

Assessment of Environmental and Social Management Systems

6.   Consistent with the requirements of the Bank PforR Policy, the proposed PforR operation does not support activities that pose high social or environmental risks such as large civil works, effluent treatment plants or disposal facilities. The activities to be supported by the Program are likely to provide significant

environment and social benefits, such as improved waste management and handling, health and safety provisions for workers engaged in the RNTCP and higher standards for infection control. The applicable environmental and social management systems are generally adequate to address underlying environmental and social risks, with noteworthy strengths of having regulations and guidelines in place for bio-medical and other waste management, and guidelines for worker safety, biosafety and infection control. The ESSA did uncover gaps in implementation, monitoring and supervision in some areas, as summarized below.

(i)   No dedicated capacity to manage EHS issues within the Program. At central level EHS capacity has been imbedded within the CTD, but at state level BMW, IC, AIC is being managed by different committees, technical specialists, and coordination needs to be strengthened at healthcare facility level.

(ii)   Evaluation and accreditation criteria for private sector C&DST labs (under NGO-PP scheme) could be strengthened further to emphasize EHS and biosafety criteria consistent with national regulations

(iii)   Need for a health advisory, biosafety training for workers involved in sputum collection and transport

(iv)   Update BMW trainings to include most relevant rules and regulations, e-waste and hazardous wastes, liquid waste and implement a training Program to all staff engaged under RNTCP.

(v)   Ensure emergency response mechanisms such as fire detection, and accident reporting and response mechanisms are functional at all IRLs.

(vi)   Need technical expertise (biomedical engineers) for maintenance and safety testing of lab equipment such as biosafety cabinets, centrifuge and air handling units.

(vii)   Servicing and decommissioning of critical lab safety equipment needs standardization to ensure lab workers always have access to all necessary equipment in good operational condition

(viii) AIC capacity needs to be strengthened at the facility level, and plans are prepared and approved according to the National Guidelines. Need for better institutional coordination with the public works department that usually undertakes construction work.

7.   The Program does not intend to do any land acquisition or resettlement, as it does not support any major construction and is limited to minor renovation and repairs within the existing footprint of the health facilities and laboratories. Screening will be conducted to rule out any adverse environmental and social impacts where any renovations and/ or expansion is planned under the program in the health facility/ laboratory or associated infrastructure. The resettlement which is to be avoided includes involuntary displacement of people who are illegally occupying areas within the grounds of the health facilities. Both health facility in-charges as well as DTOs will be trained by the social safeguard officer at the State TB Cell. The focus states account for 51.5 million people from the tribal population (49 percent of India's tribal

population) and are both scheduled V and Scheduled VI areas, as defined under the Constitution of India with special legislative and judicial provision including customary rights in scheduled-VI areas. The NSP 2017-25 also recognizes that there has been limited progress in the form of a special action plan for tribal populations. It is even more important to strengthen the TB control activities in these difficult areas, given that some of these areas have been reporting a high incidence of not only drug sensitive but also drug resistant TB cases. In order to extend the incentives designed for tribal population and for tribal areas, CTD recommends following designated tribal areas (tribal districts and blocks and scheduled areas) as per the Ministry of Tribal Affairs. However, field visits in tribal districts suggests gaps in understanding and extending the incentives in tribal areas. It requires CTD to clearly spell out the mechanism for identifying the tribal areas as part of the Program guidelines and strengthens data collection and monitoring of tribal population transport reimbursement and other incentives. In addition, the following related social issues were identified: (a) access to TB services in hilly and remote areas, and to some of the key population, (b) knowledge and awareness about TB especially among poor and marginalized population, (c) stigma reduction, (d) weak community support system, and (e) lack of nutritional care and support for TB patients. While the NSP 2017-2025 also highlights most of these issues and provides overall policy guidance, the issue remains in translating them into effective implementation. And hence, the program has moderate social risk.

8.   Over the last three years the central level internal evaluations (CIEs) and Joint Monitoring Mission (JMM) in 2015, has observed weak engagement with NGOs to carry out various social mobilization activities in many states and lack of ACSM activities. The ACSM implementation require further analysis and introspection and updating the RNTCP partnership guidelines to this effect, and further monitoring and follow up. Additionally, a more coherent Social and Behavior Change Communication (SBCC) strategy required to be prepared, updated and adopted as the earlier communication strategy is outdated and currently not being followed. In order to strengthen the activities for tribal people, CTD need to update the RNTCP tribal action plan with changing context. As the Program plans to engage with private providers for TB notifications and link the patients to nutritional support, it will require additional focus on communication and mobilization of people to learn about the provisions under the Program.

9.   **Gender:** Women and girls make up nearly one million of the estimated 2.8 million TB cases in India each year; it is the fifth leading cause of death among women in the country, accounting for nearly 5 percent of fatalities in women aged 30–69. Although more men are affected by TB, women experience the disease differently and also experience the impact of stigma disproportionately. The rapid assessment of gender and TB in India reveals the differential aspects of TB among women including the fact that women may be diagnosed late or not diagnosed at all due to added risk of socio-cultural barriers. This includes women delaying seeking care for TB ailments because of the high burden of household work combined with the deprivation of health awareness, mobility, access to resources and decision-making powers. These factors considerably influence TB case detection and adherence to treatment. In addition, with more than half of all women in the India being anemic and one in five underweight, risks for contracting TB increase. To address this, a technical expert group is being constituted by CTD to develop and finalize the collaborative framework for TB and Women in India, including the development of Programmatic interventions to address the socio-cultural barriers. The key Program action required is the development and adoption of framework for TB among women and is further detailed under the proposed PAP actions.

10.   **Citizen Engagement:** The CTD aims to enhance Community Engagement for a people centered and community led TB Response under the RNTCP. This is proposed to be achieved by creating TB Forums at State and District level for working collaboratively with and through communities to address issues affecting their well-being, including influencing systems and serving as catalysts for changing polices, Programs and practices that are more patient sensitive. The scope of community engagement is envisaged as: (a) providing patient support services through community participation - including awareness creation and stigma reduction, screening for TB and TB-related morbidity, referring for diagnosis of TB and related diseases, providing treatment adherence support, linking social support to patients, and helping address equity and non-discrimination issues; and (b) Community Empowerment activities for sustainable community engagement by informing, empowering and institutionalizing, and building an accountability platform by creating a mechanism of feedback on TB care services to the providers at all levels using community monitoring tools. The scope defined for community engagement is much wider than the terms of reference developed for the TB forums at State and District level, which lacks in community empowerment and accountability aspect. The key Program action required are: (a) building an accountability mechanism by modifying and adding to their composition, roles and responsibilities, and terms of reference of the Central, State and District Forums; (b) creating TB forums at the State and district level, as per the expanded scope with an improved accountability mechanism. And is embedded as the Intermediate Result indicator under the Intermediate Results Area #4 of the Program on Strengthening RNTCP Institutional Capacity and Information Systems. This will be measured through the following: (a) Government approval to the revised Terms of Reference of State and District TB Forum with expanded scope with respect to an accountability mechanism, and (b) the number of state and districts conducting Annual TB Forum meetings and submitting minutes to STC (by districts) and CTD (by states). The Program also will also introduce an incentive mechanism through small disbursements every year for incremental increases in a number of states and districts conducting Annual TB Forum meeting.

Conclusion and Recommendations

11.   **The ESSA concludes that the Program has a moderate environmental and social risk.** There is no land acquisition and/ or resettlement anticipated under the Program. Based on the assessment of the environmental and social management system applicable to the proposed PforR, it is concluded that the Government of India (GoI) has established a comprehensive set of environmental and social management systems. Such systems are in line with the core principles and key planning elements as defined in the Bank Policy for PforR. The overall potential environmental and social risks for this PforR, is rated as moderate and can be effectively mitigated within the existing environmental and social management systems.

12.   The key social risk emerges from capacity gaps to deal with tribal issues, ACSM, communication, and the Program being gender responsive. In addition, the key environmental and social risk emerges from the Program not having adequate and dedicated human resources for addressing environment and social risks. The key environmental risks also emerge from (i) lack of dedicated capacity at State level to plan and monitor BMW, IC and AIC activities (ii) shortage of dedicated biomedical engineers to support lab safety (iii) Management of infection control associated with TB related diagnostic and treatment services and (iv) management of the incremental increase in biomedical and other wastes generated through Program supported activities. There are no high impact activities associated with the PforR boundaries such

construction of large buildings, central bio-medical waste treatment facilities, and effluent treatment plants (these activities are not eligible for including under the Program).

Recommendations for Program Action

13.   The ESSA proposes the following recommendations, which are Inputs to the PAP:

Action 1: Develop Protocols/SOP for servicing and decommissioning key lab safety equipment.

Action 2: Update RNTCP tribal action plan to strengthen outreach in tribal and hilly areas, ACSM and SBCC.

Action 3: Central, State and District TB Forum strengthened for improving the accountability mechanism

  i. Building accountability mechanism by the modifying/ adding to their composition, roles and responsibilities, and terms of reference of the Central, State and District Forums.
  ii. State and district creating TB forums as per the expanded scope with improving accountability mechanism.

Action 4: CTD Strengthens Data Collection and Monitoring of Tribal Population Transport Reimbursement, and strengthen DBT mechanism. Annual CTD report to capture coverage and trends in DBT for tribal populations.

Action 5: Development and adoption of framework for TB among gender. This will include:

  i.   Analysis of context specific, socio-cultural norms and overlapping health concerns that are likely to amplify the incidence of TB amongst women in participating states
  ii. Specific Programmatic interventions towards addressing socio-cultural barriers
  iii. Include gender specific data for TB monitoring.

Disclosure and Consultations

14.   This draft ESSA is being disclosed in-country and on the World Bank's external website, to serve as the basis for discussion and receipt of formal comments. A multi-stakeholder workshop on this ESSA and the PforR was held in Delhi in November 2018. Following incorporation of the feedback received from the other sources, the revised ESSA will be re-disclosed in-country and on the World Bank's external website, prior to Board consideration.

15.   The ESSA preparation process involved extensive stakeholder consultations. During ESSA preparation, World Bank environmental and social specialists undertook recurrent meetings and consultations with different stakeholders, experts, technical specialists including relevant government institutions at the national level in CTD, State, District TB officers in Mumbai, Pune, Udaipur, Lucknow and Hyderabad. Also, free and prior informed consultation (FPIC) was conducted in tribal areas of Pune and Udaipur districts.

16.   Section V provides more detailed descriptions of the scope of these recommendations and provides indicative costs and timetables for implementation.   If these inputs to the PAP are successfully implemented, the overall environmental and social management system for the Program will have been considerably strengthened and set on a more sustainable path. This is also true for RNTCP Program to be implemented throughout India, since the improvements in environmental and social management systems and capacity are likely to extend beyond the life of the Program.

I. INTRODUCTION

A. Environmental and Social Systems Assessment: Purpose and Objectives

1.   This Environmental and Social Systems Assessment (ESSA) has been prepared by a World Bank ESSA Team for the proposed Program Towards Elimination of Tuberculosis, 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 (PforR) Financing Policy, PforRs rely on country-level systems for the management of environmental and social effects. The PforR Policy requires that the Bank conduct a comprehensive ESSA to assess the degree to which the relevant PforR Program's systems promote environmental and social sustainability. Additionally, the ESSA is in place to ensure that effective measures are in place to identify, avoid, minimize, or mitigate adverse environmental, health, safety, and social impacts. Through the ESSA process, the Bank ESSA Team develops recommendations to enhance environmental and social management within the Program, which are both included in the overall management action plan.

2.   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.

3.   This ESSA assesses or considers the extent to which the Program's environmental and social management systems are adequate for and consistent with six core environmental and social principles (hereafter, Core Principles), as may be applicable or relevant under PforR circumstances. The Core Principles are listed below and further defined through corresponding Key Planning Elements that are included under each Core Principle in Section III.

(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.

4.   An additional purpose of this ESSA is to inform decision making by the relevant authorities in the borrower country and to aid the Bank's internal review and decision process associated with the Program Towards Elimination of TB (PTETB). 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 counterparts in CTD and States and will become legally binding agreements under the conditions of the new loan.

B. ESSA Methodology

5.   The proposed Program Towards Elimination of TB (PTETB) is a well-defined subset of the government National Strategic Plan (2017-2015) of the Revised National Tuberculosis Control program. The PTETB focuses (i) scaling up private sector engagement; (ii) rolling out TB patient management and support interventions; (iii) strengthening diagnostics and management of DR-TB; and (iv) strengthening program management capacity and information systems. The interventions planned are expected to result in environmental and social benefits. Adverse effects that are sensitive, diverse and unprecedented on the environment and people are not foreseen. However, planned efforts are essential to ensure that the Program interventions will result in sustainable social and environmental benefits. As required by the Bank Policy on Program-for Results Financing, an Environmental and Social Systems Assessment (ESSA) was conducted during Program preparation to assess the adequacy of the environmental and social systems of Government of India, and the Revised National Tuberculosis Control Program and identify specific strengthening measures.

6.   The focus of this assessment has been on understanding the social and environmental risks, benefits, impacts and opportunities of the NSP 2017-2025. The study looks at the social and environmental checks and balances that exist in the country and institutional level rules, policies and guidelines, map the risks and gaps, and suggest the possibilities for implementation, and institutional strengthening. It reviews the appropriateness of existing and planned infrastructure, equipment, technologies and institutional mechanisms for planning and monitoring for environment health and safety, and compliance to existing rules and regulations.

7.   The following actions were undertaken as part of the assessment from 14 October to 5 November, 2018: (a) a comprehensive review of government policies, legal frameworks, Program documents, national guidelines for RNTCP and other assessments of India's environmental and social management systems (Refer to Annex 2 for more details) (b) interviews and consultations were conducted with relevant experts and officials from CTD, State and District TB officers, Technical staff in IRLs, DR-TB centres, DMCs and District Hospitals (a summary of the interviews and consultations is attached in Annex 3, the task team had detailed questionnaire-based discussions with officials who manage the programs in the States.); (c) district level consultations with tribal populations, NGOs, and District TB officers, community members and beneficiaries from Pune and Udaipur.

8.   The task team also conducted on-ground reconnaissance of various health Care facilities, designated microscopy centres, intermediate reference laboratories, ART centres, DR-TB centres at Pune, Mumbai, Udaipur and Hyderabad to understand (i) the activities involved, (ii) institutional mechanisms, and (iii) on-site risks related to implementation and operations in TB diagnostics and treatment. Central Bio-Medical Waste Treatment Facilities were also visited in Lucknow and in Virudhanagar, Tamil Nadu.

	Site Visits Undertaken	Officials Met
1	**Hyderabad – STDC**, State Reference Lab, EQA Lab, and BPHRC (Private C&DST Lab under NGO PP Scheme)	▪ Dr. Sumalatha (State Epidemiologist) ▪ Mr. Srikant (IRL, Microbiologist) ▪ Mr. Anil Kumar (Technical Officer) ▪ Dr. Sneha Shukla (WHO- Consultant), IRL Lab staffs
2.	Lucknow, UP (Discussion with State TB officer and Visit to SMS Watergrace, Mediwaste management CBWTF)	▪ Dr. Santosh Gupta, State TB officer

3.	**Udaipur (Rajasthan):**
	
	  i. DMC lab, CBNAAT lab in District TB Clinic (inside Maharana Bhupal Hospital campus) Haathipole, Udaipur
	  ii. RNT- Medical college- DMC Lab, MDRTB ward,
	  iii. BMWM, BADI, Udaipur
	  iv. RNTCP-laboratory, Gitanjali Medical College & Hospital, Udaipur
	  v. Jhadol PHC in tribal area, SWACH NGO training centre at Jhadol block
		▪ Dr. Dinesh Kothari (DTO)
		▪ Dr. D. S. Rao (S.M.O)
		▪ Dr. Sanjay Sinha (WHO- consultant)
		▪ Mr. B.K. Gupta(NGO – ALERT, and member Child Welfare Committee)
		▪ Mr. Naresh Paneri and Mr. Tyag Narayan (NGO – SWACH)
		▪ Dr. Manoj Arya (RNT medical college)
		▪ Laboratory technicians
		▪ Dr.S.K. Lohadiya, Head, Dept. of TB & respiratory disease, Geetanjali Medical College & Hospital
		▪ All STS and STLS of the district
		▪ Free and prior informed consultation (FPIC) with tribal community in Jhadol block, including discussion with MO, ANM and other outreach staffs of Jhadol PHC and tribal TB patients; discussion with NGO (SWACH) extension workers placed in each trbal village/ panchayat of the block working as TB extension worker (called Swach Mitra).

4.	**Pune:**
	
	  i. IRL lab
	  ii. DMC lab
	  iii. TB ward and Rural health centre
	  iv. Dimphe Khurd Tribal PHC, Awegaon
		▪ Dr. Padmaja Jogeshwar, STO
		▪ Dr. P.L. Mane, AD HS; Dr. Sanjay Darade DTO
		▪ Dr. Sandeep Bharaswadkar WHO consultant,
		▪ Dr. Vaibhav Saha WHO consultant
		▪ Ms. Shilpa Balyam C&DST STDC (IRL- microbiologist)
		▪ Dr. Balaji Lakade Medical Officer PHC
		▪ Dr. Udawant & Dr. Sayali
		▪ TB ward and other lab staff
		▪ MO, ANM, STS, STLS, other PHC staffs including four ASHAs associated with PHC and working in tribal villages;
		▪ FPIC with tribal community and patients

5.	**Mumbai:**
	
	  i. Pt. MM Shatabdi Hospital, Govandi
	  ii. CBNAAT lab
	  iii. TB diagnostic centre (DR TB centre)
	  iv. Microbiology Lab, Sir JJ hospital
	  v. 2nd October Health post- Bhoiwada, Parel
	  vi. TB Hospital- SEWRI, (CBNAAT and Biochemistry Lab)
		▪ Dr. Shalini Bhagat Dy Director TISS;
		▪ Ms. Shweta Bajaj Sr Program Manager, Saksham TISS
		▪ Dr. Narender G. Sutar DTO, CBNAAT lab
		▪ Dr. Dhayagude BMW incharge
		▪ Dr. Shubhangi Mankar SMO DRTB
		▪ Dr. Ameeta A. Joshi, MD (Microbiologoy) SJJ hospital
		▪ Dr. Ajay Dhawale, DTO
		▪ Dr. Lalitkumar D Anande, Medical Superitendent GTB hospital, Sewree, Mumbai
		▪ Dr. Amit Karad, WHO consultant

9.   The ESSA review process seeks to describe and assess the systems for managing environmental and social effects of a proposed Program. The World Bank drew on a wide range of data, sources, and inputs during the ESSA review process, including the following actions:

(a) **Assessment of the environmental and social effects of the Program**: The ESSA Team assessed the potential for the Program to cause adverse environmental and social effects, either due to its design and Program components or due to gaps in Program systems. Such risks were assessed at various levels to be moderate.

(b) **Comprehensive desk review of policies, legal framework, Program documents, and other assessments of environmental and social management systems**: The review examined the set of national policy and legal requirements related to environment and social management, waste management, infection control, biosafety, occupational health and safety management, and construction of small civil works. The review also examined technical and safeguards documents from previous World Bank projects and Programs including the Second National Tuberculosis Control Project (2006-11), and The Accelerating Universal Access to Early and Effective Tuberculosis Care Project, which ran from (2014-2018) including Safeguard Diagnostic Reviews. The ESSA Team also reviewed assessments of relevant environmental and social management systems for the Tamil Nadu Health System Reform Program (P166373).

(c) **Institutional analysis**: An institutional analysis was carried out to identify the roles, responsibilities, and structure of the relevant institutions responsible for implementing the PTETB funded activities, including coordination between different entities at the National, State and District levels. The assessment of capacity of key institutions to plan, monitor and implement required environmental and social management actions needs strengthening, better coordination with other departments and medical directorates. An important input for this assessment was an evaluation of the previous track record of these institutions in management and such risks in the context of previous projects and Programs.

10.   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 have been discussed and agreed with the Central TB Division, State TB officers, and IRLs (of the PTETB Focus States).

11.   This draft ESSA will be updated based on the feedback received from stakeholders and experts prior to finalization of the program, and the updated document will be made publicly available in accordance with the Bank's policy on Access to Information. The final ESSA will be disclosed prior to World Bank Board consideration of the Program.

II. PROGRAM DESCRIPTION AND POTENTIAL ENVIRONMENTAL AND SOCIAL EFFECTS

A. Program Context

12.   With the world's second largest population, India has made substantial contributions to global economic and human development and overall poverty reduction over the last three decades. Achievements include India's increased share of the global gross domestic product (GDP) from 1.8% in 2005 to 2.7% in 2010. India's own GDP has grown steadily and become more diversified and resilient; growth is expected to continue at around 7% per annum. While robust economic growth has availed resources to address critical development challenges across various sectors, stark inequalities remain. Notably, India reduced the population living in extreme poverty from 45% in 1994 to 22% in 2012; life expectancy rose from 58 years in 1990 to 69 years in 2016, and several health outcomes have improved. However, sustaining India's economic growth depends on the government's ability to reach all segments of society with critical services and resources. India is still marked by disparities between urban and rural areas, as well as structural inequalities by gender, tribe and caste. Addressing these inequalities will require increasing access, quality, and utilization of human development services, including health.

13.   Despite substantial achievements in improving health outcomes since 1990, India still faces tremendous challenges in health care access, quality, and utilization. Quality of care is a significant and complex challenge. India's demographic and epidemiological transition calls for an aggressive response to persisting communicable diseases and a burgeoning burden of non-communicable diseases (NCDs). India's health expenditures are relatively low; National Health Accounts 2014-2015 indicate that India spends I(INR) 3,800 (US$56) per person, while other lower middle-income countries spend around US$233 per person on health. In addition, there is a weak correlation between per capita health expenditures and outcomes across states. TB is a prime example of a persisting communicable disease challenge for India. TB kills around 480,000 people every year in India. Over the last 20 years, India has contributed to almost 25% of the global TB burden, where an estimated 480,000 people die from the disease annually.

