

May 21, 2007

Doug Stevens, Chief Financial Officer Population Services International 1120 19th St. NW. Suite 600 Washington DC 20036

Reference; Manufacturing LLINS in Tanzania: Vision to Reality

Subject: Cooperative Agreement No. 621-A-00-07-00016-00

Dear Mr. Stevens;

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to **Population Service**International (PSI), hereinafter referred to as the "Recipient", the sum of \$30,000,000 to provide support for a program titled "Manufacturing LLINS in Tanzania: Vision to Reality" as described in the Schedule of this award and in Attachment B, entitled "Program Description."

This Cooperative Agreement is effective and obligation of \$4,650,000 is made as of the date of this letter and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date of May 24, 2007 and ending March 23, 2008. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to **Population Service International (PSI)**, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), and Attachment C (the Standard Provisions), all of which have been agreed to by your organization.

Please sign the original and all enclosed copies of this letter to acknowledge your receipt of the Cooperative Agreement, and return the original and all but one copy to the Agreement Officer.

Sincerely yours,

Kenneth P. LuePhang Agreement Officer

Kenneth P. Loc PL

Attachments:

A. Schedule

B. Program Description

C. Standard Provisions

621-A-00-07-00016-00

ACKNOWLEDGED: Population Service International (PSI).
BY:
TITLE:
DATE:

A. GENERAL

- 1. Amount Obligated this Action:\$4,650,000
- 2. Total Estimated USAID Amount: \$30,000,000
- 3. Cost-Sharing Amount (Non-Federal):\$ 2,700,000
- 4. Activity Title: Manufacturing LLINS in Tanzania: Vision to Reality
- 5. USAID Technical Office: USAID/Tanzania
- 6. Tax I.D. Number: 560942853
- 7. DUNS No.:040054827
- 8. LOC Number:72001584

B. SPECIFIC

Fund Account: CD/2007/2008 SC: 621-MAARD-0011-A049-7003

Amount:\$4,650,000

C. PAYMENT OFFICE

USAID/M/FM/CMP/GIB RONALD REAGAN BUILDING 1300 PENNSYLVANIA AVE., NW WASHINGTON, D.C. 20523-7700

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Attachment A

SCHEDULE

A.1 PURPOSE OF COOPERATIVE AGREEMENT

The purpose of this Cooperative Agreement is to provide support for the program described in Attachment 2 to this Cooperative Agreement entitled "Program Description."

A.2 PERIOD OF COOPERATIVE AGREEMENT

- 1. The effective date of this Cooperative Agreement is **May 24, 2007.** The estimated current completion date of this Cooperative Agreement is **May 23, 2009.** Subject to approval from the Government of Tanzania, this date will be extended to **May 23, 2011,** pending the extension of Project Assistance Completion Date (PACD).
- 2. Funds obligated hereunder are available for program expenditures for the estimated period May 24, 2007 to March 23, 2008.

A.3 AMOUNT OF COOPERATIVE AGREEMENT AND PAYMENT

- 1. The total estimated amount of this Cooperative Agreement for the period shown in A.2.1 above is \$30,000,000.
- 2. USAID hereby obligates the amount of \$4,650,000 for program expenditures during the period set forth in A.2.2 above and as shown in the Budget below. The Recipient will be given written notice by the Agreement Officer if additional funds will be added. USAID is not obligated to reimburse the Recipient for the expenditure of amounts in excess of the total obligated amount. The continuation of activities depends on the results and determination of yearly assessment and availability of funds.
- 3. Payment will be made to the Recipient by Letter of Credit in accordance with procedures set forth in 22 CFR 226

A.4 COOPERATIVE AGREEMENT BUDGET

The following is the Agreement Budget, including local cost financing items, if authorized. Revisions to this budget shall be made in accordance with 22 CFR 226.

Item	Year 1	Year 2	Year 3	Year 4	Total
Personnel	\$184,100	\$194,356	\$204,074	\$214,275	\$796,805
Fringe benefits	\$77,784	\$82,199	\$86,308	\$90,623	\$336,914
Travel	\$21,414	\$64,880	\$91,364	\$71,530	\$249,188
Equipment	\$4,000	\$94,500	\$4,411	\$0	\$102,911
Supplies	\$4,021,525	\$7,957,429	\$6,393,166	\$5,756,247	\$24,128,367
Contractual	\$134,400	\$269,538	\$152,697	\$160,332	\$716,967
Other	\$412,606	\$938,459	\$705,552	\$344,873	\$2,401,490
Total Direct Cost	\$4,855,829	\$9,601,361	\$7,637,572	\$6,637,880	\$28,732,642
Indirect Charges	\$294,042	\$308,745	\$324,182	\$340,389	\$1,267,358
Total USAID Program Cost	\$5,149,871	\$9,910,106	\$7,961,754	\$6,978,269	\$30,000,000
Cost Share	\$2,700,000	-	-	-	2,700,000
Total Program Cost	\$7,849,871	\$9,910,106	\$7,961,754	\$6,978,269	32,700,000

A.5 REPORTING AND EVALUATION

1. Financial Reporting

The Recipient shall submit an original and two copies quarterly. Financial Reports shall be in keeping with 22 CFR 226.52.

In accordance with 22 CFR 226.52, the SF 269 and SF 272 will be required on a quarterly basis. The recipient shall submit these forms in the following manner:

- (1) The SF 272 and 272a (if necessary) must be submitted via electronic format to the U.S. Department of Health and Human Services (http://www.dpm.psc.gov). A copy of this form shall also be submitted at the same time to the Agreement Officer and the Cognizant Technical Officer.
- (2) The SF 269 or 269a (as appropriate) shall be submitted to the Cognizant Technical officer with one copy to the Agreement Officer.
- (3) In accordance with 22 CFR 226.70-72, the original and two copies of all final financial reports shall be submitted to M/FM, the Agreement Officer (if requested) and the CTO. The electronic version of the final SF 272 or 272a shall be submitted to HHS in accordance with paragraph (1) above.

2. Program Reporting

The Recipient shall submit the following repots the Cognizant Technical Officer.

1. Annual Implementation Plan (2 copies)

The Recipient will prepare and submit to the CTO an annual implementation plan on a schedule established by the CTO. The first implementation plan to be submitted will not necessarily be for a full year or may be for more than a full year, depending upon the start date of the agreement. Annual implementation plans should be organized into the following sections:

- a) Work Plan: The work plan serves several purposes including as a guide to program implementation, a demonstration of links between activities and Expected Results, a basis for budget estimates and the foundation for the monitoring and evaluation plan. The work plan, at a minimum, should include:
 - (i) Brief situation analysis that details current situation of insecticide procurement and distribution
 - (ii) Indicators to be monitored and reported on;
 - (iii) Milestones toward achieving Expected Results;
 - (iv) Activities to be accomplished that year related specifically toward the achievement of milestones:
 - (v) Level of effort required in terms of key staff and support staff time and financial resources;
 - (vi) Partner involvement and contributions to achieving the results;
 - (vii) Timeline.

Work plans should be organized to clearly link activities to the Expected Results. The work plan will be negotiated with the CTO in consultation with NMCP managers, USAID Strategic Objective (SO) team leaders as appropriate, and mission Population, Health and Nutrition officers and Foreign Service National (FSNs) and will outline key activities to be

accomplished for the year. Work plan budgets should delineate an overall budget, a budget per Expected Result and budget per activity.

b) Management Plan: Coordination and communication with the NMCP and a wide range of partners, both internal to USAID and public/private sector partners, other cooperating agencies (CAs), other donors, etc. is key to the achievement of the activities described in this RFA. Recipients should demonstrate a willingness to partner with non-traditional partners and partners new to USAID and utilize diverse human resources effectively. Implementation plans will need to specify clear lines of supervision, accountability, decision-making and responsibility among staff. In the case of proposed prime/sub relationships, especially in cases of geographic separation of collaborative institutions, clear lines of communication should be established. Special attention will need to be paid to ensuring efficiencies in operational and financial management. Recipients should address how they intend to manage the operational partnerships in order to maximize the input and utility of all partner organizations, collaboratively and effectively.

2. Quarterly Performance Monitoring Reports (2 copies)

The performance monitoring report shall be submitted to the CTO and NMCP as the case may apply within 30 days following the end of the reporting period. Reports should briefly document on-going activities, and relate actual accomplishments toward the Expected Results and milestones. The last performance monitoring report of the year should be a summation of the results and progress toward results made during that year. The successful applicant will participate in PMI-NMCP monthly coordination meetings to report verbally and in written form the activities in the previous time period and proposed activities for the next period. The reports must also include the following:

- a) Summarize results of all activities under this award.
- b) Explanation of quantifiable output of the programs or projects, if appropriate and applicable;
- c) Reasons why established goals were not met, if appropriate; and,
- d) Analysis and explanation of any cost overruns or high unit costs (recipients must immediately notify USAID of developments that have a significant impact on award-supported activities).
- e) Reports will include an accounting of insecticide procured, distributed and used.

Notification must be given to USAID in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. These notifications must include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

3. Response Report and Presentations (1 copy)

The successful applicant is required to provide a response report to include follow-on recommendations and the next steps for proper response to any activities contained in this agreement. This report may be made at any time as required by the NMCP and/or USAID.

The successful applicant will be required, from time to time, and at the end of the project, to prepare presentations, press releases, speeches or briefs on any activity under this agreement.

3. Final Report

The Recipient shall submit the original and one copy to M/FM, the Agreement Officer (if requested), and the CTO and one copy, in electronic (preferred) or paper form of final documents to one of the following: (a) Via E-mail: docsubmit@dec.cdie.org; (b) Via U.S. Postal Service: Development Experience Clearinghouse, 8403 Colesville Road, Suite 210 Silver Spring, MD 20910, USA; (c) Via Fax: (301) 588-7787; or (d) Online:

http://www.dec.org/index.cfm?fuseaction=docSubmit.home.

The final performance report shall include:

An executive summary of the recipient's accomplishments in achieving the Expected Results and conclusions about areas in need of future assistance; an overall description of the recipient's activities and attainment of results during the life of the Cooperative Agreement; an assessment of progress made toward accomplishing the Expected Results; significance of these activities; important research findings; comments and recommendations; a section on how the program will be sustained after termination of USAID funding, and a fiscal report that describes how the Recipient's funds were used. See 22 CFR 226.51

A.6 INDIRECT COST RATE

Pending establishment of revised provisional or final indirect cost rates, allowable indirect costs shall be reimbursed on the basis of the following negotiated provisional or predetermined rates and the appropriate bases:

Type	Effective Period		Indirect Cost Rates		
Type	From	Through	Fringe Benefits (a)	Overhead (b)	
Provisional	10-01-06	Until amended			

Base of Application:

- (a) Total US based direct and indirect labor dollars.
- (b) Total US based direct labor and associated fringe benefit dollars.

Note: Fringe benefits for local field direct labor are reimbursed as other direct cost.

A.7 TITLE TO PROPERTY

Property Title will be vested with the Cooperative Country.

A.8 AUTHORIZED GEOGRAPHIC CODE

The authorized geographic code for procurement of goods and services under this award is 935.

A.9 COST SHARING

The Recipient agrees to expend an amount not less than \$2,700,000 in in-kind cost share.

A.10 PROGRAM INCOME

The Recipient shall account for Program Income in accordance with 22 CFR 226.24 (or the Standard Provision entitled Program Income for non-U.S. organizations). Program Income earned under this award shall be added to the project.

A.11 SUBSTANTIAL INVOLVEMENT

USAID will be substantially involved in the following areas.

Approval of the recipient's Implementation Plans.
 USAID will have the right to approve the proposed work plans on a yearly basis before implementation. All significant changes in the work plan by the recipient occurring after approval of the yearly work plan will require additional approval by USAID

2) Approval of specified key personnel.

The following positions have been designated as Key personnel positions.

<u>Position</u> <u>Name</u>

a) Chief of Party - Dr. Jane Miller
 b) Accountant - - To Be Determined.
 c) Operations Manager - To Be Determined
 d) Supply Chain Manager - To be Determined

3) Agency and recipient collaboration or joint participation.

Where there are specific elements in the Program Description for which USAID's technical knowledge would benefit the recipient's successful accomplishment of stated program objectives, the joint participation of USAID and the recipient can be authorized. Where the Agreement Officer is satisfied that there is sufficient reason for Agency involvement and that involvement is specifically tailored to support identified elements in the Program Description, the following are examples of appropriate levels of substantial involvement:

- Collaborative involvement in selection of advisory committee members. USAID may also chose to become a member of this type of committee. Advisory committees shall concern themselves only with technical or programmatic issues and not routine administrative matters;
- ii. Concur on the selection of subaward recipients and/or the substantive provisions of the subawards:
- iii. Approval of the recipient's monitoring and evaluation plans;
- iv. Agency monitoring to permit specified kinds of direction or redirection because of interrelationships with other projects. All such activities must be included in the Program Description and negotiated in the budget of the award.

A.12 SPECIAL PROVISIONS

A.12.1 USAID DISABILITY POLICY (DEC 2004)

(a) The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. government agencies, host country counterparts, governments, implementing organizations and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities. The full text of the policy paper can be found at the following website:

http://www.usaid.gov/about/disability/DISABPOL.FIN.html.

(b) USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women and children with disabilities.

A.12.2 EXECUTIVE ORDER ON TERRORISM FINANCING (FEB 2002)

The Contractor/Recipient is reminded that U.S. Executive Orders and U.S. law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the responsibility of the contractor/recipient to ensure compliance with these Executive Orders and laws. This provision must be included in all subcontracts/subawards issued under this contract/agreement.

A.12.3 FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (JAN 2002)

Funds in this [agreement, amendment] may not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government's delegation to an international conference sponsored by a public international organization, except as provided in ADS Mandatory Reference "Guidance on Funding Foreign Government Delegations to International Conferences" or as approved by the AO.

A.12.4 SELF SUSTAINING.

The Recipient shall require that the sub-recipients provide a strategy to become self sustaining, after the end of the grant (or contract) period. The Recipient shall review and agree to receiving this self sustaining strategy which includes capacity building prior to issuance of subawards. The subs shall also require the same from their sub sub-recipients. The Recipient shall report to the Agreement Officer (with a copy to the CTO) the number of subawards issued and how many of these are faith based organizations, or are new organizations which have not done business before with USAID or with the U.S. Government. The subs shall also submit the same information (in relation to their sub sub-recipients) to the Recipient who will forward this data to the Agreement Officer, (with a copy to the CTO).

-End of Schedule-

Attachment B **PROGRAM DESCRIPTION**

The Recipient revised program description titled Manufacturing LLINS in Tanzania: Vision to Reality submitted to USAID/Tanzania on May 18, 2007 is hereby attached (attachment B) and made a part of this award.

ATTACHMENT C

STANDARD PROVISIONS FOR U.S., NONGOVERNMENTAL ORGANIZATIONS

I. MANDATORY STANDARD PROVISIONS FOR U.S. NONGOVERNMENTAL RECIPIENTS

1. APPLICABILITY OF 22 CFR PART 226 (May 2005)

- a. All provisions of 22 CFR Part 226 and all Standard Provisions attached to this agreement are applicable to the recipient and to subrecipients which meet the definition of "Recipient" in Part 226, unless a section specifically excludes a subrecipient from coverage. The recipient shall assure that subrecipients have copies of all the attached standard provisions.
- b. For any subawards made with Non-US subrecipients the Recipient shall include the applicable "Standard Provisions for Non-US Nongovernmental Recipients." Recipients are required to ensure compliance with monitoring procedures in accordance with OMB Circular A-133.

[END OF PROVISION]

2. INELIGIBLE COUNTRIES (MAY 1986)

Unless otherwise approved by the USAID Agreement Officer, funds will only be expended for assistance to countries eligible for assistance under the Foreign Assistance Act of 1961, as amended, or under acts appropriating funds for foreign assistance.

[END OF PROVISION]

3. NONDISCRIMINATION (MAY 1986)

(This provision is applicable when work under the cooperative agreement is performed in the U.S. or when employees are recruited in the U.S.)

No U.S. citizen or legal resident shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity funded by this award on the basis of race, color, national origin, age, handicap, or sex.

[END OF PROVISION]

4. NONLIABILITY (NOVEMBER 1985)

USAID does not assume liability for any third party claims for damages arising out of this award.

[END OF PROVISION]

5. AMENDMENT (NOVEMBER 1985)

The award may be amended by formal modifications to the basic award document or by means of an exchange of letters between the Agreement Officer and an appropriate official of the recipient.

[END OF PROVISION]

6. NOTICES (NOVEMBER 1985)

Any notice given by USAID or the recipient shall be sufficient only if in writing and delivered in person, mailed, or cabled as follows:

To the USAID Agreement Officer, at the address specified in the award.

To recipient, at recipient's address shown in the award or to such other address designated within the award

Notices shall be effective when delivered in accordance with this provision, or on the effective date of the notice, whichever is later.

[END OF PROVISION]

7. SUBAGREEMENTS (June 1999)

Subrecipients, subawardees, and contractors have no relationship with USAID under the terms of this agreement. All required USAID approvals must be directed through the recipient to USAID.

[END OF PROVISION]

8. OMB APPROVAL UNDER THE PAPERWORK REDUCTION ACT (December 2003)

*Information collection requirements imposed by this cooperative agreement are covered by OMB approval number 0412-0510; the current expiration date is 04/30/2005. The Standard Provisions containing the requirement and an estimate of the public reporting burden (including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information) are

Standard Provision
Air Travel and Transportation
Ocean Shipment of Goods
Patent Rights

Burden Estimate

1 (hour)

.5

.5

Publications	.5
Negotiated Indirect Cost Rates -	
(Predetermined and Provisional)	1
Voluntary Population Planning	.5
Protection of the Individual as a	1
Research Subject	

22 CFR 226	Burden Estimate
22 CFR 226.4049 Procurement	
of Goods and Services	1
22 CFR 226.3036	
Property Standards	1.5

Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be sent to the Office of Procurement, Policy Division (M/OP/P) U.S. Agency for International Development, Washington, DC 20523-7801 and to the Office of Management and Budget, Paperwork Reduction Project (0412-0510), Washington, D.C 20503.

[END OF PROVISION]

9. USAID ELIGIBILITY RULES FOR GOODS AND SERVICES (April 1998)

(This provision is not applicable to goods or services which the recipient provides with private funds as part of a cost-sharing requirement, or with Program Income generated under the award.)

- a. Ineligible and Restricted Goods and Services: USAID's policy on ineligible and restricted goods and services is contained in ADS Chapter 312.
 - (1) Ineligible Goods and Services. Under no circumstances shall the recipient procure any of the following under this award:
 - (i) Military equipment,
 - (ii) Surveillance equipment,
 - (iii) Commodities and services for support of police or other law enforcement activities,
 - (iv) Abortion equipment and services,
 - (v) Luxury goods and gambling equipment, or
 - (vi) Weather modification equipment.
 - (2) Ineligible Suppliers. Funds provided under this award shall not be used to procure any goods or services furnished by any firms or individuals whose name appears on the "Lists of Parties Excluded from Federal Procurement and Nonprocurement Programs." USAID will provide the recipient with a copy of these lists upon request.
 - (3) Restricted Goods. The recipient shall not procure any of the following goods and

services without the prior approval of the Agreement Officer:

- (i) Agricultural commodities,
- (ii) Motor vehicles,
- (iii) Pharmaceuticals,
- (iv) Pesticides,
- (v) Used equipment,
- (vi) U.S. Government-owned excess property, or
- (vii) Fertilizer.

Prior approval will be deemed to have been met when:

- (i) the item is of U.S. source/origin;
- (ii) the item has been identified and incorporated in the program description or schedule of the award (initial or revisions), or amendments to the award; and
- (iii) the costs related to the item are incorporated in the approved budget of the award.

Where the item has not been incorporated into the award as described above, a separate written authorization from the Agreement Officer must be provided before the item is procured.

