# INITIAL ENVIRONMENTAL EXAMINATION AMENDMENT #2

## PROJECT/ACTIVITY DATA

<table>
<thead>
<tr>
<th><strong>Project/Activity Name:</strong></th>
<th>Health Systems Strengthening (HSS) Project</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Geographic Location(s) (Country/Region):</strong></td>
<td>Uganda/East Africa</td>
</tr>
<tr>
<td><strong>Amendment (Yes/No), if Yes indicate # (1, 2...):</strong></td>
<td>Yes, #2</td>
</tr>
<tr>
<td><strong>Implementation Start/End:</strong></td>
<td>December 14, 2017 - December 31, 2021</td>
</tr>
<tr>
<td><strong>If Amended, specify New End Date:</strong></td>
<td>September 30, 2025</td>
</tr>
<tr>
<td><strong>Solicitation/Contract/Award Number:</strong></td>
<td>TBD Multiple (2 New activities)</td>
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<tr>
<td><strong>Implementing Partner(s):</strong></td>
<td>TBDs and Joint Medical Stores (JMS)</td>
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<tr>
<td><strong>Bureau Tracking ID</strong></td>
<td><a href="https://ecd.usaid.gov/document.php?doc_id=52644">Uganda HSS Project IEE Amd. 2</a></td>
</tr>
<tr>
<td><strong>Tracking ID/link of Other, Related Analyses:</strong></td>
<td>NA</td>
</tr>
</tbody>
</table>

## ORGANIZATIONAL/ADMINISTRATIVE DATA

| **Implementing Operating Unit(s):** | USAID/Uganda |
| (e.g. Mission or Bureau or Office) | |
| **Other Affected Unit(s):** | NA |
| **Lead BEO Bureau:** | AFR |
| **Funding Account(s) (if available):** | GHP-HIV |
| **Original Funding Amount:** | For HSS Project: $406,372,310 |
| **If Amended, specify funding amount:** | a) Local procurement of HIV commodities: $294,934,269 |
| **If Amended, specify new funding total:** | b) Warehousing and distribution of locally procured HIV commodities: $22,620,070 |
| **Prepared by:** | USAID/Uganda Health Systems Strengthening Project Management Team (HSS-PMT); USAID/Uganda Mission Environmental Officer |
| **Date Prepared:** | December 17, 2019 |
ENVIRONMENTAL COMPLIANCE REVIEW DATA

<table>
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<th>Analysis Type:</th>
<th>☒ Environmental Examination</th>
<th>☐ Deferral</th>
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<tr>
<td>Environmental Determination(s):</td>
<td>☐ Categorical Exclusion(s)</td>
<td>☒ Negative with Conditions</td>
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<td>IEE Expiration Date:</td>
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<tr>
<td>Additional Analyses/Reporting Required:</td>
<td>EMMPs</td>
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<tr>
<td>Climate Risks Identified (#):</td>
<td>Low ___ X ___ Moderate ___ X High ______</td>
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THRESHOLD DECISION MEMO AND SUMMARY OF FINDINGS

PROJECT/ACTIVITY SUMMARY

This amendment will add two new activities to the HSS IEE. USAID interventions under these activities will include:

a. Procurement of HIV commodities through local procurement agents, with a funding level of $295 million, to support the transition to local partners as mandated by Office of the U.S. Global AIDS Coordinator (OGAC); and

b. Warehousing and distribution of these locally procured HIV commodities, with a funding level of $22.6 million.

a. Local Partner Procurement of HIV commodities:

This activity will transition USAID’s procurement of HIV commodities needed for the private not-for-public (PNFP) sector from USAID’s central Global Health Supply Chain Program–Procurement and Supply Management (GHSC/PSM); and Global Health Supply Chain/Rapid Test Kits (GHSC/RTK) to multiple local procurement agents under Task Orders managed directly by USAID/Uganda. This transition will occur over a five-year period and move from 25 percent ($20.4 million) of the total PNFP sector requirement in year one to 100 percent in year four ($84.5 million). The total estimated cost of this procurement is $295 million over five years. USAID intends to award an Indefinite Delivery Indefinite Quantity (IDIQ) contract to multiple vendors. This activity is in support of the President’s Emergency Plan for AIDS Relief (PEPFAR) strategy of increasing the percentage of Country Operational Plan (COP) budgets that are directed toward local partners as Primes as well as in support of USAID’s Journey to Self-Reliance.

The primary objective of this activity is to ensure that 90 percent of HIV/AIDS commodities are delivered on time and in-full to the client, i.e., the central warehouse that USAID will designate. This objective is supported by the following sub-objectives:

1. Develop and maintain a robust program management system to ensure the effective and efficient delivery of contract services and the achievement of performance standards contained in the contract;
2. Develop and maintain a competitive and transparent procurement process to procure required commodities that:
   - fully complies with all applicable USG contracting laws and regulations,
- leverages volume purchasing to achieve significant reductions in the current costs of supplies, and
- achieves the best value to the USG (best value refers to product quality, availability, on-time delivery and price);

(3) Maintain contingency plans and product risk profiles;

(4) Contribute to the maintenance of a quality assurance (QA) program to obtain and manage the required documentation and verify that supplies meet contractual and product specifications; and

(5) Establish an efficient and cost-effective freight forwarding system to ensure on time delivery to the USAID-designated central warehouse in Kampala, or other locations as designated by USAID.

These different components must perform in a smooth, interconnected and seamless manner for the Project to succeed in providing the needed commodities and support.