14.   TB outcomes have stagnated over the past five years. Particularly, drug-resistant TB is a major public health threat to India. TB is one of the world's top anti-microbial resistant pathogens, mostly due to inadequate treatment. Resistance to first-line drugs is known as Multidrug Resistant TB (MDR-TB). Inappropriate management of MDR-TB can then lead to a highly lethal form of extensively drug-resistant TB (XDR-TB). Resistant forms of TB require more expensive drugs with higher levels of toxicity, case fatality, and treatment failure rates. Unfortunately, India has the world's highest number of multi-drug resistant TB (MDR-TB) cases and the health systems are ill-equipped to adequately respond to drug-resistant TB (DR-TB), with DR-TB outcomes lagging global and regional trends. These resistant forms of TB threaten to erode India's health and developmental gains. Many TB cases remain undiagnosed and/or inadequately treated. Despite increases in total new TB cases reported by providers to the RNTCP, India still accounts for approximately one third of the world's three million people with TB each year who are not diagnosed, treated, or officially registered by a national TB Program. There are a combination of gaps and challenges that contribute to India's persistently high levels of TB, which include: (i) fragmented health care provision through diverse providers, including the unregulated private sector that accounts for over half of TB cases treated in India; (ii) quality gaps in diagnosing and managing TB in both public and private sector; (iii) lack of adherence to treatment resulting from various behavioral and socio-economic factors; and (iv) significant limitations in the diagnostic laboratory network.

B. The Government of India's Program

15.   It was in this context that the Government of India (GoI) launched the new National Strategic Plan (NSP 2017-2025) for the Revised National Tuberculosis Control Program. As articulated in the NSP, the GoI aims to support high impact interventions and implementation reforms to accelerate the country's progress toward elimination of TB. These include switching to a more effective treatment regimen for drug-susceptible TB and introducing shorter regimens for drug resistant TB. The overall objectives are to: (i) improve TB outcomes and diagnosis and treatment of the millions of private sector patients, (ii) provide incentives to private providers to follow standard protocols for diagnosis and treatment; and (iii) notify cases to the government. The government has supported its Program through an investment of US$535 million in 2017. The RNTCP's implementation has been supported in the past by the World Bank, WHO, Gates Foundation, Global Fund and other bilateral donors.

C. Bank Financed PforR Scope, Objectives, and Key Results Areas

16.   In response to the government's request for support, the World Bank has prepared PTETB to support and enhance the aims of the RNTCP NSP 2017. The Bank and the Government of India agreed to develop and support RNTCP using the World Bank's PforR instrument. The PTETB will emphasize a well-defined subset of the government Program. The Program was carved out of the NSP by results area, geographical area with the selection of priority states, and timeframe. Of several NSP result areas, the Program focuses on four: (i) scaling up private sector engagement, (ii) rolling out TB patient management and support interventions, (iii) strengthening diagnostics and management of DR-TB, and (iv) strengthening Program management capacity and information systems. These results areas are inter-linked and mutually reinforcing. In terms of geographical area, considering both the estimated TB burden and the gap between private notification and the estimated TB burden, the GOI selected nine states for the Program: *Uttar Pradesh, Maharashtra, Bihar, Rajasthan, Madhya Pradesh, Karnataka, West Bengal, Assam, and Tamil Nadu*.

17.   The PforR will also focus on the institutional capacity of RNTCP at the National, State and District levels in select states which will include staff vacancies. This is also considered as a disbursement linked indicator which is an essential pre-condition for success of the activities under RNTCP. The PforR Program expenditure boundary, would include procurement of first-line and second-line anti-TB drugs, equipment, and laboratory materials by the Central TB Division (CTD). At the state level, relevant expenditure categories include: private sector support (PPM, NGO, PP support), salaries and benefits, honorarium, patient support and transportation, and supervision and monitoring. All the remaining States will still benefit from cross-cutting, systems interventions under the Program. In terms of timeframe, the Program is a fraction of the NSP (five years out of seven remaining years of the NSP).

18.   The **Program Development Objective** (PDO) of the proposed PTETB *is to improve the coverage and quality of TB control interventions in the private and public sector in targeted states of India*. The Program includes four result areas as specified below, these results areas are inter-linked and mutually reinforcing areas, which are summarized below with their relevant PDO indictors.

19.   The PforR focuses on four key result areas, summarized as follows:

   (a) <u>**Result Area 1: Scaling-up Private Provider Engagement:**</u> The aim of the GOI's efforts to scale up private sector engagement is to ensure timely diagnosis and notification, and effective management of TB among patients, in line with Standards of TB Care in India. The NSP envisages an initial doubling of the number of patients detected and treated, with most of the increase coming

from engagement of private healthcare providers. The array of private sector providers includes: Rural Health Practitioners chemists and pharmacies, laboratories, qualified AYUSH providers, qualified allopathic Bachelor of Medicine General Practitioners, and specialists, including pulmonologists or chest physicians. Until recently, their engagement has been sporadic and small-scale.

The new GOI approach to scaling up private provider engagement include (i) direct engagement by RNTCP staff; (ii) contracting of intermediary agencies; and (iii) a hybrid model in which the roles are shared. All models are increasingly powered by digital systems for large-scale monitoring and strategic purchasing, built around version 2.0 of the Nikshay case-based registration information system, including direct electronic payments and new adherence support technologies. These approaches rest on a foundation of regulations that would otherwise be difficult to enforce. The transformative nature of India's NSP and the scale of its ambition are unprecedented among TB High-Burden Countries. The PTETB PforR will help the GOI build the many institutional capacities on both the public and the private sides of the partnership—that will be required to succeed.

(b) **Result Area 2: Rolling out TB Patient Management and Support Interventions:** TB control outcomes depend on the extent to which patients seek early care, and on treatment adherence and completion. It is for this purpose that the GOI is rolling out TB patient support as one of its strategic interventions to eliminate TB.

Providing treatment enablers in the form of financial incentives and nutritional support can provide for increased adherence and treatment success rates and is one of the recommended interventions under the WHO End TB Strategy. To meet these twin objectives of adherence and treatment support, the GOI is rolling out a scheme for incentives for nutritional support to TB patients called Nikshay Poshan Yojana (NPY). This Program will adopt a DBT mechanism for transfer of monetary support and incentives to patients. To support NPY, RNTCP will use Nikshay, a web-based case monitoring application already utilized by health employees at various levels across India. The support to tribal patients will be part of the Program Action Plan as the GOI is still strengthening data management and recording systems for this scheme.

(c) **Result Area 3: Strengthening Diagnostics and Treatment of Drug-Resistant TB:** The aim is to scale-up DR-TB interventions in India to aggressively respond to the continued complex and costly DR-TB challenge. The proposed PTETB PforR, directs efforts at the key bottlenecks for DR-TB control. Proposed activities under the Program involve incentivizing achievement of universal DST. Testing is the most essential activity for DR-TB control to succeed. The RNTCP's policy to offer free diagnostics services for drug-resistant TB increases the value proposition that the RNTCP can offer to private providers for complying with TB notification. The PTETB PforR will support airborne infection control and increase advocacy and attention to a neglected but important area of epidemic control and in retaining human resources for health to address DR-TB. Facility-by-facility infection control assessments and plans are the globally-recommended best practice**.**

(d) **Result Area 4: Strengthening RNTCP Institutional Capacity and Information Systems:**

The management of the TB Program is well embedded within the MOHFW and the National Health Mission (NHM), as well as the general health system at the State and District levels. The CTD is the nodal agency for the TB Program nationally. The RNTCP institutional staffing structure and information systems have been evolving with the expanding TB Program. However, substantial gaps

remain in human resource staffing and skills mix to match the goals of the NSP at Central and State levels, particularly in the nine states supported by the PTETB PforR. In addition, while improvements in information systems through the Nikshay system since its launch in 2012 are encouraging, it continues to lag behind the needs of a fast expanding Program. PTETB will support the MOHFW to develop and implement a human resource plan to enable the TB Program to adequately staff to match the scope and implementation needs of the NSP and roll out a performance-based mechanism between the CTD and states.

20. The results chain (see Table 1 below) includes a description of activities within each of the results areas, which collectively aim to achieve the PDO. Indicators and outcomes within each of the Results Areas have been defined to monitor the progress of the Program. A set of these indicators will be used as the Program's DLIs, which are bolded in Table 1. The remainder will be monitored through the Program Results Framework. More detailed descriptions of the activities under each results area are included in Section II.

Table 1: PTETB Program Results Chain

Results Area	Activities	Intermediate Indicators/Outputs	`Outcomes / PDO Results
Result Area 1: Scaling-up Private Provider Engagement:	(i) Identify and support TB patients in the private sector (ii) Provide incentives to private providers (iii) Improve quality of treatment in private sector (iv) Strengthen central and state institutional capacity to engage private providers and provider – patient engagement system (v) Strategically purchase TB services from private providers (vi) Develop and roll-out national tools and guidelines for private sector engagement (vii) Improve enforcement of India TB standards of care (viii) Scale up of RNTCP Call Centre from 50 Seater to 100 Seater	(i) Increased number of TB cases diagnosed and put on treatment (ii) Increased number of public-private agencies contracted (iii) Increased proportion of TB patients and private providers receiving incentives (iv) Technical Support Unit (TSU) integrated at state level and CTD level to support activities related to Private Sector Engagement (v) Proportion of privately notified TB patients that have microbiological confirmation in targeted states	(i) Number of TB notifications from private providers in targeted states (ii) The increase in private notifications, net of any decrease in public notifications (iii) Treatment success rate of private sector-notified TB patients
Result Area 2: Rolling out TB Patient Management and Support Interventions	(i) Develop Nikshay information system (ii) Support Nikshay Poshan Yojna (iii) Support to tribal patients (iv) Integration of Nikshay with PFMS (v) Financial Support through DBT	(i) Nikshay information system enhanced and supporting DBT& private sector (ii) Development of modules for all 4 DBT schemes (Nikshya Poshan Yojana, Tribal TB Patients, Private Providers and Treatment Supporters) in Nikshay 2.0 (prior result) (iii) Proportion of districts implementing digital signature certificate (DSC) based approval process for DBT payment	Proportion of beneficiaries receiving financial support through DBT (Annually, by category of DBT scheme) (i) Notified Public TB patients (ii) Notified Private TB patients (iii) Private sector providers
Result Area 3: Strengthening Diagnostics and Treatment of Drug-Resistant TB:	(i) Expanding and incentivizing drug-susceptibility testing and monitoring (ii) For achievement of universal DST. (with a focus on private sector engagement) (iii) improving airborne infection control in high-risk settings, by increasing advocacy and attention to this area (iv) Strengthen Airborne infection control assessments and plans (v) Strengthen diagnostic services in public sector – include TB sample transportation (vi) Strengthen notification of all TB patients with known Rifampicin susceptibility status	(i) Increased TB surveillance capacity in RNTCP (ii) Proportion of RR-TB patients with follow-up culture results documented by 9 months of treatment (iii) Strengthened sputum transportation systems in priority (iv) Facilities having AIC plans prepared according to National Guidelines	(i) Proportion of notified pulmonary TB patients with known Rifampicin-susceptibility status (ii) Proportion of privately notified pulmonary TB patients that have microbiological confirmation
Result Area 4: Strengthening RNTCP Institutional Capacity and Information Systems:	(i) Develop human resources plan to match scope and ambition of NSP (ii) Better performance-based management contract between CTD and states (iii) Implement HR Plan to improve CTD and state capacity (iv) Update supervision and monitoring guidelines to include integration of routine assessment and improvement of data completeness and quality (v) Building in the mechanism of data deduplication (of patients and providers) and reconciliation of different provider types.	(i) Improved staffing at CTD and state level (ii) Better informed & empowered communities in priority states (iii) Completion of annual institutional (CTD, NIRT, NTI, BMHRC, NRLs, STDCs) strengthening activities compared to agreed annual plans (iv) Development and implementation of a performance-based management mechanism between CTD and states (v) Conduct TB Forums at State and National Levels	RNTCP institutional capacity to achieve select NSP objectives strengthened (private sector, DR-TB and patient support)

D. Program Implementation Arrangements

21.   The MoHFW will implement the PTETB and will be responsible for overall oversight and implementation of the Program activities. The CTD provides national leadership, financing, regulatory oversight, and capacity building support - responsibility for translating the NSP into implementation plans rests with the states.

22.   Under the direction of the MoHFW, CTD will be the main implementing agency of the Program, with responsibility to prepare the annual work plan and budget and carrying out Program activities. RNTCP management is well embedded within the MOHFW and the national health mission (NHM) and within the general health system at the state and district levels. The institutional structure of the RNTCP Program is outlined in Table 2 below:

Table 2. Institutional Structure of RNTCP

Level	Administrative Head	Technical Head	General Health System
Central	Secretary – Health & Family Welfare, Additional Secretary (Health), Joint Secretary in charge of TB	Deputy Director General-TB	
State	Principal Secretary- Health and Family Welfare and Mission Director- NHM	State TB Officer	Director- Health Services
District	District Collector/Deputy Commissioner	District TB Officer	District Health Officer/Chief Medical Officer/Civil Surgeon

(a) *At National Level:* The Deputy Director General (TB) reports to the Director General of Health Services. A Joint Secretary (Public Health) is responsible for the Program, reporting to the Additional Secretary and Director of the NHM (formerly the National Rural Health Mission). The Additional Secretary and NHM Director in turn report to the Secretary of Health and Family Welfare. CTD focuses on policy development, technical oversight, monitoring and evaluation and capacity-building. Several committees and research institutes provide technical guidance to CTD. All Laboratory related planning, monitoring and infrastructure support is managed by full time Deputy Additional Director General, Labs.

(b) *At State level*: Administrative and financial management structures of RNTCP are merged with those of the NHM. The MOHFW and each state and union territory have entered into a memorandum of understanding for implementation of the NHM, which includes the RNTCP. The State TB Officer in the State TB Cell is part of the NHM State Program Management Unit, reporting to the Director of Health Services and the Director of the NHM in the state. The State TB officer— with team support—oversees district level Program implementation, reviews staff training, undertakes minor procurement, prepares technical and financial reports, ensures quality control, and monitors Program indicators.

(c) *At District* (or municipal corporation) level: The Chief District Health Officer/Chief District Medical Officer or an equivalent functionary in the district is responsible for all medical and public health activities, including TB control. The District TB Officer at the District TB Centre manages the RNTCP and coordinates with other Programs and departments. The District TB Officer is assisted by a Medical Officer and supervisors of TB/HIV coordination, public-private mix (PPM), and advocacy, communication and social mobilization (ACSM), as well as other staff.

(d) **At Sub-district level**: The TB Unit manages day-to-day RNTCP services. Planned alignment of TB Units with the block-level administrative structures of the NHM (Block Program Management Units) will mean that the responsibilities of the Block Medical Officer will include the RNTCP (along with other health Programs and services), with a Medical Officer (TB Control) or Program Officer focusing on TB services and a Senior Treatment Supervisor, and a Senior TB Laboratory Supervisor providing support. There are currently 2,700 TB Units, for average coverage of one TB Unit per 500,000 population. As there are about 5,900 sub-district administrative units in the country, alignment with NHM's sub-district structures will mean more than a doubling of the number of TB Units to increase coverage to one TB Unit per 200,000 population—100,000 in tribal, desert, remote and hilly regions. The subsequent increase in Senior Treatment Supervisors will provide additional supervisory and management capacity, notably to handle MDR-TB services and expanded public-private engagement.

23.   The Program Key Results, DLIs, and intermediate indicators will be regularly measured and reported. CTD will have overall responsibility for coordinating, monitoring, and reporting on the Program's progress according to agreed results indicators. The CTD has over twenty years of experience with implementing World Bank supported Programs, including successful implementation of a TB project which had DLIs. The CTD will report on DLI achievement and provide evidence to the World Bank in line with the agreed verification protocol. In addition, the CTD working with the WHO as the IVA will commission surveys (telephone and in person) and assessments of relevant DLIs, PDO indicators and intermediate results indicators.

E. Description of Program Activities and Identification of Environmental and Social Effects

24.   This sub-section describes the activities to be implemented under each of the Results Areas followed by a discussion of the potential environmental and social effects that could arise from each activity. The sections below summarize the environment and social risks of the whole PTETB program, followed by the environmental and social effects grouped under each Results Area. Results Area 3 accounts for a preponderance of environmental effects, followed by Results Area 1. Results area 2 and 4 have minimal environmental effects, and do not raise any notable concerns. Overall, the proposed Program is expected to a moderate level of environmental and social risks.

25.   ***Environmental and Social Screening*** As required by the Bank PforR Policy, and Directive, the Bank team carried out screening exercise for the PforR to identify and exclude potential investment areas or activities that may have high risk environmental and social issues, as well as opportunities, or warrant further analysis through the ESSA. The purpose of the screening was to: (i) identify program activities likely to have significant adverse impacts on the environment and/or affected people (those activities are not eligible for the PforR and should not be included under the Program); and (ii) determine the priority areas for further attention during the environmental and social system assessment. The completed screening checklist is provided in Annex 4

26.   ***Environmental Benefits***: PTETB Activities are likely to introduce positive environmental, health, and safety provisions for healthcare and lab workers in high-risk settings (DR-TB Centres, ART Facilities and Tb Containment Labs) by (i) reducing the risk of contracting TB and preventing other potential infections and diseases (ii) Providing training and awareness to healthcare works and staff on use of PPE (iii) introducing regimented health check-up and screenings for all workers. At the same time, the Program will strengthen environmental systems for better management and monitoring for medical waste, infection control, and accident management at facility level. Under Results Area 3, the PTETB will also have a dedicated focus on implementation of airborne infection control (AIC) measures as an integral component of Environment health and Safety.

27.   ***Environmental Opportunities:*** Based on the assessments of environmental benefits possible opportunities to improve environmental performance include (i) upgrade existing RNTCP technical and operational guidelines to avoid, mitigate, and manage environmental health and safety risks, (ii) enhance safety provisions and cleanliness in healthcare facilities and labs, which is important not only for better management of environmental aspects but also for direct impact on health outcomes, (iii) introduce changes in health and safety conditions of informal and formal workers linked to the handling and transportation of infectious substances and (iv) generate training and capacity building activities for HCFs to maintain appropriate logs of all categories of wastes, immunization of workers involved in BMWM, and accidents/spills. (v) Introduce better coordination with the State pollution control boards, and public works department for implementation of civil works that will support the outcomes of the Program (i.e. ventilation systems) This will ultimately strengthen linkages with reporting under the BMWM Rules, 2018, as mandated by the CPCB/SPCB.

28.   ***Environmental Risks:*** of the Program are likely to be associated with (i) infection control associated with TB services, including safe handling of clinical and infectious waste, sputum, sharps (slides) generated from diagnosis and treatment services (ii) adequate disposal of all waste streams including bio-medical waste, solid wastes, e-waste, plastics, pharmaceuticals, hazardous waste (x-ray developer) and liquid waste streams (chemical reagents, wastewater effluents) so that there is no contamination to surrounding environments and impacts on nearby communities, (iv) ensuring all lab safety equipment (Bio safety

cabinets, fire detection systems, air handling units and centrifuges to be kept in good working condition; and, (v) public and worker exposure to infectious diseases.).

29.   These risks are well defined, site-specific and easily managed within the current system and technical guidance available. However, with inadequate attention and poor management, these issues can pose greater risk to worker and public health and safety. There are no high impact activities associated with the PforR boundaries such construction of large buildings, central bio-medical waste treatment facilities, and effluent treatment plants (these activities are not eligible for including under the Program

30.   Adverse impacts associated limited physical works/renovations supported under the PforR include dust, noise, and solid waste generation, but these are expected to be minor in nature. These would include renovation works for laboratory upgradation, and implementation of AIC measures, all works will be carried out within existing facilities, and there will be no expansion of facilities. There is also a minimal risk of construction safety concerns. There are no anticipated adverse impacts to natural habitats, physical cultural property, natural resources. Overall, there is a moderate risk that undertaking the activities described above would result in impacts to surrounding environments (water, soil and air quality) and on worker and public health and safety.