- b. Source and Nationality: The eligibility rules for goods and services based on source and nationality are divided into two categories. One applies when the total procurement element during the life of the award is over \$250,000, and the other applies when the total procurement element during the life of the award is not over \$250,000, or the award is funded under the Development Fund for Africa (DFA) regardless of the amount. The total procurement element includes procurement of all goods (e.g., equipment, materials, supplies) and services. Guidance on the eligibility of specific goods or services may be obtained from the Agreement Officer. USAID policies and definitions on source, origin and nationality are contained in 22 CFR Part 228, Rules on Source, Origin and Nationality for Commodities and Services Financed by the Agency for International Development, which is incorporated into this Award in its entirety.
 - (1) For DFA funded awards or when the total procurement element during the life of this award is valued at \$250,000 or less, the following rules apply:
 - (i) The authorized source for procurement of all goods and services to be reimbursed under the award is USAID Geographic Code 935, "Special Free World," and such goods and services must meet the source, origin and nationality requirements set forth in 22 CFR Part 228 in accordance with the following order of preference:
 - (A) The United States (USAID Geographic Code 000),
 - (B) The Cooperating Country,
 - (C) USAID Geographic Code 941, and
 - (D) USAID Geographic Code 935.

- (ii) Application of order of preference: When the recipient procures goods and services from other than U.S. sources, under the order of preference in paragraph (b)(1)(i) above, the recipient shall document its files to justify each such instance. The documentation shall set forth the circumstances surrounding the procurement and shall be based on one or more of the following reasons, which will be set forth in the Recipient's documentation:
 - (A) The procurement was of an emergency nature, which would not allow for the delay attendant to soliciting U.S. sources,
 - (B) The price differential for procurement from U.S. sources exceeded by 50% or more the delivered price from the non-U.S. source,
 - (C) Compelling local political considerations precluded consideration of U.S. sources.
 - (D) The goods or services were not available from U.S. sources, or
 - (E) Procurement of locally available goods and services, as opposed to procurement of U.S. goods and services, would best promote the objectives of the Foreign Assistance program under the award.
- (2) When the total procurement element exceeds \$250,000 (unless funded by DFA), the following applies: Except as may be specifically approved or directed in advance by the Agreement Officer, all goods and services financed with U.S. dollars, which will be reimbursed under this award must meet the source, origin and nationality requirements set forth in 22 CFR Part 228 for the authorized geographic code specified in the schedule of this award. If none is specified, the authorized source is Code 000, the United States.
- c. Printed or Audio-Visual Teaching Materials: If the effective use of printed or audio-visual teaching materials depends upon their being in the local language and if such materials are intended for technical assistance projects or activities financed by USAID in whole or in part and if other funds including U.S.-owned or U.S.-controlled local currencies are not readily available to finance the procurement of such materials, local language versions may be procured from the following sources, in order of preference:
 - (1) The United States (USAID Geographic Code 000),
 - (2) The Cooperating Country,
 - (3) "Selected Free World" countries (USAID Geographic Code 941), and
 - (4) "Special Free World" countries (USAID Geographic Code 899).
- d. If USAID determines that the recipient has procured any of these goods or services under this award contrary to the requirements of this provision, and has received payment for such purposes, the Agreement Officer may require the recipient to refund the entire amount of the purchase.

This provision must be included in all subagreements which include procurement of goods or services which total over \$5,000.

[END OF PROVISION]

10. DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS (January 2004)

- a. The recipient agrees to notify the Agreement Officer immediately upon learning that it or any of its principals:
 - (1) Are presently excluded or disqualified from covered transactions by any Federal department or agency;
 - (2) Have been convicted within the preceding three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, receiving stolen property, making false claims, or obstruction of justice; commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects your present responsibility;
 - (3) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b); and
 - (4) Have had one or more public transactions (Federal, State, or local) terminated for cause or default within the preceding three years.
- b. The recipient agrees that, unless authorized by the Agreement Officer, it will not knowingly enter into any subagreements or contracts under this cooperative agreement with a person or entity that is included on the Excluded Parties List System (http://epls.arnet.gov). The recipient further agrees to include the following provision in any subagreements or contracts entered into under this award:

DEBARMENT, SUSPENSION, INELIGIBILITY, AND VOLUNTARY EXCLUSION (DECEMBER 2003)

The recipient/contractor certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

c. The policies and procedures applicable to debarment, suspension, and ineligibility under USAID-financed transactions are set forth in 22 CFR Part 208.

[END OF PROVISION]

11. DRUG-FREE WORKPLACE (January 2004)

- a. The recipient agrees that it will publish a drug-free workplace statement and provide a copy to each employee who will be engaged in the performance of any Federal award. The statement must
 - (1) Tell the employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in its workplace;
 - (2) Specify the actions the recipient will take against employees for violating that prohibition; and
 - (3) Let each employee know that, as a condition of employment under any award, he or she
 - (i) Must abide by the terms of the statement, and
 - (ii) Must notify you in writing if he or she is convicted for a violation of a criminal drug statute occurring in the workplace, and must do so no more than five calendar days after the conviction.
- b. The recipient agrees that it will establish an ongoing drug-free awareness program to inform employees about
 - (i) The dangers of drug abuse in the workplace;
 - (ii) Your policy of maintaining a drug-free workplace;
 - (iii) Any available drug counseling, rehabilitation and employee assistance programs; and
 - (iv) The penalties that you may impose upon them for drug abuse violations occurring in the workplace.
- c. Without the Agreement Officer's expressed written approval, the policy statement and program must be in place as soon as possible, no later than the 30 days after the effective date of this award or the completion date of this award, whichever occurs first.
- d. The recipient agrees to immediately notify the Agreement Officer if an employee is convicted of a drug violation in the workplace. The notification must be in writing, identify the employee's position title, the number of each award on which the employee worked. The notification must be sent to the Agreement Officer within ten calendar days after the recipient learns of the conviction.
- e. Within 30 calendar days of learning about an employee's conviction, the recipient must either

- (1) Take appropriate personnel action against the employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973 (29 USC 794), as amended, or
- (2) Require the employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for these purposes by a Federal, State or local health, law enforcement, or other appropriate agency.
- f. The policies and procedures applicable to violations of these requirements are set forth in 22 CFR Part 210.

[END OF PROVISION]

12. EQUAL PROTECTION OF THE LAWS FOR FAITH-BASED AND COMMUNITY ORGANIZATIONS (February 2004)

- a. The recipient may not discriminate against any beneficiary or potential beneficiary under this award on the basis of religion or religious belief. Accordingly, in providing services supported in whole or in part by this agreement or in its outreach activities related to such services, the recipient may not discriminate against current or prospective program beneficiaries on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice;
- b. The Federal Government must implement Federal programs in accordance with the Establishment Clause and the Free Exercise Clause of the First Amendment to the Constitution. Therefore, if the recipient engages in inherently religious activities, such as worship, religious instruction, and proselytization, it must offer those services at a different time or location from any programs or services directly funded by this award, and participation by beneficiaries in any such inherently religious activities must be voluntary.
- c. If the recipient makes subawards under this agreement, faith-based organizations should be eligible to participate on the same basis as other organizations, and should not be discriminated against on the basis of their religious character or affiliation.

[END OF PROVISION]

13. IMPLEMENTATION OF E.O. 13224 -- EXECUTIVE ORDER ON TERRORIST FINANCING (March 2002)

The Recipient is reminded that U.S. Executive Orders and U.S. law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the recipient to ensure compliance with these Executive Orders and laws. This provision must be included in all contracts/subawards issued under this agreement.

[END OF PROVISION]

14. MARKING UNDER USAID-FUNDED ASSISTANCE INSTRUMENTS (December 2005)

(a) Definitions

Commodities mean any material, article, supply, goods or equipment, excluding recipient offices, vehicles, and non-deliverable items for recipient's internal use, in administration of the USAID funded grant, cooperative agreement, or other agreement or subagreement.

Principal Officer means the most senior officer in a USAID Operating Unit in the field, e.g., USAID Mission Director or USAID Representative. For global programs managed from Washington but executed across many countries, such as disaster relief and assistance to internally displaced persons, humanitarian emergencies or immediate post conflict and political crisis response, the cognizant Principal Officer may be an Office Director, for example, the Directors of USAID/W/Office of Foreign Disaster Assistance and Office of Transition Initiatives. For non-presence countries, the cognizant Principal Officer is the Senior USAID officer in a regional USAID Operating Unit responsible for the non-presence country, or in the absence of such a responsible operating unit, the Principal U.S Diplomatic Officer in the non-presence country exercising delegated authority from USAID.

Programs mean an organized set of activities and allocation of resources directed toward a common purpose, objective, or goal undertaken or proposed by an organization to carry out the responsibilities assigned to it.

Projects include all the marginal costs of inputs (including the proposed investment) technically required to produce a discrete marketable output or a desired result (for example, services from a fully functional water/sewage treatment facility).

Public communications are documents and messages intended for distribution to audiences external to the recipient's organization. They include, but are not limited to, correspondence, publications, studies, reports, audio visual productions, and other informational products; applications, forms, press and promotional materials used in connection with USAID funded programs, projects or activities, including signage and plaques; Web sites/Internet activities; and events such as training courses, conferences, seminars, press conferences and so forth.

Subrecipient means any person or government (including cooperating country government) department, agency, establishment, or for profit or nonprofit organization that receives a USAID subaward, as defined in 22 C.F.R. 226.2.

Technical Assistance means the provision of funds, goods, services, or other foreign assistance, such as loan guarantees or food for work, to developing countries and other USAID recipients, and through such recipients to subrecipients, in direct support of a development objective – as opposed to the internal management of the foreign assistance program.

USAID Identity (Identity) means the official marking for the United States Agency for International Development (USAID), comprised of the USAID logo or seal and new brandmark, with the tagline that clearly communicates that our assistance is "from the American people." The USAID Identity is available on the USAID website at www.usaid.gov/branding and USAID provides it without royalty, license, or other fee to recipients of USAID-funded grants, or

cooperative agreements, or other assistance awards

(b) Marking of Program Deliverables

- (1) All recipients must mark appropriately all overseas programs, projects, activities, public communications, and commodities partially or fully funded by a USAID grant or cooperative agreement or other assistance award or subaward with the USAID Identity, of a size and prominence equivalent to or greater than the recipient's, other donor's, or any other third party's identity or logo.
- (2) The Recipient will mark all program, project, or activity sites funded by USAID, including visible infrastructure projects (for example, roads, bridges, buildings) or other programs, projects, or activities that are physical in nature (for example, agriculture, forestry, water management) with the USAID Identity. The Recipient should erect temporary signs or plaques early in the construction or implementation phase. When construction or implementation is complete, the Recipient must install a permanent, durable sign, plaque or other marking.
- (3) The Recipient will mark technical assistance, studies, reports, papers, publications, audio-visual productions, public service announcements, Web sites/Internet activities and other promotional, informational, media, or communications products funded by USAID with the USAID Identity.
- (4) The Recipient will appropriately mark events financed by USAID, such as training courses, conferences, seminars, exhibitions, fairs, workshops, press conferences and other public activities, with the USAID Identity. Unless directly prohibited and as appropriate to the surroundings, recipients should display additional materials, such as signs and banners, with the USAID Identity. In circumstances in which the USAID Identity cannot be displayed visually, the recipient is encouraged otherwise to acknowledge USAID and the American people's support.
- (5) The Recipient will mark all commodities financed by USAID, including commodities or equipment provided under humanitarian assistance or disaster relief programs, and all other equipment, supplies, and other materials funded by USAID, and their export packaging with the USAID Identity.
- (6) The Agreement Officer may require the USAID Identity to be larger and more prominent if it is the majority donor, or to require that a cooperating country government's identity be larger and more prominent if circumstances warrant, and as appropriate depending on the audience, program goals, and materials produced.
- (7) The Agreement Officer may require marking with the USAID Identity in the event that the recipient does not choose to mark with its own identity or logo.
- (8) The Agreement Officer may require a pre-production review of USAID-funded public communications and program materials for compliance with the approved Marking Plan.
- (9) Subrecipients. To ensure that the marking requirements "flow down" to subrecipients

of subawards, recipients of USAID funded grants and cooperative agreements or other assistance awards will include the USAID-approved marking provision in any USAID funded subaward, as follows:

"As a condition of receipt of this subaward, marking with the USAID Identity of a size and prominence equivalent to or greater than the recipient's, subrecipient's, other donor's or third party's is required. In the event the recipient chooses not to require marking with its own identity or logo by the subrecipient, USAID may, at its discretion, require marking by the subrecipient with the USAID Identity."

(10) Any 'public communications', as defined in 22 C.F.R. 226.2, funded by USAID, in which the content has not been approved by USAID, must contain the following disclaimer:

"This study/report/audio/visual/other information/media product (specify) is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of [insert recipient name] and do not necessarily reflect the views of USAID or the United States Government."

(11) The recipient will provide the Cognizant Technical Officer (CTO) or other USAID personnel designated in the grant or cooperative agreement with two copies of all program and communications materials produced under the award. In addition, the recipient will submit one electronic or one hard copy of all final documents to USAID's Development Experience Clearinghouse.

(c) Implementation of marking requirements.

- (1) When the grant or cooperative agreement contains an approved Marking Plan, the recipient will implement the requirements of this provision following the approved Marking Plan.
- (2) When the grant or cooperative agreement does not contain an approved Marking Plan, the recipient will propose and submit a plan for implementing the requirements of this provision within [*Agreement Officer fill-in*] days after the effective date of this provision. The plan will include:
 - (i) A description of the program deliverables specified in paragraph (b) of this provision that the recipient will produce as a part of the grant or cooperative agreement and which will visibly bear the USAID Identity.
 - (ii) the type of marking and what materials the applicant uses to mark the program deliverables with the USAID Identity,
 - (iii) when in the performance period the applicant will mark the program deliverables, and where the applicant will place the marking,
- (3) The recipient may request program deliverables not be marked with the USAID Identity by identifying the program deliverables and providing a rationale for not marking these program deliverables. Program deliverables may be exempted from USAID marking requirements when:

- (i) USAID marking requirements would compromise the intrinsic independence or neutrality of a program or materials where independence or neutrality is an inherent aspect of the program and materials;
- (ii) USAID marking requirements would diminish the credibility of audits, reports, analyses, studies, or policy recommendations whose data or findings must be seen as independent;
- (iii) USAID marking requirements would undercut host-country government "ownership" of constitutions, laws, regulations, policies, studies, assessments, reports, publications, surveys or audits, public service announcements, or other communications better positioned as "by" or "from" a cooperating country ministry or government official;
- (iv) USAID marking requirements would impair the functionality of an item;
- (v) USAID marking requirements would incur substantial costs or be impractical;
- (vi) USAID marking requirements would offend local cultural or social norms, or be considered inappropriate;
- (vii) USAID marking requirements would conflict with international law.
- (4) The proposed plan for implementing the requirements of this provision, including any proposed exemptions, will be negotiated within the time specified by the Agreement Officer after receipt of the proposed plan. Failure to negotiate an approved plan with the time specified by the Agreement Officer may be considered as noncompliance with the requirements is provision.

(d) Waivers.

- (1) The recipient may request a waiver of the Marking Plan or of the marking requirements of this provision, in whole or in part, for each program, project, activity, public communication or commodity, or, in exceptional circumstances, for a region or country, when USAID required marking would pose compelling political, safety, or security concerns, or when marking would have an adverse impact in the cooperating country. The recipient will submit the request through the Cognizant Technical Officer. The Principal Officer is responsible for approvals or disapprovals of waiver requests.
- (2) The request will describe the compelling political, safety, security concerns, or adverse impact that require a waiver, detail the circumstances and rationale for the waiver, detail the specific requirements to be waived, the specific portion of the Marking Plan to be waived, or specific marking to be waived, and include a description of how program materials will be marked (if at all) if the USAID Identity is removed. The request should also provide a rationale for any use of recipient's own identity/logo or that of a third party on materials that will be subject to the waiver.

- (3) Approved waivers are not limited in duration but are subject to Principal Officer review at any time, due to changed circumstances.
- (4) Approved waivers "flow down" to recipients of subawards unless specified otherwise. The waiver may also include the removal of USAID markings already affixed, if circumstances warrant.
- (5) Determinations regarding waiver requests are subject to appeal to the Principal Officer's cognizant Assistant Administrator. The recipient may appeal by submitting a written request to reconsider the Principal Officer's waiver determination to the cognizant Assistant Administrator.
- (e) Non-retroactivity. The requirements of this provision do not apply to any materials, events, or commodities produced prior to January 2, 2006. The requirements of this provision do not apply to program, project, or activity sites funded by USAID, including visible infrastructure projects (for example, roads, bridges, buildings) or other programs, projects, or activities that are physical in nature (for example, agriculture, forestry, water management) where the construction and implementation of these are complete prior to January 2, 2006 and the period of the cooperative agreement does not extend past January 2, 2006.

[END OF PROVISION]

15. REGULATIONS GOVERNING EMPLOYEES (AUGUST 1992)

(The following applies to the recipient's employees working in the cooperating country under the agreement who are not citizens of the cooperating country.)

- a. The recipient's employees shall maintain private status and may not rely on local U.S. Government offices or facilities for support while under this cooperative agreement.
- b. The sale of personal property or automobiles by recipient employees and their dependents in the foreign country to which they are assigned shall be subject to the same limitations and prohibitions which apply to direct-hire USAID personnel employed by the Mission, including the rules contained in 22 CFR Part 136, except as this may conflict with host government regulations.
- c. Other than work to be performed under this award for which an employee is assigned by the recipient, no employee of the recipient shall engage directly or indirectly, either in the individual's own name or in the name or through an agency of another person, in any business, profession, or occupation in the foreign countries to which the individual is assigned, nor shall the individual make loans or investments to or in any business, profession or occupation in the foreign countries to which the individual is assigned.
- d. The recipient's employees, while in a foreign country, are expected to show respect for its conventions, customs, and institutions, to abide by its applicable laws and regulations, and not to interfere in its internal political affairs.
- e. In the event the conduct of any recipient employee is not in accordance with the preceding

paragraphs, the recipient's chief of party shall consult with the USAID Mission Director and the employee involved and shall recommend to the recipient a course of action with regard to such employee.

- f. The parties recognize the rights of the U.S. Ambassador to direct the removal from a country of any U.S. citizen or the discharge from this cooperative agreement award of any third country national when, in the discretion of the Ambassador, the interests of the United States so require.
- g. If it is determined, either under (e) or (f) above, that the services of such employee should be terminated, the recipient shall use its best efforts to cause the return of such employee to the United States, or point of origin, as appropriate.

[END OF PROVISION]

16. CONVERSION OF UNITED STATES DOLLARS TO LOCAL CURRENCY (NOVEMBER 1985)

(This provision applies when activities are undertaken outside the United States.)

Upon arrival in the Cooperating Country, and from time to time as appropriate, the recipient's chief of party shall consult with the Mission Director who shall provide, in writing, the procedure the recipient and its employees shall follow in the conversion of United States dollars to local currency. This may include, but is not limited to, the conversion of currency through the cognizant United States Disbursing Officer or Mission Controller, as appropriate.

[END OF PROVISION]

17. USE OF POUCH FACILITIES (AUGUST 1992)

(This provision applies when activities are undertaken outside the United States.)

- a. Use of diplomatic pouch is controlled by the Department of State. The Department of State has authorized the use of pouch facilities for USAID recipients and their employees as a general policy, as detailed in items (1) through (6) below. However, the final decision regarding use of pouch facilities rest with the Embassy or USAID Mission. In consideration of the use of pouch facilities, the recipient and its employees agree to indemnify and hold harmless, the Department of State and USAID for loss or damage occurring in pouch transmission:
 - (1) Recipients and their employees are authorized use of the pouch for transmission and receipt of up to a maximum of .9 kgs per shipment of correspondence and documents needed in the administration of assistance programs.
 - (2) U.S. citizen employees are authorized use of the pouch for personal mail up to a maximum of .45 kgs per shipment (but see (a)(3) below).

- (3) Merchandise, parcels, magazines, or newspapers are not considered to be personal mail for purposes of this standard provision and are not authorized to be sent or received by pouch.
- (4) Official and personal mail pursuant to a.1. and 2. above sent by pouch should be addressed as follows:

Name of individual or organization (followed by letter symbol "G")
City Name of post (USAID/____)
Agency for International Development
Washington, D.C. 20523-0001

- (5) Mail sent via the diplomatic pouch may not be in violation of U.S. Postal laws and may not contain material ineligible for pouch transmission.
- (6) Recipient personnel are NOT authorized use of military postal facilities (APO/FPO). This is an Adjutant General's decision based on existing laws and regulations governing military postal facilities and is being enforced worldwide.
- b. The recipient shall be responsible for advising its employees of this authorization, these guidelines, and limitations on use of pouch facilities.
- c. Specific additional guidance on Recipient use of pouch facilities in accordance with this standard provision is available from the Post Communication Center at the Embassy or USAID Mission.