This activity includes the following considerations:

- Limited to HIV commodities for the PNFP sector including antiretroviral drugs (ARVs), opportunistic infection medicines, Viral Load and Early Infant Diagnosis reagents, TB-related tests, HIV rapid test kits, other laboratory supplies, commodities for voluntary medical male circumcision and other HIV/AIDS-related commodities.
- A progressive transition over a three-year period of what GHSC/PSM and GHSC/RTK procures currently to local procurement agents;
- Total TEC funding of $295 million over a five-year period.

b. Warehousing and Distribution of locally procured HIV commodities Activity:

The purpose of this activity is to ensure the warehousing of locally procured HIV commodities listed above and their distribution to PNFP facilities around the country. The TEC is $22.6 million over a five-year period. This activity does not include any construction or rehabilitation of warehouse facilities. The activity will:

1. Receive, inspect and store HIV commodities:
   - Concur with amounts and timelines for purchase of commodities by local procurement agents to ensure that commodities will be consumed within a reasonable period, i.e., 9 months;
   - Receive and inspect the commodities received for damage, shortages, expiration dates, and any other factor deemed necessary for the inspection of medical products; and
   - Provide appropriate storage conditions for products including cold-chain, adequate security measures, and any other storage requirements as specified for each product and according to internationally accepted Guide to Good Storage Practices for Pharmaceuticals published by World Health Organization (WHO).
   - The warehousing facilities in Kampala that shall receive the commodities, have both solar power (back up) and hydro power electricity installations.

2. Package and distribute commodities:
● Package and distribute products to authorized points of service once every two months in types and quantities specified in accurate and reasonable orders made by health facilities;
● Maintain an up to date database of all designated points of service which have been identified as eligible to receive USAID-procured HIV commodities and provide the previous month’s Distribution and Stock Status Report;
● Participate in the monthly commodity security group meetings and other supply chain-related meetings with GOU, USG, Implementing Partners relative to the warehousing and distribution of HIV commodities as necessary; and
● Provide supportive supervision to SDPs who receive HIV commodities from contractor in order to improve order quality and provide a bimonthly report to USAID describing the sites supported, problems encountered that led to poor order quality and solutions implemented.

3. The destruction of unusable products:
   ● Provide USAID with a list of expired items or unusable items so that the process of destruction is initiated; and
   ● Hand over the items for destruction to the vendor appointed by USAID and will follow up to ensure that destruction is carried out in accordance with NDA/National Environmental Management Authority (NEMA) guidelines.

USAID and GOU inspectors will be allowed access to inspect all commodities and services, as well as access to all relevant documents, personnel, and facilities associated with this activity.

ENVIRONMENTAL DETERMINATIONS

Upon approval of this document, the determinations become affirmed, per Agency regulations (22 CFR 216). The following table summarizes the environmental determinations for the below HSS project/activities:

<table>
<thead>
<tr>
<th>TABLE 1: ENVIRONMENTAL DETERMINATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities</td>
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<tr>
<td></td>
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<tr>
<td>Local partner procurement of HIV commodities Activity</td>
</tr>
<tr>
<td>Warehousing and Distribution of Locally Procured HIV commodities</td>
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</tbody>
</table>

CLIMATE RISK MANAGEMENT

All details in this section remain as described in the original IEE, (File Name: Uganda_ Health_ Systems Strengthening_ Project IEE_082318 and is cross referenced in this amendment. This additional analysis documents the results of the activity-level Climate Risk Management process for Local Partner

¹ Deferrals must be cleared through an Amendment to this IEE prior to implementation of any deferred activities. USAID/IPs may utilize the Environmental Screening Tool to assess impacts of deferred activities.
Procurement of HIV Commodities and the warehousing and distribution of these locally procured commodities in accordance with ADS 201.

The climate risk analysis established that climate risks were low for procurement; and moderate for the TB components of the local service delivery activity, and the storage and distribution components of the supply chain management systems. For these two components, climate risk management options will need to be identified and implemented. Extreme weather events like heavy rains, floods and heat will likely affect stored health supplies. Heavy rains and floods could also damage roads and affect distribution of supplies. Results of a 2019 study in The Journal of global infectious diseases (see link here) also showed that TB notification rates were higher at a higher temperature. Climate-proofing of the storage and distribution systems and the TB interventions under the LSD activity is therefore required.

The recommended climate risk management actions include installing air conditioning systems, ensuring storage rooms are well ventilated and roofed, using the pallet and shelf system, installing temperature readers, having standby refrigerators for cold chain, installing backup generators, etc. The Project will also ensure that supply distribution plans are informed by weather forecasts, and that stocks delivered will adequately cover long periods of up to four months to ensure no breaks in the supply chain. The selected delivery trucks will be those specially designed to withstand weather conditions (e.g. refrigerated for cold chain, leak-proof and are four-wheel drive) as relevant. TB diagnosis and treatment interventions will also be informed by seasonal/regional temperature forecasts where relevant. These climate risk management options will be integrated into activity design, solicitation and implementation plans.

BEO SPECIFIED CONDITIONS OF APPROVAL

1. The negative determinations recommended in this IEE are contingent on full implementation of specified conditions and a set of general monitoring and implementation requirements specified in Section 5 of the original IEE, (File Name: Uganda_ Health_ Systems Strengthening_ Project IEE_082318) and are cross referenced in this amendment.

2. Additional BEO Conditions related to health care waste management are specified in Section 5 below.

3. An additional BEO Condition requiring a Comparative Energy Analysis for Healthcare Commodities Warehouses can be found in Section 5.3, Table 5B below.

