INTEGRATED SAFEGUARDS DATASHEET
APPRAISAL STAGE

I. Basic Information

Date prepared/updated: 07/28/2005 Report No.: 33586

1. Basic Project Data

Country: India	Project ID: P078539
Project Name: Second National Tuberculosis Control Project	
Task Team Leader: Birte Holm Sorensen	
Estimated Appraisal Date: April 2, 2005	Estimated Board Date: March 9, 2006
Managing Unit: SASHD	Lending Instrument: Specific Investment Loan
Sector: Health (100%)	
Theme: Other communicable diseases (P);Health system performance (P);Decentralization (S)	
IBRD Amount (US$m.): 0.00 IDA Amount (US$m.): 165.00 GEF Amount (US$m.): 0.00 PCF Amount (US$m.): 0.00 Other financing amounts by source: BORROWER/RECIPIENT 41.00 Financing Gap 0.00 41.00	
Environmental Category: B - Partial Assessment	
Simplified Processing Simple [] Repeater [X]	
Is this project processed under OP 8.50 (Emergency Recovery) Yes [ ] No [ ]	

2. Project Objectives

India has already reached the global targets of 70% case detection rate and 85% cure rate on a nationwide basis in areas where DOTS is being implemented. However, there are large differences in program performance across the country, with many districts not yet having reached the global targets. On the other hand there are many areas of the country where DOTS has now been implemented for five or more years, and the expectation would be that ? if the program is functioning effectively ? the incidence of smear-positive TB should start to decline in those areas. In accordance with these observations, the Program Development Objective (PDO) of the proposed operation is: (i) to achieve the global targets of 70% case detection and 85% cure rate in 100% of the districts; and (ii) for the zones where DOTS has been under implementation for five or more years, the incidence of smear-positive TB starts to decline. The two key indicators to track progress towards the PDO (annex 3) are as follows: (i) the number of districts that have achieved a detection rate of at least 70% and a cure rate of at least 85%; and (ii) the incidence of smear-positive TB in zones where DOTS has been implemented for five years or more.

The proposed operation would support the Revised National Tuberculosis Control Program Phase II, henceforth referred to as RNTCP II, which has been defined by the

GOI in their Project Implementation Plan (PIP) dated May 31, 2005. This document has been prepared by the Central TB Division (CTD) of the Ministry of Health and Family Welfare (MOHFW), GOI, through extensive consultations with state and district representatives, representatives from the leading TB research institutions as well as IDA and other donor representatives during program preparation.

While emphasis in the previous phase of RNTCP was on introduction of DOTS in a uniform manner across the country, the RNTCP II will increasingly target the states and districts which have below average performance in the form of case detection rate below 70% and/or cure rate below 85% through additional technical and managerial support from the center. A provision is made for additional financial inputs to weaker Empowered Action Group (EAG) states and a special provision has been made for additional contractual posts in these states. In addition the EAG states will be more closely monitored and supervised by the CTD. The North Eastern states with large tribal populations and geographically difficult areas will be provided an allocation which is 1.3 times the regular norm and special incentives will be made available for health workers who work in tribal communities. With DOTS available throughout the country, major emphasis will now be given to Information Education and Communication both at national and state level with additional Communications Facilitators for every five districts engaged by the program.

The Government has recognized that although a strong public sector DOTS program is essential, it is not sufficient to reach all TB patients. A number of pilot activities therefore have addressed issues such as including non-public providers in RNTCP, provision of services to urban slum populations, ensuring that HIV positive persons suspected of TB have access to diagnosis and treatment, and ensuring that multi drug resistant patients receive treatment. These activities will be scaled up in RNTCP II.

The challenges ahead for RNTCP II lie in (i) maintaining the current momentum of the program, of the strict clinical standards and of an effective IEC strategy throughout the country over a period of ten to fifteen years, especially as the larger, weaker states are fully included in the program; and (ii) expansion of DOTS availability to ensure that ?hard to reach? groups, patients who seek treatment from non-RNTCP providers, HIV positive and MDR patients have adequate access to effective TB treatment. These aspects are essential for achieving the long term goal of reducing TB incidence and will be addressed through this program.