Table 3 Institutional Responsibilities for Environmental Risks

	Risks	Institutional responsibility	Documents
1	Generation of Bio medical waste management (applicable to all facilities where biomedical waste is generated)	HCFs are responsible for management of all the EHS issues related to the medical waste management within the HCF this includes segregation, bar coding, storage of BMW, immunization of workers, trainings, treatment of liquid wastes and monitoring reporting. Collection and Disposal of BMWM is conducted by the Private sector that operates Central Bio-medical waste treatment facilities. State health departments provide support in the form of training, waste management auditing, preparation of hospital-specific BMWM plans, procurement of materials and supplies, and construction of on-site disposal facilities. Funds for BMWM are provided by NHM, but State TB officers are provision for consumables in annual planning. State Pollution Control Boards are designated to organize training programmes to staff of health care facilities and municipal workers on bio-medical waste.	Bio-medical Waste Management Rules RNTCP Environmental Assessment and Bio Medical Waste Management Plan
2	Increases in generation of E-Waste	Manufacturers producer, consumer, bulk consumer, collection centres, dealers, e-retailer, dismantler and recycler involved in	Environment (Protection) Act, 1986 Protection Act E-waste (Management)

			Rules, 2018
	(applicable to all facilities where e-Waste is generated)	manufacture, sale, transfer, purchase, collection, storage and processing of e-waste or electrical and electronic equipment listed in Schedule I, including their components, consumables, parts and spares which make the product operational. Responsibilities of Government for environmentally sound management of E-waste include (i) ensuring allocation of space for e-waste dismantling and recycling(ii) ensures recognition and registration of workers involved in dismantling and recycling and (iii) undertake annual monitoring and to ensure safety and health of workers involved in dismantling and recycling CPCB Grants Authorization and Renewal of Extended Producer Responsibility - and monitoring of its compliance to manufacturers, bulk consumer, collection centres, dealers, e-retailer, dismantlers and recyclers.	
	Incremental generation of Plastic waste (applicable to storage, transport, handling, recycling / reuse disposal of plastic wastes) Key plastic wastes generated include sputum cups and Cartridges.	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.	Plastic Waste Management Rules 2016
3	Infection Control and worker safety Health and environmental risks arise out of poor infection control practices and unsound environment management systems such as (i) inappropriate disinfection, (ii) poor sterilization techniques, (iii) inadequate use of protective gears, (iv) poor	MoHFW is responsible for supervising and controlling the infectious diseases within the HCFs in accordance with the Indian Public Health Standards and the Infection management and Environmental Plan Policy Framework. It is monitored as part of the NHM. HCF level BMW and IC committees are also responsible for establishing and operating the system of occupational health and safety protection, including training, monitoring and provision of protective gear.	IMEP comprises of a Policy Framework document which gives a broad overview and contains generic guidance to central and state level institutions on the type of systems and processes to be established for infection control and bio-medical waste management and a set of operational guidelines/manuals for healthcare workers at primary level

		bio-medical waste handling, treatment and disposal practices, (v) unhygienic and unsanitary conditions and inadequate potable water within the healthcare facilities.		healthcare level Healthcare Worker Surveillance for Tuberculosis in India-Handbook (Screening and diagnosis of workers) Hospital Waste Management Guidelines. (BMWM good practices, training requirements, management and administration requirements and co-ordination between hospital and other agencies)
4	Bio-safety	CTD ensures that all IRL and C&DST laboratories implement appropriate biosafety norms according to BSL 3 standards. NRLs conduct an external quality assurance process of all labs every two years for re-accreditation. NRL also provides training to all STDC and IRL staff on lab safety and biosafety		WHO Guidelines for Bio-safety RNTCP Technical Guidelines for Infrastructure, Equipment and Consumables for TB containment Lab
5	Airborne Infection Control (AIC) Applicable to all high-risk settings DR-TB centres, ART centres, and C&DST Laboratories	The RNTCP integrates AIC and general health system guidelines prepared by National Airborne Infection Control Committee, MoHFW, GoI and Central TB Division (CTD). National and State Airborne infection control committees promote the incorporation of infection control considerations into health facility design, construction, renovation, and use and conduct surveillance and assessment at all levels of the health system. The airborne infection control activities at the district level are coordinated and undertaken by the Sub-Committee on Biomedical Waste Management / Infection Control (SCBMW/IC) under the District Health Society (DHS). They should function under guidance and close coordination with the SAICC, State Health Society and with the TB Sub-Committee under DHS (NRHM).		National Airborne Infection Control Guideline's, 2010
6	Civil works	Civil works pertaining to new health care facility is carried out by Public works department.		National Building codes National Policy Relevant State PWD specifications

			The National Policy on Safety, Health and Environment at workplace

Institutional and Capacity Risk: Within RNTCP environment, health and safety aspects such as BMWM, IC, and AIC are being managed at different levels, and by different technical specialists and committees. There is no standardized state level approach to plan and roll out activities pertaining to EHS. Further to this, necessary budgets for PPE, consumables, disinfectants are provided under the general health system and not separately for RNTCP. The treatment of TB requires higher adherence and vigilance in the use of PPE. There is a shortage dedicated biomedical engineers to support lab safety, and there needs to be a stronger connect with the NHM to utilize support in terms of manpower, technical capacity, and budget for their maintenance.

There is scope for strengthening the existing technical and operational guidelines to include EHS aspects and ensuring full coverage of activities under the NSP, through careful program planning, capacity building and monitoring. There is a risk that given the high Program targets in the NSP, CTD may inadvertently overlook the environmental aspects, which would decrease the overall effectiveness of the interventions. Lack of appropriate monitoring and supervision may lead to improper management of wastes and lack of attention to worker safety and site maintenance.

While CTD has prepared and implemented training programs for the staff on environment or social related aspects under previously supported Bank projects, there potential risks that can emerge due to improper planning, execution and management of various activities. While the proposed operations would not lead to significant risks, the specific action which need to be addressed to prevent any risks include (a) arrangements for safe disposal of all wastes as part of various operations (b) occupational and public safety risks for workers and the communities. It is recommended that the modification and updating of the existing Guidance documents to ensure full coverage of EHS aspects is undertaken in Program implementation and operations.

The activities supporting the results areas broken out by relevant environmental sphere or issue area are described in detail below:

Table 4 Key Environment Risks and Gaps and Potential Measures to Align with ESSA Core Principles

Sl. No.	Cross-Cutting Areas of Risks/ Impacts	Key Risk and Gaps	Potential Measures to align with ESSA Core Principles
1	Incremental generation of Bio Medical Waste Management	*Incremental increase in BMW generated such* (i) sharp waste (slides); (ii) chemical waste (e.g., reagents, solvents, etc.); (iii) infectious waste (sputum etc.); (iii) general waste (plastics, cartridges, packaging) and (v) e- waste (e.g., batteries, older medical equipment, There are health risks from exposure to poorly managed medical waste and through	**Risk- Moderate** Currently the BMWM Rules, 2016 and amended 2018 confirm with same requirements of WBG EHS guidelines. Waste is being segregated at facility level, Colour coded bins and bags are being utilized. Collection, transport and final disposal is managed through private operators who also manage CBMWTFs. Pollution monitoring (air emissions, treated effluents) from CBMWTF are monitored by the CPCB.

		contact with infected sharps, skin infections through poor disposal practices. Risks arise in decentralized facilities, wastes are not collected on time (they can become breeding grounds for vector-borne infections) and lack of adequate investment in continuous/rigorous training to staff on safe handling and management of biomedical waste.	All States under the PTETB Program have access to CBMWTF. Overall, while the infrastructure and equipment for safe biomedical waste disposal is available, there is a need to strengthen BMWM systems, including an overall waste management plan (include e-wastes, chemicals, pharmaceuticals) including trainings and reporting. There is need for dedicated capacity to help states plan and implement activities relating to BMWM.
2	Small civil works/ renovations work required for (CBNAAT Lab, x-ray facilities, TB containment labs, and for AIC controls	Given that works will take place within existing facilities, the visitors and patients, particularly the inpatients, may be exposed to noise and dust. Solid wastes generated would have to be collected and disposed appropriately in municipal landfill. Current construction management practices are carried out as per the National Building Codes which contain the general building requirements, fire safety requirements, structural design and construction (including safety), and sustainability. These are adequate in addressing infrastructure integrity, health and safety aspects. and management of negative environmental impacts related to construction activities. No prior permission is required from Pollution Control Board, and no EA/ EIA is required by country system due to small nature of civil works.	**Risk- Minimal** Such impacts are site-specific and can be effectively mitigated by measures such as screens, water spray, dust-net, use of low-noise equipment, following The National Building Codes will effectively alleviate any risks and aligns with Core Principle 1 and 2. Capacity should be built for health specialists to understand engineering interventions important for health outcomes (for example ventilation systems)
3	Disposal of Hazardous Wastes	Due to expansion in diagnostics, in particular x ray facilities, there will be an increase in x-ray wastes such as fixer and rinse solutions, films and discarded lead aprons. These Waste should not be burned, incinerated, or landfilled. These wastes must be given or sold to the authorized recyclers of the Pollution control boards for metal recovery	**Risk – Minimal**. The increase in x ray waste will be negligible. For x ray equipment, the licensing, safe use, and proper decommissioning are regulated to avoid potential impacts. Wastes from x-ray film processing are regulated by the CPCB under the Hazardous Waste Rules Waste. Implementation is adequate.

| 4 | Disposal of Liquid Wastes (Chemicals and wastewater) | With expansion in diagnostics and lab capacity, there will be an incremental increase in chemical regents (disinfectants, dyes, reagents) and wastewater being disposed. The BMWM rules 2016 provide the guidelines for disposal of all HCF related waste and are adequate in addressing all risks/impacts arising. If wastewater is not adequately disposed as per the rules it may polluted water sources with microbiological pathogens and hazardous chemicals.

There are no records to document whether treated effluent quality from HCFs/Labs meets the required standards BMWM Rules 2016. Moreover, decentralized labs (DMCs) do not always have connections to sewer systems, and disinfected effluent/chemicals are disposed into a soak pit. | **Risk- Moderate**
As per the BMWM Rules 2016, and Technical Guidelines for Infrastructure in TB Containment Labs, the chemical liquid waste from HCFs/Labs must be collected through a separate drainage system leading to Effluent Treatment Plant (ETP). HCFs with large standalone labs such as NRLs and IRLs install ETP for separate collection and disinfection of infectious waste from laboratory. The combined discharge shall conform to the discharge norms given in Schedule II.

For middle and small healthcare facilities and labs such as DMCs/ rural locations having no system of separate ETP the liquid waste is needed to be onsite chemically disinfected with chlorine solution in a tank before mixing with other wastewater and ultimately discharged in sanitary sewer system or septic tank/soak pit system.

Treated water should conform to the standards of liquid waste as listed in Schedule II of BMW Rules, 2016 Chemical disinfection is to be performed by Hypochlorite Solution or equivalent disinfectants. (following IMEP and WHO guidelines for Infection Control in Healthcare Facilities). Chemical disinfection performed must meet the standard of chemical disinfection as listed in Schedule II of BMW Rules, 2016.

Any risk of untreated wastewater being disposed in water bodies is significantly averted if ETPs are installed. In smaller establishments, appropriate mechanisms of disinfection, pre- treatment and final disposal to septic tank and soak pit system should be adopted.

As good practice, the effluent quality from HCFs/Labs having ETPs needs to be monitored regularly to ensure that treated effluent meets the required standards BMWM Rules 2016 Schedule II |
| 5 | Disposal of Pharmaceutical Waste/ expired drugs | Expired TB drugs need to be suitably disposed according to the BMW handling Rules. Lack of adequate implementation may result in expired drugs being | **Risk- Minimal**
According to BMW Management rules HCFs are required to send expired medicines sent back to manufacturer or crushed and dispose of secure land fill or handed to |

		diverted to the market or inappropriately disposed in water bodies/dumpsites.	CBMWTF to be disposed of through incineration. This adequately addresses any adverse impacts that may arise from inappropriate disposal of pharmaceutical waste, for HCFs with or without linkages with CBMWTFs. This aligns with Core Principle 1.
6	Accidents and Fire Safety	The risk of fire in TB containment labs is a concern due to electrical fire, the storage, handling, and presence of chemicals, and other flammable substrates. All labs do not have fully functional fire detection systems/alarms. Currently Reporting on Accidents/spills and other hazards is mandated under the BMWM Rules, 2016, but implementation remains weak, particularly for decentralized facilities.	**Risk- Moderate** Infrastructure guidelines for TB containment labs require appropriate fire safety systems, and accident remediation (water supply for emergency shower and eyewash). The risk arises when these systems are not maintained appropriately and not in working condition. To align with ESSA core principles, it is proposed as a supplementary action that these systems are reviewed in the next External quality assurance (EQA) process of the IRLs, where deficits exist these should be mitigated.
7	Worker Health and Safety	Health care and lab workers are exposed to general infections, and other potential infectious materials during TB care and treatment, as well as during collection, handling, treatment, and disposal of health care waste. The Program will not result in increased exposure to general infections or in handling of wastes. There are other provisions where lack of adequate attention could result in worker health and safety being compromised, this is particularly relevant to high risk settings such as (i) TB containment labs (ii) DR-TB and ART centres. These areas include (a) regular health screening and checkup of workers (b) Unhygienic and unsanitary conditions at healthcare facilities can increase the risk to workers to contract hospital acquired infections (c) Inpatient treatment of DR-TB carries the risk of airborne infection and requires substantial investment in advocacy, communications (signages, campaigns) behavior change (cough etiquette, use of PPE), and implementation of AIC	**Risk- Moderate** The BMWM Rules also specify use of PPE, healthcare worker immunization, use of autoclave machines, and health and safety trainings. Each facility is required to have a working infection control plan according to the requirements under IMEP standards These requirements are aligned with core principle 3. Given that the activities under the PforR will enhance treatment of DR-TB- health care facilities and TB containment labs, capacity to manage infection control and airborne infection control needs to be built. to increase the effectiveness of the Program interventions. The Program will include a results indicator on Airborne infection control, so that facilities can be audited, and remedial measures can be implemented to confirm to national guidelines.

		infrastructure (segregation, ventilation systems).	
Sl. No.	Activity Cluster	Key Risk and Gaps	Potential Measures to align with ESSA Core Principles
Result Area-1: Scaling-up Private Provider Engagement			
2	*Identify and support TB patients in the private sector*, provide incentives to private providers, improve quality of treatment in private sector, strengthen central and state institutional capacity to engage private providers and provider – patient engagement system *Strengthen diagnostic services in public sector –* include TB sample transportation, strategically purchase TB services from private provider, Develop and roll-out national tools and guidelines for private sector engagement, improve enforcement of India TB standards of care, and scale up of RNTCP Call Centre from 50-Seater to 100 Seater.	No adverse environmental impacts, the activities will be beneficial to the Program. However, private sector services need to be monitored to ensure they meet national standards on environment health and safety	**Risk- Moderate** *Private sector compliance with biomedical waste, lab safety and EHS criteria:* As partnership guidelines will be revised and purchasing of services from private sector will be increased, there is a risk that private Labs (C &DST) will not meet essential criteria for EHS and BMW management. This will need to be strengthened under the Program *Strengthening of sputum/TB sample collection, transportation and linkages* with NGO partnership would require protecting shipping personnel/ postal workers, laboratory staff, and the public from inadvertent exposure to infectious agents during transport and receipt of specimens. Though guidelines exist for packing of sputum sample, transport is not always done according to recommended protocols, and workers are not provided with adequate biosafety training, spill kits and awareness. This will need to be strengthened under the Program
Result Area 2: Rolling out TB Patient Management and Support Interventions			
1	Develop Nikshay information system, support Nikshay Poshan Yojna, support to tribal patients, integration of Nikshay with PFMS, and financial Support through DBT	There are no risks or impacts associated with this activity cluster.	
Result Area 3: Strengthening Diagnostics and Treatment of Drug-Resistant TB			
1	Expanding and incentivizing drug-susceptibility testing and monitoring for	All IRL and C &DST labs/ TB containment labs need to meet the requisite biosafety standards to be fully operational. Gaps have	**Risk- Moderate** *Maintaining Biosafety in TB containment labs:* Assessments relieved that there are gaps in

| | | achievement of universal DST (with a focus on private sector engagement) | been observed in infrastructure and staffing capacity which can impact service delivery and continuity.

Protection of workers and ensuring their health and safety is essential in preventing any lab acquired infections. | C&DST labs conforming to the WHO standards for Biosafety. These gaps span the (i) laboratory design and facilities, (ii) age and servicing of critical equipment, and (iii) health surveillance of workers. The Program proposes specialized units to ensure availability of biomedical engineers and provisions for annual Maintenance of equipment to ensure it is always in working condition.

Occupational risks to acquire TB Inpatient treatment of DR-TB carries the risk of airborne infection and requires substantial investment in advocacy, communications (signages, campaigns) behavior change (cough etiquette, use of PPE), and implementation of AIC design and infrastructure (segregation, ventilation systems). Capacity to plan and implement at the HCF level would also require strengthening if DR-TB treatment is to be scaled up all levels –
national, state, and local/health care facility levels. AIC capacity will be strengthened at District IC committee and IC officers in medical colleges.

Annual maintenance of lab equipment such as biosafety cabinets, centrifuge and AHU needs is an issue, and needs standardization in servicing. Lab workers should be provided this equipment in good operational condition so that there are no adverse impacts on their health. This was also outlined in the NSP as a challenge for the diagnostics. Older equipment would also require decommissioning and appropriate disposal according to the e-waste handling rules. The Program will develop an SOP on serving and AMC for all critical lab equipment and will standardize the practice throughout the country.

Poor or nonexistent disaster/fire safety and emergency response arrangements For DST services, it is critical that TB containment labs brought under the RNTCP conform to the standards and have regulated access control, fire detection and safety mechanisms, and accident reporting mechanisms. These provisions are critical to ensuring safety within the premises due to the storage, handling, and presence of |

			chemicals, pressurized gases, and other flammable substrates. The Program will support IRLs will all key safety infrastructure needed to meet EHS standards.
2	Improving airborne infection control in high-risk settings by increasing advocacy and attention to this area Facility-by-facility infection control assessments and plans	Implementation of AIC plans (administrative and environmental controls) will be overall beneficial from environment and health standpoint. Any impacts associated with upgradation of ventilation systems are covered in minor civil works mentioned above.	**Risk- Minimal** Covered in risks associated with minor civil works.
3	Strengthen notification of all TB patients with known Rifampicin susceptibility status	No impacts/ Risks	
Result Area 4: Strengthening RNTCP Institutional Capacity and Information Systems			
1	Develop human resources plan to match the scope and ambition of NSP, better performance-based management contract between CTD and states, implement HR Plan to improve CTD and state capacity, conduct TB Forums at State and National Levels, Update supervision and monitoring guidelines to include integration of routine assessment and improvement of data completeness and quality, building in the mechanism of deduplication (of patients and providers) and reconciliation of different provider types	There are no direct environmental impacts associated with this activity cluster.

All staffing vacancies associated with RNTCP network and the NSP will be filled through the Program. A standalone DLI has been included to incentivize this.

There is no dedicated capacity on environmental management in CTD or the states. Hence, record keeping on trainings, occupational health and safety, accidents etc. is not always updated and well maintained. | **Risk- Moderate** With the hiring of key laboratory staff and biomedical engineers, any risks arising from low staffing and technical capacity in the laboratory network will be adequately addressed. The States and the Centre need a nodal officer on environmental monitoring to address all activities (BMWM, IC and AIC) that have been identified to have potentially significant impacts on the environment and worker health and safety. |

(a) **Social Effects**

31.   The key risks and gaps to the activities supporting the result areas and potential measures to align with ESSA core principles, is presented in Table 4 below.

Table 5. Key Social Risks and Gaps and Potential Measures to Align with ESSA Core Principles

Sl. No.	Activity Cluster	Key Risk and Gaps	Potential Measures to align with ESSA Core Principles
Result Area-1: Scaling-up Private Provider Engagement			
1	Identify and support TB patients in the private sector, provide incentives to private providers, improve quality of treatment in private sector, strengthen central and state institutional capacity to engage private providers and provider – patient engagement system	Low likelihood of any negative social effects. This in fact provides further opportunity for better social outcome. However, the key area that requires strengthening is the IEC/ SBCC to inform patients in private sector on linkages and benefits provided to TB patients by Government.	Given about 80 percent of TB patient makes first contact at private provider, scaling up engagement with the private sector provides an opportunity to not only have better adherence to recommended treatment regime, but also build linkages to Nikshay Poshan Yojna for nutritional support especially to the poor. A comprehensive IEC/ SBCC will further help in this and raise demand side awareness on TB, apart from helping in stigma reduction.
2	Strengthen diagnostic services in public sector – include TB sample transportation, strategically purchase TB services from private provider, Develop and roll-out national tools and guidelines for private sector engagement, improve enforcement of India TB standards of care, and scale up of RNTCP Call Centre from 50-Seater to 100 Seater.	The incentive for sample transportation in tribal and difficult to reach areas require streamlining and monitoring. Also, the call centre is expected to act as grievance registration system and hence requires proper mechanism for escalation of grievances.	The Program action is informed by the RNTCP operational guidelines to be updated including mechanism for strengthening data collection and monitoring of Tribal Population Transport Reimbursement. Additionally, developing a Grievance Redressal policy, which should be like a Standard Operating Procedure with defined escalation matrix, etc.
Result Area 2: Rolling out TB Patient Management and Support Interventions			
3	Develop Nikshay information system, support Nikshay Poshan Yojna, support to tribal patients, integration of Nikshay with PFMS, and financial Support through DBT	While the GoI claims that more than 91.7 percent of the population (as per Census 2011) have Aadhaar card, and over 99 percent of the adult population above the age of 18 years have been assigned Aadhaar number, support to tribal patients using DBT is still being considered a difficult	Already aligned with core principle #5. The program further intends to address this issue for seamless transfer of incentives through DBT mechanism.

Sl. No.	Activity Cluster	Key Risk and Gaps	Potential Measures to align with ESSA Core Principles
		area by CTD and being prioritized under the Program.	
Result Area 3: Strengthening Diagnostics and Treatment of Drug-Resistant TB			
4	Expanding and incentivizing drug-susceptibility testing and monitoring for achievement of universal DST (with a focus on private sector engagement), improving airborne infection control in high-risk settings by increasing advocacy and attention to this area, facility-by-facility infection control assessments and plans, strengthen notification of all TB patients with known Rifampicin susceptibility status	Strengthening diagnostic services and linkage with treatment provides opportunity for better social outcome given in many areas especially the tribal and difficult to reach areas, travelling for diagnostic services not only poses financial burden but also cause in delay in initiating treatment. The strengthening of diagnostic services and treatment of DR-TB does not require any major construction and is limited to minor renovation and repairs within the existing footprint of the health facilities and laboratories.	Already aligned with core principle #5. However, screening will be conducted to rule out any adverse social impact where any renovations and/ or expansion is planned under the program in the health facility/ laboratory or associated infrastructure. A screening checklist is presented in Annex-6.
Result Area 4: Strengthening RNTCP Institutional Capacity and Information Systems			
7	Develop human resources plan to match the scope and ambition of NSP, better performance-based management contract between CTD and states, implement HR Plan to improve CTD and state capacity, conduct TB Forums at State and National Levels, Update supervision and monitoring guidelines to include integration of routine assessment and improvement of data completeness and quality, building in the mechanism of deduplication (of patients and providers) and reconciliation of different provider types	The key risks emerge from the gaps in human resources to at CTD as well as at State TB cell to plan and implement partnerships, ACSM and psycho social support (PSS) activities in a coherent manner, adequate capacity of the existing human resources at district and sub-district level on ACSM, SBCC activities, and proper procurement capacity to source in services from NGOs and other partners.	The Program plan to reorganize the CTD and STCs into four sectoral divisions with dedicated staffs including for partnerships, ACSM and psycho social support (PSS) activities, and plans to build capacity of staff at all levels for different Program components including procurement. In addition, the Technical Support Unit (TSU) is planned to be placed at CTD and STCs for further support.