IMPLEMENTATION

All details in this section remain as described in the original IEE, (File Name: Uganda_ Health_ Systems Strengthening_ Project IEE_082318) and is cross referenced in this amendment.
USAID APPROVAL OF INITIAL ENVIRONMENTAL EXAMINATION

PROJECT/ACTIVITY NAME: Health Systems Strengthening Project Amendment #2

Approval: Richard Nelson, Mission Director

Clearance: Rick Somarriba, Deputy Mission Director

Clearance: Laura Gonzales, Resident Legal Officer

Clearance: Tim Stein, Supervisory Program Officer

Clearance: Heather Smith-Taylor Director, Health and HIV/AIDS Office

Clearance: Jessica Okui, Mission Environmental Officer

Clearance: (see attached)

Clearance: Cleared by email

Clearance: Colin Quin, AFR Climate Change Advisor

Clearance: Robert Bagyenda, Ag. Climate Integration Lead

Concurrence: Brian Hirsch, Africa Bureau Environmental Officer
INITIAL ENVIRONMENTAL EXAMINATION

CONTENTS

1.0 PROJECT/ACTIVITY DESCRIPTION 9
   1.1 Purpose and Scope of IEE 9
   1.2 Project/Activity Overview 9
   1.3 Project/Activity Description 9

2.0 BASELINE ENVIRONMENTAL INFORMATION ................................................................. 11
   SUMMARY OF GENERAL CONDITIONS IN UGANDA 11
   2.1 Locations Affected and Environmental Context 11
   2.2 Applicable and Appropriate Partner Country and Other International Standards (e.g. WHO), Environmental and Social Laws, Policies, and Regulations 11

3.0 ANALYSIS OF POTENTIAL ENVIRONMENTAL RISK ....................................................... 12
   ACTIVITY 1: Procurement of HIV commodities 12
   TABLE 3A. POTENTIAL IMPACTS - Procurement of HIV Commodities 12
   ACTIVITY 2: Warehousing and distribution of hiv commodities 12
   TABLE 3B. POTENTIAL IMPACTS – Warehousing and Distribution of HIV Commodities 12

4.0 ENVIRONMENTAL DETERMINATIONS............................................................................. 14
   4.1 RECOMMENDED ENVIRONMENTAL DETERMINATIONS 14
   TABLE 4: ENVIRONMENTAL DETERMINATIONS 14
   4.2 CLIMATE RISK MANAGEMENT 14

5.0 CONDITIONS AND MITIGATION MEASURES................................................................. 15
   5.1 CONDITIONS 15
   5.2 AGENCY CONDITIONS 16
   5.3 MITIGATION MEASURES 17
   ACTIVITY 1: Hiv commodities 17
   TABLE 5A. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 1 17
   ACTIVITY 2 : Warehousing and Distribution of Commodities 20
   TABLE 5B. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 2 20
   ACTIVITY3: Local Service Delivery Error! Bookmark not defined.
   TABLE 5C. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 3 Error! Bookmark not defined.
6.0 LIMITATIONS OF THIS INITIAL ENVIRONMENTAL EXAMINATION .....................23
7.0 REVISIONS ..................................................................................................................23
ATTACHMENTS: ..............................................................................................................23
  ANNEX 1: Climate Risk Management 24
  Project Climate Risk Management Summary Table (Detailed table in Annex 2) 24
I.0 PROJECT/ACTIVITY DESCRIPTION

I.1 PURPOSE AND SCOPE OF IEE

The purpose of this amendment # 2 to the Initial Environmental Examination (IEE) File No. Uganda_Health Systems Strengthening_Project_IEE_082318, approved 08/22/2018 for USAID/Uganda’s Health Systems Strengthening Project, is to provide a preliminary review of the reasonably unforeseeable effects on the environment of the following USAID interventions: local partner procurement of HIV commodities, and local partner warehousing and distribution of locally-procured HIV commodities in accordance with the requirements of Title 22 of the Code of Federal Regulations (CFR) Part 216, as below. Upon approval, these respective determinations become affirmed per 22 CFR 216, and specified conditions become mandatory obligations of implementation. This analysis also documents the results of the additional Climate Risk Management process for the two new activities in accordance with USAID policy, specifically, ADS 201 mandatory reference 201mal_042817.

This IEE is a critical element of USAID’s mandatory environmental review and compliance process meant to achieve environmentally sound activity design and implementation. Potential environmental impacts should be addressed through formal Environmental Monitoring and Mitigation Plans (EMMPs) and/or Environmental Assessments (EAs), if needed.

Implementing partners are responsible for monitoring the environmental mitigation measures for their activities per the conditions of the IEE. The EMMP describes the impacts identified in the IEE and the mitigation measures planned to minimize or eliminate the environmental impacts of project activities (ADS 204 Supplement Section 5).

I.2 PROJECT OVERVIEW

The Local Partner Procurement of HIV-Commodities activity covers a five-year implementation period (October 2020 – September 2025), at a TEC of $295 million. The Local Partner Warehousing and Distribution of HIV Commodities activity covers a five-year implementation period (December 2020 – December 2025), at a TEC of $22.5 million. These activities shall be implemented through Indefinite Delivery/Indefinite Quantity (IDIQ) Task Orders (for procurement) and Cooperative Agreements, and Fixed Award Amount. and Cost Reimbursement Contract (for warehousing and distribution).

I.3 ACTIVITY DESCRIPTIONS

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
</table>
| Local Partner Procurement of HIV commodities | **Brief Description:** The objective of this activity is to ensure the effective and progressive transition for the procurement of HIV commodities intended for the private not-for-profit sector from central mechanisms (GHSC/PSM, GHSC/RTK) to local partners (procurement agents). The purpose of the activity is to ensure uninterrupted supplies of HIV health commodities in support of USG-funded public health initiatives in Uganda. These commodities shall include: ARVs, opportunistic drugs, viral load and early infant diagnosis (VLED), HIV test kits, voluntary medical male circumcision (VMMC) kits, and other laboratory tests supplies. The project provides direct procurement of HIV commodities under PEPFAR, only.  
**Key outcomes or performance targets to be achieved:** By year four of this five-year process, all HIV commodities funded by the USG in Uganda will be procured by |

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I.3 ACTIVITY DESCRIPTIONS

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<tr>
<th>Activity</th>
<th>Description</th>
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<tbody>
<tr>
<td>local partners (procurement agents). These local partners will have improved strategic planning and implementation related to supply chain management and commodity security.</td>
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**Type of Action:** Indefinite Delivery Indefinite Quantity (IDIQ) Task Orders  
**Budget Estimate:** $295 million  
**IP:** TBD; Multiple Partners TB

| Local Partner  
Warehousing and  
Distribution of HIV  
commodities | Brief Description: The purpose of this activity is to warehouse and distribute to private not-for-profit (PNFP) facilities those HIV commodities that are procured by local procurement agents; package and distribution commodities; and destruction of unusable products. This activity does not include any construction or rehabilitation of warehouse facilities. |

**Key outcomes or performance targets to be achieved:**  
The proper storage of HIV commodities procured by local procurement agents and distribution to PNFP facilities. These local partners will have improved strategic planning and implementation related to supply chain management and commodity security and improved in-country logistics including effective and efficient delivery of health commodities to service sites. Reverse logistics, including collection and destruction of expired commodities, will be undertaken by the GHSC/PHM implementing mechanism.

