Annual Program Statement (APS) for Medicines Quality Assurance Systems Strengthening Program (MQASSP)

APS Issuance Date:	**March 20, 2019**
APS Closing Date:	**March 19, 2020**
Question Due Date and Time:	**March 25, 2019, 3 p.m. EDT**
Closing Date and Time for Round 1 Concept Papers:	**April 22, 2019, 11 a.m. EDT**

Subject: Annual Program Statement (APS) Number: 7200AA19APS00004 for the Medicines Quality Assurance Systems Strengthening Program (MQASSP)

Dear Prospective Applicants:

The United States Agency for International Development (USAID) is seeking concept papers from qualified applicants for the **Medicines Quality Assurance Systems Strengthening Program (MQASSP)**. This Annual Program Statement (APS) publicizes the intention of the United States Government (USG), as represented by the United States Agency for International Development (USAID), Bureau for Global Health (GH), to obtain concept papers, full applications and issue awards to sustainably strengthen medical product quality assurance systems in low and middle-income countries (LMICs) including advancing global innovations in this area.

USAID anticipates requesting multiple Rounds of applications under this APS as follows:

Round 1: Promoting the Quality of Medicines Plus (PQM+) Program
Round 2: iMQA - Innovations for Medicines Quality Assurance
Round 3: iMQA - Innovations for Medicines Quality Assurance

USAID reserves the right to issue fewer or additional Rounds. This APS contains detailed instructions regarding Round 1. Any additional Rounds will be published through an amendment to this APS. Interested organizations should read the APS and follow the instructions for submitting a concept paper.

The APS and any future amendments can be downloaded from www.grants.gov. All interested parties are highly encouraged to register on www.grants.gov to receive automatic notification of amendments to this APS. It is the responsibility of the applicant to download the full APS document through the web page mentioned above. USAID bears no responsibility for data errors resulting from transmission or conversion processes. Any questions regarding this APS may be submitted to IHSIP@usaid.gov by the date and time specified in this cover letter.

This APS is issued under the Foreign Assistance Act of 1961, as amended. Awards under this

APS are subject to 2 CFR 200 and 2 CFR 700 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. The applicable Catalog of Federal Domestic Assistance (CFDA) Number for this effort is 98.001.

Issuance of this Notice does not constitute a binding commitment on the part of the Government to issue an award, nor does it commit the Government to pay for costs incurred in the preparation and submission of any concept papers, engagement, collaboration, co-creation, or full applications. USAID reserves the right to fund any or none of the applications submitted under this APS.

Sincerely,

Boryana Boncheva
Supervisory Agreement Officer
Office of Acquisition and Assistance
M/OAA/GH/GHI

TABLE OF CONTENTS

Medicines Quality Assurance Systems Strengthening Program (MQASSP) APS

SECTION A: PROGRAM DESCRIPTION

A.1 Statement of Purpose

The goal of the MQASSP APS is to sustainably strengthen medical product quality assurance systems in low- and middle-income countries (LMICs) including advancing global innovations in this area. The purpose of this APS is to publicize the USG's plan to fund one or multiple grants or cooperative agreements to address the goal of the APS.

The APS expected results include:

Objective 1: Governance for medical product quality assurance systems improved
Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved
Objective 3: Financial resources for medical product quality assurance optimized and increased
Objective 4: Supply of quality-assured essential medical products of public health importance increased
Objective 5: Global medical product quality assurance learning and operational agenda advanced

Any resultant awards will be issued under the authority of the Foreign Assistance Act of 1961, as amended) and will be subject to 2 CFR 200 and 2 CFR 700 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

Contingent upon availability of funds there may be multiple Rounds for this APS that will all aim to meet the Statement of Purpose mentioned above. Specifics for Round 1 are discussed in the following sections.

A.2 Round 1: Promoting the Quality of Medicines Plus (PQM+) Program

A.2.1 Technical Context

USAID's Office of Health Systems (OHS) works across the Agency's entire global health portfolio and provides technical leadership and direction in health systems strengthening. This includes the critical component of strengthening country systems to ensure the quality and safety of medical products (i.e., drugs, vaccines and other biologics, and devices) and protect against the harms of substandard[1] and falsified[2] medical products. USAID's approach is to ensure that its investments support sustainable local change and improve system performance in a way that facilitates country transition from reliance on donor aid and technical assistance.

[1] Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both. Approved during the Seventieth World Health Assembly; https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

[2] Medical products that deliberately/fraudulently misrepresent their identity, composition or source. Approved during the Seventieth World Health Assembly; https://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1

USAID's Vision for Health Systems Strengthening (https://www.usaid.gov/what-we-do/global-health/health-systems/usaids-vision-health-systems-strengthening) highlights the importance of strengthening health systems and provides guidance to achieve four strategic outcomes: financial protection, quality essential services, equitable population coverage, and responsiveness. According to USAID's Vision, "A health system is defined as consisting of all people, institutions, resources, and activities whose primary purpose is to promote, restore, and maintain health." Health systems strengthening (HSS) comprises the strategies, responses, and activities that are designed to sustainably improve health system performance. Strengthening a health system means working across and improving the six internationally-accepted and interrelated HSS functions: human resources for health; health finance; health governance; health information; medical products, vaccines, and technologies; and health service delivery. USAID focuses its HSS approach on integrated programs and projects that will help meet USAID's Global Health goals of Preventing Child and Maternal Deaths, Controlling the HIV/AIDS Epidemic, and Combating Infectious Diseases.

USAID's Vision includes priority objectives for each of the six HSS functions. Under the medical products, vaccines, and technologies function, these include: 1. Strengthen supply chain components to ensure the uninterrupted supply of quality-assured medical products; 2. Strengthen medical product regulatory capacity and pharmaceutical sector governance to promote transparency and accountability; and 3. Increase and enhance human and institutional capacity to manage pharmaceutical systems and services including ensuring efficacy, projecting patient safety, and combating antimicrobial resistance (AMR), all of which are affected by medical product quality.

A.2.2 Geographic Scope

This Award will work at the global level and will direct its efforts to USAID focus countries. USAID anticipates a need for medical product quality assurance systems strengthening in up to 55 countries prioritized under USAID's efforts for Preventing Child and Maternal Deaths, Controlling the HIV/AIDS Epidemic, and Combating Infectious Diseases. Responding to needs of non-priority countries will be assessed on a case-by-case basis. For a list of the 55 priority countries, please refer to page 4 of the USAID Global Health Report Brochure, available here: https://www.usaid.gov/sites/default/files/documents/1864/USAID-Global-Health-Report-Brochure-508.pdf.

A.2.3 Relationship to Other USAID Programs

This Award complements other USAID global health mechanisms working in health systems strengthening and specific areas of the medical products, vaccines, and technologies health system function. Related USAID mechanisms include:

- The **Medicines, Technologies, and Pharmaceutical Services** (MTaPS) Contract was awarded in September 2018 to Management Sciences for Health Inc. and their consortium, Boston University, FHI 360, International Law Institute Uganda—African, Center for Legal Excellence, the New Partnership for Africa's Development (NEPAD) Planning and Coordinating Agency, Overseas Strategic Consulting, Ltd., and Results for Development

(R4D). MTaPS is a 5-year contract. The MTaPS program is designed to provide technical assistance to LMICs to strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and other health technologies and medicines-related pharmaceutical services. MTaPS is a cross-cutting health systems project managed out of OHS. The program is expected to end in September 2023.

- The **Integrated Health Systems** (IHS) Indefinite Delivery, Indefinite Quantity (IDIQ) Contract was awarded in September 2018. Prime holders of the multiple-award IDIQ include Abt Associates Inc., Management Sciences for Health Inc., Palladium International LLC, University Research Co. LLC, and small businesses Banyan Global and EnCompass LLC. The purpose of IHS IDIQ is to work across four objectives -- increased financial protection, increased coverage to all populations, increased quality of essential health services, and improved responsiveness -- in an integrated way to advance country health systems development. Task orders under the IDIQ may be issued through 2023 and are expected to end by September 2025.

- The **Health Systems Strengthening Accelerator** (HSS Accelerator) Cooperative Agreement was awarded in September 2018 to Results for Development (R4D) to provide catalytic support to countries as they tackle health systems challenges and to accelerate progress toward self-sustaining health systems. The HSS Accelerator is focused on addressing issues that require multiple systems functions to act in concert; benefit from reformed institutional structures and processes at the system, district, or community level; and require consensus around best practices. The program is expected to end in September 2023.

- **Human Resources for Health 2030** (HRH2030) Cooperative Agreement was awarded in September 2015 to Chemonics International Inc. and works to improve the accessibility, availability, acceptability, and quality of the health workforce needed for countries to achieve expanded health coverage and to improve health outcomes by focusing on workforce performance and productivity, strengthened and expanded education systems, human resources for health management, leadership and governance, partnerships, and financing. The program is expected to end in September 2020.

- The **One Health Workforce (OHW)** Cooperative Agreement was awarded in November 2014 to the University of Minnesota. This project was designed to respond to recent and ongoing global health threats -- which have underscored a critical need for health workers that are prepared to manage diseases that cross human, animal, and environmental health sectors -- by promoting the use of innovative curricula and programs in classrooms, online, and in the field and by developing faculty capacities for One Health teaching and research. The OHW program is creating a workforce with the necessary multi-sectoral technical expertise and practical skills to address the threat of emerging infectious disease around the world. The program is expected to end in November 2019.

- The **Infectious Disease Detection and Surveillance** (IDDS) Cooperative Agreement was awarded in May 2018 to ICF International, Inc. (ICF). ICF leads the program's consortium: FHI360, PATH, Metabiota, Abt Associates, the African Society for Laboratory Medicine,

and Gryphon Scientific. Collectively, the team brings a suite of adaptable tools, approaches, and lessons learned from successful projects worldwide to strengthen diagnostic networks, establish integrated disease surveillance, conduct implementation research, foster health innovations, and build resilient, locally owned health systems. The program is designed to operationalize global and U.S. Government initiatives and strategies to reduce global health threats posed by infectious diseases, focusing on strengthening of disease detection networks and surveillance systems, including One Health networks to address zoonotic other infectious disease priorities including AMR. The program is expected to end in May 2023.

- The **Global Health Supply Chain** (GHSC) Program is a suite of awards designed to increase the availability of quality-assured public health medicines. USAID considers PQM+ a part of the GHSC Program, which in addition to PQM+ and MTaPS, includes the following awards:

    - The **Global Health Supply Chain Quality Assurance** (GHSC-QA) Contract was awarded in January 2015 to FHI360 and serves as the primary vehicle through which USAID assures the quality of health commodities procured with USAID funding in support of USAID global health programs by implementing an overarching quality-assurance (QA) program and risk-based quality-control strategy. FHI360 capitalizes on relationships with international stakeholders and also provides short term technical assistance to Missions related to strengthening the QA system in-country through the GHSC-QA Contract. The GHSC-QA Contract is scheduled to end in January 2020.

    - The **Global Health Supply Chain Procurement and Supply Management** (GHSC-PSM) single-award IDIQ Contract was awarded in April 2015 to Chemonics International Inc. The purpose of the GHSC-PSM IDIQ is to ensure uninterrupted supply of medical products to prevent suffering, save lives, and strengthen supply chain systems in LMICs. The following task orders were awarded under the IDIQ: Task Order 1 for HIV/AIDS (1/11/2016 - 11/28/2020), Task Order 2 for Malaria (4/1/2015 - 4/30/2020), Task Order 3 for Population and Reproductive Health (PRH, 4/20/2015 - 11/28/2020), Task Order 4 for Maternal, Newborn, and Child Health (MNCH, 9/16/2016 - 9/15/2021), and Task Order 5 from the USAID Kenya Mission (9/30/2016-9/29/2021). Task orders under the IDIQ may be issued through 2020 and are expected to end by April 2023.

    - The **Global Health Supply Chain Rapid Test Kits** (GHSC-RTK) Contract was awarded in February 2015 as a small business set aside to Remote Medical International (RMI) and serves as the singular means of procuring HIV Rapid Test Kits (RTKs) within the GHSC Program. The primary objective of this Contract is to ensure the availability of approved HIV RTKs using a global procurement strategy. The project is expected to end in February 2020.

    - The **Global Health Supply Chain Technical Assistance** (GHSC-TA) multiple-award IDIQ was awarded in March 2015 with a five-year base period of performance and joint ceiling of $500 million. There are four prime IDIQ holders: Axios International, Inc. (small business), Chemonics International Inc., Logistics Management Institute (LMI), and Guidehouse (formerly PricewaterhouseCoopers).

These awards aim to strengthen country management of medical products, providing technical assistance to ensure the long-term availability of medical products in public and private health services worldwide. These awards serve all health elements (HIV, family planning, malaria, maternal and child health and nutrition (MCHN), tuberculosis (TB), etc.). The following five task orders have been awarded under the GHSC-TA project: a Tanzania Task Order (6/10/16 - 6/9/2021), South Africa Task Order (10/1/2016 - 9/30/2021), Côte d'Ivoire Task Order (2/28/2017 - 3/1/2022), Francophone Task Order (2/8/2017 - 2/7/2022) and a National Supply Chain Assessment Task Order (7/19/2016 - 7/18/2019).

- The **Global Health Supply Chain Business Intelligence & Analytics** (GHSC-BI&A) Contract was awarded in May 2014 to Intellicog. This Contract serves as a primary vehicle through which USAID houses GHSC Program data, performs analysis, and understands data trends. In addition, dashboards and data visualizations are created that show trends at the global and country levels. The data collected is harmonized across supply chain contractors to ensure the programs run seamlessly. The project is scheduled to end in April 2019, after which data collection, storage and analysis for the GHSC program will continue through Digital Square, a Cooperative Agreement with PATH. As a global public good within Digital Square, supply chain data will be used to build greater collaboration both within USG and externally with other global donors and country stakeholders.

- The **Global Health Supply Chain Project Last Mile** (GHSC-PLM) was awarded in June 2014 to an alliance between USAID, the Coca-Cola Company, the Coca-Cola Foundation, the Global Fund to Fight AIDS Tuberculosis and Malaria (GFATM), the Global Environment and Technology Foundation (GETF), and the Bill and Melinda Gates Foundation. The objective of GHSC-PLM is to improve the delivery of medicines in developing country markets and, in particular, to those citizens residing in and around the last mile of the medical product supply chain by leveraging Coca-Cola's business intelligence in supply chain and marketing. The project is expected to end in June 2019.

PQM+ is a follow-on mechanism to the **Promoting the Quality of Medicines (PQM) Program.** PQM was awarded in September 2009 with a performance period through September 2019 and implemented by the U.S. Pharmacopeial Convention (USP) to help assure the quality and safety of priority medicines by strengthening medical product quality assurance systems in developing countries. As one of USAID's key responses to the proliferation of poor quality medical products in LMICs, PQM's technical mandate focuses on strengthening national medicines regulatory capacity for medical product quality assurance; supporting international pre-qualification schemes and selected pharmaceutical manufacturers to increase the supply of quality-assured essential medical products of public health priority; strengthening drug quality control laboratories and systems to monitor the quality of medical products in the national marketplace; and advocating for the importance of medical product quality assurance as well as the need for greater investments in this critical area. PQM partners with regional and national regulatory authorities, national quality control laboratories, academic institutions, and other international organizations to strengthen local capacity to carry out key quality assurance functions, including

medical product registration, inspections of medicine producers and distributors, and post-marketing surveillance. See hyperlink: http://www.usp-pqm.org/.

USAID has a vast array of programs outside of the Bureau for Global Health including in areas related to MQASSP such as economic growth, public financial management, customs reform, and engagement of local organizations.

A.2.4 Guiding Principles

Utilize a systems strengthening approach that considers the five health systems functions (governance, human resources, information, financing, and service delivery) as they relate to the sixth function: medical products, vaccines, and technologies, specifically within the context of quality assurance systems strengthening. By considering all health systems functions (not just medical products) and their interactions with each other within the country context, there is increased likelihood that improvements in medical product quality assurance systems performance will be sustained and country systems made more self-reliant.

Build on and strengthen existing systems. When and where appropriate, build on existing systems/processes and customize tools and approaches for strengthening medical product quality assurance to improve buy-in and acceptance from local governments and counterparts, the potential for sustainability, the scalability of health programs, and cost effectiveness from both a financial and human resource capacity perspective. LMICs are not homogeneous and are in various stages of development. USAID expects the applicant to adapt proposed tools and approaches to enhance existing systems, taking into account current capabilities and local and regional contexts. This will include \integration of the private sector into the development of locally-relevant strategies for strengthening medical product quality assurance systems, including regulatory capacity development.

Support integration, where programmatically feasible, across disease-specific programs (e.g., routine post-marketing surveillance systems for product quality), medical product quality assurance systems actors and functions (e.g., addressing fragmentation of regulatory quality assurance responsibilities), and inclusion of medical product quality considerations in procurement, storage, distribution, recall, and national AMR action plans, particularly in the context of country efforts to expand health coverage.

Support country-led coordination and ownership by working with partner country governments and other stakeholders including civil society, industry and professional associations, and private sector to dialogue effectively with each other and with donors, cooperating agencies, etc. on national health priorities, proposed solutions and strategies, and resource requirements. This may include stakeholder and donor mapping in addressing the medical product quality assurance systems strengthening needs, supporting collaborative work planning, and contributing to country-led coordination efforts (e.g., as informed by the World Health Organization (WHO) Global Benchmarking Tool[3] (GBT) for regulatory systems assessment and institutional development planning).

[3] https://www.who.int/medicines/regulation/benchmarking_tool/en/

Strengthen the capacity of local organizations/institutions/entities and mechanisms for their engagement to address sustainability of medical product quality assurance systems. Priority will be given to identifying promising organizations (e.g., educational institutions and professional associations and networks) and strengthening their governance, technical competence, financial systems, and monitoring and evaluation capabilities. In addition, although many operations within medical product quality assurance systems are inherently governmental, the applicant should seek opportunities to strengthen local non-governmental and non-state actors (e.g., that provide assistance with good manufacturing practices) where relevant. USAID expects the applicant to assess and employ proven and innovative methodologies to capacitate local and regional entities (e.g., regional regulatory harmonization initiatives) in medical product quality assurance, with a particular focus on establishing mechanisms for south-to-south capacity building, information sharing, and engagement opportunities. USAID also anticipates the use of transition awards as relevant, allowing Missions to issue direct awards to local organizations subsequent to PQM+ as described in ADS 303.3.6.5.b(3).

Prioritize and optimize allocation and use of resources. The applicant should consider every opportunity to analyze and strengthen medical product quality assurance systems leading to more optimal configurations (e.g., of regulatory systems) that reduce waste and increase efficiency in the allocation and use of resources. The applicant should assist stakeholders to improve their processes for conducting cost-benefit analyses and considering alternatives to inform investment decisions (e.g., decisions around procurement of lab equipment, sampling and testing protocols). Sub-objective 3.1, as reflected in the Program Description, focuses on this area in particular; however, it is also a guiding principle of PQM+ given its critical importance in achieving the overall goal and objectives of the program.