III. ASSESSMENT OF ENVIRONMENTAL AND SOCIAL MANAGEMENT SYSTEMS AND IMPLEMENTATION CAPACITY

A. Introduction

32.   This section provides a summary assessment of whether the program's environmental and social management systems are adequate for and consistent with the core principles and key planning elements contained in the PforR Policy, as relevant to the Program. It also assesses whether the involved institutions have the requisite capacity to implement these systems' requirements. An in-depth description and analysis of the Program's systems and implementation capacity are found in Annex 2.

33.   As noted earlier, the PforR Policy requires the proposed Program to operate within an adequate environmental and social management system that can manage environmental and social effects (particularly adverse impacts and risks) identified during the ESSA process. This includes (a) an adequate legal and regulatory framework and institutional setting to guide environmental and social impact assessment and the management of environmental and social effects, and (b) adequate institutional capacity to effectively implement the requirements of the system.

34.   This section assesses whether the Program's environmental and social management systems are consistent with the core principles and key planning elements contained in the PforR Policy and whether the involved institutions have the requisite capacity to implement these systems' requirements. Both elements (e.g. Program systems and capacity) are necessary towards ensuring that the environmental and social effects identified in Section II are effectively managed. Through both analyses, the ESSA team has identified gaps in both areas, which are addressed in Inputs to the Program Action Plan and Supplemental actions.

35.   A *Program system*s constituted by the rules and "arrangements within a Program for managing environmental and social effects,"[1] including "institutional, organizational, and procedural considerations that are relevant to environmental and social management"[2] and that provide "authority" to those institutions involved in the Program "to achieve to achieve environmental and social objectives against the range of environmental and social impacts that may be associated with the Program."[3]This includes existing laws, policies, rules, regulations, procedures, and implementing guidelines, etc. that are applicable to the Program or the management of its environmental and social effects. It also includes inter-agency coordination arrangements if there are shared implementation responsibilities in practice.[4]

36.   *Program capacity* is the "organizational capacity" the institutions authorized to undertake environmental and social management actions to achieve effectively "environmental and social objectives against the range of environmental and social impacts that may be associated with the Program."[5] This ESSA has examined the adequacy of such capacity by considering, among other things, the following factors:

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1 Drawn from *Program-for-Results Financing: Interim Guidance Notes on Staff Assessments*, "Chapter Four: Environmental and Social Systems Assessment Interim Guidance Note," Page 77, paragraph 1.
2 Ibid, page 82, paragraph 12.
3Ibid., Page 77, paragraph 2, and page 82 paragraph 12.
4Based "Chapter Four: Environmental and Social Systems Assessment Interim Guidance Note,"*Program-for-Results Financing: Interim Guidance Notes on Staff Assessments*.
5Ibid., Page 77, paragraph 2, and page 82 paragraph 12.

(a) Adequacy of human resources (including in terms of training and experience), budget, and other implementation resources allocated to the institutions;

(b) The adequacy of institutional organization and the division of labor among institutions;

(c) Effectiveness of interagency coordination arrangements where multiple agencies or jurisdictions are involved; and

(d) The degree to which the institutions can demonstrate prior experience in effectively managing environmental and social effects in the context in projects or Programs of similar type and magnitude.

37.   This ESSA examines and discusses only those aspects of the proposed Program's environmental and social management systems and related capacity that the ESSA Team found to be relevant considering its identified environmental and social effects. This section provides a *summary assessment* of the Program's systems and capacity as they relate to each of the core principles and key planning elements. The text and tables below clarify the instances in which one or more of the Core Principles or Key Planning Elements are not relevant to the Program and are thus inapplicable. More in depth discussion and analysis of the Program's systems and capacity are found in Annex 2 and 3

38.   Overall, the applicable environmental management systems are generally adequate to address underlying environmental and social risks, and noteworthy strengths are strong regulations and guidelines on biomedical waste management, general waste management, and infection control. The provisions of the existing environmental legal and regulatory framework are adequate but require enabling institutional and technical capacity for compliance. While the provisions of the Biomedical Waste Management & Handling) Rules, (as amended on March 2018), Infection Management and Environment Policy Framework (IMPS) are being implemented, provisions of other relevant environmental acts such as, hazardous, solid, plastic and e-waste Rules applicable to RNTCP require additional capacity building efforts.

39.   There exist National and RNTCP Program guidelines for addressing the following risks (i) patient and worker safety, (ii) biosafety, (iii) air borne infection control, (iv) packaging and transport of infectious sputum samples and (v) Surveillance and screening of TB workers. There is scope for strengthening the existing technical and operational guidelines to include EHS aspects and ensuring full coverage of activities under the NSP, through careful program planning, capacity building and monitoring.

40.   The applicable environmental and social management systems is generally adequate to address underlying environmental risks, and noteworthy strengths are having national regulations and guidelines in place for bio-medical and other waste management, guidelines for laboratory biosafety, general infection control and surveillance of TB workers, though efforts are required to strengthen implementation, and institutional coordination to achieve sustainable outcomes.

41.   Although there are comprehensive national guidelines covering institutional, administrative and infrastructure needs for airborne infection control (AIC), implementation has been limited to a few pilot centers, and each health facility is responsible for how they implement the provisions in guidelines, with different capacity resulting in varied practice. AIC is critical to ensuring worker safety in high risk settings. The program results framework includes an audit of healthcare facilities in the select states, to support implementation of AIC measures in high risk settings.

42.   The ESSA did uncover gaps in some areas, as summarized below, which will need to be addressed through the Program Action Plan (PAP) and supplemental actions.

B. Core Principle 1 - Environmental and Social Management

43.   **Core Principle 1:** *Assessment of the degree to which the Program Systems promote environmental sustainability in the Program design; avoid, minimize or mitigate against adverse impacts; and promote informed decision-making relating to a Program's environmental effects.*

This is determined as relevant and applicable. India has an adequate legal framework for environmental, health and safety, and waste management (including hospital, general, plastics and liquid wastes) backed by a set of comprehensive laws, regulations, technical guidelines and standards, which apply nationwide. Over the decades, it has gradually evolved into a comprehensive system that is generally consistent with the PforR.

Certain interventions under the Program would require mitigation actions and sustainable approaches to better manage Program's environmental effects. These include, among others (i) Strengthen environment health and safety monitoring capacity in CTD and States on BMW, IC, and AIC (ii) Support accreditation criteria for C&DST labs to include enhanced EHS and biosafety criteria (iii) Update BMW trainings to include management of all wastes including e-waste and hazardous wastes, to all staff engaged under RNTCP (iv) Ensure emergency response mechanisms such as fire detection, and accident reporting and response mechanisms are functional at all HCFs and Labs (v) AIC and IC capacity is strengthened at facility level through the public health system (vi) develop guidance for State and District TB officers to understand and implement EHS aspects as part of national guidelines/ regulations.

Adverse impacts associated limited physical works/renovations supported under the PforR include dust, noise, and solid waste generation, but these are expected to be minor in nature and limited to the healthcare facility. A screening checklist is attached in Annex 6 to screen all EHS, BMWM and IC measures at the HCF level, and also for any adverse impacts that may arise through renovation works, so that the requisite mitigation can be implemented. The screening will be conducted by the healthcare facility in charge, with guidance from DTO.

C. Core Principle 2 – Natural Habitats and Physical Cultural Resources

44.   **Core Principle 2: Assessment of the degree to which the Program systems avoid, minimize, and mitigate against adverse impacts on natural habitats and physical cultural resources resulting from the Program**

This is determined as not applicable. The analysis confirmed that Program investments would neither impact nor convert critical natural habitats or impacts physical and cultural resources. This Core Principle will not be applicable to the Program and the PforR as there will be no new construction or expansion of facilities, all renovation works will be undertaken in existing facilities within Program States.

D. Core Principle 3 – Public and Worker Safety

45. **Core Principle 3: Assessment of the degree to which the Program Systems protect public and worker safety against the potential risks associated with (a) construction and / or operation of facilities or other operational practices developed or promoted under the Program; (b) exposure to toxic chemicals, hazardous wastes, and otherwise dangerous materials; and (c) reconstruction or rehabilitation of infrastructure located in areas prone to natural hazards.**

This is determined as highly applicable. The government systems have management and supervision systems for work safety and ensures the screening of safety issues and occupation hazards, construction work safety. Overall, the legal framework of environmental management in India, and RNTCP guidelines in this regard is consistent with the Bank PforR Policy and Directive, but requires capacity strengthening to implement.

This is determined as applicable. TB diagnosis and treatment exposes healthcare and lab workers to risks associated with exposure to TB, hazardous materials, infections, as well biosafety, and would require mitigations These include, among others: (i) Improving occupational health and safety practices at healthcare facilities through infrastructure design, AIC, infection control, protocols for addressing accidental spills; (ii) Providing protective clothing and personal safety equipment, as required; (iii) Ensuring safe storage, segregation, transport and disposal of biomedical and hazardous wastes; (iv) good practices with regards to cleanliness, hygiene and general waste management; (v) worker and public health and safety focusing on emergency response; fire safety (vi) maintenance of critical lab safety equipment (vii) training for workers in sputum collection transport on biosafety and use of spill kits and (viii) having qualified biomedical engineers and technical staff available to service, maintain and conduct safety testing on critical lab equipment in the IRLs.

E. Core Principle 4 – Land Acquisition

46. The Program does not intend to do any land acquisition or resettlement, as it does not support any major construction and it is limited to minor renovation and repairs within the existing footprint of the health facilities and laboratories. Hence, this principle is not applicable. However, screening will be conducted to rule out any adverse social impact where any renovations and/ or expansion is planned under the program in the health facility/ laboratory or associated infrastructure. A screening checklist with this effect is presented as Annex-6 of the report. The screening for all civil works will be conducted by the healthcare facility in charge with guidance from DTO. The resettlement which is to be avoided includes involuntary displacement of people who are illegally occupying areas within the grounds of the health facilities. Both health facility in-charges as well as DTOs will be training by the social safeguard officer at the State TB Cell.

F. Core Principle 5 – Indigenous Peoples and Vulnerable Groups

47. The focus State under the Program accounts for 49 percent of the total tribal population in India. The key social concern relevant to indigenous people and vulnerable group emerges from the access, knowledge and outreach, and addressing stigma and discrimination. Hence, the core principle is applicable.

Access to TB Services in Tribal and Difficult to Reach Areas

48.   According to Census 2011, the tribal population accounted for 8.6 percent of the country's population with over 104 million people across 750 different tribes living in different parts of India. The nine focus states i.e. Assam, Bihar, Karnataka, Maharashtra, Madhya Pradesh, Rajasthan, Tamil Nadu, West Bengal and Uttar Pradesh account for 51.5 million (49 percent of tribal population) of the 104 million tribal population in India and includes good number of districts under Schedule -V and Schedule -VI areas as per constitution. Of the 177 high priority tribal districts and 672 high priority tribal sub-district having more than 10,000 tribal population and more than 50% population belonging to tribal community in the country, the nine focus states have 50 high priority tribal districts and 115 high priority tribal sub-districts[6]. While the lack of access to health services, poor health literacy and high level of malnourishment in the remote tribal[7] and hilly areas has been a known factor influencing health seeking behavior, the NSP 2017-25 further informs that some of the states with tribal and hilly terrains in India have been reporting a high incidence of not only drug sensitive but also drug resistant TB cases. Hence it becomes even more important to strengthen the TB control activities in these difficult areas. The Tribal Action Plan followed by RNTCP in the earlier World Bank project identified poor physical access of tribal population to diagnosis and treatment under the RNTCP due to difficult terrain and sparsely distributed tribal population in forest and hilly regions. The key actions identified in the tribal action plan of the earlier project included (a) Promote closer supervision of tribal areas by RNTCP staff, (b) Encourage tribal populations to report early in the course of illness for diagnosis and among other activities provide travel reimbursements of Rs. 750 to patient and one attendant for travel for follow-up and treatment, and (c) Enhance treatment outcomes amongst tribal populations by enhance culturally appropriate outreach and ACSM activities along with IEC in local language. While the action identified under the tribal action plan is still valid, it required updating to the current context and CTD to closely monitor the RNTCP activities in tribal areas including streamlining the incentives and support mechanisms through DBT to tribal patients such as tribal patients transport reimbursement. Discussion with members of tribal community, local NGOs, and health care facility staffs during field visit to tribal areas of Pune district in Maharashtra and Udaipur district in Rajasthan further elaborates on these issues and stress upon strengthening service provision and outreach using ACSM activities to address the same. Also, RNTCP shall follow the list of tribal districts and sub districts as per the Ministry of Tribal Affairs list articulating them and also presented in the Annual Report 2017-18 describing the State/ UT and District wise list of ST Priority Sub-Districts. The RNTCP tribal action plan to be updated with the changing context and with focus on filling gaps and strengthening measure for implementation.

ACSM Activities Including Social and Behavior Change Communication (SBCC)

49.   Since the inception of the RNTCP Program, ACSM is seen as a cross cutting, supportive strategy that focuses on all aspects of TB care for diagnosis and treatment interventions, strengthening social support systems for TB care and community interventions to reduce stigma. The NSP 2017-25 further focuses on ACSM for improvement in early identification of symptoms of TB and referrals from community aiding in early case detection, support for treatment adherence, combating stigma and discrimination, people's empowerment, and mobilizing political commitment and capacity building for decentralized planning. However, the JMM 2015 observed that ACSM activities were accorded low priorities with very small budget and have impacted the forging of partnerships with various stakeholders including private sector, NGOs, CBOs, community groups, and local self-governments etc. in improving provision of care for TB patients. The already overburdened staff at STC and DTC tend to do things that are budgeted and monitored, and whereas community engagement falls in either with very low on the priority list. This is further echoed in

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[6] https://tribal.nic.in/writereaddata/AnnualReport/AR2017-18.pdf

various evaluation documents including the Central level internal evaluation (CIE) reports of 2017. The need for a revised communication strategy is further enhanced given that the Program now plans to engage with a range of private sector stakeholders including community who have been mainly resorting to private sector for TB treatment.

50.   Analysis of the budget provision under the RNTCP Partnership Guidelines for community level partnership suggests INR 250,000 per annum for one million population on pro-rata basis for population covered. This includes NGOs staff salary, cost of activities and transportation, and mobility to undertake activities in the area of coverage. The NGO partner is expected to undertake a certain minimum number of activities every month as per the agreed plan within the assigned geographical area/population within the district. An analysis of Census 2011 data of districts suggests that about 195 (i.e. 30 percent of the districts) of the then 640 districts in the country, are below one million in population, and are mostly the tribal and remote districts with spread out geographic landscape and difficult to commute areas as presented in Table 5 below. Will low population base, the pro rate budget will also be lower, while to cover these districts by any means, require more budgetary allocation including for transport etc.

Table 5. **Population Ranges for Districts in India (As per Census 2011)**

Population Size Class	No. of Districts (out of 640 as per Census 2011)	% Districts	Remarks
< 0.2 million	51	8%	Most of the districts from North East India
0.2 - 0.5 million	45	7%	Large proportion of North-east districts, some from Uttarakhand and some tribal districts
0.5 - 1 million	99	15%	Remaining North-east districts, large proportion from HP, J&K, Assam, and some from Jharkhand, Odisha, Chhattisgarh, and Madhya Pradesh
< 1 million	**195**	**30%**	**Mostly Schedule-V and VI districts and other tribal and remote districts**
> 1 million	**445**	**70%**	
Total Districts	**640**	As per Census 2011	

51.   By providing inadequate budget for ACSM, it not only results in exclusion of these areas for ACSM activities, but it also presents difficulties in districts that are more than one million but are geographically spread-out and have forested and difficult to reach pockets. To address this, the National Partnership Guidelines must be updated with revised financial norms and mechanism for strengthening ACSM activities for community engagement and social mobilization across all districts especially for the poorer, hilly and remote districts including the tribal districts. Discussion with CTD suggest moving away from the prescribed rigid financial guidance for ACSM, instead providing lumpsum budget to state to accordingly plan their ACSM activities including in tribal and difficult to reach areas.

Issues Related to TB Associated Stigma Reduction and Addressing Discrimination

52.   Stigma has an adverse impact on the health and health seeking behavior of people with TB. In India, stigma related to TB is rampant and many people refrain from telling anyone, even family members, that they have or suspect that they have TB. In some cases, persons with TB have lost their jobs after disclosing this at the work place. Some patients travel to distant clinics to avoid being seen taking treatment by their neighbors, or go to private clinics, which are perceived to offer more privacy, both of which increase the likelihood that treatment will be discontinued for financial reasons[8]. TB-related stigma is a well-recognized barrier to timely screening, diagnosis, care seeking, and adherence to treatment. TB patients further and experience discrimination at work, in healthcare contexts, within families, and in communities; their families, people they associate with or those at higher risk of infection due to social determinants of health also encounter discrimination. The NSP 2017-25 also acknowledges the intangible costs related to social stigma associated with their illness by the TB patients and their family and requires among other activities a sustained campaign to combat stigma. The strategic intervention to address this has been through the ACSM activities along with Social and Behavior Change Communication (SBCC).

53.   While the national level media campaign has helped and made a good impact on conveying the threat of TB to the public at large, at the local field level it is very limited as observed by JMM 2015 and various CIE reports. Discussions at CTD level suggests that the current communication strategy is quite old and requires updating or preparing a coherent social and behavior change communication (SBCC) strategy and action plan and adopting the same for addressing the communication requirement of the Program.

G.   Core Principle 6 - Social Conflict

54.   While there are some social conflict affected areas including the presence of left wing extremist (LWE) areas in the nine Program focus states, it is important to note that the Program interventions does not exacerbate any social conflicts as it is trying to improve upon the overall health of the residents and attempting to reach out to all vulnerable pockets for TB case finding and linking them to treatment. Exclusion of any groups in terms of caste, religion, and/ or geography by the program activities is not expected.

55.   Considering the nature of the PforR activities, OP 7.50 International Waterways or OP 7.60 Disputed Territories are not applicable to the PforR. All risks/ effects analyzed, and mitigation suggested would be applicable to public and private sector facilities and workers. The revised monitoring system should also be expanded to all entities under the Bank funded PforR.

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[8]See Tanu Anand et al., Perception of Stigma Towards TB Patients on DOTS and Patients Attending General OPD in Delhi, 61 INDIAN J. TUBERCULOSIS 35, 35 (2014); D. Somma et al., Gender and Socio-Cultural Determinants of TB-Related Stigma in Bangladesh, India, Malawi and Colombia, 12 INT'L J. TUBERCULOSIS & LUNG DISEASE 856, 858-60 (2008) ("India had the highest item-adjusted stigma index (1.17)")

H. Gender

56.   While TB is seen as a men's disease[9], the number of women with TB globally as well as in India is very high. Twenty-seven percent of the world's 10.4 million new TB cases, and 29 percent of the 1.8 million annual deaths are from India. Women and girls make up nearly 1 million of the estimated 2.8 million TB cases in India each year; it is the fifth leading cause of death among women in the country, accounting for nearly 5 percent of fatalities in women aged 30–69[10]. Although more men are affected by TB, women experience the disease differently, and gender disparities play a significant role in how men and women access healthcare in the public and private sectors. Women also experience the impact of stigma disproportionately. The rapid assessment of gender and TB in India[11] reveals the differential aspects of TB among women including that women may be diagnosed late or not diagnosed at all due to added risk of socio-cultural barriers. This includes women delay seeking care for TB ailments because of high burden of household work combined with the deprivation of health awareness, mobility, access to resources and decision-making powers. The rapid assessment found that a high level of stigma associated with TB diagnosis exists among both unmarried and married women. The unmarried women were anxious that they might not get married if they had TB and as a consequence, families hide TB diagnosis status, marrying off the women and later sending them to a relative's home to begin treatment which may cause delay in treatment and/or non-adherence to the treatment regime. For already married women, the fear of being divorced or being sent back to their natal family is an obstacle to accepting TB diagnosis and treatment. The constant struggle and priority for women and their families is to get married and stay married rather than get diagnosed, start TB treatment and adhere to it until cured. These factors considerably influence TB case detection and adherence to treatment. In addition, malnutrition substantially increases risk of TB among women with more than half of all women in the India being anaemic and one in five are underweight. To address this, a technical expert group is being constituted by CTD to develop and finalizing the collaborative framework for TB and Women in India, including develop Programmatic interventions to address the socio-cultural barriers.

57.   The key Program action required is the development and adoption of a framework for TB among women. This will include:

- Analysis of context specific, socio-cultural norms and overlapping health concerns that are likely to amplify the incidence of TB amongst women in participating states.
- Specific Programmatic interventions towards addressing socio-cultural barriers.
- Include gender specific data for TB monitoring

I. Citizen Engagement

58.   The CTD aims to enhance Community Engagement for a people centered and community led TB Response under the RNTCP by creating TB Forums at State and District level for working collaboratively

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9 Globally more men are seen to be diagnosed with TB than women and the ratio is approximately 60:40 between men and women. More men die of TB globally, both as a proportion of total cases and in absolute numbers. This has given TB the image of being a 'men's disease'. The Global TB Report 2018 mentioned in 2017, 64% of cases were among men and boys, and 36% were among women and girls.