**Type of Action:** Cost Reimbursement Contract  
**Budget Estimate:** $ 22.5 million  
**IP:** TBD
2.0 BASELINE ENVIRONMENTAL INFORMATION

SUMMARY OF GENERAL CONDITIONS IN UGANDA

All details in this section remain as described in the original IEE, (File Name: Uganda_ Health_ Systems Strengthening_ Project IEE_082318 and is cross referenced in this amendment.

2.1 LOCATIONS AFFECTED AND ENVIRONMENTAL CONTEXT

These three activities shall take place in different locations in the country and a variety of environmental conditions shall be encountered as follows: The procurement and warehousing of HIV commodities will take place in Kampala; the distribution of HIV commodities will occur at PNFP facilities around the country. The country’s environmental baseline is summarized the original IEE, (File Name: Uganda_ Health_ Systems Strengthening_ Project_ IEE_082318 and is cross referenced in this amendment.

2.2 APPLICABLE AND APPROPRIATE PARTNER COUNTRY AND OTHER INTERNATIONAL STANDARDS (E.G. WHO), ENVIRONMENTAL AND SOCIAL LAWS, POLICIES, AND REGULATIONS

All details in this section remain as described in the original IEE, (File Name: Uganda_ Health_ Systems Strengthening_ Project IEE_082318) and is cross referenced in this amendment.
3.0 ANALYSIS OF POTENTIAL ENVIRONMENTAL RISK

ACTIVITY 1: PROCUREMENT OF HIV COMMODITIES

TABLE 3A. POTENTIAL IMPACTS - PROCUREMENT OF HIV COMMODITIES

<table>
<thead>
<tr>
<th>Project/Activity</th>
<th>Potential environmental and social impacts</th>
</tr>
</thead>
</table>
| Procurement of HIV Commodities          | **Procurement, storage, management and disposal of public commodities:** Pharmaceutical drugs, including anti-malarial, have specific storage-time and temperature requirements and may expire or lose efficacy before they are used, particularly in remote areas where demand is low and/or infrequent. Pharmaceutical waste may also accumulate due to inadequacies in stock management and distribution and/or lack of a routine system of disposal.  

The effects of pharmaceutical waste in the environment are different from conventional pollutants. Drugs are designed to interact within the body at low concentrations to elicit specific biological effects in humans, which may also cause biological responses in other organisms. Their main pathway into the environment is through household use and excretion and through the disposal of unused or expired pharmaceuticals.  

Effects on aquatic life are a major concern in disposal of pharmaceuticals. A wide range of pharmaceuticals have been discovered in fresh and marine waters globally, and even in small quantities some of these compounds have the potential to cause harm to aquatic life. Additional health risks related to disposal are that burning pharmaceuticals and plastic medical supplies at low temperatures or in open containers results in release of toxic pollutants into the air. Also inefficient and insecure sorting and disposal may allow drugs beyond their expiry date to be diverted for resale to the general public. Reverse logistics, including collection and destruction of expired commodities, will be undertaken by the GHSC/PHM implementing mechanism. |

ACTIVITY 2: WAREHOUSING AND DISTRIBUTION OF HIV COMMODITIES

TABLE 3B. POTENTIAL IMPACTS – WAREHOUSING AND DISTRIBUTION OF HIV COMMODITIES

<table>
<thead>
<tr>
<th>Project/Activity</th>
<th>Potential environmental and social impacts</th>
</tr>
</thead>
</table>
| Warehousing and Distribution of HIV Commodities | **Storage, management and disposal of public commodities:** Pharmaceutical drugs, including anti-malarial, have specific storage-time and temperature requirements and may expire or lose efficacy before they are used, particularly in remote areas where demand is low and/or infrequent. Pharmaceutical waste may also accumulate due to inadequacies in stock management and distribution and/or lack of a routine system of disposal.  

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4.0 ENVIRONMENTAL DETERMINATIONS

4.1 RECOMMENDED ENVIRONMENTAL DETERMINATIONS

The table below summarizes the recommended determinations based on the environmental analysis conducted. Upon approval, these determinations become affirmed, per 22 CFR 216. Specified conditions, detailed in Section 5, become mandatory obligations of implementation, per ADS 204.

**TABLE 4: ENVIRONMENTAL DETERMINATIONS**

<table>
<thead>
<tr>
<th>Projects/Activities</th>
<th>Categorical Exclusion Citation (if applicable)</th>
<th>Negative Determination with Conditions</th>
<th>Positive Determination</th>
<th>Deferral</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Activity 1:</strong> Procurement of HIV Commodities</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Activity 2:</strong> Warehousing and Distribution of HIV commodities</td>
<td>X</td>
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4.2 CLIMATE RISK MANAGEMENT

All details in this section remain as described in the original IEE, (File Name: Uganda_ Health_ Systems Strengthening_ Project IEE_082318) and is cross referenced in this amendment. This additional analysis documents the results of the activity-level Climate Risk Management process for Local Partner Procurement of HIV Commodities, and the warehousing and distribution of these locally procured commodities in accordance with ADS 201.

The climate risk analysis established that climate risks were low for procurement and moderate for the TB interventions of the LSD activity, and the storage and distribution components of the supply chain management systems. Extreme weather events like heavy rains, floods and heat will likely affect stored health supplies. Heavy rains and floods could also damage roads and affect distribution of supplies. Results of a 2019 study in The Journal of global infectious diseases (see link here) also showed that TB notification rates were higher at a higher temperature. Climate-proofing of the storage and distribution systems and the TB interventions under the LSD activity is therefore required.

