Standards Alliance: Phase 2

Quarterly Report

Q1 January 1st to March 31st, 2022

Submission Date: April 30, 2022

Agreement Number: 7200AA19CA00012

Activity Start Date and End Date: July 12, 2019 to July 11, 2024

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1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date And End Date:	July 12, 2019 – July 11, 2024
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractors/Subawardees:	Ethical Apparel Africa, AdvaMed, ASTM International, NSF, AWWA, ACI, CWSC, IAPMO
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	Q1 2022 – February 1st to April 30th, 2022

1.1 Program Description/Introduction

Standards form the foundation of world trade and the efforts of the Standards Alliance help to create fertile ground for reciprocal trade with the U.S. Through increased adherence and understanding of standards and conformity assessment principles, participating nations will become more competitive in the global market, be more prepared for bilateral trade agreements, and be more capable of protecting their citizens from hazardous goods.

The Standards Alliance Phase 2 (SA2) will engage target populations including, but not limited to, foreign government officials and ministries responsible for standards, trade and consumer protection; foreign private sector; industry groups; civil society; consumer interest groups; business professionals; trade policy experts; and academia. The objective of this initiative is to build on the past successes, lessons learned and impact measured to-date of the first iteration of the Standards Alliance to support the capacity of developing countries in the areas of legal and regulatory framework, standards development, conformity assessment procedures, and private sector engagement. Achieving these goals also helps companies succeed globally by increasing market access for U.S. companies through more predictable and transparent avenues for trade and investment in partner markets/regions.

The implementing partner for this cooperative agreement is the American National Standards Institute (ANSI). ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. ANSI's mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. Because of ANSI's unique role as a coordinating body and a bridge between the private and public sectors, the Institute can build partnerships and foster collaborative solutions for national and global priorities. And ANSI is a membership organization, providing members with the broadest access to up-to-date standards policy information and opportunities for participation, leadership, and influence. Finally, ANSI also promotes the use of U.S. standards

internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

The Standards Alliance Phase 2 will include activities in markets representing a variety of geographical regions and levels of economic development, subject to the agreement of USAID. In consultation with USAID Missions, U.S. government, and private sector experts, ANSI will select the countries/regions based on demonstrated commitment and readiness for assistance, as well as U.S. private sector interest and development impact. ANSI expects to engage on both a national and regional level when appropriate, and to engage partners in the Latin America, Africa, Middle East/North Africa, and Indo-Pacific regions.

SA2 Focus on Medical Devices to Support COVID-19 Response

In June 2020, USAID further recognized the critical role of standards and conformity assessment in supporting public health and safety through an obligation of $3.5 million to the SA2, which is part of the more than $1 billion the agency has committed to aid the global COVID-19 pandemic response. This SA2 project will promote regulatory convergence in the context of COVID-19, good regulatory practice (GRP), and the adherence and adoption of medical device international standards. These objectives will also establish an efficient medical device regulatory environment and framework that will facilitate the COVID-19 response and diminish technical barriers to trade—thus promoting the exportation of quality U.S. medical devices. AdvaMed—a U.S. based trade association and ANSI member—will be the primary private sector partner of the project, and there will be select partner countries in Latin America, Africa, and Southeast Asia, with overflowing impacts within those regions.

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The first quarter of 2022 entailed the continued implementation of activities under all approved subawards and the introduction of some projects to relevant USAID Missions. The MDRC program in particular continued to make significant progress this quarter via several webinars, outreach with key stakeholders, critical meetings, and the finalization of the Tier One Gap Analysis report on Good Regulatory Practice. ANSI also continued to monitor the COVID-19 pandemic throughout Q1 and will continue to adjust activity implementation accordingly.

2.2 Non-COVID-19 Related Activities Activity Implementation Progress

AFRICA

Development Objective #1: Countries have developed their national quality infrastructure

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

Partner countries: West Africa

Under this activity Pivot, per the Annual Work Plan for Year 3, has been developing workshops on renewable fuel with ECOWAS.

The original intention defined in the Annual Work Plan for Year 3 was to hold Clean Renewable Fuels Workshops for Ghana, Nigeria, Senegal. However, based on outreach and feedback from the Center for Renewable Energy and Energy Efficiency (ECREEE) Togo and Gambia were the only ECOWAS countries that showed strong interest in hosting a workshop on this topic. Pivot underlined that those two countries were ultimately chosen because:

- They demonstrated need for clean fuels based on current baseline cooking data and reliance on solid and unclean fuels.
- Their petroleum imports for transport and significant opportunity to replace 5 to 10% of it with bioethanol.

Of their trade relationships with the US and prospective opportunity for increased trade. Togo and The Gambia met the criteria and both countries were listed as two of five ECOWAS countries recommended as top prospects for US trade by the US Foreign Agricultural Services (FAS) in late 2019.

Togo:
Workshop planning began to amplify in January, 2022 after having identified speakers and defining logistics for the event. ANSI played a key coordination role to oversee the preparation of the workshop. The agenda was edited, finalized, and approved by ECREEE and presented to the Ministry of Energy in Togo.

Taking uncertainty around international travel, still cause by the pandemic, into account it was determined the workshop should move forward under a hybrid format. Stakeholders already in the country could attend in person and speakers would present virtually.

The workshop then, ensued from March 17 to March18, 2022 in Togo. A virtual platform hosted by ANSI was used to connect speakers with the conference center. The workshop featured an introduction to bioethanol, adjacent sector impacts, the importance of smart policy and standards, implementation of bioethanol projects, and a panel discussion followed by a discussion around next steps.

The Gambia:
The development of the workshop in The Gambia followed the same model as the one in Togo. Additionally, the objective of the event was the same (i.e introduce local stakeholders to bioethanol, adjacent sector impacts, the importance of smart policy and standards, and implementation of bioethanol projects).

This event for similar reasons was also hybrid and took place from March 21 to 22, 2022 in The Gambia.

Follow-up, for both workshops, has begun and is in progress to gather feedback and determine concrete action steps leading to in-country implementation of workshop topics. Pivot has connected with a couple of individuals from the conferences who reached out with several of their collaborators. Pivot also continues to follow up through emails/newsletter correspondence with all workshop participants and has received some initial feedback from the post-workshop survey.

ASTM E3050 is currently under review but once it is approved, Pivot plans to circulate it and see how they can encourage partnerships (MoU) between the local standards organizations and ASTM to give them access to the standard. Pivot is also continuing to work with ECREEE to push out a regional fuel standard/adopt the ASTM standard as well, which would impact those countries

Activity #2 – Support for African Organization for Standardization (ARSO)

Partner countries: Continent Wide

In Q1, ANSI, ARSO, and the Personal Care Product Council (PCPC) worked to narrow down a suitable time frame for the next webinar on Good Manufacturing Practices for Cosmetics scheduled for the next quarter of 2022.

The webinar is set to take place during the week of May 9 from 8:00 – 9:00 am EST. PCPC and ANSI shared a draft agenda and brief synopsis of what will be covered during the webinar for review by ARSO's leadership and are awaiting comments and a confirmed date. For this webinar, experts from PCPC will provide an overview of the importance of Good Manufacturing Practices for cosmetics in ensuring consistent quality. Speakers will expand upon the ISO standard for cosmetics GMP and provide top-level insight into aspects of practical implementation.

Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy

Partner countries: Ghana, Uganda, Zambia

Activity #3.1 – Conduct deskwork to gather information about relevant laws, regulations, policies and standards in target countries from online sources and CWSC's network of contacts

Deskwork continues in Ghana, Uganda, and Zambia and as such there is no detailed implementation progress to report yet. The initial deskwork research is complete and fieldwork will be used in Q2 2022 to validate deskwork and fill in gaps. CWSC's focus in Q1 2022 was on finding and examining the available documents related to WASH and standards in each country.

Activity #8 – Utility Management Standards Training for water sector utilities

Partner countries: Malawi, Zambia, and Lesotho

USAID, ANSI, and AWWA held introductory calls that gave a project overview for the USAID Missions in Zambia, Malawi, and the South African Mission (for Lesotho). In Q1, the final concurrence needed to begin work in Africa was approved for Zambia.

Activity #8.1 – AWWA to conduct a needs assessment survey to identify specific utility management standards of greatest interest to water sector utilities in Zambia, Malawi, and Lesotho and recruit a cohort of gender-diverse training participants from 15+ utilities

AWWA circulated a draft needs assessment survey for review that will be sent to African utilities in Q2 2022. This will identify specific utility management standards and will allow AWWA to begin tailoring workshops to fit the needs of water utilities within the three African countries. In Q1, A kickoff call with

ROCKBlue was held to discuss workshop preparation, outreach, needs assessments, program sustainability, and ROCKBlue lessons learned from their local work with African countries.

Malawi:
AWWA, ROCKBlue, ANSI, USAID, and the Malawi Mission joined a call to begin work in Malawi. AWWA, ROCKBlue, and the Malawi Mission will remain in contact for outreach to utilities in Malawi.

Activity #8.2 – Develop training materials and agenda by AWWA staff and subject matter experts (SMEs)

AWWA secured a team of subject matter experts (SMEs) through an RFP process which includes the co-leader who developed the G-series standards to deliver the technical content for the workshops in Africa.

Development Objective #2: Private sector actively participates in countries' national quality infrastructure

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

Partner countries: West Africa (Côte d'Ivoire, Ghana, Nigeria, Senegal)

Activity #5.3 - Maintain regular consulting meetings to raise public and private sector awareness and understanding of relevant international standards

During this quarter the focus of the implementation program was centered around the organization of a 3-day Workshop on petroleum standards in early March 2022 for all four partner countries. ANSI participated in meetings with the API (American Petroleum Institute) to define budget and logistics for the workshop during this period.

