U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

FEB 22, 2001

MEMORANDUM FOR ALL CONTRACTING OFFICERS AND NEGOTIATORS

FROM: M/OP, Mark S. Ward, Director /s/

SUBJECT: Expedited Acquisition and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives

CONTRACT INFORMATION BULLETIN 01-04

This CIB serves two purposes:

1) To inform USAID's acquisition and assistance workforce that the Administrator recently approved an Action Memorandum entitled "Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives" (attached, see "the December 19 Memorandum"),

and

2) To provide implementation guidance for using the various waivers approved by the Administrator to facilitate implementation of activities under the HIV/AIDS and Infectious Disease Initiatives. We are issuing a separate CIB for Personal Services Contracts.

On December 19, 2000, the Administrator approved the following Recommendations:

A. Approval of Obligations Not Covered by Existing Strategic Objectives (SOs).
B. Grants and Cooperative Agreements. Authorization For Other Than Fully Competitive Procedures.
C. Procurement of Goods and Services. Authorization For Other Than Full and Open Competition
D. Use of Small Businesses, Small Disadvantaged Businesses, and Minority Serving Institutions
E. Source and Origin Waiver

The December 19 Memorandum (attached) contains the Issue for Decision, the Essential Factors, a list of the Recommendations, the HIV/AIDS and ID strategy for USAID's planned response to the crisis (Tab A), and the Administrator's Determination and Finding Regarding Procurement Procedures for Activities for the HIV/AIDS and Infectious Disease Initiative (Tab B). Please be sure to read the attachment very carefully and be familiar with its contents.

Note that the list of actions recommended by the HIV/AIDS and Infectious Disease Senior Management Team (SMT) to be pursued includes the following:

6. Making maximum use of "wholesale" instruments such as grants-under-contracts (with the authorized dollar amount of grants increased to an appropriate amount), umbrella grants, leader/associate assistance instruments, indefinite quantity contracts, and other arrangements designed to provide fast track assistance and contracting.

The appropriate implementation of other actions on that list, as well as the intended increase to the dollar amount of grants (in the parentheses above), is being considered separately. We will provide you with guidance when available.

On January 11, 2001, the Administrator approved a second Action Memorandum (attached, see "the January 11 Memorandum") authorizing the procurement in Code 935 countries of testing kits identified in Tab 1 of the Action Memorandum. The Administrator also delegated the authority to AA/M to amend the Tab 1 approved list to add new Code 935 testing kits.

A General Policy Notice is being issued concurrently with this CIB to establish the procedures the operating units are to follow to apply the authorities approved in the attached Action Memoranda. The operating unit (as defined in the ADS Glossary, at http://www.usaid.gov/pubs/ads/glossary.pdf) will forward the approved decision memorandum, as more fully described in the Notice, to contracting officers (COs) and agreement officers (AOs) when an activity falls under the Initiatives. COs and AOs must include a copy of this decision memorandum in the file for each award they make for this activity and provide copies to the Agency Competition Advocate as described below.

Specific Guidance for each Recommendation:

A. Approval of Obligations Not Covered by Existing Strategic Objectives (SOs).

This Recommendation applies primarily to the activity approval process, as covered in ADS 201, and only indirectly affects USAID's A&A Staff. All other relevant actions addressed in ADS 201, particularly 201.3.6 "Activity Planning" and its subsection 201.3.6.3 "Pre-Obligation Requirements", are still required, unless otherwise waived in the Action Memorandum.

B. Grants and Cooperative Agreements. Authorization of Less than Fully Competitive Procedures.

The approval of this Recommendation constitutes the written justification required in paragraph (1)(e) of ADS E303.5.5d to use less than fully competitive procedures under the authority of paragraph (5) of ADS 303.5.5d. Note that this Recommendation contains two parts. The first part applies to awarding non-competitive amendments to existing awards, while the second part applies to using less than fully competitive procedures for new awards. Agreement officers are to work closely with the activity manager and SO team to determine what should be the "practicable" number of sources to solicit given the urgency of the HIV/AIDS and Infectious Disease Initiative, but the Agreement Officer has the ultimate authority to decide.

C. Procurement of Goods and Services. Authorization For Other Than Full and Open Competition

The approval of this Recommendation, which includes the determination and findings in Tab B, constitutes a justification for other than full and open competition authorized in AIDAR 706.302-70(b)(3)(ii). Synopsis in the Commerce Business Daily in accordance with FAR 5.201 is not required when this exception to full and open competition is used, per AIDAR 705.202(b).

Once the head of the operating unit approves the decision memorandum determining that the activity falls under the Initiatives, the contracting officer must work closely with the Activity Manager and SO team to determine the most effective level of competition. The Determination and Finding in Tab B states that prior to using informal competitive procedures for a particular procurement, as authorized by the determination, requesting offices will consider the feasibility of using full and open competition or other contracting authorities, such as contracting with the Small Business Administration under the 8(a) Program. The Contracting Officer has the ultimate authority to decide what is "practicable" under the specific circumstances. Note that the last sentence of the approved Recommendation states: "However, in the case of follow-on extensions, it is understood that the existing contractor is the only practicable source."

We also anticipate that substantial sole source procurement will take place in the procurement of testing kits. For example, prudent testing kit procedures require that when an individual tests positive for HIV, he is immediately retested, preferably twice, using a different brand of kit with different procedures. This avoids confirmation of a false positive due to duplicating procedural errors. Thus a stock of specific different types of testing kits will be required. Although contracting officers are to compete the procurement of these test kits to the extent practicable under the circumstances, certain factors are expected to severely limit competition, including, but not limited to, the need to comply with a host country essential drug list or national formulary, market availability and the need to maintain an adequate supply of specific kits to facilitate re-testing at test locations. Contracting officers may determine that only one practicable source exists.

D. Use of Small Business, Small Disadvantaged Business, and Minority Serving Institutions

Although the formal statement described in this Recommendation is still to be issued, the Recommendation itself serves to specifically remind Contracting and Agreement Officers of the availability of the existing authorities in FAR 19.5 to make awards to Small Business concerns, in FAR 19.8 to make awards to Small Disadvantaged Business (SDB) concerns through SBA's 8(a) Program (FAR 19.8), and in ADS 321 to make assistance awards to Minority Serving Institutions (MSIs). The Office of Small and Disadvantaged Business Utilization (OSDBU) is available to help identify Small Business and SDB concerns, and the MSI Coordinator, in the Office of General Counsel, can provide information on MSIs.

E. Source and Origin Waiver

Approval of this Recommendation constitutes a written waiver of USAID's source and origin requirements in 22 CFR 228 to include Geographic Code 935. The Recommendation, however, includes a preference for procuring from the U.S. to the extent practicable, and does not include pharmaceuticals, testing kits, or condoms. The January 11 Memorandum is a separate waiver for testing kits only; pharmaceuticals and condoms are still subject to Agency-wide restrictions and source, origin, and nationality requirements.

Reporting Procedures

Contracting and agreement officers are responsible for electronically forwarding copies of the decision memorandum from the operating unit and a summary statement of the resulting award to the Agency Competition Advocate at the following e-mail address: Agency Competition Advocate. Use the following format for the summary statement:

1. Award number (be sure this number clearly indicates if the award is an initial award, a modification or amendment, a purchase order, a task order, or a modification to either a purchase order or task order)
2. Name of Awardee
3. Obligated Amount of Award
4. Total Estimated Cost of Award
5. Period of Performance (Effective date and estimated completion date)

Be sure to attach the decision memorandum to the e-mail.

Please direct any questions about this CIB to Diane Howard, M/OP/P.

Attachments:
- The December 19 Memorandum
- The January 11 Memorandum

USAID/General Notice
POLICY GC and M/OP
03/06/2001

Subject: Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives

This notice provides information and guidance to Agency staff about certain procurement and assistance procedures to facilitate implementation of activities under the HIV/AIDS and Infectious Disease Initiatives (the "Initiatives"), as recently authorized by the Administrator. This notice contains four attachments:

- General Policy Notice. This contains general information and guidance to the Agency on these expedited procedures.

- Contract Information Bulletin (CIB). The CIB contains more specific guidance for Agency acquisition and assistance staff.

- Action Memorandum dated December 19, 2000, "Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives" ("the December 19 Memorandum").

- Action Memorandum dated January 11, 2001, "The HIV/AIDS and Infectious Disease Initiatives: Source and Origin Waiver for HIV/AIDS Diagnostic Materials (testing kits) ("the January 11 Memorandum").

Points of Contact: Any questions concerning this Notice may be directed to Michael Kitay, GC/G, 202-712-5019 or Diane Howard, M/OP/P at 202-712-0206.

Notice 0310

December 19, 2000

ACTION MEMORANDUM

TO: The Administrator

FROM: GC, Singleton B. McAllister
M/OP, Mark Ward

SUBJECT: Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives

ISSUE FOR DECISION

Whether to approve the use of other than full and open competitive procurement and exceptions to competition for assistance, as well as other waivers, to facilitate implementation of activities under the HIV/AIDS and Infectious Disease Initiatives.

ESSENTIAL FACTORS

The Global AIDS and Tuberculosis Relief Act of 2000 authorizes funding to combat the worldwide HIV/AIDS epidemic and control the spread of tuberculosis. The FY 2001 Foreign Operations, Export Financing, and Related Programs Appropriations Act, in the Child Survival and Disease Programs Fund account, provides $300,000,000 for HIV/AIDS programs, and $125,000,000 to combat other infectious diseases. Additional funds are appropriated in other accounts.

Congressional findings detailed in the legislation clearly indicate the emergency nature of the situation. HIV/AIDS will soon become the worst epidemic of infectious disease in recorded history. More than 36,100,000 people in the world today are living with HIV/AIDS. 95 percent of the infected population live in the developing world. Of children aged 14 and under, more than 4,300,000 have died

from AIDS and 1,400,000 are living with the disease. In the year 1999 alone 620,000 of those children became infected, 90 percent at birth from mother-to-child transmission (MTCT). Worldwide there have been an estimated 21,800,000 deaths from AIDS, of which more than 80 percent occurred in Sub-Saharan Africa. It is estimated that at the end of 1999, 13,200,000 children had lost at least one parent to AIDS. Some estimates predict that this number of AIDS orphans could increase threefold or more in the next ten years. The U.S. Census Bureau statistics show life expectancy in parts of Sub-Saharan Africa falling to around 30 years of age within a decade, mostly due to HIV/AIDS. In addition, an estimated one-third of the entire world population has been exposed to tuberculosis, which causes about 2 million deaths each year, and new drug-resistant strains are growing rapidly.

USAID's planned response to this crisis in certain defined high and low prevalence countries is outlined in the strategy attached as Tab A ("HIV/AIDS and ID Strategy"), approved by the HIV/AIDS and Infectious Disease Senior Management Team (SMT). Tab A consists of two documents: "USAID's Expanded Response to the Global HIV/AIDS Pandemic, Tuberculosis and Malaria" and "USAID's Expanded Response to the Global HIV/AIDS Pandemic". The HIV/AIDS and ID Strategy, among other things, establishes the following international targets to be accomplished by the year 2007:

1. Reduce HIV prevalence rates among 15-24 year olds by 50 percent in high prevalence countries.

2. Maintain prevalence below 1 percent among 15-49 year olds in low prevalence countries.

3. Provide access to interventions to reduce MTCT to 25 to 50 percent of infected mothers in high prevalence countries.

4. Help local institutions provide care and support to 25 to 50 percent of HIV infected persons in high prevalence countries, and expand access to tuberculosis screening and prevention services as broadly as possible.