Develop strategic partnerships with and enabling environment for USG, international, and regional stakeholder engagement. In addition to country actors, multiple regional and international stakeholders are engaged in helping to assure the quality of medical products and combat substandard and falsified products. This is a result of increased global awareness and recognition that quality-assured, safe, and effective medical products are essential to achieve health outcomes. USAID expects the applicant to incorporate USAID's Private Sector Engagement Policy and leverage investments with other donors, the private sector, and other initiatives. Strategic partnerships should be fostered and information shared with USG entities and international and regional stakeholders to ensure that efforts are coordinated and approaches harmonized.

Provide global technical leadership, including advocating for the use of proven tools and interventions and facilitating coordination, dialogue, and consensus among donors, multilateral organizations, global initiatives, and other public and private stakeholders to advance the state-of-the-art in medical product quality assurance systems strengthening. Objective 5 focuses on this area in particular; however, it is also a guiding principle of PQM+ given its critical importance in achieving the overall program goal and objectives.

A.2.5 Program Description

Recognized by the international health community as a critical barrier to the achievement of desired health outcomes, substandard and falsified medical products can cause treatment failure and adverse events, increase morbidity and mortality, and contribute to the more rapid emergence and spread of AMR to existing and new therapies. In addition to representing a significant public health threat, these poor quality medical products waste scarce resources, undercut the market for pharmaceutical manufacturers of quality-assured medical products, erode the public's confidence in the health system, and risk undermining past, current, and future investments.

Good quality medical products contribute to improving not only health but also productivity, economic growth, and social stability – all outcomes consistent with the development goals of USAID. For example, the availability of quality-assured medical products plays a critical role in building well-governed states, in so far as quality-assured medical products promote trust and participation in health services, which in turn promote trust in government.

The USG and other donors make considerable investments to assure the quality of medical products donated to country health programs. However, the quality of medical products manufactured locally or imported into partner countries also has serious impact on country health systems and for the success of USG-supported programs. Substandard and falsified medical products represent a threat to public health worldwide but pose a particular problem in developing countries. To a large extent, this is due to the fact that most developing countries do not have the technical, human, institutional, and financial capacity to fully regulate their pharmaceutical markets and protect their supply chains. Fewer than one third of WHO member states have well-functioning and integrated medical product regulatory systems, a fraction of which are in LMICs.[4] According to the WHO, "Weak regulatory capacity limits the ability of national regulatory agencies to ensure the quality, safety and efficacy of medicines and vaccines and regulate new products [... and] creates a risk that poor-quality or substandard and falsified medical products enter markets."[5]

Although USAID has been involved in the field of medical product quality assurance systems strengthening since the mid-2000s, significant challenges that are inimical to public health persist. Some of those challenges stem from systemic limitations in implementing needed interventions to assure the quality and safety of essential medical products on a sustainable basis. Even though USAID has been successful in supporting and in initiating progress toward institutionalization of solutions and incorporation of best practices into country medical product quality assurance systems, these systems are less than resilient and available funding is less than adequate to address the challenges at hand.

As such, PQM+ is not simply a continuation of the current PQM program. It represents an enhancement in programming for medical product quality assurance systems strengthening particularly as countries embark on their journey to self-reliance. Reflecting the high-level concern regarding the increased evidence of substandard and falsified medical products in

[4] http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf
[5] http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf

LMICs, PQM+ is designed to work across five interrelated and complementary objectives to facilitate increased technical leadership and global advocacy, collaboration with international partners, and provision of support to integrate and strengthen country medical product quality assurance systems.

The goal of PQM+ (Round 1 under the MQASSP APS) is to sustainably strengthen medical product quality assurance systems in LMICs. To achieve this goal, the application of good governance principles to the legal, policy and regulatory functions must be strengthened; the capacity of country and regional institutions and stakeholders needs to be improved to support regular, in-country quality assurance activities; medical product quality assurance efforts need to be supported by optimized information systems and financial and human resources in both the public and private sectors; limited health resources must be generated, invested, and used efficiently; and evidence-based approaches that build on existing health systems and integrate current and future health sector goals and reforms must be developed and applied, advancing the global medical product quality assurance systems strengthening learning, policy, and operational agenda.

Supporting the achievement of the goal for Round 1 are five Objectives and related Sub-objectives, which are pictured and described below.

PQM+ Results Framework

Goal: Sustainably strengthen medical product quality assurance systems in LMICs				
Objective 1 Governance for medical product quality assurance systems improved	**Objective 2** Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved	**Objective 3** Financial resources for medical product quality assurance optimized and increased	**Objective 4** Supply of quality-assured essential medical products of public health importance increased	**Objective 5** Global medical product quality assurance learning and operational agenda advanced
Sub Obj 1.1 Evidence-based medical product quality assurance legislation, policies, and regulations developed/updated and/or implemented	**Sub Obj 2.1** Sustainable systems for market authorization/registration, inspection, and licensing functions of medical product regulatory agencies improved	**Sub Obj 3.1** Allocation and use of investments for medical product quality assurance systems strengthening optimized	**Sub Obj 4.1** Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/dossiers supported	**Sub Obj 5.1** Evidence-based approaches and tools developed and/or applied

Sub Obj 1.2 Systems that facilitate transparency and accountability promoted	**Sub Obj 2.2** Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened	**Sub Obj 3.2** Sustainable resources mobilized	**Sub Obj 4.2** Capacity to conduct bioequivalence studies for dossier submissions strengthened	**Sub Obj 5.2** Research and analysis to support medical product quality assurance systems strengthening conducted
Sub Obj 1.3 Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted	**Sub Obj 2.3** Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported		**Sub Obj 4.3** Capacity for market intelligence and analytics of public health pharmaceutical markets increased	**Sub Obj 5.3** Advocacy on the importance of medical product quality assurance for public health, including the link between medical product quality and antimicrobial resistance supported
Sub Obj 1.4 Links among the medical product quality assurance systems and other sectors developed and fortified	**Sub Obj 2.4** Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported		**Sub Obj 4.4** Health coverage schemes that incorporate medical product quality requirements supported	
	Sub Obj 2.5 Competence, efficiency, and expansion of the medical product quality assurance workforce improved		**Sub Obj 4.5** Monograph development and use supported	

Objective 1: Governance for medical product quality assurance systems improved

Governance is defined as the process of decision-making and the process by which decisions are implemented and is identified by the WHO as the most critical of the six functions of a health system.[6] Improving governance in health systems through the development and implementation

[6] https://www.who.int/healthsystems/strategy/everybodys_business.pdf

of effective governance frameworks (e.g., laws, policies, regulations, guidelines, standard operating procedures (SOPs), clarity regarding roles and responsibilities) and application of good governance principles (e.g., transparency, accountability, and participation) strengthens the foundation and basic structure of medical product quality assurance systems. These improvements are associated with more effective information sharing, integration, communication, and relationships among stakeholders, including donors and host-country counterparts, suppliers and clients, and providers and patients[7] and have been demonstrated to positively impact health outcomes. [8]

Sub Obj 1.1. Evidence-based medical product quality assurance legislation, policies, and regulations developed/updated and/or implemented

Country medical product quality assurance systems, in particular regulatory systems, require that roles, responsibilities, and relationships be specified in laws, policies, regulations, and SOPs to articulate lines of authority and relationships. Legislation supports implementation of national medicines policies and includes provision for the establishment of national regulatory agencies responsible for assuring that only medical products meeting acceptable standards of quality, safety, and efficacy are registered and available in a country. Many countries lack adequate regulation regarding manufacturing of medical products (including medical devices and biologics), clinical trial oversight, and post-marketing surveillance to monitor product quality and safety. Medical product quality assurance is a complex domain that brings to the fore political sensitivities among national policy makers and also directly affects economic interests. Governance structures supporting medical product quality assurance systems must be flexible to adapt to contextual changes such as increased volume of local production, development of relationships with regional economic communities, introduction of new medicines and other health technologies, and need for multi-sectoral collaboration to combat criminal activities related to falsified medical products and to address the product quality drivers of AMR. **The applicant should** work with host country and regional stakeholders to identify and undertake needed legal, policy, regulatory, and other governance reforms in the medical product quality assurance arena.

Sub Obj 1.2. Systems that facilitate transparency and accountability promoted

The high value of medicines and other health technologies combined with the absence of transparency and data visibility make pharmaceutical systems particularly vulnerable to problems associated with weak governance, including lack of accountability, leading to health systems resource leakage (e.g., through waste, corruption, and fraud). Efforts of countries and international stakeholders to combat substandard and falsified medical products will continue to be hindered if data on the true extent of the problem are not available.[9,10] Poor governance can occur within medical product quality assurance operations (e.g., product registration/pre-marketing authorization, procurement/payment decisions that fail to account for quality, product

[7] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67659/How-to-Note-corruption-health.pdf
[8] https://www.imf.org/external/pubs/ft/wp/2000/wp00116.pdf
[9] https://www.who.int/alliance-hpsr/resources/FR_webfinal_v1.pdf
[10] https://www.nap.edu/catalog/18272/countering-the-problem-of-falsified-and-substandard-drugs

quality testing decisions and information sharing) and in the legislation and regulation of medical products.

Opportunities for mismanagement and abuse increase in the absence of transparent and accountable systems, for example, when policies are not coherent and/or enforced, roles and responsibilities are ill-defined, when conflicting interests are not addressed, and information is not made available. Improved SOPs provide clarity regarding roles and responsibilities and support the implementation of laws, policies, regulations, and guidelines. This, together with the generation, accessibility, and use of high-quality information by relevant stakeholders, ensures transparency, allows for responsible oversight and accountability, and for appropriate legal action to be taken. Further, to be effective, laws and regulations should also set out legal sanctions that allow for transparent and appropriate enforcement actions.
The applicant should support countries to increase transparency and accountability throughout medical product quality assurance systems, including structures for data collection and dissemination and mechanisms for oversight and enforcement, particularly as interventions are designed and implemented. **The applicant should** also support transparency to help ensure that the actions of governments, management boards, oversight committees, and the like are recorded and publicly available **and should** support public-private dialogue on product quality assurance systems between regulators and industry.

Sub Obj 1.3. Fragmentation addressed and coordination across entities (public and private) with medical product quality assurance responsibilities promoted

Because of the way they have historically evolved, many LMIC medical product quality assurance systems have diffuse mandates across a spectrum of entities creating fragmentation. For example, regulatory system quality assurance operations do not operate in an integrated and coherent fashion. This creates inefficiencies, wastes resources, generates delays and bottlenecks, presents opportunities for poor decisions and malfeasance, and ultimately causes regulators and others to be ineffective in protecting the public health. **The applicant should** assist in addressing fragmentation within the medical product quality assurance systems by supporting country stakeholders to develop and execute integrated system improvement plans. **This should** be accomplished in coordination with international stakeholders including through the use of the WHO Global Benchmarking Tool.

Sub Obj 1.4. Links among the medical product quality assurance systems and other sectors developed and fortified

Regulators and other stakeholders in the medical product quality assurance systems are challenged to collaborate with other sectors including law enforcement, education, customs (e.g., ensuring only registered medical products enter the country and that customs procedures do not compromise product quality), finance (e.g., budget allocations, public financial management, tax incentives), agriculture (e.g., quality-assurance of products for use in animals), and economic development (e.g., pharmaceutical industrial development plans, business enabling environment). To the latter, LMICs are making substantial investments in the growth of their pharmaceutical industries (e.g., in the context of the African Union's Pharmaceutical Manufacturing Plan for Africa), requiring intervention both within and external to medical

product quality assurance systems.

The applicant should identify opportunities to support stakeholders in the medical product quality assurance system to effectively engage with other sectors. Interventions should consider both technical requirements related to medical product quality assurance as well as their relationship to other sector development goals (e.g., development of a Good Manufacturing Practices (GMP) roadmap in line with economic industrial development plans).

NOTE: While USAID has identified this Sub-objective as an area of importance, the applicant should limit activities to those that directly further the achievement of the program goal and objectives and that are determined in close consultation with USAID Mission, USAID/Washington health elements, and Agreement Officer's Representative (AOR) staff. For example, PQM+ is not intended to work directly on comprehensive customs, tax, law enforcement, and economic development reform.

Objective 2: Country and regional regulatory systems to assure the quality of medical products in the public and private sectors improved

A key obstacle to assuring the quality of medical products and combating substandard and falsified products is the lack of institutional, financial, technical, and human resources among medicines regulatory authorities in developing countries. In a WHO assessment of 26 LMIC regulatory authorities, a common weakness observed included "a fragmented legal basis in need of consolidation, weak management structures and processes, and a severe lack of staff and resources"[11]. Medical product quality assurance worldwide depends on the capability of the regulatory system in each country to safeguard the quality, safety, and efficacy of the medical products in the public and private sectors and protect the public health. Country medical product regulatory systems are responsible for registration, licensing, inspection, post-marketing surveillance, pharmacovigilance, advertising and promotion control, and clinical trial oversight, thereby ensuring the quality, safety, and efficacy of medical products that are allowed to enter and circulate within national markets. While the supply of substandard and falsified medical products is a global challenge, "the populations most vulnerable are those in countries who do not have the facilities or the regulatory authorities to regulate and police the drug supply"[12].

Countries often lack information about their regulatory system capacity and a strategic institutional development plan to address deficiencies. The WHO Global Benchmarking Tool is the current standard for assessing the maturity of regulatory systems in USAID-supported countries. The GBT process facilitates coordinated, complementary efforts of donors and partner governments to support a single institutional development plan, therein avoiding duplication of effort and leveraging available resources. USAID works in concert with the WHO, World Bank, Bill & Melinda Gates Foundation, NEPAD, and others to facilitate LMIC regulatory systems strengthening, including through support for the GBT. PQM+ should engage in such efforts.

NOTE: It is not intended for the applicant to work comprehensively on improving pharmacovigilance (PV) systems, except for components directly related to medical product

[11] http://apps.who.int/medicinedocs/en/m/abstract/Js17577en/
[12] https://www.ndm.ox.ac.uk/paul-newton-poor-quality-medicines

quality (e.g., ability of PV system to identify product quality problems as a suspected cause of adverse drug reactions). This technical area is covered by other USAID global health projects (such as MTaPS).

Sub Obj 2.1. Sustainable systems for market authorization/registration, inspection, and licensing functions of medical product regulatory agencies improved

Countries require support to strengthen the medical product quality assurance components of national medicines regulatory systems, specifically market authorization/registration, inspection, and licensing, as well as quality components related to pharmacovigilance and clinical trial oversight. **The applicant should** support countries to strengthen medical product quality assurance-related aspects including in registration of medical products, licensing decisions, pharmacovigilance, and inspection capability to ensure compliance with GMPs, Good Laboratory Practices (GLPs), Good Clinical Practices (GCP) etc. to assure the quality of medical products.

Sub Obj 2.2. Sustainable post-marketing surveillance systems and medical product quality control laboratory capacity strengthened

Regulatory systems in many USAID-supported countries are handicapped by vertical, donor-dependent, fragmented, and/or under-resourced post-marketing surveillance and laboratory systems. Surveilling for the quality of medical products on the market is an essential function of a regulatory system both within the public and private sectors among donated, imported, and locally-produced products, from the manufacturing facility and to point of use. **The applicant should** support countries to develop sustainable, integrated post-marketing surveillance systems to routinely monitor for substandard and falsified medical products and enable appropriate and effective regulatory action against these products.

A fully functional medicines regulatory system includes quality testing capabilities both for initial screening and for advanced laboratory testing to detect substandard and falsified products. The use of screening technologies provides an initial indication about the quality of products and flags potential problems requiring confirmatory product testing. Compendial testing in laboratories that are ISO 17025 accredited and/or WHO prequalified meet international standards and provide results about product quality that are reliable and can be used as the basis for regulatory actions. **The applicant should** assist countries to develop appropriate, integrated screening and laboratory testing scheme(s) to support both pre-marketing authorization and post-marketing surveillance that meet international standards and are operationally and financially sustainable.

As an intermediate step toward sustainable post-marketing surveillance, **the applicant should** be available to support monitoring the quality of specific medical products such as for disease control programs on a short-term basis to demonstrate and raise awareness of quality issues where they exist and make the case for routine post-marketing surveillance including all product categories. This may include product quality testing on an ad hoc basis (e.g., within a particular locality, national disease program, or specific product category such as those for use in animals). However, the applicant should note that USAID employs other mechanisms to routinely test for

the quality of products donated by USAID to host countries and it is not intended for PQM+ to engage in quality testing for such purposes.

Sub Obj 2.3. Regional harmonization to strengthen medical product quality assurance regulatory capacity and networks supported

WHO and others recognize that LMIC medical product regulatory systems operate in perpetually under-resourced environments and require prioritization of resources and innovative solutions to ensure they can meet their public health mandate. Regional harmonization and/or convergence of regulatory requirements (e.g., model laws, common technical documents) and coordination of regulatory processes (e.g., joint dossier reviews, regional post-marketing quality surveillance, GMP inspections) among countries are approach to improving regulatory capacity and efficiency. This can speed the introduction of quality-assured, safe, and effective medical products, thereby promoting greater access. An example of this is the NEPAD African Medicines Regulatory Harmonization (AMRH) initiative. Further, professional networks -- such as the PQM-supported Network of Official Medicines Control Laboratories (NOMCoL) in Africa, now known as the African Medicines Quality Forum (AMQF) operated through AMRH -- can facilitate south-to-south information sharing, capacity building, and dissemination of best practices. **The applicant should** support regional regulatory harmonization/convergence efforts and professional networks. This may include providing support to countries for the joint registration of medical products, for example through the WHO Collaborative Registration Procedure.[13]

Within the area of medical product quality assurance, countries are additionally challenged to tackle the movement of poor quality products (e.g., unregistered, substandard, falsified) across borders. **The applicant should** support countries to share standardized information on substandard and falsified products, rely on/use information from other countries for appropriate regulatory actions, and collaborate with regional and/or international efforts such as the WHO Global Surveillance and Monitoring System.

Sub Obj 2.4. Adoption of data standards and integrated information systems to support regulatory medical product quality assurance functions supported

Fragmented information systems generate data that is not connected, coherent, and/or interoperable, and is not standardized. The information flow does not enable decision making that is evidence-based, transparent, and accountable and inhibits the efficiency of operations. Even when there is adoption of international standards, they are not necessarily implemented. For country regulatory information management systems to be effective, adoption of and compliance with international standards is required. Such information systems support the mutual reliance of various actors within the regulatory system as well as between country regulators. **The applicant should** promote the linkage and interoperability of regulatory and other quality assurance-related information systems, allowing for information sharing, data aggregation, coordination of efforts, work sharing, and improved regulatory practices.