10   https://www.newsdeeply.com/womenandgirls/community/2017/03/24/time-address-devastating-impact-tb-indias-women
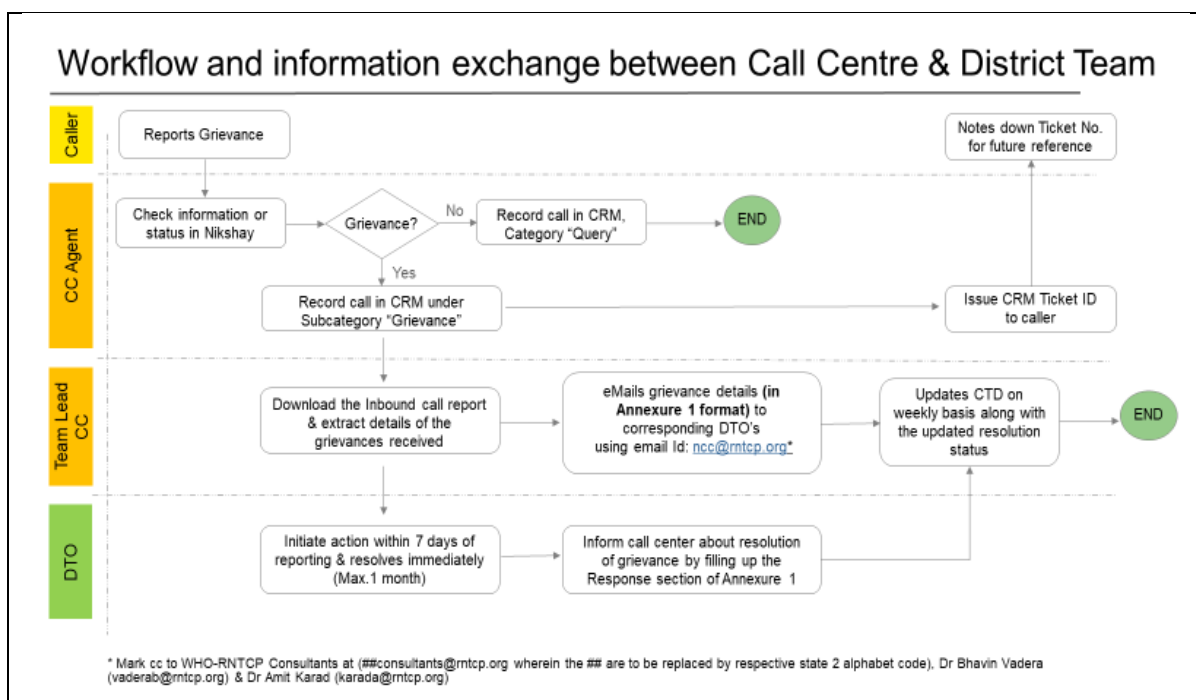
11 http://www.reachtbnetwork.org/wp-content/uploads/2018/09/REACH-CRG-Gender-Assessment-2018.pdf

with and through communities to address issues affecting their well-being, including influencing systems and serving as catalysts for changing polices, Programs and practices, more patient sensitive. The scope of community engagement is envisaged as follows: (a) Providing patient support services through community participation - including awareness creation and stigma reduction, screening for TB and TB-related morbidity, referring for diagnosis of TB and related diseases, providing treatment adherence support, linking social support to patients, and helping address equity and non-discrimination issues; and (b) Community Empowerment activities for sustainable community engagement – by informing, empowering and institutionalizing, and building accountability platform by creating mechanism of feedback on TB care services to the providers at all level using community monitoring tools. While the scope defined for community engagement is much wider than the terms of reference developed for the TB forums at State and District level which lacks in community empowerment and accountability aspect. The key Program action required is (a) Building accountability mechanism by the modifying and adding to their composition, roles and responsibilities, and terms of reference of the Central, State and District Forums; (b) State and district creating TB forums as per the expanded scope with improving accountability mechanism. And is embedded as the Intermediate Result indicator under Intermediate Results Area #4 of the Program on Strengthening RNTCP Institutional Capacity and Information Systems. This will be Measured through (a) Government approval to revised Terms of Reference of State and District TB Forum with expanded scope with respect to accountability mechanism, and (b) Number of state and districts conducting Annual TB Forum meeting and submitting minutes to STC (by districts) and CTD (by states). The Program also introduces an incentive mechanism through small disbursement every year for incremental increase in number of states and districts conducting Annual TB Forum meeting.

J. Grievance Redress Mechanism

59.   The RNTCP National Call centre "Nikshay Sampark" has a mechanism to receive inbound and make outbound calls. The calls include queries regarding services available under the Program, as well as grievances related to various aspects of Program implementation. All grievances registered by Call Centre Executives is escalated to the Centre In-charge and Team Lead for further processing. The team lead is identified as a nodal point at call centre. All grievances reported by the nodal person using a standardized format from the official email id of Nikshay Sampark i.e. nikshay.sampark@rntcp.org. All emails from nodal point will be marked to the respective District TB Officer (DTO) and State TB Officer (STO) where the patient/caller is residing currently/registered. The prime responsibility of resolution of grievances is with the DTO. All grievances are supposed to be followed up for initiating action within 7 days of reporting and should be resolved maximum within 1 month. Once the response has been received from STO/ DTO, the call centre then make call to patient/ person on the response and record whether the grievance has been resolved and whether the patient/ person is satisfied with the response. A separate cumulative line list of all grievances in excel format to be maintained and shared with CTD on weekly basis along with updated (final) resolution status.

Workflow and information exchange between Call Centre & District Team

Caller
- Reports Grievance
- Notes down Ticket No. for future reference

CC Agent
- Check information or status in Nikshay
- Grievance? — No → Record call in CRM, Category "Query" → END
- Yes → Record call in CRM under Subcategory "Grievance"
- Issue CRM Ticket ID to caller

Team Lead CC
- Download the Inbound call report & extract details of the grievances received → eMails grievance details **(in Annexure 1 format)** to corresponding DTO's using email Id: ncc@rntcp.org* → Updates CTD on weekly basis along with the updated resolution status → END

DTO
- Initiate action within 7 days of reporting & resolves immediately (Max.1 month) → Inform call center about resolution of grievance by filling up the Response section of Annexure 1

* Mark cc to WHO-RNTCP Consultants at (##consultants@rntcp.org wherein the ## are to be replaced by respective state 2 alphabet code), Dr Bhavin Vadera (vaderab@rntcp.org) & Dr Amit Karad (karada@rntcp.org)

60.   To strengthen further, the RNTCP should have a proper Grievance Redressal Policy. While the Program envisages increasing the capacity of call centre from 50-100 seats, it would be good to have well-laid policy which should be like a Standard Operating Procedure with defined escalation matrix, etc.

IV. DISCLOSURE AND CONSULTATION

A. Disclosure

61.   This draft ESSA will be disclosed in-country and on the World Bank's external website, prior to formal appraisal of the relevant PforR, to serve as the basis for discussion and receipt of formal comments. A public multi-stakeholder workshop on this ESSA and the PforR is schedule to take place in Delhi, in November 2018. Following incorporation of the feedback received from the workshop and other sources, the revised ESSA will be disclosed in-country and on the World Bank's external website.

B. Stakeholder Consultations

62.   Consultations with relevant institutions, Program affected peoples, experts, and beneficiaries are essential in the proper planning and preparation of development projects and Programs, to ensure effective identification and assessment of environmental and social effects, and to recommend measures to improve environmental and social management capacity. Stakeholder consultations are an integral part of the ESSA process and will be carried out consistent with applicable World Bank principles. The Bank has and will continue to engage in other formal and informal consultations as needed prior to finalization of this ESSA and the PforR. The points of discussions were to collect information as an input for the followings activities:

   i.   Assessment of relevant environmental and social management systems related to the PforR principles

   ii. Assessment of the capacity and performance related to the environmental and social management procedures and processes relevant to The Program, and past performance on previous Bank Funded operations

   iii. Development of an action plan to enhance environmental and social management capacity and performance of the PforR Program; and

   iv. Development of performance monitoring and implementation support Program.

63.   Table 6 below outlines a summary of the formal and informal consultations held till date are they contributed directly to important parts of the ESSA and the major findings and recommendations received.

Table 6 Formal and Informal Consultations held

Sl. No.	Location	Sites Visited	Officials/ People Met
1	**Hyderabad, Telangana**	• STDC • State Reference Lab • EQA Lab, • BPHRC (Private C&DST Lab under NGO PP Scheme)	Dr. Sumalatha (State Epidemiologist), Dr. Sneha Shukla (WHO Consultant), Mr. Srikant (IRL, Microbiologist), Mr. Anil Kumar (Technical Officer) IRL Lab staffs
2.	**Lucknow, UP**	• District TB Hospital • Central Biomedical Waste	Dr. Santosh Gupta, State TB officer

Sl. No.	Location	Sites Visited	Officials/ People Met
		Treatment Plant by M/s Watergate	
3.	**Udaipur, Rajasthan**	- DMC lab, - CBNAAT lab in District TB Clinic (inside Maharana Bhupal Hospital campus) Haathipole, Udaipur - RNT- Medical college- DMC Lab - DR-TB ward, BADI, Udaipur - RNTCP-laboratory, Geetanjali Medical College & Hospital, Udaipur	Dr. Dinesh Kothari (DTO), Dr. D. S. Rao (S.M.O), Dr. Sanjay Sinha (WHO- consultant), Mr B.K. Gupta(NGO – ALERT, and member Child Welfare Committee); Mr. Naresh Paneri and Mr. Tyag Narayan (NGO – SWACH); Dr. Manoj Arya (RNT medical college); Laboratory technicians; Dr.S.K. Lohadiya, Head, Dept. of TB & respiratory disease, Geetanjali Medical College & Hospital; All STS and STLS of the district
4.	**Udaipur, Rajasthan**	- Jhadol PHC in tribal area, - SWACH NGO training centre at Jhadol block	Free and prior informed consultation (FPIC) with tribal community in Jhadol block, including discussion with MO, ANM and other outreach staffs of Jhadol PHC and tribal TB patients (men and women); discussion with NGO (SWACH) extension workers placed in each tribal village/ panchayat of the block working as TB extension worker (called Swach Mitra).
5.	**Pune, Maharashtra**	- IRL lab, - DMC lab - TB ward - Rural health centre	Dr. Padmaja Jogeshwar, STO Dr. P.L. Mane, AD HS; Dr. Sanjay Darade DTO; Dr. Sandeep Bharaswadkar WHO consultant, Dr. Vaibhav Saha WHO consultant; Ms. Shilpa Balyam C&DST STDC (IRL- microbiologist); Dr. Balaji Lakade Medical Officer PHC; Dr. Udawant & Dr. Sayali ,TB ward and other lab staff.
6.	**Pune, Maharashtra**	Dimphe Khurd Tribal PHC, Awegaon	MO, ANM, STS, STLS, other PHC staffs including four ASHAs associated with PHC and working in tribal villages; FPIC with tribal community and patients including men and women
7.	**Mumbai, Maharashtra**	Pt. MM Shatabdi Hospital,	Dr. Shalini Bhagat Dy Director TISS;

Sl. No.	Location	Sites Visited	Officials/ People Met
		▪ Govandi, CBNAAT lab, ▪ TB diagnostic centre (DR TB centre); Microbiology Lab, Sir JJ hospital and BMWM; ▪ 2nd October Health post- Bhoiwada, Parel; and Group of TB Hospital- SEWRI, CBNAAT and Biochemistry Lab	Ms. Shweta Bajaj Sr Program Manager, Saksham TISS; Dr. Narender G. Sutar DTO, CBNAAT lab; Dr. Dhayagude BMW incharge; Dr. Shubhangi Mankar SMO DRTB; Dr. Ameeta A. Joshi, MD (Microbiologoy) SJJ hospital; Dr. Ajay Dhawale, DTO; Dr. Lalitkumar D Anande, Medical Superitendent GTB hospital, Sewree, Mumbai and Dr. Amit Karad, WHO consultant

C. Summary of Multi-Stakeholder Workshop

The Bank-sponsored multi-stakeholder workshop in New Delhi on 26 November 2018, it was attended by CTD, State TB officers from Karnataka, Assam, Maharashtra, and UP from and civil society. Major points raised by the participants are summarized below and provided in detail in Annex 7. The participants concurred with the ESSA findings and issued raised, and subsequent mitigations. In addition, the participants had the following suggestions to strengthen environment and social performance under the Program

(a)   States require flexibility for planning and implementing Tribal Strategy. The State incentive grants can be utilized for showcasing innovations in this area

(b)   In order to operationalize TB forums at State and district level, and support State TB cell, it would be useful to engage a professional agency/ institution.

(c)   Creation of specialized unit in NTI Bangalore that can cater to servicing and maintenance of key lab equipment (bio-safety cabinets, AHUs, and centrifuge). This would cater to the 64 IRLs in India. This would effectively transition this responsibility from NGO FIND which was providing technical support to RNTCP laboratory network, which was created under another externally supported project to RNTCP.

(d)   Hiring of State officers/experts to supervise, monitor and strengthen BMW, IC and AIC.

(e)   Hiring of State social expert to supervise and monitor the implementation of social safeguards activities, including citizen engagement, ACSM, gender, tribal health issues.

(f)   Mainstream AIC capacity and responsibilities to plan and implement with IC officers of medical colleges and district IC committees so that capacity and knowledge built remains institutionalized.

(g)   Creation of easy to understand guidance handbook for environment health and safety management for STOs and DTOs to include key aspects of BMWM, IC and AIC.

(h)   Develop abbreviated guidelines for planning and retrofitting DR-TB centers to conform with national guidelines on AIC, IC and BMWM. This includes guidance on consumables (PPE, chemicals, vendors, suppliers)

(i)   Bio-medical engineers at the district level posted under NHM can be utilized to provide support for RNTCP lab network (DMC and TU)

V. INPUTS TO THE PROGRAM ACTION PLAN

A. Introduction

64.   This section summarizes the measures that the ESSA Team recommends be taken during Program implementation to address important gaps identified above between the Program system and the PforR core principles and key elements as well as to address any capacity shortcomings.

65.   The ESSA recommends the following actions for inclusion in the Program Action Plan (a) Establishment of environment and social experts at state level (providing full-fledged program planning and management with due considerations on environmental and social Aspects), and (b) Strengthening of RNTCP Technical and Operational Guidance. At CTD level; institutional guidelines and capacity to align the Programs towards better environmental and socially sustainable operations need improvement. There is scope for improving the existing technical guidelines and documents through careful program planning, capacity building and monitoring.

66.   During implementation, the World Bank will continue to consult with Program counterparts and provide support to help resolve implementation issues. The Bank will also monitor PAP implementation as part of Program Performance The recommendations and proposed actions are described in detail below.

B. Recommendations to be Included in the PAP.

Table 7 below presents the actions that the ESSA Team recommends be included in the Program Action Plan (PAP).

Action Description	Responsibility	Recurrent	Frequency	Due Date	Completion Measurement
1. Update RNTCP tribal action plan to strengthen outreach in tribal and hilly areas, ACSM and SBCC.	CTD	No	Onetime	December 31, 2019	Approved Updated RNTCP Tribal Action Plan
2. Develop SOP for servicing and decommissioning key lab safety equipment.	CTD	No	Onetime	December 2019	SOP published on CTD webpage and shared with IRLs

3. Central, State and District TB Forum strengthened for improving the accountability mechanism by: i. Building accountability mechanism by the modifying/ adding to their composition, roles and responsibilities, and terms of reference of the Central, State and District Forums. ii. State and district creating TB forums as per the expanded scope with improving accountability mechanism.	CTD	Yes	Annual; Increase in number of states and districts conducting Annual TB Forum meeting.	December 31, 2019	Government approval to revised Terms of Reference of State and District TB Forum with expanded scope with respect to accountability mechanism. Measured through number of state and districts conducting Annual TB Forum meeting and submitting minutes to STC (by districts) and CTD (by states)
4. CTD Strengthens Data Collection and Monitoring of Tribal Population Transport Reimbursement, and strengthen DBT mechanism for the same. Annual CTD report to capture coverage and trends in DBT for tribal populations	CTD	Yes	Continuous	December 31, 2019	Data Collection and Monitoring Plan for Tribal Populations Annual TB Report with data on DBT for Tribal Populations
5. Development and adoption of framework for TB among genders. This will include: i. Analysis of context specific, socio-cultural norms and overlapping health concerns that are likely to amplify the incidence of TB amongst women in participating states ii. Specific Programmatic interventions towards addressing socio-cultural barriers iii. Include gender specific data for TB monitor	CTD	No	Onetime	December 31, 2019	Framework for TB Among Women Adopted by CTD for Program Management Purposes

C. Recommendations to Environmental and Social Action Plan as part of PIP

There are opportunities for improving and strengthening the way in which CTD manages environmental and social impacts and risks associated with its activities, particularly in relation to capacity building for waste management, accidents/ biosafety and infection control measures. Discussed below are actions required for appropriate management of identified environmental and social concerns.

67.   It was also recommended to include an intermediate results indicator on airborne infection control. The CTD will conduct an annual audit of AIC measures in select states, accordingly, recommendations will

be made to strengthen implementation, capacity and address gaps. The costs relating to the external annual audit will be included.

Action Description	Responsibility	Timeframe	Indicators
Strengthening environmental, health and safety management capacity			
1. Hiring of Environment and Social Experts in Program selected states (as part of HR plan)	CTD	As per RNTCP staffing plan	E & S experts in place in all 9 focus states and at CTD
2. Training and capacity building of medical and lab workers on key environment health and safety issues. (key training areas are provided in Annex 5)	CTD	Preparation of Training calendar by August, 2019	Detailed training calendar prepared
3. The CTD formulates and adopts health and safety advisory for staff/workers involved in the transport of sputum. All persons transporting specimens should follow the new advisory issued under the RNTCP and be provided with training on biosafety and spill kits in case of accidents.	CTD inconsultation with NRLs	August 2019	Health and Safety Advisory for Sputum Transportation Published and disseminated to State TB Units for implementation
4. Review and Strengthen EHS and biosafety criteria in selection and evaluation of private sector laboratory for C&DST under PP scheme	CTD	December 2019	Updated documents notified and under implementation
5. Grievance Redressal SOP. While the Program envisages increasing the capacity of call centre from 50-100 seats, it would be good to have well-laid policy which should be like a Standard Operating Procedure with defined escalation matrix, etc.	CTD	March 31, 2019	Approved Grievance Redressal SOP
6. Updating/ preparing a coherent social and behavior change communication (SBCC) strategy and action plan and adopting the same	CTD	December 31, 2019	Approved revised SBCC strategy
7. Strengthen coordination with PWD engineers on healthcare facility infrastructure needs (ventilation systems, ETPs, BMW management)	CTD and State TB officers.	June 2020	Workshop held with CTD, States, Experts and PWD representaitves. Workshop proceedings will be used to furthur strenghten planning in new healthcare facilities.
8. Creation of specialized unit in NTI Bangalore (with bio-medical engineers, microbiologists) that can cater to servicing and maintenance of key lab equipment in IRLs	CTD and NRL	December 2020	Specialist unit notified and operational under RNTCP
Monitoring of Environmental and Social management			

Action Description	Responsibility	Timeframe	Indicators
9. Supervising AIC measures in high risk settings (i) communication tools (ii) behavior trainings conducted.	State TB officers	Annual	Implementation of AIC measures according to national guidelines.
10. Updating Central Level Internal Evaluation (CIE) and State Level Internal Evaluation (SIE) for specific areas such as (a) Outreach in tribal and hilly areas, (b) ACSM, (c) SBCC, (d) State and districts TB Forum meeting, and (e) gender responsiveness	CTD and State TB Officer	August 2019; Annual Monitoring	Annual report of CIE and SIE submitted to CTD

ANNEX 1: List of Document Reviewed

National Guidelines Relevant to the Project
1. RNTCP Environment Assessment and Biomedical waste management report (2013) https://tbcindia.gov.in/WriteReadData/l892s/1185049634Environment%20Management%20Plan%202020 13%20Final.pdf
2. Government of India, National Health Mission: Infection Control and Environmental Plan

http://nrhm.gov.in/about-nrhm/guidelines/nrhm-guidelines/infection-management-and-environment-plan-imep.html

3. The Indian Public Health Standards http://nrhm.gov.in/about-nrhm/guidelines/indian-public-health-standards.html

4. National Guidelines for Airborne Infection Control (2010) https://tbcindia.gov.in/showfile.php?lid=2858

Bio-Medical and other Waste Management

5. CPCB Biomedical Waste Management Rules (2016) and Amendments issued (2018) http://cpcb.nic.in/uploads/Projects/Bio-Medical-Waste/Amendment_BMWM_Rules2018.pdf

6. Technical guidelines issued by CPCB http://cpcb.nic.in/technical-guidelines-2/
    i. Guidelines for Management of Healthcare Waste in Health Care Facilities as per Bio Medical Waste Management Rules (2016)
    ii. Guidelines for CBWTFs (2003).
    iii. Guidelines for BMW Incinerators (2003). Draft Guidelines for Bio-medical Waste Incinerator (2017)
    iv. Guidelines for Bar Code System for Effective Management of Bio-Medical Waste
    v. Standards for treatment and disposal of Bio medical waste by Incineration
    vi. Environmentally Sound Management of Mercury Waste Generated from Health Care Facilities.

Revised National Tuberculosis Control Program

7. RNTCP partnership Guidelines (2014)
8. Standards for TB care in India
9. National Strategic Plan (2017-22) for Tuberculosis
10. Guideline for PMDT India (2017)
11. AIC Risk Assessment for 35 HCF (2015)
12. Technical and Operational Guidelines for Tuberculosis Control in India, 2016
13. TB India Report 2017
14. TB India Report 2018
15. Supervision and Monitoring Strategy in RNTCP, March 2012
16. Joint Monitoring Mission, 2012
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ANNEX 2: Description of Environmental and Social Management System and Capacity and Performance Assessment

A. Introduction

1.   This section describes the existing environmental and social management system of the institutions applicable in the implementation of the proposed Program. It provides an overview of the policy and legal framework and a profile of the roles and responsibilities of institutions involved in the environmental and social assessment and management.