These ambitious targets, together with targets related to infectious diseases will require procurement and assistance instruments to be in place in the shortest possible time. Though full and open competition works well to maximize participation by the private sector community, we will need expedited action to meet the targets. This concept is echoed in the Conference Report accompanying the FY 2001 Appropriations Act that states:

> "The managers are aware that the HIV/AIDS and tuberculosis crises require extraordinary efforts on the part of the United States Government. USAID is encouraged to use, as appropriate, its existing waiver authorities regarding financing and procurement of goods and services, and grant making, in order to expedite the provision of HIV/AIDS and tuberculosis assistance and enhance the efficiency of that assistance."

As directed by the SMT in its meeting on November 9, 2000, certain actions needed to expedite the USAID response will be pursued by GC and OP for approval at lower levels. Those actions include:

1. Increasing the numbers of experienced contracting officers (COs) in Washington and the field dedicated to the Initiatives by rehiring former USAID and other federal agency COs under personal service contracts (PSCs) or on expert/consultant status, and delegating to them authority to sign contracts, grants and cooperative agreements. Although such individuals are not normally given authority to sign A&A instruments, exceptions to this restriction may be approved by AA/M. Consideration will also be given to obtaining the services of experienced contracting officers through a Cooperating Agency Service Unit or Franchise Business Activity (CASU/FBA).

2. Authorizing the use of other than full and open competition to hire PSCs for HIV/AIDS and infectious disease work overseas. This would represent a return to USAID's pre-1997 policy for PSC hiring. It would enable USAID missions to obtain required technical help in the shortest possible timeframe.

3. Ensuring the maximum use of existing authority in ADS 321 to award grants to Minority Serving Institutions using less than fully competitive procedures.

4. Ensuring maximum use of existing authorities to award contracts to 8(a) firms, small businesses, and small and disadvantaged businesses using less than fully competitive procedures.

5. Increasing the grant making authority of USAID mission directors to $2,000,000 for use in circumstances when services of an Agreement Officer are not readily available, subject to legal and procurement office local staff review. (If necessary, ad hoc delegations can be requested in a greater amount).

6. Making maximum use of “wholesale” instruments such as grants-under-contracts (with the authorized dollar amount of grants increased to an appropriate amount), umbrella grants, leadership/associate assistance instruments, indefinite quantity contracts, and other arrangements designed to provide fast track assistance and contracting.

7. Reviewing the technical feasibility of some procurement of pharmaceuticals, testing kits, and condoms from non-U.S. sources, if required for timely program implementation. Waiver documentation will be developed as soon as possible based on the results of this review.

In addition we recommend that you approve the following blanket waivers which will both expedite specific activities and signal the sense of special urgency felt at the highest level. The waivers would be effective immediately and would remain in force throughout the life of the HIV/AIDS and ID Strategy, estimated to be through the year 2007. The waivers would cover activities funded from all sources of funding (e.g., SEED or ESF funding) and U.S.-owned local currency accounts. The waivers would apply to prior year funding still in the pipeline as well as future fiscal year appropriations. Specific guidance to be developed by GC and OP and approved by the SMT will specify when the use of the waiver authorities is most appropriate. Records will be kept on all uses of the waiver authorities. The situation will be reviewed on an annual basis to determine the adequacy of the waiver authorities or their continuing need.

Normal USAID waiver authorities will, of course, also remain available for use in situations where they are needed to meet program objectives, e.g., the authority recommended in Section B(1) below authorizing an extension of grants and cooperative agreements for up to a two-year period, would not preclude a waiver for a longer period authorized pursuant to ADS 303.5.5(d)(1).

RECOMMENDATIONS

A. Approval of Obligations Not Covered by Existing Strategic Objectives (SOs). Existing approved Strategic or Special Objectives may not cover some activities contemplated by the HIV/AIDS and ID Strategy. ADS 201.3.3.5 provides that in special foreign policy situations where it is necessary to initiate activities prior to completion and approval of a strategic plan, a temporary one-year exemption may be issued. We recommend that you approve such a one-

year exemption for all HIV/AIDS and Infectious Disease Initiative activities contemplated by the HIV/AIDS Strategy.

Approve:_________________

Disapprove:_________________

Date:_________________

B. Grants and Cooperative Agreements. Authorization For Other Than Fully Competitive Procedures. In order to meet the HIV/AIDS and ID Strategy targets, USAID must select its grant-financed partners and get them operational in the shortest possible time frame. For this purpose we recommend:

1. Authorizing non-competitive amendments to existing grants and cooperative agreements for additional work similar to that performed under the original agreement. These extensions would be limited to a two-year period, in order to provide the time to obtain subsequent support on a more competitive basis.

2. Authorizing awards of new grants and cooperative agreements using less than fully competitive procedures. This authority would extend to all types of grants and cooperative agreements, including Leader/Associate awards for Leader/Associate Assistance instruments provided they include pre-award established ceilings. While formal advertising would not be required, applications would be solicited from as many sources as practicable under the circumstances.

Pursuant to ADS 303.5.5(d)(5) competition is not required for assistance awards when justified by circumstances which are determined to be critical to the objectives of the foreign assistance program. Based upon the global life-threatening nature of the HIV/AIDS and infectious disease epidemics we recommend that you make this critical objectives finding and authorize the use of other than fully competitive procedures in making awards under the above described assistance instruments.

Approve:_________________

Disapprove:_________________

Date:_________________

C. Procurement of Goods and Services. Authorization For Other Than Full and Open Competition. We recommend that flexible and expedited procurement procedures be approved for USAID direct contracting for the delivery of goods and services. Specifically, we recommend that such procurement be undertaken through limited competitive procedures that are quicker as well as less labor intensive than the FAR full and open competitive procedures. As in (B) above, this would apply to follow-on extensions of existing contractual efforts, as well as to new procurements.

Under the USAID Acquisition Regulations (AIDAR) the Administrator of USAID may determine in writing, with supporting findings, that compliance with full and open competitive procedures would impair foreign assistance objectives and would be inconsistent with the fulfillment of the foreign assistance program. AIDAR 706.302-70(b)(3)(ii). As USAID Administrator, you have the authority to make such a determination with respect to entire programs, such as the HIV/AIDS and Infectious Disease Initiatives. The expedited procedures would be utilized for quick reaction activities where the impact of U.S. assistance will need to be evident in a very short time frame. Your approval below will also serve as approval of the formal written determination with supporting findings at Tab B. The Agency Competition Advocate has reviewed the determination. While formal advertising would not be necessary, solicitation would be made from as many sources as practicable under the circumstances. However, in the case of follow-on extensions, it is understood that the existing contractor is the only practicable source.

Approve:_________________

Disapprove:_________________

Date:_________________

D. Use of Small Businesses, Small Disadvantaged Businesses, and Minority Serving Institutions. We think that it is important at the outset of the program to have a formal statement issued by top Agency management on the importance of including Small Businesses, Small Disadvantaged Businesses, and Minority Serving Institutions

(MSIs) in the implementation of these initiatives. In that statement, Agency staff would be reminded that legal mechanisms now exist to make awards to these firms and institutions using other than full and open competition --- namely, by using: 1) set-aside authority under the Small Business Act to make awards to Small Businesses and to 8(a) Small Disadvantaged Businesses, and 2) the authority contained in USAID's Automated Directives System (ADS) Section 321 to award grants and cooperative agreements to MSIs via limited competition among these institutions. The inclusion of such information in the statement would help offset any downward trend in USAID in contracting with Small and Small Disadvantaged Businesses, similar to the trend verified government-wide in a study commissioned by the SBA and by recent USAID reports on MSIs submitted to the White House and OMB. The decline government-wide has been attributed to the agencies' use of IQC's and of bundling of government contracts. We recommend that as soon as decisions contained in this memorandum are made, we prepare such a statement for your signature for distribution to USAID staff.

Approve:_________________

Disapprove:_________________

Date:________________

E. Source and Origin Waiver. Under the Development Fund for Africa legislation, Development Assistance (DA) and Child Survival and Disease (CSD) funding utilized for activities in Africa enjoy a liberalized source and origin requirement. Normal USAID source/origin/nationality requirements do not apply to procurements made with that funding. As a matter of policy, procurement from the United States is maximized whenever practicable, consistent with program objectives. We recommend that Geographic Code 935 (which includes all countries, excluding only the foreign policy restricted countries) be established as a pre-authorized source/origin/nationality code for any goods and services procured under the HIV/AIDS and ID Strategy, in accordance with an order of preference requiring U.S. procurement to the extent practicable.

As is the present case in Africa, motor vehicles would be included in the waiver, and your approval below constitutes the "special circumstance" finding required by FAA 636(i), for vehicles procured for the HIV/AIDS and Infectious Disease Initiatives. However, procurement of

motor vehicles from non-U.S. sources will be held to an absolute minimum, and done only when necessitated by required specifications, spare parts, and maintenance capabilities. As is the present case in the Africa Bureau, pharmaceuticals are not covered under the waiver. However, as indicated above, OP, GC and others will be reviewing the technical feasibility of, and preparing separate waiver documentation for, some procurement of pharmaceuticals, testing kits, and condoms from non-U.S. sources, if required for timely program implementation.

22 CFR 228.51(a)(3) and 22 CFR 228.53(c) provide that a source and origin waiver for goods or services may be authorized when it is found necessary to promote efficiency in the use of United States foreign assistance resources, including to avoid impairment of foreign assistance objectives. The regulation, as well as the underlying statute (FAA 636i), provides that such waivers must be made on a "case-by-case" basis, and GC confirms that this waiver limited to the HIV/AIDS and ID Strategy meets that standard.

We recommend that you make the above finding and authorize the waiver of source and origin requirement for goods and services purchased for the HIV/AIDS and Infectious Disease Initiatives to be made from Geographic Code 935, as discussed above.

Approve:________________

Disapprove:________________

Date:_________________

USAID's Expanded Response to the Global HIV/AIDS Pandemic, Tuberculosis and Malaria

Introduction

PART A : HIV/AIDS

I. Our Commitment

II. What We Will Achieve

III. What We Will Do

IV. Where We Will Do It

V. What Are The Resource Needs

VI. How We Will Do It

- Expanding Partnerships
- Building the Capacity of Our Partners
- Building USAID Capacity

VII. Developing and Introducing New HIV/AIDS Prevention and Care Approaches and Technologies

VIII. How Will We Measure Our Achievements

IX. Timeline for Disbursements: FY 2001-2002

Introduction

The global community continues to underestimate the scope, severity and impact of the AIDS pandemic and the parallel tuberculosis epidemic. At the end of 1999, HIV/AIDS prevalence (See Appendix 1) among adults nationally exceeded 20% in 7 countries in the developing world-all in Africa-and was above 10% in 9 additional countries. In another

41 countries, prevalence equals or exceeds 1%. 22 of these are in Africa, 11 are in Latin America, 4 in Asia and 1 in Eurasia. In contrast, HIV/AIDS prevalence in the United States was 0.6% at the end of 1999. 1994 was the first year when country level HIV prevalence statistics were validated by host country governments. Just 6 short years ago, there were no countries with rates exceeding 20% and only 5 countries where national rates exceeded 10%.