[13] https://extranet.who.int/prequal/content/collaborative-registration-faster-registration

Sub Obj 2.5. Competence, efficiency, and expansion of the medical product quality assurance workforce improved

The country medical product quality assurance system requires an adequate number of skilled staff capable of managing the key functions of the regulatory system, as well as other pharmaceutical workforce with medical product quality assurance requirements (e.g., those that work in manufacturing, procurement, and supply chain). The pharmaceutical workforce, including quality assurance professionals (e.g., regulatory affairs professionals, quality control specialists, and laboratory personnel), is a critical part of the health system but is frequently overlooked, including in health sector workforce strategic planning. Training programs within educational institutions may be deficient and not linked to workforce demand and to operational needs of the regulatory system. **The applicant should** seek opportunities for sustainably raising the competence and efficiency of quality control, regulatory, and laboratory personnel. **The applicant should** seek to work with educational and training institutions to sustainably improve their capability and/or undertake reforms to produce a qualified workforce to address the needs of the country medical product quality assurance systems. **The applicant should** engage with professional associations and/or accreditation efforts to establish appropriate standards of practice and continuing education programs. **The applicant should** support government and industry to design and operationalize effective human resource practices and training programs.

Objective 3: Financial resources for medical product quality assurance optimized and increased

In addition to presenting a substantial risk to public health, including contributing to the emergence and spread of AMR, poor quality medical products represent a major waste of scarce health resources. WHO cites the use of substandard and falsified medical products as one of the leading sources of inefficiency in health systems due to inadequate pharmaceutical regulatory structures/mechanisms and weak procurement systems.[14] Significant resources are wasted in LMICs on inefficient and poorly-defined medical product quality assurance operations, which also are chronically underfunded and understaffed. As countries move to expand coverage of essential health services as part of their commitments toward meeting the U.N. Sustainable Development Goals (SDGs), addressing the challenge of mobilizing sustainable domestic resources -- balanced with foreign assistance -- and optimizing the allocation and use of such resources for the strengthening of regulatory systems and other quality assurance-related practices is critical.

Sub Obj 3.1. Allocation and use of investments for medical product quality assurance systems strengthening optimized

A country's effective and efficient allocation and use of existing (and new) resources for medical product quality assurance significantly influences its ability to increase access to life-saving, quality-assured medical products and address challenges in markets that are flooded with harmful substandard and falsified medical products. Although better policies and regulations are needed in many country contexts (Obj 1), an equal if not greater need in many countries is more resource-efficient, well-defined, and streamlined processes, procedures, and systems (Obj 2) to

[14] https://www.who.int/whr/2010/10_chap4_tab01_en.pdf

support the effective and efficient allocation and use of resources that are already available. Regional regulatory harmonization (SO 2.3) can play an important role in furthering this goal, by allowing medicines regulators to rely on each other's work and avoid duplication of effort, as no country has the financial and human resources to carry-out all regulatory functions effectively.

The applicant should seek to strengthen medical product quality assurance systems such that waste is reduced and efficiencies are introduced in the allocation and use of resources for medical product quality assurance operations, and that cost-savings are reinvested in the quality assurance systems. **This should** include support to countries for analysis of investments (e.g., costing of medical product quality assurance operations within laboratory, market authorization/approval, licensing, and surveillance units), use of risk-based approaches to inform and prioritize medical product quality assurance systems improvements in line with internally-accepted best practices (e.g., as identified through implementation of the WHO GBT), and consideration of reliance and work sharing through regional harmonization efforts.

Sub Obj 3.2. Sustainable resources mobilized

As countries progress on their path to self-reliance and as donor assistance declines, health systems are increasingly faced with competing priorities for resources. Health sector managers require the capacity to conduct evidence-based analyses and rationale to support increased allocation of domestic resources. Through these analyses and advocacy efforts, countries will be able to demonstrate value-for-money and the public health impact of investments in medical product quality assurance, including the health and monetary costs to the public and private sectors of inaction. **The applicant should** support country medical product quality assurance stakeholders to draw upon international experience and best practices to increase domestic resource mobilization (e.g., regular budget allocations) and introduce appropriate cost-recovery approaches that are reinvested in the quality assurance systems (e.g., product application fees, drug quality laboratory testing fees).

Despite historic investments of donors and other international agencies in improving the availability of quality-assured medical products for disease-specific programs, relatively fewer investments have been made to strengthen integrated country medical product quality assurance systems that impact the entire health system. Additionally, there has been a lack of coordination among donors, international agencies, and country stakeholders and poor alignment with country priorities about investment decisions. **The applicant should** support countries to coordinate and leverage donor investments that ultimately lead to the sustainable mobilization of domestic resources rather than creating donor dependency. In keeping with the above, **the applicant should** also advocate for increased funding opportunities and develop the capacity of country stakeholders to solicit funding from multilateral initiatives.

Objective 4: Supply of quality-assured essential medical products of public health importance increased

Global medical product shortages exist for priority health programs, especially those that have small, commercially unattractive markets (e.g., second-line TB medicines) or high-volume, low value markets (e.g., certain MCHN or neglected tropical disease (NTD) products) despite being critical medical products for saving lives in LMICs. Targeted interventions to address these issues are covered in the sub-objectives below.

Sub Obj 4.1. Pharmaceutical manufacturers for Good Manufacturing Practices (GMP) and medical product regulatory submissions/dossiers supported

Various factors influence whether pharmaceutical manufacturers produce quality-assured essential medical products for domestic and global markets. This includes their technical capacity and incentive to: adhere to local and international GMPs, submit market authorization applications ("dossiers") to regulatory authorities and/or pre-qualification programs, and adhere to international quality standards above and beyond domestic requirements such that their products can be procured by on the global market and/or by international agencies. The WHO Prequalification Program is considered a standard for prequalification of some, but not all, priority medical products by many international agencies and requires manufacturers to meet defined standards of acceptable quality, safety, and efficacy for their products to be become prequalified. **The applicant should** support selected pharmaceutical manufacturers to comply with GMPs as defined within the national context and internationally-accepted standards. **The applicant should** also provide assistance in the preparation of dossiers required for national registration and/or pre-qualification at the international level for essential medicines and health technologies for country health systems and of priority to USAID health programs.

Sub Obj 4.2. Capacity to conduct bioequivalence studies for dossier submissions strengthened

To obtain market authorization, including in LMICs, bioequivalence studies to demonstrate therapeutic equivalence for generic products are frequently required. Pharmaceutical manufacturers that supply LMIC markets may conduct these studies themselves or use contract research organizations (CROs) (i.e., clinical research organizations) to conduct them on their behalf; these studies need to follow GCPs and GLPs as defined by countries and by international bodies (e.g., to achieve WHO prequalification). CROs may also be required to be licensed and their studies may need to be approved by the national medicines regulatory authority. Because bioequivalence studies only approximate larger clinical trials conducted on the innovator product that established safety and efficacy, it is critical that bioequivalence studies are conducted appropriately and their results are reliable,[15] whether by a CRO or the manufacturer itself. This is particularly needed in LMIC settings with limited regulatory capacity including in the area of clinical trial oversight. In conjunction with support to manufacturers under SO 4.1, **the applicant should** improve capacity to conduct bioequivalence studies where relevant for priority health products.

[15] https://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex09.pdf?ua=1

Sub Obj 4.3. Capacity for market intelligence and analytics of public health pharmaceutical markets increased

A number of USAID-priority countries are developing local pharmaceutical industries with two main aims: public health security and economic growth. These manufacturers face challenges both reaching country and international quality standards as well as competing in the local and global pharmaceutical market. This is compounded when markets for quality-assured medical products are undercut by substandard and falsified medical products. Key elements that would support a stronger local pharmaceutical industry include improved regulatory systems that consistently demand quality products, business intelligence (including market opportunity analysis), and market analytics that identify the production steps that are achievable and profitable. In conjunction with support for dialogue between regulators and industry stakeholders under Sub-Objective 1.2, **the applicant should** work with manufacturers and/or regulators to understand the local and global market potential for priority medical product(s), identify any market barriers that exist, and identify potential solutions using relevant models that meet international best-practices.

Sub Obj 4.4. Health coverage schemes that incorporate medical product quality requirements supported

As countries move to expand health coverage schemes, including through Universal Health Coverage, as part of their commitment to achieve the SDGs, health systems experience pressures (both positively and negatively) that impact the quality of health products required for essential health services. Sustainability of the health benefits package, including the medicines benefits package, requires policy instruments and priority-setting strategies in the health benefits package design, implementation, monitoring, and evaluation processes to provide the maximum value for the covered population, given the available financial resources. This is especially true when determining which medical products should be included or excluded from the package, since inclusion of medical products without quality assurance requirements can result in poor health outcomes and high costs to the individual and the system (e.g., due to treatment failure, other side effects, and the need to switch to more expensive products). **The applicant should** support countries to strengthen their decision-making processes and methods such that health coverage schemes, including health benefit package design, implementation, monitoring and evaluation policies and processes, incorporate medical product quality requirements as relevant.

Sub Obj 4.5. Monograph development and use supported

Countries and the majority of USAID health programs require legally-enforceable, internationally-recognized public quality standards (known as “pharmacopeial monographs” or “monographs”) to achieve their objectives by allowing for the quality testing of priority medical products. These monographs enable the availability of quality-assured medical products by allowing for quality testing during production, procurement, and post-marketing surveillance. **The applicant should** have the ability to support the development and use, particularly at the country level, of pharmacopeial monographs and their corresponding reference standards/substances (chemicals used for testing products according to the pharmacopeial monographs). When no internationally-recognized monographs exist for medicines of direct

relevance to USAID priority health programs, **the applicant should** contribute to meeting this need.

NOTE: The Agency supports the use by USAID-supported countries of any internationally-accepted pharmacopeial monographs (The International Pharmacopoeia, British Pharmacopoeia, etc.) not only those developed by USP.

Objective 5: Global medical product quality assurance learning and operational agenda advanced

Over the last two decades, improving medical product quality assurance and combatting substandard and falsified medical products in LMICs have increasingly gained attention and investment from policy makers. As medical product quality assurance continues to gain in importance, USAID will play an active role in the continued development and implementation of strategic approaches, interventions, and tools based on international best practices, including through PQM+. Technical leadership in moving the medical product quality assurance agenda forward is essential, given the sizable and growing pharmaceutical markets for both imported and locally-produced products in LMICs, plans to expand coverage of health services and products, and the recent recognition that poor quality medical products contribute to the emergence and spread of AMR. The accomplishment of this objective requires engagement with global, regional, and country stakeholders.

Sub Obj 5.1. Evidence-based approaches and tools developed and/or applied

There is a need to develop an evidence-base on the application of approaches and tools for use at the country, regional, and/or international level to promote medical product quality assurance systems strengthening and to combat substandard and falsified medical products in LMICs. A dearth of evidence related to the impact of pharmaceutical management interventions exists, including those related to medical product quality assurance, on health systems strengthening and health outcomes in LMICs. This includes, but is not limited to, cost-effective medical product quality screening technologies appropriate for limited-resource settings. It also includes approaches to apply best practices in structure, staffing, management, and financing of various medical product quality assurance operations, determined in conjunction with international stakeholders (e.g., in line with the WHO Global Benchmarking Tool). **The applicant should** support the development and application of evidence-based approaches and tools designed to promote medical product quality assurance systems strengthening and assess the effects of substandard and falsified medical products on health system performance and health outcomes. To facilitate such collaborations, **the applicant should** conduct technical mapping of medical product quality assurance-related activities currently being undertaken by relevant stakeholders.

Sub Obj 5.2. Research and analysis to support medical product quality assurance systems strengthening conducted

Drawing on international best practices (e.g., as identified through Sub-Objective 5.1), there is a need to conduct research and analysis to better understand how well and how sustainably medical product quality assurance systems are functioning in LMICs. Best practices need to be defined around LMIC medical product quality assurance systems, including, but not limited to:

the costing of regulatory quality assurance functions, the optimal configuration of medical product quality assurance systems, the interplay between national health reforms (e.g. expanded health coverage) and medical product quality assurance systems, and how national AMR plans include medical product quality considerations. **The applicant should** identify a research agenda and conduct such research and analysis with the goal of it being translated into policy and practice and utilized for advocacy, awareness building, and systems strengthening efforts. It is expected for **the applicant to** publish and present these findings in peer reviewed journals and at international conferences and other relevant fora.

Sub Obj 5.3. Advocacy on the importance of medical product quality assurance for public health, including the link between medical product quality and antimicrobial resistance supported

Global technical leadership and advocacy are needed as regional and international initiatives and partnerships in the health arena multiply. This includes playing an active role in relevant policy discussions or initiatives with major partners to promote quality-assured medical products and combat substandard and falsified medical products. This should be done independently, as a partner of USAID and/or through operational partnerships with international stakeholders (see MQASSP Guiding Principle "Develop strategic partnerships with regional and international stakeholders"). **The applicant should** support USAID to engage with and build on these and other initiatives, working in synergy with other stakeholders, including regional and international organizations. In doing so, **the applicant should** collaborate with other international donors and technical assistance efforts as appropriate to avoid duplication and enable coordinated analytical and assistance efforts. **The applicant should** undertake efforts to raise awareness about the need to invest in promoting medical product quality assurance systems strengthening and the dangers of substandard and falsified medical products.

Continued technical leadership is necessary to provide a platform to undertake effective global and country-level advocacy about the importance of medical product quality assurance in terms of health outcomes. One area requiring particular attention and advocacy is the role of poor drug quality in contributing to the emergence and spread of drug resistance. Despite recent significant efforts to call attention to this problem, awareness of the connection is still nascent. Target audiences include both international and national stakeholders **The applicant should** work at the global level and with countries to raise awareness of the link between poor drug quality and AMR and to advocate for the inclusion of strengthened medical product quality assurance systems in national AMR frameworks, with the imperative to expand the scope of antimicrobial stewardship within national action plans to include concerns for drug quality.

A.2.6 Gender Equality and Female Empowerment

The Award will align with Agency-wide commitments mandated by USAID's Gender Equality and Female Empowerment Policy. As described in the Policy, USAID investments are aimed at achieving three overarching outcomes: 1) to reduce gender disparities in access to, control over, and benefit from resources, wealth, opportunities, and services; 2) to reduce gender-based violence and mitigate its harmful effects on individuals; and 3) to increase capability of women and girls to realize their rights, determine their life outcomes, and influence decision-making.

The ability to identify and address gender constraints is an important element in the design of appropriate and sustainable programs that support equitable access to health services. Gender norms and the imbalance in power dynamics between men and women are often reflected within health systems and institutions, especially concerning access to quality-assured medical products and use of pharmaceutical services. **The applicant should** take these policy objectives into consideration and integrate gender issues during the design, implementation, and monitoring and evaluation of program activities. This will require moving beyond merely counting the number of men and women reached. Indicators should reflect the fact that males and females are not homogenous groups and should further disaggregate by income, region, caste, race, ethnicity, disability, and other demographic and/or social characteristics as relevant. **The applicant should** incorporate gender considerations into all aspects of the program, to address women's empowerment and the constructive engagement of young girls and boys, adolescent girls and boys, adult women and men, and older women and men. Program activities should demonstrate an understanding that gender inequalities change across the human life cycle as people age and assume new roles in their families and communities.

The applicant should address gender inequities in training and educational opportunities, helping to balance opportunities for women in positions of leadership and management. Solutions to inequalities must consider the specific needs of gender groups, to address the distinct needs of different groups or cultures. **The applicant should** investigate country or culturally-specific issues related to gender, women's empowerment, and medical product quality assurance systems strengthening. This should include efforts to identify potential adverse impacts and/or risks of gender-based exclusion and other unintended consequences of project activities for both genders. Empowering civil society and women's organizations to participate in advocacy and educational opportunities must increase the ownership and sustainability of these efforts.

Women must be empowered to serve in a stewardship role, be educated to understand and manage their own care and the care of their families, and be encouraged to demand quality-assured medical products and services from their providers, government, and the private sector. The role of civil society, specifically women's groups, to act as empowered consumers and shape market responsibility can be extremely powerful. Interventions and communication must be designed around contextual analysis that must be specific to a country or region.

As part of the system for monitoring, evaluation, and learning **the applicant should** undertake gender analyses and adhere to reporting requirements to demonstrate that gender issues are being addressed, monitored, and evaluated with sex-disaggregated data and appropriate gender-related and female empowerment indicators. In addition, **the applicant should** consider strategies to monitor gender-based inequities and promote solutions.

[Note: The Program Description of Rounds 2 and 3 (if issued) will be added here through amendments to this APS.]

[End of Section A]

SECTION B: FEDERAL AWARD INFORMATION

B.1 Funding

The expected total estimated amount for all cooperative agreements and/or grants to be awarded under this APS will be approximately $180 million USD. For Round 1, USAID intends to award one (1) cooperative agreement with a total estimated amount of up to $160 million. USAID reserves the right to fund any one, or none, of the applications submitted or to fund applications that fall below the stated dollar threshold. The funding for the award(s) resulting from this APS may be provided through the USAID Bureau for Global Health offices, as well as USAID mission field support. As determined by the source of funding, awardee(s) will be expected to comply with specific USAID regulations governing particular funding streams.

B.2 Period of performance

The period of performance anticipated for the cooperative agreement awarded under Round 1 of this APS is not expected to exceed five years in duration. For Round 1, the anticipated start date for the award(s) is on or about July 31, 2019.

B.3 Expected number of awards

One (1) award is expected to be made as a result of Round 1 under the MQASSP APS. One (1) to two (2) additional awards are expected to be made in successive Rounds under this APS. The actual number of awards under the MQASSP APS is subject to the availability of funds and the viability of applications received. USAID reserves the right to issue fewer or more awards than the number noted above, including the right to issue no awards through this APS.

B.4 Scope

For Round 1's concept papers and full applications, applicants must propose approaches to achieve all five Objectives and the respective Sub-objectives under each Objective. The scope for subsequent Round(s) will be included in amendments to this APS.

B.5 Expected implementation mechanism

For Round 1, USAID intends to award one (1) cooperative agreement. For subsequent Rounds under the MQASSP APS, the resultant awards may be grants and/or cooperative agreements. For cooperative agreements, USAID will make a determination on the intended substantial involvement by the Agency upon award. The specific areas of USAID substantial involvement will include, but not be limited to, approval of the recipient's implementation plans, approval of Key Personnel, as well as Agency and recipient collaboration and joint participation, including approval of the substantive provisions of subawards, Monitoring, Evaluation, and Learning (MEL) Plans, and other activities as determined, based on the selected Program, and negotiated with the recipient prior to award.

[End of Section B]

SECTION C: ELIGIBILITY INFORMATION

C.1 Eligible Entities

Through this APS, USAID seeks to make awards to organizations and/or partnerships that can make concrete contributions to sustainably strengthen medical product quality assurance systems in LMICs including advancing global innovations in this area.

