

IEG

ICR Review

Independent Evaluation Group

1. Project Data:		Date Posted : 12/14/2009	
PROJ ID : P075056		Appraisal	Actual
Project Name : Food And Drugs Capacity Building Project	Project Costs (US\$M):	72.92	30.59
Country: India	Loan/Credit (US\$M):	54.03	27.71
Sector Board : HE	Cofinancing (US\$M):	18.89	2.88
Sector(s): Health (100%)			
Theme(s): Health system performance (67% - P) Child health (33% - S)			
L/C Number: C3777			
	Board Approval Date :		06/05/2003
Partners involved :	Closing Date :	06/30/2008	06/30/2008
Evaluator :	Panel Reviewer :	Group Manager :	Group:
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2. Project Objectives and Components:

a. Objectives:

According to the Development Credit Agreement, the project development objective (PDO) was "to improve the quality and safety of food and drugs through: (i) the strengthening of consumer and other stakeholder education to enhance public awareness and knowledge of: (A) issues of food safety and quality, and (B) issues regarding drug quality and misuse of drugs; (ii) support the development of recommendations and options for appropriate policies and measures on food and drug issues; and (iii) the strengthening of: (A) the regulatory framework for food and drugs, and (B) public-private partnership." The Project Appraisal Document shortens this statement, giving the PDO as "to improve the quality and safety of food and drugs in India by strengthening the regulatory framework and incorporating components of consumer education and private-public partnerships." This review will assess the achievement of the desired outcomes listed in both versions of the PDO, improving the quality and safety of food and drugs.

b. Were the project objectives/key associated outcome targets revised during implementation?

No

c. Components (or Key Conditions in the case of DPLs, as appropriate):

The project contained three components :

1. Policy Development, Program Coordination and Monitoring (original US\$ 7.0 million; actual US\$ 6.1 million), including activities for (a) policy development, with policy studies and reviews to underpin the formulation of policy and institutional reforms, and workshops and consultations with stakeholders; (b) program coordination, with the establishment and operation of a central Program Coordination Unit (PCU); (c) central facilities and staffing, with the improvement of central physical facilities for food and drugs oversight and related staffing; and (d) monitoring activities, with the implementation of household surveys to assess public perceptions and knowledge about quality and safety of foods and drugs, the organization of independent audits of public and private laboratories, and the establishment and operation of a computerized management information system to enhance information flows and coordination between the central and State regulatory agencies .

2. Food Safety (original US\$ 44.3 million; actual US\$ 12.8 million), including activities to strengthen the Government's oversight and regulatory capacity for food safety at the central and State levels, to educate consumers on matters related to food safety, and to upgrade related skills in the private sector .

3. Drugs Safety and Quality (original US\$ 21.6 million; actual US\$ 11.7 million), including activities to strengthen the Government's oversight and regulatory capacity for ensuring drugs quality at the central and State levels, to educate consumers on matters related to drugs quality and safety, and to upgrade related skills in the private sector .

d. Comments on Project Cost, Financing, Borrower Contribution, and Dates:

At closing, US\$24.9 million of the loan had been disbursed, with US\$36.4 million undisbursed. The main reason for incomplete disbursement was delay and failure in recruiting staff as planned and delays in civil works and equipment procurement, as well as a Government decision not to extend the project . According to the TTL, the project was not extended because of Government dissatisfaction with the process and results of a Detailed Implementation Review (DIR) review. Also, due to exchange rate fluctuations, the total loan available increased from US\$ 54 million equivalent at the time of project approval to US\$ 61.2 million. 87% of planned spending was carried out on Component I, 29% of planned spending on Component II, and 54% of planned spending on Component III. In March 2007, SDR 3.2 million was reallocated from Category 4 (Incremental Operating Costs) to Category 3(b) (other services including surveys, Information, Education and Communication (IEC) and Management Information System (MIS) services). The ICR does not explain the reason for this reallocation . The Government contributed US\$2.9, or 15%, of the planned US\$18.9 million, reflecting low Government commitment and attention to the project .

3. Relevance of Objectives & Design:

Relevance of Objectives and Design is rated *Modest*, based on Substantial relevance of objectives and Modest relevance of design.