2.   The Government of India 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.

B. Environmental and Social Management Systems

The provisions of the existing environmental legal and regulatory framework are adequate but require enabling institutional and technical capacity for compliance*.* While the provisions of the Biomedical Waste Management & Handling) Rules, 1998 – (amended on March 2018) 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 these wastes. The existing policy framework has a clear emphasis on BMWM, infection control and occupation health and safety at the workplace. The existing national and state laws and regulations provide a strong framework for environmental management in the Program. They cover a wide range of aspects relevant to the Program including management of different types of wastes (plastics, e-waste and hazardous wastes).

There are also guidelines/SOPs on lab operations which include National guidelines of Airborne Infection Control, Infection Management and Environment Plan (IMEP) guidelines, standards for TB care in India, Biosafety manuals for DST labs, RNTCP technical specifications on TB lab consumables, equipment and infrastructure. CPCB also has published guidelines/ toolkits on implementation of the BMW rules. Thus, the existing policy, legal and regulatory framework is adequate in its coverage of environmental aspects pertaining to the relevant Program activities. However, application of the legal and regulatory provisions is not consistent in the selected states due to lack of capacity and monitoring.

C. Environmental and Social Laws, Regulations and Policies

Several relevant national and state level laws, regulations and policies were analyzed for the proposed Program. The analysis examined whether or not there are significant gaps that prevent the realization of the environmental and social objectives as included in the ESSA core principles. Table 8, provides a detailed analysis of the legal and regulatory framework applicable to the Program.

Adequacy of legislative framework on environmental aspects. The provisions of the existing environmental legal and regulatory framework are adequate but require enabling institutional and technical capacity for compliance. While the provisions of the Biomedical Waste Management & Handling) Rules, 1998 – as amended up to March 2018 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 ambit of the rules has been expanded to include:

(a) camps for vaccination, blood donation, surgical or any other healthcare activity;
(b) Phasing out chlorinated plastic bags, gloves and blood bags within two years;
(d) Training and immunization for all health care workers regularly;
(e) Bar-Coding for bags or containers containing bio-medical waste for disposal;
(f) Reporting major accidents;
(g) More stringent standards for incinerator to reduce emission of pollutants; and
(h) Existing incinerators to achieve the standards for retention time in secondary chamber and Dioxin and Furans within two years.

Adequacy of legislative framework on social aspects. The existing legislative framework is adequate to ensure social sustainability and the interest of marginalized and vulnerable population including the SC and ST population, but require strengthening institutional capacity to comply. It ensures the following: (a) protection of the interest of SC and ST population, (b) non-discrimination based on religion, race, caste, and gender, (c) transparency with the right to information, (d) the right to fair compensation in case of land acquisition. However, it requires to strengthen rights-based approach for TB, to help empower affected communities seek health services and commodities as part of their right to health, and listen to their voices while tailoring the response, and involve them as partners and participants in the development of the most socially appropriate rights-based strategies to address TB effectively[12]. The focus states account for 51.5 million of the tribal population (49 percent of the India' tribal population) and have both scheduled V and Scheduled VI areas as defined under the Constitution of India with special legislative and judicial provision including customary rights in scheduled-VI areas. While the legislative framework is adequate, institutional capacities requires strengthening both at CTD level as well as state level to incorporate culturally appropriate outreach mechanisms in these areas.

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12 http://www.reachtbnetwork.org/wp-content/uploads/2018/09/REACH-CRG-LEA-2018-Full-Version.pdf

Table 9 Environmental and Social Laws, Regulations and Policies that are relevant to the Proposed Program

Sl. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Program and key Findings
1	The Constitution of India (especially, Articles 15,16 and 46)	The Indian Constitution entitles individuals with TB to certain rights. The Constitution protects the rights to life, health, non-discrimination, privacy, informed consent, housing and food. These rights are safeguarded either explicitly or implicitly under the "Fundamental Rights" part of the Constitution (Articles 13 to 35) and are enforceable in courts. Fundamental rights are interpreted in light of the "Directive Principles of State Policy" part of the Constitution (Articles 36 to 51). While Directive Principles are not themselves directly enforceable in courts as legal rights, they do establish specific duties that the government must strive to fulfil when making laws.	Relevant to the overall Program
2	Bio-medical Waste Management(Amendment) Rules,2018	Schedule 1: Categorization and Management Schedule 2: Standards for treatment and disposal of BMW Schedule 3: Prescribed Authority and duties 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 WWTPs should install compact on-site sewage treatments (i.e. primary and secondary treatment, disinfection) to ensure that wastewater discharges meet applicable thresholds	Highly relevant to the entire Program (cover labs, healthcare facilities/hospitals and clinics) Rules are adequate, however it is the enforcement of rules that remains weak. The BMWM Rules are equivalent to the WBG EHS Guidelines for Healthcare Facilities as they cover good practices such as labelling, colour bins/ bags and symbols for hazardous materials and waste. They emphasize waste reduction, segregation, storage, transportation (manifest), treatment and handling (with autoclave, incineration), health workers' occupational health and safety and public health and safety. On solid BMW there is good overall capacity and compliance. On liquid BMW, there are significant gaps in treatment and disposal of wastewater from hospitals. Other provisions of the rules

Sl. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Program and key Findings
			that are directly relevant to the Program:

All the HCFs irrespective of The type of treatment and quantity of bio-medical waste generated need to obtain authorization under BMWM Rules, 2016

State and District advisory committees on BMW should be established and advise SPCBs etc. in the handling of medical solid and liquid wastes.

All states covered under the Program have access to central biomedical waste treatment facilities. Private hospitals in India have had to comply with the requirements of the Biomedical Waste Rules using their own resources. Public hospitals are provided budget to implement BMW management.

The Private sector partnership scheme under RNTCP requires all private labs for C&DST testing to submit information on how BMW is managed at the lab, but more emphasis should be provided on trainings, and immunization of health workers who are in contact with such wastes. |
| 3 | E-Waste (Management and Handling) Rules 2011 as Amendment up to 2018 | There are policies governing the responsible disposal of e-waste generated by bulk Consumers 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 crore | Relevant as it is applicable for all HCFs and Labs under RNTCP, including private sector. The disposal of E-wastes to be done at the specified collection centres and reported annually. |

Sl. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Program and key Findings
		or more than 20 employees).	
4	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 centres, either on its own or through the authorized waste collection agency	Relevant as hospitals and labs are generators of large quantity of plastics, including non-reusable types.
5	Hazardous Waste Rules, 2016	To address the appropriate management of all x ray wastes developer so that they are safely handled and disposed.	Relevant to all HCFs and Labs as management of x-ray wastes and by products. Expansion of diagnostic services will require check x-ray service to be provided at district and block levels. Equipment would be upgraded, and new equipment would be installed. At the same time medical staff managing developer and fixers would need to be trained in their safe handling.
5	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 with regard to 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 to any renovation/upgradation work for expansion of diagnostic services and DR-TB centres/ wards.
6	The Building and Other Construction Workers (Regulation of Employment and Conditions of Service) Act, 1996 (27 of 1996) The Workmen's Compensation	There are guidelines/policies concerning public safety and worker safety integrated into infrastructure and public amenities These acts aim to improve health, safety, and general wellbeing of workers and workplaces by promoting occupational	Relevant- To address employment and conditions of service of building and other construction workers and to provide for their safety, health and welfare measures.

Sl. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Program and key Findings
	Act National Policy of Safety, health and Environment at Work Place, 2009	health and safe practices in order to eliminate occupational accidents and diseases, hence achieve better productivity in the workplaces.	
5	Water (Prevention and Control of Pollution) Act 1974 Air (Prevention and Control of Pollution) Act 1981 Environment Protection Act 1986 and 1996	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.	Relevant to all HCFs, Labs and Central Biomedical Waste Treatment Facilities- largely complied with
6	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
7	The Indian Medical Council Act 1956 The Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulations 2002)	Provisions are applicable to practicing doctors and medical professionals to provide quality service to the patients or healthcare seekers.	Relevant to entire Program
8	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
9	Infection Management and Environment Policy Framework, 2007:	IMEP has been mainstreamed within the NHM for infection control and worker safety- emphasis on capacity building and training, applicable to all healthcare centres.	Relevant- However, compliance and implementation on the ground has been disjointed, driven by different implementing agencies and multiple stand-alone training modules. Since RNTCTP is part of a general health system, conforming to IPHS and implementation of IMEP is the responsibility of each health facility under the public health system. With the enhancement

Sl. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Program and key Findings
			in capacities of health managers/administrators, health facilities will be better positioned to develop and articulate plans and budgetary requirements in their annual plans for robust implementation of IMEP.

The Central TB Division will allocate sufficient budget to support monitoring and review of airborne infection control measures for DR-TB inpatient wards under RNTCP's Programmatic Management of Drug-Resistant TB (PMDT) activities. |
| 10 | CPCB has brought out Guidelines that are relevant for the health sector

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 Bio medical waste by Incineration

Environmentally Sound Management of Mercury Waste Generated from Health | 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 license to the CTF operators, which are largely private sector players. | Relevant- BMW is listed as hazardous waste due to its infectious characteristics. |

Sl. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Program and key Findings
	Care Facilities.

CPCB Manual on Hospital Waste Management | | |
11	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.; and (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.
12	The Right to Fair Compensation and Transparency in Land Acquisition, Rehabilitation and Resettlement Act, 2013	Aims to ensure, a humane, participative, informed and transparent process for land acquisition with least disturbance to the owners of the land and other affected families and provide just and fair compensation to the affected families whose land has been acquired or proposed to be acquired or those that are affected by such acquisition and make adequate provisions for their rehabilitation and resettlement and for ensuring that the cumulative outcome of compulsory acquisition should be that affected persons become partners in development leading to an improvement in their post-acquisition social and economic status.	Not applicable as no land acquisition or resettlement is anticipated.
13	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 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	Relevant and applicable to all health care facilities and directorates

Sl. No.	Applicable Act/ Regulation/ Policy	Objective and Provisions	Relevance to the Program and key Findings
		with more than 10 employees.	
14	Fifth and Sixth Schedule Areas in the Constitution of India	In the Sixth scheduled area, the Constitution of India makes special provisions for the administration of the tribal dominated areas in four states viz. Assam, Meghalaya, Tripura. The Sixth scheduled areas have autonomous districts and autonomous regions with certain legislative and judicial powers. In the Scheduled Areas, involvement of tribal councils and communities, incorporating their views and culture specific needs will enhance their participation in the Program. Under the provisions of Fifth Scheduled Areas, the State should set up a Tribes Advisory Council (TAC) to advise the State Government on matters of welfare and development of the Scheduled Tribes in the State.	Relevant to the overall Program – Among the focus states, Assam comes under sixth schedule while Maharashtra, Rajasthan, Madhya Pradesh has scheduled-V areas and districts where Panchayat (Extension to the Scheduled Areas) Act - PESA is applicable.
15	The Panchayat (Extension to the Scheduled Areas) Act, 1996	The Ministry of Panchayati Raj, GoI, under this Act mandates for the Fifth Schedule areas to make legislative provisions in order to give wide-ranging powers to the tribes on matters relating to decision-making and development of their communities. The PESA Act empowers the Gram Sabha (the council of village adults) and the Gram Panchayat to take charge of village administration. Under the Act, Government of India stipulates to conduct consultations and obtain consent for the development Program from the tribal advisory council (TAC), Gram Sabha and the Gram Panchayat under the Fifth Schedule Areas.	Relevant to the Program – All Tribal Sub Plan (TSP) districts as 'High Priority Districts' under National Rural Health Mission. Also, the Gram Sabha have control over local institutions and functionaries including the Health Sub-centres and Anganwadi centres.

D. Institutional Framework

The implementing agency of the proposed PTETB PforR is the MOHFW. At the central level, the MOHFW's CTD is the primary responsible agency for the day-to-day implementation of the NSP 2017-25 and will provide Program leadership, management, and regulatory oversight to ensure

adherence to technical standards. At state and district levels, a multi-stakeholder health society is responsible for Program planning budgeting and administration. State government health services under the NHM, including state and district TB officers within state Departments of Health and Family Welfare (DOHFW), will be responsible for implementation of TB services. RNTCP services and systems are highly-standardized, and anti-TB medicines are procured centrally by MOHFW to ensure quality and uniformity of treatment.

E. Borrower's Past Experience in Managing Environmental and Social Risks

MOHFW has had more than twenty years of experience in working with World Bank and with more than three projects over this period clearly shows their prior experience in implementation of Bank safeguard policies. MOHFW has a continuous and long engagement with the Bank on health and nutrition projects.

The proposed Program is a continuation to the three earlier projects supported by World Bank to RNTCP since 1997. As part of second phase of the Bank supported RNTCP, the Central TB Division (CTD) of the MOHFW, developed an Environmental and Bio-medical Waste Management (BMWM) Plan. This plan was in line with the IMEP operational guidelines and policy framework and included specific activities such as: (i) Training modules for Medical Officers and Laboratory Technicians; (ii) vaccinations for all health staff as a preventative measure; (iii) dissemination of guidelines, standards, protocols to health facilities to enhance knowledge of health workers and support implementation of IMEP; and(iv) systems for recording and monitoring of waste disposal. The third project, the AUAEETC is also closed, the institutional setup is still functional and active in CTD, and the environment management framework for bio medical waste management and capacity building remains relevant. Over the years, BMW has seen considerable improvement at all levels of healthcare facilities. This is indicative of good borrower capacity to deal with the environmental and social aspects of the proposed Program.

Since RNTCTP is a part of general health system, conforming to Indian Public Health Standards (IPHS)and implementation of IMEP is the responsibility of each health facility under the public health system. It is also important to note that while health-care waste management is implemented by the Department of Health, with support from municipal bodies and private service providers for disposal, environment management issues including water, sanitation-related diseases, and solid waste management are state subjects and the responsibility is also shared by various municipal bodies. Implementation and execution is carried out through state departments (Public Health Engineering or Rural Development Engineering) or State Water Boards along with the urban local bodies.

Engagement under previous projects has helped CTD in developing guidelines for most of its activities including those associated with reaching out to tribal and difficult areas, ACSM, and communication, they should be updated with the current context and the agenda set forth in the NSP 2017-25. This includes institutional reorganizing, building capacity at all levels, updating 'Partnership guidelines', 'Technical and Operational Guidelines for TB Control in India' and monitoring mechanisms and tools such as Central Level Internal Evaluation (CIE) and State Level Internal Evaluation (SIE), specific to the areas mentioned above to address the issues raised in the NSP 2017-25 and the guidance suggested therein. In addition, there is need to build capacity to address gender concerns of the RNTCP Program and the citizen engagement that are being foreseen through TB Forum mechanism at National, State and District levels.

Table 9 Institutional Set up under RNTCP

Level	Technical Head	RNTCP positions	Capacity to be reviewed for

			environmental management
Central	Deputy Director General-TB	DDG (TB) and consists of 4-5 full time staff from the central health service of the rank of ADDG/DD (this includes dedicated staff for labs)	NRLs
State	State TB Officer	▪ Director (STDC) ▪ Epidemiologist (APO) ▪ MO – STC ▪ TB-HIV Coordinator ▪ PPM Coordinator ▪ DR -TB Coordinator ▪ State IEC Officer ▪ State Accountant ▪ Technical Officer- ▪ Proc. and Logistics ▪ DEO-STC ▪ Pharmacist - SDS ▪ Store Assistant - SDS	IRL and C&DST labs State TB Cell
District	District TB Officer	▪ Senior MO – DR TB Centre ▪ Counsellor – DR TB Centre ▪ SA – DR TB Centre ▪ MO – DTC ▪ MO-TC ▪ Senior DR TB –TB HIV supervisor ▪ District PPM Coordinator ▪ Accountant ▪ Senior Treatment Supervisor (STS) ▪ Senior TB Lab Supervisor (STLS) ▪ Lab. Techs. (LT) – RNTCP Contractual ▪ Tuberculosis Health Visitor (TBHV)	District Hospitals, which include ART centres DR TB centres District TB centres
Sub district	Block Medical Officer	▪ Medical Officer (TB Control)/ Program Officer focusing on TB services Senior Treatment Supervisor ▪ Senior TB Laboratory Supervisor	TB Unit + BPMU (NHM) BMW and AIC committees DMCs

Notwithstanding the already built capacity within the borrower's institutions, a detailed assessment of all the relevant institutional stakeholders was undertaken to identify any critical and/or significant gaps, as well as smaller shortcomings for effectively managing the environmental and social issues of the RNTCP. In addition to assessing the institutions at the national and state level, the ESSA also reviewed some of the ongoing national health programs. The institutional assessment has contributed to the resulting recommendations and Program actions that will support the further building   of   borrower   capacity.

Table 10: Capacity Gap Analysis of Relevant Institutions Related to the Proposed Program

Institution	Roles and Responsibilities	Capacity Gap Analysis
National Level Institutions		
Ministry of Health and Family Welfare (MoHFW) and Department of Health (state level)	- Deals with health care, including awareness campaigns, immunization campaigns, preventive medicine, and public health services - Heads many statutory bodies, such as, Medical Council of India (MCI), Indian Nursing Council, Dental Council of India, and Pharmacy Council of India (PCI) - Provides funds under NHM for BMWM. State health departments also have provided assistance to government hospitals for HCW management in the form of personnel training, waste management auditing, preparation of hospital-specific plans, procurement of materials and supplies, and construction of on-site disposal facilities. - Publication of list of registered health care facilities with regard to bio-medical waste	- No significant gaps identified, MOHFW is well equipped to handle their current Programs and have well laid out guidelines and processes for implementation within the applicable legal and regulatory framework. Health schemes are quite inclusive and well implemented. - RNTCP management is well embedded within the MOHFW and the national health mission (NHM) and within the general health system at the state and district levels. The RNTCP, as an integral part of the NHM is implemented through India's public health system. All disease specific Programs integrated under the NHM are committed to adoption of the IPHS and implementation of the Biomedical Waste Management Rules and the Infection Management and Environment Plan (IMEP). - The role of Departments of Health in monitoring the operations of CBMWTFs is typically unclear, though as the generator of waste and purchaser of its services, they should have the right to review and supervise the facility and its operations. This responsibility is limited to the CPCB and SPCBs. - The responsibility for ensuring the implementation of the IMEP

	generation, treatment and disposal. ▪ Coordinates with State Pollution Control Boards for organizing training programmes to staff of health care facilities and municipal workers on bio-medical waste.	lies with the MoHFW, which is the implementing agency for the NRHM. The overall responsibilities will be with the Secretary (MoHFW). The specific responsibility will be with the Infrastructure Division for Infection Management & Environment Plan (IMEP) and with Immunization Division for issues pertaining to AD syringes
Central Tuberculosis Division (CTD)	▪ The central TB division (CTD) is the nodal agency for the TB Program nationally. ▪ Responsible for policy and Program formulation and implementation of the Revised National TB Control Program (RNTCP), and preparation of Technical and Operational Guidelines for the same. ▪ The NSP 2017-25 made several recommendations to improve the institutional structure of the TB Program. One of them was to set up the national TB elimination board, a policy making body at the highest level chaired by the Prime Minister and a similar board at the state level. It also recommended implementing TB elimination efforts in a 'mission mode'. ▪	▪ While CTD is headed by the DDG (TB) and consists of 4-5 full time staff and also has contractual staff such as national consultants and experts in procurement and finance who are either supported from the domestic budget or through donor agencies, they are not adequate and need reorganizing as well as adding specific skills as suggested under the NSP. ▪ There no dedicated full-time staff looking at Environment Health and safety aspects of the Program (which includes general IC measures, and airborne infection control measures for the protection of health care staff and other patients, lab construction, and disposal of bio medical and e -wastes) Currently, DCDG Labs within CTD is looking at all aspects of labs including biosafety, and sufficient knowledge and capacity has been built to oversee this aspect. ▪ Lack of bio-medical engineers at state/regional level that can support lab equipment testing, service and maintenance. ▪ Through consultations with CTD, it was revealed that staff are

		aware of environmental, health and safety management, and aware of their responsibilities and duties designated by the laws and regulations.
		▪ With respect to implementation on environmental and social safeguard activities, the key gaps in CTD includes dedicated and skilled manpower to plan and implement partnerships, advocacy, communication and social mobilization (ACSM) and psycho social support (PSS) activities in a coherent manner.
		▪ Capacity related to M&E and citizen engagement also needs strengthening.
Ministry of Tribal Affairs (MoTA)	▪ Nodal Ministry for overall policy, planning and coordination of Programs for development of STs	▪ No significant gaps identified, as the mandate and functions of the ministry support welfare of indigenous people. The Ministry lists out the ST priority areas and the Scheduled Areas as per constitution and present them regularly in their Annual Report for easy reference and to be followed by CTD for RNTCP.
Ministry of Social Justice and Empowerment (MoSJ&E)	▪ Responsible for bringing marginalized sections of the society viz. Scheduled Castes, Backward Classes, Persons with Disabilities, Aged persons etc. into the mainstream of development by making them self-reliant. ▪ Through the Scheduled Castes Development Bureau, implements Scheduled Caste Sub-Plan (SCSP) which is an umbrella strategy to	▪ No significant gaps identified ▪ Support for marginalized section is well mainstreamed in sector Programs ▪ While interventions under the RNTCP/ NSP 2017-25 do not result in any adverse impacts and/or risks. However, most of the SC community are poor and marginalised and forms part of the lower socio-economic category of population along with STs and hence given poor living conditions vulnerable to TB. The Active

	ensure flow of targeted financial and physical benefits from all the general sectors of development for the benefit of SCs.	case finding (ACF) should also prioritize SC dominant areas for TB case findings.
MoEF&CC Central Pollution Control Board State Pollution Control Boards (SPCB) and Pollution Control Committees (PCC)	▪ The MoEFCC is the nodal agency for planning, promoting, coordinating and overseeing the implementation of environmental Programs. The Hazardous Substances Management Division in the MoEF is responsible for the overall implementation of the rules related to waste management (solid and health-care). ▪ The Central Pollution Control Board (CPCB) establishes standards, compiles data and plays an advisory role to the MoEF on technical matters. It Prepares Guidelines on bio-medical waste Management for the Ministry. ▪ The CPCB is the key authority at national level for regulation of air pollution, water pollution with regards to construction activities and disposal of construction wastes. ▪ CPCB, the State Pollution Control Boards	▪ Although the MoEFCC/ CPCB has notified the BMWM Rules, 2016 and 2018 (draft) implementing agencies specified in the rules (such as municipalities, hospitals and district authorities) do not fall under its administrative control. Attempts at enforcement therefore need to be strengthened, especially within the public health-care sector. Better institutional coordination could help strengthen BMW management ▪ Collection, Transport and final disposal of BMW is in most cases done by certified agencies in the private sector that provide the colour coded bags and bar codes, CPCB monitors this aspect through annual reports from SPCBs and CBMWTFs along with online monitoring. ▪ There is little involvement of the Central Pollution Control Board (CPCB) in identification of training development needs, development of SOPs on environmental health and safety management, and biomedical waste management. ▪ Collection of other solid waste (other than the biomedical waste) from the health care facilities is carried out per the Municipal Solid Waste (Management and handling) Rules, 2000 by the municipality.