The recommended climate risk management actions include installing air conditioning systems, ensuring storage rooms are well ventilated and roofed, using the pallet and shelf system, installing temperature readers, having standby refrigerators for cold chain, installing backup generators, etc. The Project will ensure that stocks delivered will adequately cover long periods of three months and beyond. The selected delivery trucks will be those specially designed to withstand weather conditions (e.g. refrigerated for cold chain, leak-proof and are four-wheel drive). These climate risk management options will be integrated into activity design and solicitation narrative and implementation plans.

---

2 Positive Determinations require preparation of a Scoping Statement and Environmental Assessment.
3 Deferrals must be cleared through an Amendment to this IEE prior to implementation of any deferred activities.
5.0 CONDITIONS AND MITIGATION MEASURES

5.1 CONDITIONS
The environmental determinations in this IEE are contingent upon full implementation of the following general implementation and monitoring requirements, as well as ADS 204 and other relevant requirements.

5.1.1 During Pre-Award:

5.1.1.1 Pre-Award Briefings: As feasible, the design team and/or the cognizant environmental officer(s) (e.g., MEO, REA, BEO) will provide a pre-award briefing for potential offerors on environmental compliance expectations/responsibilities at bidders’ conferences.

5.1.1.2 Solicitations: The design team, in coordination with the A/CO, will ensure solicitations include environmental compliance requirements and evaluation criteria. A/CO will ensure technical and cost proposal requirements include approach, staffing, and budget sufficient for complying with the terms of this IEE.

5.1.1.3 Awards: The A/COR, in coordination with the A/CO, will ensure all awards and sub-awards, include environmental compliance requirements.

5.1.2 During Post-Award:

5.1.2.1 Post-Award Briefings: The A/COR and/or the cognizant environmental officer(s) (e.g., MEO, REA, BEO) will provide post-award briefings for the IP on environmental compliance responsibilities.

5.1.2.2 Workplans and Budgeting: The A/COR will ensure the IP integrates environmental compliance requirements in work plans and budgets to comply with requirements, including EMMP implementation and monitoring.

5.1.2.3 Staffing: The A/COR, in coordination with the IP, will ensure all awards have staffing capacity to implement environmental compliance requirements.

5.1.2.4 Records Management: The A/COR will maintain environmental compliance documents in the official project/activity file and upload records to the designated USAID environmental compliance database system.

5.1.2.5 Host Country Environmental Compliance: The A/COR will ensure the IP complies with applicable and appropriate host country environmental requirements unless otherwise directed in writing by USAID. However, in the case of a conflict between the host country and USAID requirements, the more stringent shall govern.

5.1.2.6 Work Plan Review: The A/COR will ensure the IP verifies, at least annually or when activities are added or modified, that activities remain with the scope of the IEE. Activities outside of the scope of the IEE cannot be implemented until the IEE is amended.
5.1.2.8 IEE Amendment: If new activities are introduced or other changes to the scope of this IEE occur, an IEE Amendment will be required.

5.1.2.14 USAID Monitoring Oversight: The A/COR or designee, with the support of the cognizant environmental officer(s) (e.g., MEO, REA, BEO), will ensure monitoring of compliance with established requirements (e.g., by desktop reviews, site visits, etc.).

5.1.2.16 Environmental Compliance Mitigation and Monitoring Plan: The A/COR will ensure the IP develops, obtains approval for, and implements Environmental Mitigation and Monitoring Plans (EMMPs) that are responsive to the stipulated environmental compliance requirements.

5.1.2.17 Environmental Compliance Reporting: The A/COR will ensure the IP includes environmental compliance in regular project/activity reports, using indicators as appropriate; develops and submits the Environmental Mitigation and Monitoring Reports (EMMRs); and completes and submits a Record of Compliance (RoC) describing their implementation of EMMP requirements in conjunction with the final EMMR or at the close of sub activities (as applicable). And where required by Bureaus or Missions, ensure the IP prepares a closeout plan consistent with contract documentation for A/COR review and approval that outlines responsibilities for end-of-project operation, the transition of other operational responsibilities, and final EMMR with lessons learned.

5.1.2.18 Corrective Action: When noncompliance or unforeseen impacts are identified, IPs notify the A/COR, place a hold on activities, take corrective action, and report on the effectiveness of corrective actions. The A/COR initiates the corrective action process and ensures the IP completes and documents their activities. Where required by Bureaus or Missions, ensure Record of Compliance is completed.

5.2 AGENCY CONDITIONS

5.2.1 Sub-award Screening: The A/COR will ensure the IP uses an adequate environmental screening tool to screen any sub-award applications and to aid in the development of EMMPs.

5.2.2 Programmatic IEEs (PIEE): PIEEs stipulate requirements for additional environmental examination of new or country specific projects/activities. The A/COR of any project/activity being implemented under a PIEE will ensure appropriate reviews are conducted, typically through a Supplemental IEE, and approved by the cognizant BEO.

5.2.3 Supplemental IEEs (SIEEs): An SIEE will be prepared for any new project/activity being planned which fall under a PIEE. The SIEE will provide more thorough analysis of the planned activities, additional geographic context and baseline conditions as well as specific mitigation and monitoring requirements.

5.2.4 Other Supplemental Analyses: The A/COR will ensure supplemental environmental analyses that are called for in the IEE are completed and documented.
5.2.5 Resolution of Deferrals: If a deferral of the environmental threshold determination was issued, the A/COR will ensure that the appropriate 22CFR216 environmental analysis and documentation is completed and approved by the BEO before the subject activities are implemented.

5.2.6 Positive Determination: If a Positive Determination threshold determination was made, the A/COR will ensure a Scoping Statement, and if required an Environmental Assessment (EA), is completed and approved by the BEO before the subject activities are implemented.