Relevance of Objectives is rated Substantial . The project supported a 15-year Government strategy to improve food and drug safety and harmonize Indian norms with internationally accepted standards . It was consistent with Bank-sponsored analytical work on the health sector, which had highlighted "government oversight" as critically important. The project also responded to a WHO estimate that one-fourth of all episodes of diarrhea in low-income countries were caused by food-borne infections, and that existing food safety regulations in India were enforced weakly and with outdated methods. The project also responded to India's growing position in the global pharmaceutical market (third in the world) and domestic drugs production, and the resulting need to ensure uniform good quality. The objectives were timely given future World Trade Organization (WTO) membership implications for India. The ICR, however, points out that there was little evidence of strong consumer demand for improved food and drug safety and quality.

Relevance of Design is rated Modest . A participatory process, including consultations with key consumer groups and industry associations, was followed during project preparation . The project's development objectives map closely to the components. This project represented a broad new area of work for the Bank . There was no assessment of the challenges involved in the procurement of complex laboratory equipment . Also, implementation in so many States led to delays. The decision to implement the project in all 35 Indian States and Territories, resulting in very small outputs in most States, diluted focus and prevented resources from being focused on those three or four States in which drug manufacturing is concentrated . Political economy analysis during project design was inadequate. The division of authority and responsibility between the central and State levels of government was not adequately taken into account and remained a major challenge throughout the project . In particular, some States lacked interest in and commitment to a project mandated by the Center, and were particularly slow in addressing human resource issues that were critical to the project's success. Also, with all States involved in implementation, there were not sufficient project funds to evoke interest and ownership of the project in each State . Accountability for decision making was diluted, and there was no forum for regular communication and discussion among key implementing entities and stakeholders. It may have been more appropriate to focus project design on a smaller number of States along with the Center, particularly since capacity in many areas was concentrated in just a few States (for example, only two States - Gujarat and Maharashtra - perform more than 50% of all tests done by State drug quality control labs in the country). It may also have been appropriate to design incentives or triggers into the release of funds, to ensure that entities at various levels were committed to and prepared for project activities . Another inappropriate design choice was the creation of separate food and drug administrations outside the Ministry of Health and Family Welfare (MOHFW), which absorbed capacity and created communication barriers . Also, the project's main outcome indicators did not reflect the development objectives; for example, there are no indicators to measure reductions in food-borne illness, reductions in poor-quality drugs, or number or percentage of labs accredited. While the PAD cites the challenges posed by lack of enforcement of food safety regulations, the project indicators focus on the development of new policies and measures without attention to their enforcement .

4. Achievement of Objectives (Efficacy):

Achievement of Objectives (Efficacy) is rated *Modest*.

Improve the Quality and Safety of Food : Modest

Outputs:

- The project contributed to the preparation and adoption of an Integrated Food Law enacted in August 2006, and the establishment of an autonomous Central Food Authority .
- Five Central Food Labs and eight State Food Labs were constructed, and six Central Food Labs and five State Food Labs underwent repairs and renovations (of a total, according to the TTL, of about 50 State food labs). In some of the weaker States, these newly built labs are not fully used or used at all .
- Hazard Analysis and Critical Control Point (HACCP) standards were developed for the five core sectors : dairy, meat & poultry, fruits & vegetables, the hospitality sector, and bakery products . These standards have been harmonized with international Codex standards . HACCP standards were also developed for the 30 most popular food items served by street food vendors; these are being distributed to vendors through home science colleges. These standards and processes have moved India away from procedures that test food samples only after an outbreak, to a proactive approach that focuses on improved food production processes .
- 1,205 people from the food sector were given unspecified training, including 473 food inspectors and 48 public analysts (against a target of 2000 inspectors and 500 analysts). Vendors were provided training through an action research program. Slow progress in training was due to poor response from food regulatory staff and failure to release funds on time. No information is provided on the quality or impact of this training .
- A mass media communication strategy for food hygiene was developed and implemented, involving a detailed media plan; according to the ICR, coverage rates exceeded targets (these rates and targets are not specified). An NGO-led outreach plan for education on food safety in rural areas was implemented . According to the ICR, 10.97 million people were reached by IEC campaigns on home food, and 16.52 million on street food.

Outcomes: No surveys were done to assess the impact of public education on food safety -related issues, making it impossible to assess progress on one of the project's three main outcome indicators (increased consumer awareness). The ICR provides no information on achievements in detection of unsafe foods or decreasing rates of food-borne illness.