	(SPCB) and Pollution Control Committees (PCC) enforce environmental legislations in the states and in union territories, respectively. Both CPCB and SPCBs/PCCs are scientific/technical organization which are also responsible for setting the technology standards of equipment, issuance of authorizations and licenses for operations of health-care facilities and their waste treatment equipment (incinerators, autoclaves etc.)	
National Reference Laboratory, (NIRT) Chennai and (NTI) Bangalore National Reference Laboratory Coordination Committee	▪ Provide Training to all IRLs and C&DST facilities on Safety in the laboratory: Disinfectants and Coping with Lab accidents ▪ Provide external quality assurance for private sector labs ▪ The laboratory network and diagnostic services are guided by the National Expert Committee on Diagnosis and Management of Tuberculosis the apex committee which provide the technical advice to the Program for the laboratory	▪ No significant gaps identified. Visits to IRLs revealed that trainings (biosafety, infection control and BMWM) are being routinely provided by the NRLs to the IRLs ▪ EQA is being conducted as per the RNTCP guidelines ▪ Reference and guidance documents issued by the NRLs is adequate for environment health and safety and biosafety management.

	policy. National Reference Laboratory Coordination Committee reviews the progress and facilitates newer initiatives. ▪ NRLs develop SOPs for the technical procedures, equipment maintenance, infection control, and recording and reporting ▪ Under NSP, National TB Institute Bangalore will be the nodal institute for building capacity of sentinel surveillance sites at labs in public and private sector.	
National, State, and District Airborne Infection Control Committees	National AIC Guidelines require a National, State and District Airborne Infection Control Committee to be established to provide coordination, and provide technical guidance for their implementation, evaluation, and revisions. The airborne infection control activities at the district are undertaken by the Sub-Committee on Biomedical Waste Management / Infection Control (SCBMW/ IC) under the District Health Society (DHS). Their primary role is sensitization of stakeholders to AIC.	▪ Multiple levels of AIC coordinating bodies have not streamlined the process in implementing recommended infection control activities. Though ToRs are provided by the national guidelines, institutional mechanisms need more clarity, for example districts are also under administrative arena of the District Health Societies.

State Level Institutions		
IRLs and C&DST facilities	▪ There is at least one IRL per state, situated in the STDC campus or an identified location in a state government hospital. ▪ The IRL provides culture and DST for the category IV services in the State and its capacity has been built with support from central level by additional training. ▪ The IRL conducts on-site evaluation visits to districts for sputum microscopy at least once a year. ▪ The IRL undertakes panel testing of STLS at each DTC. The IRL ensures the proficiency of staff performing RNTCP smear microscopy activities by providing training to laboratory technicians and STLS. ▪ In additional to IRLs, RNTCP also involves the microbiology department of Medical colleges for providing diagnostic services for drug resistance Tuberculosis, Extra-pulmonary Tuberculosis (EP-TB) and research. The RNTCP provides additional human resources, equipment's and training to C & DST	▪ There are HR issues critical for sustaining C/DST laboratory services which require urgent attention. Vacant positions and lack of qualified manpower, including dedicated biomedical engineers. ▪ Technical Specifications provided for C&DST lab infrastructure, consumables and equipment is adequate ▪ Biosafety Guidance manual is comprehensive and adequate to maintain environment health and safety standards and in line with the WBG WHS guidelines for healthcare facilities ▪ EHS criteria for Accreditation private sector / medical college mycobacteriology laboratory for culture and DST under RNTCP can be strengthened further to build in (i) repotting mechanisms for accidents/ spills (ii) trainings and (iii) servicing of key safety equipment.

	laboratories.	
State TB Cells	▪ State TB Cells oversee the work at state and district levels towards planning and implementation of RNTCP Program activities and works under the Principal Secretary- Health and Family Welfare and Mission Director- NHM. ▪ Given that health is under state mandate, STO is administratively accountable to the State Government and technically coordinate with CTD for implementation of RNTCP Program. ▪ The State TB Cell is headed by State TB officer (STO) and supported by Director State TB Training and Demonstration Centre (STDC), Deputy STO and contractual staff like TB-HIV coordinator, PPM coordinator, DRTB coordinator, State Accountant, Procurement Officer etc.	▪ While the NSP envisages further strengthening of the State TB Cell, the key gaps in planning and implementation of environmental and social safeguard activities require dedicated and skilled manpower to plan and implement the following: (a) Partnerships, advocacy, communication and social mobilization (ACSM) and psycho social support (PSS) activities in a coherent manner; (b) Air-borne infection control measures and bio-medical waste management. ▪ It also requires strengthening in the inter-institutional coordination mechanism with NHM and other health directorates, as well as with other departments such as Women and Child Development (WCD) and Department of Tribal Affairs for effective implementation of environmental and social safeguard activities.
National Health Mission	▪ Works to pool all resources available in implementation of the Programs	▪ No significant gaps identified on the social side except a better coordination will help bring synergy

(NHM)	▪ All National Health Programs at the State and District level are brought under one umbrella of NHM ▪ Provides funding support for BMWM through CTFs ▪ Has six financing components i.e. (1) NRHM-RCH Flexi pool, (2) NUHM Flexi pool, (3) Communicable disease Flexi pool, (4) Flexible pool for Non-communicable disease (NCD) including Injury and Trauma, (5) Infrastructure and Maintenance, and (6) Family Welfare Central Sector components ▪ Funding for TB Program is through NHM Communicable disease Flexi-pool under two separate budget lines for (a) General Component, and (b) Externally Aided component.	▪ While adequate funding is provided, need to improve monitoring of BMWM. ▪ Infection control and environmental guidelines for HCFs have been prepared, though dissemination of guidelines to health facilities to enhance knowledge of health workers needs to be enhanced.
Public Works Department (PWD)	▪ Constructs and maintains buildings of various Government Departments ▪ Will construct or rehabilitate and repair healthcare facilities and laboratories including for TB unit	▪ Coordination between PWD (engineers and architects) and State committees on AIC would facilitate better implementation of AIC plans- Health facility design should consider TB infection control as integral part of building plans.
Tribal Welfare	▪ Implements the Programs related to the welfare of Scheduled Tribe population in the	▪ No significant gaps identified ▪ TSP planning and implementation with detailed guidelines and

Department	state for their socio-economic advancement. In some states also implement the Program related to welfare of Scheduled Caste population. ▪ Nodal department for the formulation and implementation of TSP at State Level	budgetary process being done well
Women and Child Department and Social Welfare Department	▪ The Women and Child Department and Social Welfare Department in some states are a separate department, while in others they are a merged department following similar mandate to their target population. ▪ Entrusted with ensuring the welfare of the poor, the down-trodden, Women, Children, Senior Citizens and trans-genders ▪ Promotes empowerment and improvement of social status of women ▪ Plans and implement nutritional support Program under the National Nutrition Mission/ ICDS Program.	▪ No significant gaps identified
State Pollution Control Board	▪ The 'prescribed authority' for enforcement of the provisions of BMW rules in respect of all the health care facilities is the respective State Pollution Control Board (SPCB)/ Pollution Control Committee (PCC).	▪ SPCBs are generally under staffed for adequate monitoring but have adequate technical capacity and role clarity.

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	- State pollution Control Board is entrusted with monitoring and ensuring compliance to environmental regulations including Biomedical Waste Management Rules, 2016 - Grant of authorization to Common Biomedical Waste Treatment Facilities. - Action against health care facilities or common bio-medical waste treatment facilities for violation of these rules. - Monitoring CBWTFs and Healthcare Facilities to ensure compliance to BMW Rules, 2016, and issue of notices, orders and penalties etc. for non-conformance as per Environment Protection Act, 1986. - Organize training Programs for staff of health care facilities and common bio-medical treatment facilities and State Pollution Control Boards or Pollution Control Committees Staff on segregation, collection, storage, transportation, treatment and disposal of bio-medical wastes. - Inventory of occupiers and data on bio-medical waste generation, treatment & disposal.	

	• Grant consent to and publish the list of registered or authorized Recyclers. (E - Waste) • Undertake and support third party audits of the common bio-medical waste treatment facilities in their State	
State Bio Medical Waste Committee	• Each state needs to constitute a committee to advise the state government and the SPCBs about implementation of the BMW rules. The committee is under the chairmanship of the health secretary include representatives from the departments of Health, Environment, Urban Development, State Pollution Control Board or Pollution Control Committee and urban local bodies.	. Coordination and participation among different stakeholders—in particular, state environmental and health agencies, local authorities, health care facility representatives, academia, and NGOs is also needed.
District and Sub-District Level Institutions		
District TB Centre	• The Chief District Health Officer (CDHO)/ Chief District Medical Officer (CMHO)/ Chief Medical Officer (CMO)/ Civil Surgeon is responsible for all medical and public health activities in the district including the TB Program. • The District Tuberculosis Officer (DTO) is	• Field visits to Pune and Udaipur districts, and analysis of sanctioned positions and vacancy suggests gaps with number of positions vacant at all levels especially at DR-TB counsellors, Medical officers and the lab assistants. • Discussion with STS and STLS suggests very low salary and absence of benefits being one of the main reasons for vacancy. • Apart from adequacy of human resources at district and block

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	responsible for planning, implementing, training, supervision and monitoring of the TB Program at the district level. Have separate budget allocated for the TB Program by the State NHM. • At the district level DTO manages the Program and is supported by DR-TB/HIV-TB coordinator, PPM coordinator and accountant as well as the MO-TC, Senior Treatment Supervisor (STS) and Senior Treatment Laboratory Supervisors (STLS) at the sub-district level.	level, a key gaps exists in DTCs coordination with CMHO/CMO managing NHM Program with separate budget and with other district level agencies/ institutions. • Discussion with DTOs suggests gap in procurement of services related capacity leading to gap in ACSM and partnership activities. • Implementation of AIC measures in DR-TB and ART centres needs strengthening.
Tuberculosis Unit (TU) at sub-district level	• TU is the nodal point for TB control Program at the sub-district level and aligned at the NHM block Program unit. The Block Medical Officer also functions as the MO-TC and is trained under RNTCP Program. • The TU has the microscopy centre and also referred as Designated Microscopy centre (DMC) under the Program.	• Mentioned as above.

Relevant National Programs

3.   **National Health Mission (NHM)**: The National Health Mission (NHM) is an overarching mission within the National Rural Health Mission (NRHM). It was launched in 2005 and the National Urban Health Mission (NUHM) in 2013 - the other Sub-mission of NHM. The vision of the NHM is the "Attainment of Universal Access to Equitable, Affordable and Quality Health Care Services", accountable and responsive to people's needs, with effective inter-sectoral convergent action to address the wider social determinants of health. The State Health Society under the Department of Health and Family Welfare (DoHFW) is responsible for implementation of NHM. NHM has six financing components i.e. (i) NRHM-RCH Flexi pool, (ii) NUHM Flexi pool, (iii) Flexible pool for Communicable disease, (iv) Flexible pool for Non-communicable disease including Injury and Trauma, (v) Infrastructure Maintenance, and (vi) Family Welfare Central Sector component. The TB Program is funded through the flexible pool for communicable diseases and implemented through the State TB Cell administratively reporting to State NHM and technically reporting to CTD at the national level.

4.   **Tribal sub plan (TSP) and Scheduled Caste sub plan (SCSP)**: The strategy of Tribal Sub Plan (TSP) has been in force since 1974, to ensure adequate flow of plan resources for the development of Scheduled Tribes. The strategy of Scheduled Castes Sub Plan (SCSP) (earlier known as the Special Component Plan for Scheduled Castes) has been in force since 1979-80, to ensure a proportionate flow of plan resources for the development of Scheduled Castes. As per the revised 2014 guideline for implementation of TSP and SCSP, funds are placed under a separate Minor Head '789' and '796' to ensure their non-diversion to any other schemes. TSP funds are earmarked by the state through their annual budget under each of the department's budget including the budget of DoHFW also earmarked in proportion to the tribal population living in the state. Many states and districts use this fund to extend their Program activities, especially the ACSM activities in tribal areas.

ANNEX-3 Stakeholder Consultations - Key Comments Received through Consultations

Sl. No.	Consultations Undertaken	Key Issues Noted	Officials/ People Met
1	Hyderabad – STDC, State Reference Lab, EQA Lab, and BPHRC (Private C&DST Lab under NGO PP Scheme)	i. Fire detection and alarm systems at IRLs not in working condition i. Health insurance not provided to contract staff at IRL ii. Health checkup before enrolment in the TB laboratory, at regular intervals thereafter, annually or bi-annually, and any biohazard incident needs stronger adherence. iii. AMCs for critical equipment is an issue and needs to be addressed. Similarly, BSCs are over 10 years old and need replacement (causing negative pressure issues) iv. Need for dedicated bio-medical engineer in labs, overall staffing capacity is weak) v. Access control systems were lacking at IRL but were in place at BPHRC vi. Accident reporting can be strengthened, and remedial measures vii. Disposal of used chemical reagents is done through disinfection and disposal in sewer (IRL) and soak pit (BPHRC) viii. Biomedical waste from labs was being segregated and disposed in correct bins. Collection system is done through private sector. ix. BPHRC is following good protocols for biosafety, health, cleanliness and safety of workers.	Dr. Sumalatha (State Epidemiologist), Dr. Sneha Shukla (WHO Consultant), Mr. Srikant (IRL, Microbiologist), Mr. Anil Kumar (Technical Officer) Dr.Sumalatha (State Epidemiologist), Dr.Sneha Shukla(WHO- Consultant), IRL Lab staffs
2.	Lucknow, UP (Discussion with State TB officer)	i. Training for Infection control for the staff is provided for time to time. However, the training needs to be strengthened for the staff which is risk-prone and works in poor environmental conditions. ii. Some of the larger HCFs have proper water and sanitation facilities but generally these need to be improved. The problem is far more acute in the Urban Areas where there is a lack of proper hygiene, water and Sanitation facilities. iii. More emphasis needs to be placed on formulation and functioning of HCF level BMW and IC Committees. iv. Implementation of AIC plans has been weak, though there have been guidelines provided for sharp waste disposal and Airborne Infection Control Trainings. v. Delays of several days has been reported in many such cases of	Dr. Santosh Gupta, State TB officer

Sl. No.	Consultations Undertaken	Key Issues Noted	Officials/ People Met
		BMW collection from lab facilities. Fresh directives, however, have been issued to alleviate this problem.	
		vi. There is no special provision for PPE for this purpose. Health check-ups etc. are also not regularly done.	
		vii. Reporting issue with respect to female patients. Social mobilization and IEC with respect to reducing stigma associated with TB among women and addressing social determinants are generally missing and need be brought under the Program.	
3.	**UDAIPUR (Rajasthan) DMC lab, CBNAAT lab in District TB Clinic (inside Maharana Bhupal Hospital campus) Haathipole, Udaipur; RNT- Medical college-DMC Lab, MDRTB ward, BMWM, BADI, Udaipur; And RNTCP-laboratory, Geetanjali Medical College & Hospital, Udaipur**	i. Detection and alarm Systems at DMC, CBNAAT labs and TB ward needs Fire augmentation. Currently not installed. ii. AIC/IC committee not formed iii. Due to heavy load of samples of CBNAAT/GeneXpert process is always delayed. Require more CBNAAT machines. iv. HR issue: shortage of staff- Laboratory technician v. Printer is requiried for reporting CBNAAT results vi. Requirement of N-95 mask (PPE) for the safety of staff working in lab/TB ward in HCFs. vii. Health insurance not provided to contract staffs at DMC, CBNAAT, RNTCP- laboratory and other staff of the HCFs. viii. Health checkup record is not maintained (a) before enrolment in the TB laboratory (b) No health checkup at regular intervals thereafter ix. AMC for critical equipment is an issue and needs to be addressed. x. Accident reporting can be strengthened and remedial measures. xi. E- waste and spill management is required in HCF. xii. Disposal of used chemical reagents is done through disinfection and disposal in municipal sewage system. xiii. Biomedical waste from labs and HCF was being segregated and disposed in correct bins. Collection system is done through private sector. xiv. CTF facilitator is collecting BMW on alternative/2nd day (within 48 hours). Need strengthen for daily/regular collection of BMW. xv. Private hospital is following good protocols for biosafety, health, fire, cleanliness and safety of workers. xvi. BMWM, Safety, PPE and IC training is requiring for the staff. Bar coding on waste disposal bags are not being done.	Dr. Dinesh Kothari (DTO), Dr. D. S. Rao (S.M.O), Dr. Sanjay Sinha (WHO- consultant), Mr B.K. Gupta(NGO - – ALERT, and member Child Welfare Committee); Mr. Naresh Paneri and Mr. Tyag Narayan (NGO – SWACH); Dr. Manoj Arya (RNT medical college); Laboratory technicians; Dr.S.K. Lohadiya, Head, Dept. of TB & respiratory disease, Geetanjali Medical College & Hospital; All STS and STLS of the district

Sl. No.	Consultations Undertaken	Key Issues Noted	Officials/ People Met
		xvii. Shortage of Slide boxes (post microscopy the slides are retained for up to 2 months).As per the guidelines slides are to be preserved up to 3 months in slide boxes.	
		xviii. Proper/adequate ventilation, maintenance and exhaust fans required in the TB ward/DMC lab (as per guidelines of ACH flow).	
		xix. While general health system through NHM has good IEC budget and activities, integrating TB in that will enhance reach.	
		xx. CMHO generally not aware of TB Program as all financial powers are vested with DTO and TB is exclusively under DTO, ensuring mechanism for CMHO to review TB Program in the district and advise and involve will help in addressing some of the gaps. TB forum could be a mechanism to do that.	
		xxi. No State and District TB forums are being initiated as the directive from Chief Secretary suggests no new forum to be created. This requires resolution by CTD.	
		xxii. Remuneration of STS and STLS are much lower and require a relook in commensurate to their work as similar positions under NHM and other departments.	
		xxiii. Financial guideline with 10 percent additional fund for tribal areas is not sufficient. Also, the financial norm for engaging NGOs for community mobilization is quite less and NGOs have to depend on other sources of fund to work as required. This should be revisited by CTD for revision.	
		xxiv. One of the major challenges at DTO level is to do proper procurement of services by NGOs and other agencies and require capacity building in this procurement of services.	
4.	Jhadol PHC in tribal area, SWACH NGO training centre at Jhadol block	i. Overall the community support the Program and see the benefit from it. ii. No tribal patients receiving the transport reimbursement as the district and the block is not notified by STC as tribal area – which is non-adherence to following Ministry of Tribal Affairs designated tribal areas. iii. The SWACH Mitras – trained volunteers by the NGO working in each of the tribal village of the block helped tremendously in case finding and linking with treatment. However, the NGO could support them through trying to source fund from NHM under the	Free and prior informed consultation (FPIC) with tribal community in Jhadol block, including discussion with MO, ANM and other outreach staffs of Jhadol PHC and tribal TB patients (men and women); discussion with NGO (SWACH) extension workers placed in each tribal village/ panchayat of the block working as TB extension