In January, the workshop location and other details were being negotiated with the Ghana Standards Authority facilitated by a local consultant in Accra. Additionally, a call was scheduled with CODINORM, the national standards body of Cote d'Ivoire. The purpose of the call was to request their assistance to identify two focal points that could participate in the project and attend the workshop in Ghana.

In February, Invitation Letters were sent to the eight focal points who were identified to participate in the program; and a survey was created to identify the current test methods being used for the various parameters and sent to the different focal points.

The 3-day Workshop was convened in Ghana from March 1 to 3, 2022. A training was conducted for the first two days of the workshop and both ANSI and API participated virtually. On the last day laboratory tours at the Ghana Standards Authority and Verity Labs were conducted.

Two follow up meetings were held in March, with Abdoul Aziz Deme (Senegal- focal point) to discuss access to the most current ASTM standards and the possible participation of the African Refiners and Distributor Association's laboratories in ASTM's Proficiency Testing Programs for petroleum. ASTM is currently working in coordination with Nigeria's NSB to organize a workshop in July in conjunction with the Nigeria Oil and Gas Conference (mentioned in section 6 of the report) in early July 2022. The ASTM workshop would continue the educational process which began in March, 2022 and would allow ASTM

to discuss in more detail the technical topic priorities of the project.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

Partner countries: Kenya, Uganda, Tanzania

Activity #6.1 – Research and identify the appropriate contacts in Kenya, Uganda, and Tanzania for the relevant government & ministries, engineering societies, and relevant university facilities.

Kenya:
In late March, the Institute of Engineers in Kenya (IEK) has confirmed their interest in signing an International Partner Agreement with ACI, and they are also interested in co-organizing a virtual seminar with ACI for the stakeholders in East Africa (Kenya, Tanzania and Uganda) to learn more about ACI (American Concrete Institute) and their various programs and initiatives that are available to them through the Standards Alliance 2 project. Efforts to continue to build this relationship are underway.

Tanzania:
The research around the interested stakeholders is at an early stage. A meeting between the USAID mission in Tanzania, ACI, an ANSI was organized in February where the USAID mission shared the contact of potentially interested stakeholders. ANSI did attempt to reach out but so far responses have been sparse.

Activity #6.2 – Begin outreach and consulting meetings with interested parties including government and ministry representatives, standards organizations, engineering associations, and/or educational institutions to introduce ACI, ACI codes/standards.

Uganda:
An effort to start outreach activities was made and a meeting with Engineer Hans Mwesigwa, Editor/Owner of 8M Construction Digest was schedule in late January of 2022. 8M Construction Digest was interested in the activity proposed by the SA2 program and an action plan was developed. Said plan includes joining Faculty Networks to get ACI materials, work with their industry contacts to build a meeting to introduce ACI, and promote ACI in Uganda with a few articles in his magazine. This was the only successful meeting to report this quarter as two other meetings with Uganda Institute of Professional Engineers (UIPE) and Engineers Registration Board (ERB) were also scheduled in late January but both relevant stakeholders were not able to attend in the end.

INDO-PACIFIC

Development Objective #1: Countries have developed their national quality infrastructure

Activity #7 – Increase the Flow of WASH Services

Partner countries: Indonesia and The Philippines

Activity #7.1 – Initiate development of new Indonesian national standard related to water faucets, based on existing international standards.

Indonesia:
Three formal standard development meetings were held in Q1 2022 on February 2, February 23, and March 8. The meetings in February were online meetings while the meeting in March, which was a consensus meeting, was held in person. All three meetings were attended by members of Technical Committee 77-02 and other stakeholders.

The draft standard has been finalized in the stage of RSNI 3. Moving forward, public comments will be put on the BSN's website (http://sispk.bsn.go.id/EBallot/DJPP)S and there will be a 2 month window to collect opinions from public.

Activity #7.2 – Conduct review of National Building Code of the Philippines (NBCP), Philippine Green Building Code (PGBC) and current technical regulations related to water efficiency

The Philippines:
IAPMO's work in the Philippines continues to be stalled while the SA2 awaits congressional notification approval before outreach with the Philippines Mission can occur. USAID is managing the congressional notification approval process and outreach.

Activity #8 – Utility Management Standards Training for water sector utilities

Partner country: India

Activity #8.1 – AWWA India to conduct a needs assessment survey to identify specific utility management standards of greatest interest to water sector utilities in India and recruit a cohort of gender-diverse training participants from 15+ utilities

AWWA completed the needs assessment in Q3 2021. As it was reference in the Q3 report, AWWA exceeded its goal of 15-20 completions of the needs assessment survey by receiving approximately 70 responses, which allowed AWWA to identify specific utility management standards. As mentioned in the Q4 2021 report, the primary interest from utilities centered on 4 primary standards[1] and developed tailored workshops to fit the needs of the utilities in India, primarily addressing their need for technical assistance on developing optimization strategies.

Outreach took place this reporting quarter to raise awareness around the India workshops and to secure participation agreements for those series of workshops. As a next step AWWA recruited about 60 registrants for the first India virtual workshops to be held July 20-21, representing 16 organizations.

Activity #8.2 – Develop training materials and agenda by AWWA staff and subject matter experts (SMEs)

AWWA secured a team of subject matter experts (SMEs) through an RFP process which includes the co-leader who developed the G-series standards to deliver the technical content for the workshops in India.

[1] ANSI/AWWA G100 Water Treatment Plant Operation and Management; ANSI/AWWA G200 Distribution System Operation and Management; ANSI/AWWA G510 Wastewater Treatment Plant Operations and Management; ANSI/AWWA G520 Wastewater Collection Systems Operations and Management

Additionally, agendas, content, and presentation material has been completed and reviewed in advance of the first workshop in India to be held virtually on April 27-28.

LATIN AMERICA

Development Objective #1: Countries have developed their national quality infrastructure

Activity #9 – Community Water Systems – Standards for safety and risk management

Partner country: Brazil

Activity #9.2 – Conduct regulatory and governmental outreach and relationship building and strengthening to facilitate discussions on the benefits of NSF/ANSI/CAN drinking water standards

This quarter, NSF engaged with:

- Brazil: ARSESP - Regulatory Agency São Paulo with point of contact Sergio Henrique Carreiro Bernardes
- ASFAMA - Associação de Fabricantes Saneamento with point of contact Pedro Taves

Activity #9.3 – Hold trainings to address barriers to trade and awareness of other issues. (Q4 2021/Q12022)

Material development update: In Brazil, informed by the Needs Assessment phase, the training materials were developed by technical staff from NSF Commercial Water team in coordination with NSF's Brazil trainer. The NSF Standard 61 material was completed this quarter. The NSF Standard 60 material is under final development by NSF's Marketing team and is expected to be completed early Q2 2022.

Training dates: With consideration of Carnival and Brazilian summer vacation time, there was a shift in planned training start from the end of the first quarter of 2022 to the end of the second quarter 2022.

Training content for participants will include:

- Regulators and health agencies, focusing on:
  - Public health benefits from the adoption and enforcement of safety standards
- Manufacturers, focusing on:
  - Commercial benefits
  - Import and export facilitation when adopting internationally adopted standards
- Consumers (including water utilities), focusing on:
  - Liability reduction when adopting safety standards
  - Best practices when acquiring safe chemicals and materials for drinking water systems

- General training content will include:
  - Importance of safety standards to reduce public health impact of unsafe water
  - Transparency and balanced stakeholder engagement of ANSI standards development process
  - NSF/ANSI 60 and 61 scope

As requested by participants, the training will be recorded, but will utilize a live Question and Answer period, which has proven to be a good approach for other NSF training events. The ON24 (https://www.on24.com/) shall be the platform used.

MIDDLE EAST NORTH AFRICA

Development Objective #1: Countries have developed their national quality infrastructure

Activity #7 – Increase the Flow of WASH Services

Partner country: Jordan

In Q3 2021, the Jordan Mission requested IAPMO hold engagement in Jordan until 2022 due to the increase of Afghan refugees in Jordan, which has impacted the availability of staff to coordinate other activities. IAPMO does not have approval to begin outreach in Jordan and as such, IAPMO did not undergo any activities in Q1 2022.

Activity #9 – Community Water Systems – Standards for safety and risk management

Partner country: Morocco

Activity #9.1 – Conduct a needs assessment to determine the guidelines and processes drinking water providers in Morocco are currently using

In Morocco, the Need Assessment phase is on-going. As an effort to improve stakeholder response, ANSI assisted with outreach by sharing additional relevant contact (IMANOR) and reaching out directly to stakeholders. Additionally, as the characterization of the regulatory framework was completed there was initiation of the development of the training content, subject to refinement as more stakeholder surveys are received.

Activity #9.2 – Conduct regulatory and governmental outreach and relationship building and strengthening to facilitate discussions on the benefits of NSF/ANSI/CAN drinking water standards

NSF engaged with the Moroccan Institute of Standardization (IMANOR), a critical in-country governmental stakeholder, who not only expressed interest, but offered to assist with outreach and promotion. NSF was glad for this offer and will be utilizing IMANOR's channels for continued outreach.

Additionally, NSF engaged with:

- IMANOR – Point of contact, Hosam Alami
- ONNE (Office National de l'Electricité et de l'Eau Potable) - Point of contact, Ilyas Mansouri
- Directorate of Water - Ministry of Equipment, Transport, Logestics & Water - Omar Binjaloun
- Water & Sanitation department within the Ministry of Interior - Abdelhafid Reffouh
- Lydec - Touria TIJANI
- Redal (Veolia company) - Omar Zourzi
- The Moroccan Association of Drinking Water and Sanitation AMEPA - Asma EL KASMI
- Ministry of Health – Whabi Rachid

Activity #9.3 – Convene stakeholders and host two training events to increase awareness of the value of the program, including addressing barriers to trade

Material Development Update: Informed by the Needs Assessment phase to date, the training materials development was initiated in Q1 2022 with NSF Commercial Water Technical staff members in coordination with the trainer for Morocco and will be refined early Q2 2022.