Improve the Quality and Safety of Drugs : Modest

Outputs:

- Nine of ten planned policy reviews/studies on drug safety were completed .
- One Central Drug Lab and seven State Drug Labs were constructed, and one Central Drug Lab and seven State Drug Labs underwent repairs and renovations (of a total, according to the TTL, of about 50 State drug labs)
- Revised GMP standards (Schedule M) were made mandatory for all drug manufacturers in June 2005, and a comprehensive Schedule M training program for small-scale industries and regulatory staff was implemented, with 1,331 staff from the private sector trained (exceeding 1,055 planned). An unspecified number of GMP inspectors across the country were nominated and trained . No information is given on the quality or impact of this training, although the Stakeholder Workshop Report and Results indicates that some labs would have preferred training that was more practical and hands-on rather than theoretical.
- A National Pharmacovigilance (NPV) program was commissioned in November 2004, building a network of reporting centers around the country .
- A new Indian Pharmacopeia was published in 2007, along with new reference standards made available to industry and drug quality control labs . On this basis, more than 300 monographs were updated and 46 new monographs prepared, and for the first time monographs for 23 botanical drugs included under the Indian Pharmacopeia Commission (IPC), established in 2004.
- 2,605 public and private sector personnel were trained in drug safety and quality (of 2,625 planned; according to the TTL, this represents 60-70% coverage), with feedback from the participants indicating an increase in

knowledge of Schedule M, process verification, validation, facility documentation, and Standard Operation Procedures. The ICR states that quality of training was well-monitored, but no additional information is provided.

- A mass media communication strategy for drug safety-related issues was developed and implemented, involving a detailed media plan; according to the ICR, coverage rates exceeded targets (these rates and targets are not specified). According to the ICR, 23.51 million people were reached by IEC campaigns on drug purchasing; the ICR does not state whether the targets of these messages were consumers, vendors, or both .

Outcomes: The total number of drug samples tested annually increased from 40,000 in 2003 to approximately 83,500 in 2008. Lab productivity has improved in Hyderabad, with the average number of samples tested per month by an analyst in a drug testing laboratory increasing from 12 to 15 (dates not specified). Capacity has increased in Gujarat in one lab from 5,000 to 6,000 samples per year (dates not specified, and no target was given). Testing labs in Gujarat and Maharashtra (States that perform the bulk of drug testing in India) were accredited by the National Accreditation Board for Laboratories. Information is not provided on other States. Capacity to conduct some new quantitative tests has been created in unspecified labs /States. Two drugs were banned by the Government based on the recommendations of the NPV advisory committee. 12,000 adverse drug reactions following administration of drugs were reported over an unspecified time period. 8,402 adulterated drugs were detected over an unspecified time period (trend data are not available). Because of lack of timely funding, however, reporting and coordination were inadequate, effective use of data were limited, and no systematic database was established. No surveys were done to assess the impact of public education on drug safety related issues, making it impossible to assess progress on one of the project's three main outcome indicators (increased consumer awareness). The ICR provides no information on achievements in improved detection of unsafe drugs, decreases in adverse drug reactions, or decreases in adverse health impacts of sub-standard or counterfeit drugs.

5. Efficiency (not applicable to DPLs):

Efficiency is rated *Modest*. The ICR states that there is no established framework for the assessment of costs and benefits of food and drug regulation. It also states that the project invested less than one cent per capita of the Indian population per year, but it does not provide information about the efficiency with which these funds were spent or evidence that these funds were spent appropriately on high-priority activities. The project could have allocated resources more efficiently to just a few States, in addition to the Center, rather than spreading limited resources to all States so that few or none had adequate funds to incentivize full commitment to project-sponsored activities (although it should be acknowledged that the political context required equity in initiatives to strengthen core public health goods such as food and drug quality and safety). Also, funds flow arrangements were made through existing State AIDS Control Societies, which in practice did not take a strong interest in the project, resulting in a situation where funds made available through these Societies could not be used efficiently. The ICR explains that many of the project's achievements were made in the last six months of the project (p. 14), in a hurry to overcome deficits before the project closed; it is highly likely that project funds could have been spent more efficiently had project activities been implemented in a more even manner throughout the life of the project. The fraud and/or corruption suggested by the results of the DIR, as cited by the ICR, also indicate inefficiency.

a. If available, enter the Economic Rate of Return (ERR)/Financial Rate of Return (FRR) at appraisal and the re-estimated value at evaluation :

	Rate Available?	Point Value	Coverage/Scope*
Appraisal	No		
ICR estimate	No		

* Refers to percent of total project cost for which ERR/FRR was calculated.