U.S. and non-U.S. public, private, for-profit, and nonprofit organizations, as well as institutions of higher education, and non-governmental organizations, are eligible to submit a concept paper. Further, the organization must be a legally recognized organizational entity under applicable law, legally registered in a country within the geographic code 937 ("the United States, the recipient country, and developing countries other than advanced developing countries, but excluding any country that is a prohibited source," per ADS 310.3.1.1). Applications from individuals will not be accepted nor reviewed.

While for-profit firms may participate, pursuant to 2 CFR 200.400(g), it is USAID policy not to award profit to prime recipients and subrecipients under assistance instruments. However, while profit is not allowed for sub-awards, the prohibition does not apply when the recipient acquires goods and services in accordance with 2 CFR 200.317 -326, "Procurement Standards." This is discussed more specifically in ADS 303sai "Profit Under USAID Assistance Instruments," which can be found at this link: http://www.usaid.gov/ads/policy/300/303sai.pdf.

Each applicant must be found to be a responsible entity before receiving an award. The Agreement Officer (AO) may determine that a pre-award survey is required in accordance with ADS 303.3.9.1 and if so, would establish a formal survey team to conduct an examination that will determine whether the applicant has the necessary organization, experience, accounting and operational controls, and technical skills – or ability to obtain them – in order to achieve the objectives of the program. Applicants who do not currently meet all USAID requirements for systems and controls may still be eligible under special award considerations and should not be discouraged from applying. USAID welcomes applications from organizations that have not previously worked with the Agency.

Organizations in developing countries are strongly encouraged to participate in the application process, inasmuch as they would support not only the goal of this APS but also USAID's objective to build the capacity of local organizations in support of country resiliency and sustainable development.

USAID strongly encourages applications from potential new partners who meet the above eligibility requirements and are willing to be subjected to a Pre-Award Responsibility Determination, which is a pre-award audit to determine fiscal responsibility (i.e., whether the prospective recipient has the necessary organization, experience, accounting and operational controls, and technical skills – or ability to obtain them – in order to achieve the objective of this APS and comply with the terms and conditions of the award).

Applicants that do not include a plan for how they will avoid, mitigate, and eliminate actual or

potential organizational conflict of interest related to the provision of technical assistance to pharmaceutical manufacturers that may arise in the event of an award to the prime, its subrecipients and/or contractors will not be eligible to participate in the application process. Please see the Mandatory Standard Provision "Conflict of Interest", Section F.2 of this APS.

Submissions from organizations that do not meet the above eligibility criteria will not be reviewed and evaluated.

C.2 Cost Share

To be eligible for award, applicants must propose a minimum cost share of 10% of the projected USAID funded amount for Round 1. Such funds may be mobilized from the Recipient; other multilateral, bilateral, and foundation donors; host governments; and local organizations, communities and private businesses that contribute financially and in-kind to the implementation of activities. For guidance on cost sharing in grants and cooperative agreements for U.S. NGOs, please see 2 CFR 200.307. For non-U.S. NGOs, all cost sharing is subject to the Required as Applicable Standard Provision "Cost Sharing"(please see the references included in Section F.2 of this APS).

C.3 Limitations on Submissions

Each applicant organization is limited to one concept paper submission per Round as the Prime applicant. There is no limitation on being included as a potential Sub-awardee. USAID discourages the use of exclusive teaming arrangements.

[End of Section C]

SECTION D: APPLICATION AND SUBMISSION INFORMATION

D.1 APS Point of Contact and Package Distribution

The preferred method of distribution of USAID assistance information is www.grants.gov. This APS contains all necessary information, web links, and materials to submit a complete concept paper for Round 1. The APS includes information regarding the full application, however this information is not exhaustive. Full applications are **not** requested at this time. The most highly rated applicant(s) will be contacted directly for requesting full application(s).

All inquiries and communication, including questions on this APS or related Amendments or Addenda, must be submitted to IHSIP@usaid.gov with "**MQASSP APS**" included in the subject line.

D.2 Submission Dates and Times

Please refer to the Key Information and Dates on the Cover Page. Concept papers and full applications must be submitted electronically via IHSIP@usaid.gov before the respective due dates and times. Please include "**MQASSP APS - [Name of Organization]**" in the subject line. Late submissions will NOT be accepted. Hard copies, whether hand delivered or by postal mail, will NOT be accepted.

D.3 Application Process

This APS utilizes a three phase process:

Phase 1: Concept Paper submission

Applicants must submit concept papers in accordance with the due dates for each Round. USAID will then conduct a Merit Review of all timely submitted concept papers based on the Merit Review criteria provided in **Section E: Application Review Information**. Amendments to the APS will contain concept paper instructions and merit review criteria for subsequent Rounds under this APS.

Phase 2: Co-creation

After review of the concept papers, USAID may issue an invitation to co-creation meetings with the most highly-rated applicant(s). Co-creation meetings, if needed, will occur over the phone or in person in Washington, DC or locations identified by USAID. For Round 1, it is not anticipated that co-creation meetings would involve more than one applicant at a time. It may be determined that co-creation meetings are not necessary - in that case, USAID may move directly to request full applications after review of the concept papers. Further details on the co-creation process (if determined necessary) will be shared with the most highly rated applicant(s).

Phase 3: Full Application

After review of the concept papers, full applications will be requested from those applicants with the most highly rated concept papers. Full application submission instructions and review criteria are included in this APS. USAID reserves the right to make changes to the full application instructions and review criteria. All applicants are encouraged to review these sections to ensure they are able to meet USAID's requirements for full applications if their concept papers are selected.

Applicants with concept papers not advancing to full application will be notified. If an organization submits a concept paper that is not successful and thereby is not invited to submit a full application in Round 1, that organization still may submit another concept paper in a future Round under the MQASSP APS if one occurs.

After review of full applications, the Agency may invite the apparently successful applicant to a co-development meeting which would occur over the phone or in Washington, DC or a location identified by USAID.

To be considered for funding under Round 1 of the MQASSP APS, applications must meet all of the requirements for the concept paper and for the full application respectively.

D.4 Content and Format of Application Submission

Content and format instructions must be followed, or applicants risk being found non-compliant and eliminated from the review. Regardless of whether a concept paper or full application, the following requirements apply for documents submitted in response to this APS, with the exception of Government-issued forms:

- 8.5 inch by 11 inch (210mm by 297mm) paper, single-spaced pages with margins no less that one inch on each border.
- Written in English.
- Minimum 12 point font for all narrative (the font should not be smaller than 12pt Times New Roman).
- Graphics/charts/tables may use a different font and size, so long as it is legible without magnification. Graphs, charts, and tables should be for illustrative purposes only and should not comprise the majority of the application text.
- Submitted via Microsoft Word or PDF formats, except budget files which must be submitted in Microsoft Excel.
- All pages after the cover page must be consecutively numbered.

Additional instructions specific to concept papers and full applications are included in the following subsections.

D.5 Concept Paper Required Content and Instructions

D.5.1 Concept Paper Technical Instructions for PQM+

Concept papers are limited to nine (9) pages total, excluding the cover page and estimated cost summary. Concept papers must follow the required content and format below.

D.5.1.1 Cover Page (not included in the 9-page limit)

- Project title;
- Funding opportunity number;
- Name and address of the applicant organization;
- Type of organization (e.g., for-profit, non-profit, university, network, etc.);
- DUNS number;
- Contact point (name, telephone, and e-mail);
- Names subrecipients and types of organizations (local non-profit, etc.).

D.5.1.2 Concept Paper Content

1. In the concept paper, the applicant must describe a clear and realistic approach to achieve the Round 1 goal and objectives, from a technical and systems strengthening perspective. As the length of the concept note suggests, applicants should be concise in their response and focus on the overall strategy to achieve Round 1 goal and objectives.

2. In addition, the applicant must describe its institutional capacity and technical expertise to address all five Round 1 objectives and their sub-objectives.

3. The applicant must describe its plans to partner with and build the capacity of local organizations to support the achievement of Round 1 goal and objectives and promote the sustainability of results.

4. Lastly, USAID is acutely aware of the possibility of an actual or potential organizational conflict of interest related to 1) providing technical assistance to manufacturers of medical products through PQM+ vs. commercial engagement with manufacturers of medical products including 2) the selection/prequalification of manufacturers as eligible for procurement and/or 3) procurement of product from manufacturers. The applicant must describe how it will avoid, mitigate, and eliminate such actual or potential organizational conflict of interest that may arise in the event of an Award to the prime, its subreceipients and/or contractors.

D.5.2 Concept Paper Cost Instructions for PQM+

USAID is not requesting cost information as part of the concept paper submission. However, applicants are encouraged to start preparing their initial budget assumptions to be able to complete the full application budget in case they are successful in the initial phase. Detailed cost instructions are included for the full application stage in the following section.

D.6 Instructions for the preparation of the Full Application

NOTE: USAID IS NOT REQUESTING THIS INFORMATION AT THIS TIME. THE MOST HIGHLY RATED APPLICANTS WILL BE REQUESTED BY USAID TO SUBMIT A FULL APPLICATION FOLLOWING THE REVIEW OF CONCEPT PAPERS. THIS INFORMATION IS NOT EXHAUSTIVE.

Additional information that is expected to be included in the request for full application at a later time includes, but is not limited to, reporting requirements and detailed requirements regarding transition awards.

D.6.1 Full Technical Application Instructions for PQM+

D.6.1.1 Organization of the Technical Application

The applicant must organize the Technical Application in the following manner:

- Cover Letter
- Table of Contents
- Acronym List
- Technical Approach
- Key Personnel & Staffing
- Institutional Experience and Capability
- Management Plan
- Performance Monitoring, Evaluation, and Learning
- Annexes:
  - Annex 1: Resumes (maximum 4 pages each), references, and signed statement of commitment for each of the Key Personnel
  - Annex 2: Staffing Matrix (maximum 2 pages)
  - Annex 3: Organizational Chart(s) (maximum 2 pages)

D.6.1.2 Page Limitations

The Technical Application is limited to 46 pages, excluding required documents indicated below. While the suggested page length per Technical Application section is given below, applicants may allocate the page count differently, provided the overall Technical Application page limit is not exceeded. USAID will not evaluate information submitted above this page limit.

D.6.1.3 Page Limitation Exclusions

The following do not count towards the page limitation:

- Cover Letter, to include:
  - APS Round 1 name and number
  - Name of applicant
  - Name of any consortium members/partnerships
  - Name, title, and signature of the authorized representative

    - Date of submission
    - DUNS number
- Table of Contents
- Acronym List
- Annexes

D.6.1.4 Technical Approach (suggested 28 pages)

(a) Detailed Technical Approach

The applicant must propose a detailed Technical Approach to accomplishing the overall goal of PQM+ through achieving the five objectives in an integrated and sustainable manner and at scale for a multi-country global award. The Technical Approach must indicate how priorities and needs will be identified and must take into account the Round 1 guiding principles. The Technical Approach should also include details on how proposed interventions will be implemented, specify which stakeholders will be engaged in the process, discuss opportunities/barriers that could speed/hinder progress, and suggest solutions to address the barriers. Merely repeating the narrative in the Program Description without sufficient elaboration will not be considered responsive.

(b) Case Study

As part of the Technical Approach, the applicant must describe an illustrative process for prioritizing, developing, and implementing a plan to address quality assurance systems strengthening in a fictitious LMIC, "Qualandia", considering the PQM+ goal and objectives and the Round 1 guiding principles. This should be based on an overall amount of $6 million USD of non-disease specific funds and be in response to a request from the USAID Mission in "Qualandia" to work comprehensively across PQM+ Objectives 1, 2, 3, and 4. It is strongly suggested that applicants limit the description to 3 pages.

Selected reference materials can be found at the following hyperlinks: 1) WHO Essential Medicines and Health Products Information Portal: http://apps.who.int/medicinedocs/en/, 2) USAID-funded Promoting the Quality of Medicines program (PQM): https://www.usp-pqm.org/, and 3) Development Exchange Clearinghouse (DEC): https://dec.usaid.gov/dec/home/Default.aspx.

D.6.1.5 Key Personnel & Staffing (Suggested 5 Pages)

(a) Key Personnel

To achieve Round 1 goal and objectives, USAID expects to partner with an organization or organizations led by a team that includes the following five (5) Key Personnel: 1) Program Director; 2) Deputy Program Director; 3) Technical Director; 4) Finance and Operations Director; and 5) Monitoring, Evaluation, and Learning Director. The proposed Key Personnel should present a complementary set of skills that demonstrate the team's ability to address the PQM+ goal and objectives and strengthen medical product quality assurance systems in priority

countries. All Key Personnel other than the Program Director must be supervised by the Program Director, thereby assuring accountability for all PQM+ program activities and operations.

The Key Personnel section of the application must provide a description of the expertise and experience of the proposed Key Personnel, including how their skills and experience will allow them to provide leadership in addressing technical and administrative aspects required to meet Round 1 goal and objectives described in the Program Description.

Desired medical product quality assurance technical skills for Key Personnel may include, but are not limited to, the following areas, which are listed in no particular order of importance:

- Market authorization/registration, inspection, and licensing functions of medical product regulatory agencies
- Post-marketing surveillance systems
- Medical product clinical trials oversight
- Pharmacovigilance, as it pertains to monitoring the quality of medical products
- Medical products regulatory control of advertising and promotion of medical products
- Good Manufacturing Practices
- Essential medicines policies
- Drug quality control laboratory strengthening
- Prequalification of medical products
- Screening technologies used for identification of substandard and falsified medical products
- Good governance for medical product quality assurance systems including civil society engagement
- Regulatory workforce capacity building and institution development
- Medical product quality assurance management information systems and data generation, analysis, and use
- Gender
- Performance monitoring and evaluation, implementation research, impact modeling
- Knowledge management, organizational learning, and communications
- Operations, financial management, contract/grants management

For each of the proposed Key Personnel, applicants are required to submit the following documents, which will be attached as an Annex and will not be counted in the overall page limitation.

- Current resume (maximum 4 pages), listing chronologically the candidates' education and work experience and describing his/her responsibilities for each position;
- Names and contact information for three professional references for each candidate;
- Signed letter of commitment.

Key Personnel may be based in the United States or elsewhere, and the applicant is encouraged to recruit some Key Personnel who are citizens of USAID priority countries listed on page 4 of the USAID Global Health Report Brochure, available here:

https://www.usaid.gov/sites/default/files/documents/1864/USAID-Global-Health-Report-Brochure-508.pdf.

Key Personnel Qualifications

Program Director

The proposed Program Director shall be responsible for oversight, administration, supervision, and management of all aspects of cooperative agreement performance, including direct supervision of other Key Personnel. S/he must have at least ten (10) years of relevant experience, strong leadership qualities, extensive developing country experience, broad technical and strong management expertise, and demonstrated success in executive-level management of large, complex medical product quality assurance systems strengthening activities focused on developing countries. S/he must have demonstrated technical competence in key technical areas of medical product quality assurance, as listed above. The proposed Program Director must possess international credibility as a technical leader in medical product quality assurance and have experience coordinating and collaborating with cooperating agencies and contractors, partner country government officials, and other donors and international stakeholders. Strong interpersonal, writing, oral presentation, and facilitation skills (in English) are required, and proficiency/fluency in a second language is preferred. Performance as an effective decision-maker and competence mentoring and supervising professional and support staff must be demonstrated. Experience with one or more disease-specific programs (e.g., HIV/AIDS, malaria, TB) is desirable. A Master's Degree (or equivalent) in medical product quality assurance, pharmacy, public health, health policy, or a related field is required. Experience working in LMICs on medical product quality assurance, pharmacy, public health, health policy, or a related field is required.

Deputy Program Director

The proposed Deputy Program Director must have at least seven (7) years of relevant experience, possess supervisory and program management experience, and have experience implementing and managing large, complex public health programs related to medical product quality assurance systems strengthening focused on developing countries. S/he must have demonstrated technical competence in key technical areas of medical product quality assurance, as described above. S/he must have demonstrated executive-level qualities; broad technical and strong management expertise and experience; mentoring, supervision, and facilitation skills; the ability to network and communicate with a wide range of stakeholders; and strong interpersonal, writing, and oral presentation skills (in English), with fluency/proficiency in a second language preferred. Experience with one or more disease-specific programs (e.g., HIV/AIDS, malaria, TB) is desirable. A Master's Degree (or equivalent) in medical product quality assurance, pharmacy, public health, health policy, or a related field is required. A key responsibility of the Deputy Program Director will be to ensure coordination and collaboration across program portfolios (i.e. USAID/Washington-funded and Mission-funded) and between headquarters and the field. Experience working in LMICs on medical product quality assurance, pharmacy, public health, health policy, or related field is preferred.

Technical Director

The proposed Technical Director must have at least seven (7) years of relevant experience, possess supervisory and program management experience, and have experience implementing and demonstrated competence in managing and providing technical assistance in developing countries in key technical areas of medical product quality assurance, as described above. S/he must have demonstrated executive-level qualities; broad technical and strong management expertise and experience; mentoring, supervision, and facilitation skills; the ability to network and communicate with a wide range of stakeholders; and strong interpersonal, writing, and oral presentation skills in English, with fluency/proficiency in a second language preferred. Experience with one or more disease-specific programs (e.g., HIV/AIDS, malaria, TB) is desirable. A Master's Degree (or equivalent) in medical product quality assurance, pharmacy, public health, health policy, or a related field is required. A key responsibility of the Technical Director will be to ensure the provision of quality technical support through PQM+ and to work closely with the Monitoring, Evaluation, and Learning Director to advance the research and learning agenda. Experience working on LMICs in medical product quality assurance, pharmacy, public health, health policy, or related field is preferred.

Finance and Operations Director

The proposed Finance and Operations Director must be experienced in budgeting, financial management and oversight, and contractual management for programs implemented in developing countries and managed centrally. S/he must have at least seven (7) years of relevant experience and strong interpersonal, writing, and oral presentation skills as well as mentoring, supervision, and facilitation skills. At least three (3) years working on financial and/or contractual management of USG programs with multiple funding sources in developing countries is required. S/he must have a Master's Degree in Business Administration, be a Certified Public Accountant, or have a related advanced degree or experience.

Monitoring, Evaluation, and Learning Director

The proposed Monitoring, Evaluation, and Learning Director must have at least seven (7) years of relevant experience designing, implementing, and supervising M&E efforts for multi-country complex programs including development of performance metrics and frameworks to benchmark systems improvements and achievement of results. S/he must have demonstrated analytical skills and experiences advising on methods to identify and evaluate best practices and state-of-the-art approaches. S/he must have demonstrated experience developing the capacity of program staff in setting goals and objectives, identifying outputs and outcomes, and collecting and using indicator data. This includes designing a system for data collection, analysis, and indicator-based reporting to support demonstration of programmatic results and their contribution to country, regional, and global improvements. In addition, s/he must possess strong management, interpersonal, writing, and organizational skills for reporting on program and study results. S/he must have demonstrated mentoring, supervision, and facilitation skills and the ability to network and communicate with a wide range of stakeholders. S/he will work closely with other Key Personnel to move the research and learning agenda forward, ensuring the timely implementation of research-related activities and that measurable progress is made. Experience working in

LMICs is preferred.