At the same time – and in part fueled by the HIV/AIDS pandemic – there has been a resurgence of tuberculosis. TB kills 2 million people each year – primarily in the developing world. TB is also the leading cause of death among HIV-positive people and accounts for one third of the AIDS deaths worldwide. Just 22 countries account for 80% of the global TB burden – half of these countries are in Asia. In Africa, 20 countries had estimated TB case detection rates of over 100 per 100,000 people in 1999 – in contrast the estimated case detection rate for the U.S. is about 3 per 100,000 people. Multi-drug resistant strains of TB are appearing in a number of countries in Eastern Europe and Eurasia and Latin America, and threaten to spread to the rest of the world.

Since 1986, the U.S. Agency for International Development (USAID) has been engaged in combating the HIV/AIDS pandemic in the developing world. USAID has become the global and US Government (USG) leader in this international fight, due to USAID's strong field presence, technical leadership, the level of its financial support, and the extensive, long-term relationships with host country institutions. These relationships in the field provide the foundation for USAID's track record for building sustainable systems, using highly participatory approaches, and applying lessons learned to enhance the effectiveness and efficiency of programs. USAID sustained investments in Uganda have resulted in a reversal of the explosive upward trends and in Senegal have kept prevalence low. Recent reports from Zambia also suggest a reversal of the epidemic in the 15-19 year olds. Building on this experience, USAID will guide the development of an overall expanded plan for USG foreign assistance to combat the AIDS pandemic, and will facilitate and coordinate the USG response in host countries. In order to utilize USG and other global resources in a synergistic manner, USAID will use its vast network of partners, both at local and international levels, to ensure optimum coordination and collaboration.

Tuberculosis is a relatively new area for USAID – comprehensive programming began in 1998. Since then, USAID has worked closely with other USG agencies, WHO, and the leading organizations in TB to put in place effective TB programs at the country level and to mount a global response to TB. These relationships and partnerships at the country level will continue to form the core of USAID's response to TB.

PART A: HIV/AIDS

Section I. Our Commitment

USAID is committed to enhancing the capacity of developing and transitional countries to protect their populations not yet infected by HIV and to provide services to those infected and others affected by the epidemic. Towards this end, USAID will strengthen its financial and technical support to countries to:

- Prevent the transmission of HIV, with a dual emphasis on high and those low prevalence countries that are deemed at risk for an impending epidemic (High prevalence is defined as >1% HIV infection in adults aged 15-49 years old. Low prevalence is defined as < 1% with the presence of risk factors that include HIV trend data and levels of risk behavior);
- Build the capacity to provide care and support for as many affected individuals, families and communities as possible, particularly in those countries most severely affected;
- Reduce significantly the social and economic impact of the epidemic on vulnerable groups and particularly within key sectors of health, education and democracy/governance; and
- Develop and introduce new HIV/AIDS prevention and care approaches and technologies. These would include a female controlled microbicide, more effective behavior change models for men, rapid STD and HIV diagnostic tests which are applicable for low resource settings, and preventive and therapeutic vaccines.

Section II. What We Will Achieve

Expected achievements for "high prevalence" and "low prevalence-at risk" countries would be different. By 2007, USAID will assist selected countries to:

- Reduce HIV prevalence rates among those 15-24 years of ages by 50% in high prevalence countries, and maintain prevalence below 1% among 15 to 49 year olds in those low prevalence countries that are deemed at risk of impending epidemics,

- Ensure that at least 25-50% of HIV/AIDS infected mothers in high prevalence countries will have access to interventions to reduce HIV transmission to their infants,

- Enable host country institutions to provide basic care and psychosocial support services to at least 25-50% of HIV infected persons in high prevalence countries, and expand information and access to TB screening and prevention services as broadly as possible,

- In high prevalence countries, enable host country institutions to provide community support services to at least 25-50% of children affected by AIDS[1], and

- Mitigate the impact of HIV/AIDS on key sectors (education, health, democracy/government) in severely affected countries.

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[1] “Children Affected by AIDS” include those in households with sick or dying parents and those children orphaned by AIDS.

The total cost from all sources for achieving these ranges of targets in all of Sub-Saharan Africa alone are estimated to be from $3-4.9 billion per year. The expected funding levels for USAID in FY 2001 could vary between $255-$530 million annually. These amounts represent 9-17% of the funding requirements for achieving the targets mentioned above and would focus on a subset of these countries. The impact of USAIDs investments will then be proportional to these funding levels. Lower funding levels would achieve the lower range for the targets noted above and would occur in a smaller number of countries. (See Section X.-What are the resource needs) However, USAID achievements could exceed the proportion of expected contributions, as it can gain efficiency for the investments due to its long experience and field presence. It is expected that our funds will also leverage other partner funding. Finalizing the actual target percentages which are attributable to USAID and the final selection of countries will depend on the resources available. See Section IV. (Where We Will Work) and Section VIII (What Are Our Resource Needs).

The above targets will be regularly reviewed and revised in the light of evolving data and ongoing analyses of the cost effectiveness of programs. In collaboration with CDC, WHO and UNAIDS, HIV sentinel surveillance systems will be improved in selected countries to report annually on HIV prevalence among 15-24 year olds. Beginning in 2001, USAID, with its partners, will begin periodic national surveys to collect information on changes in reported sexual behavior and to measure the quality and coverage of care and support services specified under this initiative. For more details, see Section VI (How Will We Measure Our Achievements)

Section III. What We Will Do

Unlike other crises due to war, famine or natural disaster, the investments made to secure the changes in risk behavior and to strengthen social and health services to address the pandemic must be immediate and intensive, but also **sustained over longer timeframes**. The importance of protecting future generations requires that our response prioritize protecting vulnerable populations, particularly children and adolescents. Given the pace and span of the pandemic, it is clear that our response cannot be "business as usual." The global USAID response should be broad in scope (multisectoral) and coverage (high and low prevalence countries) in order to make a sustained and cost-effective difference. USAID will focus particularly on sub-Saharan Africa, because most countries have prevalence over 1% and critical countries on the other regions of the world.

Five factors will define the programmatic expansion of USAID programs as new resources are made available. USAID will help countries:

- Prioritize implementation of proven interventions that can be rapidly taken to nationwide scale.
- Focus prevention and care interventions to reach the most vulnerable populations in high transmission areas.

- Expand country capacity to track the epidemic, implement programs, measure their impact, coordinate donor and other partner activities and utilize resources effectively.
- Adapt and utilize development interventions and increase the capacity of various development sectors (e.g., education, microfinance, etc) to reach and respond to communities impacted by HIV.
- Strengthen country commitment to build aggressive and sustained local involvement needed to curb the epidemic and significantly reduce the impact on individual communities.

Using the array of mechanisms available to USAID, we will meet the dual challenge of rapidly scaling up HIV prevention interventions known to be effective, while building the capacity for sustaining them. Known prevention interventions that we will expand include combined use of mass media and targeted interpersonal communication strategies, diagnosis and treatment of sexually transmitted infections, increasing access to male and female condoms, and voluntary HIV counseling and testing.

In addition to expanding the traditional approaches to prevention, USAID will broaden its array of interventions to include new and emerging areas. These will include:

- Prevention of mother to child transmission;
- Increasing access to care and treatment services for opportunistic infections, particularly TB;
- Providing assistance to children affected by the pandemic; and
- Creating a multi-sectoral response to the epidemic.

- PREVENTION OF MOTHER TO CHILD TRANSMISSION

  The number of infants infected each year through mother-to-child transmission (MTCT) is growing with the increasing number of women infected with HIV. About 55 percent of all new infections in Africa occur among women most of whom are in their childbearing years. MTCT is estimated to be the cause of about 10 percent of all *new* HIV infections each year representing about approximately half-a-million infants.

  Recognizing that comprehensive interventions can reduce transmission rates by 20 to 50 percent, USAID will primarily assist countries with high HIV prevalence to establish MTCT prevention programs. These programs will set standards; promote voluntary counseling and training; provide training to health care workers; establish linkages to community based care services, and scale up primary prevention for all women. USAID will assist in the management, logistical support, and if necessary procurement of antiretroviral drugs for the purpose of reducing mother to child transmission.

- CARE AND TREATMENT

  In developing countries basic HIV care services are minimal. Few infected persons know their HIV status; most health care workers lack the training to treat HIV and its

associated infections; and the capacity to use state-of-the-art antiretroviral treatment exists only in a few select settings, unavailable to the vast majority of those infected. But even in the absence of antiretroviral drugs there is much that can be done to improve the well-being of HIV infected persons and their families.

USAID places highest priority on assuring access to a basic package of care that includes treatment of tuberculosis, treatment and prevention of other opportunistic and AIDS related illnesses, and the provision of palliative care to reduce suffering and enhance the quality of life. To achieve this USAID will work with countries to establish linked networks of hospital, clinic, faith-based, and community-based services. At the same time, USAID will also invest in the expansion of effective TB prevention and control programs in key countries, (see Part B for details).

The special case of tuberculosis: Tuberculosis is a growing epidemic itself with 2 million deaths per year worldwide. Because it is the leading cause of death for persons with AIDS, efforts to treat and prevent tuberculosis will receive special attention. A package of care services will be developed for HIV infected persons that includes an evaluation for TB disease, provision of preventive therapy, as well as improvement and expansion of TB treatment programs.

- PROVIDING ASSISTANCE TO ORPHANS AND OTHER CHILDREN MADE VULNERABLE BY HIV/AIDS

Globally, AIDS has killed the mother or both parents of an estimated 13.2 million children. Many additional children have lost a father to AIDS; others are living with and often caring for a parent who is ill. Ninety-five percent of the children orphaned by AIDS live in Africa. The overwhelming majority of children orphaned and otherwise made vulnerable by HIV/AIDS are living within their extended families and communities. Unfortunately AIDS is undermining family and community capacity to protect and care for the growing number of vulnerable children.

Additional funding would enable USAID to help build and support community responses through which public, private, and voluntary sector donors in the industrialized world can channel resources to national and grassroots programs in the countries hardest hit by HIV/AIDS. The most promising interventions to strengthen family and community capacities to protect and care for orphans and other vulnerable children are (1) systematic community mobilization and capacity building and (2) microfinance services. Paired, these two approaches can be mutually supportive and produce significant, sustainable results.

USAID will also use additional funds to support interventions that improve access to education for the most vulnerable children in areas seriously affected by HIV/AIDS. This will include a wide variety of interventions, ranging from policy reforms to

direct interventions to enable orphans and other vulnerable children to return to or stay in school.