6. Outcome:

Based on Modest relevance, Modest efficacy, and Modest efficiency, the project's outcome is rated as Unsatisfactory.

a. Outcome Rating : Unsatisfactory

7. Rationale for Risk to Development Outcome Rating:

India's status as a leading exporter of Active Pharmaceutical Ingredients (APIs) and finished generic drugs, as well as internal pressure from companies that depend on international markets, should ensure that the issue of drug

regulation remains high on the Government's agenda. Permanent institutional development by the Central government has been significant, with the creation of an independent Food Authority and an analogous Drug Authority expected to be approved soon by the Indian Parliament. Budget provision for these institutions at the central level is adequate, and training for both Government and private sector staff has taken place. In some places, however, at both the Central and State levels, there are insufficient personnel to carry out an increased level of activity, jeopardizing the sustainability of achievements. The Government demonstrates less interest in ongoing attention to food safety than to drug safety, indicating higher risk to development outcome in the food safety area. The Government has indicated that it would prefer small-scale technical assistance projects to another centrally managed lending program for either food or drugs.

a. Risk to Development Outcome Rating : Moderate

8. Assessment of Bank Performance:

Ensuring Quality -at-Entry is rated Moderately Unsatisfactory . During preparation, the Bank identified risks and lessons learned from previous health-sector projects in India and in other countries. Lessons successfully taken into account include the need to align with international standards for food and drugs, and the desirability of enlisting professional media agencies in public health education strategy development and implementation. Some risks, however, were not sufficiently identified and/or mitigated. Human resource considerations, in particular the administrative steps necessary and time requirements for creating positions and recruiting public servants, were not adequately investigated and addressed during project preparation. The Bank did not foresee the need for a full-time Project Coordinator, resulting in inadequate progress in implementation throughout. There was significant overestimation of costs of equipment and civil works at appraisal; according to the TTL, this accounted for less than 10% of the project's under-run in expenditure. Institutional mechanisms for procurement were not reviewed in sufficient detail, resulting in later implementation delays and for the majority of the under-run in total project expenditure due to incomplete or cancelled procurements. Adequate incentives were not provided and built into project design to ensure that use of funds and financial management procedures at the State level were in compliance with the Bank's policies. In addition, appropriate incentives were not provided to ensure that inspectors and laboratory analysts took advantage of their enhanced skills and improved infrastructure to do a more effective job. The project might have benefited from a Computerized Project Management (CPM) application at appraisal.

Quality of Supervision is rated Moderately Unsatisfactory . A Quality of Supervision Assessment carried out in September 2006 found supervision to be proactive, with the team appropriately identifying the need for a full-time project coordinator, strengthening relationships with consumer activists and the private sector, and working well with development partners. The ICR notes that the team had high staff continuity and a good skills mix, and that it identified problems in a timely manner. The Bank's procurement and financial management staff worked closely with PCU staff to explain rules and procedures as necessary. However, the ICR does identify major shortcomings, including a failure to reduce some of the project's complexity that had resulted in slow disbursement and poor performance. The ICR indicates that Bank staff and management were "complacent" (p. 20), failing to take actions other than meetings and correspondence in order to motivate the client to address the problems that were affecting performance. Bank staff also apparently assumed (incorrectly) that there would be a project extension that would provide time to address deficiencies. Bank staff did not proactively identify and address issues related to possibly corrupt or fraudulent practices in the procurement and implementation of equipment and civil works. The Bank also failed to ensure that sufficient data were collected to enable assessment of the project's achievements.

a. Ensuring Quality -at-Entry: Moderately Unsatisfactory

b. Quality of Supervision : Moderately Unsatisfactory

c. Overall Bank Performance : Moderately Unsatisfactory

9. Assessment of Borrower Performance:

Government Performance is rated Moderately Unsatisfactory . The Government demonstrated strong initial commitment to reform, including the preparation of Letters of Undertaking, an Environmental Management Plan, and site surveys for major civil works. During implementation, it demonstrated strong commitment to policy reform, but it was less attentive to institutional reform. In particular, human resources issues were pervasive throughout the project, and Government addressed these problems too little and too late. State governments varied in their level of commitment, with better-off states like Maharashtra and Gujarat providing enhanced state budgets for food and drug activities, while others did not even create or fill necessary positions under the project.