(b) Staffing Plan

Applicants must propose a staffing plan that includes a narrative section in the main body of the Application and a matrix as part of the Annexes. The narrative must describe how the skill set of the proposed non-key personnel positions (managerial, technical, and operational) complement that of the proposed Key Personnel and how the skill sets of the entire team contribute to the overall success of the program. The staffing matrix must depict the managerial, technical, and operational skill sets needed to implement the Award. The staffing matrix must be two (2) pages maximum, be attached as an Annex, and will not be counted in the overall page limitation; for each individual already identified and for TBD positions, the matrix must indicate whether the personnel are proposed as full time or non-full time (and if non-full time, what percent (%) LOE).

D.6.1.6 Institutional Experience and Capability (Suggested 3 Pages)

The applicant must describe its team's experience and capability, including that of any proposed subrecipients, to plan and implement multi-country, technically-complex programming needed to support the range of activities needed to accomplish the Round 1 goal and objectives outlined in the Program Description; produce results and innovations in quality assurance systems strengthening in developing countries in the technical areas covered in the Program Description; and manage proposed institutional relationships, subrecipients, and resources.

D.6.1.7 Management Plan (Suggested 5 Pages)

In this section, the applicants must include:

- A management plan narrative that illustrates the management structure and staff for the prime and all subrecipients. The narrative must describe the roles, responsibilities, and clear lines of authority of staff, partners, and subrecipients, with an emphasis on engaging local resources where possible per the Round 1 guiding principles.
- A clear approach to managing technical and financial reporting of multiple funding sources, harmonizing program logistics, personnel, travel, and procurement systems, while taking advantage of organizational strengths, emphasizing cost-effectiveness, and avoiding duplication of effort. The applicant must also describe concrete steps for close communication, coordination, collaboration, and knowledge sharing with USAID/Washington, USAID Missions, and other U.S. Government partners, as well as international, regional, and local partners that implement complementary quality assurance systems strengthening programs.
- A clear plan for how it will avoid, mitigate, and eliminate actual or potential organizational conflict of interest that may arise in the event of an Award to the prime and/or its subrecipients, related to the following: 1) providing technical assistance to manufacturers of medical products through PQM+ vs. commercial engagement with manufacturers of medical products including 2) the selection/prequalification of

manufacturers as eligible for procurement and/or 3) procurement of product from manufacturers.

- An organizational chart that illustrates the management structure of both full-time and non-full time staff for prime and all subrecipients. The organization chart must be two (2) pages maximum, be attached as an Annex, and will not be included in the overall page limitation.

D.6.1.8 Performance Monitoring, Evaluation, and Learning (Suggested 5 Pages)

Applicants must provide an abridged Monitoring, Evaluation, and Learning (MEL) Plan that includes:

(a) Preliminary Indicator Table and Data Collection and Reporting Plan

Applicants must propose an Indicator Table listing key indicators to appropriately quantify, analyze, and track progress toward achieving the Round 1 goal and five objectives of the program (as per the Program Description). As part of the Table, the applicant must specify ambitious but achievable life-of-program performance targets or milestones for the Round 1 goal and five objectives, data collection methods, type and source of information, and frequency of collection.

The applicant must also include a Data Collection and Reporting Plan narrative describing its intended approach to monitoring, evaluation, and learning that is in alignment with the proposed Indicator Table, incorporating a description of how indicator data will be regularly collected and reported to USAID/Washington and Missions with realistic and cost-effective methodologies, and how results of activities will be tracked in the field and at the global-level. In addition, applicants must describe how baseline data will be collected within six (6) months of award allowing for necessary disaggregation by gender and funding unit. Given that multiple Missions may contribute to a particular country program or activity, applicants must also describe how they will monitor technical and financial indicators and report results specific to each unit providing funds into the Award, while still ensuring results can be aggregated and reported for the Award as a whole.

To achieve the outcomes outlined in USAID's Gender Policy, the applicant must include disaggregation of data by gender (when appropriate) to report on how the program benefited men and women. Progress of all related activities will be measured and verified using gender-sensitive performance indicators. All indicators related to people or populations must be disaggregated by sex, and included in program reports. Additionally, program activities must be implemented in a manner that promotes fair, equitable, and meaningful inclusion of both men and women in all program activities.

(b) Knowledge Management, Learning, and Communications Plan

As part of the abridged MEL Plan, the applicant must propose a Knowledge Management, Learning, and Communication Plan, including a research and learning agenda, based on the Round 1 goal, objectives, and guiding principles. The Plan must describe the use of data by

clearly-defined stakeholders/end users, articulate how the applicant will prioritize and operationalize the research and learning agenda, and include strategies to highlight links between medical product quality assurance systems strengthening and improved health outcomes. The plan must specify three (3) illustrative implementation research questions to advance the field of medical product quality assurance systems strengthening in a LMIC context by filling existing knowledge gaps.

D.6.1.9 Full Cost Application Instructions for PQM+

The Cost Application is to be submitted as a separate attachment from the Technical Application. There is no page limit on the Cost Application. Applicants are encouraged to be as concise as possible, but still provide the necessary details. The Cost Application must illustrate the full period of performance using the budget format shown in the SF-424A. Please note that construction is not permitted under this program.

Prior to award, applicants may be required to submit additional documentation deemed necessary for the AO to assess the applicant's risk in accordance with 2 CFR 200.205. Applicants should not submit any additional information with their initial application.

The Cost Application must contain the following sections:

1) Cover Page
2) SF-424 Forms
3) Budget and Budget Narrative
4) Approval of Subawards
5) Dun and Bradstreet and SAM.gov Registration
6) Certifications, Assurances, and Other Statements of the Recipient

For apparently successful applicants, when requested by the AO:

7) History of Performance
8) Branding Strategy & Marking Plan

Detailed instructions are as follows:

1) Cover Page

The Cost Application Cover Page must contain the same information as the Technical Application Cover Page.

2) SF-424 Form(s)

The applicant must submit the application using the SF-424 series:

- SF-424
- SF-424A

- SF-424B

Forms and instructions can be found at the following link: https://www.grants.gov/forms/sf-424-family.html.

Failure to accurately complete these forms could result in a non-funded application.

3) Budget and Budget Narrative

The Budget must be submitted as one unprotected Excel file (MS Office 2000 or later versions) with visible formulas and references and must be broken out by project year, including itemization of the federal and non-federal (cost share) amount. Files must not contain any hidden or otherwise inaccessible cells. Budgets with hidden cells lengthen the cost analysis time required to make award and may result in a rejection of the cost application. The Budget Narrative must contain sufficient detail to allow USAID to understand the proposed costs. The applicant must ensure the budgeted costs address any additional requirements identified, such as Branding and Marking. The Budget Narrative must be thorough, including sources for costs to support USAID's determination that the proposed costs are fair and reasonable. Construction is not permitted under this APS.

The Budget must include the following worksheets or tabs and contents, at a minimum:

a) Summary Budget, following the guidance and format laid out in this section, inclusive of all program costs (federal and non-federal), broken out by major budget category and by year for activities implemented by the applicant and any potential sub-recipients for the entire period of the project.

b) Detailed Budget, including a breakdown by year, by budget category, by budget line items, and by headquarters, regional and/or country offices (if applicable) for all federal funding (core and field support) and cost share and/or resource leverage for the entire implementation period of the project.

c) Detailed Budgets for each sub-recipient, for all federal funding and cost share, broken out by year, by budget category, by budget line items, and by headquarters, regional, and/or country offices (if applicable) for the entire implementation period of the project.

Budget Guidance

Applicants must submit a detailed budget following the below guidance. It is expected that the Total Estimated USAID Amount (TEA) of Round 1 of the program will not exceed $160 million. Given that a significant portion of this program will consist of field support, which is largely undefined at this time, a subset of the TEA will be used to determine reasonableness and realism of proposed costs. USAID will not ask applicants to provide detailed budget for a significant portion of future field support at this time. During implementation the recipient will submit cost information for the proposed field support and core through the work plan, which will require AOR approval at that time.

The following budget detail is requested for evaluation:

Applicants are required to propose a detailed budget for three illustrative field support countries: Bangladesh, Kenya, and Senegal. Additionally, a budget must be prepared for home office support. These countries are listed here solely for the purposes of the evaluation process. Actual implementation of activities may take place anywhere within the place of performance of the cooperative agreement. Applicants are requested not to contact host government counterparts and/or USAID Mission employees in the three illustrative countries.

These budgets may be included in one Excel workbook with separate tabs for the individual budgets. The Key Personnel proposed for PQM+ are expected to expend a portion of their effort on the below noted illustrative budgets.

1. One large field support budget is based on Bangladesh:

    i. The total estimated amount of the field support is not expected to exceed $18 million
    ii. The field support commences in month 4 of Year 1 of the program
    iii. The field support will end at the end of month 9 of Year 5
    iv. Assume a large office is established in-country
    v. Assume one expatriate personnel as part of the in-country staff.

2. One small field support budget is based on Kenya:

    i. The total estimated amount of the field support is not expected to exceed $12 million
    ii. The field support commences in month 4 of Year 1 of the program
    iii. The field support will end at the end of month 9 of Year 5
    iv. Assume a small office is established in-country
    v. Assume one expatriate personnel as part of the in-country staff.

3. Short-Term Technical Assistance field support budget is based on the Senegal:

    i. The total estimated amount of the field support is not expected to exceed $5 million
    ii. Assume no office is established in-country
    iii. Assume one full time local consultant
    iv. STTA is provided by HO/U.S.-based personnel

4. The home office budget assumptions are as follows:

    i. The total estimated amount is not expected to exceed $5 million
    ii. The budget covers the entire program period
    iii. The budget includes a portion of the proposed Key Personnel salaries.

Applicants must provide a narrative justifying the rates for each cost category proposed with

supporting information as further specified under the following cost categories. Any assumptions should be clearly stated. Applicants should keep in mind that it is their responsibility to ensure that the information provided is sufficient to provide a basis for USAID to determine that the costs proposed are reasonable and realistic. All proposed individual sub-awards should include the same cost element breakdowns in their budgets, as applicable.

As part of the budget narrative, applicants are requested to describe their approach and methodology for cost control during the implementation of the program.

The applicant is requested to submit summary tables for the program as follows. Applicants are required to provide an estimate for direct costs and indirect costs for both the detailed portion of the budget and the additional field support. During implementation, the recipient will use its Government-approved provisional indirect rates, or the 10% de-minimis rate per 2 CFR 200.414, or propose all costs as direct costs.

Please provide a summary table for the three (3) field support and the home office support costs in the below format:

Description	**Year 1 ($)**	**Year 2 ($)**	**Year 3 ($)**	**Year 4 ($)**	**Year 5 ($)**	**Total ($)**
Personnel						
Fringe Benefits						
Travel						
Equipment						
Supplies						
Subawards and Contracts						
Other						
Total Direct Charges						
Indirect Charges						
Total Estimated USAID Amount						
Cost Share						
Total Estimated Program Amount						

Please also provide an overall summary table according to the following:

Description	**Total HO support**	**Total Bangladesh field support**	**Total Kenya field support**	**Total Senegal STTA field support**	**Additional field support**	**Total**
Personnel					[Do not provide budget detail for additional field support.]	[Do not fill in these totals.]
Fringe Benefits						
Travel						
Equipment						
Supplies						

Subawards and Contracts						
Other						
Direct Charges						
Indirect Charges						
Total Estimated USAID Amount	[NTE[16] $5,000,000]	[NTE $18,000,000]	[NTE $12,000,000]	[NTE $5,000,000]	[NTE $120,000,000]	[NTE $160,000,000]
Cost Share						
Total Estimated Program Amount						

Note: Applicants must fill in all empty, unshaded fields in the above table including the direct and indirect charges under the additional field support column, as applicable. Applicants must estimate the direct charges and indirect charges for this category.

Budget Categories

The detailed budgets must contain the following budget categories and information, at a minimum:

1. Salaries and Allowances – Must be proposed consistent with 2 CFR 200.430 Compensation - Personal Services. The applicant's budget must include position title, salary rate, level of effort, and salary escalation factors for each position. Allowances, when proposed, must be broken down by specific type and by position. Applicants must explain all assumptions in the Budget Narrative. The Budget Narrative must demonstrate that the proposed compensation is reasonable for the services rendered and consistent with what is paid for similar work in other activities of the applicant. Applicants must provide their established written policies on personnel compensation. If the applicant's written policies do not address a specific element of compensation that is being proposed, the Budget Narrative must describe the rationale used and supporting market research.

2. Fringe Benefits (if applicable) – If the applicant has a fringe benefit rate approved by an Agency of the U.S. Government, the applicant must use such rate and provide evidence of its approval. If an applicant does not have a fringe benefit rate approved, the applicant must propose a rate and explain how the applicant determined the rate. In this case, the Budget Narrative must include a detailed breakdown comprised of all items of fringe benefits (e.g., superannuation, gratuity, etc.) and the costs of each, expressed in U.S. dollars and as a percentage of salaries.

3. Travel and Transportation – Provide details to explain the purpose of the trips, the number of trips, the origin and destination, the number of individuals traveling, and the duration of the trips. Per Diem and associated travel costs must be based on the applicant's normal travel policies. When appropriate, provide supporting documentation as an attachment, such as company travel policy, and explain assumptions in the Budget Narrative.

[16] Not to Exceed

4. Procurement or Rental of Goods (Equipment & Supplies), Services, and Real Property – Must include information on estimated types of equipment, models, supplies, and the cost per unit, and quantity. The Budget Narrative must include the purpose of the equipment and supplies and the basis for the estimates. The Budget Narrative must support the necessity of any rental costs and reasonableness in light of factors such as: rental costs of comparable property, if any; market conditions in the area; alternatives available; and the type, life expectancy, condition, and value of the property leased.

5. Subawards – Specify the budget for the portion of the program to be passed through to any subrecipients. See 2 CFR 200.330 for assistance in determining whether the sub-tier entity is a subrecipient or contractor. The subrecipient budgets must align with the same requirements as the applicant's budget, including those related to fringe and indirect costs.

6. Other Direct Costs – This may include other costs not elsewhere specified, such as report preparation costs, passports and visas fees, medical exams and inoculations, as well as any other miscellaneous costs that directly benefit the program proposed by the applicant. The applicant should indicate the subject, venue, and duration of any proposed conferences and seminars, and their relationship to the objectives of the program, along with estimates of costs. Otherwise, the narrative should be minimal.

7. Indirect Costs – Applicants must indicate whether they are proposing indirect costs or will charge all costs directly. In order to better understand indirect costs, please see Subpart E of 2 CFR 200.414. The application must identify which approach they are requesting and provide the applicable supporting information. Below are the most commonly used Indirect Cost Rate methods:

   Method 1 - Direct Charge Only
   Eligibility: Any applicant
   Initial Application Requirements: See above on direct costs

   Method 2 - Negotiated Indirect Cost Rate Agreement (NICRA)
   Eligibility: Any applicant with a NICRA issued by a USG Agency must use that NICRA
   Initial Application Requirements: If the applicant has a current NICRA, submit your approved NICRA and the associated disclosed practices. If your NICRA was issued by an Agency other than USAID, provide the contact information for the approving Agency. Additionally, at the Agency's discretion, a provisional rate may be set forth in the award subject to audit and finalization. See USAID's Indirect Cost Rate Guide for Non Profit Organizations for further guidance.

   Method 3 - De minimis rate of 10% of modified total direct costs (MTDC)
   Eligibility: Any applicant that has never received a NICRA
   Initial Application Requirements: Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as

a non-Federal entity chooses to negotiate an indirect rate, which the non-Federal entity may apply to do at any time. The applicant must describe which cost elements it charges indirectly vs. directly. See 2 CFR 200.414(f) for further information.

Method 4 - Indirect Costs Charged As A Fixed Amount
Eligibility: Non U.S. non-profit organizations without a NICRA may request, but approval is at the discretion of the AO.
Initial Application Requirements: Provide the proposed fixed amount and a worksheet that includes the following:

- Total costs incurred by the organization for the previous fiscal year and estimates for the current year.
- Indirect costs (common costs that benefit the day-to-day operations of the organization, including categories such as salaries and expenses of executive officers, personnel administration, and accounting, or that benefit and are identifiable to more than one program or activity, such as depreciation, rental costs, operations and maintenance of facilities, and telephone expenses) for the previous fiscal year and estimates for the current year
- Proposed method for prorating the indirect costs equitably and consistently across all programs and activities of using a base that measures the benefits of that particular cost to each program or activity to which the cost applies.

If the applicant does not have an approved NICRA and does not elect to utilize the 10% de minimis rate, the AO will provide further instructions and may request additional supporting information, including financial statements and audits, should the application still be under consideration after the merit review. USAID is under no obligation to approve the applicant's requested method.

8. Cost Sharing – The applicant should estimate the amount of cost-sharing resources to be provided over the life of the agreement and specify the sources of such resources, and the basis of calculation in the budget narrative. Applicants should also provide a breakdown of the cost share (financial and in-kind contributions) of all organizations involved in implementing the resulting award.

Prior Approvals in accordance with 2 CFR 200.407

Inclusion of an item of cost in the detailed application budget does not satisfy any requirements for prior approval by the Agency. If the applicant would like the award to reflect approval of any cost elements for which prior written approval is specifically required for allowability, the applicant must specify and justify that cost. See 2 CFR 200.407 for information regarding which cost elements require prior written approval.

4) Approval of Subawards

The applicant must submit information for all subawards that it wishes to have approved at the time of award. For each proposed subaward the applicant must provide the following:

- Name of organization
- DUNS Number
- Confirmation that the subrecipient does not appear on the Treasury Department's Office of Foreign Assets Control (OFAC) list
- Confirmation that the subrecipient does not have active exclusions in the System for Award Management (SAM)
- Confirmation that the subrecipient is not listed in the United Nations Security designation list
- Confirmation that the subrecipient is not suspended or debarred
- Confirmation that the applicant has completed a risk assessment of the subrecipient, in accordance with 2 CFR 200.331(b)
- Any negative findings as a result of the risk assessment and the applicant's plan for mitigation.

5) Dun and Bradstreet and SAM.gov Requirements

USAID may not award to an applicant unless the applicant has complied with all applicable unique entity identifier (DUNS number) and System for Award Management (SAM) requirements. Each applicant (unless the applicant is an individual or Federal awarding agency that is exempted from requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d)) is required to:

(1) Provide a valid DUNS number for the applicant and all proposed sub-recipients;

(2) Be registered in SAM before submitting its application. SAM is streamlining processes, eliminating the need to enter the same data multiple times, and consolidating hosting to make the process of doing business with the government more efficient (www.sam.gov).