The Government of India has recently launched the National Rural Health Mission (NRHM), an initiative to improve the health status of the rural people by promoting convergence of several centrally schemes including RNTCP. Several components of the NRHM, such as merging the different state and district health societies into one; making the Chief Medical Officer overall responsible for program implementation at district level; supporting a local female volunteer, ASHA, in every village; and inclusion of Panchayat Raj Institutions and civil society groups in participatory health planning at local and district level are likely to strengthen the capacity of the states, especially the weaker states, and thereby facilitate implementation of the RNTCP.

3. Project Description

To achieve the PDO, two broad outputs are required: (i) DOTS services consolidated through enhancement of the quality of public DOTS provision; and (ii) expansion of TB services to generally under-served populations. During the first year of this program, DOTS would have been introduced in all districts of the country. Focus would now be on achieving program consolidation throughout the country and inclusion of necessary additional components to expand and increase the program reach.

Output one: RNTCP services consolidated. This output aims at sustaining the quality of public TB services across the country. To have an impact on the incidence and mortality due to TB, quality services must be maintained for many years. The previous phase mainly focused on start-up to ensure provision of DOTS across the country. For sustained quality public service provision, special emphasis would now be given to the quality of laboratory services, supervision and monitoring, continuous operations research, advocacy and health communication and strengthening of institutional capacity to implement the program.

Quality of laboratory services would be consolidated through (i) establishment of a network of intermediate reference laboratories (IRL) at state level to allow intensified supervision of laboratory activities at district level; (ii) introduction of a comprehensive laboratory quality assurance (QA) mechanism based on regular supervision of staff at all levels, proficiency testing with slide panels and blind cross-checking of slide samples from all diagnostic centers; (iii) ensuring the routine reporting of QA results to state- and central levels to allow targeted interventions for quality improvement.

To improve supervision and monitoring the RNTCP II would strengthen the system of supervision at all levels of the program. Central TB Division (CTD) would specifically target low performing states for their regular visits; every year a few randomly selected districts would be visited by a team from CTD and data validated. State TB officers would regularly supervise the districts and likewise select a number of districts every year for in-depth supervision and validation of data. District TB officers would travel for 15 days every month to supervise laboratory and other field staff as well as the DOTS providers. This is one of the first DOTS programs worldwide to use a comprehensive, computerized management information system for data collection and transmission; this system would be on-line for all districts early in the program period. To monitor the impact of the RNTCP on the incidence of tuberculosis, ARTI surveys will be repeated every 3 years; survey outcomes from the 2008 survey in zones where DOTS has been implemented for more than five years would provide the first evidence of program impact on TB incidence. The program would continue to employ contractual staff for field level supervision i.e. the Senior Treatment Supervisors (STS) and the Senior TB Laboratory Supervisors (STLS) but increase the number of staff in low performing areas.

Operational research to generate an appropriate and continuous flow of information would receive priority attention in order to make TB control in India more effective. The RNTCP would communicate the research agenda widely and engage

individuals/organizations to undertake research. Priority topics would include strengthening service delivery to and demand for services from marginalized groups and HIV/TB co-infected persons, further development of Public Private Mix (PPM) models, and new areas such as pediatric DOTS and DOTS+ .

Information, Education and Information (IEC) would be strengthened to (i) create awareness of TB symptoms and demand for free DOTS services, with the drugs provided in patient-wise boxes , among the public and the health providers; (ii) advocate for political, administrative and community-level commitment to TB control in India; (iii) enhance patient-provider communication and counseling to help ensure patient compliance and patient-friendly service. A process rather than products orientation would promote interpersonal interactive communication and needs-based planning using a three-step package (formative research, strategy development and monitoring). The CTD would provide leadership, manage the national level media and advocacy sub-component, and oversee capacity building in the states. Detailed state and district IEC plans would ensure contextual relevance and wide reach of information. Additional contractual staff to facilitate communication would be provided for every five districts and special attention would be paid to social issues such as stigma and gender, hearing the voices of beneficiaries, and reaching marginalized and vulnerable groups and patients living with HIV.