Many States did not expedite necessary clearances for civil works, delaying implementation . MOHFW failed to provide guidance, support, and adequate staffing to the PCU; overall, the Ministry 's central food and drug unit's staff was not fully involved in the project . It took months (years in some cases) in clearing the bid evaluation reports for equipment purchases . There was weak monitoring of laboratory output, with even the central laboratories not reporting on all five agreed lab capacity indicators . High staff turnover both caused and exacerbated these problems; during implementation, the Joint Secretary in charge of the project in MOHFW changed four times, and the Director reporting to the Joint Secretary on the project also changed four times . Many of the project's achievements took place during what the ICR calls a "sprint to the finish" (p. 14) under new project leadership at MOHFW, after a final supervision mission in February 2008 presented a range of serious implementation deficits . The ICR notes that the new team on the client side was able to achieve significant improvements in these final months of the project .

Implementing Agency Performance is rated Unsatisfactory . According to the ICR, project coordination was weak throughout the project period . Since the beginning and for the most part throughout, routine project management was left to the PCU, which consisted entirely of consultants . The Director overseeing the PCU changed four times over the life of the project, and there was a high rate of attrition among consultants in the PCU . Compliance with financial management aspects was inconsistent, with delays in financial reporting and in submission of audit reports . This resulted in periodic discontinuation of SOE-based disbursements . There were delays in financial reporting from the large number of implementing entities (albeit with low levels of expenditure), and there was inadequate attention and follow-up to these issues by the Central Procurement Management Unit (CPMU) . In the last two years of the project, it was impossible for the Bank to get a list of contracts issued at the State and Central levels, resulting in the Bank not being able to conduct the post review of these contracts . According to the ICR, a 2007 DIR review found significant indicators of corrupt and/or fraudulent practices in procurement/implementation of equipment and civil works .

a. Government Performance :Moderately Unsatisfactory

b. Implementing Agency Performance :Unsatisfactory

c. Overall Borrower Performance :Moderately Unsatisfactory

10. M&E Design, Implementation, & Utilization:

M&E Design: Modest. According to the ICR, the MOHFW had adequate methods for collecting information related to the project's key indicators . Those indicators, however, focused on outputs (development of policy, increased consumer awareness and knowledge, increased capacity for food and drug testing, development of standards and procedures) rather than on outcomes directly related to the project's development objective . There were no indicators, for example, on the implementation of policy, improved consumer or vendor behaviors, decreased food-borne illness, improved detection of poor-quality drugs, decreased adverse drug reactions, or implementation of procedures in priority food sectors .

M&E Implementation : Modest. The project established a computerized Management Information System (MIS), provided hardware to 101 project locations, and completed 5-day user training for selected staff in all locations . The project also conducted two surveys : a national household survey covering 20,250 households across the country to assess household behaviors relating to food and drug safety and quality; and a street food survey on the safety and quality of street foods . There were no follow-ups to these surveys due to lack of time, however, and no evaluation of the impact of media campaigns and NGO awareness- and knowledge-raising activities .

M&E Utilization : Negligible to Low . Data collected were not regularly or consistently used for decision making . The ICR states that the street food survey was implemented together with action research to demonstrate which tools can be used to modify provider behavior successfully, but no information is provided about what these tools are or whether and how they were implemented . There is no information about dissemination of results of the survey, and the findings are not reported in the ICR .

a. M&E Quality Rating : Modest

11. Other Issues (Safeguards, Fiduciary, Unintended Positive and Negative Impacts):

Safeguards: There were no major safeguard issues related to implementation of the project .