(3) Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal Awarding Agency.

The registration process may take many weeks to complete. Therefore, applicants are encouraged to begin the process early. If an applicant has not fully complied with the requirements above by the time USAID is ready to make an award, USAID may determine that the applicant is not qualified to receive an award and use that determination as a basis for making an award to another applicant.

DUNS number: http://fedgov.dnb.com/webform
SAM registration: http://www.sam.gov

Non-U.S. applicants can find additional resources for registering in SAM, including a Quick

Start Guide and a video on how to obtain an NCAGE code, on www.sam.gov, navigate to Help, then to International Registrants.

6) Required Certifications and Assurances

The applicant must complete the following documents and submit a signed copy with their application:

(1) "Certifications, Assurances, Representations, and Other Statements of the Recipient" document found at http://www.usaid.gov/sites/default/files/documents/1868/303mav.pdf

(2) Assurances for Non-Construction Programs (SF-424B)

(3) Certificate of Compliance: Please submit a copy of your Certificate of Compliance if your organization's systems have been certified by USAID/Washington's Office of Acquisition and Assistance (M/OAA).

7) History of Performance

The apparently successful applicant will be asked to provide history of its performance. Applicants should not provide this information unless requested by the AO.

If requested by the AO, the applicant must provide information regarding its recent history of performance for all its cost-reimbursement contracts, grants, or cooperative agreements involving similar or related programs, not to exceed five awards, as follows:

- Name of the Awarding Organization;
- Award Number;
- Activity Title;
- A brief description of the activity;
- Period of Performance;
- Award Amount;
- Reports and findings from any audits performed in the last two years; and
- Name of at least two (2) updated professional contacts who most directly observed the work at the organization for which the service was performed with complete current contact information including telephone number, and e-mail address for each proposed individual.

If the applicant encountered problems on any of the referenced Awards, it may provide a short explanation and the corrective action taken. The applicant should not provide general information on its performance. USAID reserves the right to obtain relevant information concerning an applicant's history of performance from any sources and may consider such information in its review of the applicant's risk. The Agency may request additional information and conduct a pre-award survey if it determines that it is necessary to inform the risk assessment.

8) Branding Strategy & Marking Plan

The apparently successful applicant will be asked to provide a Branding Strategy and Marking Plan to be evaluated and approved by the AO and incorporated into any resulting award.

9) Funding Restrictions

Profit is not allowable for recipients or subrecipients under this award. See 2 CFR 200.330 for assistance in determining whether a sub-tier entity is a subrecipient or contractor.

Construction will not be authorized under this award.

USAID will not allow the reimbursement of pre-award costs under this award without the explicit written approval of the AO.

Except as may be specifically approved in advance by the AO, all commodities and services that will be reimbursed by USAID under this award must be from the authorized geographic code specified in this APS and must meet the source and nationality requirements set forth in 22 CFR 228.

10) Potential Request for Additional Documentation

Upon consideration of award or during the negotiations leading to an award, applicants may be required to submit additional documentation deemed necessary for the AO to make an affirmative determination of responsibility. Applicants should not submit the information below with their applications. The information in this section is provided so that applicants may become familiar with additional documentation that may be requested by the AO. The information submitted should substantiate:

1. Bylaws, constitution, and articles of incorporation, if applicable.
2. Whether the organizational travel, procurement, financial management, accounting manual and personnel policies and procedures, especially regarding salary, promotion, leave, differentials, etc., submitted under this section have been reviewed and approved by any agency of the Federal Government, and if so, provide the name, address, and phone number of the cognizant reviewing official. The applicant should provide copies of the same.

[End of Section D]

SECTION E: APPLICATION REVIEW INFORMATION

E.1 Relative Importance of Merit Review Criteria

USAID will review concept papers and full applications on the basis of the below technical merit review criteria, listed in descending order of importance. All subcriteria within each criterion are also listed in descending order of importance, unless otherwise stated within the criteria.

E.2 Concept Paper Merit Review Criteria for PQM+

USAID will review the concept papers according to the following concept paper merit review criteria. The degree to which:

1. The applicant presents a clear and realistic overall technical approach to achieve the PQM+ goal and objectives, from a technical and systems strengthening perspective.

2. The applicant presents a team with appropriate institutional capacity and technical expertise to address all five Round 1 objectives and their sub-objectives.

3. The applicant's approach to partnering with local organizations and building their capacity supports achievement of program objectives and promotes the sustainability of results.

4. The applicant presents a convincing plan for how the prime applicant, its subrecipients and/or contractors will avoid, mitigate, and eliminate actual or potential organizational conflict of interest related to providing technical assistance to manufacturers of medical products vs. organizational commercial engagements with manufacturers of medical products.

E.3 Full Application Merit Review Criteria

USAID will review the full applications based on the following full application merit review criteria:

No.:	Technical Evaluation Criteria
E.4.1	**Technical Approach**
(a)	Detailed Technical Approach
(b)	Case Study
E.4.2	**Key Personnel and Staffing**
(a)	Key Personnel
(b)	Staffing Plan
E.4.3	**Institutional Experience and Capability**
E.4.4	**Management Plan**
E.4.5	**Performance Monitoring, Evaluation, and Learning**
(a)	Preliminary Indicator Table & Data Collection and Reporting Plan

(b)	Knowledge Management, Learning, and Communications Plan

E.3.1 Technical Approach

Subcriterion (a) below is **significantly** more important than (b).

(a) Detailed Technical Approach

The degree to which the applicant's technical approach to achieving the goal and objectives of PQM+ is convincing, feasible, and addresses the requirements laid out in Section D.6.1.4.

(b) Case Study

The degree to which the applicant's approach to prioritizing, developing, and implementing a plan to address medical product quality assurance systems strengthening in a fictitious LMIC, "Qualandia," is convincing and addresses the requirements laid out in Section D.6.1.4.

E.3.2 Key Personnel and Staffing

(a) Key Personnel

The degree to which the applicant's proposed Key Personnel have appropriate skills and experience to provide effective leadership for the successful implementation of the Award.

(b) Staffing Plan

The extent to which the proposed staffing plan includes personnel positions with an appropriate balance of managerial, technical, and operational skills sufficient to successfully implement the Award.

E.3.3 Institutional Experience and Capability

The degree to which the applicant and all proposed subrecipients demonstrate experience and capability to implement the Award addressing the requirements laid out in Section D.6.1.6.

E.3.4 Management Plan

The extent to which the applicant's management plan convincingly addresses the requirements laid out in Section D.6.1.7.

E.3.5 Performance Monitoring, Evaluation, and Learning

(a) Preliminary Indicator Table and Data Collection and Reporting Plan

The extent to which the applicant presents a convincing and realistic Indicator Table and Data

Collection and Reporting Plan narrative addressing the requirements laid out in Section D.6.1.8(a).

(b) Knowledge Management, Learning, and Communications Plan

The extent to which the applicant presents a convincing and informed Knowledge Management, Learning, and Communications Plan addressing the requirements laid out in Section D.6.1.8(b).

E.3.6 Cost application review

The cost application of the apparently successful applicants will be reviewed for cost reasonableness and cost realism. Cost share will not be a part of the evaluation and will be considered as an eligibility criterion in the application process.

[End of Section E]

SECTION F: FEDERAL AWARD ADMINISTRATION INFORMATION

F.1 Federal Award Notices

USAID cannot make awards under this APS until it has appropriated, allocated, and committed funds through internal USAID procedures. While USAID anticipates successfully completing these procedures, potential applicants are notified of these requirements and conditions. The AO is the only individual who may legally commit the USG to the expenditure of public funds. Applicants are prohibited from charging or incurring costs to the proposed award prior to receipt of either a fully executed Award or a specific, written authorization from the AO.

F.2 Administration

Awards will be made under relevant federal regulations and agency policy. For U.S non-governmental organizations, awards must be administered according to 2 CFR 200 and 2 CFR 700, and USAID Standard Provisions will apply (http://www.usaid.gov/policy/ads/300/303maa.pdf). For non U.S. non- governmental organizations, USAID provisions for non U.S. non-government organizations will apply (http://www.usaid.gov/policy/ads/300/303mab.pdf).

F.3 Additional Information

The request for full application will contain additional information in this section, such as the type, frequency, and means of submission of award reporting requirements. Information about program income and information detailing how the Agency will ensure environmental soundness and compliance in design and implementation will be included.

F.4 Program Income

Program Income earned under the resultants awards will be added to the Total Estimated Amount (exclusive of cost share) in accordance with 2 CFR 200.307(e)(2).

F.5 Environmental Compliance

Any resultant awards under this APS will be subject to the Environmental Compliance policy in 22 CFR 216. Please review the Initial Environmental Examination in Appendix B of this APS.

[End of Section F]

SECTION G: FEDERAL AWARDING AGENCY CONTACT(S)

The Applicant may contact the following USAID personnel via email only regarding this APS. Applicants must use the IHSIP@usaid.gov email address in contacting the point of contact.

Primary Point of Contact:

Boryana Boncheva
Supervisory Agreement Officer
Office of Acquisition and Assistance
M/OAA/GH/GHI

[End of Section G]

APPENDIX A: ACRONYM LIST

ADS	Automated Directives System
AIDS	Acquired Immunodeficiency Syndrome
AMR	Antimicrobial Resistance
AMRH	African Medicines Regulatory Harmonization
AMQF	African Medicines Quality Forum
AO	Agreement Officer
AOR	Agreement Officer's Representative
APS	Annual Program Statement
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
CRO	Contract Research Organizations
DEC	Development Exchange Clearinghouse
DUNS	Data Universal Numbering System
GBT	WHO Global Benchmarking Tool
GCP	Good Clinical Practices
GFATM	The Global Fund to Fight AIDS Tuberculosis and Malaria
GH	USAID's Bureau for Global Health
GHSC	Global Health Supply Chain
GHSC-BI&A	Global Health Supply Chain Business Intelligence & Analytics
GHSC-PLM	Global Health Supply Chain Project Last Mile
GHSC-PSM	Global Health Supply Chain Procurement and Supply Management
GHSC-QA	Global Health Supply Chain Quality Assurance
GHSC-RTK	Global Health Supply Chain Rapid Test Kits
GHSC-TA	Global Health Supply Chain Technical Assistance
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
HO	Home Office
HRH	Human Resources for Health
HRH2030	Human Resources for Health 2030
HSS	Health Systems Strengthening
IDDS	Infectious Disease Detection and Surveillance
IDIQ	Indefinite Delivery, Indefinite Quantity Contract
IHS	Integrated Health Systems
iMQA	Innovations for Medicines Quality Assurance
IR	Intermediate Result
LMIC	Low and Middle-Income Country
MEL	Monitoring, Evaluation, and Learning
MNCH	Maternal, Newborn, and Child Health
MQASSP	Medicines Quality Assurance Systems Strengthening
MTaPS	Medicines, Technologies, and Pharmaceutical Services
NEPAD	The New Partnership for Africa's Development
NGO	Non-Governmental Organization
NOMCoL	Network of Official Medicines Control Laboratories

NTD	Neglected Tropical Diseases
OAA	USAID's Office of Acquisition and Assistance
OH	One Health
OHS	Office of Health Systems
OHW	One Health Workforce
PQM	Promoting the Quality of Medicines Program
PQM+	Promoting the Quality of Medicines Plus Program
PRH	USAID's Office of Population and Reproductive Health
PV	Pharmacovigilance
SAM	System for Award Management
SDG	U.N. Sustainable Development Goals
SOP	Standard Operating Procedure
STTA	Short-Term Technical Assistance
TB	Tuberculosis
TEA	Total Estimated USAID Amount
USAID	United States Agency for International Development
USD	US dollars
USG	United States Government
WHO	World Health Organization

[End of Appendix A]

APPENDIX B: INITIAL ENVIRONMENTAL EXAMINATION

[This page is intentionally left blank]

COVERSHEET

INITIAL ENVIRONMENTAL EXAMINATION

Medicines Quality Assurance Systems Strengthening Program (MQASSP)

1. EXECUTIVE SUMMARY

1.1. PROGRAM/ACTIVITY DATA

Program/Activity Number	XXXX
Program/Activity Title	Medicines Quality Assurance Systems Strengthening Program (MQASSP)
Country/Region	Global
USG Foreign Assistance Framework	Functional Objective: Investing in People Program Areas: Health (HL) Program Element: HL.5: Other Public Health Threats Program Sub-Element HL.5.3: Cross-cutting Health Systems Strengthening (Other Health)
Period Covered	FY2019- FY2024
Life of Project Amount	$180,000,000 (PQM+: $160,000,000; iMQA: $20,000,000).
IEE Amendment	No
IEE Prepared By	Elizabeth Lugten, GH/OHS
Management Unit Contact Point	Alison Collins, GH/OHS

1.2. ENVIRONMENTAL ACTION RECOMMENDED

Categorical Exclusion	**x**	**Negative Determination**	**x**
Positive Determination			

Project does not cover the following activities	This IEE does NOT include activities related to pesticides and vector control. An amendment to this IEE will be required prior to funding or implementation of any activities in these categories.

1.3. THRESHOLD ENVIRONMENTAL DETERMINATIONS

Activity or Activity Category	**Recommended Determination**
1. Convening meetings and workshops **2. Facilitation of collaborative learning and information transfer/research utilization**	**Categorical exclusion**, per: ● 216.2 (c)(2)(iii) for analyses, studies, academic or research workshops and meetings.

3. Secondary data analysis	
4. Development Research Activities involving market, formative, behavioral research	**Categorical exclusion**, per: ● 216.2 (c)(2)(iii) for analyses, studies, academic or research workshops and meetings
Activities involving social science, implementation, health services, operational research	**Negative Determination with conditions**, per CFR 216.3(a)(2)(iii), for activities that may have an effect on the physical and natural environment, but will not have a significant effect as a result of limited scope, carefully controlled nature, and effective monitoring. **Conditions:** The implementing partner must have access to technical expertise to (a) assess planned activities for potential impact on medical waste issues (generation, handling, disposal) and to develop, monitor, and report on implementation of management and mitigation plans, (b) ensure that research protocols, findings, and recommendations adequately and correctly address medical waste management issues, when appropriate, and (c) ensure that training and communication materials are accurate and reflect sound medical waste management standards and practices. The implementing partner must submit all technical and research materials and reports directly or indirectly related to medical waste management to the USAID COR/AOR.
5. Procurement, storage, management, distribution and disposal of public health commodities	**Negative Determination with conditions**, per CFR 216.3(a)(2)(iii), for activities that may have an effect on the physical and natural environment, but will not have a significant effect as a result of limited scope, carefully controlled nature and effective monitoring. **Conditions:** The implementing partner must have access to technical expertise to (a) assess planned activities for potential impact on medical waste issues (generation, handling,

	disposal) and to develop, monitor, and report on implementation of management and mitigation plans, and (b) ensure that training and technical assistance materials are accurate and reflect sound medical waste management standards and practices. The implementing partner will consult with the recipient(s) of the public health commodities to assess the potential impact on medical waste management and how to mitigate this impact within the scope of the award. This process, including actions taken and results, will be documented in the EMMP and EMMR. The implementing partner must submit all technical materials and reports directly or indirectly related to medical waste management to the USAID COR/AOR for review with an informational copy to the GH Bureau Environmental Officer.

1.4. SUMMARY OF IMPLEMENTATION, MONITORING, AND REPORTING MEASURES

A list of conditions and instructions for the AOR will be provided by the Global Health Bureau Environmental Officer to be inserted here. These conditions include, but are not limited to:

1. **Environmental Management Training.** The GH AOR and Activity Manager(s) assigned to this program are to enroll in and successfully complete the Bureau for Global Health Environmental Management Process Training course. The course is offered through GHPOD.

2. **Climate Change.** GH projects awarded after October 1, 2016 are required to follow USAID/GH guidelines for the screening of activities for climate resiliency to comply with EO 13677.

3. **Provision of the IEE.** The AOR shall provide the Implementing Partners with a copy of this IEE and brief the Implementing Partner on their environmental compliance responsibilities.

4. **AOR monitoring responsibilities.** As required by the ADS 204, the AOR will actively monitor and evaluate whether the conditions of this IEE are being implemented effectively and whether new or unforeseen consequences arise during implementation not identified and reviewed in this IEE. If new or unforeseen consequences arise, the

team will suspend the activity and initiate appropriate, further review, in accordance with 22 CFR 216.

5. **Annual compliance documentation and reporting.** The Implementing Partners are responsible for the preparation of an Environmental Mitigation and Monitoring Plan (EMMP) and submitting the completed plan to the AOR for review and approval with the project workplan and prior to initiating work on the activity. The EMMP template is included with the IEE. The EMMP will outline the environmental impacts that can be reasonably anticipated from the implementation of the program activities, the mitigation measures to address the impacts, monitoring measures, and frequency of inspection. The AOR is responsible for reviewing and approving the EMMP and providing a copy to the Global Health BEO for review and concurrence.

   The Implementing Partner is responsible for annually preparing and submitting to the AOR an Environmental Mitigation and Monitoring Report (EMMR) to document compliance with the conditions of this IEE. The EMMR must be submitted to the AOR within 45 days after the end of each fiscal year. The EMMR template is attached to the IEE.

6. **Integration of compliance responsibilities in prime and subcontracts, agreements, and grants.** The AOR shall ensure that the cooperative agreement document references and requires compliance with the conditions set out in this IEE, as required by ADS 2014.3.4(a)(6) and ADS 303.3.6(3)(e). The Implementing Partner shall assure that subcontracts, agreements, and grants reference and require compliance with relevant elements of these conditions.

7. **Assurance of sub-awardee, -grantee, -contractor capacity and compliance.** The Implementing Partner shall assure that sub-awardees, grantees, contractors have the capability to implement the relevant requirements of this IEE. The Implementing Partner shall, if appropriate, provide training to sub-awardees, -grantees, and -contractors in their environmental compliance responsibilities.

8. **Pesticides or pesticide products.** Any program activities conducted under this Agreement involving the procurement, use, research or disposal of pesticides and/or larvicides and their waste products will require a supplemental IEE, SEA, or PERSUAP based on consultations with the Bureau Environmental Officer for Global Health.

9. **Compliance with human subject research requirements.** The AOR in consultation with the BEO for the Global Health Bureau shall assure that the Implementing Partner and sub-awardees demonstrate completion of all requirements for ethics review and adequate medical monitoring of human subjects who participate in research trials carried out through this agreement. The BEO for Global Health may request copies of documentation from the AOR to demonstrate compliance with applicable requirements of human subject trials. 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.