Efforts to set training dates, and location will be initiated after Ramadan (April 1 – May 2), in Q2 2022.

2.3 COVID-19 Related Activities Implementation Progress

AFRICA

Development Objective #4: Countries have COVID-19 plans that leverage their NQI in a trade-facilitating manner

Activity #11 – COVID-19: Surgical Mask Production Project

Partner country: Ghana

Implementation of this activity has faced delays because Ethical Apparel failed to pass the pre-qualification testing for the surgical face masks they are trying to produce in Ghana. The results for both bacterial filtration efficiency (BFE) and submicron particulate filtration efficiency were fine but the submicron particulate efficiency results were too low by up to 4% from the targeted 98%. This will make for a difficult adjustment in materials because in order to try to improve differential pressure by going to a slightly lower weight material meltblown layer or other layers, filtration efficiency may be sacrificed, which needs a higher boost in performance.

The feedback and test results have required Ethical Apparel to resource the mask fabric options again and the next round of sampling is due in Ghana to make into surgical masks by end of April 2022. Therefore, depending on the results from the sampling implementation for this activity could start next quarter. Despite delays with production of surgical masks, Ethical Apparel has been able to produce a large quantity of general use masks which they are currently selling with Ghana – currently they are able to produce one million general use masks per month.

GLOBAL

Development Objective #4: Countries have COVID-19 plans that leverage their NQI in a trade-facilitating manner

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Global

Partner countries: Brazil, Colombia, Ghana, Indonesia, Kenya, Mexico, Peru, South Africa, and Vietnam

Activity #12.1 – The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (the Coalition) will lead in implementing and managing a dedicated COVID-19 Medical Device work stream at the global level on behalf of the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA) working in conjunction with the IMDRF. (Q3 2021 – Q2 2022)

The MDRC team and the Inter-American Coalition for Regulatory Convergence (the Coalition) supported the execution of the first session of an international webinar series on "The Use of Self-Testing to Confront COVID-19" in March 2022.The event counted over 160 participants with 76% of them being from the private sector. The series is by the Latin American Alliance for In Vitro Diagnostic Development (ALADDIV), in partnership with the London School of Hygiene and Tropical Medicine (LSHTM), The International Diagnostics Centre (IDC), and supported by Brazilian Chamber of Laboratory Diagnostics (CBDL), and ALDIMED, the Association of Medical Devices in Latin America.

Africa

Partner countries: Ghana, Kenya, South Africa

Activity #12.3 – Tier One GRP Implementation (foundational): Gap Analysis and Stakeholder Assessment (Q3 2021 – 2022)

Regional:
At the regional level a priority for the entirety of the program will be to ensure that the implementation of the AfCFTA and the obligations that derived from it are taken into account by all stakeholders. In that sense the MDRC team has been involved this quarter in conversations with representatives from the Department of State, Department of Commerce (DoC), and USAID in D.C. and Accra to discuss engagement with the AfCFTA Secretariat and Tier One government stakeholders in Ghana. MDRC emphasized the importance and effectiveness of operationalizing international trade obligations (such as those in the AfCFTA and WTO TBT agreements) at the National Regulatory Authorities (NRA) level. Indeed, lack of compliance with these obligations creates health and emergency response bottlenecks in the supply chain and regulatory approvals processes, prevents medtech products from getting to patients, and inhibits NRAs from properly addressing COVID-19. Given the limited bandwidth of the Secretariat, the priority should be securing the backing from local trade ministries to strengthen future engagement with the Secretariat. For this the MDRC team will rely in part on local US embassies. In Ghana, for instance, officials at the Embassy in Accra agreed to continue facilitating outreach with Tier One ministries. This includes outreach with the local AfCFTA coordination office, focused on national private sector-oriented implementation of the agreement.

To ensure that all key regional stakeholders would be involved in the effort of operationalizing international trade obligations the MDRC team via ANSI started a coordination effort with the African Organisation for Standardisation (ARSO). As the body responsible for harmonizing standards and conformity and assessment procedures on the continent, ARSO is an important partner to the project, and the effort in reducing barriers to trade in all African project countries.

During the outreach effort, ARSO underlined that a major problem in many African countries is a disconnect or lack of communication between national standards bodies and regulatory authorities. As a key component of COVID-19 recovery, both parties are in line and agree that trade and health authorities should focus on proper implementation of international treaty obligations – particularly those pertaining to GRPs and standards and conformity assessment (notably develop a joint WHO/WTO guidance document on trade-related elements that apply to NRAs). Both of these items are important steps towards orienting NRAs in the implementation and operationalization of regulatory reliance and recognition while avoiding the development of new health and trade obstacles.

Related to the AfCFTA, ARSO is in support of the creation of a parallel guidance document in the African context, perhaps between ARSO and the AfCFTA Secretariat. It also shared with the team copy of its MOU with the AfCFTA Secretariat.

Finally, ARSO also shared details of its recently launched project to introduce and incorporate international standards relevant to recovery from the pandemic with national regulators across Africa. Notably ARSO is collaborating with Pharmacy and Poison Boards (PPB) on this project and is developing an MOUs to that effect. ARSO has an institutional connectivity with Kenya's PPB, the African Medical Devices Forum (AMDF), and AfCFTA Secretariat on that topic. Deeper collaboration could be leveraged here between these bodies and advancing joint ARSO-MDRC objectives. To that end MDRC invited ARSO to participate in relevant workstreams and capacity building with AMDF. ARSO even expressed openness towards having an MOU with AMDF. As of the date of reporting ARSO indicated it would discuss internally on how MDRC may help advance ARSO's objectives and would consider developing a concept note for MDRC's consideration.

South Africa:
The MDRC team has been coordinating with the USG for project implementation in South Africa. The MDRC team engaged with representatives from the U.S. DoC and USTDA:

- DoC agreed to assist MDRC in outreach to Tier One ministries and facilitate subsequent engagement with relevant local or regional stakeholders and working groups as appropriate. It noted it does not have standing meetings with counterparts in Tier One ministries, and this process could take some time. During the meeting with DoC a special attention was given to determine how the project works and could leverage the resources of global bodies, such as the Global Harmonization Working Party (GHWP) and Medical Device Regulators Forum (IMDRF). At the end of this reporting period the USG's International Trade Administration (ITA) in South Africa had informed the MDRC team that it had sent outreach on behalf of the project to its contacts at the Ministry of Trade in February. ITA noted that it briefed other local USG partners on MDRC, such as those in the Department of State.
- With the USTDA Office of Sub-Saharan Africa discussion centered around the RFP and how to provide technical assistance on reliance-based protocols for healthcare products to South African Health Products Regulatory Authority (SAHPRA). MDRC and the agency provided overviews of previous engagement and envisioned work with SAHPRA in order to ensure proper alignment and dovetailing of the initiatives. USTDA confirmed the scope of its project

covers medical devices. Once the contractor is confirmed, it would provide technical assistance to review SAHPRA's capacities, extend recommendations on how to improve those capacities, and execute trainings to operationalize those recommendations. MDRC emphasized that any workstream with SAHPRA should properly differentiate between medical devices and pharmaceuticals and facilitate compliance with international trade obligations. USTDA envisions that the contractor could be chosen during the next quarter and will operate in-country for about two to four years once the project begins. Because SAHPRA's limited bandwidth to incorporate foreign assistance, MDRC highlighted the importance of forming a USAID-USTDA-CDRH-MDRC inter-agency coordination group. This group would serve to increase the alignment of USG aid to SAHPRA, minimize the resource impact on SAHPRA, and dovetail related meetings with USG agencies. USTDA also mentioned that an increase in U.S. medtech exports is a success metric/indicator for a USTDA – SAHPRA initiative.

The formal process of workstream development with SAHPRA began this quarter. The team and USTDA underlined that aligning efforts around the work being done with AMDF the development of the workstream trainings on foundational GRP implementation and EUA was necessary. Bi-weekly meetings were implemented to facilitate the design of those trainings. During those meetings a final content and schedule of capacity-building activities through June 2023 were decided. These activities will span around an array of topics, including implementation of GRPs, and convene private sector representatives. SAHPRA shared the terms of reference for its ongoing collaboration with the South African Medical Technology Industry Association (SAMED) and also agreed on having SAMED participate in future MDRC coordination meetings related to program scheduling. Additionally, MDRC noted the USTDA-supported SAHPRA RFP to provide technical assistance on reliance-based protocols for healthcare products. Finally, MDRC informed SAHPRA that MDRC has recommended to USTDA, with the concurrence of USAID and the U.S. Food and Drug Administration (FDA), the establishment and support of a USG inter-agency coordinating mechanism to ensure alignment between all U.S. government-funded aid projects pertaining to medical devices and proper differentiation in capacity building between medical devices and medicines.

During this quarter the MDRC also started an outreach effort with the Medical Device Manufacturers of South Africa (MDMSA), an association of companies that manufacture medical devices within South Africa to discuss how the parties can collaborate on MDRC. During the conversation the MDRC team noted that the global medtech industry works toward the reduction of every type of unnecessary barrier between its technologies and patients in the global fight against COVID-19, including tariff and non-tariff barriers (NTBs). MDRC emphasized, however, that the project scope does not include tariffs and local-production aspects. Instead, it is focused on resolution of NTBs pertaining to the regulatory framework and customs-related elements. MDRC briefed MDMSA on the project's ongoing work with SAHPRA and the workstream's relationship with SAMED technical dialogue with the regulator. The MDMSA Chairperson informed MDRC that they sit on several of the SABS technical committees and is a member of an ARSO technical committee. The parties agreed that moving forward, MDRC will continue working with SAMED as a primary contact, interfacing with MDMSA as helpful and appropriate to the project objectives.