Appropriate institutional capacity would be ensured at all levels to maintain program quality. It would include: (i) reorganizing and strengthening CTD through the provision of equipment and adequate physical facilities, and by having new units established and program managers in charge of supervision and monitoring, human resource management and development, financial management, procurement, advocacy and health communication, and epidemiology/surveillance to better address weaker areas; (ii) strengthening managerial capacity at state level and implementation capacity at district level through hiring of additional contractual staff; (iii) technical assistance to support CTD?s efforts to further decentralize the program?s activities in a phased manner and encourage states to take ownership, and assigning additional WHO consultants to large and poorly performing states; (iv) support to states? efforts to provide quality training to all staff involved in the program, as well as DOTS providers; and (v) assistance to public and private medical colleges to revise their curricula to include DOTS as the prescribed treatment for TB, to provide training on DOTS implementation and monitoring to the faculty, to support existing state level TB task forces in defining their roles and plans of action, and to support the continued creation of active task forces in medical colleges.

Output two: RNTCP outreach to target special groups expanded. This output aims to maximize the inclusion of TB patients under DOTS. With expansion of DOTS to all districts in the country the program would now implement appropriate strategies to ensure that services reach (i) the poor, tribal people and other ?hard to reach groups?; (ii) patients who consult non-RNTCP health service providers; (iii) patients infected with HIV/AIDS; (iv) pediatric cases; and (v) multi-drug resistant TB cases.

Despite country wide coverage of the RNTCP, the poor, tribal and other ?hard to reach? groups still do not adequately avail of its services. A Social Assessment has been undertaken to prepare an overview of who is not being reached in the current program and provide insights into how the program can better ensure that their needs are addressed. Based on this assessment, on a Tribal Plan, and on documentation of the numerous positive experiences with accommodating the needs of special groups around the country, each state would implement these activities as appropriate to the conditions of their state. Special incentives will be provided to health staff working in difficult and tribal areas and additional financial and managerial support extended to below average performing areas.

The first point of contact for patients is most often the non-public health care providers (the term non-public health care providers, here, refers to the large range of providers who are not part of the Ministry or Directorates of Health and Family Welfare of the central or state governments). The program would seek to identify and successfully treat, under the RNTCP, as many of the presently unregistered and undetected cases as possible and promote the involvement of non-public health care providers in the RNTCP and in DOTS provision. In continuation of the current efforts that appear to be yielding results, RNTCP II would provide additional support in the form of training for non-public providers. It would also provide additional technical assistance in the states to: (i) draw from the experiences of current Non Governmental Organizations (NGO) and Private Practitioner (PP) schemes and revise them, if necessary; (ii) prepare a framework for phased expansion of Public Private Mix (PPM), develop tools for implementation and indicators to monitor progress; and (iii) undertake operational research to assess the effect of PPM related interventions on case detection, treatment success, equity in access and financial protection for the poor.

Under the RNTCP II, the aim of HIV/TB coordination would be to ensure optimal synergy between the two programs at both state and district level for prevention and control of both diseases. This would be accomplished primarily through joint planning, sensitization, health communication and training in both programs, ongoing HIV surveillance among TB patients, and intensified TB case finding among people living with HIV/AIDS. Training in both programs would include management of TB in HIV patients, including those on anti-retroviral drugs, and implementation of infection control to prevent the spread of TB in HIV/AIDS clinical care facilities. Activities would be targeted to all states and districts with a high HIV/AIDS prevalence. In addition, the number of state level HIV/TB coordinators would be increased from the current six to fourteen to ensure coverage of all states with a high HIV prevalence.

Standardized drug regimens for the treatment of pediatric cases in 'patient-wise' boxes would be introduced along with ensuring the availability of the necessary diagnostic facilities for pediatric cases and appropriate staff training. The existing recording/reporting system would be modified to allow adequate evaluation of case-finding and treatment outcomes for pediatric cases.

To address the problem of Multi Drug Resistance (MDR), laboratory capacity at state level for the performance of sputum culture- and drug sensitivity testing would be established in a phased manner. This would include routine surveillance systems for levels of drug resistance against anti-TB drugs, clinical centers at the state level for the treatment of MDR cases, and gradual expansion of access to drug resistance testing and treatment of MDR-TB for cases who fail treatment under the RNTCP category two drug regimen. Due to the high cost of second line drugs, DOTS+, and rigorous compliance requirements, facilities would be carefully selected based on their demonstrated ability to implement DOTS and to comply with strict quality assurance requirements.