Sl. No.	Consultations Undertaken	Key Issues Noted	Officials/ People Met
		Tribal Sub Plan head for doing other activities.	worker (called Swach Mitra).
5.	**Pune: IRL lab, DMC lab, TB ward and Rural health centre**	i. AIC committee not formed ii. Sample for GeneXpert analysis always collected from other districts within 2-3 days by courier iii. HR issue: shortage of staff- Laboratory technician iv. Space between bed to bed is not followed as per rules in TB wards v. BMWM training requires to the staff and bar coding on waste disposal bags are not being done. vi. Stock shortage of BMW collecting color polybags vii. Health insurance not provided to contract staffs at DMC, RNTCP, IRL laboratory and RHC. viii. AMC for critical equipment is an issue and needs to be addressed. ix. Accident reporting can be strengthened and remedial measures. x. E- waste and spill management is required in HCF. xi. Disposal of used chemical reagents is done through disinfection and disposal in municipal sewage system. xii. Biomedical waste from labs and HCF was being segregated and disposed in correct bins. Collection system is done through private sector. xiii. Ventilation, repairing and maintenance require in DMC lab.	Dr. Padmaja Jogeshwar, STO; Dr. P.L. Mane, AD HS; Dr. Sanjay Darade DTO; Dr.Sandeep Bharaswadkar WHO consultant, Dr. Vaibhav Saha WHO consultant; Ms. Shilpa Balyam C&DST STDC (IRL-microbiologist); Dr. Balaji Lakade Medical Officer PHC; Dr. Udawant & Dr. Sayali, TB ward and other lab staff.
6.	Dimphe Khurd Tribal PHC, Awegaon, Pune	i. Overall the community support the Program and see the benefit from it. ii. ASHAs and ANMs linked to PHC doing active case finding and are able to link TB patients to treatment. iii. One of the challenge faced is for x-ray facility not being nearby and no transportation assistance from the Program for the same being received.	MO, ANM, STS, STLS, other PHC staffs including four ASHAs associated with PHC and working in tribal villages; FPIC with tribal community and patients including men and women
7.	**Mumbai: Pt. MM Shatabdi Hospital, Govandi, CBNAAT lab, TB diagnostic centre (DR TB centre); Microbiology Lab, Sir JJ hospital and BMWM;**	i. AIC committee formed. Need strengthened. ii. Behavior changes of staff towards the adopting safety and BMWM, Awareness for Air borne disease control/ / health safety and general cleaning of the hospital. iii. Shortage of PPE/masks/gloves for Laboratory staffs iv. HR issue: shortage of staff- Laboratory technician, Doctors and Counselors	Dr. Shalini Bhagat Dy Director TISS; Ms. Shweta Bajaj Sr Program Manager, Saksham TISS; Dr. Narender G. Sutar DTO, CBNAAT lab; Dr. Dhayagude BMW incharge; Dr. Shubhangi Mankar SMO DRTB; Dr. Ameeta A. Joshi, MD

Sl. No.	Consultations Undertaken	Key Issues Noted	Officials/ People Met
	2nd October Health post- Bhoiwada, Parel; and Group of TB Hospital- SEWRI, CBNAAT and Biochemistry Lab	v. Health insurance is not provided to contract staffs at CBNAAT, Microbiology laboratory, DRTB centre and other staff of the HCFs. vi. Health checkup record is not maintained in CBNAAT laboratory and health checkup is not being at regular intervals. vii. Shortage of BMW collecting color polybags supply viii. Hub cutter/ needle cutter is not available ix. E- waste and spill management is required in HCF. x. Dispose of chemical reagents through disinfection and disposal in municipal sewage system. xi. Biomedical waste from laboratory and HCF being segregated and disposed in correct bins. Collection system is done through private sector. xii. Microbiology lab of Sir JJ hospital is following good protocols for biosafety, health, fire, cleanliness and safety of workers. xiii. BMWM, Safety, PPE and IC training is requiring for the staff. Bar coding on waste disposal bags are not being done. xiv. DRTB centre requires MRT, CT scan, and Sonography machine.	(Microbiologoy) SJJ hospital; Dr. Ajay Dhawale, DTO; Dr. Lalitkumar D Anande, Medical Superintendent GTB hospital, Sewree, Mumbai and Dr. Amit Karad, WHO consultant

Photographs of Consultations and Site Visits Undertaken

	Discussion with Dr Sanjay Darade DTO, Lab technician Mr. Patole and other Lab staff DMC lab, District TB Hospital, Pune
	Patient Help desk, Geetanjali Medical college and Hospital, Udaipur
	PHC lab, Mann, Pune with Dr. Sanjay Darade DTO and Dr. Balaji Lakade Medical Officer and staff of Rural Health Centre, Mann Pune
	Discussion with District hospital TB wards on-duty Medical Officer Dr. Udawant, Dr. Sayali and Dr Sanjay Darade, DTO, Pune

		Discussion with Dr. Rokade, Medical Officer, PHC Mann, Dr. Sanjay Darade DTO and PHC Staffs
		World Bank Consultant Mr. Ranjan Verma discussion with DTO Dr. Dinesh Kothari, Dr. Sanjay Sinha (WHO Consultant), Mr. B.K. Gupta(NGO-ALERT) and Mr Naresh Paneri, Mr Tyag Narayan (NGO-SWACH) and other staffs of District TB Clinic, Udaipur.
		Facility exclusively for TB patients in Department of TB and Respiratory Disease, Geetanjali Medical College and Hospital, Udaipur
		FPIC with tribal TB patients and village level volunteers (SWACH Mitra) working on TB in tribal areas of Jhadol Block, Udaipur

		Discussion with STS and STLS from different TUs of Udaipur along with DTO
		National Consultation in New Delhi

ANNEX-4 Supplemental Environmental and Social Risk Screening Worksheet

This section provides a program definition and describes the scope of the proposed Program, including its major investments, activities, and geographic coverage.

Risk	Assessment
Associated or Likely Social and Environmental Effects *(This section describes the potential benefits, impacts and risks that are likely to be associated with the Program.)* Environmental effects: • Potential loss or conversion of natural habitats? • Potential pollution or another project externalities? • Changes in land or resource use? Social effects: • Nature/scale of involuntary resettlement or land acquisition required? • Potential impacts on vulnerable communities? • Changes in resource access? • Are Indigenous Peoples affected?	There will be no loss or conversion of forests and natural habitats, as all Program activities will take place within existing facilities in rural and urban areas. GoI has rigorous regulations and policies for the protection and conservation of forest and wildlife areas hence any potential loss or conversion of natural habitats would not be permitted under the context of the Program activities. The key sources of pollution under the project will be the incremental increase in bio-medical and liquid waste generated through the expansion in diagnostics and treatment, this is of moderate or minimal risk. This ca be effectively mitigated by the existing waste management rules and regulations for medical, liquid and solid wastes. There is no major construction activity supported under the PETB, only minor renovation works will be supported for improvement in lab equipment, safety, and implementation of airborne infection control measures. There will be no adverse impacts on land or resource use. The Program does not intend to do any land acquisition or resettlement as it does not support any major construction and is limited to minor renovation and repairs within the existing footprint of the health facilities and laboratories. However, in order to rule out any adverse social effects and exclude activities/ sub-activities leading to land acquisition and/ or resettlement, screening will be conducted in facilities where any repair, renovation and/or expansion is proposed under the program. There will be no change I resource access and/or affect tribal population habitats.
Environmental and Social Context *(This section describes the geographical coverage and scope of the Program and environmental and social conditions in the Program area that may have*	The PTETB PforR will focused in 9 states Uttar Pradesh, Bihar, Maharashtra, Rajasthan, Madhya Pradesh, Tamil Nadu, Karnataka, West Bengal and Assam. Interventions will take

significance for Program design and implementation.)
 Environment:
     ○ Does the environmental setting of Program pose any special challenges that need to be taken into account?
     ○ Program activities in or near sensitive habitat areas?
     ○ Potential cumulative or induced effects?
 Social:
     ○ Area of social sensitivity such as Indigenous Peoples; vulnerable groups; conflict zones?
     ○ Potential cumulative or induced effects?
	place within existing health care facilities and RNTCP laboratory network in urban and rural environmental settings. There will be no new construction activity/healthcare facilities, the PTETB will support renovation works, and installation of new equipment in existing laboratories and TB facilities. The environmental footprint will be limited to existing facilities and will not impact natural habitats and physical cultural resources. The PforR will not involve any investment in or near sensitive natural habitats.
	
	 Any new labs which come on board through PP scheme will comply with stringent accreditation criteria for private sector labs to comply with good biomedical waste and worker health and safety management.
	
	 The key effects screened include the incremental increase in biomedical waste, and other general waste generated through the implementation of the PTETB Program, worker and public health and safety, biosafety in TB containment laboratories. Through screening, site visits and consultations, it was found that the potential risks and impacts can be avoided or minimized or mitigated.
	
	 The program provides for special incentives in the tribal and difficult to reach areas for transportation to patients and sputum sample transportation to enhance access. However, in recent years some of these areas have been reporting a high incidence of not only drug sensitive but also drug resistant TB cases. The NSP 2017-25 also recognizes that there has been limited progress in the form of a special action plan for tribal populations and requires enhancing access and coverage not only through screening and treatment mechanisms, but also by adopting culturally appropriate ACSM and communication activities. With program intending to engage with private sector this is even more important, and RBTCP plans to position a dedicated staff at national as well as state level to coordinate these activities. The program does not anticipate or promote and exclusion of any groups in terms of caste, religion, and/ or geography by the program activities is not expected.

Program Strategy and Sustainability
(*This section situates the Program, and its environmental and social management systems, within the country's broader development strategy, with particular emphasis on identification of factors that may impede successful Program management over time.*)
 	
    o   Strategic context: What is the long-term vision of this Program in relation to the country's development strategy?
    o   Does it include explicit environmental and social management objectives?
    o   Do Program activities commit, constrain or alter decisions of future generations?
    o   Are there any potential roadblocks to ensuring the environmental and social sustainability of the Program after implementation?
	This PforR is a well-defined subset of GoI's new National Strategic Plan (NSP) for 2017-2025, which encompasses several high impact interventions and implementation reforms to accelerate the country's progress and priority interventions toward elimination of TB which is aligned with the global End TB Strategy and Sustainable Development Goal targets. The PforR will ensure the environmental and social sustainability under the context of governments' continuous investment on the TB detection and treatment. through previously supported bank and other donor funded projects, there has been substantial capacity building in CTD.
	
	There are few bottlenecks in ensuring the environmental and social sustainability of the PforR after implementation. The Government of India is placing more emphasis on Biomedical waste management rules, 2018, have been updated to include more stringent provisions. CTD through RNTCP is improving institutional arrangements and providing more resources to enhance institutional capacity on infection control and AIC measures. There is also increased emphasis on worker health and safety, the Ministry of labour has prepared a preliminary draft on Code on Occupational Safety, Health and Working Conditions, 2018, by amalgamating 13 labour laws relating to safety and health standards, health and working conditions, welfare provisions for the workers. The focus on prioritizing and inclusion of tribal community, people living in difficult areas, migrants, slum dwellers, people with HIV, and other vulnerable communities, women and children are already identified as part of the key population that the NSP has prioritized for achieving its goal. The proposed program aims to develop strategy in reaching out to key population and address their access to TB screening and treatment related issues.

Institutional Complexity and Capacity (*This section describes organizational, administrative and regulatory structures and practices, as they relate to environmental and social assessment, planning and management.*) o Does the Program involve multiple jurisdictions? or implementing partners?	CTD has already implemented three Bank funded projects for Tuberculosis care and management. While these projects are now closed, the institutional setup is still functional and active, and the environment management framework for bio medical waste management and capacity building remains relevant. Over

- Capacity or commitment of counterpart to implement regulations and procedures? - Is there a track record of commitment and implementation experience on environment and social aspects? - Are there any known institutional barriers that would prevent the implementation of this Program? - Is there sufficient institutional capacity to address the environmental and social impacts of this Program?	the years, BMW has seen considerable improvement at all levels of healthcare facilities. This is indicative of good borrower capacity to deal with the environmental aspects of the proposed program. RNTCP is a part of the National Health Mission (NHM), and TB diagnostic and treatment services are integrated in the government health system nationwide. State level BMW and AIC committees are responsible for providing technical guidance to the facilities. The collection, transport and disposal of medical wastes are carried out by specialized agencies in the private sector that also operate the treatment and disposal facilities. The stigma reduction and discrimination issues associated with TB requires a sustained advocacy and social mobilization (ACSM) activities and Social and Behavior Change Communication (SBCC). The mechanism for implementation of ACSM and SBCC have been well thought out and evolved over the last three projects, though requires updating with changing context and strengthening implementation. This PforR will involve national, state and district level institutions for environmental, social, and health and safety management, and their roles are clearly defined. environmental and social concerns will be effectively addressed by monitoring and quality assurance through the RNTCP institutional network. The institutional capacities will be adequate to manage the environmental and social risk associated with the PforR.
Reputational and Political Risk Context *(This section describes environmental and social issues, trends or other factors that may cause the program, the country, or the Bank to be exposed to significant reputational or political risk.)* - Potential governance or corruption issues Are there any political risks associated with this sector or proposed Program? - Is the sector or Program known to be controversial?	There are no potential governance issues, and the sector is not controversial.
Overall Assessment: *(This section describes the overall risk profile for the Program, based on the team's subjective weighting*	The proposed activities under this PforR, are suitable to be supported according to the World Bank PforR Policy, and Directive. There

and aggregation of all factors identified above. Environmental and social risk factors should be summarized separately). Is the proposed Program suitable for PforR or would it be better suited to a specific investment loan?	are no large infrastructure investments/ activities that pose a risk of potentially significant and irreversible adverse impacts on the environment and health that would normally be considered Category A-type investments under investment lending policies. The environmental and social risk is moderate and can be effectively managed under the current EHS and environment and social system.

ANNEX-5 Suggestive Topics for Capacity Building on Environmental Health and Safety Aspects

	Area	Topics	Stakeholders
1	Awareness on national guidelines and legislation including development of required guidance material	▪ Government of India and state environmental guidelines, legislation, and project guidelines on BMWM and infection control.	CTD, State and District TB officers And TSUs /implementing agencies
2	Occupational Health and safety	▪ Safety concerns, operationalization of safety procedures, PPE and their use, safety equipment.	All HCF workers, and lab staff under the Program
3	Safety in Laboratories	▪ Safe Disposal of Hazardous and Chemical wastes ▪ Prevention of laboratory-acquired infections ▪ Accidents and Spills	Laboratory Staff
4	Sputum Collection and Transport	▪ Practices for Safe Collection of Sputum ▪ Biosafety and use of Spill Kits	Laboratory and Sputum Transport Workers
5	Development of Facility Level Airborne Infection Control plans	▪ All high-risk areas for TB transmission should have an airborne infection control plan and a facility person or team responsible for AIC. ▪ Plans should be formulated as per national guidelines and provide area-specific AIC and IC recommendations for the facility including the laboratory which should have its own specialized standard safety procedures.	State and District TB officers

ANNEX – 6 Safeguard Screening Checklist

FOR PRELIMINARY ASSESSMENT OF HEALTH CARE FACILITIES

(This screening format needs to be filled under the guidance of health care facility/ Laboratory in-charge to rule out any adverse environment and social impacts due to program intervention.)

1	Name of the District	
2	Name of the Block	
3	Name of the Health Facility/ Laboratory	
4	Category of health facility/ Laboratory	
5	Requirement of Land for any renovation and expansion beyond exiting land available with the health facility	Yes/ No (If Yes, give details below; In case No – Q.6 to Q.11 are not applicable)
6	Is the site identified for the proposed activities under the program	Yes/ No (If Yes, give details below)
7	Is there a need to acquire the land for proposed activities	If Yes- Activity not eligible No
8	Any other specific information related to land	Give details
9	Are there any squatters living on the proposed land	Yes / No (If Yes, give details below)
10	Are there any commercial structures on the land proposed	Yes/ No (If Yes, give details below)
11	Is the land proposed is being used for common property resources - such as water supply structure; sanitation structures; power supply infrastructure etc. or approach way	Yes/ No (If Yes, please write details about the structure and its use by local residential/ commercial/ institutions)
12	Is there any encroachment or any claim on the proposed land	Yes/ No (If yes, give details of from when and what kind)
		If Yes, report to STO/ CTD for necessary action
13	Are there photographs of the construction site/ land enclosed	Yes/ No
14	Has there been any 'Yes' answer to any of	Yes/ No

	the screening point # 9,10, 11 and 12 above	If Yes, Report to STO/ CTD for necessary action
15	Does this facility contain high risk setting? (DR-TB Centre, ART Centre, TB Containment Lab) If Yes • Are the requisite systems of AIC being followed? • Health Checkup of Workers being conducted? • Immunization of Health workers being conducted? • Is PPE readily available? • Are healthcare and sanitary workers trained on IC and BMW management?	Yes/ No Yes/ No Yes/ No Yes/ No Yes/ No Yes/ No Yes/ No
16	Has the state/district AIC officer/ committee approved the required renovations?	Yes/ No
17	If facility is a Lab • Is all Lab Safety Equipment in Working Condition? (BSC, AHU, Centrifuge) • Is there fire detection system operational • Is there a biomedical engineer to oversee engineering protocols of equipment and conduct safety tests?	Yes/ No Yes/ No
18	Is BMW being suitably segregated, collected and disposed?	Yes/ No
21	Is there a dedicated officer/ committee on BMW, IC, AIC at facility level?	Yes/ No
26	Is liquid waste and wastewater being generated from the facility suitably disposed? Is an ETP required for the facility?	Yes/ No Yes/ No
27	Will renovation activities have an impact on air quality, noise and impact patient health or treatment within the HCF?	Yes/ No
28	If Yes to #27 have the requisite mitigations been incorporated into the construction contract?	Yes/ No
29	Does the renovation work involve removal of asbestos sheeting/pipes?	Yes/ No

	If yes, then is will be required to be dealt with as per the national guidelines on hazardous waste management rules.	

In-charge of Health care facility/ Laboratory

Name…………………………….

Designation: …………………….

Phone No. ……………………..

Signature ………………………

Date: ………………………….

District TB Cell/ DTO

Name: …………………………………………

Designation: …………………………………………….

Phone No. ………………………………..

Signature…………………………………………

Date: …………………………………….

ANNEX -7 Multi-stakeholder Consultation workshop

1.   A multi-stakeholder consultation workshop was held in New Delhi on 26 November 2018 on the draft ESSA. The Purpose of the consultation was (a) to gather to share ESSA findings and seek views from a wider range of stakeholders connected to the programme (b) establish consensus on environmental and social effects of the programme, and proposed PAP actions and (c) agree on measures for monitoring environmental and social management performance

2.   The participants agreed with the key ESSA findings and recommendations and provided additional actions for environment and social system strengthening. During the preparation and appraisal process for the PforR, the actions recommended below will be clarified through consultations with program counterparts and specific agreements will be made to address recommendations by including them in the Program Action Plan (PAP) and/ or Program Implementation Plan. Implementation of these actions will result in the environmental and social management system for the Program considerably strengthened and set on a more sustainable path which will likely extend beyond the life of the Program.

3.   The participants and CTD were informed about disclosure process for the ESSA, and period for public comment prior to ESSA finalization.

Table 9: Key Comments Received Through Consultations and Responses

S. No.	Comments/Suggestions from Participating Stakeholders	How the Program Design Addresses These
1	• Biomedical waste management requires significant capacity strengthening at all levels to be implemented successfully.	• Dedicated capacity at State level- expert/ specialist who can support BMW, IC and AIC planning and implementation with the STO
2	• Biosafety, BMWM and equipment with respect to IRL, DMC and TU level labs requires standard operating procedure. • Maintenance and repair of IRL equipments	• A guideline specific to different types of facilities for BMW management to be prepared by CTD. • Develop a specialized unit in NTI for supporting IRLs across states
3	• Airborne infection control is poorly understood and poorly implemented. • AIC and waste management committee/ Officer is mandatory and shall be implemented • DTOs capacity building required on AIC • AMC for all equipments to be ensured • Engineer's at NHM and PWD requires capacity building on methods	• Requires CME with AIC as a topic • Infection control committee should have the AIC as part of it. • Make designated person for AIC at district level • Allocate funds for AMC and phasing/ replacement of equipment • Update and develop fact sheet for BMW and AIC including PPEs
4	• Biosafety guidelines of procurement and maintenance of equipments from IRL lab should be made available	• Potential vender list to be prepared and circulated/ published by NRL/ CTD.
5	• Tribal health action plan for TB is the requirement of the day and should be prepared in culturally appropriate manner. • Given the heterogeneous nature of tribal	• Program should give flexibility to state for planning and implementing tribal action plan for TB. • State incentive money can be used for

S. No.	Comments/Suggestions from Participating Stakeholders	How the Program Design Addresses These
	population across state and district, there should be flexibility at state and district level to plan based on local context and implement.	showcasing innovations in tribal health.
6	• Stigma and discrimination being one of the important areas in dealing with TB, focused and continued communication with target community is important.	• SBCC to incorporate the communication strategy for stigma reduction.
7	• Monitoring for incidence of TB cases and treatment outcome for women and children should be streamlined.	• The framework for development and adaptation
8	• Currently there is a shortage of biomedical engineers, and microbiologists are conducting the tasks of engineering controls	• Need to utilized bio medical engineers under NHM to support RNTCP lab network. • Creation of specialized unit in NTI Bangalore for this purpose that can travel to all 64 IRLs and provide technical support.
9	• Additional capacity needed at State level to support environment and social aspects- BMW, IC, and AIC	• Environment expert at State level • AIC to be mainstreamed with IC officer in medical college and IC committee and district level. • State officer on social safeguards to be hired
10	• State and district level capacity to roll out citizen engagement and accountability mechanisms is very weak and needs strengthening	• State level expert institution to be hired to support roll out of TB forums at state and district level
11	• No guidance to health professionals/ health system on implementation of engineering measures such as ventilation systems, effluent treatment plants etc. • Civil engineers/PWD supporting health centre construction are not sensitized to the needs of health care facilities and specific requirements of DR_TB centres.	• Develop abbreviated guidelines for planning and retrofitting DR-TB centres to conform with national guidelines on AIC, IC and BMWM. This includes guidance on consumables (PPE, chemicals, vendors, suppliers)
12	• No clarity on budget head for consumables (chemicals, disinfectants, and PPE) for RNTCP specifically- as budget is part of NHM and health facility as a whole. Though TB care requires higher adherence to use of PPE to protect worker health and safety • C& DST labs are not covered under NHM and hence budget is dependent on the medical college.	• State Environment expert to support STOs on better planning of PPEs in annual planning/ PIP, and facilitate better coordination with NHM
13	• No guidance on use of plastics, Styrofoam (sputum transport) in Maharashtra due to plastic ban as part of Government program.	• State TB cell to further discuss with CTD on alternative mechanisms
14	• Need up to date guidance on Environmental practices and norms (given many updates in policies, regulations and guidelines) for RNTCP environmental management systems to conform to national systems.	• Preparation of guidance tools for STOs and DTOs under institutional capacity building.

Stakeholder Consultation on Environmental and Social Systems Assessment (ESSA)

November 26, 2018

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