5.2.7 Compliance with human subject research requirements: The AM, A/COR shall assure that the IP and sub-awardees, -grantees, and -contractors demonstrate completion of all requirements for ethics review and adequate medical monitoring of human subjects who participate in research trials carried out through this IEE and ensure appropriate records are maintained. All documentation demonstrating completion of required review and approval of human subject trials must be in place prior to initiating any trials and cover the period of performance of the trial as described in the research protocol.

5.3 MITIGATION MEASURES
The mitigation measures presented in this section constitute the minimum required based on available information at the time of this IEE and the environmental analysis in Section 4. These measures shall provide general direction for completing the project/activity Environmental Mitigation and Monitoring Plan (EMMP) and/or the EA and PERSUAP, if required.

ACTIVITY 1: HIV COMMODITIES

TABLE 5A. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 1

<table>
<thead>
<tr>
<th>Activity</th>
<th>Mitigation Measure(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity 1: Local Partner Procurement of HIV Commodities</td>
<td>Negative Determination, subject to the following Condition(s):</td>
</tr>
<tr>
<td></td>
<td>• Where USAID support increases the delivery of healthcare services, such as through the provision of supplies, equipment, and/or staffing, USAID will take responsibility for ensuring the proper management of medical waste from that facility; including, but not limited to, proper handling, labeling, treatment, storage, transport and final disposal.</td>
</tr>
<tr>
<td></td>
<td>• When USAID supports healthcare service delivery in partnership with other actors, including the host country, the GRA, NGOs, CSOs, etc., USAID will ensure appropriate, sufficient, and sustainable medical waste management through collaboration. If significant deficiencies* in medical waste management persist in spite of collaborative efforts, USAID must reallocate its resources to either independently close those gaps or to work in facilities where medical waste is properly managed.</td>
</tr>
<tr>
<td></td>
<td>* Significant deficiencies are defined as not meeting “minimum approaches” as established by WHO Guidance for each of the following aspects of medical waste management: health care waste management policy; planning; waste minimization; segregation, storage and transport; treatment and disposal;</td>
</tr>
</tbody>
</table>

* Significant deficiencies are defined as not meeting “minimum approaches” as established by WHO Guidance for each of the following aspects of medical waste management: health care waste management policy; planning; waste minimization; segregation, storage and transport; treatment and disposal.
USAID must regularly monitor the state of healthcare waste management in the healthcare facilities it supports, and USAID should request reports on that monitoring with the same regularity as it receives reports on other programmatic objectives of the activity.

When reports or other information indicate significant deficiencies in the management and disposal of medical waste in a given facility, USAID will commit its resources (independently or through collaborative efforts) to a speedy correction of significant deficiencies. In this case, USAID will request from implementing partners or prepare internally a Corrective Action Plan that will resolve the subject deficiencies as quickly as possible, not to exceed 6 months from the initial indications of deficiencies.

As applicable, all efforts to strengthen or improve health commodity supply chains (e.g., pharmaceuticals, diagnostic tests kits (including HIV test kits), VMMC disposable kits etc.), including procurement, storage infrastructure, and distribution must address and take all practicable efforts to assure that adequate facilities, procedures and capacities are in place to properly manage expired, used, obsolete or surplus commodities and/or that plans and strategies incorporate and provide for such management. In any instance that a USAID project controls commodity at end-of-life, appropriate end-of-life management must be assured. Mandatory references for “appropriate end of life management”: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals. https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1


Any healthcare waste generated by USAID-funded training, capacity building and/or technical assistance activities must be appropriately managed, including disposal, following WHO guidelines as well as the Government mandatory procedures and guidelines. https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sessionid=29E4FC7B647745587FF832EB6C1E8EED?sequence=1

Training, supervision, curricula development and other health care workforce capacity building must address appropriate management practices concerning the proper handling, use, and disposal of medical waste, including blood, sputum, and sharps, when techniques or care situations being addressed would generate and require disposal of hazardous or highly hazardous waste.
Activity | Mitigation Measure(s)
---|---
| waste (e.g. sharps, afterbirth from delivery, waste from screening for HIV or STDs, sputum samples for diagnosis of TB). Note that this condition applies to activities targeting home care AND community health workers, not just those in clinics and health facilities. Wherever relevant, appropriate disposal mechanisms in home-based and community-based situations that are cost effective and safe must be identified and appropriately incorporated in training, protocols, and guidelines. This includes training home care and community health workers to deliver positive messages about personal and household hygiene, sanitation, and proper disposal of condoms and other potentially harmful materials. Otherwise, and in all cases, implementing partners conducting activities involving procurement, storage, management and/or disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, must ensure, to the greatest extent practicable, that they and/or the medical facilities and operations involved, as appropriate, have adequate procedures and capacities in place to properly manage and dispose of such commodities.
● Consignees for any pharmaceutical drugs procured under these activities must be advised: (1) to store the product according to the information provided on the manufacturer's Materials Safety Data Sheet (MSDS); (2) that, if disposal is required due to expiration or any other reason, the preferred method of disposal is to return to the manufacturer. If that is not possible, then the preferred disposal method is as per the WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals (www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf).


Note: The Local procurement agents shall not be responsible for disposal of pharmaceutical waste, and non-reusable commodities. This reverse logistics shall be handled by a separate Field Support Mechanism - Global Health Supply Chain Procurement and Supply Management (GHSC/PSM) contract, which is COP funded. The GHSC/PSM contract shall use local firms; registered and certified for; storage, transportation, and disposal of hazardous waste; by the National Environment Management Authority.