[END OF PROVISION]

18. INTERNATIONAL AIR TRAVEL AND TRANSPORTATION (JUNE 1999)

(This provision is applicable when costs for international travel or transportation will be paid for with USAID funds. This provision is not applicable if the recipient is providing for travel with private funds as part of a cost-sharing requirement, or with Program Income generated under the award.)

a. PRIOR BUDGET APPROVAL

In accordance with OMB Cost Principles, direct charges for foreign travel costs are allowable only when each foreign trip has received prior budget approval. Such approval will be deemed to have been met when:

- (1) the trip is identified. Identification is accomplished by providing the following information: the number of trips, the number of individuals per trip, and the destination country(s).
- (2) the information noted at (a)(1) above is incorporated in: the proposal, the program

description or schedule of the award, the implementation plan (initial or revisions), or amendments to the award; and

(3) the costs related to the travel are incorporated in the approved budget of the award.

The Agreement Officer may approve travel which has not been incorporated in writing as required by paragraph (a)(2). In such case, a copy of the Agreement Officer's approval must be included in the agreement file.

b. NOTIFICATION

- (1) As long as prior budget approval has been met in accordance with paragraph (a) above, a separate Notification will not be necessary unless:
 - (i) the primary purpose of the trip is to work with USAID Mission personnel, or
 - (ii) the recipient expects significant administrative or substantive programmatic support from the Mission.

Neither the USAID Mission nor the Embassy will require Country Clearance of employees or contractors of USAID Recipients.

- (2) Where notification is required in accordance with paragraph (1)(i) or (ii) above, the recipient will observe the following standards:
 - (i) Send a written notice to the cognizant USAID Technical Office in the Mission. If the recipient's primary point of contact is a Technical Officer in USAID/W, the recipient may send the notice to that person. It will be the responsibility of the USAID/W Technical Officer to forward the notice to the field.
 - (ii) The notice should be sent as far in advance as possible, but at least 14 calendar days in advance of the proposed travel. This notice may be sent by fax or email. The recipient should retain proof that notification was made.
 - (iii) The notification shall contain the following information: the award number, the cognizant Technical Officer, the traveler's name (if known), date of arrival, and the purpose of the trip.
 - (iv) The USAID Mission will respond only if travel has been denied. It will be the responsibility of the Technical Officer in the Mission to contact the recipient within 5 working days of having received the notice if the travel is denied. If the recipient has not received a response within the time frame, the recipient will be considered to have met these standards for notification, and may travel.
 - (v) If a subrecipient is required to issue a Notification, as per this section, the subrecipient may contact the USAID Technical Officer directly, or the prime may contact USAID on the subrecipient's behalf.

c. SECURITY ISSUES

Recipients are encouraged to obtain the latest Department of State Travel Advisory Notices before travelling. These Notices are available to the general public and may be obtained directly from the State Department, or via Internet.

Where security is a concern in a specific region, recipients may choose to notify the US Embassy of their presence when they have entered the country. This may be especially important for long-term posting.

d. USE OF U.S.-OWNED LOCAL CURRENCY

Travel to certain countries shall, at USAID's option, be funded from U.S.-owned local currency. When USAID intends to exercise this option, USAID will either issue a U.S. Government S.F. 1169, Transportation Request (GTR) which the Recipient may exchange for tickets, or issue the tickets directly. Use of such U.S.-owned currencies will constitute a dollar charge to this cooperative agreement.

e. THE FLY AMERICA ACT

The Fly America Act (49 U.S.C. 40118) requires that all air travel and shipments under this award must be made on U.S. flag air carriers to the extent service by such carriers is available. The Administrator of General Services Administration (GSA) is authorized to issue regulations for purposes of implementation. Those regulations may be found at 41 CFR part 301, and are hereby incorporated by reference into this award.

f. COST PRINCIPLES

The recipient will be reimbursed for travel and the reasonable cost of subsistence, post differentials and other allowances paid to employees in international travel status in accordance with the recipient's applicable cost principles and established policies and practices which are uniformly applied to federally financed and other activities of the Recipient.

If the recipient does not have written established policies regarding travel costs, the standard for determining the reasonableness of reimbursement for overseas allowance will be the Standardized Regulations (Government Civilians, Foreign Areas), published by the U.S. Department of State, as from time to time amended. The most current subsistence, post differentials, and other allowances may be obtained from the Agreement Officer.

g. SUBAWARDS.

This provision will be included in all subawards and contracts which require international air travel and transportation under this award.

[END OF PROVISION]

19. OCEAN SHIPMENT OF GOODS (JUNE 1999)

(This provision is applicable for awards and subawards for \$100,000 or more and when goods purchased with funds provided under this award are transported to cooperating countries on ocean

vessels whether or not award funds are used for the transportation.)

- a. At least 50% of the gross tonnage of all goods purchased under this agreement and transported to the cooperating countries shall be made on privately owned U.S. flag commercial ocean vessels, to the extent such vessels are available at fair and reasonable rates for such vessels.
- b. At least 50% of the gross freight revenue generated by shipments of goods purchased under this agreement and transported to the cooperating countries on dry cargo liners shall be paid to or for the benefit of privately owned U.S. flag commercial ocean vessels to the extent such vessels are available at fair and reasonable rates for such vessels.
- c. When U.S. flag vessels are not available, or their use would result in a significant delay, the Recipient may request a determination of non-availability from the USAID Transportation Division, Office of Procurement, Washington, D.C. 20523, giving the basis for the request which will relieve the Recipient of the requirement to use U.S. flag vessels for the amount of tonnage included in the determination. Shipments made on non-free world ocean vessels are not reimbursable under this cooperative agreement.
- d. The recipient shall send a copy of each ocean bill of lading, stating all of the carrier's charges including the basis for calculation such as weight or cubic measurement, covering a shipment under this agreement to:

U.S. Department of Transportation, Maritime Administration, Division of National Cargo, 400 7th Street, S.W., Washington, DC 20590, and

U.S. Agency for International Development, Office of Procurement, Transportation Division 1300 Pennsylvania Avenue, N.W. Washington, DC 20523-7900

- e. Shipments by voluntary nonprofit relief agencies (i.e., PVOs) shall be governed by this standard provision and by USAID Regulation 2, "Overseas Shipments of Supplies by Voluntary Nonprofit Relief Agencies" (22 CFR Part 202).
- f. Shipments financed under this cooperative agreement must meet applicable eligibility requirements set out in 22 CFR 228.21.

[END OF PROVISION]

20. LOCAL PROCUREMENT (April 1998)

(This provision applies when activities are undertaken outside the United States.)

a. Financing local procurement involves the use of appropriated funds to finance the procurement of goods and services supplied by local businesses, dealers or producers, with

- payment normally being in the currency of the cooperating country.
- b. Locally financed procurements must be covered by source and nationality waivers as set forth in 22 CFR 228, Subpart F, except as provided for in mandatory standard provision, "USAID Eligibility Rules for Goods and Services," or when one of the following exceptions applies:
 - (1) Locally available commodities of U.S. origin, which are otherwise eligible for financing, if the value of the transaction is estimated not to exceed \$100,000 exclusive of transportation costs.
 - (2) Commodities of geographic code 935 origin if the value of the transaction does not exceed the local currency equivalent of \$5,000.
 - (3) Professional Services Contracts estimated not to exceed \$250,000.
 - (4) Construction Services Contracts estimated not to exceed \$5,000,000.
 - (5) Commodities and services available only in the local economy (no specific per transaction value applies to this category). This category includes the following items:
 - (i) Utilities including fuel for heating and cooking, waste disposal and trash collection;
 - (ii) Communications telephone, telex, fax, postal and courier services;
 - (iii) Rental costs for housing and office space;
 - (iv) Petroleum, oils and lubricants for operating vehicles and equipment;
 - (v) Newspapers, periodicals and books published in the cooperating country;
 - (vi) Other commodities and services and related expenses that, by their nature or as a practical matter, can only be acquired, performed, or incurred in the cooperating country, e.g., vehicle maintenance, hotel accommodations, etc.
- c. The coverage on ineligible and restricted goods and services in the mandatory standard provision entitled, "USAID Eligibility Rules for Goods and Services," also apply to local procurement.
 - d. This provision will be included in all subagreements where local procurement of goods or services is a supported element.

[END OF PROVISION]

21. VOLUNTARY POPULATION PLANNING ACTIVITIES – MANDATORY REQUIREMENTS (MAY 2006)

Requirements for Voluntary Sterilization Programs

(1) None of the funds made available under this award shall be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any individual to practice sterilization.

Prohibition on Abortion-Related Activities:

- (1) No funds made available under this award will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to any person to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for or against abortion. The term "motivate", as it relates to family planning assistance, shall not be construed to prohibit the provision, consistent with local law, of information or counseling about all pregnancy options.
- (2) No funds made available under this award will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

22. NEGOTIATED INDIRECT COST RATES - PROVISIONAL (Nonprofit) (April 1998)

- a. Provisional indirect cost rates shall be established for each of the recipient's accounting periods during the term of this award. Pending establishment of revised provisional or final rates, allowable indirect costs shall be reimbursed at the rates, on the bases, and for the periods shown in the schedule of the award.
- b. Within the earlier of 30 days after receipt of the A-133 audit report or nine months after the end of the audit period, the recipient shall submit to the cognizant agency for audit the required OMB Circular A-133 audit report, proposed final indirect cost rates, and supporting cost data. If USAID is the cognizant agency or no cognizant agency has been designated, the recipient shall submit four copies of the audit report, along with the proposed final indirect cost rates and supporting cost data, to the Overhead, Special Costs, and Closeout Branch, Office or Procurement, USAID, Washington, DC 20523-7802. The proposed rates shall be based on the recipient's actual cost experience during that fiscal year. Negotiations of final indirect cost rates shall begin soon after receipt of the recipient's proposal.
- c. Allowability of costs and acceptability of cost allocation methods shall be determined in accordance with the applicable cost principles.
- d. The results of each negotiation shall be set forth in a written indirect cost rate agreement signed by both parties. Such agreement is automatically incorporated into this award and shall specify (1) the agreed upon final rates, (2) the bases to which the rates apply, (3) the fiscal year for which the rates apply, and (4) the items treated as direct costs. The agreement

- shall not change any monetary ceiling, award obligation, or specific cost allowance or disallowance provided for in this award.
- e. Pending establishment of final indirect cost rate(s) for any fiscal year, the recipient shall be reimbursed either at negotiated provisional rates or at billing rates acceptable to the Agreement Officer, subject to appropriate adjustment when the final rates for the fiscal year are established. To prevent substantial overpayment or underpayment, the provisional or billing rates may be prospectively or retroactively revised by mutual agreement.
- f. Failure by the parties to agree on final rates is a 22 CFR 226.90 dispute.

[END OF PROVISION]

23. PUBLICATIONS AND MEDIA RELEASES (MARCH 2006)

a. The recipient shall provide the USAID Cognizant Technical Officer one copy of all published works developed under the award with lists of other written work produced under the award. In addition, the recipient shall submit final documents in electronic format unless no electronic version exists at the following address:

Online (preferred)

http://www.dec.org/submit.cfm

Mailing address:
Document Acquisitions
USAID Development Experience Clearinghouse (DEC) 8403
Colesville Road Suite 210
Silver Spring, MD 2091 0-6368
Contract Information
Telephone (301) 562-0641
Fax (301) 588-7787

E-mail: docsubmit@dec.cdie.org

Electronic documents must consist of only one electronic file that comprises the complete and final equivalent of a hard copy. They may be submitted online (preferred); on 3.5" diskettes, a Zip disk, CD-R, or by e-mail. Electronic documents should be in PDF (Portable Document Format). Submission in other formats is acceptable but discouraged.

Each document submitted should contain essential bibliographic elements, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) strategic objective; and 6) date of publication;:

- b. In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost shall be credited to the award unless the schedule of the award has identified the profits or royalties as program income.
- c. Except as otherwise provided in the terms and conditions of the award, the author or the recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of or under this award, but USAID reserves a royalty-free nonexclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use the work for Government purposes.

[END OF PROVISION]

24. PARTICIPANT TRAINING (April 1998)

- a. Definition: A participant is any non-U.S. individual being trained under this outside of that individual's home country.
- b. Application of ADS Chapter 253: Participant training under this award shall comply

- with the policies established in ADS Chapter 253, Participant Training, except to the extent that specific exceptions to ADS 253 have been provided in this award with the concurrence of the Office of International Training.
- c. Orientation: In addition to the mandatory requirements in ADS 253, recipients are strongly encouraged to provide, in collaboration with the Mission training officer, predeparture orientation and orientation in Washington at the Washington International Center. The latter orientation program also provides the opportunity to arrange for home hospitality in Washington and elsewhere in the United States through liaison with the National Council for International Visitors (NCIV). If the Washington orientation is determined not to be feasible, home hospitality can be arranged in most U.S. cities if a request for such is directed to the Agreement Officer, who will transmit the request to NCIV through EGAT/ED/PT.

[END OF PROVISION]

25. TITLE TO AND CARE OF PROPERTY (COOPERATING COUNTRY TITLE) (NOVEMBER 1985)

- a. Except as modified by the schedule of this cooperative agreement, title to all equipment, materials and supplies, the cost of which is reimbursable to the recipient by USAID or by the cooperating country, shall at all times be in the name of the cooperating country or such public or private agency as the cooperating country may designate, unless title to specified types or classes of equipment is reserved to USAID under provisions set forth in the schedule of this award. All such property shall be under the custody and control of recipient until the owner of title directs otherwise or completion of work under this award or its termination, at which time custody and control shall be turned over to the owner of title or disposed of in accordance with its instructions. All performance guarantees and warranties obtained from suppliers shall be taken in the name of the title owner.
- b. The recipient shall maintain and administer in accordance with sound business practice a program for the maintenance, repair, protection, and preservation of Government property so as to assure its full availability and usefulness for the performance of this cooperative agreement. The recipient shall take all reasonable steps to comply with all appropriate directions or instructions which the Agreement Officer may prescribe as reasonably necessary for the protection of the Government property.
- c. The recipient shall prepare and establish a program, to be approved by the appropriate USAID Mission, for the receipt, use, maintenance, protection, custody and care of equipment, materials and supplies for which it has custodial responsibility, including the establishment of reasonable controls to enforce such program. The recipient shall be guided by the following requirements:
 - (1) Property Control: The property control system shall include but not be limited to the following:

- (i) Identification of each item of cooperating country property acquired or furnished under the award by a serially controlled identification number and by description of item. Each item must be clearly marked "Property of (insert name of cooperating country)."
- (ii) The price of each item of property acquired or furnished under this award.
- (iii) The location of each item of property acquired or furnished under this award.
- (iv) A record of any usable components which are permanently removed from items of cooperating country property as a result of modification or otherwise.
- (v) A record of disposition of each item acquired or furnished under the award.
- (vi) Date of order and receipt of any item acquired or furnished under the award.
- (vii) The official property control records shall be kept in such condition that at any stage of completion of the work under this award, the status of property acquired or furnished under this award may be readily ascertained. A report of current status of all items of property acquired or furnished under the award shall be submitted yearly concurrently with the annual report.
- (2) Maintenance Program: The recipient's maintenance program shall be consistent with sound business practice, the terms of the award, and provide for:
 - (i) disclosure of need for and the performance of preventive maintenance,
 - (ii) disclosure and reporting of need for capital type rehabilitation, and
 - (iii) recording of work accomplished under the program:
 - (A) Preventive maintenance Preventive maintenance is maintenance generally performed on a regularly scheduled basis to prevent the occurrence of defects and to detect and correct minor defects before they result in serious consequences.
 - (B) Records of maintenance The recipient's maintenance program shall provide for records sufficient to disclose the maintenance actions performed and deficiencies discovered as a result of inspections.
 - (C) A report of status of maintenance of cooperating country property shall be submitted annually concurrently with the annual report.

d. Risk of Loss:

- (1) The recipient shall not be liable for any loss of or damage to the cooperating country property, or for expenses incidental to such loss or damage except that the recipient shall be responsible for any such loss or damage (including expenses incidental thereto):
 - (i) Which results from willful misconduct or lack of good faith on the part of any of the recipient's directors or officers, or on the part of any of its managers, superintendents, or other equivalent representatives, who have supervision or direction of all or substantially all of the recipient's business, or all or substantially all of the recipient's operation at any one plant, laboratory, or separate location in which this award is being performed;
 - (ii) Which results from a failure on the part of the recipient, due to the willful misconduct or lack of good faith on the part of any of its directors, officers, or other representatives mentioned in (i) above:
 - (A) to maintain and administer, in accordance with sound business practice, the program for maintenance, repair, protection, and preservation of cooperating country property as required by (i) above, or
 - (B) to take all reasonable steps to comply with any appropriate written directions of the Agreement Officer under (b) above;
 - (iii) For which the recipient is otherwise responsible under the express terms designated in the schedule of this award;
 - (vi) Which results from a risk expressly required to be insured under some other provision of this award, but only to the extent of the insurance so required to be procured and maintained, or to the extent of insurance actually procured and maintained, whichever is greater; or
 - (v) Which results from a risk which is in fact covered by insurance or for which the Recipient is otherwise reimbursed, but only to the extent of such insurance or reimbursement;
 - (vi) Provided, that, if more than one of the above exceptions shall be applicable in any case, the recipient's liability under any one exception shall not be limited by any other exception.
- (2) The recipient shall not be reimbursed for, and shall not include as an item of overhead, the cost of insurance, or any provision for a reserve, covering the risk of loss of or damage to the cooperating country property, except to the extent that

- USAID may have required the recipient to carry such insurance under any other provision of this award.
- (3) Upon the happening of loss or destruction of or damage to the cooperating country property, the recipient shall notify the Agreement Officer thereof, shall take all reasonable steps to protect the cooperating country property from further damage, separate the damaged and undamaged cooperating country property, put all the cooperating country property in the best possible order, and furnish to the Agreement Officer a statement of:
 - (i) The lost, destroyed, or damaged cooperating country property;
 - (ii) The time and origin of the loss, destruction, or damage;
 - (iii) All known interests in commingled property of which the cooperating country property is a part; and
 - (iv) The insurance, if any, covering any part of or interest in such commingled property.
- (4) The recipient shall make repairs and renovations of the damaged cooperating country property or take such other action as the Agreement Officer directs.
- (5) In the event the recipient is indemnified, reimbursed, or otherwise compensated for any loss or destruction of or damage to the cooperating country property, it shall use the proceeds to repair, renovate or replace the cooperating country property involved, or shall credit such proceeds against the cost of the work covered by the award, or shall otherwise reimburse USAID, as directed by the Agreement Officer. The recipient shall do nothing to prejudice USAID's right to recover against third parties for any such loss, destruction, or damage, and upon the request of the Agreement Officer, shall, at the Governments expense, furnish to USAID all reasonable assistance and cooperation (including assistance in the prosecution of suits and the execution of instruments or assignments in favor of the Government) in obtaining recovery.
- e. Access: USAID, and any persons designated by it, shall at all reasonable times have access to the premises wherein any cooperating country property is located, for the purpose of inspecting the cooperating country property.
- f. Final Accounting and Disposition of Cooperating Country Property: Within 90 days after completion of this award, or at such other date as may be fixed by the Agreement Officer, the recipient shall submit to the Agreement Officer an inventory schedule covering all items of equipment, materials and supplies under the recipient's custody, title to which is in the cooperating country or public or private agency designated by the cooperating country, which have not been consumed in the performance of this award. The recipient shall also indicate what disposition has been made of such property.

g. Communications: All communications issued pursuant to this provision shall be in writing.

[END OF PROVISION]

26. PUBLIC NOTICES (MARCH 2004)

It is USAID's policy to inform the public as fully as possible of its programs and activities. The recipient is encouraged to give public notice of the receipt of this award and, from time to time, to announce progress and accomplishments. Press releases or other public notices should include a statement substantially as follows:

"The U.S. Agency for International Development administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 120 countries worldwide."

The recipient may call on USAID's Bureau for Legislative and Public Affairs for advice regarding public notices. The recipient is requested to provide copies of notices or announcements to the cognizant technical officer and to USAID's Bureau for Legislative and Public Affairs as far in advance of release as possible.