Grassroots groups urgently need funds and food to support home care for people living with AIDS and to integrate the identification and support for vulnerable children into such programs These programs need ongoing access to food and medicines to treat the most common opportunistic infections. This can enable parents living with HIV/AIDS to live longer and more comfortably, and greatly benefit their children. These programs can also be strengthened to become an initial point of identification and support for children whose safety and well-being is being undermined by HIV/AIDS.

- CREATING A MULTI-SECTORAL RESPONSE TO THE EPIDEMIC:

Multisectoral approaches to prevention and care: USAID will continue to use multisectoral approaches for HIV/AIDS prevention, care and treatment, support for orphans, and to assess the effects of the epidemic on households, communities and different sectors of society. USAID expects to intensify assistance to families and communities to cope with the social and economic impacts of the epidemic. In order to better understand and respond to the economic stresses due to infection, USAID will support innovative methods of income generation, microenterprise development, vocational skills development, revolving funds, savings and credit, and insurance. In addition, USAID will work to increase access to education for children affected by HIV, and will enhance food security for households affected by HIV. We will insure appropriate use of HIV/AIDS funding for non-health sector activities through indicators that have a measurable and direct impact on HIV/AIDS prevention or mitigation.

Reducing the impact on sectors of society: The HIV/AIDS epidemic is a development crisis that impacts all sectors of the economy in terms of loss of manpower and demand for various services e.g. health, education, democracy and governance. Realistic assessments of manpower shortages due to HIV/AIDS in these key sectors must be done and updated as the epidemic progresses. Adverse impacts on each sector need to be mitigated in order for the economy to achieve modest growth. In addition, different sectors have to work together to provide care and support to affected families and individuals as well as promote preventive measures among high risk groups and high transmission areas. USAID will continue to work with the education sector to assess the impact of HIV/AIDS on the sector and assist in the design of appropriate responses to reduce the impact of HIV on the sector. It will also help the health, democracy and governance, and economic sectors undertake similar assessments and design activities. USAID has developed toolkits for such assessments for all sectors. In addition, USAID will provide support to countries to strengthen the management of key aspects of the program and generate necessary public and political commitment for dealing with the epidemic.

Section IV. Where We Will Do It

USAID envisions three groups of countries for HIV/AIDS assistance programs:

- **Basic HIV/AIDS Programs**: Currently, USAID implements HIV prevention programs in 47 developing countries. These programs would continue to provide assistance and would focus on targeted interventions for those identified populations who engage in high-risk behavior. In these countries, there would also be an increased emphasis on maintaining credible surveillance systems in order to monitor HIV trends and allow timely warning of impending concentrated epidemics of HIV.

- **Intensive Focus Countries**: Within the LIFE Initiative, 15 countries were identified for significant scaling up of prevention activities and expanding services to provide care and support for those persons infected with HIV and their families. Under this expanded response, and depending on the level of available resources, this initial list of intensive focus countries would be enlarged. Intensive Focus countries would be determined by the criteria in Section VI. and countries from all regions of the world would be evaluated. Within this augmented response, it would be expected that in high prevalence countries no less than 80% of the country population would be provided a comprehensive package of prevention and care services. This nationwide coverage would occur within three to five years and would be achieved through careful coordination with donors, lending agencies and other resources. In "low prevalence-at risk countries," no less than 80% of targeted high-risk populations would be provided services. The goals presented in Section III would apply to all of these intensive focus countries. Selected "Intensive Focus" countries will also be targeted for increased resources for expanded tuberculosis programs. Expansion of HIV/AIDS and TB efforts will be closely coordinated and form the basis for model "care and treatment" efforts. (See Part B for more details)

- **Rapid Scale-Up Countries**: A small subset (two to four) of the "intensive focus" countries would be immediately identified to serve as settings for extremely rapid scaling up of prevention programs and enhancement of care and support activities. Intensive monitoring and evaluation systems would allow detailed tracking of financial obligations, expenditures and measurement of the impact of interventions. We would expect massive increases in program coverage and intensity to occur within one to two years. At least one rapid scale-up country will also be targeted for expanded TB resources.

Rapid Scale Up

The allocation of additional resources for intensified programs will be based on several criteria. A matrix has been developed to rank the countries according to these criteria. Data is being obtained from USAID health officers, UNAIDS and from cooperating agency reports. For the purposes of this exercise, large countries, such as India and Nigeria, will be disaggregated and assessed at the state or province level in order to truly capture the complexity and scope of the pandemic within these countries. The criteria for consideration as an "intense focus country" include the following. A more detailed description of the criteria is presented in Appendix III

The relative **severity** of the epidemic

- The **magnitude** of epidemic
- The **impact on economic and social sectors**
- The **risk of a rapid increase in prevalence**
- **Availability of other sources of funding**
- **Return on investment**
- **Enabling Environment**
- **Security** and safety issues
- **US Foreign Policy and national interests**

Section V. What Are the Resource Needs

Four potential funding scenarios are envisioned. In order to achieve the targets that are presented, it is expected that this funding be sustained over a minimum of five years. With augmented funding, not only would the number of Intensive Focus and Rapid Scale-Up countries increase, but the spectrum of interventions would expand to allow more emphasis on care and support efforts and critical research and development of new tools.

Funding Amount	**Geographic Focus**	**Interventions:** Prevention, care, orphans, capacity building, monitoring systems, commodities, research, expanded partners
$ 255 million	47 basic programs, which include up to	

	18 Intensive Focus countries, including 2 Rapid Scale-Up countries	
$ 320 million	47 basic programs which include up to 25 Intensive Focus countries, including 4 Rapid Scale-Up countries	
$ 400 million	47 basic programs which include up to 30 Intensive Focus countries, including 4 Rapid Scale-Up countries	
$ 530 million	47 basic programs which include up to 35 Intensive Focus countries, including 5 Rapid Scale-Up countries.	

Section VI. How We Will Do It

Expanding Partnerships

To carry out this major increase in AIDS programming quickly, USAID will mobilize the collective capacity of a wide range of partners worldwide—from national governments, NGOs, faith-based organizations, business groups and the military in developing countries, to multilateral organizations and US-based public, non-profit and commercial institutions. USAID will work with national governments to develop policies, laws and programs and to make resource allocations needed to minimize HIV transmission, provide services, and care for the affected. USAID will also encourage the expansion of global efforts for coordination and sharing of lessons learned

USAID will work with indigenous and international non-governmental organizations that are uniquely positioned to provide information and services to hard-to-reach groups at high risk, like men who have sex with men, commercial sex workers, IV drug users, and

adolescents. USAID will work with faith-based organizations that can tap their extensive and committed networks of members to educate people in HIV prevention, set community standards for protecting adolescents, and care for the affected. USAID will work with the private business sector and the military in their capacity as major employers to educate their workforces on prevention, and to incorporate attention to HIV into their health and benefits programs. In keeping with its commitment to make a difference in the lives of people, the Agency will emphasize the creation of an enabling environment for program implementation, including improving relevant policies, building capacity and strengthening the commitment of policymakers and the private sector. Wherever possible, this will also include strengthening the links between national HIV/AIDS and national TB programs.

USAID will work in countries with USAID Missions and options will be explored to reach selected "non-presence countries." To enhance country level programs, improvements are urgently needed in regional and global efforts for coordination and sharing of lessons learned. Multilateral organizations, including the UNAIDS, the World Health Organization and the World Bank can play special coordination roles because they have the systems in place to convene the international community, set standards for addressing HIV, mobilize donor resources, and share lessons learned rapidly. US based institutions, including universities, community groups, and local and state governments, will be valuable partners because they can share their experience addressing similar issues in the United States with developing country partners and provide them with assistance in training and capacity building. By tapping this wide range of partners, USAID also will be able to monitor and evaluate the cumulative effect of a wide array of activities and identify and share innovations widely with all those involved.

USAID will provide ongoing support for UNAIDS in its role to coordinate the international community at country level. USAID will maintain the lead role in coordinating the USG's expanded response to the AIDS pandemic. To ensure coordination at the policy level among USG agencies, USAID will continue to participate on the White House ONAP Task Force. To ensure optimal coordination at the programmatic and operational level, we will use our collaborative experience with CDC as a model to expand existing USAID/CDC working groups to include new USG partners. In addition, we will ensure that USAID staff are assigned explicit responsibility for coordination with key USG partners.

Building the Capacity of Our Partners

The Agency's extended experience in family planning and child survival has demonstrated a critical need to invest in the building up of both human and institutional capacity in the regions and countries where we work. It will be necessary to scale up existing mechanisms and to create new procurements which involve the partnering of U.S. institutions with host country counterparts, be they academic institutions, non-governmental organizations, or national and local level governments.

To maximize impact and build sustainable capacity, a training package would be developed and include both long- and short-term training for host-country personnel. Through new and existing arrangements with host country and regional training institutions, U.S. academic institutions (including HBCUs) and U.S. NGOs, training programs would be designed to provide the required HIV/AIDS technical, program and policy skills. Specially designed programs would produce "leaders" who would acquire skills needed to respond to HIV/AIDS challenges over the next ten years.

Building Capacity at USAID

Over the past 13 years USAID's HIV/AIDS activities have been constrained by a number of obstacles, including limited numbers of staff, lengthy and ponderous procurement procedures, and lack of access to critical health-related commodities. These obstacles must be overcome if USAID is to succeed in its efforts. The Agency must approach the expanded HIV/AIDS activities as an urgent and compelling global crisis, and that USAID does everything possible to implement effective programs with minimal delay.

- Staffing: To successfully implement an expanded program, it is imperative to recruit and retain human capacity with the appropriate skills. Rapid and flexible mechanisms are needed if USAID is to attract skilled individuals to serve in technical and support (such as Office of Procurement and Financial Management) functions. Specifically, this will require PSC authority in Washington, an increase in the TAACS ceiling and additional OE resources.

- "Swat" Teams: To help missions develop and finalize plans for a rapidly implementing an expanded response to HIV/AIDS and tuberculosis, project development “swat” teams, including both technical and procurement personnel would be made available for two to eight week periods to assist in the design of country-level strategies. A "virtual" team that would be responsible for providing overall consistency and feedback would support these teams from AID/W.

- Training: USAID staff, including direct hires, New Entry Program personnel (NEPS), FSNs and U.S. nationals, would participate in specially designed programs to gain technical, programmatic and political skills to respond to the AIDS pandemic and to implement effective TB programs. Through assistance relationships between U.S. institutions (including HBCUs), U.S. government agencies and U.S. NGOs, training would include interventions to reduce mother-to-child HIV transmission, innovative interpersonal behavior change strategies, how to support children affected by AIDS, and the multiple elements of a prevention to care continuum. Optimum use must be made of “in-service” training, the use of “state of the art” courses, and individual learning methodologies.

- Procurement of Service Related Agreements: Streamlined, simplified, accelerated service procurement mechanisms must be put into place in order to program resources in an expedited manner. This may require statutory language to enable us

to expedite the procurement process, including the modification of existing contracts. In addition, USAID needs to be able to allocate funding for HIV/AIDS and infectious diseases – particularly TB -- outside of the normal OYB setting process.