(GHSC/PSM COR is: Xavier Tomsej. Email: xtomsej@usaid.gov)
## ACTIVITY 2: WAREHOUSING AND DISTRIBUTION OF COMMODITIES

### TABLE 5B. SUMMARY OF MITIGATION MEASURES FOR ACTIVITY 2

<table>
<thead>
<tr>
<th>Activity</th>
<th>Mitigation Measure(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity 2: Local Partner Warehousing and Distribution of HIV Commodities</td>
<td><strong>Negative Determination</strong>, subject to the following <strong>Condition(s)</strong>:</td>
</tr>
<tr>
<td></td>
<td>• Where USAID support increases the delivery of healthcare services, such as through the provision of supplies, equipment, and/or staffing, USAID will take responsibility for ensuring the proper management of medical waste from that facility; including, but not limited to, proper handling, labeling, treatment, storage, transport and final disposal.</td>
</tr>
<tr>
<td></td>
<td>• When USAID supports healthcare service delivery in partnership with other actors, including the host country, the GRA, NGOs, CSOs, etc., USAID will ensure appropriate, sufficient, and sustainable medical waste management through collaboration. If significant deficiencies* in medical waste management persist in spite of collaborative efforts, USAID must reallocate its resources to either independently close those gaps or to work in facilities where medical waste is properly managed.</td>
</tr>
<tr>
<td></td>
<td>* Significant deficiencies are defined as not meeting “minimum approaches” as established by WHO Guidance for each of the following aspects of medical waste management: health care waste management policy; planning; waste minimization; segregation, storage and transport; treatment and disposal; wastewater management; waste management costing; health and safety practices; hygiene and infection control; training, education and public awareness.</td>
</tr>
<tr>
<td></td>
<td>• USAID must regularly monitor the state of healthcare waste management in the healthcare facilities it supports, and USAID should request reports on that monitoring with the same regularity as it receives reports on other programmatic objectives of the activity.</td>
</tr>
<tr>
<td></td>
<td>• When reports or other information indicate significant deficiencies in the management and disposal of medical waste in a given facility, USAID will commit its resources (independently or through collaborative efforts) to a speedy correction of significant deficiencies. In this case, USAID will request from implementing partners or prepare internally a Corrective Action Plan that will resolve the subject deficiencies as quickly as possible, not to exceed 6 months from the initial indications of deficiencies.</td>
</tr>
<tr>
<td></td>
<td>• As applicable, all efforts to strengthen or improve health commodity supply chains (e.g., pharmaceuticals, diagnostic tests kits (including HIV test kits), VMMC disposable kits etc.), including procurement, storage infrastructure, and distribution must address and take all practicable efforts to assure that adequate facilities, procedures and capacities are in place to properly manage expired, used, obsolete or surplus commodities and/or that plans and strategies incorporate and provide for such management. In any instance that a USAID project controls commodity at end-of-life, appropriate end-of-life management must be assured. Mandatory references for “appropriate end of life management”: WHO</td>
</tr>
<tr>
<td>Activity</td>
<td>Mitigation Measure(s)</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Guidelines for Safe Disposal of Unwanted Pharmaceuticals.</td>
<td><a href="https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1">https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1</a></td>
</tr>
<tr>
<td>• Any healthcare waste generated by USAID-funded training, capacity</td>
<td>building and/or technical assistance activities must be appropriately managed, including disposal, following WHO guidelines as well as the Government mandatory procedures and guidelines.</td>
</tr>
<tr>
<td>building and/or technical assistance activities must be appropriately</td>
<td><a href="https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1">https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1</a></td>
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<tr>
<td>managed, including disposal, following WHO guidelines as well as</td>
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<tr>
<td>the Government mandatory procedures and guidelines.</td>
<td></td>
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<tr>
<td>• Training, supervision, curricula development and other health care</td>
<td>workforce capacity building must address appropriate management practices concerning the proper handling, use, and disposal of medical waste, including blood, sputum, and sharps, when techniques or care situations being addressed would generate and require disposal of hazardous or highly hazardous waste (e.g. sharps, afterbirth from delivery, waste from screening for HIV or STDs, sputum samples for diagnosis of TB). Note that this condition applies to activities targeting home care AND community health workers, not just those in clinics and health facilities. Wherever relevant, appropriate disposal mechanisms in home-based and community-based situations that are cost effective and safe must be identified and appropriately incorporated in training, protocols, and guidelines. This includes training home care and community health workers to deliver positive messages about personal and household hygiene, sanitation, and proper disposal of condoms and other potentially harmful materials. Otherwise, and in all cases, implementing partners conducting activities involving procurement, storage, management and/or disposal of public health commodities, including pharmaceutical drugs, immunizations and nutritional supplements, must ensure, to the greatest extent practicable, that they and/or the medical facilities and operations involved, as appropriate, have adequate procedures and capacities in place to properly manage and dispose of such commodities.</td>
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<tr>
<td>workforce capacity building must address appropriate management</td>
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<tr>
<td>practices concerning the proper handling, use, and disposal of</td>
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<td>medical waste, including blood, sputum, and sharps, when techniques</td>
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<td>or care situations being addressed would generate and require</td>
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<td>disposal of hazardous or highly hazardous waste (e.g. sharps,</td>
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<tr>
<td>afterbirth from delivery, waste from screening for HIV or STDs,</td>
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<tr>
<td>sputum samples for diagnosis of TB). Note that this condition applies</td>
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<td>to activities targeting home care AND community health workers, not</td>
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<td>just those in clinics and health facilities. Wherever relevant,</td>
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<tr>
<td>appropriate disposal mechanisms in home-based and community-based</td>
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<tr>
<td>situations that are cost effective and safe must be identified and</td>
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<tr>
<td>appropriately incorporated in training, protocols, and guidelines.</td>
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<tr>
<td>This includes training home care and community health workers to</td>
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<td>deliver positive messages about personal and household hygiene,</td>
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<td>sanitation, and proper disposal of condoms and other potentially</td>
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<tr>
<td>harmful materials. Otherwise, and in all cases, implementing</td>
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<tr>
<td>partners conducting activities involving procurement, storage,</td>
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<tr>
<td>management and/or disposal of public health commodities, including</td>
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<tr>
<td>pharmaceutical drugs, immunizations and nutritional supplements,</td>
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<tr>
<td>must ensure, to the greatest extent practicable, that they and/or</td>
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<tr>
<td>the medical facilities and operations involved, as appropriate,</td>
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<tr>
<td>have adequate procedures and capacities in place to properly manage</td>
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<tr>
<td>and dispose of such commodities.</td>
<td></td>
</tr>
<tr>
<td>• Consignees for any pharmaceutical drugs procured under these activities must be advised: (1) to store the product according to the information provided on the manufacturer’s Materials Safety Data Sheet (MSDS); (2) that, if disposal is required due to expiration or any other reason, the preferred method of disposal is to return to the manufacturer. If that is not possible, then the preferred disposal method is as per the WHO /NEMA Guidelines and for Safe Disposal of Unwanted Pharmaceuticals (<a href="http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf">www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf</a>).</td>
<td></td>
</tr>
<tr>
<td>WHO guidelines for “Safe management of wastes from health-care activities” Section 8.11.3 (<a href="https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1">https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1</a>).</td>
<td></td>
</tr>
</tbody>
</table>
Activity | Mitigation Measure(s)
--- | ---