Fiduciary: Disbursements under the project were discontinued in February 2008, due to non-receipt of acceptable audit reports for both the Central and State components for the year 2006-2007 . The Bank received many complaints

about procurement, including some alleging fraud and corruption in procurement processes . According to the ICR, the project was selected for a Detailed Implementation Review (DIR) in 2007, with that review finding indicators of potentially corrupt and fraudulent practices in the procurement and implementation of equipment and civil works, such as inconsistent treatment of bidders, submission of fraudulent documentation, and inappropriate rejection of bidders; widespread deficiencies in the implementation of equipment and civil works such as payment for incomplete civil works and uninstalled equipment; and weaknesses in the Bank 's identification and handling of these indicators and deficiencies. The ICR states that, of 38 equipment contracts reviewed by the DIR, 29 (76%) contained indicators suggesting that bidders were favored through problematic procurement processes . Procurement officials appeared to have employed favoritism when awarding contracts to bidders that failed to meet performance criteria while disqualifying other bidders that apparently met, or could have met, the criteria . The ICR points out that the MOHFW conducted a comprehensive review of the DIR report and submitted responses and proposed actions with timelines . Remedial actions were also initiated by the Bank . The Region provides additional information that the task team refused to reimburse expenditures incurred by States that failed to comply with procurement post review requirements, and where post reviews found non-compliance with Bank procedures, mis-procurement was declared.

12. Ratings:	ICR	IEG Review	Reason for Disagreement /Comments
Outcome:	Moderately Satisfactory	Unsatisfactory	Based on modest relevance, modest efficacy, and modest efficiency . Project design was overly complex and ambitious, with insufficient political economy analysis to clarify roles and responsibilities of the Center and the States. The project did not measure outcomes that would enable a clear assessment of achievement of objectives. Project resources could have been more efficiently allocated to fewer States, rather than being spread thinly across the entire country .
Risk to Development Outcome:	Negligible to Low	Moderate	Significant human resource issues remain unresolved, and the commitment of some States to reform remains low.
Bank Performance :	Moderately Unsatisfactory	Moderately Unsatisfactory	
Borrower Performance :	Moderately Unsatisfactory	Moderately Unsatisfactory	
Quality of ICR :		Satisfactory	

NOTES:

- When insufficient information is provided by the Bank for IEG to arrive at a clear rating, IEG will downgrade the relevant ratings as warranted beginning July 1, 2006.
- The "Reason for Disagreement/Comments" column could cross-reference other sections of the ICR Review, as appropriate .

13. Lessons:

(These lessons are IEG's. The ICR contains a very long list of separate, more detailed lessons .)

- **Particularly when embarking on reform in a complex, new, and difficult area, significant prior analytic work is crucial .** In this case, prudent political economy analysis would have pointed to a less complex project, more diligent consideration of Center-State relations, roles, and responsibilities, better attention to policy - and institution-building at the Center and State levels, and more effective interaction with stakeholders . It would have enabled more efficient focus on areas where achievements were more important and possible, avoiding activities and goals that were not operationally feasible in a Bank -sponsored project.
- **Particularly for a project of this complexity, a strong implementing agency is essential .** A PCU staffed only

by consultants, with low job security and high turnover, is inadequate . In this case, it was judged, for reasons of sustainability, to be preferable to use existing structures for project management rather than to create an entirely new and separate Project Management Unit . Sustainability concerns, however, must be balanced with concerns about continuity and effectiveness .

- **Human resource planning is as important an element of capacity building as any other part of project design, preparation, and implementation** . In this case, the administrative steps necessary and time requirements for creating positions and recruiting public servants could have been investigated and addressed more proactively and on a higher level, avoiding delays in creating and filling positions .
- **The Bank should not hesitate to take decisive action in restructuring a project if implementation quality is chronically weak or deficient** . A hurry-up approach to correcting deficiencies in the final few months of implementation is inefficient; a more comprehensive redesign could have opened the door to more significant achievements and effective measurement and attribution of those achievements .

14. Assessment Recommended? Yes No

Why? This project was the first of its kind for the Bank, offering lessons in an important regulatory area . The project also offers valuable lessons on the need for effective political economy and institutional analysis .

15. Comments on Quality of ICR:

The Quality of ICR is rated as, on balance, Satisfactory. The ICR presents a straightforward accounting of the project's achievements and shortcomings. Data on outputs is clearly presented. A long list of carefully constructed and useful lessons is provided. The ICR does not, however, distinguish between outputs and outcomes, and it assigns ratings subjectively rather than on established criteria. The ICR Basic Information Sheet lists incorrectly the identity of the Project Team Leader at ICR.

a. Quality of ICR Rating : Satisfactory