4. Project Location and salient physical characteristics relevant to the safeguard analysis

The project will be implemented nationally.

5. Environmental and Social Safeguards Specialists

Ms Ruma Tavorath (SASES)
Ms Varalakshmi Vemuru (SASES)

6. Safeguard Policies Triggered	Yes	No
Environmental Assessment (OP/BP 4.01)	X	
Natural Habitats (OP/BP 4.04)		X
Forests (OP/BP 4.36)		X
Pest Management (OP 4.09)		X
Cultural Property (OPN 11.03)		X
Indigenous Peoples (OD 4.20)	X	
Involuntary Resettlement (OP/BP 4.12)		X
Safety of Dams (OP/BP 4.37)		X
Projects on International Waterways (OP/BP 7.50)		X
Projects in Disputed Areas (OP/BP 7.60)		X

II. Key Safeguard Policy Issues and Their Management

A. Summary of Key Safeguard Issues

1. Describe any safeguard issues and impacts associated with the proposed project. Identify and describe any potential large scale, significant and/or irreversible impacts:
Environment

The environment issues of this project are well defined, site-specific and mitigateable. The primary issue is that of proper management of clinical and infectious waste materials (primarily needles, sputum cups and slides) given the infectious, communicable and opportunistic nature of the diseases involved under the scope of the project.

Indigenous Peoples (Tribal Community)

It is recognized that the highest burden of TB is borne by the disadvantaged groups of the society who have been characterized as "hard to reach population" and include the poor - both urban and rural, tribal communities and specifically women. In order to increase the treatment reach especially for the tribal community the proejct needs to (i)

bridge the gaps related to information, access and providers, and (ii) facilitate the tribal community to overcome socio-economic and cultural barriers to treatment seeking.

2. Describe any potential indirect and/or long term impacts due to anticipated future activities in the project area:
Improved services will result in increased waste generated. Unmanaged and inefficient disposal of waste generated from TB units could result in spread of infections, increased emissions and land pollution through improper burning of plastic waste.

The project seeks to improve treatment outcomes for TB affected populations, but at the same time needs to concentrate on the social aspects of treatment to address the "hard to reach population" especially the tribal community.

3. Describe any project alternatives (if relevant) considered to help avoid or minimize adverse impacts.
n/a

4. Describe measures taken by the borrower to address safeguard policy issues. Provide an assessment of borrower capacity to plan and implement the measures described.
The Central Tuberculosis Division has undertaken an Environmental Assessment which details the current practices under RNTCP Phase I. The assessment revealed that while basic Infection Control and waste management practices are instituted, many of the practices need improvement. RNTCP centers are currently practicing infection control by chemical treatment of biomedical wastes. Disposal methods remain weak and most infectious waste is dumped or burnt in open pits.

Based on the findings and gaps observed in the EA, the CTD has prepared an Environmental and Biomedical Waste Management Plan. The main modality of implementation of the Action plan is by compliance with the technical guidelines for disposal of bio-medial wastes as per revised RNTCP guidelines. Specifically the guidelines will encourage use of bio-degradable plastic like polypropylene, discourage incineration of plastic waste, discourage open dumping of slides and sharps, adoption of Universal precautions and encourage waste reporting of centres to their prescribed authority. The Plan focuses on upgradation of existing training modules; training (Laboratory technicians, Medical officers, STLS and Class IV employees); procurement of environmentally-friendly laboratory consumables, appropriate civil works and awareness and monitoring to ensure sustained behavioural change and continued compliance with Biomedical guidelines.

The Plan will need to be strengthened before Negotiations, after consultations with the state-level stake-holders.

Under RNTCP I, the CTD had prepared a Manual for Laboratory Technicians, and rolled-out the necessary training. Implementation is done at the state level, but CTD has proved to have satisfactory management capacity and has provided the required guidance

and know-how. It also has a monitoring and reporting system in place. However, RNTCP II aims to address existing weaknesses in implementation.