Finally, MDRC updated CDRH on the project's current implementation status in South Africa and at the regional level. This includes information on the finalized roadmap and workstream for capacity building with SAHPRA. At the regional level, CDRH shared that an African Union (AU) delegation representing the African Medicines Agency (AMA) will be traveling to Washington D.C. in early May 2022. The delegation is reportedly seeking to learn from structure of the FDA and the nature of its relationship with the private sector. AdvaMed and pertinent Department of State persons will connect to align on the best timing and format for a meeting with the AU delegation. MDRC indicated it was working with African

regional industry partners to begin a GMTA Africa working group to coordinate industry and capacity building on the continent.

Activity #12.4 – Tier Two: Medical Device Sector-Specific Regulatory, Standards and Conformity Assessment Convergence: Stakeholder Assessment (Q3 2021)

Regional:
An important regional work undertaken this quarter was the development of a coordinated and consistent USG approach to medtech aid provision in Africa. Indeed, the U.S. Food and Drug Administration Center for Devices and Radiological Health (CDRH), USAID, and USAID project teams of MDRC and PQM+ put in place a framework to ensure that medtech aid provision is clearly differentiated from that for medicines. The framework is threefold: (1) the two sectors are distinct in terms of industry and international regulatory reference documents; (2) many COVID-19 medtech regulatory convergence bottlenecks derive from a lack of understanding by NRAs on these differences; (3) the importance of properly differentiating between the sectors in the provision of medtech capacity building within USG-funded projects to mitigate the risk of NRAs improperly conflating the two sectors.

To avoid the provision of funds to building capacity of NRAs in a manner not-consistent with their legal obligations, the MDRC team at the regional level, is allocating with PQM+ more efforts to promote compliance of NRAs with international treaty obligations, such as the WTO TBT agreement. This leverage and is line the agreement by PQM+ to support and facilitate MDRC's admission to AMDF technical working group. MDRC provided an overview of GRP, the relevant requirements under the TBT agreement as components of GRP, and their connections in the context of the projects' implementation. While some NRAs may have initial hesitancy to embrace trade topics it relevant to underline here again that lack of compliance with these obligations creates, as stated under sub activity 12.3, bottlenecks and delays for NRAs in their ability to combat Covid 19. In an effort to ensure compliance with the aforementioned obligations MDRC reiterated its recommendation that the development of SOPs for NRAs to comply with international obligations should serve as a prioritized methodology for remedying bottlenecks, strengthening regulatory processes, and facilitating patient access to vital medical technologies. As of the time of reporting PQM+ agrees on the importance of GRP implementation, noting that many aspects of its project are aligned with this approach.

The MDRC team provided written feedback on the AMDF Strategic Plan 2022-2027 and 2022 Work Plan. The feedback included immediate guidance on how MDRC can contribute to their implementation. MDRC feedback was submitted in conjunction with the SAMED, The Southern African Laboratory Diagnostic Association (SALDA), and Mecomed. Throughout the quarter the MDRC team provided additional explanation on the nature of GRP implementation at the Tier Two level, including through the prioritized methodology of implementing trade and related legal obligations in the medtech context as they apply to NRAs.

In line with this effort AMDF's has a planned Regional Training Workshops slated for the end of 2022. While specific dates for those trainings have not been set, the MDRC team will provide input and feedback on those trainings and their curricula. The objective will be to ensure both the MDRC and AMDF trainings complement and support one another. Starting in the next quarter the team will support the review and dissemination of AMDF's recently published Guidelines for use by NRAs. These documents provide important strategies and principles to guide NRAs in medtech regulation.

Related in part to the above MDRC met with USP to continue alignment on their projects' work in Africa; and discussed engagement with the African Medicines Regulatory Harmonization (AMRH) initiative, of which the AMDF is a technical committee. USP spoke to the two bodies' structures and its ongoing

relationship with the AMDF. MDRC and USP discussed MDRC's recommendation that the compliance with international obligations should serve as a prioritized methodology for the operationalization of AMDF objectives.

Another implementation update relevant to tier two is the development a GMTA working group in coordination with Mecomed, with the aims of coordinating the strategy and approach of the medtech industry in Africa. Such a group would work with relevant regional and local stakeholders towards accelerating regulatory convergence, adoption of GRPs and international standards, proper differentiation between medtech and medicines, and advancement of ethical business practices. To that end, the team and Mecomed had several meetings to coordinate this effort throughout the quarter. This initiative was thus introduced to the Mecomed Sub-Saharan (SSA) taskforce, overviewing its work advancing regulatory convergence in Africa. The MDRC team emphasized the importance of leveraging a whole-of-government approach, the implementation of GRP, and compliance with international legal obligations in resolving bottlenecks and trade barriers. At the end of this reporting period the MDRC team had a meeting with Mecomed, SAMED, and MedTech Europe to discuss a draft proposal for the GMTA working group's scope, objectives, initial work items, and structure. With the aim of advancing this proposal at the GMTA meeting in May 2022 to finalize a proposal that could be shared during the next quarter.

Given the efforts the MDRC team is also carrying out with AMDF the team discussed with Mecomed the work around PQM+ to ensure that all initiatives are aligned. To that both stakeholders provided comments on AMDF's recently published Guidelines for use by NRAs, particularly around misalignments with international obligations and agreed on the need for capacity building for AMDF on that topic in the next quarters.

The MDRC team also engaged with Mecomed for the potential role of Tier Two government stakeholders in Kenya, Ghana, and South Africa attending Mecomed's upcoming regional forum in Q2 2022. This forum would serve as an opportunity to convene those stakeholders in a regional context and execute a regional Tier Two training. As well as continued discussions on Mecomed's June 2022 regional medtech forum for the Middle East and Africa. Mecomed confirmed it envisions participation from African countries, including Egypt, Algeria, Morocco, Kenya, Ghana, and South Africa.

Ghana:
The team started conversations with Ghana's Ministry of Health to introduce the project, its methodology, and envisioned partnership in the country. The Ministry is supportive of the project, indicating it is well-positioned to bolster the Ministry's efforts to strengthen the regulatory system. It emphasized the importance of leveraging WHO guidance and ensuring all activities are aligned with WHO recommendations and benchmarks. Taking the ministry's input into consideration the team shared an overview of its objectives and proposal for project implementation. This document serves as an outline to the potential scope of partnership for advancing Tier Two work in Ghana alongside the Ministry and other relevant stakeholders.

Kenya:
In keeping with an effort to inform all relevant local stakeholders of the MDRC project one of the first activities, in this country, undertaken this quarter was to present the program to the Customs and Border Control Department. The team emphasized its whole-of-government approach to advancing the implementation of GRP and resolving bottlenecks for medical devices in reaching points of care; and noted it is also working with individual agencies to develop agency- or ministry-specific workstreams, such as with the Pharmacy and Poisons Board, to build capacity in those particular contexts. It made clear that these workstreams are flexible, and differ according to the needs of each agency or ministry and that the timeframe of the project goes until 2024. Assessment of the buy in of the Customs and Border Control

Department is still pending.

Another stakeholder to whom the project was presented to was the Kenya Bureau of Standards (KEBS). KEBS formally agreed to partner to advance MDRC objectives. MDRC explained its methodologies building workstreams at the country, regional, and global levels, including how it partners with regional bodies such as the AMDF and ARSO.

The team also met with the TIC Council and their Government Services Committee to review MDRC cooperation in Kenya. MDRC overviewed the project and its engagement with PPB, KEBS and the Customs. MDRC expressed its desire to collaborate with TIC Council where appropriate to forward MDRC objectives. TIC provided additional information on the KEBS PVoC Program required for medtech market access.

Finally, the last new stakeholder that MDRC (and Mecomed) introduced the project to, this quarter, was MEDAK's new Chair, Vice Chair, and broader team. MDRC overviewed the project, its methodologies and objectives, and current implementation status in Kenya. MEDAK reconfirmed its interest in partnering with MDRC. The attendees discussed PPB's issuance of draft guidelines as part of its WHO GBT assessment. MDRC and MEDAK agreed that the guidelines' limited notification and shortened comment period were counter to WHO. Furthermore, MEDAK agreed to partner with MDRC towards identifying stakeholders and facilitating logistical decisions relevant to future capacity building; particularly addressing concerns pertaining to KEBS's PVoC program and the need to properly differentiate the medtech sector from medicines. The role KEBS and MEDAK's members' play KEBS's technical committe was also discussed.

In addition to presenting the project to new stakeholders, the MDRC team continued its engagement with PBB in Kenya during this quarter. The updates focus around the draft MOU, which was shared by PPB's legal department. An MOU MDRC confirmed it would discuss with USAID potential signatories and witnesses to the MOU. After different drafts and reviews from the legal departments at ANSI, AdvaMed, and USAID. USAID advised that it would not participate as a signatory to the MOU (MEDAK and Mecomed agreed to sign as witnesses). The focus for the MDRC team in its PBB partnership remains on developing a system of stakeholder notification and comment in line with WTO obligations. PPB noted it is working with its IT department to advance elements of that system, including publishing draft guidelines directly to the PPB website. This is all the more relevant since AMDF is currently focused on strengthening member state NRAs so they can perform regulatory functions. PPB therefore could potentially be a case study for AMDF consideration in implementing international obligations through the MDRC workstream.

The engagement with PQM+ in Kenya also continued this quarter. In particular both stakeholders discussed the roll of the WHO in Kenya, which has an office in-country, and reviewed PPB's issuance of over ten draft guidelines as part of its WHO GBT assessment. MDRC noted that the guidelines' limited notification and shortened comment period were themselves counter to WHO guidelines and not in line with GRPs. As a result, MDRC and PQM+ noted they could only provide limited comments on those guidelines. It was also noted that the comment period did not allow enough time to properly collect and submit comments (which can in part be due to the political context on the ground).