- Commodities: _The majority of people living in high HIV/AIDS prevalence countries do not have access to a) drugs for basic palliative care, including TB; b) condoms for the prevention of sexually transmitted infection (STI), c) basic treatment for STIs, d) testing services that enable them to determine their HIV-status e) or to drugs to combat HIV associated infections. Hospitals that provide care and support lack basic commodities necessary to safeguard both patients and health care personnel, such as gloves and sterilization equipment.

  USAID proposes to devote a portion of its HIV/AIDS budget to improving client access to the commodities essential to prevent the transmission of HIV and to mitigate the effects of HIV infection on individuals, families, and communities. The Agency has over three decades of experience in providing a range of contraceptive commodities in support of its worldwide family planning programs. This long-term investment and experience has resulted in the development at USAID of the premier contraceptive/condom management capability among donors. The Agency would explore similar mechanisms for procuring and delivering these critical commodities.

- Multisectoral Programming: USAID will coordinate its own development activities so that they are focussed and geared towards HIV/AIDS prevention and mitigation efforts. In addition, each sector will work with counterpart agencies in the countries to help them assess the impact of HIV/AIDS and develop and implement appropriate responses to reduce the impact. In addition, USAID will support innovative economic interventions to reach households coping with infection and children orphaned by AIDS. Since no single agency can provide all the resources for mitigating the impact on HIV/AIDS, USAID will focus its work on assessing the level of impact on these sectors and will help countries mobilize alternative resources for such mitigation. USAID will use procurement mechanisms in other sectors, if these activities adhere to current guidance on use of CSD funds. These activities must have a direct and measurable impact on HIV/AIDS indicators.

Section VII. Developing and Introducing New HIV/AIDS Prevention and Care Approaches and Technologies

USAID has provided technical leadership in developing new technologies and approaches to health and health-related issues for many years. USAID will use that experience to expand knowledge and develop tools for both individuals and programs to

improve global effectiveness and efficiency in combating HIV/AIDS. As the pandemic expands in countries with very limited resources, research to identify sustainable and cost-effective responses is urgently needed.

- Identifying Approaches: USAID will continue to support activities designed to identify the most effective components of HIV/AIDS prevention strategies-- from interventions designed to change individual behavior, to larger arenas, such as the impact of policy changes. In addition, interventions to improve care, support, and service delivery will be tested and refined. Finally, USAID will disseminate and utilize these findings in order to replicate and scale-up these newly identified and successful interventions.

- Technology Development: USAID is unique among bilateral donors in that the Agency supports a portfolio of reproductive health technology research and development. The HIV/AIDS pandemic has challenged the world to develop new technologies to allow women and men to protect themselves from infection. As part of a comprehensive STI/HIV prevention strategy, USAID will invest in research on the development, use and appropriate introduction of existing and new prevention and care technologies, including vaginal microbicides; improved male and female condoms; rapid, simple diagnostic tests for HIV and other sexually transmitted infections; effective therapeutic regimens for HIV infected persons; and for the development of preventive and therapeutic vaccines.

  To enhance country level programs, there is an urgent need to improve regional and global efforts for coordination and sharing of lessons learned. USAID will continue to monitor and evaluate the effect of its activities and the potential for innovation.

Section VIII. How We Will Measure Our Achievements

Programmatic Reporting

Over the last several years, USAID has provided leadership in monitoring and evaluating HIV/AIDS programs. USAID will continue to expand and develop these systems in order to routinely monitor, evaluate and report on the progress of the Agency's HIV/AIDS programs worldwide.

Progress and Impact Measurements: An expanded monitoring and evaluation system will collect information on the national and USAID program levels:

- **Reduction of HIV Transmission - National Level:** USAID's most important objective is to reduce the rate of HIV transmission. USAID, in collaboration with CDC, UNAIDS, WHO and others, will improve and expand National Sentinel Surveillance Systems. Sentinel Surveillance Systems in all selected countries will report annually on HIV incidence rates to measure the overall effect on the pandemic of national (including USAID) HIV/AIDS prevention and mitigation programs. **Standard Indicator:** HIV seroprevalence rates for 15-24 year olds

- **Changes in Sexual Behavior – National and USAID Program Level:** Monitoring changes in sexual behavior is important to both measure the success of and to improve the efficiency and coverage of National (and USAID) HIV/AIDS programs. The implementation of routine (every 3-5 years), standardized national sexual behavior surveys will begin **in 2001. Standard Indicators:** Number of sexual partners; Condom use with last non-regular partner

- **Coverage of Target Populations – USAID Program Level:** USAID will report annually on the Agency's progress toward implementing its HIV/AIDS programs and increases in the proportion of the target population(s) covered by these programs. Information systems collecting routine data will be strengthened. In each selected country, USAID will establish a system to aggregate this information and report on USAID activities at the country level. USAID will establish this reporting system and begin reporting in **2001.**

- **Standard Indicators:**

  Total condoms sold (Condom Social Marketing Programs)

  % of target population requesting an HIV test and receiving counseling (VCT Programs)

  % of target orphans/vulnerable children (OVC) with access to community services (OVC Programs)

  % of target population with access to drug treatment to reduce mother-to-child HIV transmission (MCTC Programs)

  % of STI cases treated according to national standards (STI Treatment Services)

  % of HIV infected person with access to basic care and psychosocial support (Care and Support Programs)

- **Intervention Effectiveness – USAID Program Level:** USAID will conduct a series of impact evaluations of the Agency's HIV/AIDS prevention and mitigation interventions to measure the relationship between program outputs and behavior change in the target populations. The results of these studies will document the effectiveness of USAID-supported interventions and the "best practices" will be identified and implemented widely. A summary of these research results will be published annually.

Reporting on Results

As outlined, USAID will report on national and program level progress annually. Additionally, USAID will allocate resources to report on USAID's global impact on the HIV/AIDS epidemic every two years.

II. Financial Reporting

On the global level, USAID will report the following financial data annually:

1. *The amounts of HIV/AIDS funds allocated to each country, each Regional Bureau, and each Global Bureau project each year;*
2. For the Global Bureau projects, the amounts allocated to core activities;
3. Yearly obligations by country (this includes both direct Mission obligations and field support designations);
4. Yearly obligations by type of activity (e.g., policy analysis and reform, prevention, care and support, children affected by AIDS, MTCT, etc.) on a worldwide basis, by region, or by country.

Section IX. Timeline for Disbursements for FY 2001 and 2002

In FY2001:

Obligations could occur to current agreements/contracts that have HIV/AIDS in their Scopes of Work/Strategic Objectives and have allowable ceiling levels and project completion dates.

Step 1. List of instruments that can accept HIV/AIDS funding generated by December,

2001

Step 2. For those instruments eligible, decisions made as to which will receive funds by April, 2001

Step 3. Percentage of obligations completed for identified instruments/activities by May, 2001

Human capacity recruitment begins.

Step 1. Recruitment notices posted by March, 2001

Step 2. Percentage positions filled by June, 2001

"SWAT" teams provide technical assistance to country strategy expansion/development in context of other partners' activities and contributions

Step 1. Number of Swat teams requested by January, 2001

Step 2. Percentage of requests completed by April, 2001

Begin technical design and internal administrative requirements to award new procurements

Step: Process indicators would need to be defined

Begin strategy design for procuring necessary commodities and providing logistics management

Step 1: Negotiations with pharmaceutical and hospital supply companies begun by February, 2001

Donor Coordination strategy begun: One donor meeting held, possibly as an annex to a UNAIDS meeting

Step 1. Two coordinating meetings with relevant USG Agencies held to discuss components of a Coordination Strategy by March, 2001

Step 2. One meeting held with UNAIDS and other interested parties to discuss coordination of commodities procurement and logistics management by June, 2001

FY2002

For ongoing agreements/contracts where the ceiling or completion date was a barrier in 2001, complete actions to amend agreements/contracts to allow obligation of funds in FY2002

Step 1. Percentage of agreements/contracts eligible amended

Step 2. Percentage of agreements amended that received obligations

Human capacity in place and oriented to USAID programs, policies and processes

Step 1. Percentage of new personnel that have completed defined training programs

Competition and Award of new agreements/contracts

Step 1. Percentage of planned agreements/contracts awarded

Global Strategy. With input from USAID/W, USAID Field Missions, the results of swat team visits, and other USG Agencies, external donors and partners, USAID defines a two-year and five-year global strategy

Step 1. Draft two-year strategy ready for circulation

Step 2. Draft five-year strategy ready for circulation

Donor Coordination strategy drafted in collaboration with others, especially UNAIDS. Second donor coordination meeting held, possibly as an annex to a UNAIDS meeting

Step 1. Draft Donor Coordination Strategy circulated to partners

Step 2. One coordinating meeting held to discuss Coordination Strategy

Step 3. One meeting held with UNAIDS and other interested parties to discuss coordination of commodities procurement and logistics management

PART B. INFECTIOUS DISEASES: EXPANDED PROGRAMS IN TUBERCULOSIS AND MALARIA

I. Summary

USAID is also developing plans to strategically allocate potential increased resources for tuberculosis and malaria. Strategies have been carefully developed to have the greatest impact on the growing epidemic of TB and increasing problem of malaria, while complementing on-going investments in cross-cutting infectious disease issues of antimicrobial resistance and surveillance.

TB. Ninety-five percent of all TB cases and 98% of the 2 million annual TB deaths occur in developing countries. TB threatens the poorest and most marginalized, and undermines economic development. Most TB deaths are among those in economically active populations. The HIV/AIDS pandemic is fueling the spread of tuberculosis – TB is the leading cause of death among HIV-positive people and accounts for one third of AIDS deaths worldwide. USAID is committed to making a significant contribution to the global effort to prevent and control tuberculosis, leading to a reduction in the morbidity and mortality associated with the disease. USAID will work to build capacity in countries most affected, to expand implementation of proven, cost-effective interventions for preventing the transmission of TB, help strengthen policy commitment and surveillance, and help ensure an adequate supply of drugs – through better drug management and support for the purchase of TB drugs. At the same time, USAID will increase its investments in the development of new tools to prevent, diagnose and treat TB; continue to contribute to global and regional TB partnership*s;* and invest in the development of an expanded cadre of TB experts – from the developing as well as the developed world.

USAID will expand TB programs in a limited number of focus countries, selected on the basis of (1) greatest need: high incidence of TB (estimated case detection rates of over 100/100,000 population) and those that significantly contribute to the global burden of TB; countries with high HIV/AIDS prevalence, and countries at risk of escalating epidemics of multi-drug resistance; (2) political commitment; and (3) technical and managerial feasibility.

Malaria. Additional malaria funding would be used to mount a strategically focused, high impact effort in support of expanded malaria control activities. Expanded efforts would complement ongoing malaria activities and be largely focused in Africa, but also include sub-regional efforts in South America and Southeast Asia. Four targeted activities are proposed: (1) Scaling up malaria prevention and control activities; (2)

Addressing malaria in complex emergencies; (3) Slowing the emergence and spread of drug-resistant malaria; and (4) Accelerating the development of new tools and approaches for malaria control

A limited number of countries and subregions will be selected for expanded resources, based on: an analysis of the national malaria burden, political commitment by national governments, the infrastructure capacity, and the overall potential for success.