Tribal Development Plan

In accordance with Bank policy on indigenous peoples outlined in its Operational Directive (OD) 4.20, the CTD has developed a Tribal Development Plan (TDP) to ensure that the tribal community would have better access to TB treatment and quality and efficient TB treatment services will be available in tribal areas. Among the major issues identified in reaching TB services to the tribals are (i) inadequate health service provisioning in tribal areas, total absence of private sector and high dependence on Traditional Healers, (ii) inadequate accountability and monitoring of health service delivery to tribals due to remoteness, (iii) poorly staffed facilities with unhelpful attitudes of staff, (iv) lack of effective IEC in tribal areas, (v) limited extension services and limitations of non-tribal staff to motivate tribals, and (vi) poor transportation facilities and high cost of reaching health facilities.

Based on extensive consultations the CTD has proposed activities and provided financial allocations for (i) improving service coverage and providing quality RNTCP services in tribal areas; (ii) improving accessibility, acceptability and utilization of services by tribal community; (iii) promoting greater participation of tribal community members and increasing inter-sectoral coordination to improve efficiency and effectiveness of TB service provision; and (iv)undertaking operational research to refine strategies during implementation.

5. Identify the key stakeholders and describe the mechanisms for consultation and disclosure on safeguard policies, with an emphasis on potentially affected people.
The CTD has discussed the preliminary Plan with the States. The Plan is to be disseminated to the states for their review and inputs. The CTD will then have further discussions with the States and revise the Plan prior to negotiations.

The TDP is based on primary data, review of available experience and consultations with tribal communities including women and leaders, NGOs and other development institutions working in Tribal areas, other civil society representatives and Health Department staff working at different levels in different states. The TDP was disclosed extensively and state-level consultations and workshops were held to finalize the TDP.

B. Disclosure Requirements Date

Environmental Assessment/Audit/Management Plan/Other:	
Date of receipt by the Bank	03/28/2005
Date of "in-country" disclosure	04/29/2005
Date of submission to InfoShop	05/11/2005
For category A projects, date of distributing the Executive Summary of the EA to the Executive Directors	
Indigenous Peoples Plan/Planning Framework:	

Date of receipt by the Bank	04/28/2005
Date of "in-country" disclosure	05/02/2005
Date of submission to InfoShop	05/11/2005

*** If the project triggers the Pest Management, Cultural Property and/or the Safety of Dams policies, the respective issues are to be addressed and disclosed as part of the Environmental Assessment/Audit/or EMP.**

If in-country disclosure of any of the above documents is not expected, please explain why:

C. Compliance Monitoring Indicators at the Corporate Level (to be filled in when the ISDS is finalized by the project decision meeting)

OP/BP/GP 4.01 - Environment Assessment	
Does the project require a stand-alone EA (including EMP) report?	Yes
If yes, then did the Regional Environment Unit review and approve the EA report?	Yes
Are the cost and the accountabilities for the EMP incorporated in the credit/loan?	Yes
OP/BP 4.10 - Indigenous Peoples	
Has a separate indigenous people development plan been prepared in consultation with the Indigenous People?	Yes
If yes, then did the Regional Social Development Unit review the plan?	Yes
If the whole project is designed to benefit IP, has the design been reviewed and approved by the Regional Social Development Unit?	Yes
BP 17.50 - Public Disclosure	
Have relevant safeguard policies documents been sent to the World Bank's Infoshop?	Yes
Have relevant documents been disclosed in-country in a public place in a form and language that are understandable and accessible to project-affected groups and local NGOs?	Yes
All Safeguard Policies	
Have satisfactory calendar, budget and clear institutional responsibilities been prepared for the implementation of measures related to safeguard policies?	Yes
Have costs related to safeguard policy measures been included in the project cost?	Yes
Does the Monitoring and Evaluation system of the project include the monitoring of safeguard impacts and measures related to safeguard policies?	Yes
Have satisfactory implementation arrangements been agreed with the borrower and the same been adequately reflected in the project legal documents?	Yes

D. Approvals

Signed and submitted by:	***Name***	***Date***
Task Team Leader:	Ms Birte Holm Sorensen	07/28/2005
Environmental Specialist:	Ms Ruma Tavorath	05/03/2005
Social Development Specialist	Ms Varalakshmi Vemuru	05/27/2005
Additional Environmental and/or Social Development Specialist(s):		
Approved by:		
Regional Safeguards Coordinator:	Mr Frederick Edmund Brusberg	
Comments:		
Sector Manager:	Ms Anabela Abreu	
Comments:		