[END OF PROVISION]

27. REPORTING OF FOREIGN TAXES (March 2006)

- a. The recipient must annually submit a report by April 16 of the next year.
- b. Contents of Report. The report must contain:
 - (i) Contractor/recipient name.
 - (ii) Contact name with phone, fax and email.
 - (iii) Agreement number(s).
 - (iv) Amount of foreign taxes assessed by a foreign government [each foreign government must be listed separately] on commodity purchase transactions valued at \$500 or more financed with U.S. foreign assistance funds under this agreement during the prior U.S. fiscal year.
 - (v) Only foreign taxes assessed by the foreign government in the country receiving U.S. assistance is to be reported. Foreign taxes by a third party foreign government are not to be reported. For example, if an assistance program for Lesotho involves the

purchase of commodities in South Africa using foreign assistance funds, any taxes imposed by South Africa would not be reported in the report for Lesotho (or South Africa).

- (vi) Any reimbursements received by the Recipient during the period in (iv) regardless of when the foreign tax was assessed and any reimbursements on the taxes reported in (iv) received through March 31.
- (vii) Report is required even if the recipient did not pay any taxes during the report period.
- (viii) Cumulative reports may be provided if the recipient is implementing more than one program in a foreign country.
- c. Definitions. For purposes of this clause:
 - (i) "Agreement" includes USAID direct and country contracts, grants, cooperative agreements and interagency agreements.
 - (ii) "Commodity" means any material, article, supply, goods, or equipment.
 - (iii) "Foreign government" includes any foreign governmental entity.
 - (iv) "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
- d. Where. Submit the reports to:

Mission Controller
USAID/Tanzania
2140 Dar es Salaam Place
Washington, D.C. 20521-2140
POC: Teresita Alberastine (talberastine@usaid.gov)

- e. Subagreements. The recipient must include this reporting requirement in all applicable
- e. For further information see http://www.state.gov/m/rm/c10443.htm. [END OF PROVISION]

subcontracts, subgrants and other subagreements.

27 FOREIGN GOVERNMENT DELEGATIONS TO INTERNATIONAL CONFERENCES (January 2002)

Funds in this agreement may not be used to finance the travel, per diem, hotel expenses, meals, conference fees or other conference costs for any member of a foreign government's delegation

to an international conference sponsored by a public international organization, except as provided in ADS Mandatory Reference "Guidance on Funding Foreign Government Delegations to International Conferences or as approved by the Agreement Officer.

These provisions also must be included in the Standard Provisions of any new grant or cooperative agreement to a public international organization or a U.S. or non-U.S. non-governmental organization financed with FY04 HIV/AIDS funds or modification to an existing grant or cooperative agreement that adds FY04 HIV/AIDS.

[END OF PROVISION]

28 USAID DISABILITY POLICY - ASSISTANCE (DECEMBER 2004)I

a. The objectives of the USAID Disability Policy are (1) to enhance the attainment of United States foreign assistance program goals by promoting the participation and equalization of opportunities of individuals with disabilities in USAID policy, country and sector strategies, activity designs and implementation; (2) to increase awareness of issues of people with disabilities both within USAID programs and in host countries; (3) to engage other U.S. government agencies, host country counterparts, governments, implementing organizations and other donors in fostering a climate of nondiscrimination against people with disabilities; and (4) to support international advocacy for people with disabilities. The full text of the policy paper can be found at the following website:

http://www.usaid.gov/about/disability/DISABPOL.FIN.html

b. USAID therefore requires that the recipient not discriminate against people with disabilities in the implementation of USAID funded programs and that it make every effort to comply with the objectives of the USAID Disability Policy in performing the program under this grant or cooperative agreement. To that end and to the extent it can accomplish this goal within the scope of the program objectives, the recipient should demonstrate a comprehensive and consistent approach for including men, women and children with disabilities.

[END OF PROVISION]

[END OF STANDARD PROVISIONS]

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LIST OF ACRONYMS

BCC Behavior Change Communications

CMAC Chemical Management Advisory Committee
HPLC High Performance Liquid Chromatography

IHRDC Ifakara Health Research and Development Centre

IMR Infant Mortality Rate

IRK (standalone) Insecticide Re-treatment Kit

IRS Indoor Residual Spraying
ITK Insecticide Treatment Kit
LLIN Long Lasting Insecticide Net

LLINWG LLIN Working Group

LSHTM London School of Hygiene and Tropical Medicine

LSTM Liverpool School of Tropical Medicine
MOHSW Ministry of Health and Social Welfare
NATNETS National Insecticide Treated Nets Program
NEMC National Environmental Management Council

NIMR National Institute of Medical Research
NMCP National Malaria Control Program

OPR Output to Purpose Review

PA Primary Agent

PMI President's Malaria Initiative
PSI Population Services International

SMITN Social Marketing of ITNs

TBS Tanzanian Bureau of Standards
TFDA Tanzania Food and Drug Authority
TNM Tanzanian Net Manufacturer

TNVS Tanzania National Voucher Scheme TPRI Tropical Pesticide Research Institute

UFMR Under-five mortality rate

WHOPES WHO Pesticide Evaluation Scheme

A. EXECUTIVE SUMMARY

Population Services International (PSI) and its partners are pleased to submit the following response to RFA USAID-TANZANIA 07-003 for Malaria Control in Mainland Tanzania. In collaboration with key partners and stakeholders, PSI will build upon its proven expertise in malaria program management and its strong local procurement and distribution capacity to meet the objectives described in the RFA.

PSI proposes a comprehensive project strategy that will advance national malaria control efforts, contributing to significant reductions in infant, children under five and maternal mortality rates in Tanzania. The proposed strategy will increase the effectiveness of insecticide-treated nets (ITNs) for malaria prevention through the procurement, distribution, monitoring and use of bundled insecticide treatment kits and stand-alone re-treatment kits (ITKs/IRKs). PSI will further increase the health impact and long-term sustainability of the proposed intervention by assisting Tanzanian net manufacturers (TNMs) with the bulk procurement of insecticide and introduction of factory pre-treatment technology. PSI will work in close collaboration with regulatory authorities, the NetMark project and other key stakeholders to ensure the successful implementation of long-lasting insecticide-treated net manufacturing in Tanzania, in accordance with generally accepted quality standards.

PSI is well-positioned to achieve the objectives of the RFA, with a proven track record for cost-efficiency and extensive experience with the clearance, storage and transport of vast volumes of high-value inventory. Since 1998, PSI has been responsible for the timely procurement and distribution of more than 20 million ITKs/IRKs in Tanzania, serving as the lead implementing agency for the SMARTNET program and playing an integral role in the Roll Back Malaria WHO ITN Technical Expert Group. The efforts of PSI's regional sales teams and national distribution partner, Nufaika, will facilitate the safe and timely movement of treatment products nationwide, including to remote rural locations. PSI will monitor product coverage, use, quality assurance, and compliance with national and international laws, regulations, ethics and best practices. The program will feature a comprehensive tracking system for insecticide supplied to the Tanzanian market. In order to address the lack of routine national insecticide resistance monitoring, PSI will also help implement a standardized and coordinated system of testing and reporting using a network of sentinel sites across Tanzania.

As the current Secretariat of the Long-Lasting Insecticide-Treated Net Working Group (LLIN WG), PSI has been at the forefront of efforts to establish LLIN manufacturing in Tanzania for the past two years. PSI has developed long-standing partnerships with the four TNMs, gaining the knowledge and earning a reputation for transparency that will be needed to effectively facilitate the LLIN technology transfer, manage subsidy issues and secure a universal agreement among manufacturers not to undercut treated nets by supplying an un-treated product to the domestic market.

The proposed candidate for Chief of Party (CoP), Dr. Jane Miller, is a highly-qualified public health professional with 12 years of leadership experience in the management of malaria prevention and control programs in Tanzania. Dr. Miller has extensive technical knowledge of insecticide use for malaria prevention and maintains excellent working relationships with all major stakeholders and partner organizations.

PSI is a capable and cost-effective partner; with co-funding from the German, Dutch and British governments; established operations in-country; and exceptional professional staff; all of which will contribute to the advancement of program objectives. Additional resources from PSI's own internal funding mechanisms and sales revenue increase the potential cost-share for this program.

B. Introduction: Situation Analysis

Malaria Burden in Tanzania B.1

The Tanzanian mainland has a population of about 38.2 million people living in 113 districts, about 10,000 villages and 6.5 million households in an area of 885,987 km².

According to the DHS, malaria is the leading cause of childhood illness and child deaths in Tanzania. The statistics available from the MOHSW indicate over 16 million cases per year, resulting in over 100,000 deaths annually, with 75% of the Tanzanian population estimated to be living in areas of constant seasonal transmission. Children under five years of age and pregnant women are at a much higher risk; hospital based data indicate a mortality rate of 12% of under-fives due to Malaria. The economic costs of malaria are estimated at 3.5% of the GDP.²

B.2 Impact of ITNs

The regular use of Insecticide Treated Nets (ITN) is estimated to reduce the clinical episodes of malaria by 50%, and to reduce severe malaria by 45%, according to the Cochrane Review in 2004.

Improved malaria prevention and treatment have played a significant role in the reduction of Tanzania's infant mortality rate (IMR) and under-five mortality rate (UFMR) between 1999 and 2004. The DHS data on the infant mortality rate (IMR) show a reduction from 99 per 1,000 live births in 1999 to 68 in 2004. DHS data on the UFMR show a reduction from 136 in 1999 to 112 in 2004. Compared with the 1996 DHS, the reduction in the IMR is from 88 to 68, and in the UFMR from 137 to 112.

Social Marketing of ITNs in Tanzania

The social marketing of ITNs for malaria prevention in Tanzania was introduced in 1998, and expanded nationwide in 2000 through the Social Marketing of ITN (SMITN) project. This project is implemented by PSI in collaboration with the National Malaria Control Program (NMCP) and funded by the British government (DfID) and the Royal Netherlands Embassy (RNE). In 2002, stakeholders demonstrated their confidence in PSI's approach by expanding this program under the name SMARTNET. In 2004, the project was extended until July 2007.

B.3.1 SMARTNET: A Unique Public-Private Partnership

The SMARTNET project has been highly effective at harnessing the capacity of commercial manufacturers to achieve health impact. The program promotes insecticide treatment and re-treatment kits (ITK/IRKs), branded locally as Ngao. PSI provides the kits free of charge to the TNMs for bundling with nets, and distributes them at a subsidized price via a dense, nationwide network of wholesalers and retailers. Commercial distribution of stand-alone ITKs enables net purchasers to treat their new nets at home.

The regular Ngao formulation is effective for about a year or up to 3 washes, while the longer-lasting Ngao ya Muda Mrefu (overbranded KO 1-2-3), introduced in 2006, offers effective protection through about 15 washes. Available research shows that on average, Tanzanians wash their nets every quarter. On this basis, Ngao ya Muda Mrefu is likely effective for at least two years for the vast majority of all users. The longer-lasting Ngao is currently bundled with the TNM's nets; the dominant brands are Safi (A-Z Textile Mills Ltd), Mmbu (Sunflag Tanzania Ltd), Afya (Textile Mills of Tanzania Limited -TMTL) and Motex (Moshi Textile Mills).

¹ Based on 2002 census and population growth 2.5% per annum

² NMCP, MOHSW

³ Lengeler C. 2004. Insecticide-treated bednets and curtains for preventing malaria. Cochrane Database Systematic Reviews: Oxford, UK.

WHOPES-World health Organization Pesticide Evaluation Scheme: promotes and coordinates the testing and evaluation of pesticides for public health

The recent OPR Report credited the SMARTNET program with several significant accomplishments⁵:

- i. Establishing a Competitive Market: By fostering competition among net manufacturers, PSI has helped ensure that net prices have remained relatively low and that product quality is high. This competition has been crucial in light of Tanzanian currency devaluations and inflationary pressure.
- ii. Reconciling Commercial and Public Health Imperatives: Mosquito nets have a dual nature. From the perspective of health professionals, they are a health product; while from the viewpoint of manufacturers, wholesalers and retailers, the net is a household commodity. Conflict may arise when recognized health imperatives are seen as counter-productive to commercial interests.

PSI's ability to operate comfortably and effectively in both domains, health and commerce, has created synergy rather than conflict. The expertise of the manufacturers and reach of the commercial distribution system has ensured that the product is widely available, while public sector efforts have ensured that it is effectively targeted and affordable. PSI's robust, transparent relationships with the NMCP/MOHSW and the TNMs have been instrumental in creating this unique balance.

- iii. Crowding-out Insecticide-less Nets: PSI's persistent advocacy and close relationship with the TNMs has ensured that every net made by the TNMs is sold bundled with insecticide. The fact that no TNM has tried to undercut the market by selling an unbundled product or used the ITKs/IRKs for the export market is testament to PSI's management abilities.
- iv. Achieving Nationwide Rural Coverage and Market Penetration: Both bundled nets and standalone ITKs/IRKs are available in every part of the country, due in large part to PSI's distribution efforts. A 2006 survey found Ngao or Ngao ya Muda Mrefu in 51% of villages sampled in remote areas of Tanzania. Coupled with successful demand creation, this rural market coverage and penetration has created a guaranteed market for the TNMs, convincing them of the long-term viability of their business and encouraging investment in their manufacturing capacity.

B.3.2 <u>Tanzania National Voucher Scheme: Targeting</u>

The Tanzania National Voucher Scheme (TNVS) has helped ensure that high-risk groups are effectively targeted with subsidies for net purchases. Funded by the Global Fund to Fight AIDS Tuberculosis and Malaria (GFATM), the scheme issues vouchers to women on their first antenatal visit to a health clinic. Women can use the vouchers to purchase nets at a highly discounted price from an accredited retailer of nets. Through this voucher system, around 1.6 million nets have been purchased to date. Close to 90% of the distributed vouchers are redeemed. The TNVS is a vital complementary activity to the social marketing of ITNs and ITKs/IRKs, facilitating net access to the poorest sections of the at-risk population. (With PMI funding, the voucher scheme has been extended to infants in 15 regions via a measles immunization program, and will be further extended to all 21 regions in PMI Year 2. The scheme will begin targeting under-fives in four regions during PMI Year 2, with the potential World Bank funding to eventually enable expansion to all regions).

B.4 The Introduction of LLINs

PSI, in collaboration with the NMCP, has been at the vanguard of innovative ITN technology. The next step is to increase effective net treatment by shifting responsibility from the consumer to the manufacturer; i.e. by pre-treating nets in the factory with longer-lasting insecticide instead of having customers treat them at home. This requires the installation and operation of new equipment and the supply of bulk insecticide to factories (rather that pre-packaged ITK/IRKs).

The continued supply of insecticide for home-based treatment of nets is required until the conversion of all nets to LLIN status is complete. A subsidy for insecticide supply will also be needed to assure that TNMs comply with the requirements of factory-based treatment with longer-lasting insecticide. The

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⁵ DfID OPR Final Report, November 2006

⁶ PSI MAP Survey, 2006.

subsidy for this should be negotiated at the outset as a strictly time-limited support. The techno-feasibility report⁷ estimated that that the cost of insecticide per net will fall from over USD 1.50 to less than USD 0.30 within five years. This low incremental cost for insecticide treatment would allow it to be passed on to the consumer and offer a sustainable option for malarial prevention in Tanzania.

PSI considers the rapid, efficient and cost-effective transformation of all nets made in Tanzania into LLINs to be the key objective of this project. PSI's knowledge and understanding of each TNM will be crucial to facilitating the technology transfer.

Effective advocacy over the course of the SMARTNET project has ensured that each of the TNMs is very receptive to the idea of factory pre-treatment. The TNMs understand the importance of LLINs on both a national and international (export sales) level. Since the GFATM and Unicef only advocate the procurement of LLINs, the manufacturers have a strong incentive to make the transition. The transition to LLINs is expected to open a large, profitable (unsubsidized) export market for the TNMs, particularly elsewhere in Africa. PSI is also currently considering re-instituting a system of transport subsidies to function as an additional incentive – this would also help address the inconsistency in net prices in different parts of the country.

Ultimately, the TNMs willingness to make the necessary capital investments will depend upon their confidence in a reliable supply of insecticide and a guaranteed market for the final product. It will also be vital to secure a universal agreement among suppliers not to undercut treated nets by supplying an untreated product to the domestic market.

PSI has contacted each of the TNMs to discuss in detail the steps necessary to transition to the pretreatment of nets in each factory. PSI developed a timetable for the completion of key steps (Annex 7) in collaboration with the TNMs. The following measures will help ensure regular communication and effective coordination of this transition:

- Each TNM will select one representative to serve as for the key contact for all LLIN-related issues:
- PSI will hold monthly, on-site meetings with each TNM
- PSI will communicate via phone with the key contact at each TNM at least once per week, and more frequently if necessary.

PSI will draft a joint memorandum of understanding (MoU) to be signed by all four TNMs, as well as USAID and PSI. By signing the MOU, TNMs will agree that they will not undercut the market for pretreated nets with untreated nets. Among other provisions, this MoU will stipulate that any TNM supplying untreated nets to the market will have its insecticide subsidy withdrawn. PSI will draw upon the experience of developing a similar MoU for SMARTNET, signed by DfID and all three TNMs that existed at the time (attached, Annex 8).

The SMARTNET experience also illustrates the TNMs' commitment to the project. DFID's initial concerns that TNMs would try to undercut the market with unbundled net sales proved to be unfounded. The TNMs have repeatedly expressed that, although profit is their primary incentive, they are proud to be a part of the effort to combat the country's leading killer of young children. Tanzania's net program has a great deal of positive international recognition and support (e.g. RBM), and the TNMs are fully aware of the consequences of backing out of the program in terms of their credibility and reputations.

C. TECHNICAL APPROACH

PSI's strategy is based on the achievement of the following objectives:

⁷ Techno Economic Feasibility: Manufacturing Long lasting Insecticide Treated Nets in Tanzania. Manan Management Analytics Pvt. Ltd.

- i. Procure, warehouse and distribute approved ITKs/IRKs to each of four Tanzanian manufacturers of mosquito nets for bundling with all polyester nets produced for sale in the local Tanzanian market.
 - PSI will tap into its existing procurement and logistics infrastructure to procure and distribute ITKs to each TNM. PSI will work with a qualified procurement agent (such as the Crown Agents) to carry-out pre-shipment. Post-shipment inspection will be done by one of the qualified Tanzanian laboratories.
- ii. Procure, warehouse and distribute approved ITKs/IRKs for sale in the private sector.

 PSI will procure the IRKs as above and distribute them to wholesalers and retailers nation-wide in collaboration with Nufaika.
- iii. Procure, warehouse and distribute approved insecticide in bulk to potentially four Tanzanian net manufacturers for use in factory pre-treatment of bed nets to be sold in Tanzania.

 PSI will procure bulk insecticide (as above) and distribute it to the TNMs using PSI's fleet of vehicles.
- iv. Monitor and ensure that the approved insecticide provided (in kits or in bulk) is used according to generally accepted quality standards and only for its intended purpose (i.e. only for nets to be sold in Tanzania).
 PSI will collaborate with laboratories (e.g. TFDA, NIMR) that will undertake chemical analysis of the pre-treated netting in order to determine that nets have been properly treated. PSI will work with a credible professional auditing firm such as PricewaterhouseCoopers (PSI's auditing partner under SMARTNET) in order to ensure that bulk insecticide is only used to treat nets for the
- v. Collaborate with the NetMark Project and any other entity in facilitating the introduction of factory pre-treatment with insecticide of locally produced nets.

 PSI will build on its existing relationships with NetMark and position as Secretariat of the Long Lasting Insecticide Nets Working Group (LLINWG) in order to ensure that pre-factory treatment happens as quickly and efficiently as possible.

As a result of PSI's efforts to support ITN manufacturers, several outcomes are expected, including:

- A significant increase in the proportion of effectively treated ITNs
- A significant increase in the proportion of households that own at least one ITN
- A sustainable supply of factory treated nets made available to the Tanzanian public after 2009
- An agreed exit plan regarding insecticide subsidy

Tanzanian market.

The logical framework in Annex 3 outlines specific targets and illustrates how each proposed indicator relates to the project objectives.

The following sections describe PSI's comprehensive strategy for achieving the above objectives. First, PSI addresses the procurement, warehousing and distribution of insecticide for bundling, pre-treatment and re-treatment of nets, followed by a section describing how PSI would facilitate the introduction of pre-treated nets. The next sections focus on the issues of quality control and auditing of insecticide use, as well as the often overlooked but essential task of routine insecticide resistance monitoring. The final section is a brief discussion of the key issues surrounding the behavior change communications that will be required to make the overall implementation of this program a success.