II. Expanded Program in Tuberculosis

Of the 2 billion people infected with tuberculosis, 8 million develop the disease, and two million die each year. Ninety-five percent of all TB cases and 98% of all TB deaths occur in developing countries. It threatens the poorest and most marginalized groups, disrupts the social fabric of society, and undermines gains in economic development. The HIV/AIDS pandemic is helping to fuel the spread of tuberculosis – TB is the leading cause of death among HIV-positive people and accounts for one third of AIDS deaths worldwide.

The U.S. Agency for International Development is committed to addressing the global burden of TB in close collaboration with our local and global partners. In 1998, as part of a new strategy expanding USAID's efforts in infectious and reemerging diseases, USAID began to develop a significant and focused program in tuberculosis. Since then, the resources available for TB have increased each year, to an estimated $20 million in FY 2000. Currently, USAID is supporting TB activities in about 10 countries. In addition, USAID has invested in TB surveillance, provided support to the global Stop TB Initiative, as well as critical research areas, including operations research for addressing multi-drug resistant TB, improved drug regimens, and the development of a new TB diagnostic.

Objective:

USAID's goal is to make a significant contribution to the global effort to prevent and control tuberculosis, leading to a reduction in the morbidity and mortality associated with the disease. There are proven, cost-effective interventions for preventing the transmission of TB; USAID will work to build capacity in countries most affected to expand the appropriate and effective implementation of these interventions. At the same time, USAID will increase its investments in the development of new tools to prevent, diagnose and treat TB, and continue to contribute to global and regional TB partnerships.

Strategy:

USAID's strategy for TB will focus on four areas:

1. Focused, expanded programs in key countries

Resources will be targeted at countries of greatest need, defined by:

- Greatest burden of TB – high incidence of TB (case detection estimated rates of over 100/100,000) and/or those that significantly contribute to the global burden of TB[2];
- Countries with high HIV/AIDS prevalence, and
- Countries at risk of escalating epidemics of multi-drug resistance.

A limited number of countries will be targeted for additional resources based on the technical criteria cited above as well as political commitment and technical and managerial capacity.

The Directly Observed Treatment, Short-Course (DOTS) strategy has proven to be a highly effective strategy for controlling TB. If implemented appropriately, DOTS has been shown to have a success rate (cure and completion of treatment) of 80% of cases on average. DOTS is an effective and affordable strategy for controlling TB, and is especially valuable in resource-poor settings.

The DOTS strategy has 5 components: political commitment; passive case detection and diagnosis using sputum smear microscopy; standardized short course treatment with direct observation of therapy at least in the initial phase; assurance of an uninterrupted supply of quality drugs; and standardized recording/reporting with systematic evaluation of treatment outcome. Implementing DOTS appropriately requires investments in strengthened health systems, trained personnel, a dependable supply of high quality TB drugs, and an effective monitoring and surveillance system. If implemented appropriately, DOTS can help prevent the spread of MDR TB, and in areas where MDR TB already has a foothold, operations research is currently underway to determine the most effective programs to combat the disease.

2. Continued investments in global and regional partnerships

USAID was one of the original supporters of the global Stop TB Initiative, an expanded global partnership across all sectors of society to ensure that every TB patient has access to TB treatment and cure, protect vulnerable populations from TB and multi-drug resistant TB, and reduce the social and economic toll that TB exerts on families and communities. USAID has continued to support this initiative and

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[2] According to WHO, 22 countries contribute over 80% of the global burden of TB. These include: India, China, Indonesia, Bangladesh, Pakistan, Nigeria, Philippines, South Africa, Ethiopia, Viet Nam, Russia, Congo (DR), Brazil, Tanzania, Kenya, Thailand, Myanmar, Afghanistan, Uganda, Peru, Zimbabwe and Cambodia.

ongoing efforts to secure these goals. In addition, USAID works with other US government agencies (HHS, including OIRH, CDC, and NIH) to maximize the resources available for TB by emphasizing the comparative advantages of each agency. The Agency is also involved in the Global Partnership to develop new anti-TB drugs, the development of a Global Drug Facility to ensure availability of quality anti-TB drugs, and support for a new international coalition (including the Royal Netherlands TB Association, The International Union Against TB and Lung Disease, the American Lung Association, the American Thoracic Society, and the WHO) to provide extensive technical assistance to TB programs in developing countries. Support for coordinated research into optimal diagnostics and treatment regimens will also play a major role in the USAID portfolio.

3. **Investment in expanding cadre of TB experts – in developing and developed world**

   Support for TB programs, including training of individuals capable of running programs, has languished for years. As a result, there are few TB experts capable of performing these responsibilities. At the same time, the increasing caseload related to the HIV epidemic, and the new threat of emerging TB strains resistant to medications used to treat it, increase the urgency of a global response. It is imperative that a cadre of experts able to deal with all aspects of the disease is developed, and that these individuals are deployed as soon as possible. USAID is therefore investing in the training and development of individuals in both developed and developing countries to ensure adequate coverage, particularly in those countries most affected. This will be accomplished through our agreements with the TB Coalition for Technical Assistance, as well as agreements with CDC, NIH, WHO, and other non-governmental organizations.

4. **Expanded research investments:**

   Increased interest in the global TB problem, formation of new global alliances, and recent technical advances in a wide range of scientific fields have catalyzed a revolution in the development of diagnostics, vaccine and new drugs for infectious diseases.

   Rapid and sensitive TB diagnostic tests are urgently needed. Deficiencies in current TB diagnostic tests in disease endemic countries leave large numbers of patients with TB undetected, impedes expansion of DOTS, and most importantly, facilitates continued transmission of disease.

   USAID will increase its support for the development of TB diagnostics appropriate for low-income countries by working with its partners to mobilize the efforts and expertise of public health workers, industry, academic researchers, donors and other partners. In the face of evidence of increasing resistance to our current arsenal of TB drugs, USAID will target support for collaborative efforts to develop cost-effective new TB drugs and combination therapies. This will add value to treatment regimens with high cure rates, low treatment and administrative costs, few side effects, and good patient compliance, thus minimizing the development of drug resistance.

Future research investments by USAID may expand to include targeted areas of TB vaccine development. Current models predict that an effective TB vaccine would save tens of millions of lives over the next three decades. There is widespread agreement that effective drug therapy regimens and effective immunization could have synergistic effects on the ultimate control of the TB epidemic.

Finally, USAID will increase its support for operational research associated with its expanded research investments in the development of new tools to prevent, diagnose and treat TB.

What we will achieve:

By 2005, depending on the availability of funding, USAID will contribute to:

- Increased number of countries that report cure rates of 85% or greater and case detection rates of 70% or more (in targeted countries).
- Increased number of targeted countries that have implemented drug resistance surveillance
- Expanded cadre of international experts (developed and developing country nationals) capable of providing technical assistance in TB programming.
- Availability of a new diagnostic, appropriate for field use.

Approaches and mechanisms:

USAID will work in close collaboration with host country partners – in the public and private sectors – either directly or in collaboration with other international partners. Our objective at the country level is to build the political commitment and local capacity to implement DOTS programs effectively – including monitoring and reporting.

Because TB is a new area for USAID, there are limited existing relationships (contracts, grantees) for implementing TB programs. To over come this, USAID/Washington will:

- Continue to work with international partners, such as WHO and CDC
- Sign an umbrella agreement with the TB Coalition -- including KNCV, the International Union Against TB and Lung Disease, American Lung

Association/American Thoratic Society, WHO, and CDC. The members of the TB Coalition already have relationships in a number of countries; USAID resources will be used to significantly expand DOTS programs in a number of targeted countries, and to provide technical assistance to TB programs worldwide.

- Provide assistance to USAID missions to include TB in bilateral agreements or develop other local assistance mechanisms
- Develop other worldwide mechanisms available for field implementation and mission use.
- In partnership with the Stop TB Initiative, invest in a global TB drug facility, that would help make TB drugs available to countries in greatest need, and le strengthen local capacity to implement TB programs.

III. EXPANDED MALARIA EFFORTS

If , as part of the Agency's FY 2001 appropriations, there are additional resources for the prevention and control of malaria (above the Agency's FY 2000 levels) additional funding would be used to mount a strategically focused, high impact effort in support of expanded malaria control activities. These "expanded" efforts would complement ongoing malaria activities and be largely focused in Africa, but also include sub-regional efforts in South America and Southeast Asia. Four special activities are proposed:

1. Scaling up malaria prevention and control activities
2. Addressing malaria in complex emergencies
3. Slowing the emergence and spread of drug-resistant malaria
4. Accelerating the development of new tools and approaches for malaria control

1. "Scaling-up" Malaria Prevention and Control Activities In Africa – where 90% of the world's malaria related deaths occur - the major challenge facing malaria control operations is ensuring effective malaria control services are widely available to those populations at greatest risk from malaria illness. Currently, less than 25% of Africa's children have access to effective pediatric services; only 10% of women at risk of complications from placental infection during pregnancy have access to intermittent treatment, despite the availability of an effective, cheap and simple treatment; and, fewer than 10% of Africa's children sleep under a bednet, and even fewer sleep under an insecticide treated one. In April of this year 31 African heads of state met in Abuja, Nigeria to discuss the threat posed to the region by malaria and explore options for its prevention and control. The major outcome of this meeting was the "Abuja Declaration" which specifically commits each country to initiate appropriate and sustainable action so that by the year 2005:

- At least 60 per cent of those suffering from malaria have prompt access to and are able to use correct, affordable and appropriate antimalarials within 24 hours of the onset of symptoms;

- At least 60 per cent of those at risk benefit form protective measures, such as insecticide treated mosquito nets; and,

- At least 60 per cent of all pregnant women who are at risk of malaria have access to presumptive, intermittent treatment.

These goals are achievable, and would save an estimated 800,000 lives, annually. But to reach them will require a significant scaling up of existing malaria control efforts, which are largely limited to the district or provincial level. As part of Africa Bureau's and Global Bureau's commitment to these goals we are proposing that as first priority, any "extra" funding available in the Agency's FY 2001 malaria budget be targeted to support "national level" malaria prevention and control efforts in up to four African countries. By

focusing these “extra” resources on a limited number of countries we expect to achieve significant reduction in the burden of malaria.

Target countries for expanded resources will be chosen based on an analysis of the national malaria burden, political commitment by national governments, the infrastructure capacity, and the overall potential for success. An initial short list of candidate countries[3] for expanded malaria control efforts will be pared to four in consultation with missions and depending on feasibility for expanding in-country efforts, either through mission funded programs, or through supplements to mission budgets.

2. Addressing Malaria in Complex Emergencies In addition, there is a growing recognition that African countries experiencing “complex emergencies” account for a rapidly growing percentage of the total deaths due to malaria in the region. This is especially true for Democratic Republic of the Congo where recent studies have shown malaria accounting for over 40% of the total deaths of internally displaced populations. A portion of the additional resources would be used to provide expanded support for malaria control activities in the DROC .