Finally, the MDRC team has been coordinating with the USG for project implementation in Kenya, having two key meetings:

- One around Kenya's TBT compliance in the development o f it's new regulatory framework for medical devices with CDRH and USTR; a second with CDRH, Department of Commerce - ITA, and USTR to discuss the project's ongoing work and strategy in Kenya.

- In the latter meeting the team provided an overview of the current state of play in Kenya, including the country's desire to manufacture the COVID-19 vaccine domestically. This provides the context for PPB's recent issuance of approximately twenty draft regulatory documents reforming the PPB regulatory process with shortened notification and comment periods. These documents are part of PPB's rapid push to become recognized by the WHO Global Benchmarking Tool Plus (GBT+) as Maturity Level 3. This maturity status is apparently a prerequisite to allowing COVID-19 vaccine production in the country which the Kenyan government has established as an urgent priority. The MDRC supports the objective to manufacture the COVID-19 vaccine locally as an important step to combating COVID-19 in Kenya and on the African continent. However, the MDRC noted that the accelerated PPB development of regulatory framework documents is being conducted in a manner inconsistent with GRP in the medical technology sector – inadvertently establishing new medtech bottlenecks to combat COVID-19 in Kenya. This process was not in compliance with other WHO guidance (such as those pertaining to GRPs) and international trade commitments (such as those in the WTO TBT Agreement). Thus, a potential WTO-WHO joint guidance document on trade-related aspects that apply to NRAs could be an important step towards orienting NRAs in the implementation and operationalization of regulatory reliance and recognition and in the avoidance of developing new health and trade obstacles. This work could advance objectives in Kenya as well as have positive effects on other WHO and WTO member countries. Lastly, the Department of Commerce noted that the struggles of the medtech sector in Kenya are representative of other sectors and the overall regulatory system in the country. As such, it suggested that the medtech sector be highlighted as part of future trade-related dialogue between USG and Kenya.

South Africa:
MDRC and SAHPRA continued the development of the Tier Two project workstream. This workstream focuses on the procedural aspects of capacity building, while SAHPRA's existing workstream with SAMED/SALDA is centered on the technical aspects. MDRC and SAHPRA discussed a tentative schedule for trainings, such as those on GRPs, through Q2 2023. This includes how those trainings would integrate experts from the public and private sectors as well as next steps on applying that expertise through multi-disciplinary and inter-institutional working groups. MDRC emphasized the importance and effectiveness of operationalizing international trade obligations at the NRA level, which go a long way towards remedying bottlenecks and strengthening regulatory processes.

Indo-Pacific

Partner countries: Indonesia, Vietnam

Activity #12.8 – Tier Two: Medical Device Sector-Specific Regulatory, Standards and Conformity Assessment Convergence: Stakeholder Assessment

Indonesia:
The MDRC team is developing, with the Ministry of Health, priorities for collaboration with the project. The Ministry indicated its desire to focus on knowledge-sharing activities and engaging a wide-array of stakeholders to build capacity. However, because the Ministry of Health indicated that the program was outside of its scope, the team also had to engage with the USAID Mission in Indonesia to discuss this issue, and ultimately reworked its proposed draft workplan with the Ministry of Health to address the Ministry's concerns and clarify its roll strengthening the overall health system rather than aiding domestic production. After those reworks and comments from the Ministry an official letter to the new Director General for

Pharmaceuticals and Medical Devices in the Ministry of Health was sent to request a meeting to "kick-off," the finalization of the workstream approval. This meeting is set to occur in the first couple weeks of Q2 2022.

MDRC and the Mission also reviewed the Special Assistant to the Health Minister comments seeking assistance on improving the governance of and strengthening human capital in pharmaceuticals and medical devices, and support for local production of medical devices. MDRC confirmed that pharmaceuticals are not within the scope of the project, stating that proper differentiation between pharmaceuticals and medical devices is key. MDRC also clarified its role in facilitating the implementation of GRP in a whole-of-government approach, engaging all relevant stakeholders. MDRC stressed that the project does not provide technical assistance for improving or favoring local production of medical devices. However, through the implementation of GRPs, the project would strengthen the domestic health system and benefit all companies (foreign and domestic).

Vietnam:
MDRC met with the leadership of the Department of Medical Equipment and Construction (DMEC) in the Ministry of Health to formally introduce the project, which appears to be in alignment with the government strategic plan through 2025 to enhance policies related to medical devices. Thus, the MDRC team started coordination with DMEC to advance the development of an official implementation workplan. At the end of this reporting period DMEC informed MDRC it finalized an official document outlining its priorities for collaboration with MDRC. It indicated it was awaiting feedback from other government stakeholders before Ministry leadership could formally approve the document.

Latin America

Activity #12.11 – The Coalition will lead regional MDRC project efforts, convene stakeholders for meetings/trainings, and provide capacity-building resources. (Q3 2021 – Q2 2022)

Partner countries for Year 3: Brazil, Colombia, Mexico

Regional:
The MDRC team held two webinars in January, as part of a series on Unique Device Identification (UDI). The series is co-led by USAID, ANSI, and AdvaMed through the Coalition and in collaboration with the FDA. The first session addressed the Vision for a Global UDI System and provided an overview of UDI and IMDRF documents. The second session brought experts from NRAs from Brazil, Colombia, Ecuador and the USA as well as from the industry and healthcare suppliers' sector, shared their experiences on the implementation of UDI.

The Colombian Medical Devices for the National Industry Association (ANDI) shared some concerns over some of the content projected as part of Webinar on Unique Device Identifiers. ANDI believed that one presentation may not have shared the most up-to-date information. MDRC and ANDI agreed to regroup once the pertinent position paper becomes available and ANDI's board has had a chance to review it.

As a continuation for the webinar series on International Standards and Conformity Assessment, the MDRC team organized three new webinars in March 2022 co-led by USAID, ANSI, and AdvaMed through the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector and in collaboration with the FDA (all recordings of the session are available at the Coalition's website: Webinar Series on Utilization of Voluntary Consensus Standards):

- The second webinar under this series convened representatives from 13 countries, 11 NRAs, and 96 industry representatives.
- The third session gathered NSBs from Brazil, Colombia, Mexico and Peru which shared their work, perspectives and engagement with regulators and the private sector. The event convened representatives from 14 countries, 11 NRAs and 56 industry representatives.
- The fourth session saw NRAs, conformity assessment bodies, and industry representatives sharing information and perspectives on their work in this area. The event convened representatives from 12 countries, 10 NRAs and 75 industry representatives.

Finally, the Coalition met with the GHWP to discuss opportunities for developing a workstream to produce GHWP documents in Spanish. The attendees considered a proposal to begin with a smaller pilot program and ensure its sustainability. As part of this proposal, the Coalition would publish the Spanish versions on its website. The GHWP agreed to discuss the proposal internally before proceeding.

Activity #12.12 – Engagement with key partners, including the Inter-American Development Bank (IDB), World Trade Organization (WTO), and Pan American Health Organization (PAHO). (Q3 2021 – Q2 2022)

Regional:
The MDRC team continued its engagement with key international organization partners this quarter. Indeed, the team met with the PAHO on two occasions:

- During the first meeting the formalizing of PAHO's partnership with the Coalition through a Technical Cooperation Agreement was discussed. While the Coalition reviews this agreement, it will seek to clarify a number of items, including the terms of future renewal. PAHO informed the Coalition it is continuing its efforts to translate IMDRF documents to Spanish. The attendees discussed recent developments from the January 29, 2022 WHO Executive Committee meeting, including its conversation on nomenclature.
- On the second meeting the team and PAHO continued their discussions on a Technical Cooperation Agreement. PAHO is completing its review of the Agreement, while MDRC is discussing the inclusion of certain financial information internally. PAHO informed MDRC that it acquired the copyright of the translated IMDRF documents and they would soon be published. PAHO is also participating in the revision of the document, "WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices." MDRC shared its proposal and draft agenda for a Regional Medical Device Regulatory Meeting in April. PAHO agreed on the inclusion of GRPs and stressed the importance of facilitating the participation of all pertinent authorities and inclusion of topics relevant to those authorities. PAHO committed to reviewing the agenda further and providing input.

Activity #12.13 – Recognition of deliverables at the Summit of the Americas (Q1 or Q2 2022)

Peru:
On 23 March, 2022 MDRC met with MinCETUR and ACR ("Análisis de Calidad Regulatoria") to align on upcoming potential engagements related to the Summit of the Americas. The attendees discussed the prospect of having Tier One Peruvian government stakeholders attend a MDRC training on the sidelines of the Summit in June 2022.

Activity #12.14 – Hire a dedicated MDRC Liaison to facilitate and coordinate the implementation of MEL Plan objectives in Colombia (pending USAID approval). (TBD)

Colombia:
MDRC and the Ministry of Health continued the discussion related to the Ministry's progress in the search for a person who will aid with the evaluation processes as well as next steps for work regarding clinical investigations.

Activity #12.15 – Updated Tier One and Two Gap Analysis Reports (Q3 2021 – 2022)

Brazil:
As it will be further developed in sub section 12.16 of this report the MDRC team pursued stronger engagement with key government stakeholders within the Ministry of Economy. Because the Secretary for Competition Advocacy and Competitiveness (SEAE - the Brazilian proto-central regulatory coordination body within the Ministry of Economy) is responsible for coordinating regulatory affairs work related to the OECD accession, it is an important stakeholder; and an engagement and review of its work was important during this quarter, since it impacts the country's GRP implementation.