C.1 Procurement, Warehousing and Distribution

C.1.1 Procurement of Insecticide

The efficient procurement of large quantities of high-value chemical product (both ITKs/IRKs and bulk insecticide) represents a complex challenge, requiring demonstrated capacity and strong management systems.

C.1.1.1 PSI's Procurement Experience and Qualifications

PSI began procuring mosquito nets and home insecticide re-treatment kits for malaria prevention in 1998. Since then, PSI has procured more than 20.7 million ITKs/IRKs (four different types), either directly or through DFID procurement agents. More than 10.2 million of these were delivered to the TNMs and bundled with nets during the SMARTNET program, while the remaining ITKs/IRKs were sold through the commercial sector as stand-alone kits.

PSI's procurement and logistics team is highly experienced in managing every aspect of the international supply chain, from demand forecasting and specification development to procurement, contracting, contract administration, air and marine transport, insurance, clearance, host country regulatory compliance, inland transport, storage, and claims. PSI's solid performance record is due to close coordination between country offices and expert headquarters staff. Over its more than 13 years of operation in Tanzania, PSI has built up logistic expertise and long-standing relationships that enable its programs to avoid extended stock-out situations for all products (including condoms and safe water products), provided that funding for such commodities is adequate.

PSI has long-standing relationships with all the major net suppliers and insecticide manufacturers (including those based and/or producing in sub-Saharan Africa). Increasing annual volumes have enabled the successful negotiation of price discount agreements for ordinary net treatment products; such discounts are applicable worldwide. PSI possesses an in-depth knowledge of the available and appropriate types of insecticide and their formulation, as well as the contract systems and lead times of suppliers. Through its Global Malaria department, PSI monitors the latest information on all ITN/LLIN innovations and sits on the Roll Back Malaria WHO ITN Technical Expert Group (among other committees). In Tanzania, in collaboration with the NMCP, PSI was responsible for assembling and hosting the LLIN Working Group (LLINWG)⁸. The purpose of the LLINWG is to facilitate the introduction of LLIN production in Tanzania while ensuring that all regulatory and quality assurance issues are addressed.

PSI's focus on sustaining effective relationships with the NMCP and TNMs, and ultimately on bottom-line health impact, provides a powerful incentive to perform. In all of its activities, PSI places great emphasis on business integrity, employing a robust set of provisions to deter fraudulent practices, and strong remedial action (including termination) if the stipulations of a contract are violated.

C.1.1.2 Procurement Management Process

PSI directly manages logistics, including forecasting, ordering, shipping, port and customs clearance and warehousing. Correct quantities of the right product are delivered in good condition, in a timely manner, at the lowest possible price.

A certificate of analysis will be obtained prior to shipment. Every batch manufactured has a certificate of analysis stating that the batch conforms to product specifications. Once the product arrives in country, PSI will move quickly to transfer product from the port into its well-maintained warehouse in Dar es Salaam, where it will be stored according to appropriate guidelines. PSI's inventory and storage system will follow the "first in/first out" principle.

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⁸ See the ToR in Annex 5

All procurement will be carried out in accordance with applicable USAID Guidelines and Office Instructions. Where necessary, PSI will be responsible for the issuance of USAID compliant invitations to bid, the evaluation of bids, and the development of bid evaluation reports. The invitations to bid will stress the importance of on-time deliveries and warn of severe penalties for late deliveries.

Currently, KO Tab 1-2-3 is the only product that has obtained WHOPES certification as effective for at least 15 washes. Therefore, PSI proposes that for the first year, procurement of the KO 1-2-3 deltamethrin tablet-plus-binder formulation for home insecticide treatment kits be sole-sourced from the manufacturer, Bayer Environmental Science (BES). Sole-sourcing from Bayer will be discontinued as soon as a suitable comparable product (in terms of efficacy and formulation) is made available from other suppliers and registered in Tanzania. PSI will work as an advocate to lower the entry barriers to the Tanzanian market for new manufacturers of longer-lasting insecticide.

Since Bayer's current price for *KO Tab 1-2-3* limits the program's ability to purchase sufficient quantities to meet the needs of the Tanzanian market in Year 1, PSI will offer a non-required cost share to fund a substantial number of treatments. PSI is confident that there will be sufficient resources to meet the increasing demand for LLINs and ITKs/IRKs given this cost share and additional stocks remaining from the SMARTNET program.

C.1.1.3 Demand and Sales Projections

Projected net and bundled insecticide requirements are based on the anticipated uptake and redemption of vouchers distributed by the TNVS for pregnant women, infants and children under five, in conjunction with a small proportion of commercial sales. The 2006 TNVS household survey indicated that 75% of pregnant women in the TNVS districts received vouchers, and that the redemption rate was 83%. Table 1 below outlines the forecast demand for each group; i.e. an estimated 75% of each target group will receive the vouchers, and an estimated 83% of those will actually redeem them. The projected demand for stand-alone IRKs is based on the number of nets that were sold bundled with conventional ITKs in 2005 and 2006. Given historical re-treatment rates, it is estimated that 50% of these 3.3 million nets will be treated in PMI Year 2, and 25% in Year 3 (since longer-lasting treatment will be used on the nets retreated in PMI Year 2, a significantly smaller number of this net crop will require re-treatment in Year 3).

A degree of market cannibalization is expected. In many households a voucher supported ITN will simply replace a commercial net that the household was planning to purchase anyways. To some extend it can also be expected that households that have redeemed multiple vouchers sell one or two of their nets to people who would otherwise have procured a commercial ITN from a retailer. This anticipated cannibalization explains the relatively low number for regular commercial sales.

Table 1: Projected Net and ITK/IRK Demand, Supply and Shortfall

	PMI Y2	PMI Y3	PMI Y4	PMI Y5	Totals
Pregnant Women Vouchers	975,165	1,003,445	1,032,545	1,062,489	4,073,644
Infant Vouchers	843,047	867,496	892,653	918,540	3,521,737
Under-Five Vouchers	3,069,915	1,290,272	843,047	867,496	6,070,731
Commercial (non-voucher)	500,000	1,000,000	1,200,000	1,400,000	4,100,000
Stand-alone IRKs	1,665,000	832,500			2,497,500
Total Demand	7,053,127	4,993,713	3,968,245	4,248,525	20,263,612
Total Budgeted under PMI	2,350,000	4,589,410	3,865,860	3,977,970	14,783,240
Total from PSI Cost-share	1,570,072				1,570,072
Stock Remaining from SMARTNET	600,000				600,000
Total Supply	4,520,072	4,589,410	3,865,860	3,977,970	16,953,312
Shortfall	2,533,055	404,303	102,385	270,555	3,310,300

The number of ITKs/IRKs that can be procured with PMI funding falls short of projected demand, and the limited resources that PSI can mobilize as a cost-share will not be sufficient to fill this gap. To address

⁹ TNVS Household Survey, LSHTM and IHRDC, 2006.

the predicted shortfall, additional funding will be required from other sources – or the ceiling on the budget for Year 1 would have to be increased. If sufficient funds cannot be made available for the provision of longer-lasting insecticides at a highly-subsidized price, the program needs to consider the provision of conventional insecticide (procured with non-PMI funds) or a pricing structure that leads to higher cost recovery.

Given these constraints, it is recommended that priority be given to needs of the TNMs for bundling. This is based on the assumption that a treatment kit is more effectively used on a new net, simply because a used net might wear out and be disposed of before the insecticide loses its effectiveness. Selling unbundled nets in order to free up ITKs/IRKs for stand-alone sales would also undermine the significant efforts made to secure a manufacturers' agreement and crowd-out such nets from the Tanzanian market.

The 2006 TNVS survey indicated that the proportion of households owning at least one ITN was 29%. This relatively low figure should be viewed in light of the fact that the ITKs/IRKs in use at the time were conventional (not long-lasting) products. PSI expects that the introduction of the longer-lasting net treatment (i.e. 100% bundling with the TNM's polyester nets) in April 2006 will have dramatically increased the number of effectively treated nets by the end of 2007. In 2006, over two million nets were sold bundled with longer-lasting net treatment and over 1.5 million longer-lasting ITKs/IRKs (*Ngao ya Muda Mrefu*) were sold as stand-alone product.

Assuming the life of polyester net to be between two and three years, the net crop by the end of 2007 will be about nine million, of which those treated with the longer-lasting product will constitute more that 70%. This implies that with the introduction of the new treatment product, capable of withstanding up to 15 washes, the percentage of households owning at least one effectively treated net will increase from 29% in 2006 to over 70% by the end of 2007.

C.1.2 TPRI Approval Process

The Tropical Pesticides Research Institute (TPRI) was established in 1979 as a para-statal organization under the Ministry of Agriculture, Livestock Development and Cooperatives. Its responsibilities are to:

- Carry out and disseminate research and evaluations of pesticide application in relation to tropical pests in a variety of environments; and
- Control the import, manufacturing, formulation, storage, distribution, sale, transportation and use of pesticides in Tanzania.

PSI has a well established working relationship with TPRI, beginning with the registration and approval of the original 'Dip-it-Yourself' net treatment kit in 1998. Although pyrethroid insecticides were registered at the time, the kit was not approved for household use or distribution through commercial channels. PSI worked closely with the institute to demonstrate how effective packaging, instructions and communications would enable correct, safe home treatment; thereby securing registration and approval.

PSI also played an important role in the registration of PermaNet, the second WHOPES-approved LLIN to enter the Tanzanian market. The TPRI is also a member of the LLIN WG, for which PSI is the Secretariat. This arrangement will help facilitate the approval and certification of factory pre-treatment by the TNMs.

PSI has substantial experience with the registration process for insecticides in Tanzania. This experience, combined with strong working relationships with the TPRI, WHOPES and NMRI, will help to ensure that new registrations are handled efficiently. Since some of the insecticide products have already been registered (including KO Tab 1-2-3), the primary focus for the registration process will be on new products.

PSI has learned valuable lessons from the approval process for KO Tab 1-2-3. The NIMR has not endorsed the promotion of this longer-lasting product (although it has not asked for its withdrawal). Similar disagreement will be avoided in the future, as the NIMR and PSI now work closely together as members of the LLIN WG. At the start of the proposed program, PSI, the relevant insecticide suppliers

and NMCP/ITN cell representatives will visit NIMR in order to discuss the available products and their current status with WHOPES and in Tanzania. Following this visit, PSI will work with the NIMR and TPRI to initiate hut and field trials if necessary. PSI will also advocate the use of data from international trials to facilitate the 'fast-tracking' of appropriate products.

Following approval and registration, the following steps must be taken to obtain final clearance for the use of any insecticide in Tanzania, including unbundled insecticide and ITKs/IRKs:

- i. PSI will provide TPRI with a completed TPRI application form (Form PRC-2) and the appendix to PRC-2, filled in with information regarding the trade and chemical name of the product, the FOB value of the product, the delivery schedule, the quantity in kilograms or liters, details of who will use the product after it is imported and the purpose for which it will be used.
- ii. PSI will provide TPRI with application fees based on the number of samples to be analyzed. A sample is defined as any quantity of insecticide not exceeding 3,000 KGs.
- iii. PSI will receive the import permit from TPRI.
- iv. PSI will inform TPRI when the bulk consignment arrives so samples can be taken for analysis before the product is distributed to end users.
- v. PSI will facilitate the clearance of goods at the port of entry.

PSI's familiarity with these steps, experience with the registration of the insecticide in Tanzania and strong working relationships with TPRI will be important assets in the implementation of this project.

C.1.3 Quality Assurance

PSI's sound, long-standing relationships with the major insecticide manufacturers will ensure the delivery of high-quality product – a vital and indispensable part of PSI's procurement approach. Manufacturers will be held responsible for any defects in order to fully protect the consumer. Defective product, such as leaking sachets and broken tablets, will be replaced free of charge by the manufacturer. All product supply contracts will be drafted and issued to suppliers by PSI.

PSI will ensure that appropriate quality assurance inspections are conducted at point-of-origin prior to shipping and upon arrival in Dar es Salaam. Post-shipment inspections will be managed carefully and expediently to prevent delays in distribution (an in-country laboratory will be contracted to do this). Final payment will be contingent upon a satisfactory inspection following TPRI stipulations, which will be conducted in-country upon receipt of goods.

C.1.4 Import Regulations and Clearance Procedure

Despite the fact that pre-shipment inspection for the goods imported into Tanzania is no longer required, PSI will continue to carry out the inspections outlined in Section 2.3 for quality control.

Demurrage charges at the port are higher for insecticides than for many other commodities since the product is considered 'hazardous' due to its chemical contents. The port allows three days as a grace period for clearance. During this period there are no charges for storage. After this, the commodity is subject to demurrage charges (see Annex 2).

In order to avoid demurrage charges, PSI will work with the relevant government agencies to complete all importation procedures prior to the arrival of the commodities at the port. This includes obtaining the TPRI import permit and obtaining the USAID and MOHSW signature on all TRA tax exemption forms. The process will be facilitated by PSI in order to explain the end use of the product. To avoid charges, PSI has learned that it is necessary to start processing the required forms at least one month before the shipment's arrival. PSI's familiarity with the process is demonstrated by the fact that no demurrage charges have been incurred since the extension of the SMARTNET program in 2004. (Import Regulations and Clearance Procedures are discussed in detail in Annex 2).

C.1.5 Warehousing and Inventory Management

The PSI warehouse in Dar es Salaam has a storage capacity of 1,650 square meters with an additional 60 square meters of office space. The warehouse was built in 2006 to meet the specific storage needs of

insecticides and the other products distributed by PSI. The insecticides are kept in designated areas separated from other products. Movement of product is monitored through Business Vision, an inventory management software package used by PSI in more than 60 countries. Quarterly physical stock counts are performed to confirm the validity of the data in the computerized warehouse management system.

The warehouse has 24-hour protection provided by a reputable security company, with one daytime guard and two at night. The Warehouse Manager has custody of the warehouse's keys. The main gate and doors are securely locked during non-working hours. The warehouse is compliant with Tanzanian Labor Laws, including fire safety precautions, ventilation and exits. PSI operates according to standard warehouse and inventory procedures, some of which are listed in Annex 2¹⁰.

C.1.6 Destruction of Damaged Product

In the unlikely event that the insecticide procured has to be destroyed, PSI will comply with the procedures required by the National Environmental Management Council (NEMC). PSI would provide the NEMC with details of the items to be destroyed and the reason, and would request permission. Following receipt of this information, the NEMC would convene the Chemical Management Advisory Committee (CMAC) in order to discuss the proposal. This meeting would involve PSI, for the purpose of clarifying the material content of the items to be destroyed and the reasons necessitating their destruction. During this meeting, NEMC would advise on the procedure to be followed. In the case of insecticides, the tablet formulation would be crushed and incinerated and the liquid formulation would be incinerated. The destruction would be carried out in the presence of NEMC officials.

The Tanzania Portland Cement Company (TPCC), a subsidiary of the Germany-based Heidelberg Cement Group, has a high-temperature incinerator suited to the disposal of insecticide and similar chemicals. Once the NEMC grants approval, defective or expired insecticide will be destroyed at this facility in the presence of an NEMC inspector. The Medical Stores Department also has an incineration facility able to handle smaller quantities.

C.1.7 <u>Distribution</u>

PSI's has experienced quantifiable success with its current social marketing distribution plan. Retail audits conducted by the Ifakara Health Research and Development Centre (IHRDC) in February 2003 and January 2005 noted very high availability of ITN products in major trading centers in rural areas. Bundled nets are available in at least one outlet in 91% of wards and *Ngao* ITKs/IRKs are available in 100% of wards. The percentage of wards with at least one outlet stocking net kits more than doubled during the two year period. ¹¹

In addition to increasing ward availability, PSI will liaise with MEDA to ensure IRK availability at all TNVS registered retailers. This will entail formalizing an agreement that requires MEDA regional managers to supply/re-supply the designated retailers with IRK supplied by PSI in addition to the bundled nets. However, because the TNVS outlets are often fundamentally different from the retailers that normally sell IRKs, it is unrealistic to expect 100% of them to sell them. Several of these outlets are in the garment/cloth business and would be uninterested in the stand-alone *Ngao*, which is usually sold by retailers of fast-moving consumer goods, and by pharmacies. While PSI will strive for the greatest coverage possible in the coming months, a more realistic target for market penetration of registered outlets would be 70% by September 2007.

PSI's 2006 MAP survey indicated that 51% of rural enumeration areas (EAs) had at least one outlet selling *Ngao*. This 51% was drawn from a small sample (190 randomly selected EAs) and offers PSI a benchmark that can be used to test coverage/distribution hypotheses; it is not a definitive figure.

The EA is the smallest demographic division in Tanzania, often comprising just 100 or fewer households. EAs often do not even have a regularly functioning outlet selling common consumer goods; the

¹¹ LSHTM-IHRDC, Retail Audit Report, 2005

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¹⁰ PSI's Procurement and Warehouse Manual

population of even the most remote EAs is usually reliant on the nearest trading center or marketplace for these needs.

IRKs are an item that households require infrequently; once a year for the regular treatment and around every two years for the longer-lasting treatment. The slow-moving nature of the product, combined with a limited (two-year) shelf-life, means that IRKs are not an attractive commercial proposition to smaller retailers.

Given the nature of consumer behavior in rural Tanzania, and the nature of the product itself, it would be inefficient to devote substantial resources to increasing IRK availability at the EA level. Instead, PSI proposes to focus on the ward level, where PSI will maintain 100% availability.

For the commercial distribution of ITKs/IRKs, PSI will work in partnership with Nufaika, a national distribution agency specializing in the delivery of fast-moving consumer goods. Nufaika is constantly expanding its presence and reach in Tanzania with eight branch offices, five stock points and 32 vehicles operating nationwide (please see Annex 1 for the Letter of Support).

PSI currently provides Nufaika with product to fulfill orders from more than 8,000 wholesalers and retailers across the country. PSI generally moves the product form Dar es Salaam to Nufaika's regional depots for distribution by the Nufaika sales force. PSI's 18 Regional Managers support Nufaika by focusing on areas that are poorly served by the commercial distribution network. PSI teams uplift product from wholesalers and take it to outlets in particularly remote, rural locations. PSI has dedicated three trucks and 10 smaller vehicles to these distribution activities in support of Nufaika. The collaboration has led to a substantial increase in the availability of PSI products across the country. Since the inception of SMARTNET, over 10.2 million stand-alone ITKs/IRKs have been sold nationwide (see Table 2 below).

Table 2: Sales of Stand-alone ITKs/IRKs, 2002-2006

	2002	2003	2004	2005	2006	Total
Ngao KO	941,430	1,110,896	1,381,607	1,732,234	373,680	5,539,847
Ngao Fendona	33,764	456,662	633,310	431,880	168,600	1,724,216
Ngao Iconet			57,960	1,012,949	343,320	1,414,229
Ngao ya Muda Mrefu (KO 1-2-3)					1,540,080	1,540,080
Total	975,194	1,567,558	2,072,877	3,177,063	2,425,680	10,218,372

A schedule for insecticide delivery will be drawn up with each TNM and updated as necessary. In over four years of supplying the four TNMs, with over 8.9 million ITKs/IRKs, there has not been a single incident when the sales of the TNMs were restricted by the late delivery of insecticides by PSI (See Table 3 below for net sales since the inception of SMARTNET).

PSI's Key Strengths: Procurement, Warehousing and Distribution

- Since 1998, PSI has been responsible for the procurement and distribution of over 21 million ITKs/IRKs.
- ➤ PSI has a close working relationship with regulatory authorities; and extensive experience with the clearance, storage and transport of vast volumes of high-value inventory. No demurrage charges for insecticide have been incurred since the extension of SMARTNET in 2004.
- ➤ PSI has earned good standing with insecticide manufacturers, as evidenced by its successful negotiation of a price decrease for conventional ITKs/IRKs from USD 1.20 to USD 0.30 the best price received by any organization.
- ➤ PSI has the proven capacity to manage distribution logistics across the country; *Ngao* ITKs/IRKs are available in 100% of rural wards. For the past four years, PSI has supplied more than 8.9 million kits to the four TNMs without a single incident of net sales being restricted due to late delivery.