3. Slowing the Emergence and Spread of Drug Resistant Malaria In recent years the Mekong Region of Southeast Asia, the Amazon Region of South America and a number of countries in Africa have experienced an ominous deterioration of their malaria situation with the emergence and spread of new and even more lethal strains of malaria that are resistant to all major antimalarial treatments, including chloroquine, mefloquine, fansidar and quinine. In all three areas, the larger concern is the further spread of drug-resistant infections and thus more extensive outbreaks. Inadequate drug policies, insufficient monitoring of drug resistance, lack of training opportunities for health providers in diagnosis and treatment, and poor public awareness of appropriate antimalarial drug use practices have exacerbated the effects of drug resistance.

USAID will give special attention to addressing the challenges posed by the emergence and spread of multi-drug resistant malaria. Given the highly cross-border nature of the threat and the need for a well coordinated effort among affected countries it is proposed that the additional resources be used to provide expanded support for regional initiatives: in the Amazonian region, the Mekong region, and Africa - to prevent and slow the emergence and spread of multi-drug resistance malaria.

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[3] Initial list of countries for consideration include Nigeria, Senegal, Uganda, Mozambique, Zambia, and Malawi

4. Accelerating the Development of New Tools for Malaria Control In addition to providing expanded support for prevention and control programs, additional resources will also be made available for support three critical research efforts: (a) the Agency's Malaria Vaccine Development Program (MVDP) and (b) the development of new drug therapies for malaria, and (c) operations research on behavioral, community, drug use and treatment regimen compliance issues as well as potential community approaches to environmental management of malaria.

Additional support for the MVDP would accelerate progress towards the availability of a malaria vaccine, which can be used as part of malaria control efforts. Similarly, extra funding for ongoing USAID supported clinical trials for new treatment therapies for malaria would ensure the timely availability of alternative treatments for malaria – an increasingly critical issue in light of the emergence and spread of resistance to existing antimalarial drugs. Lastly targeted and expanded operations research efforts will help guide treatment policy and practice, as well as behavior change communication.

Expanded Malaria Programs - Summary

Special Activity	Target	Expected Outcome
1. "Scaling-up" Malaria Prevention and Control Activities	Four Target Countries*: Nigeria, Senegal, Uganda, Zambia, Malawi, Mozambique	Accelerated expansion to the national level of a high impact malaria package.
2. Addressing Malaria in Complex Emergencies	Democratic Republic of the Congo	Expanded access of life-saving services to highly vulnerable internally displaced populations
3. Slowing the Emergence and Spread of Drug Resistant Malaria	Sub-regional initiatives in the Mekong, Amazon regions, and subregions in Africa	A highly coordinated approach to the threat of multi-drug resistant malaria
4. Accelerating the Development of New Tools for Malaria Control	(a) malaria vaccine (b) new treatment therapies (c) operations research	Accelerated availability of vaccine and treatments, and improved treatment protocols and regimens.

* The final selection - from six to four countries - will be done in dialogue with prospective Missions.

Appendix I: Adult HIV Prevalence greater than 1% by Country at the end of 1999

GLOBAL

Rank	Country	% prevalence	Rank	Country	% prevalence
1	Botswana	36	20	Burkina Faso	6
2	Swaziland	25	21	Congo	6
3	Zimbabwe	25	22	Togo	6
4	Lesotho	24	23	Haiti	5
5	Zambia	20	24	Dem. Republic of Congo	5
6	South Africa	20	25	Nigeria	5
7	Namibia	20	26	Gabon	4
8	Malawi	16	27	Bahamas	4
9	Kenya	14	28	Cambodia	4
10	Central African Republic	14	29	Ghana	4
11	Mozambique	13	30	Guyana	3
12	Djibouti	12	31	Sierra Leone	3
13	Burundi	11	32	Eritrea	3
14	Rwanda	11	33	Liberia	3
15	Cote d'Ivoire	11	34	Dominican Republic	3
16	Ethiopia	11	35	Angola	3
17	Uganda	8	36	Chad	3
18	United Rep. of Tanzania	8	37	Guinea-Bissau	3
19	Cameroon	8	38	Benin	2

39	Thailand	2	47	Guinea	2
40	Mali	2	48	Guatemala	1
41	Belize	2	49	Niger	1
42	Myanmar	2	50	Suriname	1
43	Gambia	2	51	Barbados	1
44	Honduras	2	52	Trinidad and Tobago	1
45	Senegal	2	53	Sudan	1
46	Panama	2	54	Ukraine	1

AFRICA

Rank	Country	% prevalence
1	Botswana	36
2	Swaziland	25
3	Zimbabwe	25
4	Lesotho	24
5	Zambia	20
6	South Africa	20
7	Namibia	20
8	Malawi	16
9	Kenya	14
10	Central African Republic	14
11	Mozambique	13
12	Djibouti	12
13	Burundi	11
14	Rwanda	11
15	Cote d'Ivoire	11
16	Ethiopia	11
17	Uganda	8
18	United Rep. of Tanzania	8
19	Cameroon	8
20	Burkina Faso	6
21	Congo	6
22	Togo	6
23	Dem. Republic of Congo	5
24	Nigeria	5
25	Gabon	4
26	Ghana	4
27	Sierra Leone	3
28	Eritrea	3
29	Liberia	3
30	Angola	3
31	Chad	3
32	Guinea-Bissau	3
33	Benin	2
34	Mali	2
35	Gambia	2
36	Senegal	2
37	Guinea	2
38	Niger	1

LATIN AMERICA / CARIBBEAN

Rank	Country	% prevalence
1	Haiti	5
2	Bahamas	4
3	Guyana	3
4	Dominican Republic	3
5	Belize	2

6	Honduras	2
7	Panama	2
8	Guatemala	1
9	Suriname	1
10	Barbados	1
11	Trinidad and Tobago	1

ASIA AND THE NEAR EAST

1	Cambodia	4
2	Thailand	2
3	Myanmar	2
4	Sudan	1

EUROPE AND EURASIA

	Ukraine	1

Appendix II: Criteria for selection of Intensive Focus Countries

1) The relative **severity** of the epidemic: measured by HIV/AIDS prevalence among the adult population aged 15 - 49.

2) The **magnitude** of epidemic: measured by the absolute number of infected persons.

3) The **impact on economic and social sectors**, including number of children orphaned by AIDS, and the decrease of critical education and health sector personnel due to AIDS mortality.

4) The **risk of a rapid increase in prevalence**: measured by a number of sub-indicators including: recent trends in the prevalence of HIV and other sexually transmitted diseases; the presence and size of populations engaging in risk behavior; the extent of international and internal migration due to economic forces, conflict, or natural disaster; levels of male circumcision; age of first marriage; assessment of women's empowerment; use of condom in last act of casual sex; and the presence of cofactors, such as wide spread alcohol use.

5) **Availability of other sources of funding** measured by GDP per capita and contributions from other donors, foundations and lending agencies.

6) **Return on investment** measured by whether the epidemic is localized and thus can be addressed with a relatively small investment or whether the epidemic has spread to the general population.

7) **Enabling Environment** measured by internal and external assessments, including the AIDS Program Effort Index (API) which is a joint effort of UNAIDS, USAID and the POLICY Project to measure the amount of effort put into national AIDS programs by both domestic and international organizations, and measured by the USAID Mission assessment of capacity.

8) **Security**: a yes or no indicator. Is the country sufficiently stable and secure for an HIV/AIDS program to be implemented?

9) **US Foreign Policy and national interests**: Consideration must be paid to each country's strategic importance to the United States.

Goal statement: USAID is committed to enhancing the capacity of developing and transitional countries to protect their populations not yet infected by HIV and to providing services to those infected and others affected by the epidemic.

USAID will work toward the following international targets by 2007:

- Reduce HIV prevalence rates among those 15-24 years of age by 50% in high prevalence countries
- Maintain prevalence below 1% among 15-49 year olds in low prevalence countries
- Ensure that at least 25% of HIV/AIDS infected mothers in high prevalence countries have access to interventions to reduce HIV transmission to their infants
- Help local institutions to provide basic care and psychosocial support services to at least 25% of HIV infected persons and to provide community support services to at least 25% of children affected by AIDS in high prevalence countries

USAID's Strategy: USAID will organize its response around three categories of countries:

(a) **rapid scale-up countries**: 4 countries will receive a significant increase in resources to achieve measurable impact within *one-to-two years.*

(b) **intensive countries**: in 13 countries and 3 targeted sub-regions, resources will be increased and targeted to reduce prevalence rates (or keep prevalence low in low prevalence countries), to reduce HIV transmission from mother to infant and to increase support services for people (including children) living with and affected by AIDS *within three-to-five years.*

(c) **basic countries**: in 25 countries and several targeted sub-regions, resources will be used to maintain technical assistance, training and commodity support and to help encourage other sources of funding and support to help the countries move towards the 2007 goals.

Countries have been designated for each of the three categories based on of such criteria as:

- Severity and magnitude of the epidemic
- Impact on economic and social sectors
- Risk of a rapid increase in prevalence
- Availability of other sources of funding
- US national interest
- Strength of host country partnerships

Prevalence Groupings in Rapid Scale-Up and Intensive Focus Countries

High prevalence		**Low prevalence**	**Targeted sub-regions**
Cambodia*	Malawi	India	West Africa
Kenya*	Mozambique	Brazil	Asia regional
Uganda*	Namibia	Russia	Caribbean sub-region
Zambia*	Nigeria	Senegal	
Ethiopia	Rwanda		
Ghana	South Africa	Tanzania	

*rapid scale-up countries

To achieve these goals in the rapid scale-up and intensive countries

- In the four rapid scale-up countries, identified with an asterisk (*) above and chosen because of their potential as model programs, USAID will work to see that significant increases in program coverage and intensity in the **targeted population** occur within one to two years.

- In the high prevalence countries and regions, USAID will *work with other donors* to see that no less than 80% of the **targeted population** be provided a comprehensive package of prevention

and care services within 3-5 years.

- In low prevalence countries USAID will *work with other donors* to see that no less than 80% of **targeted high-risk population** in the program areas be provided a comprehensive package of prevention activities within 3-5 years.

- In order to achieve the ambitious goals of this strategy, the 17 countries and 3 sub-regions identified as intensive and rapid scale-up locations will have first claim on *additional* USAID resources (direct-hire and non direct-hire staff, budget, commodities, and AID/W central bureau technical support). Additional resources refer to resources that are over and above what was planned at FY 2001 CP levels (see below). Technical support will include strategy and program development, policy dialogue with host country officials and other donors, program monitoring and reporting, among other support needs.

In the basic countries, USAID will continue its efforts to support host country efforts to deal with the pandemic

- AID/W support for basic programs will continue in order to ensure that these countries as well are moving towards the 2007 goals.

- In basic countries USAID will fund programs at FY 2001 CP levels as warranted, based on analysis of needs, Agency capabilities, pipelines and the availability of other USG and other donor resources.

- In these countries, USAID will also assist country institutions to identify additional sources of funding to expand programming.