SEAE, released the results of the first applications made under the FIARC (Intensive Framework on Regulatory and Competitive Evaluation) Program. Which the team is currently reviewing. The team also presented the project's objectives and methodologies for implementing GRP to the SEAE; noted that one area for potential work is in the implementation of the U.S.-Brazil ATEC Trade Protocol and that one issue may be Brazil's lack of a central regulatory coordinating body. SEAE is currently considering partnering with MDRC to better align its GRP.

Mexico:
The MDRC team identified through its workstreams with Mexico that Mexican Farmacopeia (FEUM) is actually a separately constituted Mexican government body and not subject to Federal Commission for Protection against Health Risks (COFEPRIS) in terms of regulatory process and compliance with GRP and WTO/TBT obligations as they apply to medical devices. This is contrary to prior understanding, as FEUM appeared on the organizational chart as a part of and subsidiary to COFEPRIS. Through the MDRC workstream, FEUM asserted it had no provisions to comply with WTO/TBT and GRP obligations, and agreed to work with the MDRC to establish related protocols. FEUM will also align this workstream with COFEPRIS's efforts. The team met with FEUM in late March 2022 to continue discussions related to the implementation of international legal obligations. FEUM proposed designing a pilot program to incorporate those obligations into existing processes while NOM-001 is updated. The attendees agreed to schedule a meeting with FEUM's Director and the Commissioner of Evidence and Risk Management on this topic during next quarter.

Additionally, MDRC and COFEPRIS are continuing discussions on GRP implementation, with COFEPRIS's Legal team proposing an in-depth review of all relevant requirements.

Lastly, due to misalignments between NOM241 and Mexico's and international standards and GRP obligations, MDRC shared options with the Mexican Association of Innovative Medical Device Industries (AMID) on how to align the technical regulation with international benchmarks. MDRC agreed to share the Coalition's position paper on the regulation so AMID could circulate among its members and decide how AMID will proceed.

Activity #12.16 – Tier One and Two Implementation Meetings and Workshops with Project

Countries and regional stakeholders (Q3 2021 – Q2 2022)

Brazil:
The MDRC team pursued during this quarter meetings with both key public and private stakeholders.

Public stakeholders

The team engaged with the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) as it is the key government stakeholder for standards harmonization in the country. INMETRO is developing regulatory model modernization process which will be taking place over the next five years and therefore there are synergies to be explored between them and the MDRC team's objectives. In that sense it was first agreed to draft proposals of priorities for collaboration and develop a formal workstream. The MDRC team also shared its success developing capacity building activities with ANVISA and recent breakthrough with INMETRO. It also provided background on its work with Latin ALADDIV, and CBDL to make standards available in Portuguese and expand engagement of stakeholders from the medical devices sector in the standardization process; and stressed the importance of engagement in technical committees.

After consideration the MDRC team and INMETRO agreed on further exploring two areas of collaboration to turn into workstreams:

- The first is for the development of a National Quality Infrastructure Policy. This work is coordinated by INMETRO and involves crafting a policy to guide standardization, accreditation, conformity assessment and metrology and technical regulation in Brazil. MDRC would potentially support the preparation of the policy and decree and facilitate the subsequent dissemination of the policy nationwide,
- The second relates to strengthening the regulatory area of post-market surveillance. INMETRO committed to crafting and submitting the relevant workplans for internal review and sharing with MDRC.

In parallel of developing a cooperation with INMETRO the MDRC team also engaged with another government stakeholder this quarter. It met with the Brazilian Inter-Ministerial Foreign Trade Chamber (CAMEX) to introduce the project, its objectives, and methodologies. CAMEX identified a foreign trade subgroup of the Meeting of Federal Regulators as a body of importance for MDRC partnership. The Meeting of Federal Regulators was initiated by the SEAE at the end of 2020 to coordinate discussion on regulatory issues of foreign trade.

Private stakeholders

The team engaged with the Brazilian Alliance of the Innovative Health Industry (ABIIS), to discuss the joint organization of MDRC trainings on strengthening technovigilance processes, practices, and regulations in post-market monitoring in Brazil.

The MDRC team and ABNT, CBDL, and ALADDIV also discussed commencing work on the operationalization of the Technical Standard "ISO 15197:2013 - In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus."

Colombia:

The MDRC team has had strong buy in with the Colombian government to pursue the beginning of the implementation of the program's objective during this quarter. The team started by proposing the development of a formal agreement with the Presidential Agency for Cooperation (ACP) to engage the Presidential Agency for Competitiveness and advance project objectives in the country.

An important area of cooperation with the Colombian government during this quarter was the continuation of the ex-post evaluation for decrees 4725 and 3770 with the National Food and Drug Surveillance Institute (INVIMA), the Ministry of Health and National Planning Department (DNP) via several key meetings. Several interviews with relevant experts were also conducted; including with the Association of Pharmaceutical Chemists (part of the original development of these decrees, the Association is an important source of information). To carry out this task the MDRC team divided it in three steps. The first area is an ex-post evaluation. Second is ex-ante evaluation for new regulation around EUA and GRPs. Third is support for the implementation of regulation. On March 9, 2022 MDRC estimated the first step was about 20% complete, with the completion of the problem tree.

MDRC and the Ministry of Health, Ministry of Commerce and DNP continued deliberations on the required level of analysis for the forthcoming decree on EUAs. The Ministry of Commerce is of the position that mandatory international notifications rules require a complete analysis. As a result, the Ministry of Health will not have enough time to issue a decree that includes both medicines and medical devices before its June 2022 deadline. After the Ministry of Health inquired with its legal office if it is possible to temporally modify the decree in accordance with the Ministry of Commerce's recommendation it decided to issue separate decrees related to EUAs for each medical devices and medicines. The Vice Minister of Health also echoed the need to adopt permanent processes and procedures regarding GRP. Therefore, with new decrees about to be issued the MDRC team during this quarter has been preparing ex-ante evaluations of the decrees for EUA and GRPs.

Related to the EUA the evaluation with have two steps. First is the ex-ante evaluation itself. This is the first of seven milestones required for the completion of the evaluation. The second step has to do with the formulation of the actual decree. At the end of this current reporting period the MDRC team estimates that the ex-ante evaluation process was about 7% complete.

On the ex-ante evaluation on clinical research. The work of the MDRC team on this topic also has two fronts. The first is related to ex-ante evaluation as well. This evaluation's problem tree is under development and is supported by the results of research which was conducted by MDRC and the Ministry over the proceeding months. The second is to provide support for the decree's final formulation. This will occur once work on the ex-ante evaluation in complete. The Ministry of Health and INVIMA completed the problem tree and objectives tree for the ex-ante evaluation on GMPs. At the end of this reporting period the MDRC team estimates this ex-ante evaluation was about 11% complete.

Moreover, during this quarter, the MDRC team also met with DNP to confirm that DNP's updated processes and procedures are ready for review to ensure alignment with the existing regulatory improvement policy and the Ministry of Health. Once formally adopted, training and application on the new processes and procedures will begin. MDRC estimated this entire process was about 50% complete at the end of this reporting phase.

Finally, a proposal to sign an agreement to reinforce MDRC's work in the country and promote the involvement of the Presidential Agency for Competitiveness was discussed; and the Presidential Agency for Competitiveness was introduced to the project. The Agency will review information shared by the team and deliberate on whether they will join the MDRC frame of work in following quarters.

Mexico:
The MDRC team has continued its partnership with the COFEPRIS to advance 2022 workstream development efforts from 2021through multiple meetings during the first quarter of 2022:

- MDRC prioritized, first, work with COFEPRIS's legal department and increasing visibility of medical devices. A discussion was also had to set up a meeting with AMID to share AMID's recently-developed system to track project performance; during which COFEPRIS requested additional information on the attendance to the Q4 2022 GRP webinar series (info shared by the team later).
- On a second meeting COFEPRIS agreed to schedule a session with the COFEPRIS IT department to assess ability to incorporate AMID's software; and proposed that MDRC prepare a report on Mexico's existing relevant international obligations (i.e. WTO/TBT) so that they may be incorporated into standard operating procedures. The team is currently preparing the aforementioned document.
- COFEPRIS and the MDRC team also discussed this quarter COFEPRIS's initial draft report for presentation at the March High Level Economic Dialogue (HLED). COFEPRIS indicated it was working on its responses to the ABD GRP Survey and was interested in learning more about how other governments (such as the U.S. and Canada) are implementing GRPs.

To consider the entry into force of the USMCA Free Trade Agreement (FTA) the MDRC team and COFEPRIS also had a meeting to start discussing support from MDRC to draft a legal checklist to promote full compliance with obligations in the agency's Standard Operating Procedures (SOPs); a checklist that would be developed after COFEPRIS's legal department has finished reviewing the agency's relevant legally-binding international obligations, including those in the USMCA.

Peru:
During this quarter the MDRC team started to have key meetings with local stakeholders such as the joint AmCham Peru – ALAFARPE (The National Association of Pharmaceutical Laboratories, la Asociación Nacional de Laboratorios Farmacéuticos) Medical Devices Committee. The MDRC team introduced the Coalition's structure, membership, and resource library – available through its website; and also presented the GRPs, their connections with international trade, the e-ping system, and the checklist to reduce technical barriers to trade (TBT).

On a subsequent meeting the Committee proposed analyzing sanitary registration procedures and comparing the results with DIGEMID's analysis in 2019. Any review of this procedure will have to be based on international standards and references. Based on the committee suggestion the MDRC team later introduced the joint AmCham Peru – ALAFARPE Medical Devices Committee to MinCETUR and ACR and discussed the expansion of the Joint Committee's analysis to technical regulations. According to ACR in early 2023 all technical regulations will be required to undergo a Regulatory Impact Analysis (RIA), therefore the Joint Committee has agreed to prepare a timeline for completing the expanded analysis.