C.2 Adoption of Factory Pre-Treatment: Turning All Nets Manufactured in Tanzania into LLINs

C.2.1 Rationale for Pre-Treated LLINs

Turning all nets manufactured in Tanzania into Long Lasting Insecticide Nets (LLINs) is a fundamental part of Tanzania's ITN strategy, and one that PSI has been working towards for the last two years. Factory pre-treatment represents the best opportunity to maximize the public health benefit of nets.

The development of LLINs has been promoted by many organizations as a response to the low retreatment rates of mosquito nets in sub-Saharan Africa. Although re-treatment rates using *Ngao* home treatment kits in Tanzania are improving as a result of PSI's sustained promotional and information/education campaigns¹², progressing to factory-treated LLINs is necessary for the following reasons:

- Treatment at the factory level will be easier, cheaper, more reliable and more equitable than the production and distribution of insecticide re-treatment kits (IRKs).
- The treatment rate will be effectively increased to 100%, resulting in a significant increase in health impact.
- Communications messages for the at-risk population will be simplified by removing the need to educate consumers about re-treatment.
- LLIN technology will reduce total insecticide consumption.
- The need for storage and handling of insecticides at peripheral levels and in households will be eliminated.
- The risk of any potential environmental impact will be minimized.

C.2.2 Current State of Tanzania's LLIN Market

Until the TNMs have created a competitive market for factory pre-treated LLINs, PSI believes it will be necessary to support the distribution and sale of existing LLINs in Tanzania. Currently only two LLINs

¹² Household surveys carried out in 2006 (Ref LSHTM/IHRDC) showed that 41.4% of respondents had treated their nets within the previous twelve months. The DHS (2004) showed that 46% of nets had been effectively treated.

have been fully evaluated through WHOPES and recommended for use as LLINs according to the WHO definition (i.e. the ability to withstand 20 washes). They both employ in-line technologies:

- Olyset® nets are manufactured by A-Z in Tanzania and the Sumitomo Corporation. They are
 made of polyethylene and comprised of about 200 denier weave, which makes them stronger
 than conventional polyester nets. The permethrin insecticide is incorporated into the polyethylene
 beads so that it is part of the fibers. Their main drawback is the high post-factory price (over USD
 6.00) which is twice the price of a polyester net bundled with Ngao.
- Permanet® nets are not as strong as Olyset® since they are made of 75-100 denier polyester. They are produced by Vestergaard Fransden and were launched in Tanzania at the end of 2006. They cost about the same as Olyset nets. Permanet offers an example of coating technology (i.e. the deltamethrin insecticide is stuck onto the surface of the fibers).

As part of the SMARTNET program, PSI has been subsidizing and promoting Olyset nets since 2006 (See Table 4 below). This was intended to prime the market for a large-scale introduction of LLINs, while ensuring the affordability of the nets to low-income high-risk groups. It would be detrimental to the development of this market if the availability and affordability of existing LLINs was adversely affected while waiting for new technology to come on line. ¹³

C.2.3 Manufacturing Technology Options for TNMs

Technology transfer assistance to the TNMs is already budgeted under the international NetMark project, funded by USAID. PSI will work closely with NetMark to ensure that the selection of technology will be based on its ability to offer a quality-assured, effective, cost-efficient solution as demanded by the TNMs, which is suitable for large-scale LLIN production in Tanzania. The two most promising options are outlined below.

C.2.3.1 Off-line Coating Technology

With technical support from USAID through the NetMark project, off-line coating technology is already available to Tanzanian manufacturers that wish to make the necessary investment. This is a batch process in which a finite number of nets (limited by the cylinder size of the washer/extractor) can be processed in each production cycle. A production lot is loaded into an industrial end-loading open-pocket washer/extractor, such as the Washex DPM 5000 apparel processing machine, and a predetermined volume of LLIN chemistry (i.e. ~ 70% wet pick-up) is injected into the machine through a custom engineered mist spray system. The LLIN chemistry is applied to the nets while they rotate and tumble within the machine's cylinder. This results in uniform distribution of the treatment across all surfaces of the net. The cycle time for LLIN treatment is typically around 30 minutes per production batch. This system can be optimized for a range of pyrethroid insecticides, giving maximum strategic and commercial flexibility to the manufacturers. Sunflag are currently in the process of procuring the necessary equipment to carrying out treatment in their factory.

In March 2006, PSI commissioned three consultants to carry out a study examining the feasibility of and costs associated with the adoption of the Anovotek process by the TNMs. The study concluded that all four TNMs were interested in the conversion but would need to make the transition at differing speeds and volumes over a two-year timeframe.¹⁴

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¹³ The current subsidy amounts to USD 2.52 per net, and was intended to last for a period of one year. PSI is engaged in discussions with the NMCP on the possibility of including Olyset nets in the TNVS program under GFATM funding, by providing a subsidy equivalent to the price of two longer-lasting ITK/IRKs.

¹⁴ Commercial production of nets treated by the Anovotek process is apparently underway in Thailand, but the company (Tana) has been reluctant to supply production figures.

C.2.3.2 In-line Coating Technology

Some concerns exist about the potential for a global roll-out of the off-line coating technology described above. The initial capital investment creates high barriers to entry, particularly for smaller net manufacturers. For this reason, manufacturers of insecticides are exploring a number of other chemical application methods and processes. The most successful to date relates to an application in-line before the stentoring process.

Several companies have been carrying out research and development (R&D) on an in-line process through which fabric (meterage) will be treated with long-lasting insecticide during the process of dyeing the nets. The concept of an in-line process is not new (e.g. PermaNet), but because it will require relatively small capital investments and promises to reduce production bottlenecks, it has generated significant interest among the TNMs and the LLIN WG. Bayer Environmental Sciences, which has been carrying out such R&D, expects their technology to become commercially available by the end of 2007.

C.2.4 Price of Long-Lasting Insecticide

With only one long-lasting treatment product currently approved and available on the market, its price is artificially high. When other products (including generics) come onto the market, the situation is expected to change dramatically. The consultants who authored the techno-economic feasibility report expect that by 2012 it will be feasible for pre-treatment costs to be borne by the TNMs.

PSI will use the promotion of the Tanzanian net brands and the provision of free insecticide as a bargaining chip with the TNMs, working closely with the agency leading the communications effort to level geographical price differences. Additionally, PSI will work to:

- Discourage rural retailers from setting higher-than-prescribed prices; all new net packaging will include a clearly printed retail price.
- Communicate the prescribed retail price via local and national radio, and other communications channels per the communications RFA. Special emphasis will be made on developing markets in underserved areas (such as Rukwa and Ruvuma) to encourage and help ensure price adherence by retailers.
- Recommend a transport subsidy to cover a portion of costs associated with net delivery in remote and hard-to-reach regions. (During SMARTNET, TNMs received subsidies to cover a portion of such costs, helping to reduce the final retail cost of nets in these locations. Costs, and consequently subsidies, per net were calculated based on travel distance and the condition of the local roads.)

There are two new long-lasting insecticide products on the horizon:

Syngenta Corp manufactures a long-lasting treatment called IconMaxx (lambdacyhalothrin 100g/l formulated as a micro-capsule suspended in water, plus a binder). It is currently in the WHOPES program and has completed Phase 1 testing (where it achieved 100% knock-down after 20 washes). Phase 2 testing is underway and data review is expected in December 2007. An IconMaxx kit will cost between USD 1.00-1.20 depending upon volume, location, mode of delivery, payment terms, etc. It is expected to be commercially available by the end of June, 2007.

IconMaxx is fundamentally designed as an ITK/IRK for use by consumers in home treatment of nets. Syngenta is already, however, exploring its bulk use or in-line treatment at the factory level. Feasibility trials conducted in conjunction with Anovotek, using IconMaxx for automated bulk LLIN production, have showed considerable promise.

BASF is currently completing development of an alphacypermethrin plus cold-binder product.
This product will be suitable for in-field or factory 'post-manufacture' use. It is expected that
the product will be available for sale and submitted for WHOPES evaluation in July/August,
2007.

C.2.6 Managing the Transition to Factory Pre-treated LLINs

PSI has built close, strong relationships with each TNM. Each manufacturer has a very different corporate identity, calling for a tailored approach by an organization that is well acquainted with them. PSI has been following closely the moves of all of Tanzanian manufacturers over the last ten years and is uniquely positioned to play a brokering role between the TNMs and the MOHSW.

In order to effectively manage the transition, it is crucial to address the following issues:

- i. Manufacturer's Agreement: PSI's experience suggests that Tanzanian consumers (in contrast to international institutional buyers) will not be willing to pay a significant premium for a factory-treated net. If treatment increases costs significantly, producers will not attempt to introduce LLINs to the domestic market. Manufacturers will only supply the lowest-cost (untreated) nets to the domestic market unless there is a public subsidy and a universal agreement among suppliers not to undercut treated nets by supplying an un-treated product to the domestic market.
 - Under the SMARTNET program, PSI responded to this situation by providing free insecticide to the TNMs for bundling with new nets in exchange for commitments from the TNMs to refrain from selling any unbundled nets. The introduction of factory pre-treated nets will require an even stronger commitment from the TNMs. PSI will work with the TNMs to ensure that each manufacturer understands the insecticide subsidy is for a specified timeframe only.
- ii. Investment Commitments: Factory pre-treatment will require the TNMs to investment their own resources in the plant, machinery and working capital associated with the technology. The TNMs will only be willing to make these investments if they can count on a reliable long-term supply of subsidized insecticide and if they have a partner they trust. The attached letters of support from the TNMs (in Annex 1) show that all four manufacturers have complete confidence in PSI's ability to fulfill this role.
- iii. Quality Assurance Regime: Concomitant with the adoption of the technology is quality assurance in factories and independent external quality control (i.e. sample testing of product to enforce treatment standards). Each TNM would have to accede to this quality control system. (See Section 4 for details.)
- iv. Consumer Education: Consumer education will be vital to establishing and maintaining confidence in an 'invisible' treatment that is as good as, or better, than a visibly bundled one. In this respect, the Ngao brand now a household name for net treatment could be stretched to convey the attributes of reliable, effective, factory-based treatment (See Section C.7 for more.). PSI will work with the TNMs to develop appropriate branding of their existing brands.

C.2.5 Addressing the Issue of Net Longevity

Net longevity is a crucial issue and can represent a potential disconnect between public health interests and commercial interests. On public health grounds, a net should last as long as possible so that fewer nets need to enter the market each year to sustain a given level of coverage.

At present, there is no consensus on the correlation between the denier count of a net and its durability (the disagreement was highlighted by a recent lengthy email exchange initiated by the NMCP following the second LLIN WG meeting). Contrary to earlier thinking, many experts now dispute that the life of polyester nets will be increased significantly by switching from a 75 to 150 denier weave. Bursting strength has not been a reliable predictor of durability. For example, Olyset nets made with a 200 denier monofilament yarn has about the same bursting strength as a 100 denier polyester net, although the former lasts much longer in real life situations. In short, much more is known about the life of the

insecticide on the net than the net itself. This is an issue which needs to be investigated as part of the LLIN process.

The quantity of nets in use will be considerably greater than expected net sales. The present estimate is that nets last two years, but technological improvements (e.g. switching to a 150 denier weave) may lead to a longer lifespan. Figure 2 shows the differences among nets in use, comparing a two-year and three-year lifespan. If the nets' lifespan can be prolonged to five years, replacement sales will reduce and it will be important to develop a different subsidy mechanism. Similarly, willingness-to-pay information regarding stronger or factory-treated nets will be valuable for the TNMs if and when a decision is made to switch to higher denier nets (PSI would assist with the appropriate market research).

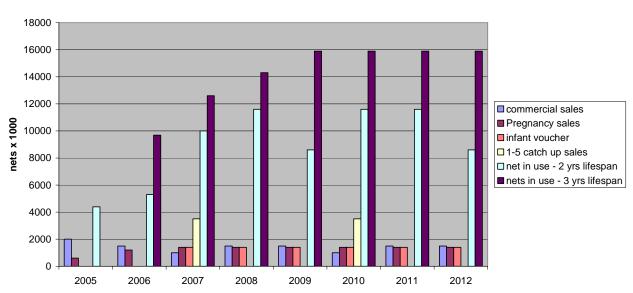


Figure 2: Net Sales and Usage: Effect of Age of Net on Net Crop¹⁶

C.2.6 Coordination with the LLIN Working Group and NetMark

In September, the NATNETS Steering Committee recommended that a Working Group (WG) be formed in order to address the complex regulatory, quality and technology-transfer issues associated with a conversion to factory-based pre-treatment. The purpose of the WG is to facilitate the conversion to LLINs while ensuring all regulatory and quality assurance issues are addressed.

At the request of the MOHSW, PSI authored the TORs for the LLIN WG, and was selected as the Group's Secretariat in December 2006. The membership of the WG comprises the Program Manager, NMCP, the ITN Cell Team Leader, NMCP representatives from PSI-Tanzania (Secretariat), the National Institute of Medical Research (NIMR), the Tanzanian Pesticide Research Institute (TPRI), the insecticide suppliers

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¹⁵ E.g. a campaign to provide all under fives with nets through vouchers would only have to occur every five years if the nets last that long.

¹⁶ DfID ÖPR November 2006

(currently Bayer, Syngenta and BASF), the TNMs (A-Z, Motex, Sunflag and TMTL), the Tanzanian Bureau of Standards (TBS) and the Tanzania Revenue Authority (TRA). Two meetings have been held to date, focal persons have been identified for each of the WG's key objectives (see ToRs), and initial feedback and suggestions have been received.

PSI will continue as Secretariat for the LLIN Working Group, ensuring that the meetings occur at least once every two months. In addition to this, PSI recognizes that each TNM and LLIN WG member will require support and assistance in order to achieve their individual objectives. PSI will play this role in the following ways:

- Prepare and implement MoUs with each TNM, outlining the technology requirements and timelines for each TNM.
- Implement monthly meetings with each TNM to assess progress and flag issues that might delay the process.
- Communicate with each insecticide supplier (including generic suppliers) to assess development of LLIN products.
- Collaborate with other LLIN WG members in order to achieve their objectives in a timely fashion.
- Collaborate with NetMark and other organizations working on LLIN technology in order to inform the above.

The Terms of Reference for the LLINWG are located in Annex 5.

PSI will inform all LLIN WG partners of relevant developments in the field of malaria prevention. The proposed CoP and staff from PSI's Global Malaria Department have an extensive network of contacts in the field, ensuring that the project will be supplied with the most up-to-date information from WHOPES, the RBM Win Group and individuals such as Pierre Guillet. Commercially sensitive information (e.g. unit costs) will be provided directly to the TNMs by the insecticide suppliers themselves.

At the start of the program, PSI will ask NetMark representatives to meet with each TNM to help assess the on-the-ground situation and examine the timelines with regard to the LLIN conversion. If the Anovotek technology is selected, PSI will examine the Dawa/Tano production process in Thailand (funds permitting/cost-shared with NetMark). PSI will schedule bi-monthly (and more frequently, if necessary) meetings with NetMark to ensure that critical knowledge and experience is shared for the duration of the transition period.

PSI will also invite firms pursuing alternative technological solutions to meet with each TNM to discuss and study their processes. These include Bayer Environmental Science and Syngenta, which are both pursuing in-line technologies.

C.2.7 Registration and Approval of LLINs and LLIN Treatment Products

Testing and certifying insecticides for public health applications is the role of the WHO Pesticide Evaluation Scheme (WHOPES) at the global level and the Tanzania Pesticides Research Institute (TPRI) in Tanzania. Although formal registration is required in each country, the WHOPES documentation provides a solid basis and high credibility for this process. This is especially true for LLINs, which require more sophisticated and long-term trials than the previous generation of insecticides.

Considering the need for realistic registration periods, WHOPES provides provisional (interim) recommendations on the use of LLINs on the condition that the process employs WHO recommended insecticide. These interim recommendations are made after LLINs have been carefully tested in laboratory and small-scale field trials, simulating the long-term use of the product. The recommendations are periodically reviewed as more information on long-term efficacy and operational acceptability becomes available through larger-scale testing and evaluation. Finally, a full recommendation is issued when long-term field trials are completed and submitted.

C.2.8 Logistics for the Provision of Insecticide for Factory Pre-treatment

In order to reduce the overall ex-factory unit price of a pre-treated net, the insecticide for pre-treatment will be supplied in bulk form. PSI will order the bulk insecticide twice a year, based on annual net sales targets. The insecticide will be stored at PSI's warehouse prior to dispatch to the TNMs.

Based on the current technology, the insecticide and binder will be supplied separately, in a two-container combination, employing the ratio of 200 liters of insecticide to 30 liters of binder (capable of treating 3,200 nets). PSI will deliver the liquids to the TNMs on a quarterly basis, in combinations of 1,000-liter and 150-liter drums to the smaller TNMs, and 6,000-liter and 900-liter drums to the larger TNMs. The volumes will be periodically reviewed based on market dynamics and the TNMs' demand forecasting. PSI will ensure that a well-qualified and equipped transportation service is employed, and that this service follows all the specific protocols associated with the product, as prescribed by the manufacturer and endorsed by the TPRI.

PSI's Key Strengths: Relationship with TNMs and LLIN Leadership

- PSI has been working to establish LLIN manufacturing in Tanzania for the last two years. Its leadership is highlighted by its role as Secretariat for the NMCP's LLIN Working Group.
- ➤ PSI has forged robust, transparent partnerships with the TNMs based on mutual trust and confidence. Experience with and knowledge of each manufacturer will be crucial to facilitate the required technology transfer, effectively manage the subsidy for the treatment, and secure a manufacturers' agreement not to undercut treated nets by supplying an un-treated product.
- > The TNM's willingness to invest in the required technology will depend upon their confidence in PSI's ability to both guarantee a market and reliably supply the subsidized insecticide.

C.3 Quality Control: Establishing and Maintaining a Sustainable System to Monitor the Quality of LLINs

TNMs will need to establish a manufacturing quality control (QC) system for any LLINs that they produce. Several quality assurance issues must be considered, with the key test being the measurement of the quantity of insecticide absorbed in the net and its bio-availability in the fiber after the manufacturing process and several washes. The homogeneity of the treatment is also an important issue directly related to the LLIN bio-efficacy. For fiber and insecticide based industrial processes QC procedures for incoming raw materials will also be introduced, including:

- *Pre-production Quality Checks:* Checking incoming chemicals, review of formulation/recipe and verification of actual weight (volume) of chemicals prior to delivery to the application machine.
- Production Controls: Checking of production work in process; production order verification; confirmation of proper machine loading; ensuring complete chemical delivery into the machine and ensuring that all standard operating practices (SOPs) are followed.

If the nets produced are under-dosed, or if the insecticide is not evenly distributed, wash-resistant, or bio-available, then these nets will not only be ineffective but could also promote insecticide resistance among malaria mosquito vectors. In addition, over-dosed nets will mean that insecticide is being wasted and, in extreme cases, even harmful to the users.

C.3.1 Testing Technology and Capacity

In February 2007, using PMI Year 1 funding, two consultants from the Liverpool School of Tropical Medicine (LSTM) were contracted by PSI to assess and report on the QC options available for LLINs in Tanzania. The consultants interviewed key personnel at each TNM and in five laboratories in order to assess their current and potential future capacity to undertake QC procedures. The TNMs were also assessed on their supply and manufacturing processes, focusing on type and quality of insecticide coming in, predicted batch sizes and current QC certification. The following sections describe the preliminary findings of the report, due by the end of March.

C.3.1.1 Technology

Determining the level of insecticide on nets after LLIN treatment involves the use of High Performance Liquid Chromatography (HPLC), requiring sophisticated equipment, scientific support and highly qualified personnel. The HPLC equipment cost is estimated between USD 70,000-120,000, while equipment service will cost USD 2,000-3,000 per year.

HPLC analysis will initially cost approximately USD 50 per sample, based on the best estimates from local and international reference centers. The cost can potentially be reduced to around USD 10 per sample with long-term contractual agreements between TNMs and external reference centers, through the introduction/development of in-house HPLC testing facilities, or through alternative new technologies.

C.3.1.2 Capacity

The consultants visited three government reference centers: the Tanzania Bureau of Standards (TBS) and Tanzania Food and Drug Authority (TFDA) in Dar es Salaam, and the Tropical Pesticides Research Institute (TPRI) in Arusha; and two research laboratories: University of Dar es Salaam and the National Institute of Medical Research (NIMR) in Tanga. Currently, only the TFDA is capable of performing insecticide analysis on nets. However, while the laboratory has up-to-date equipment suitable for high throughput sampling, the capacity is likely to be small (100-200 samples per month) due to other demands on the equipment. The NIMR laboratory has adequate equipment but currently does not have staff qualified to carry out the analysis.