*Mandatory references for “appropriate end of life management”: WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals.*
www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf

*“Healthcare Waste” chapter, USAID Sector Environmental Guidelines*  

**Comparative Energy Analysis for Healthcare Commodities Warehouses:** Where USAID’s IP’s are involved in the management and/or operation of warehouses for healthcare commodities procurement, and that does not already have backup solar-energy generation capabilities, the IP will conduct a comparative analysis of sources for backup energy generation, specifically, examining the environmental, climate, and budgetary implications of the use of fossil fuels versus green energy backup energy supply. The IP, in conjunction with the AOR/COR, will be required to complete this analysis and file with the EMMP for the activity. The A/COR and MEO must review and approve the analysis. When comparisons favor solar to fossil fuel-powered generators, solar power should be preferred.

*Note:* The Local procurement agents shall not be responsible for disposal of pharmaceutical waste, and non-reusable commodities. This reverse logistics shall be handled by a separate Field Support Mechanism - Global Health Supply ChainProcurement and Supply Management (GHSC/PSM) contract, which is COP funded.

The GHSCPSM contract shall use local firms; registered and certified for; storage, transportation, and disposal of hazardous waste; by the National Environment Management Authority.

(GHSC/PSM COR is: Xavier Tomsej. Email: xtomsej@usaid.gov)
6.0 LIMITATIONS OF THIS INITIAL ENVIRONMENTAL EXAMINATION

The determinations recommended in this document apply only to projects/activities and sub-activities described herein. Other projects/activities that may arise must be documented in either a separate IEE, an IEE amendment if the activities are within the same project/activity, or other type of environmental compliance document and shall be subject to an environmental analysis within the appropriate documents listed above.

Other than projects/activities determined to have a Positive Threshold Determination, it is confirmed that the projects/activities described herein do not involve actions normally having a significant effect on the environment, including those described in 22 CFR 216.2(d).

In addition, other than projects/activities determined to have a Positive Threshold Determination and/or a pesticide management plan (PERSUAP), it is confirmed that the projects/activities described herein do not involve any actions listed below. Any of the following actions would require additional environmental analyses and environmental determinations:

- Support project preparation, project feasibility studies, or engineering design for activities listed in §216.2(d)(1);
- Affect endangered and threatened species or their critical habitats per §216.5, FAA 118, FAA 119;
- Provide support to extractive industries (e.g. mining and quarrying) per FAA 117;
- Promote timber harvesting per FAA 117 and 118;
- Lead to new construction, reconstruction, rehabilitation, or renovation work per §216.2(b)(1);
- Support agro-processing or industrial enterprises per §216.1(b)(4);
- Provide support for regulatory permitting per §216.1(b)(2);
- Lead to privatization of industrial facilities or infrastructure with heavily polluted property per §216.1(b)(4);
- Research, testing, or use of genetically engineered organisms per §216.1(b)(1), ADS 211
- Assist the procurement (including payment in kind, donations, guarantees of credit) or use (including handling, transport, fuel for transport, storage, mixing, loading, application, clean-up of spray equipment, and disposal) of pesticides or activities involving procurement, transport, use, storage, or disposal of toxic materials. Pesticides cover all insecticides, fungicides, rodenticides, etc. covered under the Federal Insecticide, Fungicide, and Rodenticide Act per §216.2(e) and §216.3(b).

7.0 REVISIONS

Per 22 CFR 216.3(a)(9), when ongoing programs are revised to incorporate a change in scope or nature, an IEE amendment will be prepared to identify and address all environmental impacts. Per ADS 204, it is the responsibility of the USAID A/COR to keep the BEO/REA and BEO informed of any new information or changes in the activity or environmental impacts, requiring revision of this environmental analysis and environmental determination.

ATTACHMENTS:

Annex 1: Climate Risk Management Table for Activities.
# ANNEX 1: CLIMATE RISK MANAGEMENT

## PROJECT CLIMATE RISK MANAGEMENT SUMMARY TABLE (DETAILED TABLE IN ANNEX 2)

<table>
<thead>
<tr>
<th>Defined or Anticipated Project Elements/Intervention Category</th>
<th>Climate Risks</th>
<th>Risk Rating</th>
<th>How Risks are Addressed at Project Level</th>
<th>Further Analysis and Actions for Activity Design/Implementation</th>
<th>Opportunities to Strengthen Climate Resilience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Partner Procurement of HIV Commodities Activity</td>
<td>Extreme weather events like hurricanes could cause water damage to commodities during shipping</td>
<td>Low</td>
<td>Ensure that commodities are properly handled, shipped and insured against water or temperature damage.</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Local Partner Warehousing and Distribution of HIV commodities Activity</td>
<td>Extreme weather events like heavy rains and floods could cause water damage to commodities in storage or in transit to health facilities.</td>
<td>Moderate</td>
<td>Ensure that commodities are properly stored, distributed and insured against water or temperature damage.</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>