- In these countries, USAID will continue to provide information, training and/or commodities, and technical assistance from Washington as warranted and as resources permit.

- In several targeted sub-regional efforts, special attention will be directed at strengthening regional institutions to deal with cross-border transmission of the disease.

In all countries

- Effective coordination with other donors and country institutions will be a central feature of the USAID strategy *in all countries*. We will actively seek partnerships with other U.S. government agencies as well as PVOs, NGOs, international agencies, the World Bank and other multilateral organizations in order to leverage our resources to achieve the goals established for 2007.

- An expanded monitoring and evaluation system to provide information on a national level as well as on USAID-financed programs will be implemented, with first priority given to rapid scale up and intensive focus countries. Program reporting will focus on reduction of HIV transmission and changes in sexual behavior. Progress and program impact will be measured against the following indicators:

  - HIV sero-prevalence for 15-24 year olds

  - % condom use with last non-regular sexual partner

  Depending on country approach, additional reporting may be required as follows:

  - % of target population requesting an HIV test and receiving counseling

  - % of target orphans/vulnerable children with access to community services

- % of target population with access to drug treatment to reduce mother-to-children HIV transmission

- % of STI cases treated according to national standards

- total condoms sold

- % of HIV infected persons with access to basic care and psychosocial support

USAID will report on progress *annually* in USAID's Annual Performance Report.

- In all programs, we will pay special attention to refugees, the internally displaced, combatants and their families, and victims of conflict, all of whom are at especially high risk.

11/13/2000

Tab B

DETERMINATION AND FINDING:

USAID Administrator's Determination Regarding Procurement Procedures for Activities for the HIV/AIDS and Infectious Disease Initiatives

Pursuant to the authority set forth in the USAID Acquisition Regulations, Section 706.302-70 (b) (3) (ii), I have determined that it is necessary to use other than full and open competitive procedures for the activities which USAID finances for the HIV/AIDS and Infections Disease Initiatives in order to avoid impairment of foreign assistance and U.S. foreign policy objectives. This determination is made in consideration of the supporting findings set forth below and will be effective from the date of signature, and subject to annual review will remain in force for the period of the Initiatives, estimated to be through the year 2007. Notwithstanding this determination, USAID will seek offers in particular procurements, from as many potential offerors as is practicable under the circumstances.

Supporting Findings:

Congress recently passed the Global AIDS and Tuberculosis Relief Act of 2000, which in conjunction with the FY 2001 Appropriations Act, provides USAID with resources to combat the HIV/AIDS and Infectious Disease epidemics now raging in the developing world.

The conference report accompanying the FY 2001 Appropriations Act emphasizes the emergency nature of the crises, and urges USAID to use existing waiver authorities regarding financing and procurement of goods and services in order to expedite assistance and enhance the efficiency of the program.

The current HIV/AIDS epidemic is the largest infectious disease epidemic ever known in recorded history, by far more devastating than the bubonic plague of the 1300s, and even greater than the worldwide influenza epidemic of 1918-1919.

In Africa alone over 5,000 persons die every single day from AIDS or AIDS related illnesses, and each year 600,000 children worldwide are infected with the disease, almost all of them through mother to child transmission.

As much as one-third of the entire world population has been

exposed to Tuberculosis, and new strains are increasingly being discovered with substantial drug resistant characteristics to medicines currently in use. Nearly 2 million people die each year from TB, and the spread of the TB epidemic is being fueled by the HIV/AIDS pandemic; persons with HIV/AIDS are 30 times more likely to develop TB.

The administrative and time consuming burdens of using fully competitive procedures will not allow USAID to respond to the crises in an effective and efficient fashion.

USAID can achieve an important measure of competition informally by seeking offers from as many sources as practicable under the circumstances.

Prior to using informal competitive procedures for a particular procurement, as authorized by this determination, requesting offices will consider the feasibility of using FAR full and open competitive procedures, as well as small business Section 8(a) procurement authorities and minority serving institutions.

All uses of this authority will be documented, and the situation will be reviewed on an annual basis to determine the adequacy of the authorities, their continued necessity, or any need for their modification.

CLEARANCE PAGE FOR ACTION MEMORANDUM requesting decision on Procurement and Assistance Procedures for the HIV/AIDS and Infectious Disease Initiatives

Clearances:

AA/LPA:JCrapa Draft date 12/14/00
AA/PPC:TFox Draft date 12/15/00
A-AA/G:BTurner Draft date 12/15/00
AA/AFR:VLowery-Derryck Draft date 12/15/00
AA/E&E:Dpressley Draft date 12/15/00
AA/ANE:RRandolph Draft date 12/14/00
A-AA/LAC:CLeonard Draft date 12/15/00
AA/BHR:HParmer Draft date 12/14/00
A-AA/M:RNygard Draft date 12/15/00
GC:Pramsey ______________ date _____
ES:RConroy ______________ date _____

GC:RMeighan:LGray:12/04/00:25874:HIV2; revised GC:MKitay;12/19/00

January 11, 2001

ACTION MEMORANDUM

TO: The Administrator

FROM: A-AA/G Barbara Turner /s/

SUBJECT: The HIV/AIDS and Infectious Disease Initiatives: Source and Origin Waiver for HIV/AIDS Diagnostic Materials (testing kits)

ISSUE FOR DECISION

Whether to authorize the procurement of testing kits from Code 935 countries (any country or area excluding foreign policy restricted countries).

ESSENTIAL FACTORS

In a December 19, 2000, Action Memorandum (See Tab 2) you approved certain waivers and expedited procedures to acquire services and commodities for the Agency's HIV/AIDS and Infectious Disease Initiatives. While the December 19th Memorandum authorizes expedited procurement procedures for testing kits, it does not waive source and origin requirements because more research was required on their availability in the United States and the efficacy and cost of offshore testing kits.

Having completed this research, we are seeking your approval of a source and origin waiver from Geographic Code 000 (United States) to Geographic Code 935 for specific testing kits identified in Tab 1. Consistent with the December 19th Memorandum, your approvals below will be in effect through the year 2007 and apply to all sources of funds including prior year funds. Records will be kept on all uses of the waiver authorities. Annual reviews will determine the adequacy of the waiver authorities and their continuing need. The list at Tab 1 will be revised and updated should U.S. manufactured testing kits, or new or improved testing kits from Geographic

Code 935 sources become available that meet USAID program requirements.

Effective counseling and testing for HIV is a critical component of any HIV/AIDS strategy. While testing provides information to individuals regarding their HIV status, it also provides information regarding the extent of the epidemic among target groups and indicates where additional resources may be needed. We anticipate that between one million to three million testing kits will be purchased annually over the seven-year life of the HIV/AIDS initiative. At an estimated average cost of $3 per test, the aggregate procurement value will be approximately 45 to 55 million dollars. However, this amount will be substantially reduced if, as expected, the average cost per testing kit is reduced as new products come on stream.

The applicable statute and regulations covering USAID's "buy America" requirements and pharmaceutical requirements (including testing kits) appear in section 604(a) of the Foreign Assistance Act, ADS section 312.5.3c(2), and in 22 CFR 228. Taken together, these sometimes overlapping regulations provide that pharmaceuticals be purchased outside of the United States only if information is available to attest to the safety, efficacy and quality of the product, or the product meets the standards of the Food and Drug Administration (FDA) or other U.S. controlling authority. ADS section E312.5.3c(3) adds a further requirement that patent laws be honored. Such items may be purchased in Geographic Code 935 countries if you determine that: 1) the items are not produced or available in the United States, or if available, they cost more than 50 percent of comparable items, or 2) offshore procurement is necessary to promote efficiency in the use of foreign assistance resources and avoid impairment of foreign assistance objectives. While the United States Centers for Disease Control and Prevention (CDC) is not a controlling authority, approval by CDC is good evidence that may be used as a basis for authorizing non-U.S. procurement of products that are not approved by the FDA.

With respect to test kits, the criteria supporting a waiver are met. The most commonly available United States testing kits are based on the Elisa Reader method. The cost per test of these kits is approximately $20. This cost is more than 50 percent higher than the cost of offshore alternatives. Further, these products require high quality lab facilities and highly trained personnel that are not

widely available in target countries. Even where this kind of physical and human infrastructure is available in urban centers, there are insurmountable logistical problems in transporting thousands of blood specimens to and from rural sites to urban laboratories. It takes days or weeks to obtain tests results using the Elisa Reader method. This is too long, given that in some target countries more than 30 percent of clients tested by these systems fail to return for the test results.

Recently, a new "simple-rapid" type of HIV test costing $1-3 per test has become available offshore. These tests are easy to use, no central laboratory is needed, and they deliver test results within a few hours instead of days to weeks. There is currently only one United States-manufactured HIV rapid test that is FDA approved. It costs about $9 and the manufacturer has recently suspended production of this product.

Tab 1 contains a list of testing kits that have been reviewed internally and found to meet all the necessary suitability and price criteria in the applicable waiver regulations cited above. CDC has reviewed and approved the items on the Tab 1 list for safety and efficacy.

RECOMMENDATIONS

A. We recommend that, based on the findings above, you authorize the procurement in Code 935 countries of testing kits identified in Tab 1.

Approve_____________________

Disapprove__________________

Date________________________

B. We recommend that you delegate authority to AA/M to amend the Tab 1 approved list from time to time to add new Code 935 testing kits when they meet the same criteria.

Approve_____________________

Disapprove__________________

Date________________________

Attachments:

Tab 1 – Approved List of Testing Kit Products and
Manufacturers
TAB 2 - December 19, 2000 Action Memo

CLEARANCE PAGE FOR ACTION MEMORANDUM requesting a source and origin waiver for HIV/AIDS diagnostic testing kits for the HIV/AIDS and Infectious Disease Initiative.

Clearances:

AA/LPA:JCrapa_______________Date_______
AA/PPC:TFox_________________Date_______
DAA/G:DGillespie____________Date_______
A-AAM:RNygard_______________Date_______
GC:SMcAllister______________Date_______
ES:RConroy__________________Date_______
M:MWard_____________________Date_______

Draft:G/PHN:AGetson, RKirkland 12/20/00; Revised GC:RMeighan, MKitay 1/9/01

Tab 1 - Approved List of Testing Kit Products and Manufacturers

Product	Price in Dollars	Source Country	Manufacturer
Bionor	NA	Norway	Bionor A/S
Capillus	$1.50	Ireland	Trinity Biotech*
Determine	$3.80	Japan	Abbott Laboratories*
DoubleCheck	$1.35	Israel	Orgenics
Genie II	NA	France	Sanofi Diagnostics Pasteur
Hema-Strip	$3.00	Singapore	Saliva Diagnostics, Ltd.*
HIV Spot	$1.20	Singapore	Genelabs Diagnostics*
HIVSav	NA	Israel	Sayvon Diagnostics Ltd.
MultiSpot	$4.00	France	Sanofi Diagnostics Pasteur*
SeroCard	$1.80	Ireland	Trinity Biotech*
Sero-Strip	$1.50	Israel	Saliva Diagnostic Systems, Ltd.*
* Parent Company is a United States based firm			