At this time, only one of the companies (A-Z) can realistically perform this insecticide testing in-house. This will require appropriate training and the employment of at least one additional technician to cope with the extra workload. However, investment in QC at this level would relieve significant pressure on national reference centers, as this would account for the majority of nets sold in Tanzania. An external laboratory would ensure that the in-house analysis is satisfactory.

Although it is unlikely that TNMs will start production of polyester LLINs until next year (Sunflag is a possible exception), PSI sees QC as a fundamental part of the project. With this in mind, PSI has already started discussions with the NIMR laboratory, which has expressed interest in being a resource for HPLC testing (please see Annex 1 for the Letter of Support). The absence of a qualified scientist to carryout the analysis could potentially be overcome if this project could help to fund such a position. This would also ensure that the responsibility for QC does not fall on a single institution.

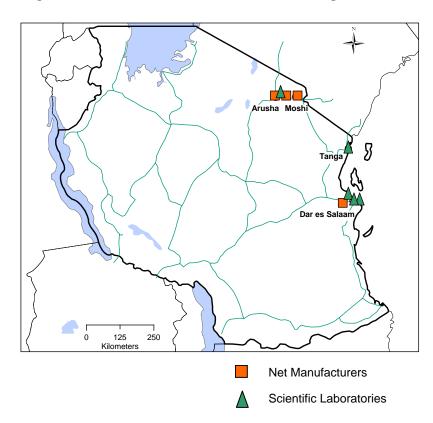


Figure 3: Location of TNMs and Potential Testing Laboratories

C.3.2 Sampling Needs

Since the LLIN technology is currently not in place, sampling needs can only be estimated with reference to other LLIN technologies. It is therefore recommended that sampling be around one per 1,500 nets, similar to the sampling carried out for Permanet. At least two pieces per net should be HPLC tested.

Based on the production of around 3 million nets per year (assuming all TNMs are producing LLINs), the overall costs will range between USD 13,300 (for Motex, 199,500 nets) and USD 122,350 (A-Z, 1,835,500 nets) per TNM, per annum. This translates, approximately, to an extra USD 0.07 per net for the entire production based on samples being out-sourced to an external reference center. Since it is anticipated that the switch to LLIN production will be gradual, budget estimates are made for around one-quarter of total nets in Year 2, one-half in Year 3 and all the nets in Year 4.

C.3.3 Start-up Phase and Training

During the start-up phase, stakeholders will be familiarized with the new technology and necessary QC requirements by relevant experts. Intensive training in the use of the new equipment, together with preproduction quality checks and implementation of proper production controls will be carried out over the course of 1-3 months. In agreement with USAID, the purchase of an additional HPLC machine will be considered for year 2.

Given the newness and complexities of LLIN production, it is vital that the TNMs are thoroughly competent in their manufacturing processes. On-going QC costs will be dependent on reliable insecticide treatment. This start-up phase could be linked with a national certification scheme to encourage good manufacturing practices and ensure reliable, effective LLIN production.

PSI's Key Strengths: Qualifications for Quality Control

- ➤ PSI has already started examining the options for this activity with the TFDA, NIMR and the TNMs. Discussions have been initiated with the NIMR laboratory, TFDA and A-Z Textile Mills in order to ensure that the responsibility for quality control does not fall on a single institution.
- As Secretariat of the LLIN Working Group, PSI has the authority and standing to institute a credible national certification scheme and to ensure that TNMs comply with a robust quality control regime.

C.4 Insecticide Auditing: Establishing and Maintaining a Tracking System for Insecticide Supplied for the Tanzanian Market

The program must ensure that ITKs/IRKs and bulk insecticide (supplied free-of-cost to the TNMs) are used strictly for the treatment of nets sold in Tanzania. This will be a particular challenge with bulk insecticide, which has greater potential for misuse in agriculture and possibly for indoor residual spraying (IRS).

PSI already employs a number of procedures to monitor the use of *Ngao* ITKs/IRKs currently supplied to the TNMs (see Section 2). However, for the purposes of this project, PSI will contract a professional audit firm (one candidate is PricewaterhouseCoopers or PwC) to set up new procedures and oversee the existing checks.

C.4.1 <u>Current Control System</u>

As stated above, PSI already deploys a robust control system to ensure that the insecticide currently being bundled with the nets produced by the TNMs is used exclusively for nets intended for the Tanzanian market.

When SMARTNET began in 2002, the different TNMs were supplied with one of three types of insecticide kit: *Ngao* (deltamethrin tablets,), *Ngao ya Maji* – Iconet (sachet of liquid lambda-cyhalothrin), or *Ngao Ya Maji* – Fendona (sachet of liquid alpha-cypermethrin). In April 2006, the longer-lasting *Ngao ya Muda Mrefu* (KO 123 tablet and binder) was introduced. All four TNMs are currently bundling their nets with this product.

PwC worked with PSI to set up a reconciliation system for the insecticide and an MIS system to track the flow of bundled nets from the net manufacturers to the Primary Agents (PA), the wholesalers receiving nets directly from the manufacturers. This process verified that the volumes declared by the net manufacturers were actually delivered to the PAs.

The reconciliation steps for the ITKs/IRKs include the following:

- PSI receives insecticide orders from the net manufacturers based on forecast demand and quarterly targets derived from annual targets. The PSI Product Manager raises the issue note, specifying the quantity of ITK/IRKs needed by each net manufacturer.
- The PSI Warehouse Manager issues the quantity specified in the issue note, together with three copies of the invoice/delivery note. These are handed to the PSI driver delivering the kits to the net manufacturers. The documents are signed and rubber-stamped by the recipient TNM, one copy is left with the TNM and the other two are brought back to the PSI office where one is attached to the invoice/ delivery book and the other given to the MIS staff who enter the delivery.

- At the TNMs, the volumes are immediately recorded in the factory's Ngao Received and Issue book (NRI). This tracks incoming stocks of insecticide from PSI alongside kits delivered to the production line.
- Before the seventh day of each month, each TNM sends monthly Ngao reconciliation forms to PSI. This form indicates the quantity of Ngao received from PSI and subsequently consumed (i.e. bundled with the nets) during the month, the quantities of nets produced (i.e. number sold plus stock in hand), and the balance of insecticide remaining.
- Every quarter, the PSI Product or ITN Marketing Manager visits each TNM and carries out an audit of the insecticide in the factory. This is conducted in order to verify the correlation between the stated utilization of the *Ngao* product and the number of nets sold.

C.4.2 Proposed Control System

PSI's collaboration with PwC during the implementation of SMARTNET has enabled the company to form effective working relationships with the TNMs, and makes them a strong candidate for the proposed work (please see the Letter of Support in Annex 1). The proposed monitoring will include five main areas, outlined below:

- i. Review the existing ITK/IRK monitoring system: This task will involve reviewing the existing monitoring information system developed by PWC for PSI in order to track insecticide use against net sales. The objective of this review will be to enhance and improve the present system if necessary.
- ii. Design a system to monitor bulk insecticide: PSI/PWC will develop a report format, design data capture forms, agree on means of communication and identify the information to be received by PSI and other key stakeholders such as the NMCP.
- iii. Collect and verify monthly reports from TNMs on behalf of PSI: PWC will follow up on monthly reports from the TNMs via phone calls, emails and visits if necessary, to ensure that these reports are submitted as agreed. Reports will be checked for consistency (e.g. closing stocks for the previous month must match opening stocks for the current month). Each month, a summary report prepared by PWC will be delivered to stakeholders.
- iv. Conduct quarterly reconciliations with each TNM to ensure that there is no leakage: This task will involve the compilation of comprehensive quarterly reports. Each TNM will be visited in order reconcile reports received against the stock available.
- v. Conduct regular and surprise audit/stock-taking with each TNM: PWC will conduct a random audit/stock-taking at each TNM once a year to ensure that the product is being used for the intended purpose. This will involve the development of an appropriate audit format and tools.

PSI's Key Strengths: Insecticide Auditing Experience

- > PSI already deploys a robust tracking system established at the start of SMARTNET, which features a reconciliation system for insecticide products.
- In PwC, PSI has a partner with established, effective working relationships with the TNMs. The present system can be effectively modified and enhanced for the tracking of bulk insecticide, and would include monthly reports from the TNMs, quarterly reconciliations and a series of surprise audits.

C.5 Insecticide Resistance Monitoring

Resistance to pyrethroid insecticides has been detected in malaria vectors in several African countries. Pyrethroids are currently the only class of insecticides recommended for treatment of bed-nets by WHOPES. Widespread development of resistance, therefore, may undermine malaria control efforts that rely upon ITNs. Furthermore, resistance to other insecticide classes and cross-resistance between insecticides (e.g. pyrethroids and DDT) may undermine the effect of indoor residual spraying (IRS). Recent evidence from Benin has suggested that both metabolic and knockdown (kdr-based) resistance mechanisms can reduce the efficacy of both ITNs and IRS.¹⁷

C.5.1 Current Status of Resistance Monitoring

A recent study demonstrated that malaria vectors remain susceptible to pyrethroids in areas of long-term ITN use in Tanzania, but that they are less vulnerable in some areas with intensive agricultural use of insecticides. These foci of reduced susceptibility (defined as 80-97% mortality in WHO bio-assay tests) may indicate areas where insecticide resistance is developing. With continued selection pressure from insecticide use in public health (via ITNs, IRS) and agriculture, it is essential to monitor the development of resistance in vector populations in order to ensure the success of vector control strategies.

Resistance surveys were commissioned by PSI in 1999 and in 2004-5 in areas where the SMITN project was first introduced ITNs in 1998. This data was combined with results from an NMCP survey conducted in 2005 at the eight NIMR field office sites, providing baseline data on insecticide susceptibility. In both surveys, standard WHO bio-assays were conducted using wild-caught malaria vectors to determine the level of susceptibility to insecticides. While use of wild-caught mosquitoes is cost-efficient and feasible in field locations, it may increase the variability in results since resistance to pyrethroids declines with increasing mosquito age. To ensure age-standardization and thereby increase the precision of results, it is necessary to test the F1 progeny of wild-caught mosquitoes, which are obtained by hatching eggs from wild-caught females and rearing the larvae in a field laboratory.

C.5.2 Proposed Resistance Monitoring

Currently there is no routine insecticide resistance monitoring system in place in Tanzania. Routine monitoring of insecticide susceptibility requires a standardized and coordinated system of testing and reporting. It is envisaged that such a system could be developed and implemented using a network of sentinel sites across Tanzania. NIMR has a network of field offices with the capacity to conduct resistance monitoring activities, and has also indicated its interest in being the principal investigators for this important activity.

In order to maximize the efficiency and sustainability of the project, it is proposed that the NIMR network be supported by external non-governmental agencies (including HealthNet and PSI) for standardization and coordination of surveys and reporting.

PSI suggests monitoring the susceptibility of malaria vectors to several classes of insecticide (pyrethroids, organophosphates, carbamates, DDT) in sentinel sites over a four-year period using a number of entomological tools. This activity will cost an estimated USD 95,000-65,000 annually, and will be amply justified by the increased health impact achieved through continuous resistance control. Other malaria prevention efforts, such as IRS, will also benefit from this intervention.

¹⁷ N'Guessan R., Corbel V., Akogbeto M. and Rowland M. 2007. Reduced Efficacy of Insecticide Treated Nets and Indoor Residual Spraying for Malaria Control in a Pyrethroid Resistant Area, Benin. Emerg Inf Dis 13(2): 199-206.

¹⁸ Kulkarni M.A, Malima, R., Mosha, F.W., Msangi S., Mrema, E., Kabula, B., Lawrence, B., Kinung'hi, S., Swilla, J., Kisinza, W., Rau, M.E., Miller, J.E., Armstrong Schellenberg, J., Maxwell, C., Rowland, M., Magesa, S. and Drakeley, C. Efficacy of pyrethroid-treated nets against malaria vectors and nuisance-biting mosquitoes in areas in Tanzania with long-term use of ITNs. TMIH submitted 05 Dec 2006.

PSI's Key Strengths: Expertise in Insecticide Resistance Monitoring

- ▶ PSI has significant experience with resistance monitoring, having commissioned surveys in 1999 and 2004-5 that provide baseline data on insecticide susceptibility. PSI seeks to highlight the importance of routine annual surveys.
- PSI's technical qualifications in resistance monitoring are demonstrated by the CoP's academic and professional experience in entomology and public health, specifically with regard to ITNs.

C.6 Behavior Change Communications

The current RFA refers to a future RFA for behavior change communications (BCC), emphasizing the importance of close coordination between the two programs as well as with other PMI activities.

PSI has vast experience and familiarity with BCC, brand development, advertising and promotional campaigns targeting the end user of its health interventions. This competency will enable the program to seamlessly integrate consumer education and demand creation activities with its efforts to increase the availability of ITKs/IRKs and to introduce locally-manufactured LLINs in Tanzania.

Advertising and promotion will be critical to educate consumers about the added benefits of LLINs and create a sustainable market. The focus of BCC messages will thus shift to factory pre-treated nets as soon as the technology is adopted by the TNMs. Communication materials will be developed based on the specific LLIN technology and packaging. PSI will conduct in-depth consumer research to develop an appealing brand identity for the new factory pre-treated nets, ensuring that they are instantly and easily recognizable. PSI anticipates that such efforts will increase awareness of the need of year-round ITN use over time, and as a result, the frequency and intensity of advertising can be scaled down in each successive year of the program.

During the SMARTNET program, PSI conducted a variety of cost-shared promotions with the TNMs, including raffles (from tickets obtained on the purchase of a net), and baby t-shirt and key-ring give-aways in the packaged nets. PSI will explore the possibility of launching these and other promotions for this program. In initial talks, the TNMs have indicated their interest in joint promotions, but also noted that their advertising budgets are constrained by tight sales margins. PSI will investigate NetMark's experience with public-private cost-shares for branded advertising in other countries. A fuller examination of this subject will be made in the response to the anticipated BCC RFA.

C.6.1 Coordination of Effort and Consistency of Communications

PSI considers the following coordination issues to be critical for the success of the BCC strategy:

- Harmonization of product (bundled net/LLIN and ITK/IRK) promotion with generic behavior change messages.
- Leveraging the universal recognition of and confidence in the *Ngao* brand, potentially continuing to employ the same brand identity for stand-alone ITK/IRKs.
- Identification and prioritization of key messages, such as greater awareness of the health gains from net use and the importance of using nets all year round.
- Concentration of program efforts in areas where voucher uptake is limited and net use is low.
- Addressing the technological change. Since Ngao is a universally recognized and trusted product (other nets are usually rejected by customers), factory treatment will require explanation.
 For example, messages might suggest that "Ngao is already on the net: we did the treatment for

you". The brand could potentially play an important role in ensuring that consumers recognize LLINs as distinct from bundled and untreated nets.

- Explanation of the new types of vouchers (infant, 1-5 years, equity) and advocacy for the prioritization of net purchases (topping-up vouchers) in household budgets; and
- Communication of the improved strength and durability of the new nets (if a switch occurs to the 150 denier weave).

C.6.2 PSI Communications Experience and Capacity

PSI has substantial experience with ITN-related BCC. For the SMARTNET project, PSI has been conducting demand creation through both branded (*Ngao*) and generic (*Malaria Haikubaliki*) campaigns with a heavy emphasis on rural penetration and exposure, employing rural promotion teams, mass-media communications (with an emphasis regional/local radio stations), road shows, mobile video unit shows, and cultural (local theater and dance) shows.

PSI's Key Strengths: Extensive BCC and Brand Development Experience

PSI has vast experience with ITN-related BCC, brand development and promotional campaigns, as evidenced by its well-recognized *Ngao* brands and *Malaria Haikubaliki* campaign. This experience and competency will enable the smooth integration of communications objectives within the program, and, should another agency lead the BCC effort, ensure that PSI is a strong and supportive partner.

D. PSI PAST PERFORMANCE AND CAPACITY

D.1 PSI Worldwide

PSI is one of the leading social marketing organizations in the world with projects in more than 60 countries on five continents. A non-profit organization established in 1970 and based in Washington, D.C., PSI has successfully designed and implemented programs to promote healthy behavior and increase the availability and use of health products in low-income settings. PSI receives funding from a wide range of sources, including major bilateral and multilateral donors, as well as some of the world's largest foundations and corporations. PSI's primary interventions focus on malaria, HIV prevention, family planning, diarrheal disease, micronutrient deficiencies and waterborne diseases.

PSI's mission is to deliver affordable and accessible health products to low-income populations, and to produce and disseminate innovative, culturally appropriate behavior change communications. PSI's social marketing approach is based on four core principles:

- To serve the poor, primarily by pricing products affordably and making them widely available.
- To achieve measurable health impact.
- To provide products and services cost-effectively, primarily by working through an existing commercial infrastructure.
- To strategically target consumers, vendors, and health care providers with communications and training programs that emphasize correct use of each product and service to promote healthy behavior.

PSI employs more than 7,000 people worldwide. PSI staff typically have expertise in public health, marketing, research, procurement, communications and product technology.

Although a non-profit organization, PSI is run like a private-sector business. It harnesses the size and strength of existing retail distribution networks, engaging thousands of wholesalers and retailers as enthusiastic sales agents for health products. PSI reinvests its sales revenues into program activities, resulting in low cost-recovery rates and reduced net cost to donors. Through rigorous financial management, PSI's overhead expenses have fallen from 11.2% in 1998 to 6.7% in 2005.

D.2 PSI and Malaria Prevention

In 1994, PSI pioneered one of the world's first operational ITN programs in the Central African Republic. Today, PSI manages malaria control projects in more than 30 countries in Africa, Asia and South America. In 2006 alone, PSI delivered more than 12.4 million ITNs, making it one of the largest distributors of ITNs in the world and an important implementing partner of the global Roll Back Malaria (RBM) program. Sales of LLINs increased by 136% last year, compared to 2005. As a result of PSI's programs, it is estimated that nearly 35 million episodes of malaria and about 140,000 child deaths from malaria were averted last year.

PSI's social marketing model for ITNs is called 'Coverage Plus.' The "plus" refers to the model's active collaboration with the commercial sector to move towards a sustainable commercial market while reinforcing public sector distribution systems. Coverage Plus can be adapted to the diverse range of ITN market contexts that are found across the malaria endemic world, as well as to variations in demand at different socioeconomic levels. The primary objective of the 'Coverage Plus' model is to cost-effectively increase ITN coverage of malaria risk groups as fast as possible. The model aims to minimize subsidy dependence for those who can afford to pay for nets, while maximizing opportunities for sustainable ITN delivery in the long-term.

PSI has devised responsive but time-limited strategies based on the cost effective targeting of subsidy. These have been designed to overcome the many challenges faced today in the malaria endemic countries of the world, especially in Africa. The strategies designed to increase access to ITNs while laying the foundations for market development include:

- Segmenting the total market: PSI targets different population groups with different ITN types sold through diverse and appropriate delivery channels.
- Targeting subsidy to vulnerable groups: To maximize efficient health impact, PSI targets highly subsidized ITNs directly to pregnant women and children under five through public health facilities.
- Creating informed demand and promoting effective use: PSI disseminates a combination of branded advertising campaigns and compelling generic communications to create demand and improve the quality of ITN use through a mix of mass media and interpersonal channels, including radio, drama, mobile video shows and antenatal consultations.
- Focusing on measurable health impact. PSI is committed to delivering bottom-line health impact. Program strategies are directly linked to delivering health impact and this is measured in terms of malaria episodes averted and child deaths averted resulting from product sales.
- Forming partnerships: PSI's principal partner in any country is the Ministry of Health and specifically the National Malaria Control Program. PSI also forms partnerships with UNICEF, WHO, NGOs and a broad range of commercial companies. This partnership is essential in coordinating activities and maximizing ITN delivery opportunities.
- *Monitoring the market*: PSI's monitoring and evaluation tools measure program progress towards the goals of increasing malaria risk group coverage and developing the market development.

The 'Coverage Plus' social marketing model plays a pivotal role in linking the public and private sectors, capitalizing on the full resources of the formal and informal private sector to make ITNs known, understood, desired, affordable and accessible to low-income populations.