10. **New or modified activities.** As part of its workplan, the implementing partner in collaboration with the AOR shall review all on-going and planned activities to determine if they are within the scope of this IEE. The Implementing Partner shall complete the screening questionnaire (Part 1 of the EMMR) with the workplan.
    a. If activities outside the scope of this IEE are planned, the AOR/COR shall assure that an amendment to this IEE addressing these activities is prepared and approved prior to implementation of any such activities.
    b. Any ongoing activities found to be outside the scope of this IEE shall be modified to comply or halted until an amendment to this IEE is submitted and approved.

11. **Compliance with Host Country requirements.** Nothing in this IEE substitutes for or supersedes Implementing Partner, sub-awardees/-grantee/-contractor's responsibility for compliance with all applicable host country laws and regulations. The Implementing Partner and sub-awardee, -grantee, -contractor must comply with host country environmental regulations unless otherwise directed in writing by USAID. However, in the case of a conflict between host country and USAID regulations, the latter shall govern.

1.5. APPROVAL OF ENVIRONMENTAL DETERMINATION AND MEASURES

1.5.1. Clearance:

Kelly Saldana	12/4/18
Kelly Saldana **Office Director, GH, OHS**	**Date**

Ali G	12/6/18
Alison Collins **AOR, GH, OHS**	**Date**

1.5.2. Concurrence:

Dennis W Durbin Digitally signed by Dennis W Durbin Date: 2019.02.19 18:02:05 -05'00'	
Dennis Durban **Global Health Bureau Environmental Officer**	**Date**

1.5.3. Distribution List:

BEO/MEO for each geographic Bureau where program is working.

SECTION 2: IEE SUPPORTING INFORMATION

2.1. PROGRAM/ACTIVITY DATA

Program/Activity Number	XXXX
Program/Activity Title	Medicines Quality Assurance Systems Strengthening Program (MQASSP)
Country/Region	Global
USG Foreign Assistance Framework	Functional Objective: Investing in People Program Areas: Health (HL) Program Element: HL.5: Other Public Health Threats Program Sub-Element HL.5.3: Cross-cutting Health Systems Strengthening (Other Health)
Period Covered	FY2019-FY2024
Life of Project Amount	$180,000,000 (PQM+: $160,000,000; iMQA: $20,000,000).
IEE Amendment	No
IEE Prepared By	Elizabeth Lugten, GH/OHS
Management Unit Contact Point	Alison Collins, GH/OHS

2.2. PURPOSE AND SCOPE

The purpose of this document, in accordance with Title 22, Code of Federal Regulations, Part 216 (22 CFR 216), is to provide a preliminary review of the reasonably foreseeable effects on the environment Medicines Quality Assurance Systems Strengthening Program (MQASSP) and on this basis, to recommend determinations and, as appropriate, attendant conditions, for these activities. Upon final approval of this IEE, these recommended determinations are affirmed as 22 CFR 216 Threshold Decisions and Categorical Exclusions, and conditions become mandatory elements of MQASSP implementation.

The purpose of MQASSP is to support partner countries to strengthen local medicines quality assurance systems, ensure the quality and safety of essential medical products and contribute to achievement of USAID's health development goals, including self-reliance, resilience, and responsiveness of national health systems.

The first of the mechanisms to be awarded under the MQASSP APS, the Promoting the Quality of Medicines Plus (PQM+) program, will be a $160 million cooperative agreement. This agreement will assist USAID partner countries to build local capacity to improve medicines quality assurance system performance and facilitate transition from donor support to domestic financing where feasible. The five objectives of PQM+ will be:
1) Improved local legal, policy, and regulatory environment for medicines quality assurance systems;
2) Improved country and regional capabilities to assure the quality and safety of medicines in the public and private sectors;
3) Improved allocation, coordination, and use of financial and human resources for medicines quality assurance;

4) Increased manufacturing capacity for the supply of quality-assured essential medicines of public health importance;
5) New evidence produced and global advocacy advanced on the public health importance of quality-assured medicines, including the link between poor quality medicines and antimicrobial resistance.

The second set of awards, Innovations for Medicines Quality Assurance (iMQA) is designed to identify and promote innovation to advance the state-of-the-art in LMIC medicines quality assurance systems strengthening across the above PQM+ objective areas. Innovations will focus on new and emerging issues and concerns in medicines quality assurance system strengthening and inform the work of PQM. It is anticipated that two prime awards (total of $20 million for both awards) will result from iMQA.

MQASSP is expected to have a ceiling of $180,000,000.

This IEE is a critical element of a mandatory environmental review and compliance process meant to achieve environmentally sound activity design and implementation.

2.3. PROGRAM OVERVIEW

2.3.1. Background

Improving medicines quality assurance and combatting falsified medicines have increasingly gained attention from policy makers. USAID has been involved in the field since the mid-2000s. USAID plays an active role in the development and implementation of strategic approaches, interventions and tools for in this area. Sustainable, self-reliant health systems require access to and appropriate use of quality-assured medicines and health technologies. Inadequate systems to assure the quality and safety of health products in USAID-supported countries leads to poor treatment outcomes and increases resistance of major infectious diseases to antimicrobial medicines.

2.3.2. Description of Activities

The **Promoting the Quality of Medicines – Plus (PQM+)** activity (OHS) will strengthen quality assurance systems and pharmaceutical production capacity in low and middle-income countries (LMIC) to assure the quality and safety of essential medicines and other health technologies of public health importance.
The **Innovations for Medicines Quality Assurance (iMQA)** activity will focus on new and emerging issues and concerns in medicines quality assurance system strengthening and inform the work of PQM+.

Work conducted under these activities will consist principally of training, technical assistance, workshops, and publication of technical documents with a specific focus on health commodities and other public health technologies.

Each category will have a number of related activities. Potential impacts of activities will be analyzed and incorporated into the EMMP more specifically to each mechanism as they are awarded.

1. Convening meetings and workshops
Stakeholder engagement, systematic multi-disciplinary analyses of advances and challenges, consensus building and communication within and across global, national, and local settings are critical to successful planning, priority setting, and roll out of applied implementation research and uptake of new or refined tools, technology, policies, and products.

2. Facilitation of collaborative learning and information transfer/research utilization
Convening stakeholders to share research findings and facilitate the integration of results into programs and policies, and ensuring the effective transfer of information across the spectrum of intended users poses no adverse environmental risks, therefore qualifying for categorical exclusion.

3. Secondary data analysis
This intervention consists primarily of conducting statistical analysis of existing data sets, which may include but are not limited to:

- Demographic and Health Surveys
- AIDS Impact Surveys
- Service Provision Assessments
- Multiple Indicator Cluster Surveys (MICS)
- National population- or facility-based surveys
- Use of data from an existing study or studies, for a new individual or combined analysis.

4. Development Research
Development research may include market, formative, social science, operational, health services, implementation and behavioral research.

Social science implementation, health services, and operational research, when USAID is supporting health facilities and service delivery research, may involve medical waste management and/or healthcare commodities.

5. Procurement, storage, management, distribution, and disposal of public health goods
Activities in this category include efforts to strengthen the supply chain of public health commodities. In some cases, commodities may be procured.

2.4. BASELINE INFORMATION AND APPLICABLE HOST COUNTRY REQUIREMENTS

2.4.1. Locations Affected

MQASSP has a global focus and activities may take place in any of the developing countries covered by a bilateral or regional USAID mission. OHS will prioritize support to countries to advance on their path toward self-reliance in medicines quality assurance. Host country environmental requirements are detailed in national laws, regulations, and policies. Research activities involving human subjects

will be carefully designed, implemented, and monitored in compliance with in-country laws and regulations, and specifically with local institutional review board (IRB) approval.

The global nature of this award requires that potential site-specific impacts are assessed at the project workplan level. As such, EMMPs will be developed and processed by Implementing Partner's for individual awards with the GH BEO, REO and MEO approval.

Changes in baseline conditions of locations due to climate change are not expected to be significant over the life of the project, though shifts in epidemiologic patterns may begin to occur. This is may affect the needs of medicines and related services.

OHS completed a Climate Risk Management Screening to evaluate the potential climate risks to the descried activities. The screening is included as an attachment using the Climate Assessment Tool on climatelinks.org. Since this program is at a global level, climate risks may need to be addressed before activity implementation in country.

2.4.2. Applicable Laws, Regulations and Policies

Mechanisms under the MQASSP program will be responsible for complying with all applicable country and environmental information identified activities that have potential to have a negative impact on the environment. The mechanisms under the MQASSP program will comply with the appropriate environmental laws and regulations established in each country in which it implements activities. Specific requirements may vary by country, but activities will conform to environmental management laws, environmental impact regulations, including health care waste management policies.

In addition AORs will consult WHO guidelines, USAID sector guidelines, and CDC, where applicable, to ensure compliance with internationally recognized environmental procedures. Research organizations are expected to provide their medical waste management procedures to demonstrate how they will manage waste for their research. In the EMMP, the implementing partner will outline how the host country environmental laws, regulations and possible permit requirements will be identified and adhered to as part of their program management. Implementing partners are responsible for documenting consultations with the relevant host country agency(ies) to ensure that environmental discharges (air, water, soil) meet host county environmental standards and permits are obtained where required.

Technical assistance to help host countries develop, implement, finance, or monitor regulations, policies, procedures, or standards that relate to medical waste management must align with WHO guidelines.

Primary Environmental Compliance References:

- WHO. *Safe Management of Wastes from Health-Care Activities* (2014)
- John Snow, Inc./USAID DELIVER Project in collaboration with WHO. *Guidelines for the Storage of Essential Medicines and Other Health Commodities* (2003)
- USAID *Sector Environmental Guidelines*

- USAID DELIVER Project. *The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities* (2011)
- USAID DELIVER Project. *Transport Management: A Self-Learning Guide for Local Transport Managers of Public Health Services* (October 2010)

2.5. EVALUATION OF POTENTIAL ENVIRONMENTAL IMPACTS

The activities under the MQASSP mechanisms are numerous and complex. Many activities do not have direct adverse environmental impacts such as information, education, communication, community mobilization, planning, management, leadership, and outreach activities. However, in the course of implementation of these activities, implementing partners should take advantage of opportunities to incorporate and improve means of addressing environmental health issues (like hazardous and infectious waste management) into service delivery systems.

Certain activities supported by MQASSP mechanisms will directly or indirectly affect the environment, or have the potential to do so. Based on the analysis conducted by the AOTR these activities could affect dire the environment:

1. Convening meetings and workshops
2. Facilitation of collaborative learning and information transfer/research utilization
3. Secondary Data analysis
4. Development research: market, formative, social science, operational, health services, implementation and behavior research, including water supply and sanitation
5. Procurement, storage, management, distribution and disposal of public health goods

Each category will have a number of related activities. Potential impacts of activities will be analyzed and incorporated into the EMMP.

The following activities eligible for Categorical Exclusion under 22 CFR 216 .2 (c) (2)(iii) are:

1. Convening meetings and workshops

Stakeholder engagement, systematic multi-disciplinary analyses of advances and challenges, consensus building and communication within and across global, national, and local settings are critical to successful planning, priority setting and roll out of applied implementation research and uptake of nor or refined tools, technology, policies, and products.

2. Facilitation of collaborative learning and information transfer/research utilization

Convening stakeholders to share research findings and facilitate the integration of results into programs and policies, and ensuring the effective transfer of information across the spectrum of intended users pose no adverse environmental risks, therefore qualifying for categorical exclusion.

3. Secondary Analysis

This intervention consists primarily of the conduct of statistical analysis of existing data sets, which

may include but not limited to:

- Demographic and Health Systems
- AIDS Impact Surveys
- Service Provision Assessments
- MICS Surveys
- National population- or facility-based surveys
- Use of data from an existing study or studies, for a new individual or combined analysis.

These activities falls **under 22 CFR 216 .2 (c) (2)(iii) eligible for categorical exclusion** and is warranted under this description.

4. Development Research

Research **not involving** activities that involve healthcare commodities, generate medical waste or conduct small scale construction or water and sanitation. Specific types of research include market, formative, social science, operational, health services, implementation and behavior research, including water supply and sanitation. Due to the nature of implementation and health services, this class of research is determined to have a **negative determination with conditions** per 22 CFR 216.3 (a) (2) (iii).

Market research, formative research, behavioral research fall under categorical exclusion per 22 CFR 216.2 (c) (2)(iii) analyses, studies, academic or research workshops and meetings.

Social science implementation, health services, and operational research, when USAID is supporting health facilities and service delivery research but not directly providing care with pharmaceuticals or involving a health or environmental impacts is determined to have a negative determination with conditions per 22 CFR 216.3 (a) (2) (iii).

5.The effects of pharmaceuticals 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, and may also cause biological responses in other organisms. There are many drug classes of concern, including antibiotics, antimicrobials, antidepressants, and estrogenic steroids. 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. Exposure risks for aquatic organisms are much larger than those for humans, because aquatic organisms have continual (and multi-generational) exposures, explores to higher concentrations, and possible low-dose effects.

Antibiotics and undiluted disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Additional health risks related to disposal include burning pharmaceuticals and plastic medical supplies at low temperatures or in open containers,

which results in release of toxic pollutants into the air, and inefficient and insecure sorting and disposal, which may allow drugs beyond their expiry date to be diverted for resale to the general public as well as storage and management of chemotherapies or radio isotope therapies.

In some countries, scavenging in unprotected insecure landfills is a hazard. Likewise, the mass procurement and distribution of commodities such as medicines and medical equipment has the potential to contribute to solid waste. Many countries do not have facilities to manage solid wastes other than uncontrolled burns. Plastics and other inorganic materials pose solid waste management issues for some countries.

Adverse impacts due to failure to properly manage resulting waste
This section is a general discussion and analysis of waste related impacts of health care activities. No recommended determinations are attached specifically to this section.

Poor waste management practices can unintentionally do harm to the communities even when overall intentions for an activity are well meaning. Improper training, handling, storage and disposal of the waste generated in facilities or activities can spread disease through several mechanisms. Transmission of disease through infectious waste is the greatest threat from healthcare waste. If waste is not treated in a way that destroys the pathogenic organisms, dangerous quantities of microscopic disease-causing agents—viruses, bacteria, parasites or fungi—will be present in the waste. These agents can enter the body through punctures and other breaks in the skin, mucous membranes in the mouth, being inhaled into the lungs, being swallowed, or being transmitted by a vector organism. Those who come in direct contact with the waste are at greatest risk.

Examples of populations who may be at risk to transmission of disease include healthcare workers, cleaning staff, patients, visitors, waste collectors, disposal site staff, waste pickers, substance abusers and those who knowingly or unknowingly use “recycled” contaminated syringes and needles. Although sharps pose an inherent physical hazard of cuts and punctures, the much greater threat comes from sharps that are also infectious waste. Healthcare workers, waste handlers, waste-pickers, substance abusers and others who handle sharps have become infected with HIV and/or hepatitis B and C viruses through pricks or reuse of syringes/needles.

Contamination of water supply from untreated healthcare waste can also have devastating effects. If infectious stools or bodily fluids are not treated before being disposed of, they can create and extend epidemics. The absence of proper sterilization procedures is believed to have increased the severity and size of cholera epidemics in Africa during the last decade.

Healthcare waste generally falls into three categories in terms of public health risk and recommended methods of disposal:
General: healthcare waste, similar or identical to domestic waste, includes materials such as packaging or unwanted paper. This waste is generally harmless and needs no special handling; 75–90% of waste generated by healthcare facilities falls into this category, and can be burned or taken to the landfill without any additional treatment.
Hazardous: healthcare wastes including infectious waste (except sharps and waste from

patients with highly infectious diseases), small quantities of chemicals and pharmaceuticals, and non-recyclable pressurized containers. All blood and body fluids are potentially infectious.
Highly hazardous: healthcare wastes, which should be given special attention, includes sharps (especially hypodermic needles), highly infectious non-sharp waste such as laboratory supplies, highly infectious physiological fluids, pathological and anatomical waste, stools from cholera patients, and sputum and blood of patients with highly infectious diseases such as TB and HIV. They also include large quantities of expired or unwanted pharmaceuticals and hazardous chemicals, as well as all radioactive or genotoxic wastes.

If a project's training activities for professional health workers or community health workers involve techniques that would generate and require disposal of hazardous or highly hazardous waste, the Implementing Partners shall be required to include training and ensure training curriculum covers best management practices concerning the proper handling, use, and disposal of medical waste, including blood, sputum, and sharps.

2.6. RECOMMENDED DETERMINATIONS AND CONDITIONS

Following from the analysis, the following determinations and conditions are recommended.

2.6.1. Recommended Determinations

Activity or Activity Category	Recommended Determination
1. Convening meetings and workshops **2. Facilitation of collaborative learning and information transfer/research utilization** **3. Secondary data analysis**	**Categorical exclusion**, per: ● 216.2 (c)(2)(iii) for analyses, studies, academic or research workshops and meetings.
4. Development Research Activities involving market, formative, behavioral research	**Categorical exclusion**, per: ● 216.2 (c)(2)(iii) for analyses, studies, academic or research workshops and meetings
Activities involving social science, implementation, health services, operational research	**Negative Determination with conditions**, per CFR 216.3(a)(2)(iii), for activities that may have an effect on the physical and natural environment, but will not have a significant effect as a result of limited scope, carefully controlled nature, and effective monitoring. **Conditions:** The implementing partner must have access to technical expertise to (a) assess

	planned activities for potential impact on medical waste issues (generation, handling, disposal) and to develop, monitor, and report on implementation of management and mitigation plans, (b) ensure that research protocols, findings, and recommendations adequately and correctly address medical waste management issues, when appropriate, and (c) ensure that training and communication materials are accurate and reflect sound medical waste management standards and practices. The implementing partner must submit all technical and research materials and reports directly or indirectly related to medical waste management to the USAID COR/AOR.
5. Procurement, storage, management, distribution and disposal of public health commodities	**Negative Determination with conditions**, per CFR 216.3(a)(2)(iii), for activities that may have an effect on the physical and natural environment, but will not have a significant effect as a result of limited scope, carefully controlled nature and effective monitoring. **Conditions:** The implementing partner must have access to technical expertise to (a) assess planned activities for potential impact on medical waste issues (generation, handling, disposal) and to develop, monitor, and report on implementation of management and mitigation plans, and (b) ensure that training and technical assistance materials are accurate and reflect sound medical waste management standards and practices. The implementing partner will consult with the recipient(s) of the public health commodities to assess the potential impact on medical waste management and how to mitigate this impact within the scope of the award. This process, including actions taken and results, will be documented in the EMMP and EMMR. The implementing partner must submit all

	technical materials and reports directly or indirectly related to medical waste management to the USAID COR/AOR for review with an informational copy to the GH Bureau Environmental Officer.

2.7. MONITORING AND REPORTING

The Implementing Partner and the AOR/COR, in consultation with the BEO, will actively monitor and evaluate whether environmental consequences unforeseen under activities covered by this IEE arise during implementation and modify or end activities as appropriate. Monitoring and reporting will be documented via the Environmental Mitigation and Monitoring Template (EMMT).