2.4 Implementation Challenges

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

COVID-19 has brought with it many complications, including the ability to plan for and host physical

workshops. These in particular have been delayed over a year, and caused additional issues when attempting to accommodate for speakers to attend physically. The workshops were necessarily adjusted, but could have been more effective if there had been additional Standards Alliance support on the ground. The virtual format was successful however, and brought on a greater number of expert presenters than would have been possible with physical attendance.

Activity #2 – Support for African Organization for Standardization (ARSO)

Communicating with ARSO representatives has been challenging. Thus, it has taken longer than originally anticipated to confirm dates for the suggested webinars under this activity. This was despite several emails and even switching to using WhatsApp messages in an attempt to ease communication channels. Although it is unclear why ARSO does not provide speedy feedback via email it appears that the switch to text messaging has proved to be effective as communication has improved between ANSI and ARSO since then.

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

The major challenge remains the organization of online workshops; two-way communication during the virtual portions of the event was challenging. Indeed, French/English simultaneous translation was provided, but it remains difficult to maintain good interpretation throughout the duration of an event.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

The lack of responsiveness from partner countries continues to be the primary challenge for implementation of this activity.

The lack of responses comes from the fact that contact information is not always up to date. This is the case in Tanzania.

Additionally, the lack of a continued dialogue with stakeholders may also come from the fact that these countries appear to have stronger ties with European counterparts. For instance, implementation of the Eurocodes in Kenya may suggest that the possible adoption of ACI codes and standards may only be a gradual development with a long-term time frame.

Activity #7 – Increase the Flow of WASH Services

There are no observed challenges in Q1 2022 for Indonesia. IAPMO anticipates that there could be challenges in Q2 2022, pending the draft standard comment period: if BSN receives negative opinions from the public regarding the content of the draft standard during the opinion window, then the technical committee must meet to discuss whether to accept or reject the opinions received.

IAPMO's work in the Philippines continues to be stalled in Q1 2022. IAPMO is awaiting congressional notification approval before outreach with the Philippines Mission can occur. USAID is managing the congressional notification approval process and outreach.

In Q3 2021, the Jordan Mission requested IAPMO hold engagement in Jordan until 2022 due to the increase of Afghan refugees in Jordan, which has impacted the availability of staff to coordinate other activities. IAPMO does not have approval to begin outreach in Jordan and as such, IAPMO did not undergo

any activities in Q1 2022.

Activity #8 – Utility Management Standards Training for water sector utilities

Participation agreements were developed and distributed in India. Several utilities have signed; however, AWWA discovered that by removing the requirement to sign the agreements that barriers to participation were removed due to not needing to circulate them more broadly through the utility management which would result in longer delays. Separately, partner ROCKBlue has also raised the same concerns for Africa. As such, partner agreement will not be required as to ensure support for the workshops. AWWA has noted that attracting a gender diverse audience has also been a priority and a challenge.

Activity #9 – Community Water Systems – Standards for safety and risk management

Building personal relationships is critical in Morocco for success when doing business or implementing a project. As such, conversations with Moroccan contacts have strongly suggested the approach of providing the training in-person. As an organization, NSF International has resumed international travel. As such, NSF requests to travel to Morocco and provide in-person engagement for Morocco. This project has received internal approved for project related travel to Morocco, as needed and approved by ANSI/USAID.

Additionally, Brazil and Morocco remain at different stages of progress and training in Brazil will occur sooner than the training in Morocco; this does not represent a concern. However, due to the slower response during the outreach in Morocco and the new identified preference for in-person training, NSF is requesting to move the completion date of the full project from July 2022 to March 2023, to ensure adequate time for project completion.

A direct request to the AO/AOR regarding this adjustment was submitted in April.

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

The major implementation challenge in Q1 2022 was the delay in workstream execution related to slower engagement by some project country governments. In Indonesia and Vietnam, MDRC experienced long periods between government stakeholder responses to project outreach. This was coupled with the observance of local religious holidays in January/February, leading to a delay in the workstream development process. However, both countries' Tier Two government stakeholders remain extremely interested in partnering with the project. MDRC is set to finalize its workstream scope in Indonesia in the early weeks of Q2 2022. This process continues in Vietnam, with the Ministry of Health having internally finalized its list of priorities for MDRC capacity building.

In Ghana, MDRC conducted outreach in July 2021 when Kenya and South Africa had secured Mission concurrence. Following extensive follow-up by MDRC and the Mission, the Ghanaian Ministry of Health responded in October 2021 to designate a point of contact. Thereafter, the point of contact did not respond to outreach until late December 2021. Following MDRC's introductory call with the Ministry in January 2022, MDRC provided the Ministry of Health with a proposal for project implementation. Despite indicating interest in partnering with MDRC, the Ministry has not responded to follow-up by MDRC.

While COVID-19 has, as expected, made in-person capacity building impossible to date, the project is

actively addressing this challenge through the execution of high-quality virtual engagements. These engagements continue to improve both in their ability to disseminate quality resources and convene relevant stakeholders from the public and private sectors.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	Participants
1	N/A	Togo/ The Gambia	Meeting between ANSI and Pivot to determine budget for the ECOWAS bioethanol workshops	Jan 11, 2022	ANSI staff and Pivot representatives
1	N/A	Togo/ The Gambia	Meetings with Standards Alliance workshop stakeholders in Togo and The Gambia	Jan 26/ Feb 18, 2022	ANSI staff and Pivot representatives
1	N/A	Togo/ The Gambia	Meetings between ANSI and Pivot to determine logistics for the ECOWAS bioethanol workshops	Feb16/March 9, 2022	ANSI staff and Pivot representatives
1	N/A	Togo	ECOWAS bioethanol workshops	Mar 17-18, 2022	35 total participants 30 Male/ 5 Female 17 public/ 18 private stakeholders
1	N/A	The Gambia	ECOWAS bioethanol workshops	Mar 21-22, 2022	29 total participants 17 Male/ 12 Female 16 public/ 13 private stakeholders
5	5.3	Côte d'Ivoire, Ghana, Nigeria, Senegal	Workshop on Petroleum Standards	Mar 1-3, 2022	8 total participants 4 Male/ 4 Female 5 public/ 3 private stakeholders
5	5.3	Senegal	Meetings to discuss access to the most current ASTM standards	Mar10/24, 2022	ANSI staff, API, and with Abdoul Aziz Deme

					(Senegal)
6	6.2	Uganda	Meeting with private stakeholder	Jan 27, 2022	ANSI staff, ACI representatives, 8M Construction Digest
6	6.1	Tanzania	Meeting with USAID Mission	Feb 23, 2022	ANSI staff, ACI, and USAID representatives
7	7.1	Indonesia	Technical Committee meeting	Feb 2, 2022	BSN Technical Committee and relevant stakeholders
7	7.1	Indonesia	Technical Committee meeting	Feb 23, 2022	BSN Technical Committee and relevant stakeholders
7	7.1	Indonesia	Technical Committee meeting: Consensus meeting	Mar 8, 2022	BSN Technical Committee and relevant stakeholders
8	8.1	Malawi	ANSI/AWWA Malawi Mission-Intro call	Jan 21, 2022	ANSI staff, AWWA, USAID representative, and Malawi Mission staff
8	8.1	Malawi	ANSI/AWWA Malawi Mission-Intro between ROCKBlue and Malawi Mission	Mar 8, 2022	ANSI staff, AWWA, ROCKBlue, USAID representative, and Malawi Mission staff
8	8.1	Lesotho	ANSI/AWWA Lesotho Mission-Intro call	Jan 25, 2022	ANSI staff, AWWA, USAID representative, and Lesotho Mission staff
12	12.11	MDRC partners	MDRC-FDA Medical Devices Webinar Series on Unique Device Identification (Session 1)	Jan 20, 2022	203 total participants 44 Male/ 158 female/ 3 undeclared 61public/142 private stakeholders
12	12.11	MDRC partners	MDRC-FDA Medical Devices Webinar Series on Unique Device Identification (Session 2)	Jan 27, 2022	237 total participants 54 Male/ 180 female/ 3 undeclared 67public/170 private stakeholders
12	12.11	MDRC partners	MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment (Session 2)	Mar 3, 2022	237 total participants 62 Male/ 161 female/ 3 undeclared 141 public/96 private

					stakeholders
12	12.11	MDRC partners	MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment (Session 3)	Mar10, 2022	167 total participants 35 Male/ 130 female/ 2 undeclared 111 public/56 private stakeholders
12	12.11	MDRC partners	MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment (Session 4)	Mar17, 2022	181 total participants 51 Male/ 129 female/ 1 undeclared 106 public/75 private stakeholders
12	12.11	MDRC partners	International Webinar Series – "The use of Self tests in the fight against COVID-19"	Mar 31, 2022	161 total participants 50 Male/ 108 female/ 3 undeclared 38 public/123 private stakeholders
12	12.12	MDRC LATAM	Coordination Meetings with PAHO	Feb 2/11 2022	MDRC team and PAHO representatives

4. RESULTS ACHIEVED

Performance Indicator #2: Number of trainings conducted about the value of using their national quality infrastructure

Under this reporting period for this performance indicator there are a total of **9** trainings to report. A breakdown of the different workshops is presented below by activity.

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

Togo

There is one training about the national quality infrastructure to report under this activity in this particular country for this quarter report.

A Workshops on Bioethanol for Clean Cooking was completed between March 17-18, 2022 which is in line with the current implementation schedule for Activity#2 for Year 3 of the SA2 program.

The Gambia

There is also one training about the national quality infrastructure to report under this activity in this particular country for this quarter report.

A Workshops on Bioethanol for Clean Cooking was also completed between March 21-22, 2022 which again is in line with the current implementation schedule for Activity#2 for Year 3 of the SA2 program.

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

There is one training about the national quality infrastructure to report under this activity in this particular country for this quarter report.