D.3 PSI in Tanzania

With more than twelve years of social marketing experience in Tanzania, PSI has built a successful, cost-effective and diversified program that addresses a broad range of public health issues. PSI promotes and distributes some of the most well-regarded health products in Tanzania, including *Salama* male condoms, *SmartNet* insecticide-treated nets, *Ngao* re-treatment kits, *Care* female condoms and *WaterGuard* point-

of-use water treatment tablets and solution. With funding from the British and Dutch governments, PSI has extensive geographic coverage in Tanzania, including 19 regional/zonal offices.

PSI has been at the forefront of Tanzania's malaria control efforts since launching the Social Marketing of ITNs (SMITN) project in 1998. In 2002, strong stakeholder confidence in PSI's approach resulted in project expansion under the name SMARTNET. More than 11.4 million nets have been sold in Tanzania by PSI and the TNMs in this period (2002-2004)I. A program evaluation conducted by DFID in 2004 described the SMARTNET program as the "Best ITN program in Africa." ¹⁹

D.4 Chief of Party Experience and Capacity

PSI proposes Dr. Jane Miller for the position of Chief of Party. Dr. Miller has more than 12 years of experience as an advocate for increased access to ITNs in Tanzania, beginning in 1994 with her work to develop and evaluate one of the first 'dip-it-yourself' kits for the home treatment of mosquito nets with the London School of Tropical Medicine and Hygiene. In 1998, Dr. Miller launched the SMITN project, which first promoted and distributed ITKs/IRKs under the brand name *Ngao*.

Dr. Miller and her team successfully managed the expansion of the SMITN project into SMARTNET, which has been hailed as an innovative public-private program and 'trail-blazer' for the global Roll Back Malaria partnership. SMARTNET demonstrated how commercial ITN production and distribution can be stimulated while ensuring equitable net coverage through the effective targeting of subsidies. As the chief technical advisor to the program, Dr. Miller led the introduction of new technology (first ordinary and then longer-lasting ITKs/IRKs) into Tanzania, resulting in a dramatic increase in access to treated nets. She also played a pivotal role in helping the TNMs eliminate taxes and tariffs on nets and polyester yarn.

Under Dr. Miller's leadership, PSI developed long-standing relationships with each of the four TNMs. Such relationships have been key to SMARTNET's success, generating not only transparency and trust, but also effective private sector incentive schemes. Since program inception, all TNMs have scaled-up net production for local markets and increased the quality of their net products through bundling with *Ngao* (unbundled nets have all but disappeared from the Tanzania market). Moreover, the successful cultivation of four competing manufacturers has benefited the commercial market and prevented the formation of a monopoly.

Dr. Miller has played an instrumental role in the institution of the LLIN Working Group, serving as a leading proponent for the switch to factory pre-treated nets in Tanzania. Her advocacy has helped convince crucial stakeholders of the importance and potential impact of the technology for malaria control in Tanzania, without sacrificing attention to the complexity of the task and the challenge of providing a time-limited supply of insecticide.

A skilled mentor, Dr. Miller focuses considerable attention to the advancement and promotion of her outstanding Tanzanian colleagues, one of whom took over as Director of the program in 2005.

Dr. Miller's qualifications for the COP position are unmatched. She has an exemplary track record in project management and leadership, as well as established relationships among the relevant public and private sector malaria partners. Her qualifications are further enhanced by impressive academic credentials in entomology and public health, and by her passionate commitment to controlling malaria in Tanzania. Please see Dr. Miller's CV in Annex 4 for details. PSI would also be pleased to provide the CVs of her well-qualified team upon request.

Dr. Miller's level of effort will be 100% on this project.

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¹⁹ DFID OPR, 2004

E. MANAGEMENT AND ADMINISTRATION PLAN

E.1 Organizational Approach

PSI's management philosophy is one of decentralization, efficiency and effective decision-making. PSI consistently seeks to avoid staff-intensive, bureaucratic and top-heavy management structures. PSI/Tanzania is empowered and responsible for the operational and financial management of its projects, achieving proposed results, and complying with USAID regulations and procedures. PSI/Tanzania will ensure that the terms of all agreements defining collaboration with the TNMs, testing laboratories, audit firms and clearing agents are upheld. PSI/Washington will provide technical assistance and back-stopping, executing proper financial and other reporting per the grant agreement. The proposed intervention's complete integration into PSI's social marketing infrastructure (alongside safe water and HIV/AIDS programs) will ensure that the personnel and levels of effort described are sufficient to meet project needs.

E.2 Reporting Structure

E.2.1 Executive Director

PSI/Tanzania is led by the Executive Director, who links field and headquarters, ensuring a synergistic relationship in which communications and information flow smoothly. He will devote 5% of his LOE to this project. The PSI/Tanzania Executive Director will monitor implementation of the proposed project through continual contact with the Chief of Party (CoP) and Supply Chain Manager.

The Executive Director has primary responsibility for integrating the project activities into PSI/Tanzania's existing platform, and allotting and ensuring an appropriate LoE from PSI/Tanzania employees involved with administration, logistics, financial management and M&E. Together with the Research Executive and CoP, the Executive Director will review the results of Projects MAP and TRaC, and external research, to direct any necessary mid-course adjustments to strategy and interventions that might be required to achieve project outputs.

E.2.2 Chief of Party

The Chief of Party is directly responsible for all procurement, distribution, quality control and monitoring activity, and oversees reporting and progress towards meeting the goals outlined in this application, and defined by the Resident Director. She will dedicate 100% of her LOE to the project.

The CoP will oversee and broker the LLIN technology transfer and quality control arrangements with the TNMs; manage the approval and registration process with the TPRI; track inventory, distribution and insecticide use with the Internal Auditor and external audit firm; facilitate quality control with the TFDA, NMRI and TNMs; supervise insecticide resistance monitoring; and coordinate communications with the PSI-Tanzania Marketing Director. The CoP will also be responsible for ensuring that PSI remains abreast of the latest national and international developments with regard to malaria prevention efforts in general and LLIN technology in particular. She will serve as the first point of contact for the proposed intervention's partners. This role will include managing the Secretariat of the LLIN Working Group.

E.2.3 Supply Chain Manager

The Supply Chain Manager will report to the CoP on all issues related to inventory management, providing additional management and supervisory oversight of programmatic, financial and administrative functions. The Supply Chain Manager will employ PSI's powerful BusinessVision® (BV) software to control ordering, receiving, storage, production process, and finally, sales and distribution. He will provide the CoP and Executive Director with information on re-order levels, stocks levels, raised purchase orders and sales orders. He will also track inventory (received quantities) against issued purchase orders in order to determine receivables or over-delivery. The Supply Chain Manager will spend 100% of his LOE on this project.

E.2.4 National Operations Manager

The Executive Director oversees the work of the National Operations Manager, who supervises product distribution. In addition to facilitating ITK/IRK sales through the national distributor, Nufaika, the National Operations Manager supervises the Regional and Zonal managers charged with uplifting product to remote rural locations. Under the Regional Managers, PSI employs a network of Commission Sales Agents (CSAs) in the field who are given incentives to actively seek new distribution opportunities in locations that are underserved by commercial distribution. The National Operations Manager will devote approximately 10% of his LOE to this project.

E.2.5 Fleet and Logistics Manager

The Fleet and Logistics Manager will be responsible for the movement of insecticide from the port of entry to the PSI warehouse, and onwards to the TNMs or (in the case of stand-alone ITKs/IRKs) the national distributor, Nufaika. He is currently responsible for a fleet of 14 Toyota Landcruisers, three 3.25-ton Mitsubishi trucks, a Nissan pick-up and a 7.8-ton Mitsubishi truck (currently being procured). He will devote approximately 35% of his LOE to this project.

E.3 Technical and Backstopping Support

PSI's local project managers will work closely with PSI/Washington and PSI's Global Malaria Program staff, benefiting from their centralized knowledge base yet remaining independently accountable as a separate project. The local project management team at PSI has access to and support from the technical services, contracts, finance, accounting and procurement departments, as well PSI/Washington's program development/fundraising efforts.

The team of experts chosen to provide technical assistance to the project combines both public sector and technical expertise with significant experience in sub-Saharan Africa. This team includes the Global Malaria Director, the Director of New Business Development, the Director of Research, the Regional Director for East Africa, the Program Managers and Program Specialists for East Africa and the Director of Technical Services.

Program information will be shared via monthly project and financial reports, as well as regular e-mail and phone contact. Direct management from the PSI/Washington and the Global Malaria Program will include several short-term technical assistance (STTA) trips to be made during the course of the project – particularly during the transition to factory pre-treatment.

E.4 Financial Management

As a U.S. based nonprofit organization that has received significant funding from USAID, PSI/Tanzania follows the administrative, accounting and auditing requirements of the Office of Management and Budget as described in Circulars A-110, A-122 and A-133. PSI has a long history of successful financial management of its activities including successful A-133 audits since its inception.

E.4.1 <u>Financial Management Systems</u>

PSI financial and administrative staff has expertise in contract procedures with various multilateral and bilateral donor agencies and host governments. These skills include subcontracting, monitoring, contract compliance, and using financial schedules. Field personnel, supervised by the Finance Director and Executive Director, oversee budgeting, cost control, expenditures, and billing.

The Executive Director is responsible for local expenditures of all project funds. Record keeping is strict and complete, uses computerized tracking systems, and accords with local and international accounting rules. PSI/Tanzania's finance department, led by the Finance Director, follows generally accepted accounting principles and the accounting system is designed to support fund accounting in which receipts and disbursements of funds are segregated and maintained by individual project agreement. Policies and procedures are established in writing to guide PSI affiliates in using the accounting system, documentation requirements, internal controls, segregation of duties, and safeguarding of assets.

E.4.2 Financial Reporting

PSI/Tanzania submits monthly financial reports to PSI/Washington summarizing local transactions by project and providing the status of assets and commodities. These financial reports are reviewed, processed, and recorded by PSI accounting and PSI expenses are added. PSI then prepares final financial reports that include all financial activity by project compared to the project's budget.

PSI-Tanzania currently manages approximately USD 9.4 million per year in donor funds and product revenues, and follows strict accounting procedures. Expenses are tracked against budgets, by project and department, and a standard budgeting format is used to ensure consistency. The Finance Director, is responsible for monthly financial and sales reporting to the Executive Director and to PSI/Washington.

Each month, financial reports are sent to PSI HQ for review and to ensure that expenses are incurred in line with overall project budgets (including product revenue accounts). In order to strengthen accounting and financial control systems, PSI is subjected to an internal audit by an accountant from PSI HQ once a year, and an annual external corporate audit by a local independent audit firm. These audits examine all transactions and reports, including taxation, bank and journal vouchers, bank reconciliation statements, status of dishonored checks, stock reconciliation and trial balances.

E.5 Branding

PSI will not register any brands developed under this CA without the reference to USAID.

F. GENDER CONSIDERATION IN THE PROGRAM

The commitment to addressing gender matters is an important component of PSI's overall malaria prevention strategy. Malaria affects all segments of the population, but children under five years of age and pregnant women are particularly vulnerable. In Tanzania, pregnant women constitute the main adult risk group for malaria. Malaria during pregnancy can result in maternal mortality and severe anemia, often leading to poor infant development and survival. The Cochrane Reviews provide evidence of the significant positive impact generated by ITN use: namely, reducing the incidence parasitaemia, low birthweight and still-births.²⁰

Both biological and social factors contribute to the varied impact malaria has on women and men, both as sufferers and as principal caregivers. While ITNs decrease the number of malaria cases and malaria death rates in pregnant women and their children, their use is often determined by gender roles and related sleeping arrangements within the household. Young children and infants typically sleep with their mother, and consequently only receive the protective benefits of the net if their mother does. Yet experience shows that when households only have one net, the male head of household (typically, the primary bread-winner) frequently appropriates the net for his own use.

As a consequence, the coordination of BCC efforts that focus on the vulnerability of pregnant women and under-fives, and that promote their prioritization for net use, will be critical to overcoming gender imbalances.

The Tanzania National Voucher Scheme (TNVS) also plays a crucial role in increasing net coverage and targeting among women and young children. The TNVS targets a subsidy exclusively at pregnant women, helping to overcome issues of affordability among the most vulnerable target demographic. While the TNVS does not directly ensure net use by pregnant women and under-fives, the targeted subsidy also helps educate consumers about the special vulnerability of these groups.

²⁰ Insecticide-treated nets for preventing malaria in pregnancy (Review). Gamble C, Ekwaru JP, Kuile FO. Cochrane Review, The Cochrane Collaboration, The Cochrane Library 2006, Issue 2

PSI's BCC efforts have always been sensitive to gender concerns, focusing on educating women about their vulnerability, and educating men about their responsibilities toward other members of the household. Similarly, close coordination between PSI, the TNMs and the TNVS has effectively targeted distribution. PSI will make certain that these key issues continue to be addressed by the LLIN Working Group, TNMs, commercial distributors and the selected BCC agency.

In addition to targeted voucher distribution, communications will be key to ensuring that most vulnerable groups (pregnant women and children under five) are prioritized for net use, and that caregivers have affordable access to the products. PSI will address this issue more fully in response to the anticipated communications RFA.

PSI-Tanzania's official gender policy, articulated in its Personnel Manual, commits the organization to the promotion of equal opportunity for all persons, regardless of sex. PSI works actively to prevent, and responds robustly to, any form of gender discrimination. PSI's hiring practices are entirely merit based, but the organization actively encourages female applicants at all staffing levels. Women are strongly represented in PSI-Tanzania's senior management; out of the eight members of the senior management team, four are female. In addition to Dr. Miller, the proposed CoP, they include the Director of HR and Administration, the Marketing Manager for HIV and Safe Water, and the Corporate Affairs Manager.

Approximately two-thirds of the TNMs' workforce is female, involved primarily in stitching fabric into nets, and on the shop floor operating machinery. PSI does not have hard data on the gender-split the retail sector, and neither is MEDA able to provide this information on TNVS registered outlets. As discussions of program implementation advance, PSI will work with the TNMs, retailers and others to promote gender equity in their work forces. Copies of PSI's and USAID's gender policies will be distributed to these partners. Partners will also be encouraged to work through women's groups to distribute and promote their products.

G. Monitoring and Evaluation

PSI employs a rigorous set of tools and methods to monitor critical indicators related to behavior (ITN ownership and use) and product distribution (bundled nets, LLINs and ITKs/IRKs), known collectively as the 'Dashboard'. These tools promote evidence-based decision-making by providing valuable, objective, and timely feedback to complement the judgment and experience of program managers, much as dashboard instruments provide information for the driver of a vehicle. The Dashboard tools enable PSI to focus effort and resources on factors critical to ITN use, on regions that are most vulnerable, and to effectively measure the impact of the program.

Data collection is carried out using hand-held computers; a method that minimizes or eliminates data-collection errors, laborious data-entry, paper/printing costs, and the need for data-cleaning. PSI is also able to directly supervise data-collection, employing and training part-time enumerators from a reliable pool of candidates, eliminating the need to employ an expensive outside agency. The use of the devices has significantly reduced costs and improved the quality of data.

The Dashboard comprises of two main components, described below, Project TRaC and Project MAP.

G.1 Project TRaC (Tracking Results Continuously)

Project TRaC comprises of population-based, multi-round tracking surveys that represent an improvement on traditional 'knowledge, attitudes and practices' (KAP) surveys. The sample size for each survey round is 1,500, distributed across the country's regions and districts via a multistage random, 'probability proportional to size (PPS)' sampling scheme. Households are selected randomly with enumerators privately conducting face-to-face interviews with the primary caregiver.

Project TRaC does more than track changes in key indicators over time; one of its key features is the inclusion of a 'segmentation' analysis. Segmentation involves dividing the at-risk population into those

that perform the desired behaviors, and those who do not. The differences between these groups of 'behavers' and 'non-behavers' are then analyzed. This exercise enables us to identify the opportunity, ability and motivation factors that influence or correlate with desired behaviors. Armed with this information, managers are better able to focus our program efforts and resources on modifying those critical factors and thus inducing sustained behavior change. Similarly, an evaluation analysis correlate changes in behavior with exposure specifically to malaria prevention communications.

In addition to isolating key information on determinants of behavior, the streamlined nature of the Dashboard approach also enables PSI to present key findings with greater frequency and faster turnaround times. This enables PSI program managers to make key decisions in an extremely timely, effective manner. PSI conducted the first survey round of Project TRaC in February 2006, the second round in March 2007 and will be conducting further survey rounds annually.

Key project behavioral indicators related to this project include:

- Proportion of households with children under five that own at least one bed net
- Proportion of households with children under five that own at least one ITN
- Proportion of nets that are effectively treated
- Proportion of children under five who slept under a net the previous night
- Proportion of children under five who slept under an ITN the previous night
- Average number of nets owned per household with children under five: all households
- Average number of nets owned per household with children under five: net-owning households
- Proportion of nets received bundled with ITKs
- Proportion of nets treated immediately after purchase

In addition to the indicators above, Project TRaC also examines and analyzes several factors related to opportunity, ability and motivation that could potentially influence net ownership, use and treatment. Opportunity factors include the availability, brand appeal, and attributes of nets and ITKs/IRKs. Ability factors include self-efficacy and malaria-related knowledge. Motivation factors include intentions, beliefs, outcome expectations and risk perception. In order to gain maximum insight, and ensure that every dimension of these behavior-change constructs is addressed, each factor is addressed by multiple items/questions in the survey. Nuanced analysis is enabled by the use of scaled responses (strongly agree, somewhat agree... etc.) rather than simple yes/no answers. Additionally, Project TRaC will measure the frequency, intensity and duration of exposure to malaria-prevention communications, and analyze the correlation between this exposure and positive behavior change.

G.2 Project MAP (Measuring Access and Performance)

Project MAP employs Lot Quality Assurance Sampling (LQAS) and Geographic Information Systems (GIS) technology to assess product availability and accessibility using pre-defined criteria. Such criteria measure both the breadth and quality of coverage (i.e. the proportion of a geographic area in which nets and ITKs/IRKs are available, as well as the proportion of an area in which the products are available *and* conform to additional minimum standards).

The LQAS method involves drawing a random sample of 19 enumeration areas (EAs) in a defined supervision area (region, zone etc.), employing a PPS scheme. A sample of 19 provides an acceptable level of error for making management decisions – at least 92% of the time it identifies whether a selected coverage benchmark has been reached and/or whether a product/service area is below the average coverage of a program area. This LQAS assessment of coverage determines the proportion of each supervision zone region in which PSI-Tanzania's products are available.

By focusing on geographic coverage rather than market penetration (although this is also measured), PSI adopts a unique and innovative approach to assessing product availability. Previously, distribution was measured by selecting a random sample of outlets and examining the proportion that stocked or sold the product. Because outlets are generally clustered together in trading centers, marketplaces and urban locales, a high degree of market penetration does not necessarily translate into availability for those who live at some distance from these locations (as most Tanzanians do).

This new approach reflects PSI's commitment to vulnerable populations – in this case, populations that do not have easy access to well-stocked markets and trading centers. A measurement of geographic coverage provides programmatic staff with knowledge that is far more relevant to their work: not merely selling health products, but selling health products to those at greatest need.

PSI/Tanzania conducted the first round of Project MAP in August 2006, establishing base-lines and decision rules for *Ngao* coverage. The next round is scheduled for August 2007, with following survey rounds to be conducted annually. In addition to Project MAP, PSI Regional Managers conduct a market penetration survey of trading centers every six months. This provides additional data, from a separate department, on the proportion of outlets in trading centers and marketplaces that are selling the product. Together, the Project MAP survey rounds and biannual data-collection by the Regional Managers will enable PSI to closely track changes in coverage and market penetration throughout the life of the project.

Key coverage/market penetration indicators include:

- Proportion of rural EAs in which nets and ITKs/IRKs are available in at least one outlet
- Proportion of rural outlets in which nets and ITKs/IRKs are available
- Proportion of trading center and marketplace outlets in which nets and ITKs/IRKs are available

G.3 Other M&E

PSI will track several indicators (targets and deadlines) related to the facilitation of factory pre-treatment of nets (please see Annex 3: Logical Framework, and Annex 7: Timetable for LLIN Conversion for details). Other critical M&E activities are addressed in the main narrative; Quality Control (Section 4), Insecticide Auditing (Section 5), and Insecticide Resistance Monitoring (Section 6).