The EMMT consists of three parts:

- ***The Environmental Screening Form***

  The AOR/COR conducts annual screenings of their projects using the Environmental Screening Form to determine whether project activities and annual workplans remain within the scope of the activities reviewed during the IEE process. For sub- projects, sub-grants, and sub-activities, Implementing Partners must annually screen their activities and submit the completed form to the AOR/COR. If an activity does not fall within the scope of this IEE, a supplemental or amended environmental document must be prepared.

- ***The Environmental Mitigation and Monitoring Plan (EMMP)***

  The Implementing Partner is responsible for submitting the Environmental Mitigation and Monitoring Plan (EMMP) to the AOR/COR for review and approval. The GH BEO concurs on the EMMP. The EMMP is submitted with the workplan, after clearance of this IEE and prior to initiating project work. Implementing Partners will use the EMMP to describe the specific actions they will undertake under each category of activity when screening reveals potential environmental impacts as outlined in Section 2.5 of this IEE. The EMMP also identifies the person responsible for monitoring compliance with mitigation measures and the indicator, method, and frequency of monitoring.
  Refer to the attached GH EMMP Template.

- ***The Environmental Mitigation and Monitoring Reporting (EMMR)***

  Annually, the Implementing Partner is responsible for completing the Environmental Mitigation and Monitoring Report (EMMR) and submitting it to the AOR/COR. The EMMRs are reviewed by the AOR/COR and the BEO (and/or MEO, as appropriate). The EMMRs ensure compliance with 22 CFR 216 and ADS 204.5 by documenting that the conditions specified in this IEE have been met for all activities carried out under PQM PLUS by reporting on the

results of applying the mitigation measures described in the EMMP and identifying outstanding issues with respect to required conditions. Verification may require digital photos and/or site visits.

The Implementing Partner for PQM PLUS will submit the EMMR on all activities within 60 days after the end of each fiscal year for the life of the project, using the guidance and forms contained in the GH IEE BOP. Any sub- awards, sub-grants, and sub-activities must incorporate provisions stipulating a) the completion of an annual environmental monitoring report and b) that activities to be undertaken will be within the scope of the environmental determinations and recommendations of this IEE. This includes assurances that any mitigating measures required for those activities will be followed.
Refer to the attached GH EMMR Template.

ANNEX A. BUREAU FOR GLOBAL HEALTH

CLIMATE RISK MANAGEMENT SCREENING

1. Program/Activity Data

Program/Activity Title	Medicines Quality Assurance Systems Strengthening Program (MQASSP)
Country/Region	Global
USG Foreign Assistance Framework	Functional Objective: Investing in People Program Areas: Health (HL) Program Element: HL.5: Other Public Health Threats Program Sub-Element HL.5.3: Cross-cutting Health Systems Strengthening (Other Health)

2. Climate Risk Management

This document serves to document the results of the Climate Resiliency Screening conducted to evaluate the potential climate risks of the described activities. In accordance with Mandatory Reference for ADS Chapter 201 on Climate Change in USAID Strategies, USAID must conduct climate risk management screening for all new, projects, and activities, as of October 1st, 2016.

USAID's Office of Health Systems completed this Climate Risk Management Screening by: 1) Consulting within technical backstops for known climate risks and the actions that have been taken under the current awards to assess them; 2) Completing the Climate Assessment Tool on climatelinks.org and referencing the "Health Annex". The assessment and other resources helped identify specific risks and opportunities to address them.

Since this program is at a global scale the climate risks will need to be addressed at the country or regional level upon award. Participants will be highly encouraged to fill out the *Climate Risk Screening and Management Tool for Activity Design* below particularly for program elements with moderate to high risk rating. Guidance in filling this out is in https://www.climatelinks.org/sites/default/files/2017-06-13%20USAID%20CRM%20Tool%20Health%20Annex.pdf.

USAID will work with implementing partner/s to continue to address these risks at the workplanning level. For countries with project elements that have moderate or high-risk rating, USAID will provide CRM orientation to and will collaborate with implementing partner/s to develop a multi-year climate risk management plan, based among others on an assessment of the country's adaptive capacity. The implementing partner shall assure that sub-grantees and subcontractors have the capability to implement CRM. The implementing partner will, if appropriate, provide orientation to sub-grantees and subcontractors on climate risk management. Per Mandatory Reference for ADS Chapter 201 Climate Risk Management for USAID Projects and Activities implementing partner/s may integrate "document(ation)

of the benefits of taking action to reduce climate change impacts and/or increase adaptive capacity" in their performance monitoring in program elements with moderate or high risk ratings.

Climate Risk is defined as the following per ADS 201.mal:

	PROBABILITY OF NEGATIVE IMPACT (increases from left to right)		
SEVERITY OF NEGATIVE IMPACT (increases from top to bottom)	Low probability Low impact **LOW RISK**	Moderate probability Low impact **LOW RISK**	High probability Low impact **LOW RISK**
	Low probability Moderate impact **LOW RISK**	Moderate probability Moderate impact **MODERATE RISK**	High probability Moderate impact **MODERATE RISK**
	Low probability High impact **MODERATE RISK**	Moderate probability High impact **HIGH RISK**	High probability High impact **HIGH RISK**

Low climate risk – the above table indicates four scenarios (in green) that would be considered low climate risk to the achievement or sustainability of project or activity outcomes. As an example, in a region expecting slight increases in temperature and precipitation, favoritism influencing the provision of assistance after crop failure may pose a low risk to a governance initiative focused on anti-corruption reform in the judiciary (low probability, low impact).

Moderate climate risk – the above table indicates three scenarios (in orange) that would be considered moderate climate risk to the achievement or sustainability of project or activity outcomes. An example of a moderate climate risk is the potential consequence of increasing sea surface temperature, causing coral reef bleaching and subsequent reduction in wild fish populations, on a coastal fisheries management and food security program (moderate probability, moderate impact).

High climate risk – the above table indicates two scenarios (in red) that would be considered high climate risk to the achievement or sustainability of project or activity outcomes. An example of a high climate risk is damage due to sea level rise coupled with increasing storm surge on planned coastal transportation infrastructure (high probability, high impact).

The following activity categories under the MQASSP may experience disruptions due to climate related risks:

1. Convening meetings and workshops
2. Facilitation of collaborative learning and information transfer/research utilization
3. Secondary data analysis
4. Development Research
5. Procurement, storage, management, distribution and disposal of public health goods

CLIMATE RISK MANAGEMENT SUMMARY TABLE

Medicines Quality Assurance Systems Strengthening Program (MQASSP)

NOTE: Low climate risk does not require the development of specific plans to address climate risk. However, moderate to high climate risk requires appropriate consideration and response to the potential risk. In some cases, the program may decide to accept the risk and will document the justification.

Defined or Anticipated Project Elements[1]	**Climate Risks**[2]	**Risk Rating**[3]	**How Risks are Addressed at Project Level**[4]	**Further Analysis and Actions for Activity Design/ Implementation**[5]	**Opportunities to Strengthen Climate Resilience**[6]
1. National Quality Assurance strengthened	Disruption of meeting or training events due to extreme weather/ climate events or infectious disease outbreaks	Low			USAID will work with implementing partners to monitor extreme weather/climatic events and infectious disease outbreaks at a country level
2. Improved country and regional capabilities to assure the	Disruption of meetings or technical assistance due to extreme weather/ climate events or infectious disease outbreaks	Low			USAID will work with implementing partners to monitor extreme
	Lack of access to facilities due to	Moderate	USAID will	USAID will work with	weather/climatic

[1] Purpose/Sub-purpose, Area of Focus, or Activity/ Mechanism, etc.

[2] List key risks related to the project elements identified through either the strategy- or project-level climate risk assessment.

[3] Low/Moderate/High

[4] Describe how risks have been addressed at the project level. If a decision has been made to accept the risk, briefly explain why.

[5] Describe CRM measures to be integrated into activity design or implementation, including additional analysis, if applicable.

[6] Describe opportunities to achieve development objectives by integrating climate resilience or mitigation measures.

quality and safety of medicines in the public and private sectors	extreme weather/climate event such as flooding that can damage infrastructure and facilities		integrate opportunities to strengthen climate resilience during activity planning and design	implementing partners and partner countries officials to monitor climate events that may affect mobility and will develop a contingency plan to ensure that facilities can be reached to the extent feasible.	events and infectious disease outbreaks at a country level. Where feasible in high risk countries USAID will train health providers and/or Ministry staff and emergency responders on Climate Change and Adaptation and Preparedness Strategies. USAID will work with implementing partners to develop contingency plans for areas with moderate/high risk to extreme climatic events to ensure health services are resilient to shocks.
3. Evidence produced and global advocacy advanced on the importance of quality assured medicines	Disruption of meeting or training events due to extreme weather/ climate events or infectious disease outbreaks	Low			USAID will leverage existing resources such as early warning systems that can detect future extreme weather/climate events as well as monitoring and
	Disruption of data collection or equipment due to extreme weather/climate events or infectious disease outbreaks	Moderate	USAID will integrate opportunities to strengthen climate resilience during	USAID will work with implementing partners to identify countries at risk of experiencing an extreme	

			activity planning and design	weather/climate event that could disrupt the health system. Once these countries have been identified, USAID will work with the implementing partner to ensure potential climate risks are addressed to the extent feasible.	forecasting of disease outbreaks linked to weather conditions that can disrupt the health system. Where feasible in high risk countries USAID will train health providers and/or Ministry staff and emergency responders on Climate Change and Adaptation and Preparedness Strategies. USAID will work with implementing partners to develop contingency plans for areas with moderate/high risk to extreme climatic events to ensure health services are resilient to shocks.
4. Quality assured pharmaceutical goods and technologies increased	Disruption of meeting or assessments due to extreme weather/ climate events or infectious disease outbreaks	Low			USAID will work with implementing partners to monitor extreme weather/climatic events and infectious
	Disruption of pharmaceutical goods or technology production	Moderate	USAID will integrate	USAID will work with implementing partners	

			opportunities for climate resilience during activity planning and design.	to identify countries at risk of shifts of disease burden or at risk for natural disaster. Once these countries have been identified, USAID will work with the implementing partner to ensure potential climate risks are addressed to the extent feasible.	disease outbreaks at a country level
5. Improved country and regional capacity to assure the quality and safety of medicines quality assurance systems	Disruption in drug/commodities production and distribution due to extreme weather/climate event or infectious disease outbreak	Moderate	USAID will integrate opportunities to strengthen climate resilience during activity planning and design	USAID will work with implementing partners to identify countries with weak supply chains and are at risk of experiencing an extreme weather/climate event that could disrupt supply chains. Once these countries have been identified, USAID will work with the implementing partner to ensure potential climate risks are addressed to the extent feasible.	USAID will leverage existing resources such as early warning systems that can detect future extreme weather/climate events as well as monitoring and forecasting of disease outbreaks linked to weather conditions that can disrupt the health system. Where feasible in high risk countries USAID will train health providers and/or Ministry staff and emergency
	Shift in disease burdens leading to outbreaks of disease that may require a surge of medical products.	Moderate	USAID will integrate opportunities to strengthen climate	USAID will work with implementing partners to identify countries at risk of shifts of	

			resilience during activity planning and design	disease burden. Once these countries have been identified, USAID will work with the implementing partner to ensure potential climate risks are addressed to the extent feasible.	responders on Climate Change and Adaptation and Preparedness Strategies. USAID will work with implementing partners to develop contingency plans for areas with moderate/high risk to extreme climatic events to ensure health services are resilient to shocks. USAID will work with implementing partners to develop contingency plans for areas with moderate/high risk to extreme climatic events to ensure health services are resilient to shocks.

Climate Risk Screening and Management Tool for Activity Design
ACTIVITY CRM TOOL OUTPUT MATRIX: CLIMATE RISKS, OPPORTUNITIES, AND ACTIONS

1.1: Defined Project Elements **Fortified**	**Sub-purpose 2 : Quality of Services**
1.2: Time-frame	• **[List time-frame]**
1.3: Geography	• **[List geog. scope]**
2: Climate Risks	• **[Enter description of climate risks]**
3: Adaptive Capacity	• **[Enter description of Information Capacity, Social and Institutional Capacity, Human Capacity, and Financial Capacity]**
4: Climate Risk Rating	[**Enter rating for each risk**: High, Moderate, or Low]
5: Opportunities	• **[Enter description]**
6.1: Climate Risk Management Options	• **[Enter management options for each climate risk]**
6.2: How Climate Risks Are Addressed	• **[Enter selected management options for each climate risk, if relevant]**
7: Next Steps for Activity Implementation	• **[Enter next steps for addressing risks in activity implementation, if relevant]**
8: Accepted Climate Risks*	• **[Enter if the risk is accepted and why, if relevant. This is required if 6.2 and 7 do not address this climate risk]**

ANNEX B. Environmental Screening Form

Medicines Quality Assurance Systems Strengthening Program (MQASSP)

Project Name: _____	**Original IEE File #/DCN:** _____
Name of Prime Implementing Organization: _____	**Date of Screening:** _____
Name of Sub-awardee Organization (if this EMMT is for a sub): _____	**Funding Period for this award:** FY_____- FY_____
Geographic location of USAID-funded activities (Province, District): _____	**Current FY Resource Levels:** FY_____
This report prepared by: Name:_____ Date: _____	**Date of Previous EMMT for this organization (if any)**: _____

Indicate which activities your organization is implementing.

	Key Elements of Program/Activities Implemented	Yes	No
1	Education, Technical Assistance, or Training Includes: strategic planning, data analysis, technical consultation, surveys, knowledge and information transfer, meetings, technical material development, outreach programs, and training services.		
2	Research and Development Includes: health-related research and development activities aimed at advancing knowledge and technology, including research and evaluation, monitoring and surveillance, programs, pilot studies, case studies, and assessments.		

3	Public Health Commodities Includes: procurement, storage, transportation, distribution, and disposal of public health commodities, including pharmaceuticals, nutritional supplements, chemicals (e.g., disinfectants, solvents, laboratory reagents, etc.), medical supplies, and family planning commodities (e.g., contraceptives, condoms, etc.).		
4	Small-Scale Construction or Rehabilitation Includes: hospitals, clinics, laboratories, voluntary and counseling testing centers, or training centers. Total surface area of the disturbed environment is under 10,000 square feet and less than $200,000 total cost.		
5	Small-Scale Water and Sanitation Includes: pond and spring improvements and installation of hand-dug wells, individual or community latrines, hand-washing stations, and small-scale septic and leach field systems.		
6	Nutrition Includes: small-scale food production, procurement and distribution of supplements, preventing undernutrition, providing nutritional care and support, and improving nutritional outcomes in programs.		
7	Vector Control Includes: procurement, distribution, or use of pesticide products such as insecticide-treated bednets, larviciding agents, and fumigants. NOTE: USAID uses USEPA's definition of pesticides, which includes "any substance intended for: preventing, destroying, repelling, or mitigating any pest. This includes herbicides, fungicides, plant regulators, and desiccants."		
8	Emergency Response Includes: coordination with outside organizations and technical experts, deployment of resources and response teams, and development of technical materials.		

DESCRIPTION OF ACTIVITIES:

Provide a description of activities with sufficient details to understand the scope and scale of the interventions. The EMMP should reference the governing IEE (GH- or country-level).

ANNEX C. Environmental Mitigation and Monitoring Plan

Medicines Quality Assurance Systems Strengthening Program (MQASSP)

Add Introduction and additional narrative here, as needed.

Category of Activity from Section 2.6 of ____ IEE	Describe specific environmental impacts of your organization's activities (based on analysis in Section 2.5 of the ____ IEE)	Description of Mitigation Measures for these activities as required in Section 2.6 of ____ IEE	Who is responsible for monitoring?	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
1. Education, Technical Assistance, Training						
2. Research and Development						
3. Public Health Commodities						
4. Small-Scale Construction						
5. Small-Scale Water and Sanitation						
6. Nutrition						
7. Vector Control						
8. Emergency Response						

Category of Activity from Section 2.6 of ____ IEE	Describe specific environmental impacts of your organization's activities (based on analysis in Section 2.5 of the ____ IEE)	Description of Mitigation Measures for these activities as required in Section 2.6 of ____ IEE	Who is responsible for monitoring?	Monitoring Indicator	Monitoring Method	Frequency of Monitoring

Prepared by:

_Signature_____ Date:_____

_Name and Title_____

Reviewed and Approved by:

_Signature_____ Date:_____

Agreement Officer's Representative/Contracting Officer's Representative

Concur:

_Signature_____ Date:_____

GH Bureau Environmental Officer

ANNEX D. Environmental Mitigation and Monitoring Report

Medicines Quality Assurance Systems Strengthening Program (MQASSP)

Add Introduction and additional narrative here, as needed.

List each Mitigation Measure from column 3 in the EMMP (EMMT Part 2 of 3)	Status of Mitigation Measures	List any outstanding issues relating to required conditions	Remarks
1. Education, Technical Assistance, Training			
2. Research and Development			
3. Public Health Commodities			
4. Small-Scale Construction			
5. Small-Scale Water and Sanitation			
6. Nutrition			
7. Vector Control			
8. Emergency Response			

Prepared by:

Signature_____ Date:_____

___Name and Title_____

Date

ANNEX E. References and Resources

22 CFR 216: http://www.usaid.gov/our_work/environment/compliance/22cfr216

ADS 200: Introduction to Programming Policy:
http://www.usaid.gov/sites/default/files/documents/1870/200.pdf

ADS 204: Environmental Procedures:
http://www.usaid.gov/sites/default/files/documents/1865/204.pdf

ADS 300: Agency Acquisition and Assistance (A&A) Planning:
http://www.usaid.gov/sites/default/files/documents/1868/300.pdf

ADS 302: USAID Direct Contracting: http://www.usaid.gov/sites/default/files/documents/1868/302.pdf

ADS 308: Awards to Public International Organizations:
http://www.usaid.gov/sites/default/files/documents/1868/308.pdf

ADS 502: USAID Records Management Program:
http://www.usaid.gov/sites/default/files/documents/1868/502.pdf

Bureau for Global Health Project Design and Approval Guidance

Environmental Compliance: Language for Use in Solicitations and Awards, An Additional Help to ADS 204: http://www.usaid.gov/sites/default/files/documents/1865/204sac.pdf

Executive Order 12114: Environmental Effects Abroad of Major Federal Actions:
http://www.archives.gov/federal-register/codification/executive-order/12114.html

Executive Order 13677: Climate-Resilient International Development: https://www.whitehouse.gov/the-press-office/2014/09/23/executive-order-climate-resilient-international-development

Foreign Assistance Act: http://www.usaidgems.org/lawsRegsPolicies/faa.htm

National Environmental Policy Act:
https://ceq.doe.gov/laws_and_executive_orders/the_nepa_statute.html

USAID Sector Environmental Guidelines: http://www.usaidgems.org/sectorGuidelines.htm