A Workshops on Harmonization of Petroleum Standards was completed between March 1 to 3, 2022. The scope of this workshop extends to all four partner countries. This is in line with the current implementation schedule for Activity#5.3 for Year 3 of the SA2 program.

Activity #7 – Increase the Flow of WASH Services

There are three BSN technical committee meetings to report under this activity for Q1 2022 on February 2, February 23, and March 8. The meetings in February were online meetings while the meeting in March, which was a consensus meeting, was held in person. All three meetings were attended by members of Technical Committee 77-02 and other stakeholders.

Activity #12 - COVID-19 Medical Device Regulatory Convergence Project

There are three training about the national quality infrastructure to report under this activity in this particular country under this quarter.

Two workshops on Unique Device Identification and a webinar on "The use of Self tests in the fight against COVID-19".

As the following activities did not have a training activity related to NQI planned for this quarter; they do not have anything to report under this performance indicator:

- Activity #2 – Support for African Organization for Standardization (ARSO)[2]
- Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy
- Activity #6 – Africa Concrete and Building Code Adoption Initiative[3]

[2] As stated in the previous section there is a need to account for difficult activity implementation conditions for this activity. Delays were created by the pandemic and also difficult communication with ARSO. In light of this situation the workshop on Good Manufacturing Practices for Cosmetics has been scheduled for next quarter.

[3] Delays were created by the pandemic and limited buy in in the partner countries. As a result, workshops are not yet ready to be rolled out under this activity since work plans are still being discussed on the ground.

- Activity #8 – Utility Management Standards Training for water sector utilities
- Activity #9 – Community Water Systems – Standards for safety and risk management

Performance Indicator #9: Number of workshop/reserve trade mission participants (Related to Technical Barriers to Trade (TBT) awareness)

Under this reporting period for this performance indicator there are a total of **3** workshop to report cumulating to a total of **585 participants**. A breakdown of the different participants in said workshops is presented below by activity.

Activity #12 - COVID-19 Medical Device Regulatory Convergence Project

There are three workshops to report under this activity under this quarter. All workshops were part of a series on International Standards and Conformity Assessment (sessions 2, 3, and 4); and were completed online respectively on March 3, 10, and 17, 2022.

- Session 2 counted 237 total participants
- Session 3 counted 167 total participants
- Session 4 counted 181 total participants

As the following activities did not have a capacity building activity planned for this quarter directly related to increasing awareness on TBT obligations; they do not have a workshop (and participants) to report under this performance indicator:

- Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops
- Activity #2 – Support for African Organization for Standardization (ARSO)
- Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy
- Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards
- Activity #6 – Africa Concrete and Building Code Adoption Initiative
- Activity #7 – Increase the Flow of WASH Services
- Activity #8 – Utility Management Standards Training for water sector utilities
- Activity #9 – Community Water Systems – Standards for safety and risk management

5. LESSONS LEARNED

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

Given the current uncertain context still created by the pandemic the workshops preparation could have started earlier. Lining up schedules and defining travel arrangements always takes longer than anticipated. The following feedback from on the ground representatives of Pivot was also shared:

- Because of the limited internet connectivity it would be ideal to host these sessions in person if at all possible (or ensure at least 1-2 speakers can be present physically). This would also allow for continued discussion after the meetings were concluded.
- In future workshops it would be helpful to include a presentation from the Ministry of Energy on policies, as well as planned and current initiatives in terms of bioethanol so that they can gain guidance from speakers.
- Include a topic on the existing funding opportunities at the level of US agencies; this was requested by the participants.

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

For future workshops API mentioned that the per diem policy needs to be made clearer, as there was confusion around what it could be used for. Moreover, participation by additional local participants should be encouraged, if the budget allows; and each country's participants should plan to make a presentation to encourage participation.

In order to dive deeper into the discussions, test procedures should be covered in detail from the text of the standards and compared to methods for the same parameters.

Finally, it may be beneficial to extend the time that the participants can meet together for technical discussions during the workshop.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

In having to deal with the restrictions brought by the pandemic the team has learned to adapt and carry out implementation via virtual meetings. This however, is not as effective as in-person meetings but is the best the team can do for now.

An important lesson is also from now on to conduct larger virtual seminars rather than smaller meetings done multiple times in order to maximize the efficiency and avoid fatigue from all stakeholders, which can be a consequence of multiple small meetings.

Activity #7 – Increase the Flow of WASH Services

IAPMO identifies that there is a need to review the capability of SMEs since they will also need to implement this standard later when it is regulated by the related Technical Institution.

Activity #8 – Utility Management Standards Training for water sector utilities

When scheduling the workshops AWWA needs to avoid hosting one in September due to elections taking place in Lesotho.

Activity #9 – Community Water Systems – Standards for safety and risk management

In Morocco, NSF realized that cultural and social factors have a big impact on how to create engagement and trusting relationships with stakeholders. Originally, NSF planned that all (or most) of the interactions would be done face-to-face with the stakeholders in the countries part of this project (meetings and training). However, NSF did not expect the COVID-19 pandemic that made it impossible for us to have in-person relationships and therefore directed all our efforts towards digital and electronic interactions.

For Brazil, NSF had no problems with this change. Culturally, and perhaps because of its size, the main stakeholders in Brazil are already used to having digital interactions and NSF did not see any difficulties with this. On the contrary, in Morocco NSF noticed that the process is very slow and inefficient.

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

In geographies where MDRC experienced limited government stakeholder engagement, the project team convened found it effective to convene relevant industry and U.S. government stakeholders to seek their support raising MDRC with relevant local contacts. In Africa, heightened coordination with U.S. government actors in particular (see Section 2.1 – Progress Narrative, Section 2.2 – Implementation Status) has worked to increase alignment in U.S. government capacity building and extend outreach to government agencies. In Southeast Asia, consistent coordination with the USAID Mission in Indonesia has help facilitate steady progress in workstream development.

The project team continues to incorporate lessons learned on virtual engagements with stakeholders, online capacity-building, and digital resource capabilities. MDRC uses its virtual platform and Zoom licenses to enable simultaneous stakeholder meetings and engagement across geographies. MDRC has learned to more effectively coordinate with local stakeholders in determining their virtual capabilities and filling the gap with MDRC technologies, including through simultaneous translation.

MDRC continues to optimize the level of resources devoted to running MDRC and the Coalition's online presence. This has heightened the Coalition's capacity to provide online modules and virtual resource library. Virtual Coalition resources have proven to be an invaluable tool for hosting and disseminating information vital to the project. MDRC will continue to look for ways to maximize the effectiveness of resources to achieve MEL Plan objectives in the current non-travel environment.

MDRC has continued to leverage the project URL www.standardsalliance-mdrc.org.

6. PLANNED ACTIVITIES FOR QUARTER 2 OF 2022, INCLUDING UPCOMING EVENTS

Activity #	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
1	N/A	TDB	Call for proposal to increase countries	N/A	May 2022	N/A	TBD

			involved in 2023				
2	N/A	Africa	N/A	Webinar on Good Manufacturing Practices for Cosmetics	May 9, 2022	Online	TBD
5	5.3	West Africa	N/A	Nigeria Oil and Gas Conference and Exhibition (NOGC)	Jun 2022	Abuja	TBD
5	5.3	West Africa	N/A	Workshop on Petroleum Standards Harmonization	Jul 5-7 2022	Abuja	TBD
6	6.1	Kenya	N/A	Seminar with the Institute of Engineers-Kenya (IEK)	TBD	Online	TBD
8	8.3	India	N/A	Virtual Workshop on AWWA Standards	Apr 27-28, 2022	Online	No
8	8.3	India	N/A	Workshop on AWWA Standards	TBD	In-person (anticipant)	No
9	9.3	Brazil	N/A	Workshop on NSF Standards	TBD	Online	No
12	12.1	Global	N/A	International Webinar Series – "The use of Self tests in the fight against COVID-19"	Apr 7, 2022	Online	TBD
12	12.5	South Africa	N/A	Workshop on Good Regulatory Practices - Trade	May 2022	Online	TBD
12	12.5	South Africa	N/A	Workshop on Good Regulatory Practices and Good Reliance Practices – WHO Guidelines	May – Jun 2022	Online	TBD
12	12.5	South Africa	N/A	Workshop on Post-Market Surveillance and Market Surveillance of MDs, including IVDs	Jun 2022	Online	TBD
12	12.5	South Africa	N/A	Clinical Trials for Medical Devices	Jun 2022	Online	TBD
12	12.5	MDRC Africa	N/A	Tier One Regional Forum: relevant stakeholders from Ghana, Kenya, and South Africa	TDB	Online	TBD
12	12.8	MDRC Indo-Pac	N/A	Tier Two Regional Forum: relevant stakeholders from Indonesia and Vietnam	TDB	Online	TBD
12	12.8	Vietnam	N/A	Tier Two local Forum -	TDB	Online	TBD

				Vietnam			
12	12.11	MDRC LATAM	Emergency Use Authorization – International References	N/A	TBD	Online	TBD
12	12.11	MDRC LATAM	IMDRF – Essential Principles & Table of Content	N/A	TBD	Online	TBD
12	12.11	MDRC LATAM	Clinical Research for MDs	N/A	TBD	Online	TBD
12	12.11	MDRC LATAM	Software as Medical Device – International References	N/A	May 2022	Online	TBD
12	12.11	MDRC LATAM	Stability Studies for medical Devices	N/A	Jun 2022	Online	TBD
12	12.11	MDRC LATAM	IMDRF - Labeling	N/A	TBD	Online	TBD
12	12.15	MDRC LATAM	Good Reliance Practices	N/A	TBD	Online	TBD
12	12.15	MDRC LATAM	Good Regulatory Review Practices	N/A	TBD	Online	TBD